Research article

Clin Ter 2018; 169 (4):e151-154. doi: 10.7417/T.2018.2071

Functional Assessment of Cancer Therapy Questionnaire for Breast Cancer (FACT-B+4): Italian version validation

O. Di Bella[1], R. A. Cocchiara[1], A. De Luca[2], F. Frusone[2], V. Aceti[2], C. Sestili[1], V. D'Egidio[1], A. Mannocci[1], M. Monti[2], G. La Torre[1]

[1]Department of Public Health and Infectious Diseases, Sapienza University, Rome; [2]Department of Surgical Sciences, Sapienza University, Rome, Italy

Abstract

Background. Improvements in breast cancer diagnosis and treatment led to an increased incidence of survivors' rate. The healthcare system has to face new problems related not only to the treatment of the disease, but also to the management of the quality of life after the diagnosis. The aim of this study was to validate the Italian version of the Functional Assessment of Cancer Therapy - Breast (FACT-B+4) questionnaire and to evaluate its reliability.

Methods. The questionnaire was administered twice, with an interval of three days between each administration, to a cohort of women of the Breast Surgical Unit, PoliclincoUmberto I. Cronbach's alpha was used as a measure of the internal consistency of the Italian version.

Results. The Italian version of the tool was administered to 55 subjects. The Cronbach's alpha for most scores registered values >0.7, both at baseline and at the follow-up analysis, therefore the subscale showed good internal consistency.

Conclusions. The Italian version of FACT-B+4 demonstrated acceptable reliability properties in the Breast Unit patients. The use of this questionnaire seemed to be effective and in line with the results derived from the English and Spanishversions. Internal consistency and validity had similar performance results. ***Clin Ter 2018; 169(4):e151-154. doi: 10.7417/CT.2018.2071***

Key words: *FACT-B, breast cancer, Quality of Life, questionnaire, validation*

Introduction

Breast cancer is the most common tumorin the female population, with a worldwide incidence of 2.4 million new cases in 2015 (1). According to the data of the Italian Association of Medical Oncology (AIOM) and the Italian Cancer Registers Association, in Italy 48 thousands new cases were estimated in 2015 (2).

Due to improvements in the diagnosis and treatment a higher survival rate has been achieved, consequently new aspects related to patient survival emerged. Therefore, particular attention is given to the assessment and protection of Quality of Life (QoL), with specific focus on the psychosocial, emotional and physical well-being of the patients (3-5).

A standardized scale has been implemented in order to measure and manage the overall health status of patients. The assessment is carried out through the administration of a questionnaire named Functional Assessment of Cancer Therapy (FACT), which provides a QoL evaluation for numerous cancers (6).

In addition to this instrument, a specific appendix was developed for breast cancer, constituting FACT-B. Although some authors concluded that the items of FACT-B could be generic and not including a sufficient number of questions to evaluate post-operative complications. The study by Maunsell et Al. considering the severity of arm problems, strongly associated with an increase in psychological problems (7), added four specific questions related to arm mobility, creating the FACT-B +4 (8).

This questionnaireis structured in two sections:

FACT-general, which is composed off our domains (physical well-being, social-family well-being, emotional well-being, functional well-being);

A disease specific domain for breast cancer, which is further divided into two sections: breast cancer subscale and arm subscale(9, 10).

Although its use is widespread throughout the world, an Italian validation has not been performed yet.

The aim of this study is to evaluate the sustainability, reliability and the validity and sensitivity of the Italian translation of the FACT-B+4 questionnaire, designed to assess the quality of life in patients with breast cancer, and to understand if the tool is applicable to the Italian setting, investigating the understanding of the questions through the Cronbach's alpha statistical indicator.

Materials and methods

The project was carried out with the aim of testing the reliability of the Italian translation of the FACT-B+4

Correspondence: Dr.ssa Ornella Di Bella, Piazzale Aldo Moro, 5 - 00185 Rome. Email:ornella.dibella@uniroma1.it

ISSN 1972-6007

questionnaire to assess the Quality of Life in women with breast cancer. Respecting the structure of the tool original version, a prospective observational study was carried out in collaboration with the Breast Unit of the Policlinico Umberto I of Rome.

The cohort of patients involved in the study was recruited between March 2017 and March 2018 among the patients of the Department of Surgery of the Policlinico Umberto who had been treated surgically for the diagnosis of breast cancer. After the informed consent to participate in the study, patients received the questionnaire at two different times. The first administration was performed six days after surgery (T0). The second administration was performed nine days after surgery (T1). It was possible to record the answers and compare them in order to derive an indication on the state of understanding and reliability of the instrument, and therefore the validity of the Italian translation.

The first phase involved language experts to translate the original questionnaire into the Italian version. Two different researchers performed the translation individually. The two different versions were compared by a third investigator who used a draft to structure the final version of the tool reaching a consensus on each item. The translation of the items was performed ensuring the content and conceptual equivalence of the meaning.

The FACT-B+4questionnaire (Functional Assessment of Cancer Therapy-Breast) consists of 40 questions: 27 about general quality of Life and 13 about breast cancer. It is further structured into five subscales: physical, family-social, emotional, functional well-being and a last part specific for breast cancer.The score is calculated in accordance with the version 4 of the FACIT measurement system: each scale and the value of some questions (specifically GP1 to GP7, GE1, GE3 - GE6, B1 - B3, B5 - B8, B10 - B13) are reversed in the calculation of the final score (11).

The result given by the sum of the scores goes from zero to 164: a higher score corresponds to major well-being of the patient.

The study included women previously diagnosed with malignant breast cancer, aged between 30 and 85. Male subjects and women under the age of 30 or over 85with a previous diagnosis of breast cancer, were excluded from this study.

To evaluate the internal consistency of the questionnaire, it was used the Cronbach's alpha statistical indicator, which measures reproducibility over time and the homogeneity of the questions. It refers to the degree to which all parts of the test measure the variables in the same way. High values have been considered those above 0.70. A descriptive analysis of the sample was performed. A correlation analysis was carried out to assess the relationship between the questionnaire scores with the variables education level and occupation of the patients.

Results

Fifty-five patients were enrolled in the study. Each individual filled the T_0 and T_1 questionnaire. The mean age of patients was 55 years (range: 33-85 years); 69% of the women were married; 36% were housewives and 52% had high school license.

The first questionnaire administration (T_0) was performed six days after the surgical treatment. The majority of the scales showed Cronbach's alpha>0.7. Physical well-being alpha was 0.812; the social-family well-being alpha was 0.747; the emotional well-being alpha was 0.593 (excluding the GE2 question from the analysis, the alpha level is corrected to 0.771)(Fig. 1); functional well-being alpha was 0.839 and the part related to breast cancer showed an alpha of 0.734.

The second questionnaire administration (T_1) was performed nine days after the surgical treatment. Again, most of the scales showed Cronbach's alpha > 0.7. Physical well-being alpha was 0.782; the social-family well-being alpha was 0.813; the emotional well-being alpha was 0.513 (excluding the GE2 question from the analysis, the alpha level is corrected to 0.651); functional well-being alpha was 0.850 and the part related to breast cancer showed an alpha of 0.716. Fig. 2 shows the results at time 0 and time 1.

Afterwards, it was performed a comparison analysis between the two questionnaire administrations results by using the Wilcoxon test for paired samples. Values showed to be significantly similar.

Internal consistency of the total FACT-B+4 indicated at T_0a score of 0.820 (Cronbach's alpha) and at T_1 0.736 (Cronbach's alpha) (Fig.2).

Discussion

The Cronbach's alpha of the Italian version resulted 0.820 at T0 and 0.736 at T1 and indicates that the sensitivity of the local language translation of the FACT-B+4 is as good as the original scale (7).

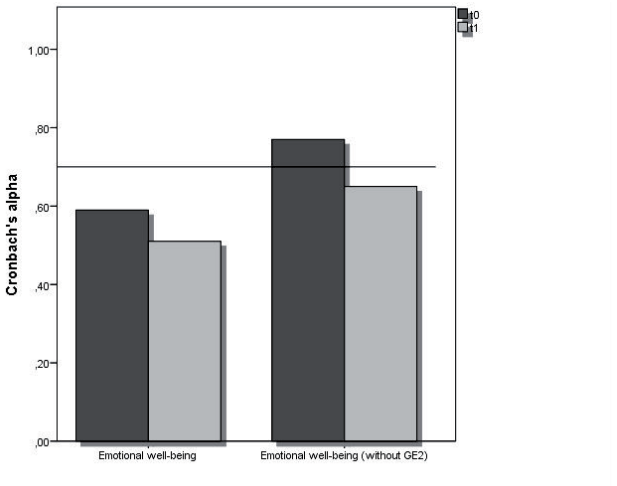

Fig. 1- Considering the Cronbach's alpha of the Emotional well-being, the scale has a value >0.7 when the question GE2 is exclude.

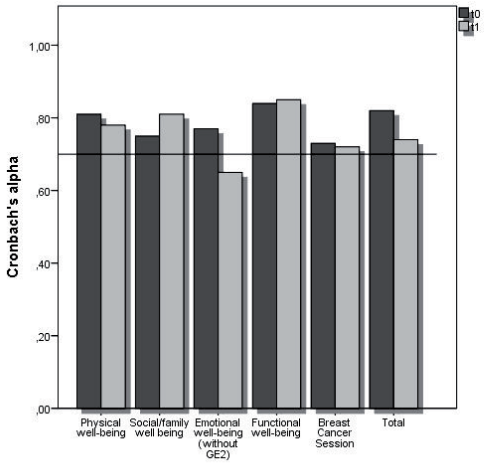

Fig. 2. Comparison between the Cronbach's alpha of the single scales at t0 and t.

Considering single subscales, the functional well-being subscale showed the highest Cronbach's alpha values, ranging from 0.839 to 0.850, indicating satisfactory internal consistency. The lowest and most difference Cronbach alfa was obtained in the emotional well-being subscore. However, many patients reported low response rates to questions related to the sexual context. Indeed the question GS7 ("I am satisfied with my sex life") highlighted the lowest answer rates.

Sex life is an important element for patient's quality of life (13), especially in our group of patients (mean age 55 years). So the lack of data on sex life could be a bias in the assessment of health-related quality of life. However, this could be fixed modifying the method of questionnaire administration (for example sending the questionnaire directly to the patient in order to make her answering the questions in a more comfortable background) and remembering to the patient that the questionnaires are completely anonymous.

The main limitation of the study is the small sample size which may prevent the ability to detect statistically significant correlations and differences.

Nevertheless, the Italian translation of the FACT-B (version 4) questionnaire was developed, tested and validated, and its sensitivity its internal consistency was found satisfactory in comparison to the original tool.

Our results are satisfying if compared to the Cronbach's alphas of the subscales of the English and Spanish versions of the questionnaire, as shown in Table 1 (8, 12).

This instrument could now be used in the Italian setting to assess the quality of life of breast cancer survivors.

In conclusion, Italian version of FACT-B+4 questionnaire could be a reliable and useful tool to assess quality of life of patient suffering from breast cancer, as well as the English and Spanish version, and could help the physician to implement new strategies to improve health-related quality of life in these patients.

References

1. https://jamanetwork.com/journals/jamaoncology/fullarticle/2588797
2. www.aiom.it
3. Darga L, Magnan M, Mood D, et al. Quality of Life as a Predictor of Weight Loss in Obese, Early-Stage Breast Cancer Survivors. Oncology Nursing Forum 2007; 34(1):86-92
4. Uster A, Ruefenacht U, Ruehlin M, et al. Influence of a nutritional intervention on dietary intake and quality of life in cancer patients: A randomized controlled trial. Nutrition. 2013; 29(11-12):1342-9
5. Hamer J, McDonald R, Zhang L, et al. Quality of life (QOL) and symptom burden (SB) in patients with breast cancer. Supportive Care in Cancer 2016; 25(2):409-19
6. Cella D, Tulsky D, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clinical Oncol 1993;11(3):570-9
7. Maunsell E, Brisson J, Deschênes L. Arm problems and psychological distress after surgery for breast cancer. Can J Surg. 1993;36(4):315-20.
8. Coster S, Poole K, Fallowfield L. The validation of a quality of life scale to assess the impact of arm morbidity in breast cancer patients post-operatively. Breast Cancer Research and Treatment. 2001;68(3):273-282.
9. Brady M, Cella D, Mo F, et al. Reliability and validity of the Functional Assessment of Cancer Therapy- Breast (FACT-B) quality of life instrument. Journal of Clinical Oncology. 1997;15(3): 974-86

Table 1. Cronbach's alpha of the Italian version of FACT-B+4 compared with the Spanish and English versions.

Scale	**Language**			
	Italian N=55		**English[8] N=279**	**Spanish[12] N=104**
	T_0	**T_1**		
Physical well-being	0.81	0.78	0.71	0.75
Social-family well-being	0.75	0.81	0.76	0.75
Emotional well-being	0.59	0.51	0.77	0.69
Functional well-being	0.84	0.85	0.81	0.92
Breast cancer subscale	0.64	0.54	0.62	0.52
Arm subscale	0.85	0.89	0.83	0.89
FACT-B+4	0.82	0.74	0.88	0.90

10. Pandey M, Thomas B, Ramdas K, et al. Quality of life in breast cancer patients: validation of a FACT-B Malayalam version. Quality of life research 2002; 11:87-90
11. Cella D. FACIT manual: manual of the functional assessment of chronic illness therapy (FACIT) scales. CORE 1997
12. Belmonte Martínez R, GarinBoronat O, Segura Badía M, et al. Validación de la versiónespañola del Functional Assessment of Cancer Therapy Questionnaire for Breast Cancer (FACT-B+4). MedicinaClínica 2011; 137(15):685-8
13. Flynn TJ, Gow AJ. Examining associations between sexual behaviours and quality of life in older adults. Age Ageing 2015; 44(5):823-8