Evaluation of Quality of Life and Quality of Sleep in Clinical Practice

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Abstract

Nocturia has been recognised as one of the most bothersome storage symptoms in patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH). It has a negative impact on quality of sleep (QoS), which might result in daytime fatigue, decreased energy/vitality, insomnia, and increased incidence of infection, and may ultimately negatively affect the patient’s quality of life (QoL). However, the evaluation of a patient with LUTS/BPH and assessment of benefits of new medical and surgical LUTS/BPH treatments are mainly focused on voiding symptoms or flow rate. The impact of storage symptoms, in particular nocturia, on the patient’s QoS and QoL is often underestimated. Commonly used instruments to measure the severity of nocturia and its impact on QoS and QoL are not specific and lack sensitivity. Potential new instruments that evaluate the consequences of nocturia on QoL are nocturia-specific questionnaires such as the Nocturia QoL (N-QoL) questionnaire. Furthermore, the assessment of “Hours of Undisturbed Sleep” (HUS) seems a useful method to evaluate the impact of nocturia on QoS. These new tools should be incorporated in clinical practice and may give better insights into the effects of LUTS/BPH treatments on the patient’s QoS, energy/vitality, and overall QoL.

1. Introduction

Nocturia, defined as the complaint that the individual has to wake at night one or more times to void [1], is one of the most bothersome lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH) [2]. A recent study reported that nocturia is the most prevalent LUTS among men in five different countries [3]. Moreover, another recent and interesting paper found that nocturia is a significant independent predictor of mortality among 70-year-old patients with known coronary heart disease and thus warrants special attention [4]. The bothersomeness of nocturia is largely due to the fact that it interferes with the quality of sleep (QoS), which may have a significant
negative impact on how the patient feels the next day. Disturbed sleep reduces the patient’s vitality and concentration, negatively affects his mood, and ultimately impairs the patient’s overall quality of life (QoL). Sleep deprivation also increases the patient’s risk of accidents at work, on the road, and at home. Disturbed sleep due to nocturia may even lead to increased long-term morbidity and mortality [5]. Furthermore, sleep deprivation has also been associated with reduced natural immune responses and cytokine levels in the blood, resulting in an increased risk of infections [6]. Another reason for concern is that nocturia might not only affect the QoS and QoL of the patients, but also their partners suffer from lack of sleep [7].

Bearing in mind the negative impact of chronic sleep deprivation due to nocturia, urologists should pay more attention to the evaluation of nocturia in both clinical practice and clinical research. In the initial evaluation of patients with LUTS/BPH suffering from nocturia, it is important to distinguish between polyuria and nocturia. This can be done by means of a 24-h voiding diary [8–10]. A clinical evaluation is mandatory to determine the underlying cause of nocturia [10]. While very little research has focused exclusively on nocturia and its impact on a patient’s QoS and QoL, a considerable amount of research has been published on the prevalence of LUTS and its treatment outcomes [11]. The symptom of nocturia has been included in several questionnaires designed to assess the presence of LUTS. In most of these questionnaires, nocturia is included as one of several items that are added together to form a score, and as a consequence, the prevalence and severity of nocturia are difficult to investigate. Specific, sensitive, and validated questionnaires, measuring the impact of LUTS/BPH on QoL, have recently been developed investigating the severity of nocturia and its impact on QoS and QoL. In this review, various instruments measuring the impact of LUTS/BPH, and more specifically nocturia, on patient’s QoS and QoL are being discussed. In addition, the evaluation of vitality/energy and QoL of patients with chronic conditions not associated with nocturia will be discussed.

2. Evaluation of energy/vitality and quality of life

The term QoL is widely used in clinical studies, often without a clear definition. It is commonly linked to the World Health Organization’s definition of health, which refers to a state of physical, emotional, and social well-being, and not just the absence of disease or infirmity [12]. The term QoL has superseded the concept of “well-being,” and serious attempts have been made to understand and define its meaning: How people subjectively report their perceived QoL, and how we might more objectively measure it [13]. Self-reported QoL levels are typically quite high, but sometimes this finding depends on how and in what order the questions are asked. There is consensus that QoL is a multidimensional concept and that the dimensions can be grouped under the broad headings of physical, functional, psychological, and social health (Fig. 1) [14]. Important concepts such as energy/vitality, pain, depression, and other cognitive functions are included within these broader headings.

Blane et al [15] developed a self-completion measure of QoL, CASP-19, covering certain needs that are common to all humans. These include

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**Fig. 1 – Schematic representation of the definition of quality of life [14].**
control (the ability to act freely in one’s environment), autonomy (the need to be free from undue interference from others), self-realisation (self-esteem), and pleasure (the need to enjoy oneself). They found that each of the domains exhibited good internal consistency, correlated well with each other, and loaded well on a latent factor. The overall scale also correlates well with the Life Satisfaction Index—Well being (LSI-W). This clearly emphasizes that QoL is not just about health status, but is also mediated by life course trajectories such as socioeconomic status, health status, marital status, personality, gender, and age.

Since improvement of QoL is an important end point in the management of LUTS/BPH, it is essential to be able to measure the QoL of patients. Instruments to measure the QoL are being increasingly used in a wide variety of patients and in many different studies. This increased use has led to the realisation that clinicians’ and patients’ judgements regarding QoL and the effects of clinical intervention differ considerably, which has increased recognition of the patients’ view when evaluating new interventions in the management of LUTS. However, there is still a lack of conformity in the use of outcome measures in both the clinical and research settings [16]. Aspects of QoL can be explored through the use of in-depth interviews or questionnaires [11]. Interviews with individuals can provide detailed information about perceptions of health and illness, and specific issues relating to the impact of symptoms on a person’s everyday life. However, interviews are time-consuming, and the most common method of assessing some aspects of QoL is through questionnaires. Questionnaires to measure the QoL can be broadly classified into two major categories: generic questionnaires designed to measure the multidimensional nature of health status and suitable for a broad range of illnesses and populations, and disease-specific questionnaires designed to measure the specific impact of a particular disease (eg, LUTS/BPH) on QoL. Before they can be used, questionnaires need to be tested for validity, reliability, and sensitivity.

Generic instruments to measure the QoL of patients include the Sickness Impact Profile (SIP) [17], the Nottingham Health Profile (NHP) [18], the EuroQol (EQ-SD) index [19], and the Short Form (SF)-36 health survey questionnaire [20,21]. The SF-36 instrument is ideally used in combination with disease-specific questionnaires. The SF-12 was developed as a much shorter, yet validated, alternative to the SF-36 [22]. Instruments such as the NHP and the SF-36 are “health-profile” measures because they comprise several different domains, each of which has its own score. This means that health-profile measures provide a detailed perspective of the patient but do not generally determine how important a given problem is. The EQ-5D is an “index” measure and questions are added together to achieve a single score. Index measures provide information about the relative value of various health states but fail to reflect specific problems that might emerge [14]. Nevertheless, all these questionnaires lack a sufficient degree of sensitivity to evaluate changes in a patient’s clinical condition.

The Functional Assessment of Chronic Fatigue Illness Therapy (FACIT) scale is a collection of health-related QoL questionnaires targeted to the management of patients suffering from chronic diseases, including cancer, multiple sclerosis and arthritis [23–26]. The FACIT scale is a 27-item compilation of general questions divided into four primary QoL domains: physical well-being, social/family well-being, emotional well-being, and functional well-being. The FACIT fatigue subscale (FACIT-F) is a 13-item questionnaire specifically measuring fatigue in patients with chronic illnesses [23]. Items included in this FACIT-F scale include “I feel fatigued”, “I have energy”, and “I need to sleep during the day”. Each item ranges from 0 (not at all) to 4 (very much) and the total score ranges from 0–52, with a higher score indicating more fatigue.

3. Impact of chronic conditions on vitality and energy

Chronic conditions, such as neuropathic pain, diabetes, and rheumatoid arthritis impair patient’s energy and vitality. This problem is clearly recognised in clinical practice. Various patient-reported
measures, such as the EQ-5D, the vitality scale of the SF-36, and the FACIT-F scale are used to evaluate the patient’s condition, as well as the impact of treatment on health-related outcomes. Patients with chronic conditions often score around 40–60 on the vitality scale of the SF-36 [27–29]. Appropriate treatment should improve the patient’s condition. The minimally important difference (MID) is defined as the smallest change in score that a patient would perceive as beneficial. MIDs should be roughly 3–5 for the SF-36 questionnaire, 3–4 for the FACIT-F scale, and 0.07 for the EQ-5D [25,30,31]. Several studies demonstrate that treatment of patients with chronic pain significantly improves the vitality subscale of the SF-36 [32,33]. In a randomised controlled trial including 549 patients with type 2 diabetes, 26 weeks of treatment with twice-daily exenatide or once-daily insulin glargine significantly improved the vitality score of the SF-36 (Fig. 2) [34]. A double-blind, placebo-controlled randomised trial in 618 patients with moderate to severe psoriasis treated with placebo or 50 mg twice-weekly etanercept showed a significant and clinically meaningful improvement in fatigue in patients on etanercept (mean FACIT-F improvement: 5.0 vs. 1.9; \( p < 0.0001 \)). The improvements in fatigue were correlated with decreases in joint pain [35].

The data above clearly show that several chronic diseases cause a major burden on patients QoL. Chronic conditions may cause fatigue, and reduce the patient’s energy and vitality and ultimately overall QoL. It is important to recognise this problem in daily clinical practice. Appropriate treatment of the problem does not only relieve the symptoms, but is often associated with relief of disease-related problems such as fatigue, loss of energy, and impairment of overall QoL. Even if treatments do not cure or prevent the disease, amelioration of unpleasant side-effects, such as loss of energy (eg, due to nocturia) compounded with difficulty in getting back to sleep, may well improve perceived QoL. The QoS of partners disturbed by men at night may also improve, as may their levels of anxiety and subsequently their relationship [36].

4. Evaluation of quality of sleep

It has been demonstrated that sleep is vital for physical and mental functioning. Lack of sleep is associated with daytime fatigue, impaired cognitive functioning, mood disturbances, increased rates of infections, depression, and impaired productivity at work. Furthermore, lack of sleep has been found to be predictive of traffic and occupational accidents, and has deleterious consequences on body systems. Moreover, it has been implicated in decreased immune functioning and increased risk of cardiovascular disease and diabetes [5]. This indicates that sleep disorders have negative consequences for health, functioning, and overall QoL, especially in elderly people. Therefore, it will be important to improve QoS, which may improve the patient’s energy/vitality levels and daytime QoL.

Sleep quality represents a complex phenomenon that is difficult to define and measure objectively. It includes quantitative aspects of sleep, such as sleep duration and sleep latency as well as more subjective aspects such as depth or restfulness of sleep. Polysomnography provides accurate information on the physiologic indices of QoS. However, it is expensive, and it requires much time for testing and interpretation of data. Actigraphy is another method for objective sleep monitoring that measures sleep activity around the clock. Alternatively, self-reported methods such as sleep diaries, sleep logs, and sleep questionnaires provide a measurement of QoS experienced by the patient. These subjective methods attempt to measure both quantitative as well as qualitative aspects of sleep and are easily administered, inexpensive, and have a wide applicability [37]. However, it should be noted that methods applying questionnaires remain subjective, since they require a variable time period spent by the patients, so subjective performance variability of the individuals completing the tests has to be considered, especially when confronted with complex and extended tests.

Several questionnaires have been developed to measure QoS. The Epworth Sleepiness Scale (ESS) [38] is a questionnaire designed to measure daytime

![Fig. 2](image-url) - In a randomised controlled trial including patients with type 2 diabetes, treatment with exenatide and insulin glargine significantly improved the vitality score of the SF-36 compared with baseline [34]. SF-36 = Short Form-36 health survey questionnaire.
sleepiness in a simple and standardized way. The Sleep Disorders Questionnaire (SDQ) [39] consists of 175 items, and its usefulness in patients with sleep disorders has been confirmed. On the other hand, the Leeds Sleep Evaluation Questionnaire (LSEQ) [40] contains 10 questions concerned with aspects of sleep and early morning behaviour. Furthermore, in a Dutch adult population, sleep problems, such as sleep onset, mid-sleep awakening, early morning awakening, and daytime sleepiness, were measured using the Sleep Wake Experience List (SWEL) [41,42]. Another instrument of subjective sleep complaints is the Basic Nordic Sleep Questionnaire (BNSQ) [43], which has been widely used in a variety of studies performed in Nordic countries. Its main difference compared with many of the previous questionnaires is the five-point quantitative scale evaluating how many nights/days per week a problem occurs.

Although many questionnaires can be used to measure QoS, they share several limitations. For instance, only a very few of them have used time intervals for assessment. In contrast, the Pittsburgh Sleep Quality Index (PSQI) [44] has been widely used to measure QoS and disturbances over a 1-mo time interval, which is clinically and scientifically useful. It is scored in seven domains: subjective QoS, sleep latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep medicine, and daytime dysfunction. The recently developed Sleep Quality Scale (SQS) [37] is a valid and reliable instrument developed to measure QoS of adults. It is scored in six domains: daytime dysfunction, restoration after sleep, difficulty in falling asleep, difficulty in getting up, satisfaction with sleep, and difficulty in maintaining sleep. Compared with the PSQI, the SQS includes more items about restorative functions after sleep, difficulty in getting up, and various daytime dysfunctions due to poor sleep. However, all these measurements were not specifically designed to assess the impact of a disease-specific condition on QoS.

5. Measuring the impact of LUTS/BPH on quality of life

Many studies have examined the impact of LUTS/BPH and have shown them to be deleterious on daily life activities and QoL. Symptoms causing the most bother include those associated with urgency, daytime frequency, nocturia, and incontinence. Treatment of patients with chronic illneses primarily aims to make patients feel better and improve their QoL. When compared with patients suffering from LUTS/BPH (IPSS 20–35), men with other chronic illnesses such as diabetes, angina, hypertension, and gout have more energy/vitality, as measured by the SF-36 QoL questionnaire (Fig. 3) [45]. The authors concluded from this study that men with severe LUTS have a poorer health status in several important QoL dimensions. Although the SIP, the NHP, and the SF-36 are established, reliable, and valid generic measures, which allow comparisons with other diseases, they are not sensitive enough to measure the impact of a specific disease such as LUTS/BPH on patient’s QoL. As a consequence, disease-specific questionnaires were developed. However, combinations of generic measures with disease-specific measures are recommended to measure the impact of a condition on QoL.

The BPH Impact Index [46] measures how much the urinary problems affect various domains of health. The BPH Health Related Quality of Life (BPH-HRQOL) questionnaire [47] was designed to explore physical, mental, social, and general aspects of QoL. This questionnaire combines disease-specific and generic aspects of QoL. Furthermore, the IPSS includes one single question that aims to evaluate the impact of the present urinary condition on QoL [48]. A questionnaire that assesses the impact of several urinary symptoms on QoL is the Symptom Problem Index (SPI) [46]. In the Veterans Affairs Questionnaire [49], the symptoms most strongly associated with changes in QoL were storage symptoms such as nocturia, frequency, and urgency. The International Continence Society Quality of Life (ICSQoL) questionnaire [50] has also
shown a strong relationship between nocturia and the general question about interference with life. Other questionnaires that measure the impact of LUTS/BPH on QoL include the BPH survey [51] and the Olmstead County Index [52]. However, these questionnaires do not look specifically at the impact of one bothersome symptom (such as nocturia) but rather at the impact of urinary symptoms in general on QoL and activities of daily living.

6. Measuring the impact of nocturia on quality of sleep and quality of life

In the field of LUTS/BPH, no clinical studies to date have evaluated the bothersomeness of nocturia, and there is even less information on the impact of nocturia on QoL. This lack of information is due to the fact that commonly used measurements are not sensitive enough. The Danish Prostatic Symptom Score (DAN-PSS) was designed to measure QoL associated with voiding problems and the degree to which patients are bothered by their urinary symptoms [53,54]. Questions about the frequency and bothersomeness of nocturia are included, but this questionnaire is not designed nor evaluated for measuring the impact of nocturia on QoL.

A large majority of experts participating in the discussion forum at the 6th International Consultation on New Developments in Prostate Cancer and Prostate Diseases (Paris, France, 24 June, 2005) agreed that sleep disturbance due to nocturia is the dominant factor affecting QoL in patients with LUTS/BPH [55]. However, no questionnaires specifically measured the impact of nocturia on QoS. Recently, a specific Nocturia Quality of Life questionnaire (N-QoL) has been developed and validated to measure the impact of nocturia on QoS. This 13-item questionnaire consists of three domains, a sleep/energy domain, a bother/concern domain, and a global QoL question, and takes about 5 min to complete. It deals with daytime energy, worry, productivity, sleep, and vitality. The N-QoL scores correlate with the energy/vitality and social functioning domains of the SF-36 [20] and with the sleep quality domain of the PSQI [44]. Another questionnaire to measure the impact of nocturia on QoL is the International Consultation on Incontinence Questionnaire-Nocturia (ICIQ-N), which is currently under development [57]. The N-QoL has become one of the modules for this questionnaire. Preliminary results show that the ICIQ-N has good levels of reliability and validity. Moreover, Cai et al [58] have recently used the N-QoL questionnaire to evaluate the impact of surgical treatment on nocturia and QoL in men with LUTS related to benign prostatic obstruction. They showed that surgical intervention leads to a decrease in the nocturia rate and an increase in QoL. Along these lines, a new questionnaire has been developed and validated to measure the severity and impact of nocturia, nocturnal enuresis, and sleep interruptions in an elderly population of men and women in Denmark [59]. This Nocturia, Nocturnal Enuresis and Sleep-interruption Questionnaire (NNES-Q) may also have a potential in clinical settings, since it is brief and provides the level and impact of nocturia, nocturnal enuresis, and sleep interruptions on QoL.

An overview of the quality of life measures in LUTS/BPH and nocturia is given in Table 1.

Nevertheless, the QoS may not only depend on the frequency of nocturnal voids, but also on the time from falling asleep to the first awakening to void. This period, defined as the Hours of Undisturbed Sleep (HUS), should be at least 3–4 h and may provide a useful method to measure the impact of nocturia on QoS [60]. The best way to measure HUS is yet to be determined. The easiest and least expensive instrument is a sleep diary/log, but its outcomes may be less reliable because of recall bias. Although the most accurate method can only be applied in a sleep laboratory, devices such as the actigraph can be used as an alternative to measure the HUS in patients with LUTS/BPH [61]. Advantages

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SIP = Sickness Impact Profile; NHP = Nottingham Health Profile; SF-36 = Short Form-36 health survey questionnaire; LUTS/BPH = lower urinary tract symptoms suggestive of benign prostatic hyperplasia; BPH-HRQoL = BPH Health Related Quality of Life; IPSS = International Prostate Symptom Score; ICSQoL = International Continence Society Quality of Life; N-QoL = Nocturia Quality of Life; ICIQ-N = International Consultation on Incontinence Questionnaire-Nocturia.
of actigraphy include its ease of use, its low cost and noninvasive nature, and its automated sleep scoring and data storage. A relatively new method to assess wakefulness, rapid eye movement (REM) sleep and non-REM sleep, is the REM view [62], but it requires additional testing to show that this device outperforms other available sleep assessment methods.

7. Conclusions

Patients with chronic diseases are likely to suffer from lack of energy and vitality, and as a consequence have decreased QoL. It is clear that this is an important problem in many disease areas. Similar to other chronic conditions, urologists should be aware of the problem of nocturia and its consequences. In light of the significant negative impact of bothersome urinary symptoms such as nocturia on the patient’s QoS and his daytime energy/vitality and QoL, the severity of nocturia should be evaluated in clinical practice. Urologists should routinely ask patients with LUTS/BPH about nocturia-related problems, such as disturbed sleep, lack of energy, and impairment of QoL. Treatments for men with LUTS/BPH should be evaluated for their ability to relieve nocturia. However, measuring the severity of nocturia and its impact on QoS and QoL remains an obstacle. Most instruments currently used for measuring the impact of nocturia on the QoL and energy/vitality of patients lack sensitivity and are not specific. Therefore, new instruments need to be included in clinical research such as the recently developed and validated N-QoL questionnaire. In addition, the assessment of HUS was suggested as a potential instrument to measure the influence of nocturia on the QoS. Furthermore, new simple and valid instruments should be developed for use in daily clinical practice.

References


