

RESEARCH ARTICLE

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Translation and Pilot Validation of the EORTC QLQ-SH22 Module in Tamil, Telugu, and Malayalam for Assessing Sexual Health-Related Quality of Life in Cancer Patients

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Abstract

Background: Sexual health is a vital component of quality of life among cancer survivors but is often under-assessed in routine care, particularly in non-English-speaking populations. The EORTC QLQ-SH22 is a validated tool developed to assess sexual health-related quality of life in cancer patients. To improve its accessibility in South India, this study aimed to translate and pilot validate the SH22 into Tamil, Telugu, and Malayalam. **Methods:** Following EORTC translation guidelines, the SH22 was translated into the three target languages through a multistep process including forward translation, reconciliation, backward translation, and external proofreading. Pilot testing was conducted with 43 patients (15 Tamil, 15 Telugu, 13 Malayalam) with pelvic malignancies. Patient comprehension and feedback were evaluated, and internal consistency was assessed using Cronbach's alpha. **Results:** Minor modifications were made to the Tamil and Telugu versions based on participant feedback, while the Malayalam version required no changes. The translated questionnaires were well accepted, and the average completion time was 15 minutes. Cronbach's alpha values were 0.82 (Tamil), 0.81 (Telugu), and 0.64 (Malayalam), indicating good to acceptable internal consistency. **Conclusion:** The Tamil, Telugu, and Malayalam versions of the EORTC QLQ-SH22 are culturally appropriate and reliable tools for assessing sexual health-related quality of life in cancer patients. These translations can support routine clinical use and research in South Indian populations.

Keywords: EORTC QLQ-SH22 Sexual health Quality of life Translation and validation Tamil- Telugu- Malayalam

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Introduction

According to GLOBOCAN 2022, there were nearly 20 million new cancer cases and 10 million cancer-related deaths globally [1]. The incidence of cancer is increasing due to factors such as aging populations, environmental exposures, and lifestyle changes. Parallely, advances in treatment—including improved surgical, radiation, chemotherapy, and immunotherapy techniques have led to better outcomes and increased survivorship [2, 3].

However, survivors often face significant quality of life (QoL) challenges, many of which remain under-addressed in routine oncology care [4, 5]. Among these, sexual dysfunction is a common yet often overlooked issue [6, 7]. Conversations around sexual health are limited due to time constraints, lack of privacy in clinics, discomfort among physicians, hesitancy among patients, and the absence of

a simple, standardized assessment tool [8].

The EORTC QLQ SH22 is a well-designed questionnaire specifically developed to assess sexual health-related quality of life in cancer patients. It is comprehensive yet easy to use and covers various relevant domains [9, 10]. While this tool is available in English and a few Indian languages, its limited linguistic availability remains a barrier to its broader use in a country like India, which is home to hundreds of spoken languages.

Given the linguistic and cultural diversity in India especially in the southern region there is a critical need to make this tool available in regional South Indian languages. Doing so will enhance its usability, allow self-reporting, reduce bias, and improve the capture of patient-reported outcome measures (PROMs).

The aim of the present study is to translate and validate the EORTC QLQ SH22 questionnaire into Telugu, Tamil,

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and Malayalam, following the standardized guidelines provided by the EORTC Translation Unit.

Materials and Methods

The translation process was carried out in accordance with the EORTC Quality of Life Group Translation Manual. Ethical approval for this study was obtained from the institutional ethics committee. Informed consent was obtained from all participating patients prior to inclusion in the pilot testing phase. After obtaining approval from the EORTC Translation Unit (TU), the translation was carried out using the official Excel-based template provided by the EORTC Translation Coordinator, which included the complete set of English items from the EORTC QLQ-SH22. A designated project coordinator was assigned to oversee and guide the entire process.

For each language Tamil, Telugu, and Malayalam two independent forward translations were performed by native speakers fluent in English. Specifically, Tamil FT1 and FT2 (Translator A and Translator B), Telugu FT1 and FT2 (Translator C and Translator D), and Malayalam FT1 and FT2 (Translator E and Translator F) produced the initial versions. These translations focused on maintaining conceptual meaning while ensuring the language was culturally appropriate and easy to understand.

Each set of forward translations was then reconciled into a single version by a third translator Tamil RC (Translator G), Telugu RC (Translator H), and Malayalam RC (Translator I) who was also fluent in both English and the respective language. This reconciled version incorporated the most appropriate phrasing from both translations, with justifications recorded for transparency.

To verify the accuracy and fidelity of the reconciled version, two backward translations were performed for each language by different individuals unfamiliar with the original English questionnaire. The backward translators included Tamil BT1 and BT2 (Translator J and Translator K), Telugu BT1 and BT2 (Translator L and Translator M), and Malayalam BT1 and BT2 (Translator N and Translator O). These translators translated the reconciled version back into English, allowing a comparison with the source text to ensure semantic equivalence.

All materials including forward translations, reconciliation notes, and backward translations were reviewed by the EORTC TU. They assessed the accuracy, clarity, and consistency of the translations and provided detailed feedback for necessary revisions.

Following this, external proofreading was conducted by language experts nominated by the EORTC TU. These proof-readers examined the draft translations for grammar, formatting, cultural appropriateness, and spelling. Their feedback was incorporated to finalize the pre-test versions.

Pilot testing was then conducted with a total of 43 native-speaking patients: 15 each in Tamil and Telugu, and 13 in Malayalam. All participants were adults diagnosed with pelvic region cancers who were either undergoing or had completed treatment. After completing the questionnaire, participants were interviewed about the clarity of the questions, emotional impact, and overall ease of understanding.

While most participants found the translations clear and comprehensible, a few changes were suggested during pilot testing. These suggestions were carefully reviewed and discussed with the EORTC Translation Unit team. Based on this collaborative evaluation, minor modifications were incorporated into the final versions to enhance clarity and cultural relevance. The final reports were submitted to the EORTC TU, and upon their approval, the translations were deemed validated and ready for clinical and research use.

Statistical Analysis

The internal consistency of the translated questionnaires was evaluated using Cronbach's alpha coefficient. Values above 0.70 were considered to indicate acceptable reliability. Feedback from the pilot testing was qualitatively reviewed, and minor linguistic refinements were made accordingly. All analyses were performed in accordance with the EORTC QLG guidelines.

Results

Pilot testing was conducted with a total of 43 native-speaking patients: 15 each in Tamil and Telugu, and 13 in Malayalam. All participants were adults diagnosed with cancers who were either undergoing or had completed treatment. After completing the questionnaire, participants were interviewed about the clarity of the questions, emotional impact, and overall ease of understanding. Demographic details and patient responses to the translated questionnaire were summarised and are provided as supplementary tables.

While most participants found the translations clear and comprehensible, a few changes were suggested during pilot testing, particularly in Tamil and Telugu versions. These were carefully reviewed in consultation with the EORTC Translation Unit and were incorporated into the final versions when deemed appropriate to improve clarity and usability.

In the Tamil pilot group, questions 10, 13, and 19 posed some comprehension challenges. Participants reported needing additional explanation to fully understand the intent of these questions. However, when the reconciled versions from the translation phase were reintroduced, patients expressed greater clarity and comfort. Based on this feedback and discussion with the EORTC TU team, the following reconciled translations were adopted into the final Tamil version (Table 1 and Appendix 1).

Question 10: To what extent do you feel comfortable communicating sexual difficulties to your partner?

Question 13: Do you experience feelings of insecurity regarding your ability to satisfy your partner sexually?

Question 19: Are you generally able to achieve orgasm in a satisfactory manner during sexual activity with your partner?

Question 10: உடலுறவு சிக்கல்களை உங்கள் துணையிடம் தெரிவிப்பதில் திருப்திகரமாக உள்ளீர்களா?

Question 13: உங்கள் துணையை திருப்திப்படுத்துவது செயலில் பாதுகாப்பின்மை உள்ளதாக உணர்கிறீர்களா?

Question 19: உங்கள் உடலுறவில் உச்சநிலையை திருப்திகரமான முறையில் அடைய முடிகிறதா?

Table 1. Final Tamil Translation of the EORTC QLQ-SH22 Questionnaire

No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
1	How important has sexual activity been to you?	1	2	3	4
2	Have you felt anxious about not being sexually active?	1	2	3	4
3	Have you felt distressed because of not being sexually active?	1	2	3	4
4	Have you felt tense because of not being sexually active?	1	2	3	4
5	Have you wanted to be sexually active?	1	2	3	4
6	Have you tried to be sexually active?	1	2	3	4
7	Have you been sexually active?	1	2	3	4
8	Have you been satisfied with your sexual activity?	1	2	3	4
9	Have you shared your thoughts about sexual problems with your partner?	1	2	3	4
10	Were you satisfied discussing sexual problems with your partner?	1	2	3	4
11	Have you felt guilty for not meeting your partner's sexual needs?	1	2	3	4
12	Has your partner understood your sexual needs?	1	2	3	4
13	Have you felt insecure in satisfying your partner?	1	2	3	4
17	Have you been sexually active?	1	2	3	4
18	Have you found sexual activity pleasurable?	1	2	3	4
19	Have you been satisfied with your ability to reach orgasm?	1	2	3	4
20	Have you felt intimacy in your sexual life?	1	2	3	4
21	Have you hesitated to express sexual interest?	1	2	3	4
22	Have doctors asked you about your sexual health?	1	2	3	4
Section B – For Female Participants Only					
No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
16	Have you felt loss of femininity?	1	2	3	4
Section C – For Male Participants Only					
No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
14	Have you had pain during sexual activity?	1	2	3	4
15	Have you felt lack of sexual interest?	1	2	3	4

In the Telugu pilot group, participants expressed difficulty understanding the term *kriyāśīla* used in Question 1, as it is rarely used in everyday language and more commonly associated with concepts like “active membership.” Instead, patients suggested using the phrase *lingika jīvitam mīku enta mukhyamu?*, which they felt better captured the meaning and was easier to understand. Though the English equivalent “How significant has an active sexual life been to you?” is slightly different in structure, the suggested Telugu version was preferred for clarity and has been included in the final version.

Additionally, in Questions 16 and 19, terms like *strītatvam* and *bhāvapatṛpti* were perceived as complex or academic. While a few well-educated respondents understood them, they were less familiar to others. Since no simpler or more culturally appropriate alternatives exist in Telugu, the original wording was retained in the final version (Table 2 and Appendix 1).

In the Malayalam pilot group, most participants found the questionnaire understandable; however, a few expressed difficulty with questions 13 and 16. These concerns were carefully discussed with the EORTC Translation Unit, and the reconciled versions of these

questions were finalized and retained in the final version (Table 3 and Appendix 1).

To assess internal consistency, Cronbach’s alpha (α) reliability testing was conducted for each language version using responses to the general items. The results were as follows:

- Tamil: $\alpha = 0.82$
- Malayalam: $\alpha = 0.64$
- Telugu: $\alpha = 0.81$

These values indicate good internal consistency for the Tamil and Telugu versions and acceptable reliability for the Malayalam version, supporting their use in clinical and research contexts.

The translated versions were submitted and officially approved by the EORTC Translation Unit, and are eligible for public use upon request through the EORTC QLQ (Supplementary Tables 1, 2,3).

Discussion

This study aimed to translate and pilot test the EORTC

Table 2. Final Telugu Translation of the EORTC QLQ-SH22 Questionnaire

Section A – For All Participants					
No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
1	How important has sexual activity been to you?	1	2	3	4
2	Have you felt anxious about not being sexually active?	1	2	3	4
3	Have you felt distressed because of not being sexually active?	1	2	3	4
4	Have you felt tense because of not being sexually active?	1	2	3	4
5	Have you wanted to be sexually active?	1	2	3	4
6	Have you tried to be sexually active?	1	2	3	4
7	Have you been sexually active?	1	2	3	4
8	Have you been satisfied with your sexual activity?	1	2	3	4
9	Have you shared your thoughts about sexual problems with your partner?	1	2	3	4
10	Were you satisfied discussing sexual problems with your partner?	1	2	3	4
11	Have you felt guilty for not meeting your partner's sexual needs?	1	2	3	4
12	Has your partner understood your sexual needs?	1	2	3	4
13	Have you felt insecure in satisfying your partner?	1	2	3	4
17	Have you been sexually active?	1	2	3	4
18	Have you found sexual activity pleasurable?	1	2	3	4
19	Have you been satisfied with your ability to reach orgasm?	1	2	3	4
20	Have you felt intimacy during sex?	1	2	3	4
21	Have you hesitated to express sexual interest?	1	2	3	4
22	Have doctors asked you about your sexual health?	1	2	3	4
Section B – For Female Participants Only					
No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
16	Have you felt loss of femininity?	1	2	3	4
Section C – For Male Participants Only					
No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
14	Have you had pain during sexual activity?	1	2	3	4
15	Have you felt lack of sexual interest?	1	2	3	4

QLQ-SH22 sexual health questionnaire into three major South Indian languages Tamil, Telugu, and Malayalam using standardized EORTC procedures. The process ensured conceptual, semantic, and cultural equivalence of the translations to the original version.

Our findings suggest that the translated versions were well comprehended by the majority of participants across all three languages. Minor linguistic adjustments were needed only in Tamil and Telugu to improve clarity. These were incorporated after pilot feedback and in discussion with the EORTC Translation Unit. Malayalam did not require any changes after pilot testing, indicating good initial translation fidelity.

Internal consistency of the translated tools was confirmed through Cronbach's alpha reliability testing. The Tamil and Telugu versions demonstrated good internal consistency ($\alpha = 0.82$ and 0.81 , respectively), while the Malayalam version showed acceptable reliability ($\alpha = 0.64$).

These results are consistent with earlier translation efforts of the EORTC QLQ-SH22 into other Indian

languages. A recent study by Krishnatry et al. [11] reported successful translation and pilot validation of the questionnaire in Hindi, Marathi, and Bangla, with Cronbach's alpha values of 0.69, 0.66, and 0.86 respectively. Their work emphasized the importance of linguistic and cultural adaptation to enhance usability and response accuracy in diverse populations. The current study builds on this foundation by expanding access to the tool among speakers of South Indian languages.

This work highlights the importance of regional language availability for sensitive domains such as sexual health. The availability of these validated tools now facilitates culturally appropriate patient-reported outcome measurements for sexual health in cancer patients in South India. Furthermore, using the SH22 in local languages may improve the quality and completeness of data collection by reducing social and linguistic barriers.

While this study provides preliminary evidence of feasibility and reliability, it is limited by its small sample size per language group and lack of formal psychometric validation beyond internal consistency. Future studies

Table 3. Final Malayalam Translation of the EORTC QLQ-SH22 Questionnaire

Section A – For All Participants					
No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
1	How important has sexual activity been to you?	1	2	3	4
2	Have you felt lack of sexual interest?	1	2	3	4
3	Have you been satisfied with your level of desire?	1	2	3	4
4	Have you been satisfied with your sexual life?	1	2	3	4
5	Have you been worried about being masculine/feminine enough?	1	2	3	4
6	Have you felt fatigued or lacked energy during sex?	1	2	3	4
7	Has treatment affected your sex life?	1	2	3	4
8	Have you been worried about reduced sexual functioning?	1	2	3	4
9	Have you talked to a doctor or nurse about sexual problems?	1	2	3	4
10	Were you satisfied with talking to your partner about sexual problems?	1	2	3	4
11	Have you felt unable to satisfy your partner's sexual needs?	1	2	3	4
12	Have you been satisfied with your level of desire?	1	2	3	4
13	Have you felt insecure about satisfying your partner?	1	2	3	4
17	Have you been sexually active?	1	2	3	4
18	Have you found sexual activity pleasurable?	1	2	3	4
19	Have you been satisfied with your ability to reach orgasm?	1	2	3	4
20	Have you felt intimacy during sex?	1	2	3	4
21	Have you had at least one orgasm during sex?	1	2	3	4
22	Have you experienced pain during sex?	1	2	3	4
Section B – For Female Participants Only					
No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
16	Have you felt a loss of femininity?	1	2	3	4
Section C – For Male Participants Only					
No.	English Item	1 = Not at all	2 = A little	3 = Quite a bit	4 = Very much
14	Have you had confidence in getting or keeping an erection?	1	2	3	4
15	Have you felt a loss of masculinity?	1	2	3	4

could include test-retest reliability, construct validity, and responsiveness analyses on larger and more diverse patient populations.

In conclusion, the Tamil, Telugu, and Malayalam versions of the EORTC QLQ-SH22 have been successfully translated and linguistically validated following EORTC guidelines. Pilot testing confirmed their acceptability and ease of comprehension among cancer patients, with good to acceptable internal consistency. These tools are now ready for implementation in clinical and research settings to assess sexual health-related quality of life in South Indian populations. Wider use of these validated regional language versions may enhance patient engagement, reduce response bias, and support culturally sensitive care.

Author Contribution Statement

All authors contributed equally in this study.

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