



## Brief report

# Validation of the FACT-B+4-UL questionnaire and exploration of its predictive value in women submitted to surgery for breast cancer<sup>☆</sup>



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## ABSTRACT

**Introduction and objective:** The early detection of upper limb complications is important in women operated on for breast cancer. The “FACT-B+4-UL” questionnaire, a specific variant of the Functional Assessment of Cancer Therapy-Breast (FACT-B) is available among others to measure the upper limb function.

**Patients and methods:** The Spanish version of the upper limb subscale of the FACT-B+4 was validated in a prospective cohort of 201 women operated on for breast cancer (factor analysis, internal consistency, test–retest reliability, construct validity and sensitivity to change were determined). Its predictive capacity of subsequent lymphoedema and other complications in the upper limb was explored using logistic regression.

**Results:** This subscale is unifactorial and has a great internal consistency (Cronbach's alpha: 0.87), its test–retest reliability and construct validity are strong (intraclass correlation coefficient: 0.986; Pearson's R with “Quick DASH”: 0.81) as is its sensitivity to change. It didn't predict the onset of lymphedema. Its predictive capacity for other upper limb complications is low.

**Conclusions:** FACT-B+4-UL is useful in measuring upper limb disability in women surgically treated for breast cancer; but it does not predict the onset of lymphoedema and its predictive capacity for others complications in the upper limb is low.

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## Validación del cuestionario FACT-B+4-MS y exploración de su capacidad predictora en mujeres intervenidas de cáncer de mama

## RESUMEN

## Palabras clave:

Evaluación de la discapacidad

Linfedema

Cáncer de mama

Alteraciones del miembro superior

**Introducción y objetivo:** La detección precoz de las complicaciones del miembro superior en mujeres intervenidas de cáncer de mama es importante. El cuestionario FACT-B+4-MS, variante del *Functional Assessment of Cancer Therapy-Breast* (FACT-B) es una escala específica de la función del miembro superior en estas pacientes.

**Pacientes y métodos:** Se valida el FACT-B+4-MS en una cohorte prospectiva de 201 mujeres intervenidas por cáncer de mama (análisis factorial, consistencia interna, fiabilidad test–retest, validez del constructo y sensibilidad al cambio) y se explora mediante regresión logística su capacidad predictora de linfedema y otras complicaciones.

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**Resultados:** El FACT-B+4-MS es unifactorial y goza de gran consistencia interna (alfa de Cronbach: 0,87), alta fiabilidad test-retest (coeficiente de correlación intraclase: 0,98), validez de constructo (R de Pearson con el "Quick DASH": 0,81) y sensibilidad al cambio. En los modelos de regresión, no aparece como variable explicativa de linfedema, pero sí de otras complicaciones del miembro superior.

**Conclusiones:** El FACT-B+4-MS es útil para medir la discapacidad del miembro superior en mujeres operadas por cáncer de mama. No predice el establecimiento de linfedema, pero sí, aunque débilmente, otras alteraciones.

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## Introduction

Lymph node surgery for breast cancer is associated with impaired upper limb such as lymphedema (less frequent after sentinel node biopsy than after lymphadenectomy), paresthesia, weakness and pain (9–68%).<sup>1–5</sup> Ute proposed to use validated self-completion tools systematically for early detection and postulated that a poor function of the upper limb within the first 3–6 months after surgery should be closely monitored.<sup>6</sup>

The disability of upper limb is measured in various ways. The "Disabilities of the Arm, Shoulder and Hand" questionnaire (DASH; 0: maximum functionality; 100: maximum disability) is being widely used, especially its simplified version ("Quick DASH"), validated in Spanish.<sup>7</sup>

The "Functional Assessment of Cancer Therapy-Breast" (FACT-B) questionnaire consists of 44 questions on the physical, social, emotional and functional dimensions of women. Every response is scored on a five-point Likert scale. Adding four questions, Coster<sup>8</sup> validated FACT-B+4 to include the upper limb functionality. Belmonte<sup>9</sup> validated the Spanish version in women coming from a screening. Women undergoing mastectomy and lymphadenectomy were underrepresented as the authors themselves acknowledge.

The FACT-B+4 upper limb subscale (FACT-B+4-UL) includes five questions, one from the first FACT-B (B3: "One or both arms are swollen or sensitive") and four from Coster (B10: "It hurts when I move my arm on this side"; B11: "I have less mobility on arm on this side"; B12: "Numb arm on this side"; B13: "My arm on this side is stiff"). The minimum and maximum disability would be represented by 0 and 20 points respectively.

Our goal is to validate the FACT-B+4-UL questionnaire in all women having undergone breast cancer surgery, not only after screening, as well as to explore their possibilities for predicting upper limb complications.

## Patients and methodology

We performed a prospective study with a cohort of women undergoing surgery plus radiation therapy for breast cancer in the Hospital Complex of Jaén. They were subsequently referred to the Rehabilitation Service from May 2010 to December 2014. The inclusion criteria were to be female and to have undergone lymph node surgery plus radiotherapy. Exclusion criteria were previous disabling changes in the upper limb and not being able to read and understand Spanish. The study was approved by the Hospital Ethics Committee. All patients signed an informed consent.

Patients completed FACT-B+4-UL one day after surgery and two months later, this time along with the "Quick DASH"; Then they were asked about their upper limb compared to the first day, being able to answer "better", "same" or "worse." The first sixty patients completed a third FACT-B+4-UL questionnaire in less than one week.

Twenty-five women were also referred to Rehabilitation for treatment of breast cancer lymphedema prior to the study.

FACT-B+4-UL and "Quick DASH" questionnaires were delivered to the patients.

The following properties of FACT-B+4-UL were determined: (a) factor analysis (major components) 24 h and 2 months after surgery; (b) internal consistency (Cronbach's alpha) 24 h and 2 months after surgery; (c) test-retest reliability (intraclass correlation coefficient) between second and third administration; (d) construct validity (Pearson's R between FACT-B+4-UL and "Quick-DASH" after 2 months); (e) sensitivity to change, evaluated in three ways: comparing FACT-B+4-UL after 24 h and after 2 months, contrasting this comparison with the self-perceived difference, and comparing women in the cohort with those recruited for breast cancer lymphedema prior to the study.

Follow-up to detect emerging cases of lymphedema and other disorders was completed in December 2015. Except for lymphedema, only the alterations occurring within the first year of surgery were considered.

Statistical analysis was performed with the R-Commander software. In addition to the methods mentioned for FACT-B+4-UL, we calculated the mean and standard deviation (SD) of the quantitative variables, whose normality had been previously verified (Kolmogorov-Smirnov). The means were compared, depending on the case, through the Student test or the variance analysis (ANOVA). The predictive capacity of FACT-B+4-UL was explored using two logistic regression models, the dependent variable being the lymphedema in one, and the remaining upper limb impairments in the other (adjustment variables: age, type of surgery and FACT-B+4 levels after 24 h and after 2 months). The accepted significance level was 0.05. With data from the Coster study,<sup>9</sup> the minimum sample size was 126.

## Results

201 women were recruited. Thirty-two could not be monitored, 8 because it was not possible to contact them and 24 because they preferred to be monitored in the nearest local hospitals. Thus, the sample consisted of 169 women (mean age: 53.1 years, SD: 12). 51.2% had undergone lumpectomy plus lymphadenectomy, 36.5% lumpectomy plus sentinel node biopsy, and 12.3% mastectomy plus lymphadenectomy. Eighteen women presented lymphedema throughout the study (10.6%) and 16 (9.5%) suffered one or more changes within the first year after surgery (pain in 12 cases, limited mobility in 5 and sensory impairment in 6).

Table 1 shows the FACT-B+4-UL levels, Cronbach's alpha and factor analysis 24 h and 2 months after surgery.

Fifty-seven of the 60 women who received a third FACT-B+4-UL questionnaire, completed it. The intraclass correlation coefficient between the second and third completions was 0.98.

The mean "Quick DASH" after two months was 20.31 (SD: 20.8); Pearson's R coefficient with FACT-B+4-UL was 0.81 ( $p=0.01$ ).

Table 2 shows the difference between FACT-B+4-UL after 24 h and after 2 months with respect to the self-perceived variation.

In the 25 cases of lymphedema associated with breast surgery prior to study, the mean FACT-B+4-UL was 8.68 (SD: 4.33), and the

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