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Preconsultation Educational Group Intervention Can Address the Knowledge Gap in Postmastectomy Breast Reconstruction

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Background: Whether to undergo postmastectomy breast reconstruction (PMBR) is a challenging, preference-sensitive decision. It is therefore paramount to optimize decision quality through ensuring patients' knowledge and aligning treatments with their personal preferences. This study assessed the effects of a preconsultation educational group intervention (PEGI) on patient knowledge, state-trait anxiety, and decisional conflict (patient uncertainty in decision making) during the decision-making process. **Methods:** This phase 3 randomized controlled trial assessed effects of a PEGI in women without active breast cancer undergoing delayed PMBR, or prophylactic mastectomy with immediate PMBR. Both groups underwent routine education before consultation. In addition, the intervention group underwent a PEGI composed of presentations from a plastic surgeon and nurse, a value clarification exercise, and shared experiences from PMBR patients before the consultation with the plastic surgeon. Before and 1-week after consultation, outcome measures were assessed using the Decisional Conflict Scale, State-Trait Anxiety Inventory, and the BREAST-Q.

Results: Of the 219 women deemed eligible, a total of 156 women were recruited and randomized. Treatment fidelity was 96% and retention was 88%. At baseline, there were no significant differences in terms of demographic or clinical status, knowledge, state-trait anxiety, and decisional conflict. Patient knowledge about PMBR improved in both groups; however, the degree of knowledge attainment was significantly greater in the PEGI group (24.5% improvement in the intervention group compared with 13.5% in the routine education group, $P < 0.001$). The reduction in decisional conflict from baseline to follow-up was greater in the intervention group compared with the routine education; however, the difference only approached significance ($P = 0.09$).

Conclusions: The provision of a preconsultation educational group intervention has been shown to significantly close the knowledge gap on PMBR in patients

seeking delayed breast reconstruction or prophylactic mastectomy with immediate breast reconstruction compared with routine education alone.

Key Words: randomized controlled trial, postmastectomy breast reconstruction, group educational intervention, shared decision making, patient uncertainty, patient knowledge, patient preferences

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Breast cancer is the most common malignancy affecting more than 200,000 women per year in North America; approximately 38% of these patients undergo mastectomy.¹ The long-term ramifications of mastectomy therefore affect a large number of breast cancer survivors and are important to consider.^{2–4} For many women, the opportunity to reconstruct the mastectomy defect can result in a reduction of psychosocial distress.^{5,6} In fact, the uptake of postmastectomy breast reconstruction (PMBR) is increasing, and its positive effects on psychosocial well-being have been well documented.^{7–10} Nonetheless, despite these demonstrated benefits, the choices for PMBR are many, and the advantages and disadvantages each option can be difficult for patients to appreciate. With no superior option,^{11,12} and many factors to consider, whether to undergo breast reconstruction is a complex preference-sensitive decision.

Assuring the quality of a preference-sensitive decision relies on 2 conditions being satisfied: the patient has adequate knowledge to make an informed decision, and the selected treatment is consistent with the patient's personal preference. Unfortunately, there is evidence that neither condition is adequately met for patients considering PMBR.^{13–17} Specifically, there is a shortage of reliable information available on reconstructive options^{18,19} as well as little agreement on the most effective method of information delivery to the patient.²⁰ Dissatisfaction with information can contribute to decision regret and can have subsequent ill effects on patients' psychological health.²¹ Furthermore, within the increasing time constraints of consultations, 2-way informational exchange and shared decision-making dialog is rarely achieved,²² thereby further deteriorating quality of preference-sensitive decisions.

A possible solution to help patients navigate through complex preference-sensitive decisions is to use a shared decision-making approach. This approach recognizes the expertise of the healthcare professional as the expert in providing treatment options, benefits, harms, and probabilities, and the patient as the expert in understanding and judging the personal importance she attaches to each option.^{13,23} A shared decision-making approach that is applied specifically to PMBR may improve patient knowledge, reduce decisional conflict, and result in a greater satisfaction in her ultimate decision to undergo PMBR. Another group has reported reduction in decisional conflict, decision regret, and depression when a decision aid booklet overviewing breast reconstruction was provided to their patient before surgery.²⁴ To expand upon such approaches, our group has previously developed a preconsultation educational group intervention for women considering PMBR.²⁵ Through a subsequent pilot randomized controlled trial,²⁶ we established the high feasibility and positive effect of this intervention in improving decision-making quality.

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The objectives of this full-scaled randomized controlled trial were to evaluate the impact of this preconsultation educational group intervention on patient knowledge, decisional conflict, anxiety level, and satisfaction with healthcare during the surgical decision-making process.

METHODS

Patients

The study was conducted at University Health Network (UHN), a tertiary cancer center, from March 2014 to December 2015. The study was reviewed and approved by the UHN Research Ethics Board, with written informed consent obtained from all patients.

Eligible patients were women 18 years or older who were referred to 1 of 3 plastic surgeons at UHN for PMBR consultation, either delayed or prophylactic with immediate reconstruction. Women were excluded if they had active or in situ breast cancer, could not communicate in English, were seeking secondary breast revision or nipple reconstruction only, had a previous consultation with a plastic surgeon, or had a cognitive impairment or significant untreated psychiatric comorbidity. Potential patients were identified through a prescreening process of patient referrals, and these women were subsequently contacted via telephone by the study coordinator to confirm eligibility. Women who agreed to participate were mailed a package containing an informed consent form, a baseline questionnaire, a breast reconstruction information booklet, and a return envelope with prepaid express postage.

Randomization and Allocation

After the patient's signed informed consent and baseline questionnaire were received, the study coordinator randomly assigned the woman to either the intervention or routine education alone. A computer-generated blocked, stratified (delayed versus immediate) randomization scheme was applied to allocate each patient into her respective treatment arm. Blocks of 12 patients (8 delayed, 4 immediate) with 6 patients per treatment arm (4 delayed, 2 immediate per arm) were used. To achieve allocation concealment, the randomization allocation list was developed by a statistician, independent from the study coordinator, using PROC PLAN in SAS. It was not possible to use a placebo, and therefore, patients were not blinded to their assigned treatment arm. In addition, the plastic surgeon leading the preconsultation educational group intervention (PEGI) was also the breast reconstruction consultation provider and thus could not be blinded.

Intervention

In addition to receiving routine education, women in the intervention arm underwent a PEGI. The content, format, and mode of delivery for the PEGI were based on the results of a formal needs assessment with breast cancer survivors and key informants led by Zhong.²⁷ The PEGI composed of presentations from a plastic surgeon and breast reconstruction nurse, a value clarification exercise, and shared experiences from patients who had undergone PMBR. The PEGI is centered on a conceptual framework based in the Ottawa Decision Framework consolidating theoretical concepts in general and social psychology, decision analysis, values, social support, and self-efficacy, to rectify decisional conflict.²⁶ This model proposes that it is unresolved decisional needs of a patient that imparts adverse consequences onto the quality of decisions.²⁸ In addition to reducing decisional conflict, the intervention is therefore designed to manage unrealistic expectations, clarify personal values, improve knowledge about surgical treatment versus alternative options, inform about the risks and benefits those options, provide social/peer support, and improve decision self-efficacy.

Outcome Measures

Before randomization, all patients completed a baseline questionnaire, containing questions on demographics characteristics, a knowledge test, the Decisional Conflict Scale, and the Spielberger State

Trait Anxiety Inventory (STAI). One week after the surgical consultation ± PEGI, patients completed a follow-up questionnaire, which included the decisional conflict scale, knowledge test, STAI, and the Functional Assessment of Chronic Illness Therapy - Treatment Satisfaction - Patient Satisfaction (FACIT-TS-PS) tool to assess patient satisfaction with healthcare for patients with chronic illness conditions.²⁹

Decisional conflict is the psychological discomfort a patient may experience as a result of the uncertainties inherent in making a preference-sensitive choice¹⁴ and is correlated with decision satisfaction, decisional regret, and overall quality of life.¹⁶ The Decisional Conflict Scale measures perception of the difficulty in making a decision that includes perceived uncertainty in choosing between options, modifiable factors contributing to uncertainty, and quality of the choice selected.³⁰ The questionnaire consists of 16 items with scores ranging from 0 to 100 (extremely high level of decisional conflict). Scores lower than 25 are associated with implementing decisions and scores exceeding 37.5 are associated with delay or feeling unsure about implementation.^{18–20,31}

The knowledge test was collected at baseline before randomization, 1 week after the consultation in the routine education group, and 1 week after the PEGI and consultation in the intervention group. The knowledge test was self-administered and consisted of 10 true or false questions (scored by number of correct responses out of 10 with a maximum score of 10).²⁶ The knowledge test on PMBR included the following topics: techniques for PMBR, timing of surgery, complication rates of surgery, and effect of PMBR on recurrence.

The STAI is a 20-item measure of situation-specific anxiety, with scores ranging from 20 to 80, and higher scores indicating greater anxiety.³² To determine control preference, patients were asked to choose from 5 statements from the Control Preferences Scale regarding the role they wish to take (active, passive, or collaborative) in decision making, as adapted previously.³³

The FACIT-TS-PS is a tool from a family of surveys developed to assess patient satisfaction with healthcare for patients with chronic illness conditions.²⁹ It contains 5 subscales, of which 4 were used (physician communication, treatment staff communication, technical competence, and confidence and trust) as well as 3 global questions regarding the quality of services.²⁹

Analysis

Data were analyzed using Stata software (Version 13; College Station, Tex) and an intent-to-treat approach. Descriptive statistics were calculated for all variables. Continuous measures that are normally distributed were summarized using means and standard deviations, with categorical measures summarized by counts and percentages. Descriptive statistics of patients' baseline characteristics were calculated and compared between 2 groups using the *t* test or Wilcoxon rank sum test for continuous variables and the χ^2 or the Fisher exact test for categorical variables. All tests were 2-sided and a *P* value of less than 0.05 was considered significant. The analysis of covariance was computed to compare treatment groups at follow-up controlling for baseline scores. Missing data were handled using multiple imputation. In addition to the overall comparison of the primary and secondary outcomes for the 2 treatment groups, subgroup analyses were performed to compare treatments for the primary outcome within the prespecified strata using an interaction test. Results from planned subgroup analyses to explore which subgroup may benefit most from the intervention are presented for exploratory data analysis.

RESULTS

Recruitment and Follow-up

From March 2014 to December 2015, 301 patients were referred to our center for PMBR and were prescreened for study eligibility (Fig. 1). Of these referrals, 56 women did not meet inclusion/exclusion criteria,

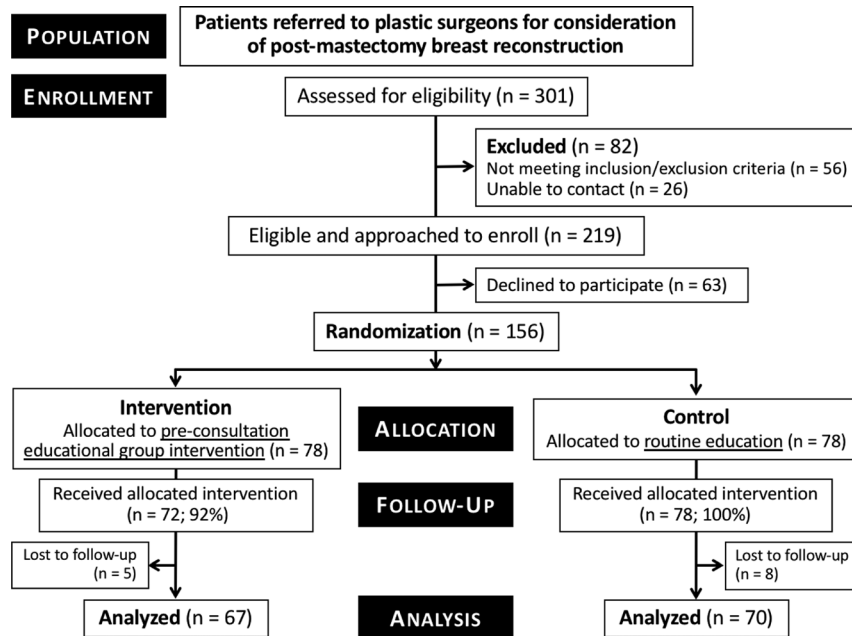


FIGURE 1. Consort diagram to assess the effect of a preconsultation educational group intervention on knowledge, state-trait-anxiety, and decisional conflict in women considering delayed or prophylactic with immediate postmastectomy breast reconstruction. Of 219 women considered eligible for the study, 156 were enrolled and randomized (71% recruitment rate). Overall completion rate was 88%.

whereas 26 could not be contacted before consultation. Of the 219 eligible patients, 156 patients agreed to participate—an overall recruitment rate of 71%. All 156 patients were randomized, 72 (92%) of those in the intervention group and 78 (100%) of those in the control group receiving their allocated intervention. One hundred thirty-seven patients completed all outcome measures, giving an overall completion rate of 88%.

Baseline Patient Characteristics

Baseline patient demographic and clinical parameters were similar between the 2 treatment arms (Table 1). Age, marital status, education attainment, employment status, and socioeconomic status did not differ between the groups. Similarly, surgical indication, whether prior chemotherapy or radiotherapy was used, and presence of comorbidities were also similar. In both groups, only 11% of women overall had previously attended a breast reconstruction information session. Patients were also comparable in measures of baseline psychosocial function including decisional conflict, state-trait anxiety, and decision control preference (Table 2). Women in both groups had a comparable level of baseline knowledge about PMBR, answering about 1 of every 2 questions correct on the knowledge assessment.

Decision Measure Outcomes

Both groups had significant reduction in decisional conflict at follow-up compared with baseline, 17.1 in the intervention group and 14.3 in the routine education group ($P < 0.05$; Table 3). The reduction in decisional conflict from baseline to follow-up was greater in the intervention group compared with the routine education; however, the difference only approached significance ($P = 0.09$).

Patient knowledge about PMBR improved in both groups after routine education with or without PEGI. The degree of knowledge attainment was significantly greater in the PEGI group (24.5% improvement in the intervention group compared with 13.5% in the routine education group, $P < 0.001$).

No significant difference was measured in anxiety level between the groups at either time points, and no significant change was observed from follow-up to baseline.

Patient-Reported Outcomes

At the follow-up time point, there was no difference between the intervention group compared with the routine education group in their satisfaction with health care provision as measured by the FACIT-TS-PS (Table 4).

DISCUSSION

Many breast cancer patients considering PMBR find the surgical decision making process to be a challenging experience. This problem is heightened when there is a lack of preexisting knowledge and when the clinical circumstance is multifaceted leaving patient feeling uncertain and distressed.³⁴ In this full-scale RCT, we have demonstrated that a preconsultation educational group intervention can significantly improve patient knowledge about PMBR compared with those who had routine education alone before their surgical consultation. By providing patients with a presentation on PMBR from a plastic surgeon, a nurse, a value clarification exercise, and peer counseling before the consultation with the plastic surgeon, the much needed knowledge gap in women considering PMBR can be addressed. This finding is in keeping with recent systematic reviews of other forms of decisional support tools similar to our intervention that have been found to improve patient knowledge.^{35,36} Unlike some studies that have found decisional support tools to also reduce decisional conflict, our study did not find that decision conflict was significantly reduced in the PEGI group compared with the routine education group when selecting PMBR treatment option.²⁶

Women in both arms of the study gained knowledge, but the magnitude of increase was greater in women receiving PEGI. In clinical circumstances where there is no single “best” treatment pathway, a sound foundational knowledge is necessary and arguably essential for sound decision making. One survey found that 43% of breast cancer survivors do not receive information about reconstructive options during treatment discussions.³¹ This is not for the lack of desire for knowledge, as it has been demonstrated that patients want as much information about their diagnosis and treatment options as possible.^{37,38} Deficiencies in knowledge about postsurgical care, complications, and physical alterations after surgery may lie at the

TABLE 1. Baseline Demographic and Clinical Characteristics by Intervention Group

	Total (N = 156*)	Intervention (n = 78*)	Routine (n = 78*)	P-Value†
	Mean (SD) n (%)	Mean (SD) n (%)	Mean (SD) n (%)	
Age	48.7 (9.3)	49 (9.4)	48 (9.3)	0.51
Marital status				
Single	117 (75)	59 (77)	58 (74)	0.74
In a relationship	38 (25)	18 (23)	20 (26)	
Education				
High school	16 (10)	6 (8)	10 (13)	0.26
College/university	111 (72)	60 (78)	51 (66)	
Graduate	27 (17)	11 (14)	16 (21)	
Employment				
Employed	103 (66)	50 (64)	53 (68)	0.61
Unemployed	53 (34)	28 (36)	25 (32)	
Income				
<\$60,000	45 (29)	20 (26)	25 (32)	0.69
\$60,000–\$100,000	51 (33)	26 (34)	25 (32)	
>\$100,000	57 (37)	30 (39)	27 (35)	
Race				
White	110 (71)	57 (74)	53 (69)	0.48
Nonwhite	44 (29)	20 (26)	24 (31)	
Indication for surgery				
Prophylactic	41 (26)	23 (29)	18 (23)	0.86
Stage 0	4 (3)	2 (3)	2 (3)	
Stage 1	18 (12)	7 (9)	11 (14)	
Stage 2	38 (24)	19 (24)	19 (24)	
Stage 3	34 (24)	15 (19)	19 (24)	
Stage 4	3 (2)	2 (3)	1 (1)	
Laterality of reconstruction				
Bilateral	29 (29)	14 (27)	15 (30)	0.77
Unilateral	72 (71)	37 (73)	35 (70)	
Chemotherapy				
Before OR	37 (24)	20 (26)	17 (22)	0.75
After OR	54 (35)	25 (32)	29 (37)	
No	65 (42)	33 (42)	32 (41)	
Radiotherapy				
Before OR	11 (7)	4 (5)	7 (9)	0.56
After OR	73 (47)	39 (50)	34 (44)	
No	72 (46)	35 (45)	37 (47)	
Active hormonal therapy				
No	81 (52)	40 (51)	41 (53)	0.87
Yes	75 (48)	38 (49)	37 (47)	
Chronic illness/comorbidities				
No	96 (63)	48 (63)	48 (62)	0.91
Yes	57 (37)	28 (37)	29 (38)	
Attended previous info session				
No	138 (89)	68 (88)	70 (90)	0.78
Yes	17 (11)	9 (12)	8 (10)	

*P value: calculated using χ^2 test or Fisher exact test for categorical variables and 2 sample *t* tests for continuous variables. *P* < 0.05 considered significant.

†Because of missing data, not every variable will have data equaling the n.

core of patient dissatisfaction with information.^{13,14} Therefore, improving patient knowledge using the PEGI model is a critical element in helping our patients make rational and high quality decisions about PMBR.

Decisional conflict, defined as uncertainly about which course of action to take when choice among competing actions involves risk, loss, regret, or challenge to personal life values, was not significantly reduced in the PEGI group compared with routine education.²⁶ Notably,

TABLE 2. Baseline Psychological and Knowledge Comparison Between Intervention and Control Groups

	Intervention (n = 78)	Routine Education (n = 78)	P
	Mean (SD)	Mean (SD)	
Decisional conflict	31.3 (12.9)	27.7 (12.3)	0.07
Spielberger State Anxiety Scale	37.5 (11.3)	37.6 (11.4)	0.96
Knowledge	50.2% (23.1%)	52.9% (20.5%)	0.52
Decision Control Preference	n	n	P
Active role	1	6	0.11
Collaborative role	76	70	
Passive role	1	2	

both groups did demonstrate a reduction in decisional conflict score (17.1 in PEGI and 14.3 in routine education); however, the difference between the 2 groups was only approaching significance ($P = 0.09$). We observed that although it is important for patients to have relevant information to a treatment choice, their individual levels of uncertainty about which course of action to take when there is no obvious “superior” option is not as directly affected as an outcome such as knowledge. Decisional conflict is a complex variable that integrates knowledge, individual style of decision making, and the necessary understanding of how a decision is aligned with one's own personal values. Despite the significant increase in knowledge, and reduction in decisional conflict experienced by women in both arms of this study, we did not observe significant differences in state anxiety scale or on patient satisfaction with health care provision between the 2 groups.

The strengths of this trial include the use of a randomized controlled design; the high recruitment rate, treatment fidelity, and a high completion rate (88%) contribute further to the validity of our study findings. Limitations include relatively restricted selection criteria of

TABLE 3. Bivariate Analysis of Intervention on Decisional Conflict, Knowledge, and Anxiety

	Intervention (n = 78)	Routine Education (n = 78)	P
	Mean (SD)	Mean (SD)	
Decisional conflict			
Baseline (n = 156)	31.3 (12.9)	27.7 (12.3)	0.07
Follow-up (n = 137)	12.3 (9.8)	13.1 (9.8)	0.62
Change	17.1 (12.1)	14.3 (11.2)	0.09
		ANCOVA	0.23
Spielberger State Anxiety Scale			
Baseline (n = 156)	37.5 (11.3)	37.6 (11.4)	0.96
Follow-up (n = 137)	32.6 (13.3)	35.8 (11.5)	0.14
Change	3.5 (10.4)	2.1 (8.8)	0.31
		ANCOVA	0.27
Knowledge			
Baseline (n = 156)	50.2% (23.1%)	52.9% (20.5%)	0.52
Follow-up (n = 137)	76.7% (12.9%)	66.8% (13.5%)	0.00*
Change	24.5% (20.5%)	13.5% (20.5%)	<0.001*
		ANCOVA	<0.001*

* $P < 0.05$

ANCOVA, analysis of covariance.

TABLE 4. Bivariate Analysis of Intervention on Patient Satisfaction With Health Care

	Intervention (n = 67)	Routine Education (n = 70)	P
	Mean (SD)	Mean (SD)	
FACIT-TS-PS			
Patient information	30.1 (7.6)	30.9 (6.4)	0.66

patients, being those who were seeking delayed PMBR or immediate PMBR with prophylactic mastectomy only. We intentionally excluded any patients with active breast cancer or in situ disease from this study, as we did not want to delay surgery in patients who needed timely treatment. Furthermore, the decisional needs of those women who had active breast cancer would be quite different from those who did not have active breast cancer.^{39,40} Because of the surgeon's involvement in PEGI as well, the study was also not blinded to the investigators. The other main limitation of this study arises from the short duration of follow-up period and the inability to correlate our findings with long-term clinically relevant outcomes. Although knowledge is an important measure of the quality of a patient's surgical decision, it does not in itself determine the patient's final experience of the surgical outcome. Therefore, we plan to conduct a future study that examines the correlation between knowledge and long-term decision regret and satisfaction with outcome in this group of patients.

In conclusion, the provision of a preconsultation educational group workshop has been shown in this RCT to significantly improve patient knowledge on PMBR in patients seeking delayed breast reconstruction or prophylactic mastectomy with immediate breast reconstruction compared with routine education alone. Our data may also suggest that a greater reduction in decisional regret can be found in patients who had undergone PEGI compared with routine education alone, a difference that approached statistical significance. These findings support the Salzburg Statement on Shared Decision Making in which a call was made for clinicians to share important decision making with patients and provide accurate information about options and uncertainties tailored to the individual patient's needs.⁴¹

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