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A decision aid to support breast cancer patients

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Background: **One of basic principles of patient protection is patient's right to make decisions for their health. In this study, the effect of a decision aid to support breast cancer patients was studied.** ***Methods*****: This clinical trial study was conducted on 60 early stage breast cancer patients who referred to Cancer Institute of Imam Khomeini Hospital of Tehran. Patients were randomly assigned into intervention (30 patients) and control (30 patients) groups. The patients in the intervention group were received decision aid package. In the control group routine care was done. Data was gathered by three questionnaires: demographic information, treatment method-decision conflict, and decision regret. Data analysis was performed by descriptive and inferential statistics like independent t-test and ANOVA using the SPSS software version 16.** ***Results:*** **Type of treatment was selected by patients, participating in decision-making and decision conflict were significantly different between two groups (p<0.05). Decision satisfaction or decision regret was not significantly different between two groups (p=0.087).** ***Conclusions:*** **The decision aid intervention, by involving patients in treatment decisions related to their health, was improved patients' awareness and confidence to start treatment. Also then, the treatment option was according to their values and priorities.**

INTRODUCTION

The patients as consumers of health care services have rights which physicians, nurses and other health professionals are responsible for preparing and protecting of these rights (1). These rights include quality of care, respect to personal beliefs and values of patients, right to know and participating in care decision making (1,2). Despite Patients' Bill of Rights was approved by the Ministry of Health and Medical Education of Iran in 2002, but these rights are still not well known and accepted (3). In most cases, the patient's health care team alone attempt to decide for patient and he/she accepts these decisions with confidence. While according to new definitions of patient rights, fundamental change has made in public perception of role of the patients, their authority and decision making (4). Legally patient should be received enough information about prescript intervention before signing the consent form and confirm that. Morally physician should be sure of the patient's knowledge of the intervention before acting (5). According to the one study, 74% of physicians and residents of Shiraz educational hospitals do not tell the patients about diagnosis of chronic incurable disease and the patients are unaware and unsatisfied of prognosis and decisions were taken for them (6).

The first condition for participating in decision-making is "having enough information" about therapeutic interventions (7). PDAs (Patient Decision Aids) are effective supportive tools designed to provide information for patients' difficult treatment or screening decisions. The main effort of DA (Decision Aid) is systematic and unbiased clarification of information for patients to make decisions based on their preferences (8). DA is different from traditional education. It emphasizes on options ahead, the detailed description of the risks and benefits of these options, clear possibilities and specific information of the same patients. So it can improve the quality of decision making, knowledge and information, illuminates the values and eliminates the unresolved contradictions in decision making (9). DA can be available in various formats such as booklets, interactive media, video or audio tapes. Of course it is not alternative for consultation or physician's visit, but is complementary or supportive (10).

Breast cancer is the most common cancer and the second mortal cancer in women in the world. Virtually every woman is in risk of developing it (11). The most current treatment options for control and treatment of this disease are aggressive procedures. These options have risk of serious side effects, and these may permanently alter a person's quality of life. Thus, decision making about treatment of breast cancer is center of attention and the patients must be able to create a balance between potential benefits of interventions against their risks and side effects and reduce of quality of life (12). Mastectomy and breast conserving therapy (lumpectomy) for early stage breast cancer are equivalent in term of recurrence rates and overall survival. Thus, this is an ideal situation for the use of decision aids, which provide information to facilitate shared decision making; because it is generally agreed that the decision making for each option should be based on woman's personal preference after she has considered the advantages and disadvantages of each procedure in discussion with the surgeon (13, 14).

In Iran no research has been done in this field and based on published studies in other countries, women with breast cancer require abundant information and are often applicant for participating in decision making; therefore, in this study was examined the effect of "decision aid" on breast cancer patients, to would be taken a step forward to implement successful teamwork in healthcare system in Iran, respect to the patients' rights and enhance the quality of their treatment, and it would be considered as a routine and supportive service.

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METHOD

Each woman with early stage breast cancer (DCIS or stage 0, stage I, stage II) can select the type of breast surgery which will be done for him. She should often select among lumpectomy (surgery of removing the tumor and a small amount of the tissue that surround it and maintaining the most tissue of the breast) and mastectomy (removing the whole of the breast). In the case of choosing the first method, maybe need to radiation therapy or chemotherapy for ensure of non-recurrence of the tumor (need to frequent returns for radiotherapy or chemotherapy, and control of procedures complications). If the patient chooses the second method, breast reconstruction surgery may be required according to her desire (costly cosmetic surgery) (15). The type of surgery that patient chooses, has impact on her appearance and how she is seemed. It has been shown that the most patients with these stages of breast cancer will have healthy life for a long time after treatment (16). Treatment is started usually a few days to a few weeks after the diagnosis; during this time patients have to meet surgeon and should know facts about surgical interventions and should think about what is important for them and then select (17).

This interventional study was a clinical trial that was conducted from 14/12/2016 to 16/03/2018. The sampling method was convenience. The samples of this study were 60 patients with early-stages breast cancer (DCIS or stage 0: the tumor size less than 2cm, without spread to the lymph nodes. Stage I: the tumor size 2-5cm, with or without spread to the underarm lymph nodes. Stage II: the tumor size 2-5cm, with or without spread to the underarm lymph nodes), were referred to the surgery clinic of Imam Khomeini Cancer Institute of Tehran University of Medical Sciences, who had inclusion criteria and randomly were assigned into two groups of intervention (n = 30) and control (n = 30).

Inclusion criteria were included: Stages I or II of breast cancer approved by cytology or pathology that are eligible for mastectomy or lumpectomy treatments; without previous history of cancer. The lack of serious non-malignant diseases such as cardiovascular, respiratory, renal is contraindications for surgery. The lack of mental incompetence like any diagnosed psychiatric disorder or addiction that prevents participating in the shared decision-making process and adherence to the protocol and the informed consent to participate in this study. Finally, have reading and writing literacy and Persian dialect language.

This study was approved by the Research Council and Ethics Committee of Tehran University of Medical Sciences with approval code of 6966/PK/91/D. The purpose and method of the study were stated to the patients and they were assured of confidentiality and anonymity of data. They were reassured that they could withdraw from the study at any time without any consequences. Lastly, written informed consent was obtained from those who agreed to voluntarily participate in the study.

The data was collected by patients' self-report and studying the reports of pathology by researcher and recording in the questionnaires. Three questionnaires were used: demographic and disease information questionnaire, O'Connor's Decisional Conflict Scale was included a question about chosen treatment for patient, a question about the decision maker person for the patient (patient or physician) and 16 questions on a 5-point Likert scale from 0 (strongly agree) to 4 (strongly disagree) that shown patient's uncertainty about choosing one of the options, factors affecting uncertainty as feel of unawareness about the benefits and risks of each treatment option, personal values, social support and understanding of appropriate decision. Score 0 meant no conflict in decision-making and score 4 meant having the greatest conflict and uncertainty in decision making. The third questionnaire was O'Connor's Decisional Regret Scale consisted of 5 questions in 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree), that questions 2 and 4 were scored reversely; Higher scores indicated greater regret. For validity of researcher-made data collection questionnaire, content validity was used; so that the literatures, texts and the faculty members' comments were used. For the validity of the decisional conflict and the decisional regret Scales, using translation-retranslation method, cultural matching and patients' understanding evaluation, the Persian version of the scales were prepared. For face validity, the scales were given to 10 patients with early stage breast cancer and the necessary changes were made. For reliability of scales, test-retest method was used and the scales were given to 10 another patients with early stage breast cancer and again two weeks later the scales were given to them and the Cronbach's alpha coefficient was calculated, that for the decision conflict scale was equivalent to 0.943 and for the decision regret scale was equivalent to 0.931, that were acceptable quantities.

To carry out the study, researcher in partnership with a breast surgery surgeon, select the eligible samples and completed the demographic and disease information questionnaire in the first meeting with patients. Intervention group was received decision aid package was included informational booklet, Audio CD and personal worksheet after visit and consultation with physician. The booklet was included key information about the disease, treatment options, advantages and disadvantages of each treatment option and its effects on patient, survival rate and quality of life in any option and requires information for decision-making, and guiding the patients between two treatment options (mastectomy or lumpectomy with radiation therapy). Audio CD was a supplement to the booklet and was in the narrative form about 20 minutes. It was guidance for using the booklet and was presenting important information and details to attract the patients. Personal worksheet was for recording final decision and any potential questions, comments or ambiguity by patients after reading the informational package. At the time of package delivery, the informational content of the booklet and CD were described by the researcher face to face to each patient. The patients were asked to study the package and consult with trustworthy persons for up to 4 days, then go back to the doctor again and announce their final decision about treatment. During this time, telephone follow up was done to answer the patients' questions and ambiguities once for each patient (especially for low-literacy patients) by project nurse (researcher). At the second visit, the questionnaire related to patient selected treatment and decision conflict was completed. The decision regret questionnaire was completed with phone or appointment 8 weeks after beginning treatment. The control group was received routine cares and treatment methods and those questionnaires were completed for them in the same way. Data were analyzed using SPSS software version 16, descriptive statistics, independent t-test and ANOVA.

RESULTS

In this study 60 patients were enrolled based on inclusion and exclusion criteria. All of these patients completed the study. Data analysis results showed that the two groups were homogenous in demographic characteristics and stage of the disease before the intervention. Most patients in this study were over 50 years old. Most patients in both groups were married and housewives and had education level of reading and writing. The majority of patients had moderate economic status and according to pathology reports, had breast tumor stage 2. Most patients

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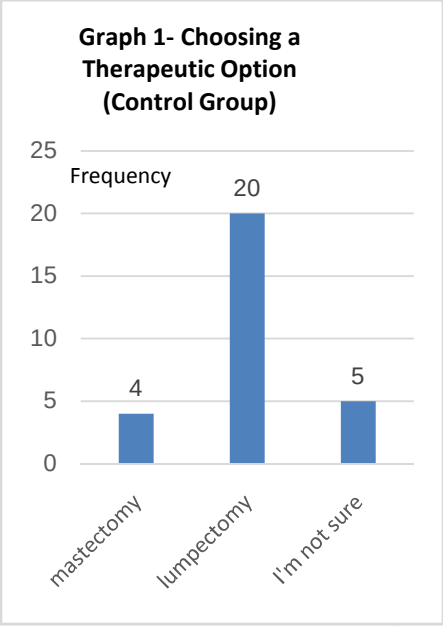
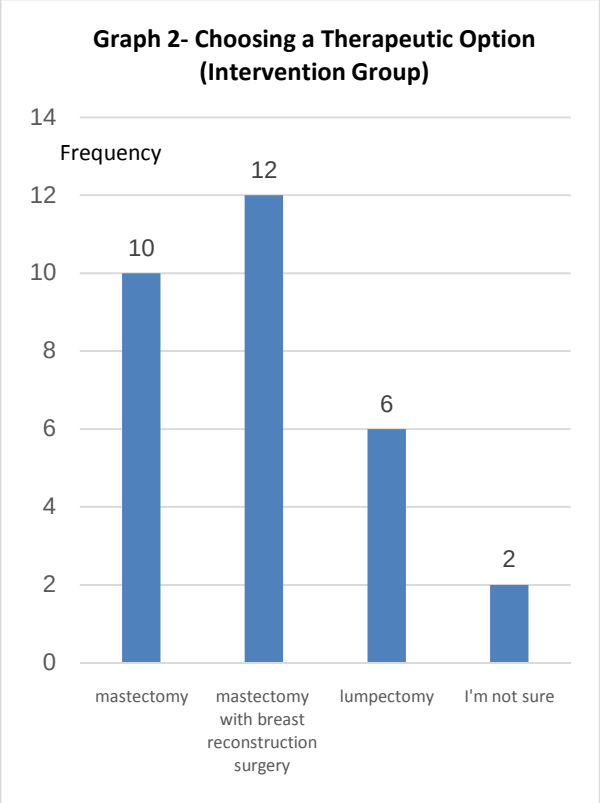
Table 1 Baseline Characteristics by Group

	Intervention n=30	Control n=30	P Value
Mean age (SD)	46.26 (12.52)	50.66 (11.59)	0.698
Marital status: Married	12 (40%)	10 (33.3%)	0.211
Level of education: Primary	22 (73.3%)	24 (80%)	0.770
Employment status: Housewife	28 (93.3%)	28 (93.3%)	1.000
Financial conditions: Medium	20 (66.7%)	20 (66.7%)	1.000
Stage of the disease: Stage	224 (80%)	18 (60%)	0.427
Family history of breast cancer: No	18 (60%)	26 (86.7%)	0.215
Previous knowledge about the disease: No	16 (53.3%)	18 (60%)	1.000

Table 2 Decisional Conflict Scale Completed as Preoperative Questionnaire

Decisional Conflict Scale	Intervention	Control	P value
Subscales	Mean (SD)	Mean (SD)	
Unawareness	2.84 (2.40)	6.3 (19.34)	0.001
Non Clear Values	3.34 (2.66)	6.36 (16.4)	0.001
Lack of Social Support	4.24 (3.86)	5.44 (20.26)	0.001
Uncertainty	10.94 (16.14)	12.22 (44.94)	0.001
Chosen Treatment Option	n (%)	n (%)	
Mastectomy	22 (73.3)	4 (13.3)	0.003
Lumpectomy	6 (20)	20 (66.7)	
Unsure	2 (6.7)	6 (20)	
Participating in Decision Making	n (%)	n (%)	
Yes (decision making by patient)	26 (86.7)	4 (13.3)	0.001
No (decision making by physician)	4 (13.3)	26 (86.7)	





had no history of breast cancer in their family and had no history of prior education or knowledge about the disease as well (Table 1).

In survey of decision conflict in all of its four sub-scales, significant differences were observed between two groups (P<0.001), so that in awareness dimension, the intervention group had higher awareness about the disease, treatment, advantages and disadvantages of treatments than the control group. In values dimension, in the intervention group the patients' individual values were identified and led decision making according to values. In social support dimension the intervention group felt more social support than the control group, and in certainty dimension, in the intervention group feeling confident was higher about decision-making and choice of treatment than the control group. As a result, conflict and uncertainty in decision-making in the intervention group were low in compare with the control group (Table 2).

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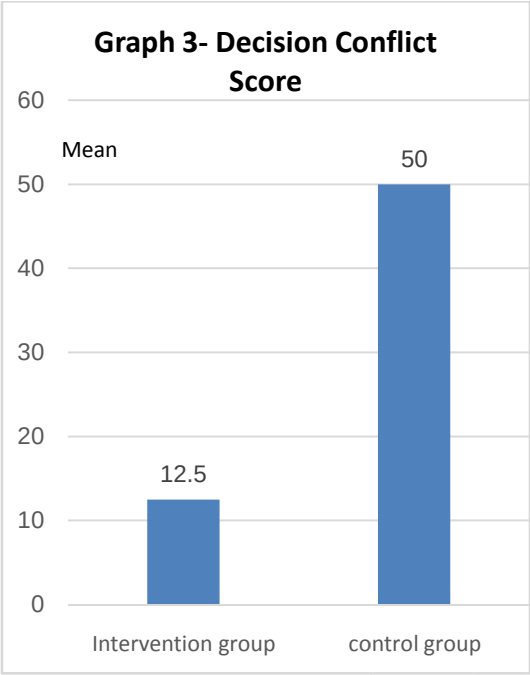
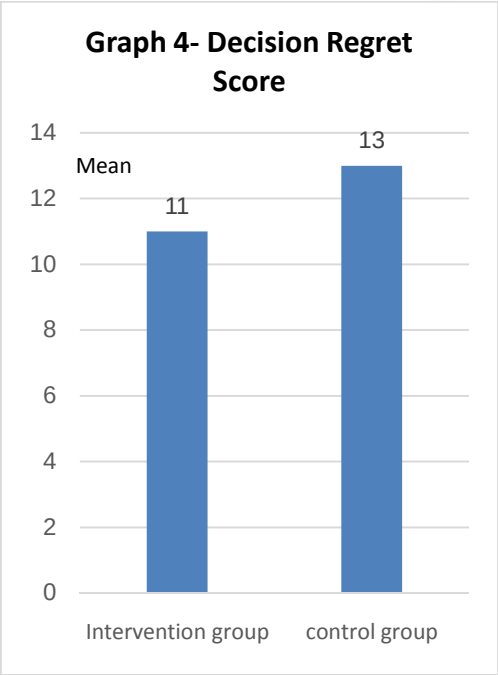
Table 3 Decisional Regret by Study Group (Postoperative Questionnaire)

Decisional Regret Scale	Intervention n= 30	Control n= 30	P value
Response= strongly agree/agree	n (%)	n (%)	
It was the right decision	18 (60)	10 (33.3)	0.502
I regret the choice that was made	2 (6.7)	2 (6.7)	0.663
I would go for the same choice if I had to do it over again	22 (73.4)	12 (40)	0.260
The choice did me a lot of harm	2 (6.7)	4 (13.3)	0.550
The decision was a wise one	20 (66.7)	12 (40)	0.384





There was a significant difference (P=0.003) between the two groups in type of treatment option was chosen by patients, so that the majority of patients in the intervention group chose mastectomy with breast reconstructive (73.3%), while the majority of patients in the control group chose lumpectomy followed by radiotherapy (66.7%). Participating in decision-making process in the two groups had a significant difference (P <0.001), so that the majority of patients in the intervention group (86.7%) had active role in decision making about their treatment options, while the majority of patients in the control group (86.7%) had not any role in their treatment decisions, and physicians made decisions instead of them (Table 2).

In Survey of decision regret, was not observed any significant difference (p=0.087) between the two groups eight weeks after operation, so that regret about deciding in all items, had no significant difference between the two groups (Table 3).

DISCUSSION

The main purpose of this study was to assess the impact of the patient decision aid for choosing surgical treatment in breast cancer. The results showed that the majority of patients in the intervention group chose mastectomy treatment, while the majority of patients in the control group chose lumpectomy with radiotherapy. In the clinical trial by D'Alimonte et al. (2012), the majority of patients with breast cancer stage I and II in decision aid group (94%) chose mastectomy and majority of control group (76%) chose lumpectomy and there was a significant difference between the two groups in this field (p= 0.003), while according to evidence, patients preferred less invasive approaches before the intervention (13). It seems that choose of this type of treatment by patients in the intervention group can be caused by their knowledge and awareness of benefits of therapeutic methods and possibility of complications' indication (reduce the risk of recurrence and lack of radiation therapy or chemotherapy following mastectomy in compare with lumpectomy), and clarification the real values and preference of patients about health and survival in return the body image after intervention.

Also, the majority of patients in the intervention group showed a preference for shared decision making, unlike the control group patients who preferred the surgeon to make a decision instead of them. According to the intervention group patients' viewpoint, having someone who knew and guided them to easily understood the requirements and options, without any bias, was an amazing method and it was really true that the final judgment was entrusted to them, after all the facts were shown to them.

In a study that was conducted by Albercht et al. (2011) for assessing the informational needs and preferences of decision-making in women with breast cancer, these women often had willing to participation in decision making about their treatment (16). In a study was conducted by Sheppard et al. (2012), the majority of patients in the intervention group (83%) strongly preferred to choose their treatment and they were satisfied because of participation in the decision-making process, while the majority of patients in the control group (72%) preferred to someone else choose instead of them (preferably a specialist physician, because of

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knowledge and enough dominance about subject) and this difference was significant in both groups ($p<0.05$) (18). In addition, in a clinical trial was done by Jibaja-Weiss et al. (2011), the majority of patients with early stage breast cancer in the intervention group (85%) chose to participate in decision making (19). In fact in these shared decisions, there is the possibility of doing different things which are according to scientific principles, and collaboration in decision-making will be led to the best decisions. This is especially very important in breast cancer that there are various types of surgery, reconstruction, chemotherapy and radiotherapy for its treatment. Although according to some physicians' viewpoint, the patients may make a decision that is harmful for them, but in fact this decision based on the patients' profit and loss criteria can be helpful for them. On the other hand, the physicians can explain the strengths and weaknesses of each option to prevent this.

Chewning et al., meta-analysis (2012) showed that according to studies, people who participate in shared decision making, feel more secure and are more committed to their treatment. Also patient's involvement leads to better judgments about the quality of care (20). In addition, patient's participation leads to greater self-efficacy that in turn will lead to better health outcomes (20, 21).

In relation to the effect of decision aid on patient decision conflict in both groups, this study showed that decision conflict in the intervention group was lower than the control group. In a study by Ozann et al. (2007) to examine the decision aid in prevention of breast cancer in high risk women, scores of decision conflict in the intervention group was less than control group and this difference was statistically significant ($p<0.001$), (22). Also D'Alimonte et al. (2012) showed that the scores of decision conflict in decision aid group was lower than the control group, so that the patients' uncertainty in decision aid group for choosing one of the options was less, awareness of benefits and risks of treatment was less, but perceived social support and perception of appropriate decision and consideration to personal values in decision making was more in them (13). Also, In the Sawkaet a clinical trial (2010) about decision aid in patients with thyroid cancer, decision conflict in the intervention group was lower than the control group (10). In the Jibaja-Weiss et al. study (2011), although no significant difference was found between two study groups in the decision conflict, but decision conflict in the intervention group tended to be lower (19).

In those studies and the present study, the protocol of decision aid led to identification of the needs of patients, positive reinforcement of health professionals' performance, decision making based on evidences, reduce uncertainty and increase understanding about the available options, increase patient participation in decision-making, improve quality of decisions and patient's more preparation to cope with the conditions ahead.

In relation to the effect of patient decision aid on decision regret 8 week after operation, the study results didn't show significant difference between the two groups. In the study by Wakefield et al. (2008) about decision aid in women at risk of breast and ovarian cancer also significant different was not found between two groups in terms of decision regret, 6 months after the intervention (23). In addition, in the study of Jibaja-Weiss et al. (2011) there was no significant difference between two groups in terms of decision regret or satisfaction after the intervention (19). These results about decision regret or satisfaction may have been created because of short follow-up period after beginning the treatment and consequently lack of observation of the positive and negative effects of this choice (treatment) on quality of life and health outcomes of patients during this short period.

CONCLUSION

In general, the results of this study showed that the relationship between the patient and the health care team and the quality of treatment decisions can be improved through shared decision making and decision aids programs. The most important aim of this study was to use its results in order to control the disease in treatable chronic diseases in the early stages, by raising awareness of patients and their participation in treatment decisions to help them to have realistic expectations about the disease and its consequences, increasing patients safety, improving adherence to treatment and their quality of life. According to researcher's observations and descriptive studies conducted in Iran, shared decision-making and decision aid programs despite having many proved advantages for clients, haven't executive ability and faced with immense administrative obstacles in hospitals and community health centers even in Tehran, despite the presence of enough specialist physicians. Existence of a determined organized system is essential to guide the program and provide individual training and necessary educational materials for patients and assist to them in all aspects and stages of treatment. The nurses and physicians collaboration as main colleagues of this program who are responsible for training and patients' follow up in all centers, and other resources such as time and extensive libraries for patients and staffs are critical to success this program.

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Conflict of Interest
None declared.

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