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Protocol for a multicentre, prospective, cohort study to investigate patient satisfaction and quality of life after immediate breast reconstruction in Japan: the SAQLA study

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ABSTRACT

Introduction The aim of breast reconstruction (BR) is to improve patients' health-related quality of life (HRQOL). Therefore, measuring patient-reported outcomes (PROs) would clarify the value and impact of BR on a patient's life and thus would provide evidence-based information to help decision-making. The Satisfaction and Quality of Life After Immediate Breast Reconstruction study aimed to investigate satisfaction and HRQOL in Japanese patients with breast cancer who undergo immediate breast reconstruction (IBR).

Methods and analysis This ongoing prospective, observational multicentre study will assess 406 patients who had unilateral breast cancer and underwent mastectomy and IBR, and were recruited from April 2018 to July 2019. All participants were recruited from seven hospitals: Okayama University Hospital, Iwate Medical University Hospital, The Cancer Institute Hospital of Japanese Foundation for Cancer Research, Showa University Hospital, University of Tsukuba Hospital, Osaka University Hospital and Yokohama City University Medical Center. The patients will be followed up for 36 months postoperatively. The primary endpoint of this study will be the time-dependent changes in BREAST-Q satisfaction with breast subscale scores for 12 months after reconstructive surgery, which will be collected via an electronic PRO system.

Ethics and dissemination This study will be performed in accordance with the Ethical Guidelines for Medical and Health Research Involving Human Subjects published by Japan's Ministry of Education, Science and Technology and the Ministry of Health, Labour and Welfare, the modified Act on the Protection of Personal Information and the Declaration of Helsinki. This study protocol was approved by the institutional ethics committee at the Okayama University Graduate School of Medicine, Dentistry, on 2 February 2018 (1801-039) and all other participating sites. The findings of this trial will be submitted to an international peer-reviewed journal.

Trial registration number UMIN000032177.

Strengths and limitations of this study

- The Satisfaction and Quality of Life After Immediate Breast Reconstruction will be the first prospective, multicentre study in Japan to investigate satisfaction and health-related quality of life (HRQOL) after immediate breast reconstruction (IBR).
- Time-dependent changes in BREAST-Q scores after reconstructive surgery will be informative and will aid patients in decision-making.
- The Decision Regret Scale has been added to better understand the impact of breast implant recall.
- The results of this study may represent the satisfaction and HRQOL of patients in relatively good condition after IBR.

INTRODUCTION

Background and rationale

Breast cancer is the most common type of cancer in Japanese women. One in 11 Japanese women will develop breast cancer over the course of her lifetime.[1] The number of newly diagnosed cases was over 76 000 in 2014,[1] and the incidence rate is increasing. In terms of age, the incidence begins to increase from the age of 30 years and peaks in the 40s to the 60s.[1] As the survival rate of breast cancer increases,[2] the health-related quality of life (HRQOL) of survivors has become more important in deciding the course of treatment.

Breast reconstruction (BR) after mastectomy is a surgical option to restore the breast shape. It has been recognised as a part of comprehensive breast cancer surgery to

improve patients' HRQOL and satisfaction.[3–9] In Japan, autologous BR has been covered by the National Healthcare Insurance (NHI) since 2006, while implant-based reconstruction has been covered since 2013. The number of immediate Breast reconstruction (IBR) cases has rapidly increased since that time and reached 4700 in 2018, with 70% being implant-based procedures.[10–12]

Despite this, some problems remain for patients making BR decisions. BR has potential risks and additional burdens compared with mastectomy without BR. Insertion of a silicone breast implant involves risks of infection, rupture and deformation caused by capsule contracture,[13–15] and autologous reconstruction involves the sacrifice of donor sites and the risk of flap necrosis.[16–18] Evidence-based information about the available reconstruction options is needed, including the possible complications, HRQOL prognosis and patients' perception of cosmetic results to help patients know what to expect after BR.[19–21]

In the past decade, patient-reported outcomes (PROs) have been used to understand how BR impacts a patient's life and to measure the value of BR.[7 22–26] Among these PROs, the BREAST-Q,[24] the first BR-specific instrument, has been most commonly used worldwide because of its high validity. It enables evaluation of the outcome of BR in terms of various aspects, such as aesthetic satisfaction, physical well-being, psychosocial well-being and satisfaction with care. Research conducted using the BREAST-Q has provided much of the important information about BR.[7–9] A recent large prospective cohort study in North America, the Mastectomy Reconstruction Outcome Consortium, enrolled over 4400 women and demonstrated that HRQOL and satisfaction after autologous reconstruction were higher than after implant-based reconstruction, and that postmastectomy radiation therapy was better tolerated.[9 27] They also investigated the recovery phase and reported that many participants may not be fully recovered at 3 months postoperatively, regardless of the reconstruction procedure, and that patients who underwent abdominal-based autologous reconstruction had lesser chest and upper extremity morbidities.[21]

Evidence regarding BR is being developed in Western countries, although there is very little evidence from Japan. Since there are physical, psychological and cultural differences between Western and Japanese women, investigations in Japanese cohorts are essential to improve medical care.[4 28 29] The healthcare environment also differs between countries, and there are some limitations in terms of BR performed under medical insurance in Japan. The acellular dermal matrix that supports the lower pole of the breast in implant-based reconstruction,[30] which is more commonly used in other high-income countries, is not available in Japan; therefore, most implant cases require a staged procedure. Risk-reducing mastectomy (RRM) for hereditary breast and ovarian cancer has been covered by the NHI since April 2020 and is limited to women who have already developed breast or ovarian cancer; therefore, currently, fewer women in Japan undergo RRM and bilateral BR.[31] Types of implants covered under the NHI have been limited to Allergan products; therefore, Allergan's July 2019 recall of Biocell textured breast implants due to the risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)[32–35] had a significant impact on women who had undergone implant-based reconstruction in Japan, as well as those who were undergoing the reconstruction.

Objective

The aim of this study, the Satisfaction and Quality of Life After Immediate Breast Reconstruction (SAQLA) study, was to investigate the satisfaction and HRQOL in Japanese patients with breast cancer following mastectomy and IBR to further understand their experience. We will focus on differences due to the reconstructive procedure so as to provide useful information for decision-making in BR. This will be the first prospective, multicentre study in Japan to investigate the time-dependent change in BREAST-Q scores, which will contribute fundamental data for future clinical research leading to new hypotheses and evidence for Japanese patients with breast cancer.

In addition, since Allergan's recall occurred during the study period, just before recruitment was closed, we will also explore how it affected our participants by watching for trends in participants opting out of reconstruction surgery or changing their chosen reconstruction procedure, and evaluating their regrets about their decision.

METHODS AND ANALYSIS

Design and setting

This study was designed as a multicentre, longitudinal, observational study. All participants were recruited from seven major BR hospitals: Okayama University Hospital, Iwate Medical University Hospital, The Cancer Institute Hospital of Japanese Foundation for Cancer Research, Showa University Hospital, University of Tsukuba Hospital, Osaka University Hospital, and Yokohama City University Medical Center. The study is currently ongoing. Recruitment began in April 2018 and closed in July 2019. A total of 406 patients are enrolled in the study and they will be followed up for 36 months postoperatively.

Patients and recruitment

The eligible subjects are those diagnosed with initial unilateral breast cancer and are scheduled for mastectomy and IBR. All participants undergo regular treatment at their participating sites. The breast reconstructive procedures include implant-based reconstruction, latissimus dorsi flap and abdominal flaps, including deep inferior epigastric artery perforator flap, transverse rectus abdominus myocutaneous flap and superficial inferior epigastric artery perforator flap, all of which are commonly practised in Japan. Potential participants were recruited at each site before surgery if they fulfilled all the inclusion criteria and did not meet any of the exclusion criteria (box 1). The time between the diagnosis of breast cancer and recruitment into the study was not set. Consenting

Box 1 Eligibility criteria

Inclusion criteria

1. Pathological diagnosis of breast cancer.
2. Planned total mastectomy (including Bt, SSM and NSM).
3. Breast surgeon determined an indication for BR and IBR is scheduled.
4. Aged between 20 and 75 years.
5. ECOG PS of 0 or 1.
6. Written informed consent provided.

Exclusion criteria

1. Reconstruction for breast conserving surgery.
2. History of breast-conserving surgery.
3. History of ipsilateral BR (re-reconstruction).
4. Heterochronic and simultaneous bilateral breast cancer.
5. Breast shape has been remarkably changed by previous surgery, such as augmentation.
6. Difficulty participating in the study due to a mental condition.
7. Doctor indicates unsuitability for the study.
8. No possession of a device such as a smartphone, tablet or PC, and inability to respond to the ePRO at home.

BR, breast reconstruction; Bt, mastectomy; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ePRO, electronic version of the Patient-Reported Outcomes Questionnaire; IBR, immediate breast reconstruction; NSM, nipple-sparing mastectomy; PC, personal computer; SSM; skin-sparing mastectomy.

participants were then registered on the electronic data capture (EDC) system and study IDs were given.

Loss to follow-up

Observation will be discontinued if a participant meets any of the following conditions: (1) cancellation of BR due to patient's intention or treatment plan, (2) reconstruction failure, (3) recurrence or metastasis of breast cancer, (4) contralateral breast cancer, (5) malignant diseases other than breast cancer, (6) death of participant, (7) withdrawal of consent and (8) researchers' judgement that it is inappropriate to continue observation.

In this study, reconstructive failure is defined as a condition in which the reconstructed breast is removed, that is, flap loss and implant removal. Patients with reconstructive failure are rather devastated; we therefore regard the administration of a questionnaire about aesthetic satisfaction to be highly inappropriate in these patients. However, patients with other complications, such as haematomas, capsular contractures or fat necrosis, which may lead to impaired aesthetic results, will be followed up.

Outcomes

Primary and secondary outcomes

The primary endpoints of this study are the time-dependent changes in BREAST-Q satisfaction with breasts scores over 12 months after surgery. BREAST-Q evaluations will be performed at baseline and at 1, 3, 6 and 12 months postoperatively, and the scores will be analysed according to the BR procedure performed. The secondary endpoints include (1) the time-dependent changes in BREAST-Q subscale scores, including psychosocial well-being, physical well-being and sexual well-being for 12 months after surgery; (2) the time-dependent changes in Eight-Item Short-Form Health Survey (SF-8) summary score and physical and mental component summary score for 12 months after surgery[36]; (3) long-term patient satisfaction and HRQOL after IBR evaluated by BREAST-Q and SF-8 for up to 36 months; (4) the burden of IBR; (5) the complication rate; and (6) bilateral symmetry measured by the 4-point Harris Scale[37] and Mamma Balance.[38]

Patient-reported outcomes

We set the questionnaire items for satisfaction and HRQOL based on a core outcome set proposed by Potter *et al*.[39] BREAST-Q will be used for the measurement of satisfaction and HRQOL related to BR. The satisfaction with general health, which cannot be evaluated with BREAST-Q, will be measured using SF-8.[36] Ad hoc questionnaires to investigate the patient burden associated with IBR and motivation for further reconstructive procedures such as revision surgery or nipple reconstruction will also be used. Since depression and anxiety of preoperative patients may affect the level of postoperative satisfaction,[40] screening for depression/anxiety will be performed with Hospital Anxiety and Depression Scale (HADS)[41 42] at baseline. The baseline questionnaire also includes data on the participants' social background, such as education level, employment, income and marital status.

Following the Allergan implant recall, the distress with regard to the decision of BR will be assessed using the Decision Regret Scale (DRS)[43 44] 1 year after completing BR.

BREAST-Q

BREAST-Q is a self-administrated rating scale consisting of 15 subscales and 121 items that measure the effect of breast surgery on patient satisfaction and HRQOL. The recall period is the past week. There is a score for each subscale, and a higher score indicates a higher satisfaction level and QOL. The following subscales are used in this study: satisfaction with breasts, satisfaction with implant, psychosocial well-being, sexual well-being, adverse effects of radiation, physical well-being of chest and upper extremity, satisfaction with abdomen, physical well-being of abdomen, satisfaction with back appearance, and physical well-being of shoulder and back. A formal Japanese version was developed,[45] and the validation of the reconstruction module has been completed (Cronbach $\alpha>0.7$, inter-rater reliability (intraclass correlation coefficient (ICC)>0.8).

Eight-Item Short-Form Health Survey

This tool is a self-administered questionnaire consisting of eight items to evaluate HRQOL: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health. Based on the eight subscales, SF-8 can calculate two summary scores: a physical and a mental component summary.[36]

Hospital Anxiety and Depression Scale

HADS is a 14-item questionnaire that evaluates depression and anxiety. There are seven depression items and seven anxiety items which are scored separately. Each item is scored from 0 to 3 points, with a maximum subscale score of 21. A subscale score of more than 8 indicates anxiety or depression.[42]

Decision Regret Scale

DRS is a self-administered questionnaire consisting of five items that measures the distress or remorse after healthcare decisions. Possible score is 0–100, where higher scores indicate stronger regret. A formal Japanese version has been developed.[44] In this study, an item will be added to determine whether the implant recall affected the response to DRS.

Medical history and physical examination

The following medical history and physical examination data will be collected by researchers from medical records: age, breast cancer clinical stage, adjuvant therapy, body mass index (BMI), smoking habits, glycated haemoglobin, American Society of Anesthesiologists classification, regular administration of steroids and breast ptosis. Surgery-related factors to be collected on the day of surgery include reconstruction procedure, mastectomy procedure (nipple-sparing or skin-sparing mastectomy), axillary dissection or sentinel node biopsy, and weight of resected specimen. The factors that influence whether participants undergo additional reconstructive procedures such as nipple reconstruction, fat injection, revision of reconstructed breast or mastopexy of the contralateral breast will be collected at 12 and 36 months after reconstruction.

Complications of surgery

Complications related to BR procedures will be divided into four categories as follows: (1) complications of the breast area common to all procedures: postoperative haemorrhage, haematoma, seroma, wound dehiscence, wound infection, and skin and nipple–areola necrosis; (2) systemic complications common to all procedures; (3) complications related to tissue expansion (TE)/implant, infection or implant explantation; (4) autologous reconstruction-related complications: emergent additional surgery for blood flow insufficiency, flap necrosis, or donor-site complications. Complications will be graded according to the Japan Clinical Oncology Group postoperative complications criteria (Clavien-Dindo classification) V.2.0. Complications will be reviewed at 1, 12 and 36 months after surgery.

Cosmetic outcomes

Objective cosmetic outcomes of the breast will be evaluated by medical staff using photographs taken at 12 and 36 months after reconstruction. The following two methods will be used for evaluation: (1) Harris scale (4-point scale)[37]: classification of the global cosmetic outcomes into four categories (excellent, good, fair or poor) and (2) Mamma Balance[38] software that digitises the position difference between the left and right nipples and objectively evaluates bilateral symmetry. The ICC of this method is 0.78.

Sample size determination

The sample size was not calculated based on a statistical perspective. The number of target participants was determined as 400 patients based on the annual number of IBR cases in the participating seven sites and consideration of the eligibility criteria.

Data collection and timelines

This study will collect data using EDC systems, Viedoc V.4 and ePRO, ViedocMe (PCG Solutions, Sweden). Data entry into the electronic case report forms will be performed by researchers using the EDC at each hospital. The PRO questionnaire will be administered to patients using ePRO at nine study time points: at baseline and at 1, 3, 6, 12, 18, 24, 30 and 36 postoperative months through the patient's own device. Participants will be given the timeline of the survey and will complete the questionnaire in the scheduled survey

Table 1 Study timeline: patient-reported outcomes

	Time after breast cancer surgery								
	Baseline	1 month	3 months	6 months	12 months	18 months	24 months	30 months	36 months
HADS	●								
BREAST-Q	●	●	●	●	●	●	●	●	●
SF-8	●	●	●	●	●	●	●	●	●
Burden of BR		●	●	●	●	●	●	●	●
Motivation for further revision									●
DRS					●*				

*12 months after the second operation for patients who had staged reconstruction.
BR, breast reconstruction; DRS, Decision Regret Scale; HADS, Hospital Anxiety and Depression Scale; SF-8, 8-Item Short-Form Health Survey.

Table 2 Study timeline: clinician-reported outcomes

	Before breast cancer surgery	Day of surgery	After breast cancer surgery		After breast reconstruction*		
	On enrolment		1 month	12 months	1 month	12 months	36 months
Medical history and physical examination	●						
Surgery-related factors		●					
Review of complications			●		●	●	●
Review of adjuvant therapy				●			
Review of additional reconstructive procedure						●	●
Cosmetic outcome (photograph)						●	●

*Second operation for staged reconstruction.

period by accessing the ViedocMe website from a browser of their own smartphone. If the patient desires, she can register her email address or phone number in the Viedoc system and receive notifications to remind her of the survey. The central data manager will monitor the completion status of the questionnaire and notify the researchers at the respective sites of incomplete assessments. Thereafter, the researcher will contact the participant to request they complete the questionnaire within the survey period. Data regarding participants' medical history, physical examination, complications of surgery and cosmetic outcomes will be gathered by medical staff and entered into the EDC system on the web at each site and linked to the PRO data. The study timeline is shown in tables 1 and 2.

Data management, data monitoring and auditing

The data centre is located in the Department of Clinical Trial Data Management, Tokyo University Graduate School of Medicine, Tokyo, Japan. No personally identifiable information will be entered into the EDC to protect participants' privacy. Data management and central data monitoring will be performed using the EDC. There will be no data monitoring committee. Similarly, auditing is also not planned for this study. Following completion of the study, the fixed data will be exported and then deleted from the EDC. The data will be stored in a public data repository.

Harms

No serious harm is expected in this observational study. Some patients might feel psychological distress when asked about their sexual well-being.[45] The estimated time to complete a survey is about 10 min, and this may be a burden.

Statistical analysis

The primary analysis of this study will describe the time-dependent changes in satisfaction with breasts score of the BREAST-Q during the 12-month postoperative period. BREAST-Q evaluation will be performed at baseline and at 1, 3, 6 and 12 months after surgery, and summary statistics at each time point will be calculated for each surgical procedure. General linear models, which include the reconstruction procedure, time point, and time-by-procedure interaction as explanatory variables, will be used to summarise the longitudinal change of the endpoints. Likelihood-based methods will be applied to analyse incomplete data. An unstructured covariance matrix will be assumed, and robust SE will be calculated for estimated parameters. BREAST-Q and SF-8 scores will be adjusted for age, BMI, breast ptosis, radiation therapy, chemotherapy, complications and other factors.

ETHICS AND DISSEMINATION

Research ethical approval

All investigators involved in the current research will conduct this study in accordance with the Declaration of Helsinki and Ethical Guidelines for Medical and Health Research involving Human Subjects (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology, and Ministry of Health, Labor and Welfare, 2015).

Consent

Before enrolling patients into this study, the researchers gave the patients an informed consent form, and the details about this study were explained according to the Ethical Guidelines for Medical and Health Research Involving Human Subjects. All the participants were informed that they had the right to withdraw consent without any disadvantages.

Trial registration

This study protocol and the informed consent form have been approved by the institutional review boards at all the participating sites. The study was registered with the UMIN Clinical Trial Registry. The protocol version is 1.2, 1 January 2020.

Access to data

Only clinical data managers at the central data centre will have access to the reported case data through the EDC system during the study. Site investigators will have access to case data within all their sites. The data manager will transfer the final dataset to the principal investigator and the data will be stored in electronic format.

Dissemination policy

The results will be analysed and reported in a form in which individuals cannot be identified. The findings of the study will be presented at conferences and published in peer-reviewed medical journals domestically and internationally.

DISCUSSION

Although the number of cases of BR is increasing in Japan, the outcomes of BR have not been adequately evaluated due to the lack of established outcome measures. Considering that the purpose of BR is to improve patients' satisfaction and HRQOL, PROs are very useful and essential. SAQLA is the first multicentre study in Japan to evaluate BR from this perspective. Our data will provide time-dependent changes in BREAST-Q and SF-8 scores following mastectomy and IBR. Information on the recovery process is helpful for patients who are to make BR decisions and can facilitate patient engagement in decision-making. It can also serve as fundamental data for future clinical research and contribute to improving healthcare surrounding BR.

Our patients were mainly recruited from university hospitals, although we included patients undergoing IBR with implant-based reconstruction, latissimus dorsi flap and abdominal flaps, which are commonly used techniques in hospitals other than university hospitals. Thus, we believe that this study sample will represent Japanese women undergoing IBR adequately. BR procedures that are performed only in a limited number of facilities, such as gluteal artery perforator flaps, total BR with fat graft and BR for breast conserving surgery, were not included. Since the trend of the surgical procedure for BR will change with the times, further research plans are expected for cases that are not included in this study but are expected to increase, such as bilateral RRM and BR.

Implant recall has had a significant impact on the field of BR in Japan. We cannot rule out the possibility that the fear of developing BIA-ALCL might decrease satisfaction and HRQOL of our participants, and therefore, the study results will be skewed. To account for that, DRS has been added to help us understand the psychological impact of implant recall while also paying attention to the discontinuation of reconstruction cases caused by the recall. We also considered making a comparison between outcomes of patients with recalled implants and those with other types of implants.

There are a few limitations to this study protocol. First, this is a hypothesis-generating observational study. The number of target participants has not been set statistically but is based on the actual number of cases in the participating seven sites instead. Therefore, although we will describe the time-dependent changes in PROs following reconstruction procedures, this study will not determine the difference between the procedures. Second, it was discussed whether the time-dependent changes in staged reconstruction should start from the primary operation (TE insertion) or the second operation (change to permanent implant or autologous tissue). The latter can be better at evaluating the recovery period of the second operation. However, we believe that it would be more beneficial to evaluate the physical and psychological well-being of patients from the primary operation itself since the extent of distress during TE insertion is one of the main concerns of patients who need to select an IBR procedure or prepare for surgery. Focusing on 12 months, we assume that cases with staged reconstruction would have a lower level of satisfaction since the downtime occupies a longer period. We would like to investigate any differences in the final aesthetic satisfaction between one-stage and staged reconstruction procedures over a 3-year follow-up period. Third, we cannot obtain results of all participants. Patients lost to follow-up may have low satisfaction and HRQOL, which can lead to bias; that is, the results of this study may represent the satisfaction and HRQOL of patients in relatively good condition, rather than represent all cases of IBR. Presumably, another research plan will be needed to understand how such 'lost-to-follow-up' patients cope with the situation, in order to have a wholistic picture of IBR. Finally, our participant group includes only women who choose BR. It would be more informative to include women who undergo other breast cancer surgeries, such as mastectomy without BR and breast conserving surgery. This will be investigated in a future study.

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