ORIGINAL ARTICLE

Translation and cultural adaptation of the Breast Cancer Treatment Outcome Scale (BCTOS) into Brazilian Portuguese

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SUMMARY

BACKGROUND: *Breast conservative treatment (BCT) is safe when it is performed in association with radiotherapy. The number of referral for BCT has increased, and it has become an important treatment modality. Patients who undergo BCT present some characteristics that are associated with better quality of life compared with patients who undergo mastectomy without reconstruction. Instruments that measure the quality of life specifically used in cases of BCT are limited. One of these instruments is the* Breast Cancer Treatment Outcome Scale *(BCTOS), which has not yet been translated into Brazilian Portuguese. It contains 22 questions and four domains (functional, aesthetic, breast sensitivity and oedema).*

METHODS: *We performed the translation and cultural adaptation process using Beaton's and EORTC translations process. In summary, the translation process is based on Portuguese translation, translation summary, reverse translation into English, expert committee, pre-test (10 patients), questionnaire review and test of the final version (6 patients).*

RESULTS: *All 16 patients were submitted to quadrantectomy and mammary radiotherapy. Lymphedema was present in 4, altered strength in 5, and altered shoulder mobility in 6 patients. Considering the questionnaire, the reconciled version determined change in 2 items. Pre-test evaluation showed difficulties in 3 patients, but the questionnaire did not change. Test evaluation showed no problems.*

CONCLUSION: *The translation of BCTOS into Portuguese will help us to evaluate the quality of life in BCT patients evaluating treatment-related sequelae and may be useful for oncoplastic surgery evaluation.*

KEYWORDS: *Breast neoplasms. Quality of life. Surveys and questionnaires. Mastectomy, segmental. Conservative treatment.*

INTRODUCTION

For over 20 years, studies that have focused on the breast treatment conservative have shown that the procedures are safe as long as they are associated with radiotherapy[1,2]. The initial indications of BCT were for tumours under 3 cm, but over the years, the allowable tumour size has increased. Currently, the concept of the breast/tumour ratio is accepted, which allows the resection of larger tumours as long as the associated margins are tumour-free. Despite a higher rate of local recurrence in this group of patients, such numbers were found to be acceptable[3]. Radiotherapy is systematically used in BCT since it reduces the risk of local recurrence[2]. We have recently witnessed the development of oncoplastic surgery, but this term has since become very broad. Oncoplastic surgery is also as-

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sociated with multiple techniques and is used both for BCT and for mastectomies with skin preservation or late reconstruction.

Early diagnosis and multiple therapeutic modalities have increased the number of patients who are submitted to conservative treatment and the survival rate of patients with breast cancer[3]. Recently, the quality of life of these patients has been questioned, and multiple quality of life questionnaires have been created[4,5]. Thus, general cancer questionnaires (EORTC QLQ C30; FACT-G) were initially created, followed by general questionnaires for breast cancer (EORTC BR23, FACT-B), with specific questionnaires associated with breast reconstruction (MBROS, BREAST -Q)[6]. Patients who undergo conservative treatment generally present higher scores in the domains related to breast satisfaction and sexual well-being compared with patients who undergo mastectomy[7]. Therefore, when patients who exclusively undergo BCT are required to be evaluated, we now have the BCTOS (*Breast Cancer Treatment Outcome Scale*[8]). The BREAST-Q questionnaire was initially developed for breast reconstruction. To evaluate conservative treatment there was a module related to mastopexy[6,9], and more recently (2016), a module related to BCT was added[10], but it has not been translated into Portuguese. No particular questionnaire is specifically used in oncoplastic surgery. We began to question the cosmetic results of BCT and its association with oncoplasty and quality of life due to the limited studies in this subject area[11] and due to the lack of a specific instrument that can be used in Brazilian Portuguese.

Created in 2001, the BCTOS is based on a review of the literature and expert opinion and is an unconventional instrument that is used in the evaluation of quality of life in patients who undergo BCT[6,8]. Many questionnaires have already been translated and validated into Brazilian Portuguese[9,12,13]; however, the BCTOS questionnaire is an instrument that has not been translated and adapted to this language.

TABLE 1. PATIENTS' CHARACTERISTICS

Variable	Category	Version 5 (n = 10)	Version 6 (n = 6)	Total
Patient's characteristics				
Age	Average (SD)	57.9 ± 9.5	59.9 ± 10.6	58.6 ± 9.6
Follow up time	Average (SD)	42.2 ± 36.7	44.9 ± 43.0	43.2 ± 35.5
Side	Right	7	2	9 (56.2%)
	Left	3	4	7 (43.8%)
Education	Absent/primary	10	4	14 (87.6%)
	High School/Higher Education	0	2	2 (12.4%)
Treatment performed				
Oncoplastic surgery	Absent	8	4	12 (75.0%)
	Present	2	2	4 (25.0%)
Axillary surgery	Lymphadenectomy	4	3	7 (43.8%)
	Sentinel lymph node	6	3	9 (56.2%)
Breast RXT	Present	10	6	16 (100%)
Fossa RXT	Absent	6	4	10 (62.5%)
	Present	4	2	6 (37.5%)
Patients' Sequelae				
Lymphedema	Absent	9	3	12 (75.0%)
	Present	1	3	4 (25.0%)
Change in Shoulder Mobility	Absent	7	3	10 (62.5%)
	Present	3	3	6 (37.5%)
Change in Hand Strength	Absent	8	3	11 (68.8%)
	Present	2	3	5 (31.2%)

SD = standard deviation; RXT = radiotherapy

MATERIALS AND METHODS

This study was methodological in nature and was initially part (translation and cultural adaptation) of a larger psychometric validation study. This research was approved by the Research Ethics Committee of the Cancer Hospital of Barretos under number 782/2014 and was conducted using patients who underwent BCT. As inclusion criteria, we selected female patients with ECOG (Eastern Cooperative Oncology Group) scores of 0 and 1 who had unilateral breast cancer and who underwent surgical treatment of breast and axilla. Radiotherapy treatment was performed for more than 12 months prior to study inclusion. All patients underwent treatment exclusively in this hospital and had the mental capacity to answer the questionnaire. The patients' characteristics are reported in Table 1.

Patients were evaluated on lymphedema, hand muscle strength and shoulder range of motion (Table 1; Figure 1). The range of motion was evaluated statically through photogrammetry with Image J® software. To measure the shoulders motion range, participants were positioned in front of Sanny Posture grids for postural evaluation, in the orthostatic position, 3 meters away from the camera used to capture the images. The camera was a SONY, model DSC-H300 and resolution of 20.1 mega pixels, fixed to a tripod level[14]. Patients were positioned, and after postural compensations, patients have done the maximum movement of flexion, abduction and extension. They were photographed bilaterally to evaluate both treated and untreated sides. Minimum change values of 10º observed were considered as sequela. The evaluation of hand muscle strength was performed with hand hydraulic dynamometer model Saehan SH5001. To perform the test, patients remained seated with their spine erect, maintaining the angle of knee flexion at 90°, shoulder positioned at adduction and neutral rotation, elbow flexed at 90°, forearm at half pronation and neutral grip, up to 30 degrees of extension, following the guidelines of the American Society of Hand Therapists[15]. Three measurements were performed, maintaining the palmar hold for 5 seconds, 60 seconds between each measurement, alternately in each hand. Patients did the palmar grip contraction using a verbal command, which was issued to indicate the beginning and end of contractions and to encourage the contraction as strong as possible[16]. The greatest measure (Kgf) of the three measurements of each member was noted[17]. It was considered a change in force a minimum difference of 12% between the affected side and the unaffected side[18]. For evaluation of lymphedema, volumetry of the upper limbs was performed through the displace-

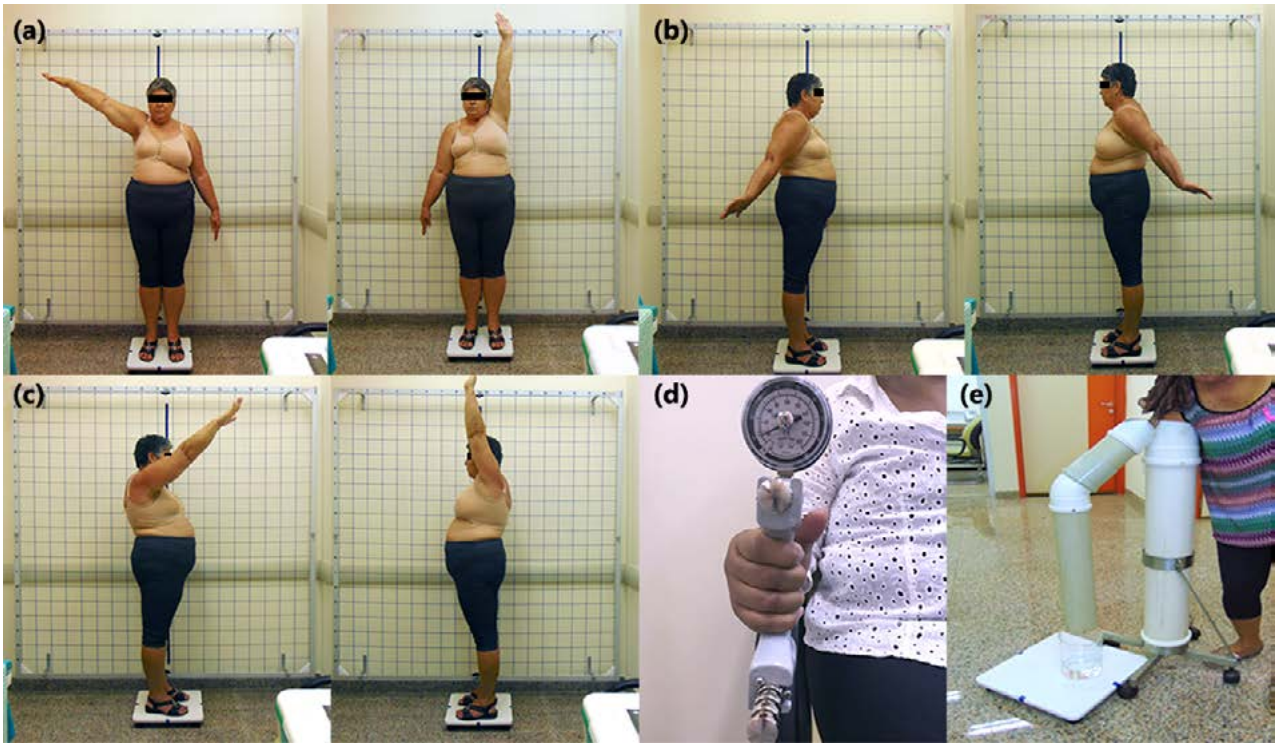

FIGURE 1. Patient's sequelae evaluation. (a) Abduction; (b) extension; (c) flexion; (d) strength of hand; (e) volumetric evaluation

ment of water proposed by Lette[19]. Before performing the volumetry, patients were marked every 5 cm from the cubital fossa on both arms to ensure that both limbs were submerged on the same level. Patients were instructed to position themselves next to the equipment and place the arm at low speed until the highest possible marking and the same procedure is performed on the other limb. The water displacement in each arm was recorded by a Becker vessel in millimetres. It was diagnosed when the difference in volume of the affected arm to the contralateral arm was higher than or equal to 200 milliliters[20].

Author (Annette L. Stanton) provided the BCTOS quality of life instrument used in this study to the research group, whose aim was to translate the instrument into the Portuguese for use in Brazil. The questionnaire consists of 22 questions and uses a 4-point Likert scale, which seeks to compare the outcome of cancer treatment in treated breast versus untreated breast. According to this scale, "1" indicates no difference, while "4" indicates a large difference between treated and untreated breast. Subsequently, calculations are performed for four domains (functional, aesthetic, specific breast pain and oedema), and the final score is the mean of all values.

For translation of the BCTOS, the methodology of translation and cultural adaptation proposed by Beaton et al.[21], which is divided into 5 phases, was used and is summarized in Figure 2. The process follows the steps described below:

- Phase 1: Translation from English into Brazilian Portuguese by two bilingual (Portuguese-English) Brazilian translators with fluency in English. The first translator is an English teacher [version 1 (v1)], while the second translator is a physician with international experience (v2);
- Phase 2: Summary of the translation by a committee of experts represented by the primary researchers (RACV, CEP): v12.
- Phase 3: Reverse translation from Portuguese into English, as performed independently by two Brazilian services for scientific translation (Editage and Scientific), with versions: v3 and v4; and

- Summary of the English version: v34.

- Phase 4: The Expert Committee (RACV, CEP) sought to compare the initial English language version with the final version, and sought to make adjustments in the Portuguese language version, which resulted in an intermediate version (v5). The researchers then independently evaluated the semantic/idiomatic, conceptual and cultural equivalences using a standardized form and an equivalence scale based on

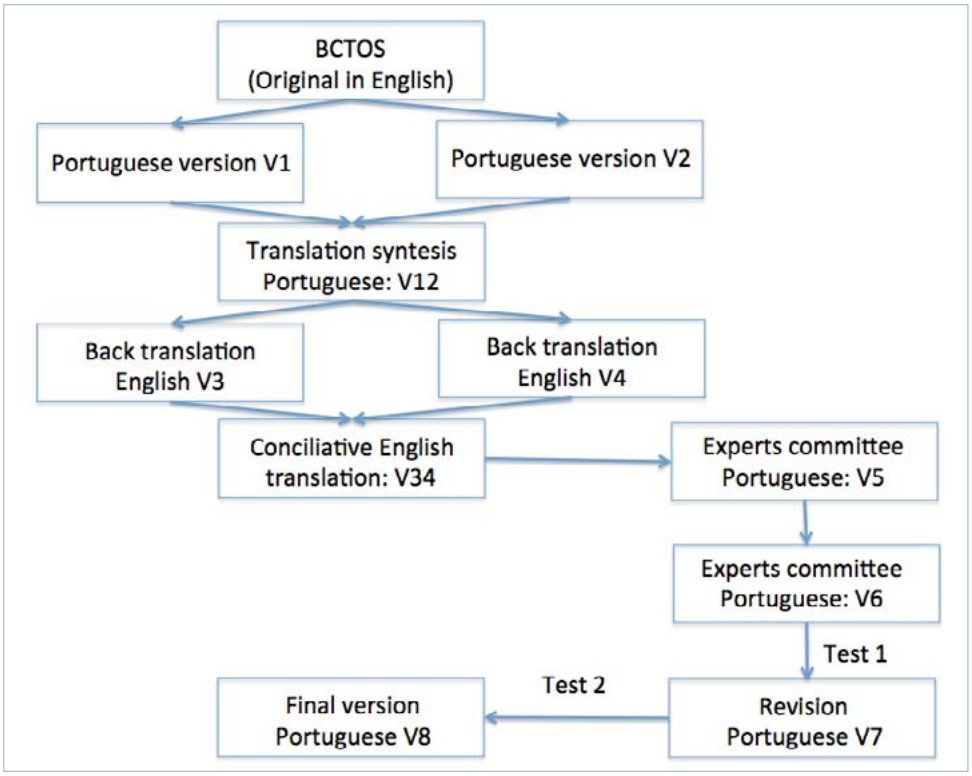

FIGURE 2. Translation process of the quality of life questionnaire according to Beaton *et al*[21].

non-equivalence (-1), impossible to evaluate (0) and equivalence (+1), by which the version was scored and suggestions were made. The intermediate version was revised, and the initial Brazilian Portuguese language version (v6) was obtained.

- Phase 5: The pre-test consisted of application of the questionnaire to 10 patients and aimed at evaluating the patients' understanding of the questionnaire using an independent evaluator (MESS), who was previously trained in the application of quality of life questionnaires. The patient's understanding, possible change suggestions and presence of an item that caused embarrassment were investigated. The interviewer evaluated understanding according to a scale, namely: I. Confused; I.II doubt; I.III. difficulty, I.IV other; II. Embarrassed; III. Need to correct or change; and IV. No understanding.

- The committee of experts reviewed the questionnaire, evaluated doubts and suggested terms to be adjusted. This resulted in version 7, which was applied by the same evaluator (MESS) to 6 patients.

- The version was revised, and the need for terms modification was evaluated, which resulted in the final version of the questionnaire (v8).

RESULTS

In the reconciled version (v5), non-equivalence was observed in relation to items 2, 10 and 13, and changes were made in items 10 and 13; this resulted in version 6, which was initially applied to 10 patients.

Table 1 presents the characteristics of the groups in the pre-test (v6) and test (v7). All patients underwent quadrantectomy and mammary radiotherapy. The average age was 58.6 years (ranging from 44.0 to 79.4 years old), and up to 87.6% of patients did not complete elementary school. In all, 56.2% of the tumours were on the right side, and fossa radiotherapy was performed in 37.5% of the patients. With respect to sequelae, 25.0% (n = 4) presented lymphedema, 37.5% (n = 6) presented with altered shoulder mobility, and 31.3% (n = 5) presented with altered strength.

In version v6 applied to the first 10 patients, difficulties were observed in 3 patients, where each patient indicated 1 or 2 nonconformities, with questioning of score (difficulty to understand the term "moderado") in item 19 (difficulty in understanding the term "rigidez"; the term "braço endurecido" was suggested), item 21 (difficulty in understanding the term "sensibilidade da mama"; the term "mama sensível" was suggested) and item 22 (difficulty in understanding the term "ajuste"). Despite the considerations indicated by the patients, this questionnaire was not altered (v7) and was once again applied to 6 patients, where no questioning was observed; this was considered the final version (v8), but versions v6, v7 and v8 remained similar. Tables 2 and 3 show the original version and the final version in Brazilian Portuguese.

DISCUSSION

The BCTOS was first published in 2001[8] and aimed at evaluating the quality of life after BCT and radiotherapy based on aesthetic measurements (breast shape) and functional status (pain and mo-

TABLE 2. TEXT FROM THE ORIGINAL ENGLISH VERSION AND FINAL PORTUGUESE (BRAZIL) VERSION.

Original/ English	Portuguese Translation
We are interested in your evaluation of your physical appearance and functioning since your breast surgery. Please rate the following items on this four-point scale, according to your evaluation at this point in time. (Note: If you have had bilateral surgery, complete the items with regard to the difference between the right and left side.)	Estamos interessados na sua avaliação em relação à aparência e funcionamento de seu corpo, desde a sua cirurgia da mama. Por favor, avalie os itens abaixo e, entre as quatro opções de resposta, escolha uma delas. Considere, para responder, como você está neste momento. (Nota: Se você operou as duas mamas, escolha a resposta considerando a diferença entre o lado direito e o lado esquerdo).
1 = no difference between treated and untreated breast and area	1 = nenhuma = nenhuma diferença entre a mama (ou a área da mama) tratada e a mama não tratada
2 = slight difference between treated and untreated breast and area	2 = leve = leve diferença entre a mama (ou a área da mama) tratada e a mama não tratada
3 = moderate difference between treated and untreated breast and area	3 = moderada = moderada diferença entre a mama (ou a área da mama) tratada e a mama não tratada
4 = large difference between treated and untreated breast and area	4 = grande = grande diferença entre a mama (ou a área da mama) tratada e a mama não tratada

bility) after treatment. Initially, the questionnaire was associated with three domains (cosmetic, functional and breast pain)[8]. The methodology used for its creation was the literature review, expert opinion, and development of conceptual model, which differs from the current model, where the patient interview was associated with the generation of the items[6]. This questionnaire was initially presented to 301 patients in the form of personal or telephone interview, with a participation rate of 66%; in total, 185 patients were eligible for the study[8]. The primary questionnaire was applied to individuals with a high level of education (average of 14.4 years, standard deviation 2.75 years), which is contrary to our study, where due to the characteristics of the service, women with a low level of education represented the majority of patients. Despite the apparent disadvantage of population with a low level of education, questionnaires that are validated in this type of population have a higher reproducibility rate for the entire population. Little difference was observed in age (58.6 x 61.6 years of age), but a significant difference was observed in relation to time after treatment (43.0 x 73.6 months).

Based on the population in the original article, 54 patients underwent lymphedema evaluation (> 2 cm difference) and clinical examination of the breast; oedema was observed in 18%, and 30% of reasonable and negative aesthetic outcomes, respectively. The aesthetic evaluation was based on the sum of the differences in size, symmetry, fibrosis and telangiectasia. Convergent validity showed objective and subjective associations with cosmesis and functional status as well as patients with lymphedema. In our population, 25% (n = 4) presented with lymphedema, and 37.5% (n = 6) presented with altered shoulder mobility, which were sequelae included in the questionnaire.

In the initial version, questions about "arm swelling" and "breast swelling" were not maintained in later versions since these questions had a low impact factor in the composition of the domains. Due to their clinical importance in relation to oedema, two items were added: "arm heaviness" and "fit of shirt sleeve"; the oedema domain was then included in further studies[22,23].

The 22-item version was translated into German and published in 2010, but the oedema domain was not evaluated. In addition to the BCTOS, the QLQ BR23 questionnaire was prospectively applied in the immediate postoperative period. A comparison was

TABLE 3. QUESTIONS FROM THE ORIGINAL ENGLISH VERSION AND FINAL PORTUGUESE (BRAZIL) VERSION.

Question	Original/ English	Portuguese Translation
1	Breast size	Tamanho da mama
2	Breast texture (hardening)	Textura da mama (endurecimento)
3	Arm heaviness	Peso do braço
4	Nipple appearance	Aparência do mamilo
5	Shoulder movement	Movimento do ombro
6	Arm movement	Movimento do braço
7	Breast pain	Dor na mama
8	Ability to lift objects	Capacidade de levantar objetos
9	Fit of shirt sleeve	Ajuste da manga da camisa
10	Breast tenderness	Mama dolorosa ao toque
11	Shoulder stiffness	Rigidez do ombro
12	Breast shape	Formato da mama
13	Breast elevation (how high the breast is)	Elevação da mama (o quão alta a mama está)
14	Scar tissue	Cicatriz
15	Shoulder pain	Dor no ombro
16	Arm pain	Dor no braço
17	Arm swelling	Inchaço do braço
18	Breast swelling	Inchaço da mama
19	Arm stiffness	Rigidez do braço
20	Fit of bra	Ajuste do sutiã
21	Breast sensitivity	Sensibilidade da mama
22	Fit of clothing	Ajuste das roupas

Functional domain: Items 5,6,8,11,15,16,19. Cosmetic domain: Items 1,2,4,12,13,14,20,22. Specific breast pain: Items 7,10,21. Oedema: Items 3,9,17,18

then made between the QLQ BR23 domains and the three BCTOS domains, and a correlation between all the scales was observed. An analysis of covariates identified that young patients exhibited a worse quality of life in all BCTOS scales[24]. In this study, a factorial analysis[24] was performed, and the same findings of the original study were observed. A later study with 138 patients evaluated the impact of quality of life on the immediate postoperative period and again one year after surgery using the same questionnaires. A similar correlation was observed between the questionnaires for the period analysed, where aesthetic and functional status were correlated with global health, and older age and poor functional status were predictors of decline in overall quality of life one year after surgery[25].

To compare the BCTOS questionnaire with objective measurements, a software for breast aesthetics evaluation was associated with the BCCT.core (breast cancer conservative treatment cosmetic results), which was used to assess 128 patients during the period prior to surgery, around the time of surgery and after a year of follow-up. It was observed that the Kappa agreement between the BCCT.core and the BCTOS was 0.34, which indicates that patients judged their aesthetic result better than the software[26].

The cross-cultural adaptation process allows the adaptation of the questionnaire to a new country and/or language, and allows the equivalence between the initial questionnaire and the version adapted to the new language. The translation should not only be linguistic, but there must also be equivalence of meaning between both questionnaires. We used the model proposed by Beaton et al.[21], with little differences in relation to the translation model used by the European Organization for Research and Treatment of Cancer (EORTC)[27], which has many of its questionnaires presented in English and several other languages. Heil et al.[24] used the model proposed by the EORTC, but in their article, the translated version in German is not presented. Access to the translated questionnaire facilitates the realization of new studies in different languages, which reflects a policy adopted by the EORTC. In this context, although BCTOS was originally written in English and translated into German, we present the Brazilian Portuguese version, which will facilitate future studies using this questionnaire.

We present the first questionnaire to be applied in Brazilian studies in patients who undergo BCT; this will serve as a foundation for studies that will evaluate the oedema domain, which was not evaluated in previous studies, the comparison with objective measures of evaluation as well as the impact of oncoplastic surgery and/or symmetrisation on the quality of life of patients who undergo BCT.

Conflict of interest: The authors declare no conflict of interest

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P.S.: This study was performed based on the author authorization. Nowaday for clinical use or to perform studies with BCTOS questionnaire, please contact Map Research Trust for the authorization.

RESUMO

INTRODUÇÃO: *O tratamento conservador da mama (TCM), desde que associado à radioterapia, é seguro. As indicações inicialmente utilizadas para o TCM se elevaram, sendo importante modalidade de tratamento. Novas modalidades, como a oncoplastia associada ao TCM, tornam-se cada vez mais presentes no cotidiano. Pacientes submetidas ao TCM apresentam alguns parâmetros associados a uma melhor qualidade de vida em relação às pacientes mastectomizadas sem reconstrução. Há limitados instrumentos de qualidade de vida a serem utilizados especificamente no TCM, sendo um deles o* ***Breast Cancer Treatment Outcome Scale*** *(BCTOS), questionário este não traduzido e adaptado para a língua portuguesa/Brasil. O BCTOS contém 22 perguntas e quatro domínios (funcional, estético, sensibilidade mamária e oedema).*

MÉTODOS: *Realizamos a tradução e adaptação cultural utilizando a metodologia proposta por Beaton e pelo EORTC. Em resumo, consiste de tradução para o português, resumo da tradução, tradução reversa para o inglês, comitê de especialistas, pré-teste (dez pacientes), revisão do questionário e teste da versão final (seis pacientes).*

RESULTADOS: *As 16 pacientes foram submetidas a quadrantectomia e radioterapia. Linfedema esteve presente em quatro, alteração da força em cinco e alteração da mobilidade em seis pacientes. Avaliando o questionário, a versão de conciliação modificou dois itens. O pré-teste mostrou dificuldades em três pacientes, mas o questionário não se alterou, fato que não se observou no teste final.*

CONCLUSÃO: *A tradução do BCTOS para o português nos ajudará a avaliar a qualidade de vida em pacientes submetidas a tratamento conservador da mama, avaliando as sequelas relacionadas ao tratamento, podendo ser útil na avaliação da cirurgia oncoplástica.*

PALAVRAS-CHAVE: *Neoplasias da mama. Qualidade de vida. Inquéritos e questionários. Mastectomia segmentar. Tratamento conservador.*

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