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The early development phases of a European Organisation for Research and Treatment of Cancer (EORTC) module to assess patient reported outcomes (PROs) in women undergoing breast reconstruction ☆,☆☆

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Abstract ***Introduction:*** A comprehensive evaluation of breast reconstruction (BRR) surgery includes measurement of patient reported outcomes (PROs). There is, however, a lack of validated BRR-specific PRO measures (PROMs) that adequately assess relevant issues. This study is developing a European Organisation for Research and Treatment of Cancer (EORTC) questionnaire/module specific for PROs in BRR to supplement the cancer-core and breast cancer EORTC questionnaires, respectively: the QLQ-C30 and QLQ-BR23.
Methods: Phases I and II of questionnaire development followed EORTC guidelines including a systematic literature review to identify all potential 'issues' (concepts relevant to PROs) and semi-structured interviews with 89 patients and 9 European multi-disciplinary health care professionals (HCPs) (Sweden, Italy and the United Kingdom [UK]). Interviewers asked participants the 'relevance' of outcomes identified in the literature and captured additional 'issues' of importance.

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Results: The literature search and interviews of patients and HCPs yielded 69 issues relating to BRR operationalised into 31 provisional items (single questions) for the module, which was conceptualised to contain five scales: treatment/surgery related symptoms (affecting the shoulder, arm and reconstructed breast), body image, sexuality, cosmetic outcomes (pertaining to three areas: breast, donor site and nipple) and overall satisfaction.

Discussion: The provisional development of the EORTC BRR module has 31 items addressing issues of importance to patients as well as HCPs. Further international testing is underway as a UK National Cancer Research Network trial to ensure that this PROM will be psychometrically and clinically robust and applicable for use in clinical trials, cohort studies, national audit and clinical practice.

1. Introduction

Of the 44,000 women diagnosed annually with breast cancer in the United Kingdom (UK) approximately 30–40% will undergo mastectomy.[1,2] There is a consensus that this surgery may have important consequences on patient reported outcomes (PROs): including the patients' self-report of psychosocial, physical, aesthetic, body image and sexual effects.[3]

Increasingly, there is an emphasis on the importance of assessing PROs as well as surgical outcomes relating to complications.[4] A PRO should assess the impact of disease, treatment and surgical intervention on various aspects of a patient's outcome, as well as being clinically meaningful, scientifically sound and practical.[4,5] The significance of assessing the patient's perspective has contributed to the inclusion of PROs into UK National Institute of Clinical Excellence (NICE) guidelines assessing clinical outcomes after breast reconstruction.[6,7]

Breast reconstruction (BRR) may either occur at the time of mastectomy (immediate) or as a delayed procedure.[8] The incidence of BRR is increasing annually with 21% of the 17,000 women after mastectomy electing a BRR.[2,9] The range of BRR procedures consists of implant only techniques, vascular pedicled flaps comprising abdominal skin, fat and muscle such as the TRAM (Transverse Rectus Abdominus) flap or the back flap using the latissimus dorsi (LD) muscle.[8] These may comprise autologous tissue only or be implant-assisted. [8] A micro vascular 'free' tissue flap using the Deep Inferior Epigastric Artery Perforator (DIEAP) transfers abdominal skin and fat.[8] Two systematic reviews on the effects of the types and timings of breast reconstruction on PROs showed that 76% (26 out of 34) of studies used generic patient reported outcome measures (PROMS) such as the Short-Form (SF)-36 questionnaire that assesses eight different health related quality of life (HRQL) domains with summary physical and mental scales.[3,10] The breast cancer symptom-specific questionnaires were the Functional Assessment of Cancer Therapy for Breast Cancer or FACT-B,[11] employed in seven studies with a further two studies choosing the European Organisation for Research and Treatment of Cancer (EORTC) Breast Cancer Module, EORTC QLQ-BR23.[12] The Hopwood Body Image Scale (BIS) was utilised in five studies.[13] No studies used validated surgery-specific questionnaires in BRR.[3,5,10]

Historically, two PROMS were psychometrically developed for BRR; the Breast-Related Symptoms Questionnaire (BRSQ) and the Michigan Breast Reconstruction Outcomes Study (MBROS) Satisfaction (MBROS-S) questionnaire with limited validity for all techniques.[5] Both the MBROS-S and the BRSQ have been criticised for no formal item reduction and content limitations like aesthetics and body image.[5] In 2009, the BREAST-Q was validated in BRR patients in the United States of America (USA).[14] This was developed using Rasch methodology to predict individual item responses and evaluate changes in an individual's HRQL. By comparison this module is aimed at assessing HRQL changes across treatment groups.[4,14,15]

The aim of this study was to develop the first European multicultural breast reconstruction-specific pre- and post-operative PROM which would allow for comparison of PROs between different BRR techniques and provide a reference point for comparisons between surgical populations and improve patients and Health Care professionals (HCPs) surgical decision-making.[2,8,16,17] This PROM is aimed for use alongside the EORTC QLQ-C30 and BR23 to assess PROs in women undergoing mastectomy for invasive breast cancer, ductal carcinoma in situ or prophylactic surgery within audits, prospective cohorts and clinical trials.

2. Methods and materials

Ethics approval was obtained from participating European centres (UK, Italy and Sweden). Eligible patients were required to have: (a) been diagnosed with breast cancer or Ductal Carcinoma in situ (DCIS) requiring mastectomy, (b) undergone breast reconstruction, (c) no other malignancy and (d) to speak and understand the respective language of the questionnaire. A purposive sample was chosen with variations of age, socio-economic characteristics and types of surgery including adjuvant treatments.

This module was developed in collaboration with the EORTC Quality of Life Group[18] that recommend 4