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International

Translation and Pilot Validation of Hindi, Marathi, and Bangla Translation of Quality-of-Life EORTC Radiation Proctitis Module (PRT-20) for Routine Clinical Use

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Abstract

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The aim of this study was to translate and validate the European Organization for Research and Treatment for Cancer (EORTC) "Radiation Proctitis" (PRT-20) module in Hindi, Marathi, and Bangla languages. The EORTC PRT-20 was translated into Hindi, Marathi, and Bangla using EORTC guidelines. Two separate translators first translated the original questionnaire into the three regional languages, following which a reconciled forward translation was compiled. This reconciled version in each language was then back-translated into English by two other translators. This back-translated version was then compared with the original the EORTC questionnaire for correctness, and the preliminary questionnaires were formed in all three languages. The EORTC translation unit approved the questionnaires. The preliminary questionnaires were administered to 30 patients (10 for each language) diagnosed with rectal or anal canal cancer who had received pelvic radiotherapy and were at risk of developing PRT. None of the patients had seen the questionnaire before. After filling out the questionnaire, each patient was interviewed for difficulty in answering, confusion, understanding, or if any of the questions were upsetting and if patients would have asked the question differently. No changes were suggested for Marathi and Bangla translations. Two modifications were suggested in the Hindi translation, which was then retested in five patients and finalized. All the suggestions were incorporated into the preliminary questionnaires, which were sent back to the EORTC for final approval. After reviewing the entire report of pilot testing for the translated quality-of-life questionaire-PRT-20 in three languages, it was approved by the EORTC translation unit. The translated questionnaires were reliable, with Cronbach α values of 0.767, 0.799, and 0.898 for Hindi, Marathi, and Bangla, respectively. The Hindi, Marathi, and Bangla translations of PRT-20 have been approved by the EORTC and can be used in routine clinical practice.

Keywords

- radiation proctitis
- rectal cancer
- PRT-20
- EORTC
- quality-of-life questionnaire

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Introduction

Pelvic radiotherapy is used for various cancers, commonly cervical, rectal, prostate, bladder, and anal canal cancers. Radiotherapy of the pelvic region increases the risk of radiation proctitis (PRT). Patients with PRT usually present with anorectal pain, rectal bleeding and/or blood clots, bowel urgency, frequent diarrhea, profuse mucus discharge, and fecal and/or mucous incontinence.[1–4] Symptoms can have profound social and psychological consequences for the patients and their families.[2]

The severity of PRT depends upon various factors, mainly the dose received by the rectum and the volume receiving a higher dose. Symptoms usually appear during or within the first 3 months of radiation treatment and are termed as acute, while later ones as late.[3,4] Radiation Therapy Oncology Group (RTOG) and Common Terminology Criteria for Adverse Events (CTCAE) have classified PRT into various grades. These grading mechanisms are routinely used by clinicians to report toxicity in practice and clinical trials. But they do not comprehensively assess the range of associated problems nor the impact on the quality of life associated. Recently, the European Organization for Research and Treatment for Cancer (EORTC) devised a proctitis module for reporting, through which patients can directly report their proctitis (QLQ-PRT-20: quality-of-life questionnaire PRT) and related symptoms. It has been validated in an international phase IV study by Halkett et al.[5]

Patient-reported outcomes (PROMs) play a major role in routine assessment and care for cancer patients. The EORTC has developed QLQs on various disease conditions available in different languages worldwide.[6,7] QLQ-PRT-20 is one of those questionnaires that especially assesses patients for PRT. This QLQ is used in routine oncology practices and many cancer-related clinical trials worldwide. Most patients visiting our institution are Hindi, Marathi, and Bangla speaking. However, QLQ PRT-20 is available in the English language (►**Table 1**), which may not be understood by our patients.

Table 1 EORTC QLQ PRT-20 (English)

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you					
	During the past week	**Not at all**	**A little**	**Quite a bit**	**Very much**
1.	Have you had a bloated feeling in your abdomen?	1	2	3	4
2.	Were you troubled by passing wind / gas / flatulence?	1	2	3	4
3.	Have you had excessive gurgling noise from your abdomen?	1	2	3	4
4.	Have you had any unintentional release (leakage) of wind or mucous?	1	2	3	4
5.	Have you had any unintentional release (leakage) of liquid stools?	1	2	3	4
6.	Have you needed to get up at night to open your bowels?	1	2	3	4
7.	Have you had abdominal pain or cramping not related to a bowel movement?	1	2	3	4
8.	Have you had pain or cramping in your rectum (deep inside the back passage)?	1	2	3	4
9.	Have you had pain /discomfort around your anal opening (back passage)?	1	2	3	4
10.	Have you had bright blood in your stools?	1	2	3	4
11.	Have you been unable to wait 15 minutes to open your bowels?	1	2	3	4
12.	Have you had the feeling of being unable to completely empty your bowels?	1	2	3	4
13.	Does passing water cause your bowels to act immediately?	1	2	3	4
14.	Have you had difficulty going out of the house, because you needed to be close to a toilet, because of bowel problems?	1	2	3	4
15.	Did your treatment restrict the types of food you can eat due to your bowel problems?	1	2	3	4
16.	Did you worry about your bowel problem?	1	2	3	4
17.	Did you feel embarrassed by your bowel problem?	1	2	3	4
18.	How unhappy would you feel if you lived the rest of your life with your bowel habit as it is now?	1	2	3	4
19.	Have you needed to take medication to control diarrhea?	Yes	No		
20.	What was the highest number of times you had to open your bowels in any 24 hours period? Please indicate number in box?				
21.	Would you like more assistance to manage your bowel problem? (optional question)	Yes	No		

Abbreviation: EORTC QLQ PRT-20, European Organization for Research and Treatment for Cancer quality-of-life questionnaire proctitis radiation 20.

For appropriate reporting of quality of life as patient-reported outcomes, patients should fill QLQs on their own. Administering QLQ in a language that is understood well by the patient is therefore important.[8–14] In this study, we translated QLQ PRT-20 into Hindi, Marathi, and Bangla. The translation process was carried out according to the standard guidelines proposed by the EORTC. After successful translations into target languages, they were pilot tested and validated for routine practice and in clinical trials as per the EORTC guidelines. The translation and the pilot testing reports were reviewed and approved by the EORTC translation unit (TU).

Methods

This project of translation and validation has been done according to the standard guidelines proposed by the EORTC[6] and after institutional ethics approval (IEC No:4076, CTRI registration No: CTRI/2022/12/047820). The project co-coordinator from the TU of the EORTC coordinated and guided the team throughout the process. This included preparing the files for translation, reviewing the translation reports, finalizing the project, and general communication. Following are the steps that were followed.

Forward Translation

During this step, the English questions were translated to Hindi, Marathi, and Bangla, respectively, by two individuals for each language. These translators were well-versed in Hindi, Marathi, and Bangla, respectively.

Reconciliation

After completion of forward translation (FT), reconciliation (RC) of translations was done by a third translator proficient in English and their respective native language. During the RC process, out of the two provided FTs, in case of discrepancy in two FTs, the closest translation was chosen with comments explaining the reason for the choice.

Back Translation

After RC, different translators translated the final Hindi, Marathi, and Bangla translations back into English. Once the process was completed by back translation (BT), the entire report was sent back to the EORTC TU for review.

Review by the EORTC TU

After verifying the process, TU reverted with clarifications and questions regarding the translations. Once the process and translations are found as per the satisfaction of the EORTC, they are sent for proofreading.

External Proofreading

The EORTC sends compiled Excel reports with FT, RC, and BT to the external proofreader for language editing. If there were any changes, it was sent back to the host translation team for discussion and finalization of translation.

Pilot Testing

After proofreading, TU prepared the preliminary questionnaire, which was pilot tested on 10 patients who were native speakers of Hindi, Marathi, and Bangla each, in accordance with the EORTC manual.[6]

The patients for the pilot tested (ten for each language) were identified as individuals more than 18 years of age, diagnosed with cancer of the pelvic region, either on pelvic radiotherapy or ones who completed and were on follow-up were considered. All patients had to willingly participate in the study after signing the written informed consent and should not have ever seen the questionnaire before. For a particular language, patients who were able to read and write in the particular language as native speakers were only considered.

QLQ Analysis

Responses filled in by patients were analyzed using a scoring method provided in the EORTC standard scoring manual specific for PRT-20 questionnaire, which can be requested by readers from the EORTC.[7]

Statistical Analysis

Internal consistency for all the three Hindi, Marathi, and Bangla questionnaire was measured using "Cronbach α" reliability test. IBM corporation released 2013. IBM SPSS Statistics for Windows has been used for conducting the analysis.

Changes

In case of any suggestions for changes from patients are received, the host team and TU reviewed them. The process of 2.1 to 6 was followed for the accepted changes. Retesting was done for another five patients in such a case.

Results

Forward Translation and Difficulties Encountered

The English questionnaire was translated into target languages namely Hindi, Marathi, and Bangla. The main objective was to retain the original meaning, which must be scientifically readable. Forward translators for Hindi and Marathi were I: UG, II: AS for both, and Bangla were I: DD and II: DC. All translators chosen had a good command on the native language as well as English and were individuals working in the medical field. The translation was carried out independently by each translator. There were 33 items, including 21 questions, four objective options and the rest for guiding how to fill out the questionnaire. The files provided by the EORTC TU had existing translations (Hindi: 16, Marathi: 13, and Bangla: 15) that were used as it is or with small modification if required. Both the FT translators tried their best to translate them accurately while retaining the original meaning.

Reconciliation

RC of FTs was done by RKm and RKt for Hindi and Marathi, and by SG for and Bangla. The RC process of a few translations is worth noting. There were no significant differences between the two sets of FTs in Marathi except in Q46, wherein "काळजी" (meaning care) and "चिंता" (meaning worry)

were used for the word "worry" by translators I and II, respectively and in this case, translation II was considered. Again, in Hindi all FTs were similar except for a few as mentioned subsequently. In Q34.word leakage was translated as "टपकना" by translator I, which is a more commonly understandable word than "रिसाव" which was translated by translator II, hence translation I was considered. In Q38, the translation for the term "deep inside" was missing in the second FT. In summary, terms that were easier to understand in the local language were chosen.

Backward Translation

The reconciled translations were then back-translated independently into English by a different set of two translators (Hindi, Marathi I: PP, II: DR, and Bangla I: AA, II: SD) who had never seen this questionnaire before. The translation report was prepared compiling all five translations, two FTs in target languages, reconciled and two BTs, and comments on the reconciled version and sent to the TU for approval.

Review by the EORTC TU

When BTs were compared with the original English questionnaire, minor changes were suggested by the EORTC TU. A few of them are below.

Hindi

In Q41, translation for "to open your bowels" (शौचालय जाने के लिए) was found vague and could also refer to urine rather than just defecation. As per the TU request, it was modified to "शौच (पैखाने) कोजानेसे."

Marathi

Word frame "passing water" in Q43 was translated as "पाणी गेल्याने" and "पाणी प्यायल्यानंतर" by translator I and II, respectively. The expected meaning was "after urination." Hence, it was requested to change. We redrafted as "लघवीला झाल्यानंतर."

Bangla

There were no significant differences in translations.

After ascertaining whether the translations were complete and conveyed the same meaning as the English base question, TU prepared the preliminary questionnaire for proofreading.

Proofreading

Proofreading was done by the EORTC TU, and the preliminary translated questionnaires formatted as per the standard the EORTC QLQ template were sent back to us for pilot testing.

Pilot Testing

Preliminary questionnaires were pilot tested in 10 patients for each language, individuals diagnosed with cancer of the pelvic region, on pelvic radiotherapy treatment, or ones who completed and were on follow-up. They willingly participated in the study after the written informed consent was obtained as per good clinical practice. None of them had ever seen the questionnaire before and all were native speakers of the language in which the questionnaire was filled. They all responded to the questionnaires completely. The median age of the entire study population was 51 (range: 22–75). All had completed at least secondary schooling in their mother tongue. After filling out the questionnaire, each patient was interviewed individually for any difficulty in answering, confusion while answering, and asked whether the questions were upsetting or offensive. They were also asked whether they would have worded any question differently.

Difficulties Encountered in the Pilot Testing

Patients did not report any modifications or suggestions during pilot testing for Marathi and Bangla. All questions were understood well and were accepted as such. In Hindi translations, there were suggestions for three questions. In Q34, one patient had difficulty in understanding the word "श्लेष्मा" (meaning mucus) and suggested "मवाद" as an alternative translation. In Q43, one patient found the sentence "आंतेंतुरंतकामकरनेलगतीहैं" confusing, and suggested "क्याआपकोपेशाबहोनेसेपैखानाभीहोजाताहैं?." Both the above suggestions were accepted by the translator's team.

In Q49, one patient had difficulty in understanding the word "दस्त" and suggested "पैखाना", but this suggestion was not accepted because "दस्त" is a classical translation of the word diarrhea as in the primary English question. In contrast, the word "पैखाना" means only stools and cannot be used as a substitute for the word diarrhea. This report was sent to TU for review. The TU suggested retesting for Q34 and Q43 on five more patients. On retesting, no further comments were received, and the amended questions were incorporated into the final version of the questionnaire. Translations were finalized in coordination with the EORTC TU and are now available on the EORTC website (►**Supplementary Tables 1–3** [available in the online version]).

QLQ Analysis

Thirty questionnaires were analyzed based on scoring information provided in the scoring manual. Mean and standard deviation was calculated for final scores. Pain and emotional function/lifestyle scores were higher than the other three symptom scales (►**Table 2**). A high item score represents a high level of symptomatology or problems.

Reliability Test

Questionnaires demonstrated high internal consistency with a Cronbach α of 0.767, 0.799, and 0.898 for Hindi, Marathi, and Bangla, respectively. At the same timescale wise Cronbach α is also calculated, wherein the most of the values were more than 0.7 (►**Table 3**) which shows that the translated questionnaires were reliable.

Discussion

The EORTC has developed the QLQ for various types of cancers and cancer-related conditions, which act as a communication tool between healthcare professionals and patients to provide clarity on a patient's health condition. In our hospital, patients from different parts of India visit us, and to facilitate proper PROMs, it is essential to have the QLQ available in commonly spoken Indian languages, such as Hindi, Marathi, and Bangla. The core questionnaire (the

Table 2 EORTC quality-of-life questionnaire radiation proctitis (QLQ-PRT-20) scores for all patients

Scales	Item numbers/ Question numbers	Number of items	Mean scores	Standard deviation
Bloating and gas	31–33, 37	4	22.5	19.5
Leakage	34, 35	2	20.6	21.8
Bowel control	36, 41–43	4	29.4	22.4
Pain	38–40	3	33.3	25.8
Emotional function/lifestyle	44–48	5	40.2	25.2

Abbreviation: EORTC, European Organization for Research and Treatment for Cancer.

Table 3 Internal consistency of questionnaires using Cronbach α reliability test for Hindi, Marathi, and Bangla languages (scale-wise)

Multi item scales	Item numbers/ Question numbers	Number of items	Cronbach α for Hindi	Cronbach α for Marathi	Cronbach α for Bangla
Bloating and gas	31–33, 37	4	0.8	0.7	0.7
Leakage	34, 35	2	0.7	0.8	0.8
Bowel control	36, 41–43	4	0.7	0.8	0.7
Pain	38–40	3	0.7	0.8	0.7
Emotional function/lifestyle	44–48	5	0.9	0.7	0.7

EORTC QLQ C30) is available in most Indian languages, but disease-specific and cancer or therapy-related condition-specific questionnaires are not always available. One such questionnaire is the EORTC QLQ PRT-20, which assesses the quality of life in patients diagnosed with pelvic region cancers who receive pelvic radiotherapy and have a high risk of developing PRT and related symptoms.

Adapting and translating PROMs are crucial and essential process to ensure their clinical usefulness in contexts and countries different from those where they were originally developed. Besides facilitating better doctor–patient communication, the availability of the QLQ in native languages would also enhance the research setting by promoting greater inclusivity of culturally diverse populations in clinical studies.[5]

The main strength of this translation exercise was that all the translators were oncologists, ensuring a solid understanding of the terminology used in the questionnaire. Although a larger patient sample could have been used for validation, the current size met the minimum recommended by the EORTC.

Conclusion

The translations of the EORTC QLQ-PRT-20 in Hindi, Marathi, and Bangla were pilot tested in 30 patients, and the comments and suggestions were resolved by TU and the translation team to generate the final approved versions. These questionnaires are translated, validated, and reliable and are now available on the EORTC website for use in routine oncology practices.

Conflict of Interest

None declared.

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