BREAST-Q Translation and Linguistic Validation to European Portuguese

Tradução e Validação Linguística do BREAST-Q para Português Europeu

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ABSTRACT

Introduction: Evaluating the impact of surgical treatment on health-related quality of life of breast cancer patients has become increasingly relevant, particularly for reconstructive procedures. The BREAST-Q consists of a broadly used patient-reported outcome measure to assess the impact of breast surgery on the health-related quality of life of these patients. The aim of this study was to translate and linguistically validate the BREAST-Q reconstructive module to European Portuguese.

Material and Methods: The translation and linguistic validation process was based on the International Society for Pharmacoeconomics and Outcomes Research guidelines and started after obtaining permission from the original authors (developers). It involved two direct English to European Portuguese translations and a back translation, maintaining conceptual and cultural equivalence, an expert panel discussion, cognitive interviews with five patients and a final consensus.

Results: The forward translations led to the revision of three conceptually distinct items. The backward translation resulted in predominantly wording discrepancies and the three conceptual disparities noted in the back translation were revised on a consensual version. All material was openly discussed with the original authors and in an expert panel meeting. One item was changed after the cognitive interviews. The final consensual version was obtained.

Conclusion: This stepwise approach allowed to linguistically validate the BREAST-Q reconstructive module to European Portuguese so that it can be used in the Portuguese population. Additionally, the applied methodology may serve to support and guide other instruments for linguistic validation.

Keywords: Breast Neoplasms; Mammaplasty; Patient Reported Outcome Measures; Surveys and Questionnaires; Translations

RESUMO

Introdução: A avaliação do impacto do tratamento cirúrgico na qualidade de vida relacionada com a saúde de doentes com cancro da mama é cada vez mais relevante, particularmente para procedimentos reconstrutivos. O questionário BREAST-Q é um instrumento de avaliação de resultados reportados pelos doentes amplamente utilizado para avaliar o impacto da cirurgia mamária na qualidade de vida relacionada com a saúde. O objetivo deste estudo foi a tradução e validação linguística do módulo reconstrutivo do questionário BREAST-Q para o Português Europeu.

Material e Métodos: O processo de tradução e validação linguística foi baseado nas normas da International Society for Pharmacoeconomics and Outcomes Research. Iniciou-se pela obtenção da autorização dos autores para realizar a tradução. Foram feitas duas traduções diretas independentes de inglês para português europeu e uma tradução reversa, mantendo a equivalência conceptual e cultural, discussão por um painel de especialistas, entrevistas cognitivas a cinco doentes e um consenso final.

Resultados: As traduções diretas levaram à revisão de três itens nos quais foram encontradas diferenças conceptuais. A tradução reversa resultou em diferenças predominantemente literárias. Apenas um item foi alterado após as entrevistas cognitivas. Todo o material registado durante o processo de tradução foi discutido abertamente com os autores originais e com o painel de especialistas, culminando numa versão final consensual.

Conclusão: Esta abordagem estruturada permitiu validar linguisticamente o módulo reconstrutivo do BREAST-Q para português europeu, permitindo a sua utilização na população portuguesa. Adicionalmente, a metodologia aplicada poderá servir de suporte e guia para outras validações linguísticas.

Palavras-chave: Inquéritos e Questionários; Mamoplastia; Medidas de Resultados Relatados pelo Doente; Neoplasias da Mama; Traduções

INTRODUCTION

Breast cancer is the most common cancer among women worldwide, apart from non-melanoma skin cancer, and the same is observed for Portuguese women. It is estimated to have accounted for 27.1% of all new cancer cases and 15.4% of all cancer deaths in 2018, corresponding to the second leading cause of cancer-related death in Portugal.[1-3] Additional reports have demonstrated an increase in breast cancer incidence and a decline in its mortality rate over the last few decades in Portugal.[4-6]

The continuous advances in breast cancer early diagnosis and treatment options may have significantly contributed to the increase in the number of cancer survivors.[7] Recent developments in breast surgical oncology, including oncoplastic and reconstructive techniques, have allowed for wider surgical modalities, with both enhanced aesthetic and safer oncological results. This change is reflected in an increasing number of surgical interventions which has a significant socio-economic impact.[8,9]

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Therefore, it is essential nowadays to consider and understand the impact of breast cancer treatment on the health-related quality of life (HRQOL) of these patients. Evaluating the long-term HRQOL outcomes of breast cancer treatment has become an important part of its management.[10,11] Several patient-reported outcome (PRO) measures have been developed and used for this purpose. Their aim is to include and ascertain the patient perceptions and satisfaction levels over the effects of certain treatments on their HRQOL.[12]

The BREAST-Q consists of a widely used validated breast surgery-specific PRO measure designed to assess breast surgery impact on HRQOL and patient satisfaction. Developed by Pusic *et al* in accordance with the international guidelines on PRO measures, it can be used to evaluate, support and compare quality metrics and surgical practices in oncologic breast and plastic surgery.[13,14] This questionnaire consists of three general modules namely "augmentation", "reduction/mastopexy" and "breast cancer". The "breast cancer" module includes four specific modules which are "mastectomy", "breast conserving therapy", "reconstruction" and "arm lymphedema". The BREAST-Q reconstructive module is subcategorized in two overarching domains of HRQOL and patient satisfaction, each with specific subthemes evaluated, either in the pre- or post-operative context (Fig. 1).

Even though the BREAST-Q has already been translated and validated by Sbalchiero *et al*[15] for Brazilian Portuguese (BR), meaningful linguistic and cultural divergences are potentially present, limiting its application in the Portuguese population. Therefore, there was a lack of an official translation and validation of BREAST-Q to European Portuguese (PT).

This study's purpose was to translate and validate the BREAST-Q reconstructive module to European Portuguese (PT). We additionally intended that this linguistic validation process could serve as an example and supportive module for the translation of other questionnaires.

MATERIAL AND METHODS

This study was approved by the Ethics Committee of Coimbra University Hospital Centre. All patients gave written informed consent.

Patient anonymity was maintained throughout all stages of validation process.

First, we contacted the QPortfolio team,[16] which incorporates BREAST-Q developers (Dr. Andrea Pusic, Dr. Anne Klassen and Dr. Stefan Cano) and obtained access to the questionnaire and permission for translation and validation to European Portuguese (PT). This process followed the recommended steps proposed by the developers QPortfolio team, primarily based on the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) steps for linguistic validation and cultural adaption of PRO instruments (Table 1).[17,18] We decided not to proceed with the adaptation from the Brazilian Portuguese (BR) version, considering the potential linguistic and cultural divergencies, which could have biased the process.[18] Instead, we opted for a direct and independent translation from the original English version to European Portuguese (PT).

The overall process of this questionnaire validation for European Portuguese consisted of six main steps (Fig. 2). All the procedures and changes made were documented in a supportive file. The steps are summarized as the following:
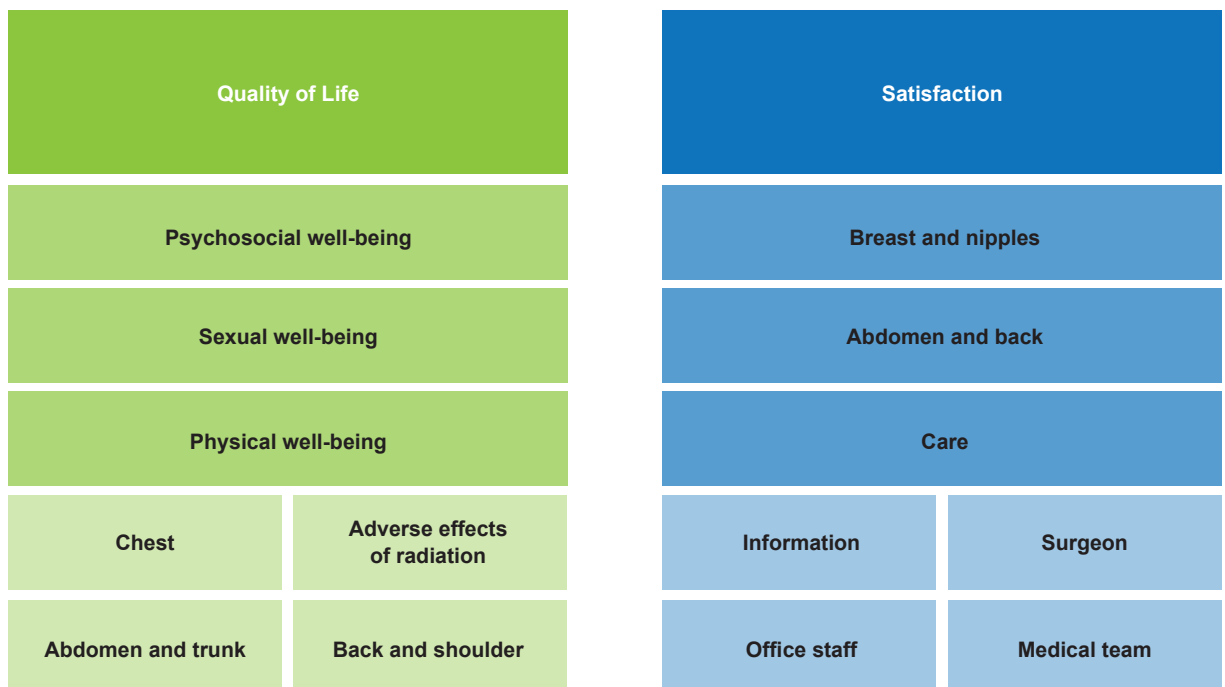

Figure 1 – Breast Q reconstruction module conceptual framework and respective domains

Table 1 – Adopted steps and comparison with ISPOR guidelines

ISPOR guidelines	Adopted steps
Preparation: the project manager/client/researcher contacts the developer, obtains permission for translation, develops concepts explanations and recruits key persons.	**1. Preparation**: authors obtained access to the instrument and granted permission for the translation and linguistic validation. A plan for the process was designed. The involved team, including the translators, was recruited.
Forward translation: at least two forward translators native in the target language carry out independent forward translations. Instrument concepts explanation should be provided to the key in-country persons and forward translators.	**2. Forward translation**: two forward translations were made independently by a translator and an experienced clinician, both Portuguese native and English fluent. A conceptual and cultural translation was requested, instead of a pure literal translation. Items difficult to translate were listed.
Reconciliation: forward translations reconciliation into a single forward translation.	Discussion and consensus between the two translators led to the consolidated version 1 (Portuguese).
Back translation: at least one backward translation of the reconciled translation into the source language.	**3. Backward translation**: an English native speaker and fluent in Portuguese translator, who had not a previous knowledge of the questionnaire, developed a backward translation. A conceptual and cultural translation was requested instead of a pure literal translation. Version 2 (English) was created.
Back translation review: back translations review against the source language version.	**4. Expert panel discussion**: all material developed on the previous steps was evaluated by the developers. The backward translation (version 2) was compared with the original English version. Vocabulary differences and discrepancies were addressed and prompted to be detailly discussed in an expert panel meeting.
Harmonization: all new translations are compared with each other and the source language version.	Four plastic surgeons and two translators composed the expert panel. All were English and Portuguese fluent. Every material produced, including the developers' addressed differences, were openly discussed and reviewed. Harmonization and consensus led to version 3.
Cognitive debriefing: harmonized translation version cognitive debriefing, usually with five to eight patients drawn from the target population.	**5. Cognitive interviews**: questionnaire version 3 was applied in five patients. The cognitive debriefing consisted of comprehensive reading and interpretation. The questions, items, or words in which there was any interpretation difficulties and any suggestions proposed by the patients were registered.
Review of cognitive debriefing results and finalization: debriefing process results are reviewed, and the translation finalized.	The results and mentioned aspects were contemplated and discussed, obtaining a consensual version 4.
Proofreading: the finalized translation is proofread.	**6. Final consensus**: proofreading was performed by two independent clinicians resulting in the final version (version 5).
Final report: report on the development of the translation is written.	A document was used to register all procedures and changes during the process.

ISPOR: International Society for Pharmacoeconomics and Outcomes Research[17,18]

Preparation

Consisted of granting access to the questionnaire BREAST-Q reconstructive module and permission for European Portuguese (PT) translation and linguistic validation. We also retrieved specific instructions and organized a plan for the process. A panel of experts composed of two plastic surgeons, a coordinator and three translators was recruited.

Forward translation

Two forward translations from the original English to European Portuguese (PT) were made independently by a professional translator and an experienced clinician from our department, both Portuguese native speakers and English fluent speakers. A rather more conceptually and culturally equivalent than pure literal translation was emphasized. Items difficult to translate were listed. The consolidated questionnaire version 1 (Portuguese) was developed after discussion between these two translators and establish-

ment of a consensus.

Backward translation

An English native speaker and Portuguese fluent professional translator produced a backward translation of version 1. Again, a conceptual and cultural rather than literal translation was emphasized. This translator did not have previous knowledge or access to the original questionnaire. Version 2 (English) was created.

Expert panel discussion

All material developed during the previous steps, including the translations, version 1 and 2, was evaluated by the developers. The backward translation was compared with the original English version. Discrepancies were addressed by the developer team. An expert panel meeting composed by two plastic surgeons, a coordinator and three translators openly discussed and reviewed every material produced,

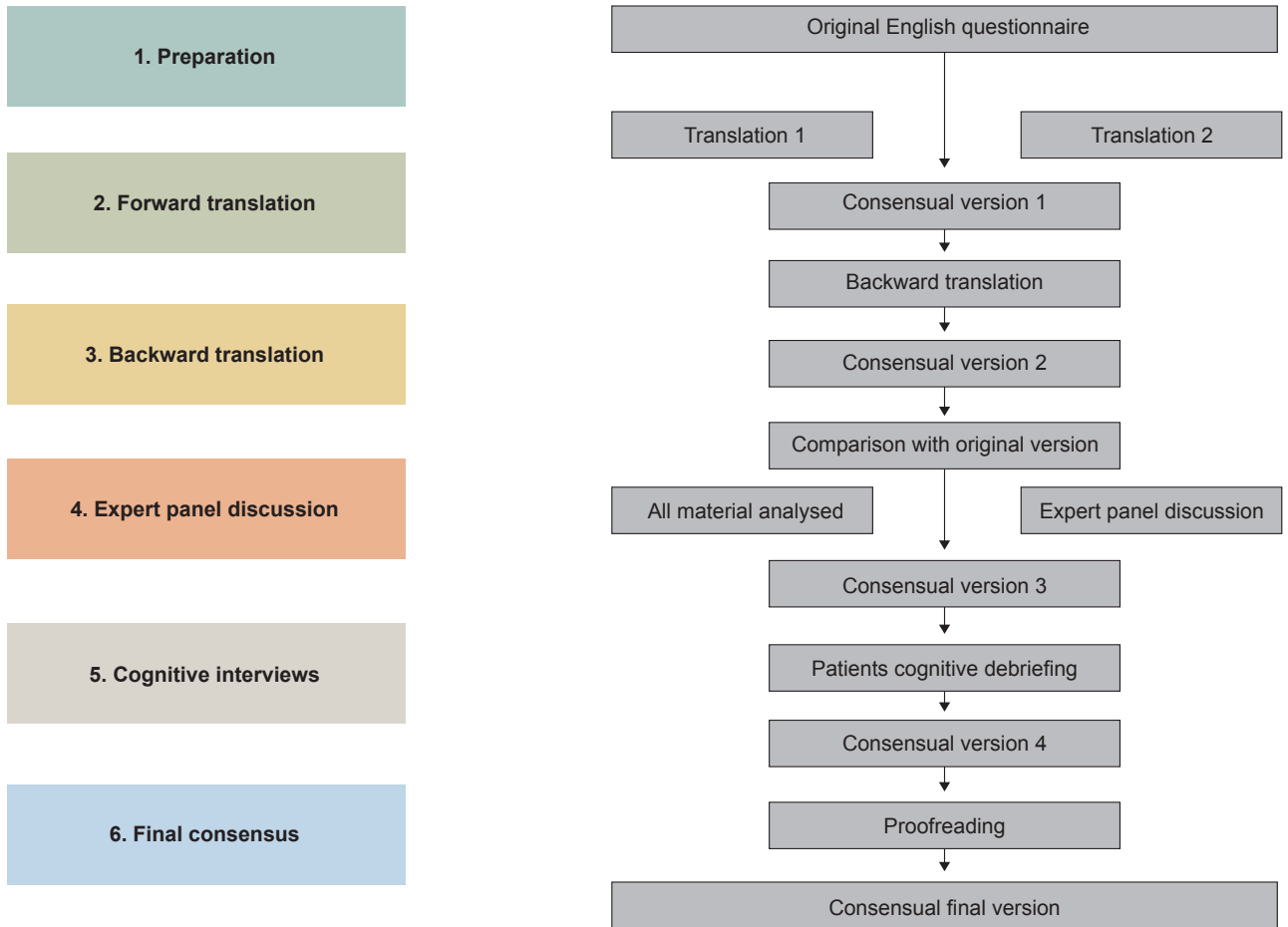|	
1. Preparation	Original English questionnaire

Figure 2 – Stages of the translation and linguistic validation process

including any disagreements between the developers. The harmonization and consensus led to version 3 (Portuguese).

Cognitive interviews

Five female patients were included in different stages of treatment and reconstructive modalities. Version 3 was applied to these patients by means of a cognitive interview. It consisted of questionnaire comprehensive reading and interpretation. The questions, items, or words in which there were any comprehension difficulties were discussed and all suggestions proposed by the patients were registered. The mentioned aspects were incorporated in version 4.

Final consensus

Proofreading was performed by two independent clinicians resulting in the final version of the questionnaire (version 5).

RESULTS

The differences observed between the two independent forward translations were predominantly literal rather than conceptual discrepancies. For instance, in the item "How your back looks?", the word "looks" was translated to "appearance" and "aspect". Apart from their literal difference, these three words are conceptually equal.

We also observed a conceptual divergence with the forward translation of three items. In the item "How comfortably do your bras fit?", the expression "how comfortably" was translated to "how comfortably" and "the manner how", however they are not conceptually equal. In the item "Tightness in your breast area?", the word "tightness" was translated to "constriction" and "tension". In "Throbbing feeling in your breast area?", "throbbing feeling" was translated to "throbbing cut sensation" and "pulsation". These items were discussed and reviewed in order to resemble the original questionnaire as much as possible in a consolidated version.

Similarly, as expected, the backward translation resulted in predominantly wording discrepancies when compared with the original English version. "Nagging feeling in your breast area?" back translated to "Discomfort in your breasts?" and "Aching feeling in your breast area?" back translated to "With the sensation of your breast being sore?" serve as examples.

Forward and backward translated versions were evaluated and discussed with the developers. Three conceptual disparities were noted between the back translation and the original English version. All material, translations and the conflicting items were addressed openly, discussed, and reviewed at the expert panel meeting. A consensual translated version for the cognitive interviews was produced.

For example, the item "Made time for your concerns?" was back translated into "Did he/she listen to your concerns?". Since "made time" and "listen" are not conceptually equal, the item was revised and retranslated. Similarly, the item "Were knowledgeable?" was back translated to "Did they have good technical knowledge in their area?". However, the word "technical" was not part of the original item. The item "Were friendly and kind?" was back translated to "Were they friendly and sensitive?". Even tough "kind" and "sensitive" are not conceptually equal, the forwardly translated Portuguese word 'gentis' can be translated to both mentioned English words. For that reason, the item was not changed.

Version 3 of the questionnaire was applied to five selected patients in the form of cognitive interviews by thorough reading and interpretation. These patients had a history of breast cancer and underwent breast reconstructive surgery after mastectomy (Table 2). In the item "The amount of rippling (wrinkling) of your implant(s) that you can see?", one patient only knew the meaning of rippling (wrinkling) because her surgeon had previously informed and explained to her. She suggested adding "skin irregularities". However, since "skin irregularities" is a more conceptually generic term and not exactly equal to "rippling" and "wrinkling", the item was not changed. Two patients had additional difficulties in the item "Abdominal bulging?". Both suggested adding the word "bloating", but the questionnaire already included the item "Abdominal bloating?". We believed that "protuberance" would be more appropriately in line with the meaning of "bulging". Thus, the item was changed to "Abdominal bulging (protuberance)?". Only one item was changed leading to the consensual version 4.

Final questionnaire proofreading allowed to address two misprints/misspelled words, culminating in the final version 5. All conceptual difficulties and changes made throughout the process are contemplated in Appendix 1 (Appendix 1: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/17427/Appendix_01.pdf).

Once the six procedural steps were completed, the final version was approved by the QPortfolio team and the copyright owners, and a validated Portuguese (PT) version of the BREAST-Q reconstructive module was obtained and available for application.

DISCUSSION

Breast cancer has an undeniable impact on the psychological and quality of life domains of patients, mainly due to the meaning that the female breast has in terms of female self-identity, body image and confidence.[10,11] Additionally, treatment most often comprises a surgical breast procedure that could include breast conserving therapy, mastectomy, either alone or with reconstruction (immediate or delayed; autologous or alloplastic), frequently combined with chemotherapy and/or radiotherapy. The diversified breast reconstructive modalities are more available and are now a common practice for these patients.[8,9] For this reason, considering the increasing number of breast cancer patients and breast surgery developments, there has been a growing interest in understanding the long-term HRQOL outcomes of breast surgical treatment, particularly for reconstructive procedures.[9,12,13]

The PRO measures provide a more comprehensive insight of patient perception of the disease and treatment impact on their HRQOL, in a more objective and standardized manner.[12] The resulting information not only allows the evaluation, monitoring and a better understanding of the outcomes, but can also help patients on their surgical treatment shared decision-making process and contribute to the improvement of the quality of the healthcare provided.[12,14]

Some tools such as the Short Form 36 (SF 36) health survey questionnaire[19] are generic and do not consider important and specific outcomes related to breast cancer and surgery. Other more specific PRO measures for breast cancer have been developed and used in clinical practice and research studies (including randomized controlled trials).[12] The European Organization for Research and Treatment of Cancer (EORTC) specific evaluation modules for breast cancer (QLQ-BR23 and -BR45) and its reconstruction (QLQ-BRECON23),[19-21] Body Image after Breast Cancer Questionnaire (BIBCQ),[22] Michigan Breast Reconstruction Outcomes Study (MBROS)[23] and Functional Assessment of Cancer Therapy-Breast (FACT-B)[24] are examples of breast cancer PRO measures.

BREAST-Q consists of a widely and increasingly used validated PRO measure in clinical practice and in research studies related with breast surgery. This useful tool has been providing relevant information on breast surgery PROs with enhanced potential to support an evidence-based approach to help the patient and surgeon on surgical decision making and optimize the standards of care provided.[12,14,25] The Breast Reconstruction Module represents the most used module in the literature, which may involve comparison between implant-based and autologous reconstruction procedures or the use of fat grafting after reconstruction, among

Table 2 – Patient characteristics

Patient	Age	Gender	Diagnosis	Condition-specific treatment
1	35	Female	Breast cancer	Delayed unilateral breast reconstruction with autologous reconstruction.
2	52	Female	Breast cancer	Immediate unilateral breast reconstruction with alloplastic reconstruction.
3	57	Female	Breast cancer	Delayed unilateral breast reconstruction with autologous reconstruction.
4	45	Female	Breast cancer	Immediate bilateral breast reconstruction with alloplastic reconstruction.
5	62	Female	Breast cancer	Delayed unilateral breast reconstruction with autologous reconstruction.

others.[14,25-28]

Various guidelines have been proposed for translation, linguistic validation or cross-cultural adaptation of questionnaires and PRO measures. However, their methods tend to have some differences particularly on their focus, such as the translation technique, focus group or concepts. For instance, some studies consider the back translation as not mandatory, while others emphasize its important role in the assessment of translation quality by comparing the original version with the back-translated version. Considering the lack of empirical evidence in favor of one specific method, a gold standard has not yet been defined. Regardless of the guideline adopted, the linguistic validation is a delicate process and should always be methodologically rigorous.[29-31] Expert committees and cognitive interviews appear similarly to play a substantial role on the equivalence with the original version.[30-32] Adopting a validated standardized guideline that seems contextually appropriate to achieve equivalence and ensuring a rigorous multistep procedure are essential for an efficient linguistic validation.[30-33] This process was based on the widely used ISPOR steps for linguistic validation and cultural adaption of PRO instruments, as proposed by the developer team.[17,18]

As expected, the forward translations were prone to having literal rather than conceptual wording differences, just like the backward translation when compared with the original version. Expert panel discussion led to a harmonized version to be applied on at least five patients, according to the ISPOR guidelines.[17,18] Our patient group consisted of a not-fully but still adequately representative range of the questionnaire's target patients. The stepwise approach and centralized revisions were key elements throughout the process. In fact, discrepancies were identified and addressed, changes documented and a final consensual translated version equivalent to the original version was attained.

Study limitations include the absence of psychometric property analysis and its validation, including acceptability, test-retest reliability, internal consistency, and construct validity. Moreover, the other BREAST-Q modules lacked translation and validation to European Portuguese.

CONCLUSION

The present study reports the linguistic validation of the BREAST-Q specific reconstructive module to European Portuguese so that it can be used in breast cancer patients undergoing reconstructive surgery. This tool could therefore be used to evaluate, support, and improve the healthcare-related quality and evidence-guided breast surgical practices on the Portuguese population. The methodology adopted in our study could additionally be used to support and guide the translation and linguistic validation processes of other PRO measures, which would enable international benchmarking.

AUTHORS CONTRIBUTION

RM, GT: Data acquisition. Design and conception of the work; draft of the paper.

SP, CD: Critical review of the manuscript.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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