CURRENT ONCOLOGY
A Canadian Cancer Research Journal

Supplemental Materials for

Mastectomy versus breast conservation therapy: an examination of how individual, clinicopathological, and physician factors influence decision making

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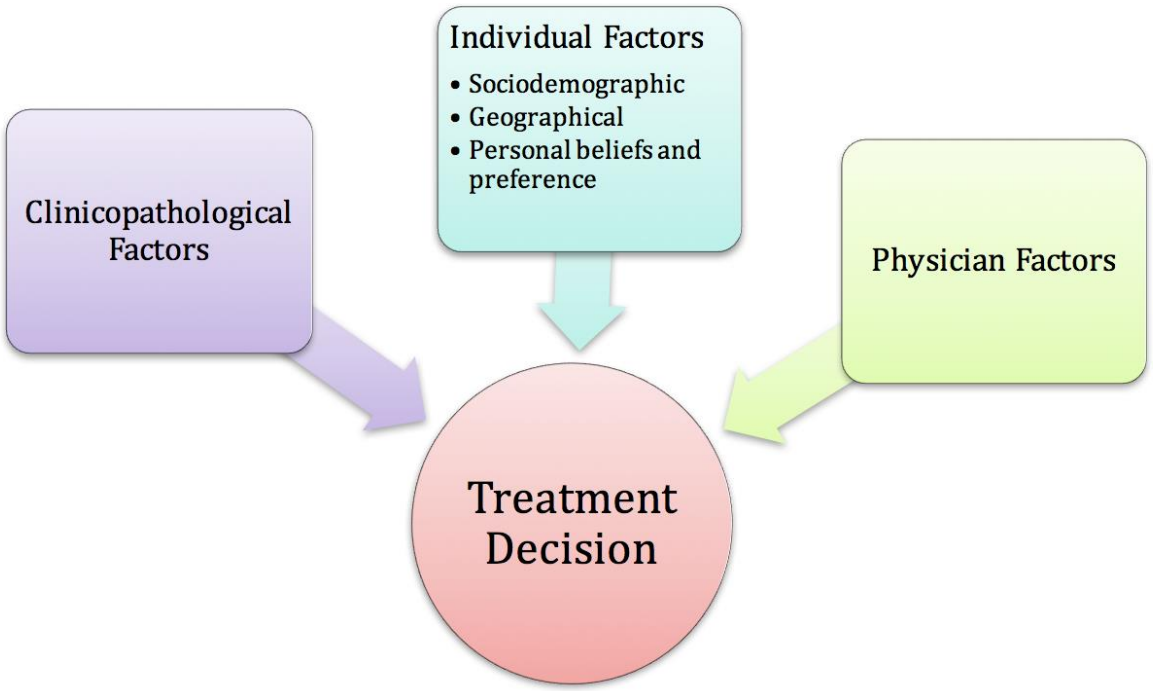
Listing of Supplemental Material(s):

Supplemental Appendix 1: Detailed Survey Development and Design

Survey Conceptual Development

The construction of our survey was based on a previously developed conceptual framework of the central influences women to choose mastectomy versus BCT – figure A1[1]. The creation of this framework was based on previous literature[2], prior theory, prior models, and our research groups initial exploratory qualitative research[3]. This framework organizes the potential influencing factors affecting women's choice between mastectomy versus BCT into three central factor constructs: clinicopathological, physician, and individual with subgroups of sociodemographic, geographical, and personal belief factors. These constructs have often been measured individually, or in fragmented combinations in the past. Through our survey, we planned to study these constructs holistically in a way that links these constructs together. By examining how each factor and their interactions influence a patient's choice, we hoped to gain greater overall understanding of this phenomenon.

Figure A1 – Conceptual framework illustrating the central constructs influencing women's choice between mastectomy versus BCT.



This figure is reproduced with permission from the rights owner[24]. Gu J, Groot G. Creation of a new clinical framework – why women choose mastectomy versus breast conserving therapy. *BMC Med Res Methodol*. 2018;18(1):77. doi:10.1186/s12874-018-0533-7

Survey Organization

The survey as a whole is aimed at capturing influences from the three main constructs: clinicopathological factors, surgeon factors, and individual factors. The survey is composed of a questionnaire and a dataset from the Saskatchewan Cancer Agency (SCA). The questionnaire is aimed at capturing individual values or preference factors, potential decisional conflict factors, travel related factors, and individual demographic factors. A dataset from the SCA, which is linked to the questionnaire data, captures clinicopathological factors for the patients. The survey as a whole can be seen in Supplementary Appendix 2.

Personal Beliefs and Preference Factors

The individual values and preference factor questions emerged from the results of our initial qualitative study, which was also based in Saskatchewan [3]. The results of that study gave us a guiding list

of factors that influenced patients' choice at an individual level. The initial qualitative process further aided in organizing these factors into dominant themes and their accompanying subthemes or secondary factors. These are displayed in Table A1. This organization directly informed how we created our questionnaire and the use of branching logic[4]. Branching logic, or skip logic, is a feature that changes what question a respondent sees based on how they answer previous questions. This was done to ensure all questions were relevant to respondents. For example, if a participant responded to an initial question about 'worry about cancer recurrence' as an important factor, they would subsequently have a follow-up question inquiring about what the reason behind that worry was with response options also based on the initial study. However, if a participant did not rate that factor as important, they were not asked specific follow-up questions. As well, there were some belief factors that are specific to either mastectomy or BCT groups only. These questions were asked of only the applicable group.

Table A1: Individual Values and Preference Factors

Mastectomy Participants

A. Worry about cancer recurrence
    a. Causes of this worry:
        i. Observed failed BCT (family / friend)
        ii. Observed mastectomy success (family / friend)
        iii. Avoiding follow-up imaging
        iv. Family history of breast cancer
        v. Age
    b. Increasing chance of cure
    c. Obtain peace of mind
    d. Get rid of all of the tissue
    e. Wanting a prophylactic mastectomy
B. Avoiding consequences of BCT treatment
    a. Avoiding potential for additional surgery
    b. Avoiding radiation therapy
        i. Travel distance for radiation treatments
        ii. S/E of radiation
C. Breast-tumor size ratio
    a. Perceived small breasts
    b. Perceived large tumor

BCT Participants

A. Mastectomy is too radical
    a. Relative to perceived tumor size
    b. Confidence in BCT procedure
    c. Perceived recovery time too long
        i. Influenced by age
        ii. Influenced by comorbidities
B. Surgeon influence
    a. Surgeon's recommendations
    b. Reputation of the surgeon
    c. Reasons behind surgeon choices:
        i. Perceived breast size
        ii. Perceived tumor size
C. Feminine identity
    a. Body image
    b. Sexuality / desirability / attractiveness
    c. Being whole / retaining one's own breast tissue

Decisional Conflict Scale

The Decisional Conflict Scale (DCS) is a 16-item questionnaire that was designed and validated by O'Connor to examine decisional conflict and other aspects of the decision-making process[5]. The scale has five sub-scales: certainty, information, clarification of values, support or pressure from others, and the respondent's perception of the quality of the decision process. The DCS has been used in the past to do the following: diagnose a patient's decisional conflict, identify the patient's decision support needs (knowledge, values clarification, support), determine the quality of the decision process, and evaluate the impact of decision support interventions [6,7]. Each item is measured on a 5-point Likert scale with total scores between 0-100, with 100 indicating extremely high decisional conflict. The DCS is designed to have the specific wording of questions adapted for each questionnaire on different topics. The DCS was adapted for use in our survey, which is also included in Appendix B.

Travel Related Factors

Travel related factors or distance to a radiation treatment center have shown varying results in the literature as to whether there is an effect on rates of BCT versus mastectomy [2]. We hypothesized that in Saskatchewan, travel distance would significantly affect rates of BCT due to Saskatchewan's large rural population. Interestingly, our initial qualitative research did not support this hypothesis, but we

decided nonetheless to include questions about travel distance to surgical and radiation treatment centers, rural versus urban living location, and lodging for radiation treatments in this survey for evaluation in case it was an important factor

Individual Demographic Factors

Demographic factors such as age, SES, and race / ethnicity have also shown varying associations with treatment choices [2]. We included questions regarding age, ethnicity, income, education, occupation, and relationship status to capture this data.

Clinicopathological Data from the Saskatchewan Cancer Agency

The researchers collaborated with the research group from the SCA to obtain clinicopathological data to link with the questionnaire participants. Data items collected were based on previous literature described in the conceptual development of the survey. Data items collected are listed below:

1. C-code
2. C-code English description
3. Morphology
4. Morphology English description
5. Behavior
6. Grade
7. Laterality
8. Multiplicity Counter
9. Tumor Size
10. Regional Nodes Positive
11. Regional Nodes Examined
12. SSF 1 – ER Assay
13. SSF 2 – PR Assay
14. SSF 14- HER2: Result of Other or Unknown Test
15. SSF 16 – Combination ER, PR & HER2
16. Overall Stage, T, N and M stage values
17. Surgery Date
18. Radiation therapy
19. Chemo therapy
20. Hormone therapy

Survey Questionnaire Design

This questionnaire was designed in accordance to best practice recommendations from Jon Krosnick and Stanley Presser [4]. Beyond obtaining the correct information from questions, we aimed to maximize optimal patient responses and minimize satisficing tendencies. Some general principles we followed were using simple familiar words, avoiding ambiguous meanings, making sure response options were exhaustive and mutually exclusive, avoiding leading or loaded questions, and only asking about one thing at a time. Following these principles meant that many of our answers included a combination of close-ended responses with an open ended 'other' response to ensure the participants could be exhaustive in their responses. A 5-point Likert scale with values from strongly disagree to strongly agree was chosen because using word labels has shown higher reliability in questionnaires and avoids acquiescence [4]. If respondents attempted to advance to the next question without responding to the question, they were prompted to answer the question, but not forced into an answer.

The order of questions was also crafted under best practice principles for this questionnaire [4]. Questions of similar topics and concepts were grouped together, which followed a funneling technique of proceeding from general to specific. Questions under the same domains of interest were randomized to prevent question order effect biases. Filter questions were included, where appropriate, to avoid asking respondents questions that may not apply to them. Questions were placed at the start of the survey that explicitly address the main topic of the survey and are the most cognitively challenging to optimize responses. Factual and demographic questions were placed at the end of the survey, as these topics are less susceptible to satisficing [4].

Questionnaire Pre-testing

This survey underwent multiple iterations of pretesting. The researcher, his supervisors, and collaborators created an initial version of the survey with the U of S Social Science Research Lab (SSRL)

survey designer. The survey then underwent pre-testing with methodology experts in survey design, as well as the Saskatchewan's Breast Advisory Group. Specific considerations that were asked to be reviewed during pre-testing included: specific wording choices, question ordering and grouping, content covered, and question appropriateness with the target population. Survey methodology experts within various departments at the U of S were consulted including in psychology, epidemiology, and the director of the SSRL. The Saskatchewan's Breast Advisory Group is composed primarily of breast surgeons, but also has representation from oncology and the SCA. Changes made to the questionnaire were iterative.

Questionnaire Piloting

To pilot the study, we collaborated with the Saskatoon Breast Health Centre. This was an external participatory pilot survey, meaning the pilot participants were not included in the main survey, and we informed the respondents that we were in a pilot phase, and asked them for constructive feedback upon survey completion. The inclusion criteria for pilot participants were the same as for our main survey – Saskatchewan women who have been diagnosed and treated for ESBC (stage one or two). Excluded from the study were women with DCIS, known BRCA, stage three or four breast cancer, male breast cancer, and inflammatory breast disease. Potential participants were those diagnosed after December 31, 2015 to avoid overlap with participant recruitment for our main survey data. 40 participants partook in the pilot process, which was about 10% our survey's goal sample size.

The Breast Health Centre nurses helped identify potential participants that met our pilot inclusion criteria. They then asked the patients if they would be interested in speaking with the researcher / interviewer, J.G., about the study when they were at the Saskatoon Breast Health Centre for an appointment. A study information pamphlet was available for the nurses to utilize as well (Appendix J). If the patient agreed, J.G. spoke to them about the study and obtained consent using the

same consent form as for the main survey. Participants were encouraged to evaluate the survey design and record problems they may have come across with any portion of the survey; pen and paper were also provided. Participants were asked to complete the survey online in a self-administered fashion; a tablet device was provided to allow participants to complete the survey on-site. Alternatively, the participants could ask the researcher to administer the survey in person. If this was requested, the interviewer entered the responses into the QualtricsTM program to maintain centralized data. Upon completion of the survey, the pilot participants were asked to provide feedback on the survey. Specific feedback questions targeted question wording, appropriateness, relevance, terminology, response categories, repetitiveness, other comments or criticisms, and general feedback. Field notes were recorded. No identifying data was recorded beyond what was asked in the survey.

Sample Size

Our sample size calculation was based on our framework and the central constructs that influence women's choice between mastectomy versus BCT (Figure A1). Our constructs include clinicopathological factors, surgeon related factors, and individual (patient-based) factors. For each of these factors we calculated sample sizes required to detect differences between mastectomy and BCT groups for one main difference of interest in each construct group. All chosen sample size values were from studies with multivariate analysis, and odds ratios were selected throughout. Based on CIHI data, there are approximately 478 Saskatchewan patients diagnosed with ESBC per year, of whom 53% initially undergo mastectomy and 47% BCT [8]. We assumed the two groups proportions to be equal, 50% each in our calculations. Sample sizes were calculated using PASS software.[9] Tests for two proportions detecting inequality using odds ratios were performed.

For clinicopathological factors, Locker et al found tumor size greater than 2cm was associated with an odds ratio (OR) of 3.03 times higher likelihood of undergoing mastectomy [10]. We wanted to

determine if this factor would likewise be significantly in our study population. If the ratio between the two groups, group A (BCT) and group B (mastectomy), resulted in anything other than the null value of 1, we would conclude that tumor size is an important variable. Sample size for this factor was calculated using data from Locker et al study, looking at the odds of outcome in group A, $p_A(1- p_A)$, compared to the odds of outcome in group B, $p_B(1- p_B)$, where p_A and p_B are the probabilities of the outcome in the two groups.

The null hypothesis: H_0: OR = 1

The alternate hypothesis: H_0: OR ≠ 1

$$OR = \frac{p_A(1- p_B)}{p_B(1- p_A)}$$

Using PASS, the sample size required to detect a difference between group A and B for tumor size was 102.

We performed similar calculations to determine sample sizes for constructs in other groups. For physician related factors, Cyran et al found that female physician sex was associated with an OR of 3.80 times higher likelihood of undergoing BCT [11]. Using this information and PASS, the sample size required to detect this difference was 78. For individual factors, we chose to test both travel distance as well as personal beliefs and values factor. Celaya et al found that travelling a distance to radiation facility greater than 60 miles was associated with an OR of 0.31 times less likelihood of undergoing BCT [12]. Based on this study, the sample size required to detect this difference was 92. Lee et al found that women who strongly valued peace of mind were associated with an OR indicating 1.88 times higher likelihood of undergoing mastectomy [13]. As the proportions of women valuing peace of mind was not given, we tested a range of possible proportions from 35% to 45% for those not valuing peace of mind choosing mastectomy. This sensitivity testing revealed that changing the proportion did not significantly

affect our sample size. Taking the above into account, the sample size required to detect this difference was 320 with a proportion valuing peace of mind choosing mastectomy being 60%.

The individual factor of peace of mind required the highest sample size to detect a significant finding of interest, and was used as a base sample size. To account for the multivariable nature of this study, potential confounders, and our hypothesis that all of these constructs may influence women's choice, we increased the sample size to account for confounding from each construct. The adjustment was calculated by increasing the sample size by 15% per each additional construct. Our final goal sample size was 423 participants.

Target Population

Our target population included all women diagnosed and treated with ESBC in Saskatchewan. ESBC is defined as women with Stage 1 or 2 cancer (AJCC 7th edition) [14]. Participants had to be residents of Saskatchewan. Excluded from this study were women with DCIS, known BRCA, Stage three or four breast cancer, male breast cancer, and inflammatory breast cancer.

Ethics Approval

Ethics approval was obtained from the University of Saskatchewan Behavioural Research Ethics Board (Beh-REB). The ethics file is Beh 15-355.

Patient Recruitment

Patient recruitment was done with the support from the Saskatchewan Cancer Agency. Through the SCA database, all patients who were treated for ESBC in Saskatchewan during an inclusive 2-year period from January 2014 to December 2015 were identified. Inclusion dates were based on the date of the procedure that lead to their pathological diagnosis, ie. biopsy date for invasive cancer. Patients were mailed an invitation letter to participate from the SCA (Appendix L). If there was no response to our

initial survey request, a single reminder invitation to participate letter was sent out at an 8-week interval from the initial letter. The initial invitation to participate letter was mailed out on December 7th, 2017 and the reminder letter was mailed out February 2nd, 2018. Closure of the survey and data collection ended on April 4, 2018. No incentive-based recruitment strategies were employed with this survey.

The SCA does track and remove deceased individuals from their database. However, if any of these patients were missed and a family member contacted and informed the researchers the individual was deceased, these numbers were tracked and removed from response rate denominator. As well, if a participant called to inform the researcher they did not meet our study inclusion criteria, we also removed these individuals from our study denominator. We tracked these with the individual survey's unique linking variable to protect the participant's confidentiality.

Based on 478 patients per year diagnosed with ESBC[8], we estimated that a recruitment response of 45% would allow us to reach the goal sample size during the 2-year period.

Survey Implementation

The proposed survey was hosted online by QualtricsTM, a program that the SSRL uses frequently. During the piloting phase of the study, servers were located in the USA and subject to US laws. The privacy of the information provided was subject to the laws of that other jurisdictions. However, at the time we conducted the primary survey, database servers were relocated to Canada and were subject to Canadian privacy laws; the data collection system at the SSRL was also changed to Voxco at this time. Participants were encouraged to complete the survey online in a self-administered fashion. Alternatively, the participants could contact the researchers and have the survey administered via a phone interview. There was a separate oral telephone script consent form that the researcher followed. (Appendix M) During the phone interview, the interviewer entered the participant responses into the Voxco program to maintain centralized data.

Data Collection and Management

All questionnaire data was collected via the Voxco system. This data can be exported to Excel. Survey clinicopathological data including tumor location, pathology, staging, and adjuvant treatment information was obtained from the SCA database. These datasets were linked using a linking variable, the individual participant code.

Each potential participant recruitment letter included a unique patient identifier. This identifier was composed of two sections: a 4-character number – character – number – character combination, and a four-digit number running from 0000 to 1000. These two components were combined to create an 8-character unique patient identifier for all patients in our target population. The first 4 characters would make incorrect entry of the unique identifier very unlikely. The last 4 digits would make it easier for the researchers, who did not have access to the master list, to link the two datasets together. With a sample size of over 400 participants and a total target recruitment population of close to 1000, this number would not be able to be used as an identifying feature. A master code sheet was kept to track the patients. The creation of a master code sheet linking identifying patient information to the data sets was created and kept within the SCA at all times. The researchers did not have access to the master code sheet at any time.

All original data files were stored in a passcode protected computer that was secured in a locked room at all times.

Data Analysis

Statistical analysis was performed using Stata 14.2 [15]. Our primary outcome was odds of mastectomy versus BCT. Independent variables included clinicopathological factors, individual patient factors, and physician factors. Baseline differences between groups were evaluated using chi-squared test for categorical data and independent sample *t* test for continuous data. Univariate logistic

regression was applied to identify key predictors of choice of mastectomy versus BCT. Multivariable logistic regression analysis was used to create the main effects model. Variables with a $p < 0.10$ in the univariate logistic regression were included in the multivariable model and backwards elimination of variables with $p < 0.05$ was then performed. Clinically important effect modifiers were individually tested for potential inclusion in the model using an interaction term. Goodness of fit was assessed using the Akaike information criterion. For missing data, we used complete case analysis when there was less than 10% and indicator method when more than 10% of missing data points to reduce bias.

Geocoding and mapping was performed in conjunction with the Spatial Division of the U of S Social Sciences Research Laboratories. Geocoding was performed by joining spatial information (latitude and longitude) to patients' home based on the first 3 letters of postal code provided. Visualizing routes and generating GIS files was done using a WebGIS solution developed by the local team to visualize patients' home location, hospital locations, and travel routes. These routes were manually edited as arcs and routes were downloaded as GIS layers. GIS layers were imported to create PDF maps using ArcGIS.

References

1. Gu J, Groot G. Creation of a new clinical framework – why women choose mastectomy versus breast conserving therapy. *BMC Med Res Methodol*. 2018;18(1):77. doi:10.1186/s12874-018-0533-7

2. Gu J, Groot G, Boden C, Busch A, Holtslander L, Lim H. Review of Factors Influencing Women's Choice of Mastectomy Versus Breast Conserving Therapy in Early Stage Breast Cancer: A Systematic Review. *Clin Breast Cancer*. January 2018. doi:10.1016/j.clbc.2017.12.013

3. Gu J, Groot G, Holtslander L, Engler-Stringer R. Understanding Women's Choice of Mastectomy Versus Breast Conserving Therapy in Early-Stage Breast Cancer. *Clin Med Insights Oncol*. 2017;11(10):1179554917691266. doi:10.1177/1179554917691266

4. Krosnick JA, Pressor S. Question and Questionnaire Design. In: Second Edition. Handbook of Survey Research. UK: Emerald Group Publishing; 2010:263-313.

5. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25-30.

6. Kryworuchko J, Stacey D, Bennett C, Graham I. Appraisal of primary outcome measures used in trials of patient decision support. *Patient Educ Amp Couns*. 2008;73(3):497-503.

7. O'Connor A, Bennett C, Stacey D, et al. Do patient decision aids meet effectiveness criteria of the international patient decision aid standards collaboration? A systematic review and meta-analysis. *Med Decis Making*. 2007;27(5):554-574.

8. Canadian Institute for Health Information. *Breast Cancer Surgery in Canada 2007-2008 to 2009-2010*. Canadian Institute for Health Information; 2012. https://secure.cihi.ca/estore/productFamily.htm?locale=en&pf=PFC1936.

9. NCSS. *PASS 14 Power Analysis and Sample Size Software (2015)*. Kaysville, Utah, USA: NCSS, LCC ncss.com/software/pass. Accessed October 15, 2015.

10. Locker GY, Sainsbury JR, Cuzick J, Group AT. Breast surgery in the "Arimidex, Tamoxifen Alone or in Combination" (ATAC) trial: American women are more likely than women from the United Kingdom to undergo mastectomy. *Cancer*. 2004;101(4):735-740.

11. Cyran EM, Crane LA, Palmer L. Physician sex and other factors associated with type of breast cancer surgery in older women. *Arch Surg*. 2001;136(2):185-191.

12. Celaya MO, Rees JR, Gibson JJ, Riddle BL, Greenberg ER. Travel distance and season of diagnosis affect treatment choices for women with early-stage breast cancer in a predominantly rural population (United States). *Cancer Causes Amp Control*. 2006;17(6):851-856.

13. Lee CN, Chang Y, Adimorah N, et al. Decision making about surgery for early-stage breast cancer. *J Am Coll Surg*. 2012;214(1):1-10.

14. NCCN Breast Cancer Panel Members. *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Breast Cancer*. National Comprehensive Cancer Network; 2014.

15. StataCorp. *StataCorp (2015) Stat Statistical Software: Release 14*. StatCorp, College Station, TX: StataCorp

Supplemental Appendix 2: Full Survey

"An Examination of Why Saskatchewan Women Choose Mastectomy Versus Breast Conservation Therapy in Early Stage Breast Cancer"

Participation in this research is voluntary, and you can stop your participation at any time. After completion of the survey, certain pre-defined data items about your pathology and from your chart will be disclosed in a de-identified manner by the Saskatchewan Cancer Agency and linked to your survey results. Please know you cannot be personally identified based on the data we collect. This research project has been approved on ethical grounds by the University of Saskatchewan Behavioural Research Ethics Board. Any questions regarding your rights as a participant may be addressed to that committee through the Research Ethics Office ethics.office@usask.ca (306) 966-2975. Out of town participants may call toll free (888) 966-2975.

For more information on the study itself please contact by email or phone Dr. Jeffrey Gu (jeg998@mail.usask.ca, (306) 262-3537) or Dr. Gary Groot (garygroot@gmail.com, (306) 653-3366). For study results, please contact the researchers in January 2018. If you do not want to participate in this project or if you want to be removed from our mailing list, please contact Serena Kozie at the Saskatchewan Cancer Agency at (639) 625-2045 or by email at serena.kozie@saskcancer.ca

There are no known risks to participating in this survey; however, as with any online related activity the risk of breach of confidentiality is possible. If you decide not to participate or withdraw from the study, your treatment and medical care will not be affected.

This survey is hosted by Voxco, a Canadian-owned and managed company whose data is securely stored in Canada. Consider printing this page for your records.

In order to complete this survey, you may be required to answer certain questions; however, you are never obligated to respond and you may withdraw from the survey at any time by closing your internet browser.

By completing and submitting the questionnaire, YOUR FREE AND INFORMED CONSENT IS IMPLIED and indicates that you understand the above conditions of participation in this study.

❍ I consent

[Linking Variable]

Please type the identification code you were provided in your recruitment letter.

Q.1 [Screener]

What was your initial treatment choice?

1. Mastectomy
2. Breast conservation therapy (lumpectomy and radiation)

Q2. [High Level Questions about personal values and beliefs]

[*All items under question 2 will be randomized for each participant*]

[*All items under question 2 will be presented 1 at a time]*

[*All items under question 2 will be presented a 5-point likert scale from strongly disagree to strongly agree]*

[All items under questions 2 will have the following pre-amble]

"Taking your time to think through each question, please indicate the extent to which you agree with the following statements. Please think back to when you made your initial treatment choice. Keep in mind that there are no right or wrong answers."

- My worry about cancer recurrence influenced my choice of therapy
- My age influenced my choice of therapy
- Other individual medical or health concerns influenced my choice of therapy
- My family history of breast cancer influenced my choice of therapy
- My previous experience with breast cancer or breast disease influenced my choice of therapy
- My breast size influenced my choice of therapy
- The tumor size influenced my choice of therapy
- The travel distance to the treatment center (for surgery or radiation) influenced my choice of therapy
- My surgeon's opinion influenced my choice of therapy
- My feminine identity influenced my choice of therapy.
- My sexuality influenced my choice of therapy
- Wanting to keep my own breast tissue influenced my choice of therapy
- Incorporating reconstruction influenced my choice of therapy
- The total time required to treat my breast cancer influenced my choice of therapy

Q2A1. These questions will be displayed for those selecting mastectomy only.

(Items still included in the randomization)

- Wanting to avoid the potential for requiring further surgery influenced my choice of mastectomy
- The length of radiation treatments required for breast conservation therapy influenced my choice of mastectomy
- Wanting to avoid radiation treatments influenced my choice of mastectomy
- Lodging or housing required in order to undergo radiation treatments influenced my choice of mastectomy
- Wanting to remove my other breast without cancer (prophylactic mastectomy) influenced my choice of mastectomy

Q2A2. (Items not included in the randomization)

- Did your doctors discuss that breast conservation therapy was a possible treatment option for you?
    - Yes
    - No
    - Do not remember
- In your decision to undergo mastectomy, please indicate your involvement in the decision-making process:
    - Completely your choice, no physician input
    - Mostly your choice, minimal physician input
    - A shared decision-between you and your physician
    - Mostly your physician's choice
    - Completely your physician's choice, no individual input

Q2B1. These questions will be displayed for those selecting breast conservation therapy only.

(Items still included in the randomization)

- The recovery time for undergoing mastectomy influenced my choice of breast conservation therapy
- Feeling that mastectomy was too radical or extreme of a procedure influenced my choice of breast conservation therapy

Q2B2. (Items not included in the randomization)

- Did your doctors discuss that mastectomy was a possible treatment option for you?
    - Yes
    - No
    - Do not remember

- In your decision to undergo breast conservation therapy, please indicate your involvement in the decision-making process:
    - Completely your choice, no physician input
    - Mostly your choice, minimal physician input
    - A shared decision-between you and your physician
    - Mostly your physician's choice
    - Completely your physician's choice, no individual input
- Did you require further surgical procedures beyond your initial lumpectomy?
    - No
    - Yes
        - Re-excision for a positive margin with lumpectomy
        - Re-excision for a positive margin with mastectomy
        - Re-excision for local recurrence with lumpectomy
        - Re-excision for local recurrence with mastectomy
        - Other, please specify:

Q3. [Follow-up / Secondary questions for personal values and beliefs]

[*All items under question 3 will use display logic for relevant questions*]

[*All items under question 3 will use the following pre-amble:]*

"You indicated BLANK was important in choosing breast conservation therapy/mastectomy."

i. If **worry about cancer recurrence** is selected, display:

Do any of the following impact your worry about cancer recurrence? Please select all that apply. [USE SELECT ALL THAT APPLY OR RATE THEM INDIVIDUALLY AGAIN]

a. Someone close to you had a negative outcome with breast conservation therapy
b. Someone close to you had a positive outcome with mastectomy
c. You would like to avoid follow-up imaging
d. You have a family history of breast cancer
e. Your age
f. Other, please specify:

ii. *If **breast size** is selected, display:* Since you selected breast size was an impacting factor on your choice of therapy. Which of the following options related to this decision.
a. Large breast size
b. Small breast size

iii. *If **tumor size** is selected, display:* Since you selected tumor size was an impacting factor on your choice of therapy. Which of the following options related to this decision.
a. Large tumor size
b. Small tumor size

iv. *If **travel distance** selected, display:* Since you selected travel distance was an impacting factor on your choice of therapy. Please explain how travel distance was an impacting factor in your choice of therapy?
a. Open-ended answer space

v. *If **surgeon influence** selected, display:* Since you indicated surgeon influence was an impacting factor on your choice of therapy, could you please explain why the surgeon suggested this option for you?
a. Open-ended answer space

vi. *If **feminine identity/feeling whole as a woman** selected, display:* Please explain how feminine identify impacted your choice of therapy.
a. Open-ended answer space

vii. *If **sexuality** selected, display:* Please explain how feminine identify impacted your choice of therapy.
a. Open-ended answer space

viii. *If **mastectomy is too radical or extreme** selected, display:* Since you indicated feeling that mastectomy is radical or extreme, were any of the following options related to this decision? Please select all that apply:
a. Your confidence in breast conservation therapy
b. Survival is equivalent between breast conservation therapy and mastectomy
c. Small tumor size
d. Recovery time would be shorter with breast conservation therapy compared with mastectomy
e. Other, please specify:

ix. If **length of radiation treatments** selected, display: You indicated length of radiation treatments required for breast conservation therapy influenced your choice of mastectomy. What options were offered to you in regards to length of radiation treatments?
a. 25 fractions taking 5 weeks
b. 16 fractions taking 3.5 weeks
c. The choice of 5 or 3.5 weeks
d. Do not remember

x. If **lodging or housing required** selected, display: You indicated lodging or housing required for radiation treatments influenced your choice of mastectomy. Were you informed that there was lodging available to you across from the cancer centre?
   a. Yes
   b. No

xi. If **total time of treatment** selected [for **mastectomy** patients] display: You indicated total time of treatment was important in choosing mastectomy. Please explain why.
   a. Open ended answer

xii. If **total time of treatment** selected [for **breast conservation therapy** patients] display: You indicated total time of treatment was important in choosing mastectomy. Which of the following impact this choice? Please select all that apply
   a. Time away from work
   b. Time away from family
   c. Time away from leisure activities
   d. Other, please specify:

Q4. [Ranking for most influential factors of therapy]

[Please select up to five factors that most influenced your choice of therapy. Please drag and drop your choices into the selection box.]

[Please take your time to think through each option, keeping in mind that there are no right or wrong answers.]

[*Options will be randomized*]

1.

2.

3.

4.

5.

Q.5. [Decisional Conflict Scale]

[*All items under question 5 will be presented in order*]

[*All items under question 5 will be presented in 1 table]*

[*All items under question 5 will be presented a 5-item likert scale from strongly disagree to strongly agree]*

[All items under questions 5 will have the following pre-amble]

Please think back to the time you made your choice of therapy and indicate the level to which you agree with the following statement.

Informed Subscale:

I knew which options were available to me.

I knew the benefits of each option.

I knew the risks and side effects of each option.

Values Clarity Subscale:

I was clear which benefits mattered most to me.

I was clear about which risks and side effects mattered most.

I was clear about which is more important to me (the benefits or the risk and side effects)

Support Subscale:

I had enough support from others to make a choice

I was choosing without pressure from others

I had enough advice to make a choice

Uncertainty Subscale:

It was clear from me what was the best choice was

I felt sure about what to choose

The decision was easy for me to make

Effective Decision Subscale

I felt I made an informed choice

My decision showed what was important to me

I expected to stick with my decision

I was satisfied with my decision

Q.5b. [Decisional Conflict Scale Addendums]

[*All items under question 5 will be presented in order*]

[All items under questions 5 will have the following pre-amble]

Please think back to the time you made your choice of therapy and indicate the level to which you agree, disagree, or unsure with the following statements.

Overall survival is the same between mastectomy and breast conservation therapy

Overall survival is higher with mastectomy

Overall survival is higher with breast conservation therapy

Local recurrence rate is the same between mastectomy and breast conservation therapy

Local recurrence rate is higher with mastectomy

Local recurrence rate is higher with breast conservation therapy

Please indicate where most of your support came from during your treatment decision-making process. Please select all that apply.

Family members

Friends

Physician

Nursing support

Social media

Other, please specify:

Q6. Demographic Factors

Finally, we would like to ask some questions about yourself.

1. Please provide your age at the time of surgery – *[Numerical]*
2. Please provide the first 3 characters of your postal code only. Your postal code will only be used to report travel-related difference by region/geography and will not be used to identify you in any way. Please use the format 'S7N'
3. Which best describes the area where you live?
    a. Urban, please specify the city you live in:
    b. Rural
4. Approximately how many kilometers (km) is your home away from the surgical centre?
5. Approximately how many kilometers (km) is your home away from the radiation centre?
6. Which city did you have your surgery in?
    a. Saskatoon

   b. Regina
   c. Moose Jaw
   d. Prince Albert
   e. Lloydminster
   f. North Battleford
   g. Swift Current
   h. Yorkton
7. Will you be staying at home or your primary residence during radiation treatments?
   a. Yes
   b. No, please specify where you will be staying:
   c. Don't know/undecided
   d. Not applicable
8. Weight + Height [*for BMI*]
   a. *[Weight → Space for lbs or kg]*
   b. *[Height → space for cm and ft+inches]*
9. What was your pre-operative breast cup size?
   a. A
   b. B
   c. C
   d. D
   e. E
   f. F
   g. G
   h. H
10. Did you have pre-operative breast MRI?
   a. Yes
   b. No
11. Were you offered reconstruction? (JUST MASTECTOMY)
   a. Yes
      i. Were you offered immediate reconstruction
      ii. Were you offered delayed reconstruction
      iii. Were you offered both?
   b. No
12. Please list all medical conditions you have:
13. What was your total annual household income in 2015?
   a. Less than $20,000
   b. $20,000 - $39,999
   c. $40,000 - $59,999
   d. $60,000 - $79,999
   e. $80,000 - $99,999
   f. $100,000 - $120,000
   g. Greater than $120,000
   h. Prefer not to disclose
14. Are you currently employed?
   a. Yes
   b. No
15. Occupation

   [display logic → only display if they are employed]

   a. [Open ended]

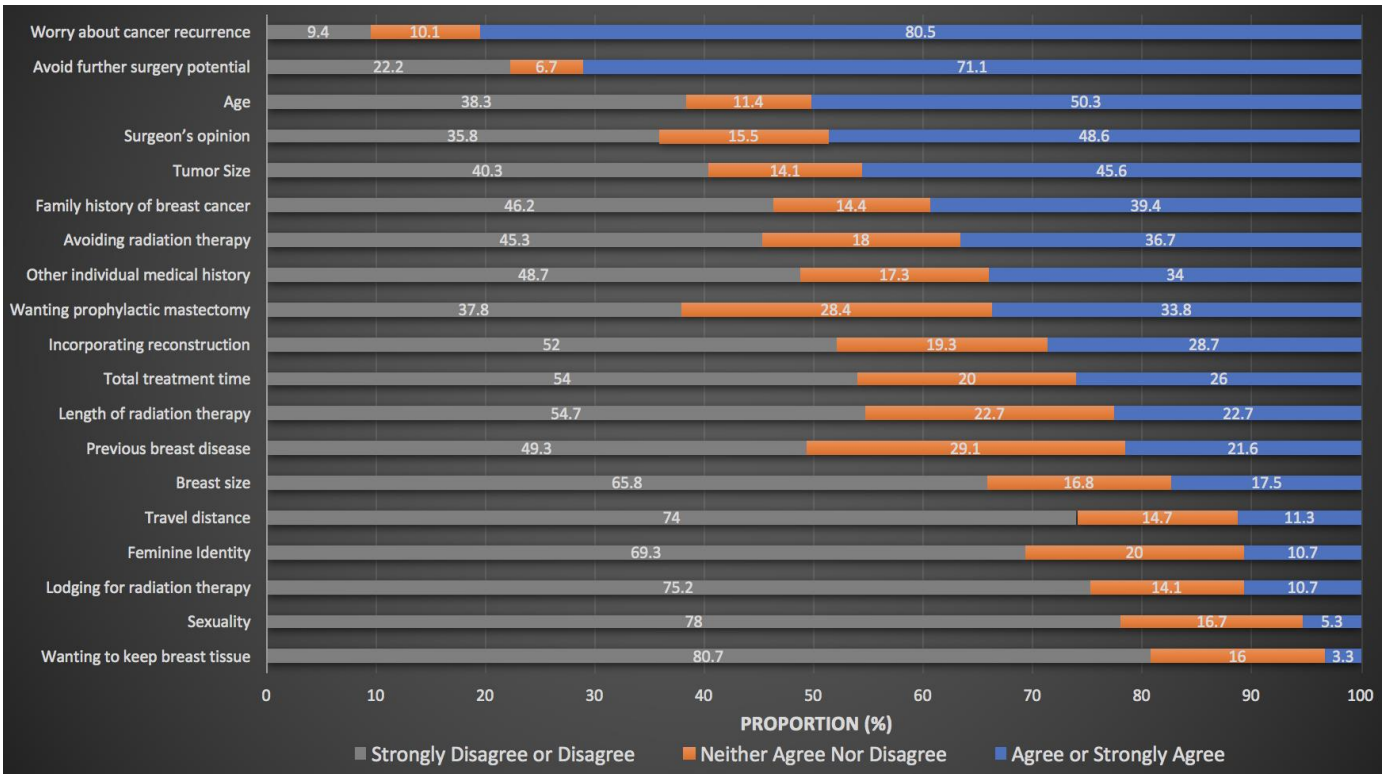
16. What is the highest level of formal education you have received?
    a. Less than high school
    b. Completed high school
    c. Some technical or community college
    d. Completed technical or community college
    e. Some university
    f. Bachelor's degree
    g. Master's degree
    h. Professional degree or doctorate
17. Were you in a relationship around the time of decision-making?
    a. Yes, I was in a relationship
    b. No, I was not in a relationship
18. Do you have children?
    a. Yes
        i. Please indicate how many children you have in the space provided:
    b. No
19. Please indicate your smoking status
    a. I have never smoked cigarettes
    b. I used to smoke cigarettes, but have quit
    c. I currently smoke cigarettes
20. What ethnicity do you identify with?
    a. Caucasian
    b. First Nation, Métis or Inuit?
    c. Asian
    d. African American
    e. Hispanic
    f. West Indian/Caribbean
    g. Other
21. At the time of your diagnoses, are you pre or post menopausal? Menopause is defined as one full year with no menses)
    a. Pre-menopause
    b. Post-menopause
22. If post menopausal, did you go through menopause because of surgical removal of your uterus or ovaries (hysterectomy or oophorectomy)
    a. Yes
    b. No
23. Have you ever been tested positive for BRCA (a genetic marker indicating high risk breast cancer)?
    a. No
    b. Yes
24. Have any of your family members ever been tested positive for BRCA?
    a. No
    b. Yes
    c. Unsure

Thank you so much for taking the time to complete this survey.

Data items not in the questionnaire. Information from the Saskatchewan Cancer Agency:

- C-code (C-code = breast, and location – quadrant)
- C-code English description
- Morphology (Gross Histology)
- Morphology English description (ie. Ductal carcinoma)
- Behavior (All would be 3 = malignant (not in situ)
- Grade (Value of 1-4, or 9=unknown)
    - 1 = Well differentiated
    - 2 = Moderately differentiated
    - 3 = Poorly differentiated
    - 4 = Undifferentiated / anaplastic
    - 9 = Unknown
- Laterality
- Multiplicity Counter (Number of tumors, ie. 1 or 2, 3.)
    - Most patients with multiple tumors have the 'North American Multiple Primary and Histology Rule' – from SEER
    - See below from more details →
- Tumor Size
- Regional Nodes Positive
- Regional Nodes Examined
- SSF 1 – ER Assay (010 = Positive or Negative or Not Done or Unknown [treated in different province])
- SSF 2 – PR Assay
- SSF 14- HER2: Result of Other or Unknown Test
- SSF 16 – Combination ER, PR & HER2
- Overall Stage, T, N and M stage values (AJCC 7th Edition)
- Surgery Date
- Radiation therapy
- Chemo therapy
- Hormone therapy

Supplementary Figure 1: Personal Belief and Preference Factors For Mastectomy Participants Only



Supplementary Figure 2: Personal Belief and Preference Factors For BCT Participants Only