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## Quality of Life Assessment After Conserving Breast Surgery and Intraoperative Radiotherapy (IORT) in Breast Cancer Patients Using the BREAST-Q Questionnaire

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## ABSTRACT

**Background:** In women undergoing breast surgery, Measurement of Patient Related Outcome Measures (PROMs) is important for improving the process of care, focusing on the patient's perspective. BREASTQ is a validated patient-reported outcome measure used increasingly in aesthetic and reconstructive surgery. Only recently a breast conserving therapy module (BREASTQ-BCT) has been available. The aim of this study was to assess patient satisfaction and quality of life using BREAST-Q questionnaire in patients undergoing breast conserving surgery (BCS) plus IORT.

**Methods:** Women undergoing BCS plus IORT for an early-stage breast cancer for at least a year were invited by telephone to participate. We scheduled dedicated outpatient visits to our center. The medical interviewer collected medical history information and administered the BREASTQ-BCT in paper format. Data were inserted in a de-identified database. Univariate regression analysis was used to identify clinicopathological variables associated with "satisfaction with breast" domain score.

**Results:** Overall, 38 women completed the questionnaire. The domains of the questionnaire that obtained the lowest scores were 'satisfaction with IORT information' and 'satisfaction with breasts' (median score 59, IQR 55-73 and 51-69.5). Weight of specimen and vascular invasion were risk factors for lower 'Satisfaction with breasts' at univariate analysis. There was a moderate-strong correlation between 'satisfaction with the breasts' and 'psychosocial wellbeing' and 'Sexual wellbeing'.

**Conclusions:** In this retrospective study, without a pre-operative questionnaire, changes in individuals' satisfaction and quality of life could not be identified. A prospective study comparing BCS plus external RT group and BCS plus IORT group could be informative.

**Introduction**

Breast cancer is the most common cancer in women in all age groups worldwide and its incidence is slightly increasing.<sup>1</sup> Breast conserving surgery

(lumpectomy/quadrantectomy) with adjuvant radiotherapy is the standard treatment for women with early-stage breast cancer, and it has proved to be equivalent to mastectomy in terms of overall survival and local recurrence of disease.<sup>2-4</sup> The purpose of adjuvant radiotherapy is to reduce the risk of local disease recurrence. Adjuvant radiotherapy treatment can be delivered intra or post-operative; patients considered at low risk of local recurrence are candidates for IORT<sup>5</sup>, which is a technique of partial irradiation of the breast by applying a single dose of

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radiation (20 Gy, 50 Kv), administered at the time of surgery. Two randomised controlled trials, TARGIT-A<sup>6</sup> and ELIOT<sup>7</sup>, have shown that IORT is non-inferior to External Beam Radiation Therapy (EBRT) in terms of local recurrence rate when delivered to patients with early breast cancers and specific tumour characteristics. IORT also has additional advantages in terms of organization.<sup>8</sup>

Although breast cancer is the leading cause of cancer-related mortality in women, this trend is slightly decreasing, and advances in diagnostic and therapeutic management of breast cancer have produced significant improvements in disease-related survival.<sup>9</sup> Currently, more than 60% of women with breast cancer live 20 years after initial diagnosis.<sup>10</sup> Therefore, the assessment of patient satisfaction with the surgical result, quality of life after surgery and well-being in a psychosocial context are of vital importance in women undergoing breast surgery. Measurement of Patient Related Outcome Measures (PROMs) after breast surgery is now included in clinical trials as an endpoint<sup>11,12</sup>, and it is believed to be important for improving the process of care, focusing on the patient's perspective.<sup>13</sup>

In 2009 the Memorial Sloan Kettering Cancer Center developed a questionnaire to elicit and quantify the patient's perception of the result after breast surgery, the BREASTQ.<sup>14</sup> Several modules have been developed for the evaluation of patients undergoing radical mastectomy, reconstructive and reductive/additive breast surgery, and more recently for BCT as well.<sup>15,16</sup> The BREASTQ-BCT Module includes five domains that explore satisfaction with the breast, effects of radiotherapy, physical, sexual and psychological well-being. Furthermore, the four domains analyze the satisfaction in relation to the information provided and the relationship with the surgeon and medical team/nurses/administrative staff. Each domain is divided into multiple questions, to which patients answer according to a numerical rating scale. Several clinical trials used the BREASTQ Modules for the assessment of patient satisfaction after radical mastectomy or reconstructive surgery<sup>17,18</sup>, while only a few apply this PROM to the evaluation of patients undergoing BCT.<sup>16</sup> In particular, patients undergoing IORT have never been evaluated through the BREASTQ-BCT Module.<sup>19</sup>

We designed a transversal observational study which, through individual administration of the BREASTQ-BCT Questionnaire and through retrospective collection of clinical and anamnestic data, aimed to evaluate the quality of life of breast cancer patients after BCS associated with IORT, at least one year after surgery. This cross-sectional study is, to the best of our knowledge, the first study which implements the use of BREASTQ-BCT Module for quality of life assessment in patients undergoing IORT.

## Methods

### *Study population*

Women aged 18-74 who underwent breast conserving surgery plus IORT for an early-stage (T1-T2) breast cancer between 2011 and november 2017 were included in the study. Patients who developed distant metastases were excluded, as were women who underwent modified radical mastectomy for local recurrence of disease since BCT.

The patients subjected to IORT were identified through the computerized operating register (Ormaweb). Subsequently, through the company filing software (Opera), the telephone numbers, personal data and an amnestic data of the patients were recovered.

Enrollment of eligible patients took place by telephone contact. We scheduled dedicated outpatient visits to our center. After signing the informed consent and data protection module, the medical interviewer collected medical history information and administered the BREASTQ-BCT in paper format, which the patient completed independently. The questionnaire was anonymous.

Clinical pathological data were collected through consultation of electronic medical records and documents. Data were inserted in a de-identified Excel worksheet (Microsoft Excel version 97-2003). Permission to use the Italian version of the BREASTQ BCT Module was obtained from the Mapi Research Trust Institute.<sup>20</sup>

BREASTQ-BCT module was developed for BCS with external adjuvant radiotherapy. Effects of radiotherapy domain included questions not applicable to intraoperative radiation therapy, so we modified the domain eliminating these questions.

### *Ethical approval*

All procedures performed in studies involving human participants were in accordance with ethical standard of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The Ethics Committee of Verona and Rovigo approved the study (Prot. n. 20876/2017). Informed consent was obtained from all individual participants included in the study.

### *Data Analysis*

The result from the BREASTQ-BCT postoperative questionnaire was analysed according to the user instructions provided by the MAPI Research Trust. The resulting score for each domain was converted to a Q-score (range 0-100) by the use of a manual scoring table, as recommended by the MAPI Research Trust. The analyses were carried out using the Microsoft Excel/SPSS spreadsheet. We used descriptive statistic including mean and standard deviation and median/IQR for parametric and non parametric data, respectively. Univariate regression analysis was used



to identify clinicopathological variables associated with "satisfaction with breast" domain score. Statistical significance was assumed to be  $p < 0.05$ .

After testing for normality, Spearman's rho correlation coefficients were calculated between 'Satisfaction with Breasts' and all other domains. They were tested at a two-sided 5% significance level. The study was conducted after obtaining the approval of the Ethics Committee.

## Results

There were 77 eligible women and they were contacted by phone. Overall, 15 women were not contactable because the phone number was not registered in the databases or because they did not answer the call. Also, 13 women were not interested in participating in the study and 2 women were not

available for other intercurrent medical conditions. In addition, 9 women had accepted to participate but did not come to the appointment. In total, 38 women completed the questionnaire and were included in the analyses.

The mean age at the time of study was 64.95 (SD=5.04). The mean age at the time of surgery was 60.62 (SD=5.79). The mean body mass index (BMI) was 26.07 (SD=4.20). The mean time from breast cancer surgery to participation in the study was 56.66 months (SD=26.84). The mean tumor diameter, evaluated by definitive histological examination, was 11.32 mm (SD=5.15). The mean surgical pathology specimen weight was 103.87 gr (SD=69.46).

The scores for each BREASTQ-BCT Module domain are summarized in Table 1. The highest scoring domain were 'satisfaction with members of

**Table 1.** Results of BREAST-Q BCT module

Question	Number of participants who replied the question (n)	Mean (95% CI)	Median (IQR)
Satisfaction with breasts	38	61.7(57.2-66.1)	59(51-69.5)
Effects of radiotherapy	38	86.3(81.5-91.1)	87(78-100)
Psychosocial wellbeing	38	79.6(73.8-85.3)	80(64-100)
Sexual wellbeing	23	63.3(54.7-62.0)	62(48-76.5)
Physical wellbeing	38	58.3(59-73.7)	61(53-66)
Satisfaction with information	36	66.3(51.6-68.4)	62(58-80)
Information about IORT	35	60(51.6-68.4)	59(55-73)
Satisfaction with surgeon	38	92.4(88.4-96.4)	100(86-100)
Satisfaction with medical team	38	94(89.8-96.4)	100(100-100)
Satisfaction with other members of office staff	38	93.8(88.4-99.1)	100(100-100)

**Table 2.** Univariate linear regression analyses of 'satisfaction with breasts' from the BREAST-Q BCT module

Variable	N	Constant (Standard Error)	Coefficient (Standard Error)	p value
Age, years	38	72.4(30.2)	-0.16(0.46)	0.725
Age at surgery, years	38	62.9(24.6)	-0.02(0.4)	0.960
BMI, Kg/M2	38	43.0(17.8)	0.72(0.67)	0.288
Family history of BC	38	60.45(3.3)	3.2(4.84)	0.513
Tumor location on pre-op imaging	39	63.0(10.6)		
Upper Outer Quadrant			-0.9(11.05)	0.935
Superior Sagittal plane			6.33(13.63)	0.645
Upper Inner Quadrant			-0.17(12.19)	0.989
Lower Outer Quadrant			-5.5(12.93)	0.673
Inferior Sagittal Plane			-13.5(14.93)	0.373
Lower Inner Quadrant			-2.0(18.29)	0.914
Tumor diameter on pre-op imaging	39	57.7(6.4)	0.37(0.58)	0.523
Surgery	39	62.2(2.4)		
Axillary surgery			-14.22(14.6)	0.337
Re-excision of margins			-3.72(10.47)	0.724
Pathology size, mm	39	61.0(5.8)	0.07(0.46)	0.751
Weight of specimen,g	39	53.0(4.2)	0.08(0.03)	0.029
Histology	39	55.0(10.3)		
IDC			6.14(10.62)	0.567
ILC			/	/
Other			7.86(11.65)	0.504
Mixed			27(17.79)	0.138
DCIS component	39	66.1(3.5)	-7.31(4.62)	0.123
Lymph-vascular invasion	39	63.1(2.3)	-22.06(9.9)	0.032
Adjuvant CT	38	62.2(2.61)	-1.8(6.08)	0.769
Time from surgery, months	39	64.2(5.7)	-0.04(0.08)	0.630
Post-operative complications	39	61.2(2.5)	3.82(6.88)	0.582

BC:Breast cancer, IDC:Infiltrating ductal carcinoma, ILC:Infiltrating lobular carcinoma, DCIS:Ductal carcinoma InSitu,CT: chemotherapy.



medical team', 'satisfaction with members of office staff' and 'satisfaction with breast surgeon', all showing a median of 100 (IQR=100-100, 100-100 and 100-86). The lowest scoring domain were 'satisfaction with IORT information' and 'satisfaction with breasts', both with a median score of 59 (IQR=55-73 and 51-69.5). The median score for 'Effects of radiotherapy' domain was 87 (IQT= 78-100).

In our study the weight of specimen and vascular invasion were risk factors for lower 'satisfaction with breasts' in univariate analysis (Table 2).

There was a statistically significant positive correlation between 'satisfaction with Breasts' and 'psychological wellbeing', 'sexual wellbeing', 'satisfaction with Information', 'satisfaction about IORT' and 'satisfaction with medical team'. Only 'sexual wellbeing' demonstrated a strong correlation. 'psychological wellbeing' and 'Satisfaction with information' demonstrated a moderate correlation. Other domains demonstrated a weak correlation (Table 3).

## Discussion

Breast conserving therapy is the most commonly performed treatment for early-stage breast cancer today. The long-term oncologic safety and efficacy of this approach have been well described. Measurement of Patient Related Outcome Measures (PROMs) is of vital importance in women undergoing breast surgery, and it is believed to be important for improving the process of care, focusing on the patient's perspective.

BREASTQ, a validated patient-reported outcome measure, has been used increasingly in aesthetic and reconstructive surgery<sup>21</sup>, and only recently has a breast conserving surgery-specific module been available.<sup>17</sup>

Therefore, only a few studies have addressed Patient Related Outcome Measures (PROMs) following BCT.<sup>16,22</sup>

This was the first study to implement the use of BREASTQ-BCT Module for quality of life assessment in patients undergoing IORT. In our study 'Satisfaction with Breasts' showed one of the lowest scores, which is lower than that reported in the literature (Table 4).

**Table 3.** Correlation between different domains of the BREAST-Q questionnaire

Domain 1	Domain 2	Correlation coefficient	Statistical significance (p value)
Satisfaction with breasts	Effects of radiotherapy	$r_s=0,20$	$p=0,22$
	Psychosocial wellbeing	$r_s=0,54$	$p=0,00$
	Sexual wellbeing	$r_s=0,73$	$p=0,05$
	Physical wellbeing	$r_s=0,11$	$p=0,50$
	Satisfaction with information	$r_s=0,58$	$p=0,00$
	Information about IORT	$r_s=0,36$	$p=0,02$
	Satisfaction with surgeon	$r_s=0,21$	$p=0,19$
	Satisfaction with medical team	$r_s=0,32$	$p=0,05$
	Satisfaction with other members of office staff	$r_s=0,14$	$p=0,38$

**Table 4.** Comparison with data from the literature.

	Our study Mean (SD)	O'Connell <sup>16</sup> Mean (SD)	Vrouwe <sup>22</sup> Mean (SD)	Dahlbäck <sup>23</sup> Median	Lagendijk <sup>24</sup> Mean (SD)	Rose <sup>25</sup> Median
Satisfaction with breasts	61.7(±14.2)	69(±20)	59.3(±21.1)	66	65.7(±22.4)	74
Psychosocial wellbeing	79.6(±18.3)	78(±22)	73.5(±21.2)	82	70.1(±21.4)	82
Sexual wellbeing	63.3(±24.9)	56(±21)	53.3(±19.5)	60	57.5(±20.3)	58
Physical wellbeing	58.3(±11.6)	76(±18)	74(±19.1)	81	71.2(±18.9)	78

BREAST-Q usually is used in conjunction with the pre-operative baseline questionnaire. Our study is retrospective, and without the pre-operative baseline questionnaire, changes in an individuals' satisfaction and quality of life could not be identified. It is possible that a lower satisfaction score reflects a lower score already preoperatively. We must also note that several patients were operated on when there was not much attention paid on oncoplastic surgery, which may have impacted the results.

We saw low scores also in the field 'information about IORT'. The reason could be that, especially in the first years of experience, counseling with the radiotherapist was aimed more at evaluating the possible indication to intraoperative radiotherapy

rather than informing the patient about the side effects of intraoperative radiotherapy.

In our study, the lowest response rate was obtained for 'sexual wellbeing'. Only 60.5% (23/38) of participants completed that domain of questionnaire. This lack of response has also been reported in other studies.<sup>16, 23</sup> The low response rates may be due to feelings of unease, cultural taboo or perceived irrelevance of the domain.

The mean score of that domain, in our study, was 63.3 (SD=24.9). 'sexual wellbeing' scores are also quite low in other studies (Table 4). Further research into the scores for this domain in women who are not undergoing breast surgery is required to determine whether these results simply reflect the sexual



wellbeing of women in the general population.

Numerous studies have attempted to identify variables that lead to a poor aesthetic outcome following breast conservation therapy. Variables such as age, race, body mass index, breast size, tumor location, tumor size, tumor palpability, resection volume, surgical technique, reexcision, scar visibility, delayed wound healing, seroma, hematoma, infection, axillary dissection, radiation technique and dose, chemotherapy and hormone therapy have documented as predictors of aesthetic outcome following breast conservation therapy.<sup>16,22</sup>

In a recent study, which analyzed the initial experience of the BREASTQ-BCT Module in a group of 200 patients, the risk factors for low score at the univariate analysis were observed to be BMI at time of surgery, change in BMI since surgery, type of axillary surgery, nodal status, size of tumour on ultrasound (mm), weight of specimen (g) and delayed wound healing (> 30 days). BMI at the time of surgery, type of axillary surgery and delayed wound healing remained independent risk factors in multivariate analysis.<sup>16</sup>

We evaluated several clinicopathological characteristics; the only two that have been shown to be risk factors for lower 'Satisfaction with breasts' ( $p < 0.05$ ) in univariate analysis included weight of specimen and lymph-vascular invasion.

The significance of lymphovascular invasion may be justified because this item is more commonly found in larger tumours requiring wider excision. We observed that there was a weak positive correlation between tumor size and weight of specimen ( $r = 0.34$ ,  $p = 0.06$ ). However, our data did not show a correlation between tumor size and lymph-vascular invasion ( $r = 0.02$ ,  $p = 0.88$ ).

There was a positive correlation between 'Satisfaction with the breasts' and some domains of BREAST-Q. The strongest correlations was with "psychosocial wellbeing" and "sexual wellbeing", which supports the importance of improving the care process, focusing on the patient's perspective and quality of life. The absence of a correlation with 'Effects of radiotherapy' in this IORT-group suggests the need to compare these results with a group undergoing external radiation therapy.

In conclusion, this is the first study to use the complete BREASTQ-BCT module in IORT setting. The domains of the questionnaire that obtained the lowest scores were 'Satisfaction with IORT information' and 'Satisfaction with breasts'.

Weight of specimen and vascular invasion were risk factors for lower 'satisfaction with breasts' in univariate analysis. There was a moderate-strong correlation between 'satisfaction with the breasts' and 'psychosocial wellbeing' and 'sexual wellbeing'.

An important limitation of this study is the small sample size; however, it may be interesting to continue with the collection of data and compare it

with an 'external radiotherapy' group to evaluate whether intraoperative irradiation involves a different aesthetic outcome and above all if it has an impact on the quality of life. It would be interesting to perform this comparison through a prospective study, so that the preoperative BREASTQ-BCT Module can also be used to compare it with the postoperative one.

### Conflict of Interest

The authors declare that they have no conflict of interest.

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