



# Spanish version of the BREAST-Q® 2.0 questionnaire—breast reduction module—: Linguistic, cross-cultural adaptation and validation

## Versión española del cuestionario BREAST-Q® 2.0—módulo de reducción mamaria—: validación lingüística y adaptación transcultural para la población española

Patients with symptomatic macromastia (SM) frequently suffer from symptoms related to their breast volume, which negatively impact their quality of life (QoL)<sup>1-3</sup>. The most effective treatment for this disease is breast reduction, which provides an improvement in QoL<sup>2</sup>. In 2009, Pusic et al developed the BREAST-Q® questionnaire<sup>4</sup>, which is a patient-reported outcome (PRO) instrument specifically designed to measure QoL and satisfaction of patients undergoing surgery; one of the BREAST-Q® modules is dedicated to breast reduction. Although the modules have been linguistically adapted to many different languages and thoroughly evaluated using psychometric tests<sup>5-7</sup>, they have not been translated into Spanish for the Spanish population.

The objectives of this study are to develop a cross-cultural adaptation of the English version of the BREAST-Q® v.2.0 breast reduction module for the Spanish population and to test its reproducibility in our population. To this end, the study included patients with SM treated at our hospital between 2017 and 2018. The selection criteria were applied to patients requesting treatment who had: a body mass index (BMI)  $\leq 30$  kg/m<sup>2</sup>, estimated breast resection  $\geq 500$  g per breast, and age over 18 years. The remaining patients were excluded.

### Development of the Spanish version of the BREAST-Q® breast reduction module

The study was approved by the regional ethics committee and authorized by the Memorial Sloan Kettering Cancer Center and Q-Portfolio. Validation was performed following the recommendations of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)<sup>8</sup>. The linguistic validation process entailed the translation into Spanish of the original English version of the questionnaire by 2 independent translators. After a conciliation meeting, a definitive consensus translation was produced. This version was re-translated back into English by an independent native English-speaking translator. Both versions were assessed by the linguistic adaptation group, producing a final consensus version of the questionnaire translated into Spanish that was approved by Q-Portfolio. The definitive questionnaire was administered to 8 patients with SM during a cognitive interview to verify that it was easily understandable. In addition, the psychometric properties of the BREAST-Q® v.2.0 breast reduction module were analyzed in a sample of 37 patients and then compared with the original version to strengthen its validity. The questionnaire was administered by personal interview.

Regarding the results, the internal consistency of the questionnaire was studied with Cronbach's alpha, with the same acceptance criteria as the original version: data loss  $< 5\%$ , Cronbach's alpha for summary coefficients  $> 0.70$ , total item correlation  $> 0.30$  and an intraclass correlation coefficient (ICC)  $> 0.70$ <sup>4,9</sup>. The results for the preoperative and postoperative versions are shown in Table 1. In the preoperative module, all the results were greater than 0.85. In the postoperative module, only one item did not reach a Cronbach's alpha greater than 0.7 (satisfaction with the administrative staff). The medical team satisfaction scale obtained negative results ( $-0.091$ ), probably because there were no differences in the answers and all the results were similar. Interobserver and intraobserver reproducibility is represented by the ICC. In addition, we wanted to compare the results of the traditional psychometric analysis with the results obtained in the original article<sup>4</sup> (Table 2), obtaining similar results, which reinforces the consistency of the validation.

The treatment of SM involves surgical breast reduction, which has a positive impact on both symptoms and QoL<sup>1-3</sup>. Despite this, there is no consensus on the selection criteria for this surgery<sup>10</sup>. Direct patient information (PRO) is an excellent tool for learning about the impact of the disease and its treatment on patients, which is particularly relevant when the disease causes psychosocial and functional sequelae that are difficult to measure with laboratory analyses or physical tests, like in SM. The BREAST-Q® is a questionnaire that measures PRO that was rigorously developed and designed to evaluate the results of different types of breast surgery<sup>4</sup>. Its advantage is that it includes 2 modules with pre- and postoperative evaluations, which allows us to quantify the baseline QoL of patients and variations in the effects of surgery. Currently, there is no linguistic adaptation of the BREAST-Q® v.2.0 breast reduction module for the Spanish population. The Spanish version of the BREAST-Q® questionnaire—Breast Reduction Module—that we have created meets international psychometric standards established and published in the original article by Pusic et al.<sup>4</sup>, which was confirmed by comparing our results with the original questionnaire.

We believe that the Spanish version of the BREAST-Q® v.2.0 —Breast Reduction Module—is valid for its use and application in the Spanish population. This instrument may be useful in the selection of patients in whom macromastia has a direct effect on QoL and who would benefit from surgical treatment, while also being able to identify opportunities to improve daily clinical practice.

**Table 1 – Psychometric analysis of the domains of the BREAST-Q®—Breast Reduction (mastopexy) Module (pre- and postoperative scales).**

	No. of items	Cronbach's alpha	ICC	95% CI
Preoperative n = 48				
Satisfaction with breasts	11	0.940	0.938	0.908–0.961
Psychosocial wellbeing	9	0.940	0.937	0.907–0.961
Sexual wellbeing	5	0.882	0.884	0.822–0.929
Physical wellbeing	14	0.888	0.884	0.830–0.927
Postoperative n = 37				
Satisfaction with breasts	13	0.922	0.902	0.848–0.943
Satisfaction with nipples	4	0.895	0.843	0.745–0.912
Psychosocial wellbeing	9	0.957	0.957	0.932–0.975
Sexual wellbeing	5	0.950	0.944	0.908–0.969
Physical wellbeing	14	0.764	0.878	0.810–0.929
Satisfaction with results	8	0.765	0.783	0.656–0.875
Satisfaction with information	12	0.916	0.889	0.787–0.954
Satisfaction with surgeon	7	0.871	0.877	0.808–0.929
Satisfaction with medical team	7	–0.091	–0.091 <sup>a</sup>	–0.738–0.377 <sup>a</sup>
Satisfaction with administrative team	7	0.466	0.687	0.501–0.821

CI: 95% confidence interval 95%; ICC: intraclass correlation coefficient.

**Table 2 – Comparison of the Spanish version with the original article (Breast Reduction Module).**

Scales	No. of items	Cronbach's alpha	
		Our study	Pusic et al
Satisfaction with breasts	13	0.922	0.91
Satisfaction with results	8	0.765	0.91
Psychosocial wellbeing	9	0.957	0.95
Sexual wellbeing	5	0.950	0.93
Physical wellbeing	14	0.764	0.83
Satisfaction with information	12	0.916	0.91
Appearance of nipples and areolas	4	0.895	0.89

Source: Pusic et al.<sup>4</sup>.

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