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# Development and Validation of Nocturia-Related Quality of Life Assessment Scale among Adults

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## Abstract

**Background** Nocturia has high impact on quality of life (QoL) based on varying geographical and cultural factors. Speculating this, nocturia-related QoL (NRQoL) assessment scale was developed precisely, appropriate to the Indian context.

**Objective** The current study aimed to develop and validate an NRQoL assessment scale for Indian adults.

**Methods** An exploratory descriptive design was performed among 420 cases and 206 controls aged 35 to 65 years from two selected tertiary hospitals in Mangaluru, Karnataka, India. The NRQoL assessment scale was formulated through the following phases: review of literature, evaluation by experts, and pretesting. Exploratory factor analysis (EFA) was performed to reduce the number of items and to define domains. Reliability, construct validity, discriminant validity, and convergent validity of the scale were calculated.

**Results** EFA resulted in the removal of seven items from a 36-item instrument, resulting NRQoL assessment scale into six domains as follows: (1) functional, (2) sleep, (3) emotional, (4) physical, (5) social and family, and (6) spiritual. The findings from the tertiary hospitals study confirmed that the scale was valid and reliable to measure NRQoL among adults.

**Conclusion** The NRQoL assessment scale is a new, valid, and reliable instrument that is well-understood by adults and can be answered quickly. It is a useful new tool that can be translated and tested in other cultures and languages.

**Keywords**
- nocturia
- quality of life
- assessment scale
- development
- reliability
- validation

## Introduction

Nocturia is one of the most prevalent and troublesome symptoms associated with the lower urinary tract. It is defined as "the need to wake up to void during the sleep hours, with each of the urinations preceded and followed by sleep." The occurrence of nocturia takes place through three principal pathological mechanisms as follows: (1) night-time urine production, (2) function of bladder, and (3) sleep.[1] There is an increase in the occurrence of nocturia with age, with rates between 30 (for men age of 50–54 years) and 60% (for men age of >70 years).[2]

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The impact of nocturia on the health-associated quality of life (QoL) of a person has been recognized to be significant.[3,4] The association of nocturnal urination with poor quality of sleep, enhanced fatigue in the daytime, and lesser extents of overall well-being has been established.[5,6] These impacts may spread moreover to partners whose sleep may be disturbed as an outcome of living with an individual with nocturia.[7]

Nocturia is one of the common storage symptoms of lower urinary tract (men, 48.6% and women, 54.5%).[8] It is not a standalone symptom but mostly associated with other irritative bladder symptoms like urinary urgency (77.2%),[9] frequency, and even with urge incontinence.[10] These tend to occur together since they share many etiologies.[11] Nocturia was oftentimes considered a symptom associated with functional issues, such as overactive bladder syndrome (OAB) or benign prostatic hyperplasia (BPH), with bladder outlet obstruction, nocturnal polyuria, and global polyuria.[12,13] Patients with bladder outlet obstruction can have overflow incontinence which is predominantly noted at night due to lack of cerebral inhibitory control at sleep. When nocturnal leakage occurs, the need to change pads or clothing and bedding is particularly troublesome and disruptive to sleep.[14] Asian and European continent studies also have shown the prevalence of nocturia among clients with BPH were ranged from 42.8 to 85.9%.[15–18]

The nocturnal urine production has increased in case of nocturnal polyuria can clinically present as increased urgency and frequency.[19] Many frail patients with significant irritable bladder symptom prefer diaper usage at night. A study by Sells et al on partners' morbidity on BPH, one of the reason for low QoL was urge incontinence. He associates the disruption of social life, and the reluctance of patients with BPH and partners to go for social events or trips was frequency, urgency, nocturia, and incontinence that cause embarrassment.[7]

Moreover, the impact of nocturia on a patient's QoL is frequently the chief determinant for pursuing health care intervention that furthermore directs the selection of options for treatment. Thus, the measurement of frequency of symptoms together with the assessment of the opinion of patients with regard to their condition and related impacts is a significant facet of nocturia's outcome measures. Consequently, there is a need for validated instruments that investigate the impact of nocturia on its own on QoL.[20]

Accordingly, there has been considerable interest in developing QoL-related instruments for nocturia. For example, Abraham et al[20] developed a nocturia QoL (N-QoL) questionnaire for men with nocturia. This scale contained 13 items and was developed with inputs from male individuals from various cultures who had nocturia. The psychometric properties of the scale were tested in the United Kingdom in a comparable population. In a related study, McKown et al[21] assessed the linguistic validity of a harmonized translation of the N-QoL questionnaire and found that its overall item comprehension rate was 96%. Consequently, it could be seen that the translation of the N-QoL was equivalent, both from the linguistic and conceptual perspectives to the original questionnaires in English (both U.K. and U.S. styles). Moreover, patients understood the questionnaire well, in general, though additional assessment of some items was suggested some languages. Holm-Larsen et al[22] developed and validated nocturia impact diary, an expanded version of the N-QoL questionnaire which was designed to be used together with the 3-day voiding diary. Another study[23] also validated the N-QoL questionnaire and highlighted its usefulness in assessing nocturia and its effect on QoL and quality of sleep. Yamanishi et al[24] assessed the Japanese edition of the N-QoL questionnaire and found it a useful instrument to predict nocturia in Japanese patients.

It was evident from these review that none of these instruments were developed or assessed specifically on Indian population. Keeping these thoughts in mind that a universal scale may not be entirely suitable for usage at a national or regional level, the researcher perceived the need to develop a standardized nocturia-related QoL (NRQoL) questionnaire that would be appropriate for Indian population across different domains of life. Hence the aim of this was to develop and validate an NRQoL assessment scale for Indian adults.

## Materials and Methods

### Participant and Procedures

The testing of the psychometric characteristics of the NRQoL questionnaire involved the usage of a quantitative survey method to obtain data. Data were collected from the departments of urology, gynecology, and endocrine of selected hospitals at Mangaluru in Karnataka, India. The study was conducted over a period of 15 months (March 2018–July 2019). The data were collected from 420 adults with nocturia, that is, persons who woke up twice or more every night to urinate, and 206 controls. The age of the participants was between 35 and 65 years.

### Instrument Development

The NRQoL questionnaire was developed over multiple stages.

### Stage I: Development of Initial Pools of Items

In the first stage of instrument development, a pool of items was generated from various sources such as review of literature, expert opinion, existing QoL assessment scales, and interviews with individuals having nocturia. During this stage, according to the content areas specified in the test blueprint, a total of 62 items were formulated. Subsequently, irrelevant items were eliminated and a total of 42 items were included in the pool.

### Stage II: Face Validity of the Initial Item Pool

Face validity "involves an overall look of an instrument regarding its appropriateness to measure a particular attribute or phenomenon."[25] During the second stage of instrument development, the objectives were to evaluate the intelligibility of the phrasing of the items present in the item pool and to create new items to add to the pool. The

 

researcher informally interviewed few patients for understanding ability and complexity in the items to give appropriate response. Some of the questions that not well understood by the participants were reframed.

### Stage III: Content Validity and Reliability

Content validity of the instrument was performed through the services of a panel of experts and a group of individuals. The experts were requested to judge how well the measuring instrument met the standards.

The 42 items in the initial pool were formulated in a structured questionnaire format. The questionnaire was submitted to 16 experts in urology, gynecology, medicine and nursing fields, and medical professional. The rating of the experts was analyzed for individual items. Concurrence was found to range from 75 to 100% for relevance and 79 to 100% for clarity. The experts suggested that 12 questions can be reframed and that 6 questions could be eliminated as they were irrelevant. The final questionnaire was administered to 30 adults with nocturia to assess the feasibility and applicability of the items.

The reliability of the questionnaire was checked utilizing Cronbach's α.[26] The results of the test showed that the 36 items had a high reliability of 0.954, that is, they could be classed as acceptable for use in the study.[27] Further, Pearson's correlation test was performed for the 36 questionnaire items. The purpose of this test is to determine the extent to which the items in the scale are linearly related to each other.[25] The value for all the items was >0.5. Therefore, all the items could be retained.

All 36 items retained for factorial validation after the opinion of the experts and concurrence of the individuals. Likert's 5-point scale ranging not at all (0), a little (1), somewhat (2), quite a bit (3), and very much(4). The higher the score, the higher the agreement with the statement, and vice versa.

### Stage IV: Construct Validity

Construct validity pertains to assess the construct regarding QoL of clients with nocturia. The data were collected from 420 adults aged 35 to 65 years with voiding over two times and 206 (controls) adults aged 35 to 65 years who voided only once a night from two tertiary hospitals in Mangaluru, Karnataka, India. A total of 1,265 adult participants were screened initially by the investigator to identify the presence of nocturia. All the patients attending the department of Urology, Gynecology, Medicine, and Endocrine (till the calculated sample size 420 adult clients) were selected. The sample size was calculated for the group I (nocturia ≥2 voids) based on the prevalence (47%) and the attrition rate was considered as 10%. However, the prevalence of 16% was considered for the group II (controls) with one episode of nocturia. The sample size estimation was done by using the formula:

$$Z\,\alpha\,2 \times (p) \times (1-p)$$
$$e^2$$

The study sample size consisted of 420 adults (group I) and 206 adults (group II). Both groups were recruited using purposive sampling. To measure this construct validity in this study, it has been assessed through exploratory factor analysis (EFA) and Confirmatory Factor Analysis (CFA). EFA is utilized to expose complex patterns in the data and to evaluate predictions. The CFA was utilized to find validity of each item in the domains and as of whole the validity of all the domains to measure nocturia related QoL among adults. EFA and CFA were performed separately for both case and control datasets.

### Convergent and Discriminant Validity

Determination of the discriminant validity, that is, the capability to distinguish between known groups, was performed through the utilization of average variance extracted (AVE) analysis to contrast the scores of persons experiencing different number of episodes of nocturia every night on average. It is assumed by discriminant validity that "items should correlate higher among them than they correlate with other items from other constructs that are theoretically supposed not to correlate."[28] AVE was also utilized to assess the convergent validity of the scale.

The AVE analysis requires the testing of the square root of the AVE value which belongs to every latent construct to determine if this is greater than any correlation between any latent construct pairs. AVE evaluates the construct's explained variance.[28]

## Results

### Participant Characteristics

The data were collected from 420 adults with nocturia and 206 controls from two tertiary hospitals in Mangaluru, Karnataka, India. The participants were informed about the purpose of the collection of data and informed consent was received from them prior to proceeding with study.

### Reduction of Items: Exploratory Factor Analysis

Prior to performing the EFA, the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy and the Bartlett test of sphericity were performed using AMOS software. The outcome of the KMO test was 0.952 which confirmed that the sample was of adequate size to perform the factor analysis of the scale. Further, the Bartlett test revealed a significant Chi-square value of 9053.207 ($p = 0.000$), denoting that the correlations among the variables were sufficient.

In the outcomes of the EFA, factors with eigen values >1 and factor loadings of ≥0.5 were regarded as acceptable. Consequently, items such as Q19, Q20, Q21, Q22, Q26, Q27, and Q33 could be removed from the scale as their factors' loadings were <0.5. The final scale contained six domains as follows: (1) functional (eight items), (2) sleep (six items), (3) emotional (four items), (4) physical (three items), (5) social and family (five items), (6) and spiritual (three items). Furthermore, reliability was tested again using Cronbach's α for these identified domains with 29 items and the reliability of each construct was found to be sufficient. The outcomes of the EFA are provided in ►**Table 1**.

 

**Table 1** Factors of NRQoL–EFA

| Old question number | New item number | Statements | Factor loading | % of variance | Cronbach's α | Domain name | Reliability of the modified domain Cronbach's α |
|---|---|---|---|---|---|---|---|
| Q1 | FUN-Q1 | I am unable to fulfil my task | 0.689 | 12.69 | 0.890 | Functional | 0.890 |
| Q2 | FUN-Q2 | I feel exhausted on the next day | 0.686 | | | | |
| Q3 | FUN-Q3 | I have unpleasant feeling to carry out task | 0.674 | | | | |
| Q4 | FUN-Q4 | I have difficulty to do household tasks | 0.655 | | | | |
| Q5 | FUN-Q5 | I have lack of concentration at workplace | 0.640 | | | | |
| Q6 | FUN-Q6 | I have to take nap during the day | 0.549 | | | | |
| Q7 | FUN-Q7 | I have lack of energy | 0.531 | | | | |
| Q8 | FUN-Q8 | I am preoccupied with night urination | 0.505 | | | | |
| Q9 | SLE-Q9 | I am dissatisfied with initiating sleep | 0.802 | 12.36 | 0.903 | Sleep | 0.907 |
| Q10 | SLE-Q10 | I am dissatisfied with feeling of rested after sleep | 0.758 | | | | |
| Q11 | SLE-Q11 | I am dissatisfied with returning to sleep after awakening at night | 0.752 | | | | |
| Q12 | SLE-Q12 | I am dissatisfied with feeling fresh felt after sleep | 0.744 | | | | |
| Q13 | SLE-Q13 | I am dissatisfied with depth of sleep | 0.739 | | | | |
| Q14 | SLE-Q14 | I am dissatisfied with duration of sleep | 0.603 | | | | |
| Q15 | EMO-Q15 | I am worried about stinking | 0.741 | 10.18 | 0.826 | Emotional | 0.826 |
| Q16 | EMO-Q16 | Disturbed due to often change of undergarments/pampers for leaking of urine | 0.706 | | | | |
| Q17 | EMO-Q17 | I restrict myself drinking fluids purposefully | 0.556 | | | | |
| Q18 | EMO-Q18 | I am anxious and depressed | 0.534 | | | | |
| Q19 | Deleted | I have dissatisfaction with my sex life | 0.489 | | | | |
| Q20 | Deleted | I feel I am financially burden to my family | 0.462 | | | | |
| Q21 | Deleted | I am worried about need for taking further treatment | 0.456 | | | | |
| Q22 | Deleted | I have difficulty to accept my illness | 0.431 | | | | |
| Q23 | PHY-Q19 | I have difficulty to lift the object | 0.806 | 10.03 | 0.875 | Physical | 0.878 |
| Q24 | PHY-Q20 | I have difficulty to walk | 0.804 | | | | |
| Q25 | PHY-Q21 | I have difficulty to climb more than 10 stairs | 0.760 | | | | |

 

**Table 1** (*Continued*)

| Old question number | New item number | Statements | Factor loading | % of variance | Cronbach's α | Domain name | Reliability of the modified domain Cronbach's α |
|---|---|---|---|---|---|---|---|
| Q26 | Deleted | I had fall | 0.485 | | | | |
| Q27 | Deleted | Overall physical health is limited | 0.449 | | | | |
| Q28 | SOFA-Q22 | I am uncomfortable to travel in long distance | 0.634 | 8.74 | 0.801 | Social and family | 0.706 |
| Q29 | SOFA-Q23 | I am having difficulty with my family relationships | 0.576 | | | | |
| Q30 | SOFA-Q24 | I am hesitant to stay in relatives house due to night urination | 0.562 | | | | |
| Q31 | SOFA-Q25 | I am feeling of disturbing others at home due to night urination | 0.530 | | | | |
| Q32 | SOFA-Q26 | I am embarrassed to attend social gathering at night due to unintentional passage of urine | 0.512 | | | | |
| Q33 | Deleted | I am worried about the prognosis of disease | 0.427 | | | | |
| Q34 | SPI-Q27 | I cannot concentrate in prayers | 0.800 | 8.22 | 0.841 | Spiritual | 0.841 |
| Q35 | SPI Q28 | I am unable to visit church/temple/mosque | 0.782 | | | | |
| Q36 | SPI Q29 | I am unable to participate in my spiritual activities | 0.720 | | | | |

Abbreviations: EFA, exploratory factor analysis; NRQoL, nocturia-related quality of life.

Following the EFA, CFA was performed to identify the dimensions and factor loading to check whether all items are loading sufficiently by the construct. The result obtained showed that each construct loaded sufficiently. The model fit indices of the scales for QoL as obtained in CFA were the Chi-Square Mean/Degree of Freedom (CMIN/DF) of 2.494, being $<5$ suggests that the model is a good fit. The Goodness of Fit Index (GRI) (0.8587), Adjusted Goodness of Fit Index (AGFI) (0.8301), and Comparative Fit Index (CFI) (0.9207) were close to 0.9 or $>0.09$, again suggesting that the model is a good fit (►**Fig. 1**).

### Construct Validity

The modified scale was utilized with controls with nocturia once at night. The mean value of controls was found to be lower than the cases and the *p*-value showed a highly significant difference. Therefore, it can be inferred that the construct is well explained by the scale, and its construct validity is good (►**Table 2**).

### Convergent and Discriminant Validity

For each construct, the AVE values must be contrasted with the squared correlation coefficients of the other constructs. For the NRQoL scale, the AVE was found to exceed the minimum value of 0.5[29] for all the subconstructs of the scale (►**Table 3**). Thus, the scale demonstrated acceptable convergent validity. Moreover, the AVE scores were greater than the squared correlations between all domain pairs. Hence, the scale was seen to demonstrate acceptable discriminant validity as well.

### Receiver Operating Characteristic Analysis

The receiver operating characteristic (ROC) curve analysis was performed to indicate the benefit of using QoL scores (►**Table 4**). The total QoL score is in the range of 0 to 116, with a higher score indicating poorer QoL. The cut-off score for QoL is 35 where $<35$ indicates a good QoL, 35 to 62 indicates moderate QoL, 63 to 89 indicates poor QoL, and 90 to 116 indicates very poor QoL (►**Table 5**). The area under the curve (AUC) for the QoL score was 0.979 (95% confidence interval [CI]: 0.968–0.990; $p < 0.01$). It can be inferred that in 97.9% of cases, at the best cut-off QoL score, the sensitivity and specificity were 97.9 and 86.4% in discriminating cases with NRQoL.

## Discussion

The NRQoL scale is, to the researchers' best knowledge, the first questionnaire to evaluate the effect of nocturia on the

 

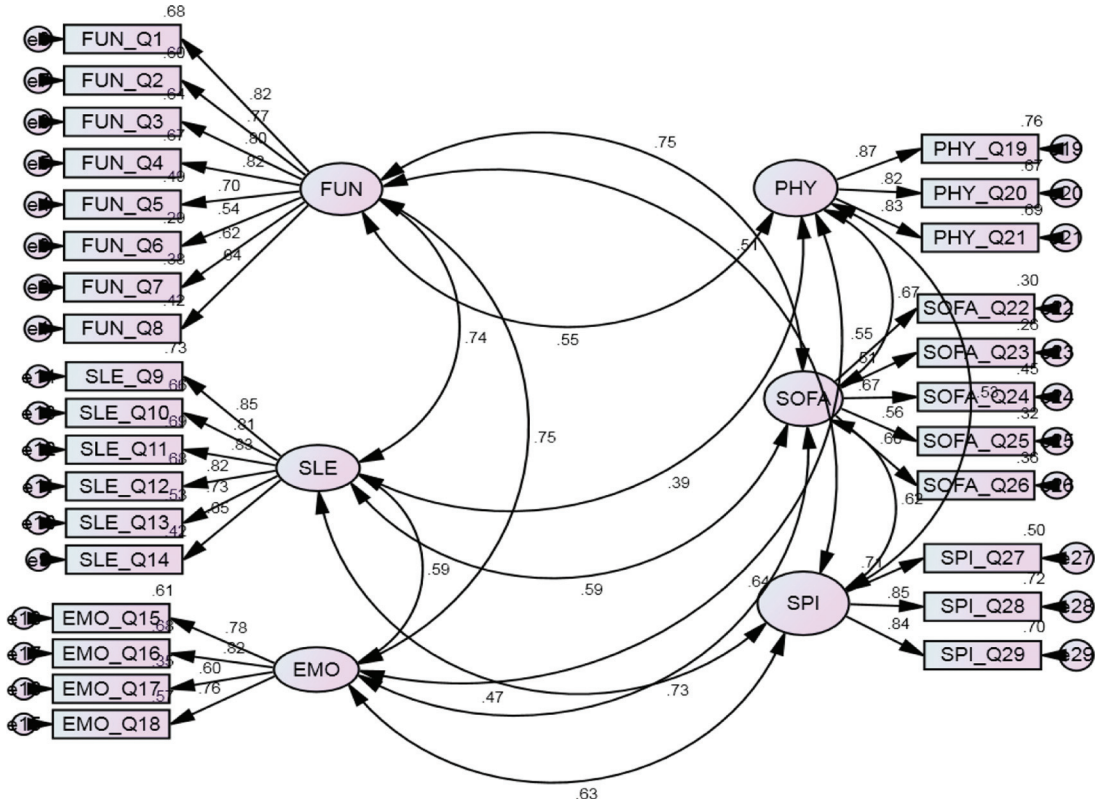


**Fig. 1** The dimensions and factor loading of the construct. Abbreviations: EMO, Emotional; FUN, Functional; PHY, Physical; SLE, Sleep; SOFA, Social and Family; SPI, Spiritual.

**Table 2** Construct validity for the scale

| Group | *n* | Minimum | Maximum | Mean | Standard deviation | *t*-Value | *p*-Value | |
|---|---|---|---|---|---|---|---|---|
| 1. Cases | 420 | 20 | 116 | 72.98 | 20.728 | 32.444 | .000 | HS |
| 2. Controls | 206 | 0 | 75 | 20.76 | 14.560 | | | |

Abbreviation: HS, highly significant.

**Table 3** Discriminant validity (average variance extracted analysis)

| Domain | Physical | Functional | Financial | Emotional | Spiritual | Sleep | Social and Family |
|---|---|---|---|---|---|---|---|
| Physical | 0.604 | | | | | | |
| Functional | 0.229 | 0.716 | | | | | |
| Financial | 0.200 | 0.307 | 0.953 | | | | |
| Emotional | 0.233 | 0.209 | 0.148 | 0.614 | | | |
| Spiritual | 0.222 | 0.200 | 0.252 | 0.229 | 0.786 | | |
| Sleep | 0.112 | 0.222 | 0.205 | 0.137 | 0.162 | 0.568 | |
| Social and family | 0.264 | 0.265 | 0.040 | 0.527 | 0.099 | 0.091 | 0.719 |

**Table 4** Test result variable(s): quality of life

| Area under the curve and 95% confidence interval | Standard error | Sensitivity | Specificity | Best cut-off value | Significance |
|---|---|---|---|---|---|
| 0.979 (0.968–0.990) | 0.006 | 97.9% | 86.4% | 35 | 0.000 |

 

**Table 5** Grading of nocturia-related quality of life (NRQoL) assessment scale among adults

| QoL grade | Scores |
|---|---|
| Good QoL | <35 |
| Moderate QoL | 35–62 |
| Poor QoL | 63–89 |
| Very poor QoL | 90–116 |

QoL of Indian adults. The scale was constructed in response to a perceived need for a standardized NRQoL questionnaire that would be appropriate for the Indian population, as it was believed that a general scale may not be entirely appropriate for usage with such a population. The scale is simple and can be self-administered taking <10 minutes to complete. Moreover, it can be utilized in the clinical environment as was demonstrated by the present study when the data were collected in the hospitals in Mangaluru. The questionnaire was developed using inputs from literature, experts, and scales already existing for assessment of QoL, and interviews with persons having nocturia. The scale's psychometric properties were assessed in a population of patients with nocturia in Mangaluru, India.

The validity of the instrument was ascertained by face, content, and constructs validity. Moreover, the internal consistency and reliability of the instrument were found to be good. The resulting instrument is a self-administered questionnaire with multidimensional aspects of QoL for both men and women. The QoL assessment of adults with nocturia has various dimensions, namely, functional, sleep, emotional, physical, social and family, and spiritual.

Subsequently, the original questionnaire was reduced from 42 to 36 items through content validity and from 36 to 29 items using EFA for item reduction. The scale and its subconstructs were found to have good internal consistency. Moreover, it demonstrated good convergent and discriminant validity.

## Limitation of the Study

The overall score on the scale and the subscales could not be utilized to differentiate between the cases and controls since no intervention was performed. Moreover, the questionnaire was developed and tested using participants from only one city in India (i.e., Mangaluru).

## Conclusion

This paper has described the development of an assessment scale for NRQoL for adults (►**Appendix A**). The psychometric evaluation of the scale revealed that it is a valid and reliable evaluation of nocturia's effect on the QoL of Indian patients. It therefore aids in generating awareness of the effect of nocturia on the QoL of persons and can thus serve to supplement clinical methods, facilitate decisions related to treatment, and, probably, assess novel treatments for this complaint.

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**Conflict of Interest**
None declared.

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## Appendix A

Nocturia-related quality of life (NRQoL) assessment scale among adults

Code Number:

The following statements are about impact of night urination on QoL. Kindly read the questions clearly and you are requested place tick mark (✔) in the box next to the response that best describes how you have felt. Please mark only one box for each statement. (Scores: not at all, 0; a little, 1; somewhat, 2; quite a bit, 3; and very much, 4)

Over the past 1 month, due to night urination——-

| Functional domain | | Not at all | A little | Somewhat | Quite a bit | Very much |
|---|---|---|---|---|---|---|
| 1 | I am unable to fulfil my task | | | | | |
| 2 | I feel exhausted on the next day | | | | | |
| 3 | I have unpleasant feeling to carry out task | | | | | |
| 4 | I have difficulty to do household tasks | | | | | |
| 5 | I have lack of concentration at workplace | | | | | |
| 6 | I have to take nap during the day | | | | | |
| 7 | I have lack of energy | | | | | |
| 8 | I am preoccupied with night urination | | | | | |
| Sleep domain | | | | | | |
| 9 | I am dissatisfied with initiating sleep | | | | | |
| 10 | I am dissatisfied with feeling of rested after sleep | | | | | |
| 11 | I am dissatisfied with returning to sleep after awakening at night | | | | | |
| 12 | I am dissatisfied with feeling fresh felt after sleep | | | | | |
| 13 | I am dissatisfied with depth of sleep | | | | | |
| 14 | I am dissatisfied with duration of sleep | | | | | |
| Emotional domain | | | | | | |
| 15 | I am worried about stinking | | | | | |
| 16 | Disturbed due to often change of undergarments/pampers for leaking of urine | | | | | |
| 17 | I restrict myself drinking fluids purposefully | | | | | |
| 18 | I am anxious/depressed | | | | | |
| Physical domain | | | | | | |
| 19 | I have difficulty to lift the objects | | | | | |
| 20 | I have difficulty to walk | | | | | |
| 21 | I have difficulty to climb more than 10 steps | | | | | |
| Social and family domain | | | | | | |
| 22 | I am uncomfortable to travel long distance | | | | | |
| 23 | I am having difficulty with my family relationships | | | | | |
| 24 | I am hesitant to stay in relatives house due to night urination | | | | | |
| 25 | I am disturbing others at home due to night urination | | | | | |

(*Continued*)

 

(*Continued*)

| | | Not at all | A little | Somewhat | Quite a bit | Very much |
|---|---|---|---|---|---|---|
| 26 | I am embarrassed to attend social gathering at night due to unintentional passage of urine | | | | | |
| Spiritual domain | | | | | | |
| 27 | I cannot concentrate during prayers | | | | | |
| 28 | I am unable to visit church/temple/mosque | | | | | |
| 29 | I am unable to participate in my spiritual activities | | | | | |

Note: QoL grades: good QoL (<35), moderate QoL (35–62), poor QoL (63–89), very poor QoL (90–116).

 