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Assessment of Breast Cancer Patients' Knowledge and Decisional Conflict Regarding Tamoxifen Use

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Breast cancer is the most common type of female cancer. Tamoxifen, a selective estrogen receptor modulator, is widely used to decrease breast cancer recurrence and mortality among patients. However, it also increases the risk of endometrial cancer. This study aimed to assess knowledge and decisional conflict regarding tamoxifen use. Between June and October 2014, breast cancer patients using tamoxifen were consecutively screened and requested to complete a survey including the EQ-5D, Satisfaction with Decision Scale (SWD), Decisional Conflict Scale (DCS), and a self-developed, 15-item questionnaire measuring tamoxifen-related knowledge. The study sample comprised 299 patients. The mean total knowledge score was 63.4 of a possible 100.0 (range, 13.3-93.3). While 73.9% of the participants knew that tamoxifen reduces the risk of breast cancer recurrence, only 57.9% knew that the drug increases endometrial cancer risk. A higher education level (≥ college) was associated with a higher, total knowledge score ($\beta = 4.291$; $P = 0.017$). A higher knowledge score was associated with a decreased DCS score ($\beta = -0.366$; $P < 0.001$). A higher SWD score was also associated with decreased decisional conflict ($\beta = -0.178$; $P < 0.001$). In conclusion, the breast cancer patients with higher levels of tamoxifen-related knowledge showed lower levels of decisional conflict regarding tamoxifen use. Clinicians should provide the exact information about tamoxifen treatment to patients, based on knowledge assessment results, so as to aid patients' decision-making with minimal conflict.

Keywords: Breast Neoplasms; Tamoxifen; Knowledge; Conflict; Decision Making; Patient Satisfaction

INTRODUCTION

Breast cancer is the most common type of female cancer worldwide. In 2014, it was estimated to account for 29% (232,670) of all new female cancer diagnoses and to be the second leading cause of female cancer deaths in the United States (1). In Korea, breast cancer constituted 13.7% (18,382) of all new female cancer cases in the same year, indicating breast was the second most common primary female cancer site next to thyroid (2). A multidisciplinary approach, including surgery, radiotherapy, and systemic therapy, is required for the treatment of breast cancer patients (3). Because human breast tissue is hormone-sensitive, the use of hormone therapy (or endocrine therapy) in estrogen and/or progesterone receptor-positive tumors constitutes a reasonable and appropriate treatment (4).

Tamoxifen, a selective estrogen receptor modulator (SERM), has antagonist effects on estrogen receptors in breast cancer cells and is used for breast cancer treatment. It has been reported that tamoxifen decreases mortality and recurrence in all stages of breast cancer (5,6). Tamoxifen is also used to reduce breast cancer incidence in high-risk women (7).

Owing to its pro-estrogenic effects on the endometrium of the uterus, tamoxifen is known to increase the risk of developing endometrial hyperplasia and even endometrial cancers (7-9). Therefore, breast cancer patients who are taking tamoxifen should be closely monitored for symptoms of endometrial hyperplasia or cancer, and advised to undergo routine gynecological check-ups (10).

Although breast cancer patients would have been informed about these precautions by clinicians before starting tamoxifen treatment, the extent to which patients are aware of the drug is not actually known. McCowan et al. reported that adherence to prescribed tamoxifen was quite lower than expected; 38% of the patients had low adherence over the treatment period. In their cost-effectiveness analysis, low adherence resulted in a loss of 1.43 life years and increased medical costs of £5970 compared to high adherence (11). To date, no published studies have assessed patients' knowledge of tamoxifen. In clinical practice, cancer patients make decisions based on their knowledge provided by clinicians (12). Therefore, such an assessment is necessary for improving overall health care.

On the basis of the above, the aim of this study was to assess

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breast cancer patients' knowledge and decisional conflict regarding tamoxifen use. Possible factors which influence knowledge and decisional conflict were also explored.

MATERIALS AND METHODS

Study population

Among the women who visited the outpatient clinic of National Cancer Center between June and October 2014, breast cancer patients who met the eligibility criteria were enrolled. Patients eligible for inclusion were those who: 1) were aged more than 18 yr, 2) were taking tamoxifen, and 3) could read and understand Korean. Consecutive eligible patients were identified, and subsequently called for participation.

A total of 332 eligible women were invited to participate. Excluding the 32 women who declined to provide written informed consent, the rest of the women were requested to complete the survey. One woman failed to complete the questionnaires, which resulted in a final sample size of 299.

Patients' characteristics

The patients' demographic and disease-related data were collected through reviews of medical records and the survey. Data included the patients' age, marital status, education level, employment, family income, childbirth, and family history. Data regarding stage and histology of breast cancer and modality of treatment were also collected. Duration of tamoxifen treatment and adherence thereto, as well as the most influential person in the decision to take tamoxifen were surveyed.

EQ-5D

The EQ-5D is one of the most commonly used instruments to measure health status. Developed by the EuroQol Group, the EQ-5D consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS) (13). The descriptive system is composed of the following five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels: no problems, some or moderate problems, and extreme problems, which are coded as 1, 2, and 3, respectively. The EQ VAS records participants' self-rated health on a vertical, visual analogue scale ranging from 0 to 100, indicating "Worst imaginable health state" and "Best imaginable health state," respectively. The Korean version of the EQ-5D has been previously validated, and was used in the current study (14).

Satisfaction with decision (SWD)

This scale was used to measure the participants' satisfaction with the decision to take tamoxifen. The SWD is composed of six items and the score on each item ranges from 1 to 5; the higher the score, the higher the satisfaction level (15). Based on the sum of the scores on all six items, the total score ranges from 6 to 30. The reliability of the SWD scale in the current study was good, with a Cronbach's alpha of 0.945.

Decisional conflict scale (DCS)

The DCS was used to measure participants' decisional conflict regarding tamoxifen use. The DCS is composed of 16 items, which make up the following five subscales: informed, values clarity, support, uncertainty, and effective decision. Each item has five response levels, ranging from 0 ("strongly agree") to 4 ("strongly disagree"). Summing up the item scores, then dividing the sum by the number of items, and multiplying the quotient by 25 could yield the total score and the score for each subscale comprising a range of 0 (no decisional conflict) to 100 (extremely high decisional conflict). The DCS scores higher than 37.5 indicate decision delay and/or uncertainty about decision implementation (16). The reliability of the DCS in the current study was also good, with a Cronbach's alpha of 0.924.

Knowledge of tamoxifen

Before starting tamoxifen treatment, clinicians explained to the patients briefly about the purpose of treatment, the drug itself, how to take, and cautions at the outpatient clinic. To measure participants' tamoxifen-related knowledge, a scale consisting of 15 true/false items was newly developed in the current study (Supplementary Table 1). The items included the scientific facts relating to tamoxifen therapy and its impact on prognosis, related complications, and side effects. Participants were requested to choose one of the three responses ("yes," "no," and "do not know") for each item. A participant would obtain one point for each correct answer and no point for each incorrect answer (including "do not know"). The total knowledge score was converted, resulting in a range of 0 to 100. During the development of this scale, five experts (Lee ES, Lim MC, Bae HS, Youm J, and Lee S) reviewed and confirmed a content validity index (CVI) of 0.8 or higher. In the current study, the scale had satisfactory internal consistency, with a Cronbach's alpha of 0.663.

Statistical analysis

Descriptive statistics were used to describe the characteristics of the participants and the results that they obtained on the scales. Univariate analyses were performed between knowledge of tamoxifen and possible predictor variables, and between DCS and possible predictor variables. For non-normally distributed variables, non-parametric tests were used, such as the Mann-Whitney *U* test and Kruskal-Wallis test. Parametric tests such as the Student's *t*-test were used for normally distributed variables.

In the multivariate analyses relating to knowledge of tamoxifen and DCS, multiple regression analyses were performed. All predictor variables with $P < 0.20$ in the univariate analyses and scale scores were included, and the backward elimination strategy was used to construct a final model consisting of variables

with $P < 0.10$ only.

We conducted these statistical analyses using STATA 13.0 (StatCorp, College Station, TX, USA). A P value of < 0.05 was considered statistically significant.

Ethics statement

We received approval for this study from the institutional review board of National Cancer Center (IRB No. 2014-0084). Written informed consent was obtained from the patients.

RESULTS

Patients' characteristics

The demographic and disease-related characteristics of the 299 breast cancer patients are presented in Tables 1 and 2, respectively. The mean age at the time of the survey and diagnosis was 45.4 yr (range, 29-75) and 44.4 yr (range, 28-73), respectively. Among the participants, 82.6% were married, 43.5% had an education level of high school or less, and 40.1% were employed at the time of the survey.

Ductal carcinoma (86.0%) was the most common histological type of breast cancer. Most of participants (90.3%) were in the early stages of the disease, as follows: carcinoma in situ (Stage 0, 13.7%), stage I (40.5%), and stage II (36.1%). A total of 74.6% of the participants underwent breast surgery and adjuvant radiotherapy with/without chemotherapy before taking tamoxifen.

Regarding tamoxifen use, the mean duration of the participants' use of tamoxifen was 15.5 months (range, 0-56). The most influential person in decision-making to take this drug was the clinician in more than two third of the participants (76.2%). Most of the participants (96.7%) showed high adherence to tamoxifen (≥ 80%) (Table 2).

Scale scores

The mean score on the EQ-5D descriptive system was reported as 6.3 (SD = 1.3; range, 5-11). The mean EQ VAS score was 75.6 (SD = 15.6; range, 20-100), and the mean SWD score was 21.8 (SD = 4.9; range, 6-30).

Knowledge of tamoxifen

The mean total knowledge score was 63.4 (SD = 17.1; range, 13.3-93.3). Fig. 1 shows the percentages of the participants who correctly responded to tamoxifen-related knowledge items. Overall, the percentages of the correct response to particular items ranged from 8.0% to 95.7%. Among the possible predictors, only age at the time of the survey and highest education level were associated with the total knowledge score, as shown in the univariate analyses ($P = 0.035$ and $P < 0.001$, respectively) (Tables 1 and 2).

In multiple regression analyses, education level (≥ College, $\beta = 4.291$; $P = 0.017$) and scores on the DCS subscale-informed ($\beta = -0.237$; $P = 0.001$), -values clarity ($\beta = -0.148$; $P = 0.027$), and -effective decision ($\beta = -0.107$; $P = 0.090$) remained in the final model. The adjusted R^2 of the model was reported as 23.7. A high education level was positively associated with the total knowledge score. Both scores on DCS subscale-informed and

Table 1. Demographic characteristics and univariate associations with knowledge of tamoxifen and the Decisional Conflict Scale

Characteristics	n	%	Knowledge		DCS	
			Mean ± SD*	*P*	Mean ± SD*	*P*
Total	299	100.0	63.4 ± 17.1		35.3 ± 14.9	
Age at survey (yr)				0.035		0.065
Mean (range)	45.4 (29-75)					
< 50	226	75.6	66.4 ± 17.0		34.3 ± 14.3	
≥ 50	73	24.4	62.2 ± 17.2		38.6 ± 16.5	
Marital status				0.794		0.106
Single/Separated/Widowed	52	17.4	66.2 ± 16.5		36.9 ± 13.4	
Married	247	82.6	65.2 ± 17.3		35.0 ± 15.2	
Highest education level				< 0.001		0.107
High school	130	43.5	61.5 ± 17.8		36.7 ± 15.4	
≥ College	169	56.5	68.3 ± 16.0		34.3 ± 14.5	
Employment status				0.137		0.471
Yes	120	40.1	66.8 ± 17.2		35.5 ± 15.6	
No	179	59.9	64.4 ± 17.0		35.2 ± 14.5	
Family income, $/month				0.730		0.016
< 4,000	149	49.8	64.9 ± 17.7		37.3 ± 15.3	
≥ 4,000	150	50.2	65.8 ± 16.5		33.4 ± 14.3	
Childbirth				0.772		0.110
Yes	257	86.0	65.3 ± 17.1		35.0 ± 15.4	
No	42	14.0	65.7 ± 17.6		37.4 ± 11.2	
Family history				0.416		0.729
Yes	53	17.7	66.7 ± 17.0		36.2 ± 12.1	
No	246	82.3	65.1 ± 17.2		35.1 ± 15.5	

*Transformed score of each survey (0-100). DCS, Decisional Conflict Scale; Knowledge, knowledge of tamoxifen; SD, standard deviation.

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Table 2. Disease-related characteristics and univariate associations with knowledge of tamoxifen and the Decisional Conflict Scale

Characteristics	n	%	Knowledge		DCS	
			Mean ± SD*	*P*	Mean ± SD*	*P*
Total	299	100.0	63.4 ± 17.1		35.3 ± 14.9	
Age at diagnosis (yr)						
Mean (range)	44.4 (28-73)					
Duration of taking tamoxifen (month)						
Mean (range)	15.5 (0-56)					
The most influential person in decision-making to take tamoxifen				0.678		0.678
Clinician	227	76.2	64.8 ± 15.6		35.2 ± 15.6	
Family	65	21.8	63.9 ± 13.1		36.1 ± 13.1	
Others	6	2.0	68.8 ± 9.0		31.3 ± 9.0	
Adherence†				0.432		0.076
≥ 80%	289	96.7	65.6 ± 16.7		35.0 ± 14.7	
< 80%	10	3.3	57.3 ± 26.1		45.5 ± 18.9	
Histology				0.283		0.646
Ductal	257	86.0	65.1 ± 17.3		35.3 ± 15.0	
Lobular	14	4.7	71.0 ± 18.8		31.6 ± 18.6	
Mucinous	9	3.0	65.2 ± 9.9		38.9 ± 9.7	
Tubular	6	2.0	57.8 ± 13.8		34.6 ± 9.1	
Others	13	4.3	68.7 ± 17.5		36.8 ± 14.6	
Stage				0.272		0.038
0‡	41	13.7	63.7 ± 19.3		39.2 ± 15.4	
I	121	40.5	64.2 ± 16.6		37.1 ± 15.6	
II	108	36.1	67.6 ± 16.5		32.3 ± 13.4	
III, IV	29	9.7	64.1 ± 18.3		33.6 ± 15.2	
Type of treatment				0.273		0.881
H only	4	1.3	56.7 ± 27.5		30.5 ± 9.2	
S+H	32	10.7	71.3 ± 14.9		32.8 ± 10.1	
S+C+H	17	5.7	64.7 ± 15.2		33.5 ± 10.7	
S+R+H	117	39.1	64.0 ± 18.0		36.7 ± 15.7	
S+R+C+H	106	35.5	64.7 ± 17.5		35.5 ± 16.2	
S+R+H+T & S+R+C+H+T	23	7.7	69.3 ± 11.1		33.2 ± 14.1	

*Transformed score of each survey (0-100); †Medication adherence regards the patient's conformance to the clinician's recommendation with respect to timing, dosage, and frequency of taking tamoxifen during the prescribed length of time; ‡Stage 0 regards carcinoma in situ. SD, standard deviation; DCS, Decisional Conflict Scale; Knowledge, knowledge of tamoxifen; S, surgery; C, chemotherapy; R, radiotherapy; H, hormone therapy (tamoxifen); T, targeted therapy.

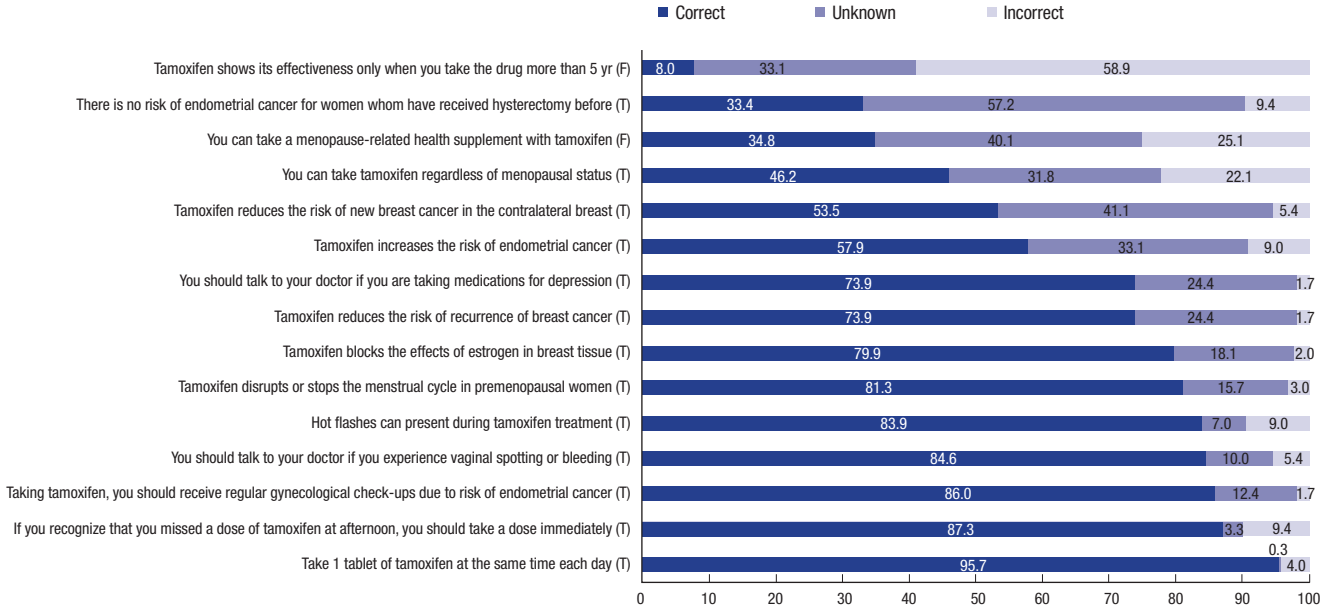

Fig. 1. Percentages of participants responding to questions on knowledge of tamoxifen.

Table 3. Multiple linear regression with knowledge of tamoxifen

Variables	B	SD	t	*P*	95% CI		R^2	Adjusted R^2
Education level								
≥ College vs. < College	4.291	1.795	2.390	0.017	0.758	7.824		
DCS subscale-informed	-0.237	0.072	-3.280	0.001	-0.379	-0.095	24.7	23.7
DCS subscale-values clarity	-0.148	0.067	-2.216	0.027	-0.280	-0.017		
DCS subscale-effective design	-0.107	0.063	-1.699	0.090	-0.231	0.017		

*Backward selection at 10% significance level. SD, standard deviation; DCS, decisional conflict scale.

Table 4. Multiple linear regression with the Decisional Conflict Scale.

Variables	B	SD	t	*P*	95% CI		R^2	Adjusted R^2
Family Income ($/month)								
≥ 4,000 vs. < 4,000	-3.456	1.485	-2.327	0.021	-6.378	-0.533		
Stage 2 vs. Stage 0	-5.148	2.367	-2.175	0.030	-9.807	-0.489		
Stage 3- 4 vs. Stage 0	-6.009	3.090	-1.945	0.053	-12.091	0.072	29.8	28.1
Knowledge	-0.366	0.043	-8.470	< 0.001	-0.451	-0.281		
SWD	-0.178	0.037	-4.806	< 0.001	-0.250	-0.105		
EQ VAS	-0.084	0.048	-1.754	0.081	-0.178	0.010		

*Backward selection at 10% significance level. SD, standard deviation; Knowledge, knowledge of tamoxifen; SWD, satisfaction with decision; EQ VAS, EQ visual analogue scale.

-values clarity were negatively associated with the total knowledge score (Table 3).

DCS

The potential score of the DCS and each subscale ranges from 0 to 100. In the current study, the mean total DCS score was 35.3 (SD = 14.9; range, 0-96.9). The mean scores on the five subscales were 34.3 for informed, 36.7 for values clarity, 37.9 for support, 34.7 for uncertainty, and 33.6 for effective decision. Among the possible predictors, univariate analyses showed that only family income and stage of breast cancer were negatively associated with the total DCS score ($P = 0.016$ and $P = 0.038$, respectively) (Tables 1 and 2).

Table 4 shows the results of multiple regression analyses for DCS. The adjusted R^2 of the model was reported as 28.1. High family income (≥ $4,000/month, $\beta = -3.456$; $P = 0.021$) and advanced stage disease, relative to stage 0 (Stage II, $\beta = -5.148$; $P = 0.030$ and Stage III-IV, $\beta = -6.009$; $P = 0.053$) remained negatively correlated with the total DCS score. The SWD score ($\beta = -0.178$; $P < 0.001$) and the total knowledge score ($\beta = -8.470$; $P < 0.001$) were significantly, inversely associated with the total DCS score; this means that patients with higher SWD scores and higher knowledge scores reported significantly lower levels of decisional conflict.

DISCUSSION

In the current study, we measured breast cancer patients' knowledge regarding tamoxifen use, and found that advanced knowledge was associated with low levels of the decisional conflict relating to taking tamoxifen.

Prior to our study, there were no standardized measures of tamoxifen-related knowledge. Thus, a new scale composed of 15 items was invented for this purpose. The strengths of this scale are as follows: 1) Items deal with, not only scientific facts relating to the medicine and its impact on prognosis, but also its possible side effects and dosage instructions; 2) Simplifying responses into three options ensured that the scoring system is easy to apply; and 3) Before it was used, five experts had reviewed and confirmed the scale's validity.

According to the results, most of the participants were aware of the exact method for taking taomxifen appropriately. With regard to the fact that tamoxifen reduces the risk of breast cancer recurrence, 73.9% of the participants gave the correct answer. In contrast, only 57.9% knew that tamoxifen increases the risk of predisposition to endometrial cancer. Fisher et al. reported that the risk of enxomtrial cancer increased two to sevenfold in tamoxifen users (7,8); this risk is also known to increase with longer duration of tamoxifen use (17). Although these are definitely major concerns for gynecologists who are taking care of breast cancer patients with tamoxifen treatment, it seems that the specific information relating to gynecologic cancer risk is not delivered appropriately to patients.

However, 86.0% of the participants recognized the importance of regular gynecological check-ups during tamoxifen treatment. This response seems to have resulted from the participants' passive experiences of their visits to gynecologists, which are encouraged by clinicians, rather than due to full understanding of the purpose of their visits. Tamoxifen use is associated with an increase in the risk of, not only endometrial cancer, but also endometrial polyps and endometrial hyperplasia. Therefore, the committee of the American College of Obstetricians and Gynecologists recommends routine gynecological care and emphasizes prompt reporting of abnormal vaginal symptoms, includ-

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ing a bloody discharge or spotting (18). It is questionable whether the participants definitely know this recommendation.

As indicated in literature, cancer patients regard their clinicians as the most common and trusted source of cancer information (12,19). Thus, clinicians have the duty to provide accurate and detailed information to patients. Considering the fact that, in the current study, the participants' education level was positively associated with their knowledge, clinicians should check individual patients' level of understanding during consultation. Simple explanations would be necessary in some cases.

A patient who makes a clinical decision may experience decisional conflict, a state of perceived uncertainty about a course of action. Perceived uncertainty could be exacerbated by a subject's disease, cognitive, affective, and social factors; in turn, these could influence decisional conflict (16). To determine factors that affect breast cancer patients' decisional conflict regarding tamoxifen, all the possible variables, including demographic and disease-related characteristics, were evaluated in the current study. Additionally, to measure patients' health status and satisfaction level, the survey included the EQ-5D and the SWD, respectively.

Interestingly, breast cancer patients with high tamoxifen-related knowledge had low levels of decisional conflict regarding tamoxifen use. Thus, it could be inferred that enhancement of patients' knowledge may reduce decisional conflict. Enhanced knowledge could lead to certainty among patients regarding their choices, which increases decision quality. A similar relationship between knowledge and decisional conflict was also reported in a study by Peate et al., which investigated young breast cancer patients' knowledge of fertility, as well as their decisional conflict (20).

The SWD score was also negatively associated with the total DCS score; patients with high levels of satisfaction with their decisions showed less decisional conflict. It is well known that SWD scores and decision certainty are significantly correlated (15). Moreover, confidence and satisfaction with patients' "own" decisions comprise a large portion of the scale. Based on literature, it is known that patients who play a more active role in decision-making are more satisfied with their decision, and may have better health outcomes than patients who play a passive role (21-23). Hack et al. (24) reported that younger patients with breast cancer prefer to play an active role in decision-making. However, whether the patients' role was active or passive was not investigated in the current study; rather, this study examined the most influential person in the decision-making process (e.g., the clinician, family, or others).

This study is the first to measure tamoxifen-related knowledge and investigate the decisional conflict relating to tamoxifen use among breast cancer patients. All possible factors which might have influenced the results of knowledge and decisional conflict assessment were explored. However, the current study also had several limitations. First, a new knowledge scale which was invented for this study may not be the best measure of tamoxifen-related knowledge. Its usefulness must be validated in multiple institutions across populations to become a standardized scale. Second, not all tamoxifen-related side effects were considered in the study. Fatigue, hot flushes, and vaginal dryness would be annoying if present among tamoxifen users. Even more serious complications such as deep vein thrombosis or pulmonary embolism may occur as a result of the drug (25). Third, each participant's knowledge of tamoxfen was assessed only once. Serial knowledge assessment (e.g., prior to tamoxifen treatment and at regular intervals during treatment) aimed at tracing changes in knowledge patterns would make it possible to provide more adequate and individualized infromation for the patietns. Lastly, owing to the non-prospective study design, the patients' decisional conflict was measured after their decision to take tamoxifen, and recall bias may have been inevitable. In near future, well designed propsective interventional studies to overcome these shortcomings are needed. A randomized controlled study of our group, which aimed to investigate the efficacy of educational program and decision aids for tamoxifen treatment in breast cancer patients, is now in the registration step.

Herein, the results of the assessment of tamoxifen-related knowledge among breast cancer patients are presented. Patients with higher levels of knowledge showed lower levels of decisional conflict regarding tamoxifen use. Since cancer patients regard their clinicians as the most common and trusted source of cancer information, clinicians should provide exact information about tamoxifen treatment, so as to aid patients' decision-making with minimal conflict. Further cohort studies are warranted to improve the quality of healthcare delivery and healthcare outcomes.

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DISCLOSURE

The authors have no conflicts of interest to disclose.

AUTHOR CONTRIBUTION

Study conception and design: Kim SI, Lee Y, Son Y, Lim MC, Lee ES. Data collection and analysis: Kim SI, Lee Y, Yun S, Joo J, Jung SY. Writing: Kim SI, Lee Y. Revision and approval of manuscript submission: all authors.

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