



TRANSLATION INTO BENGALI AND VALIDATION OF THE CERVIX CANCER SPECIFIC EORTC CX24 QUALITY OF LIFE QUESTIONNAIRE.

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ABSTRACT

Introduction: Cervical Cancer is the second most common cancer among women in India. Assessment of Quality of Life (QoL) of these patients is vitally important. The EORTC QLQ C30 core domain for all cancers and the Cervix Cancer specific CX24 domains are amongst the most common instruments available for assessment of QoL. However, as these are developed in English, and the QoL instruments need to be self answered, there is an unmet need to have vernacular (regional) language versions. We thus aimed to translate the EORTC CX24 into Bengali.

Materials And Methods: After necessary permissions, the CX24 English questionnaire was first forward translated into an intermediary Bengali version, which was then back translated into English and this was compared to the original English version. The Bengali version was then pilot tested and modifications incorporated to arrive at the final Bengali translation.

Results: A total of four ladies whose mother tongue was Bengali but who were fluent in English translated the questionnaire – two each for the Forward and Back translations. Discrepancies in the translation process were mainly linguistic and were solved by mutual discussion to arrive at a culturally adapted socially acceptable literatim translation. Pilot testing was done on 15 women with breast cancer. The entire process was explicitly documented and took about nine weeks.

Conclusion: The Bengali translation of the EORTC CX24 domain was done as per stipulated rules and ratified by the EORTC. It is available for download, free of cost, from the EORTC QoL website for academic researchers across the globe. It will be of immense help to assess the QoL of Bengali speaking cervical cancer patients and formulate better care for them.

KEYWORDS : EORTC, CX 24, Quality of Life, Cervix cancer, Bengali, translation

INTRODUCTION

Cervical cancer accounted for 6,04,127 cases and 3,41,831 deaths globally in the year 2020 being the fourth most common cancer in women globally both in terms of incidence and mortality.[1] In India, Cervical cancer is a major health problem – being the second most common cause of incidence and mortality among females with cancer with an estimated 1,23,907 cases being diagnosed during 2020 and 77,348 (about two thirds) dying from it.[1] The relatively higher mortality from cervical cancer in India is due to most cases presenting late, in advanced stages.[2]

There has been tremendous progress in the management of cervical cancer over the last few decades, especially with improvement in conformal external beam radiotherapy with concomitant chemotherapy and image guided adaptive brachytherapy – both in terms of local control and survival.[3,4] However, because of the late presentation, and inadequate treatment facilities in developing countries, some patients cannot be completely cured.[5] Therefore, maintaining the quality of life (QoL) assumes paramount importance in the continuum of care of these patients with advanced cervical cancer.[6-10]

Various instruments have been used to assess the health related quality of life in Cervix cancer patients including the European Organization for Research and Treatment of Cancer Quality of Life Questionnaires (EORTC QLQ C30 and the Cervix cancer specific module CX24) and the Functional Assessment of Cancer Therapy – Cervix (FACT-Cx).[11-13] These QoL questionnaires need to be self answered and therefore their availability in the native (vernacular) language is absolutely essential to obtain proper responses. The EORTC CX24 has been translated into various languages across the globe. [14-16]

Considering the fact that Bengali (Bangla) is one the most common spoken languages across the world and second most common, after Hindi, in terms of numbers in India as well as the most common spoken language in Bangladesh,[17] we decided to translate the EORTC CX24 module into Bengali.

The aim of the study was :

1. To translate the EORTC CX24 version 1.0 cervix cancer specific quality of life questionnaire into Bengali.
2. To validate the translation by pilot testing in the population where it is intended to be used.

MATERIALS AND METHODS

The EORTC Quality of Life questionnaires consist of a core questionnaire domain (the 30 question QLQ C-30) which is non specific and cancer subsite specific domains like the 24 question CX24

for cervical cancer.[18, 19] [Figure 1] Each question has four responses arranged in a qualitative Likert like scale with responses from 1 (not at all) to 4 (very much). The 24 questions in the CX24 domain pertain to cervical cancer symptoms faced due to the disease as well as treatment over a recall period of the last 1-4 weeks – including physical, psychological, social and sexual wellbeing.

Figure 1: EORTC CX24 version 1.0 English

The Bengali translation of the EORTC CX24 version 1.0 module was undertaken with the author as the Translation Coordinator (TC) upon receipt of explicit permission by mail from the EORTC Quality of Life Translation office using the EORTC Translation Manual. The translation was carried out in the following steps :

Forward Translation

The original English language version of the CX24 questionnaire was administered to two separate individuals both of whom were native speakers of Bengali and fluent in English. They independently translated the questionnaire into Bengali to yield the two Forward Translations (FT1 and FT2). The TC then consulted (by mail, telephone and personal meetings) both the Forward Translators to arrive at a consensus – a mutually acceptable reconciled first intermediate Bengali Forward Translation (FT).

Back Translation

The reconciled first intermediate Bengali Forward Translation (FT) of the CX24 questionnaire was now administered to two other women both of whom were also native speakers of Bengali and fluent in English. They independently translated the Bengali version of the questionnaire back into English to yield the two Back Translations (BT1 and BT2). The TC then consulted both the Back Translators to arrive at a consensus – a mutually acceptable reconciled final English

Back Translation (BT).

EORTC Translation office review

All translations (FT1, FT2, FT, BT1, BT2 and BT) were sent to the EORTC Translation Office for review along with Curriculum Vitae of all the Translators as per prescribed format. At all points during the translation process, differences of opinion arising between the translators and methods how they were resolved were documented by the TC in the Translation Report. The BT was compared, question by question, word for word, independently by the TC and the Translation Office with the original CX24 English version to compare if the wordings matched. Any deviations were clarified, documented and resolved. In this process the reconciled Bengali forward translation was refined to produce the second intermediate Bengali Forward Translation (FT Final).

Pilot Testing

The second intermediate Bengali Forward Translation (FT Final) was now administered to 15 patients of cervical cancer – comprising both early and locally advanced disease, receiving external beam radiotherapy with concurrent chemotherapy and brachytherapy and some who were on follow up after completion of treatment. This was done to ensure a truly heterogenous and therefore representative population for pilot testing. Each patient was asked if any of the questions were incomprehensible, difficult to understand (wording), offensive or confusing. Modifications suggested were discussed with the Translators and the Translation Office of the EORTC and subsequently incorporated, if deemed appropriate, to arrive at the final Bengali questionnaire.[Figure 2]

Figure 2 : EORTC CX24 Bengali Translation

Statistical Validation

Cronbach's alpha was calculated for the final Bengali translated CX24 questionnaire to test the internal validity.

RESULTS

The translation process has already been detailed above.

Step I : Forward Translation

The original English language version of the CX24 questionnaire was administered to two women (a college student and an architect). They independently translated the questionnaire into Bengali to yield the two Forward Translations (FT1 and FT2) within a time frame of about two weeks. There were discrepancies noted for the following questions :

a)Question 31: Have you had cramps in your abdomen? : FT1 used the word 'cramps' as "*jontronadayok khil*" while FT2 used "*pete tan*". Neither of the translations were perfect and after some deliberation, the phrase "*jontronadayok bhabe pet kamrechhilo*" was accepted mutually.

b)Question 37: Did you have difficulty emptying your bladder? : FT1 used the phrase 'emptying your bladder' as "*prosrab shesher shomoy osubidha bodh*" while FT2 used "*sompurno mutro tyage osubidha*". Both the words "*prosrab*" and "*mutra*" meant 'urine' in Bengali. After discussion, the latter version was finally considered more appropriate with a slight modification to yield "*sompurno poriman prosrab tyag korte osubidha*".

c)Question 40: Have you had tingling or numbness in your hands and feet? : FT1 translated the phrase 'tingling and numbness' as "*shihoron*

ba osharotwo" while FT2 used "*obosh othoba jhonjhon*". The latter was considered more acceptable.

d) Questions 41: Have you had irritation or soreness in your vagina or vulva? : FT1 translated the phrase 'irritation or soreness' as "*jwala jontrona*" while Forward translator 2 translated it as "*ashwasti ba khotobhab*". The two translations were combined to yield the phrase "*jwala jontrona ba khotobhab*" which was ultimately considered appropriate.

e) Question 42: Have you had discharge from your vagina? : FT1 translated the phrase 'discharge' as "*khoron*" while FT2 used "*srab*". Both versions were ultimately incorporated.

The mutually acceptable reconciled first intermediate Bengali Forward Translation (FT) was thus produced.

Step II : Back Translation

The reconciled first intermediate Bengali Forward Translation (FT) of the CX24 questionnaire was now administered to two other women (a high school teacher and a housemaker). They independently translated the Bengali version of the questionnaire back into English to yield the two Back Translations (BT1 and BT2) within a further time frame of about two weeks. There were discrepancies noted for the following questions :

a)Question 32: *Paikhanar beg dharon korte ki apnar osubidhe hoyechhilo?* : The word "*paikahanar*" was translated by BT1 as "bowels" and by BT2 as "motions". The latter was considered more acceptable with the modification as "Have you had problems in controlling your stools/ motions?".

b)Question 41: The phrase "*khotobhab*" was translated by BT1 as "soreness" and by BT2 as "pain". The version of the former was considered more appropriate.

c)Question 48 : The phrase "*ashonka*" was translated as "worried" and as "felt anxious" by BT1 and BT2 respectively. The version of the former was continued with.

The mutually acceptable reconciled final English Back Translation (BT) was thus produced.

Step III : EORTC Translation office review

In general, the BT was very similar to the original English version of the CX24 questionnaire – the main criteria for consideration of acceptability of the translated version. All deviations and the processes used to arrive to a consensus were captured in the Translation report. Queries were raised about some of the questions and resolved by mutual discussion with the Translators. The queries are briefly discussed below :

a)Question 31: The accepted reconciled final English Back Translation (BT) contained the phrase "painful" which was not there in the original English CX24. The TC got back to the Translators and it was agreed that the term "painful" could be omitted and therefore, in the Bengali translation, the phrase "*jontronadayok*" was also omitted.

b)Question 37: The phrase "fully emptying your bladder" in the BT was different from original English CX24 where "fully" was absent. Upon query, it was agreed that, the presence of the phrase "*sompurno*" in the Bengali translation was necessary to convey the correct meaning of the question but the word "fully" could be dropped in the BT. The Bengali translation, was thus unaltered.

c)Questions 50: The term "*sexual activity*" in the original English CX24 was forward translated as "*jouno shomporko*" and consequently back translated as "sexual intercourse". It was argued that the word activity would better encompass the entire gamut of sexual closeness – not merely the act itself and was therefore better. However, the exact verbatim translation of "activity" would be "*kriyakolap*" which was not in colloquial usage while "*jouno shomporko*", a much more broad term would be easily acceptable and understandable. After discussions, it was decided to overlook the BT and keep the Bengali translation unchanged.

In this process the reconciled Bengali forward translation was refined to produce the second intermediate Bengali Forward Translation (FT Final) which was accepted by the EORTC Translation office as the Bengali Translation of CX24 and all Translators including the TC. This process took about another three weeks.

Step IV : Validation by Pilot Testing

The second intermediate Bengali Forward Translation (FT Final) was now administered to 15 patients of cervical cancer. The median age of

the patients was 56 years (range 29–64 years). Sixty percent were post menopausal. All had Squamous Cell Carcinoma. Forty percent had FIGO stage IIB and IIIB disease respectively. All patients received radiotherapy and 86% received concomitant chemotherapy (all with Inj. Cisplatin weekly). All received or were planned to receive Brachytherapy. Ten patients were undergoing treatment and five were on follow up.

All patients were self administered the Bengali translation of the CX24 and asked to fill it up in privacy without any time constraints. Informed consent was obtained for the purpose. They were then individually interviewed by the TC regarding their perception of the questionnaire. None of the patients felt any of questions to be incomprehensible, misleading or confusing. All of them agreed that the wording were not offensive or inappropriate and that the translation was culturally adapted and socially acceptable. Only one patient had a difficulty understanding the word “*khoron*” in Question 41. Interestingly, ten patients stated that they were not sexually active in the period mentioned, so they would not be answering Questions 50–54.

Statistical Validation

Cronbach's alpha (a measure of internal validity) was calculated based on the responses provided by the pilot testing cohort to validate the Bengali translation. The values ranged from 0.71 to 0.84 for the questions which showed acceptable internal validity.

The pilot testing and validation took a further period of two weeks. The second intermediate Bengali Forward Translation (FT Final) was now submitted to the EORTC Translation office, where, after final review it was accepted as the Bengali translation of the CX24 questionnaire. [Figure II]

DISCUSSION

The EORTC QOL questionnaires consist of a core domain (the QLQ C30) and subsite specific domains, of which the Cervix Cancer specific domain is the 24 question CX24 to assess the quality of life of cervical cancer patients. As the original questionnaire is in English, and self administration and answering is mandatory, translations in vernacular (regional) languages is required. We undertook the Bengali translation as it has previously not been done and was a substantial unmet need to enable assessment of quality of life of Breast Cancer patients who speak Bengali.

The translation was undertaken as per method prescribed by the EORTC Quality of Life Translation Office – with a forward translation followed by a backward translation detailed above. All discrepancies (mainly linguistic) were mutually discussed by the TC with the Translators and mutually acceptable solutions (literatim translations) sought. The whole process was documented in detail and ratified by the EORTC.

Once the second intermediate Bengali Forward Translation (FT Final) was arrived upon, it was pilot tested among 15 patients of cervical cancer. The pilot testing process was unremarkable, the translation was deemed culturally adapted and socially acceptable and no modifications were required. The entire duration of the process was approximately nine weeks. The Cronbach's alpha measuring internal validity was acceptable. The Bengali translation was thus adapted by the EORTC subsequently.

CONCLUSION

Assessment of quality of life is of paramount importance for all cancer patients including those with cervical cancer, the second most common cancer in Indian women. We undertook translation and subsequent validation, by pilot testing of the EORTC CX24 Cervix Cancer specific quality of life questionnaire into Bengali. The translation process was conducted as per methods described by the EORTC Translation manual and completed successfully within nine weeks. The culturally adapted, socially acceptable Bengali translation of CX24 is now available free for download upon reasonable request at the EORTC website for academic researchers world wide. We are sure that this will immensely help Bengali speaking cervical cancer patients to express quality of life issues they face themselves across the globe and Oncologists and other healthcare workers formulate better paradigms of care based on these findings.

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