Treatment Decisions and Breast Cancer: Psychosocial Outcomes
Protocol 2013-0752
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1.0 OBJECTIVES

Breast cancer is the most common cancer for women in the U. S. and an estimated 232,340 women will be diagnosed in 2013.[1] After diagnosis, women and their physicians must consider many treatment-related decisions which are often made quickly while women are still adjusting to the news of their diagnosis. For women with unilateral breast cancer, another option is the removal of the cancer-free breast (contralateral prophylactic mastectomy, CPM). In our research, more than 59% of women with breast cancer have initial interest in CPM; thus, this is an issue that affects the majority of women with breast cancer. The use of CPM in patients with sporadic unilateral invasive breast cancer increased by 150% from 1993 to 2003 and its use continues to increase.[2,3] While CPM reduces the risk of developing a contralateral breast cancer, there is no evidence that it reduces breast cancer mortality or overall death.[4] Women with early stage sporadic breast cancer have a 0.5 to 0.75% annual risk of developing contralateral breast cancer[5-8] and for most, the risk of distant metastatic disease is greater than the risk of developing a contralateral breast cancer. Despite evidence that adjuvant endocrine therapy reduces the risk of contralateral breast cancer,[9-11] an increasing number of women choose CPM; however, the outcomes of these patients are not well understood. Much of our knowledge about prophylactic mastectomy is from studies of high risk women who have a 40-65% lifetime risk of developing breast cancer[12,13] and represent less than 10% of breast cancer patients. Thus, little information is available to help average risk women make this important and irreversible healthcare decision. This study will provide the data critical to inform women about the likely psychosocial outcomes if they undergo CPM or receive standard of care (no CPM). We expect the results will improve patients' understanding of the benefits and risks of CPM and guide the development of evidence-based practices to enhance the individualized treatment decision-making process.

Specific aim is to:

1) To prospectively examine the psychosocial outcomes of women with sporadic breast cancer who have CPM versus those who do not. We will also determine the impact of patient and physician characteristics on the outcomes. We hypothesize that women who have CPM will have more decisional regret (the primary outcome), cancer-specific distress, cancer worry, and fear of recurrence and lower satisfaction with their decision than those who do not have CPM.

2.0 BACKGROUND AND RATIONALE

Breast cancer is the leading cause of cancer among women in the U.S., affecting approximately 226,870 women annually.[14] The majority of patients (93%) are diagnosed with operable disease and undergo surgical management of the affected breast with either breast conserving surgery or mastectomy.[15] It is well recognized that adjuvant systemic chemotherapy has substantially reduced the probability of dying from breast cancer.[16] Among women with hormone-positive breast cancers, adjuvant treatment with tamoxifen or aromatase inhibitors reduces the risk of developing a contralateral breast cancer by

approximately 50%.[9] In fact, it is estimated that the combination of mammography screening and adjuvant systemic therapies have contributed to a 30% overall reduction in breast cancer mortality over the past decade.[17]

Despite these major achievements over the past two decades in reducing breast cancer mortality through evidence-based practices, there has been a rising incidence of CPM. The combined annual rate of CPM (~8%) in population-based studies of women with invasive breast cancer or ductal carcinoma in situ[2,3] translates into over 18,000 potentially over-treated patients based on an expected 226,870 new breast cancer cases in 2013.[14] Rates of CPM are even higher in academic medical centers and were estimated to be between 14-28% from 2006 to 2007.[18-20] These higher than average annual rates of CPM at centers that offer multidisciplinary care may reflect an increasing trend in the numbers of patients with sporadic breast cancer electing to undergo CPM and the availability of plastic surgery expertise for reconstruction. Our previous studies with breast cancer patients suggest that, before meeting with their surgeon, 59% of women indicated they had at least some interest in CPM. Hawley et al. reported in a population-based survey of women from Detroit and Los Angeles that among women undergoing a mastectomy of their affected breast, 53% said that they considered CPM.[21] Thus, the topic of this proposal affects the majority of women with stage I-III breast cancer.

Patients perceive that CPM with reconstruction is associated with a reduced risk of surgical complication because it is the removal of a healthy breast.[22] However, in addition to increased medical cost, CPM with reconstruction has surgical morbidity. Several studies have shown surgical reoperations are common among women who receive prophylactic mastectomy and reconstruction.[23-25] Frost et al reported that 27% of women had at least one unanticipated reoperation after CPM[24] and Barton et al[26] and Crosby et al[22] reported that 27% to 66% of women had at least one complication. This means that at least one-third of patients might not have experienced a surgical complication if they had they had not chosen CPM. The reason for the increasing incidence of CPM at a time when medical advancements have significantly improved the lives of women with early-stage breast cancer is poorly understood yet has a profound impact on patient surgical morbidity, the economic burden of cancer treatment and cancer survivorship.

Previous research that has examined decision making about women's choice of mastectomy or breast conservation therapy for treatment of early-stage breast cancer has found that multiple factors influence women's surgical decisions including demographic characteristics (e.g., age, race, marital status) and women's own perceptions and values.[27] Physicians have also been found to influence surgical decision making.[28] For women who are at high genetic risk for cancer, readiness to engage in genetic testing was associated with perceptions that the benefits outweigh the risks[29] and research suggests that medical, psychological and social context factors affect women's decision making.[30] Anxiety and worry, for example, have been associated with BRCA testing and management decisions.[31] Research has also found that, among those who prefer to be involved, shared decision making is associated with better psychosocial adjustment.[32-34] The current proposal includes these factors as well as other variables that are hypothesized to influence decision making about CPM.

Another important gap in knowledge is how CPM for women with unilateral sporadic breast cancer affects their psychosocial adjustment following surgery. This information

is essential to provide women and their physicians with guidance about making the decision to have CPM. The studies that have been conducted to date have been primarily retrospective[35-38] and they have included women with breast cancer who are at higher risk of contralateral breast cancer (e.g., BRCA 1/2 mutation carriers).[39,40] In addition, the lack of a control group in these studies limits our ability to ascertain whether CPM is associated with better or worse psychosocial outcomes.[36,37,41,42] Frost et al[42] retrospectively collected data on a cohort of women who had CPM from 1960 to 1993. The first questionnaire was administered on average 10.7 years and the second one 20.2 years after receiving CPM. In this retrospective study, 90% of women were satisfied or very satisfied with their decision. Women who were dissatisfied reported adverse body image and adverse symptoms or complications.[42] Forty-four percent of the sample reported adverse effects of CPM for one or more social or psychological domains. Most adversely affected were body appearance, feelings of femininity, and sexual relationships. Importantly, all women in this cohort had a family history of breast cancer and therefore the findings may not reflect the experiences of average risk breast cancer patients. Nonetheless, prior research suggests that a proportion of women who undergo CPM experienced decreased satisfaction with appearance despite overall high satisfaction with their decision.[37,38] It is not known whether the outcomes of average-risk women would be similar or not. Given that their risk of contralateral breast cancer is lower and for women with estrogen receptor (ER)-positive disease there are alternative approaches to further reduce risk (e.g., taking tamoxifen or aromatase inhibitors), there is reason to believe that their experiences may be quite different. Rolnick et al[43] examined what women wished they had known before prophylactic surgery (both women who had CPM and women who had bilateral prophylactic mastectomy) and found that more than 58% of women wished they had more information before having CPM.[43] Specific areas of reported insufficient information were about reconstruction and implants and complications such as pain, scarring and numbness. Women also reported wishing they had more information about the potential for negative emotions following surgery. These results suggest areas of concerns of women with unilateral sporadic breast cancer following CPM, but a prospective, comprehensive study is needed in order to examine these issues in average risk women.

3.0 RESEARCH DESIGN AND PROCEDURES

Study Population. Patients will include women seen at MDACC (n=245) or K-S (n=100) who meet the following inclusion criteria: ductal carcinoma in situ (DCIS) or Stage I-III newly diagnosed sporadic unilateral invasive breast cancer; over age 18; and able to speak, read, and write in English. Patients with previous breast cancer, prior history of prophylactic mastectomy or are known to have a germline gene mutation that predisposes them to an increased risk of breast cancer (e.g., BRCA1, BRCA2), and/or if they are considered at high risk for contralateral breast cancer on the basis of a strong family history of cancer will be excluded.[44] Based on our estimates over the past 5 years and the data from our completed R21 study, we expect that at least 10-15% of women who come for surgical treatment for ductal carcinoma in situ (DCIS) or Stage I-III unilateral breast

cancer will opt for CPM. Thus, for patients approached at their initial surgical consult appointment, we will screen all eligible patients during the 27-month recruitment period for initial interest in CPM (see section below) at the time of recruitment to identify women who are and who are not initially considering CPM. Spouse/partner eligibility: married or living with partner for at least 1 year, 18 years or older, able to speak, read and write in English.

Study Procedures.

After completing the initial set of questions (patient information/demographics questions for all patients and screening questions for patients seen at initial surgical consult), patients who consent to the study will be given questionnaires to complete at five time points: baseline (around the time of study enrollment), and approximately 1, 6, 12, and 18 months following their surgery for breast cancer. For participants who prefer to complete the study survey(s) electronically, participants may complete on-line versions of the same survey(s) using REDCap (Research Electronic Data Capture).

Participants will receive a $20 gift card after completing the study questionnaire at each time point to compensate them for their time and effort. They can receive up to $100 in gift cards if they complete questionnaires at all 5 time points. Parking reimbursement will be provided for patients and spouses participating in the optional interview if he/she opts for an in-person interview at MD Anderson.

Study Measures**.** The domains chosen for study measures are based on the Integrated Model of Behavior[45,46] and Ottawa Decision Framework[47] as well as results of our R21 study of decision-making and CPM.

Background Information. Participant will complete demographic information (i.e., age, race, ethnicity, marital status, education, and occupation). Medical variables (i.e., date of breast cancer diagnosis, method of detection, tumor histology, nuclear grade, stage, human epidermal growth factor receptor (HER2/neu), estrogen receptor (ER) and progesterone receptor (PR) status, and weight and height at diagnosis) will be extracted from patients' charts.

Cancer-Specific Distress. Cancer-specific distress will be measured with the Revised Impact of Events Scale (IES). The IES assesses two common categories of responses to stressful events: intrusion and avoidance. The IES has good internal consistency reliability (0.70 to 0.85).[48] For this study, patients will be asked to rate the frequency of intrusive thoughts and avoidance behaviors related to their cancer.[48,49]

Breast Cancer Worry Scale. Breast cancer worry will be assessed with a 4-item scale developed by Lerman et al.[49,50] These items assess the extent to which worry about breast cancer interferes with women's daily functioning.

Fear of Cancer Recurrence. Fear of recurrence will be assessed with a 5-item scale that measures patients' beliefs and anxieties about disease recurrence.[51,52] It has been used with a variety of cancer populations and the psychometric properties of this measure have been well-established.[53,54]

Satisfaction with Decision Scale. A measure of women's satisfaction with their surgery decision.[55] It has been used with a variety of healthcare decisions

and has been shown to have good reliability and validity.[55] It will be administered at 1, 6, 12 and 18 months post-surgery.

Decisional Regret. This brief scale measures distress or remorse about the surgical decision.[56] It has been used to assess regret with a variety of healthcare decisions and has been shown to be reliable and valid.[56] It will be administered at 1,6,12 and 18 month assessments.

4.0 Statistical Considerations.

Analytic Methods:

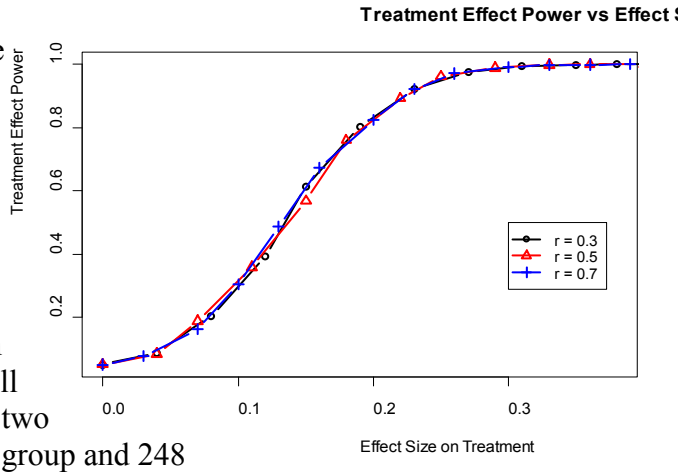
General: Our first steps will be to summarize patients' baseline demographic, risk behavior, and disease-related information using descriptive statistics. This will include means, standard deviations, medians and ranges for continuous variables and frequencies and percentages for categorical responses. Descriptive statistics will be summarized separately for each group and for each group over time for psychosocial variables. Groups of women will include women who have had CPM and those who have not had CPM. For women for whom we have information on their initial interest in CPM, the latter category of women also being categorized by those who initially had an interest in CPM versus those who did not have an interest in CPM. We will compare information about these groups of women for continuous variables using t-tests, analyses of variance (or their nonparametric equivalents such as Wilcoxon rank sum tests) or for categorical variables chi-square tests or Fisher's Exact tests. Group comparisons tested for significance will include the two primary groups of CPM versus no CPM and also for the women for whom we have information on their initial interest in CPM, the three following groups: initial interest and had CPM, initial interest but did not have CPM, and no interest and did not have CPM.

Our initial primary analyses for each psychosocial variable will evaluate women's psychosocial outcomes over time using a general linear model (PROC GLM in Statistical Analysis Software (SAS)) incorporating information over time (baseline and 1, 6, 12, and 18 months post-surgery) with the psychosocial variable being the dependent variable and whether or not the women had CPM the independent variable. We will determine if the psychosocial variable (on average) differs between the groups, if there are differences over time (averaged over groups), and whether or not these differences of time are different for different groups (a group by time interaction). Analyses will be made in SAS version 9.3 (SAS Institute Inc., Cary, NC, USA).

Missing Data. Because we are using patient-reported outcomes, some individuals will fail to complete all questionnaires. PROC GLM in SAS is designed to handle this type of missing data and will give unbiased estimates of effects over time provided that the probability of having missing data depends only on the covariates in the model. We will check this assumption by looking at predictors of missing data. We will also run analyses to examine whether study participants who drop out of the study early differ from those who do not. With the use of PROC GLM, we will be able to include all participants in the analysis, even those with missing values for some time points and those who drop out early. We will also use alternative multiple imputation methods to estimate missing values using differing assumptions if the data appear to not be missing at random. Several

strategies will be used to decrease the chance of missing data and non-compliance. Forms will be reviewed upon receipt to ensure all items are completed, and if incomplete, participants will be contacted to determine if the question was deliberately skipped and, if not, to get a response. Patients will be contacted numerous times by mail and by phone to ensure questionnaire completion. Scheduling of follow-up visits will coincide with clinic visits, and as such, missing data will be kept at a minimum.

Sample size: Given information from the recently completed R21 study and rates over the past 5 years, we estimate that approximately 11.5% of women meeting eligibility criteria will have CPM. All power analyses assume a significance level of 0.05 and a two-sided test. Assuming a 10% attrition rate and an additional loss of 10% of patients due to eligibility changes post-enrollment, we will enroll approximately 345 participants to ensure that approximately 311 participants continue on study to yield complete data on at least 280 participants. Therefore, about 32 women will have CPM, and 248 will not. For comparisons of these two groups of women, a sample size of 280 (32 in the CPM group and 248 in the non CPM group) at 18 months post-surgery will provide 80% power to detect an effect size of 0.54 or greater for the continuous dependent variables.



Since the primary psychosocial outcomes (such as decisional regret distress and scale) include repeated measurements that are correlated within subjects, our approach will utilize linear mixed model analysis (LMM, a special case of generalized linear mixed modeling in which each outcome variable is continuous). For the LMM analyses of continuous dependent variables across time (baseline, 1, 6, 12, and 18 months post-surgery), we calculated detectable effects based on a wide range of homogeneous correlations, namely, 0.3, 0.5, and 0.7, between repeated measurements. To simplify the power calculation procedure, we assume that there is no interaction between treatment and time points. The detectable effects of treatment are presented in Table 3. The calculations were done using PASS 2005 (Power Analysis and Sample Size Software). We provide a brief explanation of the results presented in the first row. In the first row, the homogeneous correlation between treatments across time points is assumed to be 0.3. A sample size of 259 (32 in the CPM group and 227 in the non CPM group) will provide 80% power to detect a standard deviation (SD) in means across groups of 0.10 (an effect size of 0.19), which corresponds to the means of 0, 0.290 (in SD unit) in the two groups. The above figure provides the power plot by effect size on treatment when the correlations (r) are 0.3, 0.5, and 0.7, respectively.

Table 3. Detectable treatment effects over time using LMM analysis with 80% power

Correlation between assessment (r)	Detectable mean diffs effects on treatment	SD of effect on treatment	Effect Size among treatment
0.3	0, 0.290	0.10	0.19
0.5	0, 0.306	0.11	0.19
0.7	0, 0.340	0.12	0.19

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