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Fibromyalgia and bladder irritability

Carolyn K. Brand
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FIBROMYALGIA AND BLADDER IRRITABILITY

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14th January 2005

ABSTRACT

Urinary tract sensory symptoms provide an additional symptomatic burden for women with fibromyalgia. The urogenital symptoms of both fibromyalgia and interstitial cystitis have been described as non-infective sensory disorders, suggesting the existence of substantial clinical overlap between the two conditions. Research suggests that although interstitial cystitis has been treated as a specific bladder condition, it may be part of the disorder of central processing of sensory information as seen in fibromyalgia.

The interstitial cystitis symptom index and problem index (ICSI/ICPI) have been used to measure lower urinary tract symptoms and to examine the impact of these symptoms in patients with interstitial cystitis. This current two phase study was designed to test the ICSI/ICPI for use within a population of women diagnosed with fibromyalgia known to be experiencing sensory bladder symptoms.


Phase I involved focus group interviews and discussions with women who reported fibromyalgia and bladder irritability (N=10). This phase was designed to identify whether the key indicators and the way in which women experienced bladder irritability were indexed by the ICSI/ICPI instrument. The second phase of the study tested the ICSI/ICPI within the fibromyalgia population for reliability and validity.

Phase II data was derived via a self-administered questionnaire issued to women (N=90) who had been diagnosed with fibromyalgia by a rheumatologist and who were experiencing lower urinary tract sensory symptoms. Data analysis revealed two separate components in urinary symptom/problem combinations within the fibromyalgia population. These components were distinct from those described in the ICSI/ICPI. Subsequently, two separate subscales were developed to form the Fibromyalgia Bladder Index (FBI). The development and testing of the FBI within the fibromyalgia population has provided an accurate measure for assessing the symptoms and symptom impact of urinary symptoms for women with this condition. The FBI has been developed as an adjunct to clinical assessment and as an outcome measure for intervention therapies for patients with fibromyalgia and bladder irritability.

Outcomes of this study form the basis to the following recommendations: further refinement of the FBI; utilisation of the index in fibromyalgia assessments; development of fibromyalgia educational, support and self help programs; pelvic fitness awareness and intervention studies.

DECLARATION

I certify that this thesis does not, to the best of my knowledge and belief:

- (i) incorporate without acknowledgement any material previously submitted for a degree or diploma in any institution of higher education;*
 - (ii) contain any material previously published or written by another person except where due reference is made in the text; or*
 - (iii) contain any defamatory material.*
- 

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The development and completion of this thesis has been a wonderful learning curve for me over the past four years. From the initial concepts, preliminary research questions and background to the study, I have woven my way through literature reviews, theoretical frameworks and measurement models, considered different methodologies and recruited wonderful women as study participants from both the east and west coasts of Australia. This research trek has continued through software packages, data collection and analysis, biostatistics, formatting, findings, discussions and recommendations. Throughout this time I have been assisted, supported, educated and nurtured by my family, colleagues and friends. They have all played a part in my transition into a researcher. My gratitude and thanks especially to

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CHAPTER 1

INTRODUCTION

Issues and challenges in relation to the measurement of genitourinary symptoms in women with Fibromyalgia (FM) are the primary themes of this thesis. The research was initiated because of my association with and clinical knowledge of symptomatology of patients who had disabling urological symptoms in conjunction with their FM. Many of these patients had not been looked at critically in a clinical setting. There has been little recognition of or intervention for the management of these urological symptoms in the population of Fibromyalgia women who already experience multiple non-bladder symptoms. This study will provide important information for women experiencing the disabling urogenital symptomatology of FM.

The research activity in bladder and urological conditions has been expanded by the establishment of various foundations supported by health care workers, researchers and patients through out the world. The USA Coalition for Urological Research and Education (CURE) (Interstitial Cystitis Association, 2003), the USA Coalition for Improved Bladder Health (National Association for Continence, 2003), the Fishbein Foundation and the Interstitial Cystitis Association (Interstitial Cystitis Association, 2004) all attest to the bother of urological symptoms in afflicted patients. The lack of progress in some areas has evoked new strategies such as the initiative by the National Institute of Diabetes and Digestive and Kidney Disease (Urology Times, 2004) where a new paradigm for Interstitial Cystitis (IC) looks at it as a chronic pain syndrome.

There are interesting new developments within the urological area, especially the increase of knowledge in the biology of up-regulation of sensory processing, central sensitisation and the possibility of some bladder conditions being visceral pain syndromes rather than end organ diseases. This is an area that needs to be

revisited to facilitate further knowledge as it has the potential to change the way clinicians consider the condition of FM and its associated bladder symptomatology. The women in this study are a group of disenfranchised people who have a challenging condition, whose non-bladder FM symptoms cohabit with bladder symptomatology that impacts on their quality of life. Their needs need to be addressed.

FM with its debilitating musculoskeletal pain has come under renewed evaluation by rheumatologists and health specialists. However, evaluation of urogenital symptoms and their impact in this debilitating chronic condition has not been undertaken. For a comprehensive evaluation in quality of life issues with multiple systems disease, specific and directive measurement tools are required.

This study explores these issues of lower urinary tract sensory symptoms in Australian women who have been diagnosed with the condition of FM. Although irritable bladder symptoms are listed as an associated symptom of the condition of FM, there is little in the literature on these symptoms of urinary urgency, urinary frequency, nocturia and bladder pain and their resultant impact on the quality of life of these women. One of the aims of this study is to quantify the impact of these bladder symptoms on the quality of life of Australian women with FM.

Interstitial cystitis (IC) is a condition of uncertain etiology that results in chronic bladder pain, urinary frequency, nocturia and urgency. O'Leary, Sant, Fowler, Whitmore and Spolarich-Kroll (1997) have designed and validated the Interstitial Cystitis Symptom Index and Problem Index (ICSI/ICPI) to capture the most significant voiding and pain symptoms and assess how problematic these urinary symptoms are for patients with interstitial cystitis. Research by Clauw, Schmidt, Radulovic, Singer, Katz and Bresette (1997a) suggests that the conditions of interstitial cystitis and FM have a significant overlap in symptomatology.

This study was undertaken to validate this Interstitial Cystitis Symptom Index and Problem Index (Appendix A) for use within a population of women diagnosed with FM who exhibit lower urinary tract sensory symptoms.

Background to the Study

FM is recognised as a distinct rheumatic disorder. It is a chronic non-degenerative, non-inflammatory, non-progressive systemic pain condition of unknown etiology. It is a complex syndrome characterised by pain amplification, diffuse musculoskeletal pain and systemic symptoms. The American College of Rheumatology (ACR) classification criteria was outlined for the diagnosis of FM in 1990 (Wolfe, Symthe, & Yunus, 1990). The diagnostic criteria for FM require patients to have wide spread pain of at least three months duration in combination with at least 11 of 18 specified tender points. Patients diagnosed with FM also present with a variety of other symptoms.

A group of international FM experts issued the Copenhagen Declaration in 1992 that was adopted by the World Health Organisation in 1993 (Wallace & Wallace, 1999). They recognised the use of the criteria of the American College of Rheumatology for research purposes, but at the same time recognised and defined FM as part of a wider spectrum. This spectrum included headache, irritable bladder, irritable bowel syndrome, painful menstrual periods, temperature sensitivities, atypical patterns of numbness and tingling, exercise intolerance, complaints of weakness, persistent fatigue, stiffness and non-restorative sleep (Wallace & Wallace, 1999). Other associated symptoms included gastrointestinal complaints, chest pain, skin problems, restless leg syndrome, dizziness, cognitive disorders, environmental sensitivity and depression. These multifactorial symptoms of FM contribute to the delay in the diagnosis of FM and increase the dilemma of its unknown etiology. Current research is attempting to unearth a more sophisticated diagnostic marker than the above criteria for the diagnosis of this syndrome.

Wolfe, Ross, Anderson, Russel and Herbert (1995) determined that FM affects between 3% and 5% of the population (according to the American College of Rheumatology classification criteria), that females outnumber males by a ratio of about 6 to 1 and that the prevalence of the syndrome increased with age. The median age for the onset of FM is from 29 years to 37 years although formal diagnosis is more often from 35 years to 53 years (Boissevain & McCain, 1991). Buskila and Neumann (1997) noted a striking familial prevalence of FM with the prevalence in

female relatives being much higher. The mechanism of FM is thought to involve a complex interaction between neuroendocrine factors and central pain mechanisms with increased sensitivity in pain pathways. Symptoms of FM can be grouped according to their organ system (Clauw et al., 1997a). These organ groups include genitourinary, musculoskeletal, neurological, gastrointestinal, cardiopulmonary and others.

Urological Symptoms

From the genitourinary group, irritable bladder symptoms similar to the irritative bladder symptoms of interstitial cystitis (IC) are listed as one of the associated disorders of FM (Littlejohn, 1996). These symptoms include urinary frequency, urinary urgency, nocturia and pelvic pain in the absence of infection. Paira (1994) found that 38 of 212 patients (18%) with FM met the criteria for the definition of female urethral syndrome with symptoms of urinary frequency, dysuria, supra pubic pain and urethral discomfort. Wolfe and colleagues (1990), in their study on signs and symptoms of FM reported that 26.3% of his sample experienced urinary urgency. In a study by Wassem, McDonald and Racine (2002) on FM patient perspectives on symptoms, irritable bladder symptoms were reported in greater than 70% of the 54 respondents.

Clauw and colleagues (1997a) considered the relationship between FM and IC. Interstitial cystitis is a complex inflammatory condition of the bladder. Although the pathophysiology of the condition is not fully understood, it is known that there is altered epithelial permeability, mast cell activation and sensory afferent nerve upregulation within the bladder (G. R. Sant & Theoharides, 1999b). Z. S. Wisniewski (personal communication, September 3, 2004) describes the typical history of a woman with IC as one who presents with pain on a full bladder with ensuing frequency. As a consequence of this, some fibrosis of the bladder can occur with the bladder shrinking down to a smaller contracted form that encourages increased urinary frequency and urgency. Bladder and/or pelvic pain on bladder filling are a major part of the urological profile of these women.

The study on IC and FM (Clauw et al., 1997a) showed the prevalence of genitourinary symptoms within three groups, patients with FM (n = 60), patients with IC (n = 30) and a control group (n = 30). These results show the prevalence of a bladder fullness sensation at 38%, 80%, and 7%, urinary urgency at 45%, 80% and 13%, pelvic pain at 45%, 77% and 7%, dyspareunia at 18%, 50% and 7%, burning with urination at 6%, 40% and 0% and vaginal pain with insertion or removal of a tampon at 15%, 23% and 3% respectively.

In a randomised community survey of 3395 non institutionalised adults, White, Speechley, Harth and Ostbye (1999a) identified clinical features that distinguished FM from other chronic widespread pain. They included in the study 100 FM cases, 76 widespread pain controls (PC) and 135 general controls (GC). From a list of 41 presented symptom items, the prevalence of urinary frequency (> 5x/day) was recorded at 32% (FM), 23.7% (PC) and 7.5% (GC). Pain with urination was recorded for 6% of those with FM, 2.7% of those with widespread pain and none for those in the general control group.

Clauw and colleagues (1997a) speculated that central neurological mechanisms that have been suspected to contribute to the pathogenesis of FM may be the same type of mechanisms operative in IC, which until now has been primarily considered to be a bladder disorder. Clauw and colleagues found that patients they studied with interstitial cystitis displayed diffusely increased peripheral nociception as seen in FM, nociception being the electrochemical process through which humans perceive pain. Erickson, Morgan, Ordille, Keay and Xie (2001) extended the inquiry into non-bladder symptoms related to interstitial cystitis. Their findings were very similar to those of Clauw and colleagues (1997), but it is not known whether any of the non-bladder symptoms found associated with interstitial cystitis were directly related to the pathophysiology. Research on neurological etiological factors rather than bacteriological etiology in the area of bladder and pelvic pain is becoming more evident.

IC like FM is a condition of unknown etiology that is treatable but not curable. For patients with IC, the most common symptoms include the irritative symptoms of urinary frequency, urinary urgency and pelvic pain. Pain can be

experienced within the pelvis, bladder, urethral and vaginal areas. IC is a complex inflammatory condition of the bladder and is seen as a major portion of the “painful bladder” disease complex that includes a large group of urologic patients with bladder and/or pelvic pain and irritative voiding symptoms with negative urine cultures (Hanno, 1992). Hanno also lists FM as an associated disease with IC because of the over representation of FM in the IC population.

Current Definition of Interstitial Cystitis

In Japan in 2003, international experts met at the inaugural International Consultation on Interstitial Cystitis (Ueda, 2003) to define areas of agreement and differences in their approach to IC and to determine a uniform IC definition. The original definition of the Division of Kidney, Urologic, and Hematologic diseases of The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for IC was developed in 1989 and was intended mainly for research purposes to ensure that a homogenous group of patients with IC were available for IC studies. The original diagnostic criteria have been found to be too restrictive for clinical purposes with the resultant potential for misdiagnosis and under diagnosis of many patients with IC (Diokno, Homma, Sekiguchi, & Yasuyuki, 2003). Hanno (1994b) found that 90% of patients meeting the original NIDDK criteria were considered by IC experts to have the disease, but 60% who did not meet these criteria were also thought to have IC. Many IC patients were therefore excluded from research studies with only the most severely affected patients included. These original criteria have been described as a de facto definition (Hanno, 1994b).

The main objectives of this International Consultation on Interstitial Cystitis in 2003 were to define the basic symptoms that encompass the condition of IC and to develop a more appropriate terminology that represents this symptom complex. Discussion from the workshops indicated that chronic pelvic pain may not always be recognised as an essential component of the symptom complex. The final consensus from the 2003 International Consultation on Interstitial Cystitis adopted the term IC/CPPS to signify the symptom complex of chronic pelvic pain (CPPS), with urinary urgency and / or urinary frequency (Diokno et al., 2003). A draft algorithm for the treatment of painful bladder syndrome (including IC) was developed at the

International Consultation on Interstitial Cystitis in Monaco in August 2004 (Appendix B). This Consultation group also worked on a definition and review of the painful bladder. This latest version will be published in December 2004 (A. Rosamilia, personal communication, September 8, 2004).

Commonalities between FM and IC

As with FM, the majority of IC patients are female. The demographic features, associated features and response to tricyclic compounds are very similar in both conditions. One epidemiological study (Koziol, 1994) showed that the main symptoms in women with IC were frequency (92%), urgency (92%) and pelvic pain (70%). Physical assessment found vaginal and suprapubic tenderness. Bladder charts revealed an average number of 21 voids per 24 hours with an average interval of 2.6 hours between voids over night. Some authors refer to the FM associated disorder of irritable bladder syndrome as “interstitial cystitis” (Littlejohn, 1996).

Alagiri and colleagues (1997) undertook a study to determine the prevalence of concomitant disease in individuals with IC and compared these results with the general population. They concluded that IC has an unexplained association with certain other chronic diseases and pain syndromes including FM. Within this survey of 2682 patients with IC, 25% reported having comorbid FM. Another study (Aaron, Burke, & Buchwald, 2000) investigated the frequency of ten clinical conditions among three groups of patients with chronic fatigue syndrome (CFS), FM and temporomandibular disorder (TMD). The patients with FM had a significantly greater number of symptoms characteristic of IC compared with the patients with CFS and TMD or control subjects.

Significance of the Study

Despite the emerging evidence on commonalities between FM and IC and the listing of bladder irritability as a symptom of FM, there appears to be little discussion between the medical specialities on the issue of bladder symptomatology in FM. Rosamilia and Dwyer (2000) suggest that many women with lower urinary tract sensory disorders present after having unsuccessfully trailed antibiotics for their

urinary symptoms. This unsuccessful treatment and a failure to cultivate uropathogens will often lead the clinician to consider an alternative diagnosis in the realm of non-infective sensory disorders of the lower urinary tract. Rosamilia and Dwyer (2000) suggest that women presenting with irritative urinary symptoms should be assessed both gynaecologically and generally. A short rheumatological list of questions on FM symptoms could assist in the urological identification of possible FM sufferers within this group of women.

Perhaps the lack of a general assessment of women with FM for these non-infective sensory disorders of the lower urinary tract is because bladder irritability is one of the less common symptoms of the FM condition. Ang and Wilke (1999) describe two types of non-specific symptoms groups of FM. They describe the first group of symptoms as fatigue, non-restorative sleep, distress and morning stiffness occurring in 75% of patients. They describe the less common symptoms occurring between 25% and 50% of patients as irritable bowel syndrome, urinary frequency, headache, subjective swelling, diffuse paraesthesia, psychological distress and functional disability.

Research on issues related to these less common symptoms of FM such as lower urinary tract symptoms is needed to increase the awareness and knowledge development of the health professional regarding the disability and frustration that these less distinguishing symptoms may cause to patients. Hunt (1995) poses the question as to whether there is a void in the research in relation to bladder irritability. Hunt (1995: 440) refers to the importance of psychological factors and stress in bladder functioning and cites Smith in the Chinese proverbial description of the bladder as 'the mirror of the soul'.

Current Bladder Research Emphasis

The Division of Kidney, Urologic, and Hematologic diseases of The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) within the United States of America recognises that IC represents only one of a number of symptom complexes of chronic pain of bladder origin. In July 2000 the NIDDK invited applications for investigators to use ongoing prospective cohort studies, clinical

trials, and large patient databases to design epidemiological, quality of life, and health resource utilisation studies for chronic pelvic pain of bladder origin and IC (Kusek & Nyberg, 2000).

This research is providing information on the broader, more inclusive disorder of the symptom complex of chronic pelvic pain, and associated symptoms of urinary frequency and urgency. This research project on the epidemiology of chronic pelvic pain of the bladder and IC has attracted significant funds as the magnitude and the impact of the burden of chronic pelvic pain of the bladder symptom complex on the health of the US population is not known. In January 2004 the NIDDK announced a request for applications for a study entitled Interstitial Cystitis / Painful Bladder Syndrome: Epidemiology (Interstitial Cystitis Association, 2004a). The funding is a \$1,000,000 per year grant for a period of 5 years. These on going research grants and international consultations on IC demonstrate the clinical need to assess bladder symptomatology in these disabling conditions.

Social and Economic Impact

The increased consultation and research funding within the area of bladder pain and irritability reflects the need within both professional and community groups to view bladder health as a priority area of health research. This focus on bladder health increases the significance and relevance of all current research in this specific area. A recent survey by the John Hopkins Bloomberg School of Public Health in the United States (G. Anderson, 2003) found that chronic health conditions in that country were a major concern. The survey found that the majority of physicians, policy makers and the public were concerned that the nation's health care system was not appropriately meeting the needs of people with chronic disease. This was a significant survey where the attitudes of 1,741 physicians, 1,663 adults from the general public and 155 health policy makers were sampled.

A study on the service utilization costs for FM patients has shown that the annual cost per FM patient in the United States of America is \$2,274 US (Wolfe et al., 1997a). Rates of hospitalization occurred at approximately once a year and outpatient medical visits at 9.8 times per year. When alternative treatments were

added, the total outpatient service was once per month. This report confirms that patients with FM report more symptoms and comorbid and/or associated conditions than other patients with rheumatological conditions. The resultant impact on medical budgets and personal costs to patients for the treatment of FM is substantial.

Health Related Quality of Life

Health-related quality of life (HRQOL) is a multidimensional construct referring to an individual's perceptions of the effect of a health condition or disease and its resultant treatment (Lose et al., 1998). Kelleher, Cardozo, and Toozs-Hobson (1995) describe quality of life as an abstract concept that encompasses a person's perception of their physical, psychological and social well being and further describe quality of life as a subjective phenomenon influenced by culture, beliefs, self-concepts and life's goals and expectations. Currently there is an increasing interest in the development of health scales and indices for measuring subject's assessment of their symptoms and for their measuring quality of life. Health related quality of life (HRQOL) is one of several elements being studied in the field of medical outcome research according to Penson and Litwin (1997). They describe HRQOL as encompassing a wide range of human experience but emphasise the involvement of the patient's perception of their own health and ability to function in life.

The impact of lower urinary tract symptoms on the quality of life on women has been well documented over recent years. Pinnock and Marshall (1997) have shown that the impact and bothersomeness of lower urinary tract symptoms on quality of life in an Australian community is a major reason for people seeking medical help. It is important to determine the increased impact and bother that these urinary symptoms could have, not only on the financial impact to the sufferer but also on the quality of life of a person already coping with the many other symptoms of FM.

Bernard, Prince and Edsall (2000) reported a significant reduction in the quality of life in FM patients. In their study of 270 subjects with FM, most rated their present quality of life as 4.8 on a 0 to 10 scale compared to a score of 8.6 prior to having FM. They estimated their future quality of life as 9.6 in the absence of FM. A

recent study on health related quality of life in multiple musculoskeletal diseases (Picavet & Hoeymans, 2004) has shown that subjects with musculoskeletal diseases had significantly lower scores on all SF-36 health status dimensions than subjects without musculoskeletal disease. In this study, the worst health related quality of life patterns were found for FM, osteoarthritis of the hip, osteoporosis and rheumatoid arthritis.

Asbring (2001) in her study on the affects of chronic illness such as FM on women found that the illness can cause a radical disruption in a woman's biography and that the illness has profound consequences for her identity, especially in relation to her work and social life. A study by Schaefer (1995) of women living with FM reveals how women attempted to gain control of their illness, their symptoms, as they struggled to maintain a balance in their life. Validating the Interstitial Cystitis Symptom and Problem Index (ICSI/ICPI) within the FM population will enable accurate assessment of the impact of one group of these symptoms, the urinary symptoms of FM.

Health Outcome Measures

Dunkl, Taylor, McConnell, Alfano and Conaway (2000) assessed the responsiveness of FM clinical trial outcome measures, and found the Fibromyalgia Impact Questionnaire to be the most responsive measure to perceived clinical status. Bennett (2001) commented on this study and wrote of the need to develop outcome measures. Bennett remarked on the need for accurate quantification of relevant symptoms and physical findings in FM for defining improvement in clinical trials.

The measurement approaches used to assess HRQOL are generic or specific (condition-specific or patient-specific). Generic scales allow for comparisons between different demographic and cultural groups as well as across different disorders, severities of disease and interventions (Patrick & Deyo, 1989). McHorney, Ware, Lu and Sherbourne (1994) comment that these scales can also be used to measure the burden of illness of populations with chronic medical conditions as compared with normals. The use of the generic scale also enables meta-analysis to produce the combined results of different studies. Condition-specific or patient-

specific questionnaires do not have to cover a large range of disorders that may be inappropriate or irrelevant for one specific problem. There are therefore more specific and relevant questions to detect changes in the patient's condition (Streiner & Norman, 1996).

The Interstitial Cystitis Symptom Index and Problem Index (ICSI/ICPI) is a condition-specific instrument designed to measure the impact of the symptoms of urinary frequency, urinary urgency, nocturia and bladder pain in patients with IC. Condition-specific instruments should include the measurement of the presence of a symptom and the bothersomeness of the symptom. O'Leary and colleagues (1997) have developed such an outcome measure for IC where the different items of urinary pain, nocturia, urgency and frequency symptoms and their bothersomeness are combined in a symptom and problem index.

This ICSI/ICPI was developed to measure lower urinary tract symptoms and their impact in patients with IC. Because there is not a precise consensus definition of what constitutes the disease of IC, it is important to have a scientifically validated instrument to evaluate symptoms. O'Leary and colleagues (1997) commented on the plethora of new therapies for the treatment of IC and the need for reliable and valid outcome measures. Their development of the ICSI/ICPI was the result of the critical need to have a uniform and reliable method to evaluate these symptoms. The authors of the index comment that apart from its adjunct role in clinical decision making, the ICSI/ICPI will be valuable to future researchers in this area. This instrument has only been validated within the IC population.

Currently there is no validated instrument available for the assessment of significant bladder irritability and bladder pain or for the assessment of how problematic these symptoms are within the FM population. Such an instrument would enable rheumatologists, urologists and medical practitioners to quickly detect specify and assess the bothersomeness of the urinary symptoms for the FM patients and enhance referral to appropriate health professionals for management. A validated instrument for measuring these lower urinary tract symptoms and their impact will also be a valuable research tool, an objective quantifiable measure, especially where intervention is directed at improving the management of this problem.

Purpose of the Study

The purpose of this study is to investigate the impact and measurement of bladder irritability symptoms in Australian women who have been diagnosed with the condition of FM. This study will test the ICSI/ICPI within the female FM population for reliability and validity.

Research Questions

To validate the ICSI/ICPI instrument within a population of women diagnosed with the condition of FM who exhibit sensory urinary symptoms.

To establish the measured impact of lower urinary tract sensory symptoms on the quality of life of women with FM.

Summary

This is the first Australian study to seek quantification of lower urinary tract sensory symptoms and their impact on women diagnosed with FM and to validate an outcome measure for the symptoms and symptom impact. The investigation plans to increase awareness and discourse within the health professions about the disability and frustration that these less distinguishing features of FM can present. The validation of a condition specific outcome measure for documenting a patient's assessment of her symptoms and for measuring her health related quality of life is a step to provide accurate quantification of symptoms for bladder bother in patients with FM.

CHAPTER 2

LITERATURE REVIEW

Introduction

Current literature on the condition, symptoms, diagnosis, associated disorders and demographics of Fibromyalgia syndrome (FM) are examined in this chapter. The key FM symptoms of pain, stiffness, fatigue, insomnia and cognitive dysfunction, as well as the psychosocial implications of FM, are discussed. Current theories and models on the etiology of FM and possible etiological theories of bladder symptomatology in FM will be considered.

Treatment options and recommendations for the management of FM will be considered, with a focus on the role of patient education, exercise, pharmacological treatment and cognitive behavioural therapy. Specific attention is given to the urogenital symptoms associated with FM and their connection with interstitial cystitis (IC), chronic pelvic pain, and vulvodynia. Current literature on measures of health status and their development in regard to FM are also included in this literature review. The issues and challenges in relation to the measurement of genitourinary symptoms in women with FM are the primary themes of this thesis. This research was initiated because of the lack of such measurement tools for these genitourinary symptoms. This research will provide important information to women with these disabling symptoms.

This review will be an extensive review on the available areas of literature covering the wide range of symptoms, etiological possibilities and treatment management strategies of FM because all of these areas may be associated with, or impact on, the urogenital influence of FM on women.

In January 2002, the World Health Organisation launched the Bone and Joint Decade. The naming of this decade was initiated in response to the identification of a world epidemic of musculoskeletal disease (Hazes & Woolf, 2000). The World Health Organisation World Global Burden of Disease Project reported that the musculoskeletal conditions represented more than half of all chronic conditions (Dieppe, 1998). The Australian Coordinator of the Bone and Joint Decade (Brooks & Hart, 2000) recognised that many musculoskeletal conditions produce chronic pain, disability and a decrease in the quality of life. They commented that the Bone and Joint Decade will attempt to bring together research, education and service to improve the life of millions of Australians who suffer each week from these conditions. Littlejohn and Morand (2002) concluded that, with the impetus that this Bone and Joint Decade will bring to research in rheumatic disease, the medical profession can expect greater understanding of disease mechanisms with a subsequent increase in treatment options.

More specific to FM is the development of one of the largest international FM research centres at the University of Michigan Centre for Chronic Pain and Fatigue Research. The report of the Senate Appropriations Committee of the USA has urged the National Institute of Health (NIH) to increase the emphasis on the neurological aspects of FM and to encourage new partnerships in FM research between the two NIH institutes. The report also encourages studies for drugs and biologicals which are Fibromyalgia-specific (Liller, 2002).

The USA Coalition for Urological Research and Education (CURE) encourages and funds research that will improve the care of patients with urological conditions. The Coalition emphasises not only the individual suffering and the financial burdens involved with urological conditions, but also the fact that urological research is the most under-funded research area in their nation (Interstitial Cystitis Association, 2003). The Coalition for Improved Bladder Health is another partnership that was formed with the aim of increasing awareness of bladder and pelvic health issues and includes a diverse collaborative group of health professional organisations.

The Fishbein Foundation and the Interstitial Cystitis Association (ICA), also piloting research programs in the United States, are providing large financial grants for research areas such as the epidemiology of IC and abnormalities in sensory nerves in the bladder of IC patients (Interstitial Cystitis Association, 2004). The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) announced in 2004 applications for a large scale five-million-dollar study entitled 'Interstitial Cystitis/Painful Bladder Syndrome: Epidemiology' (Urology Times, 2004). It is against this backdrop of advances in rheumatic and urological disease research and increasing awareness that the current study on Fibromyalgia and bladder irritability has evolved.

Fibromyalgia (FM) has mainly been the domain of the rheumatologist until now, with the primary focus on pain management. This horizon is expanding with multiple health specialities now having input into the research and intervention strategies for the many facets of this multi-dimensional disorder (Busch, Schachter, Peloso, & Bombardier, 2002b). This literature review will include the primary and associated symptoms of this condition with particular focus on one of the associated symptoms, the urogenital symptoms. The lack of research specifically in the area of the genitourinary symptoms of FM, and the measurement and impact of these symptoms, is apparent. Recent research into the etiological factors contributing to FM and consideration of studies in the area of effective treatment and management will act as background to further discussion of these urogenital symptoms.

Fibromyalgia

Fibromyalgia is a chronic musculoskeletal pain syndrome characterised by widespread pain and predictable tenderness at numerous anatomical sites, together with other characteristic clinical manifestations (Wolfe et al., 1990). The World Health Organisation has classified FM in the International Classification of Diseases as non-articular rheumatism. It is thought to be a pain amplification syndrome related to increased sensitivity of dynamic components of the pain system (Littlejohn, 1996). *Fibro* refers to the fibrous tissue of ligaments and tendons, *myo* refers to muscle and *algia* refers to pain (Jain et al., 2004).

Bennett (2002d) describes the current paradigm of FM as a complex pain syndrome in which abnormalities of central sensory processing interact with some peripheral pain generators and psychoneuroendocrine dysfunction, generating a wide spectrum of symptoms and distress. The classic primary symptoms of FM are the diffuse pain, fatigue, stiffness and non-restorative sleep. Associated symptoms include morning stiffness, gastrointestinal symptoms, genitourinary problems, paraesthesia, temperature sensitivity, thoracic pain and dysfunction, cognitive disorder, vestibular problems, oesophageal dysmotility, headaches, restless leg syndrome, dizziness and anxiety.

Littlejohn (2001) distinguishes between two different types of chronic musculoskeletal pain syndromes, one involving pain generation and the other being pain amplification. The pain generation syndromes include the myofascial pain syndrome and segmental spinal dysfunction. The pain amplification syndromes include FM, regional pain syndrome and complex regional pain syndrome.

The International Association for the Study of Pain, in its classification of chronic pain, defines FM as diffuse musculoskeletal aching and pain with multiple tender points (Merskey & Bogduk, 1994). They describe the syndrome as chronic with remissions being uncommon. Jain and colleagues (2004) in the Canadian Consensus Document on FM classify FM as one of the large group of soft tissue pain syndromes. They describe the soft tissue pain syndromes as characterised by pain from the periarticular structures located outside of joint capsule and periosteum, namely ligaments, tendons, fascia, bursae and muscles.

FM associates with significant disability. Kaplan, Schmidt and Cronan (2000) have demonstrated that patients with FM obtain lower scores on a validated measure, the Quality of Well Being Scale, than patients diagnosed with chronic obstructive airways disease, rheumatoid arthritis, atrial fibrillation, advanced cancer and some other chronic diseases. This is indicative of the quality of well being and the significant disability experienced by people with FM.

Diagnosis

In 1990, the American College of Rheumatology published criteria (Wolfe et al., 1990) for classification of patients as having FM. These criteria are also often used for clinical diagnosis. The criteria comprise widespread pain defined as pain on the left and right sides of the body, as well as above and below the waist, for three months duration, together with the presence of abnormal tenderness on digital palpation, at 11 or more out of 18 specifically designated sites. These sites are deemed 'tender points' when 4 kilograms of palpation pressure induces pain. For a 'tender point' to be positive, the subject must experience the palpation as painful and not just tender. These classification criteria are research based and are validated and rigid. The tender points of the classification criteria are as follows:

- Bilateral occiput at the suboccipital muscle insertion.
- Bilateral low cervical at the anterior aspects of the intertransverse spaces at C5-C7.
- Bilateral trapezius at the mid point of the upper border.
- Bilateral supraspinatus at origins above the scapula spine near the medial border.
- Bilateral second rib at the second costochondral junctions just lateral to the junctions on the upper surfaces.
- Bilateral lateral epicondyle 2cm distal to the epicondyles.
- Bilateral gluteals in the upper outer quadrants of buttocks in anterior fold of the muscle.
- Bilateral greater trochanter posterior to the trochanteric prominence.
- Bilateral knee at the medial fat pad proximal to the joint line.
- Axial skeletal pain in the cervical spine, anterior chest, thoracic spine or lower back must also be present.

These classification criteria were designed as a tool to standardise research into FM. The ACR classification criteria have pain at the centre of their definition. They do not encompass the other symptoms of sleep disturbance, fatigue, cognitive dysfunction, psychological distress, irritable bowel, irritable bladder and other concurrent symptoms. Crofford and Clauw (2002a) suggest that by excluding symptoms other than pain, the ACR criteria fail to encapsulate the essence of the FM

syndrome. These authors recognise that one of the strengths of these criteria, from a research point of view, is that FM patients who meet the ACR criteria are at the extreme end of the pain and tenderness spectrum.

A diagnosis is fundamental to managing any medical condition, but it can be particularly problematical when dealing with patients who suffer with chronic and musculoskeletal pain (King, 2004). King describes a diagnosis as a process whereby data provided by or gained from the patient are integrated with scientific knowledge to identify the nature and cause of a medical condition. King offers four distinct diagnostic strategies each with a distinct rationale. These include: the Gestalt or 'heuristic' method that is a product of a rapid process of pattern recognition that is based on the clinician's previous experience; the hypothetico-deductive strategy where a short list of possible diagnostic alternatives is considered; the exhaustive diagnostic strategy involving a comprehensive assessment of all aspects of the patient and his/her symptomatology; and the algorithm strategy providing an evidence-based algorithm with rational alternatives.

Many clinicians see a need to develop better criteria for clinical diagnosis in the community, recognising that the ACR classification criteria address only two domains of this multi-faceted disorder, namely pain and tenderness. Because of the growing recognition of the need for better information about all of the objective abnormalities in people with FM, and the need for an integrated approach to the diagnosis, a Canadian consensus document on FM has been developed (Jain et al., 2004). An expert subcommittee from Health Canada established the terms of reference and selected the Expert Medical Consensus Panel representing treating physicians, teaching faculty and researchers (Jain et al., 2004). This consensus document includes a clinical case definition, diagnosis and management of FM.

Russell (2004) sees the development of this document as the next step in a longer term plan. He comments that, since the development of the ACR 1990 Classification Criteria for the Fibromyalgia Syndrome, it has been apparent that it is necessary to determine what to include in a clinical case definition for use in community medicine. This clinical case definition from Health Canada will be refined and validated by the international scientific community and it will be of

interest to the FM community of both health care professionals and patients to follow its influence within Canada and within other international medical communities.

Demographics

FM is a disease of various age groups, affecting more women than men. It is the third most common diagnosed rheumatic disorder after osteoarthritis and rheumatoid arthritis. FM affects between 2% and 6% of the population. A community prevalence study by Wolfe, Ross, Anderson, Russel and Herbert (1995) has shown the overall prevalence at 3.4% in women and 0.05% in men. This study showed an even higher prevalence 7% in older women between the ages of 65 and 79 years. Prevalence shown in the London Fibromyalgia Epidemiology Study (White et al., 1999a) was 4.9% for women and 1.6% for men.

Male patients have been shown to have fewer symptoms, fewer tender points, less common 'pain all over' symptoms, fatigue, morning fatigue and irritable bowel symptoms than women (Yunus, Inanici, Aldag, & Mangold, 2000). The reasons for this variation are unclear but seem multifactorial. Yunus (2002b) describes these gender differences as a composite of biology, psychology and sociocultural factors. Gijbbers (1997) suggests that although women may be constitutionally more prone to pain than men, their attitudes to pain allow women to report on their pain in a way less likely to be biased by psychosocial issues. Gijbbers also suggests that the essential difference between the sexes is that women are more discriminating than men in their perceptions of pain-related sensations and that they develop a repertoire of strategies that help them cope with pain more efficiently.

The usual age range at diagnosis of FM is 34 to 53 years although the age at onset is usually between 29 to 37 years (Boissevain & McCain, 1991). It has been diagnosed in children and older people. The prevalence of FM increases with age and is commonly associated with comorbid disorders (Wolfe et al., 1995). Patients can endure many years of pain and associated dysfunction before a correct diagnosis is made.

Although the majority of FM patients experience pain and fatigue, there is no obvious tissue damage identified on clinical evaluation. Kramis (1998) describes FM

as ‘pain without tissue pathology’, which undermines the individuals’ credibility and interferes with all aspects of their life. Wagner (1997) describes chronic pain as having no function and being destructive both physically and psychologically. The definition for pain set out by the International Association for the Study of Pain (Merskey & Bogduk, 1994) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. This definition fits the pain of FM very well. Wolfe and colleagues (1997a) concluded that patients with established FM, who were followed in a tertiary hospital setting for seven years, showed markedly abnormal scores for pain, functional disability, fatigue, sleep disturbance and psychological status.

Littlejohn (1996) has stated that the commonness of the problem of FM, together with its potential for serious disability, makes it a major cause of loss of health quality for the individual and a significant economic loss to the community. A six-year prospective study of a cohort of FM patients by Baumgartner and colleagues (2002b) examined the long term prognosis in patients with FM. Their results showed that most of the symptoms remained stable. Although pain had increased, some aspects of the patients’ quality of life had improved. An Australian two-year outcome study from a rheumatology community practice showed a remission in approximately 25% of the patients (Granges, Zilko, & Littlejohn, 1994). Wolfe and colleagues (1997a) followed up 538 FM tertiary hospital referred patients over a seven-year period to find that their markedly abnormal scores for pain, functional disability, sleep disturbance, fatigue and psychological status did not change significantly over that time. Fifty-nine percent of the study participants rated their health as fair or poor. Possibly, community-managed FM patients may have a better prognosis than those patients severe enough to attend tertiary institutions.

A recent research study (Giesecke et al., 2003) supports the clinical impression that there are distinct sub groupings of FM patients. Giesecke and colleagues noted that although the ACR criteria for FM were used to identify people with pain and tenderness, these individuals were not a homogeneous group. The researchers recognised that, as well as patients experiencing different clinical symptoms, there was the influence of the biologic, psychological and cognitive factors on their symptom expression. One group of FM patients exhibited extreme

tenderness, but no associated psychological and cognitive factors. Another group exhibited moderate tenderness with normal mood levels. A third group exhibited significant mood and cognitive factor influences on their symptomatology (Giesecke et al., 2003).

Key Symptoms of Fibromyalgia

Yunus (Baldry, 2001) divides and describes the symptoms of FM as musculoskeletal symptoms, non-musculoskeletal symptoms and associated symptoms. The musculoskeletal symptoms are listed as pain at multiple sites, stiffness, hurting all over and swollen feelings in soft tissue. The non-musculoskeletal symptoms include fatigue at most times of the day, morning fatigue, poor sleep, and paraesthesia. Associated symptoms as listed by Yunus (Baldry, 2001) include self-assessed anxiety, headaches, dysmenorrhoea, irritable bowel symptoms, restless leg syndrome, self-assessed depression, sicca symptoms, Raynaud's syndrome and female urethral syndrome.

Littlejohn (2001) comments that most patients with FM experience a fluctuating set of symptoms occurring over months or years. He also includes the symptoms of cognitive dysfunction, dizziness, irritable bladder syndrome, multiple chemical sensitivities and neurally mediated hypotension. The main symptoms reported on in this literature review include the key symptoms of FM and include pain, non-restorative sleep and insomnia, cognitive dysfunction, autonomic nervous system and neuroendocrine dysfunction.

Pain

Until the 1960s, pain was thought only to be a response to tissue damage. The medical community understood only the Cartesian view of pain at this time. Melzack (1996) describes this Descartes' concept of pain as that produced by a direct transmission system from injured tissue in the body to a pain centre in the brain. He comments that this concept of pain has dominated pain therapy until recent times.

In 1965, the Melzack-Wall Gate Control Theory (Melzack, 1996) suggested that a mechanism in the dorsal horns of the spinal cord acted as a gate that facilitated or inhibited the transmission of pain from the body to the brain. Melzack's Gate Control Theory encompassed the dynamic action of brain processes. The Gate Control Theory did not include the long term changes in the central nervous system resulting from the noxious input or other external influencing factors (Loeser & Melzack, 1999). Melzack (1996) commented that this theory does not explain some of the chronic pain conditions.

Govind, (2004) in discussing pain management, states that “for treatment to be logical, rational and biologically plausible, an understanding of the mechanisms and an appreciation of the pathophysiology remains paramount - as exemplified by the successful treatment of hypertension, gastric ulcer and asthma. Devoid of this basic understanding, treatment may be empirical or at best a ‘guesstimate’” (p.1). At the recent International Association for the Study of Pain (IASP) Neuropathetic Pain Meeting, there was debate on the current IASP definition for neuropathic pain (Siddal, 2004). Some delegates took a broad approach of nervous system dysfunction to neuropathic pain and included conditions such as FM and irritable bowel syndrome while others preferred a narrower definition such as evidence of a nervous system lesion (Siddal, 2004). There is still non-consensus on the definition of neuropathic pain within the confines of the International Association for the Study of Pain.

The Pain of Fibromyalgia

Bennett (2002e) identifies four major sites of pain in FM patients as peripheral tissues, the spinal cord, the brain and the descending modulation. These sites reflect the input of the peripheral pain generators, dorsal horn sensitisation, psychological influences and the modulating influence of the descending pathways. Pain therefore can be modified or influenced by various physiological and psychological factors.

Pain is the primary symptom of FM and is often described as ‘pain all over the body’. The International Association for the Study of Pain, in their classification of chronic pain (Merskey & Bogduk, 1994), describe the pain of FM as widespread

aching of more than three months duration, perceived as deep pain and usually referred to muscle or bony prominences. The common areas are cervical, thoracic and lumbar spines. Pain in the trunk and proximal girdle is described as aching while distal limb pain is perceived as associated with swelling, numbness and stiffness. Pain intensity fluctuates daily, and although the pain can move from one area of the body to the other, it is usually continuous (Merskey & Bogduk, 1994). In the ACR 1990 criteria report, 97% of patients had widespread pain. Over 75% of patients had pain in the cervical area, posterior thorax or lower lumbosacral area and 56% had pain in at least 15 of the zones when the body was divided into 30 regions (Wolfe et al., 1990).

Jain and colleagues (2004), in the Canadian Consensus Document on FM, describe the pain of FM as any combination of burning, searing, tingling, shooting, deep aching, stabbing, sharp and/or feeling bruised all over. They list the characteristics of FM pain as allodynia, hyperalgesia, persistent pain, pronounced summation effects and after-reaction to repetitive stimuli and tenderness on examination. Other listed features of FM pain include widespread pain, non-anatomical distribution, delay in onset following injury, pain felt in areas of perceived sensory deficit, diffuse arthralgia, shortness of breath and chest pain, low back pain, leg cramps, generalised stiffness and chronic headache (Jain et al., 2004).

The core components of FM are chronic musculoskeletal pain and abnormal soft tissue tenderness, without tissue damage. Although muscle exhibits signs of tightness, examination does not reveal inflammation, degenerative changes or abnormal neurological signs. Maquet, Croisier, Renard and Crielaard (2002) compared muscle performance in women with FM and healthy women free of muscle and joint disease. The variables reflecting muscle strength, muscle fatigue, resistance and static muscle endurance were diminished in the FM group.

Overview of the Pain of Fibromyalgia

Zimmerman (1991) describes the pain of FM as a complex interaction of nociceptive, neuropathic and other dysregulatory central nervous system and psychosomatic mechanisms. Nociceptor pain results from the excitation of specialised nervous sensors that signal potentially harmful stimuli. Zimmerman

(1991) commented on metabolic deficiencies and neurogenic inflammation resulting from the release of Substance P and other neuropeptides from peripheral nerve endings, as possibly resulting in the chemical sensitisation of nociceptors and hyperalgesia. The neuropathic pain as described by Zimmerman is due to pathological mechanisms within the nerve cells and fibres in the peripheral and central nervous system. He suggests that the possible resultant neuronal hyperexcitability encouraged by 'a disturbed axonal transport system' may be causative factors of pain in FM.

Cook, Lange, Ciccone, Liu, Steffener and Natelson (2004) discuss the emergence of brain imaging as an investigative tool, which has resulted in an increased understanding of the complexities of the nociceptive system in humans. The function of the nociceptive system in patients with FM was examined using functional magnetic resonance imaging (Cook et al., 2004). These studies concluded that subjects with FM were significantly more sensitive to experimental heat pain, and exhibited greater activity than controls, over multiple brain regions, in response to painful and non-painful stimuli. The authors conclude that these results provide support for a physiological explanation for FM pain, and comment that FM symptoms may be being maintained by amplified neural responses to afferent sensory stimuli. Their results indicate that brain responses to sensory stimuli in regions of the brain responsible for sensory, cognitive, and emotional aspects of the pain experience are increased in FM.

Borg-Stein (2002) describes peripheral pain generators within local musculoskeletal, neurological and other sources as increasing in FM patients. Borg-Stein divides peripheral pain generators into five major categories: joint and cartilage, enthesopathies, soft tissue pain, neuropathic pain, and visceral pain. She recommends a methodical search for these nociceptive peripheral pain generators, to decrease the total pain burden by decreasing the perpetuation of central sensitisation and decreasing the stimulus. She comments that FM sufferers are more able to participate in exercise programs if these peripheral musculoskeletal and neurologic pain generators are found and appropriately treated. These pain generators have features that distinguish them from the widespread pain of FM.

Chronic Pain and Its Impact

As scientific inquiry into the neurobiology of chronic pain increases, the multiplicity of symptoms in FM becomes more understandable. The concept is emerging that FM is positioned toward the more painful end of a continuous spectrum of chronic pain (Bennett, 2000).

In this area of chronic pain, Staud (2002) comments on the neuroplasticity of the brain where the central nervous system can learn and change, where the central nervous system adjusts and remodels itself if there is a need for different modifications or different expressions. FM sufferers fall into the category of chronic pain. The American Pain Society has created the phrase “Pain: The Fifth Vital Sign” to increase the awareness of pain treatment among health professionals (Clark 2004). They are encouraging health professionals to consider pain as the fifth vital sign and to assess patients for pain every time they check for pulse, blood pressure, core temperature and respiration. Jackson (2002) also refers to pain as the fifth vital sign. She describes chronic pain as the type of pain that does not serve any known purpose and that has outlived its usefulness, and describes chronic pain as a signalling system stuck on the ‘on’ position.

Blyth (2003) believes that chronic pain such as musculoskeletal conditions and injury should be a recognised health priority in the public health arena in Australia. He describes chronic pain as waiting on the sidelines to be recognised. Though there is evidence on the efficacy of treatments for chronic pain, the health care policy on chronic pain is minimal in Australia (Blyth, 2003).

Chronic pain can affect people’s identity, interrupt behaviour, interfere with functioning and affect their sense of who they are (Harris, Morley, & Barton, 2003). Harris and colleagues (2003) have shown that depression and adjustment problems, in chronic pain patients, can result from extended interference with social roles and personal identity rather than momentary frustrations. McCracken and Eccleston (2003) recommend the acceptance-based approach to chronic pain rather than the coping strategies that have been dominant in clinical and research areas. Their research results from a chronic pain study have shown that the ‘coping with chronic pain’ variables were weakly related to acceptance of pain and unreliably related to

pain adjustment, while the 'acceptance of chronic pain' was associated with less pain, disability, depression and pain-related anxiety (McCracken & Eccleston, 2003).

Two independent cross-sectional studies on the acceptance of pain (Viane et al., 2003) have confirmed the value of acceptance of pain in predicting well-being in patients suffering from chronic pain. The researchers found that the acceptance of chronic pain was strongly related to engagement in normal life activities and the recognition that pain may not change. They conclude that the acceptance of chronic pain is best envisaged as the shift away from pain to non-pain aspects of life, together with a shift away from the search for a cure and acknowledging that their pain may not change (Viane et al., 2003).

Staud (2002) refers to pain as not just a biological phenomenon, but as a psychological and social phenomenon. Sator-Katzenschlager, Schiesser and Kazek-Langenecker (2003) studied the effects of effective pain reduction on mood, behavioural and cognitive outcome measures in chronic pain patients. Significant reductions in pain intensity were accompanied by improvement in behavioural and cognitive dimensions, while mood and psychological well-being did not improve (Sator-Katzenschlager et al., 2003).

Gender-related Differences in the Experience of Pain

In the United States of America and other Western cultures, more women than men seek medical advice for symptoms of functional pain disorders (Chang & Heitkemper, 2002). The authors of a study on gender differences in irritable bowel syndrome suggest that influencing factors may be gender-related differences in visceral sensitivity, central nervous system pain processing, neuroendocrine, and autonomic nervous system and stress reactivity. Research in this area (Naliboff et al., 2003b) has shown that different areas of the brain are stimulated in reaction to pain depending on the gender. In response to the same painful stimulus, the female brain showed greater activity in the emotion-based limbic system, while in men, the analytical-based centres of the cognitive regions resulted in greater activity (Naliboff et al., 2003b). This issue of gender-related pain differences might be relevant to FM sufferers, because the majority of sufferers are female.

Hoffman and Tarzian (2001) have commented that even though women more readily seek treatment for pain than men, they are less likely to receive it. The authors comment on several important questions around the biological origins of pain, gender differences related to pain and possible gender bias in the treatment of pain. They note the differences in the psychological factors influencing pain in how men and women attribute different meaning to their experience of pain.

Pain of Urogenital Origin

Pain of urogenital origin is a specific field in the area of chronic pain conditions. There are many specialities and multi-disciplinary centres for the management of pain involved with research into pain from the urinary tract. These include urologists, urogynaecologists, gynaecologists, surgeons, anesthesiologists, neuroscientists, psychologists and physiotherapists amongst many health professionals. It is recognised that many patients who experience pain of urogenital origin often suffer immensely and without the benefit of specific pain relief strategies (International Association for the Study of Pain, 2000). Researchers (Wesselmann, Burnett, & Heinberg, 1997) explain pain syndromes of the urogenital and rectal areas as well described but poorly understood and under-recognised focal pain syndromes. They list vulvodynia, orchialgia, urethral syndrome, penile pain, coccygodynia, prostatodynia, perineal pain, proctalgia fugax and proctodynia in this list of pain syndromes. The etiology of these pain syndromes often remains unknown.

Pain Outcomes

Bennett (2000) describes some of the possible end results of chronic pain as depression, marital relationship issues, vocational problems, medication dependency, sleep disorders, physical fatigue, personality changes, functional disability, emotional fatigue, painful movements, muscle deconditioning and stress increases.

A recent Australian study (Oldroyd et al., 2003) explored the views of general medical practitioners on the care of the patient with a chronic disease. This qualitative study revealed consistent themes regarding the complexity of chronic disease management. Tension from the differences between the patients and their general practitioners' goals for care, time-consuming aspects of care and the lack of structure preventing the practitioner from being involved in structured

multidisciplinary care of their patients were all included in the emerging themes. Recommendations from the study included changes to assist the medical general practitioners in moving from acute care to providing longer term care as part of a multi-disciplinary team (Oldroyd et al., 2003).

Fatigue

The International Association for the Study of Pain describes fatigue as affecting 80% of people with FM and describes its severity as severe enough to interfere with daily activities (Merskey & Bogduk, 1994). Wolfe, Hawley and Wilson (1996) describe fatigue as a poorly understood symptom that is prevalent in several rheumatic conditions. Fatigue for FM patients is often worse in the morning with many of them experiencing unrefreshed sleep. Jain and colleagues (2004) note that the type of mechanism that generates fatigue can classify fatigue and assist in its assessment. They refer to the following classification in assessing fatigue: structural fatigue, muscular fatigue, arousal fatigue, motivational fatigue, oxygenation fatigue and metabolic fatigue.

Nicassio, Moxham, Schuman, and Gevirtz (2002) evaluated the three predictors of fatigue in patients with FM as depression, sleep quality and pain. Their findings indicate a dysfunctional, cyclical pattern of heightened pain and non-restful sleep underlying the experience of patients' fatigue. In a study to determine diurnal rhythm characteristics of pain, stiffness and fatigue in patients with FM, the ratings of pain, stiffness and fatigue were found to be significantly correlated and revealed diurnal and possible weekly rhythmicity (Bellamy, Sothorn, & Campbell, 2004). A structured, evidence-based review of all available literature on the coexistence of fatigue and pain has been completed (Fishbain et al., 2003). Of the 17 reports that met the quality criteria, 94.1% indicated there was an association between fatigue and pain. Additionally, 100% of a subgroup of 13 reports indicated there may be an etiological relationship between fatigue and pain (Fishbain et al., 2003). The researchers recommend that future research directions consider these possible mechanisms for the relationship between fatigue and pain.

Soderberg, Lundman and Norberg (2002) clarified the meaning of fatigue and tiredness as narrated by women with FM and healthy women. These results inform us that tiredness and fatigue are experienced differently by women with FM compared to healthy women who experience fatigue. For women with FM, the findings revealed four major themes: the body as a burden, an interfering obstacle, an absent presence and being in hope of alleviation. For healthy women, the main theme was of needing natural recovery. This study has shown that fatigue experienced and narrated by women with FM is quite different from the experience of tiredness as explained by healthy women.

The majority of patients with FM and all patients with chronic fatigue syndrome experience fatigue (Clauw & Chrousos, 1997b). These two conditions share overlapping clinical features. These authors suggest that current studies have not shown that poor sleep is the primary cause of these illnesses. However, the authors attribute some of the symptoms and physiological abnormalities to poor sleep such as the disruption of the circadian secretion of hormones released during sleep.

Guymer and Clauw (2002) describe fatigue as one of the most prevalent features of FM, affecting between 76% and 81% of patients. For management of the fatigue, they suggest a multi-modal treatment model that incorporates both pharmacological and non-pharmacological methods. The non-pharmacological methods include patient education on sleep hygiene, exercise management, energy expenditure and activity pacing. Pharmacological treatment includes the tricyclic antidepressants and serotonin reuptake inhibitors. Arnold, Keck and Welge (2000) undertook a meta-analysis and review of antidepressants for use in FM. Nine of sixteen trials were suitable for meta analysis. When compared with placebo, the tricyclic medications were associated with effect size larger than zero for all measurements. The largest effect was apparent in sleep quality. The authors recommend further randomised, double blind, placebo-controlled parallel designs where the antidepressants are administered at therapeutic dose ranges (Arnold et al., 2000).

Non-restorative Sleep and Insomnia

The International Association for the Study of Pain describes sleep disturbance as affecting 75% of people with FM and describe the feeling on waking as unrefreshed and tired (Merskey & Bogduk, 1994). Patients are encouraged to develop good sleep hygiene, to maintain low impact exercise, to pace their daytime activities, to slowly wind down activity in the evening, to use a supportive mattress and pillow, and to effectively manage any psychological problems. They are encouraged to continue with low dose tricyclic antidepressants or other prescribed medication where appropriate. Moldofsky (2002) suggests that tricyclic drugs may provide long term benefit for improving sleep, but queries the continuing benefit of these medications beyond one month in the reduction of pain. Growth hormone is reported to improve symptoms, but the high economic cost and the need for an injection restrict its use (Moldofsky, 2002).

Research to characterise the patterns of electroencephalographic sleep and its association with sleep and pain in people with FM concluded that alpha intrusion during sleep can be of different patterns (Roizenblatt, Moldofsky, Benedito-Silva, & Tufik, 2001). Roizenblatt and colleagues (2001) detected three distinct patterns of alpha sleep activity in FM patients: phasic alpha that was simultaneous with delta activity in 50% of patients, tonic alpha that was continuous through non-REM sleep in 20% of patients and low alpha activity in 30% of patients. The authors report that 83.7% of control subjects exhibited low alpha activity. The phasic alpha intrusion pattern correlated better with clinical manifestations of FM (Roizenblatt et al., 2001).

Electroencephalographic evidence of rapid alpha wave intrusion into slower delta wave deep sleep periods in FM patients are shown to be significantly greater than in controls (Boissevain & McCain, 1991). Shaver, Lentz, Landis, Heitkemper, Buchwald and Woods (1997) found on polysomnography, that FM patients had more level I transitional sleep, more sleep-state changes and a higher sleep fragmentation. Studies by Affleck, Urrows, Tennen, Higgins and Abeles (1996) showed that, with FM patients, one night of poor sleep was followed by a significantly more painful day and another poorer night's sleep. Tryptophan, an amino acid that is the precursor of serotonin, is a significant neurotransmitter in the pathways related to level IV

sleep. The reduced concentration of tryptophan in relation to other plasma amino acids suggests an abnormality in serotonin metabolism (Bennett, 1993).

Italian researchers (Sarzi-Puttini et al., 2002) evaluated daytime hypersomnia in patients affected by FM (n=30) and found that the occurrence of daytime hypersomnia in these patients is linked to a greater severity of FM symptoms and evidence of greater polysomnographic alterations. Patients with daytime hypersomnia displayed a higher number of tender points ($p < 0.01$), a higher subjective pain score ($p < 0.05$) and more fatigue ($p < 0.05$). These patients had significantly less effective sleep than FM patients with no daytime hypersomnia ($p < 0.05$), with a lower proportion of level III sleep ($p < 0.001$), level IV sleep ($p < 0.001$) and twice as many arousals as per hour of sleep ($p < 0.01$) (Sarzi-Puttini et al., 2002).

A common cause of sleep deprivation for FM patients is restless leg syndrome, an unpleasant sensation in the lower limbs resulting in an urge to frequently move the legs. Yunus and Aldag (1996) investigated the prevalence of restless leg syndrome and leg cramps in FM patients to find these symptoms were significantly more prevalent in FM patients and in those with rheumatoid arthritis than in normal controls.

It is now recognised that sleep deprivation is a very serious health and safety risk factor within our communities and workplaces. The research focus on sleep is reflected in the Woolcock Institute of Medical Research 2nd Annual Sleep Loss Symposium held in Sydney, Australia in November 2004. Internationally there is increased interest in the health issues resulting from chronic sleep loss. Lamberg (2004) refers to the harm on health and quality of life of 70 million individuals in the United States of America because of chronic sleep loss and sleep disorders. The United States Surgeon General, R H Carmona, is cited in Lamberg (2004) commenting on sleep problems costing their nation \$15 billion in health care expenses and \$50 billion in lost productivity annually. The National Centre on Sleep Disorders Research in the United States aims to increase recognition and treatment of sleep disorders to cut health costs, treat sleep disorders and improve public health and quality of life of sufferers (Lamberg, 2004).

This deprivation of restorative sleep is also an area of continuing research specifically in the FM area as non-restorative sleep is a major symptom for FM sufferers that can contribute to fatigue and intensify pain.

Cognitive Dysfunction

Patients with FM frequently report a decline in cognitive functioning, memory and mental alertness. This is also referred to as neurocognitive dysfunction. Jain and colleagues (2004) describe this as cognitive fatigue rather than a fixed impairment. They list the symptoms of cognitive dysfunction as: cognitive fog; problems with linguistic performance; dyslexia; difficulty with writing, reading mathematics, word retrieval and speaking; and short term memory dysfunction. Researchers (Park, Glass, Minear, & Crofford, 2001) evaluated FM patients for the presence of cognitive deficits and tested the hypotheses that these abnormalities would fit into a model of cognitive ageing. They concluded that cognitive impairment, especially memory and vocabulary deficits, were evident although they found that the cognitive defects were not global. Their results show that there is cognitive dysfunction in FM patients and that it is related to pain.

One study on sleep, daytime symptoms and cognitive performance in patients with FM (Cote & Moldofsky, 1997) concluded that, rather than an impairment in accuracy, the cognitive performance of FM patients was affected by a slower speed in information processing, possibly due to pain, non-restorative sleep and mental fatigue. Sephton, Studts, Hoover, Weissbecker, Lynch, Ho, McGuffin and Salmon (2003) investigated the biological and psychological factors associated with memory function in FM. Although the authors suggest that their interpretation of results is limited by the lack of contrasting data from an age-matched healthy sample, the study suggests that hypocortisolism and depressive symptoms are factors underlying the cognitive deficits in FM.

Associated Disorders and Other Symptoms of Fibromyalgia

Claw (1995a) comments on the significant overlap between FM and other systemic illnesses/syndromes such as somatoform disorders, chronic fatigue

syndrome and Persian Gulf Syndrome. He lists these overlapping conditions as headaches, irritable bowel syndrome, temporomandibular dysfunction, non-cardiac chest pain, myofascial pain syndrome and urogenital symptoms. Clauw, when interviewed by Meisler (2000), described a spectrum of regional syndromes that involve different areas of the body in which there is a bidirectional relationship with FM. These include migraines, interstitial cystitis, non-cardiac chest pain and mitral valve prolapse. The ACR Criteria for the Classification of FM (Wolfe et al., 1990) includes the following as symptoms: sleep disturbance, 'pain all over', fatigue, morning stiffness > 15 minutes, anxiety, headache, prior depression, irritable bowel syndrome, sicca symptoms, urinary urgency, dysmenorrhea history and Raynaud's disease. Some of these associated disorders and symptoms will now be considered.

Irritable Bowel Syndrome

Irritable bowel syndrome and FM share many similarities. Both conditions are defined and diagnosed by symptom-based criteria. Both are defined as a symptom complex. There is no biological marker for either condition and the pathophysiologic basis for both is still unclear. In 1989, a group of investigators and experts on functional gastrointestinal disorders proposed a set of criteria known as the 'Rome' criteria. An updated set of criteria, the 'Rome II' was first published in 2000 (Fennerty, 2003). Fennerty describes the criteria as useful in ensuring similar patients are enrolled in clinical research projects, but adds they are much less useful as a diagnostic tool in clinical practice. Similar to the criteria for FM, this classification criterion is research-based and is validated and rigid. The other criteria mentioned for the diagnosis of FM are the diagnostic criteria, which are clinically based, non-validated and 'softer'. Fennerty (2003) adds that, because of the limitations of the existing diagnostic criteria for IBS, the 'Rome III' criteria will soon need to be developed.

The American Gastroenterology Association (AGA) medical position statement list three interrelated factors that affect the symptoms of IBS (American Gastroenterological Association, 2002). These include altered gut reactivity, a hypersensitive gut with enhanced visceral perception and pain and dysregulation of the brain-gut axis which may be associated with an increased stress reactivity and

altered perception and modulation of visceral afferent signals. This medical position statement also acknowledges that IBS adversely affects the health-related quality of life of patients. This includes impairment of their physical, emotional and psychosocial roles to a degree that exceeds that found in patients with other medical conditions (American Gastroenterological Association, 2002). Olden (2003) comments on the progress in IBS research in finding enhanced visceral hypersensitivity in the colon and rectum as well as altered processing of signals to the brain and raises the question as to which neurotransmitters play a role in the altered processing of neural sensation in IBS patients. The similarities between the research paths of both FM and IBS are significant and noticeable.

One study (Sperber et al., 1999) has shown that FM and IBS co-exist in many patients. In their IBS study, 25 of the 79 IBS patients (31.6%) and 3 of the 72 controls (4.2%) had FM. Irritable bowel syndrome is a functional disorder of the gastrointestinal tract that presents as chronic abdominal pain and changed bowel function without evidence of laboratory or structural abnormalities on routine testing (Sperber et al., 1999). A further study by Sperber and colleagues (2000) evaluated the use of the Functional Bowel Disorder Severity Index (FBDSI) as a measure of the severity of disease among patients with IBS. This study included FM patients with IBS. An association was found between the FBDSI and IBS patient status with IBS non-patients, patients with IBS only and patients with both IBS and FM having increasingly severe scores.

The Visceral Sensitivity Index (VSI) has been developed and validated as a reliable, valid measure of gastrointestinal symptom-specific anxiety (Labus et al., 2004). Labus and colleagues acknowledge that anxiety, related to gastrointestinal sensations and symptoms, may play a significant role in the pathophysiology and health outcomes of patients with IBS. This 15-item scale may be useful for clinical assessment and treatment outcome studies. In the first prospective study of its kind, researchers have indicated that familial aggregation of IBS may occur (Kalantar, Loche, Zinsmeister, Beighley, & Talley, 2003). These findings need to be replicated in larger studies. The authors state that further studies will need to carefully evaluate the roles of intrafamilial, environmental and inherited factors in the etiology of these conditions.

Veale, Kavanagh, Fielding and Fitzgerald (1991) suggest that primary FM and IBS may be different expressions of a common pathogenic process. The authors suggest that abnormalities of the central nociceptive processing may be present in IBS. They describe visceral hypersensitivity or decreased pain thresholds to distension of the gut as biological markers for IBS. Their studies suggest that patients with IBS may have cutaneous hyperalgesia similar to that experienced by patients with FM. In a prospective case-controlled study (n= 32), urinary frequency and urgency and the urodynamic findings of detrusor instability were significantly more common in women with irritable bowel syndrome ($p < 0.05$) (Monga, Marrero, Stanton, Lemieux, & Maxwell, 1997). The authors comment that these findings are indicative of an irritable bladder in the irritable bowel syndrome supporting the concept that irritable bowel syndrome may be part of a more generalised disorder of smooth muscle.

Temporomandibular Joint Dysfunction

A majority of FM patients suffer with temporomandibular joint dysfunction syndrome (Silver & Wallace, 2002). The authors found that symptoms associated with this dysfunction included teeth grinding, jaw clenching, and spasm in the temporomandibular joints with resultant localised pain and headaches. One study (Rhodus, Friction, Carlson, & Messner, 2003) on the prevalence and profile of oral symptoms in an FM population has shown that there was a significant prevalence in temporomandibular dysfunction in an FM population (67.6%) compared to controls (20%) ($p < 0.001$).

Chest Wall Symptoms

Chest pain, palpitations and discomfort of the costochondral margins and chest wall are common in people with FM (Silver & Wallace, 2002). Cetin and Sivri (2001) have shown that dyspnea is a common symptom for patients with FM. The authors note that it is not associated with pulmonary function, but rather chest wall discomfort and pain. Studies suggest that FM patients have a significantly increased incidence of mitral valve prolapse with a greater than 20% incidence compared to 2% recorded with healthy controls (Freed et al., 1999). This may be due to the

dysautonomia in FM causing diffuse smooth muscle dysmotility that could be responsible for some of the associated FM symptoms such as mitral valve prolapse and non-allergic rhinitis (Clauw, 1995a).

Restless Leg Syndrome

Silver and Wallace (2002) describe restless leg syndrome as periodic limb movement disorder or nocturnal myoclonus and associate it with the alpha anomaly in non REM sleep in FM patients. This restless leg syndrome is found in approximately 15% of people diagnosed with FM (Silver & Wallace, 2002).

Headaches

Silver and Wallace note that over half of patients with FM experience headaches, and that many of these patients experience these headaches daily or many times per week. Wassem, McDonald and Racine (2002) found that headaches were one of the listed symptoms of FM, reported in greater than 70% of 54 study respondents. Kim (2004) cites Bernstein's study from the American Headache Society Annual Meeting in 2004, where three quarters of FM patients were shown to have chronic headaches (n=100). The survey from the department of anaesthesiology at the University of Pittsburgh has shown that 76% of FM patients had regular headaches and, of those, 21% had migraine with aura and 27% had migraine without aura. Kim (2004) cites Bernstein in describing headaches as an integral part of FM for these patients, a part of the pain dysregulation of FM syndrome.

Autonomic and/or Neuroendocrine Dysfunction

Petzke and Clauw (2000) present an overview of findings of studies that assess aspects of the sympathetic nervous system function in FM. These reviewed studies included the areas of muscle sympathetic activity, microcirculation, heart rate variability, tilt table testing, endogenous pain modulation and biochemical markers (Petzke & Clauw, 2000). Jain and colleagues (2004) list autonomic dysfunctions as dizziness, neurally mediated hypotension and vertigo, loss of thermostatic and vasomotor stability, neurogenic or trophic oedema, sicca syndrome, cardiac and

respiratory irregularities, intestinal irregularities and bladder dysfunction. Also listed are the neuroendocrine dysfunctions of loss of adaptability and stress tolerance, weight gain, hypothyroidism, and dysmenorrhoea. Also listed are associated signs such as musculoskeletal asymmetry and muscle dysfunction.

Other Findings

Cold intolerance is a common symptom of FM. Wolfe and colleagues (1990) have shown that approximately 30% of FM patients experience this cold intolerance and that some may develop Raynaud's disease. Multiple sensitivities can result from the disordered sensory processing in people with FM with many sensations being amplified (Slotkoff, Radulovic, & Clauw, 1997). Dizziness is also a common symptom experienced by patients with FM.

Recent findings from a genetic linkage study (Weissman, Gross, Fyer, & Heinman, 2004) indicate a possible syndrome in some families with panic disorder. This syndrome includes bladder problems such as IC, thyroid disorders, chronic headaches/migraines and mitral valve prolapse. Weissman and colleagues (2004) suggest that the range of symptom disorders includes disorders associated with IC such as FM, celiac disease and irritable bowel syndrome and further suggest that many or all of these conditions may share underlying pathophysiologic features.

Swezey and Adams (1999) investigated the associations of bone mineral density and osteoporosis in patients with FM and healthy controls. The researchers concluded that in this study FM was frequently associated with osteoporosis and recommended appropriate prophylactic strategies. Further studies are necessary to consider the impact of the lack of exercise due to pain and fatigue on the decreased bone mineral density.

Psychosocial Implications

Physical trauma or emotional stress can trigger and/or exacerbate the symptoms of FM. Crofford and Clauw (2002a) state that as well as the neurobiological mechanism, behavioural factors can have an effect in symptom

expression in some FM patients. The effects of pain and other symptoms of FM can result in changed behaviour patterns and coping skills. These non-biologic factors play a major role in symptom expression in all rheumatic diseases, not just FM (Crofford & Clauw, 2002a). Jain et al (2004) refer to the common assertion that FM symptoms result from an underlying depression or other psychological issues, but state that this is not supported by available data.

Psychosocial health is often used as an umbrella term under which diverse research inquiries are carried out (Martikainen, Bartley, & Lahelma, 2002). The Oxford English Dictionary defines 'psychosocial' as 'pertaining to the influence of social factors on an individual's mind or behaviour, and to the interrelation of behavioural and social factors' (Simpson & Weiner, 1989). Schaefer (1995) writes of the psychosocial aspects of living with FM in describing acceptable ways of living with the pain and discomfort of FM as a struggle to find balance.

Soderberg, Lundman and Norberg (1999), in their study on women's experience of living with FM, showed women with FM lived lives significantly influenced by their illness. This study of women's experiences of living with FM was defined according to the themes of loss of freedom, threat to integrity and struggles to achieve relief and understanding. This loss of freedom embraced a body in pain, suffering from fatigue and from a loss of energy, living a changed life every day and having economic restrictions. The theme of threat to integrity emerged from the loss of credibility and the invisibility of the illness, together with the lack of knowledge about FM and a negative societal attitude. Women's struggle to achieve understanding and relief reflected the need to find an explanation for the condition, to seek relief and to plan one's daily life in accordance with the illness (Soderberg et al., 1999).

Researchers Soderberg and Lundman (2001) further considered transitions experienced by women with FM. These transitions are described as transitions in patterns of daily living, family life, social life, working life and learning to live with the changes caused by FM. The authors referred to FM as the "choreographer of activities and relationships" (p.617). In this study by Soderberg and Lundman (2001), women described these transitions as invisible to almost everyone except

themselves, but felt that other people viewed them as healthy beings. “It is like living in two different worlds simultaneously, the world of the sick and the world of the healthy” (p. 617).

Mannerkorpi, Kroksmark and Ekdahl (1999) have shown how patients with FM experience their symptoms in everyday life and they illuminated qualitative differences in FM patients’ experiences and their management of symptoms. The study findings reveal four different patterns of perceiving and managing symptoms: *Struggling*, where patients perceived they managed their lives by mobilising their psychological and physical strength to manage pain and fatigue; *Adapting*, where patients perceived they managed their day by planning their activities on the basis of their assumptions of limitations; *In despair*, where patients despaired because they could no longer cope with their pain and life situations; *Giving up*, where patients had given up many activities of daily life and felt that symptoms dominated their lives (Mannerkorpi et al., 1999).

Toombs (1992) writes of the taken-for-grantedness of daily living being interrupted by illness, as well as the experience of illness as a loss of wholeness. Toombs describes this loss of wholeness as not just the recognition of specific symptoms, but rather as a profound loss of total body integrity where the painful body disrupts the fundamental unity between one’s body and one’s self. For patients, the contradiction between their perception of their illness and the lack of medical objective findings, together with the long investigative periods, is very stressful (Hendriksson, 1995). Being given a diagnosis is a relief, but presents the new stress of managing this chronic, incurable condition.

FM and chronic fatigue syndrome (CFS) have an elusive etiology. There are no objective measures and both conditions are difficult to diagnose (Asbring & Narvanen, 2002). Accordingly, the potential for stigmatisation of women with these conditions needs evaluation. Asbring and Narvanen (2002) investigated whether women experienced their illness as stigmatising and examined the strategies women used in avoiding such compartmentalisation. Their findings have shown that the women felt they were being challenged by others about the truthfulness of their illness experience, and their moral character was being questioned. They also

described the ‘psychologising’ of their symptoms as stigmatising (Asbring & Narvanen, 2002). This is compounded by the lack of objective findings that can verify a physical illness that can encourage health care professionals to consider psychological factors as the precipitators of the illness.

Asbring and Narvanen (2004) interviewed 12 women with FM and 13 women with CFS in a study defining the potential for the patients to gain control over their situation during the health care process, and to have some influence on the outcome of this process. The women described various strategies they utilised with health care providers to influence this process. These strategies included gaining control through knowledge, and using power strategies such as changing doctors, not following advice, confrontation, persuasion and insistence in directing treatment wishes.

The stress of diagnosis and management of FM has a profound effect not only on the women diagnosed, but also on their family members. A study from the husband’s perspective of living with a woman with FM (Soderberg, Strand, Haapala, & Lundman, 2003) identified several themes: increasing responsibility and work in the home; being an advocate for and supporting the wife; learning to see the woman’s changing needs; changing relationship between spouses; changing relationship with friends and relatives; deepening relationship with the children; and lacking information and knowledge about FM.

A recent Australian study (Infante et al., 2004) explored the perceptions of patients with chronic conditions about the nature and quality of their care in general practice. Participants in the study included 76 consumers in 12 focus groups in two Australian states. The results of the study described three emerging priorities. The first centred on the quality of doctors, including their technical competence, interpersonal skills, consultation time for patients and continuity of care. The second priority was for the general practitioners to develop closer links with consumer organisations and support groups and to pass the information to their patients. Many participants felt that their general practitioners were ‘good’ at the management of the condition, but were ‘weak’ in recognising the emotional impact of chronic illness. There was also the expectation that the practitioners should not only know the medical side of a condition, but also the psychological and social impacts of the

disease. Participants also emphasised the need for general practitioners to continue professional development especially with respect to management and treatment of chronic illness. In a disease like FM, where the diagnosis has no pathological quantification, there is a sense of helplessness and/or disempowerment in doctors to treat a condition they are not sure exists.

Etiology of Fibromyalgia

The etiology of FM is multifactorial but specific etiology is still elusive. FM has been subjected to scientific scrutiny in the past 10 years with more than 1000 publications produced in peer-reviewed journals. The majority of people with FM enjoyed a relatively pain-free and active lifestyle before the onset of FM symptoms. Buskila and Neumann (1997) have shown that the prevalence of blood relatives of patients with FM being diagnosed themselves with FM was 26% with the prevalence in female relatives being 41%. The mean tender point counts of both young male and young female relatives in this study were significantly higher than in controls, being 6.1 vs. 0.2 ($p < 0.01$) in males and 4.4 vs. 0.4 ($p < 0.01$) in females. The mean tender point counts of adult relatives were even higher than controls with 4.0 vs. 0.04 ($p < 0.01$) for males and 10.3 vs. 0.28 (< 0.01) for females. Buskila and Neumann concluded that patients with FM do have a higher prevalence of FM and more tender points than an age-matched group within the general population. They conclude that this trait is the result of genetic and environmental factors.

The symptoms of FM reflect alterations in pain perception, mood and sleep and may be a stress-related illness as its onset often coincides with a stressful situation, either physical or psychological (Pillmer, Bradley, Crofford, Moldofsky, & Chrousos, 1997). Abnormalities in pain perception occur such as allodynia, which is pain with innocuous stimulation, and hyperalgesia, which is an increased sensitivity to pain stimuli. Both of these abnormalities are present in patients with FM. Recent attention for an explanation of this pain is on the central nervous system, rather than on peripheral causes.

The main symptom of FM is chronic widespread pain. At the 10th World Congress on Pain, FM was frequently referred to as the classic example of the

‘central pain state’. This indicates that peripheral tissue causes of pain cannot be easily identified in most FM patients and suggests that most of the action is at the level of the spinal cord and above (Bennett, 2002a). Researchers are therefore focusing more on the role of the central nervous system rather than on the musculoskeletal system in an effort to explain the symptoms of FM. A disorder of the central processing of sensory information from the nociceptor and mechanoreceptor systems can result in numerous neurophysiological changes that are observed in FM sufferers.

Tissue damage does not need to be present for a patient to experience pain. Schug (2002) suggests that pain should not be considered to be acute or chronic, but rather as physiological or pathological pain. He describes physiological pain as having only a biological function like pulling away from heat to protect the body and pathological pain as having no biological function as healing is complete. Schug observes that spontaneous pain occurring in the absence of an apparent stimulus is caused by the upregulation of the lack of inhibition and that pain sensitisation is an exaggerated response to pain. Littlejohn (1998) describes FM as the result of central sensitisation, an increase in the excitability and responsiveness of neurones in the spinal cord. This central sensitisation leads to an increase in the activities in higher brain centres and is perceived as more intense and prolonged pain. This hyperexcitability is mediated by the activation of neurones with *N*-methyl-D-aspartate (NMDA) receptor sites by some excitatory amino acids (Pillmer et al., 1997). The release of these amino acids and their effect on the dorsal horn neurones are increased by some neuropeptide transmitters like dynorphin, Substance P (SP) and calcitonin gene-related peptide (Pillmer et al., 1997).

Bennett (1998a) uses the terminology “disordered sensory processing” to encompass the concept of allodynia where light touch evokes severe pain. He suggests this non-nociceptive pain is usually dependent on central sensitisation that has been induced by prior or ongoing nociception and that an understanding of this non-nociception pain is relevant to the current understanding of FM. Different treatment strategies from those used to treat nociceptive pain are required for the treatment of non-nociceptive pain.

Bennett (2002a) comments that an understanding of the detailed mechanisms of neurochemical receptor interactions will be central to the development of new drugs for treating chronic pain conditions. As a rheumatologist, Bennett (2002a) is increasingly convinced that FM is primarily a neurological disorder that is presenting as a musculoskeletal pain syndrome.

Staud (2002) sought to obtain evidence that input into central nociceptive pathways is abnormally processed in individuals with FM. It was concluded that central pain processing is abnormal, that pain memory is increased, that FM pain correlates with heat and mechanical 'wind-up', and that these differences are due to clearly established biological mechanisms (Staud, 2002). This is one reason why pre-emptive analgesia is currently of great interest to pain researchers, because pretreating with an analgesic agent, peripheral and central sensitisation associated with major tissue insult or disease may decrease (Sidebotham, Schug, & Petcu, 1997). These authors state that unrelieved pain can be the most distressing of human conditions and should attract the time and effort of medical researchers.

Nociception is activity induced in neural pathways by stimuli that are potentially harmful. Nociception is not a passive, one-directional process, but a complex interaction between ascending and descending pathways that has the ability to alter the relationship between stimulus and response (Rao, 2002). Nociceptive stimuli from the periphery are relayed to the central nervous system via either unmyelinated C fibres or myelinated A δ fibres that terminate in the dorsal horn. These fibres synapse with dorsal horn interneurons and projection neurones (Rao, 2002). Willis and Westlund (1997) explain that a subset of dorsal horn neurones project supraspinally via the spinothalamic tract and other pathways, thus forming the basis of pain perception in the brain.

The neuropharmacology of the dorsal horn neuron is complex, with excitatory and inhibitory neurotransmitters present. The complicated detailing of these neurotransmitters and the research findings in relation to chronic pain are far beyond the scope of this literature review. However, Substance P-mediated neurotransmission has been the subject of animal studies replicating chronic pain (Rao, 2002). Rao remarked that the role of Substance P-mediated neurotransmission

in human nociception processing is controversial. Substance P is a neuropeptide stored in the secretory glands of sensory nerves and is released by axonal stimulation. Substance P has multiple biological effects that include stimulation of muscle, pain nociception, immune cell functions, plasma extravasation and many other inflammatory effects (Luber-Narod et al., 1997). Several studies (Russel et al., 1994; Vaeroy, Helle, Forre, Kass, & Terenius, 1988) have shown that the neuropeptide Substance P occurs in the cerebrospinal fluid of patients with FM two to three times higher than in control subjects. Substance P lowers the threshold of synaptic excitability, which allows for the unmasking of normally silent interspinal synapses (Coderre, Katz, Vaccarino, & Melzack, 1993). De Vane (2001) describes the physiological role of Substance P as a modulator of nociception that is involved in the signalling of the intensity of noxious or aversive stimuli.

Recent genetic studies with mice and the development of Substance P antagonists have redefined this neurotransmitter as an integral part of the central nervous system pathways implicated in psychological stress (De Vane, 2001). Current research focus is on clinical applications of Substance P antagonists to enhance treatment of diseases linked with emotional response and with the interpretation of sensory input into the brain (De Vane, 2001).

The concept of neurogenic inflammation is based on the release of Substance P and related peptides by an axon reflex mechanism. Saban, Saban, and Bjorling (1997) investigated peptide-induced release of inflammatory mediators by the urinary bladder and concluded that the peptides evaluated induced changes that may directly regulate the participation of these peptides in the pathogenesis of cystitis. Callsen-Cencic and Mense (1997) also questioned whether alterations in the expression of neuropeptides and nitric oxide synthase in the neuronal pathways to the bladder might be involved in the hyperexcitability of the bladder with the development of cystitis.

Rao (2002) describes how the behavioural state of central sensitisation may be the result of alterations in the ascending or descending neural pathways of the brain and spinal cord. Behbehani (1995) describes the major components of the descending nociceptive system. He describes the periaqueductal gray as a central

structure in this linkage, linking the cortex and other higher structures with the dorsal horn and processing both ascending and descending nociceptive information. The monoamines, serotonin and noradrenaline, have a central role in this descending modulation. The place of the descending system in chronic pain is a subject for current research in seeking answers for management for chronic pain in FM. Rao (2002) cites a number of studies showing reduced spinal noradrenaline outflow results in chronic hyperalgesic states in laboratory animals.

As well as neurotransmitter abnormalities, hormonal and biochemical abnormalities are detectable in patients with FM (Clauw, 1995a). Insulin-like growth factor I (IGF I/somatomedin C) is a hormone produced in the liver, primarily in response to the growth hormone. Most patients with FM have low serum levels of IGF I. Bennet (1993) suggests a disruption of the neuroendocrine axis that controls growth hormone production could be the link between disturbed sleep and muscle pain because this hormone is produced mainly during level IV sleep. Studies have shown that treating these patients with human growth hormone leads to an improvement of symptoms (Bennett, Clark, & Walczyk, 1998b). Bennett (2004) notes that suboptimal growth hormone secretion, resulting in a state of adult growth hormone deficiency, may occur in chronic inflammatory disease, chronic corticosteroid use and FM. He describes the need to evaluate the under- and over-secretion of growth hormone for practising rheumatologists.

The hypothalamic-pituitary-adrenal (HPA) axis has been described as a complex brain-to-body pathway involving the hypothalamus, pituitary and adrenal glands. Adler, Kinsley, Hurwitz, Mossey, and Goldenberg (1999) describe the HPA axis, and the autonomic nervous system, as the major pathways for the body's responses to stressful conditions such as pain, exercise, trauma or infection. Both systems are influenced by genetic factors, environmental factors and chronic illness (Adler et al., 1999). Crofford and colleagues (1994) examined basal and stimulated HPA axis and related hormone levels in patients with FM. Their results showed that HPA function is altered in patients with FM. Crofford (2002b) refers to the evidence of the HPA axis involvement in acute and chronic pain and questions whether the HPA axis abnormalities in FM reflect pre-existing vulnerability to the FM spectrum of the disease or if chronic somatic symptoms as seen in FM alter HPA axis activity.

Further studies by Adler and colleagues (1999) have shown that patients with FM have an impairment of the hypothalamic-pituitary portion of the hypothalamic-adrenal axis and the sympathoadrenal system. This results in reduced adrenocorticotrophic hormone (ACTH) and epinephrine responses to hypoglycaemia.

Neeck and Riedel (1999) postulate that the distortion of the hormonal pattern in FM patients can be attributed to hyperactivity of the corticotropin-releasing hormone (CRH). The authors suggest that this hyperactivity is driven and sustained by the stress from chronic musculoskeletal pain and/or by changes in the CNS mechanism of nociception. Neeck and Riedel (1999) concluded from their studies of the entire endocrine profile of sixteen FM patients and seventeen controls that the pattern of hormonal deviations in patients with FM is a CNS adjustment to chronic pain and stress and is a specific entity of FM.

Martinez-Lavin (2002) suggests that dysautonomia may play a central role in the pathogenesis of FM because autonomic nervous system (ANS) dysfunction is frequently found in patients with FM. Martinez-Lavin describes the ANS as a dynamic system with intense and instantaneous onset of action and dissipation that works closely with the endocrine system, especially the hypothalamic-pituitary-adrenal axis and the growth hormone axis. Because the ANS regulates the function of most of the organs and systems of the body, it is the main homeostatic system. Martinez-Lavin (2002) proposes a pathogenic model of 'sympathetically maintained pain' suggesting that the hyperactive sympathetic nervous system can result in constant fatigue, morning stiffness, sleep disorders, intestinal irritability and other FM symptomatology. Raj, Brouillard, Simpson, Hopman and Abdollah (2000) have shown abnormal responses to two tests of autonomic nervous system functioning in patients with FM. The authors comment that further research is needed to ascertain if dysautonomia has an influence in the pathogenesis of FM or if dysautonomia results from FM.

Using neuroimaging to measure the change in regional cerebral blood flow produced by pain in patients with FM, Bradley, McKendree-Smith, Alberts, Alarcon, Mountz and Deutsch (2000) identified lower than normal blood flow levels to two major pain processing areas in the brain, the thalamus and the caudate nuclei.

Kwiatk, Barnden, Tedman, Jarrett, Chew, Rowe and Pile (2000) confirmed, in their work using single-photon-emission computed tomography (SPECT) brain scans on cerebral blood flow, that there is reduced regional cerebral blood flow (rCBF) in the right thalamus as well as the pontine tegmentum in the brain stem of patients with FM. The authors conclude that the pathophysiological significance of these changes in FM patients needs to be clarified with further research.

Because FM patients suffer other symptoms, such as sleep abnormalities, fatigue, irritable bowel and bladder symptoms and others as well as pain, Clauw and Chrousos (1997b) and Littlejohn (1996) question how the pathophysiology of these other symptoms is related to central sensitisation. Various hypotheses have been considered and published by researchers but this is still an ongoing area of active debate and research as knowledge in the area of pain medicine continues to grow.

Etiology of Bladder Symptomatology in FM

Al-Chaer (2000) describes visceral pain as having the capacity to become the consuming focus of one's life. Al-Chaer describes the clinical impact of pain from internal organs (visceral pain) as outweighing somatic pain because of the high incidence of algogenic (pain causing) conditions, which affect the viscera, and the tendency of these conditions to be chronic or recurrent. McMahon (2004) describes the sensory innervation of the viscera as serving a number of important functions, including the transmission of visceral sensations such as pain. He comments that the transduction properties of visceral afferents are not stable and can be altered by numerous factors. These altered properties of all neurobiological systems are described as forms of plasticity. McMahon (2004) describes the functionally relevant forms of plasticity in the context of visceral sensory neurones as those that affect the encoding and transmission of sensory information, and comments on the increased excitability of sensory neurones causing functional consequences and contributing to chronic pain states.

Butrick (2004) describes the visceral silent afferents as all having the capacity to transmit pain. He notes that 10% of the afferents are silent in the skin compared with 30%-80% of the visceral afferents being silent. These silent afferents can

become active with prolonged stimulation and have a major role in tissue sensitisation (Butrick, 2004). Cervero (1994) states that the bladder does have the highest neural density and the greatest proportion of silent C-fibres of any viscera.

Cervero and Laird (1999) question the conventional view of visceral pain as simply a variant of somatic pain, based on the belief that a single neurological mechanism is responsible for all pain. The authors acknowledge that the two pathways have much in common, but note that there are important differences. They comment on the lack of specialised clinicians with expertise in the management of visceral pain leading to a range of treatment by a range of specialists treating visceral pain as a symptom and not as a distinct neurological entity.

Cervero and Laird (1999) comment that, although the mechanisms of visceral pain differ between organs and organ systems, there are two common principles that apply to visceral pain. The first is that, because neurological mechanisms of visceral pain differ from those mechanisms in somatic pain, the findings from somatic pain cannot therefore be extrapolated to visceral pain. The second principle is that the perception and psychological processing of visceral pain is different from that of somatic pain. Cervero and Laird refer to five important clinical characteristics of visceral pain as: not all viscera are sensitive to pain; it is not always linked to visceral injury; it is diffuse and poorly localised; it is referred to other locations; and it is accompanied by motor and autonomic reflexes such as nausea and muscle spasm.

Cervero and Laird (1999) refer to the challenge to established paradigms on the transmission of visceral pain, stating that there are two distinct classes of nociceptive sensory receptors that innervate internal organs. The first class of receptors has a high threshold to natural, mainly mechanical stimuli, where stimulus intensity and nerve activity are evoked entirely by stimuli within the noxious range. These high threshold receptors have been identified in a number of organs and organ systems, including the ureter, urinary bladder and uterus. The second class of receptors has a low threshold to natural, mainly mechanical, stimuli where nerve activity of these low threshold receptors is evoked by stimulation of different intensities from innocuous to noxious (Cervero & Laird, 1999). These receptors have also been described in organs, including the urinary bladder (Cervero & Laird, 1999).

Cervero and Janig (1992) also suggest that a large component of the afferent innervation of internal organs consists of afferent fibres that are usually quiescent and become activated only when inflammation is present. This theory proposes that these sensory receptors contribute to the signalling of chronic visceral pain, with long term alterations of spinal reflexes and abnormal autonomic regulation of internal organs.

Overall, visceral pain is not the focus of this FM study. However, the symptoms of visceral pain from the urogenital system are to be considered. Although both irritable urinary symptoms and irritable bowel syndrome are listed as associated symptoms of FM, more research is being undertaken in the area of irritable bowel syndrome than in the urogenital pain arena. Cervero and Laird (1999) cite a number of studies lending support to the hypothesis that functional abdominal syndromes such as irritable bowel syndrome may be the result of visceral hypersensitivity that causes patients to become more aware of gastrointestinal activity. These authors suggest that this heightened awareness could be the result of sensitisation of the peripheral nociceptors or of some alterations of the central processing that result in an increase in the activation of visceral nociceptive pathways.

Costa, Glise and Graffer (2004) acknowledge that, through neural information from the viscera, the central nervous system plays an important role in health and disease, but that not much of the visceral afferent information reaches our conscious experience, except in circumstances where it produces unpleasant sensations such as pain, discomfort and nausea.

Giamberardino, De Laurentis, Affaitati, Lerza, Lapenna and Vecchiet (2001), from the Department of Medicine and Aging from the University of Chieti, in Italy, researched the clinical observation that algogenic conditions of one internal organ can affect reactivity to painful stimuli of other visceral areas, with over-lapping of sensory projections. Results indicate that algogenic conditions of the female reproductive organs enhance pain and referred hyperalgesia from the urinary tract. The authors point out that the female reproductive organs, and the urinary tract, have common sensory projections to spinal cord segments. Giamberardino and colleagues (2001) suggest increased afferent signals from one visceral domain, such as the

reproductive organs, towards the central nervous system, increase the excitability of viscerovisceral convergent neurones in the spinal cord. This then results in the central effect of the input from the second internal organ, the urinary tract being amplified and resulting in 'viscerovisceral hyperalgesia'. These researchers have provided evidence of an interaction of sensory nerves from different viscera resulting in the development of pain symptoms.

Ishigooka, Zermann, Doggweiler, Schmidt, Hashimoto and Nakada (2001) explored the potential of chronic bladder irritation in an animal model, resulting in central sensitisation. Bennett (2001) states that the understanding of visceral pain leading to central sensitisation is gaining ground in both the clinical and experimental arenas. He comments that this is of particular importance to rheumatologists who endeavour to treat and manage the associated symptoms of FM such as irritable bowel and bladder syndromes.

Researchers (Yoshimura, Seki, Chancellor, de Groat, & Ueda, 2002) hypothesise that in some chronic bladder conditions, the hyperexcitability of the C-fibre afferent pathways, which during bladder filling are normally silent, may be the mechanism for bladder pain and urgency. Yoshimura and colleagues (2002) consider C-fibre afferent pathways in urinary frequency and pain in painful bladder syndromes as targets for treatment of this condition. Their focus is on the modulation of activity of bladder afferent pathways, preventing bladder pain by interfering with the steps involved in altering C-fibre activity. Yoshimura and colleagues (2002) suggest that a mechanism by which pain is induced involves chronic tissue inflammation that can lead to some functional changes in C-fibre afferents, and that the normally silent fibres appear to have specific functions in signalling noxious events in the bladder. Their study concludes that the hyperexcitability of C-fibre afferent pathways is likely involved in pain associated with painful bladder syndrome. This area of urogenital pain is a major focus for pain researchers in this early 21st century.

Felson, (2003/2004) as president for the Society for Basic Urological Research, comments he is encouraged by the research on pain and sensory mechanisms in both bladder processes, sensation and pain, and urothelial cell

function. Felson describes their urological societal research as attempting to understand the fundamental disease processes as this is what translates into treatments and cures.

Hypotheses Explaining Fibromyalgia

Chaitow (2003) summarises a number of hypotheses explaining the evolution of FM. He refers to the chronobiological hypothesis by Moldofsky, the genetic hypothesis by Goldstein, the integrated hypothesis by Bennett, the nociceptive hypothesis by Wolfe and the stress hormone hypothesis by Goldenberg and Adler. A brief synopsis of each hypothesis is delineated here.

Moldofsky's chronobiological hypothesis suggests that FM is the result of altered biological rhythms, including diurnal physiological functions and environmental influences, together with psychosocial and behavioural influences (Chaitow, 2003). Goldstein's hypothesis considers a genetic predisposition in the etiology FM. Chaitow (2003) lists a number of studies where genetically acquired traits such as joint hypermobility and mitral valve prolapse are reported as more common in the FM population than in the general population. There are also indications of familial tendencies in the development of FM. Bennett's integrated hypothesis (Chaitow, 2003) considers blending both the central and peripheral nervous system etiologies. The nociceptive hypothesis by Wolfe (Chaitow, 2003) proposes pain amplification resulting from chronic pain stimulus, progressing under the influence of genetic factors, somatic disease, sleep disturbance and psychological factors with the evolution of FM.

Clauw and Williams (2002) present a model that unifies some studies and hypotheses on the role of altered central nervous function. The model, known as the Chronic Multisymptom Illness (CMI), is described by the authors as the constellation of stress-mediated symptoms and syndromes that can occur in two forms within the individual. The first form is described as a systemic or widespread symptom expression and includes FM and chronic fatigue syndrome (CFS). The second format is described as single organ or single region symptom expression and includes conditions such as migraine or tension headaches and irritable bowel syndrome.

Clauw (1995a) also presents a unifying hypothesis to describe the spectrum of symptoms and syndromes that are associated with FM. He comments that, although multiple non-rheumatic features initially seem unrelated, they can be divided into four categories based on the underlying cause and clustering of cohorts of patients. Clauw describes these four categories as: neurologic as seen in sleep disturbance, paresthesias, vestibular and cognitive symptoms and mood disturbances; smooth muscle dysmotility as seen in irritable bowel, bladder symptoms, and migraine headaches; increased skeletal muscle tone as seen in myalgias, TMJ syndrome and tension headaches; and irritative or inflammatory symptoms as seen in cystitis, rhinitis, and pharyngitis. Clauw (1995a) postulates that a different effector arm of the nervous system results in specific symptomatology mediating each group of symptoms. This integrated hypothesis is the basis of the theoretical framework for this thesis.

In detailing this integrated hypothesis, Clauw (1995a) suggests that genetically vulnerable individuals may be asymptomatic throughout life until a ‘triggering’ event, although some may have always been aware of some of the allied conditions such as migraines or cystitis. Many may stop exercising as a result of this ‘triggering’ event and that may increase the symptoms. Clauw describes the resultant adaptive stress response activating both the hypothalamic pituitary adrenal (HPA) axis and the sympathetic system.

Clauw (1995a) states that once the latent CNS hyperactivity is apparent then all or some of the effector arms of the central nervous system can be involved. Clauw suggests that an elevated ratio of excitatory to inhibitory neuromodulators is responsible for this spectrum of conditions, the region of the central nervous system being affected being reflected in the symptomatology. More than one of the effector arms of the central nervous system can be activated at any one time. Clauw (1995a) cites studies by Mayer and Raybold, White, Stevens and Upton and Whorwell, Lupton, Erduran and Wilson in demonstrating this concurrent activation by studies on irritable bowel syndrome where there is both diffuse smooth muscle dysmotility of the intestines, oesophagus, bladder and bronchus as well as increased visceral nociception. The literature discussed in the etiology of bladder symptomatology in this thesis indicates both neurogenic inflammation and increased visceral nociception

are involved in the irritative and bladder pain sensations in women with FM. Because several arms of the nervous system contribute to specific symptoms, Clauw (1995a) suggests that a multi-disciplinary approach for examining symptoms and systems concurrently is more likely to provide effective treatments.

It is obvious from the various hypotheses that there are numerous evolving concepts in the etiology of FM. In summary, the evolution of understanding of the plasticity of the nervous system, the interaction between somatic and visceral pathways and the expansion of information on neurotransmitters are together increasing our understanding of etiological factors in the development of FM and therefore in management strategies.

Treatment /Management of FM

Clauw (2000) commented that not all health care professionals are interested in the diagnosis and management of patients with FM while others see the FM patient as difficult. Clauw suggests that this perception of difficulty may be because the physician is unable to improve the condition of the patient, or their demands exceed the physician's capabilities. He recommends the early diagnosis of FM, before the chronicity of the condition results in dysfunction and disability.

Millea and Hollaway (2000) suggest that the physician's supportive counselling skills and openness to try new treatment strategies with refractory cases are an important part of the management strategy for FM. Bauman, Fardy and Harris (2003) discuss patient-centred care being about the sharing of the management of an illness between the patients and their doctor and the evidence of this patient-centred care having a favourable impact on chronic health conditions, including chronic musculoskeletal conditions. The main features of this patient-centred care, featuring doctor-patient interaction, include shared goal setting, with written management plans, supportive community-based programs with a focus on health promotion and healthy lifestyles. Effective patient-centred care results in a partnership between the doctors and patients where the patients can talk freely about the emotional and psychological issues related to their chronic condition and not just the associated physical symptoms.

The pain of FM is not caused by peripheral inflammation, but rather by a central nervous system defect and therefore different treatment interventions are necessary (Clauw, 2000). The author encourages extended medical consultations with FM patients until there is an understanding on the part of the physician of the problems the patients are experiencing and for the patients to understand that the treatment will involve patient participation.

There is no one specific treatment for FM. Once the patient is diagnosed with FM, the treatment should be individualised, with regular assessment to monitor treatment efficacy. The condition is managed by a number of specific approaches to address the symptoms. This multimodal approach includes education, psychological, exercise and medication regimes. Education about the condition is paramount and it is extremely validating for the patient to receive a diagnosis usually after a long search for an answer to their pain and the impact of associated symptoms. Although FM is not life threatening, it is a quality of life threatening condition, and treatment and management must focus on all aspects of appropriate medical and self-management techniques. The approach to address specific symptoms is imperative. One example is the symptom of bladder irritability. Education on normal bladder function, good bladder habits and bladder management strategies would be included for women with these specific bladder symptoms.

A six-year prospective study of a cohort of patients with FM has shown that some symptoms of FM can persist for years, but some aspects of quality of life improve over time because of coping strategies patients can develop with or without professional assistance (Baumgartner, Finckh, Cedraschi, & Vischer, 2002a). A longitudinal study (Fitzcharles, DaCosta, & Poyhia, 2003) examining the outcome of FM with standard medical care was favourable, with almost half of the sample reporting clinically meaningful improvement. The authors suggest that, because of the current thinking on the pathogenesis of FM of central dysregulation of the pain-processing mechanisms, it may be possible that with time there could be a resetting of the pain threshold. Fitzcharles and colleagues (2003) suggest that some treatment interventions may facilitate the shift of this pain threshold towards normal.

Littlejohn and Walker (2002b), in considering a realistic approach to managing patients with FM, note that, because FM probably arises from a disordered neurophysiology, the effects embrace thoughts, emotions and cognitions because of the influence of central control inputs. The biopsychosocial model of pain combines the notions that, at the physiological level, changes are initiated by trauma or pathology, whilst at the psychological level variables are reflected in the attention to internal sensations and this attention and behavioural responses can be influenced by social and environmental variables (Nicholas, 2000). The Council of the Australian Pain Society has recently published a paper on Pain Management Programs for Chronic, Persistent or Long Lasting Pain (Speldewinde & O'Callaghan, 2002). This program is based on the bio-psycho-social model as the authors state that simple analgesics, opioids and interventional techniques often help with the nociceptive component, but do not always address the larger psychological aspects of an individual's suffering.

Bennett (2002e) also emphasises a rational approach to the management of FM by adopting a holistic approach based on the bio-psycho-social approach to management. He discourages treating the diagnosis of FM as a unified entity, but rather recommends that attention be given to twelve separate management issues. These are listed as diagnosis and evaluation, education, pain, fatigue, sleep, psychological disorders, endocrine dysfunction, dysautonomia, deconditioning, cognitive dysfunction, the existential crisis and associated syndromes. Bennett (2002e) states that the concept that FM symptomatology results from the amplification of incoming sensory impulses has revolutionised the understanding of FM and created a more rational approach to treatment.

A review of multi-disciplinary treatment studies for patients with FM (Oliver, Cronan, & Walen, 2001) has shown that these programs are generally effective. Based on these findings, the authors have recommended that future researchers utilise reliable and valid measures designed for patients with FM. Creamer, Singh, Hochberg and Berman (2000) have shown that a non-pharmacological intervention for FM that included education, relaxation, and Qi Gong movement therapy weekly for eight weeks resulted in significant improvement in signs and symptoms in FM. Results from an evaluation on comparing the efficacy of pharmacological and non-

pharmacological treatments of FM by Rossy and colleagues (1999) have shown that the optimal intervention for FM includes exercise and cognitive behavioural therapy as well as appropriate medications for the symptoms of sleep deprivation and pain.

A pilot study by Pfeiffer and colleagues (2003) to determine the effects of a 1.5-day multi-disciplinary outpatient treatment program for FM has shown that improvements compared favourably with those results from longer interventions. The program was divided into an introductory program including education on FM and self-management techniques, occupational therapy focusing on energy conservation and ergonomics and physiotherapy focusing on stretching techniques, posture, body mechanics, strength, endurance and aerobic exercise. The efficacy of the program was assessed by the use of validated outcome measure assessment tools. This short intervention program (n=78) did show a significant improvement on the Fibromyalgia Impact Questionnaire score (51.3 - 44.7, $p < 0.002$) but did not significantly improve depression ($p < 0.06$), life fulfilment ($p < 0.53$) and physical impairment ($p = 0.11$).

Sprott (2003) notes that because subgroups within the FM population have been determined, uniform recommendations for treatment cannot be given. He recommends individual adapted measures to accommodate the differences between FM sufferers within the subgroups. Sprott (2003) asks the question as to why FM patients respond differently to different treatments. He suggests it may be due to the differences in the etiological pathogenic mechanisms within the identified FM subgroups and lists these as disturbances in the inhibitory system, neuro-endocrine disturbances, neuropeptide disturbances and decreased secretion of growth hormone. Sprott reminds us that treatment regimes are based on an unknown etiology and that a long term effective intervention must focus on managing the symptoms associated with FM.

Patient Education

Understanding the implications of a diagnosis of FM is very important for the patients who often have spent many years, many dollars and emotional energy seeking a diagnosis or a solution for their pain and dysfunction. It is important that

patients understand what FM is, that it is not life threatening, that there is no ‘cure,’ that it is non-inflammatory, that they may always be symptomatic and that they must take responsibility for their own well being and FM management. Patient education on FM is available through many resources, support, education and pain management groups.

Ramos-Remus, Salcedo-Rocha, Prieto-Parra and Galvan-Villegas (2000) report that the prevalence and morbidity rate of rheumatic diseases are increasing with non-medical causes playing an important role in the morbidity and disability of patients. They suggest because the majority of rheumatic diseases have no cure and many have poor outcomes that contributing factors to this may include comorbid conditions, drug side effects and the non-medical causes of morbidity. In addressing this issue, the authors suggest that the outcome of chronic disease may be influenced by the action of the person with the disease as much as by the health professional and therefore suggest that chronic diseases may respond to lifestyle modification as well as medical intervention.

Hill (1997) defines patient education as any combination of learning experience designed to improve patients’ behaviours and, as a result, improve their health status and long term outcome. Ramos–Remus and colleagues (2000) define self-management as activities that a person undertakes to improve health, to prevent disease and to decrease the chance of illness. They detail the goal of self-management programs as remodelling interpretative structures to improve the patients’ behaviours and to increase their self-efficiency. The authors describe interpretive structures as those a person uses to interpret and respond to any event. They further describe these structures as culturally acquired within a personal, cultural, social, political and economic environment and as significant personal factors in the knowledge, attitudes and behaviour used by individuals. This interpretive framework within the disease context is described as the way society and patients perceive, categorise or give meaning to a disease (Ramos-Remus et al., 2000).

The timing of any patient education program is important. Ramos-Remus and colleagues (2000) recommend that patients with chronic disease should commence

these programs following adequate time for the reaction of diagnosis, denial period and acceptance of the disease. They describe patient education as a strategy rather than one program and recommend that education is implemented as programs and assessed as interventions. The aim is to reshape the interpretive structures of patients and not just to provide educational information.

A study on the impact of a health education program on the quality of life of persons with FM (Bosch, Saenz, Valls, & Vinolas, 2002) has shown that health education modified the patients' perception of quality of life, reduced their pain, increased their understanding of FM and reduced dependence on the health system. Another prospective randomised study (Langer, Ehlebracht-Konig, & Mattussek, 2003) demonstrated that patient education leads to an improvement of knowledge, self-efficacy, self-help activities, improvement in helplessness and pain, and reduces both temporary and permanent disability.

Jain and colleagues' (2004) recommendations for patient education include being informed about FM and sources of support, knowing of early warning systems to prevent crashes, establishing a simple, serene, slow and supportive environment, relaxation and stress management, keeping the body warm, conserving energy, and avoiding aggravating factors. Patients are encouraged to establish personal boundaries, to maximise sleep and maintain a balanced diet.

Patient education extends into the arena of pain management. Cooper, Booker and Spanswick (2003) discuss one strategy for education in pain management to improve pain outcomes for patients that differs from the routine clinical practice. Rather than their focus being on the abolition of pain, it is on the restoration of function despite pain. Patients are made aware that activity-related pain does not equate with activity-related tissue damage, allowing them to confidently reintroduce physical activity into their daily routines (Cooper et al., 2003).

Exercise

Exercise is always recommended as part of the prescription for the management of FM. For many FM patients, fear that movement of an already painful body will increase their pain and disability often prevents them from undertaking

exercise training and/or programs. Jain et al (2004) have stated that exercise must be specific to the pathophysiology of FM and that the exercise intensity should be adapted to the patients' individual capacity and limitations. Individualised exercise programs should include warm up and cooling times, stretching, strength training, endurance training to increase conditioning, balance, pacing and patient control over the intensity and duration of the exercises (Jain et al., 2004). Clauw (2000) recommends a step approach towards exercise intervention, beginning with a non-demanding and short exercise period.

The Cochrane Musculoskeletal Group (Busch, Schachter, Peloso, & Bombardier, 2002a) systemically reviewed the efficacy of exercise training as a treatment for FM. They concluded that supervised exercise training does have beneficial effects on physical function and symptoms in patients with FM. A recent study (Richards & Scott, 2002) concluded that prescribed aerobic exercise is a simple, effective, inexpensive and available treatment for FM. However, the researchers found that compliance to an exercise program is a problem that may need to be addressed by cognitive behavioural therapy and the provision of explanations for initial increase in symptoms.

Gowans, deHueck, Voss and Richardson (1999) evaluated the efficacy of a six-week exercise and educational program for patients diagnosed with FM. The randomised controlled trial study (n=41) showed that short term exercise and educational programs could produce some immediate and sustained benefits for patients. The subject's physical function was assessed by a modified six-minute walk test with a significant improvement in the intervention group ($p < 0.05$). Similarly the program increased the intervention group subjects' sense of well being as indicated by the visual analog scale in the Fibromyalgia Impact Questionnaire (FIQ) that measured 'days felt bad' ($p < 0.05$). The intervention group also showed significantly greater decreases in morning fatigue as measured by the FIQ visual analog scale that gauged fatigue on waking ($p < 0.05$). It is difficult to monitor whether the benefits were related to the exercise, education or both, because both interventions were given. The authors reflect that further studies will be needed to show if such gains can be improved and sustained for sufficient time to be clinically beneficial to FM

patients. Further studies are also needed to distinguish between the effects of each intervention.

Gowans and deHueck (2004) recommend further investigation into the benefits of low intensity exercise and the development of strategies for long term compliance with exercise regimes by people with FM. The authors also encourage enhanced access to community exercise programs and progression exercise instruction specific for people with FM.

Persell (2002) determined that a 12-week graded aerobic exercise plan resulted in more improvement in a validated self-rated change in global impression scale and decreased tender point counts compared with a relaxation and stretching program for adults with FM (n=136). For the primary outcome, the improvement in a validated self-rated change in global expression scale, 24/69 patients (35%) in the exercise group and 12/67 (18%) in the relaxation group improved ($p = 0.03$).

Similarly, a study by Gandhi, DePauw, Dolny and Freson (2002), examining the effects of a 10-week (20 session) exercise program on quality of life of women with FM (n = 21), concluded that significant improvements were made in the range of motion ($p = 0.0003$) and in the FIQ scores ($p = 0.0049$) of the exercise groups, but the tender point count and the tender point severity scales were unaltered. This area of research between physical activity and health-related quality of life and outcomes is complex. Although the beneficial effects of participating in regular exercise are known, the dose response relationships between physical activity and health-related quality of life are unclear (Brown et al., 2004).

One influence on exercise prescription could be the fatigue factors that accompany FM. Bujak, Mikdashi, Kalappa, Keyser, and Handwerker (2002) considered aerobic capacity in their studies of people with FM. Aerobic capacity is determined by measuring peak oxygen intake. If a person scores more than 27% below their expected oxygen intake, they are considered to have functional aerobic impairment. In this study, functional aerobic impairment was observed in 6 of the 11 FM study participants, but in none of the 11 controls. Bujak and colleagues (2002) are continuing to look for molecular mechanisms underlying this impairment to develop interventions that may improve aerobic capacity.

The majority of patients who have experienced the symptoms of FM for some time tend to be deconditioned muscularly because of their inability to exercise without exacerbating the pain. Although the exercise emphasis for FM management has been mainly on aerobics, a recent pilot study (Rooks, Silverman, & Kantrowitz, 2002) has shown that a program of progressive strength training and cardiovascular exercise was safe and well tolerated in women with FM. This study also showed that the introduction of progressive strength exercises, together with cardiovascular endurance training, did not exacerbate their FM symptoms. Patient characteristics that may impact on the success of an exercise program for FM and similar conditions have been listed by Ambrose, Lyden and Clauw (2003) as: a readiness to adopt a new exercise regime that may increase pain at the beginning; the ability to accept self-management for their FM; unrealistic expectations; fear of an increase in pain and fatigue; and past experiences with exercise and social support.

Recommendations from the 6th International Conference on Chronic Fatigue Syndrome, Fibromyalgia and Related Illnesses included a low level aerobic interval exercise as an exercise alternative for people with FM (Lapp, 2003). This exercise regime involves exercising for 3 to 5 minutes followed by the same time period resting to allow the body to recover and then exercise and rest again. This option for exercising is often more palatable for the FM sufferer who can experience a flare up of symptoms due to excessive exercise (Lapp, 2003).

For women with bladder irritability symptoms associated with FM, their ability to exercise is often inhibited by the anxiety of urinary urgency and urinary frequency. The fear of not being able to get to the toilet in time to void, the anxiety of an urge or stress incontinent episode and/or the increased pressure and pain on the bladder resulting from exercising, all contribute to poor compliance to any exercise program. To date, there have been no studies on the effect of exercise specifically on the bladder irritability symptoms of FM.

Pharmacological Treatment of FM

Clauw (2000) comments that, in clinical practice, the view is widely held that the interventions of education, exercise and cognitive behavioural therapy are more

effective when they are combined with symptom-based pharmacological therapy. Barkhuizen (2001) lists symptoms amenable to pharmacological therapy as pain, sleep disturbance, mood disturbance, fatigue and associated disorders. Until there is a clearer understanding of the pathophysiologic mechanisms causing the symptoms of FM, pharmacological treatment should be aimed at individual symptoms (Barkhuizen, 2001). He suggests guarding against polypharmacy and prescription for symptoms that impact on activities of daily living and quality of life.

Barkhuizen (2001) notes that, even though evidence-based medicine dictates that the use of medication should be based on the results of randomised placebo-controlled clinical trials, FM poses a challenge to researchers because it is a complex disorder with multiple symptoms, lacking clear etiology and objective physical findings. Jain and colleagues (2004) anticipate that the optimal therapy for FM in the future will be the use of a limited cocktail of low dose medications which each target a specific receptor known to be involved with the pathogenesis of FM. Duggan (2002), in his presentation on Central Transmitters: Prospects for Pain Control, spoke of the most centrally acting drugs affecting brain function by their action at the synapses by modifying the release, action or inactivation of neurotransmitters.

Russel (2003) describes FM as a syndrome that is underserved by the medical profession and the pharmaceutical industry. He asks questions regarding the management of FM, such as what kinds of biochemical and physiological changes predispose people to developing FM and can these changes be manipulated by physiological or psychological interventions? Russel also asks which steps in the nociceptive process could be altered to produce clinical benefits. For now, the complexity of FM defies pharmacological cure or significant relief of symptoms.

Anti-inflammatory medicines are non-effective in reducing pain, as FM is not an inflammatory disease. A trial of non-steroidal anti-inflammatory drugs is often used to manage peripheral pain such as that resulting from osteoarthritis. Narcotic medications are controversial in the management of FM and other chronic pain conditions. There does remain some concern about the addictive properties of opioids. They may increase cognitive dysfunction or gastrointestinal problems and remain a controversial topic for treatment of FM (Barkhuizen, 2001).

Analgesic therapy includes the use of tricyclic antidepressants with documented analgesic effects (Goldenberg, Mayskiy, & Mossey, 1996). A meta-analysis of nine studies on the use of antidepressants in FM (Arnold et al., 2000) found a moderate improvement in pain and sleep and a modest improvement in fatigue, tenderness and stiffness. Another meta-analysis of 13 published, good quality, randomised, placebo-controlled trials (O'Malley, Balden, Tomkins, Santoro, & Kroenke, 2000) suggests that antidepressants reduce the symptoms of FM. The authors have suggested further research to assess the relative efficacy of different types of antidepressants as well as whether the efficacy is independent of an effect on depression. Lawson (2002) suggests that tricyclic medications are most effective when administered with other therapies such as selective serotonin reuptake inhibitors which affect the modulation of the neurotransmitters, serotonin and noradrenaline.

The selective serotonin reuptake inhibitors have been shown to have a minimal effect on pain in FM, but some benefit in the emotional component of pain and mood disorders (Jung, Staiger, & Sullivan, 1997). Sleep hygiene measures are usually implemented before medication for poor sleep patterns. Medication to improve sleep includes pure sedatives acting on benzodiazepine receptors, sedating antihistamines and sedating antidepressants (Barkhuizen, 2001).

Data presented by Crofford and Arbor (2002c) showed improvement in the core symptoms of FM of pain, sleep and fatigue from a double-blind, placebo-controlled study on the new drug pregabalin. This study involved 529 patients diagnosed with FM. Pregabalin-treated patients trialling 450mg/day for eight weeks showed significant improvements in pain compared to those who received placebos. Jancin (2004) cites Buskila at the annual 2004 European Congress of Rheumatology in describing pregabalin as an efficient agent that gives significant improvement in the widespread pain, sleep disruption and fatigue due to FM. Buskila commented that these improvements and a good safety profile were as much as could be expected of any proposed therapy, given the gaps in the current understanding of the basis of FM (Jancin, 2004). Crofford (2002c) speaks of the need for new treatment options that are both effective and well tolerated because of the debilitating and difficult to treat symptoms of FM.

Many of the available medications for pain have been developed for lessening acute rather than chronic pain. Mechanisms that lead to chronic pain are different from those of acute pain. Clauw, when interviewed by Meisler (2000), suggested that, within the next three to five years, we can expect to see new classes of medications that will be developed for the management of chronic pain alone.

Clauw, presenting at the 2003 American College of Rheumatologists Annual Scientific Meeting (Ross, 2003), has suggested that the drug milnacipran, which was in its phase II clinical trial and had shown to provide statistically significant improvement of pain in FM, could dramatically change the way FM is treated. The phase II study was a 12-week randomised, double-blind, placebo-controlled trial at several centres across the United States of America (n=125). The results showed 37% of FM patients reported a 50% reduction in pain compared to 14% of placebo patients (Franklin, 2003). Further studies need to be completed to confirm these data. Milnacipran belongs to a group of drugs known as SNRIs (serotonin norepinephrine reuptake inhibitors). Milnacipran is a dual acting reuptake inhibitor that acts on two neurotransmitters, norepinephrine and serotonin, which are involved in the central modulation and processing of chronic pain (Kranzler, 2003).

Littlejohn (2004) comments that pharmacological information to date suggests that drugs such as duloxetine, a serotonin and norepinephrine reuptake inhibitor, may be more efficacious in the treatment of FM. A recent randomised, double blind, 12-week trial (Arnold et al., 2004) has shown that duloxetine-treated patients improved significantly more ($p = 0.027$) on the total score of the Fibromyalgia Impact Score (FIQ) but not on the FIQ pain score ($p = 0.130$). In this trial, the intervention group also showed a significant decrease in Brief Pain Inventory average pain severity scores ($p = 0.008$), Brief Pain Inventory average interference from pain score ($p = 0.004$), number of tender points ($p = 0.002$), and FIQ stiffness score ($p = 0.048$) (Arnold et al., 2004). The duloxetine-treated patients also significantly improved in mean tender point pain threshold ($p = 0.002$), Clinical Global Impression of Severity (CGI-Severity) scale and Patient Global Impression of Improvement (PGI-Improvement) scale ($p = 0.033$) (Arnold et al., 2004). The men in this study did not show any significant improvement on any efficacy measures. The

researchers recommend further studies to study the long term efficacy of duloxetine in FM.

Recent trials of duloxetine have also shown it to be effective for women with stress urinary incontinence (Cardozo, 2004). Cardozo refers to duloxetine as the first pharmacological agent that has been developed in large randomised controlled trials for the management of stress incontinence in women. Michel and Peters (2004) describe lower urinary tract function as being tightly managed by a complex neural network. They describe the pelvic nerves as suppliers of key signals for micturition, and the hypogastric and pudendal nerves as suppliers of key signals for urine storage. Urethral closure depends on an intact striated urethral sphincter that is innervated by the pudendal nerve. The tone and contraction of the striated urethral sphincter is increased by the central neurotransmitters of serotonin and noradrenaline. Duloxetine, as a powerful and balanced serotonin and noradrenalin reuptake inhibitor, is thought to increase the concentrations of these neurotransmitters, with a resultant increase in the activity of the striated urethral sphincter and increased bladder capacity (Michel & Peters, 2004). Results of the randomised placebo-controlled trials (van Kerrebroeck, 2004) show that duloxetine 80mg/day is an effective and safe treatment for women with urinary incontinence

The Food and Drug Administration Arthritis Advisory Committee of the United States of America has proposed guidelines for use in the design trials of drugs for FM (Franklin, 2003). This advisory committee has recommended that trials of FM treatments should last at least six months and that all patients entering the trial should meet the 1990 diagnostic criteria set down by the American College of Rheumatology. The committee recommended that the drug manufacturers demonstrate an effective end point as indicators for the treatment for FM. This end point could include some improvements in pain, patient global assessment and function (Franklin, 2003). It was also suggested that end points for symptom-specific indicators for pain, sleep difficulties and fatigue be included.

Sewitch, Dobkin, Bernatsky, Baron, Starr, Cohen and Fitzcharles (2004) identified the determinants of medication non-adherence in women with FM (n= 127). Sixty (47%) women were non-adherent to medication, with 20 (33.3%) being

intentionally non-adherent and 24 (40%) unintentionally non-adherent. Unintentional non-adherence was predicted by community status, not being under a rheumatologist care plan, decreased disease activity, less use of instrumental coping and increased patient-physician discordance, while intentional non-adherence was predicted by a shorter time under a rheumatologist's care and greater patient-physician discordance (Sewitch et al., 2004).

Cognitive Behavioural Therapy

Price (2004) describes pain as having many neurological and psychological dimensions that are processed in the brain. This subsequently triggers pain as a sensation and evokes an emotional response to that pain. Price concludes that there is no single, all-encompassing pain response centre existing in the brain. He states that although pain sensations are activated by neurones in the brain, these sensations occur within the context of psychological and physical factors that are responsible for the cognitive and evaluative component of pain. Price (2004) likens the sensory dimension of pain being embedded in the emotional dimension in the same way that height is a determinant of weight.

The Australian Association for Cognitive and Behavioural Therapy (Australian Association for Cognitive and Behavioural Therapy, 2004) defines cognitive behavioural therapy (CBT) as a focused approach to the treatment of different types of emotional, behavioural and psychiatric problems which assists individuals in identifying unhelpful thoughts and behaviours and learning healthier skills and habits.

Cognitive behavioural therapy is one method used to assist patients with FM to cope with their symptoms and to improve their quality of life by focusing on self-control and coping strategies. In one randomised controlled study, (Williams, Cary, Groner, Chaplin, Glazer, Rodriquez and Clauw, (2002), the cognitive behavioural therapy consisted of six hour-long group sessions with an experienced therapist that focused on teaching patients skills to improve their physical functioning. Results from this study found that 25% of the patients who had behavioural therapy experienced a significant increase in physical functioning after the treatment

compared with only 12% of patients who did not receive it. Both groups of patients had the same level of pain one year following treatment. Williams and colleagues (2002) suggest that previous studies have shown mixed results because of the differences in how the therapy was administered. Their data suggests that the inclusion of cognitive behavioural therapy in a medical regime for FM can benefit physical functioning in a subset of patients.

A meta-analysis of 49 studies of FM treatments (Rossy et al., 1999) found that cognitive behavioural therapy and exercise were superior to pharmacological agents. The authors conceded that it is likely that the cognitive behavioural therapy and exercise produced positive results because they targeted more than one symptom. Long term relief of symptoms is seldom achieved for patients with FM. The current management philosophy is to assist the patient to adapt to a lifestyle dispersed with pain, fatigue and numerous other associated symptoms. As noted previously, there is some evidence that FM can be helped but not cured by a multi-disciplinary approach incorporating education, aerobic exercise, cognitive behavioural therapy and management of associated syndromes (Bennett, 2002b).

Nielson and Jensen (2004) examined the association between the treatment process variables of beliefs, and coping strategies and treatment outcomes of pain severity, activity level, emotional distress and life interference related to a four-week multi-disciplinary FM treatment program. Outcomes of the intervention resulted in an increased sense of control over pain, a belief that one is not necessarily disabled by FM, knowledge that pain is not necessarily a sign of some damage, decreased guarding, increased exercise, seeking support, activity pacing and use of self-statement for coping. Nielson and Jensen (2004) observe that their findings were consistent with a cognitive behavioural model of FM.

The research on the sub-grouping of Fibromyalgia patients on the basis of pressure-pain thresholds and psychological factors (Giasecke et al., 2003) has implications for rehabilitation interventions for FM patients. Uniform recommendations for treatment for all FM sufferers cannot be given because of the diversity within the patient group (Spratt, 2003). Spratt recommends individual

adapted measures should be emphasised to differentially treat these FM subgroups when identified.

Fibromyalgia and Bladder Symptoms

Irritable bladder symptoms similar to the irritative bladder symptoms of interstitial cystitis (IC) are listed as one of the associated disorders of FM (Littlejohn, 1996). These symptoms include urinary frequency, urinary urgency, nocturia and pelvic pain in the absence of infection. Although the focus of this current research on FM is not on the development of knowledge of the neurobiology of bladder pain and its associated symptoms of urgency, frequency and nocturia, a brief overview of some recent research findings related to lower urinary tract sensation is important as background for this study.

Rothenberg (1999) describes FM as a condition that involves the loss of pain regulation in the central nervous system resulting in pain amplification. Abnormal levels of central nervous system neurotransmitters then result from this excessive pain stimulation. The imbalance of neurotransmitters affects the body's hormonal response to stress, resulting in abnormalities in the autonomic nervous system. Rothenberg comments that these abnormalities in turn affect the involuntary functions and that their impact contributes to conditions such as irritable bowel and irritable bladder.

With all neurologic reflex mechanisms efferent activity results from afferent input (Fowler, 2002). Adequate sensory input is a prerequisite for conscious bladder control (Wyndaele & De Wachter, 2003). Sensory nerve cell bodies from the dorsal root ganglion project to the lower urinary tract and the spinal cord. The motor innervation of the bladder and urethra originates from the lumbosacral area (S2-S4) and travels by the parasympathetic pelvic nerves. The sensory nerves from the bladder run with the motor supply. Poorly localised sensations of pain and distension enter with the sympathetic fibres at a higher level (Abrams, 1997).

Sensory receptors are present in the human bladder in the detrusor muscle and in the suburothelial layer. The sensory nerves supplying the bladder are myelinated A-delta or unmyelinated C-fibres (Wyndaele & De Wachter, 2003).

Wyndaele and De Wachter note that both the afferent A-delta and C-fibres in the pelvic and hypogastric nerve are able to signal non-painful sensations during bladder fillings and suggest that these afferents may also signal noxious events resulting in abnormal symptoms such as urgency and pain. They further comment on the plasticity of the bladder afferents where the number of active primary afferents is not static, resulting in changes in bladder sensation in various pathological conditions.

Wyndaele (1998) and Wyndaele and Wachter (2002) studied cystometrical sensory data from a normal population during cystometric bladder filling. The normal pattern of bladder sensations on filling is described during cystometry as three distinct sensations. The first sensation is described as just that of the bladder filling, the second as the first desire to void and the third as a strong desire to void. A fourth sensation of pain can be added if bladder filling continues after the volume of full bladder sensation.

Wyndaele and De Wachter (2003) report the first sensation of filling occurring at a mean of 40% of bladder filling and the first desire to void at a mean of 59% of total bladder capacity. They refer to this system of sensations as warnings that enable us to integrate bladder function in every day life. It has been suggested that if this system of sensations malfunctions, where the first sensation of filling is absent, then the other sensations occur at significantly smaller volumes (Wyndaele, 1993) and this may cause urgency (Klein, 1988). Wyndaele and De Wachter (2003) suggest that, if the sensations come at too low volumes, they may cause frequency and nocturia. These authors describe urgency as a pathological sensation where one experiences a continuous desire to void sometimes even after micturition. In many women diagnosed with FM, the cause for this urgency cannot be identified.

Urinary Definitions

The standardisation of measurements and a consensus on terminology help to prevent confusion, assist in understanding the pathophysiology of conditions and define what is normal and abnormal (van Kerrebroeck & Weiss, 1999). Urogenital symptoms of FM include urinary frequency, urinary urgency, nocturia, bladder and/or pelvic pain and vulvodynia. These urogenital symptoms associated with FM

are often referred to as the irritable bladder syndrome, interstitial cystitis or lower urinary tract symptoms. Urinary definitions used in this study will conform to the standards recommended by the International Continence Society except where specifically noted.

The International Continence Society (ICS) is recognised as the international governing body for the standardising of urological terminology. The following urinary definitions are from the Standardisation of Terminology of Lower Urinary Tract Function: a report from the standardisation sub-committee of the International Continence Society (ICS) (Abrams et al., 2002b). These definitions are compatible with the WHO publication ICIDH-2 (International Classification of Functioning, Disability and Health) published in 2001 and the ICD10, the International Classification of Disease. The following definitions are from the Standardisation of Terminology in Lower Urinary Tract Function from the ICS.

Lower Urinary Tract Symptoms

The urogenital tract symptoms of FM are lower urinary tract symptoms (LUTS) and are defined from the individual's perspective. Urinary symptoms as defined by the International Continence Society (ICS) are divided into the three groups of storage, voiding and post micturition symptoms. Definitions relevant to this study are listed here.

Storage symptoms are experienced during the storage phase of the bladder and include:

- increased day time frequency, the complaint by the patient who considers that she/he voids too often by day.
- nocturia, the complaint that the individual has to wake at night one or more times to void.
- urgency, the complaint of a sudden compelling desire to pass urine which is difficult to defer.
- urinary incontinence, the complaint of any involuntary leakage of urine.
- stress incontinence, the complaint of involuntary leakage of urine on effort or exertion or on sneezing or coughing.

- urge urinary incontinence, the complaint of involuntary leakage accompanied by or immediately preceded by urgency.
- mixed urinary incontinence, the complaint of involuntary leakage of urine associated with urgency and also with exertion, effort, sneezing or coughing.
- other types of incontinence which may be situational such as the report of incontinence during sexual intercourse or giggle incontinence.

Bladder Sensation Definitions

- Normal is where the individual is aware of bladder filling and increasing sensation up to a strong desire to void.
- Increased is where the individual feels an early and persistent desire to void.
- Reduced is where the individual is aware of bladder filling but does not feel a definite desire to void.
- Absent is where the individual reports no sensation of bladder filling or desire to void.
- Non-specific is where the individual reports no specific bladder sensation but may perceive bladder filling as abdominal fullness, vegetative symptoms or spasticity.
- Voiding symptoms are experienced during the voiding phase.
- Post-micturition symptoms are experienced immediately after micturition such as feeling of incomplete emptying being a self-explanatory term for a feeling experienced by the individual after passing urine.

Genital and Lower Urinary Tract Pain

Pain discomfort and pressure are part of a spectrum of abnormal sensations felt by an individual. The ICS terminology report recommends that genital and lower urinary tract pain should be characterised by type, frequency, duration, precipitating and relieving factors and by location as defined in the following:

- Bladder pain is felt suprapubically or retropubically usually increasing with bladder filling and may persist after voiding.
- Urethral pain is felt in the urethra and the individual indicates the urethra as the site.
- Vulval pain is felt in and around the external genitalia.

- Vaginal pain is felt internally, above the introitus.
- Perineal pain is felt in the female, between the posterior fourchette (posterior lip of the introitus) and the anus.
- Pelvic pain is less well defined than, for example, bladder, urethral or perineal pain and is less clearly related to the micturition cycle or to bowel function and is not located in any single pelvic organ.

Syndromes as described in the ICS terminology report are varying combinations of symptoms that cannot be used for precise diagnosis. The use of the word, 'syndrome', is justified only if there is at least one other symptom in addition to the symptom used to describe the syndrome. The syndromes are functional abnormalities for which a precise cause has not been found. It is expected that appropriate assessment has excluded obvious pathologies. The ICS terminology report lists two syndromes, the urogenital pain syndrome and the symptom syndrome suggestive of lower urinary tract dysfunction.

Urogenital Pain Syndromes

These are all chronic conditions. Pain is the major complaint, together with complaints including lower urinary tract, bowel, sexual, or of a gynaecological nature:

- Painful bladder syndrome is the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms such as increased daytime and night-time frequency, in the absence of proven urinary infection or other obvious pathology.
- Urethral pain syndrome is the occurrence of recurrent episodic urethral pain usually on voiding, with daytime frequency and nocturia, in the absence of proven infection or other obvious pathology.
- Vulval pain syndrome is the occurrence of persistent or recurrent episodic vulval pain, which is either related to the micturition cycle or associated with symptoms suggestive of urinary tract or sexual dysfunction and where there is no obvious pathology or proven infection.
- Vaginal pain syndrome is the occurrence of persistent or recurrent episodic vaginal pain which is associated with symptoms suggestive of urinary tract or

sexual dysfunction and where there is no proven vaginal infection or other obvious pathology.

- Perineal pain syndrome is the occurrence of persistent or recurrent episodic perineal pain, which is either related to the micturition cycle or associated with symptoms suggestive of urinary tract or sexual dysfunction and where there is no proven infection or other obvious pathology.
- Pelvic pain syndrome is the occurrence of persistent or recurrent episodic pelvic pain associated with symptoms suggestive of lower urinary tract, sexual, bowel or gynaecological dysfunction and where there is no proven infection or other obvious pathology.

Symptom Syndromes Suggestive of Lower Urinary Tract Dysfunction

Urgency, with or without urge incontinence, usually with frequency and nocturia, can be described as either the overactive bladder syndrome, urge syndrome or urgency-frequency syndrome.

Measuring Signs Suggestive of Lower Urinary Tract Dysfunction

The bladder diary records the times of micturitions and voided volumes, incontinence episodes, pad usage, fluid intake, degree of urgency, the degree of incontinence and other relevant information. The following measurements can be extracted from bladder diaries:

- Daytime frequency is the number of voids recorded during waking hours and includes the last void before sleep and the first void after waking and rising in the morning.
- Nocturia is the number of voids recorded during a night's sleep. Each void is preceded and followed by sleep.
- Nocturnal polyuria is defined by the nocturnal urine volume >20-30% of the total 24 hour urine volume.
- Twenty-four-hour frequency is the total number of daytime voids and episodes of nocturia during a specified 24-hour period.
- Maximum voided volume is the largest volume of urine voided during a single micturition.

Urodynamic Observations and Conditions

Urine flow is defined either as continuous or intermittent. The continuous flow curve is defined as a smooth arc-shaped curve, or a fluctuating one where there are multiple peaks during a period of continuous urine flow.

- Flow rate is defined as the volume of fluid expelled via the urethra per unit time. It is expressed in ml/sec.
- Voided volume is the total volume expelled via the urethra.
- Maximum flow rate is the maximum measured value of the flow rate after correction for artefacts.
- Voiding time is the total duration of micturition.

(Abrams et al., 2002b)

Lower Urinary Tract Symptoms

Lower urinary tract symptoms (LUTS) can be classified as storage symptoms, emptying symptoms or both (Blaivas, 2000). Urinary frequency, urgency and pain are classified as storage symptoms. Sensory urgency is described as an uncomfortable need to void unaccompanied by detrusor instability.

Within the medical literature, lower urinary tract symptomatology in the male population has been more extensively studied than that for the female population. An Austrian study (Schatzl et al., 2001) compared the prevalence and severity of lower urinary tract symptoms (LUTS) in both sexes and determined their effect on everyday life as 'botherness'. The women's results (n=1191) showed the mean increase in LUTS from the youngest (20-39 years) to the oldest (> 70 years) age group was 23.6% (3.9%/decade). In all decades, the irritative storage symptoms were higher in the women's group. The researchers reported that urinary urgency and frequency were more bothersome in older individuals, while nocturia and voiding symptoms were almost equally bothersome for both younger and older study participants.

Gillespie (2004) reviews the literature on the generation of excessive sensory urges of the bladder. Urological opinion is that low bladder tone during the filling

phase is maintained by reducing the parasympathetic excitatory micturition reflex and encouraging the inhibitory sympathetic elements to facilitate 'accommodation' (Ruch, 1960). Gillespie explains the bladder as rhythmically active during the filling phase, the activity being generated in the bladder wall, and describes this as 'autonomous' activity in the non-micturition phase. Gillespie notes that this rhythmic activity is an intrinsic property of the bladder wall and that the frequency and magnitude of these transient contractions could be affected by parasympathetic and sympathetic neural inputs. This autonomous activity entails waves of contraction and localised stretches of the bladder wall. These complex events may involve a network of pacemaker cells and connecting interstitial cells motivated by excitatory and inhibitory neural inputs (Gillespie, 2004). Modulation by central nervous system activity can affect the amplitude and frequency of the autonomous activity with resultant changes in bladder sensations.

Lower urinary tract symptoms (LUTS) in women can produce significant bother and affect their quality of life (Scarpero, Fiske, Xue, & Nitti, 2003). Scarpero and colleagues determined whether the degree of bother caused by lower urinary tract symptoms correlated with a woman's quality of life and whether this varies with a woman's age and continence status. Using the American Urological Association Symptom Index (AUASI), this study has shown a strong correlation between urinary symptoms and problems caused by these symptoms ($n=1232$, $p < 0.001$) and also that the correlation existed throughout various age groups and was independent of their continence status. A similar pattern was shown for the correlation between urinary symptoms and quality of life. With the diversity of symptomatology of diseases such as FM that do not yet have absolute classifications or biological/biochemical markers, how do we give advice to people with these symptoms? How do we treat 'bother'?

Urinary Frequency

Increased urinary daytime frequency is described by the International Continence Society as the complaint by the patient who considers that she/he voids too often by day (Abrams et al., 2002b). The incidence of urinary frequency in community-dwelling women ($n=886$) was reported at 20% (Glenning, 1985).

Significant correlations between urinary frequency and bother have been shown in another community-dwelling population (Swithinbank et al., 1999). In this study (n = 2075), over 50% of women found voiding nine times a day or more was a problem for them. The mean age of responders was 52 years with an age range of 19-97 years. The authors found that the most prevalent symptoms were not necessarily the symptoms the women reported as being most problematic. Swithinbank and Abrams (2000) found only 5% of women with a voiding frequency of 1 to 6 times a day and 17% of women who voided 7 to 8 times a day found it bothersome.

Urinary Urgency

Urinary urgency is described by the International Continence Society as the complaint of a sudden compelling desire to pass urine which is difficult to defer (Abrams et al., 2002b). Urgency is described as a pathological sensation that is experienced as a continuous desire to void, as a sensation that does not necessarily ebb post micturition and one that is experienced differently from the sensation of bladder fullness (Wyndaele & De Wachter, 2003). A large study (Swithinbank et al., 1999) on community-dwelling women in Britain (n=2075) has shown that one of the most common urinary symptoms was urgency (61%). Only 37% of these women with urgency reported this symptom as problematic. The authors comment that this study has highlighted the importance of prevalence studies on urinary symptoms as well as the perceived impact caused by the symptoms. This perceived impact may be more useful in assessing the demands for treatment.

Treatment for sensory urgency firstly includes the treatment of detectable conditions. When there is no obvious abnormal pathology, a pharmacological approach using drugs that impair bladder sensation and/or neurotransmitters of pain signals may be considered (Blaiwas, 2000).

Nocturia

Nocturia, as described by the International Continence Society, is the complaint that the individual has to wake at night one or more times to void (van Kerrebroeck & Weiss, 1999). The authors of the Standardisation of Terminology in

Nocturia for the International Continence Society (van Kerrebroeck et al., 2002) comment that although a person may consider that one night time void is normal, they still do have nocturia. The authors also note that, in the situation where the desire to void may not be the trigger that wakes people at night yet they need to void when they wake, these individuals are still considered to have nocturia.

Nocturia is a condition that is now recognised as a clinical entity in its own right and not a symptom of some other disorder (van Kerrebroeck et al., 2002). It has been reported as one of the most common causes of sleep disturbance (Middlekoop, Smilde van den Doel, Neven, Kamphuisen, & Springer, 1996). Schatzl and colleagues (2000) have shown that the number of people with nocturia of two or more times increased with age: below 30 years (3.1%), between 30 to 59 years (7.2%) and over 60 years (26.7%). The age-adjusted extrapolation to the general population (> 20 years of age) of women in Austria showed that 11.8% of women experience nocturia of two or more times and that the nocturia affects the quality of life of two thirds of these women (Schatzl et al., 2000).

Weiss and Blaivas (2003) list pathological conditions such as cardiovascular disease, diabetes mellitus, lower urinary tract obstruction, anxiety, primary sleep disorders, and behavioural and environmental issues as factors that may result in nocturia. They attribute nocturia to nocturnal polyuria, diminished nocturnal bladder capacity or a combination of both factors.

Middlekoop and colleagues (1996) have reported the prevalence of nocturia to be 58% and 66% in women and men of 50 to 59 years and 72% and 91% in women and men over 80 years of age. A recent study on nocturia and its effect on health-related quality of life and sleep (Coyne et al., 2003) found that nocturia was widely prevalent and increased with age. It was demonstrated that incremental increases in the number of voids per night had increased negative effects on sleep, symptom bother and health-related quality of life. Lose, Alling-Moller and Jennum (2001) have shown that the prevalence of nocturia is more common in parous women and increases with age, with more than 50% of women > or = to 80 years of age experiencing nocturia. The authors note that although nocturia is one of the most bothersome of the lower urinary tract symptoms, with a significant impact on quality

of life, few women seek medical assistance because they accept it as part of aging (Lose et al., 2001). Swithinbank and colleagues (1999) in their large British study (n =2075) found 19% of women reported nocturia as a urinary symptom with 63% finding the nocturia troublesome. The mean age of responders was 52 years with an age range of 19 to 97 years.

The impact of nocturia on quality of life in a Dutch population has revealed that nocturia can lead to sleep insufficiency with subsequent decrease in mental and physical health. Researchers (van Dijk et al., 2004) selected 1000 adults after stratification to complete a written questionnaire. The 819 respondents were distributed over three groups: a target group (n=189) who were bothered by \geq one void per night, a reference group I (n=120) with no bother but \geq two voids per night and a reference group II (n=510) with 0-1 voids per night. The results have shown that the perceived impact on life was highest in the target group ($p < 0.05$). The target group also showed more sleep problems and scored lower on quality of life scores than reference groups I and II ($p < 0.05$). Van Dijk and colleagues (2004) suggest that doctors routinely check for nocturia when patients present with sleep problems. This would be particularly pertinent for FM sufferers, many of whom already experience insomnia and unrefreshed sleep that is unrelated to their bladder symptomatology.

Fiske, Scarpero, Xue and Nitti (2004) studied 1232 patients showing that as the number of nocturia episodes increases, the bother increases ($p < 0.0001$) and is independent of age and continence status. Fiske and colleagues (2004) propose from this study that clinically significant nocturia in women be classified as two or more episodes per night. They also suggest that two episodes of nocturia be considered mildly clinically significant, three episodes as moderate and four or more episodes to be severe nocturia. This classification system is given as a guide only in the diagnosis and treatment of women with nocturia.

Kobelt, Borgstrom and Mattiasson (2003) assessed the effect of nocturia on productivity, vitality and utility in a selected group of professional active individuals with nocturia compared with matched controls. The researchers tested the hypothesis that a lack of sleep due to frequent sleep interruptions could decrease a person's

daytime energy and activity levels. The study group (n=203) with nocturia experienced a lower level of vitality and utility with greater impairment of work and activity. Symptom severity correlated with all three measures of productivity, vitality and utility. The women participants were more affected than the men. The researchers concluded that waking at night to void diminished the participants overall well being, vitality and productivity and resulted in a significant level of indirect and tangible costs (Kobelt et al., 2003).

Walmsley and Staskin (2003) stress the importance of considering the non-urologic etiologies in the differential diagnosis of a patient presenting with nocturia. The authors comment that this is even more important if the patient has failed to respond to lower urinary tract directed therapy or if surgery is being considered. Voiding diaries are an essential part of the assessment of patients with nocturia as they give information on low nocturnal bladder capacity, increased night time urine production and behavioural and environmental factors. Because of the insomnia already experienced by people with FM, the increased burden of nocturia may have an increased detrimental effect on their hours of effective sleep. As previously mentioned in this text, it is now recognised that sleep deprivation is a very serious health and safety risk factor within our communities and workplaces. The impact, therefore, on women already struggling with non-bladder symptoms of FM can have significant bother and health effects.

Bladder Pain

Bladder pain is felt suprapubically or retropubically, usually increasing with bladder filling, and may persist after voiding, while painful bladder syndrome is the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms such as increased daytime and night time frequency, in the absence of proven urinary infection or other obvious pathology (Abrams et al., 2002b). Two types of pain have been described in the bladder: a sharp pain suprapubically or in the perineal region; a painful pressure in the lower abdomen (Wyndaele & De Wachter, 2003). Blaivas (2000) describes these two types of pain as one that occurs immediately before, during or after voiding, and the pain that is felt when micturition is delayed. Blaivas comments on the many other permutations of pain that may not

be associated with the lower urinary tract but are included with the differential diagnosis.

Fibromyalgia Bladder Irritability and Interstitial Cystitis

Data from their study examining clinical features and peripheral nociception in parallel cohorts of FM and IC patients suggested to Clauw and colleagues (1997a) a significant overlap in symptomatology in both IC and FM. A questionnaire questioning the presence of 47 different symptoms that are common in FM was completed by 60 FM patients, 30 IC patients and 30 controls. The authors suggest that the data, together with near identical common natural histories, demographics and response to therapy, indicate that both FM and IC may share some common pathogenic etiologies.

Lutgendorf, Kreder, Rothrock, Hoffman, Kirschbaum, Sternberg, Zimmerman and Ratcliff (2002b) showed that the abnormalities of the hypothalamic-pituitary-adrenal feedback system resulted in poor regulation of the inflammatory response. This suggests that dysregulation of the HPA feedback mechanism could result in inadequate regulation of inflammation in IC, allowing chronic inflammation to become established. In commenting on this study, Bennett (2002c) notes that, as IC symptoms are exacerbated by stress, dysregulation affecting the stress response system could contribute to the pathophysiology of IC. Bennett also comments on the relevance of these findings to understanding the association of FM with some other inflammatory states as IC is a common morbidity with the FM syndrome.

The urogenital symptoms experienced by women with FM have numerous descriptive terms. Interstitial cystitis (IC) is the term often used in the literature describing the urogenital symptoms of FM. The irritable bladder symptoms experienced by women with FM are similar to the irritative bladder symptoms of IC. These urinary symptoms include urinary frequency, urinary urgency, nocturia and pelvic pain in the absence of infection with the most definitive symptom being pain. Sand (2004) suggests that, in all women who present with chronic pelvic pain (CPP) and with the urinary symptoms of urgency and frequency, IC should be suspected as

(Wesselmann, 2004) an isolated or concurrent etiology in the absence of other pathologic entities such as infection or tumour.

Urogenital pain often goes together with voiding disturbances and sexual dysfunction (Wesselmann, 2000). A study on the relationship between some bladder symptoms and sexual activity in women (Patel et al., 2004) concluded that women who experienced urinary frequency and/or urge incontinence were less sexually active. The authors also noted that women who expressed a greater degree of bother related to abdominal pain or genital pain were less likely to enjoy sexual activity and were more likely to experience sexual thoughts or fantasies. As women with FM often experience both abdominal pain from irritable bowel symptoms and genital pain, this study highlights a possible impact on their capacity to sexually express themselves as women.

Women with FM also experience chronic pelvic pain. Vulvodynia, dyspareunia and vaginismus are common and can be multifactorial (Weiss, 2000). Vulvodynia is a chronic pain disorder characterised by constant or recurring complaints of vulvar pain or discomfort. This study examines vulvodynia symptoms and dyspareunia and their impact on women diagnosed with FM.

Effective outcome measures for urogenital symptoms need to be revisited and developed as our knowledge of these symptoms and their impact improves. This is important not only in the primary areas of urological disease, but also in the areas where urinary symptoms are associated symptoms of other conditions such as FM. There is currently no questionnaire available specifically to aid in assessing the urological symptoms or impact on women with FM. Such a questionnaire would assist in determining the nature of the problem, the extent and frequency of the symptoms, and the impact the condition has on the patients' well being and activities of daily life. Pre-and post-treatment validated questionnaires for these specific conditions can clearly indicate treatment outcomes. Such questionnaires can also be helpful in prevalence studies for the wider population (Graham & Dmochowski, 2002). The current study tests the Interstitial Cystitis Symptom and Problem Index (ICSI/ICPI) within the FM population for reliability and validity to provide such a

questionnaire for this specific FM population of women with irritable bladder symptoms.

Interstitial Cystitis

Wein and Hanno (2002) describe IC as an elusive disease that evades diagnosis, defies a defining etiology and resists treatment. The characteristics of IC are similar to those of an acute urinary tract infection, being suprapubic pressure and pain, urgency and frequency of voiding. The most dominant symptom of IC is pain. Ratner (2001 a), in describing a severe case, notes frequency occurring as often as 60 bathroom visits per day and nocturia as often as every 20 to 30 minutes, leading to chronic sleep deprivation. Ratner (2001b) describes patients when a diagnosis is not made as being left to manage severe, debilitating symptoms with no support. Failure to diagnose IC can lead to depression with some patients left in such pain that they commit suicide (Ratner, 2001 a). Ratner (2001b) explains that IC can be an organ-specific disease in some patients while it may be a systemic condition in other patients. A majority of patients with IC report dyspareunia (Ratner, Slade, & Greene, 1994).

In 2004 researchers at the University of Maryland School of Medicine (Interstitial Cystitis Association, 2004) completed the first total description of the structure of a toxin known as the antiproliferative factor (APF) which inhibits the growth of bladder epithelial cells. This finding may lead to a diagnostic test for IC as APF was found in the urine of approximately 95% of IC sufferers.

Because of the lack of a definitive diagnostic marker and a lack of distinct pathophysiology for IC, a diagnosis of IC is made on a constellation of clinical features as well as exclusionary criteria as with FM. MaLossi and Chai (2002) have posed the question of how do you treat a disease that has an unknown etiology? The multitude of etiological theories has resulted in many different treatment regimes developed from a trial and error approach. It is recommended that treatment be guided by an objective assessment of IC symptoms (MaLossi & Chai, 2002). One of the validated questionnaires they recommend is the ICSI/ICPI so clinicians can monitor symptoms through different treatment regimes.

Recently in the United States of America, the Social Security Administration announced an official Policy Interpretation Ruling for IC for the processing of IC-specific disability claims (Chesnut & Perilli, 2003). Instead of defining the disease in terms of quantifiable disease markers, a ruling emphasises the functional limitations that a given disease imposes on those who have the condition. It is of interest that this is occurring at a time when more and more syndromes like IC, IBS, vulvodynia and FM are being diagnosed without unique disease markers.

Both FM and IC share common features such as similar demographics, irritable bowel syndrome, headaches, history and aggravating factors. Data from the study by Clauw and colleagues (Clauw et al., 1997a) indicate that IC and FM have significant overlaps in symptoms including an increased peripheral nociception. The authors speculate that IC that has been treated until now as a specific bladder condition may be part of the disorder of the central processing of sensory information as seen in FM. Blaivas, Chaikin, Evans and Sant (1999) reinforced this speculation at a symposium on the management of the painful bladder syndrome. In discussing the etiology of bladder pain, these presenters spoke of some patients' pain being mediated by central pain mechanisms in the spinal cord and other patients suffering chronic centralised pain 24 hours a day because of the up-regulation of the spinal cord.

Ratner (2001b) acknowledges that the relationship between IC and other associated related disorders will become known when the pathophysiology of each disorder becomes known. Ratner writes that some IC patients are at greater risk of developing certain disorders. She lists these disorders as irritable bowel syndrome, vulvodynia, FM, endometriosis, chronic fatigue immune dysfunction syndrome, asthma, sensitive skin and migraines. It is because of the possible common etiologies, that Ratner (2001b) questions whether IC is a systemic disease in some patients and an organ-specific bladder disease in others. Alagiri, Chottiner, Ratner, Slade and Hanno (1997) have shown the twelve most common conditions associated with IC. Vulvodynia and FM are ranked fourth and fifth on this list of associated conditions.

Wesselmann and Burnett (1999) describe chronic non-malignant pain syndromes of the urogenital tract of longer than six months duration as well described, poorly understood and frustrating for both patient and physician. Wesselmann and Burnett are very conscious of the controversy that surrounds these pain syndromes and describe the controversy as ranging from questioning the existence of symptoms to the dismissing of the symptoms as psychosomatic. The authors comment strongly that much of this controversy is offset by the extensive available literature confirming their organicity. They acknowledge that cures for urogenital pain are uncommon but caution toward invasive and irreversible procedures. Instead, they encourage further research into neuroanatomy, neurophysiology and neuropharmacology (Wesselmann & Burnett, 1999).

Falvey (2001) also indicates concern for delay in diagnosis because of the misconception that the symptoms are psychological and notes the delay in a diagnosis can prevent the use of some coping strategies which may be used if a definite diagnosis was given. Falvey also reports on the patients with IC being very sensitive to sensory stimuli, with the resultant lower tolerance threshold which may be seen to be over-reacting to underlying pathology. Because of these factors, Falvey (2001) encourages a conceptual shift by those who treat IC patients to consider that negative psychological effects are the result of, and not the cause of, the disease.

Burkman (2004) comments that because the pathogenesis of IC is unclear and multi-factorial, this often delays diagnosis and can impact on treatment options and resultant quality of life for the patient. In the USA, women see an average of eight clinicians during a five to seven year period before obtaining an accurate diagnosis of IC (Curhan, Speizer, Hunter, Curhan, & Stampfer, 1999). According to Sand (2004), women with IC are frequently misdiagnosed with, and are treated for, either recurrent urinary tract infections or an overactive bladder syndrome. This may also be the case with FM women who have the bladder irritability symptoms of urinary urgency, frequency and pain.

A population-based study among patients with Sjogren's syndrome has demonstrated a strong association of Sjogren's syndrome with interstitial cystitis-like

symptoms (Leppilahti et al., 2003). The O'Leary-Sant interstitial symptom and problem index questionnaire (O'Leary et al., 1997) was used to assess the symptoms and symptom impact. The researchers' results suggest the possibility of a shared etiology of the two conditions.

Wesselmann (2001) observes that IC shares many features with other chronic, non-malignant visceral pain syndromes. Wesselmann advocates a different approach to successfully treat chronic visceral pain associated with IC. This approach concentrates on three separate concepts: that a spectrum of insults can lead to chronic visceral pain; that the different underlying pathogenic pain mechanisms may require different pain management strategies; that the multiple different pathogenic pain mechanisms may co-exist in the same patient and can require different pain management regimes (Wesselmann, 2001). It is anticipated that this conceptual approach to treatment may result in new insights into the pathophysiology of IC and the development of new treatment options for patients with IC and for patients with other chronic visceral pain syndromes (Wesselmann, 2001).

Brookoff (1997) discusses the consequence of bladder inflammation in IC as hypersensitivity of the chemosensitive afferent bladder nerves resulting in hyperalgesia. Following further inflammation, mechanoreceptive nerves in the bladder wall generate pain signals in response to a small increase in intravesicular pressure resulting in allodynia. With time, the persistent pain signals from the bladder to the central nervous system result in changes to the dorsal horn of the spinal cord, resulting in central sensitisation where the dorsal horn can transmit pain signals to the brain with minimal peripheral stimulation. Brookoff (1997) describes how, with this persistent pain over years, the pain signal becomes embedded in the central nervous system and the condition can become incurable. Brookoff comments that, although patients with severe pain from IC may not be cured, their pain can be eased.

Elbadawi (1997) presents a critique of current concepts of IC and presents a proposal regarding the responses invoked by neurogenic inflammation. His proposal encompasses sensory nerve excitation, the release of neuropeptides and activated differential secretion of potent mast cell mediators. Radziszewski, Borkowski and

Majewski (2002) state that, although no etiopathogenesis-based treatment has been proposed for bladder conditions of interstitial cystitis, painful bladder or overactive bladder, it is tempting to think that these conditions may represent different manifestations of 'neurogenic inflammation of the bladder' where previously silent C-fibres may be engaged.

Dysregulation of the hypothalamic-pituitary-adrenal axis may be linked to interstitial cystitis symptomatology. One study (Lutgendorf et al., 2002a) measured salivary and urinary cortisol levels in 48 patients with interstitial cystitis and in 35 age-matched controls. Although salivary or cortisol levels were similar in both groups, in the cystitis group the morning cortisol levels were linked to less pain and the higher urinary-free cortisol levels represented less overall symptomatology. Patients with morning cortisol levels less than 12.5 nmol/L were almost 13 times more likely to have higher urinary urgency. As a result of these findings, the researchers suggest that the regulation of the hypothalamic-pituitary-adrenal axis may be associated with IC symptomatology. Fitzpatrick, DeLancey, Elkins and McGuire (1993) recognised a sub-group of patients in whom interstitial cystitis and vulvar vestibulitis co-existed and suggested that the co-existence of these non-infectious inflammatory syndromes involving a disorder of the urogenital sinus-derived epithelium have a common etiology.

Parsons and Koprowski (1991) have shown that a variant of the interstitial cystitis syndrome, with decreased significant pain, can be clinically improved by retraining of the individual's voiding pattern. Chaiken, Blaivas, and Blaivas (1993) confirm the short term effects of behavioural therapy in selected patients with symptoms of interstitial cystitis. The treatment consisted of diary keeping, timed voiding, controlled fluid intake, and pelvic floor muscle training techniques.

Of interest is the paper by Kusek and Nyberg (2001) on the epidemiology of IC where the authors suggest a broader definition of chronic pelvic pain of the bladder, but recognise that specificity may be problematic, as there are numerous causes of chronic pelvic pain not related to the bladder. Hanno (2003) suggests that the current clinical definition of IC is too restrictive for clinical use and results in

many patients being undiagnosed and untreated. Hanno (2004) suggests that a new paradigm is needed through which we can view this chronic pain syndrome.

In March 2003, a group of renowned IC specialists met in Japan for the International Consultation on Interstitial Cystitis to formulate a restatement of the diagnostic criteria for IC. As mentioned in the introduction, the final consensus from the 2003 International Consultation on Interstitial Cystitis adopted the term IC/CPPS to signify the symptom complex of chronic pelvic pain (CPPS) with urinary urgency and/or urinary frequency (Diokno et al., 2003).

The original NIDDK research criteria for IC have been universally used in research settings and through time have become widely adopted as a definition of the disease, although there is disparity in clinics around the world and no consensus as to the best practice in diagnosing IC for clinical purposes (Payne, Terai, & Komatsu, 2003). Payne and colleagues comment on the problem of this research criteria being used for clinical diagnosis having resulted in the under diagnosis of IC for many patients, with a resultant lack of appropriate treatment.

The International Consultation on Interstitial Cystitis in 2003 also considered the current status of diagnostic markers and potential use of these diagnostic markers in IC for understanding the etiology and pathophysiology of IC, to enable a definitive diagnosis of IC and to allow for a rational treatment algorithm (Keay, Takeda, Tamaki, & Hanno, 2003). The most promising diagnostic marker that comes closest to meeting all of these criteria is the antiproliferative factor (APF) which appears to be made by bladder epithelial cells from IC patients, but not by asymptomatic controls.

As mentioned in Chapter 1 of this thesis, The International Consultation on Interstitial Cystitis in Monaco in 2004 has developed a draft algorithm for the treatment of painful bladder syndrome, including IC. The group also worked on an all-encompassing definition and a review of the painful bladder. This review included discussions on definitions, bladder diaries, urological investigations, medication, trans-electrical nerve stimulation, diet, education, hydrodistension, neuromodulation, intravesical botulinum A, augmentation, cystectomy and referral to pain clinics (A. Rosamilia, personal communication, September 8, 2004).

As well as the International Consultation on Interstitial Cystitis being established, the Interstitial Cystitis Clinical Research Network (ICCRN) was formed in 2003. The ICCRN is the combination of two programs from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the Interstitial Cystitis Database Study and the Interstitial Cystitis Clinical Trials Group. The ICCRN was established by NIDDK's division of Kidney, Urologic and Hematologic Diseases to develop and conduct randomised clinical trials for the evaluation of new therapies for IC. The ICCRN comprises 10 clinical centres throughout the United States of America, and a data coordinating centre for protocol development, quality control, data analysis and data management quality (National Institute of Diabetes and Digestive and Kidney Diseases, 2004).

The Bladder Research Progress Review Group was also formed in the United States of America by the NIDDK of the National Institute of Health to examine the current state of bladder research in their country and to develop a plan for future bladder research. The significant financial investment in this research will have an effect on the quality of life of many people and will dramatically decrease the psychological, emotional, societal and financial burden of bladder disease. The aim of this group is to outline future critical research on the basic science of the lower urinary tract and clinical studies of bladder disease and conditions. This group will be vigorously investigating the neurovascular influences of the lower urinary system because the nervous and vascular systems are involved in almost every disorder of the lower urinary tract.

Fibromyalgia and Pelvic Symptomatology

Fibromyalgia and Chronic Pelvic Pain

Establishing a differential diagnosis in this group of women with chronic pelvic pain is difficult. Chronic pelvic pain (CPP) can be specifically of bladder origin. The Standardisation of Terminology in Lower Urinary Tract Function from the International Continence Society (Abrams et al., 2002b) defines pelvic pain syndrome as the occurrence of persistent or recurrent episodic pelvic pain associated

with symptoms suggestive of lower urinary tract, sexual, bowel or gynaecological dysfunction and where there is no other obvious pathology. The American College of Obstetricians and Gynaecologists (American College of Obstetrics & Gynaecology, 2004) has recently developed new guidelines for the clinical management of chronic pelvic pain. Their proposed definition of chronic pelvic pain lists the symptoms of non cyclical pain of at least six months duration involving the pelvis, anterior abdominal wall, lower back and/or buttocks, with these symptoms being serious enough to cause disability or to need medical care (American College of Obstetrics & Gynaecology, 2004). Where there is no clear indication of the etiology for pain, treatment is directed at the relief of symptoms.

Stone and Mountfield (2000b) offer possible etiological explanations as undetectable irritable bowel, the vascular pain from dilated pelvic veins, and altered spinal cord and brain processing of stimuli in women with chronic pelvic pain. Howard (2003) writes that disorders of the reproductive tract, gastrointestinal system, urological organs, musculoskeletal system and the psychoneurological system may be responsible for CPP in women. He questions why, for some women, these disorders lead to a chronic syndrome while with others the condition is cured with initial treatment regimes. Howard suggests that the different responses may be due to changes in visceral nerves or to altered nociceptive processing.

Because of the different etiological possibilities for CPP, the treatment of chronic pelvic pain may consist of two approaches. One approach is to treat the chronic pain as a diagnosis and the other is to treat the disorder that is causing or contributing to the pain (Howard, 2003). This author suggests that pain is no longer a symptom after 4-6 months and that, after this period of time, the symptom becomes the disease, chronic pain. In these cases, Howard recommends the diagnosis of chronic pain that allows pain-directed therapies to begin with the result that the patient may move toward a more normal existence that is not dominated by pain.

CPP syndromes affect an estimated 9 to 15 million women in the United States of America (Mathias, Kuppermann, Liberman, Lipschutz, & Steege, 1996). Studies have shown that IC is the cause of CPP in a large number of these women (Burkman, 2004). Burkman describes IC as a chronic pelvic pain symptom (CPPS)

of bladder origin discernible by the symptoms of urinary frequency, urinary urgency and pelvic discomfort or pain in the absence of obvious bladder pathology such as bladder cancer or urinary tract infections. However, a differential diagnosis can be extremely difficult.

Because of the prevalence of this CPP condition, and health costs associated with it, Stone and Mountfield (2000b) state that randomised controlled trials of medical, surgical and psychological interventions are urgently required. Pelvic pain in women can be either acute or chronic. The issues of undiagnosed chronic pelvic pain in women are significant. One study by Zondervan, Yudkin, Vessey, Dawes, Barlow and Kennedy (1999) revealed that 28% of patients with chronic pelvic pain were never given a diagnosis. Mathias, Kuppermann, Liberman, Lipschutz and Steege (1996) showed that in the United States of America 61% of patients with chronic pelvic pain had an unknown etiology. Stones, Selfe, Fransman and Horn (2000a) estimate, according to a population-based estimate, that chronic pelvic pain affects 15% of women.

These women, as well as experiencing pain, suffer the psychosocial impact of chronic pelvic pain affecting changes in mood, disruption of activities of daily living and relationships issues. A study by Zondervan (2001b) has shown that there is high symptom-related anxiety in women with chronic pelvic pain and emphasised the need for more information about, and the possible causes of, this condition. The study known as the Oxfordshire Women's Health Study Survey in the United Kingdom showed a substantial overlap between chronic pelvic pain, urogenital symptoms and irritable bowel syndrome. This study showed approximately half of the women with chronic pelvic pain had at least one other symptom; 39% had irritable bowel syndrome while 24% had genitourinary symptoms.

Sand (2004) observes that CPP can result from the combination of urogenital syndromes such as vulvodynia and IC. The difficulty of differential diagnosis in this area of pelvic pain and lower urinary tract pain and symptoms is evident. The possible diagnostic blend of FM, chronic pelvic pain, lower urinary tract pain, vulvodynia and irritable bowel syndrome pain is indeed perplexing to both clinicians and researchers.

Fibromyalgia and Vulvodynia

The International Society for the Study of Vulvovaginal Disease (ISSVD) (National Vulvodynia Association, 2002b) defines vulvodynia as chronic vulvar discomfort or pain, especially that characterised by complaints of burning, stinging, irritation, or rawness of the female genitalia. Vulvodynia is highly individualised. It can vary in its persistence and its location. Pain can be spontaneous, constant or intermittent, localised or diffuse. Vulvodynia can have a major impact on quality of life, impacting on activities of daily living and sexual activities.

Rodke (1996) comments on the experiences of patients with vulvodynia who experience all of the problems of a chronic pain syndrome without the assurance of knowing what causes their pain and if there is any relief available. Pezzone (2003), in workshop discussions on vulvodynia, details chronic pelvic pain disorders, inclusive of those affecting the pelvis, such as irritable bowel syndrome and interstitial cystitis and those affecting the pelvic floor, such as vulvodynia, urethral syndrome and prostatodynia. He notes that many of the conditions share a common predisposition, a shared etiological factor and a possible cross-sensitisation via neural cross talk. Pezzone suggests that the frequent overlapping of irritable bowel, vulvodynia interstitial cystitis and other chronic pelvic pain disorders may indicate irregular neuronal interactions allowing the irritation of one organ to co-sensitise other organs.

Wesselmann (2002) questions whether there is a connection between IC and vulvodynia, noting that they often occur in the same patient with the conditions developing simultaneously or one preceding the other. The author notes that vulvar vestibulitis (pain at the introitus) is more commonly associated with IC.

At the joint meeting of the American Pain Society and the Canadian Pain Society in Vancouver 2004, implications for the classification, assessment and diagnosis of women with vulvodynia were presented (Fisher, Robert, Jarrell, Carlson, & Taenzer, 2004). Chronic vulvar pain was described as a medical issue that has been neglected by the scientific community and, as a result, consensus on a classification system with validated terminology and diagnostic criteria does not exist. The authors note that the term 'vulvodynia' is used inconsistently and is

applied to vulval conditions with known and unknown etiologies, a former example being vulvar dermatoses and the latter being vulvar vestibulitis syndrome (VVS) and dysesthetic vulvodynia (DS).

Fisher and colleagues (2004) considered the pain profiles of women with unexpected chronic vulval pain and found considerable overlap in the characteristics of their pain, with resultant questioning of the validity of the separate terminology for VVS and DV. For this current study, the terminology 'vulvodynia' is used to describe chronic vulvar discomfort or pain, especially that characterised by complaints of burning, stinging, irritation, or rawness of the female genitalia as described by the International Society for the Study of Vulvovaginal Disease. A study by Pukall, Baron, Khalife and Binik (2004) showed that women with vulvar vestibulitis syndrome (VVS) reported significantly higher pain intensities and unpleasantness ratings in response to palpation to non-genital body areas, suggesting that these women may have a more generalised sensory abnormality. A rheumatologist undertook the physical examination and the examination technique used was one typically used for the diagnosis for FM.

Dyspareunia, one of the distinguishing characteristics of vulvar vestibulitis syndrome (VVS), is currently classified in the Diagnostic and Statistical Manual of Mental Disorders (DSM) as a sexual disorder rather than as a pain disorder (Pukall, Kao, & Binik, 2004). The DSM excludes dyspareunia from the category of Pain Disorder even though it meets all of the criteria for inclusion. The DSM specifies two types of pain, sexual and non sexual but Pukall and colleagues correctly note that many chronic pain conditions, such as FM, that interfere with sexual functioning are not classified as sexual dysfunction. Pukall and colleagues recommend that vulvodynia be evaluated from a pain perspective with a resultant multi-modal approach to treatment.

The first epidemiological study on chronic vulvar pain by the National Vulvodynia Association in the United States of America (National Vulvodynia Association, 2002a) suggested that almost 20% of American women have suffered from chronic vulvar pain at some time in their lives. Some 40% of these women did not seek any treatment for their condition. The National Institutes of Child Health

and Human Development in the United States have commenced a randomised placebo-controlled trial on the use of tricyclic antidepressants for chronic vulvar pain (National Vulvodynia Association, 2002a).

Masheb, Brondolo and Kerns (2002) conducted a multi-dimensional evaluation of women with chronic vulval pain. Participants (n=131) included 57 women with vulval discomfort and 74 healthy controls. Their findings suggest that the experience of persistent vulvar pain, rather than the level of intensity of pain, accounted for disturbances in functioning and feelings of well being. The analysis of data from standardised measures of pain severity, physical functioning and affective disorder confirmed the concomitant dysfunction in these domains (Masheb et al., 2002). There was no relationship between pain severity and affective distress. Their findings also showed that although these women scored in the range for marital satisfaction, they were not as maritally satisfied as their peer group.

There is no cure for vulvodynia. Some treatments offer symptom relief such as tricyclic antidepressants, anticonvulsants, nerve blocks, interferon, biofeedback and diet modification (National Vulvodynia Association, 2002b). McKay, Kaufman, Doctor, Berkova, Glazer, and Redko (2001) showed that electromyographic biofeedback of pelvic floor musculature is an effective approach to vulvar vestibulitis, a part of the spectrum of vulvodynia. The aim of the biofeedback exercises is to rehabilitate and strengthen dysfunctional pelvic floor muscles, to relieve ongoing spasm in the muscles and to break the cycle of chronic vulvar pain (Rodke, 1996).

A further study (R. Anderson, Wise, & Namazi, 2002) suggests that some patients with vulvodynia may experience improvement in vulvar and/or urinary symptoms following a combination of surface electromyography assisted biofeedback, internal myofascial release and progressive relaxation. Pudendal nerve blocks are also used for pain relief in women who suffer from chronic vulvar pain. If the women respond positively to the initial diagnostic block, then a series of pudendal blocks may be taken as the most appropriate therapeutic approach (Daneshfar, 2004).

Fibromyalgia and Sexuality

FM is a chronic disease. With the genitourinary symptoms experienced by women with FM, the possibilities and implications of sexual difficulties or dysfunction are significant. Webster (2003), in her findings from a study on understanding the changes in sexuality experienced by women with IC, describes the experience of women with IC as having to make major changes in most dimensions of their lives. She lists the major psychological self-care strategies adopted by women with IC as information seeking on their condition, self-validation, being responsible for their own health and rejecting psychological explanations (Webster, 2003). Webster considers broader definitions of sexuality than some, describing sexuality in terms of being integrated, individualised and a unique expression of oneself.

Sex makes an important contribution to the quality of life in many patients who live with chronic disease and to their partners (McInnes, 2003). McInnes describes a number of biological, psychological, and social effects that can impact on people with chronic disease. She includes the biological alterations of sexual desire, sexual capacity and activity being altered through interference with neural integrity of the genitalia as well as medication side effects, limitations on sexual response and activity due to pain and fatigue and the negativity of altered body image. The psychological effects can include anxiety, loss of self-esteem, depression, or grief of the loss of the 'old' self. McInnes (2003) refers to the precipitation of an emotional crisis with alterations to sexual function and sexual relationship that result from the limitation or cessation of sexual activity because of chronic illness.

McInnes (2003) defines sex as a vital part of day-to-day living with chronic illness, providing important boosters for patient's quality of life and allowing the patient with chronic illness to feel normal again. The improvement of doctor-patient communication about sexual issues, recommended by McInnes, places the emphasis on doctors for an attitudinal change towards sexual health issues, acquiring knowledge especially on the impact of illness on sexuality and acquiring the skills to implement these skills (McInnes, 2003). A study on the constructions of sexuality for midlife women living with chronic illness (Kralik, Koch, & Telford, 2001) has shown that the issues of sexuality are an important health concern for women with

long term illness and emphasises that the women should be given the opportunity to openly discuss sexuality issues with their health professionals.

Vulvodynia can have a major impact on quality of life of women with FM, impacting on activities of daily living and sexual activities. Vulvodynia is listed as an associated FM condition (Wallace & Wallace, 1999). Vulvodynia can result in dyspareunia which is recognised as a sexual pain disorder (A. Graziottin, 2003). Graziottin describes the psychosexual factors of loss of libido and arousal disorders as associated with, or secondary to, sexual pain disorders. The author advocates that the psychobiology of this experience of sexual pain should be addressed with an integrated, comprehensive and patient-centred perspective.

Measurement of Urological Symptoms

This review has considered issues and challenges in relation to the measurement of genitourinary symptoms in this population of women diagnosed with FM, thereby providing an information passage through the process of this research. This research was initiated because of the lack of measurement tools for the genitourinary symptoms of this population. To assess effective intervention therapy for these difficult to manage urinary symptoms, it is imperative that current updated measurement tools are developed as our knowledge in the urological area increases.

Scientifically validated health outcome measures were first applied to urological patients early in the 1990s with the development of the new benign prostatic hyperplasia symptom index. This provided a better understanding of the patients' perception of their disease and helped optimise clinical decision making to achieve outcomes that mattered most to the patients (O'Leary, Barry, & Fowler, 1992). The authors encouraged the development of such indexes for other disease entities in urology that demand a quantitation of the illness experience from their patients' perspective. Litwin (2002) comments that, in the treatment of urogenital diseases, the traditional goal has been to maximise survival but now, for patients with non life threatening conditions, their quality of life has taken on new meaning and value.

Shojania, Mariani and Lindberg (2002) describe science as grinding slowly with each new observation and investigation seeking 'truth'. They describe our best versions of truth as coming about as a continuum, noting that in one year much is observed and reported, some of which lasts and some which does not. Shojania and colleagues (2002) also comment that, although it is sometimes difficult to separate those that are transient from those that have more perseverance, scientific truth is a moving target, a work in progress. So too are measures of health status a moving target. Guyatt, Kirshner and Jaeschke (1992) speak of the health status measurement literature as a jungle. They referred to it as an underbush of confused terminology and contradictory conceptualisation.

The ICSI/ICPI is a disease specific instrument focusing on the symptoms and impact of urinary dysfunction in the IC population. Most symptom questionnaires give a numerical score to the symptom under study. The symptom index is the group of items used to measure symptoms that are related (Graham & Dmochowski, 2002). A symptom score is the numerical value derived from the use of the index (Hines, 1996). Graham and Dmochowski (2002) ask how we can be confident about the score generating a true reflection of the symptoms. Psychometrics that measure the response to phenomena that is not easily quantifiable govern the development of such questionnaires. The validity and reliability of such questionnaires are determined by statistical methods. The symptom score is a reflection of the questionnaire used to obtain the score. The psychometric testing of the questionnaires provides the assurance that symptom questionnaires actually measure symptoms (McDowell & Newell, 1996).

Van der Vaart, de Leeuw, Roovers and Heintz (2003) comment that the consequences of symptoms for a person's well being are also determined by the individual's psychosocial adjustment to the symptoms. They note that this is especially true for chronic conditions that are not life threatening, but which threaten quality of life where the effect is felt in physical, social and emotional functioning. Van der Vaart and colleagues (2003) therefore recommend measurements of well being or health-related quality of life as well as symptom measurements in outcome assessments of treatment for urogenital dysfunction. The ICSI/ICPI reflects this

recommendation in that it measures both the symptoms and the problems of the urological dysfunction of women with IC.

The Interstitial Cystitis Symptom and Problem Index

The Interstitial Cystitis Symptom Index (ICSI) and the Interstitial Cystitis Problem Index (ICPI) are dual tools for quantifying the severity and impact of interstitial cystitis. O'Leary, Sant, Fowler, Floyd, Whitmore and Spolarich-Kroll (1997) developed this index specifically for IC patients. The development of this index was preceded by a pilot study and a subsequent study using a longer initial questionnaire. These preliminary studies indicated the symptoms that best described IC were burning, frequency, nocturia, bladder pain and back pain. The urgency symptoms affected 90% of the IC patients. Seventy per cent of the IC patients had daytime frequency compared with 16% without IC. Eighty per cent of the IC patients experienced nocturia compared with 10% without IC. Ninety-six per cent of IC patients experienced bladder discomfort, pressure or pain compared with 27% reporting occasional pressure and 15% reporting pain (O'Leary & Sant, 1999).

The final ICSI/ICPI captures the most important voiding and pain symptoms and indicates the extent of how problematic these symptoms are for patients with IC. The four symptoms of urinary frequency, urinary urgency, nocturia and pain are used in both of the indices, the symptom index and the problem index. These items compared well with a larger panel of items to discriminate between patients with interstitial cystitis and controls. O'Leary and colleagues (1997) showed excellent internal consistency and test-retest reliability for both questionnaires in a community population with a convenience sample of patients with IC. A following study (Lubeck, Whitmore, Sant, Alvarez-Horine, & Lai, 2001) evaluated the psychometric properties of the ICSI in a prospective clinical drug trial in patients with IC and was found to be a valid, reliable and responsive measure of IC symptoms.

This ICSI/ICPI developed for the interstitial cystitis population will be tested for reliability and validity within the FM population for women who experience these same symptoms of urinary frequency, urinary urgency, nocturia and bladder pain. Recommendations by Graham and Dmochowski (2002) for such validation of

instruments within specific populations include adequacy of instrument testing, simplicity of use and application to clinical practice.

Summary

In summary, Rothenberg (1999) describes FM as a syndrome that involves a loss of pain regulation in the central nervous system that may cause pain amplification. The excessive pain stimulation appears to then lead to abnormal levels of central nervous system neurotransmitters such as serotonin, norepinephrine and Substance P. The imbalance in these neurotransmitters can then produce problems with the body's hormonal response to stress, resulting in inappropriate levels of cortisol, catecholamines, growth hormones and possibly thyroid hormones. All of these can cause abnormalities in the autonomic nervous system. Rothenberg (1999) highlights these abnormalities as contributing to irritable bowel syndrome, neurally mediated hypotension, irritable bladder symptoms, vascular headaches, chronic fatigue and non-restorative sleep disorders.

Littlejohn and Morand (2002) have predicted that the impetus from the current Bone and Joint Decade will increase research within the discipline of rheumatology with resultant greater understanding of disease mechanisms and a subsequent increase in treatment options. This research on FM and bladder irritability will increase our knowledge of the urinary symptoms and their impact on women with this condition and will extend the awareness of this problem to a more multi-disciplinary medical arena. The validation of the ICSI/ICPI instrument within the FM population will assist in determining the nature of sensory urinary symptoms, the extent and frequency of the symptoms and the impact these symptoms have on the patients' activities of daily living and quality of life. Having a validated outcome measure for sensory urinary symptoms in the FM population should encourage further intervention research into this debilitating condition.

CHAPTER 3

FRAME OF REFERENCE

Theoretical Framework

Theoretical frameworks provide a structure for guiding systematic enquiry and examining relationships amongst relevant variables. These theories and relationships are then validated through research and form the basis for further development and possible refinement of the theories (Polit & Hungler, 1989). These authors describe theories as efficient mechanisms for bringing together and summarising known facts from various studies to more effectively explain scientific findings. The authors also comment that research performed within the context of a theoretical framework is more likely to result in effective and significant findings. The benefit of theoretical frameworks is that they enable a research finding to be presented in a more generalised and meaningful way that allows the researcher to combine his/her observations and facts in a more organised format.

The Theory

The theoretical framework and measurement model for this study on FM and bladder irritability is based on previous research findings and relevant theory related to Fibromyalgia (FM), central nervous system sensitisation, irritable bladder sensory symptomatology, interstitial cystitis and instrument development. The literature provides direction for the study design and the Interstitial Cystitis Symptom and Problem Index (ICSI/ICPI) instrument validation methods used within the FM population.

The theoretical framework guiding this investigation is based on three specific areas of literature:

- the genitourinary symptoms of women with FM
- the similarity of these symptoms to symptoms experienced by women with the condition of IC
- the involvement of central nervous system mechanisms that contribute to the pathogenesis of FM that are similar to the mechanisms underlying IC.

Although the musculoskeletal features of FM define the condition, there are many other symptoms that are apparent in individuals with this condition. The urogenital symptoms of FM are urinary urgency, urinary frequency, nocturia and pelvic pain. IC is a condition characterised by symptoms of urinary urgency, urinary frequency, nocturia and pelvic pain. Both conditions can be classified as non-infective sensory disorders of the lower urinary tract.

Research by Clauw and colleagues (1997a) suggests that the central nervous system mechanisms thought to contribute to the pathogenesis of FM may be operative in IC. The postulation that these conditions may share a similar etiology and the evidence that both conditions have similar clinical symptomatology provide rationale to undertake a study to validate, for use within the FM population, an instrument developed for the IC population. This instrument, the Interstitial Cystitis Symptom Index and Problem Index (ICSI/ICPI), has been developed and validated to measure lower urinary tract symptoms and their impact in patients with IC (O'Leary et al., 1997).

Aaron and Buchwald (2000) noted numerous clinical conditions that share common symptomatology such as pain. They described the frequency of ten clinical conditions among patients with chronic fatigue syndrome (CFS), FM and temporomandibular disorder (TMD) and found that patients with FM had significantly more symptoms characteristic of interstitial cystitis than did patients with CFS or TMD. A survey by Alagiri, Chottiner, Ratner, Slade and Hanno (1997) also showed that of 2682 patients with IC, 25% reported having comorbid FM. This overlap of IC and FM symptomatology gives further impetus for this current study to validate an outcome measure for the FM population that has been found to be valid and reliable for use within the IC population.

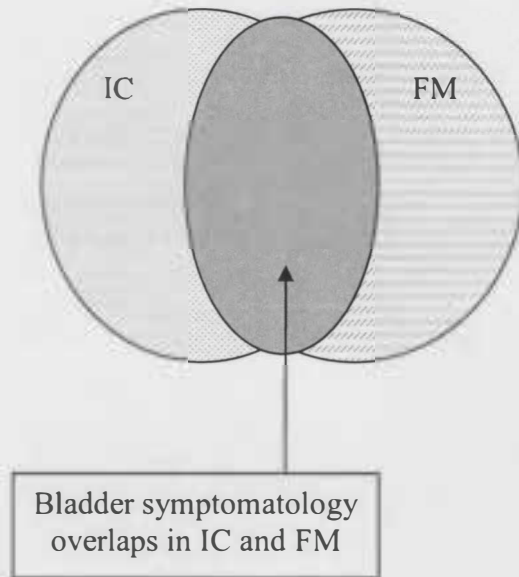


Figure 1: Overlap of Sensory Urinary Symptoms in Interstitial Cystitis (IC) and Fibromyalgia (FM)

Currently there is no validated instrument to measure lower urinary tract sensory symptoms or their impact on women diagnosed with FM. Lose and colleagues (1998) suggest that research on lower urinary tract symptoms in adult women is limited by the lack of standardised outcome variables for use within this population. They encourage studies that lead to the development and standardisation of outcome measures and comment that success in this regard will enhance knowledge of actual treatment as well as stimulate the development of new treatment options.

Often the scientific evaluation of the outcome of intervention is based on pre-test and post-test evaluation. Lose and colleagues (1998) note that the reliability of some methods and measurements is often unclear, leading to inaccurate interpretations of the results of the intervention. They state that the reliability of a test depends on the accuracy and reproducibility of the method. Valid and reliable measurement scales not only guarantee consistency in measuring patient progress, but provide a basis for the development of evidence-based practice (O'Connell et al., 2002). This study has used the ICSI/ICPI through two study phases to provide a validated and reliable tool for the measurement of sensory urinary symptoms and their impact in women with FM.

The theoretical links that describe the common pathogenic mechanisms between the two conditions of FM and IC provide a foundation for the psychometric testing of the instrument. The development of a valid and reliable instrument to measure these urinary symptoms will provide a means of subsequent testing regarding these conditions in future research.

The Framework

The theoretical framework underpinning this research on bladder irritability symptoms in women diagnosed with FM is displayed in Figure 2. The literature indicates that the majority of research studies on FM in the last decade have focused on the central sensitisation of the central nervous system, as the most likely etiological factor in the development of FM. An adaptation of the integrated etiological hypothesis proposed by Clauw (1995a) is the basis of the theoretical framework for this study.

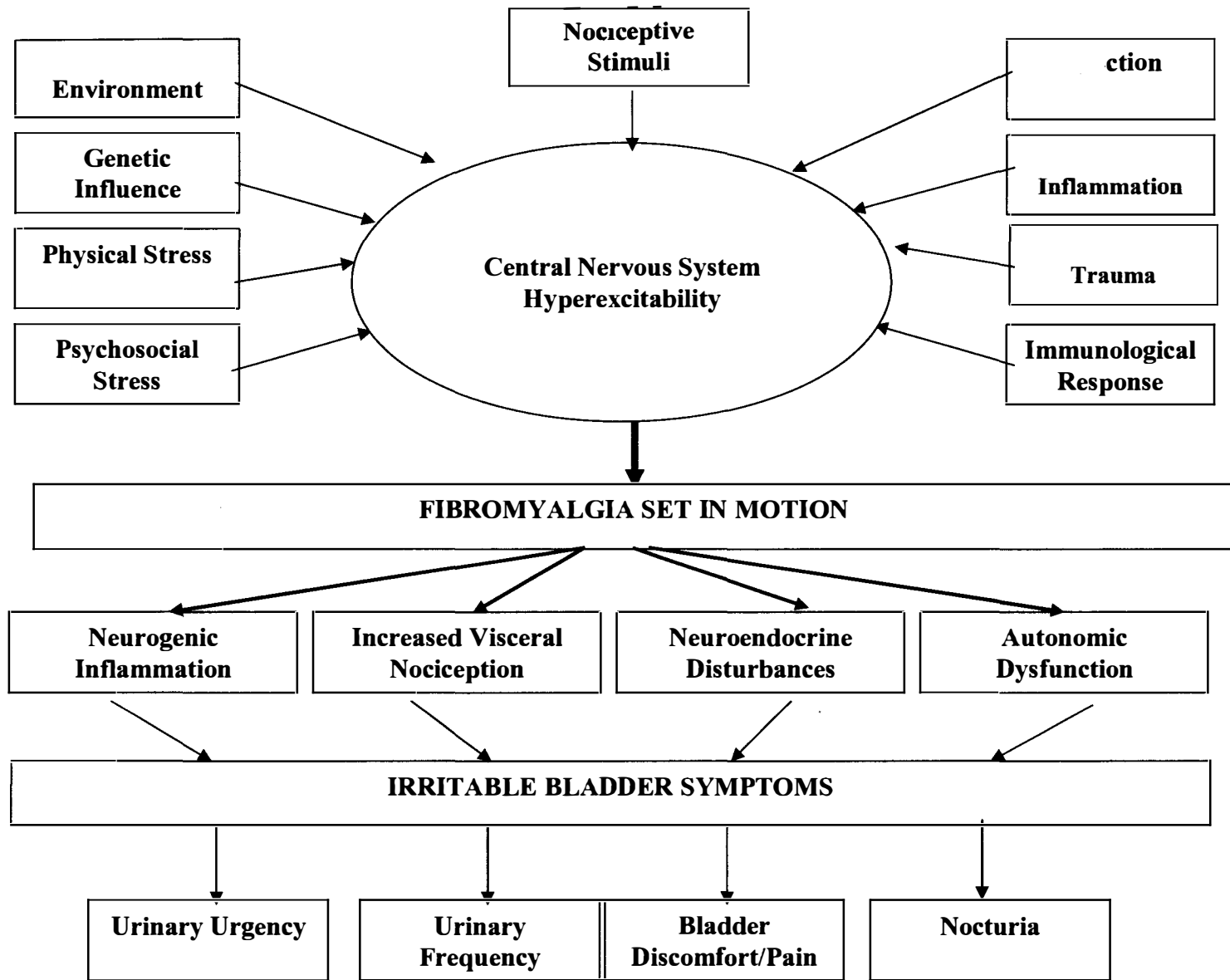


Figure 2: Theoretical Framework

Multifactorial Etiology of Fibromyalgia

The following discussion gives direction and momentum to this theoretical framework, commencing with the multifactorial etiology of FM. Many factors impact on the human system to initiate and to maintain the central nervous system hyperexcitability state seen in FM. These include genetic influences, environment, physical and psycho-social stress, infection, inflammation, trauma, immunological response and continued nociceptive stimuli.

Studies have shown that genetic factors may predispose people to a genetic susceptibility for the development of FM. Buskila and Neumann (1997) have found that blood relatives of FM patients have a higher prevalence of FM and more tender points than an age-matched group within the general population.

Pillmer, Bradley, Crofford, Moldofsky and Chrousos (1997) suggest that FM may be a stress-related illness, because it is often associated with a stressful physical or psychological situation. Littlejohn (2004) notes the influence of psychosocial impact on patients with FM. He refers particularly to studies of the stress axis, with emphasis on the hypothalamic-pituitary-adrenal axis which displays abnormalities in many patients with FM. Littlejohn describes the pathophysiology of FM as a range of complex and integrated neurobiologic mechanisms which are responsive to stress and emotion. Wallace and Wallace (1999) note that, when FM patients are asked what they think caused their FM, the most common replies are trauma, infection and stress.

Central Nervous System Hyperexcitability

As a peripheral cause of pain cannot be easily identified in most FM patients, it has been suggested that most of the 'action' is at the level of the spinal cord and above (Bennett, 2002a). Researchers are therefore focusing more on the role of the central nervous system rather than on the musculoskeletal system in an effort to explain the symptoms of FM. A disorder of the central processing of sensory information from the nociceptor and mechanoreceptor systems can result in numerous neurophysiological changes that are observed in FM sufferers. Yunus and

Inanici (Baldry, 2001) define central sensitisation as hyperexcitability of the central nervous system neurones which results from peripheral noxious stimuli. This can lead to an exaggerated response to a normally painful stimulus known as hyperalgesia. Similarly, allodynia, a painful response from a normally non-nociceptive stimulus such as touch, can occur. There is also an increased duration of response after a brief stimulus (Staud, 2002).

Clauw (1995a) notes that once central nervous system hyperexcitability is apparent, then all or some of the effector arms of the central nervous system can become involved. He suggests that the elevated ratio of excitatory to inhibitory neuromodulators is responsible for the resultant spectrum of conditions, the region of the central nervous system being affected being reflected in the symptomatology. A clinical spectrum of FM encompassing neurogenic inflammation, increased peripheral and visceral nociception, neuroendocrine disturbances and autonomic nervous system dysfunction can result, with symptoms being evident in any or all of the effector arms of the central nervous system (Clauw, 1995a). This etiologic hypothesis presented by Clauw is delineated in Figure 3.

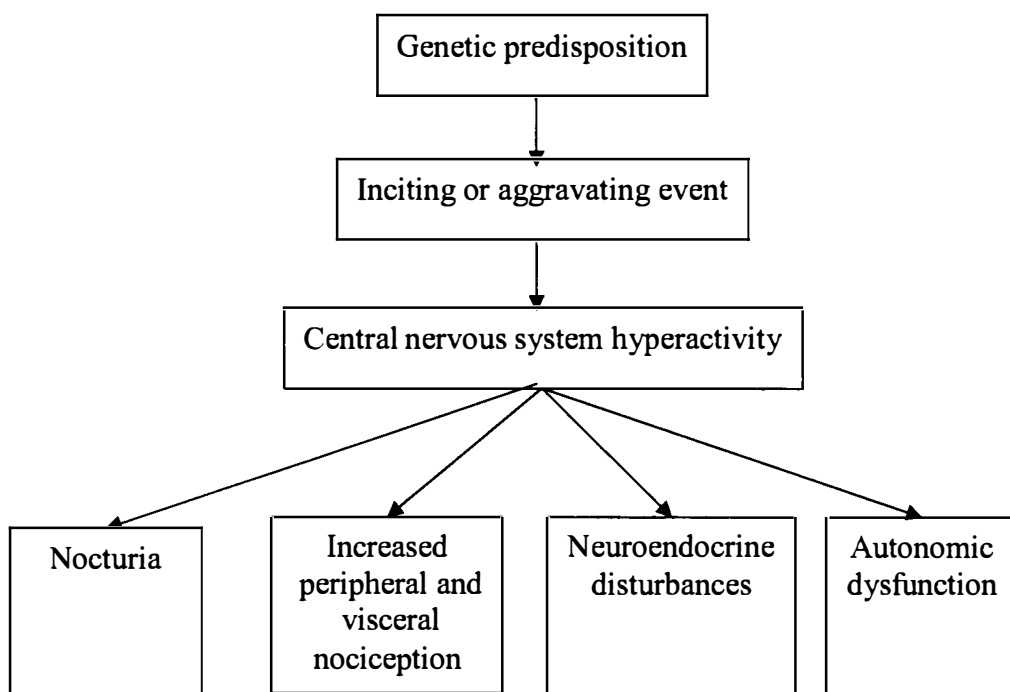


Figure 3: Etiological Hypothesis for Fibromyalgia. Adapted from Clauw (1995a)

These four mechanisms of neurogenic inflammation, increased peripheral and visceral nociception, neuroendocrine disturbances and autonomic dysfunction, may all individually or collectively impact on bladder symptomatology and influence lower urinary tract function in women with FM.

Neurogenic Inflammation

Neurogenic inflammation is described as ‘inflammation caused by an injurious stimulus of peripheral neurons and resulting in the release of neuropeptides that affect vascular permeability and help initiate pro-inflammatory and immune reactions at the site of injury’ (Medical Dictionary Online, 2004). The concept of neurogenic inflammation is based on the release of Substance P and related peptides by an axon reflex mechanism. Investigation on peptide-induced release of inflammatory mediators by the urinary bladder, has shown that the peptides evaluated induced changes which may directly regulate the participation of these peptides in the pathogenesis of cystitis (Saban et al., 1997). Similarly, Callsen-Cencic and Mense (1997) questioned whether alterations in the expression of neuropeptides and nitric oxide synthase in the neuronal pathways to the bladder might be involved in the hyperexcitability of the bladder with the development of cystitis.

A theory by Cervero and Janig (1992) suggested that a large component of the afferent innervation of internal organs consists of afferent fibres that are usually unresponsive to stimuli until they are activated by inflammation. Cervero and Janig suggest these sensory receptors contribute to the signalling of chronic visceral pain, to long term alterations of spinal reflexes and to abnormal autonomic regulations of internal organs.

Butrick (2004) states that IC is not an end organ disease but a visceral pain syndrome involving chronic neurogenic inflammation, primary afferent overactivity and central sensitisation which lead to the perpetuation of pain. Butrick (2004) cites Birder and deGroat who have shown that neuronal-like properties of urothelial cells enable cells to have a sensory function and interact chemically with afferent nerves. Brookoff (1997) believes the consequence of bladder inflammation in IC is

hypersensitivity of the chemo-sensitive afferent bladder nerves resulting in hyperalgesia. With increasing inflammation, mechanoreceptive nerves in the bladder wall can generate pain signals in response to a small increase in intravesicular pressure, resulting in allodynia (Brookoff, 1997).

Elbadawi (1997) describes responses brought into play by neurogenic inflammation as sensory nerve excitation, the release of neuropeptides and activated differential secretion of potent mast cell mediators. Radziszewski and colleagues (2002) consider that the painful bladder may represent different expressions of 'neurogenic inflammation of the bladder' where previously silent C-fibres may be activated.

Increased Peripheral and Visceral Nociception

The altered properties of visceral afferents that result from the instability of the transduction properties of these nerves are described as forms of plasticity that can affect the encoding and transmission of sensory information (McMahon, 2004). This increases chronic pain states by increasing the excitability of sensory neurones. Butrick (2004) showed that silent visceral afferents become activated with prolonged stimulation and produce tissue sensitisation and pain in the bladder. The bladder has the highest neural density and the greatest proportion of silent C-fibres than any other viscera (Cervero, 1994).

Cervero and Laird (1999) suggest that increased awareness of visceral hyperactivity could come about from sensitisation of the peripheral nociceptors or of alterations of central processing with an increased activation of the visceral nociceptive pathways. Giamberardino and colleagues (2001) further showed that algogenic conditions of one internal organ can affect reactivity to painful stimuli of other visceral areas, such as in the female pelvic reproductive organs and urinary tract. Yoshimura and colleagues (2002) hypothesise that the hyperexcitability of the C-fibre afferent pathways may be the mechanism for bladder pain and urgency and are focusing on treatment of these symptoms by modulating the activity of bladder afferents pathways.

In a study on the relationship between FM and interstitial cystitis, Clauw and colleagues (1997a) showed significant overlaps in symptoms, which included increased peripheral nociception. They suggested that IC may be part of the disorder of central processing of sensory information. This theory was discussed within a forum at a urology symposium on management of the painful bladder syndrome where bladder pain in IC was described as being mediated by central pain mechanisms in the spinal cord (Blaivas et al., 1999). Likewise, Wesselmann (2001) revealed the similarities between IC and other chronic, non-malignant visceral pain syndromes in her conceptual common approach to treatment for both conditions. Other studies have implicated the urogenital system in the central nervous system sensitisation process. These studies, already referred to in the literature review of this thesis, include articles by Al-Chaer (2000), Costa, Glise and Graffer (2004), Bennett (2002c) and Ishigooka and colleagues (2001).

Neuroendocrine Disturbances

As well as neurotransmitter abnormalities, hormonal and biochemical abnormalities are detectable in patients with FM (Clauw, 1995a). The hypothalamic-pituitary-adrenal (HPA) axis is a complex brain-to-body pathway and is central to the stress response. FM is characterised by an under active stress response. Clauw (1995a) suggests that the decreased capacity in response to stressors in both the neuroendocrine and autonomic nervous systems provides a pathway where stressful events could exacerbate symptoms associated with one or more of the effector arms of the nervous system.

Jain and colleagues (2004) describe a loss of adaptability and stress tolerance associated with dysfunction of the HPA axis in patients with FM. In relation to the abnormalities apparent in the HPA axis in FM, Crofford (2002b) questions whether the axis abnormalities reflect pre-existing vulnerability to the FM condition or whether the chronic pain alters the HPA axis activity.

Bennet (1993) suggests a disruption of the neuroendocrine axis that controls growth hormone production could be the link between disturbed sleep and muscle pain because this hormone is produced mainly during level IV sleep. Sleep

disturbance with FM is intricately linked with voiding at night. Whether nocturia is due to bladder sensation messages or to the 'just in case' voiding when one is already awake is as yet unknown. Results of a study by Lutgendorf and colleagues (2002a) suggest that the dysregulation of the HPA axis may be linked to interstitial cystitis symptomatology.

Autonomic Nervous System Dysfunction

The autonomic nervous system (ANS) is described as a dynamic system with intense and instantaneous onset of action and dissipation that works closely with the endocrine system, especially the HPA axis and the growth hormone axis (Martinez-Lavin, 2002). Because the ANS regulates the function of most of the organs and systems of the body, it is the main homeostatic system of the body. Abnormal sensory symptomatology of the lower urinary tract in women with FM may be partly due to abnormalities of the ANS. Martinez-Lavin (2002) suggests that dysautonomia may play a central role in the pathogenesis of FM because autonomic nervous system dysfunction is frequently found in patients with FM.

Zermann, Ishigooka, Doggweiler and Schmidt (1998) describe lower urinary tract function as a complex multi-level and multi-neuronal interaction, involving facilitation and inhibition at many levels of the CNS. They further describe the coordination of lower urinary tract function as being mediated by reflex pathways regulated in the lumbo-sacral and thoracolumbar spinal cord as well as by reflex and voluntary mechanisms in the brain stem and cortex (Zermann et al., 1998). These researchers note that, in research on the central innervation of the lower urinary tract, the spinal cord and pontine micturition centre have been investigated thoroughly while the role of the higher centres has been ignored.

Recent experiments on the whole bladder of the guinea pig (Gillespie, Harvey, & Drake, 2003) show neurogenic control by two separate mechanisms, the parasympathetic system fundamental to micturition and a second system generating non-micturition activity, with the central nervous system coordinating both systems. The bladder is rhythmically active during the filling stage (Gillespie, 2004). Gillespie describes the activity generated in the bladder wall at this time as autonomous

activity. This activity involves contraction and localised stretches of the bladder wall, thought to be initiated by a network of pacemaker cells and connecting interstitial cells that are impacted upon by excitatory and inhibitory neural inputs. Gillespie (2004) suggests that escalation of autonomous activity as excessive excitatory inputs or failure of inhibitory inputs may contribute to uncontrolled bladder activity in the filling phase.

Gillespie (2004) proposes a hypothesis that bladder overactivity is due to inappropriate non-micturition activity. He suggests that this autonomous bladder hypothesis may make it possible to control the initiation and modulating of pathological non-micturition activity without interfering with the micturition reflex. This area of etiological research into sensory bladder neurology is ongoing.

In summary, the mechanisms of neurogenic inflammation, increased visceral nociception, neuroendocrine disturbances and autonomic dysfunction all have the capacity, individually or collectively, to influence the functioning of the lower urinary tract of women within this FM population. These mechanisms do not function in isolation. Pillemer and colleagues (1997) demonstrate this in their description of triggering events which may initiate changes in the HPA axis and the autonomic nervous system that can result in sensitisation of the central nervous system via neuropeptides with the resultant alteration of nociceptive processing.

The Measurement Model

There is currently no questionnaire to specifically assess urological symptoms or their impact on women with FM. Such a questionnaire would assist in determining the nature of the problem, the extent and frequency of the symptoms and the impact the condition has on the patient's sense of well-being and activities of daily life. Pre-treatment and post-treatment-validated questionnaires for these specific conditions can clearly indicate treatment outcomes.

It is important that current updated measurement tools are developed as our knowledge in the urological and FM areas increases. It is recommended that measurements of health-related quality of life, as well as symptom measurement, be

included in outcome measures for urological dysfunction (van der Vaart et al., 2003). The ICSI/ICPI responds to this recommendation by measuring both symptoms and impact of IC. This is important not only in the primary areas of urological disease, but also in the areas where urinary symptoms are associated symptoms of other conditions such as FM.

The measurement model is based upon literature that describes sensory bladder symptomatology experienced by women with FM. The bladder symptomatology includes urinary frequency, urinary urgency, bladder pain/discomfort and nocturia. The measurement tool trialled for validation within the FM population is the ICSI/ICPI, a measurement tool already validated for measuring urinary symptoms and their impact for patients with IC. The ICSI/ICPI is a condition-specific instrument that measures the sensory urinary symptoms of frequency, urgency, pain and nocturia and their impact within the IC population.

Because of the apparent, reported overlap of symptoms between IC and FM, especially the sensory urinary symptoms, the ICSI/ICPI was identified and tested for validation within the FM population of women with urinary symptoms. The measurement model for this validation procedure is displayed in figure 4. This current study has tested and modified the ICSI/ICPI for the FM population, producing a validated instrument for women with FM who experience bladder irritability.

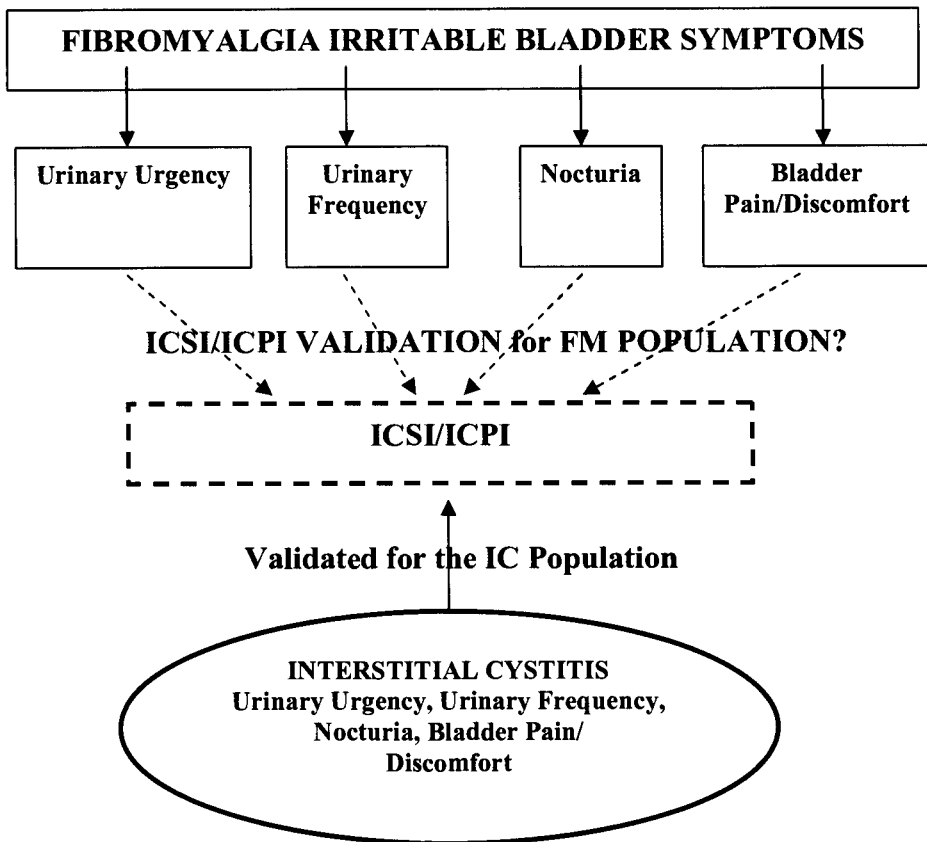


Figure 4: Fibromyalgia Urinary Symptoms and Impact Measurement Model

CHAPTER 4

METHODOLOGY

Introduction

This chapter includes the methods and procedures used to conduct Phases I and II of this research on Fibromyalgia (FM) and bladder irritability. The first component of this chapter describes the methods and procedures of Phase I, while the second component describes the methods and procedures related to Phase II of the research.

Research Plan

This research involved a two-phase program of research to validate and test an existing instrument within a new population of women diagnosed with FM who experienced symptoms of bladder irritability. Phase I used a qualitative research approach. Focus groups with women who had been diagnosed with the condition of FM and who experienced bladder irritability symptoms were conducted. Phase II tested the instrument within this new population for reliability and validity. The findings of the focus group were incorporated into the second phase of this study. An example of this was the finding of the symptoms and impact of vulvodynia in women from the focus groups. As a result, a vulval symptoms questionnaire was developed as a data collection method for this symptomatology for Phase II of the study.

Ong (1993) suggests an approach to research that draws on a wide spectrum of methodologies which can be integrated as the most appropriate approach to the multi-dimensional and multi-disciplinary issues encountered in the health field. Herbert and Higgs (2004) comment that, despite the philosophical and methodological differences between quantitative and qualitative research paradigms,

research across the paradigms can provide complementary ways of learning. Herbert and Higgs note that this can be particularly relevant in the area of health care because this area is involved with both the physical and social world of people.

Within the physiotherapy profession, Ritchie (1999) credits qualitative research as a means of ‘adding the humanistic mission to result in the best practice in physiotherapy’ (p.251). This move within the physiotherapy profession embraces the specific needs of the patients as well as developing evidence-based practice. Ritchie discusses the obligation we have as physiotherapists to refine the art and science of good health care through systematically combining patient-focused care and evidence-based practice, a qualitative as well as quantitative approach to our research.

The two research methodologies were combined in this study to enable information from the focus group discussions to be interpreted in the development of the data collection instrument for Phase II of the study. Barbour (1999) recommends the consideration of the contributions that a qualitative component can make to research that is mainly using quantitative methods grounded in the quantitative paradigm. In this study, it was important that the research did not progress towards structured questionnaires without firstly undertaking some qualitative work to establish relevant questions and issues. New relevant variables for the data collecting questionnaires were identified as a result of the qualitative methodology of the first phase of this study.

Methodology Phase I

Design

Focus groups were the method of gathering data on the symptoms and impact of lower urinary tract sensory symptoms on women with FM. A descriptive design was used for this phase of the study. Information from relevant literature and qualitative methods were combined to develop the format for data collection. An interview guide was used to outline the relevant topics for the group discussions and to elicit thoughts, ideas and perceptions about the participants’ symptoms (Appendix

C). Group participants were all women who had been diagnosed with FM by a rheumatologist and who had experienced sensory bladder symptoms. The conducted interviews and discussions were to ensure that the key indicators and the way in which the participants experienced bladder irritability were compatible with and inclusive in the ICSI/ICPI instrument to be validated in Phase II of this research.

Why Focus Groups as the Data Collection Method?

Relevant literature and focus groups were used as the qualitative method of data collection for this first phase of this research. Benoliel (Polit & Hungler, 1989) describes four broad areas in which unstructured qualitative approaches have merit. One of these areas describes a person's adaptation to critical life experiences such as chronic illness. Portney and Watkins (1993) describe qualitative research as seeking to describe the complex nature of human beings and how humans perceive their own experiences. They continue to explain the purpose of qualitative inquiry as examining such experiences with a holistic approach that focuses on the true nature of the participant's 'reality'.

The focus group has been described as a guided interactional discussion for generating rich experiential information (Carey & Smith, 1994). Basch (1987) commented that the focus group interview is a technique of qualitative research that determines feelings and opinions about an identified topic. The topic to be addressed in this research is bladder irritability symptoms experienced by women who had been diagnosed with FM.

Greenbaum (Diloroi, Hockenberry-Eaton, Maibach, & Rivero, 1994) states the benefits of focus group data collection as allowing for the combination of elements of group process theory and qualitative research methods as well as enabling the group facilitator to establish a permissive environment encouraging in-depth discussion of the research topic. Krueger and Morgan (Asbury, 1995) note that, by design, focus groups rely more on the dynamic of the group interaction to stimulate thought processes, with resultant verbal contributions of the participants, thereby providing the researcher with a richer and more detailed perspective.

Based on the above rationale, and in considering the various approaches available for qualitative data collection, the focus group was deemed to be the most appropriate for this research project. Because of the intimacy of this research topic on bladder function and dysfunction, individual interviews as a method of data collection for this project were considered. However, the interactive components of a focus group were considered and focus groups were selected as the means of data collection because it would provide more detailed and complete information on symptoms and impact.

Dilorio, Hockenberry-Eaton, Maibach, and Rivero (1994) suggest that information from focus groups can provide an excellent basis for the development of research instruments. The person who has the symptom can most correctly supply the symptom and impact scale related to their condition. Basch (1987) describes the benefit of focus groups in the development of quantitative instruments because the group interaction reveals appropriate response categories, language usage, vocabulary and vernacular used by the research participants. For this FM research, the women in the focus groups were able to elicit thoughts, ideas and perceptions about their bladder symptoms. They were able to describe the increased impact on their lives that resulted from the involvement of their bladder in their overall FM symptomatology.

Population and Sample

Participants for the focus groups in this first phase of the study were women from Perth, Western Australia who had been diagnosed with FM by a rheumatologist and who experienced lower urinary tract sensory symptoms.

Recruitment

Recruitment for this stage of the research was via a rheumatologist. Following a meeting with the rheumatologist, where I explained the research and its methodology, he was provided with copies of the Phase I information sheet for participants (Appendix D). The rheumatologist organised for these information sheets to be attached to a letter to FM patients from his medical practice database

asking for expressions of interest in the FM study, or mentioned the study to potential participants at the time of consultation (Appendix E). This method of recruitment therefore ensured that all participants had been diagnosed with FM by a rheumatologist. Participants were asked to telephone the researcher directly if they were interested in the research. Through this method of recruitment, the privacy of the patients was protected.

Potential participants were screened over the telephone. The first twenty women who called, who expressed an interest in the phase of the study and who met the inclusion criteria, were invited to join the focus groups. All participants experienced at least two of the sensory urinary symptoms associated with FM. These sensory symptoms included urinary frequency, urinary urgency, nocturia and a constant awareness of the bladder, or discomfort, or, pain in the bladder.

The Focus Groups

The three focus groups were all conducted on university premises, which were readily accessible for the majority of participants. Car parking on the premises was arranged free of charge. Care was taken to ensure that the meeting room was friendly and had an appropriate temperature. Seating was arranged around a rectangular table setting to encourage interaction, with the moderator placed adjacent to the participants and not at the end of the table as a leader figure. Because of the impact of the participants' urinary symptoms, close proximity to toilets was considered. Participants were given name badges for first names only and introductions were given. The total number of women in the focus groups was 10. There were four women in the first group, four women in the second group and two women in the third group.

A co-facilitator, another women's health physiotherapist, was present and talked to the participants prior to the commencement of the session regarding issues of confidentiality, consent forms and the recording of, and format of, the session. Information was also given about the purpose of the study and benefits of the research. Prior to the commencement of the session, all participants signed consent forms for participation in the study (Appendix F). The co-facilitator's role included

minimising interruptions, recording the session, providing refreshments and acting as an observer of non-verbal behaviour or other non-recordable dynamics within the group. These observations were imparted to the researcher/facilitator at the debriefing session between the facilitator and co-facilitator following the focus groups.

The three focus groups, with the total number of ten participants, resulted in a sense of completeness of information and experience on the research topic. The discussions from these three focus groups provided multiple aspects of living with FM and its associated bladder symptoms. After the third focus group, most of the information given became repetitive, suggesting that most 'new' information had been obtained. Information redundancy was achieved.

Data Collection and Protocol

All three focus group sessions were audiotaped to enable accurate retrieval of data. The semi-structured interview, based on the relevant literature and validated questionnaires planned for use in the second phase of this research, was used to elicit information about the participants' bladder and non-bladder FM symptomatology. The interview guide used for the focus groups was partly derived from the Interstitial Cystitis Symptom Index and Problem Index, the voiding and pain indices being validated for use within the FM population. This was to ensure that the key symptoms and the impact on these women were compatible with, and inclusive in, the ICSI/ICPI instrument.

Questions from the Fibromyalgia Impact Questionnaire, the Kings Health Questionnaire and the SF-36 Health Questionnaire were also used during the focus groups. These questionnaires formed part of the main data collection instrument for Phase II of this research. The rationale for adding relevant sections of these questionnaires to the interview guide was to expand the collected data to include issues concerning the effect of bladder problems on physical as well as psycho-social aspects of women's lives. Demographic information questions were also included in the interview guide.

Questions from the interview guide were discussed at length to ensure participants' understanding of symptom descriptions, symptom comprehension, word comprehension, and the arrangement of numerical values in relation to symptoms and impact. All relevant information from the focus group participants was considered in refining the instrument for data collection for Phase II of this research. Some minor changes were made in the demographic questionnaire as a result of the focus group discussion re the comprehensibility of the questionnaire. The interview/discussion format of the focus groups successfully encouraged participants to become involved with the answering of questions, often followed by a discussion of their personal experience of the specific topic.

Data Analysis

Ingleton and Seymour (2001) refer to the various mechanical and creative processes interwoven into the production and analysis of data. The analytical process of this qualitative study reflects this intertwining of personal knowledge and experience of the researcher as a physiotherapist continence adviser, the study participants' comments, conversations, accounts and experience of their personal experience with FM and the information, and interpretation from the relevant literature.

Goldman and McDonald (Henderson, 1995) comment that qualitative analysis begins during the group session itself. They recommend that the group moderator be continually alert to analytical implications during the process of the focus groups. This was certainly the case in the collection of the data from this focus group of women with FM and bladder irritability. As the semi-structured interview was based on validated FM and urinary symptom and problem indexes, the questions were directed to the participants' symptom range and the impact of the symptoms on their lives. The shared symptom and impact experience of these women seemed to give them not only permission to talk about an intimate and often taboo subject, but also to share their stories, which they did, almost with a sense of urgency. Henderson (1995) acknowledges that the perceptions, beliefs, opinions and attitudes that result from data collection in focus groups are subjective. Henderson also comments that

the different backgrounds of qualitative practitioners provide a conversion mechanism giving interpretation to what respondents say.

Portney and Watkins (1993) describe qualitative data analysis as primarily an inductive process reflecting a constant interplay between the observed reality and theoretical conceptualisation of that reality. Because of the narratives involved in interview response, qualitative data have to be reduced to derive meaning from them for summary and presentation (L. G. Portney & Watkins, 1993). A process of coding and content analysis can achieve this process.

Coffey and Atkinson (1996) refer to coding as condensing the bulk of the data set into units for analysis by creating categories and generating concepts from within our data. Essentially coding is a method of organising qualitative data. However, Coffey and Atkinson (1996) suggest that coding data can be part of the analytical process as giving codes to data and generating concepts enable us to rigorously review what our data are saying. The authors continue by acknowledging that, as coding links different segments of the data together, it creates categories of data defined as being about a particular theme or concept. Coffey and Atkinson (1996) recognise therefore that codes, data categories and concepts are related to one another.

Computer software packages such as NUD.IST are used for the coding of the qualitative data. Coffey and Atkinson (1996) refer to this computer software use as 'the code-and-retrieve program'. These programs allow the researcher to identify segments of data by attaching code words to them. The data are then explored for segments that can be identified by the same code. Coffey and Atkinson discuss the move from coding to interpretation in various stages. The first stage is the retrieval and categorisation of the data. The second stage is the playing with, exploring, splicing and linking the created codes and categories. The next stage is the interpretation, described by the authors as the transformation of the coded data into meaningful data.

This was the process used for the data analysis from the transcripts of the three focus groups for this research. With the assistance of NUD.IST software, data were identified, coded, retrieved and all segments identified by the same code were

collected together for further analysis. This involved the identifying of themes, patterns and responses and finally led to the interpretation.

The interpretation and testing of emergent ideas in qualitative analysis are described by Ingleton and Seymour (2001) as the researchers demonstrating that ‘they have opened up their minds to a range of possible interpretations of qualitative data, and therefore have captured, as far as possible, the essence of the everyday world under study’ (p. 231). This ‘capturing’ of the essence of the world of symptoms and impact of urinary irritability on women with FM began.

The 80 pages of transcripts for this research were transcribed, read and re-read by me as the primary investigator to ensure absolute immersion into the data. Through the reading and the re-reading of the transcripts, thoughts and recollections of the group dynamic and expression were noted. Following detailed analysis of the transcripts, primary codes were identified. As recommended by Miles and Huberman (1984) the codes were first developed as chunks of words that go together and reconfigured as the data expanded. These primary codes were then superimposed on to the transcripts to verify their placement. My academic supervisor (LK) and a second research investigator (AP) verified these codes as being representative of the data, following numerous meetings where the coding was revisited.

Emerging themes from the coded data were recurrent. My academic supervisor and a third individual with qualitative research experience (JW) reviewed thematic configuration and participated in discussions of the interpretation of these emerging themes. The development of an audit trail and the use of second and third researchers to verify coding of the data established the rigour of the data analysis. An audit trail is the researcher’s progressive documentation of the data collection, the categorising and organising of the data and the data analysis (Macnee, 2003). Lincoln and Guba (1985) describe the audit trail as a method of confirmability, the consistency and repeatability of the decisions taken during the process of data collection and analysis. Some of the findings from Phase I were instrumental in some changes to the data collection instrument used in Phase II.

Methodology Phase II

Design

This phase of the research involved the testing of the Interstitial Cystitis Symptom and Problem Index (ICSI/ICPI) within the FM population for reliability and validity. A cross-sectional study design of a group of women with FM and bladder irritability was used to test the ICSI/ICPI instrument for reliability and validity for use within the FM population. The instrument for data collection was a self-administered questionnaire. This questionnaire included a demographic questionnaire (Appendix G), the ICSI/ICPI (O'Leary et al., 1997) (Appendix A), the Fibromyalgia Impact Questionnaire (Burckhardt, Clark, & Bennett, 1991) (Appendix H), the Kings Health Questionnaire (Kelleher, Cardozo, Khullar, & Salatore, 1997) (Appendix I), the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) (Ware & Sherbourne, 1992) (Appendix J) and the Vulval Symptoms Assessment Scale (Appendix K). The vulval symptom assessment scale was developed as a result of the findings from the focus group of Phase I of this research to gauge the extent of vulval symptoms and their impact in this study population.

The rationale for including the Fibromyalgia Impact Questionnaire, the Kings Health Questionnaire and the SF-36 questionnaires was to expand the collected data to include issues concerning the effect of bladder problems on physical as well as psycho-social aspects of women's lives, the impact of the condition of FM on these women and their general health. The demographic questionnaire outlined socio-demographic information and illness and disease specific factors. As there is no gold standard for assessing lower urinary tract sensory symptoms of women with FM, validity was assessed by comparing the ICSI/ICPI with the score that patients obtained from similar reliable measures such as the Kings Health Questionnaire (Kelleher et al., 1997), the Fibromyalgia Questionnaire (Burckhardt et al., 1991) and the SF-36 Questionnaire (Ware & Sherbourne, 1992). It was anticipated that women with more FM and bladder symptoms would score higher in the ICSI/ICPI.

Population and Sample / Inclusion and Exclusion Criteria

Data were collected via the self-administered questionnaire administered to 90 women who met the inclusion criteria. Women were recruited from two Australian state capital cities, Melbourne and Perth.

Inclusion Criteria

- All subjects were female and between the ages of eighteen years and sixty-five years inclusively
- All subjects experienced at least two sensory bladder symptoms.
- Rheumatologists have diagnosed all subjects in the study with fibromyalgia.
- All subjects in the study have undergone a non-invasive urological screening by a urologist or urogynaecologist to eliminate conditions with abnormal pathology.
- All subjects understand spoken and written English.

Exclusion Criteria

Subjects were excluded from the study if any of the following criteria applied:

- Under the age of eighteen years or over the age of sixty-five years. The increase in urinary symptoms in the aged is well documented. Therefore the inclusion of women over sixty-five years of age in this study could create a significant confounding factor.
- Pregnancy
- Current urinary tract infection
- Recurrent urinary tract infection
- A diagnosis of bladder conditions with abnormal pathology resulting from the urological screening.
- Neurological disorders (apart from that due to FM)
- Presence of a urinary catheter
- Drugs that can cause irritative symptoms eg. cyclophosphamide or tioprofenic acid
- Carcinoma of the bladder
- Inability to understand spoken and written English.

Recruitment

A number of different methods of recruitment were employed. In Perth, women were recruited through referral by rheumatologists. This study's research proposal was presented to Perth rheumatologists at their monthly research meeting, explaining the need for participants in the study who had been diagnosed with FM by rheumatologists. Research information letters (Appendix L) were sent to 12 rheumatologists with follow-up visits to eight of the practitioners.

A number of rheumatologists assisted the recruitment process by sending letters to their FM patients asking if they were interested in finding out more about the study and, if so, to contact the researcher directly. Some rheumatologists mentioned the study to patients during consultation if the patient met the rheumatological inclusion criteria of the study. General information sheets for surgeries, as well as notices on rheumatology clinic waiting room notice boards, were made available to the participating medical practices (Appendix M).

Two media releases from the Edith Cowan University public relations department were distributed during the recruiting period to local newspapers and media outlets (Appendix N). This resulted in excellent coverage by a number of the local newspapers. Recruitment advertisements continued in the community sections of some of the community newspapers during the recruitment period. Similar advertisements were also placed in: the "Arthritis Today" newsletter of the Arthritis Foundation of Western Australia; "Pipeline", the newsletter of the Continence Foundation of Australia (WA); the Australian Physiotherapy Association newsletter; and the Women's Health and Continence Physiotherapists national group newsletter. Information on the study and recruiting information was published in the Gazette of Edith Cowan University and on the post graduate discussion board of the University. Details of the research project, together with requests for recruitment assistance, were emailed to eleven of the Western Australian Divisions of General Practice of Medicine. The Women's Information Service from the State Government's Office for Women's Policy also publicised the research through their monthly newsletter.

Recruitment in Melbourne, Victoria was very successful following a short presentation at a Fibromyalgia one-day meeting in Melbourne organised by Arthritis

Victoria. Approximately 500 people attended the meeting. Information sheets, with a tear off 'expression-of-interest' section, were available at the meeting. The research information was also emailed to all members of the Victorian Rheumatology Association via the association's office in Melbourne.

Approximately 500 women expressed an interest in the study during the recruiting period of 18 months. An initial telephone interview with all of these women confirmed their continued interest in the study and ensured they met the preliminary inclusion criteria. Many women did not meet the inclusion criteria for the study, but wanted to talk with someone about their condition and management of FM. These women were offered information about services such as the FM support groups and/or the Continence Advisory Service. A total of 120 women was recruited for the study. Of this number, 90 women completed both steps of Phase II of the study, 70 women from Perth and 20 women from Melbourne.

Data Collection and Protocol

All participating women were mailed information packs prior to their screening appointment. Included in the pack were information sheets on this phase of the study (Appendix O), a consent form (Appendix P), a three-day bladder diary with instructions on use (Appendix Q), details of their appointment and a thank you message for their participation. Melbourne participants were also sent the data-collecting questionnaire and asked to complete it after their screening.

Participation in the study was described as two steps: firstly, a non-invasive urological screening and secondly, a questionnaire completion. All of the women understood that, if there were any abnormalities in the findings from the screening, they would be referred to their general medical practitioner for investigation and would be unable to participate in the study. Perth participants were screened at a metropolitan urology clinic under the direction of a urologist and urology nurse. A urogynaecologist screened Melbourne participants at a Melbourne continence clinic. The urological screening (Appendix R) involved a subjective assessment, the interpretation of the three-day bladder diary, a mid-stream urine sample, urinary flow rate reading and a bladder scan. In the absence of other bladder pathology, and

following the assessment by the urologist, urogynaecologist or continence nurse, these women were recruited into the study.

The subjective assessment involved taking a detailed medical history with particular emphasis on current bladder and FM symptoms and medications. This assessment was conducted by either the urologist, urogynaecologist or continence nurse following the urine sampling and flowmetry. The three-day bladder diary, completed by all participants prior to their appointment, provided semi-quantitative data on micturition patterns including fluid intake and urinary output. Frazer (2003) describes the frequency/volume charts as an excellent and simple method of displaying symptoms, while Abrams and Klevmark (1996) describe the frequency/volume charts or urinary diaries as the most important tool in the investigation of lower urinary tract symptoms.

Although it required commitment and time by participants to complete a three-day bladder chart prior to their urological assessment, it was necessary because previous results have shown poor agreement between subjectively estimated frequency and chart-determined frequency (McCormack, Infante-Rivard, & Schick, 1992). A recent study by Ku, Jeong, Lim, Byun, Paick and Oh (2004) has shown that seven days, the most commonly recommended diary duration, does not affect patient compliance, but rather this extended seven-day diary is associated with patient burden. Nygaard and Holcomb (2000) have shown that the results of the first three days of the bladder diary correlate with those of the last four days indicating that this three-day diary is an appropriate outcome measure for lower urinary tract symptoms. The increased patient burden on the FM study participants in this study was therefore not necessary and a three-day bladder diary was deemed sufficient.

Free flowmetry provided a measure of the speed of the bladder emptying. The urinary flow rate is a composite measure of the interaction of the detrusor pressure and the urethral resistance. As urine flow rates are dependent on voided volume, with the larger the voided volume resulting in the greater flow rate in millilitres per second, all participants were asked to refrain from voiding for at least an hour prior to testing. The free flowmetry was combined with the measurement of residual urine by ultra sound bladder scanning to give evidence of voiding efficiency. The urologist

cited various reasons for non inclusion in the study for twelve of the women. These included patient histories of autoimmune disease, Bornholm disease, Behcet's syndrome, coccygectomy, other neurological symptomatology, recurrent urinary tract infections and minimal urinary symptoms

Following the urological screening, recruited participants were asked to complete the self-administered questionnaire. Some questionnaires were completed immediately after the screening, while others were posted back to the researcher in the provided addressed, stamped envelope. To ensure data for the test-retest of the ICSI/ICPI, a repeat ICSI/ICPI questionnaire was sent to the participants as soon as the first questionnaire was returned to the researcher. Participants were asked to complete this second ICSI/ICPI questionnaire and return it to the researcher as soon as possible. The average time from the mailing out of and receiving the second ICSI/ICPI questionnaire back was ten days. A number of participants did not return the retest questionnaire before 30 days and a few were not returned. Because of the possibility of changing symptoms within the month in this FM population, any retest ICSI/ICPI questionnaires returned after four weeks were not included in the test/retest analysis. Eighty-three of the 90 (92%) study participants participated in the retest sample.

Data Analysis

Assessment was made for internal consistency reliability, test-retest reliability and concurrent validity of the ICSI/ICPI instrument. Reliability indicates the reproducibility of a scale, indicating what proportion of a patient's test score results are true and what proportion is caused by individual variation (Penson & Litwin, 1997). Internal consistency reliability is a measure of the similarities of a person's response across several items and indicates the homogeneity of the scale while test-retest reliability measures the question response stability over time (Penson & Litwin, 1997). Validity refers to the degree to which the scale measures what it is supposed to measure. Concurrent validity is described by Penson and Litwin as a more quantitative approach to assessing the performance of instruments and involves correlation of scale scores with results from other established tests.

Cronbach's alpha coefficient was used to assess internal consistency reliability. A criterion of at least 0.70 was pre-set as the acceptable level for internal consistency reliability (Nunnally & Bernstein, 1994). Internal consistency reliability also involved assessment of inter-item correlation with an expected value of between 0.30 and 0.70 (Carmines & Zeller, 1979). Item-to-total correlations were examined to determine whether 50% of these values achieved a correlation of between 0.40 and 0.70 (Carmines & Zeller, 1979). Stability over time was assessed using the test-retest procedure as estimated by the intra-class correlation (ICC). Examining the simple correlations between the ICSI/ICPI and other similar instruments provided evidence for concurrent validity assessment.

Factor analysis was undertaken to assess the internal structure of the scale and to identify relevant subscales for use in the FM population. Multiple regression analysis was also used to identify factors associated with bladder symptoms.

Ethical Considerations (Phase I and Phase II)

Ethics approval for this research was obtained from the Edith Cowan University Committee for the Conduct of Ethical Research. All participants in both phases of this study were fully informed of the purpose of the study and were provided with an information sheet describing the process of their involvement. Informed consent forms were signed and dated by all participants and the researcher. The consent form indicated that the subject was free to discontinue participation at any time during the study without prejudice.

Taped interviews from Phase I were transcribed by the researcher. The tape recordings were then erased. There were no names or identifying information on the questionnaires in this study. Medical assessment forms from the urological screening for Phase II of this study were secured in a locked filing cabinet in the researcher's office. All hard copy raw data and signed consent forms were secured in locked filing cabinets. Consent forms and data files were stored separately. Only the researcher and principal supervisor had access to these records. Code numbers were used on all documents and computer data entries to ensure participants' privacy.

Only the researcher and primary supervisor had password access to the computer data.

The researcher acknowledged the sensitivity and personal nature of this area of research and at all times acted in a professionally appropriate manner. The researcher has worked clinically in the urology area as a physiotherapist continence adviser, assessing and treating pelvic floor dysfunction for the past fifteen years. Continence Foundation brochures were made available to all women who requested information on bladder symptoms and/or good bladder habits. Information on FM support groups was made available to women who requested information on group support.

Following the analysis of Phase II data, the findings of both phases of the study were reviewed, recorded and form the essence of the following chapters on findings and discussion of this study on FM and bladder irritability.

CHAPTER 5

RESULTS AND DISCUSSION: PHASE I

Introduction

This chapter documents the findings from the qualitative analysis of Phase I of the research. It also describes the participants in terms of their demographic characteristics, the preparation of the data for analysis, the analysis steps and the results. The results are interpreted in relation to existing literature.

Who Participated?

Sixteen women were recruited for the focus groups. To accommodate personal commitments and preferences, the focus groups were offered at different times during the day. Some women were unable to keep their appointments to participate in the groups. The final numbers in the three focus groups were four, four and two, totalling ten participants (n = 10). Each focus group was of two hours duration

Demographic Characteristics of the Focus Group Participants

The majority of the women were Australian born (seven of ten). The women's ages ranged from 25 to 58 years with an average age of 47 years. The number of biological children per woman ranged from zero to three, with an average number of two children per woman. Most of the women had tertiary qualifications (seven of ten). Occupations included professional positions (four), homemaker (three), clerical (one), retired (one), and one was receiving a disability pension. All participants reported being treated for FM by a rheumatologist between 1993 and

2001. However, all women had experienced pain and disruption for years before the diagnosis was given. Main health concerns apart from FM were listed as osteoporosis (three), headaches (two), gastric reflux (two), osteoarthritis (two) and tinnitus (two). Prescription drugs included antidepressants for sleep enhancement and reduction of pain (four), hormone replacement therapy (three), anti-inflammatory medication (two), thyroxine (two), aldactone (two), ditropan (one) and cholesterol medication (one). Five women were postmenopausal, one was perimenopausal and four were premenopausal.

Non-Bladder Symptoms

The findings from this study confirmed those found in other qualitative studies on the experience of people diagnosed with FM. Raymond and Brown (2000) depicted the patient's journey as a continuum that included the onset of symptoms, a search for a diagnosis, and a phase of coping with the illness. Asbring (2001) described FM as a chronic disease that can result in a radical disruption in a woman's biography that can have profound consequences for her identity. Both the FM journey and the resultant adaptive changes were evident in these Australian women who participated in these focus groups.

The findings from this study reveal the enormity of the impact that FM has on the lives of women. The unpredictability of the symptoms and the resultant constantly changing management strategies undertaken by these women demonstrate the notable impact of FM on their lives. So challenging and unpredictable is it that it becomes difficult for women to predict symptomatology and therefore plan their lives. FM seemed to encroach from all corners of their living space, impinging on their every experience and tethering them within restricted physical, emotional, social and psychological boundaries. The impact of these four components is depicted in Figure 5 below as a puzzle image.

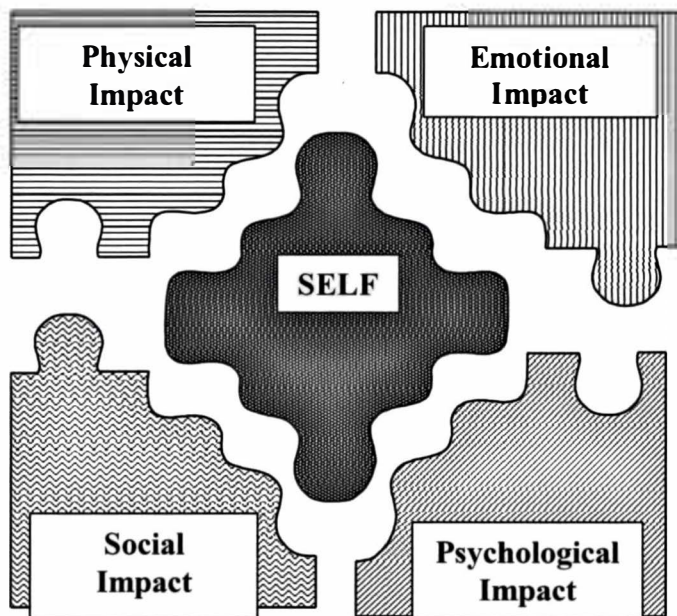


Figure 5: The Tethering Effect of Non-Bladder Symptoms on Women with Fibromyalgia

Although tethered and contained by these restrictions, the women still enjoyed a certain freedom of movement, expression and experience within limited boundaries. The women described the impact of this symptomatic tethering even before the discussion included their bladder symptoms. They lived within the confines that FM and its bladder effects dictated to them. This is their story.

Emerging Themes

The Physical Impact of Fibromyalgia

Pain was the dominant FM feature experienced by the women in the focus groups. Their pain was evident in the way they sat, the way they moved and emotionally in the description of their pain. The pain from the pelvis, from the back, from the neck, the feet, the ribs, the pain that caused these women to drag themselves through most days, was all consuming. The women described their pain as interfering and impacting in all aspects of their lives.

When you get the real FM pain, you get it everywhere, your hands hurt, your feet hurt, your head, your back, your vulva, your legs, your internal organs hurt, your cheeks hurt. It is all part of the syndrome isn't it? Like the whole body. (Focus group 1 E)

From migraines to trying to walk down the stairs, from early morning stiffness heralding the start of their day, the women were exhausted. Within the groups, the collective impact on each other validated the expression and experience of their pain. Early in the discussion, there was a sense of awareness and relief that there were other women who lived similar lives affected by FM. The head nodding in affirmation when one woman talked of not knowing what it was like to live without pain reflected the ongoing non-verbal agreement between these women.

I was going to the doctor because the pain was so intense...and I was doing my exercises in the morning because after midday I am of no use to anybody. I had to talk to myself with positive thoughts in my mind...I don't know what it is to live without pain. (Focus group 1 F)

Their descriptions of the relentlessness of their pain was consistent with the statement by Hathaway (2004) in his article on 'Chronic Pain and Fibromyalgia: trapped in a World of Hurt' where he described pain as 'a relentless taskmaster that demands constant consultation before even the most mundane activities are attempted' (p.1).

For the majority of women in the group, sleep was a luxury. Unanimously the women agreed that when they were able to obtain more sleep they felt better "all around". Four to six hours sleep each 24 hours allowed them to function "to a certain extent during the day". Most of the women knew that if they did not get sufficient sleep their pain could be worse. This pain contributed to less sleep and finally total exhaustion. This was reflected by reports of 'dragging one's self through each day'. There was an initial resistance to the use of medication to improve sleeping patterns. However, the women eventually had to accept the use of medications in order to sleep. Four of the ten participants were on antidepressant medication to improve the quality of their sleep.

I have been much better since I have been on doxipine this year. I am really anti medication. I have to be honest about that. But this year I really gave in and it just got so bad, I just wasn't coping...I just got to the

point where I was so tired and run down that I went on to doxipine.
(Focus group 2, All)

The need to be self-sufficient and non-reliant on drugs prompted the women to seek alternative treatments or to just charge ahead with their lives and suffer the consequences. Four of the women in the groups had tried non-prescription medication to try to find relief from their symptoms. Physiotherapy treatment was popular with some of the women, providing them with short term relief.

The primary approach for treatment of FM is a change of lifestyle to ease demands on the body and medication for pain and sleep management. The majority of women in the groups were very self-sufficient, goal setters and self-driven. It was of interest to note that, of the ten women in the focus group, seven had completed a tertiary education.

The pain and fatigue of FM resulted in significant muscle deconditioning and poor aerobic fitness levels for most of the participants. They spoke of their inability to be involved in family physical activities and were aware that their partners' lives were also affected by their illness.

The Emotional Impact of Fibromyalgia

The diagnosis of FM usually follows years of looking for answers and solutions to a pot-pourri of symptoms. Although FM research has discovered some of the biological markers of FM, some are illusive and some techniques necessary for locating the diagnostic markers are too invasive. As a consequence, people with FM are often classified as experiencing psychosomatic symptoms or possessing poor coping skills to deal with life issues. This was the experience of some of the women in the focus groups.

I went and asked my GP if he would take my FM seriously. I asked him if he had heard of FM and did he believe in it. And I sat down and he said that he didn't know enough, "but this is what I know and yes I believe in it" ...I just think it would be fantastic to wake up one morning and know that I felt alive, awake and well. It would be fantastic! (Focus group 3, S)

For all women, the diagnosis of FM was a validation of their symptoms and distress, accompanied by a feeling of relief because a diagnosis had finally been

obtained. However, their diagnosis also triggered a sense of foreboding about their health future. At the time of diagnosis, most women were given pamphlets about their condition, a prescription for medication and advice to increase their exercise and change their lifestyle. Some were given the diagnosis and told that there was no treatment for the condition and they would have to make changes in their lives to accommodate FM. Five of the ten women had not met or heard of anyone else having this diagnosis. The feeling of isolation and sense of 'where to from here' was overwhelming for them. This sense of aloneness was compounded by a lack of FM knowledge, support and understanding from their general medical practitioners.

The women in the focus groups were driven in their search for answers to improve their health and to improve the quality of their lives. Through their pain and disability they maintained seeking, hopeful and generous personalities.

I feel more inspired by talking about what research is out there to actually help the problem. And that is what I like about Dr _'s group that we talk about things that actually help. E talks about DHEA and we talk about other things. There is urgency for us to get on and try and make do and get on with life. (Focus group 1 V)

I just think it would be fantastic to wake up one morning and think, 'I feel alive and well'! It would be fantastic. I hobble into the shower and I hobble out of my car at work. (Focus group 2 All)

The emotional impact of FM on the women was more than adapting to the physical distress they endured. It was coping with a disability that affected all sections of their lives. For one young woman, FM even impacted on her future plans of becoming a mother.

It is funny because I now have concerns because I am thinking of starting a family in the next couple of years. I have concerns about do I want a female child because I am frightened of passing on these things that I have lived with. I would prefer not to and would it be different if I had a son. Can I still pass that sort of thing on to a male child? (Focus group 2 J)

This grieving for future loss and constant adaptation was intertwined with grieving for the loss of lifestyles they enjoyed prior to the onset of FM. The grieving in some was hidden behind well-developed coping facades. The common experience of FM shared by the women in the focus groups was very disarming for some,

resulting in tears of frustration and pain. The unspoken permission to just 'be herself', the anger tethered and controlled for so long and the anguish of living with constant pain were quietly evident during the discussions and at times erupted into hostility demanding of answers.

The women's frequent use of humour lightened many of the more difficult moments. Comments such as 'I stopped trampolining sometime ago' or 'Mum and I find retail therapy is a great help' created relief through laughter and light-hearted response.

The Social Impact of Fibromyalgia

Kitzinger (1994) wrote that group participants of a focus group provided an audience for each other that greatly enhanced communication and enriched data collection. She concentrates on the interaction amongst research participants and describes this interaction as the participants becoming co-researchers, taking the research topics into new and unexpected directions.

This interaction was apparent in the focus groups. Because the women shared a common diagnosis, they shared an understanding of each other's challenges. They communicated, they agreed, they disagreed, they questioned and demanded answers. There was a collective response as well as individual responses from the women, especially in this area of the social impact of FM.

Your comment earlier about having your FM in perspective...that is fine until someone asks you how you are. They want you to say fine. Don't they! I mean they don't want to hear you say, 'I am bloody awful again today'. Do you know what I mean? You actually have to learn to mask it and get on with it. Otherwise people would think you are a hypochondriac. (Focus group 2, All)

FM is often described as an invisible illness as the majority of women with this condition appear physically normal. For the majority of women with FM there is no obvious disability. Sveilich (2005) reveals that people who live with unseen illnesses and chronic conditions 'often conceal their physical challenges and project themselves to the world in a particular manner that is contrary to the way they feel.

These individuals choose to wear the mask of normalcy and often appear just fine, despite having to contend with a host of invisible and difficult challenges' (p. 20). In Soderberg and Lundman's study (2001), women described other people viewing them as healthy beings.

Most of the women in the focus groups fought to maintain this illusion of wellness within their family, work and community groups. Therefore, normal expectations were placed upon them. These women fought to maintain a normal day-to-day existence with their family and work environments. For a few of the women these expectations were insurmountable, but for others there was no option but to 'get on with it'.

Do you want it to control me or for me to control it? That was the mindset I took. I think when you first find out what is going on you get very keen and read everything and say, 'Yes, I have got that and I have got that so poor me'. But then really on a relative scale you sort of think, well I want to enjoy life, so let's get on with it. (Focus group 2 All)

Patients with FM frequently report a decline in cognitive functioning, memory and mental alertness. The women referred to this mental confusion and forgetfulness as 'fibro-fog'. They described their episodes of cognitive dysfunction as mental blackouts that increased when their FM was flared. They described the effects this had on their ability to function effectively at home and in the work place. The effects varied from emotional despair to absolute acceptance. Above all, their resilience and determination to move on with their lives was inspiring.

The Psychological Impact of Fibromyalgia

The women in the focus groups described the psychological impact of FM in many ways. They spoke at length of the avoidance of stress in their daily lives. Stress can exacerbate the symptoms of FM (Davis, Zautra, & Reich, 2001). The women in the group attempted every day to avoid unnecessary stress, to live within their energy restraints, tethered by the impact of their symptoms. However, for all of the women, this loss of freedom, the fatigue and the pain increased their stress, their sense of frustration and their anger. Most of the women were attempting to bridle this impact with a quiet determination to move on with their lives.

One day I am ok and the next I am not. When I am not I do my best and when I am well I do my best as well. I take it as it comes. I can't handle stress any more. So I try to make my life as less stressful by not worrying so much and just take one day at a time. (Focus group 2 An)

The symptoms of FM can affect all organ systems of the body. The symptoms are unpredictable and variable. As a result, these symptoms of FM layer themselves on to their sufferers without finite definition, resulting in overall body pain and fatigue. This psychological impact of their disability extends into their families and work environments. The grief experienced by the women regarding the loss of the lives they enjoyed before FM, such as camping with the children and working in full time professional positions, was vocalised and discussed.

I used to run 5 kilometres a day. I had the muscle tone of an athlete. I now couldn't run to save my life. I have been on a downhill slide for the past three or four years. It is so frustrating. I am only 25 years old and I feel like a grandma...I get really upset because my husband met me when I was still doing a little bit of modelling and I was a size 10 and I was this beautiful skinny little blond and that. Now I am so self-conscious because I have put weight on and I don't want to do those sorts of things and sometimes I don't even want to be undressed in front of him and it gives you all those sorts of feelings that I never had before. And I am so young. That is sad. I just find that so sad. (Focus group 2 J)

They talked of trying to lead normal lives, but found that sometimes it was easier to retreat. Their anger at their loss of life style and the frustration of continuing symptomatology were evident in all of the women in the groups. The blending of the tolerance of their symptoms, hopes, optimism, frustration and a knowing of ineffective medical knowledge and management of FM created interesting interactions and comments within the groups.

Do you get angry that your children have really lost their Mum? I get angry because my daughter was eight when I started with the symptoms and she has lost her Mum because there was a lot I couldn't do with her...You do, you do struggle on. But there are some things you would like to do like go and run and dance around the park. But you can't, can you! (Focus group 2, Ja)

The physical, emotional, social and psychological impact of FM on the lives of these women was very evident. For most of the women, the impact of FM decreased their range of movement and choices in life, but not their resilience. They

had learned to move effectively, to live and to enjoy their lives within the boundaries that FM had set.

Morse (1997) has developed a model, 'Responding to Threats to Integrity of Self', a five-stage model of recovery and rehabilitation. This theory was developed for use in the understanding and supporting of patient responses to either acute or chronic illness. The theory concentrates on the individual and how he/she seeks self-comforting strategies to manage his/her experience. The five stages of the model include: Vigilance; Disruption, enduring to survive; Enduring to live, striving to regain self; Suffering, striving to restore self; Learning to live with the altered self (Morse, 1997). Morse describes stage five as the major task, that of learning to live with the altered self, learning to accept the consequences of their experience and accepting that life will not be the same again. She describes the experience of learning to revalue life, to appreciate different things, to establish different goals and to reprioritise aspects of life.

This fifth stage described by Morse encapsulates the experience of the women with FM who participated in the focus groups. They were learning to live with the altered self.

Bladder Symptoms

Previous studies by Clauw and colleagues (1997a), White and colleagues (1999a) and Pairs (1994) have shown the prevalence of genitourinary symptoms in patients with FM. This current study is the first research on bladder irritability symptomatology in Australian women with FM. The effects of the bladder symptoms were very significant for the women participating in the focus groups. FM impinged on every aspect of these women's lives. The further impact of the urogenital symptoms of FM on their lives was enormous, further restricting their freedom of movement and available choices. The dual impact of non-bladder and bladder symptoms combined to increase the challenges for these women to find the most manageable way through each day.

All of the women in the focus groups experienced a range of sensory urinary symptoms. Following the interview guide items of the ICSI/ICPI index, the women were asked about the urinary symptoms of urgency, frequency, nocturia and pain or burning in the bladder and how problematic these symptoms were. Further discussion was elicited by following the questions of the Kings Health Questionnaire. This questionnaire allowed the women to expand on to the effect that their bladder dysfunction had on their daily roles, physical activities, social lives, personal relationships, emotional health, and sleep and energy capacity. Their accounts are described below.

The Impact of Urinary Frequency

Some of the women from the focus groups were not aware that their urinary symptoms could be part of the condition of FM. Day time urinary frequency is described as the complaint by the patient who considers that she voids too often during the day (Abrams et al., 2002a). Urinary frequency was a significant symptom for the women in the focus groups. Urinary frequency ranged from 'less than one in five times' to 'almost always'. The impact of their urinary frequency ranged from 'a very small problem' to 'a big problem'. Some of the women were very conservative in their description of how problematic urinary frequency was for them. One woman voided from 15 to 25 times a day and described it as a nuisance. Another described her frequency as part of her life and she dealt with it. She visited the toilet so often during the day that it had 'become her day'. She chose to forget about it and to 'get on with her life'.

Well, I mean you have really got to time your outings and if I do go out it is only for a short time. Just before I came here I had to go and pick up some macca and I had to go to the toilet. I left, and it was only a five-minute drive but as soon as I got there I had to go again and when I finished and got my things I had to go again and now I am here. I haven't been yet but I have crossed my legs at the moment (Focus group 1, T)

Unknowingly some of the women were increasing the irritability of their bladders by decreasing their fluid intake, feeling that if they drank less they would void less often. For some women this was a way of saving time. One of the participants drank a maximum of 400mls per day. All the women knew where the nearest toilet was situated. They spoke of knowing 'all the toilets in the city'. The

women spoke of their fear of aggravating their bladder problems and their anxiety at managing everyday and family activities in relation to their bladders.

It is difficult because if you can't find a toilet if you are out...If it is a problem finding the toilet when you are out then it is a matter of how often you are out. If you are out all day and every day, then it is a major problem. Or someone else who is at home all day with access to the toilet, it is not a problem. (Focus group 2, A)

Existing urinary frequency can be aggravated by a 'just-in-case' behaviour where women will void just in case they may not be able to find a toilet when they next need to void. This self-induced frequency compounds and aggravates the existing problem. Textbook descriptions of this self-induced frequency were given by most of the women. One woman described how she voided before leaving home to do the shopping at a centre ten minutes from her home. On arriving at the shopping centre, her first stop was the toilet. Another spoke of her pre-bedtime voiding pattern. Every night she voided four times within the 20 minutes before getting into bed, then another three voids while reading in bed for an hour and then waking every two hours to void during the night.

But when I am awake that feeling is there 100% of the time. I also have found that I go to the toilet more than I ever have before. And I am already thinking ahead, before I leave home I will go. When I left home tonight I went, and I arrived in the building and I went because I just know that if I don't go at regular intervals I am going to need to excuse myself. (Focus group 2, A1)

The urinary frequency impacted on the women's ability to travel short and long distances by car or by plane. Some of the women would rather stay at home than cope with the inconvenience and embarrassment resulting from their urinary frequency and urgency.

The same with travel...I have a daughter living in a remote area. We go about one and a half hours inland and it always has to be that I am always saying to my husband, 'How many kilometres to the next stop' and saying all the time that we are going to have to stop. If I can't make it I just have to stop and open the car door and go by the side of the road. I ask him to tell me if a car is coming because I can't see and quickly pull my pants down and go to the toilet and pull up. I find it quite upsetting...I didn't go up there the last time she asked me. (Focus group 1, E)

Urinary frequency for the majority of women caused a disruption in their lives. It impacted on their family lives, their working lives and their social lives. One woman spoke of having to resign from her professional position as a counsellor because she was unable to spend an uninterrupted hour with her clients because of her urinary frequency. Another spoke of her love of the theatre, but the demands of her bladder dictated where she sat in the theatre and dictated its own interval. The activity created by the women regularly going to and from the toilet during the two-hour focus group was evidence of the demands made on them by their bladders. The frustration of the bladder dictating to these women what they did and where they went was summed up by (T) in her comment 'We never go anywhere'. However, the resilience and humour of these women, despite their disability, were notable.

People do comment though. People say to me, 'But you have just been, why do you want to go to the toilet again when you have just been?' I just say, 'Well I have got to go! What do you want? Do you want me to wee on the carpet or are you going to let me go?' I mean I just make a joke of it. There is no other answer because when you have got to go, you have got to go, but it can be off putting to people you don't know because you have gone to seek the toilet again. But that has been the way it has been...and then you get someone who stops you on the way to the toilet. I just have to say that I will come back to you, just give me a moment.
(Focus group 3, A)

Using the ICSI/ICPI questionnaire, the women in the focus groups were asked how many times during the last month had they had to urinate less than two hours after they had finished urinating. Figure 6 displays the proportion of women with varying urinary frequencies. They were also asked how much of a problem frequent urination was for them during the past month. Figure 7 displays this impact of urinary frequency on the women in the focus groups.

ICSI Urinary Frequency

n = 10

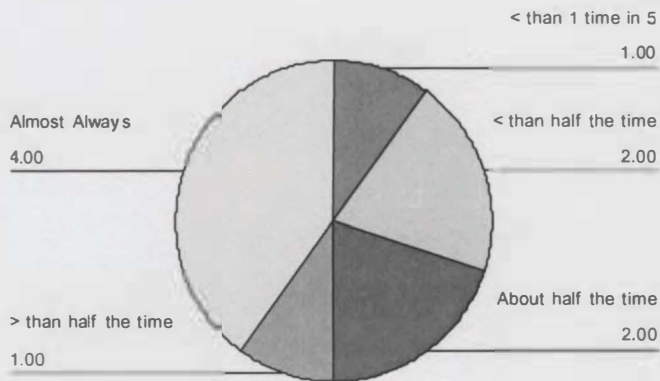


Figure 6: Proportion of Women in the Focus Groups with Varying Urinary Frequency

ICPI Urinary Frequency

n = 10

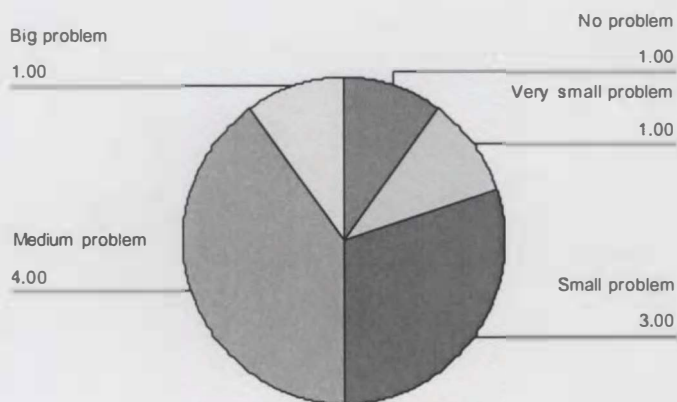


Figure 7: Impact of Urinary Frequency on Women in the Focus Groups

The Impact of Urinary Urgency

Urinary urgency is described as the complaint of a sudden compelling desire to pass urine that is difficult to defer (Abrams et al., 2002a). This was a significant symptom experienced by women in the focus groups. The unpredictability of the urge to urinate was a fear that encouraged self-induced frequency, an increase in urinary frequency because of 'voiding-just-in-case' behaviour. The majority of women in the group experienced this urgency/frequency combination. Just listening to the pouring of the drinking water from the jug to the glass during the group discussion was enough to prompt the desire to void in some women.

The women expressed fear of being 'caught out' in many situations. They described embarrassing episodes of urgency in the gym, at the office river cruise Christmas party, travelling on aeroplanes, during their daily walking regime, and the urgency of the 'key-in-the-door' situation when arriving at home. One woman had her personal key to the staff toilets to enable her to 'make it'. As with urinary frequency, some kept their fluids restricted because of the unpredictability of, and the anxiety associated with, the urinary urgency.

It is just the urgency. It just catches me out. At work some of the people must think I am nuts because suddenly I will get up and go to the loo. You are going to the bathroom and that is it. You can't concentrate on anything else suddenly, just suddenly. They must think I am odd! (Focus group 3, S)

Some of the women experienced a constant sensation of needing to void. Some described this as a burning sensation even when on voiding they only 'passed a few drops'. One woman described this urgency as being more apparent and difficult to control when her other FM symptoms were heightened.

This urinary urgency placed another demand on these women whose capacity to manage yet another symptom was already extended beyond normal limits. The fear of their urinary urgency extending to urge incontinence increased the stress on the women.

When I have the urge to go, I get really stressed. When I am out and I am in the car and I have to go home, it is like you just want to put the accelerator right down and go through all the traffic lights because it is really painful. I find that when you hold on, I find you are using all the

muscles in your legs and your back. You are doing everything to hold on and it is very painful. I don't leak, but I find that I use every muscle in my body and once I have gone, I am pretty wiped out. (Focus group 1, V)

One of the important treatment regimes for people with FM is to maintain some form of exercise to increase endorphin levels, to maintain levels of aerobic fitness and to maintain muscle integrity. This was hampered for some by their urinary urgency. Walking was often restricted to parks and areas where public toilets were available. Some experienced the need to stop and stand still and wait during their walk to manage the urgency. Swimming is encouraged as an appropriate form of exercise for people with FM because of the minimal weight-bearing impact when exercising in water. For some of the women, their urgency was aggravated in these situations because they experienced the need to void as soon as they entered the water.

The frustration of repeat visits to their general medical practitioners for urine cultures to check for urinary tract infections added to their list of medical maintenance. The women felt that, because they were experiencing acute symptoms of urinary urgency, frequency and discomfort, they therefore must have a urinary tract infection.

I thought I must have had a bladder infection so I will go to my doctor. He did two or three urine samples and came back with nothing, completely clear. The problem just seemed to be getting worse and worse and worse. I just felt I needed to go 100% of the time, all the time, continuous. I could go to the toilet, go and sit in my seat and then feel as though I needed to go straight back again. (Focus group 2, J)

The women were asked to respond to the ICSI/ICPI question on urinary urgency: How often during the last month had they felt the strong urge to urinate with little or no warning? Figure 8 displays the proportion of women with varying urinary urgency. They were also asked how much needing to urinate without warning over the past month had been a problem for them. Figure 9 depicts the response to this question.

ICSI Urinary Urgency

n = 10

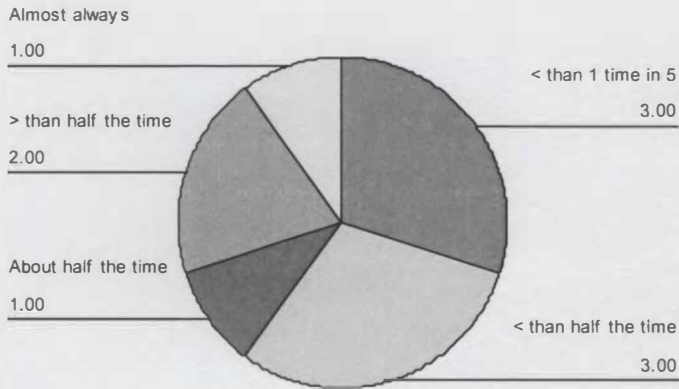


Figure 8: Proportion of Women in the Focus Groups with Varying Urinary Urgency

ICPI Urinary Urgency

n = 10

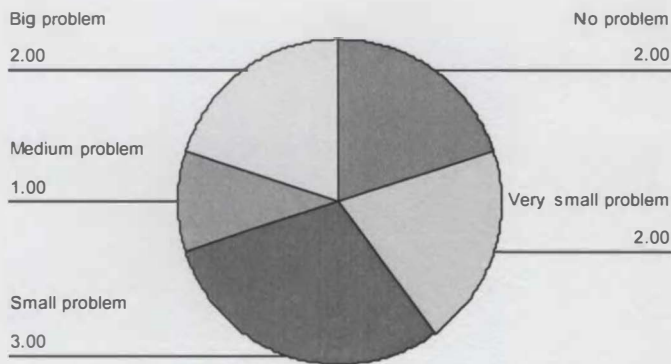


Figure 9: Impact of Urinary Urgency on Women in the Focus Groups

The Impact of Nocturia

Nocturia refers to a person’s need to wake at night one or more times to void (Abrams et al., 2002a). Hetta (1999) comments that the importance of sleep can be gauged by considering the consequences of insufficient sleep. Sleep deprivation has a deleterious effect on frontal lobe functioning, impacting on concentration and intellectual skills (Hetta, 1999). Hetta lists the effects of sleep deprivation as fatigue

and sleepiness, reduced concentration and co-ordination, problem-solving difficulties, reduction in creativity, mood alterations, muscle stiffness and an increased risk of infections. Nocturia has a profound effect on a person's mental and physical health. Jennum (2002) describes nocturia as an annoying and potentially damaging symptom because it fragments sleep and may therefore result in adverse consequences.

For women with FM, nocturia is more difficult to define. Coyne and colleagues (2003) state that nocturia is not a benign symptom. This was certainly evident from the participants in the focus groups. What factors cause these women to get up at night to void more than the acceptable once per night after they have gone to sleep? Is it the insomnia that is such a significant feature of FM that causes the women to void many times during the night because they are awake for long periods? Is it the musculoskeletal pain that wakes these women from sleep and, when awake, they feel the need to go to the toilet? Is it the irritability of the bladder that wakes women from sleep and results in nocturia? Or is it the anxiety about the possibility that they may not sleep again that night that impacts on bladder behaviour? The women in the focus groups who voided more than once during the night were unsure of the reason they were up going to the toilet at night. Excerpts from the focus groups demonstrate these issues.

But the worse thing is having the burning sensation and getting up so many times at night. I feel as though I have got to go and when I go at night time I get up many many times. (Focus group 1, F)

In winter, if the pain wakes me up I can't sleep because of the pain and the combination of going to the toilet and the winter, I wake up more. The pain is all over muscle pain...I am just a wreck. In summer the pain is not as bad. In summer it is the urge to go to the toilet that wakens me. (Focus group 3, A)

If my sleep is not deep then it just niggles and niggles and niggles. You have just got to get up and go or else you won't go back to sleep. But I think it might be the sleep in the first place. I don't know. (Focus group 3, S)

Whatever the reason, the end result was disturbed sleep with increased fatigue and increased pain the following day. Some of the women felt their nocturia was a small problem because, although it was annoying, they could 'handle' it. For

one woman, it was a small problem because she did not know what sleep meant. She was grateful if she had three hours maximum sleep during a night. Others felt that their bladder disturbed them because they were light sleepers. This deprivation of restorative sleep in FM patients has a major impact on their sense of well being and management of their symptoms.

I wake up every two hours. If I have four hours of continuous sleep, I am happy...Do I feel worn out and tired? Fancy asking me this? I couldn't say anything about if my bladder affects my sleep because I am awake anyway. I definitely feel worn out and tired all the time. (Focus group 1, T)

Tricyclic medications in doses lower than those used to treat depression are often prescribed for women with FM to provide the benefits of reducing sleeplessness and for pain management. The tricyclic medication can increase the amount of delta wave sleep, improve the availability of serotonin to nerve cells and enhance the effects of endorphins that can decrease pain (Wallace & Wallace, 1999). The anticholinergic effects of the tricyclics also result in relaxation of the bladder, decreasing the intensity of bladder contractions and decreasing frequency by delaying the desire to urinate (Hanno, 1994a)

Four of the ten women in the focus groups were taking tricyclic medication primarily for the relief of FM symptoms rather than for the bladder effects. Medications for the treatment of the variety of symptoms of FM can impact positively on the quality and amount of sleep with a resultant positive impact on the bladder. These medications would probably be impacting positively on their bladder irritability without the women necessarily being aware of this secondary effect. One woman was medicated with ditropan, an anti-cholinergic drug used for urinary frequency, urgency and incontinence.

I went to see my doctor about my sleep to get some tablets because I used to be exactly like that until I found a GP who had chronic fatigue. That was the first thing he said to me, 'We will get your sleep sorted out first and then we will worry about everything afterwards'. It made such a difference to my life, a huge difference. That was the big turning point for me. (Focus group 3, A)

The women were asked to respond to the ICSI/ICPI question on nocturia: How often during the last month had they most typically got up at night to urinate?

Figure 10 displays the proportion of women with varying nocturia episodes. They were also asked how much had getting up at night to urinate over the past month been a problem for them. Figure 11 shows this impact of nocturia on the women in the focus groups.

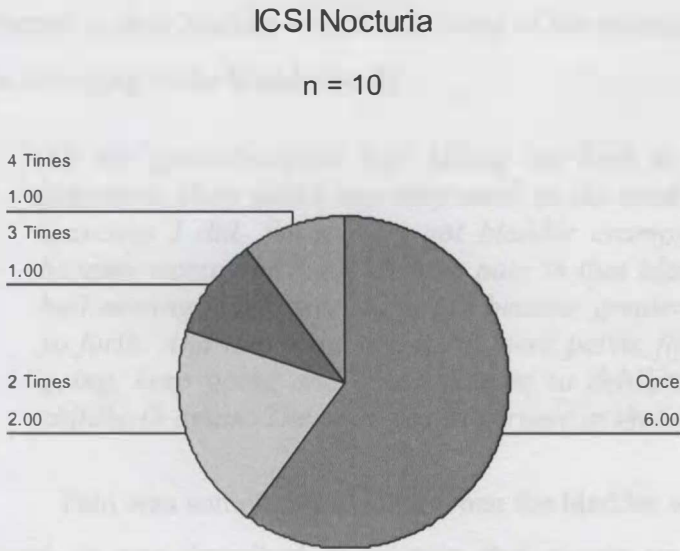


Figure 10: Proportion of Women in the Focus Groups with Nocturia

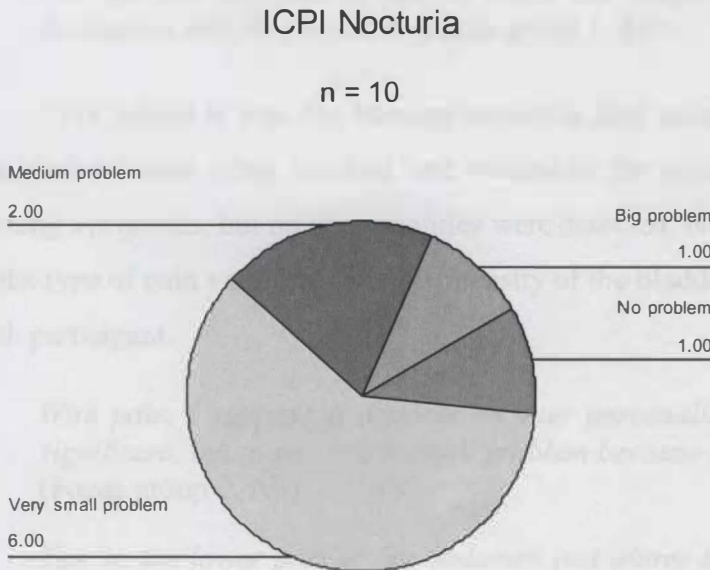


Figure 11: The Impact of Nocturia on Women in the Focus Groups

The Impact of Bladder Pain, Burning, Discomfort or Pressure

For the women in the focus groups, pain and discomfort in the bladder often accompanied urinary urgency. This was described as a sharp pain or the burning sensation 'that is always there'. For some women the bladder discomfort was worse when their FM was 'flaring'. Pain from their musculoskeletal system seemed to be reflected in their bladder symptoms. Some of the women described their bladder pain as a cramping in the bladder itself.

All the gynaecologists kept telling me was to do more pelvic floor exercises. They said I was very weak in the area. The more pelvic floor exercises I did, the more I got bladder cramps. The bladder cramps became worse and I got chronic pain in that bladder area. It felt like a ball moving inside me. The urges became greater to go to the toilet and so forth. And they kept saying do more pelvic floor exercises, just keep going, keep going and I just became so debilitated. It was like giving childbirth again. The pain was so chronic in that area. (Focus group 1,V)

Pain was sometimes evident when the bladder was emptying or at the end of a void. It was described as 'a pain that shoots up the bladder'. Some of the participants described their bladder symptoms as a discomfort or pressure rather than pain or burning. Some commented that their abdomens felt swollen.

For me the problem is not so much the burning or pain, but the discomfort and the pressure. (Focus group 1, F)

For others it was the burning sensation that accompanied urinary urgency. The women were often checked and rechecked for urinary tract infection for the burning symptoms, but no abnormalities were detected. Not only did the descriptions of the type of pain vary, but also the intensity of the bladder/pelvic pain differed with each participant.

With pain, I suppose it depends on your personality. I mean it is quite significant, but to me, it is a small problem because on the scale of things (Focus group 2, All)

Yes, in the lower part of the abdomen just above this bone. Yes, it is a feeling of um...at the beginning I thought it was inflammation so I got checked and there was no inflammation, especially not being active sexually. I have been checked through and through and there was no inflammation. And it is getting worse. (Focus group 2, An)

For some women, the bladder pain was just part of the whole spectrum of body pain, just another sore part of the body. It was part of the larger problem and was not singled out from the rest of the body pain.

The women were asked to respond to the ICSI/ICPI question on bladder pain, if, during the past month, they had experienced pain or burning in the bladder. Figure 12 depicts the proportion of women with varying bladder pain experiences. They were also asked how much had burning, pain, discomfort or pressure in their bladder been a problem for them over the past month. Figure 13 shows this impact of bladder pain on the women in the focus groups.

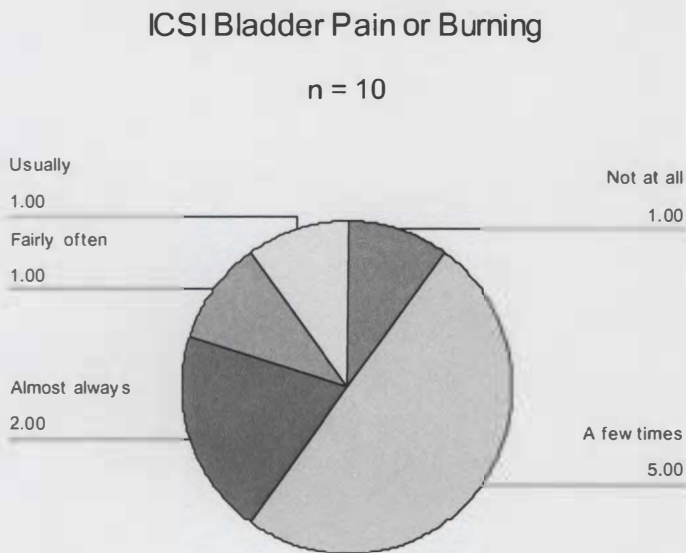


Figure 12: Proportion of Women in the Focus Groups with Bladder Pain/Burning/Pressure/Discomfort

ICPI Bladder Burning, Pain, Discomfort or Pressure

n = 10

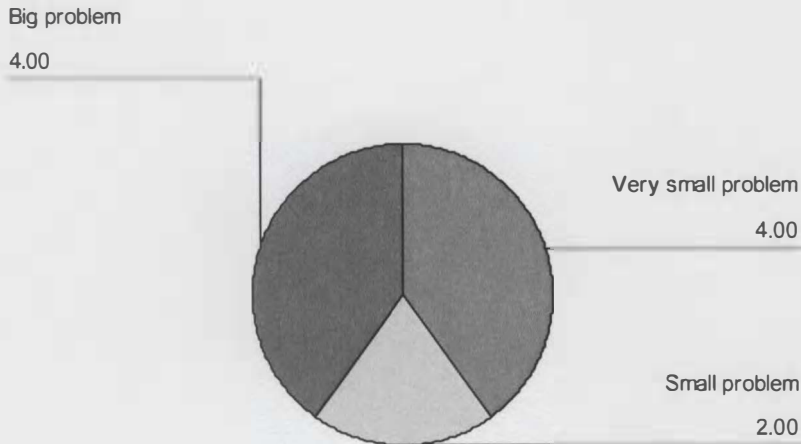


Figure 13: Impact of Bladder Pain/Burning/Pressure/Discomfort on Women in the Focus Groups

Stress Urinary Incontinence and Urge Urinary Incontinence

Stress urinary incontinence is the complaint of involuntary leakage on effort or exertion or on sneezing or coughing (Abrams et al., 2002a). Urge urinary incontinence is the complaint of involuntary leakage accompanied by, or immediately preceded by, urgency (Abrams et al., 2002a). Although the literature shows that urinary incontinence is not a major symptom for women diagnosed with FM who experience bladder irritability, it is of interest to note the incidence of incontinence within the focus groups.

Four of the ten women did not experience any stress urinary incontinence. Three women experienced a little, two women experienced it moderately and one woman experienced a lot. Three of the ten women did not experience any urge urinary incontinence. Three women experienced it a little and four women experienced it moderately. Data on the incidence of both stress and urge urinary incontinence will be recorded from Phase II of this study.

Vulvodynia

An unexpected cause of pain for the women in the focus group was the pain associated with vulvodynia-like symptoms. The International Society for the Study of Vulvovaginal Disease (National Vulvodynia Association, 2002b) defines vulvodynia as chronic vulvar discomfort or pain, especially that characterised by complaints of burning, stinging irritation or rawness of the female genitalia.

Julian (1997) recommends that vulvodynia needs to be managed as a pain syndrome rather than as a pain secondary to an underlying disease or as a problem with an obvious cure. Silver and Wallace (2002) describe vulvodynia as an associated symptom of FM. Reed, Haefner, Punch, Roth Gorenflo and Gillespie (2000) comment on the controversy in regard to the nature and etiology of vulvodynia. They note the absence of abnormal dermatological physical findings, the lack of infectious and allergy or oncologic aetiology in the genital region. Their research findings determined that a primary psychological cause of vulvodynia was not supported.

Within the focus groups, four of the ten participants experienced significant vulvodynia symptoms.

My problems came more from the vulvodynia than the bladder. Real burning pain of the vulva and I went from gynaecologist to gynaecologist trying to find out what the problem was and they did swab upon swab upon swab and found nothing... They did biopsies of different areas. They did it from the vulva, right up in the cervix and they always found chronic inflammation, but no pathogens present. (Focus group 1, V)

The symptoms described included dyspareunia, burning pain of the vulva, skin soreness, chaffing and irritation of the skin in the vulval area. There were few interventions offered that gave symptom relief.

Well, when I have intercourse is my main issue. It hurts during intercourse and after intercourse although I am not so bad now, but I used to puff up like a balloon and have to go and get iceblocks and pat myself. (Focus group1, E)

The women spoke of changes of sexual behaviour because of their pain and a fear of increasing their pain. The dyspareunia combined with the urinary urgency that

some of the women experienced with sexual intercourse affected their sexual activity. One women described having sexual intercourse as ‘something you paid for’ with pain over the next two or three days together with the added concern of infections. Some chose to not be sexually active because ‘between that and being squeezed and touched being so painful I thought I don’t need this, leave me alone’ (Focus group 2, An). Another young woman spoke of her avoidance of a physical relationship when she had other FM symptoms as well as vulvodynia symptoms. She commented that because she knows what it would feel like, it is not something she would like to feel.

What happens with us is that I have only been remarried for three years and my husband felt he was the cause of it so he was sort of reluctant to initiate and then I would think ‘what is wrong with me’ so we had some trouble initially. We went and had a bit of a talk with the doctor and she said, ‘It is not you, it is her make up’ and that was embarrassing and having to go to the toilet often (Focus group 1, E)

For the women who lived with partners, the centrality of their relationship was very important. They were very aware of the need to consciously include their husbands in aspects of their lives where and when energy allowed.

The vulvodynia symptoms hampered their FM walking regime because of the severe chaffing of the skin of the vulva and on the inside of their thighs. They wore loose-fitting under garments or ‘boxer’ shorts to minimise the friction on the perineum.

When it is really bad when I used to get that burning, even the edges of my underwear would drive me crazy. I would want to pull at my pants and relieve it. So that was really bad. (Focus group 1,E)

Vulvodynia symptoms increased the demand on these women, not only by having to endure more symptoms, but also having to seek out relief and treatment strategies. This extra symptomatology increased the demand on their time and energies. Some of the women consulted with different health professionals in their attempt to find answers for and relief from the vulvodynia type symptoms. A sexual health practitioner who suggested that their symptoms might be part of a more enveloping syndrome first suggested a diagnosis of FM to two of the women. The women had not connected their musculoskeletal symptomatology with the

vulvodynia symptoms. Further consultations with rheumatologists confirmed a diagnosis of FM. Women did not think of their symptoms as being potentially related. As well, some self-consciousness about their vulvodynia symptoms may have limited their disclosure of the problem, as was expressed by the following participant.

To me it stopped me going back to work so it has had a real impact for me. I find it hard to talk about. Even in this group it has been difficult. It is not easy. (Focus group 1, V)

Because of the vulvodynia-like symptoms experienced by the women with FM in these focus groups, the Vulval Symptom Assessment (VSAS) (Appendix K) was developed to collect data about this symptom in Phase II of this study. The VSAS was developed as a two-part questionnaire to assess the incidence of vulvodynia symptoms and the impact of these symptoms on women with FM.

The Impact of Urogenital Symptoms

The responses of the women in relation to their urogenital symptoms reflected anguish, humour, frustration, embarrassment, resignation, determination and acceptance. The impact of FM (Figure 5) was dramatically increased when urogenital symptoms were present (Figure 14). These urogenital symptoms encroached on the already restricted dimensions of their lives. One would expect that, for many, this increased burden of sensitisation of the urogenital system would be the final insult and result in self-absorption and self-pity.

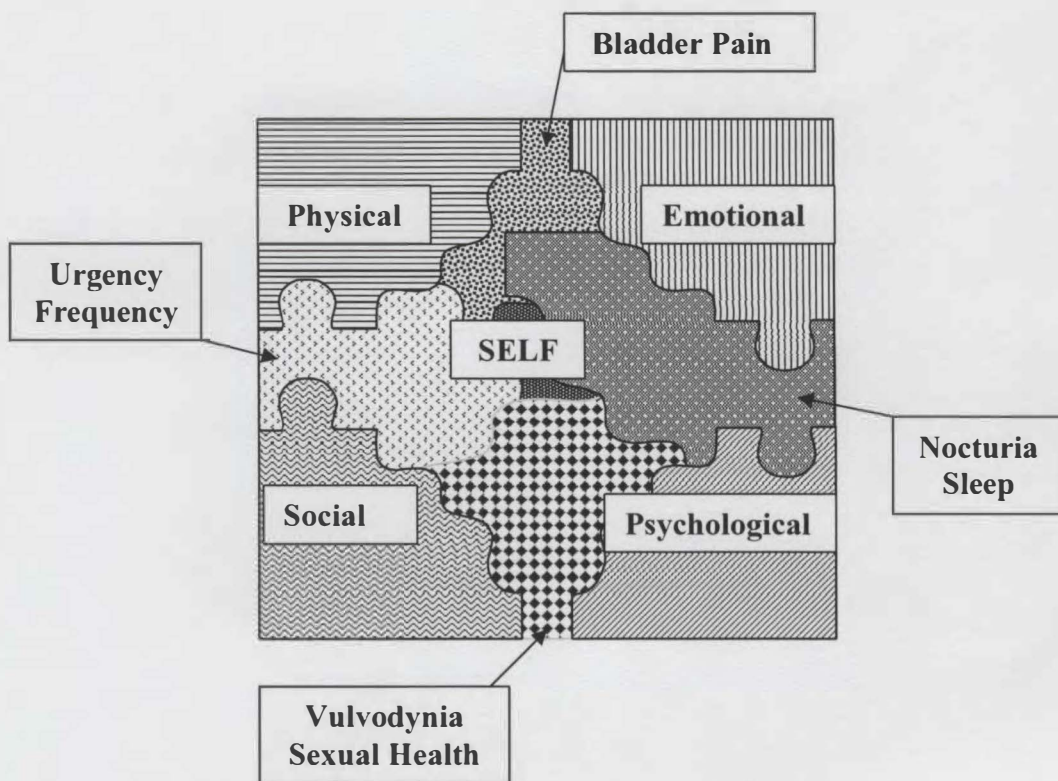


Figure 14: The Increased Tethering Effect and Impact of Non-Bladder and Urogenital Symptoms on Women with FM, Depicting Illness in the Foreground

The urogenital symptoms encroached on an already restricted space in the women's lives, increasing the demands on their patience, their capacity to experience life and their significant relationships. This increased burden of sensitisation of the urogenital system stretched the capacity of these women to re-evaluate their life styles, to appreciate different things, to establish different goals and to reprioritise aspects of life as described by Morse (1997) in learning to live with their altered self.

The unpredictability of bladder symptoms, combined with the randomness of other FM symptoms, challenged the women daily in most of their roles. Their daily roles had to be constantly reassessed and adapted to accommodate their bladder symptomatology. One woman adapted to her severe urinary urgency and frequency by 'working around the toilet' and, because there were two toilets in her house, she could work at either end of the house! Another spoke of her learning to adapt to and cope with her bladder symptoms and only then would she feel confident enough to seek work outside of the home again. Others spoke of their symptoms with acceptance and humour. One woman spoke of being able to turn on the lights of the

city with the pressure that came from her bladder and, because of her frequency/urgency, she was able to find a toilet by smell. Overall, the frustration of always having to make allowances for their urogenital symptoms accentuated the tethering effect of the already existing physical, emotional, social and psychological impact of FM on their lives. The increased impingement on the self by the urogenital symptomatology is diagrammatically represented in Figure 14.

Chronicity of Symptoms of FM

FM is not a life-threatening disease, but it is a quality of life threatening disease. Data obtained from the three focus groups revealed the impact of the chronicity of the symptoms and its impact on their quality of life. The unpredictability and chronicity of the multitude of symptoms from FM constantly challenged these women and their families. These women's experiences of living with the chronicity of FM were multifaceted and enduring.

Paterson (2001) presents a shifting model of chronic illness, The Shifting Perspectives Model of Chronic Illness. This model was derived from a metasynthesis of qualitative research reported from the experiences of people with chronic illness. The model suggests that living with a chronic illness is an ongoing and continually shifting process where an illness-in-the-foreground or a wellness-in-the-foreground perspective has specific functions in a person's world. Paterson (2001) describes the illness-in-the-foreground perspective as a focus on the sickness, suffering, loss or burden associated with living with chronic illness. She describes the wellness-in-the-foreground perspective as viewing the chronic illness as an opportunity for meaningful change in relationships, a re-visioning of what is possible and normal. These perspectives of chronic illness are not static.

This model of chronic illness framed many of the dynamics experienced by the ten women in the focus groups. The women reflected this shifting perspectives model of chronic illness. The pre-diagnostic phase and the immediate post-diagnostic phase could be described as the illness-in-the-foreground perspective. Pre-diagnosis the women knew they had a health problem, they sought numerous medical opinions, but remained frustrated and in pain during this long phase without any diagnosis or

resolution. On diagnosis, one woman spoke of being overwhelmed ‘knowing there was something new wrong with you’. Another woman spoke of being wary and upset when diagnosed. For some of the women, the diagnosis of FM was a relief, a validation of their experiences of a multitude of symptoms experienced over many years. One woman developed an instant wellness-in-the-foreground perspective, seeking management strategies for her FM on the day of diagnosis.

I know that when I was diagnosed, on the way home my husband said to me, 'The specialist said you should not work. So it would be better if you didn't'. And I said, 'Hey! Do you want it to control me or for me to control it' and that was the mind set that I took. I think the diagnosis was such a huge relief. It put it into some sort of perspective. But if you said to me on any given day, 'Are you without pain?' Well the answer is no, never but some days it is not even a conscious thought and then you have other days where you just drag yourself through the day. So I think, I really think that your mental attitude to it (Focus group 2, All)

A few women in the focus groups had stayed within the illness-in-the-foreground perspective where they focused on the illness, the pain, the loss and the strain of living with a chronic illness. The diagnosis of FM for them was a negative and destructive event resulting in absorption with their disabilities. This illness-in-the-foreground perspective (presented in Figure 14) shows the impact of FM nonbladder, bladder and urogenital symptoms.

However, the majority of women in the focus groups were challenged by their diagnosis and embraced a more wellness-in-the-foreground perspective in coping with FM (Figure 15). Paterson (2001) describes this appraisal of their chronic illness as an opportunity for change and for the woman to develop harmony between her self-identity and the identity shaped by the illness. The majority of the women in the focus groups portrayed this in a seeking, self-educating and inquiring mode.

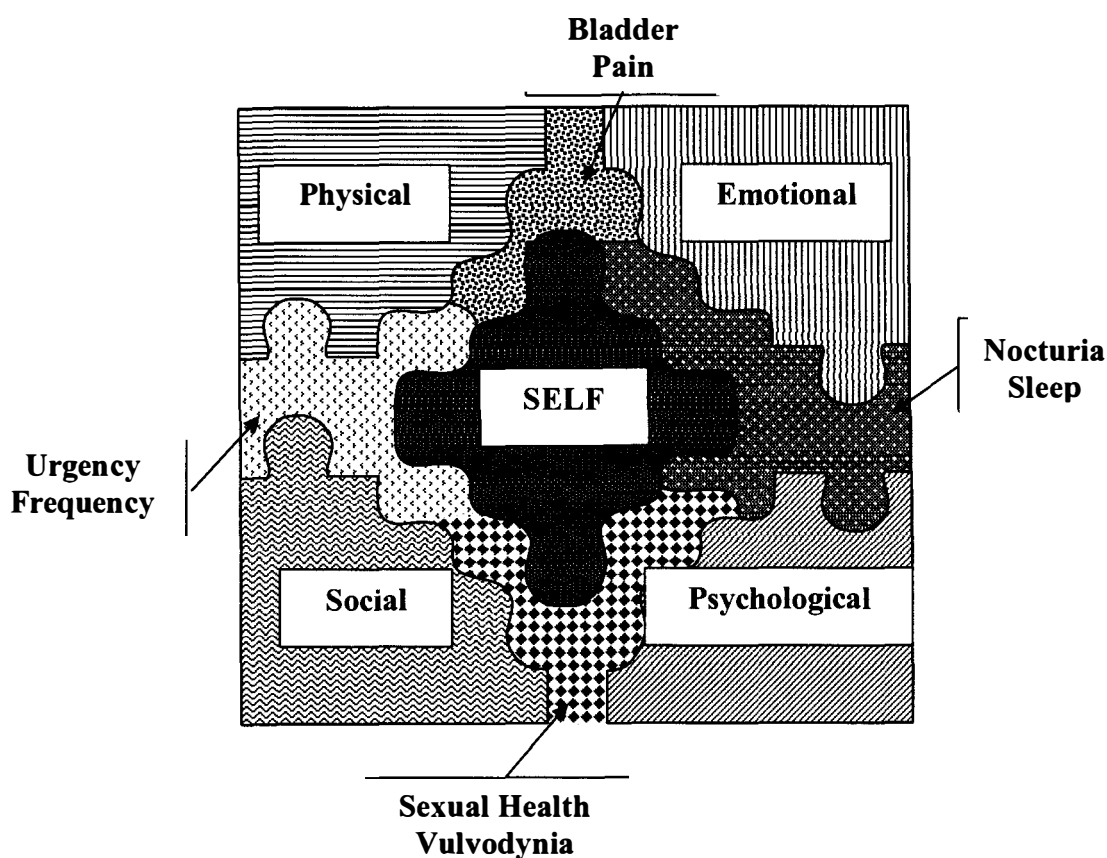


Figure 15: The Increased Tethering Effect and Impact of Non-Bladder and Urogenital Symptoms in FM, Depicting Wellness in the Foreground

The emphasis on FM in the group discussions did frame and highlight the reality of their condition at that time. For some, the emotions of maintaining such an organised regime to maintain a ‘normal’ life surfaced via anger, fear, tears and absolute fatigue. Paterson (2001) recognises this as a major paradox of living in the wellness-in-the-foreground perspective. She reminds us that, through this wellness-in-the-foreground perspective, chronic illness is in the background but the management of the illness is always in the foreground. The focus group discussions and sharing of FM experiences and information brought the reality of living with FM and its chronicity momentarily to the foreground for all of the participants.

Conclusion

The findings from the focus groups of Phase I of this study have confirmed that the key urinary symptoms and their impact for women diagnosed with FM who experience bladder irritability are compatible with, and inclusive in, the ICSI/ICPI. These sensory symptoms included urinary frequency, urinary urgency, nocturia and bladder pain, burning, discomfort or pressure. This qualitative study has been valuable in confirming these sensory symptoms of FM and directing the choice and formation of questionnaires for data collection for Phase II of this research on FM and bladder irritability. New relevant variables for the data collecting questionnaires were identified as a result of the qualitative methodology of this first phase.

CHAPTER 6

FINDINGS – PHASE II

Introduction

This chapter documents the participants' characteristics and the statistical analysis of the data in Phase II of this study.

Demographic Profile of Participants

All participants in the study were women between the ages of 18 to 65 years who had been diagnosed with FM by a rheumatologist based on typical clinical presentations. All women experienced at least two sensory bladder symptoms and all underwent a urological screening to confirm their suitability for inclusion in this study. The typical participant can be described as an Australian-born well-educated woman, aged between 40 and 60 years, married or in a relationship, and with two children. The demographic profiles of the study participants are displayed in Table 1.

Table 1: The Demographic Profile of Study Participants. Frequency and Percentage Distribution of Study Participants According to Demographic Variables

Country of Birth	n = 90	(%)
Australia	56	(62.2%)
United Kingdom	22	(24.4%)
Europe	1	(1.1%)
Asia	4	(4.4%)

Other	7	(7.8%)
<hr/>		
Age	n = 90	(%)
<hr/>		
24-30	4	(4.4%)
31-40	6	(6.6%)
41-50	27	(29.8%)
51-60	40	(44.4%)
61-65	13	(14.3%)
<hr/>		
Relationship Status	n = 90	(%)
<hr/>		
Never Married	7	(7.8%)
Married/De Facto	56	(62.2%)
Widow	2	(2.2%)
Separated/Divorced	25	(27.8%)
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Number of Children	n = 90	(%)
<hr/>		
None	14	15.6%
One Child	11	12.2%
Two Children	37	41.1%
Three Children	19	21.1%
Four or More Children	9	10%
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Highest Level Education	n = 90	(%)
Primary	1	1.1%
Secondary	28	31.1%
Apprenticeship/Diploma	18	20%
Tertiary/University	43	47.8%

Occupation	n = 90	(%)
Homemaker	26	28.9%
Clerical/Computing	7	7.8%
Professional	19	21.1%
Trade	2	2.2
Retired	10	11.1
Other	26	28.9

The typical participant had experienced FM symptoms for 5 to 20 years ($m = 13.2$, $s.d. = 10.3$), although diagnosed only within the past five years. Apart from FM, her main health concerns involved conditions affecting the neurological, digestive and musculoskeletal systems. Prescription medications were taken mainly for their effects on the central nervous system to ease the symptoms of FM, especially to relieve musculoskeletal pain. She had a surgical history of hysterectomy and other surgeries of the reproductive tract. Table 2 presents the demographic profiles of the study participants according to disease variables.

Table 2: The Demographic Profile of Study Participants. Frequency and Percentage Distribution of Study Participants According to Disease Variables

Self Diagnosis of FM	n = 86	(%)
O – 5 Years	19	21%
6 – 10 Years	29	32.1%
11 – 20 Years	26	28.7%
More than 20 years	12	14.4%
Medical Diagnosis	n = 87	(%)
0 – 5 Years	47	52.2%
6 – 10 Years	30	33.3%
11 – 16 Years	10	12.1%
Non FM Health Concerns	n = 90	(%)
Musculoskeletal System	43	47.8%
Neurological System	30	33.3%
Digestive System	30	33.3%
Cardiovascular System	21	23.3%
Reproductive System	11	12.2%
Pulmonary System	11	12.2%
Endocrine System	10	11.1%
Urological System	6	6.7%
Haematologic System	6	6.7%
Integumentary System	4	4.4%

Medications for :	n = 90	(%)
Central Nervous System	59	65.6%
Musculoskeletal System	36	40%
Other Pain Medication	20	22.2%
Cardiovascular System	17	18.9%
Alimentary System	16	17.8%
Endocrine System	10	11.1%
Respiratory System	8	8.9%
Contraception	5	5.6%
Hormone Replacement	32	35.6%
Genitourinary System	2	2.2%
Surgical History	n = 90	(%)
Hysterectomy	43	47.8%
Other Reproductive	37	41.1%
Urological	8	8.9%
Digestive	29	32.2

Internal Consistency Reliability of the Interstitial Cystitis Symptom and Problem Index

Internal consistency reliability of the four-item Interstitial Cystitis Symptom Index and four-item Problem Index (ICSI/ICPI) within this population (n = 90) was assessed using Cronbach's alpha coefficient. This measure of internal consistency reflects how well the scale items measure the same underlying attribute (Pallant, 2001). Nunnally and Bernstein (1994) describe internal consistency as describing

‘estimates of reliability based on the average correlation among items within a test’ (p. 251). A criterion of at least 0.70 was pre-set as the acceptable level for internal consistency reliability (Nunnally & Bernstein, 1994). Internal consistency reliability also involved assessment of item-to-total correlations with an expected value of between 0.40 and 0.70 (Carmines & Zeller, 1979).

The Symptom Index

The Symptom Index (ICSI) achieved an internal consistency estimate, as measured by Cronbach’s alpha coefficient, of 0.60. Item means ranged from 1.26 (s.d. = 1.1) to 3.26 (s.d. = 1.3). The possible range of scores was 0 to 5. The item means, standard deviations and possible item scores for each item are shown in Table 3 (n = 90).

Table 3: The Symptom Index: Item Mean, Standard Deviation and Possible Score Ranges

Item	Item Mean	s.d.	Possible Score Ranges
1. Urinary Urgency	2.59	1.44	0 - 5
2. Urinary Frequency	3.26	1.34	0 - 5
3. Nocturia	2.58	1.32	0 - 5
4. Bladder Pain	1.26	1.10	0 - 4

The overall mean score for the Symptom Index was 9.68 (s.d. = 3.52). The possible range was 0 to 19. Item-to-total correlations ranged from 0.26 to 0.54. The two items referring to nocturia and pain achieved lower item-to-total correlations, contributing to the slightly lower Cronbach’s alpha coefficient for this symptom index.

The Problem Index

The Problem Index (ICPI) achieved an internal consistency estimate, as measured by Cronbach's alpha coefficient, of 0.71. Item means ranged from 2.19 (s.d. = 1.1) to 2.47 (s.d. = 1.2). The possible range of scores was 0 to 4. The item mean, standard deviation and possible item scores for each item are shown in Table 4 (n = 90).

Table 4: The Problem Index: Item Mean, Standard Deviation and Possible Score Ranges

Item	Item Mean	s.d.	Possible Score Ranges
1. Urinary Urgency	2.20	1.11	0 - 4
2. Urinary Frequency	2.47	1.02	0 - 4
3 Nocturia	2.47	1.22	0 - 4
4. Bladder Pain	2.21	1.20	0 - 4

The overall mean score for the Problem Index was 9.33 (s.d. = 3.33). The possible range was 0 to 16. The item-to-total correlations ranged from 0.36 to 0.67. This is just outside of the acceptable range of 0.40 to 0.70 (Carmines & Zeller, 1979).

The Combined Symptom and Problem Index

A secondary exploratory analysis was undertaken with the combined use of the eight-item Symptom and Problem Index to determine if the symptom and problem subscales were distinct, or whether a different scale substructure existed for the FM population (n=90). The combined index (ICSI/ICPI) achieved an internal consistency estimate, as measured by Cronbach's alpha coefficient, of 0.81. Item means ranged from 1.26 (s.d. =1.10) to 3.26 (s.d. =1.35). The possible range of scores was 0 to 9 for questions on frequency, urgency and nocturia and 0 to 8 for questions on bladder pain. These score ranges represent the combined symptom and

impact scores of urgency, frequency, nocturia and bladder pain. The overall mean score for the combined Symptom and Problem Index was 19.01 (s.d. = 6.40). The possible range was 0 to 35. Item-to-total correlations ranged from 0.37 to 0.66. This is within the acceptable range of 0.30 to 0.70 as specified by Carmines and Zeller (1979).

Factor Analysis

For further validation of the ICSI/ICPI instrument within this FM population, a factor analysis was undertaken to assess the internal structure of the scale. The structure of the eight-item ICSI/ICPI scale was examined using Principal Component Factor Analysis with Varimax Rotation. Pallant (2001) suggests that the larger the sample size for factor analysis, the better. Nunnally and Bernstein (1994) recommend ten cases for each item. Therefore, 90 cases were sufficient to assess the eight-item scale. Pallant (2001) also recommends that, for a factor analysis, at least 50% of the inter-item correlations should be greater than 0.30. The data met these criteria with 20 of the 28 inter-item correlations being above 0.30. Results of the Principal Component Analysis revealed two components with eigenvalues greater than 1.00 (3.520 and 1.505). These two components explained a total of 62.82% of the variance. The screeplot showed a distinct curve drop after the second component. These two components were retained for further analysis.

Table 5: Item and Factor Loadings > 0.40 and Explained Variance for Two Components Based upon PCA Varimax Rotation.

Items	Factor Loading Component 1	Factor Loading Component 2
ICPI Bladder burning, pain, discomfort or pressure	.803	
ICSI Bladder pain or burning	.782	
ICSI Urinary urgency	.685	
ICPI Urinary urgency	.684	
ICPI Urinary frequency	.599	.507
ICSI Nocturia		.865
ICPI Nocturia		.802
ICSI Urinary frequency	.417	.648
% of Variance explained	34.32%	28.5%

The rotated solution revealed a pattern of interpretable loadings. According to Kim and Mueller (1978), a factor loading should be greater than 0.40, and the differences between factor loadings should be greater than 0.15 to be interpretable.

The symptoms of, and problems associated with, bladder pain, burning and urinary urgency loaded on Component 1. The symptoms and problems of nocturia all loaded on to Component 2. The symptom of urinary frequency also loaded on to Component 2. The problem of urinary frequency loaded on both components with the difference between the factor loadings being less than 0.15. This item was judged to be more interpretable as a Component 2 item.

This pattern of loading of urinary symptoms and impact within the FM population clearly displays two separate components of symptom and problem combinations as distinct from the original ICSI/ICPI developed for the interstitial cystitis population. These two components form the two subscales of the resultant

newly developed Fibromyalgia Bladder Index. The first subscale is identified as the Bladder Urgency and Pain Subscale and the second subscale is identified as the Bladder Frequency and Nocturia Subscale.

Fibromyalgia Bladder Index

This newly developed Fibromyalgia Bladder Index comprises the two subscales, the Bladder Urgency and Pain Subscale and the Bladder Frequency and Nocturia Subscale.

Table 6: The Two Subscales of the Fibromyalgia Bladder Index

Bladder Urgency and Pain Subscale	Bladder Frequency and Nocturia Subscale
<ul style="list-style-type: none"> • Symptom of bladder pain or burning 	<ul style="list-style-type: none"> • Symptom of nocturia
<ul style="list-style-type: none"> • Problem of bladder pain, burning, discomfort or pressure 	<ul style="list-style-type: none"> • Problem of nocturia
<ul style="list-style-type: none"> • Symptom of urinary urgency 	<ul style="list-style-type: none"> • Symptom of urinary frequency
<ul style="list-style-type: none"> • Problem of urinary urgency 	<ul style="list-style-type: none"> • Problem of urinary frequency

Factor analysis was used to identify the structure of the scales. This end result is a more precise instrument, reflecting the reality of symptom and symptom impact experiences of women within the FM population. The grouping of bladder pain and urinary urgency combines the sensory components of bladder irritability in the FM population. The grouping of nocturia and urinary frequency seems obvious when one considers the plethora of influences affecting a person lying awake at night. The effects of urinary frequency on bladder capacity, the effects of bladder capacity on sleep, the effects of insomnia on frequency as well as body pain, human behaviour, thoughts and expectations are all possible implications and/or causative factors.

The Fibromyalgia Bladder Index is displayed in Table 7. The wording of the index is exactly the same as that used in the ICSI/ICPI. As the original purpose of the

study was to validate the ICSI/ICPI within the FM population, data was collected using this Interstitial Cystitis instrument. The data collected was in response to these ICSI/ICPI questions. The analysis of the data has produced a more specific configuration of the eight questions of the original ICSI/ICPI index for the FM population. Although the sensory urinary symptoms and impact are similar for both the interstitial cystitis and FM populations, the ICSI/ICPI and the Fibromyalgia Bladder Index represent each population more specifically.

Table 7: The Fibromyalgia Bladder Index – Bladder Urgency and Pain Subscale

Q1. *During the past month, how often have you felt the strong need to urinate with little or no warning?*

- 0. - Not at all
- 1. - Less than 1 time in 5
- 2. - Less than half the time
- 3. - About half the time
- 4. - More than half the time
- 5. - Almost always

Q2. *During the past month, how much has the need to urinate with little warning been a **problem** for you?*

- 0. - No problem
- 1. - Very small problem
- 2. - Small problem
- 3. - Medium problem
- 4. - Big problem

Q3. *During the past month, have you experienced pain or burning in your bladder?*

- 0. - Not at all
- 1. - A few times
- 2. - Fairly often
- 3. - Usually
- 4. - Almost always

Q4. *During the past month, how much has burning, pain, discomfort, or pressure in your bladder been a **problem** for you?*

- 0. - No problem
- 1. - Very small problem
- 2. - Small problem
- 3. - Medium problem
- 4. - Big problem

The Fibromyalgia Bladder Index – Bladder Frequency and Nocturia Subscale

- Q1. *During the past month, have you had to urinate less than 2 hours after you finished urinating?*
- 0. - Not at all
 - 1. - Less than 1 time in 5
 - 2. - Less than half the time
 - 3. - About half the time
 - 4. - More than half the time
 - 5. - Almost always
- Q2. *During the past month, how much has frequent urination during the day been a **problem** for you?*
- 0. - No problem
 - 1. - Very small problem
 - 2. - Small problem
 - 3. - Medium problem
 - 4. - Big problem
- Q3. *During the past month, how often did you most typically get up at night to urinate?*
- 0. - Not at all
 - 1. - Once
 - 2. - 2 times
 - 3. - 3 times
 - 4. - 4 times
 - 5. - 5 or more times
- Q.4 *During the past month, how much has getting up at night to urinate been a **problem** for you?*
- 0. - No problem
 - 1. - Very small problem
 - 2. - Small problem
 - 3. - Medium problem
 - 4. - Big problem

Internal Consistency Reliability of the Fibromyalgia Bladder Index

Internal consistency reliability of the new eight-item Fibromyalgia Bladder Index was assessed using Cronbach's alpha coefficient. The two new subscales were also assessed individually to measure how reliably the items on these subscales were measuring the same underlying attribute.

The Fibromyalgia Bladder Index achieved an internal consistency estimate, as measured by Cronbach's alpha coefficient, of 0.81. Item means ranged from 1.26 (s.d. = 1.1) to 3.26 (s.d. = 1.3). The item means, standard deviations and possible item scores for each of the eight individual items of the Fibromyalgia Bladder Index are shown in Tables 8 and 9 (n = 90). The overall mean score for the Fibromyalgia Bladder Index was 19.01 (s.d. = 6.4). The possible range was 0–35. The inter-item correlation ranged from –0.03 to 0.062. Item-to-total correlations ranged from 0.37 to 0.61. A separate analysis of the internal consistency of both subscales of the Fibromyalgia Bladder Index was also conducted and is reported below.

Internal Consistency Reliability of the Bladder Urgency and Pain Subscale

This subscale achieved an internal consistency estimate, as measured by Cronbach's alpha coefficient, of 0.76. Item means ranged from 1.26 (s.d. = 1.1) to 2.59 (s.d. = 1.4). The item means, standard deviations and possible item scores for each item are shown in Table 8 (n = 90).

Table 8: The Bladder Urgency and Pain Subscale: Item Mean, Standard Deviation and Possible Score Ranges

Item	Item Mean	s.d.	Possible Score Ranges
1. Urinary Urgency Symptom	2.59	1.4	0 - 5
2. Urinary Urgency Problem	2.19	1.1	0 - 4
3. Bladder Pain Symptom	1.26	1.10	0 - 4
4. Bladder Pain Problem	2.21	1.20	0 - 4

The overall mean score for the Bladder Urgency and Pain Subscale score was 8.24 (s.d. = 3.73). The possible range was 0 to 17. The inter-item correlation ranged from 0.36 to 0.62. This is the acceptable range of 0.30 to 0.70 (Carmines & Zeller, 1979). Item-to-total correlation ranged from 0.54 to 0.59, meeting the acceptable range of 0.40 to 0.70 (Carmines & Zeller, 1979).

Internal Consistency Reliability of the Bladder Frequency and Nocturia Subscale

This subscale achieved an internal consistency estimate, as measured by Cronbach's alpha coefficient, of 0.76. Item means ranged from 2.50 (s.d. = 1.2) to 3.26 (s.d. = 1.35). The item means, standard deviations and possible item scores for each item are shown in Table 9 (n = 90).

Table 9: Bladder Frequency and Nocturia Subscale: Item Mean, Standard Deviation and Possible Score Ranges

Item	Item Mean	s.d.	Possible Score Ranges
1. Urinary Frequency Symptom	3.26	1.34	0 - 5
2. Urinary Frequency Problem	2.47	1.01	0 - 4
3. Nocturia Symptom	2.58	1.31	0 - 5
4. Nocturia Problem	2.47	1.22	0 - 4

The overall mean score for the Bladder Frequency and Nocturia Subscale score was 10.77 (s.d. = 3.77). The possible range was 0 to 18. The inter-item correlations ranged from 0.30 to 0.58. This is within the acceptable range of 0.30 to 0.70 as specified by Carmines and Zeller (1979). The item-to-total correlations ranged from 0.52 to 0.60. This is within in the acceptable range of 0.40 to 0.70 (Carmines & Zeller, 1979).

Test-Retest Reliability of the Fibromyalgia Bladder Index

Of the 90 women who received the second ICSI/ICPI questionnaire, 87 returned the questionnaire. Only 83 questionnaires were included in this analysis as four were returned after 30 days. These four were not included because of the possibility of measuring different symptom intensities a month later rather than a retest of the questionnaire. The test-retest reliability of the Fibromyalgia Bladder Index subscale 1 on Urgency and Bladder Pain showed an intraclass correlation of 0.84 ($n = 83$). Test-retest reliability on the second subscale of Frequency and Nocturia reveals an intraclass correlation of 0.79 ($n=83$). Both subscale values are higher than the minimal required value of 0.70. Individual test/retest correlations of the eight individual items show correlations ranging from between 0.62 to 0.82. The test-retest reliability of the total Fibromyalgia Bladder Index within this FM population shows an intraclass correlation of 0.85 ($n=83$), indicating that the index is stable over time. These test-retest results are demonstrated in Figures 19, 20 and 21.

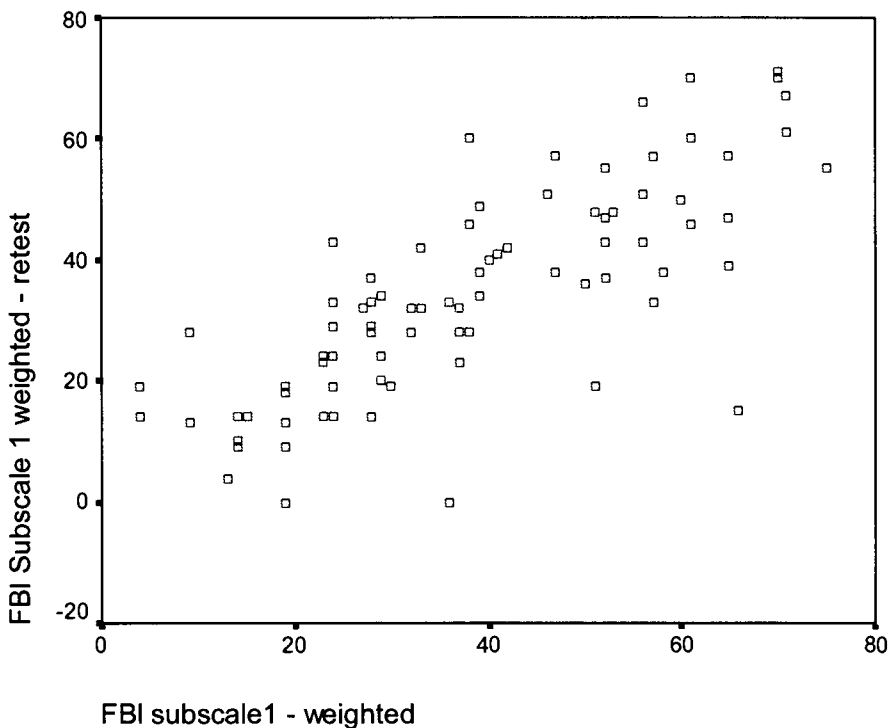


Figure 16: Test-Retest of the Urgency and Pain Subscale of the Fibromyalgia Bladder Index

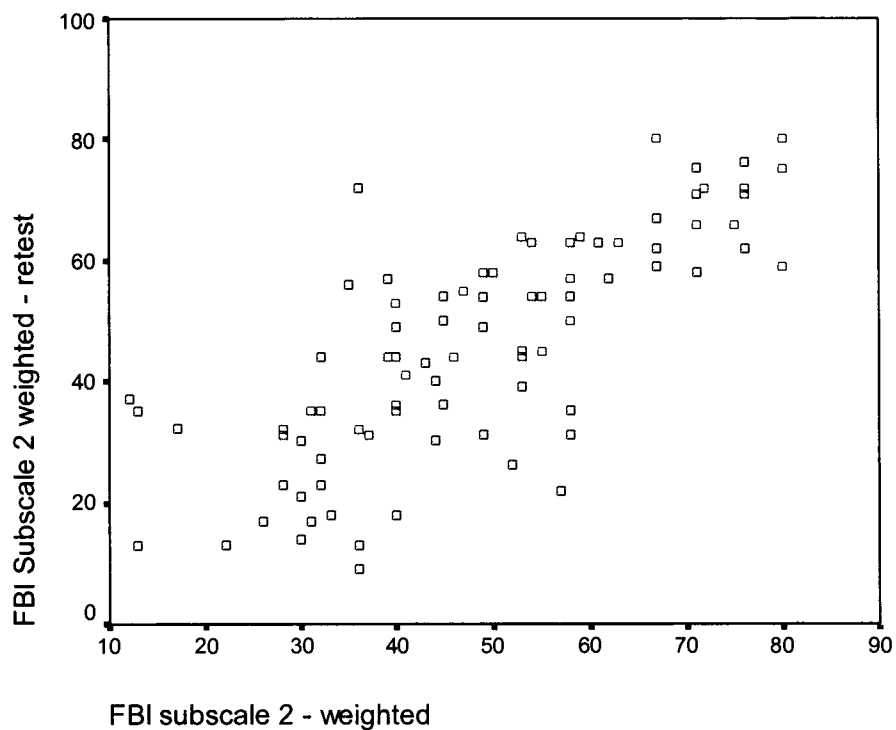


Figure 17: Test-Retest of the Frequency and Nocturia Subscale of the Fibromyalgia Bladder Index

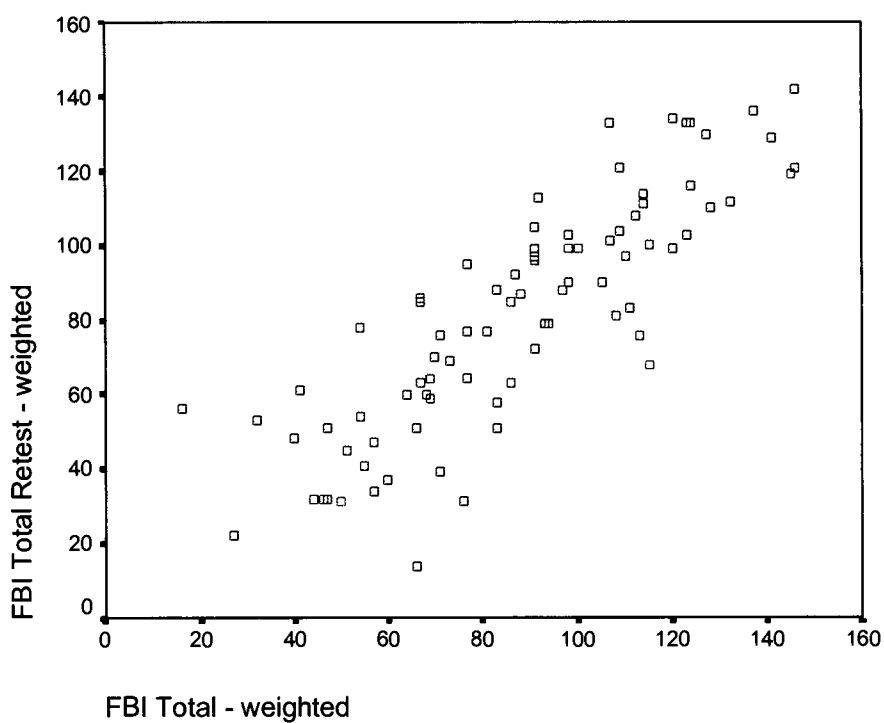


Figure 18: Test-Retest of the Combined Subscales of the Fibromyalgia Bladder Index

In summary, both of the subscales of the Fibromyalgia Bladder Index have demonstrated stability over time, as measured by test-retest reliability estimates.

Concurrent Validity

Concurrent validity was assessed by examining the simple correlations between the Fibromyalgia Bladder Index, the Kings Health Questionnaire and the Fibromyalgia Impact Questionnaire. The Kings Health Questionnaire was developed and validated as a condition-specific quality-of-life questionnaire for the rapid assessment of urinary incontinence in women (Kelleher et al., 1997). Although developed for incontinent women, the questionnaire indexes aspects of general health and bladder problem impact and severity, as well as the six domains of role, physical and social limitations, personal relationships, emotions and sleep. The Fibromyalgia Impact questionnaire was designed to assess the current health of patients with FM. It is a brief, 10-item instrument that measures physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and well being. The results of the correlations between both the Fibromyalgia Bladder Index and the Kings Health Questionnaire and the Fibromyalgia Impact Questionnaire are shown in Table 10.

Table 10: Concurrent Validity of the Fibromyalgia Bladder Index: Pearson Correlation Coefficients between the Fibromyalgia Bladder Index, Kings Health Questionnaire and the Fibromyalgia Impact Questionnaire

	Kings Health Questionnaire Total Score	Fibromyalgia Impact Questionnaire Total Score
Fibromyalgia Bladder Index (Total)	0.735 (p = 0.000)	0.433 (p = 0.000)
Subscale 1: Bladder Urgency and Pain	0.459 (p = 0.000)	0.391 (p = 0.000)
Subscale 2: Bladder Frequency and Nocturia	0.782 (p = 0.000)	0.347 (p = 0.002)

The size of the value of Pearson’s correlation (r) can range from –1.00 to 1.00, indicating the strength of the relationship between the variables. The negative

refers to the direction of the relationship and not the strength. Pallant (2001) cites Cohen in suggesting the following guidelines in interpreting values of the strength of the correlation between 0 and 1: $r = 0.10$ to 0.29 small; $r = 0.30$ to 0.49 medium; $r = 0.50$ to 0.10 large.

As shown in Table 10, there was a significant positive correlation between the total Fibromyalgia Bladder Index with the total Kings Health Questionnaire. Individual correlations between the Fibromyalgia Index and the individual Kings Health Questionnaire's domains ranged from 0.351 to 0.615. There was a significant positive correlation between both of the individual subscales of the Fibromyalgia Bladder Index with the Kings Health Questionnaire and the Fibromyalgia Impact Questionnaire. The correlation between the Urgency and Pain Subscale and the Kings Health Questionnaire was not as high because the latter is designed more specifically for incontinence rather than for the sensory bladder symptoms of pain and urinary urgency. Individual correlations ranged from 0.136 (Kings Health Questionnaire sleep and energy domain with the Urgency and Pain Subscale) to 0.663 (Kings Health Questionnaire bladder effects on life with the Frequency and Nocturia Subscale).

Significant positive correlations were also evident between the Fibromyalgia Bladder Index and the Fibromyalgia Impact Questionnaire (Table 10). There was also a significant correlation between both of the individual subscales of the Fibromyalgia Bladder Index and the Fibromyalgia Impact Questionnaire. Individual correlations ranged from 0.198 (Fibromyalgia Impact Questionnaire question asking, In the past week, how tense, nervous or anxious have you been? with the Frequency and Nocturia Subscale) to 0.433 (Fibromyalgia Impact Questionnaire total score with the total Fibromyalgia Index). Significant correlations were evident between the Fibromyalgia Impact Questionnaire and all nine domains of the Kings Health Questionnaire ($r=0.352$ to 0.589 , $p=0.002$ to 0.000). These findings provide evidence for the concurrent validity of the new instrument, the Fibromyalgia Bladder Index, and confirm that it is not redundant in relation to the Kings Health Questionnaire.

In summary, this assessment has provided evidence that the Bladder Urgency and Pain and the Bladder Frequency and Nocturia subscales yield reliable and valid estimates for assessing the symptoms and impact of bladder symptoms for women

with FM. The index, consisting of two subscales, has demonstrated internal consistency reliability, acceptable test-retest reliability and evidence of concurrent validity.

Descriptive Statistics of the Sample Population

The following tables summarise the level of distress exhibited by this sample population as measured by the new Fibromyalgia Bladder Index, the Kings Health Questionnaire, the Fibromyalgia Impact Questionnaire, the SF-36 and the Vulval Symptoms Assessment Scale.

Fibromyalgia Bladder Index

The Fibromyalgia Bladder Index comprises the Bladder Urgency and Pain Subscale and the Bladder Frequency and Nocturia Subscale. In order to develop meaningful total scores for these subscales, the items in the Fibromyalgia Bladder Index were weighted because some of the items of the questionnaire were scored out of four while others were scored out of five. Weighting was undertaken by multiplying the five-answer questions by four, and the four-answer questions by five to give an equal score out of 20 for each question. With four questions on each of the two subscales, the highest possible score on each subscale is 80 (4 x 20) and 160 (8 x 20) on the combination of both subscales. Table 11 shows the frequencies of the two individual and combined subscales of the Fibromyalgia Bladder Index.

Table 11: The Fibromyalgia Bladder Index: Descriptive Statistics

Item	Urgency and Pain Subscale 1	Frequency and Nocturia Subscale 2	Fibromyalgia Bladder Index
n	90	90	90
Mean	38.63	48.00	86.63
Median	38.00	48.00	87.50
Std. Deviation	17.49	16.79	29.33
Possible Score Ranges	0 - 80	0 - 80	0 - 160

The above statistics of the Fibromyalgia Bladder Index indicate the level of distress that women with FM can experience with bladder sensitivity symptoms. Both subscales 1 and 2 reveal the symptoms and impact of urgency/pain and frequency/nocturia respectively.

The Kings Health Questionnaire

The Kings Health Questionnaire is a valid and reliable instrument for the assessment of quality of life in women with urinary incontinence, a higher score indicating a greater impairment of quality of life.

Table 12: The Kings Health Questionnaire Domains. Descriptive Statistics: Item Mean, Standard Deviation and Possible Score Ranges

Domains: Total Score	Item Mean	s.d.	Possible Score Ranges
Describe Health	50.28	23.25	0 - 100
Bladder Affects Life?	61.48	25.44	0 - 100
Role Limitations	38.58	29.69	0 - 100
Physical Limitations	40.23	31.60	0 - 100
Social Limitations	17.05	24.01	0 - 100
Personal Relationships	21.24	31.39	0 - 100
Emotions	24.37	25.71	0 - 100
Sleep/Energy	73.60	24.47	0 - 100
Severity Symptoms	28.46	26.59	0 - 100

This current study is specifically reporting on the sensory bladder symptoms and their impact as experienced by women with FM. For this reason, the individual question findings, as well as the main domain findings of the Kings Health Questionnaire, are presented (Table 13). For the individual questions on the Kings Health Questionnaire, participants were asked what their bladder problems were and how much these problems affected them. They were asked to choose only the problems that they had at that time and to leave out the questions that did not apply to them. This accounts for the difference of the sample size for each question.

Table 13: The Kings Health Questionnaire Individual Questions on Bladder Problems and Impact. Descriptive Statistics: Sample Size, Item Mean, Standard Deviation and Possible Score Ranges

Question	n	Item Mean	s.d.	Possible Score Ranges
Do you have frequency and how much does it affect you?	84	2.11	.78	1 - 3
Do you have nocturia and how much does it affect you?	84	2.04	.81	1 - 3
Do you have urgency and how much does it affect you?	84	1.94	.80	1 - 3
Do you have urge incontinence and how much does it affect you?	54	1.50	.75	1 - 3
Do you have stress incontinence and how much does it affect you?	55	1.65	.80	1 - 3
Do you have nocturnal enuresis and how much does it affect you?	6	1.17	.41	1 - 3
Do you have leaking with intercourse and how does it affect you?	10	1.80	.92	1 - 3
Do you have frequent water works infections and how much does it affect you?	14	1.71	.83	1 - 3
Do you have bladder pain and how much does it affect you?	61	1.69	.79	1 - 3
Do you have difficulty passing urine and how much does it affect you?	33	1.58	.75	1 - 3

The Kings Health Questionnaire data has provided some information on both sensory and motor urinary symptoms within this study population. Approximately 60% of the women experienced some level of urge and/or stress incontinence, approximately 7% experienced nocturnal enuresis, approximately 11% experienced

leakage on intercourse, and approximately 16% had frequent urinary tract infections, while approximately 37% experienced difficulty in passing urine.

The Fibromyalgia Impact Questionnaire

The Fibromyalgia Impact Questionnaire (FIQ) assesses the current health status of people with FM. The questionnaire has 10 items. Higher scores on the FIQ indicate an increased impact of FM on functioning, with final scores for each domain ranging from 0 (no impairment) to 10 (maximum impairment). The domains include physical functioning (focus on large muscle tasks), feeling good, work missed, able to do work, pain, fatigue, felt rested in morning, stiffness, anxiety and depression. The original FIQ reported by Burckhardt and colleagues (1991) was used for this data collection. The final FIQ score is the sum of the scores for physical impairment, feeling good, pain, fatigue, rested, stiffness, anxiety, and depression scales. The descriptive statistics for the Fibromyalgia Impact Questionnaire are displayed in Table 14. Iversen (2003) notes that there are no clear norms available for this instrument. She lists a number of studies with FIQ results. The results of this current study are included for comparative data (Table15).

Table 14: The Fibromyalgia Impact Questionnaire. Descriptive Statistics: Sample Size, Item Mean, Standard Deviation and Possible Score Ranges

Domains	n	Item Mean	s.d.	Possible Score Ranges
Physical Impairment	79	3.33	2.06	0 - 10
Feel Good	89	6.67	2.74	0 - 10
Pain	89	5.89	2.33	0 - 10
Fatigue	90	7.59	1.93	0 - 10
Rested	90	7.92	1.85	0 - 10
Stiffness	90	6.95	2.03	0 - 10
Anxiety	90	5.76	2.71	0 - 10
Depression	90	4.92	2.85	0 - 10
Total FIQ Score	77	48.9	13.25	0 - 80

Table 15: Fibromyalgia Impact Questionnaire. Results from Five Independent Studies on Fibromyalgia. Descriptive Statistics: Sample Size, Mean Age, Mean Total FIQ Score, Standard Deviation and Mean Duration of FM

Study	n	Mean Age	Mean Total FIQ Score	s.d.	Mean Duration of Illness
Pankoff et al (2000)	28	51.3	49.7	11.4	
Goldenberg et al (1995)	332	44.3	54.8	19.6	
Martinez et al (1995)	44	43	47.28	13.9	5.3 years
Fitzcharles & Esdaide (1997)	82	48	57	20.5	
Brand (Current study)	90	51	48.90	13.25	13.2 years

MOS SF-36 Health Survey

The MOS SF-36 (Medical Outcome Study Short Form-36) Health Survey is a comprehensive and precise measurement of general health status developed by Ware, and Sherbourne (1992). The SF-36 has been validated for adults in the United States of America and the United Kingdom. The Australian Bureau of Statistics used this measure in the 1995 National Health Survey (McCallum, 1994). McCallum notes that generally psychometric validity testing supported the validity of the SF-36 for a sub group of the Australian population and comments that the use of the SF-36 allows national and international comparisons of general health status. This enables comparisons of health-related quality of life between different health populations.

The SF-36 is an eight multi-item scale measuring a person's perception of the following health concepts: physical functioning, role limitations due to physical problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health. These eight concepts measure the physical and mental dimensions of health. It also includes a question on reported health transition showing the change in health status over a year. The content and scoring of the SF-36 Health Survey, as recommended by the authors, was adhered to, ensuring

reliable and valid scores (Ware, Kosinski, & Gandek, 2002). The scores range from 0 to 100 for each domain. Higher scores on the SF-36 reflect a minimal impact on health status while low scores signify a greater level of impact. Ninety women in the current FM study completed the SF-36 questionnaire. Their SF-36 scale scores are shown in Table 16.

Table 16: The SF-36 Questionnaire. Descriptive Statistics: Sample Size, Item Mean, Standard Deviation and Possible Score Ranges

Domains	n	Item Mean	s.d.	Possible Score Ranges
Physical Functioning (Q 3 a-j)	88	45.40	24.05	0 - 100
Role: Physical (Q 4 a-d)	88	12.22	25.43	1 - 100
Bodily Pain (Q 7+8)	89	31.80	16.84	1 - 100
General Health (Q1+11a+11b+11c+11d)	90	42.74	22.56	1 - 100
Vitality (Q 9a+9e+9g +9i)	90	23.50	17.28	1 - 100
Social Functioning (Q 6+10)	89	50.56	25.49	1 - 100
Role: Emotional (Q 5a, b, c)	87	38.70	41.57	1 - 100
Mental Health (Q 9b+9c+9d +9f +9h)	87	57.38	20.63	1 - 100

Within this study population, participants rated their mental health and social functioning most positively. The effects of physical health on role performance, vitality, and bodily pain were rated as having the most negative impact.

The Australian population norms for the SF-36 from the 1995 National Health Survey (Australian Bureau of Statistics, 1995) provide a benchmark for comparison with the descriptive statistics from the current study on Fibromyalgia. Schlenk and colleagues (1998) examined health-related quality of life as measured by the SF-36 across patient populations with chronic disorders in the United States,

including FM. Table 17 compares the descriptive statistics for each SF-36 scale for the following four studies: this current Australian FM study; Schlenk and colleagues' (1998) FM participants in the chronic disorder population study (USA); the female population norms for the SF-36 of Australia (Australian Bureau of Statistics, 1995); and the female population norms for the SF-36 of the United States of America (Ware et al., 2002).

It is of interest to note that the findings for the current Australian study on FM and bladder irritability reveal a poorer state of health as shown by the SF-36 descriptors than in the other three studies. The item means for all eight SF-36 domains were lowest in the Australian FM population. The specific impact of the urinary symptomatology measured in this current study may be greater because of the verification of urological symptoms in this population. The small FM sample used in the FM USA study and their less rigorous approach to the confirmation of bladder symptomatology may also account for the lower level of quality-of-life distress in the Australian population.

Table 17: Current FM Study Descriptors for the SF-36, Australian Female Population SF-36 Norms, United States of America Female Population SF-36 Norms, Descriptors for the SF-36 FM Participants in Chronic Disorder Population Study (USA). Descriptive Statistics: Sample Size, Item Mean, Standard Deviation and Possible Score Ranges

Domains	Population	n	Item Mean	s.d.	Possible Score Ranges
Physical Functioning (Q 3 a-j)	Current FM Study	88	45.40	24.05	0 - 100
	FM Study (USA)	18	61.67	24.01	0 - 100
	Australian Norms	97	81.1	24.3	0 - 100
	USA Norms	1412	81.47	24.60	0 - 100
Role: Physical (Q 4 a-d)	Current FM Study	88	12.22	25.42	1 - 100
	FM Study (USA)	18	38.89	37.60	1 - 100
	Australian Norms	9736	78.8	36	1 - 100
	USA Norms	1412	77.77	36.2	1 - 100

Bodily Pain (Q 7+8)	Current FM Study	89	31.80	16.84	1 – 100
	FM Study (USA)	18	39.22	20.78	1 - 100
	Australian Norms	9729	75.7	25.4	1 – 100
	USA Norms	1412	73.59	24.25	1 - 100
General Health (Q1+11a+11b+11c+11d)	Current FM Study	90	42.74	22.56	1 – 100
	FM Study (USA)	18	60.06	22.37	1 - 100
	Australian Norms	9729	75.7	25.4	1 – 100
	USA Norms	1412	70.61	21.50	1 - 100
Vitality (Q 9a+9e+9g +9i)	Current FM Study	90	23.5	17.28	1 – 100
	FM Study (USA)	18	32.78	22.44	1 - 100
	Australian Norms	9755	62.5	20.1	1 – 100
	USA Norms	1412	58.43	21.47	1 - 100
Social Functioning (Q 6+10)	Current FM Study	89	50.56	25.49	1 – 100
	FM Study (USA)	18	61.11	24.21	1 - 100
	Australian Norms	9782	84.1	22.9	1 – 100
	USA Norms	1412	81.54	23.74	1 - 100
Role: Emotional (Q 5a, b, c)	Current FM Study	87	38.70	41.57	1 – 100
	FM Study (USA)	18	53.70	44.49	1 – 100
	Australian Norms	9682	81.6	33.6	1 – 100
	USA Norms	1412	79.47	34.43	1 - 100
Mental Health (Q 9b+9c+9d +9f +9h)	Current FM Study	87	57.38	20.63	1 – 100
	FM Study (USA)	18	68.22	15.85	1 - 100
	Australian Norms	9721	74.6	17.3	1 – 100
	USA Norms	1412	73.25	18.68	1 - 100

The Vulval Symptom Assessment Scale

The Vulval Symptom Assessment Scale (VSAS) (Appendix K) was developed specifically for this study following the findings from the Phase I focus groups. Four of the ten women in the focus groups experienced moderate to severe vulvodynia-like symptoms of dyspareunia, vulval pain, irritation, burning and rawness. As there is no validated data-collecting tool for these symptoms within the FM population, the VSAS was developed as an initial screening tool to gauge if vulval symptoms were a significant problem in this population of women. The VSAS consists of five questions on vulval symptoms and four questions on the impact of these symptoms on quality of life. Possible score ranges are from 0 to 3 with the higher score indicating a greater symptomatology and impact. The findings are detailed in the following Table 18

Table 18: The Vulval Symptom Assessment Scale. Descriptive Statistics: Sample Size, Item Mean, Standard Deviation and Possible Score Ranges

Domain	n	Item Mean	s.d.	Possible Score Ranges
SYMPTOM				
• Burning	90	.72	.87	0 - 3
• Stinging	90	.63	.87	0 - 3
• Irritation	90	.92	.88	0 - 3
• Rawness	89	.67	.89	0 - 3
• Pain	89	.82	.90	0 - 3
IMPACT				
• Daily activities	89	.49	.71	0 - 3
• Physical activities	87	.46	.73	0 - 3
• Social activities	87	.31	.62	0 - 3
• Sexual activities	73	.71	.92	0 - 3

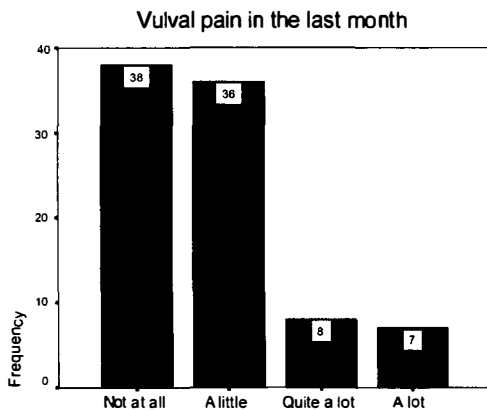
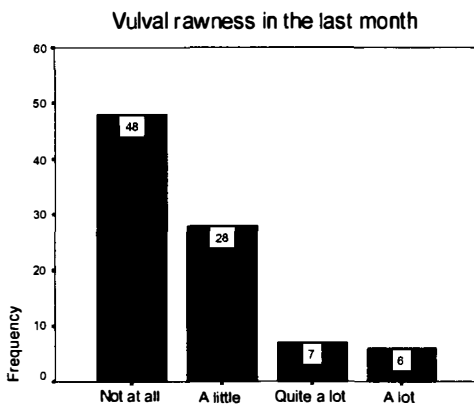
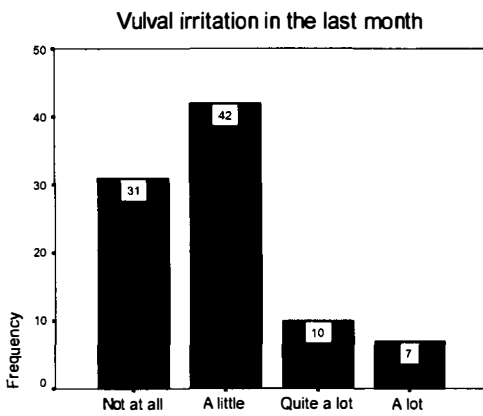
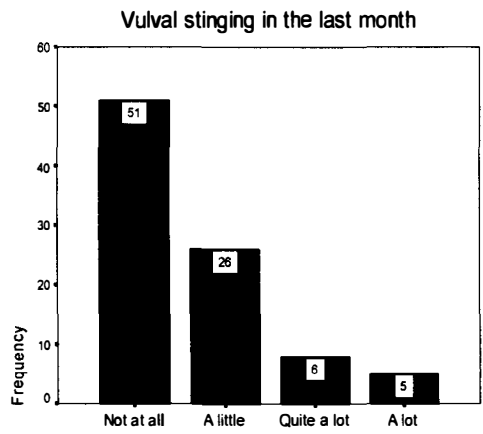
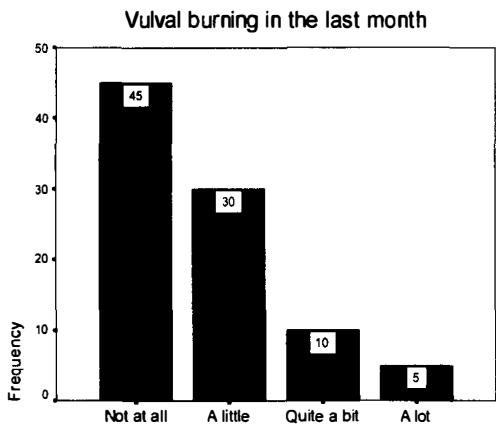


Figure 19: Visual Summary of the Distribution of Vulval Symptoms

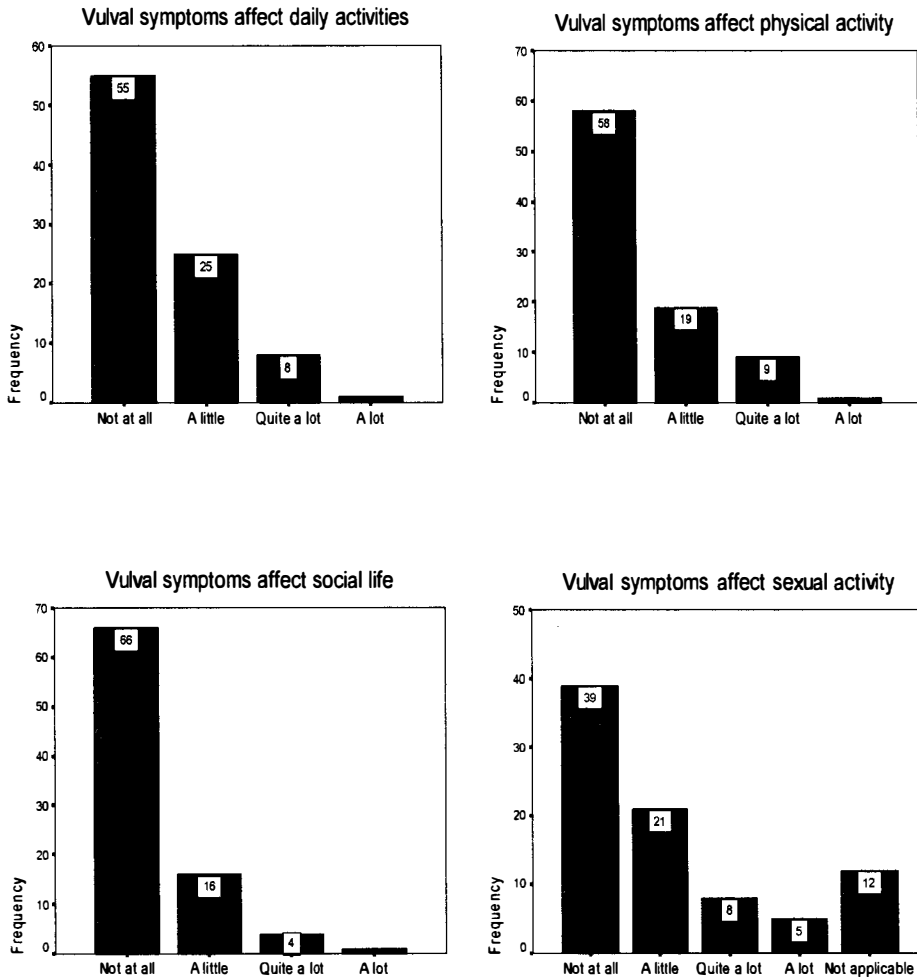


Figure 20: Visual Summary of the Distribution of Vulval Symptom Impact

The relative sizes of the means and the standard deviations reflect the skewed distribution followed by the VSAS items, with most subjects taking relatively low values (0 or 1) on individual items and a smaller number taking appreciably higher values (2, 3 or 4). Figure 19 and Figure 20 display the participants' scores on vulvodynia-like symptoms and symptom impact respectively.

Factor analysis was undertaken to assess the internal structure of the scale. The structure of the Vulval Symptom Assessment Scale (VSAS) was examined using Principal Component Factor Analysis with Varimax Rotation. Results of the Principal Component Analysis (Table 19) revealed two components with eigenvalues greater than 1.00 (5.937 and 1.089). These two components explained a total of

78.070% of the variance. The screeplot showed a distinct curve drop after the second component. These two components were retained for further analysis.

Table 19: The Vulval Symptom Assessment Scale Item and Factor Loadings > 0.40 and Explained Variance for Two Components Based upon PCA Varimax Rotation.

Items	Factor Loading Component 1	Factor Loading Component 2
Experience burning in vulval area	.824	
Experience stinging in vulval area	.883	
Experience irritation in vulval area	.688	.436
Experience rawness in vulval area	.699	.466
Experience pain in vulval area	.800	
Vulval symptoms affect physical activities		.904
Vulval symptoms affect social activities		.878
Vulval symptoms affect daily activities		.885
Vulval symptoms affect sexual activities	.636	.517

The vulval symptoms loaded on Component 1 and the impact of the vulval symptoms loaded on to Component 2. Although the impact of vulval symptoms on sexual activities loaded on both components, the difference between the components was less than 0.15. This item was judged to be more interpretable as an item 2 component. This loading pattern of vulval symptoms and vulval impact within the FM population clearly displays two separate components, the vulval symptom and vulval impact factors.

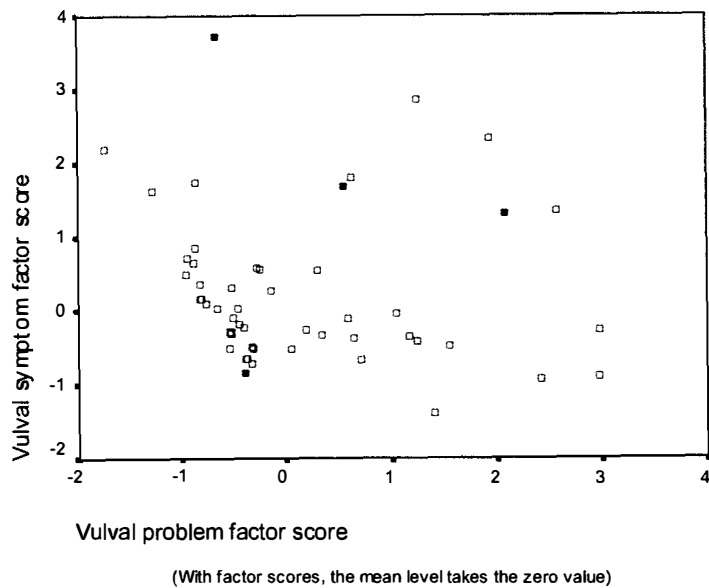


Figure 21: Plot of Participants' Scores on Both VSAS Factors

A plot of the subject scores on the two VSAS factors presents an integrated picture of the distribution of the subjects in the context of the levels of their vulval symptoms and vulval problems, and confirms the skewed patterns noted at the individual VSAS item levels. For both vulval symptoms and vulval problems, the majority of subjects clusters at relatively low levels with a smaller number exhibiting dramatically higher symptom and vulval problem experiences. Factor scores are scored so that the mean level takes the value zero. The higher the score, the higher the levels of symptoms or symptom impact/problem the patient experiences. A score of +3 on the problem factor is someone who is experiencing a lot of problems while a score of -1 on the problem factor is someone who is experiencing very few problems.

To confirm that the items measured by the VSAS constituted a separate construct and were not included in the FBI, correlations amongst the Fibromyalgia Bladder Index subscales and the Vulval Symptom and Vulval Impact Scales were analysed. Only one of the correlations was significant. The correlation between the Fibromyalgia Bladder Index Subscale of Urgency and Pain and the Vulval Impact score was significant, although relatively modest in magnitude ($r = 0.331$, $p = 0.005$). None of the other correlations was significant. This suggests that the separate assessment of vulval symptoms and their impact is important and distinct, and

therefore it cannot be assumed that these vulval symptoms are encapsulated within the Fibromyalgia Bladder Index.

Predictive Ability of Urinary Symptoms and Problems on the Fibromyalgia Bladder Index

Hassard (1991) explains regression analysis as an elegant and informative way of testing the possible existence of, and describing a relationship between, a dependent variable and one or more explanatory or independent variables. For this study, it provides a technique for examining the possibility of the women's demographic and health profile characteristics having an influence on their Fibromyalgia Bladder Index scores and providing some insight into the possible predictive values of these independent variables. The aim of the multiple regression here is to determine which of the independent variables have a genuine relationship with either of the subscales of the Fibromyalgia Bladder Index and to determine the strength and nature of the relationship (Hassard, 1991).

Is it possible that some of the independent variables can predict the women in this study who scored highly on the Urgency and Pain Subscale and the Frequency and Nocturia Subscale? How well can these variables predict a particular outcome and which variables in the set of variables is the best predictor of the outcome (Pallant, 2001)? What variables are the predictors of pain/urgency and frequency/nocturia in this FM population?

Variables from the Fibromyalgia Impact Questionnaire, the Kings Health Questionnaire, The SF-36 Health Survey, the Vulval Symptom Assessment Scale, the participants' age and the number of years since self-diagnosis of FM from the demographic questionnaire were all entered into a forward stepwise multiple regression as independent variables. Tables 20 and 21 show the results of this analysis for the Pain and Urgency Subscale while Tables 22 and 23 show the results from the analysis for the Frequency and Nocturia Subscale.

Table 20: Regression Analysis: Pain and Urgency Subscale. Variables Entered

Step	Variables Entered
1.	Kings Health Questionnaire. Total Score for Emotions:
2.	SF-36 Questionnaire. Total Score for General Health Questions:

Table 21: Regression Analysis: Pain and Urgency Subscale. Model Summary

Step	R	R Square	F	df.	p
1.	.466a	.217	24.384	1,88	p = 0.000
2.	.525b	.276	16.570	2,87	p = 0.000

a. Predictors: Kings Health Questionnaire. Total Score of Emotions

b. Predictors: Kings Health Questionnaire Total Score of Emotions, SF-36 Questionnaire general health questions 1+11a+11b+11c+11d

The Kings Health Questionnaire score from the emotions domain enters on the first step and explains 21% of the variance in the Urgency and Pain Subscale. The Total Score for this emotions domain is a composite of the three individual questions: ‘Does your bladder problem make you feel depressed?’; ‘Does your bladder problem make you feel anxious or nervous?’; and ‘Does your bladder problem make you feel bad about yourself?’

The MOS SF-36 Health Survey general health questions enters on the second step in a negative relationship with the outcome and explains an additional 5.9% of the variance, for a total of 27.6% of the variance in the Urgency and Pain Subscale explained. The total score for the MOS SF-36 general health questions is a composite of the individual questions: ‘In general, would you say your health is excellent, very good, good, fair, or poor?’; ‘I seem to get sick a little easier than other people: definitely true, mostly true, don’t know, mostly false, definitely false?’; ‘I am as healthy as anyone I know: definitely true, mostly true, don’t know, mostly false, definitely false?’; ‘I expect my health to get worse: definitely true, mostly true, don’t

know, mostly false, definitely false?'; 'My health is excellent: definitely true, mostly true, don't know, mostly false, definitely false?'

Both predictors in this model achieved statistical significance ($p = 0.000$). Once these predictors had been entered into the model, no other explanatory variables achieved statistical significance.

In summary, the Kings Health Questionnaire emotional domain (Do bladder problems make one feel depressed, nervous, anxious or bad about oneself?) is highly predictive of a woman's score on the Pain and Urgency Subscale. The greater the feelings of depression, anxiety and lack of self worth, the higher the subscale score. The MOS SF-36 Health Survey general health questions score is also highly predictive of the score on the Pain and Urgency Subscale, with a low MOS SF-36 general health questions score being predictive of a high Pain and Urgency score. The poorer the subjects' perceptions of their current health status, and the more negative their perceptions of their future health prospects, the higher their Pain and Urgency score is likely to be.

Table 22: Regression Analysis: Frequency and Nocturia Subscale. Variables Entered

Model	Variables Entered
1.	Kings Health Questionnaire. Total Score for Affects Life?
2.	Kings Health Questionnaire. Total Score for Sleep / Energy
3.	Kings Health Questionnaire. Total Score for Physical Limitations

Table 23: Regression Analysis: Frequency and Nocturia Subscale. Model Summary

Model	R	R Square	F	df	p
1.	.663a	.439	68.973	1,88	p = 0.000
2.	.761b	.579	59.928	2,87	p = 0.000
3.	.782c	.612	45.138	3,86	p = 0.000

a. Predictors: Kings Health Questionnaire. Total Score of Affects Life?

b. Predictors: Kings Health Questionnaire. Total Score of Affects Life? Kings Health Questionnaire. Total Score of Sleep/Energy

c. Predictors: Kings Health Questionnaire. Total Score of Affects Life? Kings Health Questionnaire. Total Score of Sleep/Energy. Kings Health Questionnaire. Total Score of Physical Limitations.

The Kings Health Questionnaire score from the bladder impact question, ‘How much do you think your bladder problem affects your life?’ enters on the first step and explains 43.9% of the variance in the Bladder Frequency and Nocturia Subscale. The Kings Health Questionnaire score from the sleep/energy domain enters on the second step and explains an additional 14% of the variance, for a total of 57.9% of the variance in the Bladder Frequency and Nocturia Subscale. The sleep and energy questions ask if your bladder problem affects your sleep and whether you feel worn out and tired? The Kings Health Questionnaire score from the physical limitation domain enters on the third step, explaining an additional 3.3% for a total of 61.2% of the variance in the Bladder Frequency and Pain Subscale. The physical limitations domain included the following two questions: ‘Does your bladder

problem affect your physical activities (eg going for a walk, run, sport, gym etc)?' and 'Does your bladder problem affect your ability to travel?' All three predictors in this model achieved statistical significance ($p = 0.000$). No other explanatory variables achieved statistical significance.

In summary, the Kings Health Questionnaire question (How much do you think your bladder problem affects your life?) is highly predictive of a woman's score on the Frequency and Nocturia Subscale, with the larger the effect on one's life, the higher one's score on the Frequency and Nocturia Subscale. The impact of the bladder on sleep and tiredness, as measured by the Kings Health Questionnaire sleep/energy score, is also highly predictive of a woman's score on this second subscale, with the greater the sleep effects and fatigue, the greater the score on frequency and nocturia. In addition, the more extensive the physical limitations from her bladder problems, the higher a woman's score on the Frequency and Nocturia Subscale is likely to be.

In order to clarify the relationship between the predictors (and, more specifically, the individual questions on which these composite predictor scores were based) and the Bladder Pain and Urgency Subscale, the 25% of the sample reporting the highest subscale scores and the 25% of the sample reporting the lowest subscale scores were identified. The top quartile reported Pain and Urgency scores of 52 or greater (out of a possible range of 0-80), while the bottom quartile reported Pain and Urgency scores of 23 or less.

Table 24 shows the predictor variable characteristics of the 25 subjects reporting Pain and Urgency scores > 51 . Note that a high score on the Kings Health Questionnaire (KHQ): Emotions (Items 1-3) indicates a greater impact on emotional health while, for the MOS SF-36 General Health Survey Questions (Items 4-8), a high score indicates better health perceptions.

Table 24: Impact of the Highest 25% of Scores (score > 51) on the Predictors of the Bladder Urgency and Pain Subscale. Item Mean, Median, Standard Deviation and Possible Score Ranges

Item	n Valid	n Missing	Item Mean	Median	s.d.	Possible Score Ranges
Does your bladder problem make you feel depressed? (KHQ)	25	0	2.36	2.00	.95	1 - 4
Does your bladder problem make you feel anxious or nervous? (KHQ)	25	0	2.56	2.00	.87	1 - 4
Does your bladder problem make you feel bad about yourself? (KHQ)	25	0	2.20	2.00	1.12	1 - 4
In general would you say your health is excellent, very good, good, fair, or poor? (SF-36)	25	0	2.12	2.00	.87	1 - 5
How true or false is this statement for you? I seem to get sick a little easier than other people. (SF-36)	25	0	2.40	2.00	1.35	1 - 5
How true or false is this statement for you? I am as healthy as anyone I know. (SF-36)	25	0	2.24	2.00	1.20	1 - 5
How true or false is this statement for you? I expect my health to get worse. (SF-36)	25	0	2.56	3.00	.92	1 - 5
How true or false is this statement for you? My health is excellent. (SF-36)	25	0	1.88	2.00	.97	1 - 5

Table 25 shows the predictor variable characteristics of the 18 subjects reporting Pain and Urgency scores of < 24. Note that a high score on the Kings Health Questionnaire: Emotions (Items 1-3) indicates a greater impact on emotional health while, for the MOS SF-36 Health Survey questions (Items 4–8), a high score indicates better general health perceptions.

Table 25: Impact of the Lowest 25% of Scores (score < 24) on the Predictors of the Urgency and Pain Subscale. Item Mean, Median, Standard Deviation and Possible Score Ranges

Item	n Valid	n Missing	Item Mean	Median	s.d.	Possible Score Ranges
Does your bladder problem make you feel depressed? (KHQ)	18	0	1.50	1.00	.79	1 - 4
Does your bladder problem make you feel anxious or nervous? (KHQ)	18	0	1.56	1.50	.62	1 - 4
Does your bladder problem make you feel bad about yourself? (KHQ)	18	0	1.39	1.00	.78	1 - 4
In general would you say your health is excellent, very good, good, fair, or poor? (SF-36)	18	0	2.81	2.70	1.16	5 - 1
How true or false is this statement for you? I seem to get sick a little easier than other people. (SF-36)	18	0	3.17	3.00	1.29	1 - 5
How true or false is this statement for you? I am as healthy as anyone I know. (SF-36)	18	0	2.83	2.50	1.15	5 - 1
How true or false is this statement for you? I expect my health to get worse. (SF-36)	18	0	3.83	4.00	.92	1 - 5
How true or false is this statement for you? My health is excellent. (SF-36)	18	0	2.67	2.00	1.28	5 - 1

In summary, the Kings Health Questionnaire emotional domain questions on the bladder problem making one feel depressed, nervous, anxious or bad about oneself predicts a high score on the Pain and Urgency Subscale. The differences of the item means of the three emotional domain questions indicate the different levels of impact for the highest 25% (Table 24) and the lowest 25% (Table 25) of the scores of the women: the higher the score, the greater the impact. For the MOS SF-36 Health Survey general health questions, a higher score indicates a better health state. This is reflected in the item means of these five items. A low score on the SF-36 general health questions predicts a high score on the Pain and Urgency Subscale. The differences of the item means of the five general health questions of the SF-36 indicate the different levels of impact for the highest 25% (Table 24) and the lowest 25% (Table 25).

In order to also clarify the relationship between the predictors (and, more specifically, the individual questions on which these composite predictor scores were based) and the Frequency and Nocturia subscale, the 25% of the sample reporting the highest subscale scores and the 25% of the sample reporting the lowest subscale scores were also identified. The top quartile reported Frequency and Nocturia scores of >57 (out of a possible range of 0-80) while the bottom quartile reported Frequency and Nocturia scores of < 36.

Table 26 shows the predictor variable characteristics of the 28 subjects reporting Frequency and Nocturia scores > 57. All five item predictors of a high score on the Frequency and Nocturia Subscale are items from the Kings Health Questionnaire. Note that a high score on the Kings Health Questionnaire: Bladder problem affects life, Sleep/Energy (Items 1 and 2) and Physical Limitations (Items 1 and 2) indicates a greater impact on health from the symptoms.

Table 26: Impact of the Highest 25% of Scores (score > 57) on the Predictors of the Frequency and Nocturia Subscale. Item Mean, Median, Standard Deviation and Possible Score Ranges

Item	n Valid	n Missing	Item Mean	Median	s.d.	Possible Score Ranges
How much do you think your bladder problem affects your life?	28	0	3.43	4.00	.69	1 - 4
Does your bladder problem affect your physical activities (eg. going for a walk, run, sport or gym etc)?	28	0	3.07	3.00	.94	1 - 4
Does your bladder problem affect your ability to travel?	28	0	2.89	3.00	.83	1 - 4
Does your bladder problem affect your sleep?	28	0	3.64	4.00	.62	1 - 4
Do you feel worn out and tired?	28	0	3.71	4.00	.53	1 - 4

Table 27 shows the frequencies and the impact that these predictors had on the 25% of women who scored the lowest on the predictor variables.

Table 27: Impact of the Lowest 25% of Scores (score < 36) on the Predictors of the Frequency and Nocturia Subscale. Item Mean, Median, Standard Deviation and Possible Score Ranges

Item	n Valid	n Missing	Item Mean	Median	s.d.	Possible Score Ranges
How much do you think your bladder problem affects your life?	21	0	2.14	2.00	.48	1 - 4
Does your bladder problem affect your physical activities (eg. going for a walk, run, sport or gym etc)?	20	1	1.70	1.00	.92	1 - 4
Does your bladder problem affect your ability to travel?	19	2	1.47	1.00	.90	1 - 4
Does your bladder problem affect your sleep?	21	0	2.33	2.00	.73	1 - 4
Do you feel worn out and tired?	20	1	3.10	3.50	1.02	1 - 4

In summary, for the Frequency and Nocturia Subscale, the item means depicted in figures 26 and 27 indicate the level of impact these five indicator items have on the women in the highest and lowest 25% of the sample of women, with the higher the score, the greater the impact. It is of interest to note that, even in the lowest scoring quarter of the sample, the score on the sleep and energy domain questions still indicated that these individuals were experiencing notable distress. This is the nature of FM, the sleep deprivation resulting in the increased effects of fatigue.

CHAPTER 7

DISCUSSION: PHASE II

Introduction

Within the area of instrument development, Waltz, Strickland and Lenz (1991) suggest that it is possible to identify an already existing instrument that is acceptable. They state that such an existing instrument may need to be modified and imply that modifying an existing instrument is usually more efficient than developing a new instrument. Such modifications do result in a new instrument and therefore the psychometric properties of the new instrument must be re-evaluated. This was the situation for this current study.

Phase II of this study involved the testing of the ICSI/ICPI instrument for reliability and validation within the female FM population. Prior to this current study, there was no valid and reliable measure for gauging sensory urinary symptoms within the female FM population. This is the first study to modify and validate such an instrument for women with FM. The aim of Phase II of this study was to validate an existing instrument for FM patients that had been developed and validated for urinary symptoms and impact within the interstitial cystitis population. This ICSI/ICPI was identified as appropriate for the FM population for a number of reasons, firstly, because of the genitourinary symptoms of women with FM and secondly because of the similarity of these symptoms to those experienced by women with interstitial cystitis. Rationale for the development of this instrument was also based on Clauw and colleagues' (1997a) work that suggests the possible involvement of the central nervous system mechanisms that contribute to the pathogenesis of FM may be operative in IC.

This current research has revealed two separate components of urinary symptom and urinary problem combinations within the FM population that are distinct from the original ICSI/ICPI developed for the interstitial cystitis population. These two separate components form the two subscales of the newly developed Fibromyalgia Bladder Index.

The Fibromyalgia Bladder Index

Munro, Visintainer and Page (1986) describe factor analysis as a tool that enables the study of variables in groupings that are not obvious, a method of reducing data so it can be easily described and used as an aid in instrument development. They describe factor analysis as the most important statistical tool for validating the structure of new instruments

Factor analysis was undertaken to assess the internal structure of the ICSI/ICPI using Principal Component Factor Analysis with Varimax Rotation. The factor analysis resulted in two components that formed the two subscales of the newly developed Fibromyalgia Bladder Index. The difference between the symptom and impact combinations of the ICSI/ICPI index and the Fibromyalgia Bladder Index are very relevant to the Fibromyalgia population.

Whereas the ICSI/ICPI consisted of two subscales, one of the symptom index and one of the problem index, results from this study suggest that the items are better grouped for the Fibromyalgia Bladder Index subscales as a combination of both symptoms and problems. This instrument therefore more appropriately measures a different grouping of bladder symptoms and symptom impact from the ICSI/ICPI for the FM population. Psychometric testing of this structure confirms that this is the most valid and reliable measurement framework for the FM population.

Bladder Urgency and Pain Subscale

The first subscale of the Fibromyalgia Bladder Index is the Bladder Urgency and Pain Subscale that consists of the symptoms of bladder urgency and bladder pain

or burning, and the problems that bladder urgency and bladder pain, burning, discomfort or pressure present. Urgency is the complaint of a sudden compelling desire to pass urine that is difficult to defer and the increased bladder sensation is like an early and persistent desire to void (Abrams et al., 2002a). For women with urinary urgency, the urge to void is often compounded by the discomfort and pain resulting from these inappropriate and urgent detrusor contractions. Bladder pain is felt suprapubically or retropubically, usually increasing with bladder filling, and may persist after voiding (Abrams et al., 2002a). The anxiety and fear of urge incontinence further compounds the impact of urinary urgency and pain.

Bladder Frequency and Nocturia Subscale

The second subscale of the Fibromyalgia Bladder Index is the Bladder Frequency and Nocturia Subscale. Bladder frequency during the day is the complaint by the patient who considers that she voids too often (Abrams et al., 2002a). It can be aggravated by urinary urgency and can result in a decrease in bladder capacity. This can exacerbate nocturia, when the woman wakes at night one or more times to void (Abrams et al., 2002a). For women with FM and nocturia, it is difficult to differentiate between the impact of FM on their bladder and the impact of their bladder on FM. One study of nocturia in community-dwelling women in the United Kingdom (Middlekoop et al., 1996) has shown the overall prevalence of nocturia in women over 19 years to be 18% and that 63% of these women experienced the nocturia as bothersome. Of the women with FM in this current study, nocturia (2 or >2 micturitions per night) was experienced by 77% of the participants. Of the women who experienced nocturia, 55% reported that this symptom was a medium or big problem for them.

Insomnia, often described as the deprivation of restorative sleep, is a major problem for FM sufferers. How much of an impact does the insomnia have on the urinary frequency? Is it a behavioural response of 'if I go to the toilet again I may be able to go to sleep?' or is it the effect of FM irritability of the bladder that results in the increased voiding? As one participant mentioned, 'My frequency does not stop just because the sun sets!' Whatever the answer, frequency and nocturia are intrinsically linked.

The Fibromyalgia Bladder Index therefore measures the two most relevant groupings of variables that impact on women with FM who experience bladder irritability. This condition-specific instrument is more specific and precise than the ICSI/ICPI for the FM population. As indicated above, it specifically reflects the reality of symptoms and symptom impact of bladder irritability for women with FM.

Reliability and Validity of the Fibromyalgia Bladder Index

Following the development of the Fibromyalgia Bladder Index, the psychometric properties of this new instrument were evaluated. Central to all measurement is a determination of the reliability of the measurement method. Portney and Watkins (1993) describe reliability as the extent that a measurement is consistent and free from error and describe a reliable instrument as one that performs with predictable consistency under set conditions. These authors also state that reliability is fundamental to clinical research because without it therapists cannot have confidence in collected data or draw rational conclusions from it.

The two indicators used to ensure reliability for the Fibromyalgia Bladder Index were internal consistency reliability measured by Cronbach's alpha coefficient, and test-retest reliability. The interpretation of reliability coefficients depends on their proximity to the value of 1. Portney and Watkins (1993) state that a coefficient below 0.50 represents poor reliability, coefficients from 0.50 to 0.75 a moderate reliability and values above 0.75 are indicative of good reliability. On this interpretation, the Fibromyalgia Bladder Index Bladder Urgency and Pain Subscale achieved good reliability with an internal consistency estimate as measured by Cronbach's alpha coefficient of 0.76. The second subscale, the Bladder Frequency and Nocturia Subscale also achieved good reliability with an internal consistency estimate as measured by Cronbach's coefficient of 0.76.

Test-retest reliability assessment establishes that an instrument is capable of measuring a variable with consistency (L. Portney & Watkins, 2000). The intraclass correlation coefficient was used in this study to analyse test-retest reliability. Administering the index to the same study sample at two intervals, two weeks apart, and then correlating the scores from both administrations of the same test completed

this assessment. Although it was the ICSI/ICPI that was administered, the items of both subscales are exactly the same as those of the Fibromyalgia Bladder Index. The test-retest of the combined subscales of the Fibromyalgia Bladder Index showed a high correlation of 0.85, indicating a reliable scale. The test-retest correlations for the subscales of 0.84 for the Urgency and Pain Subscale and 0.79 for the Frequency and Nocturia subscales confirmed that the individual subscales are also highly reliable.

Following the reliability testing of the Fibromyalgia Bladder Index, it was important to test its validity by examining the simple correlations between it and other similar instruments. Criterion-related validity was tested as concurrent validity by measuring the correlation of the Fibromyalgia Bladder Index with established validated measures. The Fibromyalgia Bladder Index was compared with the 'gold standard' urinary Kings Health Questionnaire and the Fibromyalgia Impact Questionnaire. Eighty-three women completed all three questionnaires. The concurrent validity of the Fibromyalgia Bladder Index was confirmed against both of these validated questionnaires with significant positive correlations.

Participants' Characteristics

The descriptive statistics of this study were used to summarise the stories of bladder irritability of these women diagnosed with FM. Approximately 80% of the women were between the ages of 30 and 60 years. Littlejohn (1996) states that FM can occur at any age, being frequent in adolescent females, reaching its main prevalence in the 30- to 40-year age group, but also common in the elderly. At the age extremes of this study population, approximately 5% of the participants were aged between 24 and 30 years, while approximately 14% of the women were aged between 61 and 65 years.

The majority of participants (62.2%) were either married or in a relationship and all but 15% of the participants had children. The demographic information revealed that approximately 50% of participants were well educated, with tertiary qualifications. Many referred to themselves as 'high achievers' in their chosen careers. However, only 21.1% were currently working in their professional capacity.

The main health concerns of the participants reflected the known impact of FM on other organ systems of the body. Participants' main health concerns involved symptoms from the musculoskeletal system (47.8%), the neurological system (33.3%), and the digestive system (33.3%). Many of these symptoms were managed pharmacologically, with 65% of participants taking medication for central nervous system impact (mainly tricyclics and selective serotonin reuptake inhibitors for pain and sleep enhancement), 40% for musculoskeletal dysfunction, 22% for other pain medication and 17.8% for gastrointestinal dysfunction.

Approximately 35% of the participants were using some form of hormone replacement therapy. This may have been an artefact of the age range of the participants because approximately 90% of the participants were over the age of 40. Further studies could consider the possible implications and symptom differences between women who were and those who were not taking hormone replacement.

Surgical histories showed a significant number of the participants had undergone a hysterectomy (47.8%), other gynaecological surgery (41.1%) and gastrointestinal surgery (32.2%). In relation to urological symptomatology, it is interesting to note that the high hysterectomy and other reproductive organ surgery rate may be suggestive of gynaecological surgery increasing sensitisation within the pelvic region. Does the increased rate of pelvic surgery indicate a predisposition or vulnerability by these women to increased visceral nociception and/or pelvic symptomatology, or is the surgical intervention itself part of the etiology and an aggravating factor of continuing symptomatology? Further studies considering the pre-surgical histories of the women could give some indication.

The high hysterectomy and other reproductive organ surgery rate and the high education level within this sample may possibly represent a selection bias. However, a comparison of this study's data with published results with similar populations using the FIQ, KHQ and SF-36 indicate that, for these well-validated indicators, the results are similar.

Impact of Bladder Irritability and Fibromyalgia on Participants

Responses from the Kings Health Questionnaire indicated that many of the women in this FM population reported that their health was fair, and that their bladder problem affected their life in a small to moderate way. The higher score on the Kings Health Questionnaire indicated a greater impairment of quality of life. The six domains of the questionnaire referred to the effects of their bladder on aspects of their lives. Responses to questions about their role and physical limitations resulting from bladder concerns ranged mainly from not at all to slightly. It is important to note that the majority of people diagnosed with FM have many and varied symptoms that impact on their activities of daily living, bladder symptoms being only one of these (Littlejohn, 1996). Few women experienced social or personal relationship limitations because of their bladder. The majority of women responded that their bladder problem affected their sleep and they were worn out and tired. Sleep disturbance affects 75% of people with FM (Merskey & Bogduk, 1994), resulting in unrefreshed sleep and tiredness on waking. This again raises the question as to whether it is this FM sleep dysfunction, the nocturia or a combination of both that is having the greatest impact on the energy and fatigue levels of women with FM and bladder symptomatology.

The Fibromyalgia Impact Questionnaire data also elucidated the experience of the women with FM and bladder irritability. For many women with bladder irritability who do not have FM, the impact on their quality of life has been well documented. Pinnock and Marshall (1997) have shown that the impact of lower urinary tract symptoms on quality of life in an Australian community is a major reason for people seeking medical help. Data from this current study on FM and the irritable bladder reveals the added burden and subsequent stress placed on these women who cope with the other multi-factorial symptomatology of FM as well as bladder symptoms. A high score on the FIQ reflected a greater impact on the health status of the woman.

Physical impairment on the FIQ was minimal for this population. This was because the FIQ assesses more the activities of daily living rather than activities such as running or lifting heavy objects as assessed in the SF-36 Questionnaire.

Depression and anxiety were the next lowest scores in this population. Although the FIQ is not a validated measure for depression, the questions of how tense or nervous they felt or how depressed or blue they were did indicate the participants' personal sense of mental well-being at the time. These findings are of interest against the backdrop of recent findings by Giesecke and colleagues (2003) whose data supported the clinical notion that there are distinct subgroups of patients with FM. Three FM groups were described by the authors as patients who experience extreme tenderness with no associated psychological or cognitive aspect, an intermediate group who exhibit moderate tenderness and experience normal mood, and the third group in whom mood and cognitive aspects can be instrumental and influential in symptom reporting. In this current study, pain, stiffness and fatigue combined with 'waking very tired and non-rested in the mornings' placed an almost suffocating burden on the women. The mean total FIQ score for this study was similar to other studies revealing the impact of FM (Table 14).

The MOS SF-36 Health Survey data measured the participants' personal perceptions of eight health domains that impacted on their quality of life. Higher scores on the SF-36 reflect a minimal impact on health status while low scores signify a greater level of impact. Results on the mental health indicators of the SF-36 were consistent with results from the FIQ. Mental health status of the participants was in the moderate range with a mean score of 57.38 within a possible score range of 1-100. These findings are in contrast to previous reports of depression and inability to cope with life stressors in FM sufferers. Although the SF-36 is not a validated measure for depression, it describes whether the people were nervous, whether they were so down in the dumps that nothing could cheer them up, whether they felt calm or peaceful and whether they felt down, or if they were happy people. The FIQ and the SF-36 are not diagnostic tools for depression, but rather screening tools that indicate potential levels of psychological distress. Low scoring for role limitations due to emotional problems impacted on the amount of time the women spent at work and other regular daily activities, on the amount they accomplished during work or daily activities, and on how carefully they did these activities. Low scoring on the bodily pain and vitality domains reflected the levels of pain and the chronicity of symptoms typical of FM.

Responses to the SF-36 indicated that the greatest negative impact from FM was in the physical role domain where the participants had to cut down on time at work, accomplished less, and were limited in their work and activities because of their physical health. These effects of physical health on role performance together with vitality and bodily pain were rated as having the most negative impact.

This was confirmed in the comparisons with Australian and United States of America population norms for the SF-36. The comparisons of the means of the SF-36 domains from this study with that of the Australian population female norms and the United States of America female norms (Table 17) truly reflects the enormous impact on the quality of life for the Australian women with FM. The scores of the women in this study were significantly lower in all SF-36 domains than those of the Australian and United States SF-36 normative data for females.

The Vulval Symptom Assessment Scale

The Vulval Symptoms Assessment Scale (VSAS) developed specifically for this study has shown that vulvodynia-type symptoms of vulval irritation, vulval pain, vulval burning, vulval rawness and vulval stinging are a reality for many women with FM who experience bladder irritability. The symptoms and symptom impact experienced ranged from a little to a lot, with 50% (45) of the women experiencing some vulval burning, 43% (39) with some vulval stinging, 65% (59) with some vulval irritation, 46% (41) with some vulval rawness and 57% (51) with some vulval pain. These vulval symptoms affected 37% (34) of the women in their daily activities, 33% (29) in their physical activities, 24% (21) in their social life and 46% (34) in their sexual activities. The inclusion of the VSAS in this study has revealed some significant vulval symptoms.

The VSAS was developed in response to the significant impact that vulval symptoms had on four of the ten women in the Phase I focus groups of this study. The focus groups were held to ensure all relevant information would be considered in the development of, or validation of, an existing instrument for bladder sensitivity issues within the FM population. The qualitative approach of the focus group has contributed to the quantitative findings of this Phase II of the study by identifying the

need for data collection on vulval symptoms and their impact within this population. The findings from the VSAS in Phase II of the study confirmed the presence of vulval symptoms and their associated impact within this FM population.

Factor analysis was undertaken to assess the structure of the VSAS scale. The analysis displayed two factors, the vulval symptom factor and the vulval impact factor. These were correlated with the two subscales of the Fibromyalgia Bladder Index (FBI). The findings displayed the VSAS as a separate construct, not included in the FBI. Only one significant and relatively modest correlation was found. This suggests that the separate assessment of vulval symptoms and their impact on women with FM is important in urogenital appraisals for these women. The VSAS data collection results have also highlighted that the impact of vulval symptoms contributes to the distress of women already coping with FM and bladder irritability.

The vulval factor scores illustrate that distinctive subgroups of vulval symptom experiences and vulval impact/problem experiences are present in this study group. Further examination of the nature of these distinct experiences could form the basis for further research, perhaps through analysis by cluster and discriminant analysis techniques. In particular, the apparent presence of a subgroup of women who experience high levels of vulval problems while experiencing relatively low levels of vulval symptoms raises questions about the nature of the differences between these women and the subgroup of women who, while experiencing similar levels of vulval symptoms, experience much lower levels of vulval problems.

Perhaps the difference between vulvodynia and dyspareunia as described below by Graziottin (2004) accounts for this as the VSAS data collection instrument for vulval symptoms and problems did not distinguish between vulvodynia and dyspareunia. A recent presentation by Graziottin (2004) describes the results of a critical review of the literature on sexual pain disorders and vulvodynia. He describes vulvodynia as a pain disorder which may be a predisposing factor to dyspareunia while dyspareunia is described as a sexual pain disorder. Graziottin describes the two conditions as etiologically different and suggests that, although they do interact and

overlap, the conditions should be kept separate from the diagnostic and treatment perspectives.

McInnes (2003) reminds us that sex is an important contributor to the quality of life for many patients with chronic illness and their partners. She emphasises that the effects of chronic illness on sexuality are multi-factorial and that they impact on all phases of the sexual response. She describes sex for someone whose life is restricted by chronic disease as a powerful source of comfort, pleasure and intimacy where a satisfying sex life can allow one to feel normal when so much else in life has changed.

Graziottin and colleagues (2004) have also shown that the overactive bladder symptoms of urgency, frequency and nocturia have a significant impact on quality of life and sexual activity and can affect sexual identity, sexual function and sexual relationships. The authors acknowledge that the combination of silence where the patient is too embarrassed to disclose symptoms and the physician is sometimes too busy to ask often results in the under diagnosis and under treatment of these urinary symptoms. According to the epidemiologic survey by Laumann and colleagues (1999), the presence of urinary tract symptoms appears to impact on sexual function. The analysis of sexual dysfunctions by risk factors in women shows that urinary tract symptoms have a risk ratio of 4.02 (2.75-5.89) of being associated with arousal disorders and a risk ratio of 7.61 (4.06-14.26) of being associated with sexual pain disorders. Because of the strong association between sexual dysfunction and quality of life, Laumann and colleagues (1999) recommend that sexual dysfunction be recognised as a significant public health concern.

Wesselmann (2004) confirms that vulvodynia has detrimental effects on the sexual life of women and their sexual partners. She notes that some patients with vulvodynia also describe additional pain syndromes, including gastrointestinal, pelvic and chronic somatic pain, have been confirmed by epidemiological studies, suggesting generalised alterations in pain modulation mechanisms in women with vulvodynia. A study by Foster (2004) on the effects of capsaicin injections in normal and vulvodynia-afflicted women has shown the pain response of the vulvodynia group of women extended far beyond the anatomic location of the primary injection

site and they experienced greater spontaneous pain and allodynia. The author suggests this as possibly indicative of a central sensitisation state, as cutaneous response to capsaicin has been proposed as an assessment tool for central sensitisation.

Further research in this area could focus on the development and validation of a vulval symptom and impact instrument, measuring the impact that these vulval symptoms have on sexual response, sexual satisfaction, sexual health and sexual activities for women in this population. Glazer (1999) comments on the lack of an interdisciplinary approach to the management of vulvovaginal pain disorders. He lists the overlapping specialities treating these conditions as pain management, gynaecology, dermatology, urology, gastroenterology, rheumatology, pathology, neurophysiology and sex therapy. The development of a validated vulval symptom assessment scale as an outcome measure specific to the FM population may promote a more focused treatment regime.

The data from this study combined with many individual vocal stories from the ninety women participants. Together they revealed a constellation of feelings of helplessness in understanding and managing their varied pelvic symptoms, distress at the impact of their symptoms and frustration at not finding ‘bladder and/or pelvic pain and discomfort solutions’.

Is there a Clinical Definition for Bladder Irritability in Women with Fibromyalgia?

The development of the Fibromyalgia Bladder Index as a validated instrument for measuring sensory symptom and impact within the FM population is a start to the understanding and the documentation of the urinary issues experienced by these women. Although this research commenced with the intention of validating the ICSI/ICPI within the FM population, a more condition-specific instrument for the FM population has been developed. This research specifies two distinct areas of symptom/impact in the two subscales, one of urinary urgency and pain, the Urgency

and Pain Subscale, and the other of urinary frequency and nocturia, the Frequency and Nocturia Subscale.

These two subscales identifying these distinct components have clinical implications. The question arises as to whether the Bladder Urgency and Pain Subscale reflects the disorder of pain amplification due to the increased sensitivity of the pain system for women with FM. Is this a chain phenomenon of sensory pain and/or increased bladder sensation resulting in increased urgency, resulting in increased frequency? Does the Bladder Frequency and Nocturia Subscale indicate increased bladder irritability resulting in increased frequency and smaller bladder capacity? Or are we looking at sleep deprivation where night becomes day in urological terms, resulting in night time frequency rather than nocturia? These questions are difficult to answer because of the multiple symptomatology, the enigmatic nature of the function and innervation of the bladder wall, and the severe implications of a lack of sleep within this FM population. Jackson (1999) confirms that nocturia is a highly bothersome symptom with a multi-factorial aetiology and recommends further research into the understanding of the aetiology of nocturia.

Within this area of bladder irritability, research is continuing in identifying and validating classification criteria for the diagnosis of certain urological/neurological conditions. This was demonstrated at the International Consultation on Interstitial Cystitis where clinicians and researchers are combining knowledge and experience to specify a definition and diagnostic protocol for interstitial cystitis (Bade, Ishizuka, & Yoshida, 2003). Bade and colleagues comment on the strict definition of IC that has developed into a universal diagnostic instrument for IC research. They feel that, for clinical practice, the criteria are too strict, which can result in the under-diagnosis of IC. They refer to the clinical definition of IC as the combination of urgency, frequency and bladder or pelvic pain in the absence of other pathology. The urological term, overactive bladder (OAB), also refers to the symptom complex of frequency, urgency and nocturia with or without urge urinary incontinence (Bade et al., 2003). Currently there are no classification criteria available to differentiate between OAB and IC. However patients with OAB by definition do not have pain, whereas this is an integral and problematic part of the IC syndrome (p 221 lines 6-7). To add to this uncertainty, what is the clinical definition

of bladder irritability in FM? Are women with FM presenting with urinary urgency, bladder pain, frequency and nocturia being diagnosed and treated for recurrent urinary tract infections, overactive bladder or IC?

The circumstances facing professionals working in the area of interstitial cystitis either as clinicians or researchers is similar to that of those working in the area of FM. There is confusion regarding the clinical diagnostic criteria because of the historically strict criteria for the research diagnosis of the conditions. Perhaps FM, like IC, is under-diagnosed? Sensory symptoms of IC and those of women with FM and irritable bladders are very similar. Although nocturia seems to be more prevalent within the FM population, the effect of insomnia on night time frequency must be taken into account.

Bade and colleagues (2003) postulate that there is a relationship between IC and OAB and that this overlap may extend to chronic prostatitis. Clauw and colleagues (1997a) in their research on FM and IC also postulate that some of the pain of IC may be caused by centrally mediated nociceptive abnormalities rather than the peripheral mechanisms involving the bladder. Sant and Theoharides (1999a) report that, although the pathophysiology of IC is not completely understood, altered epithelial permeability, mast cell activation and sensory nerve upregulation play pivotal roles. Van De Merwe, Yamada and Sakamoto (2003) at the International Conference on Interstitial Cystitis in Kyoto 2003 recognised that IC was often associated with other diseases such as FM.

Kahn, Tatro, Parsons, and Willems (2004) in their study on the incidence of IC in patients with vulvodynia have shown a significant majority of patients with vulvodynia have a positive potassium sensitivity test which indicates that their pain may have a bladder component such as interstitial cystitis. The authors recommend that IC be considered in the differential diagnosis of patients with vulvodynia and encourage further research into the relationship between these two diseases.

At the 3rd International Consensus on Incontinence in Monaco in 2004, a committee was formed to provide a consensus on painful bladder syndrome. This is the first time since the International Consensus on Incontinence was formed under the auspices of the World Health Organization in 1998 that painful bladder syndrome

has been specifically addressed. Following an extensive literature review, a diagnostic and treatment algorithm (Appendix B) was formulated and presented. The algorithm provides a more liberal definition of painful bladder syndrome/interstitial cystitis compared with the previous NIDDK criteria (Rosamilia, 2004). The initial history and symptom assessment includes bladder pain with or without the sensation of urinary urgency, urinary frequency and nocturia.

The development of the Fibromyalgia Bladder Index will be beneficial in monitoring the clinical status of FM patients who experience bladder irritability symptoms. The index is not a diagnostic instrument developed to help formulate a diagnosis, but rather it has been developed as an adjunct to clinical assessment and possibly as an outcome measure for intervention therapies for the patient with FM.

Strengths of the Study

Recently the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the National Institutes of Health (NIH) in the United States of America conducted a 'Fibromyalgia Program Assessment' to provide expert recommendations for FM research portfolios (NIAMS, 2003). Approximately forty currently funded researchers, scientists, representatives of patient advocacy groups and NIH staff attended. One of the listed main challenges in conducting FM research was identified as confusion or inconsistency regarding appropriate outcome measures. The development of the condition-specific questionnaire, the Fibromyalgia Bladder Index, is a beginning in meeting this need for validated and reliable outcome measurements.

This research is the first of its kind in Australia. The relationship between FM and IC was first researched in the United States of America when Clauw and colleagues (1997a) found many current symptoms were similar for the FM and IC populations. This Australian research has added to this knowledge by developing a urinary outcome measure validated for the FM female population who experience bladder sensitivity. The methodology of the research is sound and confirms the theoretical framework that guided this investigation.

For the patient with FM and bladder irritability symptoms, this research will increase the medical and public awareness of the urogenital implications associated with FM. The significant consultation in the FM area as seen in the Canadian consensus document on FM (Jain et al., 2004) and the development of a painful bladder syndrome committee at the recent International Consensus on Incontinence (Rosamilia, 2004) gives a strong indication of the direction of future research and continuing consultation in these two areas.

Limitations of the Study

The sample was not randomly selected because of the difficulty of recruiting sufficient women for the study. It would have been preferable to also have a control group of FM women who did not experience sensory bladder symptoms. This would have enabled a greater focus on the impact of sensory urinary symptoms on the quality of life for women already impacted on by the non-urinary symptoms of FM.

This study did not compare the differences in urological symptoms between the groups of women who were of different educational levels, women of different menopausal status, women on different hormone replacement therapy protocols or between women who had and who had not had gynaecological/pelvic surgery. These group variables should be included in further analysis.

Subsequent studies with other populations and samples are required to further explicate the predictive capabilities of the Fibromyalgia Bladder Index and calculate appropriate cut off scores that may be useful in making interpretations.

However, given the scope of this two-phased study and the time limits associated with this doctoral research, the findings emerging from this work make a substantive contribution. Further testing in the context of post-doctoral studies should involve testing of a larger sample, including a control group, now that a tool has been developed and tested and the merits of pursuing this line of inquiry have been demonstrated.

CHAPTER 8

RECOMMENDATIONS AND CONCLUSIONS

Introduction

The Fibromyalgia Bladder Index assesses the important domains of urinary urgency, urinary frequency, nocturia and bladder pain and discomfort in the female FM population. This new instrument, the Fibromyalgia Bladder Index, has demonstrated respectable psychometric properties that indicate that it is a specific and potentially helpful additional outcome measure for research and clinical use in the Fibromyalgia population. The use of the Fibromyalgia Bladder Index by clinicians when assessing women with FM and bladder irritability may help to identify women who suffer significantly from these bladder symptoms and/or problems and assist in quantifying these symptoms. This index may therefore have a place in rheumatology and urology clinics to assess the urinary symptoms and their impact on women with FM and expedite treatment regimes.

Radley and Jones (2004) comment that within the area of urogynaecology and pelvic floor medicine, clinician-administered instruments have been shown to lack sufficient reliability and objectivity and more accurate measures of health-related quality of life are achieved through the use of self-completed questionnaires. These self-administered health status measures/instruments provide information about patients' observations of their own health and can be used for both clinical and research purposes. In the development of such instruments, Radley and Jones (2004) describe questionnaire validation as an extended process that includes not only the psychometric testing of the instrument, but also an evaluation of its performance in practice.

To date, there has been little in the medical literature to increase practitioners' awareness of the severity and impact of FM irritable bladder symptoms on women. Therefore, the Fibromyalgia Bladder Index may add to the assessment tools available for such a thorough assessment of FM symptomatology. Yunus (2002a) emphasises the necessity of a thorough medical and psychological evaluation in helping to achieve a proper diagnosis, assess severity, recognise both aggravating and relieving features of FM symptoms and recognise associated conditions.

Recommendations

This research was initiated because of my association with and clinical knowledge of symptomatology of patients who had disabling urological symptoms in conjunction with their FM. The purpose of this study was to investigate the impact and measurement of these bladder irritability symptoms in Australian women who had been diagnosed with FM and to quantify these symptoms through the development of an appropriate outcome measure/instrument. This has been achieved with the validation of the Fibromyalgia Bladder Index within the FM population of women who experience sensory bladder symptoms. The theoretical framework formulated at the commencement of this study has provided direction for this study by providing a guide for examining variables and their relationships. The theory was based on the relevant literature, previous research findings and current research.

This study has contributed to the knowledge of bladder irritability symptoms and the impact of these symptoms on the quality of life of these women. Together, these outcomes form a sound foundation for the following six areas of recommendation: further refining of the Fibromyalgia Bladder Index; utilisation of the index in FM assessments; development of FM educational, support and self help programs; pelvic health and pelvic fitness awareness; intervention studies, and the development of a vulvodynia index.

Further Refining of the Fibromyalgia Bladder Index

The development and validation of the Fibromyalgia Bladder Index may act as a catalyst for further research into this area of FM and bladder irritability. A

continuation of this research is recommended to develop a scored index with specific cut-offs to help interpret severity of symptoms on the Fibromyalgia Bladder Index.

The use of valid and reliable assessment measures ensures consistency in measuring the progress of a patient from pre- and post-intervention assessments and encourages the development of evidence-based practice (O'Connell et al., 2002). Therefore, a third phase to this study on FM and bladder irritability is recommended. This phase would be of a pre-test/post-test study design to assess any changes resulting from intervention to assess the sensitivity of the Fibromyalgia Bladder Index to detect any resultant changes and responses. Such an intervention could include bladder health educational programs that cover bladder education, good bladder habits, bladder training and pelvic floor muscle education and training. These programs could be conducted by physiotherapy and nurse continence advisors.

Use of the Fibromyalgia Bladder Index in FM Assessments

The primary aim of treatment in chronic, incurable conditions is to enable the patient to live an occupied and productive life and, therefore, palliation of symptoms should be the primary goal of care (Bennett, 2002e). As quality of life is severely impaired with FM patients, Bennett recommends the use of questionnaires that provide details on quality of life as providing the best assessment of change in a patient's overall state of health.

Radley and Jones (2004) extend this notion further by suggesting the routine implementation of these types of instruments in urogynaecology clinical practice. However, these authors recognise that the application of individual condition-specific instruments in clinical practice is limited by the narrow specification of each questionnaire. Therefore, this would necessitate the use of many individual questionnaires to adequately address most areas of pelvic floor symptomatology. Radley and Jones are aware of the increased time burden that paper-based instruments would create for study participants, health care providers and practice managers. They suggest that this is the reason that condition-specific questionnaires are not used in mainstream clinical practice.

With these limits in mind, they recommend the implementation of computer interviewing as one option for managing challenges of busy clinics. Radley and Jones (2004) cite studies by Velikova, Wright and Smith on automated collection of quality-of-life data, comparing paper and computer touch screen questionnaires. Studies by Kleinman, Leidy, Crawley, Bonomi and Schoenfeld (2001) have shown that the reliability and validity of electronic questionnaires are compatible with paper questionnaires. Buxton, White and Osoba (1998) have shown the quality of electronic questionnaire-acquired data to be high, with good test-retest reliability. This computerised technology may offer a realistic method for the collection and monitoring of clinical data. An electronic pelvic floor symptoms assessment (e-PAQ) has already been developed and enables participants to provide comprehensive assessment of symptoms, data entry and immediate data analysis (Radley & Jones, 2004). The e-PAQ is currently being evaluated within the continence area. Radley and Jones state that this electronic assessment, the e-PAQ, was developed within the area of urogynaecology because of the need to comprehensively evaluate symptoms in the related areas of bowel, bladder, vaginal and sexual function.

The development of a single electronic instrument such as the e-PAQ that combines paper-based questionnaires into a single instrument that is acceptable to patients, while maintaining data integrity and minimising respondent burden, is an attractive proposition for the assessment of patients with FM. Following a diagnosis of FM, a combination of valid and reliable indexes relevant to the patient's specific symptoms could be completed and kept on record, following the initial consultation, to provide baseline data for continuing assessment and management. With the future introduction of computerised questionnaires with immediate data entry and analysis, the use of multiple condition-specific questionnaires for conditions such as FM is feasible.

For women with urological symptoms of FM, the Fibromyalgia Bladder Index could be included as one of these specific measures as part of an FM primary assessment and/or pre-intervention questionnaire. The Fibromyalgia Bladder Index will monitor the symptoms and impact of sensory bladder symptoms via the Urgency and Pain Subscale and the Frequency and Nocturia Subscale, presenting clear indications of bladder symptoms and impact at different time intervals.

An Australian study assessed the use of quantitative clinical measurements being used by rheumatologists in the longitudinal follow up in outpatient practice of patients with rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and FM (Bellamy et al., 1999). Rheumatologists agreed that outcome measures for use in clinical practice should include simplicity, brevity, ease of scoring, reliability and validity, and sensitivity to change. Following the completion of studies on the sensitivity of the index to monitor change, the Fibromyalgia Bladder Index, a simple eight-item validated reliable outcome measurement tool for women with FM and bladder irritability will meet the above criteria.

Education

This study has identified a need for increased education of health care professionals with respect to urinary symptomatology within this population. Professional education for health professionals would include information for primary care medical general practitioners, rheumatologists, urologists, physiotherapists and continence advisors on the sensory urinary symptoms and impact experienced by women with FM. Education on the multifaceted symptomatology of FM would include information on the urogenital symptoms.

Goh, Samanta, Cavendish and Heney (2004) emphasise the need to recognise and prioritise the teaching of rheumatology in the undergraduate curriculum and to develop a core curriculum that is acceptable worldwide. One of their recommendations is the assessment of rheumatological conditions by the use of reliable and validated tests. The authors also recommend the acquisition of skills for appropriate attitude development in managing patients with chronic conditions (Goh et al., 2004).

The study has also identified a need within the female FM population for increased awareness of urogenital symptomatology. The development of self-help/support groups within local communities for patients with FM with a focus on patient education and support is also recommended. The development of an Australian FM information pamphlet for patients is an essential part of this patient

education and could be distributed via health professionals at times of clinical consultation.

The literature also documents the positive effects of exercise on pain, self-efficacy, sleep, fatigue and quality of life in the FM population. There is a need for further research in this area, with an emphasis on the pelvic health and pelvic fitness of women with FM. Education on good bladder habits, bladder training and exercises and awareness of the pelvic floor and abdominal musculature specific to pelvic awareness and stability should form part of exercise programs for FM. The Fibromyalgia Bladder Index will increase the awareness of the specific symptoms and impact of sensory bladder symptoms within the female FM population and perhaps open the doors to a more inclusive treatment protocol for the re-education and maintenance of pelvic fitness in these women.

Intervention Studies Specifically for Urological Symptoms/Impact of FM

This study has identified women with FM who experience sensory bladder symptoms that have a significant impact on their quality of life, adding to their existing FM burden. Further research may quantify with objective testing more specifics regarding bladder function in these women with FM. Urodynamic cross-sectional profiles encompassing measurement of bladder capacity, sensory urgency and bladder instability, together with cystoscopy and histology of bladder biopsies in patients with FM who also have bladder symptomatology would provide more information on these irritable bladders prior to intervention therapy.

Evidence-based guidelines for the optimal treatment of FM have recently been developed (Goldenberg, Burckhardt, & Crofford, 2004). These guidelines resulted from a search of all human trials of FM (randomised controlled trials and meta-analyses of randomised trials) using the Cochrane Collaboration Reviews and extensive medical data bases. The final guidelines suggest that, notwithstanding the chronicity and complexity of FM, there are non-pharmacological and pharmacological interventions that do have clinical benefit. Based on current evidence, these authors recommend a program that emphasises education, some medications, exercise, and cognitive therapy (Goldenberg et al., 2004). To date, there

have been no specific treatment programs encompassing the evidence-based guidelines for optimal treatment as suggested by Goldenberg and colleagues (2004) for this area of urogenital symptoms in women with FM.

The theoretical framework for this study described the central nervous system hyperexcitability being responsible for the resultant spectrum of conditions in FM (Clauw, 1995a). As mentioned by Clauw, the clinical spectrum of FM, encompassing neurogenic inflammation, increased peripheral and visceral nociception, neuroendocrine disturbances and autonomic nervous system dysfunction, can result with symptoms being evident in any of the effector arms of the central nervous system. This study has focused on the urogenital symptomatology. A randomised controlled intervention study on specific assessments and treatment protocols for urogenital symptoms for women in this population is indicated.

Further research in the area of FM and bladder irritability should be undertaken. The lower levels of quality of life in the Australian FM sample reported in this study, compared with those of the USA chronic disorder population study as illustrated by the SF-36 measurement of general health status raises questions about the rationale for these differences. One interpretation for these differences may be that this current Australian study captures the urinary distress more completely because all participants met the study inclusion criteria of having at least two sensory urinary symptoms. The data reported in the United States study did not involve recruitment of women specifically with bladder symptoms. Therefore the combination of FM and urinary symptoms may account for the poorer quality of life scores obtained in this Australian study. A larger randomised, controlled study of the FM population in Australia would provide more evidence of the specific impact of urinary and non-urinary symptomatology in this population.

Development and Psychometric Testing of a Vulval Symptom/Impact Index

This current research within the FM population of women with urinary symptoms has shown the presence and impact of vulvodynia-like symptoms. Vulvodynia is described as an under-diagnosed, and difficult to treat gynaecological disorder (Masheb, Lozano, Richman, Minkin, & Kerns, 2004). Their recent research

on subtypes of vulvodynia showing the absence of differences between subtypes on standardised measures of pain, sexual function, psychological function and quality of life suggests little clinical significance of these subtypes and buttresses the theory that vulvodynia represents a continuum of chronic vulvar pain.

There is a need to reach a consensus for the diagnostic criteria for vulvodynia (Masheb et al., 2004). Gibbons (2004) speculates that the lack of an accurate diagnosis or access to contemporary therapy for chronic vulvar pain is partly caused by the current confusion in classification and the multitude of treatments advocated. Although further research and consultations into the area of vulvodynia and dyspareunia and the accurate classification of these conditions should be prioritised, the development and testing of a specific instrument for vulval symptoms and impact within this FM population and within the non-FM population who experience vulval symptoms could provide further insight into this chronic pain condition.

Conclusion

The boundaries of evidence-based medicine on FM and other central sensitivity syndromes are expanded by Yunus (2004) to include the phenomenological aspects of mind, perceptions, feelings and suffering. Yunus refers to Cassel's definition of suffering as that which can be defined as the state of severe distress associated with events that threaten the intactness of a person. For patients with a chronic disease, this intactness can be threatened or lost as a result of the anguish, misery, loss of control and sense of hopelessness and helplessness resulting from the chronicity (Yunus, 2004). He describes suffering as a phenomenological condition, as an entity that goes beyond structural pathology.

One of the difficulties for women with a diagnosis of FM is the lack of objective pathology and diagnostic markers. As a result, it is possible for the health professional to underestimate the impact of the disease and therefore the suffering that these patients experience. For the FM patient, the added impact of urological symptoms may increase morbidity and, therefore, suffering may be intensified. Masi, White and Pilcher (2002) suggest that a person-centred approach can assist in the subgroupings of patients for greater specificity in care programs and in improved

clinical investigations. The authors define a person-centred approach as an attention to major biopsychosocial issues of individuals. They suggest that this person-centered approach can enhance the patient/doctor relationship and assist in prioritising the patient's goals in treatment plans (Masi et al., 2002).

For the health professional, specific FM indexes could elucidate some of the very specific symptoms pertinent to this population that impact on quality of life for FM patients. Use of such specific indexes is recommended as a clinical tool to possibly enhance this person-centred approach. This possibility could be demonstrated in the clinical setting where specificity of information from the Fibromyalgia Bladder Index could encourage collaborative management of the patient between rheumatology and urology disciplines, with increased positive outcomes for the patient.

With this person-centred approach in mind, it is worthwhile to conclude by placing the results of this study in the context of the personal burdens experienced by women living with a chronic illness such as FM who manage both non-bladder and bladder FM symptoms. The concluding quotation reminds us of the relevance of this work.

“Having a chronic illness or living with chronic pain changes not only how you do things but who you are. In the face of extraordinary physical challenges, some have an easier time than others honing in on the strength and hearty wisdom necessary to reinvent a different life and new vision for the future. Inevitably, a former self, as well as a previous way of being in the world, fall away and give rise to a new way of functioning and embracing life” (Sveilich, 2005).

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APPENDICIES

Appendix A: Interstitial Cystitis Symptom and Problem Index (ICSI/ICPI)

SYMPTOM INDEX

- Q1 *During the past month, how often have you felt the strong need to urinate with little or no warning?*
- 0. not at all
 - 1. less than 1 time in 5
 - 2. less than half the time
 - 3. about half the time
 - 4. more than half the time
 - 5. almost always
- Q2 *During the past month, have you had to urinate less than 2 hours after you finished urinating?*
- 0. not at all
 - 1. less than 1 time in 5
 - 2. less than half the time
 - 3. about half the time
 - 4. more than half the time
 - 5. almost always
- Q3 *During the past month, how often did you most typically get up at night to urinate?*
- 0. none
 - 1. once
 - 2. 2 times
 - 3. 3 times
 - 4. 4 times
 - 5. 5 or more times
- Q4 *During the past month, have you experienced pain or burning in your bladder?*
- 0. not at all
 - 1. a few times
 - 2. fairly often
 - 3. usually
 - 4. almost always

PROBLEM INDEX

During the past month, how much has each of the following been a problem for you?

Q1 Frequent urination during the day?

- 0. no problem
- 1. very small problem
- 2. small problem
- 3. medium problem
- 4. big problem

Q2 Getting up at night to urinate?

- 0. no problem
- 1. very small problem
- 2. small problem
- 3. medium problem
- 4. big problem

Q3 Need to urinate with little warning?

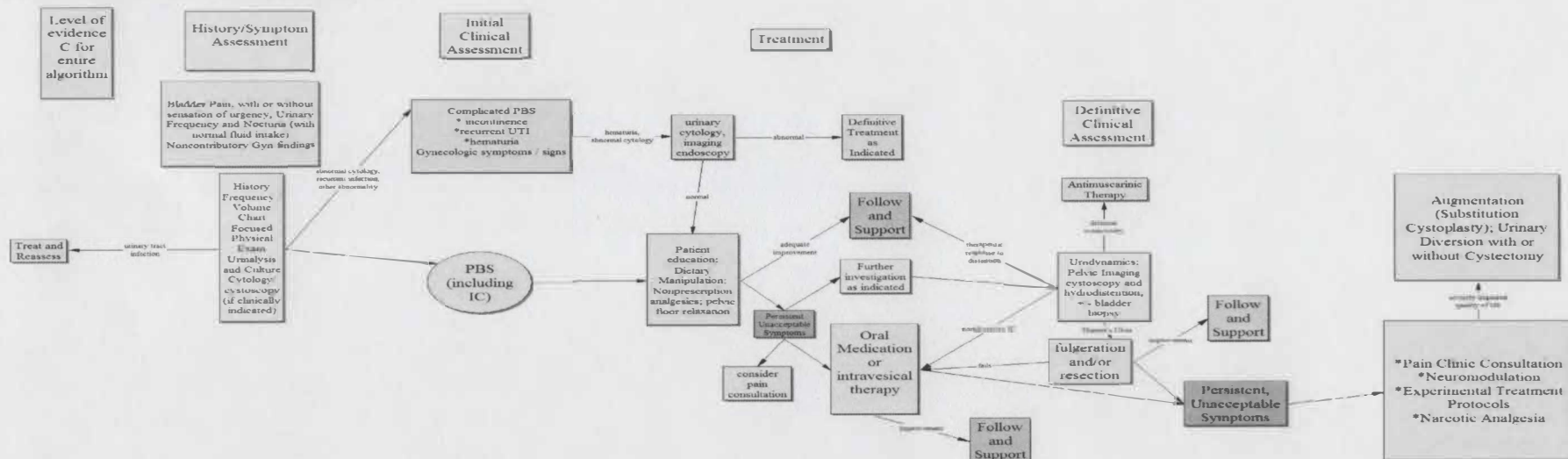
- 0. no problem
- 1. very small problem
- 2. small problem
- 3. medium problem
- 4. big problem

Q4 Burning, pain, discomfort, or pressure in your bladder?

- 0. no problem
- 1. very small problem
- 2. small problem
- 3. medium problem
- 4. big problem

Appendix B: Draft algorithm for the treatment of painful bladder syndrome (including IC)

Painful Bladder Syndrome (Including IC)



Appendix C: Interview guide – Phase 1

I am interested to know what bladder symptoms you are experiencing and how these symptoms affect your daily life. We will be discussing your experience of these symptoms in relation to a specific questionnaire that has been developed to measure the severity of the symptoms and how much of a problem they are for you.

1. During the past month how often have you felt the strong need to urinate with little, or no warning?
2. How would you specifically describe how often you get this strong urge?
3. During the past month, have you had to urinate less than 2 hours after you finished urinating?
4. How would you specifically describe how often you had to urinate less than 2 hours after you finished urinating?
5. During the last month, how often did you most typically get up at night to urinate?
6. During the past month, have you experienced pain or burning in your bladder?
7. How would you specifically describe how often you have experienced this?
8. Do you experience pain or burning in any other part of your pelvis other than your bladder?
9. During the past month, has frequent urination during the day been a problem for you?
10. Describe how much of a problem this has been.
11. During the past month, has getting up at night to urinate been a problem for you?
12. Describe how much of a problem this has been.
13. During the past month has the need to urinate with little warning been a problem?
14. Describe how much of a problem this has been.
15. During the past month, has burning, pain, discomfort or pressure in your bladder been a problem?
16. Describe how much of a problem this has been.
17. Are there any other bladder problems or issues that affect you that we have not discussed?

Appendix D: Phase 1 Information Sheet

Fibromyalgia and Bladder Irritability

My name is Kaye Brand. I am a registered Women's Health Physiotherapist with many years' experience in physiotherapy management of bladder problems. Currently I am undertaking a PhD research study at the Edith Cowan University at Churchlands. This study will cover aspects of the condition of fibromyalgia and its effects on the bladder.

The first phase of the study will involve your participation in a focus group. The focus group is a group interview with 6-10 women where discussion on issues related to the effects of bladder irritability and fibromyalgia will be discussed. The discussion will last for approximately 2 hours and at a time of day that suits the majority of participants. Only first names will be used in this group discussion. The group discussion will be tape recorded. If there is any reason why you would feel more at ease in discussing your experience of this problem individually with me rather than in a group, that can be arranged at a time and place convenient for you.

The information gathered in this discussion will be helpful in establishing a questionnaire to reflect the real experiences of women with bladder problems associated with their fibromyalgia. This questionnaire will then be part of the second larger phase of this study.

Participation in this study is voluntary. If you choose to not be involved in this focus group phase of this study, I will recognise and respect your right of choice. You may withdraw from this study at any time.

For those participating in the study, be assured that no other person will have access to your name. Following the transcribing of the interview the tape recording of the focus group discussion will be erased. I may need to contact some of the participants to ensure that I have interpreted your experiences correctly. Names and contact details of the group participants will then be destroyed.

If you wish to be involved in the second phase of this research, please advise me at the end of the focus group discussion.

If you have any queries you can contact me by telephone on Tel during office hours or by email at My supervisor at Edith Cowan University Professor Linda Kristjanson can also be contacted on if you require any further information.

Thank you so much for participating in this study.

Kaye Brand

Appendix E: Recruitment Letter from Dr. to Patient (at consultation)

FIBROMYALGIA - IS IT AFFECTING YOUR BLADDER?

Currently there is some research being undertaken at Edith Cowan University in Perth on Fibromyalgia and its effect on the bladder. Kaye Brand is a Physiotherapist currently undertaking this research on fibromyalgia and bladder irritability. Kaye has a particular interest in fibromyalgia and has for many years worked as a Physiotherapist continence adviser treating women with bladder problems.

Fibromyalgia is a syndrome that can affect many different areas of the body. For some women with fibromyalgia, their bladders can become more sensitive than normal and this can create some discomfort and sometimes cause a change in their bladder patterns.

The first phase of the study will involve participation in a focus group. The focus group is a group interview/discussion with 6-10 women where discussion on issues related to the effects of bladder irritability and fibromyalgia will be discussed. The discussion will last for approximately 2 hours and at a time of day that suits the majority of participants. The information gathered in this discussion will be helpful in establishing a questionnaire to reflect the real experiences of women with bladder problems associated with their fibromyalgia. This questionnaire will then be part of the second larger phase of this study.

If you do have bladder symptoms, I do hope that you will be interested in participating in this research. It is important that research continues into this condition of fibromyalgia. It is pleasing that this research is being done here in Western Australia. For details on what your involvement will be if you wish to participate or any details on the research, please contact Kaye Brand at Edith Cowan University, Churchlands

Telephone Wk

Mob

Email

Appendix F: Phase I Consent Form

FIBROMYALGIA AND BLADDER IRRITABILITY

I have been given a copy of an information sheet giving details about the study on fibromyalgia and bladder irritability being conducted by Physiotherapist Kaye Brand at Edith Cowan University. I have read and understand the information about the research and my participation in this phase of the study.

I understand that my name and address will be viewed only by the researcher and that following the completion of this phase of the study, these personal details will be destroyed. I also understand that following the transcribing of the group interview, the tape recording of this interview will be erased.

I know that my participation in this study is strictly voluntary and I know that I have the right to withdraw at any time. If I have any questions about the study I know that I can call the researcher Kaye Brand. I can reach her by phone on or email..... I also know that if I have any problems or concerns about the study I can call the researcher’s supervisor Professor Linda Kristjanson on

I agree to participate in this study. I have received a copy of this consent form. I have been assured that my identity will not be revealed while this study is being conducted or when the results of the study are published.

Date

Participant’s Signature

Researcher’s Signature

Appendix G. Demographic Questionnaire

Information About You

- Q1 IN WHICH COUNTRY WERE YOU BORN? (CIRCLE ONE NUMBER)
- | | |
|------------------------|---|
| AUSTRALIA | 1 |
| UNITED KINGDOM | 2 |
| EUROPE | 3 |
| ASIA | 4 |
| OTHER (SPECIFY): _____ | 5 |
- Q2 WHAT IS YOUR AGE IN YEARS
- Q3 WHAT IS YOUR MARITAL/RELATIONSHIP STATUS? (CIRCLE ONE NUMBER)
- | | |
|------------------------------|---|
| NEVER MARRIED | 1 |
| MARRIED / DE FACTO | 2 |
| WIDOW | 3 |
| SEPARATED / DIVORCED | 4 |
| OTHER (PLEASE SPECIFY) _____ | 5 |
- Q4 HOW MANY CHILDREN DO YOU HAVE?
- Q5 WHAT IS THE HIGHEST LEVEL OF EDUCATION YOU HAVE COMPLETED? (CIRCLE ONE NUMBER)
- | | |
|------------------------------|---|
| PRIMARY SCHOOL | 1 |
| SECONDARY SCHOOL | 2 |
| APPRENTICESHIP/TRADE/DIPLOMA | 3 |
| TERTIARY/UNIVERSITY | 4 |
- Q6 WHAT IS YOUR CURRENT OCCUPATION? (CIRCLE ONE NUMBER)
- | | |
|------------------------------|---|
| HOMEMAKER | 1 |
| CLERICAL/COMPUTING | 2 |
| PROFESSIONAL/MANAGEMENT | 3 |
| TRADE | 4 |
| RETIRED | 5 |
| VOLUNTARY | 6 |
| OTHER, PLEASE DESCRIBE _____ | 7 |

Q7. HOW LONG DO YOU THINK YOU HAVE HAD FIBROMYALGIA? _____

Q8. WHAT YEAR WERE YOU FIRST DIAGNOSED WITH FIBROMYALGIA?

--	--	--	--

Q9. PLEASE LIST YOUR MAIN HEALTH CONCERNS APART FROM FIBROMYALGIA:

10. PLEASE LIST THE MAIN PRESCRIPTION MEDICATIONS YOU ARE CURRENTLY TAKING AND FOR WHAT CONDITION:

MEDICATION	FOR	MEDICAL CONDITION
_____		_____
_____		_____
_____		_____

11. PLEASE LIST ANY PELVIC OR ABDOMINAL SURGICAL OPERATIONS YOU HAVE HAD.

12. ARE YOU GOING THROUGH OR HAVE YOU BEEN THROUGH THE MENOPAUSE (CHANGE OF LIFE)? (CIRCLE ONE NUMBER)

- No 1
- CURRENTLY GOING THROUGH 2
- BEEN THROUGH 3
- DON'T KNOW 4

13. ARE YOU CURRENTLY TAKING HORMONE REPLACEMENT THERAPY (HRT)? (CIRCLE ONE NUMBER)

YES	1	TABLET?	<input type="checkbox"/>
		CREAM?	<input type="checkbox"/>
NO	2		

Appendix H: Fibromyalgia Impact Questionnaire (FIQ)

		Always	Most times	Occasionally	Never				
1	<i>Are you able to:</i>								
	a) Do shopping	0	1	2	3				
	b) Do laundry with a washer and dryer	0	1	2	3				
	c) Prepare meals	0	1	2	3				
	d) Wash dishes/cooking utensils by hand	0	1	2	3				
	e) Vacuum a rug	0	1	2	3				
	f) Make beds	0	1	2	3				
	g) Walk several blocks	0	1	2	3				
	h) Visit friends/relatives	0	1	2	3				
	i) Do yard work	0	1	2	3				
	j) Drive a car	0	1	2	3				
2	<i>Of the 7 days in the past week, how many days did you feel good? (Circle the number)</i>	0	1	2	3	4	5	6	7
3	<i>How many days in the past week did you miss work because of your fibromyalgia? (Circle the number of days. If you don't have a job outside the home, leave this item blank)</i>	0	1	2	3	4	5	6	7

For the next items, please place a # on the line which best describes your abilities or feelings for the PAST WEEK.

4. *When you did go to work, how much did pain or other symptoms of your fibromyalgia interfere with your ability to do your job?*

No problem

Great difficulty

5. *How bad has your pain been?*

No pain

Very severe pain

6. *How tired have you been?*

No tiredness

Very tired

7. *How have you felt when you got up in the morning?*

Awoke well rested

Awoke very tired

8. *How bad has your stiffness been?*

No stiffness

Very stiff

9. *How tense, nervous or anxious have you felt?*

Not tense

Very tense

10. *How depressed or blue have you felt?*

Not depressed

Very depressed

Appendix I: Kings Health Questionnaire

Health Questionnaire

1	How would you describe your health at present?	(Please tick one answer)
	Very Good	<input type="radio"/>
	Good	<input type="radio"/>
	Fair	<input type="radio"/>
	Poor	<input type="radio"/>
	Very Poor	<input type="radio"/>

2	How much do you think your bladder problem affects your life?	(Please tick one answer)
	Not at all	<input type="radio"/>
	A little	<input type="radio"/>
	Moderately	<input type="radio"/>
	A lot	<input type="radio"/>

We would like to know what your bladder problems are and how much they affect you. From the list below choose **ONLY THOSE PROBLEMS** that you have at present. **LEAVE OUT** those that do not apply to you.

How much do they affect you?

To choose please tick in circle	A Little	Moderately	A lot
FREQUENCY; going to the toilet very often	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
NOCTURIA; getting up at night to pass urine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
URGENCY; a strong and difficult to control desire to pass urine.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
URGE INCONTINENCE; urinary leakage associated with a strong desire to pass urine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
STRESS INCONTINENCE; urinary leakage with physical activity eg coughing, sneezing, running	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
NOCTURNAL ENURESIS; wetting the bed at night	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
INTERCOURSE INCONTINENCE; urinary leakage with sexual intercourse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
FREQUENT WATERWORKS INFECTIONS	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
BLADDER PAIN	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty PASSING URINE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
OTHER – SPECIFY;	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Below are some daily activities that can be affected by bladder problems. How much does your bladder problem affect you?

We would like you to answer every question. Simply tick the circle that applies to you.

3. ROLE LIMITATION		Not at all	Slightly	Moderately	A lot
To what extent does your bladder problem affect your household tasks (eg cleaning, shopping, etc)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your bladder problem affect your job, or your normal daily activities outside the home?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. PHYSICAL LIMITATIONS		Not at all	Slightly	Moderately	A lot
Does your bladder problem affect your physical activities (eg going for a walk, run, sport, gym etc)?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your bladder problem affect your ability to travel?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. SOCIAL LIMITATIONS		Not at all	Slightly	Moderately	A lot
Does your bladder problem limit your social life?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your bladder problem limit your ability to see/visit friends?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. PERSONAL RELATIONSHIPS	Not Applicable	Not at all	Slightly	Moderately	A lot
Does your bladder problem affect your relationship with your partner?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your bladder problem affect your sex life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your bladder problem affect your family life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7 EMOTIONS	Not at all	Slightly	Moderately	All the time
Does your bladder problem make you feel depressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your bladder problem make you feel anxious or nervous?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does your bladder problem make you feel bad about yourself?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. SLEEP/ENERGY				
Does your bladder problem affect your sleep?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Do you feel worn out/tired?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Do you do any of the following? If so, how much?	Never	Sometimes	Often	All the time
Wear pads to keep dry?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Be careful how much fluid you drink?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Change your underclothes when they get wet?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Worry in case you smell?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Get embarrassed because of your bladder problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix J: Medical Outcomes Study 36-Short Form Health Survey (SF-36)

This questionnaire asks for your review about your health, how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1 In general, would you say your health is:	(Circle one)
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now?	(Circle one)
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse than one year ago	4
Much worse now than one year ago	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities?	(Circle one number on each line)		
Activities	Yes limited a Lot	Yes limited a Little	No, not limited at all
a) Vigorous activities, such as running, lifting heavy objects, Participating in strenuous sports	1	2	3
b) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, playing golf.	1	2	3
c) Lifting or carrying groceries	1	2	3
d) Climbing several flights of stairs	1	2	3
e) Climbing one flight of stairs	1	2	3
f) Bending, kneeling or stooping	1	2	3
g) Walking more than one kilometre	1	2	3
h) Walking half a kilometre	1	2	3
i) Walking 100 metres	1	2	3
j) Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?	(Circle one number on each line)	
	Yes	No
a) Cut down on the amount of time you spent on work or other activities	1	2
b) Accomplished less than you would like	1	2
c) Were limited in the kind of work or other activities	1	2
d) Had difficulty in performing the work or other activities	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?	(Circle one number on each line)	
	Yes	No
a) Cut down on the amount of time you spent on work or other activities	1	2
b) Accomplished less than you would like	1	2
c) Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?	(Circle one number on each line)
Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. How much bodily pain have you had during the past 4 weeks?	(Circle one number on each line)
No bodily pain	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	(Circle one number on each line)
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks	(Circle one number on each line)					
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a) Did you feel full of life?	1	2	3	4	5	6
b) Have you been a very nervous person?	1	2	3	4	5	6
c) Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d) Have you felt calm and peaceful?.	1	2	3	4	5	6
e) Did you have a lot of energy?	1	2	3	4	5	6
f) Have you felt down?	1	2	3	4	5	6
g) Did you feel worn out?	1	2	3	4	5	6
h) Have you been a happy person?						
i) Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc)?	(Circle one)
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

11. How TRUE or FALSE is each of the following statements for you?	(Circle one number on each line)				
	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a) I seem to get sick a little easier than other people	1	2	3	4	5
b) I am as healthy as anybody I know	1	2	3	4	5
c) I expect my health to get worse	1	2	3	4	5
d) My health is excellent	1	2	3	4	5

Appendix K: Vulval Symptom Assessment Scale

VULVAL SYMPTOMS ASSESSMENT SCALE

Some women with bladder irritability also have vulval symptoms. These questions are about irritation and pain that women sometimes experience in the vulval area. The vulval area is the genital area that extends from the place you urinate from (wee from) to the area just behind the vagina.

Physical Concerns (Please circle **one** number.)

Q1 During the past month, have you experienced any **burning in the vulval area?**

- 0 - Not at all
- 1 - A little
- 2 - Quite a bit
- 3 - A lot

Q2 During the past month, have you experienced any **stinging in the vulval area?**

- 0 - Not at all
- 1 - A little
- 2 - Quite a lot
- 3 - A lot

Q3 During the past month, have you experienced any **irritation in the vulval area?**

- 0 - Not at all
- 1 - A little
- 2 - Quite a lot
- 3 - A lot

Q4 During the last month, have you experienced any feelings of **rawness in the vulval area?**

- 0 - Not at all
- 1 - A little
- 2 - Quite a lot
- 3 - A lot

Q5 During the last month, have you experienced any **pain in the vulval area?**

- 0 - Not at all
- 1 - A little
- 2 - Quite a lot
- 3 - A lot

Quality of Life (Please circle **one** number)

Q 6 To what extent do your vulval symptoms affect your daily activities?

- 0 - Not at all
- 1 - A little
- 2 - Quite a lot
- 3 - A lot

Q 7 To what extent do your vulval symptoms affect your physical activity?

- 0 - Not at all
- 1 - A little
- 2 - Quite a lot
- 3 - A lot

Q 8 To what extent do your **vulval symptoms affect your social life?**

- 0 - Not at all
- 1 - A little
- 2 - Quite a lot
- 3 - A lot

Q 9 To what extent do your **vulval symptoms affect your sexual activity?**

- 0 - Not at all
- 1 - A little
- 2 - Quite a lot
- 3 - A lot

Appendix L: Recruiting Information Letters for Rheumatologists

FIBROMYALGIA AND YOUR BLADDER

There is research currently being conducted into this area and the researcher needs your assistance in recruiting 100 women with fibromyalgia and bladder symptoms!

The Research

Although its musculoskeletal features define the condition of Fibromyalgia, there are many other symptoms that are apparent in individuals with this condition. These include the genito-urinary symptoms of urinary urgency, urinary frequency and pelvic pain. Like Fibromyalgia, Interstitial Cystitis is also a condition of unknown etiology characterised by symptoms of urinary urgency, urinary frequency, nocturia and pelvic pain. Both conditions can be classified as non-infective sensory disorders of the lower urinary tract.

The suggestion of mutual etiology for both of these conditions (Clauw et al., 1997) and the knowledge that both these conditions share clinical symptomatology offers sufficient incentive to undertake a validation process within the Fibromyalgia population of an instrument developed for the Interstitial Cystitis population. Currently there is no validated instrument to measure lower urinary tract sensory symptoms or their impact on women diagnosed with fibromyalgia who experience bladder irritability.

Within research today, there is an increasing interest in the development of health scales and indices for measuring subject's assessment of their symptoms and for measuring their quality of life. The validation of the Interstitial Cystitis instrument within the Fibromyalgia population would enable Rheumatologists, Urologists and health practitioners to quickly detect, specify and assess the bothersomeness of the urinary symptoms for the Fibromyalgia patient and enhance referral to appropriate health professionals for management. A validated instrument for measuring these lower urinary tract symptoms and their impact will also be a

valuable outcome measure especially where intervention is directed at improving the management of this problem.

The Researcher

This research on the validation of a instrument for measuring sensory urinary symptoms within the fibromyalgia population is being conducted by Kaye Brand, a PhD candidate and Women's Health Physiotherapist from Edith Cowan University in Perth, Western Australia.

The Recruitment

Kaye is currently recruiting 100 women for the second phase of this research. Women in the study must be between the ages of eighteen years and sixty-five years inclusively, have been diagnosed with Fibromyalgia by a Rheumatologist and have bladder symptoms. Recruitment will be taking place in Perth until the end of this year 2002 . An information flyer for your fibromyalgia patients or as a notice in your consulting rooms is also attached to this notice. If you have patients who have Fibromyalgia and bladder irritability and who may be interested in the study, please ask them to contact :

Kaye Brand Tel:

Email

Ref: Clauw DJ, Schmidt M, Radulovic D, Singer A, Katz P & Bresette J. (1997). The Relationship between Fibromyalgia and Interstitial Cystitis. *Journal of Psychiatric Research*, 31(1), 125-131

FIBROMYALGIA – IS IT AFFECTING YOUR BLADDER?



Currently there is research being conducted at Edith Cowan University in Perth on Fibromyalgia and its effect on the bladder. The researcher, Kaye Brand is a Physiotherapist who has a particular interest in Fibromyalgia and has for many years worked as a Physiotherapist continence adviser treating women with bladder problems.

Fibromyalgia is a syndrome that can affect many different areas of the body. For some women with Fibromyalgia, their bladders can become more sensitive than normal and this can create discomfort and sometimes cause a change in their bladder patterns.

Kaye is interested in hearing from women who have been diagnosed with Fibromyalgia, who have bladder irritability problems and who may be interested in taking part in this research.

You can help! If you do have bladder symptoms associated with your Fibromyalgia, please consider participating in this research. Each piece of information contributes to our understanding about this condition.

To find out further details about the research, please contact (before July 30th)

Kaye Brand, Edith Cowan University

Telephone

Email:

Appendix N: Media Release for Study Recruitment

PRESS / MEDIA RELEASE

August 2002

RESEARCH ON FIBROMYALGIA AND THE BLADDER

Researchers at Edith Cowan University (ECU) are seeking women aged 18-65 years who have been diagnosed with the condition Fibromyalgia to volunteer as participants for a research project.

This research project will be exploring issues of bladder symptoms in women with the condition of Fibromyalgia and the impact that these symptoms have on the quality of life of these women.

Kaye Brand, a Edith Cowan researcher, says that Fibromyalgia is estimated to affect between 2 to 4% of the population, and is the most commonly diagnosed rheumatological disorder after osteoarthritis. The symptoms of Fibromyalgia can be severely debilitating and are characterised by chronic and widespread pain and stiffness throughout the body, sometimes accompanied by fatigue, poor sleep, and other associated symptoms.

One of the associated symptoms of Fibromyalgia is bladder irritability. These bladder symptoms include urinary frequency (going to the toilet very often), urinary urgency (an urgent need to 'go'), bladder pain or pressure or a feeling of bladder fullness.

The symptoms of a chronic illness like Fibromyalgia can radically disrupt a woman's life activities and identity. This research will determine the increased impact these urinary symptoms have on the quality of life of a woman already coping with other symptoms of Fibromyalgia.

One outcome of the research is to produce an assessment format to be used by health professionals that will enable accurate assessment of the symptoms and impact of these urinary symptoms within the female Fibromyalgia population.

This is the first research of its kind to be undertaken in Australia among female sufferers of Fibromyalgia and will be undertaken at a number of sites in Perth and Melbourne.

Kaye is seeking 100 women with both Fibromyalgia and bladder symptoms as volunteers for this project.

Interested women should contact Kaye Brand at Edith Cowan University.

Tel: or email:

Appendix O: Phase 11 Information Sheet

FIBROMYALGIA AND BLADDER IRRITABILITY

My name is Kaye Brand. I am a registered Women's Health Physiotherapist with many years' experience in physiotherapy with special training in bladder problems. Currently I am undertaking a PhD study at Edith Cowan University, Churchlands in Perth, Western Australia. This study will cover aspects of the condition of fibromyalgia and its effects on the bladder.

For women taking part in this phase of the study on fibromyalgia and your bladder your participation will involve two steps.

Step 1

All women will be assessed at the consulting urology rooms at the Hospital under the supervision of urogynaecologist Dr This appointment will take about 30 minutes. This assessment will confirm that it is appropriate for you to participate in this study.

The assessment will include:

- Talking with the urologist/urogynaecologist about your bladder.
- Providing a urine specimen for a urine test.
- Having a bladder scan which involves a small hand held scanner applied to your lower abdomen to show pictures of your bladder on a screen. This is not uncomfortable and poses no risk to you.
- Keeping of a three day bladder diary at home. Keeping a bladder diary involves recording how often and the amount of fluid you drink, how often you empty your bladder and the amount of urine you pass each time you empty your bladder. You will also be recording if and when you get a strong urge to empty your bladder and if you experience any bladder or pelvic pain.

Information obtained from the medical assessment will be kept securely at the researcher's University office.

Step 2

This step involves answering a questionnaire about your general health, your fibromyalgia and how it affects you, your bladder habits and the way your bladder habits affect your daily life. The questionnaire will take approximately 30 minutes to complete. The questionnaire can be completed after the screening or at home and posted back to me in the supplied stamped and addressed envelope. Within two weeks of completing the questionnaire, you will be required to complete another short two page questionnaire. This is a usual research procedure when answering questionnaires as part of a study and helps to identify if your health responses change over time. This second questionnaire will be sent out to you two weeks after I receive your first questionnaire. You will need to post it back to me in the supplied, stamped and addressed envelope as soon as possible. No name or identifying information will be included on the questionnaire.

The information gathered from the questionnaires will be used to finalise a specific questionnaire scale suitable for women with fibromyalgia who have bladder problems. The scale will measure their urinary symptoms and how these symptoms affect their daily life.

Participation in this study is voluntary. If you choose to not be involved in this study there is no problem. You may withdraw from this study at any time. No other person apart from the researcher, the urology nurse and the urologist/urogynaecologist will have access to your name. Names and contact details of the participants from this stage of the study will be destroyed unless you wish to participate in the next phase of this study.

If you wish to make contact with me or if you have any queries, you can contact me by telephone on (freecall) or during office hours or by email at My supervisor at Edith Cowan University, Professor Linda Kristjanson can also be contacted on if you require any further information.

Thank you so much for participating in this study. It is so appreciated!

Yours Sincerely

Appendix P: Phase II Consent Form

FIBROMYALGIA AND BLADDER IRRITABILITY

I have been given a copy of an information sheet giving details on the second phase of the study on fibromyalgia and bladder irritability being conducted by Physiotherapist Kaye Brand at Edith Cowan University in Perth, Western Australia. I have read and I understand the information about the research and my participation in this phase of the study.

I understand that my name and address will be viewed only by the researchers and that following the completion of this phase of the study, these personal details will be destroyed unless I intend to be involved in the next study phase. I know that my participation in this study is strictly voluntary and I know that I have the right to withdraw at any time.

If I have any questions about the study I know that I can call the researcher Kaye Brand. I can reach her by phone on or emailIf I have any problems or concerns about the study I know I can also call Ms Brand’s Supervisor Professor Linda Kristjanson on

I agree to participate in this study. I have received a copy of this consent form.

Date

Researcher’s signature

Participant’s Signature

Appendix Q: Bladder Diary

BLADDER DIARY

Identification

Code Number

Initials

Diary Starting Date

Investigator

YOUR BLADDER DIARY

This bladder diary is an important part of this study. For three consecutive days before your clinic appointment we would like you to keep a record of your bladder patterns by using the attached charts.

- Please fill in the diary as accurately as possible.
- Please complete this diary for three consecutive days.
- For each day, please record the date, the time you get up in the morning and the time you go to bed.
- Each diary day starts when you get up in the morning and finishes when you get up the next morning (i.e. approximately 24 hours).
- Everytime you urinate (wee) you should record the time and place an X into the urination column on your chart. You should urinate into a measuring jug marked in mls. Record how much urine you passed into the volume box in the volume column before emptying the jug.
- Everytime that you feel a strong urge to empty your bladder, please record the time and place an X mark in the urgency column (XX for severe urgency).
- Whenever you experience bladder and /or genital pain, please note the time and place an X in the bladder pain column or genital pain column (XX for severe pain)
- If you leak urine, record the time and place an X mark in the leakage column.
- Continue to fill in your diary for episodes such as needing to urinate or experiencing urgency that occur during your sleeping period
- Please record how much you drink during the day under the fluid intake column.

DEFINITIONS OF TERMS USED IN THE BLADDER DIARY

- **Urination:** Passing urine in the toilet

- **Urgency:** A sudden compelling desire to pass urine that is difficult to control.

- **Bladder Pain:** The pain that is felt above the pubic bone (on your pubic hair line). This usually increases with bladder filling. It may stay after you have emptied your bladder.

- **Genital Pain:** The pain that is felt around the external genitals, in the vagina, or between the vagina and the anus.

Please place any comments you feel are relevant at the top of the page of your bladder chart.

Date

dd mm yy

Time of getting up : AM

Time of going to bed : PM

Patient initials

	Time (am/pm)	Urination (x)	Volume (mls)	Urgency (x) (xx)	Pain (Bladder) (x) (xx)	Pain (Genital) (x) (xx)	Incontinence (x)	Sleep Interruption (x)	Fluid Intake (1 cup = 250 mls)
<input type="text"/>	<input type="text" value="8"/> AM	X	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="0"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text"/>	<input type="text" value="9"/> AM	X	<input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="0"/>	X	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text" value="1"/> <input type="text" value="0"/>	<input type="text" value="3"/> <input type="text" value="0"/> AM	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	X	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text" value="1"/> <input type="text" value="1"/>	<input type="text" value="3"/> <input type="text" value="4"/> AM	X	<input type="text"/> <input type="text" value="4"/> <input type="text" value="0"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text" value="1"/> <input type="text" value="2"/>	<input type="text" value="4"/> <input type="text" value="5"/> PM	X	<input type="text" value="1"/> <input type="text" value="1"/> <input type="text" value="0"/>	X	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text"/>	<input type="text" value="5"/> <input type="text" value="8"/> PM	X	<input type="text"/> <input type="text" value="7"/> <input type="text" value="0"/>	X	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text"/>	<input type="text" value="3"/> <input type="text" value="6"/> PM	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	X	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text"/>	<input type="text" value="5"/> <input type="text" value="2"/> PM	X	<input type="text"/> <input type="text" value="5"/> <input type="text" value="0"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text"/>	<input type="text" value="7"/> <input type="text" value="0"/> PM	X	<input type="text"/> <input type="text" value="3"/> <input type="text" value="0"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> mls

Appendix R: Urological Screening Assessment

UROLOGICAL SCREENING

Name: -----

Address: -----

Telephone: -----

Age: -----

General Practitioner: -----

Address/Tel: -----

Past History:

Fibromyalgia -----

General -----

Surgical -----

Current Symptoms: -----

Current Medications: -----

