Sleep and quality of life in men with lower urinary tract symptoms – and their partners

Helén Marklund-Bau

Department of Clinical and Experimental Medicine, Division of Surgery, Faculty of Health Sciences
Linköping University, SE 581 85 Linköping, Sweden
and
Department of Medicine and Health, Division of Nursing Science, Faculty of Health Sciences
Linköping University, SE 581 85 Linköping, Sweden

Linköping 2009

"Minds are like parachutes. They only function when the are open

Sir James Dewar (1877-1925)

To Johan, Emelie and Olivia

"The important thing is never to stop questioning"

Albert Einstein

"If all pulled in one direction, the world would keel over"

Yiddish proverb

"Fall seven times, stand up eight"

Japanese proverb

ABBREVIATIONS

AUA	American Urological Association
BII	Benign Prostatic Hyperplasia Impact Index
BMI	Body Mass Index (weight in kg/height in m^2)
BNSQ	The Basic Nordic Sleep Questionnaire
BP	Bodily Pain
BPE	Benign Prostatic Enlargement
BPH	Benign Prostatic Hyperplasia
BPO	Benign Prostatic Obstruction
CIC	Clean Intermittent Catheterization
EP	Enlarged Prostate
GH	General Health
HRQOL	Health Related Quality Of Life
ICS	International Continence Society
IPSS	International Prostate Symptom Score
LIQ	Linköping Incontinence Questionnaire
LUTS	Lower Urinary Tract Symptoms
MCS	Mental Component Summary score
MH	Mental Health
PCS	Physical Component Summary score
PF	Physical Functioning
PSA	Prostate Specific Antigen
QOL	Quality Of Life
RE	Emotional Role limitations
RP	Physical Role limitations
SE%	Sleep Efficiency
SF	Social Functioning
SF-36	36-item Short Form questionnaire
SOL	Sleep Onset Latency
SPI	Symptom Problem Index
SPSS	Statistical Package for the Social Sciences
TUIP	TransUrethral Incision of the Prostate
TUMT	TransUrethral Microwave Thermotherapy
TURP	TransUrethral Resection of the Prostate
UI	Urinary Incontinence
USI	The Uppsala Sleep Inventory questionnaire
VT	ViTality
WHO	World Health Organization

GLOSSARY

Clean intermittent catheterisation (CIC)	Drainage or aspiration of the bladder or a urinary reservoir with subsequent removal of the catheter by using a clean technique. This implies ordinary washing techniques and use of disposable or cleansed reusable catheters [1].
Condition	A physical disorder [2].
Co-morbidity	The simultaneous appearance of two or more psychiatric or physical illnesses [2].
Disease	A disorder in humans, animals, or plants with recognizable signs and often having a known cause [2].
Indwelling catheter	A catheter that remains in the bladder, urinary reservoir or urinary conduit for a period of time longer than one emptying [1].
Inguinal hernia	A bulge of a tissue, a structure, or part of an organ through an opening in the abdominal wall of the inguinal region [3].
Lower urinary tract symptoms (LUTS)	Defined from the individual's perceptive who is usually but not necessarily, a patient within the healthcare system. Symptoms are either volunteered by, or elicited from, the individual or may be described by the individual's caregiver [1].
Nocturia	The complaint that the individual has to wake at night one or more times to void, and is the number of void recorded during a nights sleep: each void is preceded and followed by sleep [4].
Symptoms	The subjective indicator of a disease or change in condition as perceived by the patient, caregiver or partners and may lead him/her to seek help from health care professionals [1].
Urinary incontinence	The complaint of any involuntary leakage of urine [1].

ABSTRACT

Aims The overall aim was to determine how lower urinary tract symptoms (LUTS) suggestive of benign prostatic obstruction (BPO) affect sleep, health related quality of life and disease specific quality of life, and how the men's urinary symptoms affect their partners.

Subjects and methods: In papers **I–II,** a descriptive design with a pre-test and post-test was used and in papers **III-IV** the design was descriptive and comparative. The method was self-administered questionnaires.

In papers **I- II**: The questionnaires were translated in the ethnographic mode. In paper **I** the reliability of the questionnaire was tested in 122 patients with LUTS/ BPO. The disease specific quality of life was studied before and after intervention in 572 consecutive patients with BPO, aged 45-94 yrs. In paper **II,** the partner specific quality of life was studied in partners to men with BPO before and after transurethral resection of the prostate (TURP). The reliability and the responsiveness of the questionnaire were tested in two groups with 51 partners each. Papers **III-IV**: A study of 239 men with LUTS, aged 45-80 yrs, and their partners (n=126) who were compared to randomly selected men from the population (n=213) and their partners (n=131). The men had an extra control group, men with inguinal hernia (n=200). Sleep and health related quality of life (HRQOL) was studied in both men and their partners. The partners' specific quality of life was also studied and the men with LUTS answered questions about urinary symptoms and disease specific quality of life.

Results: Papers **I-II:** All the tested questionnaires showed an acceptable reliability and responsiveness**. I:** Before and after intervention the prevalence of urinary incontinence was 46 % and 16 % respectively. **II:** Partners were affected by the patients' BPO symptoms before and improved after the patients TURPs. **III:** Most sleep variables were significantly impaired in men with LUTS compared to one or both of the control groups. The men with LUTS had a significantly higher prevalence of insomnia (40 %) than both control groups and significantly lower sleep efficiency (49 %) than men with hernia. The men with LUTS were significantly impaired in most domains of the health related quality of life compared to men in the population. **IV:** There were no significant differences between the two partner groups regarding the quantity and quality of sleep or the health related quality of life.

Conclusions: All tested questionnaires showed an acceptable reliability and responsiveness.

The prevalence of urinary incontinence before and after intervention was higher than earlier reported.

Men with LUTS had significantly poorer sleep quality, reduced sleep efficiency and a higher prevalence of insomnia than men in the population and men with inguinal hernia. The HRQOL is impaired in men with LUTS compared to men in the population and men with inguinal hernia.

Partners are affected by the patients' symptoms, and it is emotional rather than practical aspects that affect them most.

Partners of men with LUTS did not differ significantly from partners in the population with regard to sleep and health related quality of life.

Key words: Benign prostatic hyperplasia; Benign prostatic obstruction; Disease specific quality of life; Health related quality of life; Inguinal hernia; Insomnia; Lower urinary tract symptoms; Population; Sleep disorders; Sleep quality.

CONTENTS

LIST OF ORIGINAL PAPERS

This thesis is based on the following papers, referred to in the text by their Roman numerals I-IV

I   Marklund-Bau H, Edéll-Gustafsson U, Spångberg A. Bothersome urinary symptoms and disease specific quality of life in patients with benign prostatic obstruction. Scand J Urol Nephrol 2007;41(1):32-41.

II   Marklund-Bau H, Edéll-Gustafsson U, Spångberg A. A Swedish version of a quality of life questionnaire for partners of men with symptoms suggestive of benign prostatic obstruction. Scand J Urol Nephrol 2008;42(2):126-31.

III   Marklund-Bau H, Spångberg A, Edéll-Gustafsson U. Sleep and health related quality of life in men with urinary tract symptoms (LUTS) suggestive of benign prostatic obstruction (Submitted).

IV   Marklund-Bau H, Spångberg A, Edéll-Gustafsson U. From the partners perspective- a study of speicif quality of life in partners of men with lower urinary tract symptoms (LUTS) compared with partners to men from the population (Submitted).

1. **INTRODUCTION**

Benign prostatic hyperplasia (BPH) may cause prostatic enlargement and voiding

problems [1]. There is, however, no consensus on well-defined diagnostic criteria [5] or

on which patients need treatment [6]. A person with bladder symptoms is said to have

lower urinary tract symptoms (LUTS) [1]. The prevalence of LUTS in the male

population is age related and is estimated to be 20-25 % for middle-aged and 40-77 %

for men ≥70 yr [7-10]. The LUTS/BPH condition is considered to be a stationary or

slowly progressive disease [11], which means that these men may live with their

symptoms for many years before treatment. This common condition is often given low

priority compared to other urological diseases. Even if the condition is benign, the

men's symptoms have an impact on their relationships, their social lives and their

lifestyle [12,13]. Their symptoms cause distress, worry and fear of future deterioration,

embarrassment about wetting or leaking, a need to plan because of urgency or frequent

voiding and night-time disruption [12]. Altogether, this raises many questions. Are there

urinary symptoms that are more bothersome than others? Is the men's sleep affected?

Are the partner affected by their men's urinary symptoms? How can we help the men to

manage their symptoms better and help them to be less bothered by them? These

questions are summarized into the overall aim in the thesis.

2. BACKGROUND

2.1. Lower urinary tract symptoms (LUTS)

2.1.1. Terminology

Benign prostatic hyperplasia (BPH) may cause prostatic enlargement and voiding

problems [1]. There is, however, no consensus on well-defined diagnostic criteria [5] or

on which patients need treatment [6]. In this somewhat confusing situation a new

terminology has been introduced. The term BPH stands only for the histological

diagnosis of benign prostatic hyperplasia and it does not say anything about prostatic

enlargement or urethral obstruction [14]. Benign prostatic enlargement (BPE) means

that the prostate is enlarged due to BPH [1]. Another cause of prostatic enlargement that

may cause symptoms is prostatic cancer. BPE may or may not cause urethral

obstruction and symptoms. Benign prostatic obstruction (BPO) means that there is an

obstruction to urinary flow caused by BPE. Prostatic cancer and urethral stricture are

other conditions that may cause urethral obstruction [1].

A person with bladder symptoms is said to have lower urinary tract symptoms (LUTS).

When this term was introduced, it was reserved for elderly men suspected of having

BPO, but nowadays it is used for any lower urinary tract symptom in any person.

Instead the terms LUTS suggestive of BPH and LUTS suggestive of BPO have been

introduced [14]. This thesis is concerned with LUTS suggestive of BPO. The

requirements for using this term are that the subject is a man aged ≥45 yrs and that other

important causes of LUTS, such as prostatic cancer, bladder cancer and neurogenic

bladder disease have been ruled out with reasonable certainty. In LUTS suggestive of

BPO, the LUTS may be caused by BPO but also by a weak bladder, an overactive

detrusor (the bladder muscle) or a subclinical neurological disease.

2.1.2. Prevalence

The prevalence of histological BPH is age related and was found to be 8 % of men 31-40 yrs, 50 % in men 60 yrs and nearly 90% in men >80 yrs [15]. The prevalence of LUTS in the male population increases with age and has been estimated to be 20-25 % for middle-aged and 40-77 % for men ≥70 yr [7-10]. Different methodologies and different definitions may explain the differences in the prevalence. The aetiology of BPH is multifactorial. Epidemiological studies indicate several risk factors for developing the disease, like smoking, obesity and chronic conditions such as hypertension and diabetes [16,17]. However, to date, the only proven factors related to the development of the disease are high age and the presence of androgens [18].

2.1.3. Definition of urinary symptoms

According to the International Continence Society (ICS), LUTS are defined from the individual´s perspective; symptoms are either volunteered by, or elicited from, the individual or described by the individual's caregiver [1].

2.1.4. Urinary symptoms

The symptoms are divided into three groups: storage, voiding, and post micturition symptoms [1]. Storage symptoms are experienced during the storage phase of the bladder. The voiding symptoms are experienced during the voiding phase and post micturition symptoms are experienced immediately after micturition [1] (Table 1). In this thesis, two storage symptoms, urinary incontinence and nocturia, were of most interest because of their negative impact on the quality of life (QOL) [19].

Table 1. Description of urinary symptoms according to the International Continence Society.

Storage symptoms	
Increased daytime frequency	The complaint by the patient that he/she voids too often by day.
Nocturia	The complaint that the he/she has to wake at night one or more times to void
Urgency	The complaint of a sudden compelling desire to pass urine, which is difficult to defer
Urinary incontinence	The complaint of any involuntary leakage of urine
Urge incontinence	Involuntary leakage accompanied by or immediately preceded by urgency
Stress incontinence	Involuntary leakage on effort or exertion, or on sneezing or coughing
Continuous incontinence	A continuous leakage
Voiding symptoms	
Slow stream	An individuals´ perception of reduced urine flow usually compared to previous performance or in comparison to others
Intermittent stream (intermittency)	Urine flow which stops and starts, on one or more occasions, during the micturition
Straining	The muscular effort used to either initiate, maintain or improve the urinary stream
Splitting or spraying	Of the urine stream
Hesitancy	Difficulties in initiating micturition that result in a delayed onset of voiding after he /she is ready to pass urine.
Terminal dribble	When he /she describes a prolonged last part of the micturition and when the flow has slowed to a dribble/trickle
Post micturition symptoms	
Feeling of incomplete emptying	A self-explanatory term for a feeling experienced by the individual after passing urine
Post micturition dribble	An individuals description of the involuntary loss of urine immediately after finished passing urine

2.1.5. Urinary incontinence

The prevalence of urinary incontinence (UI) in the male population varies from 2.8-34 % depending on different definitions, age and methodology [20-22]. Urinary incontinence may affect patients with BPO [23,24] but the symptom either before or after intervention has not been well studied [25]. In a study with 480 patients tentatively diagnosed with BPH, 37 % reported incontinence [26]. The prevalence of UI in 98

consecutive men with BPH before and two years after transurethral resection of the prostate (TURP) was 12 % and 3 %, respectively [27].

2.1.6. Nocturia

A common and bothersome urinary symptom is nocturia [28-30], which also increases with age [31,32]. The ICS has defined nocturia as "the complaint that the individual has to wake at night one or more times to void" [3].

The most common cause of nocturia is an increased nocturnal diuresis, but it may also be caused by a diminished functional bladder capacity. The origin of an increased nocturnal diuresis is complex and includes several factors such as somatic diseases; for example diabetes mellitus and heart failure, endocrine alterations and sleep apnoea [29,33]. By defining nocturia as two or more nocturnal voidings, Schatzl et al. [34] estimated nocturia to affect 32 % of men ≥60 years.

2.1.7. Diagnostic investigations

The diagnostic methods that may be used in men with LUTS suggestive of BPO are listed in table 2. The examinations are performed to obtain a more exact diagnosis, i.e. BPO, weak bladder or idiopathic overactive detrusor, which may influence the choice of treatment. Examinations are also performed to find the relatively few patients that have other diagnoses such as urethral stricture or bladder diverticulum and the few cases with prostatic or bladder cancer where there were no obvious suspicion of a malignancy from the beginning. There is no unanimous opinion about how patients with LUTS suggestive of BPO should be examined, which for example is reflected in the different guidelines of the European Association of Urology [35] and the American Urologic Association [36]. The only investigation that can with certainty verify that the patient has an obstruction is the pressure-flow study [35-36]. Since this investigation is time-consuming and expensive, it is not used in all patients. Many, or most patients are

Table 2. Diagnostic investigations used in men with Lower urinary tract symptoms (LUTS) suggestive of Benign prostatic obstruction (BPO).

Diagnostic method	Description	Obtained information
Medical history	-	Previous urological and other diseases
Symptom assessment	IPSS[a] or other validated symptom score LIQ[b]	No diagnostic information Correlated to bother Evaluate urinary incontinence
Bother assessment	SPI[c], BII[d] and/or the bother question in the IPSS[a]	Need for treatment
Digital rectal examination	-	Prostate size Suspicion of prostatic cancer
Flow measurement	Flow rate during a voiding. Maximum flow rate the most used parameter.	Degree of voiding impairment
Timed micturition	The time to void the first 100 ml	Degree of voiding impairment
Frequency/volume chart	Time and voided volume for all voidings during >24 h	Degree of voiding impairment Large diuresis during night or day
Residual urine	Usually measured with ultrasound	Degree of voiding impairment
Pressure-flow study	Flow rate and bladder pressure during voiding	Urethral resistance Bladder contractility
Dip stick analysis	Erythrocytes, leucocytes and nitrite in urine	May find an infection
Prostate specific antigen (PSA)	Blood sample	Correlated to prostate size Suspicion of prostatic cancer
Transrectal ultrasound (TRUS)	Transrectal ultrasound investigation	Prostate size
Urethrocystoscopy	Inspection of the urethra and bladder	Prostate size May find other diseases

[a] International Prostate Symptom Score (IPSS), [b]Linköping Incontinence Questionnaire (LIQ), [c]Symptom Problem Index (SPI), [d]The BPH Impact Index (BII)

treated when the urologist thinks that the probability that the patient has BPO. Combination of examinations that often are used is: assessment of bother with history and IPSS, assessment of flow rate with flow measurement or timed micturition, assessment of prostate size with digital rectal examination or transrectal ultrasound and the absence of signs of other relevant diseases. The pressure-flow study is then reserved for patients that have an equivocal result on these examinations. It is also an accepted

practise to perform fewer investigations before drug therapy than before surgical therapy.

2.1.8. Treatment

There is no general agreement on which patients should be treated and how the treatment method should be chosen [5,6]. An overview of the treatment methods is given in table 3. TURP and open adenoma enucleation are regarded as the best methods and they are used as the golden standard in trials. The drugs are not very efficient and if the patient is severely obstructed he may be improved but not cured by the drug therapy. TUMT may have a treatment effect close to TURP [37]. When the patient can not void and has an indwelling catheter, the standard treatment is TURP or open operation, but there is a study which shows almost the same result with TUMT [38]. When treating patients without an indwelling catheter, the choice is between a less efficient treatment with low risks and a more efficient treatment with higher risks. The decision is not straightforward and has to be discussed with the patient.

2.1.9. Follow up

All patients who receive treatment require a follow-up but how this follow-up is performed varies a greatly deal. A minimum follow-up is to assess the IPSS, to perform flow measurement or timed micturition and to assess that the patient is satisfied 3-6 months after treatment [35].

Table 3. Overview of the treatment methods in men with Lower urinary tract symptoms (LUTS) suggestive of Benign prostatic obstruction (BPO).

Method	Comments	Improvement [a]
Watchful waiting (WW)	Information about the disease Reassurance Advice	IPSS [b]: 1 point Q_{max} 2 ml/s bother question IPSS [b]: 0 point
Placebo	From drug trials	IPSS [b]: 3 point Q_{max} 1 ml/s bother question IPSS [b]: 0,5 point BII [c]: 1point
Sham treatment	For example sham Transurethral microvawe treatment (TUMT)	IPSS [b]: 6 point Q_{max} 1 ml/s bother question IPSS [b]: 1 point

Drugs		
Alpha-blockers	Relaxation of smooth muscle in urethra and prostate	IPSS [b]: 6 point Q_{max} 2-3 ml/s bother question IPSS [b]: 1-1,5 point BII [c] 2 point
5-alpha-reductase inhibitors	Inhibits the testosterone effect and decreases prostate volume	
Anticholinergic drugs	Inhibits bladder contractions and improves urgency	
Combinations of drugs	Earlier only alpha-blocker + 5-alpha-reductase inhibitor but now also combinations with anticholinergics	

Minimally invasive		
Transurethral microwave treatment (TUMT)	Outpatient procedure no general anaesthesia prostatic tissue destroyed by heating	IPSS [b]: 10 point Q_{max} 4 ml/s bother question IPSS [b]: 2 point
Transurethral needle ablation (TUNA)	Not used in Sweden nowadays	

Surgery		
Transurethral incision of the prostate (TUIP)	1-2 incisions in the bladderneck/prostate	IPSS [b]: 12 point Q_{max} 8 ml/s bother question IPSS: 0point-
Transurethral resection of the prostate (TURP)	Removal of the prostatic adenoma in small pieces via the urethra	IPSS [b] 15 p Q_{max} 11 ml/s bother question IPSS [b]: 3,5 point
Open adenoma enucleation	Removal of the prostate adenoma in one piece via an abdominal incision	IPSS [b]: 10 point 15 ml/s bother question IPSS [b]: 0 point
Laser operation	Several methods, some out-dated and the new ones still considered experimental	IPSS [b]: 15 point Q_{max} 10 ml/s bother question IPSS [b]: 3,5 point

[a] From the AUA guideline on the management of BPH. [b] International Prostate Symptom Score (IPSS), [c] The BPH Impact Index (BII)

2.2. Quality of life (QOL)

The Encarta World English Dictionary defines quality as " the general standard or grade of something, a characteristic of somebody or something and excellence of a characteristic" [2]. The quality of life (QOL) is a multi-dimensional concept and theoretically incorporates all aspects of an individual's life. There are many definitions of the QOL concept; it has been defined in a macro perspective (societal, objective) and micro perspective (individual, subjective terms) [39] The QOL brings different things to different people and priorities vary according to people's socio-demographic characteristics [39].

2.2.1. Disease specific quality of life

The disease specific quality of life has no overall definition, the concept can be seen as the individual's interpretation of aspects of life and the range of activities that have been affected by the condition [40].

Disease specific quality of life questionnaires usually contain a list of symptoms relevant to the condition. The scale of a disease-specific measurement is more clinically and socially significant to specific conditions. It is aimed to discriminate more finely between the levels of severity of the condition and also to be more sensitive to the clinical outcomes [40]. When reporting of morbidity, the patterns depend on the symptom tolerance level, pain threshold, attitudes towards illness and self-care. Further, the expectations and demands of others, family, social and cultural factors and knowledge and understandings of experienced symptoms. Sometimes a domain specific scale is required, for instance when the disease specific scale neglect the area of interest [39].

In studies where the disease specific QOL has been assessed in men with LUTS/BPH, voiding symptoms seem to be more prevalent whereas storage symptoms like urgency

and nocturia are more bothersome [19]. In a longitudinal study of 6439 men with BPH managed with watchful waiting or pharmacotherapy, nearly 50 % reported that their urinary problems were associated with physical discomfort and worry about their health. Bothersomeness was reported by 60 % and 26% reported that a urinary problem kept them from performing their usual activities [41].

In a study of 125 men with LUTS, factors related to bother were studied. The results showed that bother reflects men's overall distress of having LUTS. Bother appears to be related to symptom severity, social limitation, self-perception and the impact of LUTS, furthermore social anxiety and embarrassment strongly relate to bother [12].

2.2.2. Health related quality of life

There is no overall accepted definition of the concept health related quality of life (HRQOL). The concept is subjective and multi-dimensional, and can be seen as a dimension of the wider quality of life concept. HRQOL can be defined as "optimum levels of mental and physical role and social functioning including relationships, and perceptions of health, fitness, life satisfaction and wellbeing" [40]. This is the clear difference between HRQOL and the QOL concept, which include adequacy of housing and income and perceptions of immediate environment.

Further, a concept of HRQOL must rest on a on a concept of quality of life as well as of a concept of health. The health concept can bee seen from different perspectives. From a medical perceptive it is seen as freedom from disease and abnormalities and from a humanistic view it includes optimal autonomy, self-mastery and positive perception of life. In a sociological perceptive health can be described from the possession of acceptable levels of physical and mental condition in order to perform a social role in the society [40].

A measure whose aim is to assess HRQOL is often referred to as a broad measure of health status and has a generic scale. The limitation of generic measures is that they are unable to identify the condition specific aspects of a disease and therefore it requires a disease specific measurement to detect clinical changes. Measuring HRQOL can be used to study the conditions´ impact on the patients' emotional and physical functioning and lifestyle and to evaluate treatment outcome [39].

Results from studies assessing the HRQOL showed that men with moderate and severe LUTS reported a poorer HRQOL in the mental health, vitality, emotional functioning and physical functioning domains [42-44] of the 36-item Short Form (SF-36) [45].

2.2.3. Well-being

A concept, which is close to that of QOL and HRQOL is the concept of well-being. There is no overall definition of this concept which can be understood as the positive self-evaluation of the individual's circumstances in life. The concept consists of dimensions like self-esteem, happiness and morale, and comprises more than the absence of physical or mental problems [39].

2.3. Self-care

Self-care is a multidimensional concept, which can be interpreted in different ways. Self-care can be seen as the basic form of care that interacts with the healthcare system. There are several models for self-care, of which Orem's model is one [46]. In this model self-care is the practice of activities that individuals perform and initiate for themselves in order to maintaining life, wellbeing and health. Orem describes "self" as the totality of an individual, including physical, physiological and spiritual needs. "Care" as the totality of the activities an individual initiates to maintain life. Caring for oneself requires the initiation of a complex series of behaviours necessitating a personal approach to self-care. People who have an illness or a disease may have a limited ability

to meet their self-care needs [46]. According to Orem there are three systems of delivery of care, which will be briefly described. The wholly compensatory care is when the patient is unable to engage in any form of action. In the partly compensatory system, the role is to compensate and assist for any self-care limitation a patient may have but the patients is involved in his own care in terms of decision-making and action. For example a patient with an indwelling catheter who needs to learn the technical aspects and the lifestyle changes with this condition. In the third or the supportive /educative system the action is to perform self-care measurements together with the patient, to be supportive and educative and teach the patient to adapt to his illness or disease. According to Orem's theory, partners and next of kin play an important role and are involved in the care of the patient [46].

2.4. Partner

2.4.1. Partner specific quality of life

In papers II and IV, the aims were to determine the impact the men's urinary symptoms have on their partners' specific quality of life. The principle of a scale to assess the partners specific QOL is the same as for scales measuring disease specific QOL. The scale has to be clinically and socially significant in relation to the specific condition of interest, in this case the men's urinary symptoms. There is little knowledge how the men's urinary problems affect the specific QOL of their partners. The studies are based on small samples and few studies have been based on validated and reliability-tested assessments.

In a population study, men aged 50-79 yrs with moderate to severe symptoms with an enlarged prostate (n=419) and their partners (n=135) experienced relationship strains like lack of physical intimacy and lack of communication [47]. Shvartzman et al. [48] telephone interviewed 215 partners of men with prostatic symptoms and found that in

86 % of the cases, the husbands' urinary symptoms had consequences on the partners' daily routines, social relationships, sexual lives and QOL. Forty-six percent of the partners reported regular awakenings, and two-thirds of them were awake 2-4 times a night. Similar results were found in a questionnaire study of 50 partners of patients with BPH waiting for surgical treatment [49]. However, the severity of the patients' symptoms was not always related to the problems reported by the partners [49]. Sells et al. [50] have developed a questionnaire to assess the specific QOL of the partners of patients with benign prostatic enlargement (BPE), and found that sleep, sex life and fear of cancer affected them most. The correlation to the severity of the husbands´ urinary symptoms was significant. There was also a significant correlation with the vitality and mental health domains in the SF-36 [50].

2.5. Inguinal hernia

Inguinal hernia is a common condition and about 25% of the male population is expected to suffer from hernia during a lifetime, with a higher incidence among the newborn, young adult and elderly men [3,51]. Inguinal hernia may present with inguinal pain, a visible or palpable lump or by more vague symptoms resulting from pressure on an organ that has become pinched within the hernia [3]. The diagnosis of inguinal hernia is performed by a physical examination [52]. The treatment of inguinal hernia is performed with surgical repair. However, the most effective method for an inguinal hernia repair is not clearly defined [51]. Inguinal hernia research has focused on its recurrence rates, costs, complications and the post-surgical pain resulting from different surgical techniques [53]. However, less is known about HRQOL, sleep and sleep disturbances related to the condition. Bitzer et al. [54] studied post-surgical pain in 342 patients. Before surgery, the SF-36 subscales, physical functioning, bodily pain and

physical role limitations were domains that most affected the patients. Mathur et al. [55] found similar results in 106 patients waiting for hernia repair.

2.6. Sleep

2.6.1. Prevalence

Epidemiological studies indicate that 40 -70 % of the population ≥65 yr suffers from chronic sleep disturbances [56]. The most common sleep complaint is frequent nocturnal awakenings, followed by difficulties falling asleep and early awakenings [57]. In a cross-sectional epidemiological study of 1485 females and males aged 50-93 yr, females reported a significantly poorer quality of sleep, more night-time awakenings, less napping and more use of sedative-hypnotic drugs compared to the males [56]. In a Swedish study, the prevalence of too little sleep was 13 % in men aged 30-69 yrs [59]. Men aged between 65-79 yrs with hypertension, angina, cardiac disease, diabetes, joint pain and depression reported a higher prevalence of insomnia [58].

2.6.2. Definition of sleep

There is no overall definition on how to define sleep. However, it is evident that sleep is an active process that relates to physiological, behavioural and psychological changes. From a behavioural perspective, Carskadon and Dements [60] define sleep as:

"a reversible behavioural state of perceptual disengagement from and unresponsiveness to the environment.… Sleep is usually (but not necessarily) accompanied by postural recumbancy, quiescence, closed eyes, and all the other indicators one commonly associates with sleeping."

Guyton [61 p 677] defines wakefulness as:

"activity in the brain directed into appropriate channels to give the person a sense of conscious awareness"

2.6.3. The importance of sleep

The reasons for sleep are not fully understood but appear to be a very important for maintaining optimal physical and mental functioning during wakefulness. The quantity and quality of sleep are main factors for physical and mental wellbeing and have great importance for the individual's daytime function [62].

2.6.4. Sleep architecture and mechanisms regulating sleep

During the night, there are stages of two types of sleep that alternate with each other, the slow-wave sleep and the rapid eve movement sleep (REM sleep) [61]. The progression of stages across the night is called the "sleep architecture" and consists of repetitive changing "sleep cycles" each lasting for 90-120 minutes. Sleep in adults lasts approximately eight hours, although this varies among individuals [62]. In slow-wave sleep, the brainwaves are very strong and of low frequency. Most sleep during the night is of the slow–wave type and is also referred to as deep sleep. Slow- wave sleep is very restful and predominates during the first third of the night and is an important factor for the recovery. The slow-wave sleep is also called "dreamless sleep" and although dreams and sometimes nightmares can occur they are usually not remembered. During REM sleep the eyes undergo rapid movements despite the fact that the person is still asleep. REM- sleep predominates in the last half of the night. This type of sleep is not so restful, and is usually associated with vivid dreaming. The dreams that occur in the REM sleep are often associated with bodily muscle activity, unlike the dreaming in the slow-wave sleep [61]. Overall, REM sleep accounts for 20-25% of "normal" sleep time while the slow-wave sleep represents about 75-80 % of the sleep [62].

With age, sleep changes in duration, fragmentation, depth [57] and sleep efficiency decreases [62].

Wakefulness and sleep are regulated by two independent and basic mechanisms; the 24-hour circadian rhythm or the biological clock and the homeostatic drive. The circadian rhythm mechanism is influenced by light and regulates the fact that we get sleepy at night and are active during the day when its light. Further, it regulates the body temperature. Increasing sleepiness leads to a lower body temperature and when its time to wake up in the morning, the body temperature increases [62]. The homeostatic sleep drive is determined by the amount of being awake and being asleep. A reduction or an increase in sleep time can modify the homeostatic drive. Sleep deprivation for example can result in higher cortisol levels, an increased thyroid activity and a catecholamine turnover, which may lead to individual's becoming more irritable [62].

2.6.5. Sleep disorders and insomnia

Problems that can be associated with sleep quality and quantity and closely associated conditions with the sleep cycle, or the physiological mechanisms of sleep, are referred to as sleep disorders [63]. Insomnia is the most commonly reported complaint in the general population and its prevalence varies between 2 and 48 % depending on different definitions [64,66].

2.6.6. Insomnia classifications and definitions

The two main classification systems for diagnosing sleep disorders are the Classification of mental and Behavioural Disorders (WHO1993); the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) and American Psychiatric Association 1994) and the International Classification of Sleep Disorders (ICSD-2); American Sleep Disorders Association2005) [63,67]. According to these systems, there is a distinction between primary and secondary insomnia. In secondary insomnia, the sleep disturbance is etiologically linked to an underlying condition, a medical illness, a mental disorder or arises from use, abuse, or exposure to certain substances, whereas

primary insomnia is seen as an independent disorder. Insomnia can also be classified

according to duration; a situational/ acute insomnia (lasting a few days), short

term/subacute insomnia (one and four weeks) and persistent insomnia (>1 month) [68].

Insomnia can be defined either broadly or narrowly. From a broad perspective, insomnia

can be defined as a sleep-wake disorder wherein sleep-specific insomnia symptoms are

associated with significant waking distress or impairment and depending on the

insomnia disorder, or other specific symptoms [65].

2.6.7. Insomnia indictors, symptoms, complaint and features

Table 4. Insomnia indicators, symptoms, complaint and features

Symptoms	Complaints and features
Falling asleep and maintaining sleep	Amount of time required to fall a sleep, duration of awakenings, a latency to sleep onset and /or time awake after sleep, a wakening occurring earlier than desired, an inability to back to sleep in relation to frequency.
Tiredness/fatigue	Daytime consequences with excessive daytime sleepiness, a mental and physical fatigue. More common among patients with a secondary insomnia.
Psychological factors	Anxiety and/ or depression, sleep anticipatory anxiety of not being able to sleep, excessive worry about lack of sleep and its potential consequences.
Neuropsychological factors	Cognitive and psychomotor performance, impairment of mental abilities involving attention, concentration and memory, muscle stiffness and increased risk for infections.

2.6.8. Sleep quality and sleep efficiency

Sleep quality is a subjective and complex phenomenon that is difficult to define and can

be described as the individual's evaluation of his sleep. The exact aspects that are

included in the concept and its relative importance vary from individual to individual

[69]. The sleep quality is logically poorer in individuals with sleep disturbances and

insomnia. The sleep efficiency (SE%) is another term of importance for the sleep and is

defined as the percent of time in bed spent asleep [68].

2.6.9. Predisposing factors for insomnia

Sleep patterns and the effects of sleep disturbance seem to be genetically regulated [70].

Age and sex are important factors since studies show that females and older people are

predisposed to insomnia [62]. Co-morbidities are important, as sleep disturbances are

associated sometimes causally with e.g. cardiovascular diseases like hypertension, angina pectoris and cardiac insufficiency or a mental disorder [29,68].

Personality factors that influence the effects can for example consist of an individual's coping strategies for stress, and practices the individual can exercise. These behaviours can be classified into two categories: practices that produce increased arousal and practices that are inconsistent with the principles of sleep organization. Examples of the latter are frequent daytime napping, a routine use of products like alcohol and caffeine in the period preceding bedtime, frequent use of the bed for activities other than napping and failure to maintain a comfortable sleep environment [67].

2.6.10. Methods for assessing sleep

There are several well-established objective and subjective methods both characterizing sleep and insomnia symptoms. Objective methods are polysomnography (PSG), which is an instrumental registration of the sleep and are primarily used for screening and quantification of sleep disturbances, and actigraphy, a registration of body movements and circadian rhythm, often combined with a sleep diary. Subjective methods are descriptions of the sleep by the patient or an observer, using questionnaires with subjective rating scales or visual analogue scales, sleep diaries, interviews and by observations [63].

2.6.11. Sleep in men with LUTS

Little is known about sleep and sleep disturbances in men with LUTS, and few studies have been based on established definitions for sleep and sleep assessments [71-73]. Nocturia is an important cause of sleep disruption in men ≥50 years [56] leading to deterioration in the quality of life (QOL) [19,29]. In 1424 individuals aged 55-84 yrs (601 men), the prevalence of nocturia as a self- perceived cause of poor sleep was 53% [74]. In a cross sectional study of 502 outpatients aged > 60 yrs with LUTS/BPH the

prevalence of nocturia was 83 % as defined as ≥ two nocturnal voidnings was 83 % [75]. Surgical treatment and its impact on nocturia were studied in men with LUTS/benign prostatic obstruction (BPO). Before intervention, the patients reported poor sleep quality, short sleep duration and low sleep efficiency with increased daytime sleepiness [76].

3. AIMS

3.1. Overall aims

The overall aim was to determine how lower urinary tract symptoms suggestive of benign prostatic obstruction (BPO) affect sleep, health related quality of life and disease specific quality of life in men, and how the men's urinary symptoms affect their partners. Based on this knowledge a second aim is to improve the management of men with LUTS/BPO with regard to diagnosis, treatment decision, counselling and evaluation of treatment.

3.2. Specific aims

-To develop and reliability test an instrument to evaluate incontinence, the Linköping Incontinence Questionnaire (LIQ) in men with LUTS, and to translate and test the reliability of the International Prostate Symptom Score (IPSS), including the bother question, the Symptom Problem Index (SPI) and the BPH Impact Index (BII).

-To describe self-reported urinary symptoms and perceived bother, including disease-specific quality of life in patients with symptomatic benign prostatic obstruction (BPO) and to identify explanatory factors for the patients' disease specific quality of life before and after intervention.

-To translate and test the reliability and the responsiveness of a Swedish version of a partner specific quality of life questionnaire for partners of BPE/BPO patients.

-To evaluate the impact the patients' urinary symptoms have on their partners' specific quality of life.

-To determine whether there are significant differences in the quantity and quality of sleep, including sleep efficiency and insomnia, and health related quality of life between men with LUTS, men from the population and men with inguinal hernia, and to identify factors related to the sleep quality and sleep efficiency.

-To determine whether there are significant differences in sleep, partner specific and health related quality of life between partners of men with LUTS suggestive of BPO and partners of men from the population. A second aim was to identify factors related to the specific quality of life of partners of men with LUTS.

4. SUBJECTS AND METHODS

Table 5. Overview of the Papers (I-IV)

Papers	Aims	Designs, methods	Subjects
I	To develop, translate and reliability test an instrument to evaluate incontinence, the Linköping Incontinence Questionnaire (LIQ)	Descriptive design with a one-group pre-test post test Translation by a native British translator. Self-administered questionnaire	Reliability test in 122 patients The response rate was 96 %.
I	To translate and test the reliability of the International Prostate Symptom Score (IPSS) including the bother question, the Symptom Problem Index, (SPI) and the BPH[a] Impact Index (BII).	Descriptive design with a one-group pre-test post test. Translation in the ethnographic mode. Self-administered questionnaire	Reliability test in 122 patients. The response rate was 96 %
I	To describe self-reported urinary symptoms and perceived bother, including disease-specific quality of life (QOL) in patients with symptomatic benign prostatic obstruction (BPO) before and after intervention and to identify factors, which predict the patients' disease specific quality of life before and after intervention.	Descriptive design with a one-group pre-test post test. Self-administered questionnaires	572 consecutively treated patients The response rate was 79 %.
II	To translate and test the reliability and the responsiveness of a Swedish version of a partner specific quality of life questionnaire for BPE[b]/BPO[c] patients.	Descriptive design with a one-group pre-test post test. Translation in the ethno-graphic mode. Self-administered questionnaire	51 partners to patients with BPO[c] waiting for TURP[d]. The response rate was 67%
II	To evaluate the impact the patients' urinary symptoms have on their partners' specific quality of life.	Descriptive design with a one-group pre-test post test. Self-administered questionnaires	51 partners to patients with BPO[c] answered questionnaires before and after TURP[d] The response rate was 67%.
III	To determine whether there are significant differences in the quantity and quality of sleep, including sleep efficiency and insomnia, and health related quality of life between men with LUTS[e], men from the population and men with inguinal hernia. A second aim was to identify factors related to their sleep quality and sleep efficiency	Descriptive and comparative design, three groups. Self-administered questionnaires	239 men with LUTS[e], control groups; 213 men from the population and 200 men with inguinal hernia. The response rate was 46, 38 and 38%, respectively.
IV	To determine whether there are significant differences in sleep, partner specific and health related quality of life between partners of men with LUTS[e], with partners of men from the population. A second aim was to identify factors related to the specific quality of life in partners of men with LUTS and the sleep efficiency.	Descriptive and comparative design, two groups. Self-administered questionnaires	126 partners to men with LUTS[e], 131 partners to men from the population. The response rate was 61 % and 78 %, respectively.

[a] Benign Prostatic Hyperplasia (BPH), [b]Benign Prostatic Enlargement (BPE),[c]Benign Prostatic obstruction (BPO) [d]TransUrethral Resection of the Prostate, [e]Lower Urinary Tract Symptoms (LUTS)

4.1 Subjects

The subjects included in the four studies were all men and the partners of men living in

the catchment areas of a university hospital and two general hospitals in the Southeast

Region of Sweden. These hospitals are the only ones within these geographical areas

and it is very uncommon to refer patients to hospitals in other areas. In papers III-IV,

both men with LUTS and men from the population and their partners answered

questionnaires. The couples were requested to answer the questionnaires separately. In

the following, LUTS is synonymous with LUTS suggestive of BPO.

4.1.1. Men
In paper I, the subjects consisted of two groups of consecutive men. The reliability tests

of the instruments were performed on 127 consecutive patients without an indwelling

catheter or clean intermittent catheterisation (CIC), who had been either referred to the

urological outpatients' clinic at a university hospital because of LUTS or were waiting

for TURP because of BPO. Seven patients were excluded, and finally, 122 patients were

studied. The study of urinary symptoms and disease specific quality of life were

performed on 720 men, aged between 45 yr and 94 yr who underwent interventions for

BPO. The patients included in the study had their treatment decision based on the

diagnosis of symptomatic BPO and they had answered questionnaires. One hundred and

forty-six patients did not answer the questionnaires. Finally, 572 patients were studied,

and of these, 123 had an indwelling catheter or used CIC.

Paper III was performed on 507men, who had been referred to the urological

outpatients' clinics. Inclusion criteria were age 45-80 yr, LUTS and that the patient

accepted the referral to the clinic. Exclusion criteria were living outside the catchment

area of the hospitals, indwelling catheter or CIC, suspicion of prostate or bladder cancer,

neurological diseases that might affect micturition, such as multiple sclerosis or diabetes

with neuropathies, or difficulties in understanding written information. Of them, 268

men declined to participate or did not answer the reminders. Finally 239 men with LUTS were included.

Two control groups were included, men from the general population and an additional group, men with inguinal hernia. A hypothesis was that the presence of any disease might affect sleep or HRQOL in an unspecific way, which was the reason why men with inguinal hernia were included. The two control groups had the same exclusion criteria as the men with LUTS. The population group were 564 randomly selected men, aged 45-80 yr. The sample was stratified according to age and geographical region to match the men with LUTS and it was obtained from the national population register, the SPAR database. Three hundred and fifty-one men declined to participate or did not answer the reminders. Seven men were excluded and finally 213 men were included. The inguinal hernia group consisted of 532 men, aged 45-80 yr, referred to the surgical outpatients clinic at a university hospital for a surgical hernia repair. Of these, 332 men declined to participate or did not answer the reminders. Finally, 200 men waiting for elective surgical hernia repair were studied.

4.1.2. Partners

The subjects of paper II were partners to patients who were aged 53 to 83 yr, without indwelling catherer/CIC on the waiting list for a transurethral resection of the prostate (TURP) at a university hospital. The reliability test was performed on the partners of 102 patients scheduled for a TURP. Twenty-six patients did not have a partner, had an indwelling catheter or had already had their TURP and thus 76 partners were included. Nineteen partners declined to participate, and five did not answer the reminders. One partner did not answer the re-test. Finally, 51 partners completed the study.

The responsiveness of the questionnaire and the evaluation of the partner's specific quality of life were performed on partners to 76 patients who visited the admission

clinic. Twenty-one partners declined to participate, one did not answer the reminders and three partners did not answer the follow up. Finally, 51 partners completed the study. Paper IV was conducted on the partners of 507 men aged 45-80 yr with LUTS and who had accepted the referral to the urological outpatients' clinic. Two hundred and sixty eight men declined to participate or did not answer the reminders and their partners were not eligible for the study. Thirty-two men did not have a partner. Thus 207 partners were included in the study. Of these, 59 partners declined to participate and 22 partners did not answer the reminders. Finally, 126 partners of men with LUTS were included.

A control group of partners to men from the general population were included. This group consisted of 564 randomly selected men aged 45-80 yr. The sample was obtained from the national population register, the SPAR database, and the men were stratified according to age and geographical region to match the men with LUTS. Three hundred and fifty-one men either declined to participate or did not answer the reminders. Seven men were excluded because of prostate disease, prostate cancer or inguinal hernia and their partners were not eligible for the study. Forty-four men did not have a partner. Thus 169 partners were included in the study. Of these, 21 partners declined to participate and 17 partners did not answer the reminder. Finally, 131 partners of men from the population were included in the study.

4.2. Design

In papers I and II, a descriptive design with a pre-test and post-test was used and in papers III-IV the design was descriptive and comparative (Table 5).

4.3. Procedure

4.3.1. Translation of the questionnaires

In paper I, the Linköping Incontinence questionnaire (LIQ) [77] was translated to English by a native British professional translator. The translations of the IPSS [78], SPI, BII [79] and the partner specific QOL [50] questionnaires and the bother question in the IPSS [78] into Swedish in papers I and II were performed in the ethnographic mode to maintain meaning and cultural content [80]. In the first step, the questionnaires were translated from the original language to Swedish and in the second step the questionnaire were back translated to the original language. Finally, the versions were compared and the differences were discussed until consensus was reached [77,81]. The independent back translations of the partner specific QOL questionnaire were performed by a Swedish speaking Native American who is a PhD in Scandinavian languages, a native English physician, PhD, who grew up in Sweden and a native Swedish technical writer with an M.A. degree in languages and education [81] (Paper II).

One native American and a native Englishman, both Swedish speaking, and a native Swedish urologist with good knowledge of the English language performed the three independent back translations of the other questionnaires. The translations corresponded well with the original versions [77] (Paper I).

With regard to the partner specific QOL questionnaire, one of the translators preferred to use a time scale instead of the quantitative original scale for the response alternatives and that some synonyms were used. An exception from the procedure described above is that the word husband has been replaced with husband/partner in the Swedish version [81] (Paper II).

The questionnaire in paper II describes aspects of the partner's specific quality of life. To identify these aspects, the authors and three independent professionals, one psychiatrist with a professor's degree and two registered nurses (RN), both with a PhD degree, separately identified one aspect for each question. The aspect proposed according to the consensus of the authors agreed best with the issue concerned was selected [81].

4.3.2. Men
The treatment decision was based on the diagnosis of symptomatic BPO, as assessed by a urologist according to a modified model of Hald [82], i.e. the patients were required to have bothersome symptoms, low maximum flow rate and an enlarged prostate. The men underwent digital rectal examination, their prostate size was estimated by transrectal ultrasound or cystoscopy, they underwent uroflowmetry, timed micturition [83-84] and urine analysis, a frequency volume chart was taken over 48 hours and they answered the questionnaires. Patients with an uncertain diagnosis also underwent pressure-flow examination (Paper I-II).

In paper III-IV, the patient's urologist decided which investigations should be performed.

In paper I, the patients without an indwelling catheter/CIC answered the IPSS, including the bother question [78], the SPI, the BII [79] and the LIQ [77] questionnaires, and patients with an indwelling catheter/CIC answered the BII and the bother question in the IPSS. The patients filled in all the questionnaires and micturition charts both before their visit to the outpatient clinic and again six months after intervention.

The treatment interventions were divided into three groups: transurethral incision of the prostate (TUIP) and transurethral microwave thermotherapy (TUMT) were the TUIP/TUMT group, α-adrenergic receptor antagonists and 5α-reductase inhibitors were the drug therapy group, and transurethral resection of the prostate (TURP) and open

surgery were the surgery group. To study age differences, the patients were divided into four age groups: 40-59 yrs, 60-69 yrs, 70-79 yrs and ≥80 yrs.

In the reliability study in paper I, the stability of the IPSS, including the bother question, the SPI, the BII and the LIQ instruments were tested with a test–retest (5 weeks) [80], i.e. the patients answered the questionnaires twice before their visit to the outpatient clinic or before their TURP.

The men studied in paper III, were referred to the urological outpatients' clinic and all referral letters had been read by the same urologist. Inclusion and exclusion criteria are described in 4.1.1 Subjects. The exclusion criterion for suspicion of bladder cancer was usually macroscopic haematuria. Prostate cancer was suspected in cases with high Prostate Specific Antigen (PSA)-values or a suspicious finding at digital rectal examination. When the study was performed, age-related reference values were used. This means that patients aged ≥65 yr with a PSA-value between 4.0 and 6.5 μg/l may have been included. Patients with unknown PSA-values were included when there was no suspicion of malignancy mentioned in the referral letter.

The men with LUTS and the two control groups filled in a package of structured self-administered questionnaires containing questions on demography, co-morbidity, sleep, sexuality and HRQOL. Furthermore, the men with LUTS answered the IPSS, the SPI, the BII, the LIQ questionnaires and the bother question in the IPSS before their consultations at the outpatients' clinic. Two reminders about the questionnaires were sent over a four-week period.

The men from the population received a mailed questionnaire with information about the study. One reminder about the questionnaire was sent over a four-week period. Men with inguinal hernia filled in the questionnaires before their consultation at the surgical

outpatients' clinic and two reminders about the questionnaires were sent over a four-week period.

4.3.3. Partners

Paper II assesses the reliability of the partner specific quality of life questionnaire [50] and was tested with a test–retest (5 weeks) [80]. The patients received a letter containing the questionnaire and information about the study, which they were asked to pass on to their partner. The questionnaires were answered by the partners before the patients' TURPs. At the retest, the questionnaires were mailed directly to the partners. The partners were encouraged to give feedback about the questionnaire.

To test the questionnaire's responsiveness and to evaluate the partners' specific quality of life, the partners answered the partner specific questionnaire both before and three months after the patients' TURPs. At the visit in the admission clinic 1-2 weeks before the patients TURPs, the men were asked to take a sealed letter with information about the study and the first questionnaire to their partners. Three months after the patients TURPs, the questionnaires were sent by mail to the partners. Two reminders were sent within four weeks to the partners in the two groups.

In paper IV a package of structured, self-administered questionnaires about demography, co-morbidity, sleep, sexuality, HRQOL and specific quality of life were answered by the partners to men with LUTS and partners to men from the population. Together with the letters giving the men their consultation time the partners received a sealed envelope containing information about the study and the questionnaires. The partners answered the questionnaires before their men's visit to the outpatients' clinic. Partners of men from the population received the questionnaire in a sealed envelope from their men.

4.4. Methods

To cover the aims of the study described in this thesis, a set of questionnaires has been used. Disease specific assessments have been combined with a generic HRQOL questionnaire together with domain-specific assessments to assess urinary symptoms and sleep.

Table 6. Measurements used in Paper I-IV.

Questionnaires	Measures	Scales No items Tot score range	Papers	Validity and reliability tested
International Prostate Symptom Score (IPSS) [78]	Self- reported urinary symptoms	0-5 7 0-35	I and III	Validity [78] and reliability [77,78] tested
Linköping Incontinence questionnaire (LIQ) [77]	Self- reported urinary incontinence	0-5 and three yes/no 1+3 0-5	I and III	Reliability tested [77]
Symptom Problem Index (SPI) [79]	Disease- specific quality of life	0-4 7 0-28	I and III	Validity [79] and reliability [77,79] tested
Bother question in IPSS [78]	Disease- specific quality of life	0-6 1 0-6	I and III	Validity [78] and reliability [77,78] tested
BPH[a] Impact Index (BII) [79]	Disease- specific quality of life	0-3 or 0-4 4 0-13	I and III	Validity [79] and reliability [77,79,] tested
Short form -36 (SF-36)[c] [45]	Health related quality of life	Eight domains 0-100	III and IV	Validity and reliability tested [45].
Partner specific QOL questionnaire [50]	Specific quality of life	0-4 or 0-6 9 0-38	II and IV	Validity [50] and reliability [81] tested
Uppsala Sleep Inventory (USI)[b] [58, 87]	Quantity and quality of sleep	1-5 7	III and IV	Validity [58, 87] and reliability tested [89]
Basic Nordic Sleep questionnaire (BNSQ) [b] [88]	Quantity and quality of sleep	1-5 18	III and IV	Validity [88] and reliability tested [89]

[a]BPH= Benign Prostatic Hyperplasia [b]more details in the text

4.4.1 Urinary symptoms

Occurrence and frequency of urinary symptoms were assessed with the International Prostatic Symptom Score (IPSS) [78] (Table 6). The symptoms were classified as mild, score 0-7, moderate, score 8-19 and severe, score 20-35 [78].

Urinary incontinence was assessed with the Linköping Incontinence Questionnaire (LIQ) [77]. The frequency and severity of UI are combined into a score and three additional questions were used to classify the type of incontinence as continuous, stress or urgency incontinence (Table 6).

4.4.2. Quality of Life

In this thesis, the QOL concept is based on the World Health Organization (WHO) definition " an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [85].

4.4.2.1. Disease specific quality of life

The frequency and the severity of urinary symptoms were measured with the Symptom Problem Index (SPI), [79], the BPH Impact Index (BII) [79] and the bother question in the IPSS [78] (Table 6).

4.4.2.2. Partners specific quality of life

Aspects of the partners' specific QOL were assessed with the partner specific QOL questionnaire by Sells et al. [50]. Psychometrical tests showed that it was accepted and seen to have relevance among partners of men with BPE [50] (Table 6).

4.4.2.3. Health related quality of life

HRQOL was assessed with the generic 36-item Short Form (SF-36) [45] The questionnaire comprises of eight domains; physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), mental health (MH) and role limitations due to emotional problems (RE) as well as two summary scores, one with a physical component (PCS) and the other with a mental component (MCS). Each of the eight domains is transformed to scores from 0 to 100, with a higher score indicating a better

HRQOL (Table 6). The questionnaire was analysed in accordance with the instruction manual [86].

4.4.3. Quantity and quality of sleep

The quantity and quality of sleep were assessed by six questions from the Uppsala Sleep Inventory (USI) [58,87] and 19 questions from The Basic Nordic Sleep Questionnaire (BNSQ) [88]. The questions refer to the past three months, with regard to sleep onset latency (SOL), time of going to bed/waking up, nocturnal sleep duration and pharmacological therapy. The severity of sleeping difficulties, nocturnal and early morning awakenings, daytime symptoms, daytime napping and snoring was assessed on a five-point scale, from 1 (never) to 5 (every day or almost every day). Sleep quality was defined as "how have you slept the past three months" rated on a five-point scale from 1 (good) to 5 (bad) [58,88]. Sleep efficiency (SE %) was calculated as the ratio of reported nocturnal sleep duration and time spent in bed multiplied by 100. A SE % of ≥85 % is considered to be satisfactory [68]. Clinical insomnia was defined as difficulties falling asleep three to five days or more a week, sleep-onset latency (SOL) or wakefulness after sleep onset of more than 30 minutes, nocturnal awakenings more than three nights a week, awakenings five times or more a night or early morning awakenings more than three times a week combined with one or more daytime symptoms. The requirement for daytime symptoms was that the subject had excessive morning sleepiness, daytime sleepiness, physical tiredness or non-restorative sleep three to five days or more a week [65,68]. Using a narrow definition, insomnia denotes a set of sleep-specific symptoms in an individual who has adequate circumstances and opportunity for sleep [65] (Table 6).

4.4.4. Demographic and co-morbidity variables

Papers III-IV report the answers given by the subjects to questions about age, marital status/ residential status, bed partners, occupational status, Body Mass Index (BMI), fluid intake in the evening, number of nocturnal micturitions and pharmacological therapy. Dichotomous questions (present/absent) were answered for the following diagnosed diseases: high blood pressure, obstructive/asthma, coronary heart disease, diabetes, psychiatric condition, joint disease/ pain, gastro-intestinal disease, anaemia, urological disease and previous urological disease.

4.5 Statistical methods

Table 7. Description of statistical methods in paper I-IV.

Statistical methods	Paper I	Paper II	Paper III	Paper IV
Descriptive statistics				
Medians (Md), quartiles (Q_1-Q_3) frequencies	x	x	x	x
Wilcoxon signed rank test				
Changes within groups	x	x		
Responsiveness		x		
Two-way X^2 test			x	x
Difference between groups, nominal data				
Kruskal-Wallis test	x		x	x
Difference between >2 groups, ordinal data				
Mann-Whitney U-test	x		x	x
Difference between 2 groups, ordinal data				
Correlation analysis				
Spearman's rank correlation coefficient (r_s)		x	x	
Reliability tests				
Spearman's rank correlation coefficient (r_s) for stability testing	x	x		
Internal consistency with Cronbach's α	x	x		
Binary logistic regression analysis				
Forward Wald	x		x	x
Power analysis			x	x
Significance level	p <0.05	p <0.05	p <0.05	p <0.05
Analysis performed SPSS[a.] Inc, Chicago, IL, USA				
SPSS version	12.0.1	12.0.1	15.0	15.0

[a.] Statistical Package for the Social Sciences

4.5.1. Binary logistic regression

Table 8. Description of the logistic regression analysis in paper I and II-IV.

Paper	Aims	Dependent variable	Independent variables
I	Identify factors for a high disease specific QOL	Bother question in the IPSS[a] (score 0-6) before intervention Dichotomised: 1 (score 0,1,2,3,) and 0 (score 4,5,6)	Age and single items of the IPSS[a], the SPI[b] and the LIQ[c] instruments before intervention
I	Identify factors for a high disease specific QOL	Bother question in the IPSS[a] (score 0-6) after intervention Dichotomised: 1 (score: 0,1) and 0 (score: 2,3,4,5,6).	Age, intervention groups, catheter/clean intermittent catheterisation (CIC), diagnosis of prostate cancer and single items in the IPSS[a], the SPI[b] and the LIQ[c] after intervention
I	Identify factors of importance for the disease specific QOL after intervention	Bother question in the IPSS[a] (score 0-6) after intervention Dichotomised: 1 (score: 0,1) and 0 (score: 2,3,4,5,6).	Age, intervention groups and single items in the IPSS[a], the SPI[b]; the BII[d] and the LIQ[c] before intervention
III	Identify factors related to the sleep quality and sleep efficiency	Sleep quality question in the BNSQ (score 1-5) Dichotomised: 0 (score: 1, 2) and 1 (score: 3, 4, 5) Sleep efficiency Dichotomised: 0 (≥85%) and 1 (<85%)	The study groups (categorical, reference= population group), age, occupational status, (categorical, reference= pensioners) bed partner, fluid intake evening, number of micturitions/night, single domains SF-36, high blood pressure, obstructive/asthma, coronary heart disease, diabetes, psychiatric condition, joint disease/pain, gastro-intestinal disease, urological disease and previous urological disease
IV	Identify factors related to the partner specific QOL and the sleep efficiency.	Overall question in the partner specific questionnaire (score 0-6) Dichotomised: 0 (scores 0,1,2,3) 1(score 4,5,6). Sleep efficiency is dichotomised: 0 (≥85%) and 1 (<85%)	Independent variables are the study groups, age, occupational status, bed partner (categorical), fluid intake evening, number of micturitions/night, high blood pressure, obstructive/asthma, coronary heart disease, diabetes, psychiatric condition, joint disease/ pain gastro-intestinal disease, anaemia, urological disease and previous urological disease. In the analysis of the specific QOL, sleep efficiency and the sleep quality question in the BNSQ questionnaire also were independent variables.

[a]IPSS =The International Prostate Symptom Score.[b] SPI=The Symptom Problem Index. [c] LIQ= The Linköping Incontinence Questionnaire [d] BII= The Benign Prostatic Hyperplasia Impact Index.
[e]The basic Nordic Sleep Questionnaire.
The dependent variable was dichotomised differently before (0 – 3 high and 4 – 6 low) and after intervention (0 - 1 high and 2 – 6 low).

4.6. Ethics

The Regional Research Ethics Committee at the Faculty of Health Sciences, Linköping University, approved the studies in papers I-IV (diary number 01-294 with additional approvals to changes in the study dated May 15, 2005; June 10, 2003; October 10, 2003 and diary number 1604 dated December 12, 2003).

These studies followed the ethical principles of autonomy, beneficence, justice and non-malfecance. First, in the letter enclosed with the questionnaires, information was given that participation was voluntary and could be interrupted at any time. If the responders declined to participate, they received information stated that these studies did not have any connections with the provision of health care was given. Information about the data collection was given and the responders were informed that all the questionnaires were kept safe and that the name of the responder was not known, since there only was a code on the questionnaire. The code list and names were kept separately by a third party. The responders were guaranteed that no one in the research team would be able to trace data on an individual basis.

Written informed consent was obtained from all responders. The aims of the study were clearly described as well as who would benefit from the results. The responders were given information about how to contact the investigators if they wanted more information about the studies. The principle of justice was applied, although responders who did not understand written information were excluded.

5. RESULTS

Detailed description of the results is given in each paper.

The questions concerning sexuality are not analysed in this thesis except the one question in the partner specific quality of life questionnaire.

5.1. External missing values

In paper I, 21 % (n= 720) of the patients did not answer the questionnaires. The oldest age group had the highest withdrawal rate, 37 % (n=109) compared to 14-21 % in the other age groups. The withdrawal rate was highest in the surgery group, 23 % (n=518), compared to 16 % (n=88) in the TUIP/TUMT group and 10 % (n=70) in the drug therapy group.

In paper III, the withdrawal rate was 54 % in the LUTS group (n= 507) and 62 % in both the population group (n=564) and in the hernia group (n=532. Within the LUTS group the withdrawal rate was 50 % at the university hospital, and 55 % and 61 % at the general hospitals. Within the population group the maximum difference between two geographical areas was 4.3 %.

In the LUTS group, men aged 65-75 yrs had a 5.8 % lower withdrawal rate than the other age groups. In the population group, the youngest age group, 45-60 yrs, had a 9.1-10.2 % higher withdrawal rate than the other age groups. In the hernia group, the men aged 75-80 yrs had a 10.2 % lower withdrawal rate and the group 45-60 yrs a 12.0 % higher withdrawal rate than the men aged 60-75 yrs. The age and geographical distributions in the LUTS and population groups were similar since sending out more questionnaires to the population group compensated a low response rate. The different withdrawal rates in the hernia group made this group older and the age was not significantly different from the other groups.

5.1.1. Internal missing values

In paper I, one missing value per instrument was replaced with the median value of the missing item [90]. Replaced missing values before and after intervention were: IPSS 21 and 27, SPI 12 and 18, and BII 10 and 13, respectively.

In paper II, the total internal missing values for the two partner groups and their two responses (n=204) were nine missing values for the question worry about operation and eight missing values for the question about sexual life. The other questions had one to three missing values.

In paper III, the total internal missing values per item were between 3 and 32 for the 653 men. For co-morbidity, the men were required to check yes and no boxes. A number of men only checked the yes boxes and the number of missing values and thus appears to be between 46 and 90. Some men with LUTS did not fill in the IPSS, the SPI and the BII questionnaires at all and missing values were between 24 and 34 (n=239).

In paper IV, the total internal missing values per item were between 1 and 11 for the 257 partners. For co-morbidity, the partners were required to check yes and no boxes. Some partners only checked the yes boxes and the number of missing values appears to be between 18 and 35 (n= 257). Twenty-three partners in the population group (n=131) did not answer the partner specific QOL questionnaire and referred to the fact that their husband/partner did not have urinary problems. In the LUTS group, four partners did not answer the questionnaire at all (n=126). Missing values per item were between 4 and 9 in total in the LUTS partners group (n=126) and between 23 and 33 in the population group (n=131).

5.2. Reliability and responsiveness

A questionnaire for evaluating incontinence (LIQ) was constructed, translated and reliability tested. The stability of the translated questionnaires, tested with the

Spearman's correlation coefficient (r_s) was 0.77 (LIQ), 0.79 (BII and the bother question in the IPSS), 0.82 (IPSS) and 0.84 for the SPI (p <0.001). The homogeneity was tested with Cronbach's α [91] and varied between 0.78 and 0.87. In the study of disease specific quality of life and in the reliability studies, the variation was 0.90 to 0.94 for the IPSS, the SPI and the BII instruments (Paper I).

The reliability test of the translated partner specific questionnaire showed a Spearman's rank correlation coefficient (r_s) between 0.59 and 0.86 for the nine questions. The Cronbach's α was found to be 0.80 in the two pooled partner groups (n=102). The questionnaire had an acceptable responsiveness except for the question worry about operation (Paper II).

The correlation analysis between the questions showed strong relations between compassion and worry about cancer and compassion and the overall specific QOL question. Weak correlations were seen between household activities and spare time activities and the overall specific QOL (Paper II).

5.3. Men

5.3.1. Urinary symptoms

The patients were divided into groups so that age differences could be studied. Before intervention men in the two youngest age groups (40-69) yrs scored higher for the IPSS and the SPI measurements. After intervention there were no significant differences between the age groups. Before intervention the median, Md and quartiles (Q_1-Q_3) values in men aged (60-69) yrs were 22 (17-27) for the IPSS, 19 (15-23) for the SPI, 8 (6-10) for the BII and 4 (3-5) for the bother question in the IPSS (n= 446) (Paper I).

In paper III, the figures in the LUTS group (Md age of 67 yrs) were slightly lower, 19 (13-26) for the IPSS, 16 (11-20) for the SPI, 7 (4-8) for the BII and 4 (3-4) for the

bother question in the IPSS. In the last group 9 % reported mild symptoms, 47 %
moderate and 44 % reported severe symptoms (n=216). Men with LUTS had a
significantly higher number of micturitions/night compared with the control groups.
The prevalence of urinary incontinence was found to be high both before and after
intervention, 46 % and 16%, respectively. Before intervention, 69 % (n=191) reported
urge incontinence, 4 % stress incontinence, 20 % mixed incontinence and 6% were
unclassifiable. After intervention, 16 % (n=532) reported UI; of whom 45 % (n=87)
reported urge incontinence, 16 % stress incontinence, 18 % mixed incontinence, 1 %
continuous incontinence and 20 % were unclassifiable (Paper I).

In paper III, the prevalence of UI was slightly lower, 37 % (n=207). Of the men 74 %
reported urge incontinence, 26 % stress incontinence and 8 % reported continuous
incontinence (n=80).

5.3.2. Disease specific quality of life

Patients with an indwelling catheter/CIC were significantly more impaired before
intervention and improved more after intervention compared to patients without an
indwelling catheter/CIC. Symptoms and disease specific QOL improved most in the
surgery group, intermediately in the TUIP/TUMT group and least in the drug therapy
group. In the regression analysis the bother of having frequency and weak urinary
stream before and after intervention were important factors for the disease specific
quality of life. Patients who were diagnosed with a prostate cancer had five times lower
odds ratio to have a good disease specific quality of life (score 0-1 bother question) after
intervention. The patients treated with drug therapy had seven times lower odds ratio of
having a good disease specific quality of life after intervention (Paper I).

5.3.3. Health related quality of life

The men with LUTS had a significantly impaired HRQOL compared to men in the population except for the bodily pain (BP) domain. Men with inguinal hernia reported poorer HRQOL in the physical functioning, physical role limitations and bodily pain domains than men in the population (Paper III).

5.3.4. Sleep quantity and quality

The men with LUTS had a significantly higher prevalence of insomnia (40 %) than men in the population (26 %) and men with a hernia (19 %). Further, in the LUTS group, men with insomnia had significantly more urinary problems than men without insomnia. The sleep quality was significantly correlated to the summed scores in the IPSS, the SPI, the BII questionnaires and the bother question in the IPSS questionnaire. The men with LUTS had a significantly lower sleep efficiency, (49 %), than men with hernia, (31 %) (Paper III).

Explanatory factors for a low sleep efficiency were high age, being employed and belonging to the LUTS group. Factors that explained a worse sleep quality, were many micturitions per night, a diagnosed joint disease/pain and a diagnosed psychiatric condition and belonging to the LUTS group. There were no significant differences in the sleep variables between the hernia group and the population (Paper III).

5.4.Partners

There were no significant differences in demography, co-morbidity and HRQOL between the two groups (Paper IV).

5.4.1. Specific quality of life

The partners were affected by the mens' urinary symptoms. Regarding the specific quality of life, compassion and worries about cancer and an operation were the aspects that affected most partners whereas spare time and household activities affected fewer

partners (Paper II and IV). Partners to men with LUTS were significantly more affected in all variables quantifying the specific QOL than partners from the population (Paper IV). Three months after the patients' TURPs the specific quality of life experienced by the partners had improved significantly (Paper II).

Being a partner to a man with LUTS was the only significant explanatory factor for a poor specific QOL (Paper IV).

5.4.2. Sleep quantity and quality

There were no significant differences between the two partner groups in the variables regarding the quantity and quality of sleep. Explanatory factor for low sleep efficiency were sharing bedroom (paper IV).

6. DISCUSSION

6.1. Methodological considerations

6.1.1. Design

6.1.1.1. External missing values

A limitation of the studies is that the withdrawal rate was rather high. There may be many reasons for this. For example, in papers III and IV there were many questions that took 30-45 minutes to answer and there were detailed questions about sexual life. In the case of paper III, the patients had a long wait from the referral to an appointment at the out-patients' clinic and patients at the general hospitals having a lower response rate which may have influenced the withdrawal rate.

6.1.1.2. Inclusion

In studies II and IV there was no way to directly include partners of men with LUTS and it was considered unethical to contact partners without the patients' permission. Because of this standpoint, the only way to include the partners was trough their husband/partners. All men, with or without a wife/partner, received the letter containing the questionnaire and information about the study, which they were asked to pass on to their partner. The men's positive or negative thoughts about the study may have played a role and affected the response rate. Thus the two partner groups in paper IV automatically became smaller than the corresponding patient and population groups. In the population group, the couple probably made a joint decision and when the man did not participate the partner was not eligible, which may explain the low withdrawal rate in this group.

A possible explanation to the low response rate in the control groups, especially in the men with inguinal hernia may be because of the wording in the information. In the letter, the men were informed that the first aim was not to study inguinal hernia and its

consequences on QOL. They were aware of being controls and not the target group, which may have caused the men to be less motivated to participate (Paper III).

6.1.2. Measurements

6.1.2.1. Urinary symptoms and disease specific quality of life

In these studies, we wanted to evaluate the men with LUTS more comprehensively and constructed a package of questions containing the IPSS including the bother question, the LIQ, the SPI and the BII questionnaires. There are several translations of the IPSS and its bother question into Swedish, of which only one has documented the translation method [92]. To our knowledge, the SPI and the BII questionnaires have not been translated to Swedish and therefore, in paper I, the questionnaires first were translated to maintain meaning and cultural content and then reliability tested.

The IPSS is a domain specific measurement and only grades the symptoms according to how often they occur and not according to their severity. It is therefore important to combine it with disease specific measurements like the SPI, the BII and the bother question in the IPSS questionnaire. The SPI measures the bother or distress of a symptom and thus considers both the frequency and the severity of the symptom. This is probably the reason why we found that more items from the SPI than from the IPSS were factors explaining the disease specific quality of life according to the logistic regression analysis. A high correlation between the items in the BII and the IPSS bother question were found since both measure disease specific quality of life. The BII has four items and therefore has a better possibility of capturing different aspects or domains of quality of life. Although the way in which patients answer the BII and the IPSS bother question is similarly, the impression is that the BII differentiates the patients better and we also found one more significant difference between the treatment groups in Paper I with the BII questionnaire.

There are several questionnaires to evaluate incontinence (DAN-PSS-1, The ICS-BPH and ICIQ) [93-95]. The specific incontinence questionnaires have many questions and we wanted one or a few questions that could be used as a complement to the IPSS. Therefore we developed a short and simple (1 question scored 0-5 and 3 additional questions) domain specific questionnaire. It is important to have in mind that the instrument only classifies the symptom incontinence and not the true cause of the incontinence. An advantage is that the questionnaire gives a quick overview of whether the patient has UI, and if so, a more detailed questioning may be needed.

6.1.2.2. Partner questionnaire

To maintain a cultural content we first translated the partner specific questionnaire which was validated by Sells et al. [50] and further tested its reproducibility and responsiveness. An advantage is that the questionnaire is based on a literature study, interviews with urologists and allied health professionals as well as patients and their partners. The questions describe aspects of the partner's specific quality of life and the answers are therefore not summed to a total score. However, in the calculations and in analogy with for example the International Prostatic Symptom Score (IPSS) [78], we choose to use the score 0 for the lowest response alternative, while Sells et al. [50] used 1 for this alternative. The score 0 is more logical since this response means that the partner is not affected by the patient's symptoms. The reproducibility measured with the Spearman's rank correlation coefficient was >0.70 for all questions except for those concerning household activities and worry about operation. The lower correlation for the question about household activities may be explained by the fact that most partners did not have any difficulties with these types of activities and answered "no" to this question and all the scale was not used. The question concerning worry about operation is not suited to the situation when an operation has already been decided or just has

been performed. The responsiveness was evaluated for each single question and was shown for all questions except the question "worry about operation". Another advantage of the questionnaire is that the questions are expressed in general terms and could be used to assess the specific quality of life of partners in the context of patients with other diseases if the words "urinary symptoms" are changed. The questionnaire can also be combined with other specific questionnaires for assessing sleep, sexual life, worry and health related quality of life. However, a disadvantage is that the questions is phrased in a leading way and this is a possible explanation to the divergent results in the questionnaire among the partners groups reported in paper IV.

6.1.2.3. USI and BNSQ

Both the Uppsala Sleep Inventory (USI) and the The Basic Nordic Sleep Questionnaire (BNSQ) questionnaires are validated and reliability tested in a Swedish population, which was the main reason for choosing these questionnaires in the studies [58,89]. They are well-established domain specific questionnaires and cover the main areas of interest and discriminate good sleepers from bad sleepers [58,89]. However, a disadvantage in this study may be that we adopted questions from both the USI and the BNSQ and combined them into one questionnaire without reliability testing.

6.1.2.4. SF-36

The 36-item Short Form (SF-36) is the most frequently validity and reliability tested questionnaire used world wide to assess generic health status. There has been criticism that the sensitivity of the questionnaire may vary depending on the type of disease [39]. Another weakness is that there are only two questions covering social relations and relationships. Further the questions do not assess the content of the relation.

6.1.3. Statistical analysis

6.1.3.1. Multiple testing

We decided not to use one of the available methods (Bonferroni or Scheffé) for adjustment of the p-value due to multiple testing in order to diminish the risk of type I error [96]. With such an adjustment the risk of type I errors decreases but the risk of type II errors increases. Instead it is possible to look at the number of obtained significances. In the SF-36 questionnaire, eight domains are tested and in the partner specific QOL questionnaire eight aspects are tested. If the significance level is < 0.05 the risk to obtain more than two significances by chance is 0.6 %. In the same way, it can be calculated that the risk of obtaining more than three significances when testing the 19 sleep variables is 1.3 %.

The pattern of most variables that the LUTS group was impaired compared to both the population and hernia groups and that there only were small differences between the hernia and population groups, indicates that the significances obtained are not caused by random variation (Paper III).

In paper IV, the pattern that there were no significances for the items in the SF-36 and the sleep questionnaires and that there were significances for all the items in the Sell's questionnaire also indicates that the significances obtained are not caused by random variation. One reason that the sleep and health related QOL variables were not significant could be that the groups are too small. On the other hand, many sleep variables were tested and the p-values do not tend to be close to the significance level, which supports the hypothesis that there are no differences between the groups.

6.1.3.2. Power analysis

It is not possible to calculate an exact power of a test if the distribution of the variable is not known. It is therefore not possible to calculate the power of the ordinal variables of

this study. Instead the power of a binary variable, which also could be a dichotomized ordinal variable, has been estimated. The power of the Mann-Whitney U-test of an ordinal variable ought to be higher than the calculated power of a dichotomized variable. When calculating the power of a binary variable not only the difference between the groups but also the absolute values of the frequencies are of importance. Therefore the power is given as examples in paper III and IV. There was a power of 80 % to detect the differences between 13 and 25 % in paper III and the difference between 10 and 25 % in paper IV.

6.2. Results

6.2.1. Men

6.2.1.1. Urinary symptoms

The men studied in paper I, had moderate to severe urinary symptoms and in paper III men with all degrees of symptoms were included, their symptoms were bothersome and their disease specific QOL were affected.

The prevalence of incontinence was shown to be higher both before (46 %) and after (16 %) intervention than is reported in other studies [25-26]**.** One possible explanation may be that the patients in our study probably had a high degree of LUTS (Paper I). In paper III the figures for UI were compatible (37 %) with earlier findings [26]**.** Even if most patients have incontinence to a low degree, it is important to evaluate this symptom both before and after intervention, for instance to know whether the patient's postoperative incontinence is a complication.

6.2.1.2. Disease specific quality of life

As expected after treatment the patients' disease specific quality of life improved. Patients with an indwelling catheter/CIC before intervention improved more than patients without an indwelling catheter (Paper I).

The logistic regression analysis was performed to find out which factors are most important for the disease specific quality of life. Since almost all the items used as independent variables are correlated to each other, the result of this analysis is not very robust. The frequency and weak stream of the SPI were shown to be explanatory factors both before and after intervention. Since the analyses were made on different data sets, it is very likely that these symptoms really are important for the disease specific quality of life. Before intervention a decision to give drug treatment was the most important factor and after intervention, a diagnosis of prostate cancer was the most important factor for the disease specific quality of life One should be cautious to generalise this result, as there was no difference between the surgery group and the drug treatment group before intervention and perhaps patients whose symptoms were too severe had been given drug therapy (Paper I).

6.2.1.3. Health related quality of life

Compared to the population, the LUTS group was significantly more impaired in all domains of the SF-36 except for the bodily pain. The most affected domains were the mental health (MH) and social functioning (SF) domains. The fact that the HRQOL is impaired further implies that well-being also is affected. Our findings correspond with results from other studies [43-44] and an important implication is that urinary problems influence many aspects of the HRQOL.

6.2.1.4. Sleep

The sleep was more comprehensively assessed with domain specific well-established sleep questionnaires compared to earlier studies and we also compared the men with LUTS with two control groups. Men with LUTS were significantly more affected in almost all sleep variables. The prevalence of insomnia in with the LUTS group was significantly higher and nearly twice as high as the prevalence in each of the control

groups, while the prevalence in the latter groups was comparable to population studies [66]. Nearly 50 % of men with LUTS had a sleep efficiency < 85 %, i.e. they spend more than 15 % of their time in bed awake. These findings indicate that LUTS have a negative impact on sleep with consequences for the quantity and the quality of sleep. In this study, it is more clearly verified that this group of patients really experiences poor sleep.

To my knowledge, this is the first study that has identified explanatory variables for poor sleep in men with LUTS. It is earlier known that high age, joint disease/pain, psychiatric condition [59] and the number of nightly micturitions are related to impaired sleep and this study confirms that the presence of LUTS also is such a factor. Employed persons may have higher sleep efficiency due to the fact that they have less time to spend in bed in relation to the sleep duration. However, it was expected that men with inguinal hernia reported poorer HRQOL in the physical functioning, physical role limitations, bodily pain and physical component summary score than men in the population and men with LUTS.

6.2.2. Partners

6.2.2.1. Specific quality of life

An increasing interest has been shown in how patients' diseases affect the partner or next of kin. To my knowledge, paper IV is the first study that has compared the specific QOL and the HRQOL, including sleep variables, of partners of men with LUTS with randomly selected partners from the population. Partners of men with LUTS were impaired in their specific QOL. As shown both in papers II and IV, the most affected aspects concerned compassion and worry about an operation or cancer [50]. However, we did not compare our results with Sells et al.'s [50] since they did not present the medians or the frequency distributions of the answers.

The overall question regarding the partner specific QOL was negatively correlated to the patients' symptoms and disease specific QOL and this unexpected result may be due to a false significance, i.e. type I error. It may, however, be true that the correlation between a patient's LUTS symptoms and the partner specific QOL is low, since it is emotional aspects that are most impaired. The partner's personal characteristics may be more important than the patient's degree of symptoms (Paper IV).

6.2.2.2. Sleep

Based on findings from earlier studies in which the partners of men with urinary symptoms reported that sleep disturbances affected them most [48-50] we studied sleep in more detail. According to the questions about awakenings and tiredness in the partner specific questionnaire partners of men with LUTS had a slightly but significantly more impaired sleep than partners in the population. In contrast to these results, we rather unexpectedly did not find any significant differences between the groups in the specific questions regarding sleep. The prevalence of insomnia was high in both groups and comparable to other studies [66]. Further, both groups had low sleep efficiency. The only independent factor that was significantly correlated to low sleep efficiency in the multivariate analysis was sleeping alone as opposed to sharing bedroom (Paper IV).

6.2.2.3. Health related quality of life

There were no significant differences in the HRQOL between partners to men with LUTS and partners from the population. In contrast to this there were great differences among the partners to men with LUTS and the partners to men from the population in the answers to the overall question in the partner specific questionnaire by Sell´s et al [50] (Paper IV).

6.2.2.4. Self- care

Men with LUTS have to cope with their condition for many years and by combining the available treatment methods and self-care according to Orem's theory the management of men with LUTS could improve.

7. IMPLICATIONS

7.1. Clinical implications

Our results have implications to improve the management of men with LUTS suggestive of BPO, which are that the patients' urinary symptoms and their impact on disease specific and HRQOL should be evaluated more systematically both before and after intervention. The IPSS is a domain specific questionnaire that does not assesses urinary incontinence or the bother the urinary symptoms causes. In these studies, a high prevalence of urinary incontinence was found both before and after intervention, which indicate that this symptom has to be assessed more methodically.

Even if the patient has high scores on the IPSS this does not give information about how bothered the patient finds his symptoms. It is therefore important to combine the IPSS with disease specific assessments like the SPI and the BII and the bother question in the IPSS. Together, these questionnaires give useful information about which symptoms affect the patient most. Due to our findings, the presence of nocturia also implicate the importance to evaluate sleep more thoroughly.

Partners of men with LUTS were emotionally affected by their men's urinary symptoms. These results confirm the need to involve the partners in the management of the LUTS patient. We also found that the mental health (MH) and the social functioning (SF) were the most affected domains in the men. Inviting the partner to attend at the consultation has benefits for the couple. They will be identically informed about the condition including treatment options. They have an opportunity to ask questions and discuss issues that are important to them. Further, it may improve their communication and it gives the partner an opportunity to better understand and cope with the patient's disease and provide support.

7.2. Research implications

Our findings raise more questions for future research:

To study whether the SPI or BII questionnaire are useful when deciding

about treatment and in the evaluation of treatments.

To further develop the partner specific quality of life questionnaire.

8. CONCLUSIONS

The constructed incontinence questionnaire, The Linköping Incontinence Questionnaire (LIQ) and the Swedish translations of the IPSS including the bother question, SPI, BII and the partner specific quality of life questionnaire to men LUTS showed an acceptable reliability.

The prevalence of urinary incontinence before and after intervention was higher than earlier reported.

Symptoms and disease specific quality of life improved most after the surgery, intermediately after TUIP/TUMT group and least with drug therapy.

Men with LUTS had significantly poorer sleep quality, low sleep efficiency and a higher prevalence of insomnia than men in the population and men with inguinal hernia.

The HRQOL is impaired in men with LUTS compared to men in the population and men with inguinal hernia.

Partners are affected by the patients' symptoms, and it is emotional rather than practical aspects that affect them most.

Partners of men with LUTS did not differ significantly from partners in the population with regard to sleep and health related quality of life.

9. SUMMARY IN SWEDISH

Populär vetenskaplig sammanfattning på svenska

Sömn och livskvalitet hos män med symptom från de nedre urinvägarna –

och deras partners

Godartad prostataförstoring (BPH) kan orsaka avflödeshinder i urinröret och

urineringsproblem. Idag råder inte samstämmighet om vilka kriterier som innefattas i

diagnosen och inte heller vilka män som ska behandlas. En person, man eller kvinna,

som har symtom från urinblåsan brukar sägas ha symtom från de nedre urinvägarna. Det

finns ingen övergripande svensk term för att beskriva symtomen, därför används den

engelska förkortningen (LUTS). Förekomsten av LUTS hos män ökar med åldern och

befolkningsstudier visar att 40-77 % av män 70 år och äldre har sådana besvär.

LUTS/BPH brukar beskrivas som en långsam sjukdom som gradvis försämras, vilket

gör att män som drabbas ofta har urineringsbesvär under många år innan de behandlas.

Sammanfattningsvis kan sägas att LUTS/ BPH är vanligt förekommande i befolkningen

men sjukdomen har en förhållandevis låg prioritet i jämförelse med andra urologiska

sjukdomar. Även om LUTS/BPH är en godartad sjukdom, så har urineringssymtom en

inverkan på männens relationer till partners och andra, deras sociala liv och på deras

livsstil. Männens symtom orsakar besvär och oro för att symtomen ska förvärras,

känslor av oro eller skam för att "kissa ofta" eller läcka urin, att planera för toalettbesök

på grund av täta urinträngningar och att vakna flera gånger under natten för att kissa.

Detta ger sammantaget upphov till en rad frågor som jag vill besvara i min avhandling.

Det övergripande syftet var att undersöka hur LUTS, där orsaken är en symtomgivande

godartad prostata förstoring, påverkar sömn, hälsorelaterad livskvalitet och

sjukdomsspecifik livskvalitet och hur männens urineringssymtom påverkar mannens

partner.

Arbete **I:** Samtliga frågeformulär som ingick i studien översattes till svenska, därefter testades formulären enligt vetenskapliga metoder. Ett enkelt frågeformulär för att undersöka självrapporterad urininkontiens utvecklades. Alla formulären testades slutligen på 122 män med LUTS. Frågeformulären användes därefter för att beskriva och undersöka urineringsymtom och sjukdomsspecifik livskvalitet hos 572 män mellan 45-94 år före och efter behandling av symtomgivande godartad prostata förstoring

Arbete **II:** Ett frågeformulär riktat till partners till män som har godartad prostataförstoring översattes. Därefter testades frågeformuläret på 51 partners vars män stod på väntelista för prostataoperation, enligt samma metod som i arbete **I.** Frågeformuläret användes därefter för att undersöka hur det är att leva med en man som har urineringsbesvär (specifik livskvalitet) före och efter mannens prostata- operation. I studien ingick 51 partners.

Arbete **III – IV:** I studien ingick 239 män mellan 45-80 år med LUTS och deras partners (antal 126) med slumpvis utvalda män (antal 213) och deras partners (antal 131) från befolkningen. I studien ingick även en kontrollgrupp, 200 män med ljumskbråck. Samtliga fick besvara frågeformulär om sömn och hälsorelaterad livskvalitet. Männen med LUTS fick dessutom besvara samma frågeformulär som i arbete **I** och alla partners samma frågeformulär som i arbete **II.**

Resultat: Samtliga frågeformulär visade en god vetenskaplig kvalitet **I-II**. Förekomsten av urininkontinens före behandling var 46 % och efter behandling 16 % **I**. Mannens urineringssymtom före prostataoperation påverkade partners specifika livskvalitet negativt, efter mannens operation förbättrades den specifika livskvalitet avsevärt **II**. Männen med LUTS hade påtagligt försämrad sömn i jämförelse med de båda kontrollgrupperna. Förekomsten av insomnia var 46 %, och lägre sömneffektivitet, 49 %, påvisades. Män med LUTS har en försämrad hälsorelaterad livskvalitet i jämförelse med

män från befolkningen och män med ljumskbråck. **III**. Partners till män med LUTS sov lika bra och hade inte någon försämrad hälsorelaterad livskvalitet i jämförelse med partners från befolkningen **IV**.

Slutsatser: Förekomsten av urininkontinens hos män med symtomgivande godartad prostataförstoring före och efter behandling var högre än andra studier visat.

Män med LUTS har en påtagligt försämrad sömnkvalitet, en lägre sömneffektivitet och högre förekomst av insomnia än män från befolkningen och män med ljumskbråck.

Män med LUTS har en försämrad hälsorelaterad livskvalitet i jämförelse med män från befolkningen och män med ljumskbråck.

Partners är påverkade av männens urineringssymtom. De är mer känslomässigt påverkade av mannens symtom än av att utföra praktiska sysslor.

Det finns ingen skillnad mellan partners till män med LUTS och partners till män från befolkningen vad gäller sömn eller hälsorelaterad livskvalitet.

10. ACKNOWLEDGMENTS

Without the help and contribution from my family, friends and "all members of the urological family" at the department Urology in Linköping it would never have been possible to complete this thesis. I wish to express my sincere gratitude to all of you. In particular I want to thank the following persons:

All men and their partners who participated in the studies and responded to the questionnaires. Thank you for giving me the time and in that way made it possible to write this thesis.

Ulla Edéll-Gustafsson, main supervisor, co-author, for believing in me from our first meeting. You have always shared your great knowledge about sleep and your experience within methodology and nursing research. Thank you for your supervision, guidance, support, enthusiasm, stimulating discussion and constructive criticism throughout this work. Not least for being a good listener and for your consideration.

Anders Spångberg, associate supervisor, co-author, for believing in me from the start and for giving me the inspiration and encouragement to write this thesis. For sharing your great experience and knowledge in urology, methodology and for your guidance in the statistical field, skilful assistance in front of the computer and patiently correcting my spelling. Thank you for support and constructive criticism throughout this work, your wisdom and for always being calm. You have always taken your time and listened to me. Not least for being a good listener and for your consideration.

Professor **Eberhard Varenhorst**, for helping me to start the work with this thesis, without your inspiration and encouragement this work would not have been possible.

Bengt Fåhreaus, Christer Ahlstrand and **Per CM Larsson**: former heads of the Department of Urology, because of their believe that nurses are important. For helping me to start the work of this thesis, and encouraged me to continue. I especially want to

Pamela Vang, Department of Management and Engineering at Linköping University, for rapid and skilful revision of the English language.

Associate Professor **Staffan Jahnson**, Department of Urology; Linköping, for valuable input at "halftime".

Gunilla Weber, Department of Urology; Linköping, for always being willing to help and for swift administrative assistance.

The "Witch-club", for always supporting me, for a lot of laughs, nice chats and not at least for your consideration.

My sister Ulla, for supporting me, for fruitful discussions, your humour, also to her husband **Fredric** and "the Edin brothers" **Alexander, Philip and William.**

My parents Asta and Olle, for always loving, supporting and encouraging me.

Emelie and Olivia, my wonderful girls, my joy and energy in life. You gave me the energy to start and complete this work. I love you!

Finally to **Johan**, for love, support, comfort and for just being Johan

11. REFERENCES

1. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourology and urodynamics. 2002;21(2):167-78.

2. Encarta World English Dictionary, North American Edition. Available from http://www.encarta.msn.com/encnet//features/dictionary

3. Rosemar A, Angeras U, Rosengren A. Body mass index and groin hernia: a 34- year follow-up study in Swedish men. Annals of surgery. 2008 Jun;247(6):1064-8.

4. Van Kerrebroeck P, Abrams P, Chaikin D, Donovan J, Fonda D, Jackson S, et al. The standardization of terminology in nocturia: report from the standardization subcommittee of the International Continence Society. BJU international. 2002 Dec;90 Suppl 3:11-5.

5. Blanker MH, Groeneveld FP, Prins A, Bernsen RM, Bohnen AM, Bosch JL. Strong effects of definition and nonresponse bias on prevalence rates of clinical benign prostatic hyperplasia: the Krimpen study of male urogenital tract problems and general health status. BJU international. 2000 Apr;85(6):665-71.

6. O'Leary MP. LUTS;ED;QOL: Alphabet soup or real concerns to aging men? Urology Suppl 2000;5(56):7-11.

7. Trueman P, Hood SC, Nayak US, Mrazek MF. Prevalence of lower urinary tract symptoms and self-reported diagnosed 'benign prostatic hyperplasia', and their effect on quality of life in a community-based survey of men in the UK. BJU international. 1999 Mar;83(4):410-5.

8. Boyle P, Robertson C, Mazzetta C, Keech M, Hobbs R, Fourcade R, et al. The relationship between lower urinary tract symptoms and health status: the UREPIK

study. BJU international. 2003 Oct;92(6):575-80.

9. Andersson SO, Rashidkhani B, Karlberg L, Wolk A, Johansson JE. Prevalence of lower urinary tract symptoms in men aged 45-79 years: a population-based study of 40 000 Swedish men. BJU international. 2004 Aug;94(3):327-31.

10. Chute CG, Panser LA, Girman CJ, Oesterling JE, Guess HA, Jacobsen SJ, et al. The prevalence of prostatism: a population-based survey of urinary symptoms. J Urol. 1993 Jul;150(1):85-9.

11. Jacobsen SJ, Girman CJ, Guess HA, Rhodes T, Oesterling JE, Lieber MM. Natural history of prostatism: longitudinal changes in voiding symptoms in community dwelling men. J Urol. 1996 Feb;155(2):595-600.

12. Glover L, Gannon K, McLoughlin J, Emberton M. Men's experiences of having lower urinary tract symptoms: factors relating to bother. BJU international. 2004 Sep;94(4):563-7.

13. Gannon K, Glover L, O'Neill M, Emberton M. Lower urinary tract symptoms in men: self-perceptions and the concept of bother. BJU international. 2005 Oct;96(6):823-7.

14. Abrams P. New words for old: lower urinary tract symptoms for "prostatism". BMJ (Clinical research ed. 1994 Apr 9;308(6934):929-30.

15. Berry SJ, Coffey DS, Walsh PC, Ewing LL. The development of human benign prostatic hyperplasia with age. J Urol. 1984 Sep;132(3):474-9.

16. Boyle P. Epidemiology of benign prostatic hyperplasia: risk factors and concomitance with hypertension. Br J Clin Pract 1994; 74(Suppl):18-22.

17. Michel MC, Mehlburger L, Schumacher H, Bressel HU, Goepel M. Effect of diabetes on lower urinary tract symptoms in patients with benign prostatic hyperplasia. J Urol. 2000 Jun;163(6):1725-9.

18. Isaacs JT, Coffey DS. Etiology and disease process of benign prostatic hyperplasia. Prostate 1989; (Suppl 2):33-50.

19. Eckhardt MD, van Venrooij GE, van Melick HH, Boon TA. Prevalence and bothersomeness of lower urinary tract symptoms in benign prostatic hyperplasia and their impact on well-being. J Urol. 2001 Aug;166(2):563-8.

20. Malmsten UG, Milsom I, Molander U, Norlen LJ. Urinary incontinence and lower urinary tract symptoms: an epidemiological study of men aged 45 to 99 years. J Urol. 1997 Nov;158(5):1733-7.

21. Boyle P, Robertson C, Mazzetta C, Keech M, Hobbs R, Fourcade R, et al. The association between lower urinary tract symptoms and erectile dysfunction in four centres: the UrEpik study. BJU international. 2003 Nov;92(7):719-25.

22. Han E, Black LK, Lavelle JP. Incontinence related to management of benign prostatic hypertrophy. The American journal of geriatric pharmacotherapy. 2007 Dec;5(4):324-34.

23. Donovan JL, Brookes ST, de la Rosette JJ, Peters TJ, Porru D, Kondo A, et al. The responsiveness of the ICSmale questionnaire to outcome: evidence from the ICS-'BPH' study. BJU international. 1999 Feb;83(3):243-8.

24. Barry MJ. Evaluation of symptoms and quality of life in men with benign prostatic hyperplasia. Urology. 2001 Dec;58(6 Suppl 1):25-32; discussion

25. AUA guideline on management of benign prostatic hyperplasia (2003). Chapter 3: Results of the treatment Outcomes Analyses.http://www.auanet.org/gudielines/bph.cfm

26. Haltbakk J, Hanestad BR, Hunskaar S. Diversity of urinary symptoms in patients tentatively diagnosed with benign prostatic hyperplasia referred to a urologic clinic in Norway. Scandinavian journal of urology and nephrology. 2004;38(6):454-61.

27. Deliveliotis C, Liakouras C, Delis A, Skolarikos A, Varkarakis J, Protogerou V.

Prostate operations: long-term effects on sexual and urinary function and quality of life. Comparison with an age-matched control population. Urological research. 2004 Aug;32(4):283-9.

28. Yoshimura K, Ohara H, Ichioka K, Terada N, Matsui Y, Terai A, et al. Nocturia and benign prostatic hyperplasia. Urology. 2003 Apr;61(4):786-90.

29. Abrams P. Nocturia: the major problem in patients with lower urinary tract symptoms suggestive of benign prostatic obstruction (LUTS/BPO). Eur Urol Suppl 2005;3(6):8-16.

30. Stanley N. The underestimated impact of nocturia on quality of life. Eur Urol Suppl 2005; 4:17-9.

31. Asplund R, Aberg HE. Micturition habits of older people. Voiding frequency and urine volumes. Scandinavian journal of urology and nephrology. 1992;26(4):345-9.

32. Asplund R, Aberg H. Health of the elderly with regard to sleep and nocturnal micturition. Scandinavian journal of primary health care. 1992 Jun;10(2):98-104.

33. Asplund R. Nocturia: consequences for sleep and daytime activities and associated risks. Eur Urol Suppl 2005; (3):24-32.

34. Schatzl G, Temml C, Schmidbauer J, Dolezal B, Haidinger G, Madersbacher S. Cross-sectional study of nocturia in both sexes: analysis of a voluntary health screening project. Urology. 2000 Jul;56(1):71-5.

35. Madersbacher S, Alivizatos G, Nordling J, Sanz CR, Emberton M, de la Rosette JJ. EAU 2004 guidelines on assessment, therapy and follow-up of men with lower urinary tract symptoms suggestive of benign prostatic obstruction (BPH guidelines). European urology. 2004 Nov;46(5):547-54.

36. AUA guideline on management of benign prostatic hyperplasia (2003). Chapter 1: Diagnosis and treatment recommendations. http://www.auanet.org/gudielines/bph.cfm

37. Mattiasson A, Wagrell L, Schelin S, Nordling J, Richthoff J, Magnusson B, et al. Five-year follow-up of feedback microwave thermotherapy versus TURP for clinical BPH: a prospective randomized multicenter study. Urology. 2007 Jan;69(1):91-6; discussion 6-7.

38. Schelin S, Geertsen U, Walter S, Spangberg A, Duelund-Jacobsen J, Kroyer K, et al. Feedback microwave thermotherapy versus TURP/prostate enucleation surgery in patients with benign prostatic hyperplasia and persistent urinary retention: a prospective, randomized, controlled, multicenter study. Urology. 2006 Oct;68(4):795-9.

39. Bowling A. Measuring health. A review of quality of life measurement scales. 3rd edn. Buckingham: Open University Press; 2005. p. 7-9, 44, 63-8.

40. Bowling A. Measuring disease. A review of disease-specific quality of life measurement scales. 2nd edn. Buckingham: Open University Press; 2001. p. 1-11, 16-8, 275-7.

41. O'Leary MP, Wei JT, Roehrborn CG, Miner M. Correlation of the International Prostate Symptom Score bother question with the Benign Prostatic Hyperplasia Impact Index in a clinical practice setting. BJU international. 2008 Jun;101(12):1531-5.

42. Hunter DJ, McKee M, Black NA, Sanderson CF. Health status and quality of life of British men with lower urinary tract symptoms: results from the SF-36. Urology. 1995 Jun;45(6):962-71.

43. Welch G, Weinger K, Barry MJ. Quality-of-life impact of lower urinary tract symptom severity: results from the Health Professionals Follow-up Study. Urology. 2002 Feb;59(2):245-50.

44. Engstrom G, Henningsohn L, Walker-Engstrom ML, Leppert J. Impact on quality of life of different lower urinary tract symptoms in men measured by means of the SF 36 questionnaire. Scandinavian journal of urology and nephrology. 2006;40(6):485-94.

45. Sullivan M, Karlsson J. The Swedish SF-36 Health Survey III. Evaluation of criterion-based validity: results from normative population. Journal of clinical epidemiology. 1998 Nov;51(11):1105-13.

46. Cavanagh SJ. Orem´s model in action. London: Macmillan;1991. p 3-31,

47. Roehrborn CG, Marks L, Harkaway R. Enlarged prostate: a landmark national survey of its prevalence and impact on US men and their partners. Prostate cancer and prostatic diseases. 2006;9(1):30-4.

48. Shvartzman P, Borkan JM, Stoliar L, Peleg A, Nakar S, Nir G, et al. Second-hand prostatism: effects of prostatic symptoms on spouses' quality of life, daily routines and family relationships. Family practice. 2001 Dec;18(6):610-3.

49. Mitropoulos D, Anastasiou I, Giannopoulou C, Nikolopoulos P, Alamanis C, Zervas A, et al. Symptomatic benign prostate hyperplasia: impact on partners' quality of life. European urology. 2002 Mar;41(3):240-4; discussion 4-5.

50. Sells H, Donovan J, Ewings P, MacDonagh RP. The development and validation of a quality-of-life measure to assess partner morbidity in benign prostatic enlargement. BJU international. 2000 Mar;85(4):440-5.

51. Neumayer L, Jonasson O, Fitzgibbons R, Henderson W, Gibbs J, Carrico CJ, et al. Tension-free inguinal hernia repair: the design of a trial to compare open and laparoscopic surgical techniques. Journal of the American College of Surgeons. 2003 May;196(5):743-52.

52. Holzheimer RG. Inguinal Hernia: classification, diagnosis and treatment--classic, traumatic and Sportsman's hernia. European journal of medical research. 2005 Mar 29;10(3):121-34.

53. Massaron S, Bona S, Fumagalli U, Battafarano F, Elmore U, Rosati R. Analysis of post-surgical pain after inguinal hernia repair: a prospective study of 1,440 operations.

Hernia. 2007 Dec;11(6):517-25.

54. Bitzer EM, Lorenz C, Nickel S, Dorning H, Trojan A. Patient-reported outcomes in hernia repair. Hernia. 2008 Aug;12(4):407-14.

55. Mathur S, Bartlett AS, Gilkison W, Krishna G. Quality of life assessment in patients with inguinal hernia. ANZ journal of surgery. 2006 Jun;76(6):491-3.

56. Middelkoop HA, Smilde-van den Doel DA, Neven AK, Kamphuisen HA, Springer CP. Subjective sleep characteristics of 1,485 males and females aged 50-93: effects of sex and age, and factors related to self-evaluated quality of sleep. The journals of gerontology. 1996 May;51(3):M108-15.

57. Van Someren EJ. Circadian and sleep disturbances in the elderly. Experimental gerontology. 2000 Dec;35(9-10):1229-37.

58. Mallon L, Hetta J. A survey of sleep habits and sleeping difficulties in an elderly Swedish population. Upsala journal of medical sciences. 1997;102(3):185-97.

59. Gislason T, Almqvist M. Somatic diseases and sleep complaints. An epidemiological study of 3,201 Swedish men. Acta medica Scandinavica. 1987;221(5):475-81.

60. Carskadon MA, Dement WC. Normal human sleep: an overview. In Kryger MH, Roth T, Demnt WC, eds. Principles and practice of sleep medicine. Philadelphia: W.B Saunders Company, 2nd ed. 1994; 16-25.

61. Guyton A C, Hall J E. Textbook of medical physiology. 11th ed. Philadelphia: Elsevier Saunders 2006 p. 667, 739.

62. Stanley N. The physiology of sleep and the impact of ageing. Eur Urol Suppl 2005; 3 (Suppl 6):17-23.

63. Morgan K, Closs J S. Sleep management in nursing practice: An evidence –based guide. Edinburgh: Churchill Livingstone 1999 p 9-15, 69-71.

64. Mallon L, Broman J-E, Hetta J. Sleeping difficulties in relation depression and anxiety in elderly adults. Nord J Psychiatry 2000;54:355-60.

65. Buysse DJ, Ancoli-Israel S, Edinger JD, Lichstein KL, Morin CM. Recommendations for a standard research assessment of insomnia. Sleep. 2006 Sep 1;29(9):1155-73.

66. Morin CM, LeBlanc M, Daley M, Gregoire JP, Merette C. Epidemiology of insomnia: prevalence, self-help treatments, consultations, and determinants of help-seeking behaviors. Sleep medicine. 2006 Mar;7(2):123-30.

67. American Academy of Sleep medicine. The international classification of sleep disorders. Diagnostic & coding manual (ICSD-2). 2 nd ed. Westchester: One Westbrook Corporate Center 2005. p 1-2,18-20,29-31.

68. Morin CM, Espie CA. Insomnia a clinical guide to assessment and treatment, New York, Kluwer Academic/Plenum Publishers;2003. pp 13-8.

69. Buysse DJ, Reynolds CF, 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatryresearch. 1989 May;28(2):193-213.

70. Edell-Gustafsson UM, Gustavsson G, Yngman Uhlin P. Effects of sleep loss in men and women with insufficient sleep suffering from chronic disease: a model for supportive nursing care. International journal of nursing practice. 2003 Feb;9(1):49-59.

71. Abrams P. Nocturia: the effect on sleep and related health consequences. Eur Urol 2005;6 (Suppl 3):1-7.

72. Schulman C C, Asplund R, Desgrandchamps F, Jonas U. The impact of nocturia on health status and quality of life in patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH). Eur Urol Suppl 2005; (Suppl 4):1-8.

73. Schneider T, Stanley N. Impact of nocturia on sleep and energy. Eur Urol Suppl 2007;(Suppl 6):585-93.+

74. Bliwise DL, Foley DJ, Vitiello MV, Ansari FP, Ancoli-Israel S, Walsh JK. Nocturia and disturbed sleep in the elderly. Sleep medicine. 2008 Aug 12.

75. Hernandez C, Estivill E, Prieto M, Badia X. Nocturia in Spanish patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH). Current medical research and opinion. 2008 Apr;24(4):1033-8.

76. Cai T, Gardener N, Abraham L, Boddi V, Abrams P, Bartoletti R. Impact of surgical treatment on nocturia in men with benign prostatic obstruction. BJU international. 2006 Oct;98(4):799-805.

77. Marklund-Bau H, Edell-Gustafsson U, Spangberg A. Bothersome urinary symptoms and disease-specific quality of life in patients with benign prostatic obstruction. Scandinavian journal of urology and nephrology. 2007;41(1):32-41

78. Barry MJ, Fowler FJ, Jr., O'Leary MP, Bruskewitz RC, Holtgrewe HL, Mebust WK, et al. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. J Urol. 1992 Nov;148(5):1549-57; discussion 64.

79. Barry MJ, Fowler FJ, Jr., O'Leary MP, Bruskewitz RC, Holtgrewe HL, Mebust WK. Measuring disease-specific health status in men with benign prostatic hyperplasia. Measurement Committee of The American Urological Association. Medical care. 1995 Apr;33(4 Suppl):AS145-55.

80. Burns N, Grove SK. The practice of nursing research: Conduct, critique, and utilization, 5th ed. St. Louis: Elsevier Saunders;2005. p. 374, pp.415-6.

81. Marklund-Bau H, Edell-Gustafsson U, Spangberg A. A Swedish version of a quality of life questionnaire for partners of men with symptoms suggestive of benign prostatic

obstruction. Scandinavian journal of urology and nephrology. 2008;42(2):126-31.

82. Hald T. Urodynamics in benign prostatic hyperplasia: a survey. The Prostate. 1989;2:69-83. Folkestad B, Spangberg A. Timed micturition and maximum urinary flow rate in randomly selected symptom-free males. Scandinavian journal of urology and nephrology. 2004;38(2):136-42.

84. Folkestad B, Spangberg A. Validation of timed micturition--a comparison of flow rates measured at home manually and electronically. Scandinavian journal of urology and nephrology. 2004;38(5):385-90.

85. The World Health Organization Quality of Life assessment (WHOQOL): position paper from the World Health Organization. Social science & medicine (1982). 1995 Nov;41(10):1403-9.

86. Sullivan M, Karlsson J, Ware JE. SF-36 Health survey. Swedish manual and interpretation guide. Gothenburg: Sahlgrenska University Hospital; 1994 (in Swedish).

87. Edéll-Gustafsson U. Sleep, psychological symptoms and quality of life in patients undergoing coronary artery bypass grafting. Ph.D. diss, Faculty of Health Sciences, Linköping University, Sweden and Faculty of Medicine, Uppsala University, Sweden, Linköping 1999.

88. Partinen M, Gislason T. Basic Nordic Sleep Questionnaire (BNSQ): a quantitated measure of subjective sleep complaints. Journal of sleep research. 1995 Jun;4(S1):150-5.

89. Edell-Gustafsson U, Svanborg E, Swahn E. A gender perspective on sleeplessness behavior, effects of sleep loss, and coping resources in patients with stable coronary artery disease. Heart Lung. 2006 Mar-Apr;35(2):75-89.

90. Reuterberg S-E. Hantering av bortfall i longitudinella studier, ett exempel. Pedagogisk forskning i Sverige 2001;3:173-94 (in Swedish).

91. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297-334.

92. Badia X, Garcia-Losa M, Dal-Re R. Ten-language translation and harmonization of the International Prostate Symptom Score: developing a methodology for multinational clinical trials. European urology. 1997;31(2):129-40.

93. Hansen BJ, Flyger H, Brasso K, Schou J, Nordling J, Thorup Andersen J, et al. Validation of the self-administered Danish Prostatic Symptom Score (DAN-PSS-1) system for use in benign prostatic hyperplasia. British journal of urology. 1995 Oct;76(4):451-8.

94. Donovan JL, Abrams P, Peters TJ, Kay HE, Reynard J, Chapple C, et al. The ICS-'BPH' Study: the psychometric validity and reliability of the ICSmale questionnaire. British journal of urology. 1996 Apr;77(4):554-62.

95. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourology and urodynamics. 2004;23(4):322-30.

96. Altman DG. Practical statistics for medical research. London: Chapman and Hall; 1991. p 168-171, 210-212, 455-499.