Linguistic validation of the reconstruction module of BREAST-Q questionnaire in Marathi: a new patient-reported outcome instrument for breast reconstructive surgery

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Background
Breast cancer is the most common type of cancer and the major cause of cancer-related mortality among women worldwide [1]. By 2020, 70% of the world’s cancer cases will be in poor countries, with a fifth in India and breast cancer is predicted to overtake cervical cancer as the most common type of cancer among all women in India [1]. Women with advanced disease or with contra-indications to breast conservation require total mastectomy. Moreover, modern breast surgical techniques have advanced from simple lumpectomy or mastectomy to more complex procedures like oncoplasty, mastopexy, augmentation and partial or whole
breast reconstruction using autologous myo-cutaneous flaps. Breast reconstruction (BR) either immediate or delayed is an attractive option as it offers great psychological and emotional benefit and is gaining popularity. However, such advanced cases also require post-mastectomy radiotherapy (PMRT) and integration of which with BR is a challenging task. PMRT not only causes skin changes in the form of fibrosis and pigmentation but also breast symptoms and fatigue which can affect quality of life (QOL) including body image. Moving away from the traditional outcome measures in the form of peri- or post-operative complications, pain control or physician reported cosmetic outcome, there is a need for patient oriented outcome measures which can be specially used for assessment of cosmetic and reconstructive breast surgery. With the increasing number of patients getting involved in their own decision making process, patients should receive adequate information regarding the various types of breast surgery, need of additional plastic surgery, types of plastic procedures, expected complications and course and the integration of adjuvant radiotherapy if required. Nowadays, the patient-reported-outcome (PRO) measures have become an integral part of clinical research for prospective as well as cross-sectional studies. Though there are a variety of PRO instruments available for breast cancer in general, they lack specificity with respect to the type of surgery and plastic procedures. BREAST-Q is one such PRO instrument designed in 2006 to evaluate outcomes among women undergoing different types of breast surgery. There are currently five BREAST-Q modules (augmentation, reduction/mastopexy, mastectomy, reconstruction and breast conserving therapy with latissimus dorsi scale) each of which is comprised of multiple scales. All the modules have pre- and post-operative measures of health-related QOL and patient satisfaction. The development and psychometric validation process of the BREAST-Q questionnaire has been published earlier and the questionnaire are also available in various foreign languages [2,3]. The present report describes the linguistic validation of the BREAST-Q questionnaire in Marathi which is the native language of the Maharashtra state. As Tata Memorial Hospital (TMH) serves as a tertiary cancer care centre in the state of Maharashtra and a sizeable number of reconstructive procedures are done every year, there was a need to translate PRO instruments for local breast cancer patients undergoing reconstructive surgeries.

**Materials and methods**

The BREAST-Q reconstruction module had not been translated or tested in Marathi. It was also confirmed from the Memorial Sloan Kettering Cancer Center and the Mapi Research Institute that the translation of the BREAST-Q reconstruction module was not currently under preparation. The linguistic validation process recommended by the Mapi Research Institute
was followed. The aim was to produce clear (easy to read and understand) and conceptually equivalent translation of the questionnaire in Marathi. The reconstruction module of BREAST-Q comprised of two sections: preoperative having 6 questions and 42 items and post-operative having 14 questions and 116 items. The methodology followed was as follows:

1. Two forward translations of the original English instrument (both pre- and post-operative modules) into Marathi were done one by a Community Medicine personnel teaching at a Medical College (A) and another by a professional translator (B), both native Marathi speakers and fluent in English.

2. Discussions were undertaken between the translators and the local project manager (Radiation Oncologist at Tata Memorial Hospital and fluent speaker of both English and Marathi) for the discrepancies or inconsistencies found in the two forward translations. This was done by personal communication and telephonic conversations. This led to the formation of Version 1 of the questionnaire (after making consensual statements agreeable to both the translators whenever required).

3. Backward translation of the Version 1 questionnaire into English was done by a senior registrar at ACTREC who had a very good command over English and Marathi. He had no access to the original English version of the questionnaire.

4. The Version 2 questionnaire was the outcome of comparison of the backward translation with the original English questionnaire and making appropriate modifications after thoroughly checking for inaccuracies and misinterpretations in the Version 1.

5. The Version 2 questionnaire was then administered to 5 patients who had never seen the questionnaire before. Each patient, after completing the questionnaire, was interviewed by the local project manager. Questions were directed at each item in the Version 2 questionnaire that they had filled with respect to difficulty in understanding, and if patients would have asked the question in any different way. They were allowed to propose alternative translation of the relevant items which they felt were difficult to understand.

6. Based on the suggestions or interpretations of this pilot testing, a Final Version of the questionnaire was formed.
Results
The evaluation of the two forward translations done by the local project manager resulted in following changes to form the Version 1 of the questionnaire.

**General comments:** The format of the instructions and response options was retained uniformly at all places both in the pre-op as well as in the post-op modules. Similarly appropriate tenses and verbs were used uniformly. All the logos, underlines, question marks and bold types as in the original English format were followed. However, the pages were increased as it was difficult to fit one full question on one page due to difference in the format of Marathi language. Hence in case the question was continued on the next page, the response options were repeated on the top row of that page. The instructions which were common between the pre-op and post-op modules were retained as such from the Version 1 of the pre-op module. Similarly, the response categories and items in relevant questions which were common in the two modules were also adopted without change from the Version 1 of the pre-op module. Only additional phrases, questions and items were asked for translation in the postop module.

**Formation of Version 1**

**a) PREOP module:** Most of the translations were adopted from the first translator (A) as the items were properly formatted, shorter and closer in meaning to the original structure of the English question. Few items were exactly similar in both the forward translations and hence were adopted as such. For the item d in question 1, the words “कपडे कालू” were replaced with “चिन्ह” after discussion as it was more appropriate and conceptually correct. Wherever two alternative words were provided by translator A (e.g. in item b question 2, items d & g question 3), an appropriate one was adopted. Certain words like “yours” (“तुमच्या”) or “at ease” (“व सहज”) which were forgotten in question 3 and 6 respectively were also added during evaluation. The translation of item o in question 3 was not found satisfactory from both the translations; hence they were contacted to retranslate the item. It was done appropriately by translator A and was adopted. Similarly, for item e in question 6 translation proposed by the local project manager was discussed with both the translators who agreed on its adoption for the Version 1. For question 4, combined phrases from both the translations were used for completeness and appropriateness.

**b) POSTOP module:** The word used by translator A “पुल्हच्या” for “reconstruction” was more appropriate than “पुल्हच्या” used by translator B. Similar to the preop module, most of the
items were adopted from translator A either unchanged or with some modification. Few items that were incompletely translated both the translators were adopted after combining the two phrases or by addition of missing words (Items i-k in question 1, items m-o in question 11). In question 2 and 8, none of the translators gave translation for the alternative words like “rippling” or “navel” respectively, as was provided in the original English version. They were contacted for the same but did not suggest any alternative word as the words “सुरक्षिता” and “बेंबी” are self explanatory for both the respective words in English. Many items in question 4-7 were common to the preop module and were adopted without change. In question 10 item e, the word “उंचवटा” is an appropriate word for “projection” which was not translated by any of the translators. Hence, it was suggested by the project manager and incorporated in brackets in Version 1 after agreement of both the translators. Overall, all the questions were translated reasonably well by both the translators. But items that were short, clear and appropriate with respect to the original English structure were adopted.

**Back translation:** This was undertaken by a Senior Registrar in the department who is native Marathi speaking and studied medicine in English medium. He had not seen the original BREAST-Q questionnaire before. He was given information regarding the questionnaire explaining that it is a quality of life assessment tool specific for breast cancer patients undergoing reconstruction for breast. He was requested to back translate to English and formulate the questions in simple English understandable by the lay patient population. Thereafter he was given no further instructions on the nature of, and not allowed to access the original English questionnaire.

**Comparison with source instrument and formation of Version 2:** The back translation of both the pre-op as well as the post-op modules was comparable to the original English questionnaire. Though back translation did not reproduce the words or phrases exactly like the original version, the meaning of the translation turned out to be exactly the same. It was very satisfactory that back translation of all the instructions, response options and individual items was nearly identical to the English version. With some minor changes in the instructions, response options and individual items of the questions in both preop as well as postop modules of the Version 1, Version 2 questionnaire was formed.
Pilot testing and formation of Final Version: The Version 2 questionnaire was then administered to 5 patients diagnosed to have breast cancer who have undergone whole breast reconstructive surgery. All patients were Indians from Maharashtra state of which Marathi is the native language: 3 from Mumbai, one from Pune and one from Solapur. All were well educated (graduates), essentially Marathi speaking (mother tongue) and hence could read and write Marathi without any difficulty.

These patients had never seen the questionnaire before and were all native Marathi speakers. Each patient after completing the questionnaire was then interviewed by the project coordinator. The aim of the pilot testing was to identify and solve any potential problems in translation by means of direct patient interview. Primarily, patients were asked whether the instruction/item/response scale was difficult to answer and/or was confusing. In addition, we attempted to identify difficult-to-understand words or upsetting or offensive expressions and whether the patient would have asked the question in a different way without changing the wording of the original item but expressing it clearly in Marathi.

All the translated questions of both the modules were well understood by all patients. None of the patients felt that the items in both the modules were difficult to understand or confusing. In fact most of them commented that the questionnaire was appropriately translated and very pertinent to the underlying condition i.e reconstructive surgery. There were only a couple of suggestions: It was suggested that the font size can be decreased. Hence in the final version the font size was reduced to 12 from 14 in both the preop as well as postop modules. As a result, each question was completed in the same page and not continued on to the next page. The title of the questionnaire contained the word “PREOPERATIVE” and “POSTOPERATIVE” which had not been translated in Marathi but only written in Marathi. Hence this was translated as “शल्यशोधक पूर्वस्था” and “शल्यशोधक पोषण” respectively and incorporated in the final version.

The Final Versions of the PREOP and POSTOP modules have been provided in the supplementary material.

Discussion
Multiple patient-reported outcome measures evaluating general as well as specific aspects of breast cancer are available in literature. These include the Short Form-36 (SF-36), Breast-Related Symptoms Questionnaire (BRSQ), Brief Symptom Inventory (BSI), Functional Assessment of Cancer Therapy—Breast Cancer (FACT-B), Body Image after Breast Cancer Questionnaire (BIBCQ), Hopwood Body Image Scale (HBIS) and the European Organization for Research and Treatment of Cancer (EORTC) questionnaire. Of these, the EORTC QLQ-
C30 and BR23 and the FACT-B questionnaires which consists of a core questionnaire and a site specific questionnaire are the most widely used instruments for reporting patient reported quality of life following breast cancer treatment. However, these are generic instrument with respect to the type of breast surgery. Hence it cannot be expected to assess all important aspects of QOL, complications and satisfaction among breast cancer patients undergoing different types of breast surgeries. Moreover, complexity of breast surgical techniques has increased nowadays and plastic surgical procedures like oncoplasty, mastopexy, augmentation and partial or whole breast reconstruction using autologous myo-cutaneous flaps are gaining popularity. Each technique of breast surgery is expected to have different types of complications and morbidity which is likely to affect patient’s quality of life. Hence PRO instruments specific to breast surgery should be used in patients undergoing such special surgical procedures.

In a systematic literature review conducted few years ago to identify PRO measures used in oncologic breast surgery patients, only 5 (QLQ BR-23, FACT-B, HBIS, BIBCQ, and BREAST-Q) of the reported 10 instruments were adequately developed and validated [4]. Of these, first three addressed non surgical issues whereas the fourth and the fifth one did not address breast reconstruction issues and conservation surgery respectively. The Michigan Breast Reconstruction Outcomes Study (MBROS) questionnaire is specific to breast reconstruction which is available in satisfaction and body image modules. However, the items were generated by expert panel without patient interviews and lacks firm psychometric testing.

As mentioned previously, BREAST-Q is a PRO instrument which has been subsequently designed to evaluate QOL outcomes among women undergoing different types of breast surgery and is currently available in five modules depending upon the type of breast surgery including breast conservation. The framework of the BREAST-Q questionnaire is different from the other known PRO instruments. It broadly covers health related QOL outcome under three domains of physical, psycho-social and sexual well being and patient satisfaction also under three domains of satisfaction with breast, outcome and care (inclusive of satisfaction with information, surgeon, medical team and office staff). Being the first questionnaire of its kind, it is currently being used in major centres across the world. As these questionnaires are usually self administered and increasing number of patients undergo reconstructive surgery at TMH, there was a need to translate the BREAST-Q questionnaire in local and national languages. This report describes the linguistic validation in Marathi language which is the local language of the State and future report would do the same for Hindi which is the national language. However, the validation process as specified by the authors or the host institute (Andrea Pusic from Memorial Sloan-Kettering Cancer Center for BREAST-Q) has to be
strictly followed before cultural adaptation of the QOL questionnaires. We followed these guidelines for translation and validation in Marathi language and submitted a detailed report of the process along with all the translated versions of the questionnaire to Mapi Research Trust in France which coordinated with the authors for approval of the entire process. No queries were received from the host institute and the translation was approved in the first go itself after we signed the requisite copyright form.

References