BMJ Open

Chinese multicentre prospective registry of breast cancer patient-reported outcome-reconstruction and oncoplastic cohort (PRO-ROC): a study protocol

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To cite: Li L, Yang B, Li H, *et al*. Chinese multicentre prospective registry of breast cancer patient-reported outcome-reconstruction and oncoplastic cohort (PRO-ROC): a study protocol. *BMJ Open* 2019;**9**:e032945. doi:10.1136/bmjopen-2019-032945

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2019-032945).

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Received 22 July 2019
Revised 29 October 2019
Accepted 07 November 2019

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ABSTRACT

Introduction Available patient-reported outcome (PRO) studies are mainly from single institution or of small sample size, and the variations across hospitals and regions were not fully analysed. A multicentre, prospective, patient-reported outcome-reconstruction and oncoplastic cohort (PRO-ROC) will be planned to assess the PROs of Chinese patients with breast cancer who will undergo breast reconstruction (BR) or oncoplastic breast-conserving surgery (OBCS).

Methods and analysis The inclusion criteria are female patients with breast cancer aged >18 years old who will undergo BR or OBCS. This cohort will include at least 10 000 consecutive patients (about 5000 patients who will undergo BR and 5000 patients who will undergo OBCS). The exposures were surgery types: BR and OBCS regardless of the techniques and materials used. The primary endpoint will be PROs, which include BREAST-Q and quality of life (European Organisation for Research and Treatment (EORTC) Quality of Life Questionnaire Core 30 (QLQ-C30) and EORTC QoL Breast Cancer-specific version (QLQ-BR23)). All patients will be followed up to 24 months after operations. All data will be prospectively collected using an app software. Data will be analysed using SPSS and Stata software.

Ethics and dissemination This study follows the Helsinki Declaration. All patients will be asked to sign an informed consent before enrolment. The results of this study will be presented at national and international meetings and published in a scientific peer-reviewed journal.

Trial registration number NCT04030845; Pre-results.

Strengths and limitations of this study

- This cohort study will be the largest cohort focusing on breast reconstruction (BR) and oncoplastic breast-conserving surgery (OBCS) in China.
- This large cohort will provide us patient-reported outcomes after BR and OBCS in China and determine the factors that affect patient satisfaction.
- This study will also provide an assessment of the complications of BR and OBCS in China and explore variables that might affect the occurrence of complications.
- This study will develop standards for indicators, risk and prognosis of BR and OBCS, and provide suggestion for future clinical practice and research.

BACKGROUND

Patient-reported outcome measures' (PROMs) is a term that applies specifically to a questionnaire used in clinical or research settings where responses are collected directly from patients.[1 2] PROMs cover various domains of a patient's experience, including quality of life (QoL), symptoms, patient satisfaction, physical and social functional abilities, and psychosocial concerns.[3 4] PROMs provide insight into how patients perceive health and treatment effects, and how treatments impact outcomes, and are helpful in determining how disease and interventions impact on patients' life.[5] Patient-reported outcomes (PROs) have become more and more popular in clinical and research settings. Mercieca-Bebber *et al*[6] showed that in 13 666 registered trials from Australian New Zealand Clinical Trials Registry, 6168 (45.1%) trials included a PRO, and the proportion of studies including PROs increased from 2006 to 2016. A randomised controlled trial (RCT) showed monitoring of common symptoms using PROMs might improve patients' survival (1-year survival rate: 75% vs 69%, p=0.05) and quality-adjusted survival (8.7 vs 8.0 months, p=0.004).[7]

In the current healthcare environment, patients and providers try to seek meaningful data to guide clinical decisions; policy makers are similarly in need of a rigorous patient-centred, comparative effectiveness data to inform national-level

decision-making.[8] PRO data can be helpful when assessing existing treatment options for patients.[9] For patients with breast cancer, there might be no statistical significance in survival benefits among different surgery options, such as oncoplastic breast-conserving surgery (OBCS) and breast-conserving surgery (BCS), and mastectomy with or without breast reconstruction (BR). But different surgery methods might be associated with different experiences and levels of stratification. Further, surgery options might influence further adjuvant treatments, and finally affecting PROs. For example, postmastectomy radiotherapy was associated with poorer outcomes in patients who underwent BR.[10] Plenty of evidence showed adjuvant radiotherapy as a risk factor for postoperative complications including capsular contracture in the reconstructed breast.[11–13]

In plastic surgery, PROs are more important as they reflect patients' perceptions of surgical results and their impact on QoL, and appraise the benefits and problems of a chosen surgical technique and further improve patient-centred care and symptom management.[1] Assessing PROs in plastic surgery could also provide surgeons with valuable insight into patients' concerns and a more complete picture of patients' symptoms and problems.[1 4] Available evidence showed BR and OBCS might be associated with improved PROs as compared with mastectomy,[14–16] although the current evidence base is limited and not adequate enough. A recent systematic review summarised the current literature on patient QoL after OBCS compared with that after BCS alone; however, the included studies were characterised by a small sample size, usually drawn from a single institution; heterogeneity in surgical techniques; and had significant methodological flaws.[15] These kinds of variations could also be observed in BR studies. The Mastectomy Reconstruction Outcomes Consortium Study showed racial, ethnic and hospital variations in clinical outcomes and PROs following BR.[17 18] High-quality, multicentre studies on BR with large sample size are few. Poor evidence from available studies might not be able to inform choices about the best method of reconstruction to use, which generates unreliable and confusing information about indications, risk factors and outcomes.[19]

To overcome the limitations of available studies and further assess the PROs of Chinese patients with breast cancer who will undergo BR or OBCS, we designed a prospective, multicentre cohort study, which was named as patient-reported outcome-reconstruction and oncoplastic cohort (PRO-ROC).

Study objectives

PRO-ROC study aimed to (1) evaluate the PROs of Chinese patients with breast cancer who will undergo BR or OBCS, and (2) analyse the variations among hospitals, standardise the surgery pathway and patient care, and generate standards for indications, risk factors and outcomes of BR and OBCS in China.

METHODS AND ANALYSIS

Study type

PRO-ROC study is a multicentre, prospective, hospital-based cohort study.

Study population

Only adult (>18 years old) female patients with breast cancer who will undergo BR or OBCS are included. No restrictions are applied to surgery types, so nearly all kinds of BR or OBCS will be included. All patients will be asked to sign an informed consent before enrolment and data collection.

Patients with breast cancer are confirmed by histopathological evaluation without distant metastasis (M0). Patients must fulfil indications of breast cancer surgery according to the National Comprehensive Cancer Network (NCCN) clinical guidelines and do not have any absolute contraindications. Both prophylactic and therapeutic mastectomies will be included. Key exclusion criteria are younger (<18 years old) patients, male, patients with stage IV breast cancer or those who refuse to undergo BR or OBCS.

Sample size

According to a survey on the breast surgery situation across hospitals in China,[20] there were about 85 772 patients who received mastectomies or BCS from 110 hospitals in 2017. About 10.7% of patients underwent BR and 8.8% underwent OBCS.

During the first stage of this cohort study (July 2019–September 2019), about 100 consecutive patients from Fudan University Shanghai Cancer Hospital were recruited to test our data collection platform. Every year in Fudan University Shanghai Cancer Hospital, there might be 600 BR and 1500 OBCS performed. We have finished the first stage of the study. During the second stage of this cohort study (October 2019–October 2020), at least 10 centres in China will participate. These centres must be hospitals with at least 50 patients who undergo BR and OBCS every year. During the third stage (October 2019–October 2020), another 10 centres will participate in this study. In total, about 20 centres will be involved.

There will be 20 centres that will participate in this cohort, and each centre will recruit 50 consecutive patients for each surgery method (BR 50 cases, OBCS 50 cases), so about 10 000 consecutive cases (BR 5000 cases, OBCS 5000 cases) will be included. The patient recruitment process will begin in October 2019 and finish in October 2022. All patients will be followed up at 24 months.

Exposures

The exposures are surgery types: BR and OBCS. BR mainly included autologous tissue flaps (latissimus dorsi myocutaneous flaps, pedicled transverse rectus abdominis myocutaneous flaps, free transverse rectus abdominis musculocutaneous flaps, deep inferior epigastric

artery perforator flaps and so on), implant-based BR, autologous flaps combined with implant reconstruction, fat graft and so on. OBCS were mainly surgeries using volume displacement or volume replacement techniques.

Outcome measures

Primary outcomes

The first primary outcomes are PROs, which include BREAST-Q and QoL (European Organisation for Research and Treatment (EORTC) Quality of Life Questionnaire Core 30 (QLQ-C30) and EORTC QoL Breast Cancer-specific version (QLQ-BR23)). BREAST-Q is a widely used PRO instrument measuring QoL and patient satisfaction in breast surgery.[21] The BREAST-Q questionnaire includes satisfaction with breast, surgical outcome, physical well-being and the surgeon, and has multiple versions of procedure-specific modules.[22 23] BREAST-Q captured meaningful and reliable information regarding QoL and patient satisfaction from patients' perspectives in both clinical practice and research settings and may be useful in clinical decision-making.[24 25] A recent systematic review showed that BREAST-Q can effectively measure patients' satisfaction and QoL in relation to different types of oncoplastic breast surgeries.[24]

The other two well-known QoL instruments that have been validated for breast cancer are the EORTC QLQ-C30 and EORTC QLQ-BR23 measures. EORTC QLQ-C30 was developed by EORTC as a general QoL tool in 1986,[26 27] and EORTC QLQ-BR23 was constructed as a breast cancer-specific QoL questionnaire module which was used in conjunction with EORTC QLQ-C30.[27 28] EORTC QLQ-C30 has 30 items that form five functional scales (physical, role, emotional, cognitive and social), a global QoL scale, three symptom scales (fatigue, pain, and nausea and vomiting), five single-item symptom measures (dyspnoea, insomnia, appetite loss, constipation and diarrhoea) and one financial impact question.[29] The QLQ-BR23 module consists of 23 items from five domains: body image, systemic therapy side effects, breast symptoms, arm symptoms and sexual functioning.[29] These two questionnaires are feasible and promising instruments to measure the levels of QoL of women with breast cancer in many countries,[26–28] and are reliable and valid measures of the QoL of patients with breast cancer in clinical research settings.[16 26 28 30]

Secondary outcomes

Secondary outcomes include patient-reported cosmetic outcomes, complications (including overall complication, implant loss, seroma, wound skin infection, nipple or skin flap necrosis, haematoma, reoperation, wound dehiscence, capsular contracture), breast aesthetics and prognosis. Prognosis was assessed using overall survival (OS) and recurrence-free survival (RFS). RFS was calculated as time from breast cancer diagnosis until locoregional or distant recurrence, or death due to breast cancer, whichever came first.[31 32] OS was defined as the time from starting the treatment to the time of death from any cause, or the date of last contact if death was not recorded before the cut-off date.

Pictures of patients (anterior, lateral, three-fourths angled view from both sides) will be taken[29] at baseline (before surgery) and at 3, 12 and 24 months postoperatively to assess breast aesthetics. For those who will undergo radiotherapy, the photographs will be taken before radiotherapy. Change in photographic breast appearance was assessed at 3, 12 and 24 months postoperatively and compared with the baseline photograph, before and after radiotherapy. Breast size and surgical deficit were scored from the baseline photographs on a 3-point scale (small, medium, large).[33 34] After radiotherapy, change in breast appearance (none/mild/marked) was scored on a pair of photographs with standard positions in comparison with the baseline photograph.[33 34] A panel of at least three independent observers blinded to patient identity, treatment allocation and radiotherapy centre scored the photographs.[33 34]

Patient and public involvement

Patients and the public were not involved in the design of the study, and in the recruitment to and conduct of the study. The development of the research question and outcome measures was not informed by patients' priorities and preferences, but the aim of this study was to evaluate and collect patients' experience, including QoL, symptoms, physical and social functional abilities, and psychosocial concerns. Healthcare providers and hospital staff will support this work through outcomes assessment and data collection. No patient advisers were involved in this study.

Follow-up

The surgeons will assess whether the patients fulfil the indicators and the patients have the intention to undergo BR and OBCS. If so, investigators will ask them to sign an informed consent. After the surgery, investigators will check whether they undergo BR and OBCS. If they do, investigators will interview them during the hospital stay, 3, 12 and 24 months after the surgery. If not, the patients will not be followed up.

Before surgery, patients' information, clinical and pathological characteristics, commodity, and breast size measurement will be recorded. During the hospital stay, only complications and pain will be assessed. Postoperatively, at 12 and 24 months, BREAST-Q, QoL (EORTC QLQ-C30 and EORTC QLQ-BR23), patient-reported cosmetic outcomes, clinician-reported cosmetic outcomes (CRO) and photographs, prognosis, and long-term complication will be evaluated. The PROs will be delivered to patients via an app software on iPad or WeChat platform. We have developed an app software that could collect patient characteristics and patient responses to PRO questionnaires. Patients could also be allowed to fill the questionnaires via WeChat platform at home and

send us pictures of their breast to inform the surgeons where they were unsatisfied with.

Data collection and management

We developed an app software to collect all information. The items we will collect include patient information, clinical and pathological data, surgery information, BREAST-Q, QoL (EORTC QLQ-C30 and EORTC QLQ-BR23), patient-reported cosmetic outcomes, complications (including overall complication, implant loss, seroma, wound skin infection, nipple or skin flap necrosis, haematoma, reoperation, wound dehiscence, capsular contracture), CRO and photographs, neoadjuvant and adjuvant treatments, and prognosis.

Statistical analysis

Data will be analysed using SPSS 21 and Stata version 12 software. The dichotomous outcomes will be expressed using proportion, and the continuous outcomes will be assessed using mean values and SE. Proportional differences between groups will be tested with Pearson's χ^2 test. t-Test will be used for continuous outcomes between two groups and one-way analysis of variance for outcomes across groups. Univariate and multivariate logistic regression analyses will be performed to examine the associations between independent variables and outcomes. All available independent variables were considered in the univariate regression model, and only significant variables ($p<0.1$) will be included for further multivariate logistic regression analyses. All tests were two-sided and a p value of less than or equal to 0.05 was considered significant.

DISCUSSION

Breast cancer surgery change with times. According to a national survey in China, the BCS rate increased from 1.29% in 1999 to 11.57% in 2008.[35] Last year, we conducted a survey on the breast surgery situation across hospitals in China; there were about 85 772 patients who received mastectomies or BCS from 110 hospitals in 2017. About 22% of patients underwent BCS and 10.7% underwent BR. However, only 4.5% of patients underwent BR in 2012.[36] Until now, no multicentre, prospective cohort studies have been conducted to investigate PROs of Chinese patients with breast cancer who received BCS or BR.

Studies showed that outcomes were scored differently by patients and professionals, and CRO and photographs might underestimate complications as compared with PROs.[33 37] Sparano *et al*[3] systematically investigated the concordance between clinician-reported symptomatic adverse events (AEs) and information obtained via PROMs in 207 cancer RCTs, and found that 64.2% RCTs showed a discordance in AEs between PRO and CRO. Brands-Appeldoorn *et al*[37] showed agreement between professionals and patients about cosmetic outcomes was fair to moderate (intraclass correlation coefficients (ICC) range: 0.38–0.50). Other studies also confirmed that the overall concordance between clinicians and patients is low.[38] This implied the importance of PRO assessments in patients with breast cancer.

The PRO scores might serve as a reference value for different types of surgery and enable prospective use of PROs in shared decision-making.[16] Using PRO in surveillance of patient satisfaction and complications might increase patient involvement in cancer treatment, which was highlighted as goals in some countries.[39] PROMs have the potential to improve quality of care with proper implementation in routine practice.[40] PROMs are subjective measurements that may enable reliable analyses of postoperative QoL and general satisfaction from the patient's perspective rather than from the surgeon's.[22] PROMs can be used to identify patients who experience a heavy burden of side effects, requiring specific attention.[41] A systematic review of 24 unique controlled trials showed PROMs are associated with improved symptom control, increased supportive care measures and patient satisfaction, and the routine use of PROMs increases the frequency of discussion of patient outcomes during consultations.[42] Monitoring of common symptoms using PROMs might improve patients' survival compared with usual care.[7]

OBCS provides an acceptable oncological long-term outcome and can be used to also treat, along with conservative surgery, a selected population of patients who otherwise would have undergone mastectomy in the past.[43] Jay *et al*[44] showed BCS appears superior to mastectomy in terms of satisfaction with breasts, sexual well-being, and now psychosocial well-being. Davis *et al*[45] revealed patients undergoing mastectomy were at an increased risk of reporting moderate-to-severe depression (Relative Risk (RR)) 1.19, 95% CI 1.09 to 1.30), lack of appetite (RR 1.11, 95% CI 1.03 to 1.20) and shortness of breath (RR 1.16, 95% CI 1.04 to 1.15) compared with those undergoing lumpectomy plus radiation based on 13 865 patients with stage I–II breast cancer. Postmastectomy BR could be offered to women undergoing mastectomy in order to restore form and function, and improve psychosocial and physical well-being, long-term health, and patient satisfaction compared with patients who have undergone mastectomy without reconstruction.[46–49] However, traditional measures are insufficient to capture the benefits of BR and OBCS; the utilisation of PROMs has become an important tool to measure the effects and allow comparison of different methods in a meaningful way from the perspective of the patient.[49]

In our study, the PROs will be assessed using BREAST-Q and EORTC-QLQ-C30/BR23. This is because these three together could comprehensively assess QoL, which was defined as the assessment of at least three domains of well-being, which are physical, emotional and social.[27] Meanwhile, we will assess the complication and cosmetic outcomes based on patient-reported data. Cosmetic outcome is an important QoL-related endpoint.[50] Lagendijk *et al*[50] showed at least BREAST-Q should be combined with a panel or BCCT.core evaluation in order to enable standardised

cosmetic outcome evaluation and corresponding patient satisfaction. In our study, we will assess cosmetic outcomes with a panel and BREAST-Q together.

Strengths and limitations

We proposed the study design and finished the discussion about study design, data collection methods and data management. This cohort study will be the largest cohort focusing on PROs about BR and OBCS in China. This large cohort will provide us PROs after BR and OBCS in China, and determinethe factors that affect patient satisfaction. This study will also provide an assessment of the complications of BR and OBCS in China, and explore variables that might affect the occurrence of complications. This study will also develop standards for indicators, risk and prognosis of BR and OBCS, and provide suggestion for future clinical practice and research. However, our study is not a randomised controlled study, which might only reflect the actual status of BR and OBCS in China. Meanwhile, the follow-up of this study was 24 months, long enough for the PROs for patients with BR, but short for the prognosis. Although this study was designed to follow up for about 2 years, we will keep an eye on the PROs and prognosis for a longer time. For patients in our centre (Fudan University Shanghai Cancer Hospital), we have our own team for survival follow-up, so the long-term survival data will be available for these patients. However, for patients in other centres, data on long-term survival will not be available.

Ethics and dissemination

This study follows the Helsinki Declaration. Patients will be told the details of the study (purpose, risk and benefits), and patients have the right to quit any time. An informed consent form will be sent to each patient prior to enrolment to ensure that each patient understands the cohort study. The process of obtaining informed consent is in accordance with the Good Clinical Practice of Pharmaceutical Products (GCP) requirements. The results of this study will be presented at national and international meetings and published in a scientific peer-reviewed journal.

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Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Approval of this study was provided by the independent ethical committee and institutional review board of FUSCC (Fudan University Shanghai Cancer Center).

Provenance and peer review Not commissioned; externally peer reviewed.

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