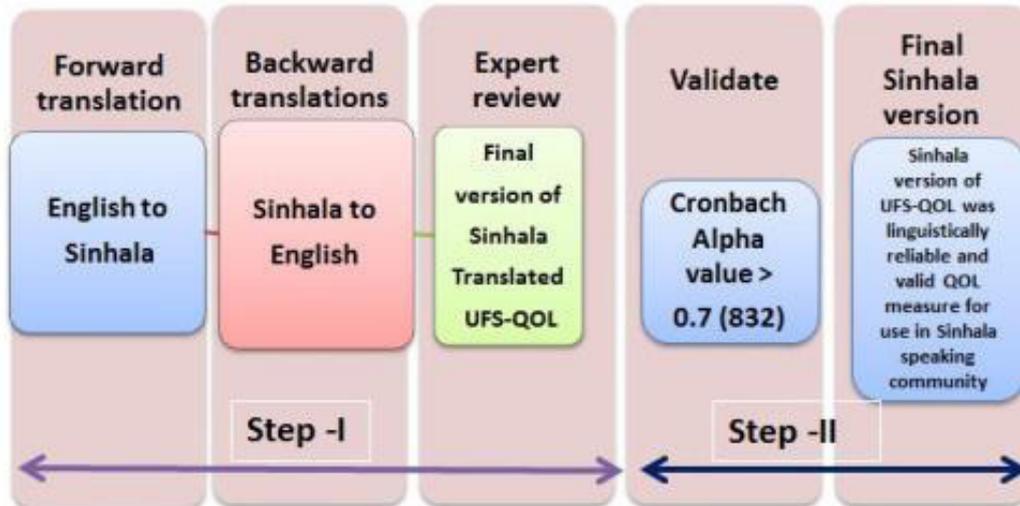# Uterine fibroid symptoms and quality-of-Life questionnaire (UFS-QOL): translation and validation study of the Sinhala version

K.P.K.R. Karunagoda, P.K. Perera and H. Senanayake

Highlights

- Currently in Sri Lanka, there is no validated Uterine Fibroid Symptom and Quality-of-Life (UFS-QOL) questionnaire in Sinhala language for clinical research.

- Established cardiovascular and interventional Radiology Research and Education Foundation (CIRREF) was adopted to develop the UFS-QOL questionnaire.

- This study confirmed that Sinhala translated version of UFS-QOL is linguistically reliable and valid QOL measure for use by Sinhala speaking community in Sri Lanka.

- This tool can be used in clinical and epidemiological researches on uterine fibroids as an acceptable tool.

SHORT COMMUNICATION

Uterine fibroid symptoms and quality-of-Life questionnaire (UFS-QOL): translation and validation study of the Sinhala version

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Abstract: The objective of this study was to translate and test the reliability and validity of the Sinhala (Sri Lankan native language) version of the UFS-QOL. This study was carried out by following two main steps. First step included the translation process and the second step focused on the validation of the translation process of UFS-QOL which was conducted at clinical setup. In the step I of the study, several minor linguistic differences were identified between two forward translations. Some of the items showed considerable variation, especially in question no 1, 9, 23 and 28. The pre- final version of the Sinhala translated questionnaire was tested on 30 patients with symptomatic uterine fibroids in Step II. All items had a 100% response rate and no participant experienced difficulty completing the questionnaire. Out of 30 participants 4 subjects (13%) were unclear with item 33 on the exact meaning of the question. After discussing with the expert committee on all the issues rose at clinical setup the questionnaire was modified and finalized. Statistical analysis shows Cronbach Alpha value is greater than 0.7, reflect adequate internal consistency. Hence, data and question/translations are reliable. Understanding the UFS-QOL context to the people is acceptable and translation work is at satisfactory level. This study shows that the Sinhala translated version of UFS-QOL was linguistically reliable and valid QOL measure for use in Sinhala speaking community in Sri Lanka. Levels of compliance were good indicating that the instrument was well accepted by patients. It could be used in clinical and epidemiological researches on uterine fibroids as an acceptable tool.

Keywords: UFS-QOL; linguistic validation; Sinhala version.

INTRODUCTION

Measurements are essential activities in the field of medical science. In order to acquire data about human subjects, objects and events proper data collection tools are important to be designed which can measure things of scientific interest. A questionnaire is a tool to collect information from respondents in scientific research. Consideration should be given accordingly on whether the questionnaire will measure quantitative or qualitative data, and what would be its mode of administration (Kazine and Khalid, 2012) .It is important to undergo a methodological validation procedure of a questionnaire to make sure that it accurately measures what it aims to do (Karin, 2012).

Uterine fibroids are most common benign tumors which occur in reproductive track of women of child bearing age and prevalence is reported as 20-25% of the worldwide reproductive age woman population (Bourdet, *et.al*. 2015). Appearance of symptoms and their impact on health related quality of life and disturbing activities of daily living are the primary indication for uterine fibroid therapy. Patient reported outcome measures are the most appropriate tool to measure the impact and outcomes of interventions (Karin, 2012).

The cardiovascular and interventional Radiology Research and Education Foundation (CIRREF), has developed the Uterine Fibroid quality-of-life questionnaire (UFS-QOL) to measure the impact of symptoms on patients health related quality of life in clinical trials (Spies, 2002).

This questioner consists of two parts; 8-item symptom severity scale and 29 health related quality of life (HRQL) items. It comprises of six domains *viz* Concern, Activities, Energy/Mood, Control, Self-consciousness, and Sexual Function. All items are scored on a five-point likert scale, ranging from "not at all" to "a very great deal" for symptom severity items and "none of the time" to "all of the time" for the HRQL items. Symptom severity and HRQL subscale scores are summed and transformed into a 0–100 point scale. The symptom severity scale and HRQL subscale scores are inversely related with higher symptom severity scores indicating greater symptoms while higher HRQL subscale HRQL subscale scores indicate better HRQL.

This questionnaire has been used in a number of studies of uterine fibroid treatment, including studies of uterine artery embolization (Spies, *et.al*, 2002; Smith, *et.al*, 2006), radiofrequency thermal ablation (Bergamini, *et.al*. 2005; Ghezzi, *et.al*. 2007), magnetic-resonance-guided ultrasound surgery (So, *et.al,* 2006; Stewart, *et.al,* 2007) and medical management (Fiscella, *et.al,* 2006; Donnez, *et.al,* 2014). The UFS-QOL has demonstrated reliability and validity among women with uterine fibroids by Spies *et al*. 2002.

The UFS-QOL was developed in English language but currently Sinhala version of the tool has not yet been validated. The cross cultural adaptation of a health status self-administrated questionnaire for use in a new country, culture and language requires a unique methodology in

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order to research equivalence between the original source and the target language (Beaton, 2000). Again the objective of this study was to translate and culturally adapt the UFS-QOL into Sinhala language.

MATERIALS AND METHODS

This study was carried out by following two main steps. First step included the translation process and the second step focused on the validation of the translation process of UFS-QOL which was conducted at clinical setup. Cronbach Alpha value was calculated as statistical analysis.

Step I- Translation of UFS-QOL questionnaire

Initial translation – support of two professionals were taken in this step. Two forward translations were made from original English document in to Sinhala independently. Both translates were bilingual with Sinhala as their first language one from the medical field and other is a Sinhala language expert. Both initial Sinhala translations were compared and translation differences were noted. Discussion was carried out with the translators and actions taken to address and resolve the problems. A single document was prepared incorporating the conclusions of the discussion.

Backward translations the document made by Sinhala language was translated back to English. Support of a non-medical background person who is qualified as an English translator was selected for the process, but the original UFS-QOL document was not provided. Object of this process was to identify the similarity of the original version and the backward translation.

Expert review – An expert committee included three translators (two forward and one backward translator) one health professional. English and Sinhala language professionals were involved with the process. This committee compared the backward translation with the original questionnaire. With this phase pre final version of Sinhala translated UFS-QOL questionnaire was developed.

Step II - Validation of the translation process of UFS-QOL

Pilot study for testing the pre final version- the pre final Sinhala version of the questionnaire was administered to randomly select 30 cases with diagnosed uterine fibroids that were recruited from a gynecology outpatient clinic of the National Ayurveda Teaching Hospital, Borella, Sri Lanka. A quiet, private location was provided for patients to complete questionnaires. No assistance was given to understand the questions or find the answers. Written consent was obtained from the participants before distributing questionnaire. Each subject who completed the UFS-QOL questionnaire was questioned about any difficulties encountered in completing the questionnaire or understanding the meaning of each question. All the responses were documented.

Raw data collected by using the translated USF- QOL from 30 patients were analyzed by using SPSS 23.0. To test the reliability in USF- QOL Cronbach Alpha was run on a sample size of 30 patients to measure the internal consistency of scaled questions.

Final version - Following the interview process of the individuals, findings were discussed and the final version was proposed. Ethical approval was obtained (ERC 17/68) for the final version of the questionnaire from the Ethics Review Committee of the Institute of Indigenous Medicine, University of Colombo and the main trial was registered in ISRCTN No: 16108738, https://doi.org/10.1186/ISRCTN16108738.

RESULTS AND DISCUSSION

In the step I, of the study several minor linguistic differences were identified between the two forward translations. Some of the items showed significant variances. They were observed for question numbers of 1, 9, 23 and 28. Some differences were also observed for the introduction sentence. (i.e. 'feelings and experiences' 'please be sure to answer every question'). These variations were discussed with the translators at the initial translation process where all of these issues were resolved. Further some of the translated words were changed to simple language as they were identified as highly technical. At the finalizing stage of the pre- final questionnaire every item was discussed by the expert committee. Few discrepancies occurred and were related to linguistic difficulties with 'worn out', and 'self-conscious of weight gain'. Translation of 'feel down hearted and blue' was shown most divergent as it has no real equivalence in Sinhala. Committee finalized the pre-final version of the translated questionnaire and it was declared that no further cross cultural adaptation was needed.

Results of the step II, pre- final version of Sinhala translated questionnaire was tested on 30 patients with symptomatic uterine fibroids. By interviewing the participants it was indicated that all items of the questionnaire were easily understood and easy for them to answer. All items had a 100% response rate and no participant experienced difficulty in completing the questionnaire. Out of 30 participants 4 subjects (13%) wondered whether item 33 was related to under garments or outer garments. It was decided to modify the questionnaire after discussing with the expert committee to ensure this question was related to outer garments.

When treating symptomatic uterine fibroids patients, preservation and/or improvement of quality of life is an important goal. There is an emerging consensus that a pragmatic definition of quality of life be adopted and operationalized as an outcome in clinical trials. UFS-QOL is a functional representation of patient's physical, psychological and social response to the disease and its treatment. The objective of this study was to translate this questionnaire from English into Sinhala by following systematic methodology. At the same time effort was taken to minimize the variations in QOL based ethnical and cultural backgrounds as it is an important part of a validation process. (Bourgois et al., 2017)

Translation of the questionnaire to the Sinhala language before it is implemented is mandatory as in the Colombo district, Sri Lanka 76.5% of the population belongs to the Sinhala community (Department of Census and Statistics Sri Lanka, 2012). Correcting the differences, including simple language for highly technical terms and searching

for the most similar words to the original idea given in English were the noticeable actions which were followed at the translation process.

Table 1: Internal consistency reliability (Cronbach's Alpha) of Symptom severity sub scale.

Item/Variable	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q1	14.9333	23.237	.479	.781
q2	14.9667	23.689	.522	.774
q3	15.3333	24.023	.456	.784
q4	15.2333	25.289	.384	.793
q5	14.7000	21.528	.628	.756
q6	14.8667	23.016	.576	.766
q7	15.3000	23.183	.579	.766
q8	14.6000	24.524	.438	.786

Table 2: Internal consistency reliability (Cronbach's Alpha) of HRQL* sub scale.

Item /variable	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q9	63.7778	176.418	.314	.816
q10	64.0000	172.706	.471	.811
q11	63.7778	174.418	.387	.814
q12	63.2778	175.507	.312	.816
q13	63.3333	169.176	.426	.812
q14	63.6111	174.252	.383	.814
q15	63.0556	170.408	.408	.812
q16	63.8889	180.340	.255	.818
q17	62.9444	177.938	.257	.818
q18	63.2778	171.271	.457	.811
q19	63.6667	183.647	.048	.826
q20	64.0556	177.585	.328	.816
q21	63.2222	170.771	.297	.819
q22	63.8889	170.810	.362	.815
q23	63.8333	168.382	.567	.807
q24	63.7778	170.065	.550	.808
q25	64.3333	179.412	.303	.817
q26	61.8889	175.634	.347	.815
q27	62.3333	161.647	.628	.802
q28	62.8333	161.794	.523	.806
q29	64.2778	175.271	.503	.812
q30	63.6667	171.647	.438	.812
q31	62.5556	191.673	-.242	.832
q32	62.9444	175.703	.245	.820
q33	63.8333	178.853	.235	.819
q34	63.8333	171.206	.495	.810
q35	63.2222	177.948	.230	.819
q36	63.5000	184.265	.033	.826
q37	63.6111	180.840	.138	.823

*HRQL – Health Related Quality of Life

Table 3: Reliability statistics (Cronbach's Alpha) of UF QOL**.

Scale	Symptom severity sub scale	HRQL sub scale	Overall
Cronbach's Alpha	.799	.821	.832
N of Items	8	29	37

**UF QOL – Uterine Fibroid Quality of Life

Table 4: Step II participants Demographic characteristics (n=30).

Characteristic		Frequency	%
Age	20 – 30 yrs	08	27%
	31- 40 yrs	14	46%
	41- 50 yrs	08	27%
Marital status	Unmarried	11	37%
	Married	19	63%
Education	Primary	07	23%
	Secondary	20	67%
	University	03	10%
History of fibroids	< 2 years	12	40%
	2 – 5 years	12	40%
	> 5 years	06	20%

The USF- QOL consisted of 37 items (α= 0.832), and the symptom severity sub scale consisted of 8 items (α= 0.799) (Table 1) and health related quality of life subscale consisted of six domains (29 items) (α= 0.821) (Table 2). Statistical analysis show a Cronbach Alpha value greater than 0.7, hence data and question/translations are reliable (Table 3). Understanding the UFS-QOL context by the people was at an acceptable level. Therefore, the translation work is at satisfactory level.

Major public involvement and engagement on translation and validation of the questionnaire provided additional value for this study. Patient and public involvement in clinical research potentially help researchers to determine whether the plan of their work is participant friendly and ethically sound (Bagley, 2016). Our expectations are that active involvement of interested public (Uterine fibroid cases) on designing an assessment tool will help to upgrade quality of research by improving power data reliability.

The strength of this study includes the obtaining ethical clearance and recruiting a broad spread of participants with symptomatic uterine fibroids with a wide age distribution and fair representation of married and unmarried cases (Table 4). Apart from the major findings it had been noticed that the study participants were enthusiastic and interested on knowing the quality of life effective level and symptom severity. They considered this tool will help to provide more close observations on their condition.

The main limitation of this study was that it was only performed in a single center while we believe that this version of the questionnaire could be used without further adaptation in other parts of Sri Lanka. Translation difficulty encountered in this study includes some of the sentences and English words which were hard to translate into Sinhala with short sentences which could give the exact meaning. However, the study shows the effectiveness of the process as majority of the cases understood the questions without any difficulty. Further testing of this document is recommended including test-retest reliability as this study mainly focuses on the linguistic validity of the Sinhala translated version.

CONCLUSION

This study shows that the Sinhala translated version of UFS-QOL is linguistically reliable and valid Quality of Life measure for use by the Sinhala speaking community in Sri Lanka. Levels of compliance were good indicating that the instrument was well accepted by patients. It could be used in clinical and epidemiological researches on uterine fibroids as an acceptable tool when fully validated.

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STATEMENT OF CONFLICT OF INTEREST

The authors declare no conflict of interest.

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