RESEARCH ARTICLE

Linguistic and psychometric validation of Sinhala version of Menopause Specific Quality of Life questionnaire

Nirmala Rathnayake*[1], Gayani Alwis[2], Janaka Lenora[3], Iresha Mampitiya[4] and Sarath Lekamwasam[5]

[1]*Department of Nursing, Faculty of Allied Health Sciences, University of Ruhuna, Sri Lanka.*
[2]*Department of Anatomy, Faculty of Medicine, University of Ruhuna, Sri Lanka.*
[3]*Department of Physiology, Faculty of Medicine, University of Ruhuna, Sri Lanka.*
[4]*Department of Gynecology and Obstetrics, Faculty of Medicine, University of Ruhuna, Sri Lanka.*
[5]*Population Health Research Centre, Department of Medicine, Faculty of Medicine, University of Ruhuna, Sri Lanka.*

Abstract: Menopause Specific Quality of Life (MENQOL) questionnaire assesses the health related quality of life (HRQOL) of postmenopausal women (PMW). It includes 29 menopausal discomforts distributed among four main domains, namely, vasomotor, psychosocial, physical and sexual. This study was designed for linguistic validation of the Sinhala version of MENQOL questionnaire and evaluation of its psychometric properties. The Sinhala version of MENQOL questionnaire was adapted following a standard methodology of linguistic validation, including forward translation, backward translation, patient testing and proof reading. It was self-administered among 200 PMW, aged 56.0±3.3 years, selected randomly from Galle, Sri Lanka, along with the previously validated Menopause Rating Scale (MRS). Two weeks after the previous administration, the MENQOL questionnaire was administered again among a sub-group of PMW (n=100) selected from the 200 PMW. Then, the psychometric properties including reliability and validity were evaluated. The MENQOL questionnaire showed a high test re-test reliability measured with intraclass correlation=0.98 (0.97-0.99). The global Cronbach's alpha was 0.95, indicating higher internal consistency. Seven factors with Eigen value exceeding one, explaining 77.11% of cumulative variance, were observed in Factor Analysis with Principal Component Analysis. It showed more explanatory factor extraction. Strong significant positive correlation between MENQOL questionnaire score and MRS score (r=0.78, p<0.001) was observed, which confirms the concurrent validity. It was observed that the self-administered, 29 item, Sinhala version of MENQOL questionnaire is a reliable and a valid menopause specific tool with satisfactory psychometric properties. Therefore, MENQOL questionnaire can be recommended to measure the menopausal discomforts and HRQOL of Sinhala speaking Sri Lankan PMW.

INTRODUCTION

Menopause is associated with biological changes that obligate a negative impact on health related quality of life (HRQOL) of middle-aged women. In postmenopausal women (PMW), the quality of life (QOL) usually denotes the features which are an aggregation of menopausal discomforts affecting their health without focusing on their general physical, psychological or environmental aspects of health (Forouhari *et al*., 2010). Hence, the QOL specific to PMW often refers to the menopausal discomforts, which adversely impact on the aspects of personal health and self-satisfaction (Forouhari *et al*., 2010). Menopausal discomforts lead to impairment of HRQOL and directly impact on the day-to-day activities including their home, work and recreational tasks (Williams *et al*., 2008).

In 1990, there were around 467 million women aged ≥50 years in the world. This number is expected to reach 1,200 million by the year 2030 (von Mühlen *et al*., 1995). Furthermore, in Sri Lanka, nearly one fourth of the women population is over 50 years (Sri Lanka, Department of Census and Statistics, 2014) and is considered to be postmenopausal. This number is expected to increase with the advancement of health technology and inventions which leads to improved

*Corresponding author (nirmala.priyanthi@gmail.com ; (iD) https://orcid.org/0000-0002-0666-2975)

health care. Further, the life expectancy of women is increasing worldwide and in most countries, women would live approximately more than one third of their life after menopause. Health and wellbeing of PMW, therefore, has become an essential component in the contemporary healthcare system.

Clinicians need to pay special attention to menopause related symptoms of women in order to provide comprehensive and holistic care. The identification of menopausal symptoms, their severity and finally HRQOL is vital, in proper evaluation of women in the postmenopausal age (Kothiyal & Sharma, 2013). Several instruments have been developed to quantify the menopausal discomforts and HRQOL (Zöllner *et al*., 2005), and these includes the Menopause Rating Scale (MRS) (Schneider *et al*., 2000)**,** Kupperman Index (Kupperman *et al*., 1953) and Menopause Specific Quality of Life (MENQOL) questionnaire (Hilditch *et al*., 1996). Among them, MENQOL questionnaire is the widely used tool (Jenabi *et al*., 2015) in research and clinical evaluation because of its descriptive nature, ability to determine the severity of symptoms and easy applicability.

It was introduced in 1996 by Hilditch *et al.* as a patient-reported outcome (PRO) tool for measuring MENQOL in early menopause; duration since menopause two to seven years (Hilditch *et al*., 1996). MENQOL questionnaire contains 29 items (menopausal discomforts) to capture the HRQOL in four main domains (Hilditch *et al*., 1996): vasomotor-3 items (1–3), psychosocial-7 items (4–10), physical- 16 items (11–26) and sexual-3 items (27–29). HRQOL of previous 30 days is assessed through evaluating both frequency and severity of all 29 menopausal discomforts in a seven point Likert scale. MENQOL questionnaire has been translated to more than 20 languages in the West and more than 11 languages in the Asian and South Asian countries with or without ensuring its psychometric properties (Sydora *et al*., 2016). Further, it has been used in numerous clinical settings in different ethnic populations worldwide (Sydora *et al*., 2016), including Asian and South Asian countries (Chen *et al*., 2008; Nisar & Sohoo, 2009; Williams *et al*., 2009; Shobeiri *et al*., 2016). However, it has not been translated or validated in the Sri Lankan context so far.

In Sri Lanka, HRQOL of PMW is not appropriately assessed in clinical settings or in research, partly due to lack of proper instruments. The researchers identified the importance of having a validated questionnaire that would provide the reproducibility and validity of study findings that are generated based on a MENQOL tool in Sri Lanka.

Hence, the current study was done to generate a questionnaire to assess the discomfort specific to menopause and thereby determine the HRQOL of local PMW. In this study linguistic validation of MENQOL questionnaire into the Sinhala language and evaluation of its psychometric properties were performed.

METHODOLOGY

Study design, setting and participants

The current validation study was carried out in Galle district; Bope-Poddala Medical Officer of Health (MOH) area in Southern Sri Lanka, during January 2017 – April 2018. Healthy, community dwelling, naturally menopaused women with an intact uterus and two to seven years duration since menopause participated in the study. The duration since menopause was selected according to the MENQOL developer's guidelines (Hilditch *et al*., 1996). Moreover, PMW who had chronic medical and surgical conditions (non-communicable diseases, cancers etc.), psychiatric disorders, debilities and injuries of musculoskeletal system, women on hormone replacement therapy and women with endocrine disorders (diabetes, thyroid disorders etc.) were excluded. Self-reported menstrual history was used to determine the postmenopausal status, based on classification of Stages of Reproductive Aging Workshop (Harlow *et al*., 2012). It was defined as absence of menstruation for a period of 12 months following the last menstruation.

Sample size calculation and sampling procedure

Sample size calculation was based on five respondents into one variable ratio (Hair *et al*., 1995). Another 10% was added to compensate the non-respondents and incomplete questionnaires; total sample size was 160 women.

Multistage cluster sampling technique was used for the selection of PMW. Three public health midwives (PHM) divisions (the smallest primary health care unit) were randomly selected out of eighteen PHM divisions in the Bope-Poddala MOH area. Women aged above 45 years and below 60 years were identified using household registers of selected areas as guides, with the support of the administrative officer of each division (Grama Niladari; GN) belonging to each selected PHM area. Houses were arranged in a single list and those who got the odd numbers were included in the study to achieve randomization. If one particular house had more than one woman in the given age range, only one woman was included to the study. Even though calculation of sample gives only 160, the research team was able to recruit 200 women for the study, following the sampling procedure during the time period.

Linguistic validation of MENQOL questionnaire into Sinhala language

The linguistic validation guidelines described by Mapi Research Trust Information Support Unit were followed for cross cultural adaptation of the Sinhala version of MENQOL questionnaire i.e., forward translation, backward translation, patient testing and proof reading.

The original English version was translated (forward translation) to Sinhala by two independent health professionals; a medical officer and a nurse who were fluent in both Sinhala and English languages. One was informed about the purpose of translation while the other was not informed. Each one produced an independent forward translation of the original items, instructions and response choices. Then the items were consolidated into a single questionnaire and synthesised as a common translation to maximise the clarity of items by the investigators. This Sinhala version was conceptually equivalent to the original questionnaire. This was easy to be understood by Sinhala people. There were no interpretation problems of the original version.

The synthesised translation was translated back into English (backward translation) by another two independent health professionals, fluent in both Sinhala and English languages, to assess the comparability with the original version and to make sure that there were no gross inconsistencies or conceptual errors. Backward translators had no access to the original version. Both back translations were combined by the investigator, compared with the original version and a pre-final Sinhala version was created.

When deciding the pre-final version, conceptual equivalence with the original version and cultural relevance to the Sinhala language was observed. A group of experts (gynecologist, physician, physiologist, anatomist, and nursing academic and forward and backward translators) independently reviewed all the versions of the MENQOL questionnaire and ensured its content validity.

The pre-final version was further assessed in a focus group discussion (FGD) with 10 PMW between 45–60 years of age, who were healthy, and who recently underwent menopause (two to seven years of menopausal duration) naturally. During the FGD, the acceptability, understandability, simplicity and appropriateness were evaluated and further, interpretation problems were evaluated. There were no problems encountered and therefore, the final version was decided.

The final Sinhala version of MENQOL questionnaire underwent a proof reading process to detect any typing, spelling or grammatical mistakes by two Sinhalese nursing academics. The final version was pre-tested among 30 PMW with above inclusion criteria with different education background selected from another MOH area in the Galle district and the face validity was ensured.

Administration of the Sinhala version of MENQOL questionnaire

The Sinhala version of MENQOL questionnaire that was adapted following the standard guidelines and the Sinhala version of MRS (Rathnayake *et al*., 2018) were self-administered among 200 PMW. All women answered the questionnaire and there were no incomplete questionnaires. After two weeks of first administration, the MENQOL questionnaire was re-administered among a randomly selected sub-group (n=100) of PMW who participated at the first administration.

In the MENQOL questionnaire, the presence or absence of menopausal discomforts (29 items) were marked and the severity was also assessed with a Likert scale (seven point); zero (absence of discomforts) to six (extremely bothered by discomforts) within the previous month (Hilditch *et al*., 1996). These 29 items of menopausal discomforts are designed to measure the HRQOL under four main domains (Hilditch *et al*., 1996) namely: vasomotor-3 items (1–3), psychosocial-7 items (4–10), physical- 16 items (11–26) and sexual-3 items (27–29). The item scores were then converted to scores ranging from 1–8: absence of discomforts = 1, discomforts are experienced but did not bother = 2, and through to extremely bothered = 8 (Hilditch *et al*., 1996).

The MRS is a validated tool for PMW in Sri Lanka (Rathnayake *et al*., 2018), that describes 11 menopausal discomforts, including somato-vegetative discomforts: items 1–3 and 11; psychological discomforts: items 4–7; and urogenital discomforts: items 8–10. If the women had experienced each discomfort within the previous month, they were asked to indicate it in a severity scale, from a zero (no discomforts at all) to four (very severe) in a five-point Likert scale. The higher ratings indicate higher intensity of difficulties and their severity (Heinemann *et al*., 2004).

Psychometric properties of the Sinhala version of MENQOL questionnaire

Reliability and the validity of the Sinhala version of questionnaire were considered. Reliability was evaluated using test-retest reliability and internal

consistency. Test-retest reliability was measured using the intraclass correlation (ICC) evaluation by comparing overall MENQOL questionnaire score at first and subsequent administrations (Arafat *et al*., 2016). Internal consistency was assessed with the Cronbach's alpha for overall score and computed for each subscale at baseline. Acceptable Cronbach's alpha value was considered as ≥ 0. 7 (Field, 2009).

Validity of the questionnaire was evaluated considering convergent validity, construct validity, discriminant validity and concurrent validity. Convergent validity was tested by item-domain correlation, considering higher correlation of each item with their respective subscale. Construct validity was evaluated by factor analysis (FA) performed with principle component analysis (PCA)while keeping Varimax with Keiser normalization as rotation method. The Kaiser-Meyer-Olkin (KMO) and Bartlett's test of Sphericity statistics were analysed and correlation matrix was observed to determine whether FA was appropriate for the data, mainly for sampling adequacy assessment (KMO>0.7), multicollinearity assessment (many coefficients in correlation matrix should be 0.3 and above), Bartlett's Test of Sphericity (should reach statistical significance) and Commonalities Coefficients (should be >0.6) (Arafat *et al*., 2016). The number of extracted components was determined by the Scree plot, percentage of variance explained by each component and number of Eigen values over one (Kaiser-Guttman rule).

Items were considered representative of a component if their individual item loading was ≥ 0.40 and in the cross-loading items, the factor, which had higher loading value, was taken as the respective factor (Arafat *et al*., 2016).

In discriminant validity analysis, mean±SD of each item was compared between the asymptomatic and symptomatic PMW, using independent sample t-test. Severity of menopausal discomforts was considered when deciding the asymptomatic and symptomatic women. Women who did not experience menopausal discomfort and who experienced discomforts but, did not bother with such discomforts (in Likert scale; 1–2) were considered as asymptomatic women. Women who experienced bothersome discomforts of any degree (mild to extremely bothered discomforts) were considered as symptomatic women (in Likert scale; 3–8).

The correlation between the overall scores of the MENQOL questionnaire and the MRS was assessed to evaluate the concurrent validity (Arafat *et al*., 2016); the Pearson correlation coefficients and Kendall's tau-b

value were observed. Furthermore, a categorical analysis was done by cross tabulating the quartiles of the total scores of MENQOL questionnaire and MRS to test the agreement between the two tools using the Cohen's Kappa value (Arafat *et al*., 2016).

Statistical analysis

The basic characteristics of PMW who participated in the evaluation of psychometric properties were presented as frequencies (percentages) or Mean±SD. Psychometric properties of the questionnaire were evaluated. SPSS 20.0 version was used for the data analysis. Statistical significance was considered as p value <0.05. Considered strengths of correlations were: between 0.10 and 0.29 - weak; between 0.30 and 0.49 - moderate; and between 0.50 and 1.00 - strong (Field, 2009).

Ethical considerations

Permission from the relevant publishers of MENQOL questionnaire, the Mapi Research Trust Information Support Unit, France, was obtained prior to the commencement of the process. Ethics Review Committee, Faculty of Medicine, University of Ruhuna, Sri Lanka granted the ethical clearance for this study (Reference number; 24.09.2014:3.2). All procedures were in agreement with the ethical standards of the Helsinki Declaration. Informed consent was signed by all individual study participants before the commencement of the data collection.

RESULTS AND DISCUSSION

Results

Characteristics of the participants

Socio-demographic characteristics of PMW who participated in psychometric properties analyses are shown in Table 1. Age, age at menopause and duration since menopause (Mean±SD) of the evaluated PMW were 56.3±3.3 years, 50.7±2.8 years and 5.6±1.8 years, respectively.

The prevalence of night sweats, muscle and joint aches, feeling tired or worn out and low backaches were higher (>82%) and the prevalence of increased facial hair, sweating, avoiding intimacy and feeling of wanting to be alone were lower (<50%) among the studied PMW (Table 2). Further, scores (Mean±SD) of vasomotor, physical, psychosocial and sexual domains and overall score were 2.51±1.23, 2.31±1.28, 2.89±1.04, 2.74±1.61 and 10.46±4.26, respectively.

Table 1: Sociodemographic characteristics of the PMW participated in the study (n=200)

Characteristics	Sub category	Frequency (%) or Mean (SD)
Age (years)		56.3 (3.3)
Age at menopause (years)		50.7 (2.8)
Duration since menopause (years)		5.6 (1.8)
Employment status	Employed	45 (22.5%)
	Non employed	155 (77.5%)
Civil status	Married	179 (89.5%)
	Single, widowed or divorced	21 (10.5%)
Living companion	With husband and children	114 (57.0%)
	With husband or children	65 (32.5%)
	Alone or living with others	21 (10.5%)
Education status	Primary education	95 (47.5%)
	Secondary education	49 (24.5%)
	Upper secondary education, degree or diploma	56 (28.0%)
Monthly income	Below 20,000 LKR	157 (78.5)
	Above 20,000 LKR	43 (21.5%)

LKR=Sri Lankan rupees (150LKR=1USD), PMW=postmenopausal women living with others include; parents, siblings, friends or other relatives

Psychometric properties of the Sinhala version of MENQOL questionnaire

Reliability and internal consistency: ICC was 0.98 (95% CI=0.97-0.99) in the overall MENQOL score, which indicate a higher test-retest reliability. The MENQOL questionnaire showed a higher internal consistency; global Cronbach's alpha; for overall MENQOL =0.95, vasomotor domain=0.83, psychosocial domain=0.93, physical domain=0.90 and sexual domain=0.89 (p<0.001).

Convergent validity: All items in the MENQOL questionnaire correlated more strongly (r>0.50, p<0.001) with their respective domain than the other domains (Table 3) indicating higher convergence in item-domain correlation analysis.

Construct validity: Seven factors with Eigen value exceeding one, explaining 77.11% of cumulative variance, were observed in the FA based on PCA (each factor responsible for 43.81%, 8.79%, 5.91%, 5.72%, 4.77%, 4.42% and 3.65% of variance, respectively) (Table 4). The items saturated in to factor one were all the psychosocial discomforts in original tool (item 4–10). Three physical discomforts (aches in back of neck or head, decrease in stamina and dry skin) were saturated together with all the sexual discomforts in factor two. Pure physical discomforts (flatulence, weight gain, increased fa-

cial hair, changes in appearance, feeling bloated) were saturated together in factor three. Combination of both physical and mental discomforts (feeling tired, difficulty in sleeping, decrease in strengths and lack of energy even though they are in physical domain in original tool) were saturated in to factor four. Factor five comprised of all three vasomotor discomforts, saturated together as in the original tool (Hilditch *et al.*, 1996). The two main musculoskeletal discomforts (aching in muscles and joints and low backache) were saturated in factor six. Two urinary discomforts (frequent urination and involuntary urination) were saturated together in factor seven (Table 4). As results suggested, the new seven factors, (factor 1–7), were named as, psychosocial, physio-sexual, physio-psychological, physical, vasomotor, musculoskeletal and urinary domains, respectively, in the Sinhala version.

Discriminant validity: Severity scores (Mean±SD) of all 29 items (menopausal discomforts) were significantly different (p<0. 001) between the asymptomatic and symptomatic women approving good discriminant validity (data not shown in a table).

Concurrent validity: Overall MENQOL score strongly correlated with the overall MRS scores (r=0.76, Kendall's tau-b=0. 65; p<0. 001), assuring strong concurrent validity. Further, when the quartiles of the overall scores of the two scales were cross tabulated to evaluate the

Table 2: Prevalence of menopausal discomforts among PMW participated in the study (n=200)

Item No.	Item	Prevalence of menopausal discomforts	
		Asymptomatic women [n (%)]	Symptomatic women [n (%)]
1	Hot flushes or flashes	67 (33.5)	133 (66.5)
2	Night sweats	35 (17.5)	165 (82.5)
3	Sweating	105 (52.5)	95 (47.5)
4	Dissatisfaction with my personal life	73 (36.5)	127 (63.5)
5	Feeling anxious or nervous	67 (33.5)	133 (66.5)
6	Poor memory	84 (42.0)	116 (58.0)
7	Accomplishing less than I used to	76 (38.0)	124 (67.0)
8	Feeling depressed, down or blue	93 (46.5)	107 (53.5)
9	Being impatient with other people	94 (47.0)	106 (53.0)
10	Feeling of wanting to be alone	110 (55.0)	90 (45.0)
11	Flatulence (wind) or gas pains	74 (37.0)	126 (63.0)
12	Aching in muscles and joints	16 (8.0)	184 (92.0)
13	Feeling tired or worn out	35 (17.5)	165 (82.5)
14	Difficulty in sleeping	70 (35.0)	130 (65.0)
15	Aches in back of neck or head	53 (26.5)	147 (73.5)
16	Decrease in physical strength	49 (24.5)	151 (75.5)
17	Decrease in stamina	48 (24.0)	152 (76.0)
18	Lack of energy	40 (20.0)	160 (80.0)
19	Dry skin	41 (20.5)	159 (79.5)
20	Weight gain	83 (41.5)	117 (58.5)
21	Increased facial hair	114 (57.0)	86 (43.0)
22	Changes in appearance, texture or tone of my skin	42 (21.0)	158 (79.0)
23	Feeling bloated	99 (49.5)	101 (50.5)
24	Low backache	14 (7.0)	186 (93.0)
25	Frequent urination	55 (27.5)	145 (72.5)
26	Involuntary urination when laughing or coughing	70 (35.0)	130 (65.0)
27	Decrease in my sexual desire	60 (30.0)	140 (70.0)
28	Vaginal dryness	80 (40.0)	120 (60.0)
29	Avoiding intimacy	102 (51.0)	98 (49.0)

Asymptomatic = Women not bothersome with menopausal symptoms

Symptomatic = Women bothered mild - extremely with menopausal discomforts

PMW = postmenopausal women

Table 3: Item-domain correlation analysis of Sinhalese version of MENQOL (29 items, 4 domains)

Item No.	Item	Physical domain (16 items)	Psychosocial domain (7 items)	Vasomotor domain (3 items)	Sexual domain (3 items)	Overall MENQOL (29 items)
1	Hot flushes or flashes	0.62	0.43	0.85	0.45	0.66
2	Night sweats	0.53	0.38	0.94	0.35	0.58
3	Sweating	0.30	0.26	0.81	0.24	0.39
4	Dissatisfaction with my personal life	0.52	0.77	0.39	0.37	0.61
5	Feeling anxious or nervous	0.72	0.79	0.46	0.53	0.77
6	Poor memory	0.72	0.90	0.40	0.62	0.80
7	Accomplishing less than I used to	0.72	0.83	0.30	0.52	0.76
8	Feeling depressed, down or blue	0.67	0.88	0.27	0.55	0.74
9	Being impatient with other people	0.65	0.85	0.30	0.56	0.73
10	Feeling of wanting to be alone	0.59	0.83	0.28	0.41	0.66
11	Flatulence (wind) or gas pains	0.70	0.48	0.41	0.43	0.66
12	Aching in muscles and joints	0.63	0.40	0.29	0.42	0.59
13	Feeling tired or worn out	0.72	0.61	0.51	0.52	0.73
14	Difficulty in sleeping	0.78	0.67	0.58	0.58	0.80
15	Aches in back of neck or head	0.71	0.50	0.52	0.55	0.70
16	Decrease in physical strength	0.65	0.52	0.14	0.35	0.59
17	Decrease in stamina	0.70	0.66	0.32	0.63	0.72
18	Lack of energy	0.75	0.62	0.23	0.54	0.71
19	Dry skin	0.68	0.54	0.41	0.58	0.68
20	Weight gain	0.60	0.31	0.61	0.30	0.56
21	Increased facial hair	0.50	0.33	0.21	0.39	0.47
22	Changes in appearance, texture or tone of my skin	0.62	0.38	0.39	0.47	0.59
23	Feeling bloated	0.73	0.56	0.50	0.50	0.72
24	Low backache	0.49	0.26	0.16	0.32	0.43
25	Frequent urination	0.52	0.35	0.43	0.36	0.51
26	Involuntary urination when laughing or coughing	0.46	0.29	0.34	0.37	0.45
27	Decrease in my sexual desire	0.58	0.47	0.32	0.89	0.65
28	Vaginal dryness	0.71	0.60	0.46	0.92	0.78
29	Avoiding intimacy	0.64	0.57	0.34	0.90	0.71

Pearson correlation was significant at < 0.001 level.

Boldness indicates the corresponding items of the subscales.

Table 4: Seven factors extracted by the factor analysis with varimax rotation (29 items)

Domain (as in original tool)	Item No.	Items	Factor (as EFA suggested in this study)						
			1	2	3	4	5	6	7
Vasomotor domain	1	Hot flushes or flashes			0.52		0.61		
	2	Night sweats					0.86		
	3	Sweating					0.85		
Psychosocial domain	4	Dissatisfaction with my personal life	0.70						
	5	Feeling anxious or nervous	0.53			0.49			
	6	Poor memory	0.75						
	7	Accomplishing less than I used to	0.74						
	8	Feeling depressed, down or blue	0.75						
	9	Being impatient with other people	0.76						
	10	Feeling of wanting to be alone	0.82						
Physical domain	11	Flatulence (wind) or gas pains			0.53	0.51			
	12	Aching in muscles and joints						0.83	
	13	Feeling tired or worn out				0.59			
	14	Difficulty in sleeping				0.45			
	15	Aches in back of neck or head		0.43			0.41		
	16	Decrease in physical strength				0.78			
	17	Decrease in stamina		0.63		0.41			
	18	Lack of energy		0.41		0.69			
	19	Dry skin		0.56	0.49				
	20	Weight gain			0.70		0.43		
	21	Increased facial hair			0.70				
	22	Changes in appearance, texture or tone of my skin		0.43	0.59				
	23	Feeling bloated			0.69				
	24	Low backache						0.89	
	25	Frequent urination							0.77
	26	Involuntary urination when laughing or coughing							0.78
Sexual domain	27	Decrease in my sexual desire		0.73					
	28	Vaginal dryness		0.72					
	29	Avoiding intimacy		0.75					

Extraction method: Principal Component Analysis, Rotation Method: Varimax with Kaiser Normalization

Table 5: Agreement between quartiles of the MRS and MENQOL

MRS score	MENQOL score			
	Quartile 1 (<6.77)	Quartile 2 (6.77-10.51)	Quartile 3 (10.51-14.04)	Quartile 4 (>14.04)
Quartile 1 (<8.0)	37	11	0	2
Quartile 2 (8.0-13.5)	8	28	8	6
Quartile 3 (13.5-20.0)	4	7	35	3
Quartile 4 (>20.0)	2	3	16	30

Cohen's Kappa = 0.50, Standard error = 0.04, p<0.001

agreement between two scales, the Cohen's Kappa value was 0.54 (SE=0.04, p<0.001), indicating a moderate strength of agreement of the two scales (Table 5).

Discussion

In this study, the newly adapted Sinhala version of the MENQOL questionnaire showed satisfactory psychometric properties indicating that it is a valid and reliable instrument to evaluate menopausal discomforts, their severity and HRQOL of Sinhala speaking PMW.

This study observed higher internal consistency, item-domain correlation in the new version of MENQOL questionnaire with seven factors emerging in the FA. Furthermore, it showed a good discriminant and criterion validity, sensitive enough in evaluating menopausal discomforts, their severity and HRQOL in PMW. The observed high internal consistency (Cronbach's alpha; 0.95) in the current study was concordant with other studies done in different countries; Turkey (0.97) (Malhan *et al*., 2008), China (0.90) (Nie *et al*., 2017), USA (individual domain between 0.78–0.86) (Van Dole *et al*., 2012) and Iran (Persian version, 0.90) (Ghazanfarpour *et al*., 2014) and the original MENQOL questionnaire development study (0.8–0.89) (Hilditch *et al*., 1996). The item-domain correlation was also concordant with the Chinese validation of MENQOL questionnaire (Nie *et al*., 2017). However, discordance with the validated Persian version, where there were minor correlations in physical and sexual domains, was observed (Ghazanfarpour *et al*., 2014).

The first FA (Hilditch *et al*., 1996) suggested four main domains. However, in the current analysis, seven factors were extracted, explaining the 77% of total variance. Somewhat similar factor extraction, six factors, has been observed in the Chinese validation (Nie *et al*., 2017). However, the Turkish validation (Malhan *et al*., 2008) revealed a factor extraction similar to the original version, explaining 78.9% variability. Higher

internal consistency and item-domain correlation among the studies is indicative of adequate consistency of the questionnaire and it works in similar pattern in different countries.

Further, in FA, two factors (psychosocial and vasomotor) were completely similar to the original structure with few unexpected factor extractions in which three items in the sexual domain were saturated together with physical discomforts. The possibility of having a combination of two extremes of discomforts together in one factor cannot be illustrated. The menopausal discomforts affecting HRQOL of PMW probably would be due to the fact that the QOL is a subjective perception dependent on their internal value system (Saxena *et al*., 1997) and the cultural or territorial variations of perception on menopausal discomforts of PMW from different backgrounds. Further, findings of the current FA was more explanatory than the original tool, because FA extracted urinary discomforts together; musculoskeletal discomforts together; sexual discomforts together; and discomforts which cannot be distinguished as physical and psychological aspects together. This is somewhat consistent with the factor extraction observed in the Chinese version validation (Nie *et al*., 2017). It was deemed that keeping urinary and sexual discomforts in separate domains is more appropriate than combining them with another domain; keeping them together with physical discomforts may dilute the severity of urinary discomforts scores. One possible reason for the saturation of musculoskeletal discomforts together in the current FA would be due to the high prevalence of musculoskeletal discomforts. Previous studies also revealed that "musculoskeletal discomforts" are the most prevalent and troublesome discomforts among PMW in the Sri Lankan context (Goonaratna *et al*., 1999; Waidyasekera *et al*., 2009; Rathnayake *et al*., 2019).

The ability of the MENQOL questionnaire to differentiate PMW who were symptomatic and asymptomatic indicates that its discriminant validity

is consistent with the Chinese validation (Nie *et al*., 2017) tested against Kuppaman's Index. Therefore, this tool could be used in making therapeutic decisions in symptomatic PMW once a suitable intervention threshold is determined. Furthermore, the tool is adequately sensitive to measure the discomforts, their severity and HRQOL appropriately, as it showed satisfactory concurrent validity measured against MRS. Cited studies, however, have not focused on concurrent validity (Malhan *et al*., 2008; Van Dole *et al*., 2012; Ghazanfarpour *et al*., 2014).

This study has a few strengths. It used a randomly selected sample of women from a semi urban setting for this analysis and although they are not representative of the entire population, they do represent a majority of PMW in the country. Further, a relatively larger sample was used for this study. The authors recommend future studies to perform confirmatory FA to verify the results observed in the current study, as they were unable to perform confirmatory FA due to the scarcity of software. Validation of different languages of MENQOL questionnaire versions is also encouraged, as Sri Lanka is a multi- ethnic country.

CONCLUSIONS

The Sinhala version of MENQOL questionnaire is a reliable and a valid tool which is informative for determining menopausal discomforts, their severity and HRQOL in PMW conversant in the Sinhala language. Researchers and clinicians can use this tool in both community and clinical setting to plan necessary investigations and treatments and for future research purposes.

CONFLICTS OF INTERESTS

The authors declare that they have no conflicts of interests**.**

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