IMPROVING MANAGEMENT OF ELDERLY MEN WITH LOWER URINARY TRACT SYMPTOMS IN GENERAL PRACTICE

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IMPROVING MANAGEMENT OF ELDERLY MEN WITH LOWER URINARY TRACT SYMPTOMS IN GENERAL PRACTICE

een wetenschappelijke proeve
op het gebied van de Medische Wetenschappen

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AGREE	Appraisal of Guidelines for Research & Evaluation
AHCPR	Agency for Health Care Policy and Research
AUA	American Urologist Association
BPH	Benign Protatic Hyperplasia
BS	Bother Score
CBO	Dutch Institute for Health care Improvement
DRE	Digital Rectal Examination
EAU	European Association of Urology
GP	General Practitioner
icc	inter cluster correlation
I-PSS	International Prostate Symptom Score
IVU	Intravenous Urography
LUTS	Lower Urinary Tract Symptoms
MESH	Medical Subject Headings
ml/s	millilitre per second
NHG	Dutch College of General Practitioners
NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health
OR	Odds Ratio
PFS	Pressure Flow Studies
PIL	Package for Individual Learning
PSA	Prostate Specific Antigen
Q_{ave}	Average flow in uroflowmetry
Q_{max}	Maximum flow in uroflowmetry
SAS	Statistical Analysis System
SCHiN	Sowerby Centre for Health Informatics at Newcastle
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
TRUS	Trans Rectal UltraSound
VV	total Voided Volume
95% CI	95% Confidence Interval

INTRODUCTION

Lower urinary tract symptoms in general practice

In this thesis we studied the evidence used in, and the possibilities of an implementation strategy for the guidelines on lower urinary tract symptoms (LUTS).[1,2] From a recent nationwide monitoring of the clinical management by the general practitioner (GP) there is some doubt whether these guidelines are followed by the Dutch GP.[3] Implementing a guideline would mean giving account for the guideline itself and for possible barriers and facilitators to change.[4] Before presenting the studies we conducted, LUTS and some of the clinical difficulties related to it will be illustrated as an introduction. Then the present evidence used in the clinical management of LUTS will be highlighted and the patients and physicians perspective on LUTS will be explored. Subsequently a possible implementation strategy for the 1997 update of the guideline is worked out. In the end the research questions surfacing from this aims of the research of this thesis will be formulated and the outline of the thesis is drawn.

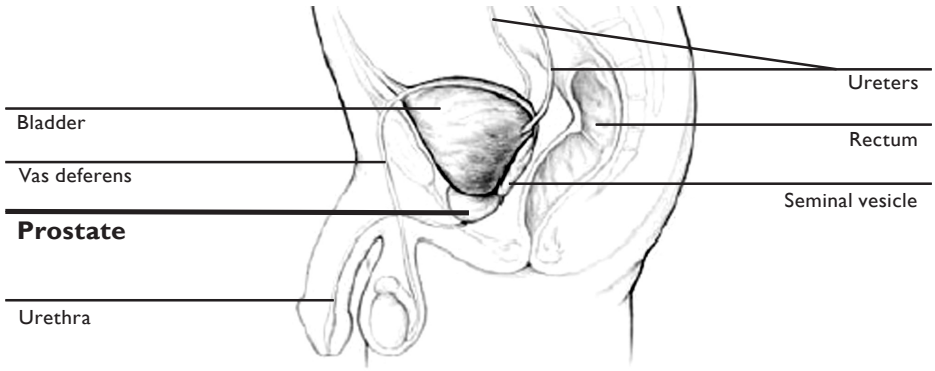
In 1977 a program of the *National Institutes of Health* (NIH) in the United States started developing 'consensus statements' in clinical management.[5] They have been developed for many clinical conditions to assist practitioner and patient in their decisions about appropriate health care.[5] In 1982 the NIH initiative was followed in the Netherlands by the *Dutch Institute for Health care Improvement* (CBO) developing consensus guidelines for medical specialists. Seven years later the first guideline on Diabetes care in the general practice was published by the *Nederlands Huisartsen Genootschap* (NHG) (*Dutch College of General Practitioners*).[6] In the following years some eighty guidelines more were developed by the Dutch College. These guidelines distinguish themselves from the CBO-guidelines as they are in general guidelines developed by and for GPs. The NHG guidelines played an important role in professionalizing general practice in the Netherlands.[7]

Benign Prostatic Hyperplasia (BPH) as a clinical diagnosis is very common; Continuous Morbidity Registration and the recent Second National Study show a prevalence of 6.8-15 per 1000 men, with an incidence of 2.5-4 men per 1000 per year.[8;9] The problem in BPH is that the relation between complaints and results of additional examinations is weak; furthermore there is a fear among patients and physicians of (missing) prostate related malignancies. These might lead to inadequate clinical management of patients presenting themselves at the surgery. In 1994 a first guideline on voiding problems in the elderly male was published as the 42nd guideline of the Dutch College covering the clinical management of the problems related to BPH.[10] This guideline was updated in 1997[1] and

adapted to a document that could be used as the basis for a shared care protocol with the urologists one year later.[2]

Lower Urinary Tract Symptoms

Traditionally, a benign enlargement of the prostate (Benign Prostatic Hyperplasia, or BPH) is thought to be the cause of voiding problems. Located below the bladder and in front of the rectum, the prostate is surrounding the urethra and normally has about the same size and shape as a walnut. The prostate gland is part of the male reproductive system producing fluid for semen, it normally evolves quickly at puberty and then maintains its size. BPH refers to a benign hyperplasia in which the prostate (pathologically) enlarges, usually after the age of 40. BPH is found in 60% of men over 60 years of age, and in up to 80% of men over 80 years of age. As the prostate enlarges it may cause obstruction of the urethra, resulting in problems when urinating. In the early stages of BPH, the bladder muscle can force urine through the narrowed urethra, but due to gradually increasing obstruction the bladder muscle gets stronger, thicker and more sensitive with complaints like urgency as a consequence. In some cases, the patient may be confronted with an emergency of an acute urinary retention.



Although BPH may cause no problems at all, about one third of men with BPH eventually will be bothered by their symptoms or develop other related problems that require treatment. Examples of symptoms are the feeling of urine retention after voiding, a weak urine stream, or nycturia.

Nowadays experts no longer think urinary tract symptoms are always caused by the prostate, but that they may also be the effect of conditions in other organs, such as the bladder; since some patients may have symptoms without having a large prostate. While the exact cause of symptoms cannot always be found, symptoms may be due to a combination of both prostate growth and increased muscle tightness in the neck of the bladder and in the prostate. It may be concluded that these complaints are neither sex, or age related, nor disease specific and so today they are referred to as Lower Urinary Tract Symptoms (LUTS).[11-13] LUTS are a very common, but generally not a life threatening, problem. Several studies have indicated that, in an open population, 30% of men over 50 years of age have LUTS that may be called bothersome and thus requiring treatment.[14-17] The treatment possibilities have increased during the last decades; with a spectrum from a considered watchful waiting, via medication and minimal interventions to surgical techniques. In general practice α-blocking medication is frequently prescribed. It can decrease the urine outflow resistance by influencing the muscle tone in the prostate and urinary tract. When the α-blockers are effective, the largest effect is reached within two weeks. However, medication has a limited effect on the complaints, both compared to placebo and invasive treatment methods. So, making a proper treatment choice is not simple and will mean carefully weighing the options. For example, a surgical treatment may relieve symptoms to a greater degree than a medical treatment, and for a longer period of time, but surgery also has a greater risk of complications, and requires a hospital stay, an anaesthetic and several weeks of recovery time.

The prostate is also often associated with prostate carcinoma. With 6897 new patients in 2001 this is the malignancy with the highest incidence in men (lung carcinoma: 6188 and colon carcinoma: 4825).[18] Prostate carcinoma has no specific early symptoms of the disease, so it is not unlikely that a patient and his physician relate voiding problems to prostate cancer (although there is no relation between prostate cancer and LUTS[19;20]). As a consequence many patients and physicians fear overlooking a carcinoma in men presenting with these complaints;[21] they try to decrease their fear by doing a PSA test. Prostate Specific Antigen (PSA) is a glycoprotein produced by cells of the prostatic ductal epithelium and is present in the serum of all men. PSA is more specific then the previously used acid phosphatase test in the diagnosis of prostate carcinoma, but it has not yet proven to be an adequate screening test for prostate cancer.[22-25]

The GP who is confronted with this diagnostic uncertainty in everyday practice is not helped with the PSA test, but with support to discuss evidence on these items and so making rational decisions in clinical management and be able to give adequate patient education.

The Evidence: Clinical Guidelines

As the population is ageing and public awareness is rising, there is a growing demand for appropriate diagnosis and effective treatment of LUTS. The increasing availability of non-invasive treatments, such as new drugs, may suggest that voiding problems can be treated more easily than before.[26] Furthermore, in the last decade the management of LUTS has increasingly shifted from the specialist to the GP in various countries.[27-32] These changes resulted in an increase of complicated questions for physicians in relation to the clinical management of voiding problems in the elder male. Guidelines could help in this by providing clear and unambiguous recommendations based on the best available evidence.

Under the auspices of the World Health Organization an international consensus committee made recommendations concerning the diagnosis of BPH in Paris 1991.[33] In 1994 the Dutch College of General Practitioners decided to develop national general practice guidelines[10] separately from the guidelines published by the National Association of Urologists one year earlier.[34] Simultaneously, guidelines on benign prostatic hyperplasia were developed in the United States (1994);[35] followed by professional organizations in various other countries as France (1995),[36] Australia (1997),[37] the United Kingdom (1997)[38] and Germany(1999).[39;40]

These clinical practice guidelines can be defined as systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.[5] Although the guidelines based on expert's opinion are not considered to be of poor quality,[41;42] most guidelines are evidence based in the sense that specific recommendations for practice are explicitly linked to the supporting evidence, if possible.[43]

The evidence supporting the guidelines is in a process of constant change. Over the period 1999 - 2003 there were no less then 2497 journal articles in MEDLINE alone with the MESH term 'Prostatic-Hyperplasia' (almost 500 annually). It has been calculated that to keep guidelines valid they have to be updated every 5 years.[44] The guideline by the Dutch College of General Practitioners had a first revision in 1997;[1] as a consequence an update was needed in 2002 to keep the recommendations in line with the current state of art.

Guideline makers have in principle access to the same science resources of research evidence (e.g., MEDLINE, Cochrane Library), and therefore, one would expect guidelines to be similar. Recently, two studies compared international guidelines on benign prostatic hyperplasia. They found that most guidelines gave largely similar recommendations, although there were differences with respect to PSA testing and imagining of the urinary tract.[45;46] A recent study on the recommendations given in diabetes guidelines showed

there was only a minor overlap between the references in the different guidelines.[47] It is not known whether differences in the evidence used are a possible explanation to variation in recommendations in guidelines on LUTS.

CLINICAL MANAGEMENT OF LUTS: EXPLORATION OF THE PROBLEM

THE PATIENTS' PERSPECTIVE

LUTS may have a significant impact on men's life in terms of degree of bother, worry, interference with daily living and psychological well-being.[48;49] Many studies explored reasons for doctors visits in patients with complaints of LUTS (Box 1).These studies show that men with moderate to severe symptoms are more likely to seek medical care than men with mild symptoms. Care seeking is not determined by symptom level alone, one may conclude that patients are not only seeking treatment for their physical complaints, but there is also a need for information on their condition.[50]

An epidemiologic study conducted in 1961 showed that far out the majority of the health problems perceived in the population are managed by the patients themselves and only some will seek medical attendance. These figures are 40 years later still applicable.[62] Many men with LUTS will be perfectly capable of caring for their own condition as well and thus

Box 1: Factors related to doctor visits in patients with LUTS

Demographic patient characteristics:

- age[51-53]
- marital status[51]
- educational level[54-56]
- income[51]

Level of complaints:

- symptom severity[51-54;56-61]
- bothersomeness[52;54;55;57;59]
- interference with daily activities in daily living[53;54;57;59]

Psychological factors:

- worry[55]
- depression[56]
- sexual desire[56]
- shame[55]

Others:

- co-morbidity[54]
- smoking[56]

they do not seek medical care.[50;56;57;59-61;63-66] They accept their chronic condition as part of their ageing process,[50;57;67] and this has to be regarded as adequate health behaviour.
But there may be other reasons influencing their decision not to present themselves to medical care, as there may be a feelings of shame and fear.[50;57] The man's perception of the care provider's ability to give relevant information or effective treatment is important as well as the patient's ability to cope with the LUTS himself.[68] Knowing what's on a man's mind may help to bring those, who will benefit the most from medical care, and where non-attendance is inappropriate, to consult their family doctor in time.
Further detailed insight in the factors that determine consultation for LUTS is essential for optimal advice and education focused on patients needs and on expectations of the elderly male population.

THE PHYSICIANS' PERSPECTIVE

In the Netherlands, almost all patients are registered with a GP in a general practice and to the majority of these patients their GP functions as a gatekeeper to specialist care. So, most patients with LUTS are initially seen by GPs, referring selected cases to a urologists. With the introduction of α-blocking medication it has become more feasible to treat these complaints completely in general practice; leading to a more active role for GPs in the diagnosis and management of lower urinary tract symptoms.[27-29;69]
Before developing an implementation strategy it is important to be aware of the GPs' attitude towards the guideline on LUTS and possible barriers in using it in daily care. To explore physicians' views on the recommendations in the guideline a 35 item questionnaire has been distributed among 141 GPs on possible facilitators and barriers with respect to the Dutch College of General Practitioners guideline on LUTS. The items where 25% or more

Table 1*: *Survey of 141 General Practitioners in relation to the guideline on Lower Urinary Tract Symptoms

Reactions recommendations made in the guideline on LUTS	**% disagreement**
PSA should only be tested in patients under the age of 70 yeas with a normal life expectancy	59.6
PSA should only be tested in patients with a dubious digital rectal examination	52.1
Medication is only indicated in men with severe complaints and not able or willing to be operated	51.1
The number of additional tests should mainly be determined by the severity of the complaints	46.1
In all men above the age of 50 years with LUTS percussion of the bladder should be performed	39.0

of the respondents disagreed upon are presented in Table 1. From this one can conclude that the recommendations on PSA testing, prescription of medication and percussion of the bladder are controversial.

To examine the physicians perspective in more detail semi structured interviews were conducted in 20 GPs on motives for their clinical management in patients with LUTS (quotes are presented in Box 2).

In general LUTS were not perceived as a life threatening disease, physicians also felt that their knowledge of this condition was adequate. They saw it as a disease area of minor significance compared to, for instance, diabetes or cardiovascular and pulmonary diseases. As a consequence they experienced no urge to follow an intensive training programme on LUTS.

The GPs interviewed had the perception that most patients would attend the surgery only if the LUTS became a nuisance (for them or their social network) or in case of an acute

Box 2: A selection of quotes by 20 GPs in relation to the clinical management of LUTS

Percussion / palpation of the bladder:

Only if history raised suspicion:

…There has to be a clear story of an acute urinary retention, then I wil consider it, but ist is no part of the routine examination…

It is a difficult skill:

… Many men are obese…men have to have a considerable retention when I would be able to find it by percussion, depending on your technique. In these cases the history will be obvious as well…

PSA-testing:

Fear of missing a carcinoma:

…In such a small town this (missing a carcinoma) will spread around, so one will be more defensive and will order the test…

…But I can recall at least three patients where we only discovered the prostate carcinoma when they already had pathological fractures, then the diagnosis is missed…

…men can have a prostate carcinoma without knowing and if they visit the surgery and I did not consider it to be useful to test for PSA and later a carcinoma is discovered; I'll be up a tree…

Patient education costs time:

…if they want a check up. I will try to explain…but I will do the test, I don't want to pay to much attention to it…

…It depends if there is time…someone must be able to deal with it as well…

…PSA testing is not that expensive…within the time I have explained why this is not an appropriate test…the test is already ordered, one knows more and one has more certainty…

As part of clinical management:

…when I doubt referral, I will order PSA as additional diagnostics…

…if I prescribe medication I always order PSA as a routine…

Medication is only indicated in men with severe complaints and not able or willing to be operated:

Surgery is a more aggressive form of therapy

…medication offers more…and if one can prevent or postpone possible complications of surgery…

…complaints in general develop gradually…one can try medications and after half a year one can consider discontinuation…after stopping some patients may stay symptom free…

…most are better helped with medication…I would prefer it myself…

urinary retention; other reasons for the patient were a need for information or fear of / questions about prostate cancer.

All interviewees thought of the digital rectal examination as a sensible, cheap and feasible examination that at least has to be done once in patients with complaints, but only three of the GPs were totally confident about their skills. An abdominal palpation or percussion was only performed in patients were history taking raised suspicion for a possible urinary bladder distension, with doubts in relation to its sensitivity.

PSA testing is common use as most physicians perform tests on a routine basis, although all were aware from their deviance of the recommendations in the guideline. Fear of missing a carcinoma was present in half of the doctors.

In cases where watchful waiting failed, GPs felt confident with the prescription of α-blocking agents (as tamsulosine and alfluzosine). All of them thought this to be in line with the preferences of patients and urologists, and with recommendations in local formularies. They further argued that surgery brings on certain risks, and always remains a possibility. The choice for medication or referral is normally left to the patient, except for more urgent conditions as defined in the guideline (i.e. complicated LUTS, suspicion of a carcinoma, failing medication).

From these explorations of the physicians' perspective it may be concluded that support in the communication between physician and patient on treatment possibilities of LUTS and on the potential (fear of) prostate cancer is needed. Can the guidelines on LUTS be implemented in a better way when attention is focused on these items.

A proper evaluation of men with complaints of LUTS is not always easy, as the prostate, the bladder, the urethra or combinations of these could be the cause of the symptoms. Although the GP is able to get an impression of the bother of the elderly patients; complaints concerning LUTS are often difficult to interpret on basis of history taking only.[70-76] In order to keep up to the rising number of patients a better tuning of general practice and specialist care is needed.

One possibility to streamline the patient evaluation is the implementation of the shared care protocol on LUTS; promoting urologists and GPs to make local arrangements for referral.[77] Making inter-professional arrangements was expected to prevent redundant work and to contribute to the efficiency of health care.[78] The studies published until now present the effect of the shared care clinics on the daily practice of the urologist. Potential effects of these clinics on the clinical management of the GP have not been reported. So before concluding that shared care is the solution to expected problems of the capacity in health care the effects of shared care on GPs' clinical management has to be studied in more detail.

Another way in fine-tuning might be the introduction of diagnostic tools from specialist to general practice care. When in doubt a GP could refer a patient to a urologist. In 84% of all patients referred to a urology outpatient clinic uroflowmetry is performed.[79] Although uroflowmetry has its limitations it may be helpful in differentiating between BPH and non-BPH causes of the patients complaints. In recent years portable uroflowmetry devices have been developed and tested, delivering results comparable with measurements on the outpatient department.[80-82] The portable devices can be taken home and so provides an instrument giving a good insight into the voiding patterns. With these instruments it has become more feasible to do a flowmetry in general practice, and so assist a more adequate referral. On the other hand there are some doubts on the feasibility of uroflowmetry in general practice; the number of new patients are not very high so one may question whether the GP will have enough routine for adequate interpretation of the diagrams and since there is no special charge for this medical examination it is not sure whether the GP is willing to make the investments to acquire the instrument. Furthermore there is little known about the willingness and ability of the patient fulfil the home measurements. So, before introduction of portable uroflowmetry in general practice on a large scale it is important to study its feasibility.

The Implementation Of Clinical Guidelines

The 1997 Dutch College for General Practitioners guideline and the shared care protocol developed in cooperation with the National Association of Urologists recommend detailed history taking, without using symptoms scores or voiding dairies.[1;2] These guidelines can be summarised as follows. Digital rectal examination (DRE), percussion of the bladder and urine analysis are considered as good clinical practice. A serum creatinine is limited to patients with suspicion of renal failure and PSA testing is restricted to few conditions (family history of prostate carcinoma, inconclusive DRE, start of medication for LUTS and a life expectancy of more than 10 years). In patients with bothersome symptoms who are not able or willing to have surgical treatment the medication of choice is an α-blocking agent, where 5α-reductase blockers are reserved for specialist care. Referral should be considered in men with complicated LUTS.
There is some doubt whether this guideline is followed by the Dutch general practitioner. Guideline monitoring data of a non random sample of GPs showed that PSA was tested in almost two thirds of all patients with voiding problems and this number is rising.[3;83]

There is a large quantity of literature on guideline implementation. In general, evidence shows that none of the approaches for transferring evidence to practice is superior to all changes in all situations. On the other hand, it may be concluded that the approach has to be focused on different levels (doctor, patient and wider environment) and tailored to specific settings. The implementation strategy should account for the guideline and barriers and facilitators to change.[4]

Preparatory interviews with 20 GPs on possible facilitators and barriers for changing routines (described before) and other explorations resulted in the development of an intervention to implement the 1997 update of the guideline on LUTS. From these interviews we extracted targets for behavioural change. In general LUTS were not perceived as a clinical problem and no urge was felt to follow an intensive training programme on LUTS. Just sending recommendations showed conflicting results,[84] on the other hand distance learning,[85] and consultation supporting materials,[86-88] have shown effects on self rated competence and care delivered. Given the relative low priority of the subject for GPs, we needed a simple, relevant, easy to participate, educational programme aimed at encouraging physicians to inform patients and facilitate shared decision making. The Programme for Individual Learning (PIL) could meet these characteristics. This interactive Continuous Medical Education programme consists of small booklets developed by the Dutch College of General Practitioners as one of their implementation strategies for clinical guidelines. Just educating physicians in order to improve their knowledge will not be enough, this knowledge will have to be shared with the patient as well. The role of the patient is changing, as patients are increasingly involved in the management of their illness and health care providers should support them in this role.[89] In the management of patients with LUTS it is considered to be important to involve the patient in making decisions based on his own preferences and needs.[90] As a consequence, patient education and shared decision-making based on the available research evidence are crucial for the adequate management of LUTS and for helping patients to cope with their illness. And patients should be educated in problem solving skills in order to promote self-management.[91]

From this it can be concluded that implementation of the recommendations made in the guideline require an easy accessible, interactive educational programme, supported by tools that can be used in the communication during the consultation of patients attending the surgery because of LUTS. It is not known what the effect of such a multifaceted implementation would be on the actual clinical management of the GP, nor what implications it would have on patient's self management.

RESEARCH QUESTIONS

Further research to the problems mentioned above has to be done. As a consequence the following research questions were formulated.

THE EVIDENCE: CLINICAL GUIDELINES

What is currently the recommended clinical management of lower urinary tract symptoms in general practice in the Netherlands according to evidence found in international literature?
What is the methodological quality of recently published national guidelines on LUTS in different countries?
To what extent can conflicting recommendations be explained by differences in the references used in support of these recommendations?

CLINICAL MANAGEMENT OF LUTS: EXPLORATION OF THE PROBLEM

Which factors explain the decision to visit a GP for lower urinary tract symptoms?
To what extent is the clinical management of patients with uncomplicated LUTS by general practitioners and urologists different and what are the potential effects of shared care on their clinical management?
What is the feasibility of a protocol for uroflowmetry in routine general practice?

THE IMPLEMENTATION OF CLINICAL GUIDELINES

What is the effect of a distance learning programme on the clinical management in general practice for patients with LUTS older than 50 years?
What are the effects of a GP oriented distant learning programme on patient outcomes, particularly patient enablement and patient evaluation of care?
What are the costs in relation to the effects of distance learning on the management of LUTS in patients older than 50 years in general practice?

THE OUTLINE OF THE THESIS

This thesis is presented in three sections. The evidence on clinical management is presented in the first two chapters. The three chapters in the second section concern an exploration of contemporary management of men with LUTS. The last section is reporting the effects

of a trial studying the effect of an implementation strategy of the 1997 update of the Dutch College of General Practitioners guideline on LUTS .

Chapter 1 provides the most recent (2004) update of the guideline on the clinical management of men of 50 years or older with lower urinary tract symptoms as formulated by the Dutch College of General Practitioners. This update is based on the systematic research by the committee with respect to changes in terminology, a new understanding of relations between LUTS and prostate carcinoma and changes in clinical management of LUTS. The summary of the guideline presented in this chapter is an update of the guideline published in 1997, the last has been used as the starting point for the rest of this thesis.

Chapter 2 presents a study concerning five recently published guidelines on LUTS. First a systematic assessment of the quality of these guidelines was performed. Then, recommendations with regards to the initial clinical management were identified and citations linked to these recommendations were collected. The evidence used in 'conflicting' recommendations was explored in a qualitative manner.

In chapter 3 the patient's perspective on LUTS is explored by a survey among 3500 men above the age of 50 years. It reports on factors determining visit to the doctor, or refraining from it, in relation to the complaints experienced.

Chapter 4 reports a survey on the knowledge of the GPs and the urologists of the guidelines and the shared care protocol on LUTS. It studies the potential effects of a shared care clinic on the clinical management of GPs and urologists.

In chapter 5 a pilot study is presented on the feasibility of uroflowmetry as an additional diagnostic instrument in general practice. Based on the literature a protocol was formulated ensuring a proper evaluation of the complaints experienced by the patient. This protocol was tested for 14 months in two different settings; comparing direct accessible uroflowmetry in the own practice with accessibility via a central laboratory.

The last section comprises three chapters reporting the effects of the randomised trial on the implementation of the 1997 update of the Dutch College of General Practitioners guideline on LUTS. This study was performed in the practices of 63 GPs during 14 months after the intervention. In this section chapter 6 reports of the effects of the intervention on the actual clinical management of the 183 included patient with LUTS by the GP. Chapter 7 presents the effects on the care as perceived by the patient; here the evaluation of care and the level to which the patient felt enabled by the GP were measured. The effects of the intervention on costs were evaluated in chapter 8.

Finally in the general discussion the results of the different studies are discussed and the main conclusions are presented.

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SECTION I

The evidence: Clinical guidelines














CHAPTER 1

Summary of the guideline **'Lower urinary tract symptoms in elderly men'** (second revision) of the Dutch College of General Practitioners

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Abstract

The underlying cause of lower urinary tract symptoms (LUTS) in middle-aged and elderly men is an improperly functioning voiding mechanism of the bladder because of ageing. Symptoms are not simply due to prostate-enlargement. In uncomplicated LUTS patients' perception of the amount of bother is very important in considering and choosing therapeutic options.

In general, for symptom relief invasive treatment is more effective than medical treatment, although invasive treatment causes more adverse effects.

LUTS and prostate cancer are different entities, and having LUTS is not associated with an increased risk of prostate cancer. This issue is discussed to clarify underlying thoughts and the practical use of this guideline.

Introduction

The Dutch College of General Practitioners (*NHG*) guideline on lower urinary tract symptoms that was published in 1997 needed revision because of new insights with regards to terminology, diagnostics and treatment possibilities. In this summary we focus on these new insights and the changes in comparison with the previous version of the guideline. Full text and the evidence used are published in *Huisarts en Wetenschap*[1] and on the website of the Dutch College of General Practitioners.[2] The guideline was summarized on page 30 and 31.

Background

Lower urinary tract symptoms are defined as a change in voiding leading to symptoms as difficulties in starting micturation, a weak flow, urge, difficulty in emptying the bladder and an increase in the voiding frequency during day and night. Terms as prostatism and benign prostatic hyperplasia were used for these complaints in the past.
The relation between the voiding problems and the size of the prostate or to what extend the urethra was obstructed was limited. In international literature the term lower urinary tract symptoms (LUTS) has been increasingly used.[3] Benign prostatic hyperplasia will be reserved to described histological changes of the prostate.

Recommendations For Diagnostics

With respect to history taking it is not only important to ask for the actual severity of symptoms, but also the bother perceived. The bother can be limited due to the gradual development and the changes in the natural course of the symptoms. On the other hand an underlying fear of prostate cancer could augment the bother perceived.[4] The bother perceived plays an important role in the clinical management.
The recommendation to perform a percussion of the bladder in every patient in order to identify urine retention in the bladder was removed from the new guideline. In daily care percussion is laborious and on second look the clinical relevance of a bladder residue was limited. After voiding almost all men appear to have some residue, and moreover

Update 2004: revision of guideline published in 1997 november 2004

LOWER URINARY TRACT SYMPTOMS IN ELDERLY MEN NHG-GUIDELINE (summary) M42

CONCEPTS

Urinary difficulty: changes in urination that lead to complaints such as hesitation before urine flow starts, weak or intermittent urinary stream, an urgent need to urinate, the feeling that the bladder has not emptied completely and increased frequency of urination.

GUIDELINES FOR DIAGNOSTICS

Anamnesis

Ask about:
- hesitation before urine flow starts, weak or intermittent urinary stream, urgent need to urinate, the feeling that the bladder has not emptied completely, changes in urinary pattern during the day and at night;
- rate of onset or rate of deterioration of the complaints;
- does it affect the night's sleep, or cause social limitations during the day, incontinence;
- pain during urination, perineal pain;
- general malaise, previous urinary tract infections.

Pay attention to:
- relevant comorbidity: diabetes mellitus, neurological disorders (e.g. CVA, Parkinson's disease, multiple sclerosis), previous urethritis (sexually transmitted diseases);
- previous urological investigations, history of urological treatment or indwelling catheter;
- medication that influences micturition: antipsycholics, (tricyclic) antidepressives, anti-Parkinson drugs, (classic) antihistamines, opiates, loopdiuretics.

Physical examination

- ★ Check for possible scar tissue on lower abdomen, phimosis.
- ★ Percussion of the bladder on suspicion of neurogenic bladder, bladder overflow and acute urine retention (see evaluation).
- ★ Conduct a digital rectal examination: pay attention to shape, texture, size and sensitivity to pressure.

Supplementary tests

- ★ Examine urine for signs of urinary tract infection (see NHG Guideline Urinary Tract Infections).
- ★ If general malaise, recurring urinary tract infections or urine retention: ultrasound of the urinary tract (exclude hydronephrosis) and serum creatinine analysis.

Evaluation

There are strong indications of urinary difficulty when older men complain of urination problems and there are no signs of a specific cause as:
- prostatitis: complaints developed rapidly, perineal pain, pressure sensitive prostate during digital rectal examination;
- urinary tract infection: positive urine sediment, nitrite test or culture;
- urine incontinence: involuntarily urinary loss, ≥ 2 times a month;
- reflex bladder: dull percussion sounds or post voiding residual urine and diabetes mellitus or a neurological disease;
- overflow bladder: continuous loss of small amounts of urine without feeling the urge, and post voiding residual urine;
- urethral stricture: history of local trauma, urological intervention or urethritis;
- acute urine retention: incompetent to urinate spontaneously within a few hours, despite a (painfull) urge and after multiple attempts and dull percussion sounds.

GUIDELINE POLICY

Patient education and wait-and-see policy

- ★ Complaints can be caused by age-related changes in bladder function and sometimes by obstruction around the urethra and in the prostate.
- ★ The common occurrence of the disorder, its benign character and varying course.
- ★ The management policy depends strongly on the patient's wishes
- ★ Certain types of medication can aggravate the complaints.

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- Advice the patient to go to the toilet regularly.
- It is important the patient takes his time to urinate.
- Ask the patient to contact the surgery immediately if complaints suggest acute urine retention.

Treatment with medication

- Medication has a limited effect on the complaints.
- Medication is limited to patients with troublesome complaints who derive insufficient benefit from following their GP's advice and are not eligible (or willing) to undergo invasive treatment.
- Choose alfluzosine 10 mg once a day in the evening after meals or tamsulosine 0.4 mg once a day in the morning after breakfast.
- In the case of slight-moderate liver function disturbances alfluzosine 2.5 mg tablet 1-2 times per day after meals.
- Beware of orthostatic hypotension (especially during the initial period of use).
- If there is no improvement within 6 weeks: medication is stopped. In patients who derive benefit: after 3 to 6 months medication is stopped to evaluate whether complaints recur.

Invasive treatment

- Indications for invasive treatments as TURP: see referral.
- Global advantages and disadvantages vary with invasive treatment: 60 to 75% of improvement, 1-25% incontinence, 1-10% erectile dysfunction and 4-61% ejaculation problems.

Check-ups

In the case of changes or deterioration in the complaints a check-up takes place and the diagnosis is reconsidered. The GP investigates whether there are:
- general malaise, new comorbidity or new medication.
- urine infection.

On certain indications, percussion of the bladder, digital rectal examination, abdominal ultrasound scanning and the creatinine level testing are performed (see Supplementary tests).
Check-ups related to the start of treatment with medication (in person or by telephone) take place
- after 6 weeks to evaluate the effect
- after 3-6 months to discuss with the patient whether the medication can be stopped

Referral

Refer on the suspicion of a neurogenic bladder disorder, overflow bladder or urethral stricture. Refer for possible invasive treatment in case of:
- Request for invasive treatment due to perceived troublesomeness;
- Recurrent urinary tract infections or recurrent acute urine retention;
- Renal function disturbances and/or hydronephrosis.

SUSPECTED PROSTATE CARCINOMA

Urinary difficulty does not form a risk factor for prostate carcinoma
If at digital rectal examination a *prostate carcinoma* is *suspected* (without clinical indications of metastases) the following practical guidelines apply to the GP:
- Refer after patient education to a urologist for further diagnostics and evaluation of the therapeutic options.
- Discuss in patients with a life expectancy of less than 10 years (>72 years and <72 in whom comorbidity has a negative influence on life expectancy) that a prostate carcinoma generally grows very slowly and quality of life will probably not improve much through medical intervention, whereas there is a considerable risk of side-effects.
- Discuss in patients with a life expectancy > 10 years (<72 without serious comorbidity) that they will possibly benefit from a medical intervention.

If there are clinical indications of metastases (general malaise, weight loss, bone pain in the back/hip) refer to a urologist.

Screening for prostate carcinoma in a patient without complaints is not advisable. If a complaint-free patient still wishes to be screened for prostate cancer despite having received information, the GP performs digital rectal examination and PSA analysis.
- PSA>4ng/ml or abnormal digital rectal examination provide suspicion for prostate carcinoma (see above).
- PSA 4-10 ng/ml and normal digital rectal examination may have several causes, after discussing the matter with the patient repeat the PSA analysis at a later date.

The complete text of the NHG guideline has been published in 'Huisarts en Wetenschap'

this increases with rising age.[5;6] Post void residual urine may give lead to hydronephrosis and renal insufficiency, but the exact pathogenesis and what men are at risk is not clear.[7] Furthermore the characteristics of percussion of the bladder as a diagnostic test are insufficient to detect or exclude a post void residue in all patients. Percussion of the bladder may be valuable if there is a suspicion of reflex bladder, an overflow bladder or acute urinary retention, since in these cases clinical relevant post void residual urine will be more easily detected. If there is a strong suspicion of urinary retention and percussion appears to be normal; a trial of catheterisation of the bladder may be necessary.

Although the digital rectal examination is of limited diagnostic value in patients with lower urinary tract symptoms, the guideline development group has decided to recommend digital rectal examination in order to be better informed on local circumstances (e.g. constipation and rectal pathology), prostatitis as a possible cause of lower urinary tract symptoms and to meet patient expectations.

Recommendations For Treatment

Due to the benign nature of lower urinary tract symptoms and its variable course this revision of the guideline focuses on shared decision making on treatment possibilities. Although in general invasive treatment options result in a better symptom improvement in comparison to drug treatment, the risk of complications is higher as well. Therefore the treatment chosen will strongly depend on perceived bother and patient's needs. A watchful waiting policy is realistic since an intervention is often not needed because of the variable course.

In pharmaceutical treatment α-receptor blocking agents are preferred (α-blockers). They decrease the outflow obstruction by altering the smooth muscle tone within the prostate and the urinary tract. Studies showed that all α-blockers appear to be practically similar effective and safe. Nevertheless, alfluzosine and tamsulosine are preferred, since patients tend to show less often treatment discontinuation due to side effects in these.[8-11] Because of the variability in natural course of the symptoms it is sound to stop medication after a period of 3-6 months and evaluate whether symptoms will recur.

In general practice there is no room for the use of 5-α-reductase inhibitors, since it lasts a considerable time until there is a clinical effect and this effect occurs in particular in larger prostates.[12]

The guideline provides furthermore general information on (dis)advantages of surgical management. Traditional surgical interventions (e.g. transurethral resection of the

prostate) as well as less invasive treatment are briefly discussed.[13] The general practitioner will refer to a urologist if a patient considers a surgical intervention. Other indications for referral are diagnostic doubts, or treatment failure on medication prescribed.

Prostate Carcinoma In Relation To This Guideline

The understanding of lower urinary tract symptoms and prostate carcinoma being two separate entities as far as cause and incidence concerned is an important change to previous versions of the guideline. The literature shows that the presence of lower urinary tract symptoms appears to be no risk factor to prostate carcinoma: the prevalence of prostate carcinoma in an open population of men with lower urinary tract symptoms is equal to those without such symptoms.[14;15] Testing for prostate carcinoma in all men with lower urinary tract symptoms visiting the surgery would mean screening, something that is still not proven sensible.[16-19] Prostate carcinoma is yet incorporated in this guideline, since men with lower urinary tract symptoms and their (general) practitioners still relate these symptoms to prostate carcinoma. Moreover the suspicion of a prostate carcinoma may rise at the performance of a digital rectal examination, with a different clinical management as a consequence. Finally, questions on screening for a prostate carcinoma are often posed. To give appropriate advice specific knowledge is needed. It is expected that clarity on the management of (questions about) prostate carcinoma will improve the implementation of this guideline.

Patients suspected of prostate carcinoma will generally be referred to a urologist for further diagnosis and treatment. With regards to the prostate carcinoma some reflections can be offered: in general it grows slowly, it does not reveal itself, or only in a disseminated stage, by complaints and it has not (yet) been proven that treatment of prostate carcinoma increases survival, whereas there may be side-effects of diagnostics and treatments.

In particular this accounts for patients with a life expectancy of less then 10 years, where it is doubtful whether life expectancy and quality of life will improve substantially, while there are possible side effects to expect. These patients can chose for clinical management by the general practitioner, possibly after referral for only diagnosing the cancer. It is important that the general practitioner stays aware of possible metastases, since treatment is than sensible with regards to reductions of symptoms and prevention of complications.

In case of a suspect digital rectal examination a prostate carcinoma is diagnosed in half of the patients, in the assumption of a 2-5% prevalence.[20] As a consequence a routine PSA-test in primary care does have no implications to clinical management: a normal PSA does not

rule out a prostate carcinoma and in case of an increased PSA always referral is needed for further evaluation. Moreover, the PSA-test is not disease specific and in its normal values age and prostate size dependent.

Men without complaints requesting screening on prostate carcinoma have to be informed on absence of evidence for the benefit of the test. It has not been established that early detection and treatment of patients with an asymptomatic prostate carcinoma provides a decrease of suffering or prevent early death. On the other hand there is the burden of the diagnostic procedures and the complications of treatment. Although men with a familial occurrence of prostate carcinoma have an increased risk of obtaining it, the benefit of early detection is also not proven in this group. Nevertheless, the general practitioner can in some occasions allow screening, on the condition that the patient is well informed about all (dis)advantages.

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CHAPTER 2

Initial diagnosis and management of lower urinary tract symptoms in elderly men

No consensus on the evidence in clinical practice guidelines

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Submitted

Abstract

Context

As guideline makers are supposed to have access to the same sources of research evidence, one would expect guidelines to be similar. Several studies showed that not all the guidelines gave the same recommendations on clinical management. In this study, we explored the use and interpretation of the evidence as a potential explanation for variation between guidelines, using lower urinary tract symptoms (LUTS) as an example.

Methods

Electronic literature databases and web sites of institutions known to develop guidelines were searched for national guidelines on LUTS. Using the AGREE-instrument, these were systematically assessed in terms of quality. Recommendations with regard to the initial clinical management were subsequently identified and their citations were collected. The evidence used in 'conflicting' recommendations was explored in a qualitative manner.

Results

Five guidelines met the inclusion criteria and were assessed. The Australian guideline scored highest on all AGREE domains. Of the 227 citations found in relation to initial clinical management, only 11.9% were used in more than one guideline. There appeared to be a correlation between the country in which a guideline was developed and the number of references, from the same country, that was used. In general, diagnostic recommendations were more often 'do's' or 'don'ts', rather than therapeutic recommendations that were more often 'optional'. The NHMRC guideline had more 'don'ts' where clear evidence was lacking, compared to the AUA guideline, which was less restrictive and left some decisions 'optional'.

Conclusions

The selection of evidence is less objective than is suggested within the concept of evidence-based medicine. For some selected topics, a certain bias in the use of evidence was found, as a few studies were the same but were used to underpin conflicting recommendations. Better worldwide collaboration is recommended between multi disciplinary developer groups. And guideline developers should report the methods for selecting the evidence explicitly.

Introduction

During the last two decades, clinical practice guidelines have been developed for many clinical conditions to assist practitioners and patients in their decisions about appropriate health care.[1] In general, guideline programmes intend to achieve optimal care for patients and sometimes cost containment as well.[2] The purpose of evidence-based guidelines is to provide specific recommendations for practice, which are explicitly linked to the supporting evidence.[3] Although guideline developers have access to the same sources of research evidence (e.g., MEDLINE, Cochrane Library) recommendations appeared to be conflicting, for instance in guidelines on breast cancer,[4;5] low back pain,[6;7] neck pain,[8] thyroid dysfunction,[9] diabetes,[10] atrial fibrillation,[11] Chronic Obstructive Pulmonary Disease,[12] uncomplicated cystitis[13] and benign prostatic hyperplasia.[14;15] We know little about the exact cause of such differences; inappropriate interpretation of research findings may have led to inadequate use of medical interventions. Experts in the guideline working group might have had conflicts of interests, which could have biased the interpretation of evidence.[16] Cultural factors might also play a role.[17] In this study, we explored the use and interpretation of the evidence as a potential explanation for variation between guidelines, using lower urinary tract symptoms (LUTS) as an example.

LUTS is a common problem, especially in elderly men. The understanding of LUTS is changing and the causal role of benign prostatic hyperplasia is questioned since one third of the voiding problems are not related to urethral obstruction.[18] As the population is aging, there is a growing demand for appropriate diagnosis and effective treatment of LUTS. The increasing availability of non-invasive treatments, such as new drugs, may suggest that voiding problems can be treated more easily than before.[19] With the introduction of α-blocking medication, the management of LUTS has increasingly shifted from the specialist to the primary care physician in various countries.[20-25] Therefore, there has been a need to develop guidelines in order to optimize the quality of care. In addition, public awareness is increasing, and LUTS are related to carcinoma of the prostate in the perception of many patients. They assume that PSA testing might help in preventing advanced disease, although this is still an issue of debate.[26-29] Guidelines could solve this problem by providing clear and unambiguous recommendations based on the best available evidence. Recently, two studies compared international guidelines on benign prostatic hyperplasia. They found that most guidelines largely gave similar recommendations, although there were differences with respect to PSA testing and imaging of the urinary tract.[14;15]

The aim of this study was to analyze in more detail the background of differences in recommendations by comparing and analyzing the citations in recent guidelines on LUTS, in particular those in support of conflicting recommendations.

Methods

Search strategy

Guidelines of LUTS were identified by a computerized search of the database of MEDLINE, CINAHL and Current Contents from 1999 - 2003. Search in free text, and/or in MESH terms included the following terms: prostatic hyperplasia, urination-disorders, urethral obstruction, bladder-neck-obstruction, micturation problems, voiding problem, urinary problems, voiding disorders, micturation disorders, urinary disorders, LUTS, lower urinary tract symptoms, BPH, family practice (standards), family physicians (standards), urology (standards), guidelines, practice-guidelines, policies, standards, protocols. The detailed search strategy is presented in appendix A. In addition, an Internet search was performed in November 2003 by searching web sites of (inter)national institutes that were expected to be related with guideline making,[2;15] supplemented with a search on www.Google.com using the following string: 'clinical guideline' OR 'clinical protocol' OR 'practice guideline' OR LUTS OR BPH OR 'prostatic hyperplasia'.) (Appendix B).

Inclusion of guidelines

Only (inter)national guidelines written (or translated) into English and published from 1999 were included. Guidelines published before 1999 were considered to be out of date.[30] The guidelines covered diagnosis and/or management of lower urinary tract symptoms in older men and included recommendations concerning the initial management of patients with LUTS. Guidelines that did not link their individual recommendations to references were excluded.

Assessment of the quality of the guidelines

An assessment of a guideline is necessary before adopting it for use in clinical practice. High-quality guidelines account for potential biases in their development, for their

internal and external validity, and their feasibility in normal practice.[31] The internationally validated and widely accepted Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument was used to appraise the guidelines. The AGREE-instrument consists of 23 items grouped into six domains (*scope and purpose, stake holder involvement, rigor of development, clarity and presentation, applicability, editorial independence*) (Appendix D). Two appraisers (RW and JB) evaluated the selected guidelines independently and scored these using the AGREE instrument. Discrepancies were resolved by discussion or by adjudication of a third reviewer (MW) blinded to the previous reviews.

Bibliographic analysis of scientific evidence underlying the recommendations

We confined ourselves to the topics related to the initial care management of patients with LUTS. We identified the recommendations in the guidelines, which were defined as any statements which promote or advocate a particular course of action in clinical primary care (appendix E).
Subsequently, we compiled citations that were explicitly linked to the recommendations or listed at the end of relevant sections. We tabulated the year of publication, authors, the country of the first author as declared in MEDLINE and the abstract for each citation. Each citation was entered into a Reference Manager database (Version 10), adding a unique identifier code for each guideline. We used the Reference Manager search facility to quantify the numbers of citations shared with other guidelines and the country of the first author as a proxy for the country of origin of the cited study.

Qualitative analysis of evidence

We defined the main topics that should be covered in the guideline. For each topic, the specific statements identified as recommendations were categorized as: positive recommendation ('do it'), negative recommendation ('don't do it'), option ('probably do it' or 'probably don't do it').[32] If the guideline did not formulate specific statements with respect to the topic, then we distinguished two other categories: 'mentioned' (text available but no specific recommendations) and 'not mentioned' (no text available covering the topic). In case of conflicting recommendations (i.e. positive versus negative), the cited studies were compared and the content of the guideline was carefully examined for justification for the choices made.

Results

Sample of guidelines

Eighteen potential guidelines were identified. Twelve of these guidelines were found in MEDLINE[33-44] and two of these were 'duplicates', as they were updated versions of another guideline in the sample.[43;44] The databases of CINAHL and Current Contents did not provide extra guidelines. The Internet search yielded eight additional guidelines.[45-52] We excluded five guidelines that were published before 1999, nine that were not in English and one that did not have any references (Appendix C). Thus, based on our criteria, five of the eighteen guidelines were included: one from the United States of America, one from the United Kingdom, one from Finland, one from Australia and one (international) European guideline.[47;49;53-55] (Table 1).

Assessment of the quality of the guidelines

The appraisal with the AGREE Instrument [31] showed that the guideline developed by the NHMRC [47] scored highest on all AGREE domains (Table 2). The guideline of the European Association of Urology [53] had the lowest score in all domains, except for clarity and presentation. The other three guidelines [49;54;55] scored intermediate.
According to the criteria for overall assessment in the AGREE Instrument Training Manual (www.g-i-n.net), the NHMRC guideline would be strongly recommended for use in practice, the SCHiN and AUA guideline would be recommended with provisos or alterations and the Duodecim and EAU guideline would not be recommended.

Bibliographic analysis of scientific evidence underlying the recommendations

The five guidelines comprised a total of 654 different references (range: 13-318 per guideline). Of these, 277 (42.4%) were linked to recommendations on initial care of patients with complaints of LUTS (Appendix E). Only 33 (11.9%) of these 277 references were used in more than one guideline (Table 3). No references were shared between four or all of the guidelines. Three references were used in three guidelines; these were the original Agency for Health Care Policy and Research (AHCPR) guideline on benign prostatic hyperplasia published in 1994 [56] and two studies on treatment of LUTS: one studying the use of terasozin and finasteride [57] and the other comparing surgery with watchful waiting.[58]

Table 1*: *General characteristics of the included guidelines

Title	Website-address	Organization (Year and country of publication)
The Management of Benign Prostatic Hyperplasia Guideline[42;54]	http://shop.auanet.org/timssnet/products/clinical_guidelines/index.cfm	American Urological Association (2003, USA)
Treatment recommendation for benign prostatic hyperplasia [34;55]	http://www.ebm-guidelines.com/home.html (http://195.236.0.10/pls/ebmg/ltk.koti?u=9010290&hakusana=)	Duodecim / Evidence-Based Medicine guidelines (2002, Finland)
European Association of Urology Guidelines on benign prostatic hyperplasia [39;53]	http://www.uroweb.nl/files/uploaded_files/guidelines/updateBPH.pdf	European Association of Urology (2002, Europe)
The management of uncomplicated lower urinary tract symptoms [47]	http://www.nhmrc.gov.au/publications/pdf/cp42.pdf	National Health and Medical Research Council (2000, Australia)
Benign hyperplasia prostate [49]	http://www.prodigy.nhs.uk/guidance.asp?gt=Prostate%20-%20benign%20hyperplasia	Sowerby Centre for Health informatics at Newcastle (SCHiN) for NHS (2003, UK)

Table 2*: *Standardized domain score according to AGREE

AGREE	AUA[54]	Duodecim[55]	EAU[53]	NHMRC[47]	SCHiN[49]
Scope and purpose	56%	22%	11%	100%	100%
Stakeholder involvement	50%	50%	0%	83%	50%
Rigor of development	86%	48%	29%	95%	62%
Clarity and presentation	67%	50%	67%	100%	100%
Applicability	13%	13%	13%	75%	50%
Editorial independence	67%	33%	17%	100%	17%

In most references, the first author originated from the United States of America. There appeared to be a clear correlation between the county of the guideline developers and the number of references used that originated from this country (Table 3).

Qualitative analysis of evidence

The format of the guidelines strongly varied: where the UK[49] and the Finnish guideline[55] summed up the recommendations, the recommendations in the NHMRC,[47] EAU[53] and AUA[54] guidelines were part of a narrative text. For most of the topics the recommendations showed no explicit inconsistency between the guidelines. In general,

Table 3*: *Number of references used in five guidelines on LUTS and their country of origin

	AUA[54]	Duodecim[55]	EAU[53]	NHMRC[47]	SCHiN[49]
Nº of references used related to initial care (reference set)	55	11	135	98	21
Nº of references used related to initial care shared with at least 1 other guideline	17 (30.9%)	2 (19.2%)	32 (23.7%)	20(20.4%)	5 (23.8%)
Origin of first author of references (countries contributing more than 5% are presented)	USA: 38 (69.1%) UK: 3 (5.5%)	USA: 4 (36.3%) UK, Italy, New Zealand: each 2 (18.2%)	USA: 57 (42.2%) UK:19 (14.1%) Netherlands: 14 (10.4%)	USA: 35 (35.7%) UK: 14 (14.3%) Australia: 6 (6%)	USA: 10 (47.6%) UK: 4 (19.1%)

Table 4*: *Conflicting recommendations *(complete table with references is presented in Appendix E)*

	AUA[54]	Duodecim[55]	EAU[53]	NHMRC[47]	SCHiN[49]
Laboratory examinations					
Creatinine	NR	R	R	NR	R
PSA	O	R	R	NR	O
Additional Examinations					
Residual volume	O	R	R	NR	NM
Transrectal ultrasound prostate	O	M	O	NR	M
Ultrasound upper urinary tract	O	M	O	NR	M
Uroflowmetry	O	M	O	NR	M
Urodynamic investigations	O	M	O	NR	M
Counseling and treatment					
α-blocking agents and 5α-reductase inhibitors	O	NM	NR	NM	NR
Phytotherapy	NR	M	M	NR	O

R: Recommended, O: Optional, NR: Not recommended, M: Mentioned in the text without giving a recommendation, NM: Not Mentioned in the guideline

diagnostic recommendations were more often 'do's' or 'don'ts', rather than therapeutic recommendations that were more often 'optional'. The NHMRC guideline had more 'don'ts' where clear evidence was lacking, compared to the AUA guideline, which was less restrictive and left some decisions 'optional'.

The recommendations on measurement of the residual volume, and the creatinine- and PSA-testing were conflicting (Table 4). 'Conflicting' recommendations and their references

Box 1: Conflicting recommendations in the initial management of Lower Urinary Tract Symptoms

Creatinine testing

Conflicting recommendations of the NHMRC, which did not recommend creatinine testing, and the EAU which recommended it, were partly based on the same studies.[56;59;60] Although both guidelines agreed that LUTS is rarely complicated with renal insufficiency, they came to different conclusions. The EAU guideline favored testing, because it assumed that measuring serum creatinine in all patients is cost effective and stated furthermore that creatinine testing was recommended in a 1997 urologists consensus conference.[61] In the AUA guideline, the panel of experts decided that creatinine is not recommended without providing any literature.

PSA testing

According to the NMHCR guideline, "*it is not recommended to estimate serum PSA as part of the normal evaluation of a man with LUTS*". Without giving the precise criteria, the EAU and the AUA still recommended PSA measurement "*when a diagnosis of prostatic carcinoma will change the decision that is to be made about which therapeutic option to use*". The AUA guideline explicitly stated that it should only be offered to patients with a life expectancy of more than 10 years. NHMRC and AUA guidelines emphasized that the patient should be fully informed about the consequences of a PSA test before ordering the test.

Three references linked to PSA occurred in more than one guideline. A study among 6630 men on the validity of the combination of PSA and DRE in the diagnosis of prostate cancer [62] was used in NHMRC to support the absence of a relation between LUTS and prostate cancer; and in AUA to support that a combination of PSA and DRE is a relatively sensitive way to exclude prostate cancer as a diagnosis. AUA and EAU used the same two references to underline that PSA is not only related to prostate cancer, but that it is also related to prostate volume in men with BPH without evidence of prostate cancer,[63] and a predictor of acute urinary retention.[64]

Measurement of the residual volume

Measurement of the post-void residual urine measurement was recommended by the EAU without any further explanation in the text. Because of the intra-individual variation and the absence of significant data on the relation with improved patient outcome it was not recommended by the NHMRC. The AUA panel considered the use of PVR measurements optional in men undergoing noninvasive therapy, because the safety of noninvasive therapy for patients with residual urine had not been documented. On the other hand, no level of residual urine mandates invasive therapy since natural course of many of these patients is uncomplicated. The only overlapping reference, concerning a randomized controlled trial comparing surgery to watchful waiting (556 men) that concluded that the level of bother, and not the residual volume, was the best predictor of success of surgery,[58] was used by the AUA and NHMRC to support this view.

are presented in more detail in Box 1. This regards only those three guidelines that were explicit about the choices made (NHMRC,[47] EAU [53] and AUA [54]).

Discussion

Our study examined the use of evidence in the development of clinical practice guidelines. We analyzed five recently published guidelines on LUTS with respect to recommendations on the initial management. The methodology assessed with the AGREE Instrument varied largely between the guidelines, which might explain the low proportion of shared evidence. Only 11.3% of the 227 references related to the initial care of the patient with LUTS were used in more than one guideline and some of these support conflicting recommendations. There also seemed to be a country-bias in the selection of references. Therefore, the selection of evidence is less objective than is suggested within the concept of evidence-based medicine. For some selected topics, we also found a certain bias in the use of evidence, because the same studies were used to underpin conflicting recommendations in some cases.

Both the AUA and NHMRC guideline have high scores in the AGREE domain of *Rigor of development*, which relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations and to update them.[31] Nevertheless, they interpreted the evidence differently in some topics. It seems that the Australian NHMRC guideline is more directive and professional orientated leading to more 'don't recommendations' compared to the AUA guidelines which contains more optional recommendations and leaves the final decision to the interaction between practitioner and patient. The AUA guideline could be considered as defensive medicine that might be explained by the US health care system, including free access to specialist care, competition between health care providers and autonomous patients with high expectations of medical care.[65]

In this study, we analyzed the quality as well as the clinical content of the guidelines. Conflicting recommendations were further analyzed by examining the references in order to explain the differences. Since the 1990s, the evidence collected in electronic databases is available to guideline developers all over the world. However, some variation in guidelines concerning the same subject cannot be excluded. This can be explained by context-specific factors such as the health care system, need for cost constraint, influence of patient preferences, and specific professional interests. In formulating recommendations these factors might even be as important as the evidence.[16] We studied guidelines on

LUTS, in which the search was restricted to the last five years to minimize differences that could be explained by scientific progress with respect to LUTS or criteria for guideline development. A previous study showed that on average half of the guidelines become outdated after 5.8 years.[30] One might ask whether our findings are transferable to guidelines in other disease areas. On the other hand, conflicting recommendations given were also found in guidelines on other topics as well.[4-13] Variation was thought to be due to the methods used to formulate recommendations (consensus versus evidence based)[5] or in the methodological quality.[7;8;11;12;15] Some authors suggested that cultural factors could explain different values of physicians as well as patients, which may result in different recommendations, even when the same evidence is used.[4;13]

The five guidelines assessed in this study were developed by credible institutes producing guidelines on several subjects; the NHMRC, Duodecim and SCHiN also produce guidelines on non-urologic subjects.

All of the guidelines, except for the EAU guideline, were very explicit about the method of searching the literature in contrast to the guidelines analyzed by Irani, *et al.*[15] Nevertheless only a small minority of the references were used in more than one guideline. This finding is consistent with other guideline studies on diabetes and cystitis.[10;13] The low proportion of shared references suggests some bias in the selection of literature. Raine, *et al.* also suggested that evidence may be used to justify pre-existing opinions.[66] On the other hand, guidelines should also be sensitive to local conditions and needs of medical care, which may account for some variations in recommendations. In that respect, it is remarkable that – despite the lack of overlap in references – the guidelines on LUTS provide similar recommendations on most topics covered by the guidelines. This might be explained by the international impact of the Agency for Health Care Policy and Research (AHCPR) guideline on Benign Prostatic Hyperplasia published in 1994.[56] This comprehensive document was seen as a standard for many years and was used as a reference in three of the five guidelines in our study. In addition, international consensus conferences on the clinical management of benign prostatic hyperplasia may also contribute to international consensus.[67]

Conclusions

Although the evidence is available worldwide, there is only little overlap between the references used in guidelines. Evidence-based medicine suggests objectivity, but the selection and use of evidence is not neutral in practice. Better worldwide collaboration between guideline developers is recommended. Guideline development demands a

balanced judgment about applicability, consistency, and clinical impact of the evidence.[68] A balanced multi disciplinary guideline developing working group being explicit about potential conflicts of interests, is necessary to rule out strong personal biases.[69] Explicit reporting of the methods used in selecting the evidence (i.e. search strategy, inclusion/exclusion criteria) and formulating the recommendations should increase the transparency of a guideline.

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APPENDICES CHAPTER 2

Appendix A: Number of records found in the three literature databases used

Number of records		MEDLINE: 1999 - 2003	CINAHL 1999 - 2003	Current Contents 1999 - 2003
#1	'Prostatic-Hyperplasia' / all subheadings in MIME,MJME	2497	-	-
#2	'Prostatic-Hypertrophy ' / all topical subheadings / all age subheadings in DE	-	196	-
#3	'Urination-Disorders' / all subheadings in MIME,MJME	1118	122*	-
#4	'Urethral-Obstruction' / all subheadings in MIME,MJME	288	-	-
#5	'Bladder-Neck-Obstruction' / all subheadings in MIME,MJME	496	-	-
#6	micturation adj problem*	1	1	2
#7	voiding adj problem*	44	6	38
#8	urinary adj problem*	48	13	39
#9	voiding adj disorder*	65	9	54
#10	micturation adj disorder*	1	0	1
#11	urinary adj disorder*	42	14	28
#12	luts	283	17	293
#13	lower adj urinary adj tract adj symptom*	684	95	595
#14	BPH	1349	108	1351
#15	Prostat* adj hyperplas*	2006	225	1707
#16	Prostat* adj hypertro*	229	43	163
#17	'Family-Practice' / standards in MIME,MJME	1291	1515*	-
#18	'Physicians-Family' / standards in MIME,MJME	204	1272*	-
#19	'Urology-' / standards in MIME,MJME	57	-	-
#20	'Physicians-' / all topical subheadings / all subheadings in DE	-	4974	-
#21	'Urologic-Nursing' /all topical subheadings/ all subheadings in DE	-	150	-
#22	'Guidelines-' / all subheadings in MIME,MJME	7277	-	-
#23	'Practice-Guidelines' / all subheadings in MIME,MJME	15009	3937*	-
#24	guideline*	42164	26902	30582
#25	protocol*	54328	9441	47021
#26	#1 or #2 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 (when available/ appropriate)	4950	555	2789
#27	#17 or #18 or #19 or #20 or #23 or #24 or #25 (when available/appropriate)	95456	40854	76287
#28	#26 and #27	214	99	114

**: where 'all subheadings in MIME,MJME' it should be read 'all topical subheadings / all age subheadings in DE'*

Appendix B: Health organisation sites searched for guidelines (countries in alphabetic order)

Australia:
* http://www.health.act.gov.au/
* http://www.health.gov.au/
* http://www.health.nsw.gov.au/public-health/
* http://www.mja.com.au/public/guides/

Austria:
* http://www.oegam.at/

Canada:
* http://dfcm19.med.utoronto.ca/
* http://mdm.ca/cpgsnew/cpgs/
* http://www.albertadoctors.org/resources/guidelines.html
* http://www.ahfmr.ab.ca/
* http://www.cancercare.on.ca/ccopgi
* http://www.cma.ca/cpgs
* http://www.ccohta.ca/
* http://www.fhs.mcmaster.ca/fammed/
* http://www.gacguidelines.ca/
* http://www.hc-sc.gc.ca/pphb-dgspsp/
* http://www.hlth.gov.bc.ca/msp/protoguides/gps/
* http://www.ottawahospital.on.ca/library/
* http://www.smh.toronto.on.ca/

Denmark:
* http://www.dsi.dk/

Finland:
* http://www.duodecim.fi
* http://www.ebm-guidelines.com/home.html
* http://www.stakes.fi/english/

France:
* http://www.anaes.fr/
* http://www.upml.fr/andem/andem.htm

Germany:
* http://www.degam.de/S5_leit_themen.html
* http://www.leitlinien.de/
* http://www.uni-duesseldorf.de/WWW/AWMF/

Greece:
* http://147.102.33.1/helsqua/greece.htm

Israel:
* http://www.goldenhour.co.il/

Netherlands:
* www.artsen.net/nhg
* http://www.cbo.nl/
* http://www.landauer.net
* http://www.paramedisch.org/

New Zealand:
* http://nzhta.chmeds.ac.nz/
* http://www.nzgg.org.nz/library.cfm

Singapore:
* http://www.gov.sg/moh/mohinfo/prof-info.html

Spain:
* http://www.aatm.es/cgi-bin/frame.pl/ang/pu.html

Sweden:
* http://www.sbu.se/admin/index.asp

Switserland
* http://www.hin.ch/htbin/Hin-Homepage.pl

United Kingdom:
* http://www.demon.co.uk/scarbpg/guides/
* http://www.eguidelines.co.uk/
* http://www.equip.ac.uk/
* http://www.healthcentre.org.uk/hc/
* http://www.leeds.ac.uk/nuffield/infoservices/UKCH/
* http://www.leeds.ac.uk/nuffield/infoservices/ECHHO/
* http://www.ncl.ac.uk/chsr/
* http://www.nelh.nhs.uk/guidelinesfinder/
* http://www.nice.org.uk/
* http://www.prodigy.nhs.uk/ClinicalGuidance/
* http://www.rcgp.org.uk/index.asp
* http://www.sghms.ac.uk/depts/phs/hceu/
* http://www.show.scot.nhs.uk/sign/guidelines/
* http://www.sign.ac.uk
* http://www.york.ac.uk/inst/crd/

United States of America:
* http://consensus.nih.gov
* http://doctorpage.com/drpage/cpgdlines.htm
* http://hstat.nlm.nih.gov
* http://medicine.ucsf.edu/resources/guidelines/
* http://primarycare.medscape.com/
* http://shop.auanet.org/timssnet/products/
* http://text.nlm.nih.gov/ftrs/
* http://www.acponline.org/sci-policy/guidelines/
* http://www.aafp.org
* http://www.ahcpr.gov
* http://www.amda.com/info/cpg/
* http://www.coloradoguidelines.org/
* http://www.icsi.org/knowledge/
* http://www.guidelines.gov/index.asp
* http://www.humana.com/providers/guidelines/
* http://www.kpcmi.org/
* http://www.medscape.com/
* http://www.medsurfer.com/pracguide.htm

Appendix C: Excluded guidelines

Name	MED LINE	URL	Reason for exclusion
Benign prostatic hyperplasia: diagnosis and treatment. Clinical practice guideline (US of A, 1994) [1]	-	http://hstat.nlm.nih.gov/hq/Hquest/db/3103/screen/DocTitle/odas/1/s/52748	A
Benign Prostatic Hyperplasia: Treatment for Lower Urinary Tract Symptoms in Older Men (UK, 1995) [2]	-	http://www.york.ac.uk/inst/crd/ehc22.pdf	A
Guidelines on management of men with lower urinary tract symptoms suggesting bladder outflow obstruction (UK, 1997) [3]	-	http://www.rcseng.ac.uk/publications/show_pub.asp?menu=publications&pub_ID=12	A
NHG-standaard bemoeilijkte mictie bij oudere mannen (Netherlands, 1997) [4]	-	http://nhg.artsennet.nl/upload/104/standaarden/M42/start.htm	A, B
Voor de praktijk. Benigne prostaathyperplasie; aanbevelingen voor transmurale zorg (Netherlands, 1998) [5]	-	http://nhg.artsennet.nl/upload/104/LTA/lta5/start.htm	A, B
Hiperplasia benigna da prostata. Orientacoes e recomendacoes na pratica clinica urologica (Portugal, 1999)[6]	+	NA	B
Hiperplasia prostatica benigna y medicina basada en la evidencia: su aproximacion a la practica clinica (Spain, 2000)[7]	+	NA	B
Hiperplasia benigna da prostata (Portugal, 2001)[8]	+	NA	B
[Clinical guideline for benign prostatic hyperplasia] (Japan, 2002)[9]	+	NA	B
Prise en charge diagnostique et therapeutique de l'hypertrophie benigne de la prostate (France, 2003)[10]	-	http://www.anaes.fr/ANAES/framedef.nsf/WebMasterparpage/71e60e94c17622aec125667f0023974b?OpenDocument	B
Leitlinien der Deutschen Urologen zur Diagnostik des BPH-Syndroms (Germany, 2003)[11;12]	+	http://www.uni-duesseldorf.de/WWW/AWMF/ll/urol-034.htm	B, C
Leitlinien der Deutschen Urologen zur Therapie des BPH-Syndroms (Germany, 2003)[13;14]	+	http://www.uni-duesseldorf.de/WWW/AWMF/ll/urol-035.htm	B, C
North Essex Guidelines for the Management of Benign Prostatic Hyperplasia (UK, ????) [15]	-	http://www.equip.ac.uk/	C

A: Guideline published before 1999, B: No translation available (PM: abstract suggested a guideline), C: Recommendation not directly linked to references or no references available

***Appendix D*: Scores according to the AGREE-instrument**

	AUA[16]	Duodecim[17]	EAU[18]	NHMRC[19]	SCHiN[20]
Scope and purpose					
1. The overall objective(s) of the guideline is (are) specifically described.	3	2	1	4	4
2. The clinical question(s) covered by the guideline is(are) specifically described.	2	1	1	4	4
3. The patients to whom the guideline is meant to apply are specifically described.	3	2	2	4	4
Standardized domain score	56%	22%	11%	100%	100%
Stakeholder involvement					
4. The guideline development group includes individuals from all the relevant professional groups.	3	2	1	4	2
5. The patients' views and preferences have been sought.	3	1	1	4	3
6. The target users of the guideline are clearly defined.	2	4	1	4	4
7. The guideline has been piloted among target users.	2	3	1	2	1
Standardized domain score	50%	50%	0%	83%	50%
Rigor of development					
8. Systematic methods were used to search for evidence.	4	2	2	3	3
9. The criteria for selecting the evidence are clearly described.	4	1	1	4	2
10. The methods used for formulating the recommendations are clearly described.	4	3	2	4	3
11. The health benefits, side effects and risks have been considered in formulating the recommendations.	4	3	3	4	4
12. There is an explicit link between the recommendations and the supporting evidence.	4	2	3	4	3
13. The guideline has been externally reviewed by experts prior to its publication.	3	3	1	4	2
14. A procedure for updating the guideline is provided.	2	3	1	4	3
Standardized domain score	86%	48%	29%	95%	62%

Appendix D*: *Scores according to the AGREE-instrument *(continued)*

	AUA[16]	Duodecim[17]	EAU[18]	NHMRC[19]	SCHiN[20]
Clarity and presentation					
15. The recommendations are specific and unambiguous.	3	3	3	4	4
16. The different options for management of the condition are clearly presented.	4	3	4	4	4
17. Key recommendations are easily identifiable.	2	2	4	4	4
18. The guideline is supported with tools for application.	3	2	1	4	4
Standardized domain score	67%	50%	67%	100%	100%
Applicability					
19. The potential organizational barriers in applying the recommendations have been discussed.	1	1	1	2	1
20. The potential cost implications of applying the recommendations have been considered.	2	2	2	4	2
21. The guideline presents key review criteria for monitoring and/or audit purposes.	1	1	1	4	4
Standardized domain score	13%	13%	13%	75%	50%
Editorial independence					
22. The guideline is editorially independent from the funding body.	3	3	2	4	2
23. Conflicts of interest of guideline development members have been recorded.	4	1	1	4	1
Standardized domain score	67%	33%	17%	100%	17%

Appendix E: Scientific evidence used in guidelines to support recommendations

	AUA[16]	Duodecim[17]	EAU[18]	NHMRC[19]	SCHiN[20]
Symptom assessment					
Detailed medical history	R -	R -	R -	R -	R -
Assessment of bother	O [21-24]	NM	R -	R [25-27]	NM
Use of symptom scores	R [28-30]	R -	R [26;29;31-43]	O [26;31;32;34;41;43-47]	R/O [29;48]
Use of voiding diary	R -	NM	R [49-54]	R -	NM
Physical examination					
Digital rectal examination	R [55;56]	R -	R [56-66]	R [31;67;68]	R -
Abdominal examination	NM	NM	NM	R -	NM
Laboratory examinations					
Urine	O [69-72]	R -	O -	R -	R [73]
Creatinine	NR -	R -	R [31;74-84]	NR [31;78;81;85]	R [73]
PSA	O/R [86-94]	R -	R [61;87;88;95-105]	NR [92;106-110]	O [73;111]
Additional examinations					
Residual volume	O [27;112]	R [113;114]	R -	NR [27;83;115-124]	NM
Transrectal ultrasound prostate	O [86;104;125]	M -	O [63;126-128]	NR [68;129]	M [130;131]
Ultrasound upper urinary tract	O -	M -	O [78;79;132;133]	NR [31;78;134]	M [130;131]
Uroflowmetry	O -	M -	O -	NR [27;31;83;122;124;135-146]	M [130;131]

Appendix E: Scientific evidence used in guidelines to support recommendations

	AUA[16]	Duodecim[17]	EAU[18]	NHMRC[19]	SCHiN[20]
Additional examinations					
Urodynamic investigations	O [22]	M -	O [31;119;139;147-160]	NR [119;124;156;161;162]	M [130;131]
IVU (intravenous urography)	NR [31]	M -	NR [78;79;132;133;163-165]	NR [31]	M [130;131]
Counseling and treatment					
Watchfull-waiting	O [27;29;87;94;166-169]	O -	O [170-173]	O [45;172;174;175]	O [27]
Medication					
α-blocking agents	O [169;176-184]	O [185-191]	O [192-204]	O [31;122;137;187;205-219]	O [31;130;220-222]
5-alpha-reductase inhibitors	O [86;89;104;145;178;179;223-227]	O [185;186;188;189;228]	O [145;167;178;185;187;197;223-225;229-248]	O [137;185;187;230;249-257]	O [130;220;224;258;259]
α-blocking agents and 5α-reductase inhibitors	O [178;187;197;260;261]	NM	NR [187;197;233;238]	NM	NR [220]
anticholnergic agents	NM	NM	NM	O [262;263]	NM
phytotherapy	NR -	M [264]	M [265-271]	NR [272-283]	O [130;220;270;284;285]
Indication referral to urologist/ surgical proc.	M [27;164;260;286-288]	M [228]	M [27;74;289;290]	M [27;74;291;292]	M [2;31;130;220;259;293]
Role of patient	M [31;294]	NM	M -	M [47]	M [295;296]

R^{xx}: Recommended and references used; O^{xx}: Optional and references used; NR^{xx}: Not recommended and references used; M^{xx}: Mentioned in the text and references used; NM: not mentioned in the guideline

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SECTION II

Clinical management of LUTS: Exploration of the problem














CHAPTER 3

Lower Urinary Tract Symptoms: social influence is more important than symptoms in seeking medical care

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Abstract

Objective

To determine associations among lower urinary tract symptoms (LUTS), symptom severity, subjective beliefs and social influences when seeking primary medical care in men aged ≥ 50 years.

Subjects and methods

A population-based survey was conducted among 5052 men aged ≥ 50 years, using patient registers of 22 general practitioners (GPs) in the Netherlands from November 1999 to May 2000. The questionnaire contained items concerning age, educational level, International Prostate Symptom Score (I-PSS), Bother Score (BS), and questions from the Health Belief Model on attitude and social influences. The study population comprised men with an I-PSS of > 7. The odds ratios (ORs) corrected for the I-PSS were calculated.

Results

In all, 3544 questionnaires (70.2%) were returned. Two groups of men with an I-PSS of > 7 were compared: those who consulted their GP in the previous 2 years because of voiding problems (268 cases) and the controls (272) who did not visit a GP for these symptoms. Cases more often thought a physician could improve their condition (OR 2.85), appeared to be more often advised by others to seek medical care (OR 6.36) and thought more often that this advice influenced their decision (OR 13.95). They also had more frequently received information from the media (OR 2.66) which affected their attendance (OR 12.52). In a multiple regression analysis, advice from others or information from the media were stronger predictors of seeking care than the influence of symptoms on daily life, the I-PSS or the BS.

Discussion

Social influences, i.e. advice from others or the media, were more important factors in the decision to seek medical care than symptom severity.

Introduction

The prevalence of LUTS is 200 - 300 per 1000 in middle aged and older men.[1-5] LUTS can have a significant effect on men's life in terms of the degree of bother, worry, interference with daily living and psychological well-being.[6;7] Nevertheless, many men with LUTS do not consult a physician,[4;8-17] so they lack the medical attention that could alleviate their symptoms and worries. Only if a patient perceives his symptoms as a problem he will consult a physician. Several studies explored the reasons why men with LUTS attended a physician;[10-14;16;18] they showed that men with moderate to severe symptoms are more likely to seek medical care than men with mild symptoms. Increased attendance to the GP was also related to a greater interference of symptoms with everyday life[11;12] and greater age.[10-12;18] However, many men with moderate to severe complaints do not seek medical care.

Different factors may be relevant in this process; it has been suggested that older men may accept chronic illness as part of ageing,[19] which may also be true for LUTS [8] and urinary incontinence.[20;21] Furthermore, men may experience a stigma associated with specific urinary symptoms such as dribbling and urgency, so it is difficult for them to discuss this with their doctor.[8] Cunningham-Burley, *et al*.[22] concluded from interviews that fear of cancer or surgery is yet another factor in a man's decision to consult a doctor. The man's perception of the care provider's ability to give relevant information or effective treatment is important, as is the patient's ability to cope with the LUTS.[23] Finally, the social network and the media may influence the man in his decision to attend a primary care physician.

An insight into the factors that determine consultation for LUTS is essential to devise advice and education focused on the needs and expectations of elderly men. In particular, this insight can help to induce those who will benefit the most from medical care, and where not attending is inappropriate, to consult their family doctor in time.

The present study aimed to determine which factors explain the decision to attend a primary care physician for LUTS beyond the influence of symptom severity, and to explain the transition from the perception of LUTS to the presentation of LUTS to the GP.

Subjects and methods

A population-based case-control questionnaire study was conducted between November 1999 and May 2000. Men consulting their GP because of LUTS in the previous 2 years were considered as 'cases'; the controls were men with LUTS who never consulted their GP for the problem. The ethical committee of the University Medical Centre Nijmegen gave approval for the study. The study was based on the practice populations of 14 practices (22 GPs) in the eastern part of the Netherlands. The practices were equally distributed over urban and rural areas (four in cities, three in 'urbanized' areas and seven in rural areas).
The aim was to recruit 198 men who had discussed their LUTS with the GP and 198 men who had not; this sample size would detect differences of 15% in dependent variables in the comparison between the groups (a = 0.05, power = 0.80, inter cluster correlation = 0.03).
Most men with LUTS do not present these problems to a physician[13;16;22] so we assumed that for each case at least one control would also be recruited. The prevalence of LUTS known to a GP is ≈ 50 per 1000 men in those men aged 50-69 years and 100 per 1000 in those aged ≥ 70 years.[24] To recruit sufficiently many 'middle-aged' men we over-sampled those aged 50-69 years. With at least 100 men who visited their GP needed in each age group, this would require 2000 men aged 50-69 years and 1000 men aged ≥ 70 years to be recruited. Assuming a 60% response rate, at least 3333 men aged 50-69 years and 1667 men aged ≥ 70 years were sent the questionnaire (5000 men in all).
GPs excluded patients with serious disease, terminal illness or limited cognitive capacity before taking a systematic random sample of 300 men (200 men aged 50- 69 years and 100 aged ≥ 70 years) from the practice registers. Six GPs had insufficient patients in their practice list (the practice was too small or had a predominantly younger population) so all patients 50-69 years and ≥ 70 years were approached. Overall, this resulted in a mean (range) sample size of 230 (103-300) patients per GP.

Variables and instruments

Men were requested to complete the anonymous questionnaire within 10 days and to return it to the research institute in a pre-stamped envelope. A written reminder was mailed to all men after 2 weeks. The questionnaires that remained uncompleted and those from men who stated they had a urinary stoma or a permanent catheter were excluded.
The self-administered questionnaire was in three parts; the first contained socio-demographic questions (age and educational level), questions on the duration of voiding problems and on GP attendance for these symptoms. The second part concerned

questions on urinary symptoms. The I-PSS was used to determine the symptom level of LUTS. The I-PSS is a validated seven-question score using a six-point answering scale (0, no complaints, to 5, many complaints). The scores of the questions were summed to give an I-PSS of 0-35. The Bother Score (BS) is a one-question score ('If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel?), using a seven-point scale of 0-6 ('delighted' to 'terrible').[25] Finally, this section contained three questions (on incontinence, adapting drinking habits and the experienced influence of complaints on everyday life) derived from the ICS-male instrument (Table 1).[26] The third part of the questionnaire focused on the patients' perceptions; 14 questions on attitudes towards voiding problems and on cues to visit a GP, derived from the Health Belief Model,[23] were included. These questions are also presented in Table 1. The questions used a three-point scale (not at all, somewhat, certainly), with two answering categories (yes/no) for 'cues'. Men answering yes to one of these three questions were asked whether this factor influenced their decision to visit a GP (no influence, some influence or much influence).

Analysis

In line with previous international publications[25] we distinguished three symptom levels, i.e. minor (I-PSS 0-7), moderate (I-PSS 8-19) and severe complaints (I-PSS 20-35). Men were considered to have voiding problems if they had an I-PSS of > 7. Two sub samples were identified in this population: (i) controls, i.e. men with voiding problems who had never consulted their GP for these problems, and (ii) cases, i.e. men who consulted their GP in the previous 2 years for their voiding problems.

All variables were dichotomised, except for age (five categories) and education (three categories). Missing values were scored as 'absence' or 'lowest possible value' of the variables. For instance a missing value in the Health Belief Model items was scored as 'no' or 'not at all'.

As symptom severity is associated with the decision to consult a GP,[4;8;10-13;15;16;18] all analyses of the Health Belief Model (Table 1) were corrected for the level of symptoms (the I-PSS as a continuous variable). Logistic regression analyses were used, using $P < 0.05$ to indicate statistical significance. All variables with significant bivariate associations in a binary correlation with 'presenting LUTS' were included, dichotomised in a multiple logistic regression model with a backward stepwise selection (I-PSS 8-19 and 20-35, age < 70 and ≥ 70). The dependent variable was consulting a GP for LUTS (cases vs -controls).

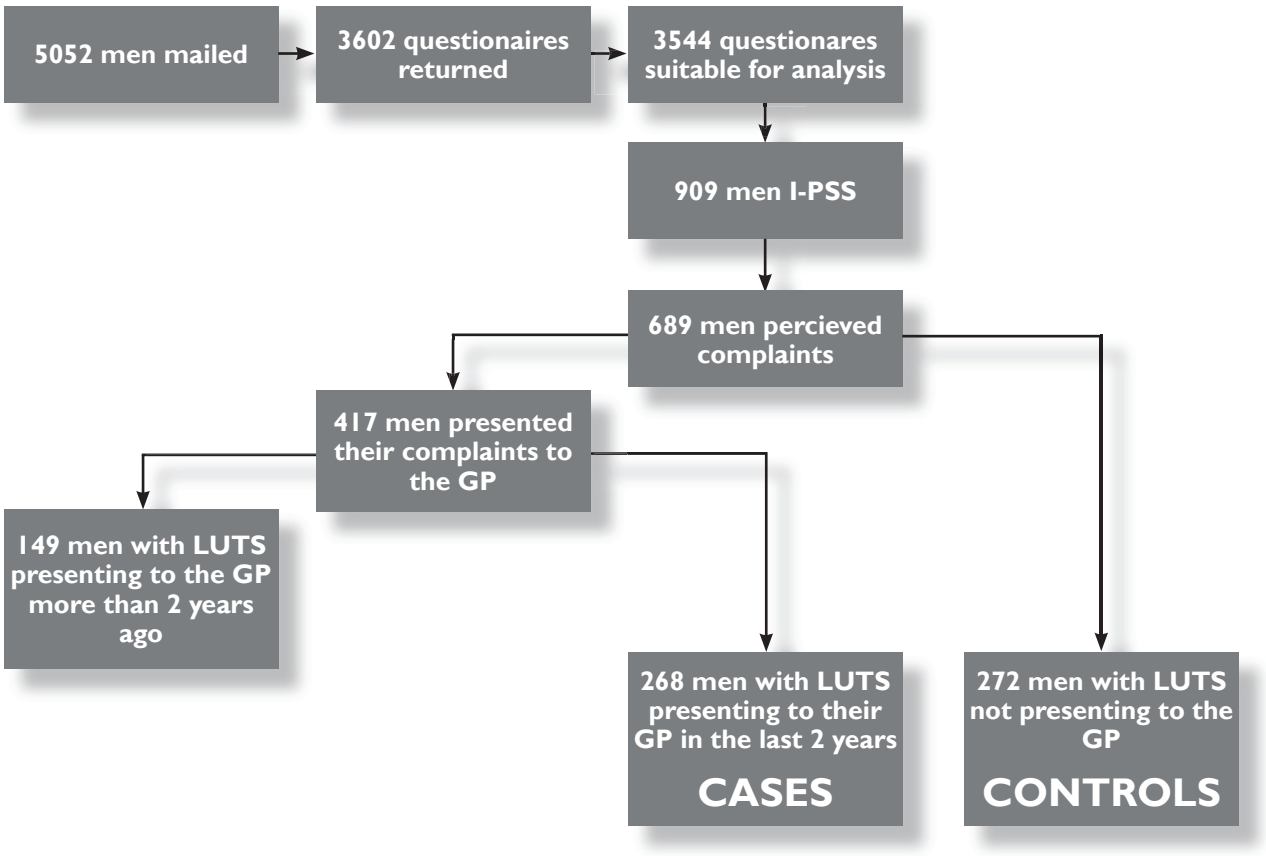
Results

Of the 5052 questionnaires sent, 3602 were returned (71.3%); 46 questionnaires were incomplete and therefore excluded (21 questionnaires were sent to a wrong address, three men had died, four had language problems, four had cognitive problems, five a serious illness, five were absent for a long period, four other reasons). Twelve questionnaires were excluded because the responders had voiding problems other than LUTS (one spina bifida, nine a urinary stoma, and two a permanent urinary catheter), leaving 3544 questionnaires (70.2%) (Figure 1) from men with a mean (SD, range) age of 63.2 (9.7, 50-96) years and an I-PSS of 5.4 (6.0, 0-35).

In all, 689 men had an I-PSS of > 7 and self-perceived voiding problems; of these, 272 men with LUTS had never consulted their GP because of their voiding problems (controls) and they were compared with 268 similar men with LUTS who had consulted their GP in the previous 2 years (cases; Figure 1).

Table 1 lists the differences in age and educational level between cases and controls. Cases were more likely to be older and to have more severe symptoms. Each I-PSS question had

Figure 1*: *Sample characteristics of the population studied



a significantly higher score in cases, except for the question: 'Over the past month, how often have you found you stopped and started again several times when you urinated'. In a logistic regression analysis, with attendance as the dependent variable, age and I-PSS were independent predictors. After correcting for the level of complaints (I-PSS) older men were still more likely to visit their GP for these voiding problems (P = 0.028, odds ratio, OR 1.237; 95% CI 1.024-1.495). A BS of ≥ 4 was also associated with a higher likelihood of consulting a GP. There was no significant difference in the mean duration of complaints between cases and controls (3.85 and 3.87 years, respectively; P = 0.969). Cases more often had incontinence, interference with their daily lives and modified their drinking pattern to prevent voiding problems. Although these three factors were significantly more common among cases, a substantial proportion of the controls also had these problems. More than half of the controls perceived their voiding problems to influence their lives; fewer said they were troubled with incontinence or prevented voiding problems by adapting drinking habits (Table 1).

Table 1 shows that only a few men were convinced that their voiding problem was serious or related to a serious disease. Corrected for the I-PSS, there was no significant difference between cases and controls in these beliefs. Cases were more likely to know enough about their voiding problems, but half the men in both groups felt in need of information and there was, after correcting for the I-PSS, no significant difference in this need between the groups. About half the men in both groups were certain that they were able to cope well with their complaints. This feeling was not significantly different between the groups. The expected improvement in their condition after treatment by a GP or a specialist was more positive among the cases. The expectation that examination or treatment of their voiding problems would be unpleasant did not affect the decision to consult the doctor. Cases even seemed to have a more negative view of examinations and treatment (Table 1).

A small majority of the cases said at least one of the three external cues (Table 1) was present before visiting the GP (54% of the cases vs 19.5% of the controls; P < 0.001, OR corrected for I-PSS 4.252, 95% CI 2.874 - 6.293). Cases were more often advised by their social network to seek medical care than were the controls. Cases more often thought that this advice influenced their decision than did the controls. Furthermore, cases more often remembered receiving information through the media (newspaper, television) about their voiding problems. Cases more often thought they were influenced by receiving information from the media in their decision to seek medical care. The cases also more often knew someone with voiding problems (Table 1).

After multiple regression analysis in which all bivariate significant factors were included, the advice from the social network to attend a physician was the strongest predictor of

Table 1: The characteristics of 272 controls and 268 cases

Variable	Controls	Cases	OR (95%CI)
Mean age [SD] years	64.3 [9.7]	66.9 [9.3]	1.028 (1.010-1.048)*
Distribution, % aged (years)			
50-59 years (%)	36.8	22.8	1.251 (1.041- 1.503)†
60-69 years (%)	27.9	34.0	
70-79 years (%)	22.8	28.7	
80-89 years (%)	5.5	7.5	
90 and more years (%)	1.5	-	
Unknown (%)	5.9	7.1	
Education			
None/basic/lower/professional	43.0	38.1	1.057 (0.850- 1.314)†
Medium general preparatory/ medium professional	27.9	36.2	
Higher general preparatory/ higher professional/ university	23.9	22.0	
Unknown	5.1	3.7	
I-PSS (all men had an I-PSS of >7)			
Mean [SD]	13.5 (5.39)	15.9 (6.04)	1.077 (1.044-1.111)*
% severe (I-PSS 20-35)	13.6	26.9	2.333 (1.503-3.620)‡
BS ≥ 4	19.9	39.9	2.683 (1.825-3.944)‡
Change clothes or wear pads when losing urine during the day	25.4	39.6	1.925 (1.334-2.778)‡
Adapting drinking habits to prevent voiding problems	36.8	48.5	1.620 (1.149-2.285)‡
Influence of voiding problems on daily life	59.2	81.0	2.933 (1.987-4.328)‡

*OR for the difference between controls and cases using logistic regression analysis, calculated as * the effect of 1-year increases in age or 1 point in I-PSS; † the effect of one age or one educational class; ‡ the effect of the difference between the dichotomised groups;*

Table 1: The characteristics of 272 controls and 268 cases, their attitudes towards voiding problems, and the cues to visit GP, with influences from the social environment and media

	Controls	Cases	OR (CI:95%) corr. for I-PSS
Attitudes towards voiding problems (% of men answering 'certainly')			
My voiding problems are serious	2.9	8.2	2.174 (0.923-5.125)
My voiding problems are related to a serious disease	1.8	3.7	1.151 (0.363-3.656)
I know enough about my voiding problems	14.0	21.3	1.766 (1.111-2.808)¶
I need more information about my voiding problems	44.5	55.2	1.349 (0.950-1.914)
I can cope well with my voiding problems	52.9	48.5	0.902 (0.638-1.275)
A GP or a specialist can treat my voiding problems well	17.3	36.9	2.846 (1.892-4.282) §
Examination and treatment of my voiding problems are unpleasant	13.2	22.4	1.652 (1.039-2.627)
Cues, and influences from social environment and media (% of men answering yes, and if yes, confirming this influence)			
Others have advised me to visit the GP[1]	7.4	36.9	6.357 (3.750-10.775)§
This advise influenced my decision to seek health care or not to visit the GP (n = 119)[2]	30.0	85.9	13.945 (4.526-42.968)§
I have received information in the masse media on voiding problems[1]	13.6	29.9	2.655 (1.708-4.128)§
This information influenced my decision to seek health care (n = 117)[2]	29.7	82.5	12.520 (4.808-32.602)§
I knew someone with voiding problems[1]	11.8	24.6	2.411 (1.507-3.856)°
The decision of this person to visit the GP with his problems influenced my decision to visit or not to visit the GP (n = 98)[2]	25.0	33.3	1.483 (0.568-3.874)
The result of the treatment of this person influenced my decision to seek health care (n = 98)[2]	31.3	33.3	1.095 (0.442-2.711)

¶ P<0.05; ° P<0.005; § P<0.001

[1] Two-answer categories (yes/no) presented as the percentage of the total answering yes; [2] three-answer categories (much/some/no influence) presented as the number answering 'some' or 'much' influence.

GP attendance. Information received from the media was also an important independent predictor. Furthermore, the expected improvement in their condition after treatment by a GP or a specialist, and the knowledge they perceived on voiding problems, appeared to be independent determinants of visiting a GP. Symptom- or complaint-related variables, e.g. bother, influence on daily life and incontinence, were also relevant, but their influence was less strong. Age, I-PSS, adaptation of drinking habits and an acquaintance with the same problem were no longer significant predictors (Table 2).

Discussion

The advice of the social network and information from the media were clearly associated with the decision to seek primary medical care in men with LUTS; the relation was stronger than with symptom severity. Furthermore, specific beliefs were related to seeking medical care, e.g. the expectation that a physician can treat the voiding problems and the patients' confidence in personal knowledge of voiding problems. Thus the decision to seek medical care in men with LUTS was associated with symptom severity and social influences.

This study confirms that symptom severity and bother are important determinants inducing men to visit a doctor for voiding problems.[4;8-18;22;27] However, the study also

Table 2: Patient factors determining care seeking after multiple regression analysis

	OR (CI:95%)
Others have advised me to visit the GP	5.547 (3.145-9.786)†
A GP or a specialist can treat my voiding problems well	2.707 (1.684-4.351)†
I have received information in the masse media on voiding problems	2.105 (1.260-3.517)‡
Examination and treatment of my voiding problems are unpleasant	1.998 (1.169-3.416)‡
Influence of voiding problems on daily life	1.913 (1.197-3.058)‡
I know enough about my voiding problems	1.788 (1.023-3.125)°
Bother Score ≥ 4	1.761 (1.100-2.820)°
Change clothes or wear pads when losing urine during the day	1.633 (1.044-2.553)°

Odds ratio: tested difference between the 2 groups: controls and cases, using multiple logistic regression analysis, method backward stepwise selection, all variables dichotomised. (°: P<0.05, ‡: P<0.01, †: P<0.001)

suggests that influences in the social environment are stronger predictors of attendance. A third of all the cases was advised by others to seek medical care. This is in concordance with MacFarlane, *et al*.,[2] who further found that the social network was not always aware of a man having LUTS; moderate symptoms (I-PSS 7-18) were known to their spouses in only half of the cases. If the severity was known, three-quarters of the women advised their partner to visit a doctor.[12] In studies of men with other medical conditions it was also found that the decision to consult a physician was more likely to be initiated by the spouse.[28;29] Apart from being advised by others, the present study also showed that information obtained from the media influenced men in deciding to consult a GP. In several other medical conditions, health education through the media is known to be change behaviour. The mass media were very effective in influencing the use of health services.[30]

Information about LUTS was collected retrospectively, i.e. after the patient decided to consult his GP or not, and after this consultation occurred. Consequently the consultation may have biased the patient's perception of symptoms in the cases. This potential recall bias should be considered when interpreting the findings, and is a problem encountered in other studies.[10;11;13;14;16;18] A prospective approach, following patients from their first perception of LUTS, would have overcome this, but such a design was beyond the resources available for this study.

Many men do not consult their GP for their LUTS, but it is questionable to what extent this reluctance is a problem. The threat to the man's health is limited and consequently the patient can and should be reassured that the existence of LUTS does not suggest that he has any condition which is likely to pose a significant health threat, now or in the future.[31] The natural history of LUTS has a very variable progression,[8;32] but one in seven not attending a GP has serious symptoms (I-PSS = 20). In the last two decades many different medications and (more or less invasive) surgical interventions have been developed, so this group particularly may inappropriately resist medical care. Furthermore, the findings emphasize the need for the careful selection of patients with LUTS, to restrict medical care only to those who will benefit from it.

The social network may have several motives for advising men to attend a GP. The spouse or relative may be afraid of a serious disease or possible complications, or she may be confronted with inconvenience from the LUTS (the smell of urine, washing clothes, disturbance during the night). Possibly the communication with the social network made it more acceptable to visit the GP for LUTS; it might be important for GPs to explore not only the bother perceived by the patient, but also the bother for his social environment. Further research should be conducted to determine the motives of the social network.

The conclusion that the media are important in the decision to present with LUTS is ambiguous. It suggest possibilities for educating men with voiding problems, i.e. the media may be used to inform men about the causes and treatment possibilities of their condition. The media may also encourage behaviour to use health care services effectively.[30] However, interest groups may misuse the mass media to raise unwanted health care demands.

As symptom severity is not the only reason for men to seek medical care there is a need to inform patients adequately, to reassure those with minor symptoms and to encourage those with more severe symptoms with major effects on daily living to seek care. The present study indicates the possibility of involving the patients' network in this task and in educating the patient.

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CHAPTER 4

Shared care and the management of lower urinary tract symptoms

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Abstract

Objective

To investigate associations between the level of shared care and the clinical management of patients with uncomplicated lower urinary tract symptoms (LUTS).

Subjects and methods

A cross-sectional survey study was conducted comprising all urologists and a random selection of general practitioners (GPs) in the Netherlands. Questionnaire responses were obtained from 182 urologists (70%) and 261 GPs (55%). The first part of the questionnaire established the physicians' characteristics and the second the level of familiarity with the national shared-care guidelines, arrangements between urologists and GPs, and the availability of a shared-care prostate clinic. The third part presented a written case of a 50-year-old man with clinical uncomplicated LUTS, and asked questions about diagnostic and therapeutic care.

Results

The clinical management of LUTS by GPs and urologists differed, particularly for diagnostic procedures. Only a minority of GPs (8%) and urologists (18%) had a shared-care clinic at their disposal. Such clinics were associated with an increase in tests ordered by the GP, e.g. creatinine levels (odds ratio, OR 3.83) and PSA levels (OR 5.93), and a decrease in choosing a watchful-waiting strategy for patients with mild symptoms (OR 0.24). Furthermore, urologists more often chose surgical intervention for moderate symptoms (OR 9.80).

Discussion

A shared-care clinic may lead to a shift in primary care towards the working style of urologists. This health care may not be as cost-effective as expected by policy makers. Prospective studies are needed to provide better insight in the health outcomes and efficiency of shared-care clinics.

INTRODUCTION

The number of men with LUTS seeking medical care is expected to rise in the future because of increasing life-expectancy and improving public awareness. Patients with LUTS are usually seen by GPs, and for selected cases by urologists.[1] With the introduction of a-blocking medication it has become more feasible to treat LUTS in primary care. In several countries GPs are taking a more active role in the diagnosis and management of LUTS.[2-5] If a patient is referred, specialists and primary care physicians both appreciate clear communication.[6-8]

Ten years ago reports were published on shared-care initiatives in the UK.[9-11] Shared care was defined as the joint participation of hospital consultants and GPs in the planned delivery of care for patients with a chronic condition, informed by enhanced information exchange beyond routine discharge and referral letters;[12] this was expected to streamline patient evaluation and help to enhance effective management.[10] In the Netherlands, a committee representing national associations of GPs and urologists published national recommendations for the shared care of LUTS.[13] These evidence-based recommendations were intended to encourage urologists and GPs to make local arrangements for referral and shared-care prostate clinics. Making inter-professional arrangements was expected to contribute to the efficiency of health care.[14]

Previous studies have presented the effect of shared-care clinics on the daily practice of the urologist; effects of these clinics on the clinical management of the GP have not been reported. The aims of the present study were to describe the common clinical management of patients with uncomplicated LUTS, and to explore the effects of the level of shared care on the clinical management of both physician groups.

SUBJECTS AND METHODS

A cross-sectional survey study was conducted in 2000 using an anonymous questionnaire. The study sample comprised 306 urologists in the Netherlands and a random sample of 500 GPs. All urologists registered and working in clinical care with male elderly patients were included; paediatric-orientated urologists, and urologists still in training were excluded. The GPs had to be registered and active in primary medical care. All physicians were asked to complete the questionnaire within 10 days and to return it to the

research institute in a pre-stamped envelope. A written reminder was mailed to those not responding at 3 and 6 weeks.

The questionnaire consisted of three parts. The first part contained background questions to establish the physicians' characteristics, i.e. gender, year of registration, practice setting, solo practice or shared (only for GPs), number of referral hospitals (only for GPs), special interest for urology (only for GPs), and size of the partnership (only for urologists). The second part focused on familiarity with the national shared-care guidelines published by the joint committee of GPs and urologists,[13] arrangements between urologists and GPs, and the availability of a shared-care prostate clinic. Three levels of shared care were distinguished: knowledge of the shared-care guideline, arrangement(s) in relation to shared care and an actual shared-care clinic. The third part concerned a written case of a 50-year-old man with clinical uncomplicated LUTS, and questions were asked about the content of diagnostic and therapeutic care delivered under normal circumstances. The physicians could answer each question on a three-point scale (routine, sometimes, or never). Missing values were scored as 'no/never' or 'lowest possible value' of the variables.

Within each professional group (GPs or urologists) the effect of shared care on the clinical management of the patient with uncomplicated LUTS was analysed. The unit of analysis was the physician. First, the consistency of the clinical management of the uncomplicated LUTS by the GP and the urologist was analysed, and second the effect of shared care on clinical management was explored. The consistency of the clinical management of the uncomplicated LUTS, by the GP and the urologist, was analysed by logistic regression, and differences between urologists and GPs expressed as odds ratios (ORs). Items concerning clinical management of the uncomplicated LUTS were considered as dependent variables, and were analysed bivariately for their association with each shared-care level. Physician characteristics and items related to the level of shared care were considered as independent variables. Items showing significant ($P < 0.01$) associations with the separate levels

Table 1: Characteristics of physicians

Characteristic	Urologists, n (%)	GPs n (%)
N	182	261
Men	182 (100)	215 (82.2)
Registered for ≥ 15 years	109 (59.9)	105 (40.2)
Practice in a rural area	-	57 (21.8)
Solo practice	-	109 (41.8)
Normally referring to one hospital	-	90 (34.5)
Special interest in urology	-	35 (13.4)
Partnership of three urologists or less	68 (37.2)	-

were analysed in a multiple regression model (stepwise forward, conditional) for their association with the shared-care level, correcting for practice setting, gender and number of years registered as a urologist or GP.

Results

Of the 306 questionnaires sent to urologists, 15 were returned blank because of wrong addresses, and another 29 addressees did not meet the inclusion criteria. Based on the corrected number of 262 questionnaires, 182 urologists (70%) responded. The GPs were effectively sent 478 questionnaires (corrections; 15 wrongly addressed, seven stopped working as a GP); of these 261 (55%) were returned. The distribution of the GP characteristics (Table 1) was not significantly different from national data on gender, age, number of years working as a GP, practice form (e.g. solo practice), or level of urbanization of the practice area.

For symptom evaluation, the I-PSS was used regularly by half of the urologists, whilst only 20% of GPs used it (Table 2). Urologists routinely requested all diagnostic laboratory tests (except for serum glucose measurements) more often than GPs. Almost all urologists routinely used PSA testing and urine analysis; these tests were also requested by most GPs, but significantly less often. If referred to a urologist, most patients with uncomplicated LUTS would undergo uroflowmetry, and the volume of the post-void residual would be determined. Lifestyle advice on coping with LUTS was given by most physicians; urologists more often provided patients with information leaflets to support their explanation. Both urologists and GPs suggested medication for patients with moderate and surgery for patients with serious complaints. Alfuzosin and tamsulosin were prescribed most as first-choice medication in both groups; finasteride appeared to be the first choice of medication of 5% of GPs.

The shared-care guideline published in 1998[13] was known to 68% of the urologists (123/182) and 18% of GPs (47/261); 40% of GPs (103/261) and 43% of urologists (78/182) were aware of at least one specific arrangement in relation to shared care in their local setting. These arrangements often concerned information transfer, i.e. information provided in the letter at discharge from specialist care (32%) or the referral letter (25%). The policy on requesting a PSA test before referral (23%), indications for referral (22%), and conditions before discharge from specialist care (26%), were all commonly reported as other examples of arrangements made.

***Table 2**: **Physician-reported clinical management of a hypothetical case of a 50-year-old man with uncomplicated LUTS** (items which are always used)*

Management	Urologists, %	GPs, %	OR (95% CI)
Symptom evaluation			
I-PSS	51.1	19.5	4.30 (2.82-6.56)
Voiding list	25.0	3.4	8.66 (4.10-18.29)
Laboratory investigations:			
serum creatinine	75.4	43.7	3.70 (2.45-5.59)
serum PSA	92.9	65.1	6.96 (3.75-12.92)
serum glucose	17.8	30.4	0.50 (0.31-0.79)
urine analysis	95.6	79.7	5.51 (2.55-11.92)
urine culture	28.2	5.2	7.19 (3.60-14.37)
Additional investigations*			
uroflowmetry*	84.6		
determination of residue*	86.3		
TRUS*	44.0		
abdominal ultrasonography*	23.1		
cystoscopy*	17.0		
urodynamics*	4.4		
IVU*	1.6		
Counselling and treatment			
Providing information			
Lifestyle advice given	92.9	90.4	1.38 (0.69-2.77)
Use of written patient information	82.4	39.5	7.19 (4.56-11.34)
Treatment			
Mild complaints and:			
watchful waiting	88.7	93.8	0.52 (0.26-1.04)
medication	11.3	6.3	
surgery	0	0	
Moderate complaints and:			
watchful waiting	1.1	14.6	0.35 (0.19-0.65)
medication	94.4	80.3	
surgery	4.5	5.2	
Severe complaints and:			
watchful waiting	0	0.4	0.80 (0.49-1.32)
medication	16.9	19.4	
surgery	83.1	80.2	
First choice medication			
Alfuzosin	21.4	36.4	0.48 (0.31-7.36)
Tamsulosin	48.4	39.1	1.46 (1.00-2.14)
Finasteride	0.5	5.4	0.10 (0.01-0.75)

**Additional investigations, urologists only.*

Only 8% of GPs (22/261) and 18% of urologists (32/182) said they had access to a shared-care clinic on prostate problems. These shared-care clinics were more common when urologists worked in hospitals with four urologists or more (24% vs 12%; OR 2.2). Fewer urologists in hospitals with small partnerships thought they needed this kind of facility than urologists in hospitals with larger partnerships (18% vs 33%; OR 2.3). There were no associations between shared-care clinics and GP characteristics. The association

of the level of shared care with specific aspects of the clinical management was explored. GPs familiar with the shared-care guideline were more likely to use the I-PSS (OR 3.00) and voiding diary (OR 6.25), as recommended by the shared-care protocol. There were no associations between clinical management and familiarity with the shared-care protocol for urologists.

A leaflet to support advice and information was more often provided by urologists who had made one or more arrangements (OR 2.93). GPs with at least one shared-care arrangement showed no differences in clinical management compared to GPs with no such arrangement.

The GPs' behaviour in the diagnostic and therapeutic approach to the patient was associated with an available shared-care clinic. The GPs more often used the I-PSS (OR 3.25), and more often requested laboratory tests (creatinine and PSA levels; OR 3.83 and 5.93, respectively). For mild complaints, a watchful-waiting strategy was chosen less often by GPs with an available shared-care clinic than by GPs with no access (OR 0.24). Urologists with shared-care clinic facilities used Trans Rectal Ultrasound (TRUS) more frequently (OR 3.70) and surgical intervention was more often chosen for moderate complaints (OR 9.80).

Discussion

In the present study we compared the care routinely delivered by urologists and GPs to a hypothetical patient with uncomplicated LUTS. In the diagnostic phase, urologists were more exhaustive in the initial symptom evaluation and request for diagnostic tests. The treatment options chosen by the two professions were similar. Familiarity with the shared-care guideline and access to a shared-care clinic were associated with the clinical management. GPs familiar with the guideline were more likely to use instruments advocated by this guideline, e.g. the I-PSS and a voiding diary. Access to a shared-care clinic was only available to a minority of the physicians, and was associated with a more active approach to the patient; more laboratory tests were used and patients with similar symptom levels were treated more aggressively.

The response rating among GPs to the questionnaire was relatively low (55%) so we cannot exclude selection bias in the results. However, response rates were similar to those in other studies in primary care urology,[1-3;15-17] and the characteristics of the population studied showed no significant differences with demographic data of the overall GP population in the Netherlands. The questionnaire contained a standardized case of a 50-year-old man

with uncomplicated LUTS. This cannot reflect the tailor-made approach of daily practice, and results have to be judged with respect to this limitation.

Most studies on variation of practice patterns have described the management of patients with complaints of LUTS/BPH by either urologists[15;18-20] or primary care physicians.[2;17;21] We used the same questionnaire for both populations to compare care management. In general, compared with GPs, urologists were more often inclined to quantify the patient's complaints by adopting scores, laboratory investigations or clinical measurement techniques. GPs more often took a 'wait and see' approach to a new patient. In their clinical management, GPs with a special interest in urology were no different from GPs that had no access to a shared-care clinic. This may reflect the composition of the patient population they manage, and their professional attitude. The management of the diagnostic process as delivered by urologists and GPs in the present study is mostly consistent with studies on variation on practice patterns published previously.[2;3;15-21] However, PSA tests were less often routinely requested by GPs in the present study (65%) than by primary care physicians in other countries (69-91%).[2;3;16;21] This might be because the Dutch guideline for GPs advises against PSA testing, whereas national guidelines in most other countries suggest it as an option in the diagnostic process.[22;23]

Several types of shared-care clinics for prostate problems have been described, each adapted to local needs and local settings.[9-11;24] Audit reports on prostate-related shared care reported that 27-59% of the patients referred to shared-care clinics could be managed by watchful waiting or pharmacotherapy.[9-11] In another study, a nurse-led prostate clinic was shown to be more cost-effective than all patients being seen in a urology clinic directly,[24] but there was no comparison to the situation where GPs managed these patients and no shared-care clinic was available. In the present study, GPs with access to a shared-care clinic less often chose a watchful-waiting policy for patients with mild symptoms, and urologists proposed surgery more often for patients with moderate symptoms. This raises the question whether these shared-care clinics are cost-effective. In a recent comment, Dunsmuir and Kirby[4] concluded that it is unlikely that shared-care clinics imply more efficient health care.

Among primary care physicians the availability of shared care seems to have led to a shift of the primary care attitude towards managing care as a specialist/urologist. Many policy makers expect shared care to be an efficient solution for (future) increases in health care needs. However, copying the specialist clinical management to primary care may not provide health care that is more cost-effective. Prospective studies are needed to provide a better insight into the health outcomes and the efficiency of shared-care clinics. Until then, a watchful-waiting approach for shared-care clinics is recommended to policy makers.

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CHAPTER 5

Quality improvement reports: Low feasibility of uroflowmetry in general practice

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Submitted

Abstract

Objective

Testing what the feasibility is of an open access facility to uroflowmetry in general practice.

Subject and methods

In a explorative study during a period of 14 months 19 general practitioners had open access to uroflowmetry as a tool in the diagnosis of lower urinary tract. After 14 months evaluative interviews were conducted.

Results

A total of 12 men had actually performed uroflowmetry. Seven of the twelve men included had a $Q_{max} \leq 10$ ml/s (possible obstruction) and two had a $Q_{max} \geq 15$ ml/s (probably unobstructed). Except for two, in none of the patients the clinical management was influenced by the uroflowmetry and medication was prescribed for their complaints. In two cases a watchful waiting policy was chosen instead, after discussion of the results with the patient. None of the patients was referred to a urologist. From evaluative interviews at the end of the study we learned that all GPs were disappointed by the low incidence of patients with LUTS presenting at their surgery. The criteria for exclusion of the patients were thought of being too strict (notably excluding patients already treated for LUTS).

Discussion

With respect to the low number of included patients and the limited effect on clinical management uroflowmetry is not considered as very useful in general practice. Most GPs felt uroflowmetry would support a more objective indication and evaluation of treatment, and thought it could be a valuable, additional tool in general practice. They preferred uroflowmetry to be supported logistically by a diagnostic centre, to be used after request by the GP. In this centre the device should be distributed after the patient is instructed, and the resultant uroflowcurve should be interpreted by a specialist as well, since the respondents felt not able to do an adequate interpretation.

Introduction

Several studies have indicated that, in an open population, 30% of men over 50 years of age have lower urinary tract symptoms (LUTS) that may be called bothersome.[1-4] More men reaching high age and the reduced taboo on LUTS are expected to increase the number of men presenting with LUTS in future years: resulting in higher consumption of medical care. Although the general practitioner (GP) is able to get an idea of the bother related to LUTS the elderly patient is confronted with. Complaints concerning LUTS are often difficult to interpret on the basis of history taking alone.[5-11]

Although the International Prostate Symptom Score (I-PSS) may clarify the subjective complaints of a patient,[12] it was originally designed to evaluate the effects of treatment over time as a monitoring instrument and it was not intended to be a discriminative or predictive index.[13;14] Without direct access to additional diagnostic tests a GP has to refer a patient with bothersome complaints to a urologist to get a better insight in the possible causes of the LUTS. A uroflowmetry is performed in 84.4% of all patients referred to a urological outpatient clinic making it the third most performed diagnostic procedure in referred patients (after digital rectal examination (97.7%) and blood and urine sampling (respectively 92.3 and 86.6%).[15] The American Urological Association (AUA) guideline on LUTS recommends measurement of the flow rate in patients with a complex medical history or with a desire for invasive therapy.[16] Although uroflowmetry has its limitations it may be helpful in differentiating BPH from non-BPH causes of the patients complaints (Box 1).

For a proper evaluation of LUTS with a uroflowmeter several measurements are needed, because of a variability between the measurements, the effect of circadian rhythms and artefacts in the measurements.[9;17-26] Circumstances on the outpatient department are know to be problematic in obtaining a spontaneous, representative flow and volume.[22;27] In recent years portable uroflowmetry devices have been developed and tested, delivering results comparable to traditional uroflowmeters.[22;28;29] These portable devices potentially could cope with all problems mentioned above; allowing measurements at home and so giving a good insight into the voiding patterns and obtaining out of office time flows as well.[11;21] With these coming available, uroflowmetry in general practice has become more feasible as well, assisting to a more adequate referral. However, evaluations of its use in normal general practice is yet limited. The aim of the study was testing the clinical relevance of uroflowmetry in general practice.

Methods

Design

Based on literature (Box 1) and discussions with experts in the field of urology (three urologists), general practice (two professors in general practice and the first author of the Dutch Guideline on LUTS) and on diagnostic procedures (two heads of laboratories and a medical technology assessment expert) a diagnostic protocol (Appendix Chapter 5) was worked out and an implementation plan was developed. A prospective observational pilot study was performed, testing the feasibility of the developed uroflowmetry protocol in general practices during 14 months (March 2001 through April 2002). The ethical committee of the Radboud University Nijmegen Medical Centre gave approval for the study.

The intervention

The uroflowmetry device

The portable, battery powered, *Danica DaCapo Home Flowmeter* is a weight transducer, measuring voided volume versus time and so calculating the flowrate.[28] It is designed to record all voidings during a period of time in a single patient. The flowmeter is delivered in a small suitcase, and can easily be set up by the patient. Before voiding the flowmeter is activated by a foot switch; it switches of automatically after a fixed amount of time (Figure 1).

Figure 1: Uroflowmeter

Box 1*: *Uroflowmetry, a more theoretical background

A pressure flow study (PFS) is considered to be the best method assessing bladder outflow obstruction according to several recent guidelines on LUTS.[47-49] Since it is an expensive, time-consuming and rather unpleasant invasive procedure,[50] it is advised to perform PFS only when invasive treatment is considered and not as a standard diagnostic procedure.[37] Uroflowmetry, on the other hand, is a non-invasive test where the urinary flow is electronically recorded while voiding. It is very well able to differentiate between normal and abnormal voiding[51] and can be used as a measurement to pre-select patients for further testing.[52-54] Being a measure of the interplay between detrusor and urethra, uroflowmetry is not able to differentiate reliably between detrusor impairment and outflow obstruction, which is considered a disadvantage.[51;52;55-60] However, when history is taken into account in an adequate way uroflowmetry can become a valuable tool.[35;36]

The uroflowmeter produces a flow-diagram from which several parameters can be obtained as: voiding time, maximum flow rate ($Q_{max,}$ also known as Peak Flow Rate (PFR)), average flow rate (Q_{ave}), and total voided volume(VV). The Q_{max} is the parameter with the highest reproducability[61] and is better able to differentiate between normal and abnormal flows.[62] The problem is the clinical relevant cut off point. A Q_{max} greater than 20 ml/s is unlikely to be associated with urodynamically-defined outflow obstruction.[63] A Q_{max} of 15 ml/s or more appeared to be adequately diagnosed as not obstructed in 42% to 75% of the cases when pressure flow studies were considered as the golden standard.[36;64;65] A Q_{max} < 15 ml/s has a sensitivity of 82 and a specificity of 38 for bladder outlet obstruction (at a Q_{max} < 10 ml/s there is sensitivity of 47 and a specificity of 70).[35] The predictive value of Q_{max} on outcome after a transurethral resection of the prostate (TURP) was reported: 71% of those with a Q_{max} over 15 ml/s improved compared to 91% of those between 10 and 15 ml/s and 92% for those less than 10 ml/s.[65] However, this study found no difference between improvement in symptom scores between groups, and measured success as a subjective analysis of 'much better' or 'no change'. The numbers of patients involved when using these cut of points may be illustrated by open population studies of men aged 55-70 years where one in five had a Q_{max}< 10 ml/s and a quarter a Q_{max} between 10 and 14.9 ml/s.[66;67] Increasing age leads to a decrease in Q_{max}; 60% of all men older then 80 years did not have obstruction despite a Q_{max} of 10 to 15 ml/s.[68] Cut-of points of 15 and 10 ml/s are generally accepted;[59;69;70] where a Q_{max} value of greater than 15 millilitre per second is generally considered normal,[48] and with a value below 10 ml/s obstruction is more probable.[16;47] Apart from patho-physiological aspects, the flow appears to be subject to a number of external factors as (psychological) stress, abdominal straining, wagging and pinching the penis during voiding.[9;28;58;59]

Considerable debate exists on whether Q_{max} can be interpreted without considering the voided volume of urine. The reproducibility of the Q_{max} was higher in volumes more then 150 ml,[61] although smaller voiding volumes may also give a reliable picture.[21;35] Numerous nomograms have been developed to tackle this problem, but there is no universally accepted single volume correction technique and so the inaccuracy of flow rates with voided volumes of less than 125-150 ml should be recognised.[71]

It may be concluded that men with LUTS and normal Q_{max} are more likely to have a non-BPH-related cause of their symptoms. Men with a Q_{max} less than 10 ml/s are more likely to have urodynamic obstruction and are therefore more likely to improve with surgery. The Q_{max} correlated better with the degree of bladder outflow obstruction assessed by pressure flow studies than the I-PSS, in a population selected on the severity of complaints.[36] Men with normal flow rates but significant urinary symptoms are more likely to have non-prostatic causes for those symptoms requiring more extensive investigation. Flow rates of the uroflowmetry are probably adequate for long term conservative treatment, such as watchful waiting and α-blockers.[72].

Practice setting

The incidence of lower urinary tract symptoms is 1.2-4.5/1000 men/year[30-32]; so an average practice with the size of 2350 patients (men and women) would be able to recruit between 1.4 and 5.2 new patients a year. Therefore the assumption was that an average GP will not be interested to do this kind of investments in a home flow meter (€ 2300.00, exclusive VAT and € 2.00 for disposable funnel and container (price level 2000)). So one apparatus had to be shared by a group of GPs. Two possible settings were studied: a surgery comprising 5-6 GPs with one uroflowmeter at their disposal on site and a group of 15 GPs being able to refer a patient to a diagnostic centre/laboratory, where the uroflowmeter is made available.

If according to the protocol uroflowmetry is indicated and patient's informed consent is obtained; the patient is instructed by a practice/laboratory assistant in operating the uroflowmeter. The device is taken home where the patient is requested to measure all voiding during 24 hours, this procedure is repeated at six weeks in accordance with the protocol. All flow curves obtained during these two measuring sessions will be at the disposal of the GP for interpretation. The GP obtained a compensation of € 20.— for each patient included. A written reminder was sent to the participating GPs every two months.

Participants

Within the city of Eindhoven 63 GPs were invited to take part in the study, of these 13 GPs showed interest. Furthermore three surgeries containing 5-7 GPs were contacted and invited to take part as a whole, of these one surgery (comprising 6 GPs) agreed. All participating GPs were instructed in a 2-3 hours session in the diagnostic work-up of the patient with LUTS and the interpretation of the uroflow curve. Furthermore one practice-assistant (in the surgery participating) and two laboratory assistants were instructed in handling the uroflowmeter and instructing the patient how to operate the uroflowmeter at home. One uroflowmeter was placed in the surgery taking part, two others were situated in a diagnostic centre at disposal of the 13 GPs.

Men aged 50 years or older visiting their GP because of LUTS were invited to take part in the study. LUTS were defined as a lasting change of urination manifesting itself in hesitancy, a weak flow, dribbling, urge, feeling of retention or increased frequency of urination during day and night.[33] Based on epidemiological data a total of 60 patients were expected to be recruited during the study. Excluded were patients already under medication for BPH, unable to perform the uroflowmetry (restricted cognitive abilities,

unable to urinate standing upright, depending on a urine catheter), with an indication for referral (carcinoma of the prostate, complicated LUTS) or in a terminal phase of a disease.

OUTCOME

Main outcome measure was the feasibility of the protocol in the daily practice of the GP, measured as the number of patients participating and fulfilling the protocol. The GP kept record of each patient in the study of diagnostic tests, therapeutic actions and referrals performed. Six weeks after recruitment (after the second day of measurement) patients were asked to complete an evaluation questionnaire with questions on: physical complaints, present I-PSS and Bother Score, health care needs, evaluation of care as received from the GP and the diagnostic centre, and attitude towards uroflowmetry.
At the end of the study a structured interview was held with participating GPs evaluating uroflowmetry as diagnostic procedure, the facilitators and barriers perceived and suggestions on improvement of the protocol for uroflowmetry in general practice.

RESULTS

The protocol was applied by 19 GPs during for 14 months; a total of 14 patients were included, of these 12 men have actually performed uroflowmetry (we were not able register the exact number of patients visiting the surgery because of LUTS). The average age of these patients was 62.5 years (range 50-81 years), with an average I-PPS of 14.4 (range 5-29) and botherscore of 3.2 (range 2-4). There were no differences in the number of patients included between the settings tested. These 12 men produced a total of 263 registered voidings during the two days of measurement: an average of 11.0 voidings per 24 hours. Half of these were without artefacts and could be used in the interpretation. Seven men (58%) had a $Q_{max} \leq 10$ ml/s and two (16%) had a $Q_{max} \geq 15$ ml/s.
At all, except one, of the first consultations the GP provisionally diagnosed the complaints as LUTS based on a benign prostatic hyperplasia; this diagnosis was not altered because of the results obtained by uroflowmetry. For all of the first consultations the GP expected beforehand to prescribe medication for the patients complaints at the end of the protocol. In two cases this expectation was not met, instead a watchful waiting policy was chosen after discussion of the results with the patient; none of the patients was referred to a urologist.

All patients evaluated the design used in the protocol as being without problems (three consultations at the surgery, installing and operating the uroflowmeter, delay in the diagnosis for more than six weeks).

Evaluation interviews with the participating GPs

Seventeen GPs agreed to the interview evaluating the study (one withdraw because of illness, another preferred not to be approached any more). In general all GPs were disappointed by the low incidence of patients with complaints of LUTS presenting at their surgery. The criteria for exclusion of the patients were experienced as being too strict (specially previous treatment for BPH). They further felt a number of patients could not be considered as candidates for home-flowmetry because of restriction in cognitive of physical abilities (*…the patient is not able to understand the device…*, *… that man was not able to void standing…*), or patients did not agree to the conditions of the study. Most GPs felt uroflowmetry would give them the opportunity to indicate and evaluate treatment more objectively, and thought of uroflowmetry as a valuable, additional tool in general practice. They preferred uroflowmetry to be supported logistically by a diagnostic centre, where the device is distributed after request by the GP. In this centre the patient should be instructed, but also the uroflowcurve should be interpreted by a specialist: as due to the low incidence they felt not having enough routine for adequate interpretation.

Discussion

A protocol for uroflowmetry in general practice was tested for a year in the practices of nineteen GPs. During fourteen months twelve patients performed uroflowmetry according to the protocol. The uroflowmetry did not influence the diagnosis and treatment made at the initial consultation, except in two cases where GP and patient refrained from prescription of medication. Participating GPs and patients perceived uroflowmetry as a positive contribution to the diagnostic work up. With respect to the low number of included patients and the apparent absence of an effect on clinical management uroflowmetry is not considered as very useful in general practice.

Our study was a prospective study of the feasibility of uroflowmetry in general practice. The results we obtained can be seen as a pilot to future studies in this field. On the basis of national data of the incidence of LUTS one would expect a total of 50-60 new patients during the test period, but only 12 men (20%) were included. Even when inclusion criteria

would be extended to monitoring men already treated with medication we expect the number patients will not be high.

The quality of the curves was lower then found in previous studies. We found half of the uroflowcurves were having artefacts making them inaccessible to interpretation; this is much more then the 10-18% found in other studies with home-uroflowmetry.[18;21;22] These differences may be due to the type of instrument used since in these studies the *P-Flow*, a hand held uroflowmeter, was used instead of the *Da CapoHome Uroflowmeter*.

Patients and GPs participating in the study were positive about uroflowmetry in general practice, although their (self-)selection may have biased them. Despite the limited consumption of uroflowmetry during the study, most of them saw a future for this diagnostic method in general practice. This future depended on the condition that logistic management was provided by a laboratory and that curves would be interpreted by a specialist. The latter may be a problem; since interpretation of curves is not easy (experienced urologists were only able to predict the actual diagnosis in 36% of the cases, 43% of the normal flows was considered as abnormal)[34] and uroflowmetry only considered to be a valuable tool when patients history is taken adequately into account.[35;36]

Home-uroflowmeter is a rather expensive diagnostic method for general practice when considered that the GP is only interested in the Q_{max} in his evaluation of the patient. Studies on simpler methods have shown to be reproducible as well: as a 5 second home flow rate,[37;38] the 'how many seconds for 100 ml' test[39;40] and the stream cup test[41] in combination with a voiding dairy.[42]

This paper describes an attempt of introducing a technique new to general practice. There are a number of techniques available to the GP in their own practice (e.g. spirometry)[43;44] or on an open access base in a hospital (e.g. endoscopy, ambulatory blood pressure measurement).[45;46]

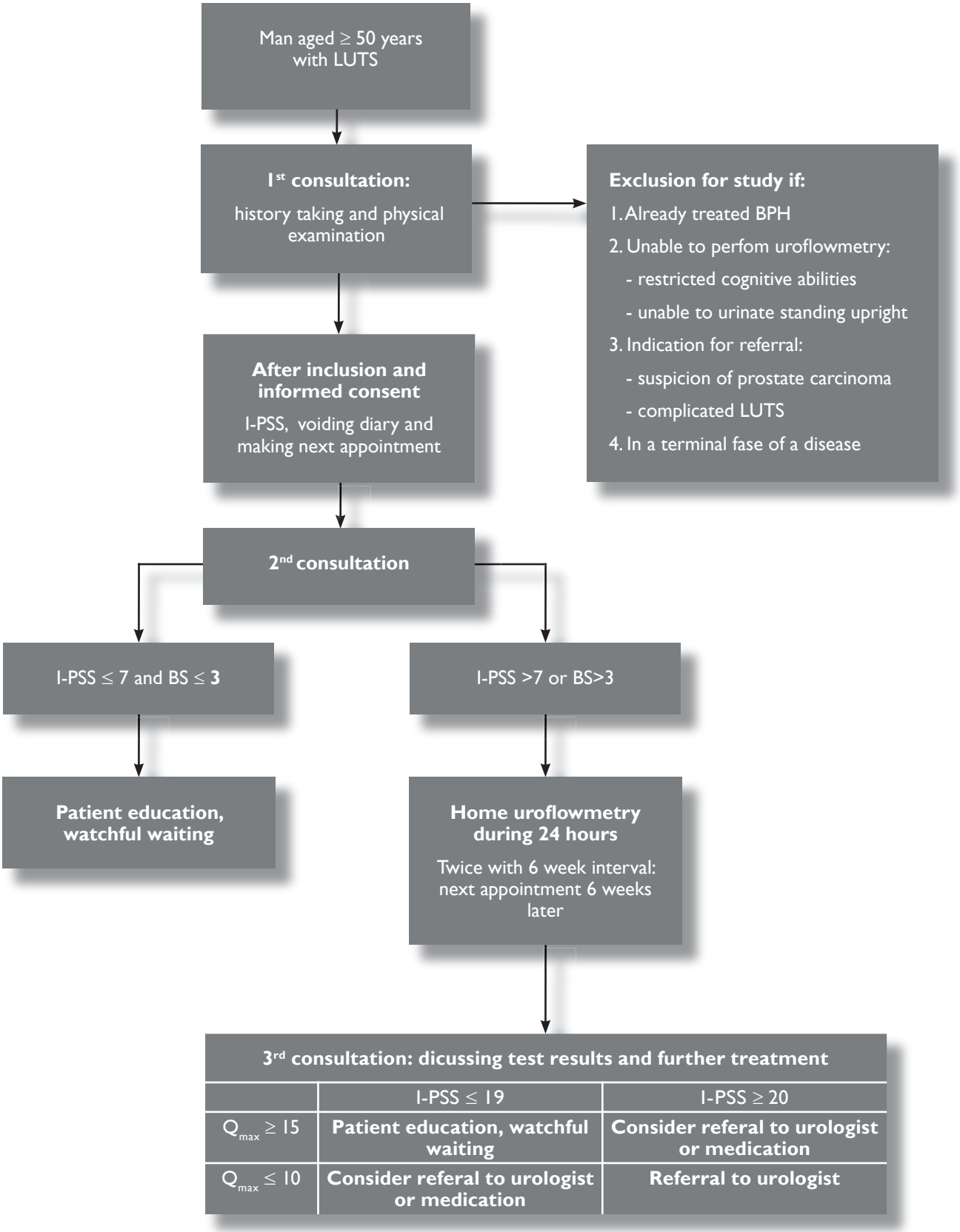
Appendix Chapter 5*: *The diagnostic protocol

The work up of a patient 50 years or older and complaints of lower urinary tract symptoms (Figure 1):

Since the problem often presents itself as a doorknob phenomenon it was advised to split the assessment of LUTS into two-three consultations (three in case of uroflowmetry):

1) The initial assessment (investigation of complaints, physical examination (Digital Rectal Examination). Explaining the I-PSS and voiding diary and handing one out to fill in at home, invite the patient to a next consultation when he has to bring a urine specimen.
2) The next two consultations. The I-PSS and the urine specimen can be talked through. At the end of the (second) consultation the further work up will be:
   a) In case of uncomplicated LUTS and a I-PSS ≤ 7 and/or a quality of life index $\leq 3 \Rightarrow$ **watchful waiting** and re-assessment when complaints are increasing
   b) In case of uncomplicated LUTS and a I-PSS ≤ 7 and a quality of life score ≥ 4 and in case of uncomplicated LUTS and a I-PSS $\geq 8 \Rightarrow$ **uroflowmetry** (Uroflowmetry will be performed twice with an interval of 6 weeks)
      i) If the mean Q_{max} of 24 hours measuring is $\geq$ 10 ml/s and I-PSS 8-19 then the policy can be a shared decision in which the GP reassures the patient and suggests **watchful waiting** and reassessment of the complaints in case of increasing complaints.
      ii) If the mean Q_{max} of 24 hours measuring is $\geq$ 10 ml/s and the I-PSS ≥ 20 or the flow $\leq$ 9 ml/s and the I-PSS 8-19 then the policy can be a shared decision in which the GP suggests **medical treatment** with an α-blocking agent and after 3 months reassessment of the complaints
      iii) If the mean Q_{max} of 24 hours measuring is $\leq$ 9 ml/s and the I-PSS ≥ 20 then policy can be a shared decision in which the GP suggests **referral to a urologist**
   c) In case of complicated LUTS (as there are hematuria, acute urine retention, indications of prostate carcinoma, prostatitis, cystitis, indications of uretral strictures (transuretral instrumentation, sexually transmitted diseases), bladder dysfunction that may be due to diabetes, neurological conditions (as MS, parkinsonism)) patients are excluded from the study and should be dealt with in the proper way of treatment (**antibiotics or referral to a specialist depending on diagnosis**).

Figure 1: Flow diagram of diagnostic work up



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SECTION III

The implementation of clinical guidelines














CHAPTER 6

Effects of distance learning on clinical management of LUTS in primary care: a randomised trial

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Patient Education and Counseling (in press)

Abstract

Objective

To determine the effect of a distance learning programme on general practice management of men with lower urinary tract symptoms (LUTS).

Subjects and methods

A cluster randomised controlled trial was performed. General practitioners (GPs) were randomised to a distance learning programme accompanied with educational materials or to a control group only receiving mailed clinical guidelines on LUTS. Clinical management was considered as outcome.

Results

Sixty-three GPs registered care management of 187 patients older than 50 years attending the practice because of LUTS. The intervention group showed a lower referral rate to a urologist (OR 0.08 (95% CI: 0.02-0.40)), but no effect on PSA testing or prescription of medication. PSA testing tended to be requested more frequently by intervention group GPs. Secondary analysis showed patients in the intervention group received more educational materials (OR 75.6 (95% CI: 3.60-419.90)).

Conclusions

The educational programme had impact on clinical management without changing PSA testing. Distance learning is an promising method for continuing education. Practice implications: Activating distance learning packages are a potentially effective method for improving professional performance. Emotional matters as PSA testing probably need a more complex approach.

Introduction

In order to optimise clinical care several countries developed guidelines on LUTS.[1;2] Guidelines developed by the Dutch College of General Practitioners recommend detailed history taking, without using symptoms scores or voiding dairies. Digital rectal examination (DRE), percussion of the bladder and urine analysis are considered as good clinical practice. A serum creatinine is limited to patients with suspicion of renal failure and PSA testing is restricted to few conditions (family history of prostate carcinoma, inconclusive DRE, start of medication for LUTS and a life expectancy of more than 10 years). In patients with bothersome symptoms who are not able or willing to have surgical treatment the medication of choice is an a-blocking agent, where 5α-reductase blockers are reserved for specialist care. Referral should be considered in men with complicated LUTS.[3;4]

With an ageing population and a rising public awareness of the prostate there is a growing demand for care of LUTS. The introduction of a-blocking medication created a shift of the diagnosis and management of LUTS from the specialist to the primary care physician in various countries.[5-10] Although there is no relation between LUTS and prostate cancer,[11] LUTS are in the perception of many patients related to the carcinoma of the prostate, leading to patient requests for PSA testing in primary care, notwithstanding the benefits of PSA are still an item of debate.[12-15] Despite the guideline a study in a non random sample of GPs showed that PSA was tested in 64.9% of all patients with voiding problems and this number is rising.[16;17] Sorum recently found three factors predicting the likelihood of ordering a PSA: possible regret over not ordering a PSA for a patient subsequently found to have advanced cancer, interpretation of guideline recommendations and diagnostic uncertainty.[18] Preparatory interviews with 20 GPs on possible facilitators and barriers for changing routines suggested that fear of prostate cancer by patient and GP was an important factor associated with PSA testing. PSA testing is presented in the media as a valid screening test and informing the patient on its true nature is time consuming.

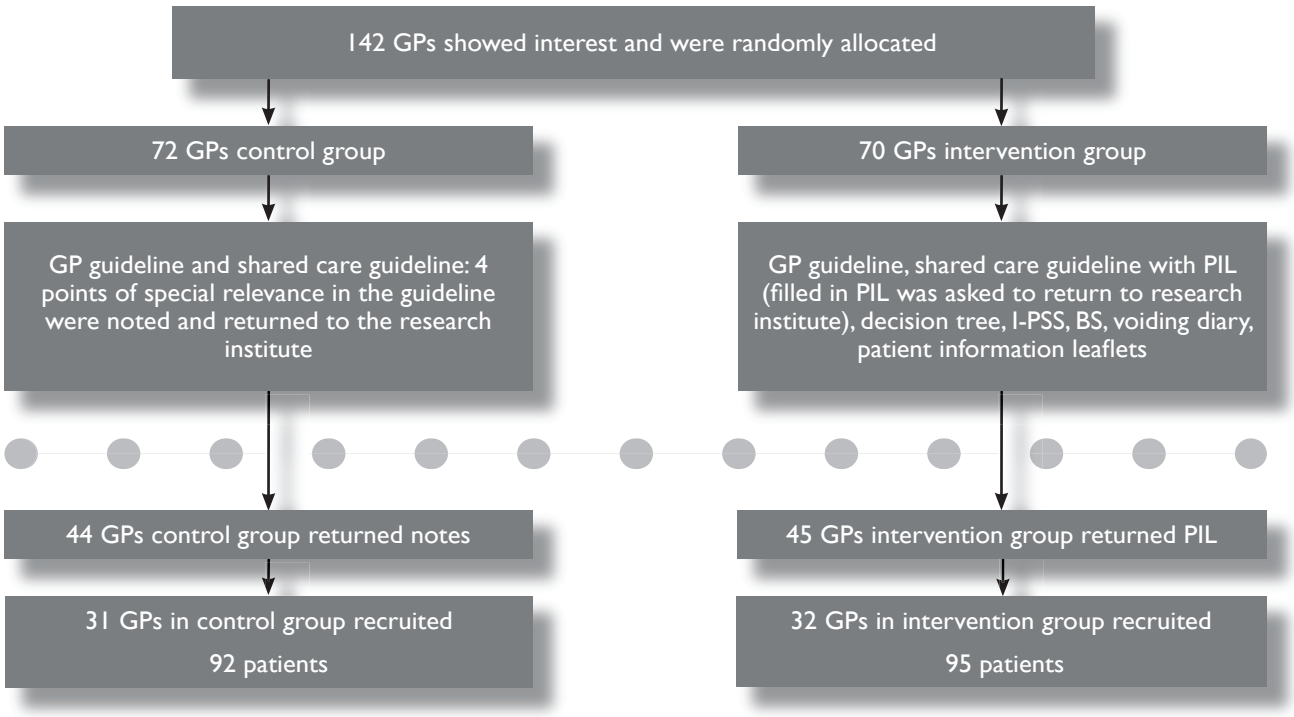
From these interviews we extracted targets for behavioural change (for instance fear of cancer was addressed by information on absence of the relation between LUTS and prostate cancer). Given the relative low priority of the subject for GPs, we needed a simple, relevant, easy to participate, educational programme aimed at encouraging physicians to inform patients and facilitate shared decision making.[3;19;20] Just sending recommendations showed conflicting results,[21] so we developed a comprehensive distance learning programme based

on the package for individual learning (PIL) which comprises the core of implementation activities of the Dutch College of General Practitioners. Recently published trials on the effect of distance learning[22] and consultation supporting materials[19;23;24] have shown effects on self rated competence and care delivered, respectively.
A study was performed to determine the effect of this distance learning programme on general practice care for LUTS patients older than 50 years.

Subjects and methods

We performed a cluster randomised trial, which was approved by the research ethics committee. Allocation of the GPs to the intervention or control group was done by an independent statistician who delivered computer-generated random numbers. The intervention group of GPs received the educational programme with distance learning and the control group received a standard set of guidelines on LUTS (which is available to all Dutch GPs[3;4]). Both groups were blinded for the intervention in the other group. Patients were also blinded for the intervention. After fulfilling the intervention (April 2001) GPs were instructed to recruit patients until June 2002.

Figure 1: Flow chart



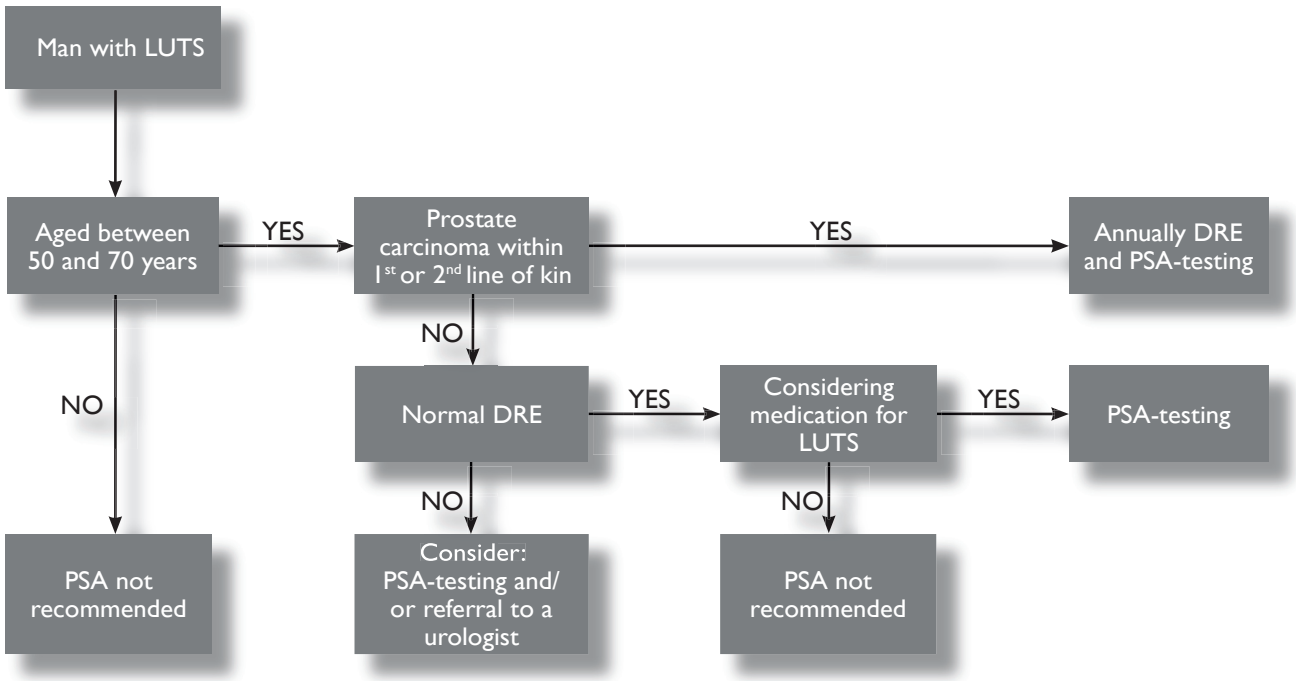
SUBJECTS

One hundred forty two GPs showed interest and were allocated to one of the two groups: 70 to the intervention group and 72 to the control group (Figure 1). All LUTS patients of older than 50 years visiting the GP were considered (note that voiding problems not a request for PSA testing defined our population). Exclusion criteria were: terminal phase of a disease, cognitive problems, known prostate carcinoma, a ureterostomy or bladder catheterisation. All others were invited and those giving informed consent formed the research group.
LUTS were defined according the guideline for GPs: persistent change in urination manifesting itself as difficulty in starting urination, weak flow, dribbling, urge, feeling of retention and/or increased frequency of urination during the day and night.[4]

INTERVENTION

All materials were sent by mail. The distance learning programme comprised (1) a package for individual learning (PIL) developed by the Dutch College of General Practitioners, (2) consultation supporting materials: a voiding diary, the international prostate symptom score (I-PSS) and Bother score (BS), (3) the guideline summarised into two decision trees (one on clinical management of LUTS and one on PSA testing (Figure 2)) and a brief

Figure 2: Decision tree on PSA testing



explanation and (4) two information leaflets for patients (on PSA testing and on treatment for LUTS). The PIL booklet consisted of a guideline based,[4] interactive knowledge test (duration < 2 hours); answers to questions on key issues were sent to a central institute and a standard set of correct answers were returned to as feedback (Box 1).
The control group of GPs received the existing national guidelines on LUTS. They were asked to study these documents, note down four points they found especially relevant and send them to the research institute in an envelope provided.

Measures

Primary outcomes were the number of PSA requests, medication prescribed and the referral rate to a urologist. Secondary outcome measures were: use of symptom scores, physical examination, laboratory tests, life style advice given, distribution of patient information leaflets and duration of the consultation.
Clinical management was evaluated by prospective recording of patient data and management immediately after consultation with an eligible patient.[25] A structured form was designed to document GP management and contained items on history taking (15 possible items), physical examinations (DRE, percussion of the bladder), additional

Box 1*: *Contence of the Distance Learning Programme

Enhancement of knowledge:

- Two documents as background information ('Benign prostatic hyperplasia; recommendations for transmural care'3 and 'Dutch College of General Practitioners guidelines on Lower urinary Tract Symptoms'4)
- Package for Individual Learning (PIL): (Small booklet , 28 pages, 2 hours work)
  - *Eight open questions reflecting on a recent male patient attending surgery with LUTS*
  - *Fourteen open questions on the clinical management of hypothetical 4 cases*
  - *Eight true/false statements on clinical management of LUTS*
  - *Six open questions on statements about (fear of) prostate cancer*
  - *Six open questions reflecting possible barriers around bladder catheterisation in case of acute urinary retention*

Consultation supporting materials:

- Dutch College of General Practitioners guidelines on Lower urinary Tract Symptoms summarised on an A5 format card.
- The guideline summarized in two decision trees:
  - *Clinical management of a patient with LUTS*
  - *Indications for PSA testing*
- International Prostate Symptom Score (I-PSS)
- Bother Score (BS)
- Voiding dairy

Patient information leaflets (each about 900 words):

- On causes of LUTS and treatment options
- On prostate carcinoma in relation to LUTS and the limitations of PSA-testing

testing (creatinine, PSA, urine sample, voiding list), information provided (life style advice, information leaflets, discussion of therapy options) and therapy (medication, referral to a urologist).
After the consultation, patients filled in a questionnaire to obtain data on age, educational level, duration of complaints and symptom level (I-PSS, BS). They returned the questionnaire in a pre-stamped envelope to the research institute.

Power

The trial was designed to detect a 20% difference in adherence to the guidelines, particularly a decrease in PSA requests from 80 to 60% (α = 0.05, power = 0.80, icc = 0.05). A total of 180 patients from 60 GPs were needed, assuming that they would be able to recruit an average of three patients each. Anticipating a loss to follow up of 30%, the aim was to include 86 GPs.

Analysis

The unit of analysis was the patient. Age, duration of symptoms, I-PSS and BS were handled as continuous variables, while all others were dichotomous. Missing data were considered to be a negative answer ('not performed' or 'not present'). The analysis compared intervention and control group with respect to outcome measures. Odds ratios were calculated with logistic regression analysis, with $P< 0.05$ as the level of statistical significance. Separate analyses were performed for a number of dependent variables reflecting professional performance (Table 3). Independent variables in these models were group allocation, I-PSS, BS and age. For data analysis we used SPSS (version 10.0). Cluster effects due to randomisation were corrected for by a multi level analysis in SAS (version 6.12) with the GLIMMIX MACRO procedure.

Results

The educational programme was completed by 89 of the GPs; 63 GPs (31 GPs in the intervention group and 32 GPs in the control group) were able to recruit patients (Figure 1). GPs in both groups studied were comparable (Table 1). A non-response analysis was performed on the 79 GPs who did not complete the educational programme or recruit patients. No differences were found (regarding age, gender, practice setting (practice size,

Table 1*: *Characteristics of the GPs *(absolute numbers and percentages between brackets; OR = odds ratio)*

	Total (*n* = 63)	**Intervention (*n* = 31)**	**Control (*n* = 32)**	**OR (95% CI)**
Mean age (SD)	47.4 (6.5)	47.7 (7.2)	47.1 (5.8)	0.98 (0.91-1.06)
< 45 years of age	18 (28.6)	9 (28.1)	9 (29.0)	1.05 (0.35-3.12)
< 15 years working as GP	28 (45.0)	14 (46.7)	13 (43.3)	0.93 (0.35-2.52)
Male	47 (74.6)	25 (78.1)	22 (71.0)	0.68 (0.22-2.14)
GP trainer	22 (35.5)	12 (37.5)	10 (32.3)	1.26 (0.45-3.56)
Solo practice	18 (28.6)	8 (25.0)	10 (32.3)	0.70 (0.23-2.10)
(Urbanised) rural area	29 (46.8)	16 (50.0)	13 (43.4)	0.77 (0.28-2.08)
>1 Hospital to refer to	36 (58.1)	22 (68.8)	14 (46.7)	2.51 (0.89-7.09)

Table 2: Charateristics of the patients included in the study *(absolute numbers and percentages between brackets; OR = odds ratio)*

	Total (*n* = 151)	**Intervention (*n* = 75)**	**Control (*n* = 76)**	**OR (95% CI)**
Mean age (years) (SD)	66.3 (9.0)	66.2 (8.6)	66.4 (9.4)	1.00 (0.96-1.03)
Age in categories				
50-59 years (%)	39 (25.8)	17 (22.7)	22 (28.9)	1.05 (0.74-1.49)
60-69 years (%)	58 (38.4)	31 (41.3)	27 (35.5)	
70-79 years (%)	43 (28.5)	22 (29.3)	21 (27.6)	
≥ 80 years (%)	11 (7.3)	5 (6.7)	6 (7.9)	
Education				
Lower (%)	58 (38.5)	25 (33.3)	33 (43.4)	125 (0.89-1.75)
Secondary (%)	47 (31.1)	25 (33.3)	22 (28.9)	
Higher (%)	35 (23.2)	18 (24.0)	17 (22.4)	
Unknown (%)	11 (7.3)	7 (9.3)	4 (5.3)	
Symptoms				
Duration >1 year (%)	80 (54.8)	40 (57.1)	40 (52.6)	1.03 (0.54-1.95)
Mean I-PSS (SD)	14.9 (7.5)	14.3 (7.8)	15.5 (7.2)	0.98 (0.94-1.02)
Mean Bother Score (SD)	3.1 (1.1)	3.0 (1.0)	3.2 (1.2)	0.84 (0.63-1.13)

urbanisation, computerisation, GP-trainership) and attitude towards (LUTS) guidelines). During the study 187 patients were recruited; 151 returned their questionnaire (Table 2).

DIAGNOSTIC PROCEDURES

No differences were found in history taking and diagnostic procedures (Table 3). A symptom score was used in about one out of five consultations despite distribution of the I-PSS in the intervention group. The voiding list, distributed as part of the intervention, was used in one out of eight consultations in the intervention group.
The GPs performed a digital rectal examination (DRE) in 82.4%, percussion of the bladder in 29.4% and PSA testing was requested in 50.3% of the consultations. Although the PIL intended to increase GP's and patient's awareness of the implications of PSA testing, PSA tests were requested 17.6% more often in the intervention group (Table 3). A considerable portion of the patients (33.9%) in the intervention group influenced the GP's

Table 3*: *Clinical management of voiding problems in the study period *(absolute numbers and percentages between brackets; OR = odds ratio corrected for clustering)*

	Total (*n* = 187)	**Intervention (*n* = 95)**	**Control (*n* = 92)**	**OR (95% CI)**
Diagnostic procedures				
I-PSS measured	38 (20.3)	22 (8.6)	16 (17.4)	2.92 (0.53-16.04)
Voiding list used	16 (8.6)	12 (12.6)	4 (4.39)	5.68 (0.61-53.27)
DRE	154 (82.4)	75 (78.9)	79 (85.9)	0.61 (0.21-1.75)
Percussion of the bladder	55 (29.4)	26 (27.4)	29 (31.5)	0.76 (0.27-2.14)
Serum PSA	94 (50.3)	56 (58.9)	38 (41.3)	2.04 (0.87-4.77)
Serum creatinine	64 (34.2)	37 (38.7)	27 (29.3)	1.43 (0.51-4.01)
Urine analysis	119 (63.6)	54 (56.8)	65 (70.7)	0.55 (0.30-1.00)
Counseling and treatment				
Lifestyle advice given	110 (58.8)	58 (61.1)	52 (56.5)	1.32 (0.48-3.63)
Consultation >15 minutes	15 (8.0)	11(11.6)	4 (4.3)	3.14 (0.52-18.86)
Wait and see policy	115 (61.5)	61 (64.2)	54 (58.7)	1.47 (0.66-3.28)
α-blocking medication	57 (30.5)	30 (31.6)	27 (29.3)	0.92 (0.35-2.41)
Finasteride	5 (2.7)	3 (3.2)	2 (2.2)	1.47 (0.24-8.99)
Referral to urologist	15 (8.1)	2 (2.1)	13 (14.1)	0.08 (0.02-0.40)

decision and the GP seemed to perceive patient's fear of cancer more often (32.1%) as a motivating factor (Table 4).

According to guidelines PSA testing should be limited to certain indications.[3;4] In our study the indications to test PSA were met by 69 patients (intervention = 39, control = 30): 85.6% were considered to have a life expectancy of at least 10 years; 6.3% of these patients had a positive family history; 13.8% an inconclusive DRE and 28.1% were receiving medication. The PSA test was ordered in 26 patients of the intervention group (66.7% of the patients with an indication) and in 15 of the controls (50.0% of the patients with an indication) (χ^2: P = 0.16). In total 118 patients in our study had, according to the guideline, no indication; in 44.9% of these patients a PSA test was requested (intervention: 53.6%, control: 37.1% (χ^2: P = 0.07)).

Counselling and treatment

The intervention decreased the number of referrals (OR 0.08) and had no other significant effects (Table 3). Life style advice was given in about 58.8% of the visits. Consultations longer than 15 minutes tended to occur more frequently in the intervention group (P = 0.066). A future consultation was planned in two thirds of the visits in both groups. In the intervention group, patient education leaflets were used in 51.6% of the contacts, compared to 7.6% in the control group (OR 75.5).

In 61.5% of the patients a watchful waiting policy was followed. Medication was prescribed to a third of the patients; the majority received an α-blocker. Plausible indications for referral mentioned in the guidelines include: bothersome LUTS and the patient's wish for surgery,

Table 4*: *Reasons for PSA request as stated by the GP *(absolute numbers and percentages between brackets; OR = odds ratio)*

PSA requests recorded	Total (*n* = 94)	Intervention (*n* = 56)	Control (*n* = 38)	OR (95%CI)
PSA request influenced by the patient	23 (24.7)	19 (33.9)	4 (10.8)	2.98 (0.78-11.44)
Reason for PSA testing				
As a routine	26 (27.7)	15 (26.8)	11 (28.9)	1.02 (0.32-3.25)
Inconclusive DRE	21 (22.3)	11 (19.6)	10 (26.3)	0.66 (0.17-2.58)
GP is anxious about cancer	26 (25.0)	14 (25.0)	12 (31.6)	0.97 (0.20-4.75)
Patient is anxious about cancer	24 (25.2)	18 (32.1)	6 (15.8)	2.24 (0.60-8.42)

or complicated LUTS. One or more of these factors were present in 44 patients in our study group (18 patients in the intervention group and 26 in the control group, P = 0.133).

Discussion

Our simple distance learning educational programme, aimed to change GP management of men with LUTS, effectively decreased the number of patients referred to a urologist and increased the number of patients provided with educational materials. We also intended enhance evidence based decision on PSA testing by providing the GP with tools to inform the patient about the (dis)advantages of this test. Although not significant, there were some indications of an unintended increase in the number of test requests. Also, the consultation time tended to increase. Other aspects of LUTS management did not change.

The few randomised trials which have been conducted using distance learning programmes did not measure effects on daily patient management.[22;23] Our study was a cluster randomised trial on GPs, not being part of a research network, delivering daily care to unselected patients during more than a year. This care was recorded with a method reflecting actual care.[25] The intervention itself was simple, flexible, not time consuming and considered pleasant by participating GPs. It did not require changes in practice infrastructure.

The study was limited since a prospective pre-intervention measurement was not feasible considering the low incidence of LUTS in general practice. Another limitation is the fact that we were able to collect data on 63 GPs of the original 142 we intended to educate. Fifty-three GPs terminated their participation to the study, this may be due to the collectively experienced workload of the Dutch GPs and their conflicts with health insurance companies during the study period. Our strategy registering normal daily care caused a further loss to evaluation of 26 participating GPs, who where motivated, but not able to include patients during the study. Furthermore, some clinical relevant outcomes (consultation time and PSA request) did just not reach significance which may be caused by the sample size.

Fear of prostate cancer in patients with LUTS is a motivating factor to visit the GP[26;27] and patients believe PSA testing offers health benefits.[28] Amongst GPs possible regret over not ordering a PSA and diagnostic uncertainty factors appeared to predict the likelihood of ordering a PSA.[18] Our distance learning intervention provided the patient and GP with information to make a balanced choice. Earlier published data showed that this positively influenced patient evaluation of care and improved patients coping with LUTS.[29] GPs

in our intervention group tended to request more often PSA testing; suggesting that the intervention did not reduce the fear of missing prostate carcinoma by not performing PSA testing. Chapple found many patients were only told the implications of PSA testing after a positive result and underlined the importance of making an informed decision.[28] Another study with self selected patients showed that a decision aid on PSA increased knowledge, but did not decrease the number of tests.[30] Studies on unselected populations without LUTS showed a decreasing effect of decision aids on PSA testing.[31;32] A paper on a qualitative analyses of patient rational showed that underlying believes and prior testing influenced intentions towards testing more than weighing of communicated risks and benefits.[33] So in our study, having prostate related complaints, patients may have already made up their minds before attending surgery and the information received on PSA testing reinforced their decision.

Without significant differences in the distribution of possible indications for referral, fewer patients in the intervention group were referred to a urologist; suggesting GPs in the intervention group were more confident about managing patients with LUTS themselves. This may explain the trend towards a longer consultation time. A recent study on a computerised multimedia decision aid to educate patients with LUTS about treatment choices has shown an increase in patient participation in the decision process, without changing the number of specialist consultations.[19] Alternatives for educating the GP like providing computerised support for a GP's decision appeared to involve many barriers for daily practice.[34]

Our intervention showed changed GP management in terms of a decrease in the number of referrals and an increase in the provision of educational materials to patients. Implementing rational PSA testing appears to be a complex and emotional subject with regard to fear of (missing) cancer and may need a different approach.

Although written educational materials have limited effects,[35] distance learning is particularly useful for GPs who live in remote or rural areas.[36] Even in a densely populated area such as The Netherlands, it can also serve a useful purpose, because of its flexible use in time. In general practice, various disorders are thought of as being 'small' (low incidence/low priority); in these cases self-education could play a role as the method is known to be effective. Just sending materials does not alter the emotions of the patient or the doctor. Although, Dutch guidelines on PSA testing are evidence based, they might be too strict for application in daily care. Guidelines in other countries emphasize the need for well informed decision making, rather than whether or not PSA is actually tested. Postponing or even refraining from referral to a urology specialist may mean greater cost efficiency.

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CHAPTER 7

The effect of a distance learning programme on patient self-management of lower urinary tract symptoms (LUTS) in general practice: *A randomised controlled trial*

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Abstract

Objective

To determine whether a distance-learning programme on LUTS provided to the general practitioner (GP) affected patient self-management

Subjects and methods

A randomised trial was performed to examine the effects of the distance-learning programme (an educational package for the GP and a patient information leaflet) compared with written guidelines on LUTS mailed to the GP. In 63 general practices (32 intervention and 31 control) across the Netherlands all patients older than 50 years presenting LUTS for the first time were invited to participate. Main outcome measures were patient evaluation of quality of care received and perceptions of enablement

Results

A total of 151 patients was included. The intervention increased patient enablement regarding maintenance of independence (OR 3.14) and coping with illness (OR 2.21). Overall enablement scores were not changed. Patients in the intervention group had more positive evaluations of general practice care received (OR 2.28 to 3.95). An explorative analysis suggested that the effects of the intervention were mediated in particular by handing out of patient information leaflets.

Discussion

A distance-learning programme on LUTS for GPs had positive effects on patient self-management. Handing out leaflets appeared to be a crucial mediating factor.

Introduction

Lower Urinary Tract Symptoms (LUTS) are bothersome, but generally not life-threatening. This chronic condition is common among men in the age group of 50 years and older. The clinical management of these complaints can be difficult.[1] A fear of carcinoma of the prostate and whether or not to test for prostate specific antigen (PSA) have to be dealt with.[2;3] In the management of patients with LUTS it is considered to be important to involve the patient in making decisions based on his own preferences and needs.[4] Consequently, patient education and shared decision-making based on the available research evidence are crucial for the adequate management of LUTS and for helping patients to cope with their illness.

A patient's decision to seek medical care for LUTS is, apart from the severity of his complaints, also driven by factors such as advice from people in his environment and information from the media.[5] Those who seek medical advice have specific expectations about the provision of information on their complaint and its management.[6] Patients are increasingly involved in the management of their illness and health care providers should support them in this role.[7] This implies that patients should be educated in problem solving skills in order to promote self-management.[8] Patient enablement reflects patient reported effectiveness of the practitioners' efforts to enhance self-management.[9;10]

Recently published trials on the effects of distance learning[11] and consultation support materials[12-15] have found effects on the self-rated competence of the primary care physician and the care delivered, respectively. We developed a comprehensive, activating distance-learning programme that aimed to encourage primary care physicians not only to improve their knowledge on LUTS, but also to change their professional performance and support communication with the patient about the subject. This study aimed to examine its effects on patient outcomes, particularly patient enablement and patient evaluation of care.

Subjects and methods

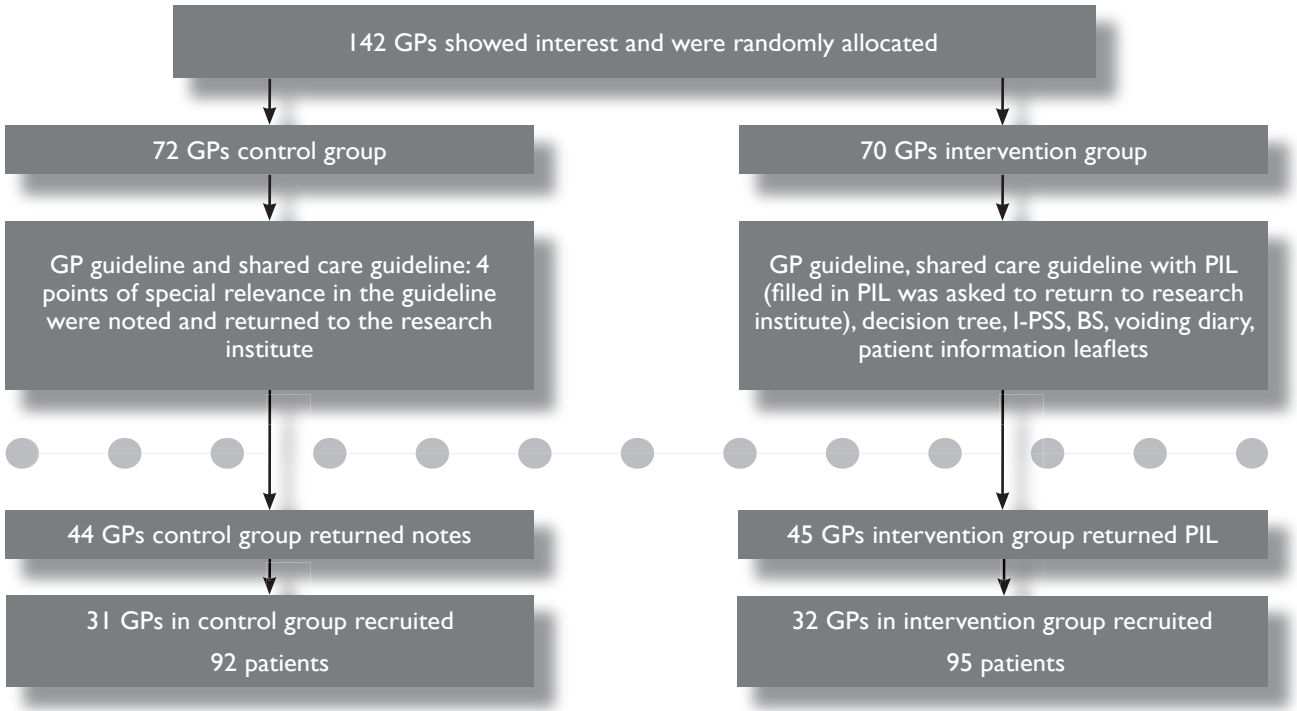
In a cluster randomised trial one group of GPs received the multifaceted distance-learning programme (the intervention group) and the other group received a standard set of guidelines on LUTS[16;17] (control group) by mail. After the intervention was delivered

(April 2001), GPs were instructed to recruit prospectively patients presenting at their surgery for the first time with LUTS over a period of 15 months. The GPs were blinded for the intervention in the other group and patients were not aware of the content of the intervention. Allocation of the GP to an intervention or control group was done by computer generated random numbers provided by an independent statistician. The project received approval from the research ethics committee.

SUBJECTS

Across the Netherlands 142 GPs were randomly allocated to one of the two groups (Figure 1). All patients visiting the GP's regular surgery hours with complaints of LUTS and older than 50 years were considered (note that voiding problems and not a request for PSA testing defined our population). Patients were excluded if they were: in a terminal phase of a disease, unable to complete a questionnaire because of cognitive problems, known to have a prostate carcinoma, a ureterostomy or depending on bladder catheterisation. All others were invited and those giving informed consent comprised the study group.

Figure 1: Flow chart



Intervention

The distance-learning programme comprised (a) a Package for Individual Learning (PIL) developed by the Dutch College of General Practitioners (NHG), as well as (b) consultation support materials: a voiding diary, the International Prostate Symptom Score (I-PSS) and Bother Score (BS), (c) LUTS guideline[16] converted into a decision tree with a brief explanation and (d) two patient information leaflets (one on PSA testing and one on treatment for LUTS). The PIL consists of an interactive knowledge test based on the LUTS guideline.[16] GPs were asked to go through all the questions as presented in the PIL; questions on key issues of LUTS had to be send to a central institute; the correct answers were then sent to the respondents as feedback. The control group was provided with the existing national guidelines[16;17] on LUTS only. They were asked to read these documents and write down four points that they had found particularly relevant and send them to the research institute in the envelope provided. All materials were directed to the physicians and it was left up to the physician whether or not materials were used.

Measures

Outcome was measured on patient level. Patients were asked to fill in a questionnaire after the consultation and send it in a pre-stamped envelop to the research institute. Patient's evaluation of the care received and experience of being enabled to cope with the complaints were the main focus of the study. A validated patient questionnaire was used to measure patient's evaluations of care.[18] Questions were related to communication and patient involvement (3 items), support (2 items), medical care (2 items) and information (3 items) (Table 2). An adapted version of a six-item patient enablement instrument was used to measure the level to which patients were able to cope with their symptoms (Table 3).[19] Additional measures were patients' perception of their complaints ('Bother Score' (BS)) and their preferences after the consultation regarding additional diagnostic procedures and surgery.

Patient variables (age, educational level, duration of complaints, symptom level (International Prostate Symptom Score (I-PSS)) and management received) were recorded as well by the patient questionnaire. Factual information on the care delivered (diagnostic procedures (DRE, PSA), counselling and treatment (lifestyle advice, information leaflets, medication and referral)) was obtained from the GPs' records of their management.

Power

A medium effect, which was expected to be clinically relevant,[20;21] regarding patient enablement or evaluation of care required a total of 138 patients from 46 GPs ($\alpha = 0.05$, power = 0.80, icc = 0.05).

Analysis

The unit of analysis was the patient. All variables (except for age, duration of complaints and I-PSS) were dichotomised. Where possible, missing items were accounted for as a negative answer ('not applicable'). Missing answers to the separate items of the patient evaluation of care questionnaire and the adapted patient enablement instrument were excluded from the analysis. Patient evaluation of care scores were obtained by adding all the items assigned the score 'good'. Scores could range from 1 to 10. The enablement scores were calculated by adding the separate items ('better/more' scored as 1, 'much better/much more' as 2). Scores could range from 0 to 12.[19] Patients who filled in less than half of the items were excluded from calculating scores.

The effect of the intervention on patient evaluation of care and patient enablement were the primary outcome measures. Analysis of the effectiveness of the intervention, corrected for a cluster effect by multi level analysis, was done in SAS (version 8.0) with the GLIMMIX MACRO procedure (dichotomous variables) and the PROC MIXED procedure (continuous variables). In this analysis, corrections were made for other possible prognostic factors, such as age, I-PSS and BS (older patients tend to be more positive about their care provider, while patients with a poorer health status tend to be more negative;[22] age was found also to affect the enablement instrument)[19] (Tables 2 and 3). The effect of the intervention on the degree to which the patients perceived their complaints as bothersome and their wishes regarding additional tests and surgery were also corrected for cluster effects.

On data at baseline significance was calculated with Students t-test and χ^2-test analysis using SPSS (version 10.0). $P < 0.05$ was taken as the level of statistical significance.

Finally, we performed explorative analyse (GLIMMIX MACRO and PROC MIXED) to identify factors which may have affected the study outcomes. Factors considered in the analyses included the intervention (PIL), patient factors (age, I-PSS, BS), PSA testing, patient education (use of information leaflets, lifestyle advice) and treatment chosen (prescription of medication, referral to a urologist).

RESULTS

POPULATION CHARACTERISTICS

A total of 89 physicians actually participated in the study, 63 of those (32 in the intervention group and 31 in the control group) were able to recruit patients (Figure 1). A non-response analysis was performed on the physicians who did not complete the educational programme or recruit any patients. No differences were found (regarding age, gender, practice setting (e.g. number of GPs at the practice, urbanisation, computerisation, GP trainership) and attitude towards (LUTS) guidelines). The physicians recruited 187 patients; 151 (81%) of them returned their questionnaires.

The patients in the two groups were comparable at baseline, with an average age of 65 years, equal variation in educational level and a mean I-PSS of 15. About half of the patients had experienced LUTS for more than a year (Table 1). In the physicians records of their management no significant differences were found between the two patient groups, except for a higher number of information leaflets handed out (OR 11.5) and a lower number of referrals to a urologist after the initial consultation (OR 0.09) in the intervention group.

Table 1: Baseline charateristics of the patients included in the study

	Total (n = 151)	**Intervention (n = 75)**	**Control (n = 76)**	
Mean age [SD]	65.2 [8.7]	65.2 [8.6]	65.2 [8.8]	P = 0.98 [a]
Education				
Lower education (%)	58 (38.5)	25 (33.3)	33 (43.4)	P = 0.55 [b]
Secondary education (%)	47 (31.1)	25 (33.3)	22 (28.9)	
Higher education (%)	35 (23.2)	18 (24.0)	17 (22.4)	
Unknown (%)	11 (7.3)	7 (9.3)	4 (5.3)	
Complaints				
Duration >1 year (%)	80 (54.8)	40 (57.1)	40 (52.6)	P = 0.93 [a]
Mean I-PSS [SD]	14.9 [7.5]	14.3 [7.8]	15.5 [7.2]	P = 0.33 [a]

[a] *Student's t-test* [b] χ^2*-test*

Patient evaluation of care

The total score on the patient evaluation questionnaire showed that the patients in the intervention group (mean score = 5.48; SD = 3.13) were more satisfied than the controls (mean score 4.01; SD = 3.22) (size of effect: 1.47 (95% CI: 0.39- 2.55)). Significant differences were found between the patients in the two groups on four out of the ten items in the patient evaluation instrument. Patients in the intervention group more often felt they had been involved in thinking about their complaints (OR 2.28). They were more satisfied about the information given on the management of their complaints (the physician had communicated his intentions (OR 3.48) and clearly explained the treatment (OR 2.57)). They were convinced more that the treatment they received helped to decrease their complaints (OR 3.95) (Table 2).

Patient enablement

More patients in the intervention group felt that they were able to cope with their illness (OR 2.21) and maintain their independence (OR 3.14). There were no significant differences in the other items in the patient enablement instrument between the two groups, or in the total sum score (mean score = 2.32; SD = 2.50) of the instrument. After the consultation half of the patients felt confident about their health and thought they were able to understand their illness (Table 3).

Other patient outcomes

Fewer patients in the intervention group expressed the wish for additional tests compared to the control group (OR 0.46 (95% CI: 0.21-0.98)). The mean Bother Score in the total population was 3.1 and there were no differences between the two groups. About one in every seven patients wanted surgery; there were no differences between the two groups.

Explorative analysis

We explored whether patient education or other aspects of professional routines influenced the patient outcomes. Handing out information leaflets appeared to have a significant positive effect on patient evaluation of care and enablement. Patients who were advised on their lifestyle were satisfied with the way the physician had tried to reassure them, but despite this, they were less confident about their health than the patients who had not been

Table 2*: *Separate items of the evaluation of care score filled in directly after the consultation

Evaluation of care	Total	Intervention group	Control group	OR corrected for age, I-PSS and BS
To what extent did the GP				
…treat your complaints in order to decrease them (n = 104)[a]	43 (41.3)	29 (58.0)	14 (25.9)	3.95 (1.70-9.15)
…tell you what he intends to do (n = 127)[a]	83 (65.4)	48 (78.7)	35 (53.0)	3.48 (1.53-7.95)
…explain the treatment in a clear way (n = 128)[a]	86 (67.2)	46 (78.0)	40 (58.0)	2.57 (1.20-5.90)
…involve you in thinking about your complaints (n = 122) [a]	63 (51.6)	37 (61.7)	26 (41.9)	2.28 (1.09-4.80)
…endeavour to decrease your complaints (n = 129) [a]	63 (48.8)	36 (55.4)	27 (42.2)	1.77 (0.86-3.64)
…reassure you about the complaints (n = 131)[a]	63 (48.1)	36 (55.4)	27 (40.9)	1.76 (0.88-3.53)
…convince you about the importance of following the advice (n = 131) [a]	75 (57.3)	41 (62.1)	34 (52.3)	1.49 (0.73-3.03)
…let you decide on the treatment (n = 88)[a]	42 (47.7)	24 (51.1)	18 (43.9)	1.34 (0.55-3.29)
…discuss treatment options with you (n = 126) [a]	65 (51.6)	33 (55.0)	32 (48.5)	1.28 (0.63-2.60)
…make you feel at ease (n = 114) [a]	53 (46.1)	28 (50.0)	25 (43.1)	1.20 (0.53-2.70)

Odds ratio calculated by multi level analysis (men that answered with 'good' were counted).
[a]Number of patients who answered the question.

Table 3*: *Separate items of the patient enablement score filled in directly after the consultation

Patient enablement	Total	Intervention group	Control group	OR corrected for age, I-PSS and BS
As a result of your visit to the doctor today do you feel you are				
…able to maintain your independence (n = 129) [a]	36 (27.9)	24 (36.9)	12 (18.8)	3.14 (1.26-7.83)
…able to cope with your illness (n = 132) [a]	48 (36.4)	29 (44.6)	19 (28.4)	2.21 (1.03-4.75)
…able to help yourself (n = 130) [a]	27 (20.8)	17 (26.2)	10 (15.4)	2.11 (0.86-5.16)
…confident about your health (n = 137) [a]	68 (49.6)	40 (57.1)	28 (41.8)	1.92 (0.85-4.33)
…able to understand your illness (n = 136) [a]	72 (52.9)	37 (55.2)	35 (50.7)	1.21 (0.60-2.43)
…able to cope with life (n = 135) [a]	47 (34.8)	25 (36.8)	22 (32.8)	1.18 (0.58-2.41)

Odds ratios are calculated by multi level analysis. (men that answered with better/much better or more/much more were counted). [a] *Number of patients that answered the question.*

advised on their lifestyle. Patients who received prescriptions for medication were less satisfied about the treatment options discussed during the consultation (Table 4). There was no relation between PSA testing and any of the outcome measures. Higher Bother Scores were related with a greater need for additional diagnostic procedures and greater preference for surgical treatment.

Table 4**: **Explorative analyses of whole population on factors affecting patient outcome

Determinants/predictors		**Odds Ratio (95% CI)**
Got leaflet	*Evaluation of care:* To what extent did the GP	
	…tell you what he intends to do (n = 127)[a]	OR: 3.97 (1.51-10.46)
	…involve you in thinking about your complaints (n = 122) [a]	OR: 3.92 (1.69-9.10)
	…endeavour to decrease your complaints (n = 129) [a]	OR: 2.46 (1.10-5.50)
	…reassure you about the complaints (n = 131)[a]	OR: 2.29 (1.03-5.07)
	…make you feel at ease (n = 114) [a]	OR: 2.82 (1.19-6.72)
	Patient enablement: As a result of your visit to the doctor today do you feel you are	
	…able to cope with your illness (n = 132) [a]	OR: 2.61 (1.20-5.70)
Got lifestyle advice	*Evaluation of care:* To what extent did the GP	
	…reassure you about the complaints (n = 131)[a]	OR: 2.91 (1.39-6.11)
	Patient enablement: As a result of your visit to the doctor today do you feel you are	
	…confident about your health (n = 137) [a]	OR: 0.42 (0.19-0.93)
Got medication	*Evaluation of care:* To what extent did the GP	
	…discuss treatment options with you (n = 126) [a]	OR: 0.40 (0.18-0.86)
	…make you feel at ease (n = 114) [a]	OR: 0.34 (0.14-0.82)
Got referral	*Patient enablement:* As a result of your visit to the doctor today do you feel you are	
	…confident about your health (n = 137) [a]	OR: 0.17 (0.03-0.94)

Only significant (P<0.05) results are presented. [a] Number of patients that answered the question

Discussion

The distance-learning educational programme that aimed to improve communication effectively enhanced patient self-management. Patients felt more able to cope with their illness and to maintain their independence. The explorative analysis suggested that the positive effects on patient evaluation of care and enablement were associated with the provision of patient leaflets in the initial consultation. Thus the intervention appeared to be mediated by handing out more patient education leaflets.

Very few randomised trials have been conducted regarding distance-learning programmes. Available studies measured the effects on physicians (knowledge of the subject or management of virtual patients as outcome measures)[11;12] rather than on patients. Our study was a cluster-randomised trial on GPs who were not in an existing research network. Patients were recruited prospectively for more than a year. The intervention was friendly (flexible, not very time-consuming (less than 2 hours) and considered pleasant by the participating physicians). It was multifaceted, did not require any changes in practice infrastructure and could be used in rural areas or by physicians with little time. The study had some limitations. After the intervention 26 GPs were unable to recruit any patients during the time of the study. And although there was a prospective inclusion of patients; no pre-intervention measurement was performed because of the low incidence of LUTS in general practice. The evaluation of complex interventions like our study may be difficult because of problems of identifying and reproducing the intervention.[23] So whether or not the interactive learning as such played a role cannot be evaluated in our design of the study. On the other hand the handing out of patient education leaflets appeared to be a significant factor after the explorative multi level analysis.

Few similar studies have been performed. Many previous studies on LUTS were done in a hospital setting and focused on decision making regarding (surgical) treatment of prostate cancer[24-27] or BPH.[28-30] Some studies were done in open populations or in the level of the initial consultation and focused specifically on PSA testing,[31-36] clarifying symptoms[35;37] or initial treatment choices.[14;38]

An interactive multimedia computer programme seemed to increase patient's participation and knowledge, and decreasing the decisional conflict.[14] Our study tested a more complex intervention by providing supporting materials combined with educating the physician, leading to a better patient evaluation of care (specially on information transfer related items) and the feeling of being better enabled to maintain independence and to cope with their illness, without affecting their complaint level. The results of our study suggested

that these decision aids also work in the daily care delivered and not only in the optimal conditions of a clinical trial.

The patient education leaflet as part of the intervention led to greater satisfaction in the evaluation of items on the transfer of information and gave patients the feeling that they could cope with their illness. Provision of information appeared to meet patient's expectations of care and enable him to cope with his complaints. The explorative analysis was not able to correct for actual events during the consultation. As these leaflets may very well only have been used in combination with verbal patient education, giving not enough credit to the physician. Patients who have been prescribed medication more often stated they were feeling less at ease and were less positive about the way treatment options were discussed. This indicates that prescription of medication may have given patients the feeling of not being taken seriously. It may give an explanation to the recently reported rapid discontinuation of medication in newly diagnosed LUTS patients.[39] Further research is needed to identify the exact causal mechanisms, but of the nine factors used in the explorative analysis PSA testing did not have any effect on the outcome measures used in this study. We expected items like reassurance on complaints or confidence in health to be related with PSA testing, since Wolf found men less confident about their health were more interested in having their PSA tested.[34;40] But requesting a PSA test showed no significant relation with any of the items of the enablement, evaluation of care or the wish for additional diagnostic procedures.

We conclude that the distance-learning package for GPs improved patients' satisfaction with care and some aspects of their enablement. The physician can achieve optimal management of LUTS by being well-informed him/herself and by providing the patient with material that he can study for himself, whether it is a simple leaflet or an advanced interactive computer programme. This study showed that a combination of evidence based information for physicians and patients contributes to improved patient outcomes.

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CHAPTER 8

Improving clinical management of lower urinary tract symptoms in primary care:

costs and patient outcomes

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Submitted

Abstract

Objective

Guidelines for primary care management of lower urinary tract symptoms in older men recommend shared decision making regarding the choice of treatment. This study aimed to determine the costs and patient outcomes of an implementation strategy to enhance uptake of these guidelines. The intervention comprised a distance learning programme for general practitioners, comprising evidence-based information, assessment of learning needs, a knowledge test, and patient education materials. The control group only received the written guidelines.

Material and Methods

A cluster randomised trial in 187 older, male patients compared costs and outcomes in the two study groups. A health care perspective was taken in the economic evaluation with a three month time horizon. The primary health outcome was the patient reported urinary symptoms at three months. Costs related to the distance learning package and the health care provided were considered, using undiscounted standardised prices.

Results

Patient-reported urinary symptoms at three months did not differ between the study groups. The mean costs per patient were € 42.71 lower in the intervention group compared to the control group, mainly because of a lower number of referrals to the urologist, but the 95% confidence intervals of the group means overlapped.

Discussion

The distance learning programme did not significantly change costs or outcomes compared to written guidelines, although there was a trend towards lowered costs. Studies with a longer follow-up period are needed.

INTRODUCTION

The population prevalence of lower urinary tract symptoms (LUTS) in middle aged to elderly men is 20-30%.[1] In several countries, guidelines have been developed for these bothersome, but not life-threatening, symptoms and pursue by large similar diagnostic and therapeutic care.[2-6] This study is based on the Dutch guidelines on LUTS.[5;7] These recommend PSA testing only in a few conditions, although GPs in various countries request PSA testing in most men with LUTS.[8;9] Medication should be restricted to patients with bothersome symptoms who are not able or not willing to have surgical treatment. Referral should be considered in men with complicated LUTS. Overall, the guidelines recommend to involve patients in decisions on the management of the symptoms.
To implement these guidelines we used a distance learning programme for general practitioners (GPs), which emphasised counselling and shared decision making with the patient. Recently published trials on the effect of distance learning[10] and consultation-supporting materials[11;12] have shown effects on self-rated competence and care provision. We have reported that our distance learning programme reduced the referral rate to a urologist, but did not change PSA testing or prescription of medication.[13] Patient perceptions of enablement and patient evaluation of quality of care received improved, but effects on patient reported symptoms were not yet studied.[14] The study presented here aimed to determine the costs and patient outcomes of the distance learning programme on LUTS.

MATERIAL AND METHODS

DESIGN

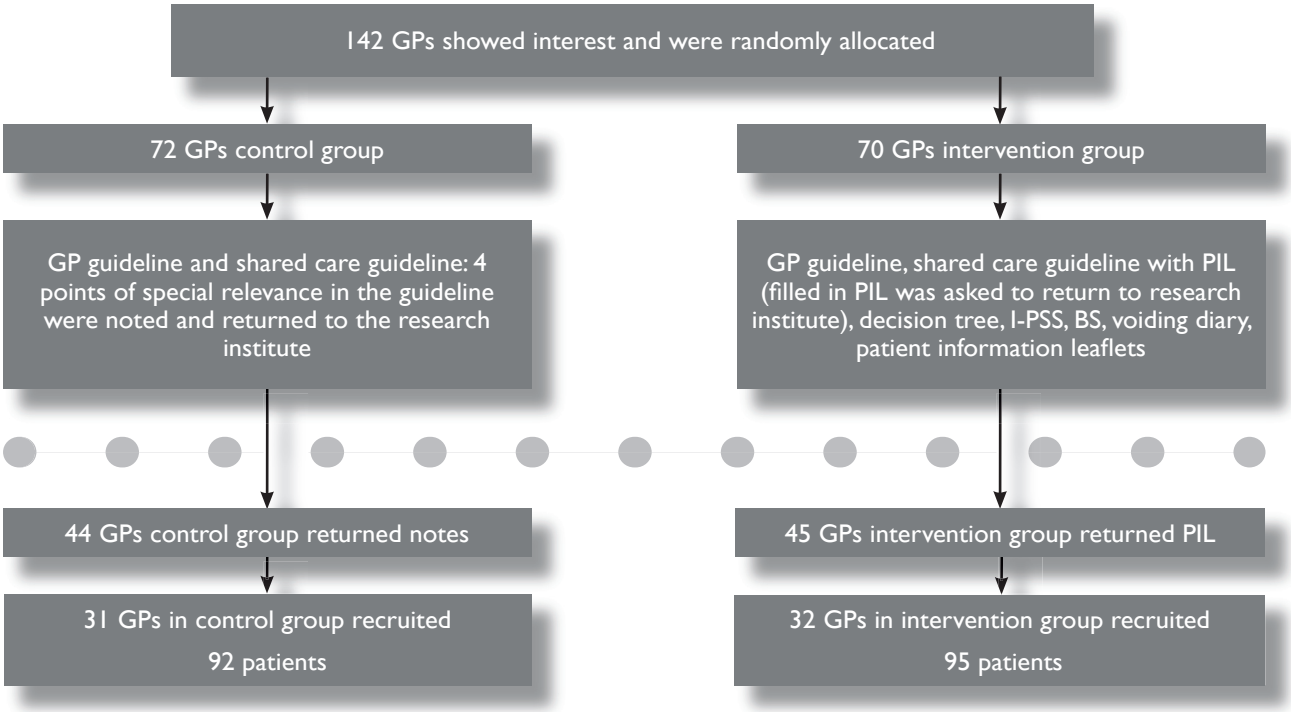
A cluster randomised trial was performed in which one group of GPs received the distance learning programme (the intervention group) and the other group received a standard set of guidelines on LUTS (control group). Details of the study have been reported elsewhere.[13;14] After the intervention GPs were instructed to recruit patients over a period of 15 months. The project received approval from the research ethics committee.

Subjects

A random sample of 1500 GPs was invited by letter to take part in the study. A total of 142 GPs showed interest and were allocated to one of the two groups: 70 to the intervention group and 72 to the control group (Figure 1). All LUTS patients of older than 50 years visiting the GP were considered. Exclusion criteria were: terminal phase of a disease, unable to complete a questionnaire because of cognitive problems, known prostate carcinoma, a ureterostomy or bladder catheterisation. All others were invited and those giving informed consent formed the research group. LUTS were defined according to the national guideline on LUTS for GPs: a persistent change in urination manifesting itself as difficulty in starting urination, a weak flow, dribbling, urge, feeling of retention and/or increased frequency of urination during the day and night.[5]

The trial was designed to detect a 20% difference in adherence to the guidelines, particularly a decrease in PSA requests from 80% to 60% ($\alpha = 0.05$, power = 0.80, icc = 0.05). A total of 180 patients from 60 GPs were needed, assuming that they would be able to recruit an average of three patients each. Anticipating a loss to follow-up of 30%, the aim was to include 86 GPs.

Figure 1: Flow chart



Intervention

The distance learning programme comprised a Package for Individual Learning (PIL) developed by the Dutch College of General Practitioners (NHG) with additional materials: (1) consultation-supporting materials: a voiding diary, the International Prostate Symptom Score (I-PSS) and Bother Score (BS), (2) the guideline summarised into a decision tree and a brief explanation and (3) two information leaflets for patients (one on PSA testing and the other on treatment for LUTS). The PIL booklet contains an interactive knowledge test based on the guideline;[5] answers to questions on key issues of LUTS are sent to a central institute and the correct answers are returned to the sender as feedback. The control group of GPs received the existing national guidelines on LUTS. They were asked to study these documents, note down four points they found especially relevant and send them to the research institute in the envelope provided.

Outcomes and instruments

Primary outcome in this study was patient reported symptom level, using the I-PSS, a validated instrument for urinary symptoms.[16] After the consultation and three months later, patients filled in a questionnaire to obtain data on age, educational level, duration of complaints and symptom level. They returned the completed questionnaire in a pre-stamped envelope to the research institute. Clinical management was evaluated by prospective recording of patient data and management by practitioners immediately after consultation with an eligible patient. A structured form was designed to document GP management and contained items on history taking, physical examinations, additional testing, information provided and therapy.

Analysis

For data analysis we used the Statistical Package for the Social Sciences (SPSS) and Microsoft Excell. The unit of analysis was the patient. The effectiveness was examined with t-test to compare patient-reported symptoms three months after the intervention, considering P-values of 0.05 as significant. The economic evaluation aimed to determine the incremental costs of the distance learning programme compared to written guidelines for GPs in terms of patient reported symptoms. A health care perspective was taken, as non-medical costs (such as patient costs related to visits to the GP and absence from work) were assumed to be absent or minimal in this elderly population. Costs and benefits were

related to a three-months period after the initial consultation of the patient with the GP, which was similar to the observation period in the randomised controlled trial. It was planned to perform a cost-effectiveness analysis, if the intervention was effective, and a cost analysis, if there was no effect.

Costs considered included material costs and GP time related to the distant learning programme or reading of the guidelines (both were fixed per patient), initial consultations (fixed on the basis of the design of the study), and costs of health care received (variable costs per patient). The costs of the development of the clinical guideline and educational programme were not included, as both had been developed for the total population of GPs in the Netherlands. Data on GP time and health care were based on physician reports. Prices referring to the year 2002 were used, based on available guidelines[17-19] (see Table 4 for a detailed description of the calculations). Discounting was not performed because of the short time period. The reliability of variable costs was examined with 95% confidence intervals, based on the observed use of resources.

Results

The educational programme was completed by 89 out of the 142 GPs who showed interest in participating in the study while 63 GPs (31 in the intervention group and 32 in the control group) were also able to recruit patients (Figure 1). These GPs were comparable with the original sample of 1500, except for a lower number of solo practices in the study sample (43.1% vs 30.2%, one-way ANOVA: $P = 0.034$). The GPs recruited 187 patients during the study; 151 of them returned their questionnaires, which showed that they were comparable at baseline (Table 1).

Table 2 shows the urinary symptoms at inclusion and three months. The distribution of scores in the population did not differ between the intervention group and the control group before or after the intervention, indicating the absence of an effect on health outcomes. In both groups the urinary symptoms decreased significantly. Four individuals developed serious symptoms between baseline and post-intervention measurement: one in the intervention group and three in the control group. The remaining individuals with serious urinary symptoms at three months after their initial consultation already reported these at baseline.

Table 3 provides an overview of the volumes and costs associated with the intervention and the health care provision. The mean fixed costs were higher in the intervention group compared to the control group (€ 51.62 versus € 44.00), mainly because of the material

Table 1: Characteristics of the patients at baseline *(absolute numbers and percentages between brackets)*

	Total (n = 151)	Intervention (n = 75)	Control (n = 76)
Mean age (years) [SD]	66.3 [9.0]	66.2 [8.6]	66.4 [9.4]
Age in categories			
50-59 years (%)	39 (25.8)	17 (22.7)	22 (28.9)
60-69 years (%)	58 (38.4)	31 (41.3)	27 (35.5)
70-79 years (%)	43 (28.5)	22 (29.3)	21 (27.6)
≥ 80 years (%)	11 (7.3)	5 (6.7)	6 (7.9)
Education			
Lower (%)	58 (38.5)	25 (33.3)	33 (43.4)
Secondary (%)	47 (31.1)	25 (33.3)	22 (28.9)
Higher (%)	35 (23.2)	18 (24.0)	17 (22.4)
Unknown (%)	11 (7.3)	7 (9.3)	4 (5.3)
Symptoms			
Duration >1 year (%)	80 (54.8)	40 (57.1)	40 (52.6)
Mean I-PSS [SD]	14.92 [7.48]	14.32 [7.77]	15.51 [7.17]
Mean BS (Bother Score) [SD]	3.07[1.11]	2.96 [0.99]	3.17 [1.20]

Table 2*: *Patient reported lower urinary tract symptoms

	Intervention	Control
At inclusion (n = 151)		
Minor (I-PSS: 0-7)	10 (13%)	9 (12%)
Moderate (I-PSS: 8-19)	49 (65%)	48 (63%)
Severe (I-PSS: 20-35)	16 (21%)	19 (25%)
At three months (n = 122)		
Minor (I-PSS: 0-7)	15 (27%)	19 (29%)
Moderate (I-PSS: 8-19)	37 (66%)	40 (61%)
Severe (I-PSS: 20-35)	4 (7%)	7 (11%)

Note: Differences between groups were not significant (P<0.05) at baseline or at three months. An analysis of the original continuous scores showed the same results.

costs related to the distance learning package. Remarkably, the GP reported time spent on self-study was similar in both study conditions: a total of 79.5 minutes per GP in the intervention group and 70.0 minutes in the control group (€ 33.47 and € 32.31 per patient, respectively). Health care provision was also similar between the two groups. The only item of health care provision, which showed significantly different volumes between the study groups, was the number of referrals to the urologist: this was lower in the intervention group. The mean costs related to health care provision was lower in the intervention

Table 3: Cost analysis

	Mean number of units per patient		Mean costs per patient (€)	
	Intervention (n=95 patients)	**Control (n=91 patients)**	**Intervention (n=95 patients)**	**Control (n=91 patients)**
Fixed costs				
Distance learning package € 18.75 (*1)	0.42	-	7.89	-
Written guidelines € 2.50 (*1)	-	0.46	-	1.15
GP self-study (minutes) € 0.75 (*2)	33.47	32.31	25.11	24.23
Initial consultations € 18.62 (*3)	1.0	1.0	18.62	18.62
Subtotal fixed costs			51.62	44.00
Variable costs				
Diagnostic tests (* 4)				
Serum PSA € 7.90	0.58	0.41	4.58	3.24
Serum creatinine € 1.35	0.39	0.29	0.53	0.39
Urine sediment € 1.35	0.45	0.53	0.61	0.72
Qualitative urine screening € 1.79	0.21	0.36	0.38	0.64
Urine culture € 2.69	0.03	0.07	0.08	0.19
Additional consultations € 18.62 (*3)	1.22	1.31	22.75	24.43
Alpha-receptor blocker € 69.65 (*5)	0.31	0.29	21.50	20.11
Finasteride € 87.32 (*5)	0.03	0.02	2.62	1.75
Referral to urologist € 305.50 (*6)	0.02	0.14	6.11	42.77
Subtotal variable costs			59.15 (34.55-88.76)	94.24 (56.90 - 131.58)
Mean total costs per patient			103.15 (78.55 -132.76)	145.86 (108.52 - 183.20)
Incremental costs per patient			-	-42.71

Legend:

**1 Costs of distance learning package based on price charged by the Dutch College of General Practitioners (including packaging and mailing). Costs of written guidelines refer to copying, packing and mailing of the guideline text. Breakdown of costs over patients based on 40 packages in intervention group and 42 packages in control group.*

**2 Volumes were based on GP reports. Answering categories: <1 hours, 1-2 hours, 2-3 hours, and >3 hours (calculations based on resp. 30, 90, 150 en 210 minutes). Four GPs reported they have spent 2-3 hours or >3 hours. Meaningfull standard error of measurement could not be determined. It was assumed that GPs did not reduce the number of consultations because of the self-study and we used 40% of the consultation price (€ 18.62, see *3) to estimate the costs of this non-consultation time.*

**3 Each included patient had an initial consultation. GPs reports on the consultation time showed that this was on average 11.1 minutes in the intervention group and 10.7 minutes in the control group (based on item with answering categories 0-5, 5-10.10-15, >20 min). Fifteen consultations were 15 minutes or longer. Follow-up consultations were based on patient reports at 3 months after the initial consultation (n = 116 responders). Non-responders were assumed to have had no contacts. The price per consultation was based on guideline prices from 1999 (Oostenbrink 2000), extrapolated to 2002 (4% inflation per year, 1 € = 2.21 guilders).*

**4 Volumes were based on GP report at initial consultation. Prices were based on Diagnostisch Kompas 2000, extrapolated to 2002 (4% inflation per year).*

**5 Volumes based on GP report and prices per month were based on Farmacotherapeutisch Kompas 2001 (extrapolated to 2002 with 4% inflation rate). The mean costs of alpha-receptor inhibitors was estimated on the basis of patients reports on medication use at 3 months, which comprised 52 patients who reported on alpha-receptor inhibitors: 5 had received prazosine (€ 8.54 per month), 19 alfuzosine (€ 26.55), and 28 tamsolusine (€ 27.83). This resulted in a mean price of € 25.51 per month (= 4.5 weeks). It was assumed that all initial prescriptions were for 6 weeks, as recommended in the guideline, and that 25% discontinued drug treatment, as found in a previous study,[21] resulting in an overall mean of 11.25 weeks. This implied overall means of € 63.78 for alpha-receptor blockers and € 81.45 for finasteride per treated patient. Pharmacy costs (€ 5.87) were included for initial prescriptions.*

**6 Volumes were based on GP reports at initial consultation and prices on Diagnostisch Kompas 2000, extrapolated to 2002 (4% inflation per year). Based on clinical experience it was determined that urological care included, as a minimum, two consultations with the urologist and ordering of a PSA test (€ 7.90), serum creatinine (€ 1.35), uroflow test (€ 125.41) and rectal ultrasound (€ 68.62). The costs of an outpatient consultation was based on guideline prices from 1999 (Oostenbrink 2000) and extrapolated as in *3, resulting in a price of € 45.81.*

group, but the 95% confidence intervals of the two group means overlapped. Likewise, the mean total costs seemed to be € 42.71 lower in the intervention group compared to the control group at three months after the initial consultation, but the 95% confidence intervals showed overlap.

DISCUSSION

The distance learning programme had no observable effect on patient reported urinary symptoms at three months after the initial consultation (the symptoms improved in both groups), while the costs per patient in the first three months tended to be lower. However, this reduction was not significant, so we conclude that the intervention did not change costs or health outcomes.

Distance learning is a promising approach, because it seems feasible for the participants and involve little costs, but few randomised trials have been conducted to test its cost-effectiveness. Available studies did not measure the effects on real patients, but on GPs' knowledge or management of virtual patients as outcome measures.[12;13;20] Our study showed that the distance learning programme reduced the referral rate and tended to increase the number of PSA tests.[13] Although ordering a PSA test is not consistent with the guideline, it may be psychologically necessary for not referring the patient.

A limitation of this study was the short follow-up period. The effectiveness of treatment by the urologist is not measured, because of waiting times for seeing the urologist and delays in treatment effects (e.g. after surgery). On the other hand, the effect of surgery or medication on urinary symptoms may be limited. Also, it might be possible that some non-referred patients may be referred to an urologist in the near future if the symptoms recur. This may be acceptable, given the non-life threatening character of the urinary symptoms. Patients with recurring episodes were also included in our sample, so this factor has already reduced the intervention effect. In the total population the average level of symptoms improved, which suggests that many patients will not be referred. Nevertheless, we cannot rule out the possibility that referral to the urologist is more efficient in the long run for some patients. Larger trials with longer follow-up are needed to examine this issue.

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GENERAL DISCUSSION














This thesis presented several studies related to evidence to and the implementation of the 1997 revision of the guideline on lower urinary tract symptoms in general practice in the Netherlands.[1;2] The guideline development, the clinical management of LUTS and an implementation strategy were examined.
This chapter summarises the most important findings and provides answers to the questions as formulated in the introduction. Subsequently the findings relating to other existing literature and main methodological issues are discussed. Finally the implications of the results for guideline developers, clinical practice and for policy makers are talked through.

Major findings and conclusions:

The evidence: clinical guidelines

According to evidence recently found in international literature the major part of the 1997 guideline on lower urinary tract symptoms in general practice in the Netherlands was still appropriate. The most important change that was made in this latest revision was the more distinct separation of lower urinary tract symptoms from prostate carcinoma; since LUTS was no longer considered to increase the risk of prostate cancer. Prostate carcinoma was still discussed to improve the guideline's applicability. Other changes were: the limited relevance to recommend bladder percussion to detect post-void urinary residue, if medication is considered alfuzosine and tamsulosine are preferred in general practice and a clearer focus on shared decision making.

In the systematic search five recently published national guidelines on LUTS were found and assessed for their methodological quality according to the criteria for good guideline development in the AGREE Instrument.[3] The National Health and Medical Research Council (NHMRC, Australia)[4] guidelines were strongly recommended for use in practice, the Sowerby Centre for Health Informatics at Newcastle (SCHiN, UK)[5] and American Urologist Association (AUA)[6] guidelines were recommended with provisos or alterations

and the Duodecim (Finland)[7] and European Association of Urology (EAU)[8] guidelines were not recommended.
The guidelines we found showed conflicting recommendations with regards to the diagnostic process (creatinine, prostate specific antigen and post-void residual volume). Diagnostic recommendations were more often formulated in 'do's' or 'don'ts' than therapeutic recommendations. The NHMRC guideline had more 'don'ts' where clear evidence was lacking, compared to the AUA guideline, which left some decisions 'optional'. Only 11.3% of the 227 references in all guidelines occurred in more than one, and the few overlapping studies were partly used to underpin conflicting recommendations.

Clinical management of LUTS: exploration of the problem

The decision to consult a general practitioner (GP) for lower urinary tract symptoms was explained only partly by the severity of complaints. Advice from the social network appeared to be the strongest predictor of GP consultations, followed by information received from the media. The expected improvement in the patients' condition after treatment by a GP or a specialist, and the knowledge they perceived on voiding problems, also appeared to be determinants. Half of the men felt they were in need of more information about their condition and only a few men were convinced that their voiding problem was serious or related to a serious disease, regardless of whether they had attended the GP or not.

The clinical management of a hypothetical patient with uncomplicated LUTS by GPs and urologists differed in the diagnostic work up; urologists reported to order tests routinely as opposed to GPs. In symptom management urologist and GPs were more comparable. Urologists more often provided patients with information leaflets to support their explanation.
The shared-care guideline[2] was better known to urologists than to GPs. A minority of both groups said to have access to a shared-care clinic on prostate problems. The availability of shared care seems to shift GPs towards care management similar to a urologist: an increase in using I-PSS and requesting tests (creatinine and PSA), and for mild complaints a watchful-waiting strategy was chosen less often. Urologists with shared-care clinic facilities showed an increase in trans rectal ultrasound use and surgical interventions for moderate complaints.

The feasibility of uroflowmetry was tested in the daily care of 19 GPs, where 12 men with LUTS were recruited during 14 months. Except for two, in none of the patients the clinical

care was influenced by the uroflowmetry. With respect to the low number of included patients and the apparent absence of an effect on clinical management uroflowmetry was not considered as very useful in general practice.
In evaluative interviews GPs were disappointed by the low incidence of patients with LUTS presenting at their surgery and exclusion criteria of the patients were regarded too strict. GPs preferred uroflowmetry to be supported logistically by a diagnostic centre and the uroflowcurve should be interpreted by a specialist, since the respondents felt unable to an adequate interpretation.

The implementation of clinical guidelines

After randomisation GPs were sent either national guidelines (controls), or a distant learning package (comprising a package for individual learning, consultation supporting materials, decision trees and patient information leaflets) (intervention).
The intervention did not change history taking and diagnostic procedures. Although not significant, the intervention group requested 18% more often PSA-tests and tended to longer consultations. On the other hand the GPs in the intervention group decreased their number of referrals to the urologist because of LUTS and their patients were more often provided with written educational materials.
Urinary symptoms decreased significantly in patients of both groups and the symptoms between the groups did not differ at inclusion and three months, indicating the absence of an intervention effect on health outcomes. Patients in the intervention group were more often satisfied with their consultation (were more often involved in thinking about their complaints, were more satisfied about communication on intentions and treatment and, were more convinced of treatment effects). Furthermore, they were better able to cope with their illness and maintain their independence. Handing out patient information leaflets appeared to be a crucial mediating factor in the positive effects on patient self-management.
Because of the material costs related to the distance learning package the mean fixed costs were higher in the intervention group. The GPs reported that time spent on self-study was similar in both study conditions. Health care provision was also similar between the two groups except for the lower number of referrals to the urologist in the intervention group. The mean total costs seemed to be lower in the intervention group compared to the control group at three months after the initial consultation, but the difference was not statistically significant.

Interpretation of findings

The evidence: clinical guidelines

The latest revision of the guideline on lower urinary tract symptoms of the Dutch College of General Practitioners was already six years old at the time a new working group was composed. A revision was needed since in common opinion guidelines should be updated on a regular base and provide recommendations based on the best available evidence.[3;9] The update of a general practice focused guideline was in particular relevant as literature indicated that with the introduction of α-blocking medication, the management of LUTS has increasingly shifted from the specialist to the GP,[10] and GPs require guidelines taking notice of a population that is different from the patients attending hospitals.[11;12] In addition, public awareness on the carcinoma of the prostate is high, and in the perception of many patients LUTS is related to this. Among patients expectations towards the PSA test in preventing advanced disease are high, although this is still an issue of debate.[13;14] Although prostate carcinoma and LUTS are not causally related, the subject of prostate carcinoma is still discussed in the guideline in order to improve the guideline's acceptability and credibility and so increasing its effectiveness in daily practice.[15]

Comparative studies on guidelines until now concluded that variation was a consequence of the methods used to formulate recommendations (consensus versus evidence based),[16;17] cultural factors,[18-20] or of the methodological quality.[17;21-24] Variation in methodological quality were caused by more or less systematic review of the literature,[17;22;23] proper external reviewing in the development process,[21;22] attention to organizational barriers and cost implications,[21;22] information on independency of developers,[21] and presence of strategies for dissemination and implementation.[17;22] The five guidelines in our study also showed a variability in the selection of evidence, which appeared to be less objective than is suggested within the concept of evidence-based medicine. Since for some selected topics, a certain bias in the use of evidence was found, and a few identical studies were used to underpin conflicting recommendations. Elements as: need for cost constraints, influence of patient preferences, specific professional interests and variation between health care systems might be as important as the evidence in formulating recommendations.[15;20;25]
Where Irani, *et al.*[24] found in their study that most guidelines lacked to be explicit on their methods used in collecting literature; all the guidelines we found, except for one, accounted for their systematic search. Nevertheless only a small minority of the references

were used in more than one guideline. This finding is consistent with guideline studies on diabetes and cystitis.[18;26] In that respect, it is remarkable that – despite the lack of overlap in references – the guidelines on LUTS provide similar recommendations on most topics covered by the guidelines. This might be explained by the international impact of the Agency for Health Care Policy and Research (AHCPR) guideline on Benign Prostatic Hyperplasia published in 1994,[27] and the international consensus conferences on the clinical management of benign prostatic hyperplasia.[28]

Guideline adherence: exploration of the problem

Many men with LUTS in our survey sample were not consulting a physician because of their complaints. Shame and fear were already mentioned as possible explanations to non attendance.[29]

On the other hand non attendance may not be beforehand a problem since LUTS are not life threatening. It is known that most of the symptoms reported in the open population are not presented to a physician.[12] Patients confronted with chronic disease have a tendency to accommodate to their illness by changing internal standards, values and the concept of quality of life.[30] And so, many men will also accept LUTS as a part of their ageing,[31] and as long as there is no grave impairment of their quality of life there is no need to mobilise these patients.

In general, the patient who visited the GP's surgery had more severe complaints and a higher interference of symptoms with everyday life and higher age.[29;32-36] However, our study suggested that influences of the social environment were even stronger predictors of GP consultation than symptom severity: as a third of all the cases were advised by others to seek medical care. The role of the spouse was already identified as being of great importance in this decision,[32;37] but one can also think of children and other (professional) caretakers.[38] The media also influenced men in searching medical care. A Cochrane review found the mass media to be very effectively in influencing the utilisation of health services although studies in this field are difficult to perform.[39] A recent Danish study questioned these effects and concluded that health items brought in the mass media were not remembered more often by patients visiting the GP compared to patients who did not.[40]

Most studies on variation of practice patterns described the management of care to patients with complaints of LUTS/BPH of either urologists [41-43] or GPs.[44;45] We used an identical questionnaire in a survey among GPs and urologists and compared the clinical management in both populations. From the results of this study one could question

whether guidelines on the management of LUTS were followed by GPs in the Netherlands, as was also discussed in similar studies performed in other countries.[41;44]
It has been reported that GPs in recent years take a more active role in the diagnosis and management of lower urinary tract symptoms.[10] Shared care as the joint participation of hospital consultants and GPs in the planned delivery of care for patients with LUTS is expected to streamline the patient evaluation and help to enhance effective management. Most studies published on shared care in urology were audit reports and present the effect of a variety of shared care clinics on the daily practice of the urologist.[46-49] Regrettably there were no studies comparing shared care clinics to a situation were GPs handle these patients. In our study we found indications that patients who run into a shared care setting risk a more 'aggressive' management since their GPs less often chose a watchful waiting policy in patients with mild symptoms and refer to urologists who propose surgery more often to patients with a moderate symptom level. This may support the earlier doubts of the efficiency of shared care clinics.[50] Thomas recently published data from a randomized trial of an open access urological clinic and found a reduction in waiting times and an increase in clinical management plans at the end of the initial hospital visit. No effects were found in costs, symptom outcomes, psychological well being and quality of life of the patients.[51]

Earlier studies performed with portable uroflowmeters have shown it to be a valuable test allowing representative flow and volume measurements at home and so giving a good insight into the voiding patterns.[52;53] No studies were found reporting the use of uroflowmetry in daily care of the GP.
Patients and GPs participating in the study were positive about uroflowmetry in general practice, although their (self-)selection may have biased them. Despite the limited use of uroflowmetry during the study, most of them saw a future for this diagnostic method in general practice. This future depended on the condition that logistic management was provided by a laboratory and that curves would be interpreted by a specialist. The latter may be a problem; since interpretation of curves is not easy (experienced urologists were only able to predict the actual diagnosis in a third of the cases, almost half of the normal flows was considered as abnormal)[54] and uroflowmetry is only considered to be a valuable tool when patients history is taken adequately into account.[55] Furthermore we found only half of the uroflowcurves were accessible to interpretation, which is rather low compared to the 82-90% found in other studies with home-uroflowmetry.[52;53] These differences may be due to the type of instrument used since in these studies the *P-Flow*, a hand held uroflowmeter, was used instead of the *Da CapoHome Uroflowmeter*.

Home-uroflowmetry is a rather expensive diagnostic method for general practice when considered that the GP is only interested in the Q_{max} in his evaluation of the patient. Studies on simpler methods have shown to be reproducible as well: as a 5 second home flow rate[56] and the 'how many seconds for 100 ml. test' [57] in combination with a voiding dairy.[58]
An attempt has been made to introduce a technique new to general practice. There are a number of techniques available to GPs in their own practice (e.g. spirometry[59;60]) or on an open access base in a hospital (e.g. endoscopy,[61] ambulatory blood pressure measurement[62]) which proved to be successful and applicable.

The implementation of clinical guidelines

There are only few randomised trials that tested distance learning programmes. Effects on daily patient management were usually not measured; they have shown effects on self rated competence, knowledge of the subject or management of virtual patients as outcome measures.[63;64] In our study we observed the effects of a distant learning programme and consultation supporting materials on actual clinical performance by the GP and quality of care perceived by the patient under normal practice conditions. An alternative approach – like providing computerised support for the GP's decision – was still to be confronted with many obstacles in daily practice,[65] but this may change in the future.
Our most importance change in the intervention group was a decrease in the number of patients referred to the urologist. Other aspects of LUTS management did not change, although there was a trend of an increase in consultation time and number of PSA-tests requested. While we observed a decrease in referrals, a recent study with a computerised multimedia decision aid, educating men with LUTS about treatment choices, has shown an increase in patient participation in the decision process, but without changing the number of specialist consultations.[66]
We also intended to enhance evidence based decision making on PSA testing by providing the GP with tools to inform the patient about the (dis)advantages of this test. GPs in our intervention group tended to request more often PSA testing; suggesting that the intervention did not reduce the fear of missing prostate carcinoma by not performing PSA testing. Fear of prostate cancer in patients with LUTS is a motivating factor to visit the GP [29] and patients believe that PSA testing can offer health benefits.[67] This leads to patient requests for PSA testing, notwithstanding the fact that the benefits of this test are still an item of debate.[13;14] Amongst GPs possible regret over not ordering a PSA and diagnostic uncertainty factors appeared to predict the likelihood of ordering a PSA.[68] Studies on unselected populations without LUTS showed a decreasing effect of decision aids on

PSA testing[69;70] and a study with self-selected patients showed that a decision aid on PSA increased knowledge, but did not decrease the number of tests.[71] Men less confident about their health were found to be more interested in having their PSA tested[70] and underlying patients' believes and prior testing influenced intentions towards testing more than weighing of communicated risks and benefits.[72] In our study patients where already having complaints and were in a sense also a self-selected population. Moreover, the GPs were stimulated to provide the patient with information on PSA testing and it seems that this increased the number of requested tests since the information received on PSA testing reinforced the patient's decision to do the test.

In our study we found limited effects of our intervention on clinical outcome, but patients seemed to be more enabled and more satisfied with the care they received. In the management of patients with LUTS it is considered to be important to involve the patient in making decisions based on his own preferences and needs.[73] Patients are known to have specific expectations about the provision of information on their complaint and its management.[74] In our patient survey we found that half of the men with LUTS were in search for information on their condition. Providing patients with adequate information is important as can also be seen in hospital studies on (surgical) treatment of prostate cancer[75-78] or BPH.[79-81] The explorative analysis suggested that the positive effects on patient evaluation of care and enablement were associated with the provision of more information (by patient leaflets) in the initial consultation.

Methodological considerations

A variety of research methods was used to answer the research questions posed in this thesis. The methods used were roughly related to the sections as presented in this thesis.

In chapter 1 results are dependent on literature available in the databases (e.g. MEDLINE, PubMed, Embase). Not all the questions formulated could be adequately answered due to absence of well performed and documented studies and many data were reflecting hospital populations. In concordance with the concept of guidelines made by GPs for GPs,[11] except for one, all members of the working group were GP. A 'professional bias' was prevented by processing comments made by a patient representative and referees in relevant professions (3 urologists, 2 pharmacists, 1 sexologist).

In the study that compared national guidelines on LUTS we confined ourselves to guidelines recently published in English. Not all the relevant guidelines may have been identified this way. Some might have been published in 'secondary' literature and most will not be published in English or within the period searched. Our decision to

limit the language and time window of guideline publication was to minimize effects due to translation, literature available to the working groups and a current standard of guideline development. Recommendations were assessed on their content in relation to the initial management to decrease potential conflicts due to differences in point of view, in clinical responsibility and clinical setting of GP or specialist. The assessment using the AGREE instrument[3] is depending on the quality of reporting of (the development of) the guideline. Current opinion is that it is important that groups presenting evidence should be transparent about how they reached judgements in the first place.[82]

The patient survey on health care seeking behaviour in relation to LUTS in chapter 3 data was collected retrospectively with a 2 year horizon with the risk of a recall bias in relation to the cues for visiting the GP. Furthermore, registering symptoms at the time of the questionnaire might have caused a possible underestimation of its effect in the group who visited the GP, since at least some of them will have obtained treatment. A prospective approach, following patients from their first perception of LUTS, would have overcome this, but such a design was beyond the resources available for this study and we would have to cope with the problem that the questionnaire might have had altered patient behaviour.

The written vignette used in chapter 5 can only be an abstract of the tailor-made approach of daily practice and results have to be judged with respect to this limitation. The response among GPs (55%) could evoke suspect on bias in the results, but the population studied showed no significant differences with data on the Dutch GP population. A possible over representation of GPs with special interest in urology could have caused an overestimation of the GPs being acquainted with shared care protocols or prostate clinics, but conclusions on these protocols effecting their management would probably persist.

Although the feasibility study of uroflowmetry in general practice was only carried out in Eindhoven this probably will not have negatively influenced study outcome; since this city has a relative long tradition of a diagnostic centre providing to GPs ambulatory diagnostics otherwise hospital based. In evaluative interviews a less strict inclusion of patients was suggested by the participating GPs. This would probably increase the number of patients, giving a better founded answer to the acceptability to the patient but not to it's value as a diagnostic tool in general practice.

The cluster randomised controlled trial presented in the last three chapters was performed without pre-intervention measurement so it was not possible to document change in behaviour of the individual GP. In retrospect this would have given more information on changes in requests for PSA. Of the 142 GPs who were randomised 52 did fulfil the requirements for participation and another 26 GPs were not able to include patients

during the time of the study. We think this loss will not have influenced the results since the GPs were randomised and loss was similar in both groups.
Clinical management was evaluated by the GP using self-reporting techniques immediately after consultation with an eligible patient. This technique has been used before and showed to be valid and alternative methods as going through the medical record can only provide information on a very limited set of clinical decisions.[83] However, this approach may have influenced their performance, but this was the case in both groups.
A further point of consideration was the short follow-up period and it might be possible that some non-referred patients may have been referred later to a urologist after recurrence of the symptoms. In the total population the average level of symptoms improved, which suggests that many patients will not be referred. Nevertheless, we cannot rule out the possibility that referral to the urologist is more efficient in the long run for some patients.

Implications and recommendations

On guideline development

Although the evidence is available worldwide, there is only little overlap between the references used in guidelines. Evidence-based medicine suggests objectivity, but the selection and use of evidence is mostly not neutral. Better worldwide collaboration between guideline developers is recommended. This could be achieved by developing clinical subject related evidence based reviews and these could be used as a basis for guidelines developed on a local level and adapted to local circumstances. These guidelines should be developed balancing applicability, consistency, and clinical impact of the evidence by a multi disciplinary working group. In an attachment to the guideline methods used in selecting the evidence (i.e. search strategy, inclusion/exclusion criteria) and formulating the recommendations should be explicitly reported.
Current indicators on working according the guidelines are based on registering actions and ignore that these actions are the resultant of a shared decision process that might well be guided by recommendations. Observational techniques that might be used to obtain information on these processes are too complex and too laborious to be used on a wide scale and are subject to problems of interpretation. And using patients surveys to get a better insight into their satisfaction or perception of quality of care will also provide

information on one facet and a happy patient may not always be an adequately treated patient. More research is needed to tackle this problem.

On practice management

It is known that the majority of the health problems that patients are confronted with are solved without seeking professional medical care and the mechanisms regulating this should be appreciated. Only part of the patients are driven by the severity of their symptoms when visiting the GP, and this should trigger the GP not only to enquire about symptoms but to ask also for other motives. We found that half of the patients were in need of information and only few thought of the problems as being serious. The aim should be to reassure those with minor symptoms and to encourage those with symptoms that have major impact on daily living to seek care. And a man who is sent by his spouse may very well not always be helped with prescribing medication, but should also be provided with content that meets the spouses needs. The patient's environment should be included in the information on the complaints and its treatment possibilities; providing patient information leaflets that can be read at home might help in this. It seems to be important for doctors to explore not only the bother perceived by the patient, but also the bother for his environment. More research is needed on the motives of the social network advising patients to attend the GP's practice. In studying this: nuisance (smell of urine, cleaning clothes/furniture, broken nights because of frequent voiding), fear of cancer and sexual problems should be included as potential factors.

Among GPs the availability of shared care seems to have led to a shift of the primary care attitude towards managing care as a specialist/urologist. Many (policy makers) expect shared care to be an efficient solution for (future) increased health care needs. But copying the specialist clinical management to general practice is unlikely to be more (cost) effective health care. Prospective studies are needed to provide better insight in the health outcomes and the efficiency of shared care clinics. And research is needed to study open access alternatives that promote sharing of care and knowledge between GPs and urologists without medicalizing the patient. For now, a watchful waiting approach regarding shared care clinics should be recommended to policy makers.

On medical education and quality improvement

Although written educational materials have limited effects, distance learning is particularly useful for GPs who live in remote or rural areas. In a dense populated area as the Netherlands this type of medical education may also be suitable to GPs in need for flexible continuous education as there are part-timers, young parents and GPs not yet settled. In general practice, various disorders are thought of as being 'small' (low incidence/low priority); in these cases self-education and distant learning could also play a role as the method is known to be effective.[84]

In such a complex problem as PSA testing, where the GP requests an inadequate test in order to minimize his own as well as the patients fear for (missing) a prostate carcinoma, just sending educational materials is probably not enough. In this case fear as well as attitude has to be changed and this requires probably a more intensive approach. A setting where after being provided with the evidence on PSA testing in the open population, the GP is enabled to test and discuss his opinions in a safe group of colleges and subsequently provided with proper patient education, could be more effective. This may be a strategy tested in future research.

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SUMMARY

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Summary

This thesis dealt with the clinical management of Lower Urinary Tract Symptoms (LUTS) in the Dutch general practice. The evidence to the management of LUTS as found in international literature was studied, as well as recent national guidelines on LUTS published in other countries. Furthermore, the behaviour of patient, general practitioner (GP) and medical specialist with regards to these complaints was explored. Finally, the effectiveness of an implementation strategy to the 1997 revision of the clinical guidelines on LUTS was evaluated.

In the **Introduction** the subject of LUTS and the problems in relation to it's clinical management were discussed. Literature and data on the patients' and GPs' perspective with regard to LUTS are presented. Questions for further research were identified that formed the basis of this thesis.

The evidence: clinical guidelines

Chapter 1 presented the work of the guideline development group assigned by the Dutch College of General Practitioners (NHG). During a year the group regularly discussed the literature found in a systematic search for its evidence and relevance to daily practice in general practice. After processing comments by reviewers it was authorised by the Dutch college.
The major part of the 1997 guideline on lower urinary tract symptoms proved to be at this time still appropriate for the clinical management of lower urinary tract symptoms in general practice in the Netherlands. The most important change was the more explicit separation of lower urinary tract symptoms from the prostate carcinoma, since LUTS was no longer considered to be associated with an increased risk of prostate cancer. Nevertheless prostate carcinoma was included in this guideline to clarify underlying issues and in order to improve its practical use.
Because of the limited clinical importance of a bladder residue, the recommendation to perform a percussion of the bladder was limited to men with suspicion of acute urinary retention, a reflex bladder or an overflow bladder. When in doubt in these cases: a trial of catheterisation of the bladder might even be necessary.

This revision of the guideline focused on shared decision making on treatment possibilities because lower urinary tract symptoms have a benign nature with a variable course in most cases, and without a clear treatment imperative in itself. Watchful waiting and prescription of α-blocking medication remained the main treatment modalities for the GP. Alfuzosine and tamsulosine were the two drugs of preference because of their acceptance by the patients. If other treatments were preferred the patient should be referred to the urologist.

In **Chapter 2** electronic literature data bases and web sites of institutions known to develop guidelines were searched for national guidelines on LUTS. Those found were systematically assessed in terms of quality using the AGREE-instrument. Recommendations with regard to the initial clinical management were subsequently identified and their citations were collected. The evidence used in 'conflicting' recommendations was explored in a qualitative manner.
We found five recently published national guidelines developed by the American Urologist Association (AUA), Sowerby Centre for Health Informatics at Newcastle (SCHiN, UK), Duodecim (Finland), the National Health and Medical Research Council (NHMRC, Australia) and the European Association of Urology (EAU). According to the criteria for good guideline development in the AGREE Instrument, the NHMRC guideline would be strongly recommended for use in practice, the SCHiN and AUA guideline would be recommended with provisos or alterations and the Duodecim and EAU guideline would not be recommended.
In the guidelines studied recommendations were notably conflicting with respect to the diagnostic process. This was most remarkable in the recommendations on testing for creatinine and prostate specific antigen (PSA) and in the measurement of the post-void residual volume. Only 11.3% of the 227 references in all guidelines were used in more than one guideline to support the recommendation with respect to the initial care of the patient with LUTS. For some topics identical studies were used to underpin conflicting recommendations. Therefore, the use of evidence seemed less self-evident and objective than aimed for within evidence-based medicine. Both the AUA and NHMRC guideline had high scores in the AGREE domain of Rigor of development, which related to the process used to gather and synthesize the evidence, the methods to formulate the recommendations and to update them. Nevertheless, the NHMRC guideline was more directive and professional oriented leading to more 'don't recommendations', compared to the AUA guidelines which contained more optional recommendations and left the final decision to the interaction between practitioner and patient.

Clinical management of LUTS: exploration of the problem

A population-based survey was conducted in **Chapter 3** among 5052 men aged ≥ 50 years. The study population comprised men with an I-PSS of > 7 and those visiting the GP because of LUTS were compared those who did not.
One in every five men above the age of 50 years appeared to have moderate to severe LUTS and only 60% of the men with symptoms consulted the surgery of their GP because of their complaints. The severity of complaints was related to visiting their GP, but this was not influenced by symptom severity alone. The advice from the social network to consult their GP appeared to be the strongest independent predictor of GP attendance, followed by information received from the media. The expected improvement in their condition after treatment by a GP or a specialist, and the knowledge they perceived on voiding problems, also appeared to be determinants of visiting a GP. Half of the men felt they were in need of more information about their condition and only a few men were convinced that their voiding problem was serious or related to a serious disease, regardless of whether they attended the GP or not.

Chapter 4 reports of a cross-sectional survey study among urologists and GPs. Questionnaire responses were obtained from 182 urologists (70%) and 261 GPs (55%). The level of familiarity with the national shared-care guidelines was explored as well as arrangements between urologists and GPs and the availability of a shared-care prostate clinic. This was related to the clinical care of a written case of a 50-year-old man with clinical uncomplicated LUTS.
We found that the shared-care guideline on LUTS, developed by urologists and GPs and published in 1998 was better known to urologists than to GPs. Given a hypothetical patient with uncomplicated LUTS, urologists reported to order tests routinely as opposed to GPs. As far as symptom management was concerned, lifestyle advice on coping with LUTS was given by most physicians in both groups, although urologists more often provided patients with information leaflets to support their explanation. Urologists and GPs showed comparable attitudes towards treatment choices for patients with moderate (medication) and with serious complaints (surgery).
A minority of GPs and urologists said to have access to a shared-care clinic on prostate problems. The association of the level of shared care with specific aspects of the clinical management was explored. Among GPs the availability of shared care seems to have led to a shift towards similar care management as a specialist/urologist. We found GPs, having a shared-care clinic at their disposal, more often used the I-PSS (a symptom score), and

requested more often laboratory tests (creatinine and PSA levels). For mild complaints a watchful-waiting strategy was chosen less often. Urologists with shared-care clinic facilities used the trans rectal ultrasound more frequently and chose more often a surgical intervention for moderate complaints.

In **Chapter 5** a third explorative study was presented where during a period of 14 months 19 GPs had open access to uroflowmetry as a tool in the diagnosis of lower urinary tract. A total of 12 men had actually performed uroflowmetry.
Seven of the twelve men included had a $Q_{max} \leq 10$ ml/s (possible obstruction) and two had a $Q_{max} \geq 15$ ml/s (probably unobstructed). Except for two, in none of the patients the clinical management was influenced by the uroflowmetry and medication was prescribed for their complaints. In two cases a watchful waiting policy was chosen instead, after discussion of the results with the patient. None of the patients was referred to a urologist. With respect to the low number of included patients and the limited effect on clinical management uroflowmetry is not considered as very useful in general practice.
From evaluative interviews at the end of the study we learned that all GPs were disappointed by the low incidence of patients with LUTS presenting at their surgery. The criteria for exclusion of the patients were thought of being too strict (notably excluding patients already treated for LUTS). Most GPs felt uroflowmetry would support a more objective indication and evaluation of treatment, and thought it could be a valuable, additional tool in general practice. They preferred uroflowmetry to be supported logistically by a diagnostic centre, to be used after request by the GP. In this centre the device should be distributed after the patient is instructed, and the resultant uroflowcurve should be interpreted by a specialist as well, since the respondents felt not able to do an adequate interpretation.

The implementation of clinical guidelines

The last three chapters reported of a cluster randomised controlled trial. A total 142 GPs were randomised to a distant learning package (comprising a package for individual learning (PIL), consultation supporting materials (voiding diary, I-PSS and BS), two decision trees (on clinical management of LUTS and on PSA testing) and two information leaflets for patients) (intervention), or were sent national guidelines (controls). In 63 general practices (32 intervention and 31 control) across the Netherlands 187 patients older than 50 years presenting LUTS for the first time were included.

In **Chapter 6** the clinical management of the GP was considered as an outcome. From their registrations no differences were found in history taking and diagnostic procedures. Although the PIL intended to increase GP's and patient's awareness of the implications of PSA testing, PSA-tests were requested even 17.6% more often in the intervention group (although not significant). The intervention decreased the number of referrals to the urologist because of LUTS (OR 0.08 (95% CI: 0.02-0.40)). There were no other effects found to be significantly changed in the intervention group, although there was a trend towards longer consultations in the intervention group. The patients in the intervention group were more often provided with written educational materials (52% versus 8%).

Chapter 7 had patient evaluation of quality of care received and perceptions of enablement as main outcome measures. Patients in the intervention group were more often satisfied with their consultation than controls. In particular they felt more involved in thinking about their complaints and were more satisfied about the way the GP communicated his intentions and explained the treatment and they were more convinced the treatment they received helped to decrease their complaints. In addition patients in the intervention group felt more able to cope with their illness and maintain their independence.
It may be concluded that the distance-learning programme on LUTS for GPs had some positive effects on patient self-management. Handing out leaflets appeared to be a crucial mediating factor. Patient who were advised on their lifestyle were satisfied with the way the GP had tried to reassure them, but despite this, they were less confident about their health than the patients who had not been advised on their lifestyle. Patients who received prescriptions for medication were less satisfied about the treatment options discussed during the consultation. There was no relation between PSA testing and any of the outcome measures. Higher Bother Scores were related with a greater need for additional diagnostic procedures and greater preference for surgical treatment.

A health care perspective was taken in **Chapter 8** reporting the economic evaluation with a three months time horizon. The primary health outcome was the patient reported urinary symptoms at three months. Costs related to the distance learning package and the health care provided were considered, using undiscounted standardised prices.
Patients in both groups compared reported a significant decrease of urinary symptoms. The urinary symptoms at inclusion and three months did not differ between the intervention group and the control group before or after the intervention, indicating the absence of an effect on health outcomes.

The mean fixed costs were higher in the intervention group compared to the control group (€ 51.62 versus € 44.00), mainly because of the material costs related to the distance learning package. Remarkably, the GP reported time spent on self-study was similar in both study conditions: a total of 79.5 minutes per GP in the intervention group and 70.0 minutes in the control group (€ 33.47 and € 32.31 per patient, respectively). Health care provision was also similar between the two groups except for the number of referrals to the urologist: this was lower in the intervention group. The mean total costs seemed to be lower in the intervention group compared to the control group at three months after the initial consultation, but the 95% confidence intervals showed overlap.

In the **general discussion** main conclusions are presented and their relation to other literature as well as the methodological considerations of the studies performed.

The text of the second revision of the guideline on LUTS of the Dutch College of General Practitioners (NHG) was added as an **appendix** to this thesis.

SAMENVATTING

Dit proefschrift gaat over het klinisch handelen bij bemoeilijkte mictie (= plasklachten) bij oudere mannen (ook wel Lower Urinary Tract Symptoms of LUTS genoemd) in de Nederlandse huisartsenpraktijk. De wetenschappelijke onderbouwing van het behandelen van bemoeilijkte mictie, zoals gevonden in de internationale literatuur, werd kritisch beoordeeld en er is gekeken naar recente, in andere landen verschenen nationale richtlijnen met betrekking tot bemoeilijkte mictie. Verder vond een onderzoek plaats naar het gedrag van patiënt, huisarts en specialist met betrekking tot deze klachten. Tot slot werd een implementatiestrategie voor de richtlijn 'Bemoeilijkte mictie bij oudere mannen' zoals deze in 1997 gepubliceerd is door het *Nederlands Huisartsen Genootschap* (NHG) geëvalueerd.

In de **inleiding** werd het fenomeen van bemoeilijkte mictie bij oudere mannen kort uiteengezet evenals de problemen die bestaan met betrekking tot het beleid bij deze klachten. Gegevens over de houding van de patiënt en de arts met betrekking tot dit klachtencomplex werden besproken. Vervolgens werden de onderzoeksvragen die de basis van dit proefschrift vormen geformuleerd.

DE ONDERBOUWING: MEDISCHE RICHTLIJNEN

In **Hoofdstuk 1** werden de bevindingen van de werkgroep die door het NHG was samengesteld om de richtlijn 'Bemoeilijkte mictie bij oudere mannen' te herzien, gepresenteerd. Gedurende een jaar werd er door deze groep literatuur, die via systematisch zoeken verkregen was, beoordeeld op de wetenschappelijke waarde en de relevantie voor de dagelijkse huisartsgeneeskundige praktijk. Na het verwerken van de commentaren van referenten uit gerelateerde disciplines werd de uiteindelijke versie door de autorisatiecommissie geaccepteerd.
Het grootste deel van de eerdere herziening uit 1997 bleek nog steeds van toepassing te zijn op de dagelijkse behandeling van bemoeilijkte mictie in de huisartsenpraktijk in Nederland. De belangrijkste verandering betrof een explicietere scheiding tussen bemoeilijkte mictie klachten en het prostaatcarcinoom. Bemoeilijkte mictie werd namelijk niet langer verondersteld gerelateerd te zijn met een verhoogde kans op prostaat

carcinoom. Desalniettemin werd het prostaatcarcinoom in deze NHG-Standaard wel behandeld om zo gerelateerde zaken nader toe te kunnen lichten en het gebruik voor de dagelijkse praktijk te verbeteren.
Door de beperkte klinische relevantie van het bestaan van een residu in de blaas na de mictie werd de aanbeveling om de blaas te percuteren beperkt tot die mannen waarbij een verdenking op een acute blaasretentie of de aanwezigheid van een reflex of een overloopblaas bestaat. Mocht er toch twijfel blijven bestaan dan kan een proefcatherisatie overwogen worden.
Deze herziening van de richtlijn stelde de gezamenlijke besluitvorming centraal bij te volgen beleid rondom behandelingsmogelijkheden. Bemoeilijkte mictie bij oudere mannen is namelijk goedaardig met een wisselend klachtenbeloop in de meeste gevallen en zonder een duidelijk obligate behandelingsstrategie. Een afwachtend beleid en het voorschrijven van een zogenaamde α-blokker zijn de behandelingsmogelijkheden die de huisarts ter beschikking staan. Alfluzosine en tramsulosine werden aangeduid als medicamenten van voorkeur, omdat deze goed door patiënten verdragen werden. Als andere behandelmogelijkheden dan afwachten of behandeling met een α-blokker de voorkeur zouden genieten dan werd geadviseerd de patiënt naar een uroloog te verwijzen.

In **Hoofdstuk 2** werden elektronische literatuurbestanden en de webpagina's van instituten die richtlijnen ontwikkelen doorzocht op de aanwezigheid van nationale richtlijnen met betrekking tot bemoeilijkte mictie. De gevonden richtlijnen werden systematisch beoordeeld met behulp van de AGREE-scorelijst. Met name aanbevelingen ten aanzien van het eerste medisch handelen bij een nieuwe patiënt werden geïdentificeerd en de bijbehorende literatuurverwijzingen verzameld. Daar waar de aanbevelingen 'strijdig' waren werd de gebruikte literatuur op een kwalitatieve manier bekeken.
Er werden vijf recent gepubliceerde nationale richtlijnen gevonden. Deze waren ontwikkeld door de American Urologist Association (AUA), Sowerby Centre for Health Informatics in Newcastle (SCHiN, UK), Duodecim (Finland), the National Health and Medical Research Council (NHMRC, Australia) en de European Association of Urology (EAU). Volgens de criteria voor goede richtlijnontwikkeling zoals geformuleerd in het AGREE-instrument zou de NHMRC richtlijn sterke aanbeveling verdienen voor gebruik in de praktijk. De richtlijnen ontwikkeld door SCHiN en de AUA zouden onder voorbehoud aanbevolen worden en de Duodecim en de EAU richtlijnen zouden *niet* aanbevolen worden.
In de onderzochte richtlijnen werden met name verschillen gevonden in de aanbevelingen die betrekking hadden op het diagnostisch handelen. Dit was het meest uitgesproken voor de aanbevelingen ten aanzien van het bepalen van het serum kreatinine, het Prostaat

Specifiek Antigeen en het meten van het blaasresidu na de mictie. Slechts 11,3% van de 227 gevonden literatuurverwijzingen werd in meer dan één richtlijn gebruikt als argument voor een aanbeveling. Voor enkele onderwerpen werd dezelfde referentie gebruikt om strijdige aanbevelingen te onderbouwen. Het gebruik van *evidence* was dan ook minder vanzelfsprekend en objectief dan verondersteld werd binnen het concept van *evidence-based medicine*. Zowel de richtlijn van de AUA als die van de NHMRC had hoge scores in het AGREE domein 'Methodologie'. In dit domein werden het proces van verzamelen en bundelen van de gegevens, alsmede de methodes gebruikt om aanbevelingen te formuleren en te zijner tijd weer te herzien, beschreven. Desalniettemin was de NHMRC richtlijn directiever en 'professional georiënteerd' en waren de aanbevelingen vaker negatief ten aanzien van het verrichten van diagnostiek of beleid in vergelijking met de AUA richtlijn. Die bevatte vaker optionele aanbevelingen en liet de uiteindelijke keuze over aan de samenspraak tussen arts en patiënt.

HET KLINISCH HANDELEN BIJ BEMOEILIJKTE MICTIE: VERKENNING VAN HET PROBLEEM

In **Hoofdstuk 3** werden de resultaten gepresenteerd van een enquêtestudie die werd verricht onder een open populatie van 5052 mannen van 50 jaar of ouder. De studie betrof de mannen die een score hoger dan 7 hadden met de Internationale Prostaat Symptoom Score (I-PSS); in deze groep werden de mannen die wel de huisarts hadden bezocht voor deze klachten vergeleken met zij die dat niet hadden gedaan.
Een op de vijf mannen van 50 jaar en ouder bleek matige tot ernstige klachten te hebben van bemoeilijkte mictie. Van deze mannen had slechts 60% hiervoor contact opgenomen met hun huisarts. De ernst van de klachten was gerelateerd met het huisartsenbezoek, maar bleek niet de enige factor te zijn. Een advies uit de sociale omgeving van de patiënt bleek de sterkste onafhankelijke voorspeller te zijn van huisartsenbezoek, gevolgd door informatie die via de media verkregen was. De verwachte verbetering van de klachten na behandeling door huisarts of specialist en de kennis die de patiënten veronderstelden zelf te hebben over bemoeilijkte mictie bleken ook determinanten te zijn in het bezoek aan de huisarts. De helft van de mannen had behoefte aan meer informatie over hun klachten en slechts enkele mannen waren er van overtuigd dat hun mictieklachten ernstig waren of werden veroorzaakt door een ernstige aandoening, onafhankelijk van of zij hun huisarts bezochten of niet.

Hoofdstuk 4 rapporteerde over een cross-sectioneel onderzoek onder urologen en huisartsen. De vragenlijsten werden door 182 urologen (70%) en 261 huisartsen (55%) ingevuld geretourneerd. Het bekend zijn met de Landelijke Transmurale Afspraak (LTA) over bemoeilijkte mictie bij oudere mannen werd hiermee geëxploreerd, evenals de aanwezigheid van werkafspraken tussen urologen en huisartsen en het beschikbaar zijn van zogenaamde prostaat-klinieken. Deze factoren werden gerelateerd aan het klinisch handelen ten aanzien van een hypothetisch 50-jarige man met ongecompliceerde bemoeilijkte mictieklachten.
De door huisartsen en urologen ontwikkelde en in 1998 gepubliceerde LTA was onder urologen beter bekend dan onder huisartsen. Urologen bleken in relatie tot de hypothetische patiënt meer routinematige onderzoeken aan te vragen dan huisartsen. Met betrekking tot de behandeling van de klachten bleken zowel door urologen als door huisartsen leefstijladviezen te worden gegeven, waarbij urologen vaker aangaven gebruik te maken van voorlichtingsfolders. Urologen en huisartsen bleken vergelijkbaar te zijn in hun houding ten aanzien van behandelopties bij de patiënt met matige (medicatie) en met ernstige klachten (chirurgie).
Een klein deel van de huisartsen en urologen gaf aan de beschikking te hebben over een transmurale kliniek voor prostaatproblemen. De relatie van de mate van transmurale zorg met het klinisch handelen werd nader bestudeerd. Onder huisartsen leek de aanwezigheid van een transmurale kliniek te leiden tot een verschuiving van het klinisch handelen naar dat van de uroloog/specialist. Het bleek dat huisartsen die toegang hadden tot een prostaatkliniek vaker gebruik maakten van de I-PSS (een symptoomscore formulier), vaker laboratorium onderzoek aanvroegen (kreatinine en prostaat specifiek antigeen (PSA) bepalingen) en bij lichte klachten minder vaak een afwachtend beleid kozen. Urologen die gebruik maakten van een prostaatkliniek deden vaker transrectale echografieën en kozen vaker voor een chirurgische behandeling bij matige klachten.

In **Hoofdstuk 5** werd een derde exploratieve studie gepresenteerd. Gedurende een periode van 14 maanden hadden 19 huisartsen rechtstreeks toegang tot een uroflowmetrie onderzoek als aanvullend onderzoek bij mannen met bemoeilijkte mictie. In deze periode waren er 12 mannen waarbij daadwerkelijk een uroflowmetrie was uitgevoerd.
Bij zeven van de 12 mannen was er een $Q_{max} \leq 10$ ml/s (mogelijke obstructie) en twee hadden een $Q_{max} \geq 15$ ml/s (waarschijnlijk geen obstructie). Bij 10 patiënten werd het medisch handelen niet beïnvloed door het verrichten van een uroflowmetrie en werd medicatie voorgeschreven. Bij de twee andere patiënten werd er na bespreking van de

resultaten gekozen voor een afwachtende houding. Geen van de patiënten was verwezen naar de uroloog.
Met het oog op het lage aantal patiënten dat geworven werd gedurende het jaar van onderzoek en het beperkte effect op het medisch handelen, werd uroflowmetrie verondersteld niet zinvol te zijn in de praktijk van de huisarts.
Uit evaluatie-interviews die na de studie werden gehouden met deelnemende huisartsen bleek dat deze met name teleurgesteld waren over het lage aantal nieuwe patiënten met mictieklachten dat zich presenteerde in hun praktijk. Hierbij werden de criteria ten aanzien van het insluiten van patiënten als te streng ervaren, met name het feit dat mannen die al onder behandeling waren niet mochten deelnemen. De meeste huisartsen gaven aan in uroflowmetrie een waardevolle aanvulling op de onderzoeksmogelijkheden van de huisarts te zien. Het zou kunnen helpen om de indicatie voor behandeling beter te stellen en daarbij ook een evaluatie van de behandeling mogelijk te maken. Zij gaven er de voorkeur aan dat de uroflowmetrie, na aanvraag door de huisarts, logistiek geregeld zou moeten worden door een diagnostisch centrum / huisartsenlaboratorium. Hier zou de patiënt na instructie het apparaat meekrijgen en zouden de verkregen metingsresultaten door een specialist beoordeeld worden. Dit gezien het feit dat de deelnemers zich onvoldoende capabel achtten voor een goede interpretatie.

HET IMPLEMENTEREN VAN RICHTLIJNEN

De laatste drie hoofdstukken beschreven een cluster gerandomiseerde studie. In totaal werden 142 huisartsen aselect verdeeld over een groep die een schriftelijk nascholingspakket (interventiegroep) of een groep die een tweetal richtlijnen over bemoeilijkte mictie kreeg toegestuurd (controlegroep). Het schriftelijk nascholingspakket omvatte een programma voor individuele nascholing (PIN), ondersteuningsmaterialen voor het consult (een plasdagboek, de I-PSS, en de klachtenscore (Bother Score: BS)), twee beslisbomen en twee patiëntenfolders (beide over beleid bij bemoeilijkte mictie en over PSA bepalingen).
In 63 huisartsenpraktijken (32 interventiegroep en 31 controlegroep) verspreid over Nederland, werden 187 patiënten ouder dan 50 die zich voor het eerst met bemoeilijkte mictie klachten presenteerden, geïncludeerd.

In **hoofdstuk 6** werd het medisch handelen van de huisarts als uitkomstmaat bekeken. Uit de registraties bleek dat er geen significant verschil was in het afnemen van de anamnese en het verrichten van onderzoek tussen de twee groepen. Hoewel de interventie er op

gericht was de huisarts en de patiënt bewust te maken van de implicaties van het bepalen van een PSA bleek dat het PSA in de interventiegroep in 17,6% van de gevallen vaker bepaald werd (hoewel niet significant). De interventie verlaagde het aantal patiënten dat in verband met mictieklachten naar de uroloog verwezen werd (OR 0,08 (95% CI: 0,02-0,40)). Er waren geen andere significante veranderingen in de interventiegroep, hoewel er wel een trend was naar een langer consult. De patiënten in de interventiegroep kregen vaker informatiefolders (52% versus 8%).

Hoofdstuk 7 had als uitkomstmaten de door de patiënten ervaren kwaliteit van zorg en de mate waarin ze het gevoel hadden in staat te zijn gesteld met hun klachten om te gaan. Patiënten in de interventiegroep waren vaker tevreden met de consultatie dan de mensen in de controlegroep. Zij voelden zich met name meer betrokken bij het bespreken van de klachten en waren meer tevreden over de wijze waarop de arts het te volgen beleid en de behandelopties besprak. Bovendien waren zij er vaker van overtuigd dat de behandeling die zij kregen hen zou helpen de klachten te verminderen. Verder voelden de mannen in de interventiegroep zich beter in staat met hun klachten om te gaan en hun zelfstandigheid te behouden. Er kan geconcludeerd worden dat de interventie een positieve uitwerking had op de zelfredzaamheid van de patiënt. Het verstrekken van patiëntenfolders bleek hierin een cruciale mediërende factor te zijn.
Uit verdere explorerende analyses bleek dat patiënten die leefstijladviezen hadden gekregen tevreden waren over het feit dat de huisarts hen probeerde gerust te stellen. Maar zij bleken uiteindelijk minder zeker ten aanzien van hun gezondheid dan zij die geen adviezen hadden gekregen. Patiënten die medicatie voorgeschreven hadden gekregen leken minder tevreden over de wijze waarop behandelopties besproken waren. Er was geen relatie tussen het testen van het PSA en een van de uitkomstmaten. Hogere klachtenscores waren gerelateerd aan een grotere behoefte aan aanvullend onderzoek en een grotere voorkeur voor een chirurgische interventie.

In **hoofdstuk 8** werd gerapporteerd van uit de optiek van de gezondheidszorg. De primaire uitkomstmaat waren de plasklachten die door de patiënt 3 maanden na de interventie gerapporteerd werden. De kosten die werden gemaakt in relatie tot de interventie en de geleverde medische zorg werden ook bekeken, waarbij uitgegaan werd van de standaardtarieven.
In de drie maanden na het geregistreerde consult werd een significante afname van de klachten gemeld door de patiënten in zowel de controle als de interventiegroep. Qua plasklachten bleek op het moment van inclusie en na drie maanden *tussen* beide

studiegroepen geen verschil te bestaan, er kon dus niet gesproken worden van een effect op gezondheidsuitkomsten.
De gemiddelde vaste kosten waren in de interventiegroep hoger dan in de controle groep (€ 51,62 tegen € 44,00), en dit werd met name gerelateerd aan de kosten van het nascholings- en consultondersteuningsmateriaal. Opvallend genoeg was de tijd die de huisartsen aangaven nodig te hebben voor het bestuderen van de toegezonden materialen vergelijkbaar: 79,5 minuten per huisarts in de interventiegroep en 70,0 minuten in de controlegroep (respectievelijk € 33,47 en € 32,31 per patiënt). Het medisch handelen was in beide groepen vergelijkbaar met uitzondering van het lagere aantal patiënten in de interventiegroep dat verwezen is naar de uroloog. Na een periode van 3 maanden leken de gemiddelde kosten in de interventiegroep lager in vergelijking met de controlegroep, maar de 95% betrouwbaarheidsintervallen overlapten elkaar.

In de **algemene discussie** werden de belangrijkste conclusies op een rijtje gezet in samenhang met bestaande literatuur. Verder werden de methodische aspecten en de implicaties van de in dit proefschrift opgenomen studies nog eens overwogen.
Als **appendix** is de volledige tekst van de richtlijn 'bemoeilijkte mictie bij oudere mannen' opgenomen zoals deze in 2004 verschenen is.

Woord van Dank

Na vandaag zal het dan eindelijk af zijn. Inmiddels 7 jaar geleden kwam er een voorstel voor een onderzoek op mijn weg dat uiteindelijk heeft geleid tot dit boekje. Het feit dat alleen mijn naam op de omslag staat suggereert dat het geheel een éénmansactie geweest is. Ik kan wel zeggen dat niets minder waar is. De vergelijking met mijn *andere baan* dringt zich hierbij op. Een huisarts kan zich alleen als een spin in het web verplaatsen dankzij de vele steunpunten van het web buiten de muren van de spreekkamer.
Hoewel ik ongetwijfeld mensen zal vergeten (waarvoor mijn oprechte excuses), is het belangrijk om stil te staan bij het feit dat deze proeve nooit gerealiseerd had kunnen worden zonder de ondersteuning van velen. De volgorde waarin deze hieronder vernoemd worden is niet geheel willekeurig, maar zegt soms meer over mijn associatieve denkpatroon (lees van de hak, op de tak) dan over het belang dat ik aan deze of gene wil toekennen.

Allereerst wil ik de 3803 patiënten, 441 huisartsen en 182 urologen, die bereid waren hun ervaringen met ons te delen, bedanken. Zonder hun vele antwoorden op nog veel meer vragen waren deze studies niet mogelijk geweest.

Richard Grol: je begeleiding was voor mij van grote waarde. Daar waar ik het soms niet meer zag zitten ging je er vaak vaderlijk voor zitten om vervolgens het perspectief weer wat te veranderen en zo de horizon weer in beeld te krijgen. Door je ervaring was je altijd snel in staat de materie waarmee ik bezig was weer op te pikken en leken de koersveranderingen in analyse en interpretatie vaak kinderspel.
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APPENDIX

Dutch college of general practitioners (NHG) guideline: Lower urinary tract symptoms in older men

(second revision)

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NB 1: The numbers between squared brackets (e.g. [23]) refer to the footnotes as presented in the original text of the guideline, that can be accessed through http://nhg.artsennet.nl/upload/104/standaarden/M42/std.htm.

NB 2: The rest of this thesis does not relate to this second revision of the guideline, but to the first revision as published in: *Huisarts Wet* 1997;**40**:114-24.

The Standard has been revised since the first revision (*Huisarts Wet* 1997;**40**:114-24).

Major revisions are

- Urinary difficulty and prostate carcinoma are separate entities.
- In practice, questions about urinary difficulty and prostate carcinoma are often combined. Prostate carcinoma is therefore still described in this Standard, but under a separate heading.
- The term 'urinary difficulty in older men' means: lower urinary tract symptoms (LUTS) in men of older than 50 years. The term benign prostate hyperplasia is now reserved for histological changes in the prostate.
- Percussion of the bladder after micturition is no longer recommended.

Introduction

The Dutch College of general practitioners guideline for urinary difficulty in older men, contains guidelines for the diagnostics and management of men of older than 50 years with urinary difficulty. The guideline does not apply to micturition problems in younger men, in women or children. Separate guidelines exist for urine incontinence and urinary tract infections [1]. The revised guideline describes new developments in the field of terminology, management choice and treatment options.
The paragraph *Guideline for diagnostics* focuses particularly on the exclusion of urinary infection or prostatitis and on the timely detection of possible complications of urinary difficulty, such as urine retention, hydronephrosis and renal function disturbances. In the paragraph *Guideline for management*, attention is paid to cooperative decision-making by the patient and general practitioner (GP), because the subjective hinder of the complaint is the central issue. A separate appendix is devoted to *Guidelines for management and technique* in acute urine retention.

The presence of urinary complaints does not form a reason to look for prostate carcinoma, because urinary difficulty is not a 'risk factor' for prostate carcinoma; the prevalence of prostate carcinoma in older men with urinary difficulty is the same as that in older men without urinary complaints [2]. As far as origin and prevalence are concerned, the two disorders are completely different entities. Diagnostic tests for prostate carcinoma (such as PSA analysis) in all men who consult their GP because of urinary difficulty, amount to screening, although it has not been established whether this is worthwhile. Owing to the fact that patients with urinary difficulty often make a connection with prostate carcinoma in general practice, a separate section on prostate carcinoma has been added to this guideline. Moreover, the suspicion of prostate carcinoma can arise during digital rectal examination, which would lead to a different management policy. Questions about screening for prostate cancer are frequently raised during consultation; specific knowledge is necessary to give good advice. It is expected that clarity about the policy concerning (questions about) prostate carcinoma will promote the implementation of the Dutch College of General Practitioners Guideline: 'Urinary difficulty in older men.'

Core messages

- Urinary difficulty does not form a 'risk factor' for prostate carcinoma.
- Urinary difficulty is caused by the combined action of static obstruction (enlarged prostate), dynamic obstruction (smooth muscle tissue in the neck of the bladder) and bladder function disturbance.
- In uncomplicated urinary difficulty, the management policy is determined by the subjective troublesome nature of the complaints and the patient's wishes.
- Owing to variation in the natural course of urinary difficulty, it is recommended to attempt to reduce the use of α-blockers after 3-6 months.

Background

Concepts

The guideline employs the following concepts:
Urinary difficulty: changes in urination that lead to complaints such as hesitation before urine flow starts, weak or intermittent urinary stream, an urgent need to urinate, the feeling that the bladder has not emptied completely and increased frequency of urination during the day and at night. The international literature uses the term lower urinary tract symptoms (LUTS) [3].
Acute urine retention: inability to urinate spontaneously with a (painfully) full bladder, despite feeling an urgent need to urinate and multiple attempts within a period of a few hours.
Benign prostate hyperplasia (BPH): nowadays the term benign prostate hyperplasia is reserved for histological changes in the prostate [3].

Causes and pathophysiology

The cause of urinary difficulty in men older than 50 years is age-related deterioration in the voiding mechanism of the bladder. The reason is still partly unclear. Factors that play a possible role include urethral obstruction [4] and (neurogenic) bladder dysfunction, whether or not caused by comorbidity [5] or medication use [6].
For many years it has been believed that hyperplasia of the prostate is responsible for the obstruction in the urethra. Patho-anatomical research has shown that benign prostate

hyperplasia develops from the age of 30 years onwards: at post mortem, benign prostate hyperplasia was found in 90% of 80-year-old men [7]. The cause of this hyperplasia is unknown and in principle, it is a normal degenerative process. Hyperplasia of the prostate does not always lead to prostate enlargement that can be felt during digital rectal examination. The size of the prostate does not correlate with the presence and severity of the complaints.
Increased or decreased activity of the detrusor urinae muscle can cause bladder dysfunction that is expressed as increased urgency, urinary frequency, urge incontinence and insufficient voiding [5].

Epidemiological data

Population surveys on older men showed that the prevalence of moderate to severe urinary complaints varied between 20% and 25% and that the prevalence increased with age. Furthermore, 60% of the men with urinary complaints consulted their GP [8]. These were not necessarily the men with the most severe complaints. Besides the severity of the symptoms, the decision to consult a doctor also depended on the manner in which the patient perceived his complaints. Important roles in the decision to consult the GP were played by anxiety for prostate cancer and by pressure from close family or acquaintances [9].
In general practice registries, the incidence varied between 2 to 4 per 1000 men per year. The incidence increased with age: from 4-9 in the age group 45-64 years, to 10-18 in the age group older than 75 years. Prevalence in these age groups were 8-19 and 36-165 per 1000 men per year, respectively [10].

Natural course

In older men, the frequency of urination increases with age. At the same time, the functional bladder capacity decreases [11]. The natural course of urinary difficulty is characterised by varying complaint patterns. Complaints can be intermittent, stable, progressive or transient [12].
Complications associated with urinary difficulty not only comprise urinary tract infections and acute or chronic retention, but also obstruction in the upper urinary tract, which can lead to hydronephrosis and renal function disturbances.

Guidelines for diagnostics

Anamnesis

The GP should ask about:

- complaints during urination [13]: hesitation before urine flow starts, weak or intermittent urinary stream, urgent need to urinate, the feeling that the bladder has not emptied completely, changes in urinary pattern during the day and at night;
- duration and course of the complaints: rate of onset or rate of deterioration of the complaints;
- perceived troublesomeness: does it affect the night's sleep, or cause social limitations during the day?
- incontinence;
- pain during urination, perineal pain;
- general malaise;
- previous urinary tract infections.

In addition, the GP pays attention to:

- relevant comorbidity: diabetes mellitus, neurological disorders (e.g. CVA, Parkinson's disease, multiple sclerosis), sexually transmitted diseases (previous urethritis);
- previous urological investigations, history of urological treatment or indwelling catheter;
- medication that influences micturition: antipsycholics, (tricyclic) antidepressives, anti-Parkinson drugs, (classic) antihistamines, opiates, loopdiuretics [6].

Very often, anxiety for prostate carcinoma lurks behind the complaint 'urinary difficulty'. There may also be sexual problems or shame about incontinence [9]. By making these issues discussible, a proportion of the patients may feel sufficiently reassured that further diagnostic tests or treatment are unnecessary.
If required, a voiding diary can be kept to record the actual amount, frequency and time of urination; moreover, the data in the voiding diary can be used during communication with the patient to help establish the degree of troublesomeness of the complaints. Urologists often use a score to measure the degree of severity (I-PSS) [13]. However, for GPs, this score does not have any advantage for diagnostics and policy.

PHYSICAL EXAMINATION

During physical examination, the GP examines the lower abdomen (scar tissue, swelling) and the penis (phimosis). Percussion of the bladder is recommended on anamnestic suspicion of neurogenic bladder disease if there is comorbidity, bladder overflow (i.e. continuous loss of small amounts of urine without feeling the urge to urinate) and acute urine retention (unable to urinate despite feeling an urgent need to). If there is doubt about residual urine in the bladder, examination by catheter will provide a definitive answer [14].

Although the value of digital rectal examination is debatable, it is often conducted in any case to obtain a complete picture of the local status and to comply with the expectations of the patient regarding the adequate evaluation of his complaints. During digital rectal examination and palpation of the prostate, attention is paid to the shape (symmetry), texture (pliable and smooth or hard and nodular), size and sensitivity to pressure [15].

A prostate that feels symmetrical, smooth and firmly pliant during palpation indicates the normal situation without abnormalities. If there are no palpable abnormalities, but the prostate is sensitive to pressure, this may indicate prostatitis. An asymmetrically shaped prostate with an irregular texture or hard nodules is suspicious of prostate carcinoma: see *Guideline policy* in the section *Prostate carcinoma*.

SUPPLEMENTARY TESTS

The GP obtains a urine specimen from all the patients to look for signs of urinary tract infection (see NHG guideline Urinary Tract Infections). It is important to establish the presence or absence of a urinary tract infection, because this will have consequences on the management policy [16].

In patients with general malaise, frequently recurring urinary tract infections or urine retention, supplementary tests are indicated for the timely detection of complications from urinary difficulty. These tests comprise ultrasound of the urinary tract to diagnose or exclude hydronephrosis [17] and serum creatinine analysis [18].

Evaluation

There are strong indications of urinary difficulty when older men complain of urination problems and there are no signs of a specific cause. In this case, the GP considers the differential diagnosis of the following disorders:
Urinary difficulty that has developed rapidly and pain in the perineum caused by pressure sensitive prostate during digital rectal examination, indicates prostatitis [19].
Painful or burning frequent urination, positive nitrite test, urine sediment [20], urinalysis or culture form grounds to suspect urinary tract infection (see NHG guideline Urinary Tract Infections).
Painful, burning or irritated sensations in the urethra with discharge or leucocytosis in the urine indicate urethritis (see NHG guideline Sexually Transmitted Diseases consultation).
Urge incontinence two or more times a month, irrespective of the amount of urinary loss, indicates urinary incontinence.
Patients with urination problems and diabetes mellitus or a neurological disease, such as CVA, multiple sclerosis or Parkinson's disease, in combination with dull percussion sounds or postvoiding residual urine upon catheterisation, may have a reflex bladder.
Continuous loss of small amounts of urine without feeling the urge to urinate, in combination with dull percussion sounds or postvoiding residual urine upon catheterisation, indicate an overflow bladder.
Patients with urination problems and a history of local trauma, urological intervention or previous urethritis, may have urethral stricture.
When a patient with a full bladder cannot urinate spontaneously, despite feeling a generally painful urge to do so and after multiple attempts within a few hours, consideration should be given to urine retention.

Guideline policy

This paragraph provides guidelines on the management policy for urinary difficulty. The management policy for acute urine retention is discussed in the appendix *Acute urine retention*. The management policies for acute prostatitis, urinary tract infection and incontinence are dealt with in the NHG guidelines Urinary tract infections and Urine incontinence.

Contribution of the patient

The NHG Standard provides guidelines for management by GPs; thus, the GP plays a central role. In addition, however, factors from the side of the patient must always codetermine the management policy. For practical reasons, this starting point is not referred to repeatedly in the guideline, but is hereby considered to have been stated with sufficient explicitness.
Whenever possible, the GP specifies his/her management policy in conference with the patient, while taking the specific patient circumstances into consideration and while recognising the patient's own responsibility, in which adequate patient education is a prerequisite.

Consideration by the GP

The personal insight of the GP is obviously an important aspect in relation with every guideline. Due consideration to the relevant factors in the concrete situation can justify well-reasoned deviation from the management policy described below, without undermining the intended function of this Standard as a model and aid.

Delegation of tasks

NHG Standards contain guidelines for GPs. This does not mean that the GP has to conduct all the tasks personally. Some of the tasks can be delegated to the practice assistant, support personnel or the practice nurse, on the condition that there is a basis of clear working agreements that dictate the situations in which the GP must be consulted and on the condition that the GP safeguards the quality. Owing to the fact that the choice of tasks that can be delegated depends strongly on the local situation, these Standards do not contain concrete recommendations.

PATIENT EDUCATION

The GP explains that the complaints can be caused by age-related changes in bladder function and sometimes by obstruction around the urethra and in the prostate; prostate enlargement cannot explain the complaints. The common occurrence of the disorder, its benign character and varying course are discussed. Owing to the fact that certain types of medication can aggravate the complaints, the GP reconsiders their use [6]. In addition, the GP gives the following advice [21]:

- Go to the toilet regularly, especially when large amounts of fluid are being consumed in a short time.
- Take your time to urinate (you might wish to adopt the sitting position).
- Take care that your bladder and penis are as empty as possible after urination.
- Contact the surgery immediately if you cannot urinate spontaneously in familiar surroundings, despite the feeling of urgency and multiple attempts within a period of a few hours (acute urine retention) [22].

There is insufficient evidence of the value of pelvic floor exercises in men with urinary difficulty [23].
In support of the verbal advice and information, the GP can give the patient an NHG folder on *Urinary problems in older men*.

Cooperative decision-making about further management

The GP explains that the choice of management policy depends strongly on the patient's wishes, because the subjective troublesomeness of the complaints forms the central issue. Subjective troublesomeness can be more severe or sometimes less severe than the symptoms (actual urinary complaints). Experience has shown that the more severe the actual urinary complaints, the greater the benefit that can be expected from possible treatment. Severity is the best predictor of the success of a urological intervention [24]. Then the next set of issues are discussed: therapeutic options (wait-and-see, medication or invasive treatment), expected effects and side-effects. Generally speaking, invasive treatment leads to greater improvement in the complaints than medication, but it involves a larger risk of side-effects. The major side-effect of treatment with medication is vertigo, while invasive treatment can involve incontinence, erectile dysfunction and ejaculation problems [24]. In view of these side-effects, the GP can advise a wait-and-see policy, whether or not in combination with medication treatment, as some patients find it easier to cope with the aid of medication. In some situations, it is necessary to refer the patient, e.g. if there are complications (see *Referral*).

Wait-and-see policy

A wait-and-see policy for patients with urinary difficulty is a realistic option. Often, owing to the variations in natural course, intervention may not be needed or necessary. In a large proportion of patients, the complaints will improve without therapeutic interventions [12;24].

Treatment with medication

Medication can be considered in patients with troublesome complaints who derive insufficient benefit from following their GP's advice and are not eligible (or willing)

to undergo invasive treatment. Alpha-blocking sympathocolytes (α-blockers) are the medication of choice; they can decrease the urine outflow resistance by influencing the muscle tone in the prostate and urinary tract. When the medication is effective, the results are rapid – the largest effect is reached within two weeks. However, medication has a limited effect on the complaints, both compared to placebo and invasive treatment methods [24]. Effectiveness is expressed in symptom improvement (mean improvement in symptoms: 20%) and in urodynamic improvement (mean improvement in outflow: 20-30%). All the available α-blockers are just about equally effective and safe [25]. All α-blockers lower the blood pressure, which can lead to orthostatic hypotension, especially during the initial period of use. In patients with normal blood pressure, the ultimate effect on blood pressure is low. Other side-effects include: nausea, vertigo, headaches, palpitations, rhinitis and abnormal ejaculation. Despite the comparable effectiveness and side-effects of α-blockers, preference is given to alphuzosine or tamsulosine [26] on the basis of differences in side-effects after discontinuation of treatment with medication.

If there is no improvement within 6 weeks, the medication is stopped. In patients who derive benefit, the medication is prescribed for 3 to 6 months. As little is known about the effectiveness of α-blockers in the long-term and as the natural course varies, the decision is taken in consultation with the patient to stop the medication to see whether the complaints deteriorate again.

The application of 5-α-reductase inhibitors, such as finasteride, is ruled out within general practice, because the clinical effect is extremely limited (even in comparison with α-blockers), it takes a long time to become effective (2-6 months) and is not relevant until the prostate has reached a certain size. At present, research is ongoing into evaluate the additional value of 5-α-reductase inhibitors in combination with α-blockers [27].

There are indications that plant medicines (phytotherapy) are effective, but as yet, there is insufficient evidence on which to base well-founded advice about their use [28].

Table 1: Dosage and use of α-blockers [26]

Alphuzosine:	10 mg tablet with regulated release	once a day in the evening after meals
	in the case of slight-moderate liver function disturbances: 2.5 mg	tablet 1-2 times per day after meals
Tamsulosine:	0.4 mg capsule with regulated release	once a day in the morning after breakfast

Invasive treatment

The term *invasive treatment* encompasses both the classic surgical interventions and other non invasive treatments (such as TUMT).
There are indications for invasive treatment (see *Referral*).
Invasive treatment can be considered further when the troublesomeness of the urinary difficulty is unacceptable to the patient, whether or not after possible treatment with medication has proved to be insufficiently effective. The GP can give global information about the advantages and disadvantages that can be expected with invasive treatment: the urologist can apply various treatment methods [29;30] with a global chance of 60 to 75% of improvement in the complaints and a risk of complications that varies according to the method chosen (incontinence 1-25%, erectile dysfunction 1-10%, ejaculation problems 4-61% [24]. If the patient wishes to consider invasive treatment, the GP refers him to a urologist. The choice of treatment depends on the availability of the different treatments, the urologist's experience with the interventions and the wishes of the patient.

Check-ups

Check-ups are conducted in the case of changes or deterioration in the complaints and when patients are taking medication. The timing of the check-ups can be left to the patient when there are changes or deterioration in the complaints. During the check-up, the GP investigates whether there are changes in the severity and nature of the complaint pattern, general malaise, new comorbidity or new medication. Urine analysis is performed to detect signs of infection. On certain indications, abdominal ultrasound scanning is performed and the creatinine level is tested (see *Supplementary tests*). If the complaints have changed or deteriorated, the GP reconsiders the diagnosis, adjusts the treatment with medication if necessary, or refers the patient on for further diagnostics or possible invasive treatment.
Check-ups related to the start of treatment with medication take place after 6 weeks (in person or by telephone) to evaluate the effect and after 3-6 months to discuss with the patient whether the medication can be stopped to judge whether the complaints increase again.

Referral

The GP refers older men with urinary difficulty in the following situations:

- For tests in aid of differential diagnosis:
  - on the suspicion of a neurogenic bladder disorder and/or overflow bladder;
  - on the suspicion of urethral stricture;
  - on the suspicion of prostate carcinoma: see *Guideline policy* in the section *Prostate carcinoma*.
- For possible invasive/surgical treatment [31]:
  - if the patient wants invasive treatment due to perceived troublesomeness;
  - if the patient has acute urine retention;
  - if the patient has recurrent urinary tract infections;
  - if the patient has renal function disturbances and/or hydronephrosis.

A separate referral indication is formed by acute urine retention with contra indications for trans urethral catheterisation (see further in the appendix *Acute urine retention*).

Appendix Acute urine retention

Guideline policy

The GP performs trans urethral catheterisation for acute urine retention, unless it can be traced back to recently or previously experienced trauma (or urethritis). In that case, it is followed by urgent referral to a urologist [32]. Together with the patient, the GP considers treatment with an α-blocker after catheterisation [33]. The catheter remains in situ for 48 hours and is then removed [34].

If the patient has a urinary tract infection, constipation, medication use [6] or alcohol use, the catheter remains in situ until the underlying cause of the retention has been resolved. If urination does not occur spontaneously after removal of the catheter, referral to a urologist is the next step.

Techniques [35]

Requirements:

- catheter set: two basins, sterile gauze, cellulose mat, gloves, anatomical forceps, catheter bag;
- standard catheter Charriere size 16-18, 10 cc syringe + (distilled) water;
- anaesthetic lubricant (sterile packaging in syringe or flask);
- disinfectant (chlorhexidine 0.05%).

Management:

- Role back the foreskin.
- Disinfect the glans penis and urethral opening.
- Slowly inject a liberal quantity of anaesthetic lubricant (15-30 ml.) into the urethra using a syringe.
- Coat the catheter tip in anaesthetic lubricant and carefully introduce the catheter into the bladder. The tip of the catheter points ventral. Introduction of the catheter is facilitated by tilting the penis slightly upwards, by pressing a finger against the perineum and by the patient slowly breathing in and out. If the catheter has trouble passing through the prostate, the penis is tilted caudal to simplify passage.
- To pass the neck of the bladder, push the catheter 3 to 4 cm further when the first urine enters the catheter. To avoid damaging the membranous urethra or the neck of the bladder, a minimum of 24 cm of the catheter must be inserted before the balloon is filled with (distilled) water. The balloon can then be filled with the stipulated amount of (distilled) water.
- Pull the catheter back gently until resistance is felt and the balloon is resting against the neck of the bladder. The catheter is connected to the collection bag and fixed to the patient's upper leg or abdomen.
- If catheterisation is unsuccessful, the patient is referred immediately to a urologist.

Bear in mind that the following complications can occur during trans urethral catheterisation:

- Lesions in the urethra, neck of the bladder or prostate due to a fausse route or filling the balloon while it is in an incorrect position;
- Infection of the urethra, bladder, prostate or epididymis.

ORIGINATION

In June 2003, a working group started the second revision of the NHG Guideline for Urinary difficulty in older men. The working group comprised: R.J. Wolters, GP in Elst and scientific researcher at the Centre for Quality of Care Research (WOK), UMC St Radboud (Nijmegen), M.G. Spigt, health science and scientific researcher in the capacity group at the University of Maastricht, P.F.H. van Reedt Dortland, GP in Breda, A.J. Gercama, GP in Rijsenhout and university lecturer in general practice medicine VUMC and M.L.F. Klomp, GP in Eindhoven and education coordinator of General Practitioner Training at the UMC St Radboud.

In April 2004, a concept of the guideline was sent to 50 GPs for review, their addresses had been picked at random from the NHG membership list. Twenty comment forms were returned. In addition, comments were received from a focus group of 8 GP tutors and a number of referees. These referees comprised: professor J.L.H.R. Bosch, urologist, professor C.H. Bangma, urologist, dr. T.J.M. Schlatmann, urologist, dr. M.H. Blanker, GP, T. Christiaens, GP on behalf of the scientific foundation of Flemish GPs, B.J. de Boer, GP on behalf of the commission to promote sexology, J. van Engeldorp Gastelaars, pharmacist on behalf of WINAp Medication Information, Mrs. J. Heymans, GP and editor of the *Diagnostisch Kompas*, A.C. van Loenen, clinical pharmacologist and chief editor of the *Farmacotherapeutisch Kompas* and L. Dijkstra on behalf of the Foundation Contact Group for Prostate Cancer. Name entry as a referee does not otherwise mean that each referee endorsed every detail of the guideline.

In July 2004, the guideline was commented on and authorised by the NHG authorization committee. Supervision of the working group and editing rested with Mrs. J.S. Starreveld, GP and scientific researcher at the Department of Guideline Development and Science of the NHG, with the support of A.C.M. Romeijnders, staff member at the same department.

Prostate carcinoma

Introduction

Prostate carcinoma grows slowly and usually develops in the periphery of the prostate, far remote from the urethra. It generally does not express itself, or not until an advanced stage, with the consequences of bone metastases or urethral obstruction. Statistics show that 42 out of every 100 men will develop a form of prostate cancer; 10 will develop physical symptoms; 3 will die from the disease [36].
Treatment for prostate carcinoma is a tricky issue: it has never been confirmed that treatment for prostate carcinoma prolongs life, whereas the treatment can involve side-effects [37]. This means that an individual patient might benefit from treatment, but sometimes might also only encounter disadvantages. In the case of metastasized prostate carcinoma, antihormonal treatment can lead to considerable temporary reduction in symptoms and improved quality of life [38].
When choosing a management policy, patients suspected of having prostate carcinoma are distinguished from those without suspicion and questions about screening.

Suspected prostate carcinoma

Guideline policy

Prostate carcinoma is suspected when digital rectal examination reveals an asymmetrical prostate, an irregular texture or hard noduli. About half of the cases actually have prostate carcinoma. The GP discusses this with the patient [39]. In this situation, PSA analysis is of very limited value, because an increased value does not confirm the diagnosis and a normal value does not exclude the diagnosis. Moreover, interpretation of a PSA analysis has various pitfalls [40]. To be certain of the diagnosis, secondary care diagnostics are necessary [41]. The question of whether it is worthwhile to follow this path and initiate intervention depends on a number of factors. When assessing the point of performing therapeutic interventions with curative intent, the life expectancy of the patient plays a central role [42]. In the case of palliative therapy, the presence of complaints from metastases plays a central role. The prognosis on the basis of the natural course [43], the effectiveness of a treatment [44], treatment-related complications [37] and expectations regarding morbidity [45] must be weighed against each other.

The following practical guidelines apply to the GP:
First, the GP establishes whether there are clinical indications of metastases (general malaise, weight loss, bone pain in the back, hips). Patients with a life expectancy of more than ten years are referred to a urologist for further diagnostics and evaluation of the therapeutic options.
In patients with a life expectancy of less than ten years – generally patients of older than 72 years [46], or younger patients in whom comorbidity has a negative influence on life expectancy – without clinical indications of metastases, it is debatable whether further diagnostics are

worthwhile. The GP explains that if the patient does prove to have prostate cancer, this generally grows very slowly. Moreover, life expectancy and quality of life will probably not improve much through medical intervention, whereas there is a considerable risk of side-effects. After receiving all the relevant information, these patients might choose to follow a wait-and-see policy, but if they choose to undergo further diagnostics and evaluation of the therapeutic options, they will have to be referred to a urologist.
If there are clinical indications of metastases, PSA analysis can be worthwhile: a PSA value of >50 ng/ml strengthens the suspicion of metastasized prostate carcinoma [47]. The GP refers the patient to a urologist for further diagnostics and evaluation of the therapeutic options [38].

In practice, the majority of patients will (want to) be referred. The GP can make it clear to the patient that it is also possible to be referred only for further diagnostic tests and that after confirmation of the diagnosis, the patient can still choose a wait-and-see policy.

Screening for prostate carcinoma

Guideline policy

The GP explains the following to a patient without complaints who asks to undergo tests for prostate carcinoma:
Prostate carcinoma is a common tumour in older men, but it only gives rise to symptoms in 10 out of the 100 men and forms the ultimate cause of death in even fewer (3 out of 100 men). Thus, far more men die *with* prostate carcinoma than from it. When prostate cancer is found by chance, it is not easy to predict whether it will become clinically relevant in individual cases. There is no evidence that the early detection and treatment of patients with asymptomatic prostate carcinoma actually decreases morbidity and mortality [48]. However, false-positive results do involve the burden of (unnecessary) diagnostic tests, while diagnostics and treatment involve co morbidity and complications.
Research has shown that patients with a positive family history have an increased risk of developing prostate carcinoma [49]. In these men, the value of performing early diagnostics for prostate carcinoma has never been demonstrated. This also applies to men from a family with hereditary prostate carcinoma.
In support of this explanation, the GP can give the patient the NHG patient folder: *Should we or should we not screen for prostate cancer?*
If a complaint-free patient still wishes to be screened for prostate cancer despite having received extensive information, the GP can agree to comply. The GP then performs digital rectal examination (DRE) in combination with PSA analysis. The risk of prostate carcinoma is small when the DRE findings are normal and the PSA value is <4 ng/ml. If either of the tests provide suspicion for prostate carcinoma, then it is best to refer the patient. If the DRE findings are normal and the PSA value is between 4 and 10 ng/ml, then after discussing the matter with the patient, it might be decided to repeat the PSA analysis at a later date, which could ultimately still lead to referral to a urologist [50].

René Wolters werd op 10 oktober 1966 geboren te Almelo. Na het behalen van het VWO-diploma aan het Pius X-College te Almelo ging hij in 1985 geneeskunde studeren aan de Katholieke Universiteit Nijmegen. Tijdens zijn studie heeft hij verschillende student-assistentschappen vervuld op zowel de medische faculteit als de faculteit voor wis- en natuurkunde. Na afsluiting van het reguliere curriculum heeft hij, onder de begeleiding van Dr. Albert Verhofstad, een jaar lang onderzoek gedaan naar de ontwikkeling van bijniermerg en haalde in mei 1990 zijn doctoraalexamen. Zijn artsopleiding heeft hij met veel plezier onderbroken voor een extra co-assistentschap tropengeneeskunde in Sengerema Hospital, Tanzania.
In aansluiting op zijn artsexamen, in mei 1993, heeft hij als dienstplichtig luitenant-arts gewerkt op de vliegbasis Deelen. Om vervolgens in juni 1994 te gaan werken als poortarts/assistent chirurgie in het Willem-Alexander Ziekenhuis te 's-Hertogenbosch.
Van september 1995 tot en met september 1998 heeft hij zijn opleiding tot huisarts vanuit Nijmegen gedaan (opleiders: Simme van der Meer, Paul Verdaasdonk en Neelco Osinga). In december 1998 is hij begonnen als huisarts-onderzoeker bij de afdeling Kwaliteit van Zorg (KWAZO/WOK) aan het Universitair Medisch Centrum St Radboud te Nijmegen.
In juli 1999 heeft hij zich samen met Mireille ter Berg als huisarts gevestigd in Elst (Gelderland). Deze praktijk is inmiddels met een derde huisarts, te weten Raymond Wetzels, uitgebreid en het volgende project (het realiseren van een HOED-praktijk (Huisartsen Onder Een Dak) in een nieuw pand met Rudy Kleerekooper en Marijke Corsten) is al weer in volle gang.
In de regio Arnhem is hij sinds 2000 actief in de Werkgroep Deskundigheidsbevordering Huisartsen (WDH) en sinds kort ook lid van de commissie kwaliteit van de regionale huisartsenvereniging.

René is gehuwd met Annette van der Meer en de trotse vader van Simone (5 jaar) en Stijn (3 jaar).