

Original Research



Consensus-based translation, cultural adaptation, and validation of the Menopause Specific Quality of Life Questionnaire for menopausal women in Sri Lanka

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Abstract

Introduction: Quality of life during menopause could be affected by distressing menopausal symptoms. Menopause Specific Quality of Life Questionnaire (MENQOL) is an instrument developed to measure menopausal symptoms and their associated degree of bother.

Objectives: To translate, culturally adapt and validate the Menopause Specific Quality of Life Questionnaire (MENQOL) for menopausal women of 45-55 years in Sri Lanka

Methods: Translation, cultural adaptation, and validation of 29 items in MENQOL were carried out in three stages. The first stage involved translation of English version of the questionnaire into Sinhala language using a consensus-based nominal group process by a panel of five experts. In the second stage, cultural adaptation of the translated MENQOL questionnaire was carried out by conducting qualitative interviews with ten post-menopausal women of 45-55 years. In the third stage, construct validity of MENQOL was assessed in a community-based cross-sectional survey conducted among 174 post-menopausal women in 45-55 age group.

Results: At the end of the translation process, the panel of experts agreed on the most appropriate translations through a voting process (consensus measurement), and appropriate translations were chosen by resolving disagreements (consensus development). The translated questionnaire named as MENQOL-S was further modified based on inputs from the interviews with post-menopausal women. Principal component analysis of the validation study data resulted in a 26-item, five factor structure for MENQOL-S.

Conclusions: MENQOL-S is conceptually and culturally appropriate for use in Sri Lanka. It could be used in community or healthcare settings to assess menopause specific quality of life among menopausal women and to assess outcome during intervention studies to improve their quality of life.

Key words: *menopause, instrument validation, post reproductive health, quality of life*

Introduction

Declining ovarian function during menopause gives rise to distressing menopausal symptoms. Quality of life of menopausal women could be affected by these distressing symptoms. Assessment of the impact of menopause on quality of life enables us to decide whether quality of life should be improved. Menopause specific quality of life is defined as “a measure of menopausal symptoms and their associated degree of bother” (1). There was no published literature on any instrument validated for use in Sri Lanka to assess menopause specific quality of life.

Menopause Specific Quality of Life Questionnaire (MENQOL) is an instrument widely used to measure condition specific quality of life related to menopause (1). It has been developed based on experiences of women going through their early post-menopausal years. Content identification for MENQOL has been based on an extensive literature search, reviewing of existing menopausal symptom lists and qualitative interviews with post-menopausal women (1). The MENQOL questionnaire contains 29 menopausal symptoms categorized into four sub scales, namely vasomotor (3 items), psychosocial (7 items), physical (16 items) and sexual (3 items). The questionnaire has been assessed for face validity among postmenopausal women while the content validity has been established by a group of experts. The authors have established construct validity and reliability as satisfactory (1). It has been translated, validated and used in different countries and sub-groups of menopausal women since its initial publication and its wide use allows comparison of menopausal experience of women across different countries and regions (2-7). MENQOL could also be utilized to monitor changes in quality of life over time in clinical as well as community settings, and before and after any intervention carried out to improve the quality of life of menopausal women (2). The objective of this study was to translate, culturally adapt and validate MENQOL for menopausal women of 45-55 years in Sri Lanka. A culturally adapted instrument reflects the cultural assumptions, norms, values, and expectations of the target population (8) as well as help to further modify any

mistranslations and allow interpretation by a different group of people other than the translators (9).

Methods

Authorization to use MENQOL for the study was obtained from the “Mapi Research Trust”. The study was carried out in three stages: consensus-based translation, cultural adaptation, and assessment of validity.

Consensus-based translation

It is recommended that translation by a group of experts is better than translation by an individual since the group's consensus ensures the cultural acceptability of the translation (10). Nominal group technique was used to translate the original English version of MENQOL to Sinhala through group consensus generation.

A team of five experts comprising a consultant obstetrician and gynaecologist, community physician, general practitioner, medical officer in psychiatry and a special grade nursing tutor participated in the nominal group discussion. This team was selected based on their expertise and experience related to healthcare of menopausal women. All the team members were proficient in both English and Sinhala languages. Each team member was given a copy of the MENQOL English and was invited to translate each of the 29 items in MENQOL into Sinhala independently. The nominal group discussion was conducted at National Institute of Health Sciences, Kalutara. At the meeting, the team presented individual Sinhala translations of the items in MENQOL and the translations were written down on flip charts. The Sinhala translations listed on flip charts were then discussed by the group. If all the group members had translated a particular item in an identical manner, that translation was included with consensus of the group. Remaining translations were subjected to voting by the team members. The voting was done on a scale ranging from 1 (total disagreement) to 10 (total agreement).

An average score of 1-3 was considered as “agreement that the translation is inappropriate”. A

rating of 4-6 was considered as “agreement that the translation is equivocal”. A rating of 7-10 was considered as “agreement that the translation is appropriate”. If more than one Sinhala translation was in “agreement that the translation is inappropriate” score range, the translation with the highest average score was selected as the single most appropriate translation to represent the item. Items that got “agreement that the translation is equivocal” (4-6 average score) were discussed and re-translated within the group. As the final step, the conceptually related translations were grouped together and cross-checked with each other to see if there were any overlapping terms or terms denoting similar meaning. At the end of this process, the group had agreed on translations that uniquely represented the original items. The MENQOL Sinhala translation produced was named MENQOL-S.

Cultural adaptation

Cultural adaptation of MENQOL-S was done by conducting interviews with 10 menopausal women in the age group 45-55 years, recruited from Padukka MOH Area. The participants were selected purposively so as to enable maximum participant diversity. All the participating women should not have had any menstrual cycle within the past 12-month period and had undergone natural menopause according to National Institute for Healthcare Excellence (NICE) Guidelines (11). Informed written consent was obtained prior to the interviews. During the interviews, women were questioned as to what each of the 29 items in MENQOL-S meant to them and how they would describe these experiences in their own words. Based on findings from this process, MENQOL-S was modified and subjected to a psychometric validation process.

Assessment of validity

Face validity of MENQOL-S was established by a panel of five multidisciplinary experts who were not involved in the translation process.

Construct validity of MENQOL-S was assessed through exploratory factor analysis (EFA). EFA was used to analyse the underlying factor structure of

MENQOL-S in Sri Lanka. EFA was considered more appropriate because the original authors had not conducted a factor analysis for MENQOL, thus it was necessary to explore the distribution of measured variables in the local context. For this purpose, a community-based cross-sectional study was conducted in Padukka Medical Officer of Health (MOH) Area in Colombo District. Study participants were women aged 45-55 years, who have not had menstrual cycles for a minimum period of one year and had undergone natural menopause according to NICE Guidelines (11). Those who had undergone hysterectomy or ovariectomy, ceased having menstrual cycles due to radiotherapy or chemotherapy, had reached menopause prematurely (before 40 years of age) and those who had been on hormonal contraceptives or hormone replacement therapy during the past three months were excluded.

It has previously been suggested that at least five times the number of variables in the instrument should be taken as the sample size when exploring the factor structure an instrument (12). According to this, for the 29-item MENQOL, the calculated sample size was 145. After accounting for cluster effect and non-response, the final sample size was 182. A cluster sampling method was used to recruit participants and a public health midwife (PHM) area was taken as a cluster. Cluster size was taken as 30 and six such clusters were selected randomly. Data were collected by visiting households in a predetermined direction. If there was more than one eligible woman in a household, lots were drawn to select one woman. A questionnaire on socio-demographic data and MENQOL-S were administered by three well trained female data collectors. Data collection was carried out after obtaining informed written consent.

Participants responded to the presence ('yes') or absence ('no') of each item in MENQOL. Those who answered as 'no' to any item were given a score of 1 and those who answered as 'yes' were given a score of 2. Next, those who responded as 'yes' (indicating the presence of the symptom) indicated the degree of bother caused by that symptom on a Likert scale ranging from 0 to 6; 0 indicating 'not at all bothered' and 6 indicating being 'extremely bothered'. Both values were added together to indicate the score for

each item and the overall score per item ranged from 1-8. Total MENQOL score was calculated by summing up the scores obtained for all the items. The initial authors had not decided a cut off for the total MENQOL score (1), while the subsequent studies have used mean domain score to compare menopause specific quality of life between groups (4).

Data analysis

An EFA using Principal Component Analysis (PCA) method with Promax rotation was carried out. The number of factors retained was decided by choosing factors with eigen values > 1 according to the Kaiser's eigen values greater than 1 rule, the scree plot, item content and the interpretability of the resulting factors (13). Items with a factor loading less than 0.3 on all factors were excluded. Each factor comprised at least three items (13) and were compared by Pearson correlation co-efficient to assess test-retest reliability. Internal consistency was assessed with Cronbach's alpha, with a value greater than 0.7 considered as satisfactory (13).

Results

Consensus based translation of MENQOL-S

There were seven items, which had been translated in an identical way by all the group members; "sweating", "aching in muscles and joints", "difficulty sleeping", "aches in back of neck or head", "dry skin", "weight gain" and "low backache". Translations of these items were accepted by the group as the only appropriate translation and were adopted without voting.

Translations for the rest of the 22 items were subjected to voting and discussion. The item "hot flushes or flashes" underwent extensive discussion before a consensus was reached on the most appropriate translation because of 'equivocal' voting. Since there was no single term commonly used in day-to-day Sinhala language to denote "hot flushes/flushes", the group was especially concerned about translating this item into Sinhala without any change in the original meaning. Two of the psychological items, "feeling anxious or nervous"

and "feeling depressed, down or blue" were discussed and translated within the group to denote "feeling depressed, down or blue" and "feeling anxious or nervous". The group could easily reach a consensus on the remaining vasomotor (1), psychological (4), physical (11) and sexual (3) items based on previously decided cut-off level (average score >7). As the final step, conceptually related translations were grouped together and checked for any overlapping translations. After discussion, the group decided that translations provided mutually exclusive meaning. The nominal group discussion was concluded with the compilation of MENQOL-S.

Cultural adaptation of MENQOL-S

MENQOL-S was modified based on results of the cultural adaptation process. The Sinhala formal term denoting menopause was used during the nominal group translation process. However, only two women out of ten had heard of this term and they too could not describe accurately what it meant. All women understood menopause when described as 'stopping of monthly menstrual cycles'. None of the women volunteered a single term to denote "hot flushes/flushes". Menopausal women expressed it as a "burning sensation" and "heat passing through the body". One woman expressed trembling and body weakness after the burning spell. Thus, it was more appropriate to include a combination of Sinhala terms rather than one term to indicate hot flushes/flushes. 'Increase in body temperature from time to time and burning sensation' was accepted as appropriately describing their experience of a hot flushes/flushes by the women. Thus, it was decided to use this combination of terms to denote hot flushes. "Getting angry more often with others" was the preferred translation provided by women for the item "being impatient with other people".

Validation of MENQOL-S

Response rate was 95.6% (N=174). Table 1 outlines the socio-demographic profile of the participants. There were five factors with an Eigen value more than 1. Out of all 29 items, 26 items loaded into the five factors. Item 15, "aches in back of neck or head", item 16 "decrease in physical strength" and item 24 "low

backache" failed to load into any factor ($r < 0.3$) and were not included in the final questionnaire. Internal consistency assessed using Cronbach's alpha statistic was > 0.7 for all five domains; 0.82, 0.76, 0.87, 0.75 and 0.86. Test re-test reliability of the five domains was 0.95, 0.88, 0.86, 0.9 and 0.95. Table 2 illustrates the rotated component matrix after PCA. Table 3 describes the domains and items under each domain of MENQOL-S.

Cut-off values of MENQOL-S

Since MENQOL-S differed from MENQOL in item

number and structure, it was necessary to define cut off values for Sri Lanka. Since the data were not distributed normally, it was decided to use the median as the cut-off point for each domain. Accordingly, 'poor menopause specific quality of life' could be identified by scores equal or above the cut-off while 'good menopause specific quality of life' could be identified by scores below the cut-off. Table 4 describes the distribution of menopause specific quality of life scores according to domains in MENQOL-S.

Table 1: Socio-demographic profile of the participants for factor analysis (N=174)

Characteristic	No.	%	
Age mean=52.24 years (SD=2.27)			
Race	Sinhala	152	87.3
	Tamil	7	4.2
	Muslim	15	8.5
	Other	0	0.0
Civil status	Unmarried	2	1.2
	Married	131	75.5
	Divorced/Separated	9	5.2
	Widowed	32	18.1
Monthly family income (Rs)	<20 000	76	43.5
	20 000 -50 000	81	46.4
	>50 000	17	11.1
Time since menopause	>5 years	100	57.3
	≤ 5years	74	42.7

Table 2: Factor coefficients of items after rotation

Item no.	Item	Component				
		1	2	3	4	5
1	Hot flushes/flushes		0.712			
2	Night sweats		0.873			
3	Sweating		0.757			
4	Dissatisfaction with my personal life	0.65				
5	Feeling anxious or nervous			0.517		
6	Poor memory	0.61				
7	Accomplishing less than I used to			0.453		
8	Feeling depressed down or blue			0.695		
9	Being impatient with others			0.822		
10	Feelings of wanting to be alone	0.455				
11	Flatulence/wind or gas pains	0.424	0.401			
12	Aching in muscles and joints	0.545				
13	Feeling tired or worn out	0.605				
14	Difficulty sleeping		0.751			
15*	Aches in back of neck/head					
16*	Decreased physical strength					
17	Decrease in stamina	0.637				
18	Lack of energy	0.808				
19	Dry skin					0.597
20	Weight gain				0.771	
21	Increased facial hair			0.524		0.474
22	Changes in appearance/texture or tone of my skin					0.792
23	Feeling bloated				0.645	
24*	Low backache					
25	Frequent urination					0.632
26	Involuntary urination when laughing/coughing	0.587				
27	Decrease in my sexual desire				0.45	
28	Vaginal dryness			0.567		
29	Avoiding intimacy				0.44	

Extraction Method: Principal Component Analysis; Rotation Method: Promax with Kaiser Normalization

*Items that failed to load into any factor

Table 3: MENQOL-S domains and the number of items under each domain after EFA

Item number	Name of the factor	Items
01	Pain, impairment and isolation	Dissatisfaction with my personal life
02		Poor memory
03		Feelings of wanting to be alone
04		Flatulence (wind) or gas pains
05		Aching in muscles and joints
06		Feeling tired or worn out
07		Decrease in stamina
08		Lack of energy
09		Involuntary urination when laughing or coughing
10	Vasomotor and sleep	Hot flushes or flashes
11		Night sweats
12		Sweating
13		Difficulty sleeping
14	Psychological and other	Feeling anxious or nervous
15		Accomplishing less than I used to
16		Feeling depressed, down or blue
17		Being impatient with other people
18		Increased facial hair
19		Vaginal dryness
20		Body image and sexual
21	Feeling bloated	
22	Decrease in my sexual desire	
23	Avoiding intimacy	
24	Physical	Dry skin
25		Changes in appearance, texture or tone of my skin
26		Frequent urination

Table 4: Distribution of menopause specific quality of life scores according to domains in MENQOL-S (N=174)

	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5
Mean	22.5747	9.3276	11.5115	7.9195	5.5862
Median	19.0	7.0	9.0	5.0	4.0
Mode	9.0	4.0	6.0	4.0	3.0
SD	11.97698	6.68720	6.83813	5.3224	3.66061

Discussion

Translation, cultural adaptation and validation are essential steps of adapting a questionnaire developed and used in another country to the local context. Translation by group consensus is considered better than traditional forward and backward translation (4). During our study, translation by consensus generation among a group of healthcare workers who are involved in day to day communication with menopausal women, ensured a more meaningful translation of menopausal symptoms than could be expected by linguistic experts. Also, the voting process facilitated consensus development by resolving any disagreements among the group.

At the same time, it was necessary to explore the cultural appropriateness of translated MENQOL-S in the community since the translations used by healthcare workers to conceptualize the items in MENQOL may not be equivalent to those used by women in the community. The cultural adaptation process helped to find the interpretation given by women in the community to describe menopause related problems they have experienced and to search for any other metaphors used among the Sri Lankan women to describe the same problem. Further, this step helped to identify if the items in MENQOL are actually acknowledged by Sri Lankan women as symptoms experienced after menopause. This exercise revealed that the concept of “menopause specific quality of life” assessed by MENQOL is existent among Sri Lankan menopausal women. It was observed that conceptualization of menopause among women is not based on the Western concept of menopause since some menopausal women were not aware that their symptoms were due to menopause nor its technical term in Sinhala language.

Face and content validity of MENQOL has been assessed during the initial development of MENQOL. Hilditch and others have constructed the four domains of MENQOL based on a score reduction method while an EFA had not been conducted at this stage (1). Thus, it was important to explore the factor structure of MENQOL relevant to the local context before using it in Sri Lanka. During the current factor analysis, the item 15, “aches in back of neck or head”, item 16 “decrease in physical strength” and item 24 “low backache” failed to load into any factor. In contrast to our study, item 'increased facial hair' has been removed from the Chinese MENQOL (3). This could be due to the low prevalence of these symptoms in the studied populations. Literature also reports that when MENQOL was validated for use in other countries, different factor structures have emerged. Chinese version of MENQOL has yielded five factors: “psychosocial”, “physical 1”, “sexual”, “vasomotor” and “physical 2” (3). The EFA of MENQOL done in Siberia has extracted two more factors (attractiveness and pain) in addition to the four original domains (7).

During Menopause Epidemiology study, United States, a confirmatory factor analysis has confirmed the original factor structure of MENQOL with the exception of a few items. “Accomplishing less than I used to” initially placed in psychological domain has been factored into the physical domain. Item “difficulty sleeping” loading was low (0.29) with the four factor structure. Items “feeling tired or worn out; accomplishing less than I used to; changes in appearance, texture, or tone of my skin; difficulty sleeping; and poor memory” have shown cross loading. Reliability measured with Cronbach's alpha was > 0.7 and acceptable for all four domains. The authors have concluded MENQOL as a sound

instrument to assess quality of life during menopause with few appropriate changes to the wording (6). MENQOL has been validated among a group of menopausal breast cancer survivors from Russia. Principal component analysis has shown that items vasomotor, psychosocial and sexual subscales load into the same factors as original version. However, the physical domain has loaded into multiple factors (5).

Comparison of the above validation studies with findings of our study shows that MENQOL is a valid and reliable instrument which could be successfully adapted to various settings to assess menopause specific quality of life. A limitation faced when comparing factor analysis results of MENQOL is that we do not have access to the original item pool collected by Hilditch et al. (1996) and we have conducted item reduction on the final instrument only. Any instrument improves with further validation studies, thus further validation studies of MENQOL-S should be attempted to see if there are more items that could be added to improve its relevance to Sri Lanka.

Conclusions and Recommendations

MENQOL-S, with five domains and 26 factors is a conceptually and culturally appropriate instrument for use in Sri Lanka to assess menopause specific quality of life among post-menopausal women. We recommend using MENQOL-S at the community and healthcare settings to assess menopause specific quality of life among menopausal women and to refer those with 'poor menopause specific quality of life' for further care. MENQOL-S could also be used to assess the improvement of quality of life during intervention studies conducted among menopausal women.

Public Health Implications

Menopause specific quality of life is a measure of the degree of bother caused by menopausal symptoms. MENQOL-S is the culturally adapted and validated Sinhala translation of menopause specific quality of

life questionnaire (MENQOL), which is a widely used instrument to measure menopause specific quality of life. MENQOL-S can be used to assess menopause specific quality of life among Sri Lankan menopausal women in community and primary healthcare settings. Given the simplicity, short time taken to administer and user friendliness of the instrument, and ease of analysis, it could be easily administered by grass root level healthcare workers such as public health midwives and public health nursing officers or primary care doctors at routine encounters or during field visits. Those with poor menopause specific quality of life as measured by the instrument could be referred for specialist care.

Author Declarations

Competing interests: The authors declare that they have no competing interests.

Ethics approval and consent to participate: Ethics clearance was granted by the Ethics Review

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