



Patient reported outcome measures in breast cancer patients

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ABSTRACT

Introduction: In the International Consortium for Health Outcome Measures (ICHOM) breast cancer outcome set Patient Reported Outcome Measurements (PROMs) form an important but rather innovative part. Few data exist on scores per type of breast surgery and how to use scores in surgical practice. We evaluated PROM scores as well as satisfaction with and expectations of the use of PROMs in breast cancer patients using the national and local patient advocate society.

Methods: Through an online survey patients were asked to report age, type of breast cancer surgery (whether Breast Conserving Therapy (BCT), mastectomy, autologous or implant breast reconstruction) and time since surgery. PROMs (EORTC-QLQ-C30/BR23 and BREAST-Q postoperative modules) were compared for the different surgeries. Additional comparison was made with literature normative and reference scores. Three questions evaluated satisfaction with PROMs and expectations.

Results: 496 patients completed all PROMs and 487 the satisfaction/expectation-questions. Significantly reduced physical functioning was reported following BCT as compared to other surgeries and literature reference values. Satisfaction scores were higher following autologous reconstruction and lower following implant reconstruction as compared to BCT. PRO scores were comparable to normative and references scores except for the 'physical functioning' (BREAST-Q) scores that reported lower in the present study. Ninety-four percent of the participants was (highly) satisfied with future PROM use.

Conclusions: Statistical significant differences were found for PROMs following different types of breast surgery. The significance of these results should become clearer through collection of future data. The great majority of participants considered PROMs as (highly) acceptable and reacted positively on their proposed future use.

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Introduction

Health outcomes embody the results of the health care delivered. Value in health care is defined as the health outcome per total cost [1]. Traditionally health outcome is reported by health care providers and consist for example of survival, recurrence or

complication rates. Multiple outcomes are often used per medical condition in order to define and compare results of health care [1]. In Value Based Health Care (VBHC) the value is defined based on outcomes important to the patient and therefore additionally consist of Patient reported Outcome Measures (PROMs). The International Consortium for Health Outcomes Measurement (ICHOM) in collaboration with health care professionals of different international institutions developed standard sets of health outcome measures for specific medical conditions [2]. Breast cancer was among the first conditions covered by ICHOM [3]. It is expected that by reporting and comparing this ICHOM breast cancer set among patients and between institutions, the value of the care delivered can be improved [1,3].

Especially for breast cancer patients in whom high survival rates are reached, Patient Reported Outcomes (PROs) are of great

Abbreviations: BCT, Breast Conserving Therapy; BVN, Dutch patients' advocates society (Dutch abbreviation for 'Borstkankervereniging Nederland'); ICHOM, International Consortium for Health Outcome Measures; PROMs, Patient Reported Outcome Measures; QoL, Quality of Life; REC A, Autologous breast reconstruction; REC I, Implant breast reconstruction; VBHC, Value Based Health Care.

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importance. Furthermore at least equal survival and recurrence rates are described in early stage breast cancer patients when comparing breast conserving therapy [(BCT) - breast conserving surgery with additional radiation therapy of the breast] and mastectomy (with/without breast reconstruction) [4–6]. Surgical treatment decisions should therefore be focused on (long-term) health related quality of life. Especially the understanding of PROMs is expected to greatly improve this complex shared treatment decision-making by giving insight in quality of life and daily functioning after certain treatment decisions. Although these PROMs comprise around 75% of the ICHOM breast cancer outcome set, not much data is available on 'reference scores' or expected scores per surgical treatment.

This study aimed to add knowledge on PROMs within a Dutch breast cancer population sample. Three breast cancer PROMs, as proposed in the ICHOM outcome set, were evaluated and compared to normative scores (obtained in non-breast cancer patients) and reference scores (obtained in breast cancer patients) available in literature. Patients were additionally asked to give satisfaction and expectation scores on the use of PROMs within clinical practice.

Material and methods

Study population

Participants were recruited via an online survey available from February 12th to March 13th 2017. The survey was available on the website of the Dutch breast cancer association [7] and the social media page of our institute [8]. The Dutch breast cancer association has a strong national online forum of approximately 2000 breast cancer patients [9]. To evaluate the PROMs following surgery or active breast cancer treatment breast cancer patients that had not undergone surgery (yet) or that had undergone surgery <6 months were excluded.

PROMs

All participants were asked to complete the PROMs as proposed in the international ICHOM breast cancer outcome set. The generic PROM EORTC-QLQ-C30 version 3, the disease specific-PROM EORTC-QLQ-BR23 version 1 and the BREAST-Q postoperative modules were used. Scores of the EORTC-QLQ-C30/BR23 range from 0 to 100. For the functional scales: 'Global Health status'/'Role functioning'/'Physical functioning'/'Emotional functioning'/'Social functioning' (EORTC-QLQ-C30) and the 'Body Image'/'Sexual functioning' (EORTC-QLQ-BR23) higher scores represent a higher quality of life. Higher scores at the symptoms scales: 'Pain'/'Fatigue' (EORTC-QLQ-C30) and 'Breast symptoms'/'Arm symptoms' represent less functioning or more symptoms experienced by participants.

The modules of the BREAST-Q used were dependent on type of surgery performed; the breast conserving therapy module, mastectomy module or the reconstructive module. For all modules scores range from 0 to 100 in which higher scores represent higher functioning/quality of life. Differences as compared to the ICHOM breast cancer set were the use of the 'Psychosocial, Physical and Sexual well-being' modules of the postoperative BREAST-Q (i.e. not only 'the satisfaction with breast' module). PROM scores were calculated according to the questionnaires' scoring protocol. Modules were judged as incomplete according to the questionnaires' protocol [10]. Normative scores (i.e. scores obtained in the general population/non-breast cancer patients) or reference scores (i.e. scores obtained in breast cancer patients) were used to compare the PROM scores of the current survey. For the BREAST-Q normative scores reported by Mundy and colleagues were used [11], who evaluated scores obtained using the preoperative modules in 1201

participants. Normative scores of the EORTC-QLQ-C30 were based on an evaluation of 7802 healthy participants [12]. Since no normative scores are available for the EORTC-QLQ-BR23 reference scores (obtained in breast cancer patients) were used [12]. The reference scores available for the EORTC-QLQ-C30 were additionally compared to the current cohort by graphically displaying the means and standard deviations of the different populations.

Procedure

Participants recruited by the Dutch breast cancer association were redirected to the survey after completion of 6 questions introducing the VBHC-initiative (data shown in online forum B-force) [9]. Participants were asked to report their age, time since surgery and the type of surgery performed. The survey was ended if participants had not undergone breast cancer surgery (yet). All other participants were directed to the PROMs. Following the completion of the PROMs participants were asked to answer three additional (self-made) questions on their satisfaction with and expectations of the routine use of PROMs (optional). The first questions asked if participants thought that PROMs used in the context of VBHC could aid in the care for future breast cancer patients (yes/no). Second, participants were asked if they experienced the PROMs as helpful to gain insight in their current functioning (yes/no). Acceptability of the PROMs was scored as; 'Very acceptable'/'Acceptable'/'Average'/'Not acceptable' or 'Other'. Surveys were considered as complete when the questions regarding the respondents characteristics were completed and all 4 PROMs were activated.

Statistics

All data were analysed with SPSS version 21 (IBM). To compare the different surgeries (i.e. BCT, mastectomy alone, mastectomy followed by implant reconstruction and mastectomy followed by autologous reconstruction) with non-parametric continuous variables (age, duration questionnaire) the Kruskal-Wallis test was used. Surgical groups and categorical variables (time since surgery, 'satisfaction and expectations'-questionnaire) were compared using the Chi-square test. The one-way ANOVA was used to compare parametric continuous variables (PROMs) between surgical groups. Post-hoc analyses were performed with the two-sided Dunnett *t*-test using breast conserving therapy as a control group. The correlation between PROMs was calculated using the Pearson correlation coefficient. A correlation coefficient (*r*) of <0.4 was rated as a 'weak' correlation, 0.4–0.59 as 'moderate' and ≥ 0.60 as a 'strong' correlation [13]. A *p*-value <0.05 was considered statistical significant. Additionally the R^2 statistic was calculated to evaluate the proportion of variance explained by the correlation between PROMs evaluated. True correspondence was evaluated for scores present in the 4th (upper) quartile of the EORTC-QLQ-C30/BR23 and the BREAST-Q (number of participants/total participants per questionnaire with scores in the 4th quartile for both questionnaires).

Results

A total of 624 patients activated the online survey of which 72.6% and 27.4% respectively from the national and local patients advocate society (Fig. 1). Twenty-four (3.8%) questionnaires contained no data and were excluded. Additional exclusions were based on 21 (3.4%) participants that had not undergone breast cancer surgery (yet), 30 (4.8%) that had undergone breast surgery <6 months and 53 (8.5%) that did not activate all 4 PROMs. Of the included participants 9 (1.8%) did not complete the 'satisfaction and

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