A PRELIMINARY EXPLORATION OF THE CONSTRUCT VALIDITY OF THE BERLIN QUESTIONNAIRE AS A MEASURE OF OBSTRUCTIVE SLEEP APNOEA IN A SOUTH AFRICAN POPULATION

A CLINICAL HEALTH PSYCHOLOGY PERSPECTIVE

by

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ABSTRACT

Clinical professionals in South Africa are generally unaware of the impact of obstructive sleep apnoea (OS A). The cost to the state of untreated apnoea may be extremely high. In primary health care encounters OSA often goes undiagnosed. The cascade of symptoms linked to OSA is profound, placing patients at risk for debilitating problems impacting on self and others. The aim of this study was to validate a questionnaire, which could be used at a primary health care level to identify patients with OSA thus cutting costs and improving efficient, effective and ethical service to patients. The Berlin Questionnaire (BQ) (Netzer et al. 1999) was administered to a clinical sample of consenting patients at a private sleep laboratory in Durban, South Africa (N = 119)(completed n = 110). Home-based sleep studies (n = 116) on a portable cardio-respiratory screening device were also obtained for objective comparison. From the results obtained in this South African sample, the BQ showed low validity and reliability (Cronbach a = 0.62 - 0.84) to individual items of the BQ. The total BQ score and high-risk symptom category analysis showed mildly significant correlations with internationally approved protocols. The BQ identified 60% of the high-risk group (AHI >5). Furthermore, risk categories were useful in predicting AHI ratings in 64% of moderate OSA cases and 25% of severe OSA cases. The BQ therefore has useful psychometric properties as an adjunct assessment tool to screen for high-risk OSA cases where resources are scant. Clinical health psychologists are in an ideal position to recognise the risk factors and symptoms of OSA. The clinical assessment and the value of the correct diagnosis will alleviate the treatment of psychological symptoms at a superficial level in primary health care facilities.

PREFACE

The experimental work described in this thesis was conducted at the Berea Sleep Laboratory in Durban, South Africa from January to November 2005.

This study represents original work by the author and has not otherwise been submitted in any form for any degree or diploma at any University. Where use has been made of the work of others, it has been duly acknowledged in the text.

The clinical assistance of Dr. D. Hooper, director of the Berea Sleep Laboratory is hereby acknowledged. Opinions expressed and conclusions arrived at, are those of the author and are not necessarily attributed to Dr. Hooper.

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LIST OF COMMONLY USED ABBREVIATIONS

AHI	Apnoea + Hypopnoea Index (a calculation based on the number of times per hour a patient holds his/her breath during sleep - sometimes referred to as the RDI (respiratory disturbance index).
ANA'S	Autonomic arousals - measure of the number of awakenings caused by activation of the autonomic nervous system - sympathetic nervous system function in relation to apnoea events.
BMI	Body Mass Index (a calculation using the height and weight of a patient - A BMI > 24 is considered overweight, >30 is considered obese)
BQ	Berlin Questionnaire
CPAP	Continuous Positive Airway Pressure - a machine, which pumps air at a constant pressure, titrated for each patient for the treatment of OS A.
EDS	Excessive Daytime Sleepiness
OSA	Obstructive Sleep Apnoea
PSG	Full Polysomnography - commonly known as a "sleep study" is done in a hospital/laboratory setting with all night monitoring by a technologist. The system records sleep related breathing disorders including brain activity (EEG) for sleep staging, respiratory channels and an oximeter to record oxygen saturation. A large number of additional parameters are available for assessing physiological function.
HypnoPTT™	Portable Sleep Study Unit for recording sleep related breathing disorders detecting cardio-respiratory signals known as Pulse Transit Time (PTT). It includes respiratory flow, autonomic micro-arousals, upper airway resistance, and oxygen saturation levels - and uses *Hypnoscan* ™ software.

CHAPTER 1. INTRODUCTION

1.1. Overview

Obstructive Sleep Apnoea-hypopnoea[1] (OSAHS) is a sleep disorder characterised by repetitive episodes of airflow reduction (hypopnoea) or complete cessation of breathing (apnoea) due to narrowing of the airway and leading to acute gas exchange abnormalities (hypoxaemia) and sleep fragmentation (Olsen, Moore, Morgenthaler, Gay and Staats, 2003). Untreated OSA is a potentially disabling condition characterised by excessive daytime sleepiness (EDS), disruptive snoring and sleep fragmentation (Netzer, Stoohs and Netzer, 1999).

The need for sleep is an essential physiological requirement. Prolonged interference with physiological renewal weakens resources for coping with even normal demands and causes vulnerability to stressors. "One thing that is for sure is that we must sleep in order to stay sane" (Berger, 1970, in Carson and Butcher, 1992, p. 10). The nature of the syndrome of OSA, in terms of the severe sleep fragmentation and oxygen desaturations, impacts on daily function. Psychological effects such as neuropsychological deficits, depression, anxiety and poor quality of life have been implicated (Aloia, 2005; Kjelsberg, Ruud and Stavem, 2005; Kryer, 2005; Macey, Hendersen and Alger, 2002; Sand, Hagen and Shrader, 2003; Strine and Chapman, 2005; Veale, Poussin, Benes, Pepin and Levy, 2002; Vonk, 2001). Dement & Vaughan (1999) refer to snoring and OSA as the "midnight stranglers". Many patients describe "choking" in their sleep (personal

[1] The British spelling (i.e apnoea and hypopnoea) as apposed to the American spelling (apnea) is used in this text. The acronym OSA is used throughout the text to denote *sleep apnoea hypopnoea syndrome* for easy reference.

communication, Dr. D. Hooper, Berea Sleep Laboratory, Durban, January, 2006). The impact of OSA is extensive.

Clinicians in South Africa need to be educated about the implications of a sleep disorder such as OSA when patients are referred to them. Treating the various conditions of this syndrome such as depression or excessive daytime sleepiness for example, may be a waste of time, resources and money while treating the core condition is a more direct, economic solution to the problem. All too often sedatives are prescribed for patients for 'insomnia' when in fact the condition causing sleep fragmentation is OSA. Sedatives are potentially lethal for an already undermined airway (Lavie, Pillar & Malhotra, 2002). Patients also frequently use alcohol to improve their sleep; alcohol can also undermine the airway and worsen OSA *(Ibid).*

The clinical condition must be treated first focusing on the root of the sleep problem, not simply whether the patient complains of not sleeping or feeling sleepy during the day (Schlebusch, 1990). Global opinion is that clinicians should be alert to the presentation of OSA and approach the management of patients who complain of symptoms such as fragmented sleep and EDS from a holistic point of view (Chokroverty 1999; Rosekind, 2005; Shamsuzzaman, Gersh and Somers, 2003; Stevens, 2004). Netzer et al. (1999) refines this theory with the opinion that "specialist intervention using specialised diagnostic equipment and intensive education of clinicians on taking a sleep history improves recognition of OSA in primary heath care" (p.485). Furthermore, management of OSA requires a multi-disciplinary team and specialised equipment (Rosekind, 2005; Wolk, Shamsuzzaman & Somers, 2003).

Specialised equipment to diagnose the disorder is overnight polysomnography (PSG) and more recently screening devices such as the Pulsatile Transit Time Hypnogram (HypnoPTT™) are rapidly gaining approval (Chokroverty, 1999; Schwartz, 2005; Katz, Lutz, Black and Marcus, 2003). The essential difference between these two systems is that firstly PSG produces sleep staging from electroencephalographic (EEG) recording and includes cardio-respiratory parameters, whilst screening devices are purely cardio-respiratory in nature; secondly PSG is performed in a controlled setting in a hospital sleep laboratory whereas screening devices are take-home units (Stevens, 2004; Stradling & Davies, 2004). Whist controversy abounds regarding the advantages and disadvantages of the two kinds of recording systems, contemporary practice argues that OS A is a breathing disorder, so it follows that breathing parameters are the most necessary to diagnose OS A (Stradling & Davies, 2004). Furthermore, the advantages of home studies outweigh those of hospital-based studies *(Ibid).* Current consensus on the diagnosis and treatment of OS A holds that a good sleep history and clinical impression obtained by the clinician, data from overnight sleep recordings and if possible, collateral information, all culminate in a report generated by the physician diagnosing the presence and severity of OSA (Chokroverty, 1999; Rosekind, 2005; Stevens, 2004; Wolk et al. 2003; Dr.D. Hooper, Berea Sleep Laboratory, Durban, South Africa, November 2006). The cost however of professional and technical resources remains problematic.

Diagnostic methods to identify OSA are certainly an elitist option in South Africa due to the lack of facilities and resources to diagnose sleep disorders. Whilst the number of sleep centres accredited in America has increased by 300%, no such accreditation exists in South Africa (Personal communication, Health Professional Council of South Africa, Pretoria, October, 2005). The recognition and investigation of sleep disorders is

relatively new in South Africa, with the first sleep laboratory being established in Cape Town in approximately 1980 (Raine, 1993). Sleep laboratories in South Africa are currently limited to the private sector, are costly and have extensive waiting lists. Patients from medium and low-income groups do not have access to health care systems providing diagnosis and treatment for sleep apnoea (Personal communication, Prof. A. Bhigjee, Department of neurology, Albert Luthuli Hospital, Durban, South Africa, October 2004; Dr.D. Hooper, Berea Sleep Laboratory, Durban, South Africa, November 2006).

Given this situation, a strong possibility exists that OSA goes undiagnosed and untreated in many individuals. For example, a clinician seldom questions the patient or partner regarding snoring or breath holding episodes during sleep, but use superficial questions regarding sleep. A focus is placed on the referring problem. One should consider the possibility that patients using psychological services in South Africa who complain of excessive daytime sleepiness, intractable hypertension, eating disorders (in particular - obesity) cognitive decline or depression may have OSA, an option that is seldom explored in clinical psychology scenarios in primary health care. Chokroverty (1999) and Stevens (2004) cite the bed-partner as the most valuable source of clinical history. Invariably, if OSA is identified it is because the bed partner, family or friend reports "choking" during sleep as an incidental during consultation.

A subjective questionnaire including the opinion of significant others therefore would be the logical answer to refining the identification of OSA in primary health settings. Netzer et al. (1999) hypothesised that a questionnaire could be used as a diagnostic tool to identify OSA and to address the current gap in terms of refining contemporary clinical evaluation. These researchers designed and validated a questionnaire addressing risk

factors for OSA in a primary health care setting, namely the Berlin Questionnaire (BQ) (Appendix A). They concluded that the BQ provides an adequate means of identifying patients who are likely to have OSA and challenged further research in other primary health care settings.

1.2. Purpose of current study

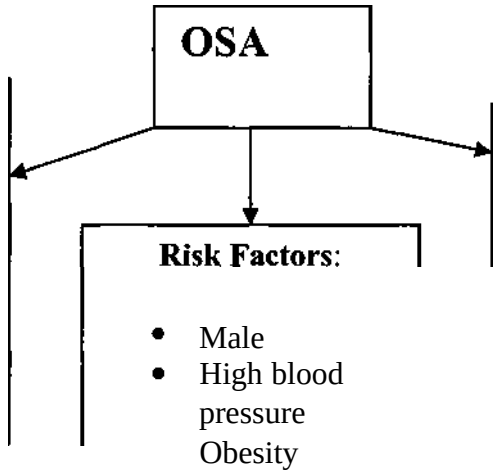
This research follows recommendations by Netzer et al. (1999) to validate the BQ in other populations. The current study sought to examine the degree to which items in the BQ were correlated with objective data from the HypnoPTT™, a portable recording device used by subjects in their homes during a full nights sleep under the guidance of a sleep physician. The HypnoPTT™ is therefore a diagnostic instrument used to identify and confirm suspected cases of OSA. Construct validity was the preferred validity technique as it is considered to be particularly robust because it is determined by correlating subjective data with reliable objective measurement (Kaplin and Sacuzzo, 2005; Zarins 2005).

The sample was drawn from a sleep laboratory in Durban, South Africa that currently services patients from Durban and surrounding areas referred by general practitioners and specialists. The laboratory is geared for patients with medical aid from the private sector. The validation of the BQ as a possible diagnostic tool seeks to promote an informed approach to clinical health psychology as a means of recognising risk factors for OSA and for early detection and prevention of a cascade of OSA symptoms (Shamsuzzaman et al. 2003).

Within the clinical health psychology model suggested by Schlebusch, (1990), this study explores the value of using the BQ as a diagnostic tool for OS A in primary health care settings in South Africa. The purpose of this investigation is to apply a practical and cost effective means of identifying a condition frequently overlooked and under diagnosed at an enormous cost to the patients and state (Boll, Perrry, Rozensky and Johnson, 2004; Foster, Freeman and Pillay, 1997; Gorin and Arnold, 1998; Petersen, 2000; Schlebusch, 1990).

1.3. Conceptual framework

The overall conceptual framework of this study is presented in figure 1-1. It places OS A as the central focus - a debilitating syndrome with complex psychological, economic and health consequences. These issues and their implications are explored in the literature review. Specifically this research project examines the construct validity of the BQ (Appendix A) with a view to its potential use as a diagnostic tool in clinical settings by comparing the BQ questions, reported by patients on body mass index, snoring, breath-holding, sleepiness factors and a history of high blood pressure, to the data recorded on the HypnoPTT™.



Economic effects:

- Self
- Local - community
- National
- Diagnostic
  - PSG
  - Hospitalisation
  - HypnPTT™
  - Home studies

Psychological effects:

- Depression and anxiety
- Cognitive deficits
- Obesity
- Behaviour
  - Snoring
  - Sleepiness
    - Daytime
    - Driving
- Social difficulties
  - Self
  - Others

Berlin Questionnaire

A <u>subjective</u> diagnostic tool for OSA

Validated in Western countries (Netzeretal. 1999)-Cost effective option at any level in primary health care.

- Diagnostic tool for OSA - home based study
- BMI
- Snoring
  - Level
  - Frequency
- Number of breath-holding events - reported by others
- EDS
- Effects of EDS
- Sleepiness whilst driving
- Reported history of high blood pressure
- Quick evaluation by clinician

HypnoPTT™

An <u>objective</u> diagnostic tool For OSA

Validated in Western countries (Schwartz, 2005) - Expensive, elitist option, generally private concerns

- Diagnostic tool for OSA
- Severity analysis according to number of breath-holding events (A+HI index)
- Snoring
- Microarousals - sleep fragmentation
- Oxygen desaturation
- Pre-test clinical evaluation of EDS, hypertension, BMI
- Physician report according to international criteria

<u>Aim</u>

To investigate the construct Validity of BQ:

To use as a diagnostic tool in clinical health psychology

Figure 1-1 Conceptual framework

1.4. **Aim**

The aim of this study is to investigate the construct validity of the BQ (Appendix A) as a diagnostic measure for sleep apnoea syndrome in the field of clinical health psychology, by comparing the BQ to objective data recorded in patients tested at a sleep laboratory in Durban, South Africa (Netzer et al. 1999; Schwartz, 2005). The objective data included respiratory events, oxygen desaturation levels, snoring and the number of autonomic arousals recorded in an overnight home-based study.

The objective of this investigation was to do a preliminary investigation of the validity of the BQ with a view to investigating its possible role as a reliable and cost-effective diagnostic/screening assessment technique for OSA as a possible health promotion strategy. The reason this was felt to be an imperative for health promotion was because the risk factors for OSA, in particular, the impact of impaired alertness on personal, relational and occupational settings is profound (Wolk et al. 2003).

It was envisaged that clinicians could use the BQ as an early detection tool to diagnose OSA vulnerability in South Africa, thus alleviating long-term biological, psychological and social effects, which may have profound impact on safety, health and productivity for individuals, communities and the nation. The need for educating health-care workers regarding the impact of OSA is vital for accurate case formulation. Furthermore, policy change at a national level in relation to cost-effective diagnostic protocols may be indicated.

1.5. Research questions

Question 1

Is there a statistically significant correlation between the BQ items 1-10 and the clinical and physiological measures of OSA, namely the AHI, snoring, ANA's and oxygen saturation levels?

Question 2

Can the BQ be considered clinically useful in the South African context as a possible screening and/or diagnostic instrument by applying the physician's final report as the dependent variable in the statistical analysis?

1.6. Organisation of chapters

Chapter two explores OSA, examines related health issues and highlights important risk factors for OSA. Chapter 3 provides an overview of the psychometric and diagnostic properties of the BQ as a self-rating scale and the HypnoPTT™ as the objective diagnostic tool. Furthermore, a critique and cost analysis of these instruments is considered. The methodology chapter - chapter 4, describes the characteristics of the study sample, the design and methods used to collect and analyse the data. Results are presented in chapter 5. Chapter 6 contains a discussion of findings, together with limitations of the current study and directions for further research.

CHAPTER 2. THE PHENOMENON OF OBSTRUCTIVE SLEEP APNOEA SYNDROME (OSA)

2.1. Introduction

In this chapter, common health information, risk factors and treatment of OSA will be discussed initially. Thereafter the impact of EDS as a public health risk will be discussed. The problem of EDS as a primary expression of OSA will be examined, in terms of its psychosocial and psychological effects. The diagnosis and treatment of OSA and the economic implications of untreated OSA will then be explored. Finally the clinical health psychology model will be explored as a means of initiating OSA diagnosis with a view to early detection of the disorder and prevention of the cascade of effects. The ways in which clinical psychologists can improve their evaluation of a patient with OSA are also suggested.

2.2. Common health information and risk factors

At present no South African literature is available to estimate the prevalence of OSA. Comparatively, OSA is considered a common problem in other countries and literature abounds..American and European studies historically suggest the prevalence rates of OSA are approximately 2% in females and 4% in males (Chokroverty, 1999; Stevens, 2004). Contemporary estimates in Europe however, purport a higher frequency of 24% in middle-aged men and 9% in middle-aged women (Garni, Pressman, Caples et al. 2004).

It would appear that African-Americans have a higher prevalence compared to other ethnic groups, although no clear evidence for this has been reported (Stevens, 2004). OSA is probably under diagnosed in women because women may present differently to men with OSA symptoms, with less well recognised snoring or apnoea and more complaints of fatigue and hypersomnolence (Loube, 2002; Porkka-Heiskanen, Dzaaja and Arber, 2005).

The risk for developing OSA increases with age and is strongly correlated with obesity and the male gender (Chokrovery, 1999; 2004; Wolk et al. 2003). Common risk factors for OSA are headache, excessive daytime sleepiness (EDS), cardiovascular disease, metabolic and sympathetic nervous system dysfunction, with hypertension topping the list (Chokroverty, 1999; Sand et al. 2003; Wolk et al. 2003; Stevens, 2004; Shamsuzzaman, et al. 2003; Verona, Winn, Babineau, Eng, Feldman and Ware, 2005). The ongoing research of Wolk et al. (2003) and Shimura, Tatsumi, Nakammura, Kasahara et al. (2005) is recognising the coexistence of OSA and obesity. All considered this data implicates OSA as a costly and major public health risk of dynamic and multi-level proportions (Aloia, 2005; Rosenthal, 2005; Rosekind, 2005; Shamsuzzaman et al. 2003; Shimura et al. 2005; Somers, 2004; Svatikova, Wolk, Garni, Pohanka and Somers, 2005; Wolk et al. 2003; WHO, 1986). The enormity of these side effects, assumes to be a heavy burden on health care if left undiagnosed and untreated (Gibson, 2005). For example, untreated OSA is associated with the prevalence of chronic hypertension in excess of 40% whereas 30% of all persons with idiopathic hypertension have OSA (Chokroverty, 1999).

Snoring is a common concomitant of OSA. American studies report primary snoring prevalence in 5-85% of male subjects (mean 32%) and 2-57% (mean 21%) in women - as reported by the bed partner (Stevens, 2004). Snoring, also known as "upper airway

resistance" on its own can cause oxygen depletion and EDS due to multiple arousals during sleep *(ibid*, p. 78). Stradling and Davies (2004) argue that these findings require replication. A recent development has been the recognition that elevated leptin plasma levels (a neurohormone which regulates body fat mass and exerts important effects on the cardiovascular system) beyond the levels seen in obese patients, are being identified in OSA patients (Wolk et al. 2003). These authors also cite other complications such as insulin resistance, systemic inflammation, endothelial and renal dysfunction in OSA sufferers.

2.3. The impact of OSA on Public health

These risk factors make OSA a global major public health hazard (Stevens, 2004; Shamsuzzaman et al. 2003; Verona et al. 2005; WHO, 1986; Wolk et al. 2003). Moreover, these physiological factors impact directly on the patient causing social and psychological dysfunction manifesting symptoms such as interpersonal relationship problems, anxiety, cognitive deficits, sexual dysfunction and depression (Aloia, Arnedt, Smith et al. 2005; Kjelsberg, Ruud and Stavem, 2005). Prout, Demos, and Morrow (2001) found that firstly, the onset of depression can often be traced to the beginning of sleep difficulties, and secondly the amount of sleep loss usually correlates with the severity of depression.

Subjects in the severe OSA range are particularly affected. The severe range refers to those subjects who hold their breath over thirty times per hour (Stevens, 2004). Feelings of depersonalisation, fatigue, tiredness, lack of energy and irritability have also been frequently reported in OSA sufferers *(ibid).* The fact that OSA and obesity frequently co-

occur and include a cluster of abnormalities broadly considered to be reflective of metabolic syndrome is a subject for rigorous contemporary discussion and research (Shamsuzzaman et al. 2003).

2.3.1. Excessive Daytime Sleepiness (EDS)

There was a time when medicine and psychology examined only constructs relating to patients who are awake. No diagnostic or treatment consideration was given to sleep or daytime sleepiness. The exact mechanisms of EDS are unclear, yet clearly research demonstrates that symptoms of daytime hypersomnolence develop gradually during the course of OSA (Guilleminault, Tilkian and Dement, 1976). Generally research reiterates that one of the most profound consequences of OSA is EDS resulting in impaired performance in perception, reasoning, judgement, decision-making, cognitive slowing, memory deficits and increased reaction time (Chokroverty, 1999; Stevens, 2004). It seems that EDS has evolved from a "virtually unknown medical condition to one of active scientific enquiry" (Rosenthal, 2005, p.485). The Epworth Sleepiness Scale (Johns, 1991, Appendix C) is a renowned questionnaire used to estimate daytime sleepiness (Stevens, 2004). Miletin and Hanley (2003) however, challenge the claim of high validation in the ESS.

There is endless controversy and debate over exactly what EDS is. Dinges (1995, p.4) defines EDS as "a neurobiological drive to sleep". Rosenthal (2005) expanded the OSA argument over thirty years ago by also suggesting that " the fluctuating nature of changes during sleep" such as the sudden dips in oxygen levels caused an "unstable state" in

metabolic and central nervous system mechanism, contribute to EDS *(ibid,* p.480). EDS is continually reported in the literature as a major consequence of OSA, yet Stradling, Barbour, Glennon and Langfornd (2002) question this claim based on their studies of sleep fragmentation and autonomic arousal saying: "these measures were not predictive of daytime sleepiness " (p.385).

The debate regarding EDS is historical with many factors being discussed, including a new baby in the house, psychiatric morbidity, chronic sleep deprivation and so forth (Thorpy, 2005). To complicate matters further, there are also disputes questioning the fact that EDS simply *reflects fatigue* rather than hypersomnolence, (Brown, 1994). Brown broadly defines fatigue as "a subjectively experienced disinclination to continue performing the task at hand" or "the results of prolonged activity" (p.298a). Another argument is that one can be fatigued yet not sleepy, but Lavie et al. (2002) argue, "people with true EDS as apposed to fatigue, often fall asleep unintentionally" (p. 109).

So to consolidate some sort of understanding of why EDS is relevant to this study, the point remains - a normal individual who gets adequate sleep should be able to maintain wakefulness during the day (Lavie et al. 2002). When an individual consistently falls asleep in passive situations it probably represents a clinical problem *(Ibid).* If wakefulness cannot be maintained, the propensity to fall asleep becomes overwhelming resulting in the inability to sustain the task at hand (Brown, 1994; Dinges, 1995). When extrapolated to real life situations these tasks could be in occupational settings, whilst driving a car, truck, train or bus or in social settings such as in church, watching television, reading in a movie, during family gatherings or while making love. Thorpy (2005) gives an overview of the clinical significance of EDS. Thorpy suggests EDS is holistic and may include medical disorders, central nervous system disorders, psychiatric disorders, medications

and primary sleep disorders such as sleep apnoea syndrome, narcolepsy, insomnia, insufficient sleep and shift work and Chronic Fatigue Syndrome.

In summary, the most common contributor to pathological sleepiness is OSA, according to Gibson (2005). Clinicians can therefore hardly ignore the implication of EDS in patients. EDS may well be a clue to an underlying OSA. A quick diagnostic assessment tool such as the BQ may therefore be a valuable instrument for early detection and recognition of OSA and the diagnosis and treatment thereof could substantially reduce the risk for EDS. This innovation could alleviate many psychosocial and psychological effects of OS A.

2.3.2. The Psychosocial and Psychological effects of OSA

Historically, snoring, breath holding and EDS has been the marker of jovial discussion at family breakfast and dinner tables and in occupational and social settings (Charles Dickens's *Pickwician Boy* is a fine example). Contemporary social dialogue centres on themes of fatigue and sleepiness on a regular basis, yet few health care clinicians investigate the origins thereof (Personal Communication, Dr. D. Hooper, Durban, South Africa, June 2006). A story recounted to the researcher by one of the patients from a sleep laboratory, goes as follows: A group of friends went camping. The patient awoke to find himself on his stretcher on the banks of the river a great distance away from the camp. His friends could not tolerate his snoring and breath-holding attacks, so they removed him from the camp. Many family and community narratives regarding clear observational data diagnostic of OSA could be recounted, the most common being the

offended wife who moves to the spare room. Business men and women have had many an embarrassing moment when asked to share a room with a colleague or travel for long distances. Generally families and individuals never consider a breathing problem, never mind one that occurs during sleep as a potential problem area that requires diagnosis and treatment. The genetic component also plays a large role. OSA is known to affect generations of men [sic]. Families often tolerate the symptoms of OSA as a familiar marker of golden moments in the family.

At a community level, Aloia (2005) maintains that neuropsychological consequences of OSA by way of decreased mental acuity can have significant negative consequences for daily function, occupational performance, productivity, motor vehicle safety and educational pursuits. Gibson (2005) reports OSA to be associated with poor performance in the workplace, a high rate of automobile accidents, with a particularly high rate in truck drivers.

Whilst few studies have evaluated quality of life issues in OSA one can assume that the psychological effects as mentioned would have a significant effect on quality of life of these patients and their partners. One study however, has contributed to a valuable understanding of the concerns patients with OSA have. In a discourse analysis Veale et al. (2002) identified abnormal fatigue, snoring, depression, excessive use of alcohol and antidepressants, loss of memory, relationship and sexual problems and fear of dying in OSA sufferers. Interestingly they cite the non-directed conversation with patients as the means by which patients revealed these concerns. They suggest these concerns may not have surfaced in a standard medical paradigm. Certain conditions are considered

embarrassing for patients. Snoring and obesity certainly fall into the social discourse, which alienates and saddens patients (Veale et al. 2002).

Obesity, which is by definition a Body Mass Index (BMI) over thirty, is a global challenge approaching epidemic proportions in the United States of America (97 million adults, with a 65% risk for hypertension in women and 78% in men) (Wolk, et al. 2003). South Africa closely follows these proportions with 29.2% of men and 56.6% of women falling into the obese range. There is no doubt that Obesity has a profound psychological impact on the lives of OS A sufferers (Puoane, Steyn, Bradshaw, et al. 2002).

Obesity is a complex public health problem, which Wolk et al. (2003) describe as interacting with race, gender, demographics, genetic, neurohormonal and socio-economic factors. These researchers hypothesise that OSA may be an important mechanism underlying the association between obesity and hypertension. There is an association between increased body weight and the risk of OSA - 10% weight gain is associated with a 6-fold increase in the odds of developing OSA. Wolk et al. (2003) however, point out that significant weight loss led to significant decrease in apnoea frequency. Furthermore, these researchers continue this debate by stating: "whereas obesity increases the risk for OSA, sleep apnoea may predispose weight gain and obesity" (p. 1068). Obesity is as yet not considered an eating disorder according to DSM-IV criteria however ICD-10 coding includes obesity in this category, which seems fitting in the face of cascading risk factors and causal relationships such as high blood pressure and heart disease (DSM-IV-TR® - 2000; Sadock & Sadock, 2003).

The BQ as an early intervention tool within the clinical health psychology forum, will surely initiate early prevention and treatment reducing these debilitating consequences and enhance quality of life to some extent. It may seem an insignificant beginning, yet Schopper (2000) again points out that the purpose of clinical health psychology is to prioritise diseases which impact on public health necessitating health promotion, disease prevention and policy reforms.

2.4. Diagnosis and treatment of OSA

2.4.1. Diagnosis of OSA - comparing full PSG and screening devices

It has been argued that OSA is simply a clinical diagnosis characterised by daytime somnolence, associated with loud snoring, choking or gasping during sleep, recurrent nocturnal awakenings, unrefreshing sleep, daytime fatigue and impaired concentration. Sleep physicians agree however that this rationale is too imprecise (Bennett & Kinnear, 1999). A number of different modalities to assist diagnosis have been used from limited channel PSG, videometry, overnight oximetry and nasal pressure monitoring in sleep laboratories. The simplest of these is overnight oximetry (recording oxygen saturation with a finger or ear probe), which is readily available, easy to apply, relatively inexpensive and can be performed at home *{ibid;* Stevens, 2004). Most intensive care units in hospitals have an oximeter. However this type of screening really goes to extreme end and it is not possible to differentiate respiratory events, cardiac fluctuations or sleep fragmentation. Furthermore, unacceptably high false-positive rates have been documented (Bennet & Kinnear, 1999).

The polysomnogram (PSG) is a test consisting of many parameters recording data during a night's sleep. This data includes electroencephalography (EEG - brain activity), electro-occulography (EOG - eye movements) electromyography (EMG - muscle activity), electrocardiography (ECG - heart activity), and data from various ancillary monitors of respiration effort and airflow, blood oxygen saturation, and audio-visual recordings (Stevens, 2004). PSG devices also record the number of snores across the night. No standard decibel level is recorded. The PSG can be extended to record virtually any parameter required.

> The "use of digital and signal processing and analysis allows the collection of virtually any number of biological processes or physical activity that can be converted into alternating or direct voltage potential" for the purpose of recording physiological variables during sleep (Stevens, 2004, p. 45).

In summary, PSG equipment or what is commonly known *as full polysomnography* may consist of systems with multiple parameters available or in contrast, may be smaller systems excluding brain waves necessary for sleep staging (EEG) and focusing more specifically on respiratory parameters. The HypnoPTT™ is a sophisticated contemporary unit making use of measuring pulsating blood transit time, and respiratory measurements recorded from a belt across the chest and a nasal thermistor, which records oral and nasal airflow through a cannula placed under the nose. Pulsitile transit time is measured by the time taken for a pulse wave to move from the aortic valve, measured from an electrode placed close to the heart to some peripheral site, typically the finger. This measurement depends largely on sympathetic nervous system function, adrenergic stimulation and the elasticity of arterial walls recorded by electrodes placed in close proximity to the heart

and an infra -red ray probe placed on the finger, measuring vascular changes in the nail bed in relation to blood pressure surges.

Thus the term *screening devices* for OSA, which are used predominantly for diagnosing OSA in hospital wards and home settings still, have reasonable accuracy for counting events despite sources of error compared to attended centre-based PSG (Netzer, 1999). Furthermore, Netzer (1999) criticises full PSG systems by stating that this method also has limitations such as *first night effect* - being in a strange environment, under observation and experiencing discomfort due to all the connections. There are therefore distinct advantages to home recording systems such as eliminating the first night effect to some degree in a familiar environment, and empowering the patient to be interactive in the evaluative process, as well as minimal connections (Stevens, 2004).

The advent of screening devices which exclude EEG and focus on respiratory channels, has made a valuable contribution to the evaluation of OSA in terms of cost effectiveness, due to the advantage of *take-home studies* and quick turn-around times (Schwartz, 2005; Stradling, & Davies, 2004).

The HypnoPTT™ in summary is therefore designed as a take-home, user-friendly unit where the patient can be recorded in their own environment (Schwartz, 2005). To diagnose OSA and evaluate severity, this screening device is considered an adequate diagnostic tool (Stradling & Davies, 2004). This device was therefore considered an adequate objective measure of OSA against which to compare the BQ questions (Stevens, 2004). The common factors linking full PSG and screening systems is the nature of the

acquired data and the scoring criteria used to elicit data diagnosing OSA (AASM Task Force report, 1999; Rechtchaffen & Kales, 1968).

A diagnosis of OSA is made when devices recording respiratory measures show complete occlusion of the airway, known as *apnoea*, or partial occlusion which is defined as a > 50% reduction in airway space, known as *hypopnoea.* The duration of events must last for more than ten seconds, and occur more than five times per hour to be called an apnoea or hypopnoea (Rechschaffen & Kales, 1968). These 'breath-holding events must be accompanied by an oxygen desaturation of more than 4% for the diagnosis to apply. OSA severity is categorised according to the Apnoea plus hypopnoea index (AHI), which is the number of times per hour the subject holds his/her breath (Stevens, 2004).

Classification of the severity of OSA varies slightly but is generally accepted as falling within the normal range when breath-holding episodes occur between 0-5 times per hour, mild between 5-15 times per hour, moderate between 15-30 times per hour and severe when the subjects holds their breath for greater that 30 times per hour (Stevens, 2004). These AHI ranges are tabulated below:

Table 2-1. Classification of the Apnoea plus Hypopnoea Index (AHI) in OSA severity according to Stevens (2004).

Normal Range	**Mild Range**	**Moderate range**	**Severe Range**
0-5 times per hour	5-15 times per hour	15-30 times per hour	> 30 times per hour

Severe OSA is also diagnosed in relation to the severity of snoring and the degree of sleep fragmentation across a night of sleep. *Micro-arousals* and *arousals* are important

markers of sleep fragmentation, which lead to daytime sleepiness and reduced alertness (Harrison & Home, 1996; Stevens, 2004). Research has also shown that this reduction in attention, reaction and performance causes *microsleeps* which are brief episodes of intrusive sleep (2-30 seconds), impacting directly on occupational and road traffic situations (Harrison & Home, 1996; Priest, Brichard, Aubert, et al. 2001).

Obviously, full PSG still stands as the ideal holistic measurement tool for OSA, and in research settings or complicated symptomatology, it is essential for fine detail. Furthermore, the clinical evaluation and final compilation of results is the responsibility of the sleep clinician. However, from a practical, cost effective, public health care perspective, the literature reviewed highlights the fact that the BQ could play a vitally important role in early diagnosis, treatment and prevention of OSA. The fact that the BQ is non-intrusive, cost effective and takes about twenty minutes to complete, makes it a viable option for OSA measurement.

2.4.2. Treatment of OSA

The treatment for OSA is multi-faceted. Conservative treatment for OSA management is weight loss and dietary management, sleeping position (patients are advised to sleep on their sides) and abstinence from alcohol and sedatives (Chokroverty, 1999). Whilst these conservative approaches to therapy work well with a group of patients who have mild to moderate OSA, the global treatment of choice for moderate to severe OSA is Continuous Positive Airway Pressure (CPAP) (Chokroverty, 1999; Shamsuzzaman et al. 2003; Somers, 2004; Stevens, 2004; Wolk et al. 2003).

CPAP effectively "gets the patient breathing again" by splinting the airway, and reversing the detrimental effects of oxygen deprivation. The basic mechanism of a CPAP machine is to open the airway by delivering room air at a calculated pressure set by laboratory staff, in relation to apnoea severity, or by automatic titration over a number of nights. Compliance with CPAP users varies substantially. Not all subjects (who are able to afford CPAP machines) continue to use them (Svatikova et al. 2005; Veale et al., 2002). Aloia (2005) alludes to subtle neuropsychological consequences of OSA and an amelioration of cognitive deficits after treatment with CPAP. Compliant subjects however report remarkable improvements in their quality of life, and preliminary evidence suggests that CPAP may reverse many of the detrimental biological effects associated with OSA (Veale, et al. 2002; Richards, 2004).

The use of a CPAP machine, enhances patients lives and can improve symptoms quite dramatically, however it is also daunting for a patient initially and may cause anxiety and depression in some patients (Veale et al. 2002). Frankly, many patients find the use of the machine humiliating and dehumanising. Side effects such as allergies, sores on the bridge of the nose and mask leaks are a constant challenge to compliance with this treatment device (Chokroverty, 1999; Stevens, 2004; Personal communication, Dr. D. Hooper, Sleep Laboratory, Durban, South Africa, June, 2006; Veale et al. 2002).

The Ear Nose and Throat (ENT) fraternity are constantly in search of a surgical procedure, which will improve the treatment of OSA and do away with the CPAP machine and are currently one of the most active groups investigating OSA. To date the only valuable surgical treatment is the removal of obstructions in the airway (for example large adenoids and tonsils - in children this is very successful) and facio-maxillary

surgery to advance the mandible in certain cases (Personal communication, Dr. D. Hooper, Sleep Laboratory, Durban, South Africa, June, 2006).

2.5. Economic implications of OSA

Rosekind (2005, p.s21) states that despite overwhelming evidence, there is "gross underestimation and very little acknowledgement of the risks and costs related to sleep loss, reduced alertness and performance for OSA sufferers". As mentioned, sleep laboratories have been established globally since the early seventies, particularly in the United States of America and Great Britain. Europe followed soon after and research in sleep medicine is expanding and gaining more credibility. Sleep research societies have been formed producing regular research publications and international conferences to disseminate information related to medical and allied professionals.

Yet despite this growth in empirical studies the investigation and treatment of sleep disorders remains a specialised and elitist prerogative.

The cost of overnight, full PSG in private practice is approximately R 2000 per patient, with the bed fee alone costing approximately R 1 100 (R 3 100 in total). CPAP machines cost approximately R 4 000 - R 17 00 to purchase. Basic systems are cheaper than more complicated systems, which record hours of usage for compliance follow up and at a higher level, deliver a dual air system, which literally breathes for the patient. These systems are known as Bi-Level or BiPAP machines (costing well over R 30 000) and are used for more severe comorbid OSA disorders such as motor neurone disease cerebro-vascular accidents or central sleep apnoea. These machines are also imported as no manufacturer exists in South Africa.

For diagnosis and treatment of OSA therefore, an individual has to outlay an amount ranging from of R 7 100 - R 20 100. Thus, only patients on medical aid, or able to afford these prices can be tested and treated for. Many medical aid societies do not recognise the need for these devices, and remain ignorant to empirical data citing only obesity as the cause for OSA and therefore exclude patients with OSA from the benefits they offer their members OSA (Personal communication, Dr. D. Hooper, director - Berea sleep laboratory Durban, South Africa, June 2006; Dr. E. Ebrahim, director, London Sleep Centre, June 2006).

In undiagnosed OSA a private patient suffering with cardiac disease, diabetes and or intractable hypertension may spend exorbitant amounts annually to cope with polypharmacy requirements. An example would be that of a patient with OSA and a persistent high blood pressure which, is uncontrolled by standard hypertensives medication (Somers, 2004). Frequently in such cases, the patient is put on to two or three different drugs in an attempt to control the blood pressure problem at a great expense. The state carries the cost for lower income patients, which can become a heavy burden on health care systems. National expenditure increases when conditions such as OSA are not diagnosed and treated. No South African statistics are available; however in the United States of America the estimated annual costs of untreated OSA is as much as $3.4. Billion per annum (Gibson, 2005). The annual cost of motor vehicle accidents, occupational accidents and absenteeism escalates incrementally with OSA severity (Rosenthal, 2005; Dinges, 1995).

With heightened awareness of OSA for clinicians, it seems pertinent to explore practical means of addressing this condition through first line primary health care clinicians.

Clinical health psychology forms an integral part of modern health care delivery services. Whilst the model assumes that patients are empowered to be more responsible for their own health, it seems important that the practitioner's understanding of the OS A syndrome and its correlation with mental health and psychosocial stressors, places the patient in a better position to become fully functional (Schlebusch, 1990; Schopper, 2000).

2.6. OSA and clinical health psychology

2.6.1. Introduction

As discussed, empirical data suggests that psychological effects such as depression, cognitive function (vigilance, memory and executive function) and anxiety, are common symptoms noted in patients diagnosed with obstructive sleep apnoea, particularly those subjects in the severe range (Aloia, 2005; Kryger, 2005; Macey et al. 2002; Vonk, 2001). These deficits have been noted particularly in relation to incidents of snoring, oxygen depletion, arousals and the number of respiratory events per hour (Aloia, 2005; Vonk, 2001). Furthermore, studies with volunteers showed that after seventy two hours of fragmented sleep, increasing psychological problems such as disorientation and depersonalisation occurred (Carson & Butcher, 1992; Dement, 1999). Psychologists consulting patients in primary health care could therefore be far more focused on behavioural symptoms at the expense of a far greater health risk. Behavioural symptoms impacting on public health are however only the surface features of OSA. An approach, which does not provide comprehensive health care, is possibly selling the system short (Petersen, 2000).

Schlebusch, (1990) suggests that biopsychosocial health care (largely contained within the clinical health and behavioural medicine models) is not simply treating psychological symptoms such as eating disorders, depression or anxiety at a surface level in the face of extensive impaired biological and neurological dysfunction, but rather requires an understanding the development of disease and mental disorders. Similarly, Olsen et al. (2003) concur with many authors that treating symptoms such as EDS, impaired vigilance, mood disorders, obesity and cognitive dysfunction, which are all features of OSA is pointless. A condition such as OSA is much broader than simply recognizing the condition and referring on for management, it impacts directly on patients and family quality of life. It requires professionals trained in recognition of the disorder.

2.6.2. The Clinical Health Psychology model and primary health care

The clinical health psychology model is patient centred and focuses on health promotion rather than disease prevention within the social structure of a medical setting in primary health care (Schlebusch, 1990). Primary health care is provided by a health professional, which is at the patient's first point of entry into the health system (Keleher, 2001). Primary health care includes the "interconnecting principles of equity, access, empowerment, community, self-determination and intersectoral collaboration and the use of appropriate technology" providing continuity of care, health promotion and education *(ibid,* p. 57). The clinician has to be alert to a mirroring of symptoms. In other words, a [sleep disorder] such as [sleep apnoea] may mask psychiatric symptoms on the one hand yet on the other hand reflective psychiatric symptoms could also mask an underlying [sleep disorder] (Boll et al. 2004; Schlebusch, 1990). Amongst the psychiatric disorders commonly linked to OSA encountered in clinical practice are major depressive disorder,

dysthymia, seasonal affective disorder, generalised anxiety disorder, somatoform disorders, dissociative disorders, and substance abuse *(ibid,* Chokroverty, 1999). Boll et al. (2004) encourages clinical psychologists to be alert to a concise explanation of any disease process in their patient.

An understanding of the development, progression and treatment of disease refines diagnosis and treatment and improves the quality of life of their patient *(Ibid).* The emphasis is on teamwork with the psychologist in a clinical and mediatory role informing and empowering the patient to identify and acknowledge their condition, understand the implications and risk factors and investigate best approaches to treatment *(ibid).* Rosekind, (2005) further supports this approach to educating the patient about his/her symptoms stating that this mode empowers him/her by causing an awareness of risk factors and initiating a change process. Boll et al. (2002) emphasize that the psychologist's role is not merely as therapist but includes drawing on the skills and knowledge of other professionals and assessments, if necessary making appropriate multi-disciplinary referrals, refining diagnosis and treatment.

Although OSA: "is a potentially disabling condition characterized by EDS, disruptive snoring, repeated episodes of upper airway obstruction during sleep, and nocturnal hypoxemia ... , recognition of OSA by community [clinicians] is however, low" (Boll et al. 2002; Netzer et al. 1999, p.490). Stoohs et al. (in Netzer et al. 1999) estimated that 20% of a primary health care patient population may have sleep-disordered breathing. Astonishingly, Netzer et al. (1999) identified a .3% case recognition rate amongst primary health care physicians. In one study, only 7% of women and 12% of men who have moderate to severe OSA received the diagnosis of OSA from a clinician.

Petersen (2004) presents a unique concept, which takes into account the role of psychologists playing a consultancy-liaison role in clinical health psychology at a primary health care level. The argument for Petersen's research is for a "new psychological professional to fill the gap for specialized services in South Africa" (p.33). This concept could be expanded to a 'new psychological professional to fill the gap in sleep disorders medicine'.

Boll et al. (2004) are critical of clinicians in terms of OS A diagnosis commenting on the fact that the diagnosis of OS A is often overlooked because patients and their clinicians are unaware of the symptoms and clinical findings of OS A. A clinical understanding of any sleep complaint must always begin with an understanding of the disorders listed in the DSM-IV-TR® and ICD10 codes (DSM-IV-TR® - 2000; Saddock & Sadock, 2003). Sleep apnoea is considered an intrinsic dyssomnia diagnosed on Axis III *(ibid). A* detailed sleep history should be obtained on intake of the patient, preferably in the presence of a bed partner or family member. Questions should include sleep habits and sleep hygiene (the routines and rituals around sleep), and medication the patient is on, alcohol consumption, history of psychiatric and/or neurological disease, medical history, family history and any psychosocial problems (Chokroverty, 1999; Stevens, 2004). The simple alternative is asking the patient to report their symptoms *(Ibid).*

Whilst it is acknowledged that clinical psychologists could improve their diagnostic skills simply by taking a more concise sleep history, further investigation is also warranted. Objective investigations such as the PSG provide this extension, however questionnaires are often the baseline investigation that can be used in a primary health care setting (Netzer et al. 1999). The questionnaire used however, must be a credible document.

Importantly, questionnaires cannot simply fill the gap; the empirical soundness of an instrument must be investigated for clinical application to be recognised and to be appropriate (Boll et al. 2004).

Sleep questionnaires such as the Epworth Sleepiness Scale (ESS) have been used extensively as a quick evaluate screening tool for daytime sleepiness (Johns, 1991) (Appendix C). The BQ has of late been used to exclude OS A in the USA and Europe (Chokroverty, 1999). Such questionnaires should not simply be accepted as clinically useful, when extrapolated to a South African population until validated in such a population. Whilst the ESS has been used extensively and proves to serve a baseline for daytime sleepiness, a more stringent screening of OS A may be provided by the BQ.

Therefore, it seems appropriate within the clinical health psychology scenario, to investigate the psychometric properties of the BQ in a South African population to refine clinical intake, and enhance diagnostic and treatment protocols. A basic tool such as the BQ could also be an intervention tool for disease prevention and health promotion shifting future outcomes in terms of risk factors and consequences of OS A.

CHAPTER 3. PSYCHOMETRIC AND DIAGNOSTIC PROPERTIES OF THE BQ AND HYPNOPTT™

3.1. Introduction

This chapter starts with a brief general evaluation of psychological assessments and explores the meaning of psychometric properties. Thereafter validity is examined in more detail, with particular reference to construct validity. The BQ is investigated as a potential diagnostic tool by way of giving a history of the BQ development and statistical analysis and a cost analysis thereof.

3.1.1. Psychometric assessment procedures

Psychological assessments are standardised procedures, which test selected variables related to a diagnostic question, whether it is for intelligence, personality or clinical conditions such as depression. For any test to be standardised a population has to be tested in surroundings which are consistent, controlled and conducive to the subject producing the best possible performance (Babbie, 2004; Kaplin & Saccuzzo, 2005). In the case of the biopsychosocial paradigm of this research, the assessment tool pertains to diagnosing sleep apnoea syndrome with a view to enhancing formulation for holistic management of the patient. Zarins (2005) states how important it is to be aware that a questionnaire that has been validated for one clinical condition is not valid when applied to another condition - it has meaning for a specific entity. The BQ is the instrument of choice selected as a potential gold standard measure already used tentatively to identify patients with OS A in the severe range when the AHI is over 5 per hour. Sharma,

Vasudev, Sinha, Banga, Pandey and Handa (2006) have recently published work done in India at a primary health care level. An accurate diagnosis would be advantageous to understand the underlying process manifesting psychological distress. In order to do this a number of psychometric properties of the questionnaire need to be investigated.

The term psychometric properties, refers to the validity and reliability of an instrument. Validity is effectively an "agreement between a measure and the quality it is supposed to measure" or "does the test measure what it is supposed to measure" (Kaplin & Saccuzzo, 2005, p. 134). The purpose therefore is to achieve precision and accuracy in our investigation (Babbie, 2004). Gregory (2004) however also points out that "a test is valid to the extent that inferences made from it are appropriate, meaningful and useful" (p. 97). Validity is the measure that represents evidence supporting the intended interpretation, or is reflective of a concept of a measure, and is central to the use of psychological testing. Validity cannot be defined if the test is not reliable. Reliability suggests that the test is relatively free of error and associations between items are consistently accurate. "In clinical settings, reliability is extremely important when tests are used to make an important decision about a patient's future" (Babbie, 2004, p. 124).

3.2. Validity

In summary, validity essentially refers to an instrument that is standardised in a large cohort and tests specifically what it is designed to test.

Kaplan & Saccuzzo, 2005 suggest that validity is divided into three categories or types of evidence:

1. *Criterion-related*
2. *Content-related*
3. *Construct-related*

Criterion-related evidence serves to confirm how well a test corresponds with a particular criterion. In this case for example the criterion might be the AHI or "breath-holding" episodes, or snoring or daytime sleepiness, which are the markers of sleep apnoea syndrome. This type of evidence also frequently has a predictive quality to it, a forecast of sorts -*predictive validity evidence.* Criterion evidence is invariably reported by professionals such as the attending physician, specialists, psychologists or technicians involved in test procedures, diagnosis and treatment of a sleep disorder. The reports of a spouse, partner or family members are also crucial.

Concurrent-related evidence is generated by simultaneous relationship between the test and criterion. *Content validity* refers to a correspondence between item content and the domain the items represent, which in health care research is most often diagnostic criteria and symptom presentation (Kaplin & Saccuzzo, 2005, p. 156). *Face-validity* is also commonly explored, although it does not have the same empirical base as the others as it is based on "appearance", in other words it requires judgment as to whether the questionnaire has meaning regarding the condition being investigated. The user-friendliness of a questionnaire is explored with the subjects and specific areas of difficulty may or may not be identified.

The key psychometric measurement of this study is that of *construct validity,* which defines a "construct" invariably in the form of an objective measure or evidence about

what the test is evaluating and is used commonly in health care scenarios. The objective measure of choice in this study is the HypnoPTT™ sleep analysis unit, which is a system gaining more recognition globally for recording parameters diagnostic of symptoms of OSA because of it's sensitivity to cardio-respiratory signals and autonomic arousals (Bennett & Kinnear, 1999). A convincing relationship should be established between the subjective and objective measures if the instrument under question is valid. *Convergent evidence* will be obtained if the measures of the selected instrument correlate well with the BQ.

Although categories for grouping are convenient to a large degree, the use of categories does not imply distinctive forms of validity and contemporary research suggests controversy regarding categorization (Kaplan & Saccuzzo, 2005). "Sometimes psychologists have been overly rigorous about making distinction amongst categories that overlap" (Messick, 1998, in Kaplan & Saccuzzo, 2005, p. 134). To a large extent, construct validity does not use single criteria as evidence but is also based on hypotheses and clinical judgement of the researchers … "we would expect that…" which provides evidence for inferences to be made. This research therefore applies a holistic approach to reporting validity and focuses particularly on contemporary research criteria and risk factors for OSA (Chokroverty, 1999; Netzer et al., 1999; Rosekind, 2005; Stevens, 2004; Stradling & Davies, 2004; Wolk, et al. 2003) in the context of subjective (BQ) versus objective (HypnoPTT™-physiological data).

3.3. The Berlin questionnaire as a potential diagnostic tool for identifying OS A

3.3.1. Background

The conference on Sleep in Primary Health Care held in Berlin, Germany in April 1996, established the need for an efficient questionnaire to screen for sleep apnoea (Netzer et al.1999). A group of physicians, from various countries and experienced in sleep disordered medicine reviewed literature to elicit factors or behaviour that consistently predicted the presence of sleep disordered breathing. The BQ focuses on risk factors for sleep apnoea such as snoring behaviour, waketime sleepiness, obesity, (BMI) and hypertension. The researchers evaluated the usefulness of using the BQ in primary care settings. They also devised a plan for high risk-grouping to simplify recognition of OS A (Table 3-1). To be considered high risk for OSA, a patient had to qualify for at least two symptom categories. The remaining patients were placed in a lower risk group (Netzer et al. 1999).

Table 3-1. Table showing the BQ High-risk grouping for OSA according to Netzer et al. (1999).

Category 1	**Category 2**	Category 3
Snoring - Persistent symptoms	Persistent symptoms	History of high blood
>3-4 x per week	>3-4 x per week	pressure
in 2 or more questions on	wake time sleepiness	Or
snoring	driving or both	BMI > 30Kg/m^2

3.3.2. The BQ as a diagnostic tool

The BQ was the first instrument validated to screen for sleep apnoea in a primary health care population (Netzer, 1999; Stevens, 2004). The current study, according to the researcher's knowledge, is the first to validate the BQ in a South African setting. A number of other studies are currently underway in Germany and the USA (Personal communication, Professor V.K. Somers, Director, Sleep Research Laboratory, Mayo Clinic, Rochester, USA, October 2004, July 2006; Suharma, Vusudev, Sinba, Banga, Pandey and Handa (2006). More than 37.5% of the outpatient's sample visiting an urban primary care physician reported risk factors (body mass index >30kg/m^2 and hypertension) for and chronic behaviours (snoring & EDS) that suggest the presence of sleep disturbances and sleep apnoea (Netzer et al. 1999). In a specialized respiratory sleep unit the ability of the questionnaire to predict an elevated AHI was similar to that of sleep studies using a portable sleep-monitoring unit categorically similar to the HypnoPTT™. The EdenTec™ produced by the same company, has four channels for recording respiratory variables and does not include the sophistication of pulse transit time measurement *(ibid).*

3.3.3. Cost analysis of the BQ

The BQ is convenient, less intrusive to the patient and less costly as clinicians can screen for OSA during patient intake. The costs incurred for printing and stationery are probably the most important factors. From a psychosocial point of view, according to the literature reviewed, the cost to patient, family and community is immeasurable if the patient is *not* tested.

3.3.4. Validity and reliability of the BO

The reliability of individual questions within the symptom categories was examined as a measure of internal validity. The Cronbach a value was 0.92 for items in category 1 and 0.63 for category 2. When questions about sleepiness behind the wheel were excluded, the Cronbach a increased to 0.86 (Netzer et al. 1999). The predictive ability of the BQ is higher when BMI and blood pressure (symptom category 3) are used in combination with snoring or sleepiness, than alone. A sensitivity of 86% for an AHI more than 5 was reported in this sample, which is higher than current strategies used in clinical practice *(ibid).* Garni et al. (2004) acknowledge that overnight sleep studies remain the gold standard for the diagnosis of OS A, yet they report an 86% predictive rate of cases for OS A and also that 97% of the cases predicted for OS A were positive on overnight PSG.

3.3.5. Critique of the psychometric properties of the BO

The BQ was used initially to screen for sleep apnoea in a specific primary heath care population and reliability and validity were not tested more extensively. Whilst the authors comment on the approach to testing being more acceptable to patients, less costly and more convenient, criticism could be leveled at the lack of personal interaction clinical evaluation of the patient, which may not suite all patients. The face validity of the BQ was not investigated. While the questions may be appropriate in an American English population, the suitability for cultural diversity is narrowed by the use of language such as "up to par" and "how often do you quit breathing".

It is important to note that the BQ is not a diagnostic measure, which relies on the reporting of symptoms, but rather a syndromic cluster of risk factors within the categories in Table 3-1. The authors state unequivocally that whilst the BQ is a sensitive diagnostic tool, it does not detract from the fact that clinical judgement is still required to detect unusual cases or recognize other causes for daytime sleepiness, other than sleep apnoea *(ibid).* Moreover, the BQ was only considered a diagnostic tool comparable to objective assessment in a specialized clinical setting; those patients already clinically suspected of having respiratory disturbance. Thorpy (2005) argues that for some clinicians a careful interview and the adjunct use of the ESS, which is short and concise, is all that is required to assess impairment in alertness, yet even this critique seems inadequate - the BQ extends the diagnostic clinical value. In other words not simply in the context of excessive sleepiness symptoms, but to risk factors for OS A (Netzer et al., 1999). Suharma et al. (2006) state: "the BQ can identify high risk subjects and can thus avoid unnecessary PSG studies especially in resource-limited settings".

3.4. The HypnoPTT™ as a diagnostic tool

3.4.1. HypnoPTT™ analysis

Essentially, the most important parameters of sleep recording for the diagnosis of OS A, are the measure of inspiratory effort, the oxygen saturation measures and the estimated number of arousals These parameters, it became obvious, could be derived from an indirect estimate of beat-to-beat blood pressure *or pulse transit time.* Whilst a lot of criticism has been leveled at the use of screening devices in the past, contemporary sleep medicine practice is shifting to more practical ways of diagnosing and treating OS A

(Personal communication Dr. D. Hooper, Berea Sleep Laboratory, Durban, South Africa, February, 2005). In particular, Stradling, et al. (2004) promotes pulsitile transit time measurement as a robust diagnostic measure for OSA.

Researchers began to study how the HypnoPTT™ could contribute to the management of OSA. They concluded that "HypnoPTT™ can provide a non-invasive estimate of inspiratory effort and a measure of arousals that together documents disease severity and response to treatment and may be very useful in managing obstructive sleep apnoea/hypopnoea syndrome" (Pitson & Stradling, 1998, p. 692).

3.4.2. Cost analysis of the HypnoPTT™

The HypnoPTT™ as described, is one of the screening systems available in South Africa to clinicians working in sleep medicine at a cost approximately R 200 000. In contrast, full PSG system can cost anything up to R 750 000 to set up. Once the HypnoPTT™ has been purchased, the usefulness as a home study unit, which is charged at a lower rate to laboratory studies (no bed fee charged), makes this unit a more cost-effective option. The unit is compact and user-friendly which makes it easy for laboratory staff to explain the procedure of recording at home. The unit can also be used from ward to ward in a hospital setting to screen in-patients (Personal communication, Dr.D. Hooper, Berea Sleep Laboratory, Durban, South Africa, June 2006; Schwartz, 2005).

The cost of setting up full PSG units has proved problematic for provincial units in SA. The only research unit currently functioning in South Africa is at the University of

Witwatersrand which relies on sponsorship for survival. Albert Luthuli Hospital in Durban has a unit available but no posts and staff to run the unit. The ENT unit at Albert Luthuli Hospital has initiated the use of portable screening devices, with the assistance of the nursing staff (Personal communication, Dr.D. Hooper, Berea Sleep Laboratory, Durban, South Africa, November, 2006).

3.4.3. Validity and Reliability of the HypnoPTT™

Pitson & Stradling (1998) investigated HypnoPTT™ and overnight full PSG and divided patients into three groups according to the severity of their disorder. Some patients were tested in the laboratory and others at home. The reproducibility between the laboratory and home studies was reasonable ($r = 0.87$ for inspiratory BP falls and $r = 0.81$ for arousals). Differences between between the groups were significant ($p < 0.001$ for inspiratory falls, /> O.0014 for BP arousals). These authors found the HypnoPTT™ instrument to be a reliable diagnostic tool for differentiating the AHI, oxygen saturations, arousals and respiratory irregularities.

3.4.4. Critique of the diagnostic properties of the HypnoPTT™

The obvious disadvantage of the HypnoPTT™ systems is the fact that EEG is excluded. This means that no brain wave activity to evaluate sleep staging and cycling is recorded. EEG waveforms are one of the most important markers of sleep pathology in scientific laboratories, and undividedly form the backbone of PSG for documenting and differentiating sleep disorders such as insomnia, restless leg syndrome, periodic limb movement disorder and nocturnal epilepsy (Chokroverty, 1999; Stevens, 2004). In

clinical settings however, when a quick diagnosis and initiation of treatment are paramount, HypnoPTT™ systems hold their own and adequately differentiate respiratory and cardiac events and arousal (Pitson and Stradling, 1998). The face validity of such a system is therefore strong however, Olsen et al. (2003) report that the construct validity of the HypnoPTT™ system is *reasonable* and should be viewed guardedly.

In a review for clinicians on OSA management and treatment, Olsen et al. (2003) are cautious regarding the use of screening instruments for diagnosing OSA. Their reservations are supported by retrospective research and the fact that reimbursement for CPAP machines is not recognized if the sleep study is not performed in a monitored hospital setting and based on at least 120 minutes of recording. All researchers however do not support this opinion. The perception that screening devices are invalid is changing rapidly in view of the distinct advantage of doing home studies and the similarity of the raw data recorded and analysed by digital software (Pitson and Stradling 1998; Personal communication, Dr.D. Hooper, Berea Sleep Laboratory, Durban, South Africa, June 2006; Stevens, 2004; Swartz, 2005). There is no doubt that in poorly resourced primary health care settings full PSG is impractical. One or two screening devices in each facility would be efficient and effective for objective diagnosis for OSA in the severe range after initial clinical and subjective evaluation is made.

CHAPTER 4. METHODOLOGY

4.1. Design

This study uses a prospective self-report survey to investigate the construct validity of the BQ in a clinical population. All patients were from an adult population sent to a sleep laboratory in Durban, South Africa for suspected nocturnal respiratory disorders (OSA is the primary referral question). Therefore no exclusion criteria or controls were used - the patients were considered a specialized group clinically screened by their physicians and referred for OSA. Test-retest reliability was not measured - the questionnaires were administered once on clinical intake.

4.2. Hypotheses

4.2.1. *Hypothesis 1*

There is statistically significant correlation between the BQ items 1-10 and the physiological measures of OSA, namely the physician's report, which includes the AHI, snoring, ANA's and oxygen saturation levels in a clinical adult South African population.

4.2.2. *Hypothesis 2*

Using the physician's report, which is a clinical evaluation including the sleep study results, as the dependent variable in statistical analysis, the BQ will demonstrate sufficient sensitivity to OSA symptoms, to justify its use as a screening and/or diagnostic instrument in the South African clinical context.

4.3. Patients

A convenience sample of OSA patients was obtained from the sleep laboratory in Durban, South Africa between June and November 2005. The study criteria included all races and gender in an adult population (>21 years old). In total, 109 subjects came to the sleep laboratory for overnight sleep studies. Ninety seven (97) patients consented to participate in the research project. Patients completed the BQ after clinical evaluation, before receiving instructions on the use of the HypnoPTT™. The respondents are representative of a socio-economic class that is able to afford private medical care.

4.4. Ethics and consent

This research was conducted in accordance with ethical guidelines, as described in the *Psychological Association of South Africa: Ethical Code for Psychologists.* The School of Psychology, University of KwaZulu-Natal (Pietermaritzburg) ethics committee and the sleep laboratory in Durban, South Africa approved the protocol of this dissertation (Reference: HSS/06056A). Human rights and professional ethics were adhered to at all times. This study is non-invasive and did not pose any harm to the subjects, cause alienation or dehumanization to those who volunteered to take part in the study. The right to withdraw at any time, not to be labeled and to privacy was guarded. No patient names or details were entered onto the questionnaires. Only coding was used. Both the researcher and the sleep physician uphold the confidentiality of the study in terms of the data recorded. All records are kept to locked cabinets in the physician's office or in the researcher's study at home.

Verbal consent was obtained from each patient prior to completing the BQ. The physician explained the facts regarding the nature of the BQ and the research project to patients in detail. He highlighted the fact that he does not rely on the BQ responses in any way to make a diagnosis of OS A. The BQ does not influence, nor is it any part of the diagnostic procedure. Netzer et al. (1999) considered verbal agreement and completion of the BQ as adequate consent. Likewise, in this study the fact that the subjects agreed to complete the BQ was considered consent, after detailed explanation of the rights of the patient using an ethical guideline consent format (Appendix D2). This included permission for the researcher to have access to patient files. This method was used in preference to written consent, which can violate the confidentiality of patients. All patients were informed regarding the confidentiality of the study. The BQ was completed in the presence of the physician. To standardised the procedure, the patients completed the questionnaire in the physician's office, which was a private, uninterrupted setting (Appendix Dl).

4.5. Procedure

The procedure was threefold. Firstly, the attending physician at the sleep laboratory obtained a sleep history during clinical intake, which included demographic data, blood pressure (reported), a Body Mass Index (BMI) calculation using the height and weight of the patient and subjective reports of sleep problems. Secondly, the patient was informed regarding the BQ and consent was obtained to complete the questionnaire. A translation into isiZulu, the local African language was provided for patients who did not speak English. All patients chose to complete the questionnaire in English. The isiZulu questionnaire was therefore not used but is available for perusal in Appendix B. It is

envisaged that this questionnaire will be available to other researchers for validation in a population including more isiZulu speakers.

Thirdly, the patient was sent home with the portable overnight home-study unit capable of recording data throughout the night. The subjects managed the HPPT™ at home, after detailed instruction. The system is user friendly, requiring the attachment of a nasal canulla, an oximeter probe attached to the index finger, and two electrocardiogram leads attached to the left chest area. These leads recorded airflow, oxygen saturation, pulsatile volume and heart rate respectively.

4.5.1. The Berlin Questionnaire (Appendix A)

Patients completed the questionnaire at the physician's desk, but the physician did not contribute to the answers in any way. The patient was able to ask the physician for assistance if they did not understand questions after the physician explained in detail the purpose of the study and gave instructions on how to complete the questionnaire. The physician reported that patients made very few enquiries; and generally found the BQ questionnaire user-friendly. The questions asked were generally regarding occasional clarification of the meaning of words or expressions such as "up to par" and "quit". Some patients felt it was important to take part in the study as they felt it contributed to research, which they said may help others in the future.

4.5.2. The HypnoPTT™

The procedure for obtaining HypnoPTT™ data during sleep was as follows:

1. The physician instructed the patient on the home recording of the HypnoPTT™ performed a dummy run with the patient and sent him/her home for the night with the HypnoPTT™ equipment.
2. The patient attached and removed the equipment, and initiated and terminated the HypnoPTT™ machine him or herself, returning the equipment to the sleep laboratory the following day.

4.6. Data analysis

The results were analysed using the Statistical Package for the Social Sciences (SPSS®' for windows, version 11.5 and 13 (SPSS®, Inc., 2006). Missing data was accounted for in the analysis as a 'no entries' due to the fact that some patients completing the BQ did not qualify for HypnoPTT™ data analysis (incomplete or spoiled studies) and vice versa and furthermore, individual variable data was missing selectively across measures of both the BQ and the HypnoPTT™. This was due to many factors such as subjects not understanding questions or simply not knowing the answer in the BQ and therefore leaving out these items, or parameters not recorded on individual physiological measures of HypnoPTT™ data. Individual variables therefore differ in the total number represented. Missing data are expressed in the percentage of completed questionnaires and in the total number of subjects for each variable.

4.6.1. Data loading and analysis

The variables questioned on the BQ asked the subject to record:

1.) Height and weight (the physician and/or researcher calculated the BMI).

2.) Snoring - yes/no

A 4-point frequency scale was used to grade each question. Most questions were coded and loaded into SPSS® according to the scales 0 = frequently; 1 = 3-4 times a week; 2 = 1 -2 times a week; 3 = 1-2 times a month and 4 = never or nearly never, or according to 0 = yes; 1 = no. The questions were also categorized (Netzer et al.1999; Sharma et al. 2006).

Category 1:

3.) Level

4.) Frequency

5.) Disturbance to others

6.) Breath-holding

Category 2:

7.) Fatigue on awakening

8.) Excessive daytime sleepiness (EDS)

9.) Sleepiness whilst driving

Category 3:

10.) A history of high blood pressure

Appropriate reversals of BQ questionnaire data were made. This was necessary to ensure that all questions were rated according to 0 = lowest value and 1/2/3/4 were incrementally the highest values.

A descriptive analysis was conducted to examine distributional characteristics and demographics of the sample. Cronbach a was used to examine reliability as a measure of internal consistency among individual questions within symptom categories (snoring, EDS, driving while sleepy and a history of high blood pressure). The Cronbach a ranges from 0 to 1.0 and reflects the extent to which the items are measuring the same thing. Pearson's Correlation coefficients was used to compare questionnaire responses to the HypnoPTT™ data. This analysis is a method of measuring a correlation between two quantitative variables that are related in a linear fashion. Multiple linear and multinomial regression analysis was applied to analyse the separate and joint influences of the BQ questions as the independent predictor variables on dependent variables. The AHI was considered the most robust dependent as well as snoring, lowest oxygen desaturation and ANA's according to international consensus (AASM Task Force report, 1999).

The data was initially evaluated in terms of the patient's characteristics and demographics. Thereafter the BQ data was examined according to each question to evaluate the prevalence of symptoms and behaviour indicative of OS A. A brief synopsis of gender was made from the BQ data. Age matched gender comparisons could not be made due to the skewed proportion of males to females. From the BQ data, the physician's result was explored using a Pearson's correlation coefficient to ascertain whether the final report represented results in line with international consensus.

All this information was then used to correlate subjective and objective data and formulate dependent and independent variables for stepwise linear and multinomial regression, which was then used to investigate the possibility of predictive relationships between BQ and HypnoPTT™ data.

This category analysis was computed in SPSS using equations to delineate each category. The computations can be viewed in Appendix H and is detailed in 4.6.4. under risk factor analysis.

4.6.2. HypnoPTT™ data loading and analysis

1. One hundred and nineteen (119) patients recorded all night sleep studies.
2. The physician downloaded the data from the HypnoPTT™ after computerised analysis, which elicits categorical results from the data acquired.
3. The physician then manually checked the raw data which can be viewed page by page, to confirm the accuracy of the computerised analysis. This is common practice in sleep laboratories - the computer often over or under scores events (Stevens, 2004; Personal communication, Dr. E. Ebrahim, London Sleep Centre, London, October, 2004; Dr. D. Hooper, Berea Sleep Laboratory, Durban, June, 2006; Prof. V.K. Somers, Mayo Clinic Sleep Research Unit, Rochester, USA, June 2006).
4. Data was saved to the main database and transferred to CD discs.

The physician generated a report (loaded as *physician result)* based on his clinical impression, the results from the HypnoPTT™ recording and international criteria for diagnosing OSA *(ibid).* This report assessing the severity of OS A reflects two aspects regarded as critical by current sleep analysis standards (Chokroverty, 1999; Olsen et al, 2003; Stevens, 2004; Personal communication, Dr. E. Ebrahim, London Sleep Centre,

London, June, 2006; Dr. D. Hooper, Berea Sleep Laboratory, Durban, June, 2006; Prof. V.K. Somers, Mayo Clinic Sleep Research Unit, Rochester, USA, June 2006, Table 4-1):

a. The data recorded by the HypnoPTT™ device is perused with particular reference to physiological data and empirical evidence as noted. The AHI, the degree of oxygen desaturation, the level of snoring and ANA's are considered gold standard measurements. All these parameters are rated according to severity prior to loading. These ratings can be viewed in Table 4-1. for snoring, AHI and oxygen desaturation.

b. The physician's clinical impression, supported by evidence as discussed above.

The HypnoPTT™ data was divided up into results pertaining to the AHI, snoring behaviour, oxygen desaturation and ANA's according to severity ratings in the mild, moderate or severe range.

4.6.3. Risk category analysis

A risk factor analysis was made to categorise patients according to low and high risk in accordance with Netzer et al. (1999). Furthermore, these researchers showed that the high-risk group had an AHI >5. Sharma et al. (2006) also applied these categories to predict an AHI >5 for high-risk BQ cases. Cases from the current study were similarly rated.

In category 1, high risk was defined as persistent symptoms (>3-4 times a week) in *two or more questions* about their *snoring* or *breath-holding* behaviour. In category 2, high risk was defined as persistent symptoms (>3-4 times a week) *waketime sleepiness, drowsy driving* or both. In category 3, high risk was defined as a *history of high blood pressure* or a *BMI more than 30 kg/m^2*. To be considered a high risk for OS A, a patient *had to qualify for at least two categories.* Those who denied having persistent symptoms or who qualified for only one symptom category were placed in lower risk (Netzer et al.1999).

These category calculations are summarised in a framework in figure 4-1.

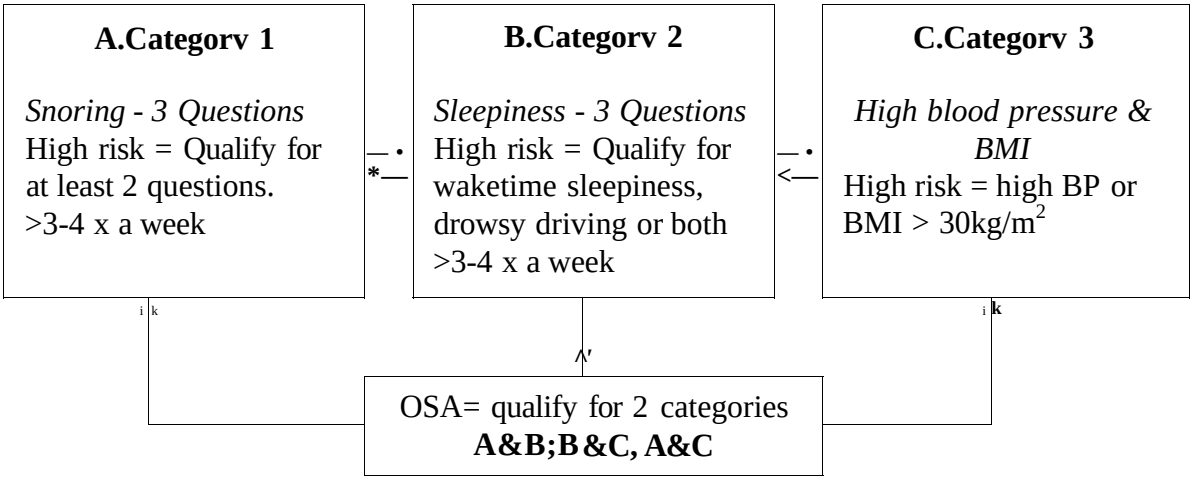


Figure 4-1. Framework showing high and low risk category calculations according to Netzer et al. (1999).

This category analysis was computed in SPSS using equations to delineate each category. Further analysis estimating the probability of an AHI>5 predicting the high-risk case was made using a multinomial logistic regression model (Appendix H).
The multinomial model was used to account for the classification of more than two classes (the rating scales) and handle the AHI ratings as the dependent variable.

Table 4-1. Table showing the ratings for HypnoPTT™ variables according to physician rating and expert consensus.

Total Snoring	Oxygen saturation level	AHI
0. <20 snores	0. Normal - >96%	0. <5 per hour - normal
1. 20-100	1. Abnormal-<96%	1. 5-20>-mild
2. 100-300	*Lowest O desat is	2. 20-30 - moderate
3. >300	used frequently	3. >30-severe
Dr. D. Hooper	Rechtchaffen & Kales, 1968	Stevens, 2004

ANA's were rated according to events less than 14 per hour, which are considered within the normal range and events over 14 per hour, which are considered abnormal.
BMI was divided into obese and not obese. A BMI >30 kg/m^2 was considered obese in accordance with international clinical agreement.

CHAPTER 5. RESULTS

Of the 124 patients seen in the sleep laboratory from June to November 2005,**119** (N) patients were booked for **HypnoPTT™** sleep studies and verbal consent obtained from the sleep physician to complete BQ's. Missing data was taken into account during analysis. The missing patients were excluded on the basis of inadequate or spoiled data acquired by the sleep system, and a few variables values, which did not record data during the night. Three (3) patients did not have successful studies and are therefore represented as "empty" cells in the data sheet. The remaining **116** and were entered for analysis.

Patients completed the BQ subjective questionnaire prior to undertaking HypnoPTT™ overnight sleep studies. One hundred and ten **(110)** patients completed BQ. Nine (9) patients did not complete the BQ. Missing cells represent individual questions not filled in by subjects. Any extra missing objective HypnoPTT™ data represents individual variables not recorded by the device or questions left out by patients in the BQ subjective data because they did not know the answers or spoiled the response (e.g. ticked two boxes in one question).

Summary of the number of patients participating in the study

- N=119
- HypnoPTT™ data: n = 116 (3 not completed - 2 recording failures, 1 patient absconded)
- BQ data: n = 110 (9 not completed)

Recording time ranged between 137 minutes and 719 minutes. The standard cut off time is less than 120 minutes therefore no studies were excluded on the basis of inadequate recording time. The average recording time was 445 minutes (approximately 7.5 hours). No patients chose the isiZulu translation - all patients completed the BQ in English.

5.1. Patients and demographics

This data is derived from the clinical intake and HypnoPTT™ data.

The mean age was 46.9 years (range 21-78, SD - 11.3).

The distribution of race shows a preponderance of white subjects (73 subjects - 61 %) followed by indian subjects (37 subjects - 31 %). There were 4 (3.4 %) black subjects and 2 (1.7 %) coloured subjects.

The following results are derived from the BQ questions (height and weight were verified by the physician).

In response to biological data the following results are noted:

BQ Question 1:

Height: The mean height of the patients was 1.7 m (SD = . 10; Range 1.4 - 1 . 9 m).

Weight. The mean weight of subjects was 98.2 kgs. (SD = 22.6, Range 54 - 185).

BMI: The mean BMI was 33.9 kg/m^2 (Obese range).

5.2. BQ data - Prevalence of symptoms

The following results are descriptive statistics from BQ data addressing each BQ question individually to examine the prevalence and severity of symptoms and behaviour. Each question was loaded into SPSS® in the same format as the questionnaire. The lowest score (0) represents the normal or low risk level and the highest score (3 or 4) the high risk level.

5.2.1. Category 1 - Risk group; Questions 2 - 6 ; Snoring and breath-holding

BQ Question 2

The majority of respondents 108 (98.2%) reported "yes" to the question *do you snore* (Figure 5-1).

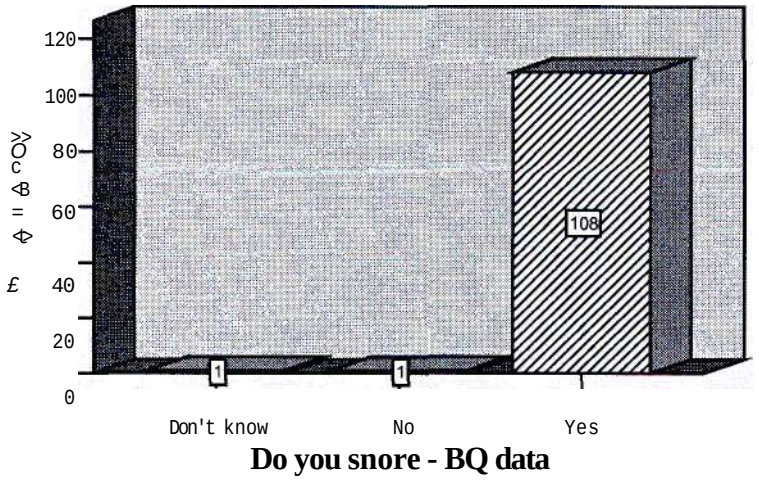


Figure 5-1. BQ 2 results showing "do you snore?" data (Missing = 9).

BQ Question 3

The majority of respondents reported high *snoring volume:* 79 (66.4%) reported that their snoring could be heard in adjacent rooms (Figure5-2).

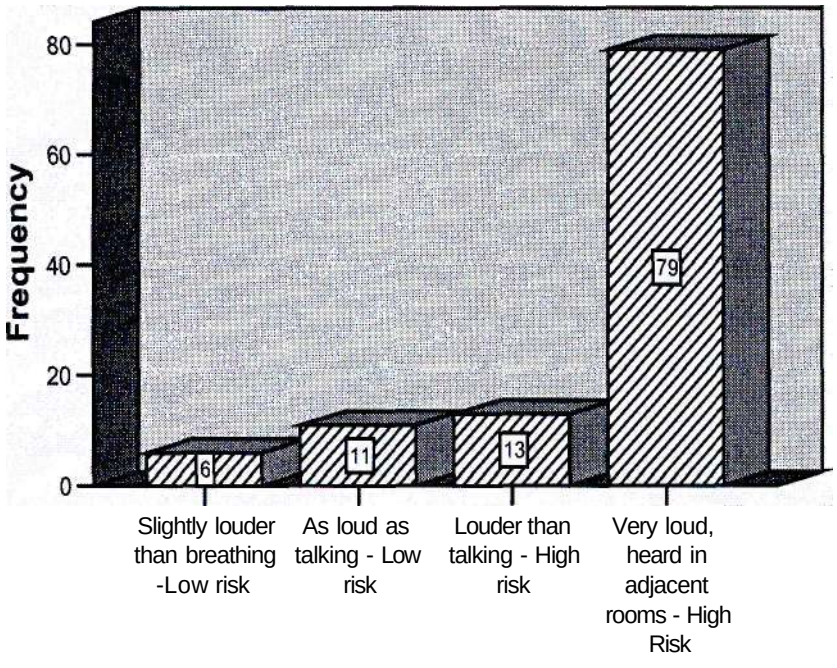


Figure 5-2. BQ 3 results showing "your snoring is".. .volume of snoring data (Missings 10).

BQ Question 4

For *snoring frequency*, 99 (83.2 %) patients reported snoring nearly every day (severe range) (Figure 5-3).

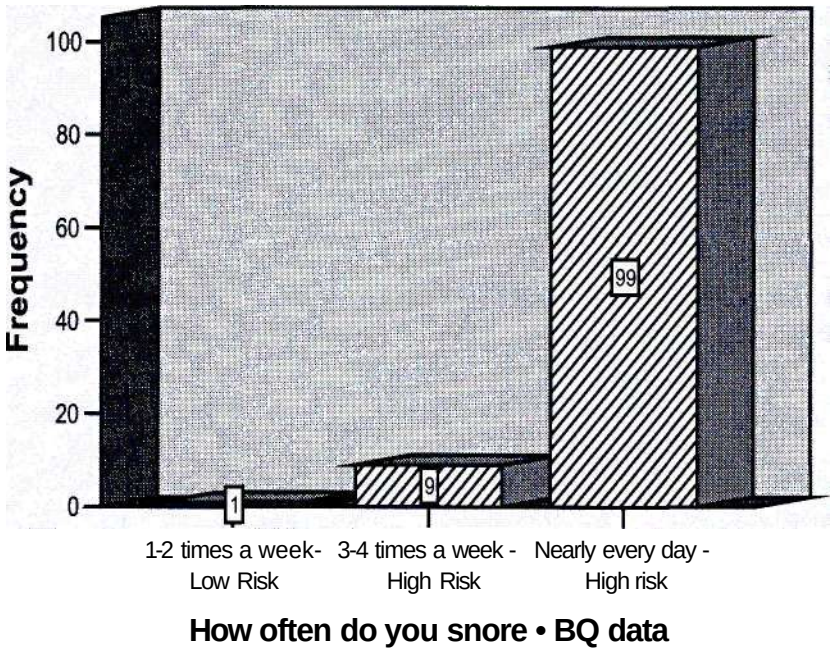


Figure 5-3. BQ 4 results showing "how often do you snore" data (Missing = 10).

BQ Question 5

Snoring bothers others, 106 (89.1 %) reported yes (Figure 5-4).

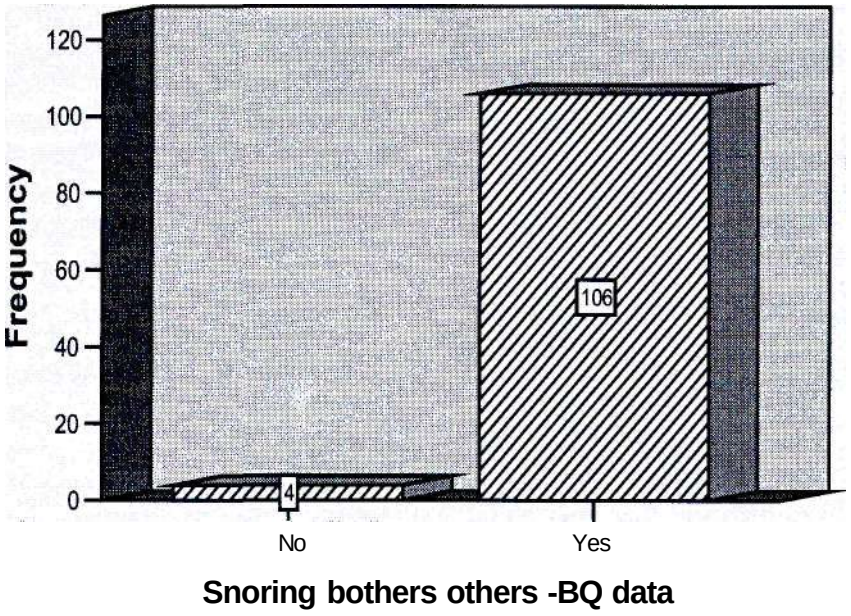


Figure 5-4. BQ 5 results showing "snoring bothers others" data (Missing = 9).

BQ Question 6

In response to the question of others observing *breath-holding events* during sleep, 51 (42.9%) breathing pauses were noted nearly every day (Figure 5-5). 20 missing entries are noted, 9 of which are missing data due to BQ's not being completed, the remaining 11 represent non-responses from patients. These patients were unaccompanied by a partner and/or slept on their own - they simply did not know if they hold their breath during sleep.

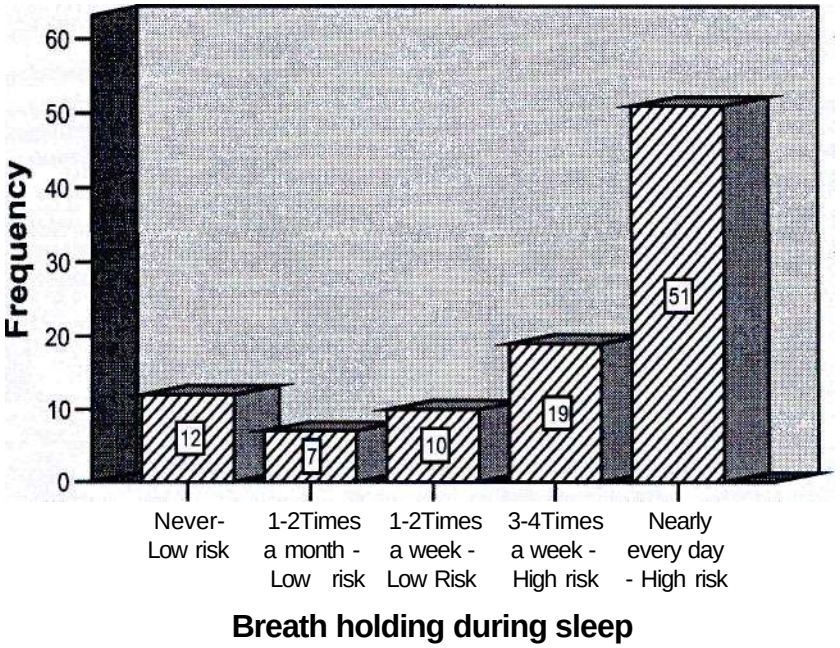


Figure 5-5. BQ 6 results showing ".. .hold your breath" data (Missing = 20).

5.2.2. Category 2 - Risk group; Questions 7-9; Sleepiness factors

BQ Question 7

In response to questions regarding *not feeling refreshed after sleep, 11* (64 %) patients complained of sleepiness on awakening (Figure 5-6).

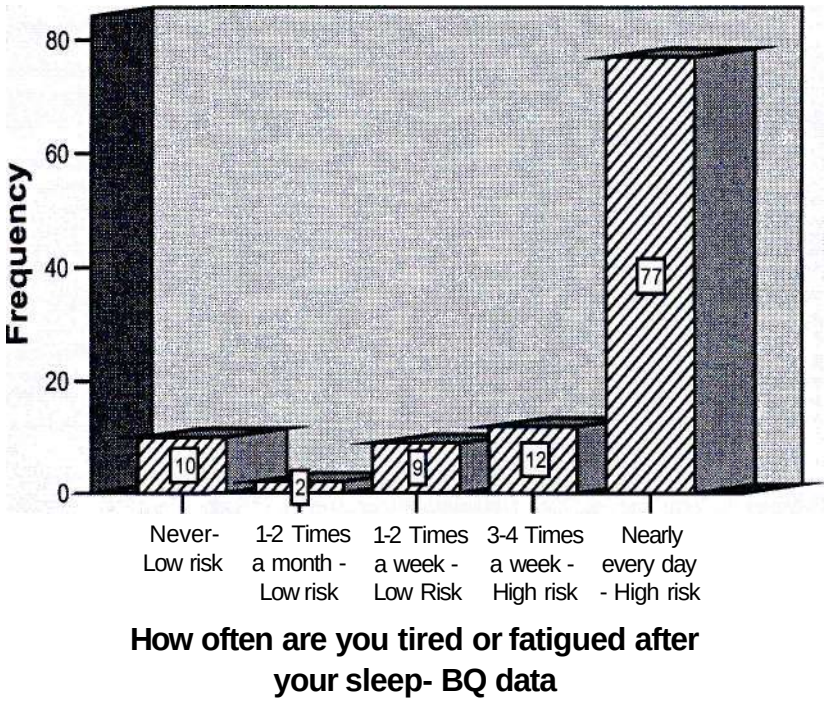


Figure 5-6. BQ 7 results showing "how often are you tired after sleep" data (Missing = 9).

BQ Question 8

On the question regarding *daytime sleepiness (EDS),* 70 (58.8 %) respondents reported feeling sleepy nearly every day (Figure 5-7). 1 participant did not respond to this question.

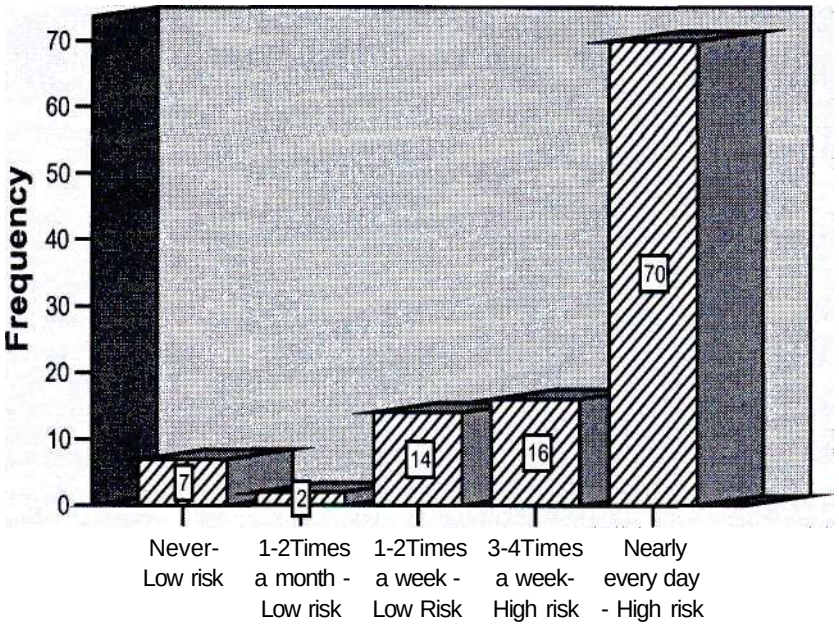


Figure 5-7. BQ 8 results showing "during your wake-time do you feel tired" (EDS) data (Missing = 10)

BQ Question 9

70 (58.8 %) Of the patients denied ever feeling sleepy whilst driving (Figure 5-8) and 13 (10.9 %) were aware of sleepiness whilst driving. One subject did not complete this question.

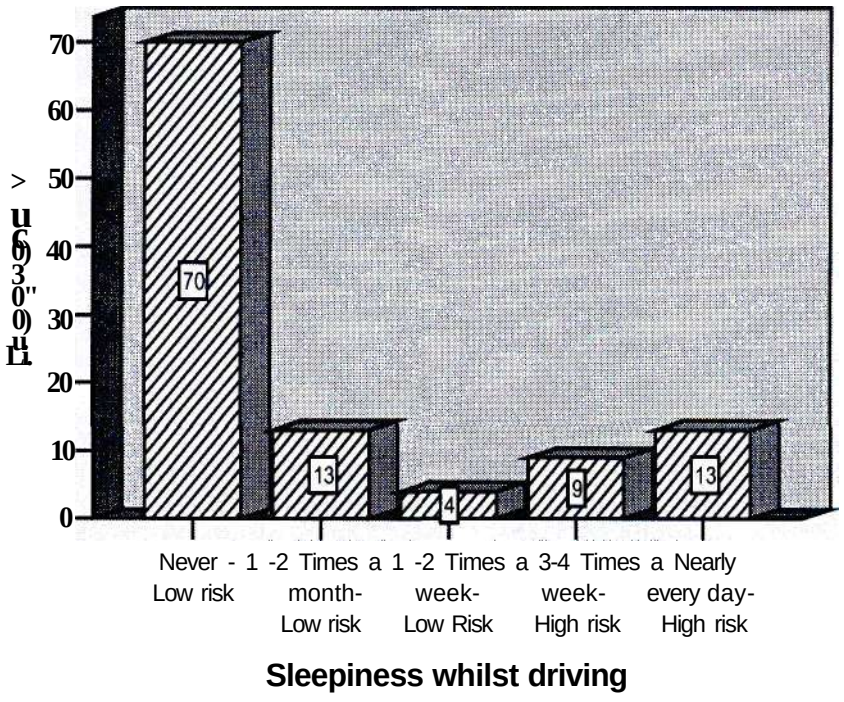


Figure 5-8. BQ results "ever nodded off while driving" (Missing = 10).

5.2.3. Category 3 - Risk group Questions 1 and 10, BMI and high blood pressure

Question 1: Body Mass Index:

Forty-eight (48, 40.3 %) of the patients have a BMI below 30kgs/m^2 and 68 (57 %) had a BMI above 30kgs/m^2 (Figure 5-9).

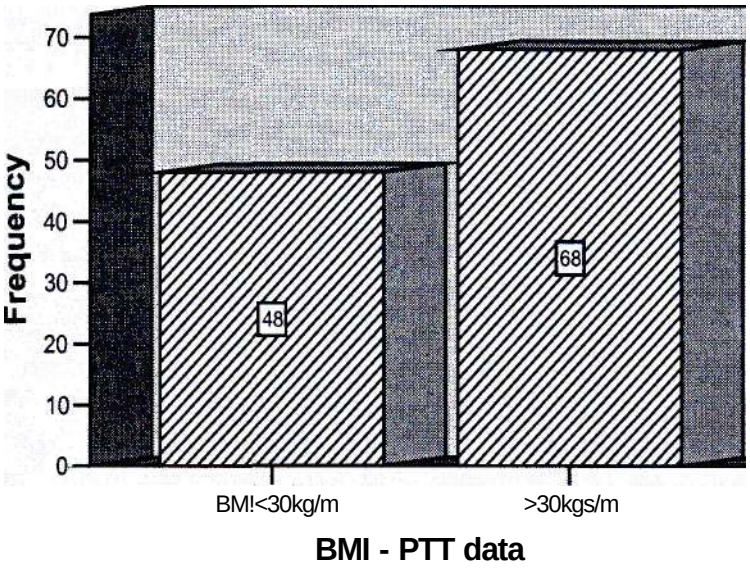


Figure 5-9. BQ results showing the BMI data (Missing = 3)

Question 10

On reports of a history of high blood pressure, 44 (37 %) patients reported a known history high blood pressure, and 66 (55%) either said they did not have a history or did not know they had suffered from high blood pressure (Figure 5-10).

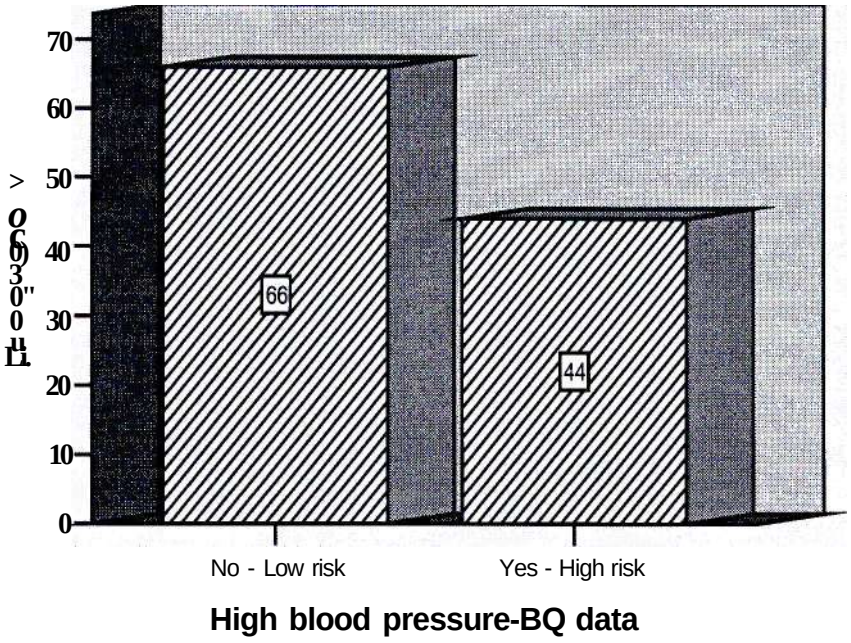


Figure 5-10. BQ 10 showing results of "history of high blood pressure" (Missing = 9).

For efficient diagnostic purposes it is generally practice when using questionnaires to develop a total score and rate this scoring according to normal and abnormal scores with a cut-off range. For example the Epworth Sleepiness Score (ESS) (Appendix C) has a maximum score of 24. Scores over 11 are considered the cut-off for sleepiness, 16 and over are rated as moderate to high levels of sleepiness (Johns, 1991). The highest total score possible for the BQ is 28 points. Figure 5-11 shows the frequencies of the BQ total scores for patients in this sample. The mean total score was 21 (SD 4.4, Range 8 - 28). 17 patients scored 23 points. Missing data is accounted by 9 full BQ's and any BQ's, which had empty questions (21). In other words if even one response was missing in the full set of questions, it was excluded.

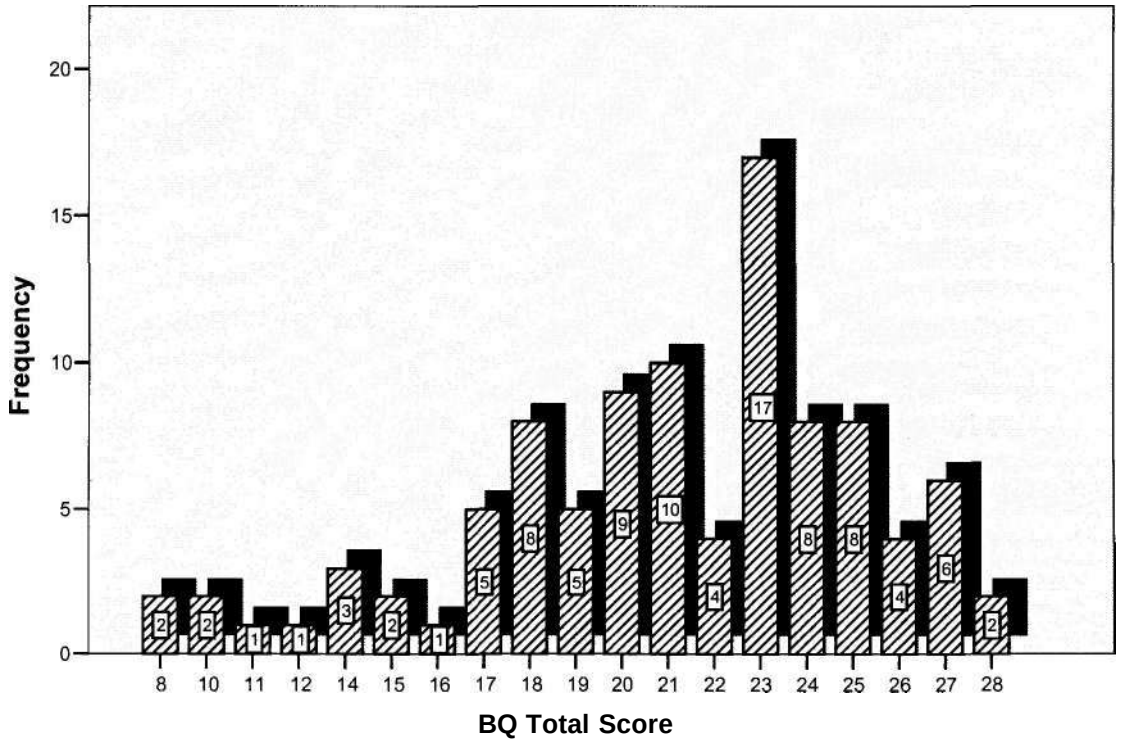


Figure 5-11. Frequency hypnogram showing the total BQ score distribution (missing = 21).

5.3. BO - Gender, culture and risk factor considerations

There are 93 (78%) males and 23 (19%) females in this sample. Statistical inferences were not possible because of the low number of females in the sample. Age-matched samples therefore could not be examined. The fact that this sample of patients from a clinical population has a high amount of males is significant in terms of historical and current empirical data quoting risk factors. Research consistently quotes high risk for OS A is the "middle aged male" (Chokroverty, 1999; Stevens, 2004). Descriptively, age distribution did not appear to be different between male and female groups:

Males - Mean age 46.8; SD 11.5; Range 26-75 years.

Females - Mean age 44.8; SD 13.6; Range 21-78 years.

5.4. HypnoPTT™ data - Prevalence of symptoms and behaviour

Heart rate was recorded throughout the night. The mean heart rate recorded was 70.1 Beats per Minute (BPM) (Range 48 - 101, SD = 10.2). The mean minimum heart rate was 45.1 BPM (Range 45 - 26, SD = 8.9) and the maximum heart rate mean was 115 BPM (Range 73-82, SD = 16.5).

As a means of finding a specific criterion-based variable to assess criterion validity, the physician's result, which is largely based on a clinical impression, and supported by HypnoPTT ™ physiological data, was selected (detailed in Chapter 4. Methodology 4.6.2). Empirical evidence consistently quantifies diagnostic protocols, which are particularly sensitive to the diagnosis of OS A (AASM Task force report, 1999).

Diagnostic criteria grades OSA into normal, mild, moderate and severe categories. This data was obtained from the physician's final report sent back to the referring physician.

Analysis of the physician result shows 64 (42.7%) subjects fell into the severe range (Figure 5-12). Fairly equal distribution is noted between moderate and mild cases. Only 8 patients fell into the normal range.

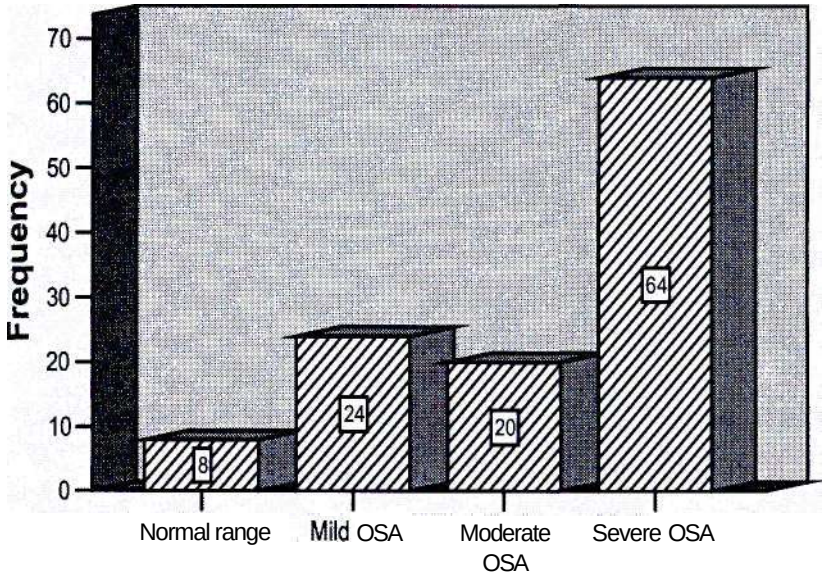


Figure 5-12. HypnoPTT™ data showing the OSA severity ratings from the physician's final report (missing = 3)

5.4.1. Examining the criteria used in the physician's report

As a starting point, it was deemed necessary to examine criterion validity in the physician's final report to verify results consist with current practice. The AHI is the most consistent variable used by most researchers. In addition the level of snoring, lowest oxygen saturation value and the total snoring value are consistently reliable variables (Stevens, 2004; AASM Task force report, 1999). Of late the use of ANA's is also being incorporated more often as a measure of sleep fragmentation, which is known to contribute to EDS. ANA's have therefore been included in the analysis (Stradling & Davies, 2004). Wolk et al. (2003) also link a BMI>30kg/m^2 with OSA severity.

Examination of the total AHI with the physician's result showed a strong relationship *(r* = .79,p < 0.01). Correlation with the ANA's was also fairly high (r = 0.58,/? < 0.01). Moderate correlations are noted between the physician's result and the lowest oxygen value *(r* = .57, p < 0.01). The BMI was significant, but with a modest correlation (r = 0.25, p < 0.01). No significance is noted between the physician's report and snoring events (r = *.05, p* < 0.05) (Table 5-1.).

Table 5-1. Correlations showing the relationship between the physician's results and HypnoPTT™ variables used globally for OSA severity rating. (Missing = 3 PTT data, 5 ANA values not recorded)

		AHI Total	**Physician Result -**	**Snoring**	**~& lowest sats**	**ANA**	**BMI**
AHI Total	Pearson Correlation	**1**	**.787(**)**	.028	707(**)	.775(**)	.279(**)
Physician result	Pearson Correlation	**787(**)**	**1**	**-.049**	572(**)	.588(**)	.245(**)
	N	**116**	116	116	116	111	116

** Correlation is significant at the 0.01 level (2-tailed).

5.4.2. AHI results recorded by HypnoPTT™

The severity of the AHI (calculated as the number of times per hour the subject held his/her breath) from the physiological data recorded, showed the majority of patients were in either the mild, moderate or severe range (35, 29.4%) (Figure 5-13).

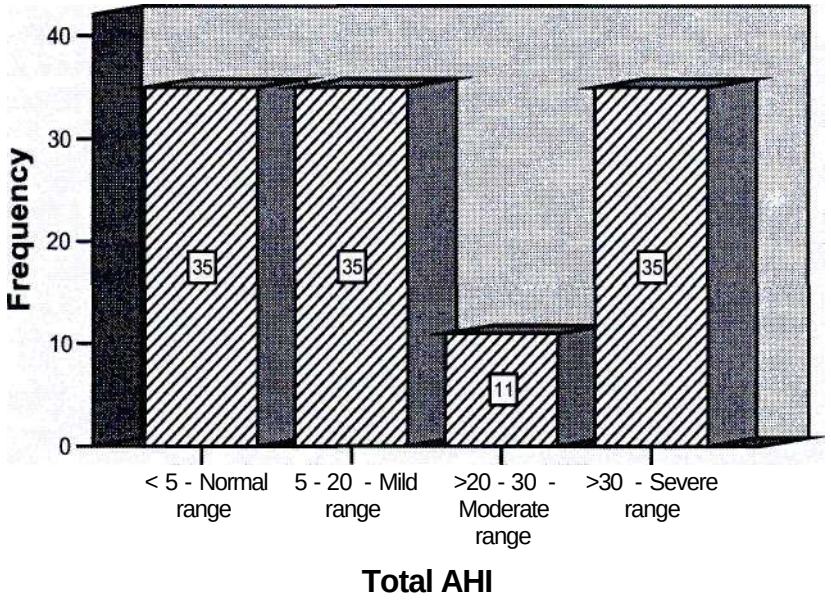


Figure 5-13. AHI severity ratings recorded by HypnoPTT™ (missing = 3).

The AHI showed significant correlations with the ANA's (r =0.78, p <0.01), the lowest oxygen value (r = .70, p <0.01) and mild significance with the BMI (r = .28,/? <0.01) (Figure 5-1). A full table of the correlation values are displayed in Appendix I.

5.4.3. Lowest oxygen saturation recorded by HypnoPTT

The mean low oxygen saturation recorded was 78.7 % (Range 49 -97, SD - 12.1). The majority of patients cluster between saturations of 85% to 95% through the night.

However 21 patients reached levels of < 60%. Figure 5-14 shows the frequency of oxygen percentage values recorded across the night.

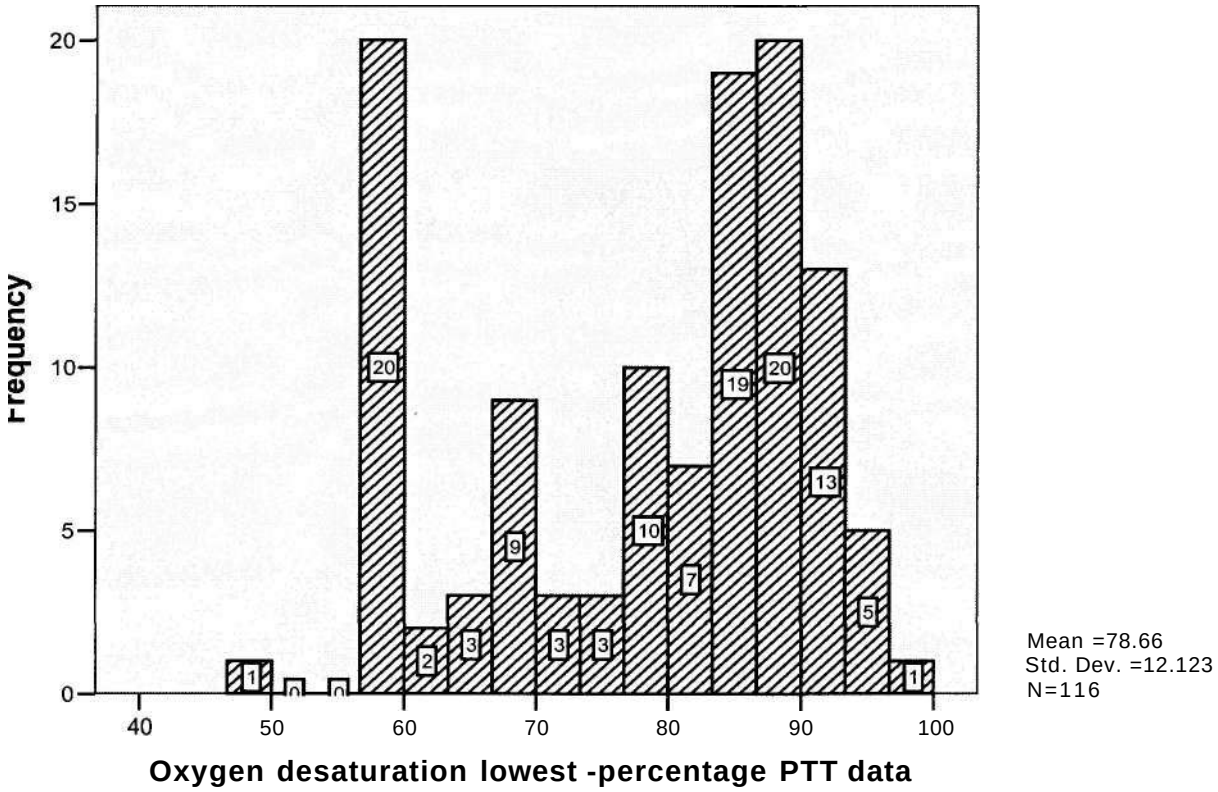


Figure 5-14. Hypnogram showing the lowest oxygen saturation values recorded the HypnoPTT™ (missing = 3).

5.4.4. Severity of snoring recorded by HypnoPTT™

Objective data indicated that in a large majority of subjects, excessive snoring occurred. Snoring was severe in most subjects (104; 8.7.48%) (Figure 5-15).

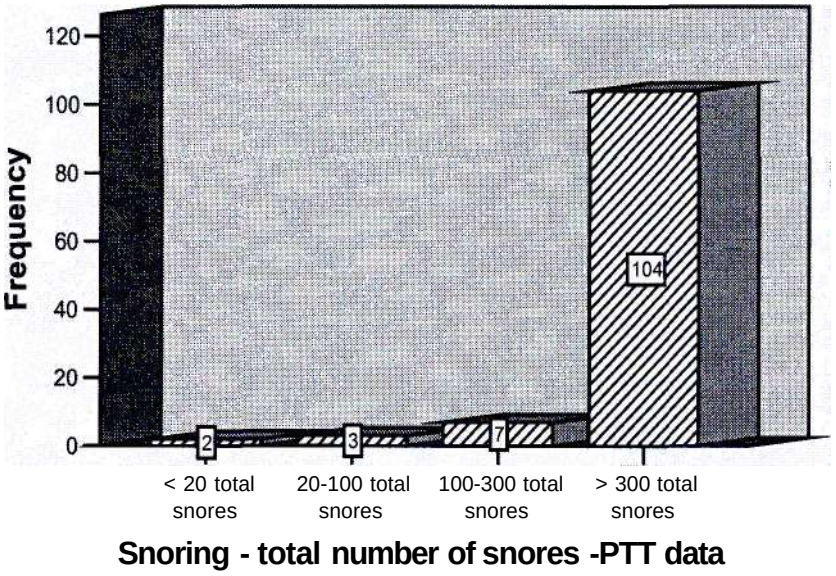


Figure 5-15. Severity of snoring recorded by HypnoPTT™ (Missing data = 3).

5.4.5. Autonomic arousals (ANA's) recorded by HypnoPTT

ANA's were graded according to events greater or less than 14 micro-arousals suggestive of sleep fragmentation. The majority of patients fell into the >14 range (111, 93%), which international criteria suggests falls within the abnormal range.

The ANA values were not recorded on 5 subjects. The number of arousals during the night ranged between 15 and 140 with the majority of subjects experiencing approximately 30-70 arousals during the night. Figure 5-16 shows the frequency of ANA's occurring across the night.

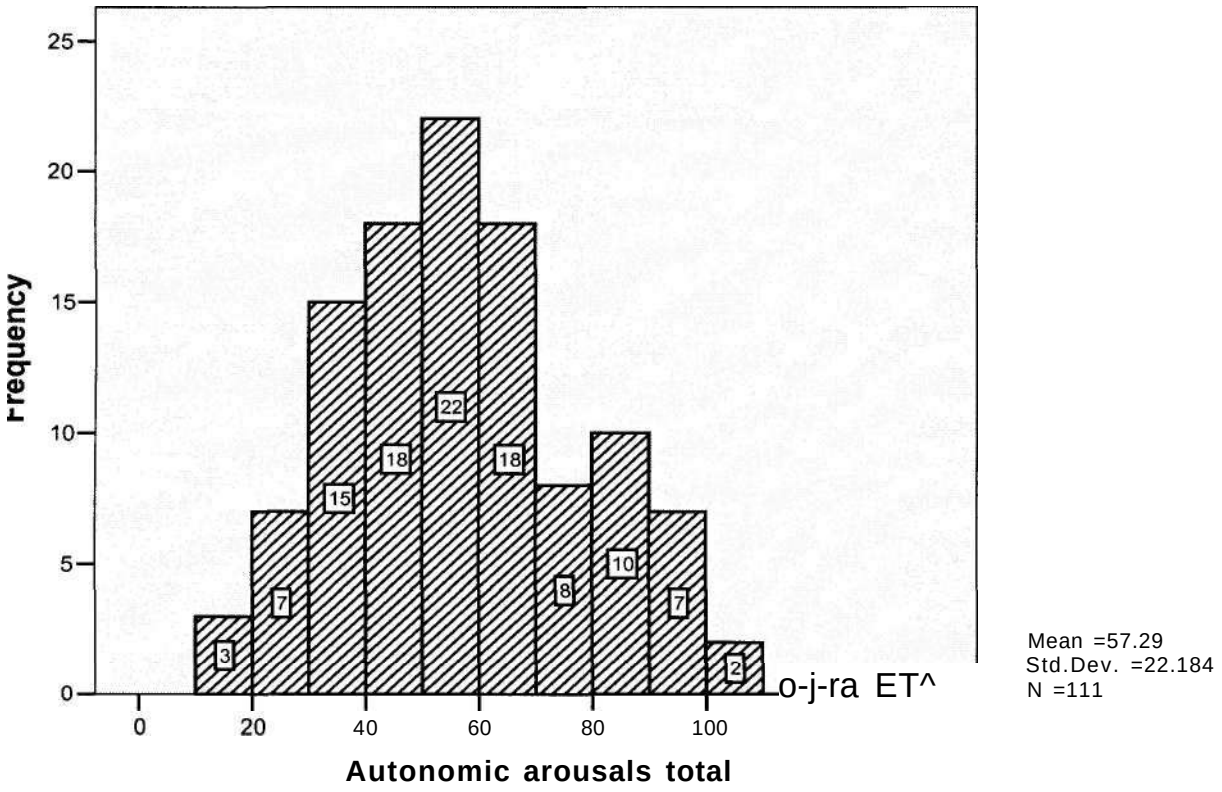


Figure 5-16. Histogram showing the frequency of ANA's across the night (Missing = 5).

5.5. Construct validity - Comparison of objective and subjective data

The validity of the BQ in this South African clinical population will be explored in this section. As discussed in the methodology, the BQ was originally the outcome of a the conference on Sleep and Primary Care involving the integration of clinical input from 120 US and German pulmonary and primary care physicians to simplify recognition of OS A. Whilst the questionnaire is undergoing validation in Europe and USA by various authors (in progress) it was highly recommended by the Mayo Clinic group researching sleep disorders as part of their screening procedure (Personal communication, Prof. V.K.

Somers, Director, Mayo Clinic Sleep Research Unit, Rochester, USA, October 2004, February 2005).

Whilst a brief discussion on validity measures will be explored, the main focus this study is on construct validity.

5.5.1. Validity assessment

5.5.1.1. Face validity

There is current empirical evidence in other populations that the BQ represents sound clinical criteria consistent with OSA symptoms, risk factors and consequences, particularly when risk factors are divided into symptom categories separating high and low risk subjects (Netzer et al. 1999; Stevens, 2004).

The categories address:

1.) Snoring

2.) EDS, driving or both and

3.) High blood pressure or a BMI > 30g/kg 2.

At a glance, the questions in particular clearly address factors, which consistently focus on commonly known symptoms such as breath-holding during sleep, risk factors such as gender, a history of high blood pressure and BMI and behaviours such as snoring and sleepiness during the day and whilst driving.

In this population however, consistent difficulty understanding Americanisms such as "quit" or "not up to par" may have caused subjects not to complete those particular questions.

5.5.1.2. Reliability and predictive validity

The reliability amongst individual questions within symptom categories was explored as a measure of internal consistency. The Cronbach a value was 0.62 for all BQ questions. All snoring and breath-holding questions which include "snoring volume"; "snoring frequency"; "snoring bothering others" and "breath-holding during sleep" (category 1) showed a Cronbach a value of 0.40.

Questions on sleepiness - "tired after sleep", "tired during wakefulness" and "sleepiness whilst driving" (category 2) produced a Cronbach a of 0.68. Consistent with Netzer et al. (1999), when sleepiness behind the wheel was excluded, the Cronbach a went up to 0.84 in category 2.

On questions regarding high blood pressure and BMI (category 3) with the Cronbach a at 0.18, are not reliable.
(Additional statistical information is available in Appendix G).

5.5.1.3. Construct validity

Construct validity was examined by correlating HypnoPTT™ data and the BQ questions 1-10. Furthermore, a stepwise multiple regression analysis model was created in order to

examine the predictive influence of dependent variables from the HypnoPTT™ data on the BQ questions 1-10. A "total BQ" score was created as a variable against which the physician's result was cross-tabulated. The highest total score possible for the BQ was calculated as 28. (Results can be viewed in Figure 5-11).

As mentioned, the AHI index was a particularly robust variable in this study. The lowest oxygen saturation value, snoring and ANA's are frequently used to predict the presence of OSA. These variables were used as the framework for statistical analysis. No significant correlations or predictive measures were found using the total AHI or linear regressions on individual BQ questions against the selected criteria as the independent variables. The *total BQ score* however showed a moderate and significant correlation with the lowest oxygen saturation level *($r = 0.42, p$* <0.01), the physician's final result *($r = 0.24, p$* <0.05) and the AHI total (r = *0.21, p* = 0.05) (Table 5-2).

Table 5-2. Table showing correlations between the total BQ score and PTT variables. (Missing = BQ - 21, PTT - 3, total missing = 24).

		PTT Result -physician	**PTT AHI Total**	**PTT 02 Low**
BQ Total Score	Pearson Correlation	**.242(*)**	**.206(*)**	**-.415(**)**
	N	**95**	**95**	**95**

* Correlation is significant at the 0.05 level (2-tailed).** Correlation is significant at the 0.01 level (2-tailed)

5.6. Risk factor category analysis

A risk factor analysis was made to categorise patients according to low and high risk by computing the possibilities and creating separate variables in SPSS . Firstly, each category was calculated (snoring, sleepiness and high blood pressure and BMI > 30kg/m). Secondly, after the final high-risk case group was computed (Case BQ), which was a combination of the three categories in various combinations (Netzer et al. 1999) (detailed in methodology Chapter 4, Table 3-1 and Appendix H) a multiple logistic regression was used to estimate the probability of an AHI >5 predicting the high risk group. The missing data is accounted for by 9 omitted BQ's and 2 BQ's with too many empty cells to qualify as a case. The following results are noted (the pie graphs can be viewed on the next page). Multinomial regression analysis was also used to refine the possible significance of the AHI to predict high-risk cases using the AHI rating criteria.

In category 1 for snoring, 97 (81.5 %) patients qualify as high-risk cases for snoring symptoms (Figure 5-17).

For category 2, 69 (58%) patients were at high risk for sleepiness symptoms (Figure 5-18).

Category 3 high-risk analysis shows only 17 (14.3%) patients qualified as high risk cases for the symptoms of high blood pressure and/or a BMI >30kg/m^2 (Figure 5-19).

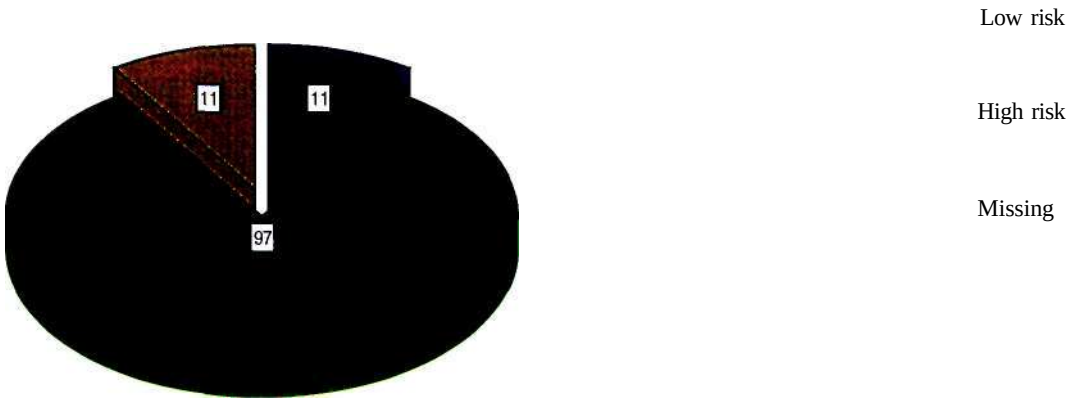


Figure 5-17. Pie graph showing risk category 1 - Snoring parameters

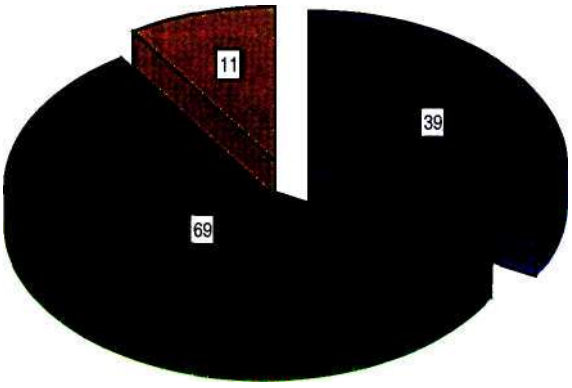


Figure 5-18. Pie graph showing risk category 2 - sleepiness parameters

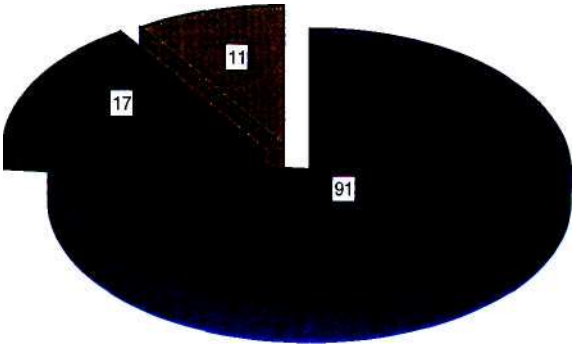


Figure 5-19. Pie graph showing risk category 3 - High blood pressure and BMI > 30kg/m parameters.

In the various combinations - qualifying for any two combinations of the high risk categories, 71 (73.1%) patients qualified as high-risk and 37 (31.1%) as low-risk cases for the presence of OSA with an AHI > 5 (CaseBQ) (Figure 5-20).

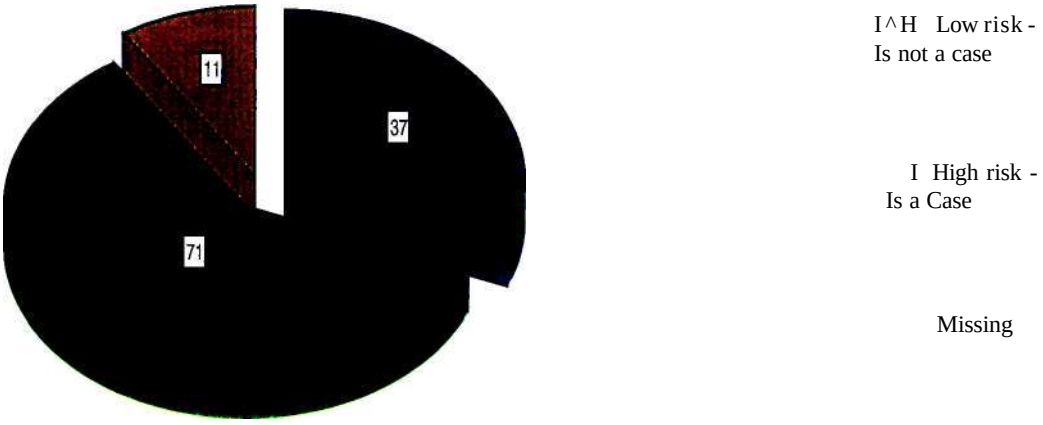


Figure 5-20. Pie graph showing high-risk category combinations = CaseBQ.

5.6.1. Using high risk cases to predict an AHI >5

The high-risk category was computed to predict an AHI >5. This analysis shows that 70 (58.8%) of the high-risk cases have an AHI >5 (Figure 5-21, Appendix H).

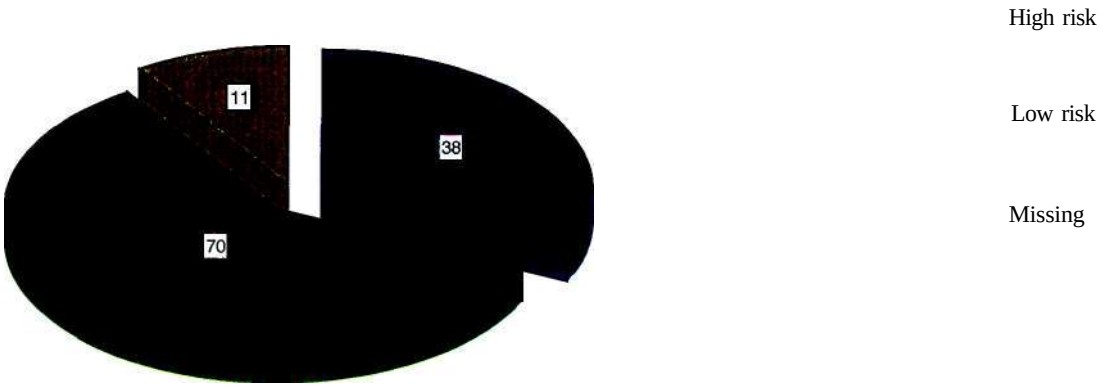


Figure 5-21. Pie graph showing high-risk cases qualifying for an AHI >5.

5.6.2. Using the AHI ratings to refine prediction of BQ high risk category

A multinomial regression analysis was used to test the BQ (variable 'CaseBQ)' as a predictor of the AHI ratings classification (<5, 5-20, 20-30 and >30 per hour). This analysis was made in order to examine the sensitivity of the BQ to identify patients in the normal, mild, moderate and severe range of OS A.

Test of the overall model-AHI (Dependent); CaseBQ (Covariate)

The Likelihood ratio and model chi-squared test (goodness of fit) analysis reflects the significance of unexplained variance in the AHI ratings (dependent variable). The AHI/CaseBQ model does not appear to be a good one, since the difference between the two ratios in the model increase in magnitude (one would expect them to decrease in a good model) (2LL = 22.17; 2LL = 35.55). Furthermore, this model is less than 0.05 *(r =13.3;p* = 0.004). One would expect a well-fitting model to be significant at the 0.05 level or better and a model shows a 'goodness of fit' when the chi-squared is not significant.

The standard error in the Wald statistics (parameter estimates — Table 5-3) of this model is inflated (Normal range SE = .569; moderate range SE = .810) suggesting Type II errors (false-negatives -thinking that the effect is not significant when it is).

Summary: The overall significance of the AHI/CaseBQ model should be viewed with caution, however based on the possible significant effect of this model to identify high-risk cases we cannot simply reject the findings of this model because many cases may been identified as false-negatives, when they were indeed cases. The parameter estimates and classification of cases indicates that the BQ is a reasonably sensitive predictor of cases in the mild range (57.1%) and severe range (80.6%) (Table 5-4).

Table 5-3. Table showing parameter estimates using the AHI rating scores and the Case BQ data (high risk group).

AHI Rating(a)	**B**	**Std. Error**	**Wald**	df	**Sig.**
Normal range <5	-.511	.327	2.446	1	.118
Mild range 5-20	-.041	.286	.020	1	.886
Moderate range 20-30	-1.609	**.490**	10.793	1	.001

a.The reference category is: >30 - Severe range. Dependent BQ = 0

Table 5-4. Table showing predicted high-risk cases for OSA using the AHI rating scores and the Case BQ data (high risk group).

Observed	Predicted				
	<5- Normal range	**5-20 Mild range**	**20-30 Moderate range**	**>30 Severe range**	**Percent Correct**
<5 Normal range	**20**	**0**	**0**	**15**	57.1%
5-20 Mild range	**7**	**0**	**0**	**24**	.0%
>20 - 30 Moderate range	**4**	**0**	**0**	**5**	.0%
>30 Severe range	**6**	**0**	**0**	**25**	80.6%
Overall Percentage	**34.9%**	**.0%**	**.0%**	**65.1%**	42.5%

The reference category is: >30 — severe range.

The fact that the use of separate high-risk category analysis may be a more sensitive AHI predictor was considered. A multinomial regression using AHI ratings and each category (cat) for snoring, sleepiness and BP + BMI, was therefore constructed.

Test of the overall model-AHI (Dependent)

Cat 1-snoring; Cat 2-sleepiness; Cat 3-BP+BMI (Covariates)

Likelihood ratio and model chi-squared test (goodness of fit) analysis shows that the category analysis combination is a well fitting model.

The difference between the two ratios in the model decrease in magnitude as one would expect (2LL = 60.40; 2LL = 41.39). Furthermore, this model is greater than 0.05 *(r =19.0; p* = .025). This model shows a 'goodness of fit' because the chi-squared is not significant O = 6.50; *p* = .369).

Cat 1 - Snoring: *r* = .903*;p* = .825

Cat 2 - Sleepiness: *r* = .12.24; *p* = .007 *

Cat 3 - BMI>30 Kg/m^2 + High blood pressure: *r* = .4.34; *p* = .226

(*Type II error possibility - assumes overall good model fit)

Standard error in the Wald statistics of this model is also mildly inflated (Table - 5-5), which suggests possible Type II inaccuracies.

Summary: The overall significance of the AHI/Category analysis model is a far more reliable measure of the sensitivity of the AHI ratings to predict the high-risk patient for OSA. The parameters estimates for snoring, sleepiness and BP+BMI are more refined showing sensitivity of the AHI to cases in the normal range (54.3% - AHI <5), the mild range (64.5% - AHI 5-20), and 25.8% in the severe range (AHI >30). Cases in the moderate range were not significant in this model. It seems that this model is more capable of refining the case recognition to include the mild cases. Interestingly, neither model is sensitive to cases in the moderate range (20-30). From a symptom point of view, snoring and BMI/BP symptoms seem to be more accurate reflections of the presence of OSA, in other words the significance values >0.05.

Table 5-5. Table showing parameter estimates using the AHI rating scores and the high-risk category groups - snoring, sleepiness and BP +BMI.

AHI Rating(a)		B	Std. Error	Wald	df	Sig.
<5 Normal range	**CatlSnore**	-.219	.994	.049	1	.825
	Cat2EDS	1.568	.623	6.328	1	.012
	Cat3BP/BMI	1.484	.862	2.963	1	.085
5-20 Mild range	**CatlSnore**	.649	1.139	.324	1	.569
	Cat2EDS	-.319	.738	.187	1	.666
	Cat3BP/BMI	.869	.680	1.635	1	.201
>20 - 30 Moderate range	**CatlSnore**	-.181	1.426	.016	1	.899
	Cat2EDS	1.053	.890	1.400	1	.237
	Cat3BP/BMI	.034	.921	.001	1	.970

The reference category is: >30 - Severe range.

Table 5-6. Classification table showing predicted high-risk cases for OSA using the AHI ratings and the high-risk categories - snoring, sleepiness and BP/BMI.

Observed	Predicted				
	<5 Normal range	**5-20 Mild range**	**>20 - 30 Moderate range**	**>30 Severe range**	**Percent Correct**
< 5 - Normal range	**19**	**14**	**0**	**2**	**54.3%**
5-20 -Mild range	**7**	20	**0**	**4**	**64.5%**
>20-30 - Moderate range	**4**	**3**	**0**	**2**	**.0%**
>30 -Severe range	**6**	**17**	**0**	**8**	25.8%
Overall Percentage	**34.0%**	**50.9%**	**.0%**	**15.1%**	**44.3%**

Summary: The overall significance of this model for diagnostic purposes is far more reliable (and therefore valid) measure than using the CaseBQ model. In other words the symptom categorization model using symptoms of snoring, sleepiness and BMI/BP refines case recognition more accurately. The parameters estimates and classification of cases indicate that in this model the BQ high-risk symptom categories are capable of identifying 54% of the cases in the normal range 0-5, which is effectively the low risk group. In the mild range (5-20) - a high-risk group, the case recognition rate is 64%. This model did not identify any cases in the moderate range but identified 26% of severe AHI range - >30 high-risk cases (Table 5-3) (Appendix K).

5.6.3. Validity and diagnostic significance of risk factor analysis findings - examining the hypotheses

For the patient to be considered high-risk, he/she experiences symptoms 3-4 times a week or more. The symptoms categories identified in this study are:

- Snoring (81 % = high risk)
- Sleepiness factors, which include feeling unrefreshed on awakening, daytime sleepiness and sleepiness at the wheel (58% = high risk)
- BMI > 30kg/m^2 and high blood pressure (14% = high risk)

The high-risk (Case BQ) group consolidates these symptoms by selecting patients based on whether they experience at least two of these symptom categories.

The sample examined in this study is a clinical population with 60 % of the cases qualifying as high-risk for OS A (CaseBQ group). In comparison Netzer et al (1999)

identified 37.5% in a primary health care USA out patient population at high-risk for OSA. Similarly Sharma et al. (2006) identified 44% as high-risk cases in an Indian primary health care out patient sample.

Internal consistency is reasonably demonstrated by a Cronbach a of 0.62 for all questions, and went up to 0.84 for sleepiness questions, excluding sleepiness behind the wheel. The comparison of the BQ (subjective) and objective sleep study findings, or construct validity suggests that the BQ is a valid instrument to identify symptoms that are considered diagnostic indicators in this clinical sample. Firstly, criterion validity is confirmed by the questions in the BQ correlating with the lowest oxygen value ($r = 0.415$, $p = 0.01$), the physician's result ($r = 0.242$, $p = 0.05$) and the AHI total ($r = 0.206$, $p = 0.05$). These parameters are all internationally recognized protocols for diagnosing OSA. The strength of this relationship is moderate however, suggesting that one cannot simply infer the presence of OSA by using the BQ in a primary health care setting at face value, for example by using a total score to diagnose the absence or presence of OSA. The questions as stated in the hypotheses then arise:

1. Can the BQ be considered useful at all in South African clinical scenarios as a screening and/or diagnostic instrument?
2. Does it have any predictive value? In other words, what is the probability that the BQ can identify cases with an AHI >5, or even ratings of the AHI from normal to severe?

In the light of categorizing the risk factors, symptoms and behaviour of OSA it seems that there is some value to be realized in using the BQ in a clinical setting.

The CaseBQ - high-risk group identified 60% of the patients with an AHI>5, which is considered moving into the abnormal range, or the range beginning to indicate the presence of OS A. Furthermore, broadly speaking, if in a model using the high-risk group (the CaseBQ model), the BQ can predict more than half (57%) of cases with an AHI <5 rating, effectively those patients who for argument's sake were referred with symptoms of snoring and sleepiness but did not present with specific OSA symptoms, and also predict up to 81% of the 'severe' cases, who may indeed have significant OSA symptoms, then it follows that this questionnaire may be valuable as an adjunct screening tool and 'symptom' diagnostic instrument in clinical settings. Statistically however, this model is unstable and may be misleading.

Statistically then, a more realistic and valid construct is found in the model using the symptom categories in combination. It seems that this model is able to refine the 81 % case recognition in the severe range for the first model. To suggest that the BQ is able to identify 65% of the cases with a mild AHI rating and 26% of the cases in the severe AHI rating group, gathers support for hypothesis that the BQ can indeed be used in South African clinical health care facilities to differentiate patients with risk factors for OSA by quantifying symptoms such as snoring, sleepiness factors and BP/BMI, in line with international consensus. The snoring and PB/BMI have greater strength for diagnostic purposes that the sleepiness factors in this study, however the research investigated consistently shows that excessive daytime sleepiness is a strong indicator of the presence of OSA and simply fragmented sleep, which is also linked to numerous other sleep disorders.

It is clear however, that the clinical impression and the ability to identify high risk factors such as obesity (BMI>30kg/m^2) and a history of high blood pressure, to recognize high-risk behaviour such as excessive snoring, breath-holding during sleep and a variety of sleepiness factors remains the most important diagnostic indicator. The importance of making an accurate diagnosis based on clinical findings, the symptomatic problems presented, collateral information and PSG investigation remains paramount. The BQ has some utility as an instrument to refine clinical intake and plan management.

CHAPTER 6. DISCUSSION

6.1. Demographics and BO findings

Descriptively, this clinical sample is a comprised predominantly of middle aged white and indian males. The average height of patients is 1.7m and a BMIkg/mg^2 of 33 kgs was reported, which is considered obese. Gender differences could not be explored due to the skewed sample. Increasingly research shows that women are under diagnosed and treated (Gibson, 2005). Interestingly, the research on obesity in this country from a sample of 13 000 men and woman >15 years old, reports that 29% of the men and 56.6% of women are obese. The obesity levels increased with age, and higher levels were found in urban African women (Puoane et al. 2002; Crowther and Pi-Sunyer, 2001). With the identification that OSA and obesity coexist (Wolk et al. 2003), it is apparent that at a public health care level, this syndrome requires our immediate attention. The current study leaves one with the impression that we have not even exposed the tip of the iceberg in the clinical health care forum. The psychological impact of obesity alone is profound; the added problem of not breathing adequately at night and the cascading consequences of OSA needs professional and specialised clinical management. Clinical health psychology is positioned ideally at a primary, tertiary level to investigate and develop policy for this syndrome.

Snoring (BQ data), which impacts on the individual and others on a daily basis, is experienced by a high proportion of the sample (81%). They also frequently have symptoms of breath holding and sleepiness in the form of not feeling refreshed on awakening and daytime sleepiness (58%). Many patients reported not frequently

experiencing sleepiness whilst driving. In the face of their severe subjective ratings of the other sleepiness questions, the latter is an interesting finding which raises the question of whether the participants were rather wary of reporting this question honestly, or that they over-reported other sleepiness questions. Empirical data suggests that subjects are reluctant to report sleepiness whilst driving for fear of restriction on driving or loss of driver's licence (Rosenthal, 2005). Subjectively, these patients reported symptoms and behaviour, which falls into a high-risk category.

A BMI >30kg/m^2 and a history of high blood pressure were reported by 57% of the subjects. Many of these patients expressed "not knowing" whether they qualified for these symptoms or not, the findings could therefore have been over or under reported. Nevertheless, if extrapolated to the general population in South Africa this figure suggests that just over half of a clinical population (in other words patients referred to specialist facilities for suspected OSA, or high-risk symptoms) could be suffering with an elevated BMI in the obese range and a history of high blood pressure. The impact on the biopsychosocial and economic areas is profound, not only in terms of mental health but prescription medication as well.

6.2. HypnoPTT™ findings

From the final analysis of the HypnoPTT™ objective findings, the average heart was not used for analysis. The physician's result proved to be a reliable indicator of the severity ratings from the HypnoPTT™ data. The AHI showed an equal distribution of patients not experiencing breath-holding to those experiencing breath-holding within the mild and severe range. Only 11 patients fell within the moderate range. The AHI in line with

empirical data showed the most robust correlations with the physician's final report (r = *.19, p* < 0.01). ANA's were also significant markers of the final report outcomes (r = .76, *p* < 0.01). In addition the lowest oxygen saturation level was also significant (r = .71, *p* < 0.01). An AHI of >5 events per hour is considered abnormal in some countries, whist others start 10. Only 35 patients in this sample do not fall within the abnormal range, which suggests that most patients in this sample will suffer the consequences of OS A if not treated. Whilst the cohort of this study will benefit from treatment, those in lower socio-economic brackets may not, unless policy changes. According to the literature reviewed, the sort of risk factors we could expect particularly in the severe range of untreated patients, would be obesity, male gender, upper airway abnormalities, cardio-vascular (particularly hypertension) and pulmonary disease, genetic predisposition. Symptoms such as headache, anxiety, depression, sexual dysfunction, cognitive impairment, reduction of grey matter in the brain, frontal lobe deficits and performance degradation, may be the presenting problems. This daunting list provides the way forward for well-supported argument regarding the impact of these risk factors and symptoms on the individual, family, occupation and community. The cost to self and state will be enormous in the untreated patients. This could be extrapolated to the number of subjects who have not been identified. No epidemiology studies have been documented in South Africa to give us an indication of the extent of the problem.

Prolonged oximetry recordings shows that the lowest oxygen saturation level mean for the sample was 78% with a range of 49-97%. This effectively means that the majority of patients saturated as low as 85-90% and in 20 patients levels fell below 60%. According to Stevens (2004) all these levels are considered low for basic physiological function and the critically low and/or fluctuation of oxygen levels may suggest the presence of

Cheyne-Stokes (noted in the late stages of cardio-vascular disease) or periodic breathing. This finding suggests that this sample of patients is at high risk for physiological deficits such as frequent autonomic arousals when the medulla is activated by fluctuating gaseous exchange (Somers, 2004). Furthermore sympathetic nervous system function is also alerted causing symptoms such as frequent urination. In addition, metabolic function is undermined *(Ibid).*

Excessive snoring and ANA's were recorded in most patients. The majority of patients experienced between 30-70 autonomic arousals during the sleep recording. This extrapolates to extreme restlessness and sleep fragmentation. Stradling & Davies (2004) define sleep fragmentation as follows. The presence of snoring increased upper airway resistance and resultant rise in inspiratory effort, which in turn causes recurrent micro-arousals - even without evidence of apnoea, hypopnoeas or hypoxia (upper airway resistance syndrome). Apnoea increases resistance to the level of prolonged partial and full arousals from sleep. The pattern of breath-holding, inspiratory effort and awakening is cyclical and persistent throughout the night. Martin (1997) produced some evidence that one night of sleep fragmentation and 'autonomic arousals' can have small effects on daytime function. The ability to measure daytime function (apart from the ESS) is disappointing but is gaining momentum, however the measurement of performance in a sleepy individual clearly shows decrements after fragmented sleep or prolonged sleep debt. The sample studied in this research are clearly at risk in terms of the profound sleep fragmentation experienced and the subsequent consequences that may ensue. The greatest concern lies with feeling sleepy whilst driving, which impacts on self and others. Micro-sleeps and early onset sleep can lead to motor vehicle accidents (Brown, 1994;

Dinges, 1995; Harrison and Home, 1996; Thorpy, 2005). Productivity is also affected, impacting on the social and occupational aspect of the patient's life (Rosekind, 2005).

6.3. Validity and reliability findings

A committee of experts gathered to discuss OS A originally designed the BQ. This group also oversaw the methodology and validation of the instrument. In particular the instrument focused on known risk factors for sleep apnoea. The purpose was to simplify the recognition of OSA. The BQ was validated in an American population. Whilst the content of the expert opinions is valued, it is well documented that psychological assessment instruments cannot simply be applied to any population on this basis; they need to be tested in other population for many important reasons such as language, culture and education. This study examined the construct validity of the BQ in a South African population. While the study focused on the construct of objective versus subjective findings, face validity, reliability, criterion validity, predictive validity and concurrent validity (the behaviour of this sample in relation to expected findings) were also examined. In particular the validation of the BQ was expected to bring about a means to increase efficiency, economy, practicality and fairness in a decision-making process for the promotion of making the right diagnosis when OSA is the underlying problem. In the clinical psychology forum it was hoped that the focus will be on the promotion of health and quality of life for patients. We expected to find a reasonable construct as the foundation for future clinical practice.

No significant correlations were found between objective and subjective data using individual BQ questions. Internal consistency using Cronbach a correlations showed

values in an average to poor reliability range, with the exception of the sleepiness parameters. Sleepiness items showed mild reliability (0.68), particularly if sleepiness whilst driving was removed (0.84). All BQ questions lowered the reliability (0.62). Snoring questions were particularly poor (0.40). These findings are not as sensitive as current research suggests (range 0.68 - 0.84). Netzer et al. (1999) calculated a Cronbach a of 0.86 - 0.92 and Sharma et al. (2006) quotes an alpha value of 0.92 - 0.96. The reason for these findings may be three fold. Firstly, this sample of patients may have overstated their problem due to psychological distress (a cry for help or exaggeration of symptoms due to consequences of OSA, particularly those in the severe range). Secondly they may not have spent enough time thinking about responses in the presence of the physician. They may have experienced feelings of self-consciousness and time urgency. Thirdly, it is likely that many patients simply did not know how to rate their symptoms without the presence of a co-habiting partner or family member. A glance at the bar graphs rating frequencies of breath-holding events and the AHI, which is effectively the objective measurement for this parameter, illustrates visually the inability of the patients to categorically rate breath-holding events (Appendix K).

Criterion validity was found to be adequate using the physician's result as a marker for frequently used criteria used to assess OSA (AASM Task Force Report (1999). The physician's result showed significant correlations with the AHI ($r = .79, p < 0.01$); ANA's ($r = .59, p < 0.01$); the lowest oxygen saturation level ($r = .57, p < 0.01$) and the BMI ($r = .25, p < 0.01$). These validity measures however cannot be extrapolated to the BQ on the basis of individual question as no consistent correlations were found between the physician's result and any singular BQ parameters. A weak relationship was found with history of high blood pressure ratings ($r == 0.20, p < 0.05$)(Appendix G), which is an

unexpected finding in terms of current empirical data. However, in support of contemporary research data this study shows that when using risk factor analysis and a multinomial regression model, the findings indicates that the predictive value of the BP/BMI combination is stronger than sleepiness factors.

Construct validity of the BQ however is supported by the correlation of the total BQ score and objective data. A moderate and significance correlation was noted between the BQ score and the lowest oxygen saturation level ($r = -.42, p < 0.01$). The physician's result ($r = .21, p < 0.05$) and the AHI total ($r = .21, p < 0.05$) also showed significant correlation.

6.4. Risk factor analysis findings

The computation of risk factors shows that 81% of the sample qualifies for a high risk for reported symptoms of snoring. On questions regarding sleepiness 58% of the sample report symptoms of sleepiness in at least two questions on sleepiness and qualify as high risk. A history of high blood pressure and/or a BMI >30kg/m^2 showed only 14.3% of the sample qualifying as high risk. Thereafter, to assess overall high risk in this sample, these categories were combined. Patients with persistent and frequent symptoms in any two of these three categories were considered at high risk for apnoea. 59.7% of the sample qualified as high risk for OS A. Being in the high-risk group predicted an AHI of >5 in 68%o of the patients. Using AHI ratings refined the analysis even further. Using the categorisation of the AHI suggests that 65% of the high-risk cases were identified in the severe range ($p = 0.001$) and 35% in the normal range ($p = 0.003$). It would seem that the BQ is a valid tool to diagnose OSA if symptoms and risk category analysis is used.

6.5. Implication of findings

The validity of the BQ was explored by Netzer et al. (1999) they did not contend that the BQ was simply a valid tool for diagnosis of OS A. They proposed that the BQ "provides a means of identifying patients who are likely to have sleep apnoea" (p.485). Sharma et al. (2006) conclude that the BQ "can identify high risk subject and thus avoid unnecessary [PSG] studies especially in resource-limited settings" (p.281). Similarly, but with far less robust findings, this study shows that whilst BQ individual questions and even categorized data do not show significant enough validity and internal consistency to use as a pure diagnostic tool at all, it seems that in this clinical sample at least half of the high risk cases are identified by an AHI >5, particularly in the high risk group. This suggests then that if the BQ is to be useful in clinical settings, it should be approached with caution in terms of simply using it to diagnose and treat OSA patients. It remains to be seen whether the findings would change in a large cohort in the general population or in community primary health care facilities.

Currently, the clinician would therefore not simply be looking for high total scores on the BQ and simply administer the questionnaire as a stand-alone diagnostic tool, but may guardedly apply the questionnaire adjunct to a good history, his/her clinical impression and the problem the patient brings. The clinician should be alert to symptoms and risk factors for OSA. The value of *making the right diagnosis* is paramount. Furthermore the clinical health psychologist should empower patients by protecting them from disease and promoting health. Educating and training other clinicians and the public is important, with a focus on health, not disease. The clinical health psychology paradigm requires disease centred protocols but health focused treatment and management interventions.

This approach in turn affects outcomes which no only impact on the individual, but on ecological systems, communities and policy reforms (Bronfenbrenner, 1979; Petersen, 2004).

Future research should focus on formulating a stepwise theoretical approach to addressing changing mental health policies for OS A which include a matrix of risk factors such as obesity and hypertension (Bickman, 2000; Chokroverty, 2004; Gibson, 2005; Gorin and Arnold, 1998; Naidoo and Wills, 2000; Petersen, n.d., 2000, 2004; Shamsuzzaman et al. 2003); Somers, 2004; Shimura et al. 2005; Veglio, 2005; WHO, 1986;Wolk et al. 2003;

6.6. Limitations of the current study and recommendations for future research

The limitations of this research warrant discussion and provide a framework for the way forward, particularly for future research.

(1) The study was conducted in a private clinical laboratory over ten months, which imposed constraints on the nature sample size and demographics of the cohort. The sample was skewed in terms of race and gender rendering inferences involving these parameters ineffectual. A pure clinical sample does however have the added advantage in this study of providing a "ready-made" high-risk group with which to compare the BQ. Future research in South Africa should be conducted in a research laboratory setting at a primary health care level using a larger sample from a geographically representative South African population. Epidemiology studies on the prevalence of OS A are also recommended. The BQ (including the isiZulu version in KwaZulu-Natal) could be useful for this endeavor (Katzenellenbogen, Joubert and Karim, 1997).

(2) The patients studied were a convenience sample referred from private physicians to a specialist physician in an elite private sleep laboratory catering for patients within a high socio-economic bracket, which cannot be considered to represent a cross-section of the South African population. Furthermore, this restricted the use of a control group for stronger inferences to be made. With these points in mind, all the conclusions reached must be considered specific to this sample and not generalised. Future research should focus on methodology capable of gender and age-matched samples.

(3) The objective sleep study measure used - the HypnoPTT™ device, is a cardio-respiratory screening device which was used in a home-based setting. The patients set up and monitored their own studies. The objective data therefore is not considered "gold standard" research data by international standards. The argument for home based studies however is strong as it helps to eliminate "first night effect" as the study in done in the patient's familiar environment. Moreover this technique involves the patient personally in his/her diagnosis and management. Increasingly, portable sleep studies are proving to be reliable, cost-effective and convenient units for diagnosing sleep apnoea and may certainly prove to be the way forward in primary health care facilities in South Africa where resources are limited and health promotion strategies need refining (Personal communication, Dr.D. Hooper, Berea Sleep Laboratory, January, 2006; Stradling et al. 2002; Stradling and Davies, 2004; Petersen, 2000, 2004; Foster et al. 1997; Keleher, 2001; Naidoo and Wills, 2000). Lastly, the methodology employed did not require full PSG protocols.

(4) The strong relationships with the AHI should be used conservatively in clinical practice due to intraindividual variability of the AHI in consecutive and follow-up studies

(Hein & Magnussen (1999). In defence however, the AHI scores were graded into mild, moderate and severe for most of the statistical analysis and other researchers consistently find the readings to fall within these categories (Stevens, 2004). The full and rated scores were used to investigate risk category groups. Future study in research facilities should consider a second or third sleep study to compare AHI findings.

(5) The most striking limitation to this study is the fact that sleep disorders are relatively untouched in this country in terms of relevant facilities for the general population and published research. Grants in the future should focus on assisting researchers who are investigating sleep disorders, in particular - OS A. The researcher of this study attempted to work with patients at a primary health care facility but it was not possible. This study us considered a pilot study for the way forward to further explore the validity of the BQ and conduct epidemiology studies.

6.7. Conclusion and recommendations

To address the aim, hypotheses and research questions of this study set out in Chapter 1, the following conclusions are reached:

(1) The BQ is not a valid and reliable stand-alone instrument for diagnosing OS A. No objective items showed correlation or predictive relationship with individual BQ items data. Cronbach °c correlations showed values in an average to poor reliability range. Sleepiness items showed mild reliability (.68), particularly if sleepiness whilst driving was removed (.84). The strength of the validity of this questionnaire lies in the categorization of risk factors and the accumulative value of the BQ questions. Category analysis of high-risk groups, using the AHI as dependent variable identified 60% of the

high-risk cases. The total BQ score correlated adequately with the lowest oxygen desaturation value *(r* = -0.42, *p* < 0.01). Mild correlations were also found with the physician's result (r = *0.25,p*< 0.05), and the AHI total *(r = 02l,p*< 0.05). All these variables are included as international protocols for diagnosing OSA. The overall sensitivity of the BQ to diagnose OSA with an AHI >5 was 59%, which is lower than Western studies.

(2) The BQ should be used guardedly as a diagnostic tool. It's usefulness lies in the ability to differentiate high risk from low risk cases, particularly using symptoms of daytime sleepiness and risk factors such as a high BMI and a history of high blood pressure, which should lead to further clinical and objective investigation. In poorly resourced primary health care facilities the BQ may be useful as an adjunct diagnostic instrument to identify clusters of symptoms indicative of the syndrome. This procedure may assist primary health care clinicians to avoid unnecessary investigation in low-risk patients and refine diagnosis, treatment and management in high-risk patients. This study highlights that fact that clinical practice remains the arena in which OSA should be recognized, diagnosed and treated. Accurate diagnosis is the key to good management.

(3) Accurate diagnosis often involves a multidisciplinary team approach. Objective assessment tools such as full PSG and screening tools for sleep disorders are essential for accurate diagnosis and treatment protocols. Clinical health psychologists in South Africa should be alert to the risk factors and behaviours indicative of OSA. OSA behaviour is complex at a number of different levels. At a physiological level the airway is undermined with resultant oxygen desaturation and sleep fragmentation. Autonomic and

metabolic function interact with genetic and environmental factors to determine the severity of risk for other diseases.

Psychological problems are a manifestation of these factors. For example the sort of depression found in OSA patients has origin in the fragmented sleep and physiological deficit experienced. Thereafter, it is compounded by personal and social difficulty in relation to the personal impact of the condition. The treatment therefore requires support, advocacy, encouragement, education and intensive psychotherapy for patients and their significant few. Family and group work may also be pertinent. Consultancy to companies, schools and other institutions may be appropriate. Research into this condition and other sleep disorders is still in the cradle in this country - many research opportunities are therefore available. We expect that the BQ will pilot these opportunities.

Furthermore, referrals for psychotherapy where symptoms such as depression, cognitive impairment, obesity, daytime sleepiness, cardio-vascular disease and hypertension are identified should be warning bells for clinicians. Furthermore, a good history, collateral information from a bed-partner and an educated approach to dealing with sleep disorders is essential. It is of utmost importance to *make the right diagnosis* before treatment commences. Treating the symptoms without investigating the root cause undermines effective and efficient clinical practice. Furthermore it belies ethical practice, particularly the "first do no harm" code.

(4) At a primary health care level in South Africa, recognition, diagnosis and treatment of OSA is currently scant. The provincial sector is neglected and elitist options remain the norm. The majority of patients in the provincial sector is undiagnosed and is frequently treated for superficially presenting problems and psychosocial complications, which

overload resources. Policy regarding OSA has not been legislated and the possible costs the state an enormous amount of money every year to treat symptoms and side effects of the condition. Good examples are hypertension and obesity. Obesity is reaching epidemic proportions in this country; many of these patients could be OSA sufferers. The personal, psychosocial and clinical impact of this syndrome is profound. Clinical health psychologists have the opportunity to diagnose and treat this condition holistically and should be educated about OSA.

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APPENDICES

APPENDIX A

THE BERLIN QUESTIONNAIRE - Netzer et al., (1999).

Completed by physician:

1. A. Height (cm):
   B. Weight (kg):
   C. BMI (kg/m^2):_____

   BMI > 30?
   - Yes
   - No

Patient: Please tick the correct box:

2. Do you snore?
   - Yes
   - No

   I_I Don't know

If you snore:

3. Your snoring is
   I_I slightly louder than breathing
   I_I as loud as talking
   I_I louder than talking
   I_I very loud. Can be heard in adjacent rooms

4. How often do you snore?
   I_I nearly every day
   n 3-4 times a week
   n 1-2 times a week
   D 1-2 times a month
   I_I never or nearly never

5. Has your snoring ever bothered other people?
   D Yes
   - No

6. Has anyone noticed that you stop breathing during your sleep?
   |~] nearly every day
   G 3-4 times a week
   I I 1-2 times a week
   Q 1-2 times a month
   I_I never or nearly never

7. How often do you feel tired or fatigued after your sleep?

I I nearly every day
n 3-4 times a week
D 1-2 times a week
D 1-2 times a month
I I never or nearly never

8. During your waketime, do you feel tired, fatigued or not able to cope?

I I nearly every day
D 3-4 times a week
D 1-2 times a week
D 1-2 times a month
I I never or nearly never

9. Have you ever nodded off or fallen asleep while driving a vehicle?

- Yes If yes, how often does it occur?
  - O nearly every day
  - D 3-4 times a week
  - D 1-2 times a week
  - n 1-2 times a month
  - I I never or nearly never
- D No

10. Do you have high blood pressure?

- Yes
- No
- Don't Know

APPENDIX B

isiZulu Translation - Berlin Questionnaire (Netzer et al. 1999)

Translated and back-translated by:

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A. Ubude(cm)
B. Isisindo (kg)
C. BMI (kg/m2)

BMI> 30?

- Yebo
- Cha

2. Uyahona?
   - Yebo
   - Cha

   I I Angazi

3. Umauhona:
   Ukuhona kwakho ku :

   I I Ngaphezu kancane nje kokuphefumula
   I I Kulingana nokuba ukhuluma
   I I Ngaphezu kokukhuluma
   I I Kuzwakala kakhulu. Kungezwakala kwelinye ikamelo

4. Ujwayele ukuhona kangaki?

   I I Cishe zonke izinsuku
   I I Kathathu noma kane ngeviki
   I I Kanye noma kabili ngeviki
   I I Kanye noma kabili ngenyanga
   I I Angihoni noma cishe angihoni nhlobo

5. Ukuhona kwakho kuyabakhathaza abanye abantu?

   - Yebo
   - Cha

6. Ukhona oke abone ukuthi uke uhiqize uma ulele?

I I Cishe zonke izinsuku
I I Kathathu noma kan ngeviki
- Kanye noma kabili ngeviki
- Kanye noma kabili ngenyanga

I I Akwenzeki noma cishe akwenzeki nhlobo

7. Kungakaki lapho uzizwa ukhathele noma ucobekile emva kokulala?

I I Cishe zonke zonke izinsuku
I I Kathathu noma kane ngeviki
- Kanye noma kabili ngeviki

| I Kanye noma kabili ngenyanga
I I Akwenzeki noma cishe akwenzeki nhlobo

8. Uma uvukile, uzizwa ukhathele, ucobekile noma ungakwazi kwenza lutho nje?

I I Cishe zonke izinsuku
| | Kathathu noma kane ngeviki
I I Kanye noma kabili ngeviki'
- Kanye noma kabili ngenyanga

I I Akwenzeki, noma cishe akwenzeki nhlobo

9. Wake wangquphazela, noma wazumeka ushayela imoto?

- Yebo

D C h a

Uma kwenzeka, kwenzeka kangakanani

I I Cishe zonke izinsuku
| | Kathathu noma kane ngeviki
I I Kanye noma kabili ngeviki
I I Kanye noma kabili ngenyanga
I I Akwenzeki noma cishe akwenzeki nhlobo

10. Unaso isifo sokwenyuka komfutho wegazi

- Yebo
- Cha

I I Angazi

APPENDIX C

EPWORTH SLEEPINESS SCALE (Johns, 1991).

How likely are you to feel drowsy in the following situations, in contrast to feeling just tired? This refers to your usual way of life in the last month. Even if you have not yet done some of these things recently try to work out how would they have affected you. Use the following scale to choose the best number for each situation.

0 = would never doze
1 = slight chance of dozing
2 = moderate chance of dozing
3 = high chance of dozing

SITUATION	CHANCE OF DOZING
Sitting and reading.	
Watching T.V.	
Sitting inactive in a public place (e.g. a theatre for a meeting).	
Lying down to rest in the afternoon when circumstances permit.	
Sitting and talking to someone.	
Sitting quietly after a lunch without alcohol.	
As a passenger in a vehicle after one hour.	
In a car, while stopped for a few minutes in traffic.	

APPENDIX D.l

CONSENT TO PARTICPATE IN RESEARCH

(Berea Skep Laboratory

A A HOOf ?r^3C«f7din) FRCS

21 <**.£erea 4001

Fax: 031 -2018420
Mobile~082 444 9649
Email: anooper0saol.com

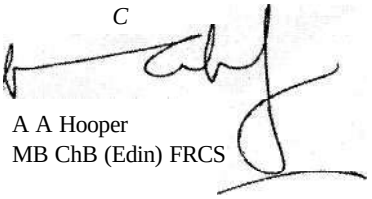
Friday, January 26, 2007

To whom it may concern

This is to certify that I have given Mrs Michelle Baker full access to the records from my practice to enable her to do her research.

Furthermore 1 personally supervised the completion of the Berlin Questionaire for each patient. I explained the nature and confidentiality of this information and each patient gave verbal consent to me personally for Mrs Baker to use the information for the purposes of her research.

C



A A Hooper
MB ChB (Edin) FRCS

APPENDIX D.2

CONSENT TO PARTICPATE IN RESEARCH

CONSENT DOCUMENT

This document was used by the sleep physician as the framework for verbal consent on intake of each subject.

You have been asked to participate in a research study in order to find out if a basic questionnaire on Obstructive Sleep Apnoea (OSA) can be used to diagnose OSA. The questionnaire you fill out and the sleep study test the doctor sends you home with, will be compared by a researcher, Ms. Michelle Baker (Intern Clinical Psychologist, University of KwaZulu-Natal, Pietermaritzburg, South Africa). The study is a preliminary study to find out if the Berlin Questionnaire can be used in a South African population to diagnose OSA, in order to cut down the costs of diagnosing the condition, and make testing accessible to all South Africans.

You have been informed about the study by the sleep physician, Dr. D. Hooper. You may contact the researcher any time if you have questions or concerns about your rights as a research subject. Dr. Hooper will give you the phone number.

Your participation in this research is voluntary, you will not be penalised or lose any benefits during the course of your sleep study if you refuse to participate or decide to stop at any stage. The researcher will need to have access to your file for data loading. If you have any objection to this please do not hesitate to inform Dr. Hooper.

If you agree to participate, you must repeat your understanding of your rights, what is expected of you, and give permission to Dr. Hooper for access to the data in your laboratory file. This is all done verbally, to protect your confidentiality. Your partner or Dr. Hooper's staff will be asked to witness your agreement to participate in the research.

Thank you

Dr. D. Hooper and Ms.M.L.Baker appreciate your participation and trust you will feel free to voice any concerns you may have during the course of completing the questionnaire and sleep study.

APPENDIX E

THE BERLIN OUESIONNAIRE RESUTS - ADDITIONAL INFORMATION

RESULTS FOR CATEGORY 1 - DESCRIPTIVE BO DATA - SNORING

Table E-l. Question 2 - Do you snore - BQ data.

Do you snore		Frequency	Percent
Valid	Don't know	1	.8
	No	1	.8
	Yes	108	90.8
	Total	110	92.4
Missing	System	9	7.6
Total		119	100.0

Table E-2. Question 3 -Your snoring. Is… BQ data

		Frequency	Percent
Valid	Slightly louder than breathing - Low risk	6	5.0
	As loud as talking - Low risk	11	9.2
	Louder than talking - High risk	13	10.9
	Very loud, heard in adjacent rooms - High Risk	79	66.4
	Total	109	91.6
Missing	System	10	8.4
Total		119	100.0

Table E-3. Question 4 - How often do you snore -BQ data.

		Frequency	Percent
Valid	1 -2 times a week - Low Risk	1	.8
	3-4 times a week - High Risk	9	7.6
	Nearly every day - High risk	99	83.2
	Total	109	91.6
Missing	System	10	8.4
Total		119	100.0

Table E-4. Question 5 - Does your snoring bothers others -BQ data.

		Frequency	Percent
Valid	No	4	3.4
	Yes	106	89.1
	Total	110	92.4
Missing	System	9	7.6
Total		119	100.0

Table E-5. Question 6 - Has anyone noticed you hold your breath during sleep - BQ. data.

		Frequency	Percent
Valid	Never - Low risk	12	10.1
	1-2 Times a month - Low risk	7	5.9
	1-2 Times a week - Low Risk	10	8.4
	3-4 Times a week - High risk	19	16.0
	Nearly every day - High risk	51	42.9
	Total	99	83.2
Missing	System	20	16.8
Total		119	100.0

RESULTS FOR CATEGORY 2 BO DATA - SLEEPINESS

Table E-6. - Question 7- Do you often feel tired after your sleep -BQ data.

		Frequency	Percent
Valid	Never - Low risk	10	8.4
	1-2 Times a month - Low risk	2	1.7
	1-2 Times a week - Low Risk	9	7.6
	3-4 Times a week - High risk	12	10.1
	Nearly every day - High risk	77	64.7
	Total	110	92.4
Missing	System	9	7.6
Total		119	100.0

Table E-7. Question 8 - During you waketime, do you feel tired (EDS) - BQ data.

		Frequency	Percent
Valid	Never - Low risk	7	5.9
	1-2 Times a month - Low risk	2	1.7
	1-2 Times a week - Low Risk	14	11.8
	3-4 Times a week- High risk	16	13.4
	Nearly every day - High risk	70	58.8
	Total	109	91.6
Missing	System	10	8.4
Total		119	100.0

Table E-8. Question 9 - Have you ever nodded off while driving - BQ data.

		Frequency	Percent
Valid	Never - Low risk	70	58.8
	1-2 Times a month - Low risk	13	10.9
	1-2 Times a week - Low Risk	4	3.4
	3-4 Times a week - High risk	9	7.6
	Nearly every day - High risk	13	10.9
	Total	109	91.6
Missing	System	10	8.4
Total		119	100.0

Table E-9. Results for total BQ score.

N	Valid	98
	Missing	21
Mean		20.96
Std. Deviation		4.393
Range		20
Minimum		8
Maximum		28

RESULTS FOR CATEGORY 3 BO DATA - BLOOD PRESSURE AND BMI

Table E.-IO. Question 1 - Body Mass Index (BMI) results - BQ data

		Frequency	Percent
Valid	BMI<30kg/m	48	40.3
	>30kgs/m	68	57.1
	Total	116	97.5
Missing	System	3	2.5
Total		119	100.0

Table E-11. Question 10 - History of high blood pressure - BQ data

		Frequency	Percent
Valid	No - Low risk	66	55.5
	Yes - High risk	44	37.0
	Total	110	92.4
Missing	System	9	7.6
Total		119	100.0

APPENDIX F

HypnoPTT™ RESUTS - ADDITIONAL INFORMATION

Table F-l. Assessment of OSA severity according to the final results generated by the physician - HypnoPTT™ data.

		Frequency	Percent
Valid	Normal range	8	6.7
	Mild OSA	24	20.2
	Moderate OSA	20	16.8
	Severe OSA	64	53.8
	Total	116	97.5
Missing	System	3	2.5
Total		119	100.0

Table F-2. AHI ratings recorded by the HypnoPTT™.

		Frequency	Percent
Valid	< 5 - Normal range	35	29.4
	5 - 20 - Mild range	35	29.4
	>20-30 -Moderate range	11	9.2
	>30 - Severe range	35	29.4
	Total	116	97.5
Missing	System	3	2.5
Total		119	100.0

Table F-3. Total number of snores recorded by the HypnoPTT™ .

		Frequency	Percent
Valid	< 20 total snores	2	1.7
	20-100 total snores	3	2.5
	100-300 total snores	7	5.9
	> 300 total snores	104	87.4
	Total	116	97.5
Missing	System	3	2.5
Total		119	100.0

Table F-4. Autonomic arousals (ANA's) recorded by the HypnoPTT™.

		Frequency	Percent
Valid	<14 arousal events per hour - normal range	3	2.5
	>14 arousal events per hour - abnormal range	111	93.3
	Total	114	95.8
Missing	System	5	4.2
Total		119	100.0

APPENDIX G

RELIABILITY AND VALIDITY STATISTICS

Reliability statistics - Internal consistency ofBQ data

Table G-l. Tables showing reliability statistics

Reliability Statistics
All BQ questions

Cronbach's Alpha	N of Items
.626	10

Snoring items
Category 1

Cronbach's Alpha	N of Items
.399	5

Sleepiness including driving
Category 2

Cronbach's Alpha	N of Items
.677	3

Sleepiness excluding driving
Category 2

Cronbach's Alpha	N of Items
.840	2

BP and BMI
Category 3

Cronbach's Alpha	N of Items
.183	2

A The AHI as dependent variable

Table G-2. AHI as dependent variable, BQ questions 1-10 as independent variables. Table showing results for regression analysis coefficients.

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	27.735	32.466		.854	.395
	Your snoring is...volume of snoring BQ data	-.129	3.342	-.004	-.039	.969
	How often do you snore - BQ data	-1.906	9.981	-.026	-.191	.849
	Snoring bothers others -BQ data	4.882	31.824	.020	.153	.878
	Breath holding during sleep	2.278	2.042	.130	1.116	.268
	How often are you tired or fatigued after your sleep- BQ data	-1.582	2.854	-.084	-.554	.581
	Excessive daytime sleepiness- BQ data	-.038	3.088	-.002	-.012	.990
	Sleepiness whilst driving	2.953	1.910	.171	1.546	.126
	High blood pressure-BQ data	9.251	5.375	.183	1.721	.089
	BMI - Berlin	9.861	5.568	.192	1.771	.080

R Lowest o2 saturation value as dependent variable

Table G-3. Multiple regression coefficient results using the lowest oxygen saturation value as dependent variable against BQ questions 3-10

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sis.
		B	Std. Error	Beta		
1	(Constant)	100.038	14.966		6.684	.000
	Your snoring is...volume of snoring BQ data	-.842	1.540	-.058	-.547	.586
	How often do you snore - BQ data	-2.935	4.601	-.079	-.638	.525
	Snoring bothers others -BQ data	4.347	14.670	.037	.296	.768
	Breath holding during sleep	-1.404	.941	-.161	-1.491	.140
	How often are you tired or fatigued after your sleep- BQ data	.906	1.316	.097	.688	.493
	Excessive daytime sleepiness- BQ data	-1.246	1.423	-.123	-.875	.384
	Sleepiness whilst driving	-2.403	.880	-.280	-2.729	.008
	High blood pressure-BQ data	-4.666	2.478	-.185	-1.883	.063
	BMI - Berlin	-4.304	2.567	-.169	-1.677	.097

C. *Snoring as dependent variable*

Table G-4. Multiple regression analysis showing the results of using total snoring as dependent variable against BQ questions 3-10

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sis.
		B	Std. Error	Beta		
1	(Constant)	3.124	.572		5.459	.000
	BMI - Berlin	-.032	.098	-.037	-.325	.746
	Your snoring is...volume of snoring BQ data	.067	.059	.134	1.145	.255
	How often do you snore - BQ data	-.179	.176	-.141	-1.020	.311
	Snoring bothers others -BQ data	.181	.561	.044	.323	.747
	Breath holding during sleep	-.016	.036	-.055	-.454	.651
	How often are you tired or fatigued after your sleep- BQ data	.041	.050	.128	.813	.418
	Excessive daytime sleepiness- BQ data	.026	.054	.075	.475	.636
	Sleepiness whilst driving	-.030	.034	-.100	-.877	.383
	High blood pressure-BQ data	-.067	.095	-.078	-.709	.481

D. *The ANA 's as dependent variable*

Table G-5. Regression analysis using ANA's as the dependent variable and BQ questions 1- 10 as independent variables

Model		Unstandardized Coefficients		Standardized Coefficients	t	Si*
		B	Std. Error	Beta		
1	(Constant)	90.921	30.771		2.955	.004
	Your snoring is...volume of snoring BQ data	-.973	3.240	-.035	-.300	.765
	How often do you snore - BQ data	-9.298	9.507	-.136	-.978	.331
	Snoring bothers others -BQ data	5.468	30.125	.025	.182	.856
	Breath holding during sleep	-2.705	2.046	-.163	-1.322	.190
	How often are you tired or fatigued after your sleep- BQ data	.458	2.897	.025	.158	.875
	Excessive daytime sleepiness- BQ data	-.687	3.067	-.035	-.224	.823
	Sleepiness whilst driving	3.442	1.826	.216	1.884	.063
	High blood pressure-BQ data	-.627	5.324	-.013	-.118	.907
	BMI - Berlin	9.769	5.484	.199	1.782	.079

APPENDIX H

RISK CATEGORY ANALYSIS - ADDITIONAL INFORMATION

SPSS category computation

Category 1 - Snoring parameters

IF ((bq2snore >2and bq3volum >2) OR (bq2snore >2and bq4often >2) OR (bq2snore >2 and bq5bothe >2) OR (bq2snore >2 and bq6brehold >2) OR (bq3volum >2and bq4often >2) OR (bq3volum >2and bq5bothe >2) OR (bq3volum >2 and bq6brehold >2) OR (bq4often >2 and bq5bothe >2) OR (bq4often >2 and bq6brehold >2) OR (bq5bothe >2 andbq6brehold >2)) CatlSnore = 1.
EXECUTE.

Category 2 - Sleepiness parameters

IF ((bq7tired >2 and bq8eds >2) OR (bq7tired >2 and bq9drivi >2) OR (bq8eds >2 and bq9drivi>2)) Cat2EDS= 1.

Category 3 - History of high blood pressure & BMI>30kg/m

IF (bqlObp =1 and bqlcbmi =1) Cat3BPBMI = 1.
EXECUTE.

Case BQ — Qualifying for at least 2 of the 3 categories

IF ((CatlSnore =1 AND Cat2EDS = 1) OR (CatlSnore = 1 AND Cat3BPBMI = 1) OR (Cat2EDS =1 AND Cat3BPBMI = 1)) CASEBQ = 1.
EXECUTE.

Risk factor category analysis

Table H-l. Risk category 1 - Snoring parameters

Category 1 - Snoring		Frequency	Percent
Valid	Low risk	11	9.2
	High Risk	**97**	81.5
	Total	108	90.8
Missing	System	**11**	9.2
Total		119	100.0

Table H-2. Risk category 2 - Sleepiness parameters

Category 2 - Sleepiness		**Frequency**	**Percent**
Valid	**Low risk**	**39**	32.8
	High risk	**69**	58.0
	Total	108	90.8
Missing	System	**11**	9.2
Total		119	100.0

Table H-3. Risk category 3 - High blood pressure and/ or BMI >30 Kgs/m^2.

Category 3 - High BP and/or high BMI		Frequency	Percent
Valid	Low risk	91	76.5
	High risk	17	14.3
	Total	108	90.8
Missing	System	11	9.2
Total		119	100.0

Table H-4. High risk cases - qualifying for at least 2 of the 3 categories

High Risk Qualifiers		Frequency	Percent
Valid	Low risk cases	37	31.1
	High risk cases	71	59.7
	Total	108	90.8
Missing	System	11	9.2
Total		119	100.0

Table H-5. High risk cases predicting an AHI >5

High risk- AHI>5		Frequency	Percent
Valid	Does not qualify	38	31.9
	Qualify as high risk cases	70	58.8
	Total	108	90.8
Missing	System	11	9.2
Total		119	100.0

Table H-6. Multinomial regression analysis using AHI ratings as dependent variable and the BQCase (high risk group) as independent variable.

AHI Rating(a)		B	**Std. Error**	**Wald**	df	Sig.	Exp(B)	**95% Confidence Interval for Exp(B)**	
<5 Normal range	Intercept	-.511	.327	2.446		.118			
	[CASE_BQ=0]	1.715	.569	9.094		.003	5.556	1.823	16.933
	[CASE_BQ=1]	0(b)			0				
5-20 Mild range	Intercept	-.041	.286	.020		.886			
	[CASE_BQ=0]	.195	.625	.097		.755	1.215	.357	4.141
	[CASE_BQ=1]	0(b)			0				
>20 - 30 Moderate range	Intercept	-1.609	**.490**	10.793		.001			
	[CASE_BQ=0]	1.204	.810	2.207		.137	3.333	.681	16.317
	[CASE_BQ=1]	0(b)			0				

APPENDIX I

CONSTRUCT VALIDITY- ADDITIONAL DATA

CORRELATION COEFFICIENTS.

Table 1-1. BQ Results for subjective and objective snoring correlation (category 1).

		AHI Total	Result - physician result - PTT data	Do you snore - BQ data	Your snoring is...volume of snoring BQ data	How often do you snore - BQ data	Snoring bothers others - BQ data	Breath holding during sleep
AHI Total	Pearson Correlation	1	.787(**)	.127	.136	.060	.133	.148
	Sig. (2-tailed)		.000	.192	.166	.538	.173	.151
	N	116	116	107	106	106	107	96
Physician Result -	Pearson Correlation	.787(**)	1	.117	.137	.014	.093	.157
	Sig. (2-tailed)	.000		.230	.161	.886	.341	.126
	N	116	116	107	106	106	107	96
	N	96	96	99	99	99	99	99

Correlation is significant at the 0.01 level (2-tailed).

Table 1-2. Correlations with the physicians result and the AHI for sleepiness questions - Category 2

		AHI Total	Result - physician result - PTT data	How often are you tired or fatigued after your sleep- BQ data	Excessive daytime sleepiness- BQ data	Sleepiness whilst driving
AHI Total	Pearson Correlation	1	.787(**)	.073	.085	.141
	Sig. (2-tailed)		.000	.458	.386	.148
	N	116	116	107	106	106
Result -physician result - PTT data	Pearson Correlation	.787(")	1	.130	.187	.099
	Sig. (2-tailed)	.000		.183	.055	.311
	N	116	116	107	106	106
	N	106	106	109	108	109

Correlation is significant at the 0.01 level (2-tailed).

Table 1-3. Correlations for the physician's result and the AHI with BMI and High Blood Pressure - Category 3

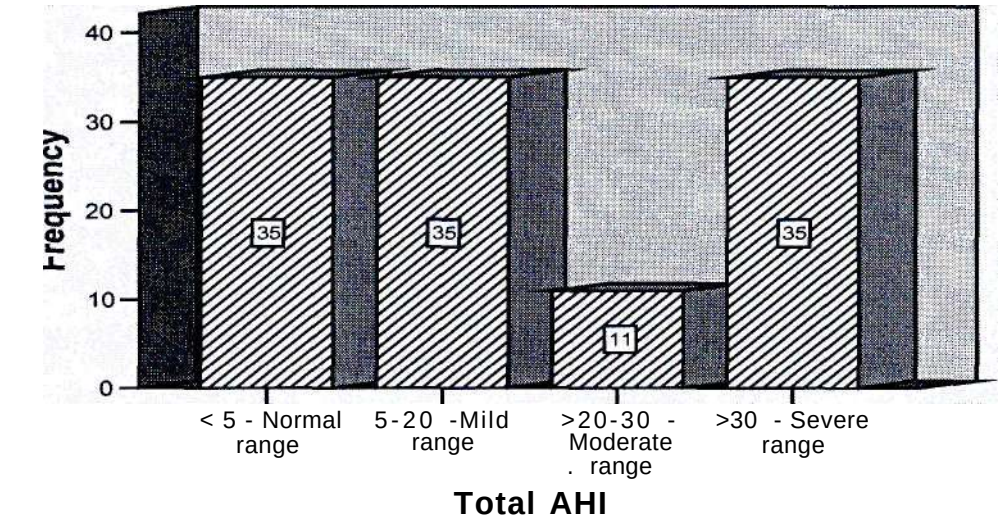
Correlations

		AHI Total	Result - physician result - PTT data	High blood pressure-BQ data	BMI-BQ
AHI Total	Pearson Correlation	1	.787(**)	.174	.187
	Sig. (2-tailed)		.000	.073	.051
	N	116	116	107	109
Result -physician result - PTT data	Pearson Correlation	.787(**)	1	.199(*)	.163
	Sig. (2-tailed)	.000		.040	.091
	N	116	116	107	109
High blood pressure-BQ data	Pearson Correlation	.174	.199(*)	1	.101
	Sig. (2-tailed)	.073	.040		.294
	N	107	107	110	110
BMI - BQ	Pearson Correlation	.187	.163	.101	1
	Sig. (2-tailed)	.051	.091	.294	
	N	109	109	110	112

** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).

APPENDIX J

VISUAL COMPARISON OF THE OBJECTIVE RECORDING OF THE AHI AND THE SUBJECTIVE ACCOUNT OF BREATH-HOLDING EPISODES



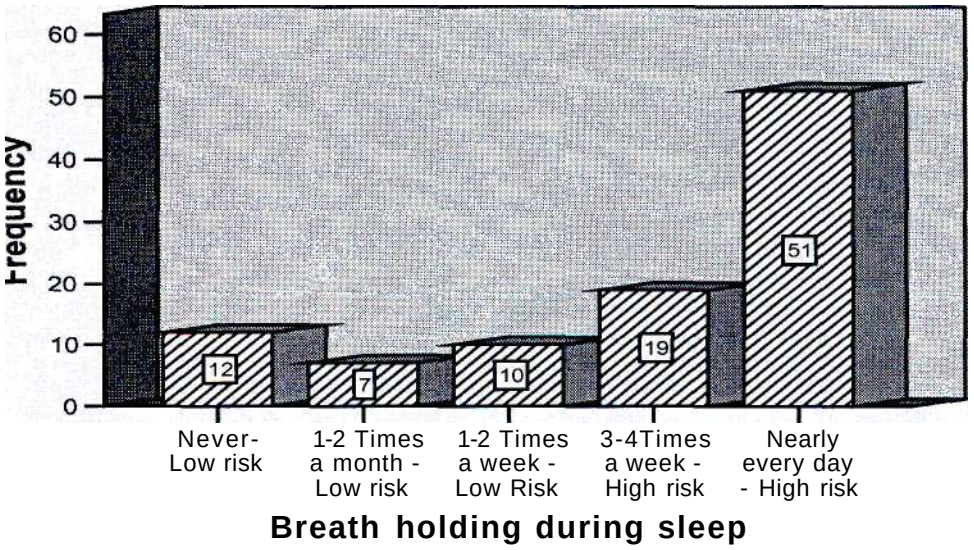


Figure J-l. Visual comparison of the AHI (objective) and breath-holding events (subjective rating).

APPENDIX K
HIGH-RISK CATEGORY ANALYSIS ALGORITHM

1. Criterion Validity - descriptive & SPSS computation

DIAGNOSTIC VALUE

Separate categories

Category 1
Snoring

81%

Category*?
Sleepiness\

58%

Category 3
BP/BMI

14%

Consensus criteria used for rating Snoring, sleepiness and BP/BMI symptoms >3-4Xper week.

1

(Qualifies as high risk for any 2 Categories)

CASEBQ

60%/

Combines categories = one group High-Risk BQ Group.

1. Construct Validity - computed in SPSS

HypnoPTT™ data
AHI>5
59%

The BQ identify >half the sample =AHI>5 (OSA risk)

3. Predictive Validity -Multinomial regression analysis

Model 1 - Case BQ & AHI Ratings (Unstable)

0-5	5-20	20-30	30+
57%	0	0	81%

Model 2 - BQ Categories & AHI Ratings (Stable)

0-5	5-20	20-30	30+
54%	64%	0	25%

Cases BQ predictive value