

# Lower Urinary Tract

Several important topics are presented in this section, including the impact of surgical treatment on nocturia in men with BPH, pelvic floor exercises for stress urinary incontinence, chronic prostatitis in puberty, introital ultrasonography, and a systematic review published work on a stent for managing BPH.

## Impact of surgical treatment on nocturia in men with benign prostatic obstruction

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### OBJECTIVES

To validate the International Consultation on Incontinence Nocturia Quality-of-life (NQoL) questionnaire in Italian (IT-NQoL) and use it to evaluate the impact of surgical treatment on nocturia in men with lower urinary tract symptoms related to benign prostatic obstruction (LUTS/BPO).

### PATIENTS AND METHODS

All men attending one urological unit between November 2004 and April 2005 were enrolled in the study. They were assessed in two groups; those with and with no LUTS/BPO. An Italian translation of the NQoL was devised, and patients then completed this and validated Italian versions of the International Prostate System Score (IPSS), the Pittsburg Sleep Quality Index (PSQI) and the Epworth Sleepiness Scale (ESS). Clinical, laboratory and instrumental data from each patient were recorded. The patients with LUTS/BPO then had surgical treatment, and 6 months later those with LUTS/BPO were asked to complete all the questionnaires again to evaluate the test sensitivity to change.

### RESULTS

Of the 109 patients enrolled in the study, 61 were affected by LUTS/BPO and 48 were not. Cronbach's  $\alpha$  for the IT-NQoL was 0.943 (95%

confidence interval, CI, 0.922–0.959;  $P < 0.001$ ) and the intra-class correlation coefficient was 0.999 (95% CI 0.998–0.999;  $P < 0.001$ ) for the total IT-NQoL score. The correlation between the test and the re-test was statistically significant ( $P < 0.001$ ;  $r = 0.999$ ) for all items. The mean (SD) IT-NQoL score showed an improvement in QoL from before, at 23.4 (10.1), to after treatment, at 3.09 (2.48) ( $P < 0.001$ ). In the LUTS/BPO group, the IT-NQoL correlated with the number of times when waking to urinate (Pearson's coefficient 0.80,  $P < 0.001$ ). There was also a correlation for ESS (0.796) and for the seven PSQI subscales (0.614, both  $P < 0.001$ ). The decrease in sleep quality, duration and efficiency resulted in an increase in daytime sleepiness ( $r = 0.639, 0.642$ ). At the 6-month follow-up, all questionnaire results were statistically different from those before treatment.

### CONCLUSIONS

The IT-NQoL is the first validated translation of the primary instrument into another language. This version is easy to use and has the same characteristic validity as the English version. Using the IT-NQoL showed that surgical treatment determines a decrease in the nocturia rate and an increase in QoL. There was also a significant increase in QoL after treatment as assessed by all the other questionnaires.

## KEYWORDS

nocturia, N-QoL, BPH, quality of life, TURP, open prostatectomy

## INTRODUCTION

The Standardization subcommittee of the ICS defined nocturia as 'waking at night one or more times to void', distinguishing it from nocturnal polyuria [1], which they defined as the nocturnal production of >33% of the total 24-h urine volume [2]. Nocturia can be caused by many factors and is often related to ageing [3]. The incidence of nocturia increases with age and authors reported a frequency of 16% in men aged 40–49 years, to 60% in men aged 70–79 years [4,5]. Some authors described nocturia as one of the most common LUTS [6], representing the third most bothersome symptom after urgency and incontinence [7] in all subjects, and the most bothersome symptom in men suspected of or having benign prostatic obstruction (BPO) [8,9]. This symptom is often associated with bladder outlet obstruction (BOO), and is amongst the LUTS suggestive of BPO that are considered the most frequent cause impairing health-related quality of life (QoL) [9]. The decrease in QoL is due to poor sleep quality, increased daytime fatigue and lower levels of general well-being [4]. Moreover, many authors reported that nocturia, in addition to bothersomeness and sleep deficits, can be a risk factor for falling [10,11]. The decrease in a patient's QoL due to nocturia represents a social and economic problem [12], and a higher prevalence of cardiovascular diseases was reported in men with nocturia [13]. The correct evaluation of nocturia and its subsequent treatment in patients with LUTS/BPO represents the key to obtaining good urinary functional results and an improvement in QoL. At present, the proper assessment and epidemiological characteristics of nocturia are difficult to define, because all questionnaires used include nocturia in one or more items, among the other LUTS. To date, there is only the International Consultation on Incontinence Questionnaire (ICIQ) Nocturia QoL (NQoL) instrument, developed by Abraham *et al.* [4]; this instrument is an easily administered, self-completed questionnaire that specifically assesses the impact of nocturia on QoL. The principal aim of the present study was to validate an Italian version of the NQoL (IT-NQoL) in patients in one centre who

were affected by LUTS/BPO and who were subsequently treated by TURP or open prostatectomy (OP). The secondary aim was to evaluate the impact of surgical treatment on QoL, measured by using the IPSS [14], the Pittsburgh Sleep Quality Index (PSQI) [15], the Epworth Sleepiness Scale (ESS) [16] and the IT-NQoL.

## PATIENTS AND METHODS

To evaluate the psychometric properties of the IT-NQoL all consecutive men attending one urological unit between November 2004 and April 2005 were selected for the study. The men were assessed in two groups, i.e. those with LUTS/BPO and those without, the latter considered as a control group. The diagnosis of BPO and the assignment to the LUTS/BPO group was made by one urologist.

The men were included in the study if they met the criteria of the 5th International Consensus Committee on BPH (Paris, 2000), voided >150 mL during uroflowmetry, with the postvoid residual urine volume (PVR) and prostate size estimated, and frequency-volume charts (FVCs) completed correctly.

All men who reported nocturia at least twice per night, had a maximum urinary flow rate ( $Q_{max}$ ) of <15 mL/s, a PVR of >100 mL measured by transabdominal ultrasonography, an IPSS total of >7, a DRE negative for suspected malignancy, and who were able to comply with the follow-up schedules, were assessed as being in the LUTS/BPO group. The patients with a  $Q_{max}$  of 10–15 mL/s were included in the study if a second uroflowmetry confirmed the previous  $Q_{max}$  and if they had a PVR of >100 mL. All men with no history of LUTS or symptoms suggestive of BPO, a history of chronic urinary diseases, and an IPSS total of  $\leq 7$  were included in the control group.

All those who were not native speakers of Italian, and those with an inability to read or write, a history of sleep disorders, psychiatric illness, neurogenic bladder dysfunction, urethral stricture, age <35 or >85 years, severe systemic disorders, LUTS or other symptoms connected with UTI, previous surgical treatment for BPO or previous prostatic biopsy positive for prostate cancer, were excluded. Those patients with incidental prostate cancer (pT1) at the pathological analysis of the prostate surgery specimen were excluded.

Men with LUTS/BPO and included in LUTS/BPO group had had various medical treatments, but reported unchanged symptoms and no improvement in QoL. At the time of completing the questionnaire all patients included in the LUTS/BPO group had had the same medical treatment with  $\alpha_1$ -adrenoceptor antagonists for >1 year. No satisfactory results were reported by all the men included in the LUTS/BPO group in terms of symptom reduction during medical treatment. On the basis of the clinical history, score results and instrumental findings, men included in LUTS/BPO group had prostate surgery (TURP or OP). Those with a prostate volume of >80–100 mL or with urologically associated diseases had OP, while others had TURP, in accordance with the 5th International Consensus Committee on BPH. The prostatic measurements analysed were: anteroposterior diameter (AP), transverse diameter (TT) and longitudinal diameter (LL). The total prostatic volume (PV) was calculated as:  $4/3\pi \times AP/2 \times TT/2 \times LL/2$  [17]. The prostatic measurements were made during TRUS, performed by the same radiologist. Within a few minutes after voiding in a comfortable and private environment, each man was scanned using transabdominal ultrasonography to measure the PVR; all PVR estimates were also made by the same radiologist. The anatomical and pathological analysis was done by the same pathologist. All patients provided signed informed consent during their interview with the urologist, who gave them the questionnaires which they completed afterward by themselves. All medical interviews were by the same urologist. After the interview with the urologist, within 7 days, all men received a thorough explanation of the FVC from the same urologist, and were asked to complete a 3-day FVC, including the time and volume of each void and their bedtime and waking time. Men were asked not to alter their usual fluid intake and voiding habits during the study. The waking and sleeping hours were calculated for each patient using the recorded wake and sleep data. All FVCs were completed before any further diagnostic or therapeutic intervention was undertaken. The present study was conducted in line with Good Clinical Practice guidelines.

LUTS and their impact on patient QoL were measured using a validated Italian IPSS; this contains seven items, each having a response scale with six choices, ranging from 0 (absence of symptoms) to 5 (symptoms

always present) [18]. Nocturia was measured by using the IT-NQoL, which evaluates the impact of nocturia on QoL using 13 items (12 directly related to nocturia and one to general QoL) [4]. The items related to nocturia (1–12) have a response scale with five choices, ranging from 0 (absence of symptoms) to 4 (symptoms always present), while the item related to QoL (13) has a response scale with 11 choices, ranging from 0 (absence of nocturia impact on subject QoL) to 10 (severe nocturia impact on subject QoL). The items related to nocturia were grouped into two subscales; one explores the relationship between the impact of nocturia on quality of sleep and energy the day after, and the other the relationship between having to get up at night to urinate and related worries. The use of the copyrighted ICIQ-NQoL version required permission, obtained from the ICIQ Group via the website ([www.iciq.net](http://www.iciq.net)), in accordance with the ICIQ Advisory board policy. The quality of sleep was measured using the PSQI, in Italian, as translated by De Gennaro *et al.* [19]. The PSQI is a simple, self-administered questionnaire which contains 19 items assessing a wide variety of factors related to sleep quality [19]. The PSQI has seven subscales on sleep quality (sleep quality, C1; sleep onset latency, C2; sleep duration, C3; sleep efficiency, C4; sleep disturbance, C5; use of sleeping medications, C6; and daytime dysfunction, C7). The overall score ranges from 0 (absence of sleep-related problems) to 21 (severe sleep-related problems). A total score of >5 is considered an indicator of severe sleep disorders [15]. The PSQI was associated with the ESS to obtain a true evaluation of daytime sleepiness. The ESS was validated in its Italian version by Vignatelli *et al.* [20] and is a self-administered questionnaire for assessing subjective average sleep propensity during real-life situations, considered as an indicator of daytime sleepiness [16]. The Italian ESS has eight items with four choices, ranging from 0 (absence of sleepiness) to 3 (sleepiness always present) with an overall score ranging from 0 (absence of sleepiness) to 24 (severe sleepiness).

All questionnaires were given to each patient and their personal details were recorded. The questionnaires were self-administered at the urology unit. The time of completion was recorded for each patient. The IT-NQoL was administered again 1 week later to evaluate the test-retest reliability. At 6 months after surgery, all patients treated for BPO were

asked to complete all the questionnaires again, and underwent uroflowmetry and a urological visit. All patients in the control group were also asked to complete all questionnaires 6 months after completing the first questionnaire.

The ICIQ-NQoL was initially translated into Italian by two urologists and a urological nurse, using a linguistic validation technique similar to that used by Collins *et al.* [21]. Another translation into Italian was made by a bilingual professional translator. The two independent translations were compared and the differences were resolved. The final version was translated back into English by another bilingual professional translator. The ICIQ-NQoL and the final IT-NQoL were compared and the differences were again resolved. The final Italian version was approved by the two bilingual professional translators, the two urologists and the nurse. While the IT-NQoL is of high quality and has been produced using an internationally recognized process, an alternative version of the ICIQ-NQoL had already been produced during the course of this study by MAPI; this latter version will be retained as the official ICIQ Italian translation, as the group can only support the use of one version, to avoid confusion. The official Italian ICIQ-NQoL can be requested via the website, [www.iciq.net](http://www.iciq.net).

The internal consistency of the IT-NQoL was evaluated using Cronbach's  $\alpha$  coefficient. The test-retest reliability was analysed using the intra-class correlation coefficient (ICC). The assessment of the construct validity of the IT-NQoL was based on a comparison between the groups (LUTS/BPO or not). We assumed that there is a difference in QoL between these groups, with the hypothesis that the nocturia level was higher in the LUTS/BPO group than the control group. The difference in distribution between the patient and the control group was calculated using the Mann-Whitney *U*-test. Pearson's coefficient was used to evaluate the correlation between all variables. Fisher's exact test and the chi-square test were used to evaluate the significance of all variables. The questionnaire mean scores before and after surgery in the LUTS/BPO group were compared using the paired-samples *t*-test. Spearman's  $\rho$  was also used to calculate the correlation between the questionnaire results before and after surgery. Statistical significance was indicated at  $P < 0.05$ . The ability of the IT-NQoL to discriminate between patients with nocturia

and the control patients without was calculated using receiver operating characteristic curves. The sample size was obtained using Cohen's formula [22]; a sample of 47 patients for each group was required for the study.

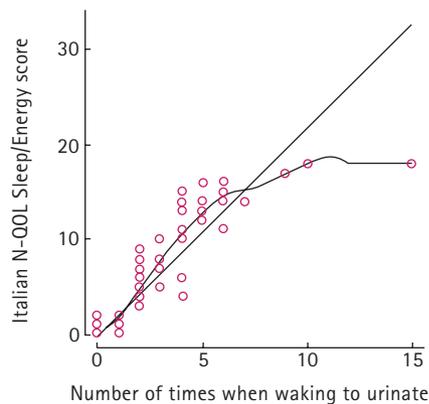
## RESULTS

In all, 111 men were recruited for the study; of all patients enrolled only two were excluded from the study because they had not completed all the questionnaires. The study included 109 men, 61 affected by LUTS/BPO and 48 controls. The patients' characteristics, clinical and laboratory data are described in Table 1. The LUTS/BPO patients had a mean (range) nocturia of 3.8 (2–15) times/night; of 61 patients, 31% reported waking to urinate twice, 23% three times and 20% four times per night. No patient in the control group reported nocturia of more than one voids/night.

All the questionnaire results for each group are reported in Table 2. No difference in difficulty was reported for completing the questionnaires between the groups. All questionnaires were easy to complete and understand by all men, regardless of their level of education. The IT-NQoL was well accepted by all patients and none omitted items. The IT-NQoL showed good convergent validity; the correlation between it and the IPSS was statistically significant ( $P < 0.001$ ) with a Pearson coefficient of 0.96. There were also significant correlations ( $P < 0.001$ ) with PSQI (0.79), ESS (0.89). IPSS item 7 (number of times when waking to urinate, NTWU) showed a significant correlation with IT-NQoL total score ( $r = 0.87$ ,  $P < 0.001$ ; Table 3). The IT-NQoL showed efficient separation between patients with nocturia and the control patients without. Considering a score of  $\geq 10$  as pathological, the sensitivity was 98% (95% CI 96–99) and specificity 100%. Cronbach's  $\alpha$  was 0.94 (95% CI 0.92–0.95) for the total IT-NQoL score, 0.81 (0.72–0.87) for the sleep/energy, 0.81 (0.73–0.87) for bother/concern and 0.87 (0.83–0.91) for QoL subscales (all  $P < 0.001$ ).

The reproducibility of the test was assessed in 48 LUTS/BPO patients and 31 controls 1 week after the first consultation; there was no significant difference between the first mean (SD) IT-NQoL score, at 15.41 (14.18), and the second, at 15.45 (14.23). The IT-NQoL had a

FIG. 1. A scatterplot showing the correlation between IT-NQoL sleep/bother subscale and the NTWU. The linear regression curve is shown.



mean (95% CI) ICC of 0.99 (0.998–0.999) ( $P < 0.001$ ). The correlation between the test and re-test was statistically significant ( $P < 0.001$ ;  $r = 0.99$ ) for all items.

At 6 months after surgery, all LUTS/BPO patients were required to complete all the questionnaires, during the urological check visit. The IT-NQoL score decreased from a mean (SD) of 23.49 (10.11) before to 8.11 (3.45) afterward ( $P = 0.009$ ) (Table 2). The IT-NQoL, IPSS, PSQ and ESS were statistically different between the patients with LUTS/BPO and the control group ( $P < 0.001$ ).

In the LUTS/BPO group, the IT-NQoL showed a significant correlation with the NTWU (Pearson's coefficient 0.80,  $P < 0.001$ ). The subscales had a correlation of 0.89 for sleep/energy, 0.86 for bother/concern and 0.88 (all  $P < 0.001$ ) for QoL (Table 3). The curve estimating the correlation between the NTWU and sleep/energy subscale was eight times larger at the maximum, with no increase in impact on the decrease in sleep/energy with more nocturia (Fig. 1). This correlation was also detected for the ESS (0.79,  $P < 0.001$ ). The PSQI subscale C7 showed the same significant correlation with the NTWU (0.61,  $P < 0.001$ ). These findings show the good convergent validity of the IT-NQoL and the severe impact of nocturia on QoL (Fig. 2). At the 6-month follow-up the decrease in the NTWU caused an increase in QoL, shown by the same decrease in the IT-NQoL, C7 PSQI subscale and ESS score.

The bother/concern subscale of IT-NQoL showed a significant ( $P < 0.001$ ) correlation

TABLE 1 Clinical, instrumental and laboratory data for patients with LUTS/BPO or controls

Mean (range) variable or n (%)	LUTS/BPO	Controls
Age, years*	69.9 (58–82)	68.4 (58–79)
Educational qualification:†		
Primary school	22 (36)	19 (39)
High school	21 (35)	15 (31)
University	18 (29)	14 (30)
<b>Baseline clinical data</b>		
Total PSA level, ng/mL	2.21 (0.80–7.10)	–
Urological disease, n		
Clinical BPH	61	0
Unilateral inguinal hernia	–	18
Bilateral inguinal hernia	–	7
Varicocele	–	11
Hydrocele	–	12
Total	61	48
FVC (24-h)		
Voiding frequency		
Diurnal	6.9 (7–12)	5.2 (3–7)
Nocturnal	3.8 (2–15)	0.41 (0–1)‡
Voided volume, mL		
Total	1216.9 (1050–1530)	1523.6 (330–1720)
Diurnal	817.9 (730–1020)	1473.6 (1330–1720)
Nocturnal	399 (280–430)	50 (0–60)
Sleeping hours	6.12 (4–9)	7.01 (5–9)
Prostate diameters, cm		
AP	4.5 (2.80–7.60)	–
TT	4.6 (3.10–6.30)	–
LL	4.7 (4.0–3.3)	–
PV, mL	55.76 (14.3–143.6)	–
Uroflowmetry data		
$Q_{max}$ , mL/s	11.7 (6–20)	–
Flow time, s	36.8 (14–79)	–
Time to $Q_{max}$ , s	10.7 (5–32)	–
PVR, mL	82.4 (0–326)	–
Treatment		
TURP	38 (62)	–
OP	23 (38)	–

No difference between groups, \* $P = 0.640$ , † $P = 0.769$ ; ‡two groups statistically different ( $P < 0.001$ ).

with C1 ( $r = 0.77$ ), C4 (0.56), C5 (0.82) and C7 (0.52) PSQI subscales (Table 3). The decrease in sleep quality, duration and efficiency resulted in an increase in daytime sleepiness ( $r = 0.63$  and 0.64).

The QoL subscale showed a significant ( $P < 0.001$ ) correlation with C1 (0.76), C5 (0.83), ESS (0.89) and IPSS (0.95) (Table 3), and with the NTWU (0.88), showing the severe impact of nocturia on QoL. There was no correlation between QoL and the prostatic measurements or uroflowmetry data. There

was no significant correlation between the NTWU and prostatic measurements (AP diameter  $P = 0.69$ , TT diameter  $P = 0.35$ , LL diameter  $P = 0.63$ ), prostate volume ( $P = 0.58$ ), PVR ( $P = 0.88$ ) or uroflowmetry variables ( $Q_{max}$ ,  $P = 0.34$ ; time to  $Q_{max}$ ,  $P = 0.54$ ; flow time,  $P = 0.68$ ).

The type of surgical treatment had no effect on QoL outcome measured with IT-NQoL ( $P = 0.43$ ), PSQI ( $P = 0.72$ ), ESS ( $P = 0.43$ ) or IPSS ( $P = 0.97$ ). At the 6-month follow-up, all questionnaire results were statistically

TABLE 2 Questionnaire results and characteristics before treatment, with the IT-NQoL sensitivity to change (results after treatment)

Questionnaire	Mean (SD) (range) or n			Mean (SD)		Spearman's ρ
	LUTS/BPO	Controls	P*	After treatment	P*	
<b>IT-NQoL (items)</b>						
Total score (1–13)	23.49 (10.11)	0.72 (1.06)	<0.001	8.11 (3.45)	0.009	–0.362
Sleep/energy (1–7)	9.52 (4.32)	0.39 (0.57)	<0.001	1.09 (0.92)	<0.001	–0.253
Bother/concern (8–12)	9.26 (4.20)	0.16 (0.37)	<0.001	1.06 (1.04)	<0.001	–0.289
Impact on QoL (13)	4.70 (1.98)	0.16 (0.37)	<0.001	0.93 (0.89)	<0.001	–0.132
Completion time, min	5 (3–7)	6 (4–7)	0.987			
Patients requiring explanations	3	–	+			
<b>IPSS (Items)</b>						
Total score (1–7)	18.31 (7.95)	0.56 (1.20)	<0.001	1.50 (2.05)	<0.001	0.89
Emptying (1)	2.44 (1.48)	0.62 (0.24)	<0.001	0.14 (0.47)	<0.001	–0.18
Frequency (2)	2.83 (1.12)	0.14 (0.46)	<0.001	0.19 (0.47)	<0.001	–0.001
Intermittency (3)	2.91 (1.33)	0.08 (0.27)	<0.001	0.22 (0.46)	<0.001	0.16
Urgency (4)	2.14 (1.83)	0.04 (0.20)	<0.001	0.37 (0.61)	<0.001	0.08
Weak stream (5)	1.67 (1.37)	0.08 (0.27)	<0.001	0.18 (0.38)	<0.001	–0.04
Hesitancy (6)	2.86 (1.17)	0.14 (0.41)	<0.001	0.27 (0.63)	<0.001	0.18
Nocturia (7)	3.42 (1.20)	0	<0.001	0.08 (0.27)	<0.001	0.26
Completion time, min	4 (2–6)	3 (3–5)	0.926			
Patients requiring explanations	5	2	+			
<b>PSQI (Items)</b>						
Total score (1–19)	3.29 (2.77)	0.62 (1.08)	<0.001	0.96 (1.04)	<0.001	0.76
Sleep quality (9)	0.62 (0.68)	0	<0.001	0.19 (0.40)	0.033	0.35
Sleep onset latency (2 + 5)	0.42 (0.49)	0.33 (0.59)	0.378	0.42 (0.49)	1.000	1.00
Sleep duration (4)	0.37 (0.63)	0.20 (0.45)	0.003	0.06 (0.24)	0.042	0.35
Sleep efficacy (h asleep/h in bed × 100)	0.45 (0.76)	0.40 (0.20)	<0.001	0.06 (0.24)	0.145	0.31
Sleep disturbances (sum 5b to 5j)	1.13 (0.34)	0.41 (0.209)	0.001	0.21 (0.41)	0.118	–0.20
Use of sleeping medication (6)	0	0	†	0	†	0
Daytime dysfunction (7 + 8)	0.27 (0.45)	0	<0.001	0	0.153	–0.30
Completion time, min	6 (4–7)	7 (3–9)	0.997			
Patients requiring explanations	1	–	+			
<b>ESS (Items)</b>						
Total score (1–8)	10.36 (2.85)	0.50 (0.98)	<0.001	2.06 (1.56)	<0.001	0.194
Completion time, min	2 (1–4)	3 (3–5)	0.906			
Patients requiring explanations	–	1	+			

\*Mann-Whitney U-test. Not measurable because: †insufficient sample difference between groups; ‡the SDs of both groups are 0.

different from those before surgery (Table 2). In the LUTS/BPO group, there was a significant reduction in NTWU. At their first consultation the LUTS/BPO and control groups were significantly different in the NTWU ( $P < 0.001$ ). At the 6-month follow-up there was no significant difference between the groups ( $P = 0.06$ ). There was no correlation between the IT-NQoL and the uroflowmetry data at the 6-month follow-up.

## DISCUSSION

The present IT-NQoL has the same characteristics as the original English NQoL;

the questionnaire had good convergent validity with the other questionnaires (IPSS, PSQI and ESS), a good internal consistency (Cronbach's  $\alpha$  0.94) and an ICC of 0.99, showing good test-retest reliability. Moreover, the IT-NQoL showed an efficient separation between patients with nocturia and those without (sensitivity 98% and specificity 100%). This questionnaire had good sensitivity to change for assessments before and after treatment ( $P < 0.001$ ). The IT-NQoL is a simple, self-administered questionnaire for evaluating the impact of nocturia on QoL, as reported in the original version [4]. Chapple [23] reported that the IPSS does not show how nocturia decreases sleep quality, or how

decreasing sleep quality affects QoL. The need for a specific method for measuring the impact of nocturia on sleep quality and on QoL is required [23] to correctly evaluate treatment outcome. The severe impact of nocturia on sleep quality is shown by the correlation between the NTWU and the sleep/energy NQoL subscale; this showed a significant maximum increase up to nocturia of eight times/night but any greater increase had no further impact on sleep quality. Lentz *et al.* [24] reported that sleep interruption in the first third of the night increases discomfort and daytime fatigue, even with no reduction of total sleep quantity. The present results showed that sleep interruption of

more than eight times had a significant effect on sleep quality in whatever part of the night. These results were confirmed by the significant correlation between the NTWU and the ESS ( $r = 0.79$ ) and C7 PSQI ( $r = 0.61$ ). Nocturia also has a severe impact on patients QoL, because it causes a condition of worry about the need to wake to urinate. This condition was shown by the correlation between the bother/concern NQoL subscale and C1 (0.77), C4 (0.56), C5 (0.82), C7 (0.52) PSQI subscales and daytime sleepiness (0.64). The condition of concern also determines the severe impact on social relationships and daytime enjoyable activities ( $r = 0.52$ ). There was no significant correlation between the prostatic diameters or uroflowmetry data and IT-NQoL, showing that nocturia related to BPO has no relationship with the prostatic dimensions or with uroflowmetry data. The IT-NQoL also showed that surgical treatment determines the decrease in the nocturia rate and increase in QoL, from the significant difference between evaluations before and after treatment (Table 2). We think that the significant response of the decreasing IT-NQoL score is probably due to improving general QoL and not only to the decrease in nocturia. These data suggest also that the IT-NQoL can correctly measure the effect that nocturia has on QoL. There was a significant increase in QoL after treatment using all questionnaires; with the PSQI there was an insignificant difference in the C7 item (daytime dysfunction) before and after treatment ( $P = 0.15$ ) but there was a correlation and a significant difference in the ESS before and after treatment ( $P < 0.001$ ). The insignificant difference in C7 before and after treatment could be accidental, probably due to sample randomization, because the correlation in PSQI total score before and after treatment was statistically significant ( $P < 0.001$ ).

In conclusion, the present IT-NQoL can be used for a valid evaluation of an important aspect of patient QoL, i.e. the impact of nocturia on sleep quality, and evaluate the change in QoL after the surgical treatment.

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TABLE 3 Correlation coefficients between IT-NQoL, IPSS, PSQI and ESS before treatment

Scale/subscale	IT-NQoL			
	Total score	Sleep/energy	Bother/concern	QoL
<b>IPSS</b>				
Total score	0.967	0.955	0.955	0.951
Emptying (1)	0.896	0.876	0.905	0.859
Frequency (2)	0.920	0.912	0.902	0.913
Intermittency (3)	0.949	0.936	0.942	0.929
Urgency (4)	0.864	0.844	0.864	0.850
Weak stream (5)	0.695	0.702	0.668	0.691
Hesitancy (6)	0.911	0.904	0.889	0.908
Nocturia (7)	0.951	0.940	0.938	0.937
<b>PSQI</b>				
Total score	0.790	0.781	0.778	0.781
Sleep quality (C1)	0.781	0.765	0.777	0.769
Sleep onset latency (C2)	0.420	0.414	0.421	0.404
Sleep duration (C3)	0.423	0.426	0.408	0.417
Sleep efficacy (C4)	0.582	0.583	0.568	0.569
Sleep disturbances (C5)	0.835	0.820	0.822	0.837
Use of sleeping medication (C6)	*	*	*	*
Daytime dysfunction (C7)	0.588	0.579	0.578	0.589
<b>ESS</b>				
Total score	0.896	0.884	0.877	0.899

\*not measurable because the SDs of both groups are 0.

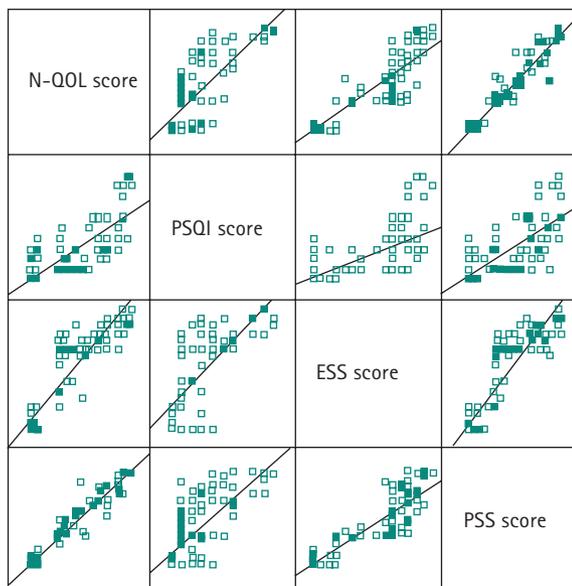


FIG. 2. Matrix form of the scatterplot, showing the correlation between IT-NQoL and IPSS, ESS and PSQI questionnaires. The linear regression curves are shown.

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#### CONFLICT OF INTEREST

None declared.

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e-mail: ktommy@libero.it
- Abbreviations:** ICIQ (NQoL), International Consultation on Incontinence Questionnaire (Nocturia QoL); QoL, quality of life; BPO, benign prostatic obstruction; AP, prostatic anteroposterior diameter; TT, prostatic transversal diameter; LL, prostatic longitudinal diameter; PV, prostatic volume; Q<sub>max</sub>, peak urinary flow rate; PVR, postvoid residual urine volume; OP, suprapubic open prostatectomy; IT-NQoL, Italian version of the ICIQ-NQoL; PSQI, Pittsburgh Sleep Quality Index; ESS, Epworth Sleepiness Scale; NTWU, number of times when waking to urinate; FVC, frequency-voiding chart; ICC, intra-class correlation coefficient.