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# BMJ Open Decision-making about mastectomy among Chinese women with breast cancer: a mixed-methods study protocol

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#### **ABSTRACT**

Introduction The prevalence of mastectomy in China is higher than its Western counterparts. Little is known about whether Chinese women with breast cancer have been involved in the decision-making process of mastectomy, the level of decisional conflict, their perceptions of mastectomy and the factors that influence them to undergo a mastectomy. This protocol describes a mixed-methods study that aims to provide an in-depth understanding of decision-making about mastectomy among Chinese women with breast cancer.

Methods and analysis A three-phase, sequential explanatory mixed-methods design will be adopted. The first phase is a retrospective analysis of medical records to determine the current use of mastectomy. The second phase is a cross-sectional survey to examine women's perceptions of involvement, decisional conflict and the factors influencing them to undergo a mastectomy. The third phase is an individual interview to explore women's decision-making experiences with mastectomy. Quantitative data will be analysed using descriptive statistics, t-test, Fisher's exact test,  $\chi^2$  test, analysis of variance, Pearson's correlation and logistic regression. Qualitative data will be analysed by the inductive content

**Ethics and dissemination** Ethical approvals for this study have been obtained from the human research ethics committees of the University of Newcastle, Australia. Zhongshan Hospital Xiamen University, China, and the First Affiliated Hospital of Xiamen University, China. Written informed consent will be obtained from the participants. Findings of this work will be disseminated at international conferences and peer-reviewed publications.

Trial registration number Not applicable.



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# INTRODUCTION

Previous randomised control trials have indicated the same survival outcomes after mastectomy and breast-conserving surgery (BCS). 1-3 Thus, many studies have provided insights into women's choice behaviour between mastectomy and BCS. 4-7 Most existing studies have focused on factors influencing surgical choices, while patient involvement, decisional conflict and decision-making experiences are underexplored. Besides, empirical evidence focusing on decision-making about

# Strengths and limitations of this study

- A three-phase, sequential explanatory mixedmethods design will produce rich knowledge about women's decision-making process.
- Women who report low, moderate and high levels of decisional conflict will be purposively selected to be interviewed to understand their different perceptions of decision-making they may hold.
- Unlike previous studies that focused on women with early breast cancer, this study will also involve women with advanced stages of breast cancer because their decision-making experiences will inform treatment counselling and patient education in different cancer stages.
- This study protocol can be limited by the nature of tertiary hospitals in a single city in China, which may reduce the generalisability of the findings.
- This study will include women who had a mastectomy within 6 months before study enrolment to minimise the recall bias.

mastectomy is rare, which remains the most commonly used surgical approach for breast cancer in many regions. 8-10 Since the surgical patterns for breast cancer treatment have changed, there is a need for research that specifically addresses changes in women's perspectives of mastectomy.

In mainland China, breast cancer is the most common type of cancer among females. 11 12 New breast cancer cases in China account for approximately 18% of all newly diagnosed breast cancers worldwide. 12 The incidence of breast cancer in China was also predicted to substantially increase. 13 14 For example, there were estimated 0.42 million new breast cancer cases in 2020 compared with 0.3 million in 2015. <sup>12</sup>

The use of mastectomy in China is significantly greater than that in Western countries. The percentage of mastectomy among women with breast cancer in Western countries is generally lower than 50%. 15-18 However, studies in China have reported that more



than 80% of Chinese breast cancer survivors have had mastectomy surgery. 19-21 Several studies have investigated surgical decision-making among Chinese women with breast cancer who live in non-China countries. A qualitative study in the USA suggested that Chinese-American women with breast cancer preferred mastectomy over BCS as they believed the mastectomy decision was safer.<sup>22</sup> Another study examined factors related to surgical choices among 184 breast cancer women in Malaysia, and found that women of Chinese ethnicity, compared with Malay and Indian women, were more likely to undergo mastectomy and they were less concerned about femininity loss caused by the removal of the breast.<sup>23</sup> Similar findings were reported in studies from Australia and Canada that included women of Chinese ethnicity.<sup>24</sup> <sup>25</sup> Currently, no study has been conducted in mainland China to understand decision-making about mastectomy among Chinese women with breast cancer.

Decision-making is complex due to the heterogeneity of this behaviour. 26 In the healthcare context, a consensus about the definition of 'decision-making' is not evident. Without a clear definition, most existing studies considered 'decision-making' from a single dimension. For example, several studies considered decision-making from the perspectives of roles and power, as well as patient involvement in making treatment decisions.<sup>27 28</sup> Glatzer et al<sup>26</sup> considered decision-making was the result of factor interactions and proposed a model consisting decision-maker factors (patients and doctors), decision-specific factors (the nature of the decision itself) and contextual factors (environment in which the decision is being made). However, as a process, decision-making is dynamic and multifaceted and may also include dimensions concerning time, 29 30 information, 31 32 supports, 33 34 interpersonal communication, 29 35 and decision outcomes. 36 37

Hence, we describe a protocol for a mixed-methods study to offer a comprehensive and in-depth understanding of decision-making about mastectomy by examining the current use of mastectomy, investigating womens' perceptions regarding involvement, decisional conflict and factors that influence their decisions in mainland China, as well as exploring Chinese women's decision-making experiences with mastectomy. The mixed-methods design, involving both quantitative and qualitative data, will enable us to obtain rich knowledge of this complex behaviour.<sup>38</sup> This study will include any forms of mastectomy as long as the women removed the cancer-affected breast, regardless of whether they had a neoadjuvant therapy or not. It includes unilateral mastectomy, bilateral mastectomy, mastectomy alone and mastectomy with immediate reconstruction.

The research questions of the mixed-methods design include:

- 1. What is the current use of mastectomy among Chinese women?
- 2. What sociodemographic and clinical factors are associated with the choice of mastectomy?

- 3. What are Chinese women's involvement in the decision-making process, levels of decisional conflict, and factors and issues they consider when making this decision?
- 4. What are decision-making experiences regarding mastectomy among Chinese women with breast cancer?

### **METHODS AND ANALYSIS**

A three-phase, sequential explanatory mixed-methods design will be adopted, where quantitative data are collected before the subsequent qualitative data.<sup>38</sup> The sequential explanatory mixed-methods design is especially beneficial to understand a behaviour or experiences in greater depth in healthcare research. In this study, the quantitative phases will be conducted first to inform the purposive sampling of the following qualitative phase based on the study aims.

The first phase is a retrospective analysis of medical records to determine the current prevalence of mastectomy. The second phase is a cross-sectional survey to examine women's perceptions of involvement in decision-making, decisional conflict and factors that influence them to undergo mastectomy. The third phase is an individual interview to explore women's decision-making experiences with mastectomy and further explain the quantitative results. An integration of both quantitative and qualitative empirical evidence from the mixed-methods study will contribute to a deeper understanding of women's decision-making concerning their mastectomy surgery.

The proposed mixed-methods study will be performed by an experienced research team, involving a PhD candidate researcher, two clinical experts and four research experts, who have rich experience in quantitative, qualitative and mixed-methods research in oncology care research. The PhD candidate researcher will collect data in China under the supervisory of these four research experts. The two clinical experts will provide essential comments on the data collection process in the study settings. The PhD candidate researcher has attended training programmes in quantitative and qualitative research and is capable of conducting interviews independently. The research team members meet fortnightly to ensure their involvement and research progressing.

This study is currently ongoing. Data collection was commenced after this study was approved by three ethical committees in September 2020. In consideration of the impact of COVID-19, three phases of this study are anticipated to be accomplished by December 2022.

# **Patient and public involvement**

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this protocol. However, before conducting the survey, two women who had undergone a mastectomy and two nurses will be invited to comment on the questionnaires and



interview questions to ensure appropriate and comprehensible for the targeted population.

# Phase one (retrospective)

Phase one is a retrospective analysis that will address the first and second research questions to investigate the current use of mastectomy among women with breast cancer from a typical tertiary hospital in China, as well as to examine the associations of sociodemographic and clinical characteristics with the use of mastectomy.

Medical notes for all female patients with breast cancer admitted at a single centre (Zhongshan Hospital Xiamen University, China) between January 2015 and December 2019 will be retrospectively reviewed. The only exclusion criteria will be male breast cancer cases. Information about the year of diagnosis, age, body mass index, marital status, ethnicity, fertility history, employment status, healthcare costs and living area and cancer stage, tumour size, the presence of lymph node invasion, the presence of hormone receptors and family history of breast cancer will be collected. Treatments women received will also be collected, including mastectomy, BCS, breast reconstruction, chemotherapy, radiotherapy, endocrine therapy and targeted therapy.

The number of consultations for breast cancer in Zhongshan Hospital Xiamen University is estimated to be 200–300 per year. Hence, it is expected that 1000–1500 breast cancer cases will be included in this data analysis. All female breast cancer cases will be included so that the selection bias can be avoided.

# Phase two (survey)

Phase two is a cross-sectional questionnaire survey addressing the third research question to investigate the levels of patient involvement and decisional conflict, as well as the factors that influenced them to undergo a mastectomy.

# Setting

Participants will be recruited using a convenience sample approach from Zhongshan Hospital Xiamen University and the First Affiliated Hospital of Xiamen University. These hospitals provide breast cancer care services to all residents in Xiamen city; thus, the sample population will likely represent the entire breast cancer population in the study area. To minimise selection bias, posters and booklets of this study will be distributed in the breast cancer clinics of these hospitals to ensure the maximum reach of the targeted population. Multiple methods of completing questionnaires will be offered to potential participants so that they are able to complete questionnaires either via face-to-face or phone or postal mails.

### Sample size

It is estimated that approximately 500 women receive mastectomy surgery in these two hospitals annually. The sample size is computed with an online sample size calculator (Raosoft). With the margin of error of 5%, the confidence level of 95%, the estimated population size of 500

and the response distribution of 50% (a response distribution of 50% provides the most conservative assumption and the largest sample size), 218 participants will be needed for this survey. In consideration of participant attrition and missing data, we anticipate recruiting 250 participants to ensure an adequate sample.

### Inclusion and exclusion criteria

Eligible patients for this survey must be females, 18 years old or above, diagnosed with breast cancer and had a mastectomy within 6 months before study enrolment. Women who are not diagnosed with breast cancer but have a mastectomy (such as women who have prophylactic bilateral mastectomy) will be excluded. Women who have had a past or present history of mental illness, who have been diagnosed with inflammatory breast cancer (an aggressive type of breast cancer with a poor prognosis) and who have had a mastectomy as a secondary surgery (such as those who have a mastectomy after BCS fails) will also be excluded.

### **Outcomes**

The primary outcomes of this survey will be the extent of patient involvement, decisional conflict and the importance of factors when women make the decision to undergo mastectomy. The secondary outcomes will include the associations between patients' sociodemographic characteristics, patient involvement and decisional conflict.

# Instruments

A sociodemographic and clinical data sheet has been developed based on previous studies about breast cancer patients. Items include questions concerning age, marital status, fertility history, education level, employment status, annual household income and insurance coverage for breast cancer treatment and cancer stage, tumour size and length of time since diagnosis and mastectomy.

The 9-item Shared Decision-Making Questionnaire (SDM-Q-9) will be used to measure the patient-perceived levels of involvement in the decision-making process (Cronbach's  $\alpha$ =0.938). It is a unidimensional structured questionnaire consisting of 9 statements, and each statement in SDM-Q-9 is rated on a 6-point Likert scale from 'completely disagree' (score=0) to 'completely agree' (score=5). Higher total scores indicate greater involvement. The Chinese version of SDM-Q-9 was validated in 660 Chinese patients and proved to be an appropriate instrument to measure patient involvement in the decision-making process (Cronbach's  $\alpha$ =0.945).

The 16-item Decisional Conflict Scale (DCS) will be used to measure the decisional conflict, including decision uncertainty, factors contributing to the uncertainty and patient-perceived effective decision-making (Cronbach's  $\alpha$ =0.78–0.92).  $^{41}$  It consists of 16 items in total, containing 5 domains: 'feeling informed' (3 items), 'uncertainty' (3 items), 'clear values' (3 items), 'support' (3 items) and 'quality of decisions' (4 items).  $^{41}$  Each item is rated on



a 5-point Likert scale from 'strongly agree' (score=0) to 'strongly disagree' (score=4). Higher total scores indicate more decisional conflict. In this study, decisional conflict will be categorised into 3 levels: a total score lower than 25 will be considered the low-level decisional conflict, and a total score above 37.5 will be considered the high-level decisional conflict, which is associated with decision delay or uncertainty about the decision. <sup>42</sup> A total score between 25 and 37.5 will then be considered the moderate level of decisional conflict. The Chinese version of DCS was validated among 471 Chinese women with breast cancer in Hong Kong (Cronbach's  $\alpha$ =0.51–0.87). <sup>43</sup>

The Choice Influence Scale (CIS), developed by Lam et al, is a compilation of prevalent factors and issues women consider when they make breast cancer treatment decisions. 44 It contains five domains: 'effects of surgery on physical appearance and sexuality and surgery-related physical suffering' (5 items), 'treatment effectiveness in achieving cure' (4 items), 'avoidance of further treatments' (2 items), 'family and friends' influence' (5 items) and 'doctor's influence' (3 items). 44 Each item is rated on a 5-point Likert scale, with the score 1 indicating 'not important at all' to score 5 'extremely important'. The mean score of each item is calculated to compare the importance of these factors. Such a list of prevalent factors is widely used in previous studies to evaluate the importance of factors in women's decisionmaking behaviours. 45-47 This study will primarily employ the CIS to assess the influence of given factors in women's decision-making of mastectomy. After analysing the results of phase one, the CIS will be amended as appropriate and more factors associated with the choice of mastectomy will be added to the factor list.

Before the survey, two women who had undergone a mastectomy and two nurses from the study setting will be invited to read and comment on the questions to ensure the questionnaires are appropriate and comprehensible for the targeted population. Minor modifications will be made based on their feedback. A similar validation process will also be conducted for interview questions in phase three.

# Phase three (interview)

Phase three will address the fourth research question and explain the results of prior quantitative data. A qualitative descriptive approach with semi-structured individual interviews will be used to explore women's experiences in decision-making about mastectomy. An interview guide has been developed by researchers based on previous studies<sup>25 48</sup> and feedback from nurses in the study setting (box 1). This interview guide will be further modified according to the results of the quantitative phases. The interview questions will be followed by probe questions, which enable a deeper exploration of the decisionmaking experiences and influencing factors. The probe questions may differ depending on women's responses to the interview questions. Interviews will be audio-recorded to ensure accuracy. The interviews will be transcribed and analysed in their original language.

#### Box 1 Ouestions for semi-structured interviews

#### Questions

- Please share your experiences with making a decision to have a mastectomy. Probe questions:
  - 1. Tell me more details about this experience.
- Please tell me about the reasons to choose a mastectomy. Probe questions:
  - 1. What factors influenced your decision?
  - 2. Since you have mentioned the impact of factor A, tell me more about this factor, and describe how it influenced you to choose a mastectomy.
  - Since you have mentioned the impact of factor B, tell me more about this factor, and describe how factor B influenced you to choose a mastectomy.
  - 4. Apart from factors A and B, how about other factors (such as access to radiation, body habitus, your perceptions that mastectomy would get you out of chemotherapy, your perceptions of availability of different choices, doctor's recommendations, family, friends and spouse)?
  - 5. Tell me the reasons why you did not choose BCS.
- Please describe your involvement in making the decision to undergo a mastectomy. Probe questions:
  - 1. Describe the level of your involvement.
  - 2. Who do you think made the final decision?
  - 3. How do you feel about your involvement in the decision-making process?
- ➤ Tell me about the information you used for making the mastectomy decision. Probe questions:
  - 1. What kind of information did you get?
  - 2. Where did you get the information?
  - 3. What do you think of the information?
- Tell me about other supports you got while making this decision. Probe questions:
  - Since you have mentioned support A (such as emotional support), please tell me more about this support.
  - 2. How about other types of support (such as financial support)?
  - 3. Did the support meet your needs? What do you think of the support you got?
- How do you feel about your decision-making process of mastectomy now? Probe questions:
  - 1. How would you describe your satisfaction with the decision-making?
- Is there anything else you would like to share with us?

# Inclusion and exclusion criteria

A purposive sampling approach will be employed. Women who complete the phase two questionnaires and report low-level, moderate-level and high-level decisional conflict will be invited to participate in an individual interview in phase three. Previous studies have suggested that 20–30 participants will be adequate to reach data saturation when exploring women's decision-making experiences. <sup>25 49</sup> In this study, we anticipate interviewing at least 7 women at each level of decisional conflict to achieve a total sample above 20. We will continue to interview participants until reaching data saturation in each group, the point at which no new information emerges. Similar exclusion criteria as those in phase two will be applied in the interview.



### **Trustworthiness**

The trustworthiness of this qualitative study will be ensured through:

- 1. Keeping a clear audit trail on data collection and analysis and the conclusions drawn.
- 2. Interviews being conducted by one researcher who is trained to ensure consistency.
- 3. Building trust and rapport between the researchers and participants.
- 4. Holding in-depth discussions among the researchers.

# Participants' privacy

In phase three, participants' privacy will be maintained. Interviews will be conducted in a private, quiet room at the hospital or at participants' accommodation according to their preference. The researchers will make an appointment with the participants to ensure their preferred time and location. Hard copies of transcripts and notes of the interviews will be locked in a specific cabinet in the researcher's office to ensure security. Only the researchers of this study have the key and will be able to access these materials. All personal information will be de-identified when reporting.

To avoid fatigue and the risk of emotional burden, the interview will last no more than 60 min. If the participants appear distressed during the interview, the interview will be stopped until they are settled. The participants may choose to continue after the break, to continue at another time or withdraw from the study. Information about counselling services in the hospital will be provided to the participants.

# **Data analysis**

# Quantitative data

Quantitative data will be analysed using SPSS software V.27. Descriptive statistics, such as the mean, median, SD, percentage and frequency, will be used to summarise patients' characteristics. In phase one, the differences in sociodemographic and clinical characteristics between surgery groups (such as the mastectomy group vs BCS group) will be analysed using the t-test, Fisher's exact test or  $\chi^2$  test, when appropriate. Multiple logistic regression will be used to examine the effect of sociodemographic characteristics and clinical history on mastectomy use. Patients with missing data will be excluded from the regression analysis. In phase two, the SDM-Q-9, DCS and CIS scores will be calculated. Analysis of variance will be used to compare SDM-Q-9 scores across different categories of each sociodemographic and clinical variable. The  $\chi^2$  test or Fisher's exact test will be used to compare patients' characteristics across three decisional conflict levels. Pearson's correlation will be used to investigate the relationships between SDM-Q-9 and DCS scores. Two-tailed p values will be adopted, and p <0.05 will be considered statistically significant.

# Qualitative data

Inductive content analysis will be used to analyse the qualitative data in phase three.<sup>50 51</sup> In the preparation

phase, we will read and re-read the data and become familiar with the text to obtain an early impression. After that, we will undertake open coding of the data. We will write down as many codes as possible to describe the content. Then, codes will be grouped into subcategories by comparing their similarities and judging their content. After generation, the subcategories will be named with content-related words. Subcategories with similar meanings will be grouped into categories and overall themes. The themes will describe women's experiences in making a decision on mastectomy.

# **Reporting of findings**

The quantitative studies will be reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement,<sup>52</sup> and the qualitative study will be reported following the Standards for Reporting Qualitative Research (SRQR) statement.<sup>53</sup> Since there were no standard guidelines for study protocols of cross-sectional and qualitative designs, the criteria of STROBE and SRQR statements were also used to guide the reporting of the current protocol to ensure quality (see online supplemental 1).

Findings from the three phases will also be integrated using a narrative approach to provide rich knowledge of decision-making about mastectomy among Chinese women with breast cancer. For example, influencing factors identified from the three phases of this study will be integrated and grouped based on similarities. They will be presented using categories, such as demographic factors, psychosocial factors and environmental factors. Such an integrated reporting approach will allow a holistic and organised understanding of the factors related to mastectomy decisions.

### **DISCUSSION**

To the best of our knowledge, this is the first mixed-methods study to investigate decision-making about mastectomy from mainland Chinese women's perspectives. The three phases of this study are closely linked, which can provide holistic findings related to the research questions. A strength of this study is the integration of multiple sources of data. Each subsequent phase builds on the results of the previous phase and, in turn, enriches the results of the previous phase. Findings from each phase can be integrated to provide more robust evidence about the decision-making of mastectomy among women with breast cancer.

The study findings will provide up-to-date information about the use of mastectomy and in-depth insights into the decision-making process among women with breast cancer in mainland China. Varied experiences may be reported by women. Women may express high levels of involvement, satisfaction and little decisional conflict. By examining the association of patients' demographic characteristics and the levels of involvement and decisional conflict, this study will identify



the particular population who are at a higher risk of being less involved and experiencing severe decisional conflict. For example, older women may report higher decisional conflict than their younger counterparts. Such findings will benefit doctors and nurses to strengthen support and guidance in decision-making for older women. Women may also express lower involvement, satisfaction and higher decisional conflict. In this case, by exploring decision-making experiences among women who have high-level decisional conflict, doctors and nurses will learn about the barriers that challenge women to make a satisfactory decision and help women cope with these challenges to achieve an effective decision.

Importantly, interventions, such as supportive resources, can be developed based on the findings of this study to facilitate effective treatment decisions among women with breast cancer. The results of this study may also contribute to clinical guidelines and strategies regarding the promotion of patients' active involvement in treatment decision-making. As many Asian countries have cultural similarities with China, the findings of this study may be pertinent to those countries. The findings may also apply to Chinese women living in Western countries.

This study protocol could be limited by the nature of tertiary hospitals in a single city in China. The selection bias might reduce the generalisability of the findings. However, to the best of our knowledge, this will be the first study to specifically capture the perspectives of Chinese women on their decisions about mastectomy. The nature of retrospective design may bring about recall bias because women will be required to recall their decision-making experiences. The recall bias will be managed by including women who have a mastectomy within 6 months before study enrolment to ensure their memories are fresh.

Several possible directions for future research can be put forward based on the findings of this study. Future research can replicate the results in selective samples, such as older women and those with smaller tumours and unifocal diseases. As making a treatment decision is a process involving different stakeholders, similar designs can be expanded to include doctors, nurses and family members to provide insights from multiple perspectives. Based on the findings, conceptual frameworks of the 'decision-making' can be proposed, as this study provides a systematic and thorough understanding of patients' decision-making experiences. Supportive tools, such as educational materials and decision aids, can be developed and future research needs to examine the effectiveness of these interventions.

# ETHICS AND DISSEMINATION Ethical considerations

The study protocol has been reviewed and approved by the human research ethics committees of the University of Newcastle, Australia (number: H-2020-0147), Zhongshan Hospital Xiamen University (number: 2020-090) and the First Affiliated Hospital of Xiamen University, China (number: 2020-026).

Written informed consent will be obtained from participants before survey. They will be given the option to consent to participate either only in the survey (phase two) or both the survey and the following interview (phase three). If participants consent to participate in the interview, they will be informed that their comments may be quoted verbatim in the report of the study's findings. A pseudonym will be used in this instance to ensure privacy. Participants will be informed of their right to withdraw from participation in this study at any time without affecting their health-care service.

### **Dissemination**

Findings of this work will be written for peer-reviewed publications and disseminated at international nursing conferences. Data related to this study will be available from the corresponding author on reasonable request after completing this study.

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Contributors All authors contributed to creating the study design and have read and approved the final manuscript. JL conducted surveys and interviews and drafted the initial manuscript. SC, SH, RL and JZ made substantial revisions to the manuscript. DG and QL contributed to obtaining the ethical approvals from two study hospitals and provided critical comments on the data collection procedure of this study. JL, DG and QL conducted participants recruitment and data interpretation.

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