Cross-cultural translation into Chinese and psychometric evaluation of a screening tool for nocturia: the Targeting the individual's Aetiology of Nocturia to Guide Outcomes (TANGO) questionnaire

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A B S T R A C T

Introduction: We conducted translation and psychometric validation of a self-administered, 22-item dichotomous response–based questionnaire to identify nocturia aetiologies and co-morbidities in adult patients.

Methods: The Targeting the individual's Aetiology of Nocturia to Guide Outcomes (TANGO) questionnaire was forward- and backward-translated, then finalised using a standardised methodology. The resulting version, a Chinese version of the TANGO [TANGO (CV)], was evaluated for internal consistency, test-retest reliability, content validity, convergent validity, criterion validity, and discriminant validity via responses from 65 participants (46 men and 19 women; mean age, 67 years, range, 50-88), in comparison with other validated questionnaires and a 4-day bladder/sleep diary.

Results: Only 0.4% of responses were missing; 3% of participants required assistance with comprehension. The Kuder–Richardson Formula 20 (KR-20) coefficient for the whole tool was 0.711. Kappa values for individual domains and the whole tool varied from 0.871 to 0.866, indicating satisfactory test-retest reliability. There was strong agreement between the sum of positive responses to each domain and the whole tool (intra-class correlation coefficient=0.878-1.000). Modest correlations (ρ=0.4-0.6) were detected between the tool and bladder/sleep diary–based parameters for convergent validity. Criterion validity was confirmed for each domain and the whole tool [ρ=0.287-0.687]. In receiver operating characteristic analysis, the tool could distinguish patients (≥2 nocturia episodes/night) from controls (≤1 nocturia episode/night) [Youden's J statistic=0.453, area under the curve=0.818, 95% confidence interval (CI)=0.683-0.953] and patients with significant nocturia distress from patients with mild nocturia distress (Youden's J statistic=0.398, area under the curve=0.729, 95% CI=0.581-0.878).

Conclusion: The TANGO (CV) was formally cross-culturally adapted and translated. Its psychometric properties (except sensitivity to change) were validated.

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New knowledge added by this study

- A Chinese version of the Targeting the individual's Aetiology of Nocturia to Guide Outcomes questionnaire, a tool to screen for nocturia aetiologies and co-morbidities, has been validated.
- The tool can be understood by patients without substantial assistance from medical staff.
- The tool can distinguish patients with significant nocturia distress from patients with mild nocturia distress.

Implications for clinical practice or policy

- The tool can be self-administered and used by multiple specialties in the treatment of patients with nocturia distress.
- The aetiologies contributing to nocturia can be rapidly identified.
- Patients can receive earlier referral to the appropriate teams/specialties to manage the underlying causes of nocturia.

夜尿症病因篩查問卷（TANGO）的跨文化中文版翻譯和心理計量驗證

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引言：此次研究目的是翻譯和使用心理計量學來驗證一份包含22條二元變項題目的自我填寫問卷TANGO，用於篩查夜尿病因並評估其在成人患者中的影響。

方法：我們把原本的TANGO問卷從英文翻譯為中文，然後翻譯回到英文，再比較原來英文版本，使用標準化的方法確立中文版問卷定稿。之後我們邀請了65名參與者（46男19女，平均年齡為67歲，介乎50-88歲之間）填寫中文版TANGO問卷、其他經過驗證的問卷和連續4天的膀胱／睡眠日記。我們比較分析以上收集的資料數據，以了解中文版TANGO問卷的內部一致性、重測信度、內容效度、收斂效度、效標效度和判別效度。

結果：未回答題目比率僅0.4%。只有3%參與者需要醫護幫助以理解問卷題目。整份問卷的庫李二十號公式（KR-20）系數達到0.711。問卷的整體及其各項領域的Kappa值在0.817至0.896之間，代表重測信度令人滿意。整體問卷及其各項領域正面得分總和的一致性很強（組內相關系數=0.878-1.000）。中文版問卷與膀胱／睡眠日記收錄的數據建立的參數的收斂效度具有適度相關性（ρ=0.4-0.6）。整體問卷及其各項領域的效標效度也得到了確認[Spearman的相關性：ρ=0.287-0.687]。接收者操作特徵曲線分析顯示中文版問卷可用於區分患者（夜尿≥一晚2次）與對照者（夜尿≤一晚1次）[Youden's J統計量：0.453，曲線下面積：0.818，95%置信區間=0.683-0.953]，亦能用於區分受夜尿輕度困擾和嚴重困擾的患者（Youden's J統計量：0.398，曲線下面積：0.729，95%置信區間=0.581-0.878）。

結論：中文版TANGO問卷是次經過正式的跨文化翻譯和改編。除了對變化的反應未經驗證之外，此中文版的心理計量特性已經得到驗證。

Introduction

A recent population survey in Hong Kong showed that 68% of men and 67% of women aged >40 years seeking medical advice for lower urinary tract symptoms (LUTS) had ≥2 nocturia episodes/night[1]; these prevalences are greater than that among individuals of similar age reported in other global studies.[2] Across urology clinics in Southeast Asian countries, nocturia has emerged as the most common presenting symptom (up to 88%) among men with LUTS requiring treatment[3]; however, at least half of these patients were dissatisfied with the results of treatment.[4]

Nocturia is no longer considered a distinct urologic disease.[5] Indeed, it is related to disorders within and outside the lower urinary tract, which are associated with diminished bladder capacity, increased rate and volume of nocturnal urine production, sleep disturbance, or a combination of these symptoms.[6] Thus, initial treatment is difficult and there is a need for a tool that captures relevant aetiological information earlier in the diagnostic pathway.

The short form of the Targeting the individual's Aetiology of Nocturia to Guide Outcomes (TANGO) is a recently developed, 22-item, dichotomous-choice, multi-dimensional, self-administered questionnaire in English with robust psychometric properties.[7,8] This questionnaire covers four thematic areas regarding aetiologies and co-morbidities related to nocturia: cardiovascular or metabolic disorders, sleep/nocturnal pain/apnoea variables, urinary tract symptoms, and mental health and well-being (including falls). This study was performed to translate and cross-culturally adapt the TANGO into Chinese, ie, to produce a Chinese version of the TANGO [TANGO (CV)], then evaluate its reliability and validity for use in Hong Kong.

Methods

Phase I: linguistic translation

We adopted the cross-cultural translation methodology described by Sperber[9] and recommended by the original authors of the TANGO.[7] Six independent bilingual translators were asked to produce six forward translations (in Chinese) of each item of the TANGO, with the goal of conceptual translation; all six forward translations were back-translated to English, yielding six back-translations.

The six back-translations (in English) were reviewed by a panel of urologists (n=4), urology nurse specialists (n=2), and staff without a medical background (n=2) who were not involved in conducting this study, to produce a preliminary draft of each item in the translated tool. Each item in the English back-translations was compared with the original English version by ranking in terms of language comparability and the interpretation similarity using a Likert scale from 1 (extremely comparable/similar) to 7 (not at all comparable/similar). Items from the back-translations with a mean score <2.50 were retained. The forward translations (Chinese) of the retained back-translated English items were reviewed and compared in a panel consensus meeting comprising four urologists, two urology nurse specialists, and two bilingual translators. These items were used to draft the final version of the translated tool, the TANGO (CV).

Phase II: psychometric evaluation

After linguistic translation, a prospective psychometric evaluation study was conducted. From December 2019 to March 2020, we recruited male and female patients aged 45 to 90 years who presented to the urology clinic for management of LUTS problems and with self-reported nocturia episodes of ≥2 per night as patient group. Exclusion criteria

were a history of prostatic surgery and/or prostate cancer, as well as the presence of active urinary tract infection, active cancer receiving treatment, bladder stone, neuropathic bladder, dependent daily activities (including feeding, bathing, and walking with assistance), diabetes insipidus, renal failure, pregnancy, and/or illiteracy. Healthy individuals of similar age with self-reported nocturia episode of ≤1 per night were recruited as controls.

After recruitment, participants completed the TANGO (CV), the Chinese version of the International Prostate Symptom Score (IPSS),[10] the International Consultation on Incontinence Questionnaire Nocturia module (ICIQ-N),[11] the Nocturia-Specific Quality-of-Life Questionnaire (NQoL),[12] the Hong Kong Chinese version of the Overactive Bladder Symptom Score (OABSS-HKC) questionnaire,[13] the Epworth Sleepiness Scale (ESS),[14] and the Chinese version of the STOP-Bang questionnaire.[15] Participants underwent assessment of their histories of hypertension, diabetes mellitus, hyperlipidaemia, cerebrovascular accident, ischaemic heart disease, peripheral oedema, and obstructive sleep apnoea; their responses were cross-checked with the diagnostic codes of the central registry and their previous medical records. Blood glucose, glycated haemoglobin (HbA1c), and estimated glomerular filtration rate were measured. Participants were also given bladder/sleep diaries to record the time and volume of each voiding event, along with their sleep information (times of going to bed, falling asleep, awakening from sleep, and rising from bed), for 4 consecutive days at home within 2 weeks after recruitment. Participants then returned the bladder/sleep diaries to the clinic and repeated the TANGO (CV).

Reliability and validity

Reliability (inter-item correlation) was determined by internal consistency based on the Kuder–Richardson Formula 20 (KR-20) coefficient, which is specifically designed for dichotomous-choice questionnaires.[16] Test-retest reliability was determined using Cohen's kappa value (κ) and the intra-class correlation coefficient (ICC) by comparing the agreement of repeat responses for each item and the congruency of the number of positive responses to the tool between recruitment and follow-up (2 weeks later). κ≥0.4 and ICC ≥0.7 were considered acceptable reliability.[17]

We examined content validity by assessing the level of missing data, which indicated acceptability and difficulty in terms of participant understanding of items within the tool. Construct validity, which reflects the theory underlying nocturia, was evaluated by comparing the number of the positive responses to each of the four domains and all four domains of the TANGO (CV) with data regarding bladder/sleep diary–based parameters, as follows:

1. Cardiovascular/metabolic domain (Questions 1-7) was compared with the bladder diary (nocturia episodes, rate and volume of nocturnal urine output between falling asleep and awakening, and nocturnal polyuria index);
2. Sleep-related domain (Questions 8-13) was compared with the bladder diary [sleeping time, sleep latency, sleep quality, and degree of vitality after sleep, using a scale from 0 (the worst) to 10 (the best)];
3. LUTS domain (Questions 14-18) was compared with the bladder diary as in (1);
4. General well-being domain (Questions 19-22) was compared with the bladder diary as in (2);
5. The whole tool (all four domains, Questions 1-22) was compared with the abovementioned parameters.

Criterion validity was estimated by comparing the number of the positive responses to each of the four domains and all four domains with the responses to items on other questionnaires evaluating similar constructs, as follows:

1. Cardiovascular/metabolic domain was compared with ESS, STOP-Bang questionnaire, ICIQ-N-4(b) and NQoL sleep/energy domain, NQoL bother/concern domain, NQoL global QoL domain, and total score of NQoL;
2. Sleep-related domain was compared with ESS, STOP-Bang questionnaire, ICIQ-N-4(b), and NQoL;
3. LUTS domain was compared with IPSS voiding (sum of scores of Questions 1, 3, 5, and 6), IPSS storage (sum of scores of Questions 2, 4, and 7), ICIQ-N-4(b), OABSS (total), and NQoL;
4. General well-being domain was compared with IPSS QoL, NQoL sleep/energy domain, NQoL bother/concern domain, NQoL global QoL domain, and total score of NQoL.

We assumed that a correlation coefficient ρ≥0.4 was moderate and acceptable[18] as evidence of construct/criterion validity.

For discriminant validity, receiver operating characteristic analysis, in combination with Youden's J statistic [ie, sensitivity–(1-specificity)], was performed to explore whether the sum of positive responses to the whole tool could be used to distinguish: (1) patients from controls; and (2) patients with significant nocturia distress from patients with mild nocturia distress (Question 12 of NQoL).

Sample size calculation

Assuming a type I error (α) of 0.05 and type II error (1-β) of 0.8, we calculated that:

1. a Spearman's correlation coefficient (ρ) of 0.4 (with ρ=0.0 for the null hypothesis) required a sample size of 46 participants[19];
2. κ=0.4 for each item (with κ=0 for the null

hypothesis) for the test-retest reliability of the TANGO (CV) required a minimum sample of 47 respondents.[17]

Assuming an attrition rate of 20%, approximately 60 participants (patients and controls) were needed.

Statistical analysis

Continuous data were reported as mean and standard deviation or median and range. Categorical data were described using frequencies and percentages. For comparisons of continuous data, Student's *t* test or the Mann-Whitney *U* test was used, depending on the data distribution; for comparisons of categorical data, the Pearson Chi squared test or Fisher's exact test was used. The Spearman's correlation coefficient was used to assess associations between parametric or ordinal data and continuous data with a skewed distribution; the Pearson correlation coefficient was used to assess associations between normally distributed continuous data. SPSS Statistics (Windows version 26.0; IBM Corp, Armonk [NY], United States) was used for data analysis. P values <0.05 were considered statistically significant.

TABLE 1. Demographic and clinical characteristics*

Characteristic	Whole cohort (n=65)	Control group (n=14)	Patient group (n=51)	P value
Sex ratio (male:female)	46:19	11:3	35:16	0.741
Age, y	67.22 ± 9.13 (50-88)	66.86 ± 9.60 (52-87)	67.31 ± 9.09 (50-88)	0.870
Height, cm	163.36 ± 7.62 (147-182)	167.58 ± 8.33 (151-182)	162.2 ± 7.06 (147-174)	0.018
Weight, kg	66.62 ± 11.89 (42-110)	74.38 ± 14.86 (56-110)	64.5 ± 10.10 (42-89)	0.005
Body mass index, kg/m^2	24.92 ± 3.77 (17.10-33.59)	26.38 ± 4.06 (20.32-33.21)	24.52 ± 3.62 (17.10-33.60)	0.102
Diabetes mellitus	16	4	12	0.732
Hypertension	32	7	25	1.000
Hyperlipidaemia	25	7	18	0.363
Cerebrovascular accident	7	2	5	0.638
Ischaemic heart disease	6	1	5	1.000
Peripheral oedema	1	0	1	1.000
Obstructive sleep apnoea	1	1	0	0.215
Median HbA1c %	6.83 ± 6.43 (4.9-57)	6.18 ± 0.60 (5.30-7.10)	7.01 ± 7.20 (4.90-57.00)	0.148
Asian-modified eGFR, mL/min/1.73 m^2	83.58 ± 20.99 (21.81-115.28)	84.88 ± 20.39 (47.87-105.96)	83.46 ± 21.48 (21.80-115.28)	0.825
IPSS Q7	2.83 ± 1.40 (0-5)	0.79 ± 0.43 (0-1)	3.39 ± 0.98 (2-5)	<0.001
IPSS total	11.60 (1-34)	2.00 (1-12)	14.00 (2-34)	<0.001
ICIQ-N-4(a)	2.88 (0-7)	0.85 (0-2)	3.24 (2-7)	<0.001
ICIQ-N-4(b)	5.00 (0-10)	0.33 (0-5)	6.80 (0-10)	<0.001
NQoL total	17.17 (1-45)	3.00 (1-20)	19.60 (1-45)	<0.001
OABSS total	4.50 (0-14)	1.45 (0-5)	5.60 (2-14)	<0.001
ESS total	4.53 (0-18)	4.60 (0-13)	4.50 (0-18)	0.968
STOP-Bang total	3.26 ± 1.31 (1-8)	3.14 ± 1.29 (2-5)	3.29 ± 1.33 (1-8)	0.706
No. of positive responses				
Cardiovascular/metabolic domain	1.03 (0-4)	1.00 (0-2)	1.11 (0-4)	0.377
Sleep-related domain	2.00 (0-4)	1.00 (0-3)	2.27 (0-4)	0.046
LUTS domain	1.83 (0-4)	0.500 (0-3)	2.16 (1-4)	<0.001
General well-being domain	0.375 (0-3)	0.071 (0-1)	0.476 (0-3)	0.022
All domains	4.95 (0-14)	2.33 (0-9)	5.67 (1-14)	<0.001

Abbreviations: eGFR = estimated glomerular filtration rate; ESS = Epworth Sleepiness Scale; HbA1c = glycosylated haemoglobin; ICIQ-N = International Consultation on Incontinence Questionnaire Nocturia module; IPSS = International Prostate Symptom Score; LUTS = lower urinary tract symptoms; NQoL = Nocturia-Specific Quality-of-Life Questionnaire; OABSS = Overactive Bladder Symptom Score

* Data are shown as mean ± standard deviation (range) or median (range), unless otherwise specified

Results

Linguistic validation

Comparability scores for each item in the TANGO (CV) ranged from 1.38 (0.52) to 2.25 (1.28), with an overall mean score of 1.70 (0.88). Similarity scores for each item ranged from 1.00 (0.52) to 2.13 (1.36), with an overall mean score of 1.63 (0.88). The TANGO (CV) is shown in the online supplementary Table.

Demographic data and patient responses to the items

This study included 65 participants, which include 51 (78.5%) patients (mean age: 67 years; 35 men, 16 women) with mean self-reported nocturia episodes of 3.39 per night (standard deviation=0.98; range, 2-5) and 14 (21.5%) controls (mean age: 67 years; 11 men, three women) with mean self-reported nocturia episodes of 0.79 per night (standard deviation=0.43, range, 0-1). The demographic and baseline clinical characteristics are shown in Table 1; the bladder/sleep diary–based parameter data are shown in Table 2. The control group had fewer positive responses (median=2.33) to items in the TANGO (CV), less nocturia distress, higher functional bladder capacity during daytime and night-time, and a lower nocturnal urine excretion rate; however, control participants reported similar prevalences of medical conditions that could cause nocturia, compared with patients who experienced ≥2 nocturia episodes/night.

All 65 participants reported that the questions in the tool were clearly presented, and they answered 99.6% of the items in the tool (total items=22 × 65=1430). Two (3%) participants required assistance with comprehension to complete the TANGO (CV). Missing responses were noted for items related to the use of antihypertensives (n=1), the diagnosis of diabetes mellitus/impaired glucose level (n=1), and unstable glucose level (n=1); three men were unable to respond to the question concerning prostate enlargement [Table 3]. In total, 41 (63%) participants reported at least one positive response (total responses=72) in the cardiovascular/metabolic domain, 48 (74%) participants reported at least one positive response (total responses=154) in the sleep-related domain, 54 (83%) participants reported at least one positive response (total responses=119) in the LUTS domain, and 21 (32%) participants reported at least one positive response (total responses=32) in the general well-being domain. The item with most positive responses was nocturia within 3 hours after going to bed (80% of participants) and the item with the fewest positive responses was the use of diuretics (0 responses) [Table 3]. Among the four thematic areas, 90% of participants had positive responses to ≥1 domain. Only three (6%) of the 51 patients with ≥2 nocturia episodes/night exhibited nocturia-

TABLE 2. Bladder/sleep diary–based parameters*

Bladder/sleep diary–based parameter	Whole cohort (n=55)	Control group (n=6)	Patient group (n=49)	P value
Age, y	66.47 ± 8.97 (50-88)	62.33 ± 6.95 (52-70)	66.98 ± 9.12 (50-88)	0.235
Nocturia episodes per night	3.65 ± 1.53 (0.75-11.25)	1.88 ± 0.96 (0.75-3.25)	3.87 ± 1.45 (2.25-11.25)	0.002
Maximum voided volume noted in bladder diary, mL	320.00 (100-2200)	475.00 (380-710)	305.00 (100-2200)	0.039
Total voided volume across bladder diary, mL	184.00 (60.80-706.25)	232.11 (171.21-706.25)	180.27 (60.82-525.64)	0.045
Maximum voided volume during nocturia, mL	305.00 (100-2200)	415.00 (300-710)	300.00 (100-2200)	0.111
Mean voided volume per nocturia episode, mL	208.89 (61.65-705.00)	292.64 (167.00-705.00)	208.46 (61.65-485.42)	0.059
Nocturnal polyuria index ratio	0.39 ± 0.12 (0.080-0.750)	0.37 ± 0.24 (0.080-0.750)	0.4 ± 0.10 (0.250-0.730)	0.599
Nocturnal urine output per night, mL	835.11 ± 460.37 (252.25-2922.65)	565.91 ± 262.55 (311.83-948.79)	868.08 ± 470.20 (252.25-2922.65)	0.131
Mean nocturnal urine excretion rate, mL/h	94.83 ± 49.81 (29.35-281.86)	68.2 ± 25.85 (30.00-102.20)	98.09 ± 51.20 (29.36-281.86)	0.041
Sleeping time per night, min	487.98 ± 91.53 (220.00-815.00)	480.21 ± 207.19 (220.00-815.50)	488.93 ± 70.31 (272.50-646.75)	0.828
Sleep latency, min	26.88 (0.75-103.75)	16.67 (0.75-62.50)	28.25 (1.67-103.75)	0.110
Sleep quality noted in bladder/sleep diary rated on 7-point Likert scale	5.97 ± 1.61 (2.25-10.00)	7.5 ± 2.17 (5.00-10.00)	578 ± 1.44 (2.25-9.00)	0.012
Vitality after sleep noted in bladder/sleep diary rated on 7-point Likert scale	6.17 ± 1.75 (2.00-10.00)	7.17 ± 2.15 (4.25-10.00)	6.05 ± 1.68 (2.00-10.00)	0.142

* Data are shown as mean ± standard deviation (range) or median (range), unless otherwise specified

related problems that were limited to a single domain.

Internal consistency and test-retest reliability

The KR-20 coefficients of the four domains of the TANGO (CV) were 0.354-0.615 (best in sleep-related and general well-being domains; worst in cardiovascular/metabolic domain), suggestive of fair to moderate subscale internal consistency. For the whole tool, the KR-20 coefficient was 0.711 (ie, >0.700), indicating satisfactory overall internal consistency. Kappa values were between 0.817 and 0.871 for items in each of the four domains and 0.866 for the whole tool, whereas ICCs were between 0.878 and 1.000 for the subtotal positive responses in each of the four domains and 0.972 for the whole tool; these findings indicated near-perfect test-retest reliability.

Construct (convergent) validity

Table 4 shows the construct (convergent) validity of the TANGO (CV). The sleep-related domain was positively correlated with sleep latency [ρ=0.471 (P<0.001)], whereas it was negatively correlated with sleep quality [ρ=-0.407 (P=0.002)] and vitality after sleep [ρ=-0.467 (P<0.001)], as reported in the bladder/sleep diary. The LUTS domain was positively correlated with the number of nocturia episodes, rate of nocturnal urine production, and volume of nocturnal urine production [ρ=0.513 (P<0.001), ρ=0.333 (P=0.016), and ρ=0.309 (P=0.026), respectively]. However, the LUTS domain was not correlated with sleep/vitality parameters. In contrast, the general well-being domain was significantly positively correlated with the rate and volume of nocturnal urine production [ρ=0.319 (P=0.018) and ρ=0.312 (P=0.021), respectively]; it was significantly

TABLE 3. Frequency distribution of responses to each item of the TANGO (CV) [n=65]*

Domain and question		Condition present	Condition absent	Responses missing
Cardiovascular/metabolic				
Q1	Leg oedema	12 (18.5)	53 (81.5)	0
Q2	Diuretics	0	65 (100)	0
Q3	Kidney disease	2 (3.1)	63 (96.9)	0
Q4	Antihypertensives	31 (47.7)	33 (50.8)	1 (1.5)
Q5	Postural dizziness	5 (7.7)	60 (92.3)	0
Q6	Diabetes mellitus /impaired glucose	20 (30.8)	44 (67.7)	1 (1.5)
Q7	Unstable glucose level	2 (3.1)	62 (95.4)	1 (1.5)
Sleep-related				
Q8	Sleep ≤5 hours	32 (49.2)	33 (50.8)	0
Q9	Poor sleep quality	36 (55.4)	29 (44.6)	0
Q10	Sleep latency	33 (50.8)	32 (49.2)	0
Q11	Sleep disrupted by nocturia	28 (43.1)	37 (56.9)	0
Q12	Nocturnal pain	3 (4.6)	62 (95.4)	0
Q13	Snoring/sleep apnoea	22 (33.8)	43 (66.2)	0
Lower urinary tract symptoms				
Q14	Nocturia ≤3 hours after sleep	52 (80.0)	13 (20.0)	0
Q15	Urgency very often	22 (33.8)	43 (66.2)	0
Q16	Urgency incontinence	10 (15.4)	55 (84.6)	0
Q17	Straining	8 (12.3)	57 (87.7)	0
Q18	Enlarged prostate	27 (41.5)	35 (53.8)	3 (4.6)
General well-being				
Q19	Poor general health	18 (27.7)	47 (72.3)	0
Q20	Daytime sleepiness	2 (3.1)	63 (96.9)	0
Q21	Fall	5 (7.7)	60 (92.3)	0
Q22	Lack of interest in daily activities	7 (10.8)	58 (89.2)	0
Subtotal		377 (26.4)	1047 (73.2)	6 (0.4)

Abbreviations: Q = question; TANGO (CV) = Targeting the individual's Aetiology of Nocturia to Guide Outcomes (Chinese version)
* Data are shown as No. (%)

negatively correlated with vitality after sleep [ρ=-0.403 (P=0.002)]. The cardiovascular/metabolic domain did not display significant correlations with the bladder/sleep diary parameters. Nonetheless, the whole tool was significantly positively correlated with the number of nocturia episodes [ρ=0.378 (P=0.006)], the rate and volume of nocturnal urine production [ρ=0.394 (P=0.004) and ρ=0.380 (P=0.006), respectively], and sleep latency very closely [ρ=0.275 (P=0.051)]; it was significantly negatively correlated with sleep quality and vitality after sleep [ρ=-0.392 (P=0.004) and ρ=-0.483 (P<0.001), respectively].

TABLE 4. Construct (convergent) validity of the TANGO (CV)*

Domain	Nocturia episodes per night	Rate of nocturnal urine production	Volume of nocturnal urine production	Mean voided volume per nocturia episode	Nocturnal polyuria index	Sleeping time per night	Sleep latency	Sleep quality	Vitality
Cardiovascular/metabolic	0.181	0.236	0.233	0.085	0.223	0.042	0.134	0.041	-0.098
P value	0.191	0.086	0.091	0.542	0.105	0.764	0.332	0.766	0.485
Sleep-related	0.219	0.147	0.166	0.005	0.091	0.028	**0.471**	**-0.407**	**-0.467**
P value	0.107	0.283	0.225	0.973	0.512	0.841	<0.001	0.002	<0.001
Lower urinary tract symptoms	**0.513**	**0.333**	**0.309**	-0.111	0.133	-0.071	0.027	-0.238	-0.200
P value	<0.001	0.016	0.026	0.435	0.348	0.618	0.851	0.091	0.158
General well-being	0.129	**0.319**	**0.312**	0.187	0.163	-0.111	0.072	-0.224	**-0.403**
P value	0.347	0.018	0.021	0.171	0.233	0.419	0.604	0.101	0.002
Whole tool	**0.378**	**0.394**	**0.380**	0.079	0.181	-0.091	**0.275**	**-0.392**	**-0.483**
P value	0.006	0.004	0.006	0.583	0.205	0.528	0.051	0.004	<0.001

Abbreviation: TANGO (CV) = Targeting the individual's Aetiology of Nocturia to Guide Outcomes (Chinese version)

* Spearman's correlation coefficients between bladder/sleep diary–based parameters and the sum of positive responses to items in each domain of the tool, with significant values shown in bold

TABLE 5. Criterion validity of the TANGO (CV)*

Domain	Epworth Sleepiness Scale total	STOP-Bang total	IPSS voiding	IPSS storage	IPSS total	IPSS QoL	OABSS total	ICIQ-N-4(b)	NQoL sleep/energy (Q1, 2, 3, 4, 5, 6, 11)	NQoL bother/concern (Q7, 8, 9, 10, 12)	NQoL global QoL (Q13)	NQoL total (Q1-13)
Cardiovascular/metabolic	0.134	**0.251**	-0.054	0.038	-0.041	0.038	0.123	-0.132	0.004	-0.153	-0.036	-0.106
P value	0.295	0.047	0.674	0.771	0.751	0.774	0.336	0.303	0.981	0.304	0.808	0.481
Sleep-related	-0.053	-0.123	**0.263**	**0.244**	**0.262**	**0.333**	0.189	**0.348**	**0.361**	**0.297**	0.253	**0.363**
P value	0.673	0.327	0.034	0.049	0.035	0.008	0.132	0.005	0.011	0.039	0.081	0.011
Lower urinary tract symptoms	0.129	**0.336**	**0.501**	**0.646**	**0.651**	**0.533**	**0.642**	**0.499**	**0.532**	**0.551**	**0.458**	**0.587**
P value	0.319	0.008	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.001	<0.001
General well-being	**0.274**	0.170	0.029	**0.295**	0.177	**0.441**	**0.364**	**0.463**	**0.409**	**0.441**	0.261	**0.457**
P value	0.027	0.175	0.821	0.017	0.159	<0.001	0.003	<0.001	0.004	0.002	0.071	0.001
Whole tool	0.162	0.165	**0.372**	**0.464**	**0.448**	**0.535**	**0.491**	**0.421**	**0.496**	**0.469**	**0.361**	**0.524**
P value	0.216	0.208	0.003	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.001	0.014	<0.001

Abbreviations: ICIQ-N = International Consultation on Incontinence Questionnaire Nocturia module; IPSS = International Prostate Symptom Score; NQoL = Nocturia-Specific Quality-of-Life Questionnaire; OABSS = Overactive Bladder Symptom Score; Q = question; TANGO (CV) = Targeting the individual's Aetiology of Nocturia to Guide Outcomes (Chinese version)

* Spearman's correlation coefficients between the sum of positive responses to items in each domain of the tool and parameters derived from other validated questionnaires, with significant values shown in bold

Criterion validity

Criterion validity was confirmed for each domain and the whole tool (ρ=0.287-0.687). Regarding criterion validity, the cardiovascular/metabolic domain was only significantly correlated with the STOP-Bang questionnaire. The sleep-related domain was not correlated with questionnaires specifically designed to assess obstructive sleep apnoea. However, this domain was strongly correlated with the IPSS, IPSS QoL, and the sleep/energy, bother/concern, and total domains of NQoL (Table 5). The LUTS domain was significantly correlated with the STOP-Bang questionnaire, IPSS, OABSS questionnaire, and NQoL; the strongest correlations involved IPSS total [ρ=0.651 (P<0.001)], OABSS [ρ=0.642 (P<0.001)], and NQoL bother/concern [ρ=0.551 (P<0.001)]. In contrast to the LUTS domain, the general well-being domain was significantly correlated with the ESS; it was also correlated with the IPSS, OABSS questionnaire, ICIQ-N-4(b) and NQoL, but these correlations were weaker than the correlations of the LUTS domain (Table 5).

Discriminant validity

Receiver operating characteristic analysis (Fig) showed that a cut-off of four positive responses on the TANGO (CV) could distinguish patients from controls (Youden's J statistic=0.453; area under the curve=0.818, 95% confidence interval [CI]=0.683-0.953; odds ratio=7.81, 95% CI=2.02-30.30; sensitivity: 83%, specificity: 62%), whereas a cut-off of five positive responses could distinguish patients with significant nocturia distress from patients with mild nocturia distress (Youden's J statistic=0.398; area under the curve=0.729, 95% CI=0.581-0.878; odds ratio=4.07, 95% CI=1.17-14.15; sensitivity: 70%, specificity: 63%).

Discussion

Current questionnaires in evaluating nocturia

The International Continence Society (ICS) defines nocturia as the need to wake at least once during the night to void. Each instance of voiding is preceded and followed by sleep.[20] A recent Delphi panel convened by the ICS[5] recommended using disease-specific questionnaires in the diagnostic pathway for nocturia. In English, there are a few psychometrically validated disease-specific measurement tools for nocturia: the NQoL, developed and validated by Abraham et al[12]; the ICIQ-N, a form of the NQoL modified from the ICIQ (https://iciq.net/iciq-nqol); and the Nocturia, Nocturnal Enuresis and Sleep-Interruption Questionnaire (NNES-Q) developed

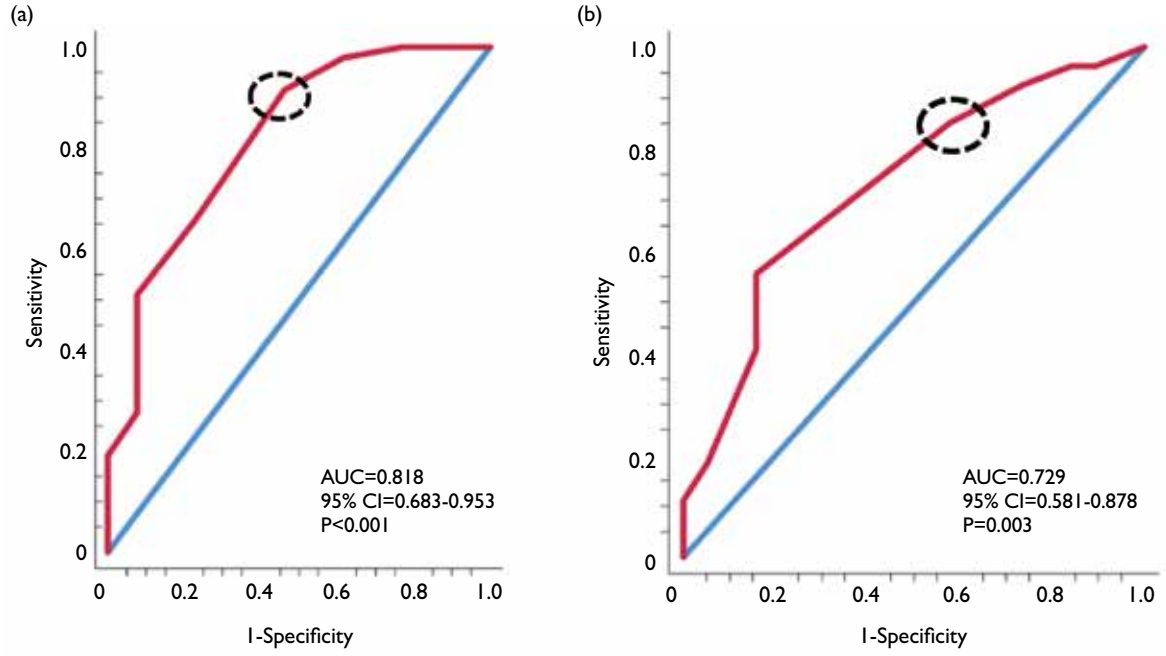

FIG. Receiver operating characteristic (ROC) curves (in red) showing sensitivity (true positives) and 1-specificity (false positives) for distinguishing (a) patients from controls and (b) patients with significant nocturia distress from patients with mild nocturia distress, based on the sum of positive responses on the TANGO (CV). Cut-off values are indicated by dashed circles. Blue lines are baseline classification due to chance

Abbreviations: AUC = area under the curve; CI = confidence interval; TANGO (CV) = Targeting the individual's Aetiology of Nocturia to Guide Outcomes (Chinese version)

by Bing et al.[21] The ICIQ-N[11] is a combined questionnaire that incorporates a bladder diary–Nocturia Impact Diary.[22] However, all of these tools mainly focus on the impact of nocturia on distress and quality of life in affected patients; none of them explore the aetiologies of nocturia.

The TANGO has emerged as a questionnaire that can capture information concerning the multifaceted nature of nocturia and identify nocturia-related co-morbidities.[7,23] This tool is expected to be useful across various medical specialties to facilitate, improve, and accelerate the process of nocturia management. Thus far, the TANGO has been translated into Dutch,[24] Arabic,[25] and Turkish.[26] However, none of these translated versions have been subjected to validity assessment using a bladder/sleep diary. To our knowledge, the present study is the first to perform such an assessment.

Translation and development of the TANGO (CV)

The ages of our study participants were similar to that of individuals in whom nocturia is commonly observed (>60 years). We found that the TANGO (CV) could be easily comprehended by patients visiting urology clinics, as indicated by the small percentage of missing responses (0.4%) and minimal need for assistance from medical staff (97%); these results suggested good content validity. The low rate of missing responses might be related to the dichotomous-choice nature of responses to items, which facilitated answers by participants.

In all, 94% of our participants with ≥2 nocturia episodes/night were affected by multiple domains of aetiological factors/nocturia-related co-morbidities; approximately 8% of patients reported experiencing falls, which is a higher percentage than in a previous study that used a nocturia-specific questionnaire (<3%).[27] The distribution of aetiologies/co-morbidities of nocturia in our study was similar to the distribution reported by a Turkish group[26]: the LUTS domain was most commonly observed, followed by the sleep-related domain, and then the cardiovascular/metabolic domain. However, the rate of poor general well-being was lower in the present study than in the Turkish study. The simple TANGO (CV) can easily capture information concerning the multifactorial nature of nocturia that could be not elucidated by other nocturia-specific questionnaires.[11,12,21,22] Thus, it will facilitate the provision of more individualised treatment for nocturia.

The KR-20 coefficient for the whole tool was 0.711 (>0.700), confirming the internal consistency of the whole TANGO (CV) tool. The highest domain-specific positive response correlation coefficient was observed in the sleep-related domain, implying that nocturia is closely related to impaired sleep quality and disrupted sleep architecture.

The high ICC value (>0.8) for each domain of nocturia-related problems confirmed the excellent test-retest reliability of the tool, in combination with the convergent validity identified in the sleep-related, LUTS, and general well-being domains of the TANGO (CV). With the exception of the cardiovascular/metabolic domain, criterion validity was also established for other domains and the whole TANGO (CV) tool; the criterion validity was the greatest in the LUTS domain, followed by the sleep-related domain and then the general well-being domain. Importantly, the original version of the TANGO[7] does not provide a symptom score, although such a score is strongly recommended in European Association of Urology guidelines as a means of quantifying symptoms and distinguishing patients with mild problems from patients with severe problems.[28] In this regard, a scoring system involving the various domains of the TANGO has recently been proposed to distinguish the relative contributions of nocturia aetiologies to treatment outcomes.[8] In the present study, we showed that by using cut-offs of four and five positive responses, respectively, the sum of the positive responses could distinguish individuals with more nocturia episodes (≥2/night) from individuals with fewer nocturia episodes (≤1/night), and patients with significant nocturia distress (Question 12 of NQoL) from patients with mild nocturia distress (Fig). These findings confirmed the discriminatory validity of the TANGO (CV).

The cardiovascular/metabolic domain demonstrated suboptimal performance in terms of internal consistency, convergent, criterion, and discriminant validity. These findings might be related to selection bias in that patients with higher cardiovascular risk were not recruited [ie, there was a low positive response rate (72 of 455 potential responses, 16%)].

Use of the TANGO (CV) in clinical practice

The TANGO (CV) can be used to investigate common aetiologies and nocturia-related outcomes across multiple medical specialties, providing guidance for subsequent treatment. For example, positive responses to Questions 1, 2, and 3 in the cardiovascular/metabolic domain and Question 13 in the sleep-related domain may indicate that desmopressin is less appropriate or even contraindicated for the treatment of nocturia, in accordance with the recent consensus report by the ICS.[5] The questionnaire can also be used as a screening tool for epidemiological studies and routine clinical work-up for nocturia. It is a simple, rapid, easily understood, and clinically meaningful tool that can help clinicians to thoroughly evaluate nocturia aetiology and related problems earlier in the

clinical pathway of nocturia treatment. Moreover, it may be useful in categorising or predicting the prognosis of nocturia in adults.

Limitations

The limitations of the current study included the fact that about 70% of the participants were men, which may limit its utility in assessment of female patients with nocturia. Additionally, the sample size was insufficient to clarify correlations among domain variables, number of positive responses, and subtotal and total symptom scores across the various questionnaires used for validation. The inclusion of patients with more pronounced illnesses within the studied domains should be considered to clearly identify relationships among nocturia, aetiologies, lower urinary tract function, and co-morbidities, as measured by bladder/sleep diaries and validated questionnaires.

Conclusion

The TANGO (CV) is a multi-dimensional, self-administered, formally translated, psychometrically validated Chinese version of the TANGO. It can be used to screen for aetiologies and measure the impacts of nocturia-related problems on affected individuals, including their quality of life. The sum of positive responses to the whole tool was significantly correlated with the degree of nocturia-related distress.

Author contributions

Concept or design: SKK Yuen, W Bower, CF Ng.
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Analysis or interpretation of data: SKK Yuen, PKF Chiu, JYC Teoh.
Drafting of the manuscript: SKK Yuen, CF Ng.
Critical revision of the manuscript for important intellectual content: SKK Yuen, CF Ng, SSM Hou.

All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

As editors of the journal, CF Ng and JYC Teoh were not involved in the peer review process. Other authors have disclosed no conflicts of interest.

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Ethics approval

The study protocol was approved by the Joint Chinese University of Hong Kong—New Territories East Cluster Clinical Research Ethics Committee (Ref No.: 2019.400), in accordance with the Declaration of Helsinki and the Good Clinical Practice guidelines. Informed consent to take part in the research was obtained from all participants.

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