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Original Article

Validity of Breast Cancer Symptom Questionnaire and Its Relationship With Breast Ultrasonography in Young Female Night Workers

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ABSTRACT

Background: This study aimed to identify the validity of breast cancer symptom questionnaire of worker's special health examination and its relationship with breast ultrasonography findings in young female night workers.
Methods: The breast cancer symptom questionnaire data of worker's special health examination and breast ultrasonography results in young female shift workers who worked in one electronic manufacture company were collected from 2014 to 2018.
Results: Of the 857 workers, 18 had a Breast Imaging Reporting and Database System category 4 or higher. Among other variables, shift work tenure alone was associated with the risk of having a Breast Imaging Reporting and Database System category higher than 4. The sensitivity, specificity, positive predictive value, and negative predictive value of the symptom questionnaire were 16.7%, 87.7%, 2.8%, and 98.0%, respectively.
Conclusion: The current breast cancer symptom questionnaire of the worker's special health examination is inappropriate due to its low sensitivity and positive predictive value. In the future, female night workers will need alternative measures for more accurate screening for breast cancer.

1. Introduction

Breast cancer is one of the most common types of cancer that occur in women. It accounts for 25.1% of all cancer types that affect women worldwide [1]. It has the highest prevalence rate among all cancer types other than skin cancer in the American female population and has the highest mortality rate after lung cancer [2]. Even in South Korea, breast cancer has an age-standardized prevalence rate of 54.9 per 100,000 people and has the highest prevalence rate after thyroid cancer (58.1 per 100,000). The age-standardized mortality rate is also 5.5 per 100,000, indicating that breast cancer has the third highest mortality rate after lung cancer and colorectal cancer [3].

In accordance with the cancer registration statistics, the incidence rate of breast cancer in Korean women gradually increased from 1999 to 2016 [3]. Although breast cancer is known occur after the age of 40 and 50, but the incidence rate of breast cancer among young women who are younger than 40 years old approximately doubled between 1999 and 2017 [4]. The fact that women in this age group actively participate in economic activities makes this problem worth noting from the perspective of industrial health science.

The risk factors of breast cancer include many factors related to female hormones (age of menarche and menopause, exogenous estrogen, birth, and breastfeeding) and drinking, as well as genetic factors [5]. Night work is also known as a risk factor of breast cancer [6–9] Experimental research has found that melatonin activates the MT1 melatonin receptors in the human breast cancer cells to suppress the expression and growth of cancer cells [10]. Therefore, light exposure at night can increase the rate of breast cancer among night workers by reducing the secretion of melatonin and promoting the growth and metabolism of breast cancer cells. Previous studies have been conducted to epidemiologically confirm this experimental evidence, and many meta-analyses have shown that the risk of breast cancer is increased due to night work [6–9,11].

Based on the results of these studies, a breast cancer symptom questionnaire was used to screen for breast cancer as part of a worker's special health examination, which had been performed

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since 2014 in the republic of Korea. To date, no study has determined the validity of the screening test or its relationship with actual diagnosis results. Therefore, the present study aimed to investigate the relationship between the results of the breast cancer symptom questionnaire and those of the actual breast cancer ultrasonography among young female night shift workers who worked in one electronic manufacture company using Breast Imaging Reporting and Database System (BI-RADS) lexicon provided by American College of Radiology for standardization of lesion description of breast ultrasound and investigate the validity of the breast cancer symptom questionnaire as a screening test.

2. Participants and methods

2.1. Research participants

The initial cohort comprised female workers who underwent worker's special health examination for 5 years between 2014 and 2018 in one electronic manufacture company located in Yeongnam (Fig. 1). A total of 11,803 female workers underwent worker's special health examination for 5 years. The breast ultrasonography is selected by the examinee among various comprehensive examination items provided by the company. So among those, a total of 1,875 female workers remained after excluding those who did not undergo a breast ultrasonography. If the breast ultrasonography was performed twice or more in 5 years, and the results were identical, the most recent result was selected and the other results were excluded. If the results were different, the results with the highest BI-RAD category were selected, and the other results were excluded. Participants with a current or past history of breast cancer or with a family history of breast cancer were also excluded. If there were missing variables in the questionnaire and participants whose BI-RADS category was 0 were also excluded. As a result, a total of 1,018 examinees were excluded, and 857 were considered eligible for the study.

2.2. General characteristics

We investigated participant age, blood pressure (BP), height, weight, HbA1C, total cholesterol, low dense lipoprotein (LDL) cholesterol, high dense lipoprotein (HDL) cholesterol, triglyceride, aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma glutamyl transferase (r-GTP), alcohol consumption, exercise, smoking, shift work tenure, working hours per week. For alcohol consumption, the individuals were categorized as a “overdrink” (consumed alcohol 1 time or more per week) or an “adequate” (consumed alcohol less than 1 time per week). For smoking, the individuals were divided into current smoker, ex-smoker and nonsmoker. For exercise, the individuals were divided into “adequate” (exercised 3 or more times per week) and “none” (exercised fewer than 3 times per week). Shift work tenure is divided into 9 years or less, 10 years to 14 years, and 15 years or more. Working hours per week were divided into 40 hours or less, 41 to 51 hours, 52 to 59 hours, and 60 hours or more.

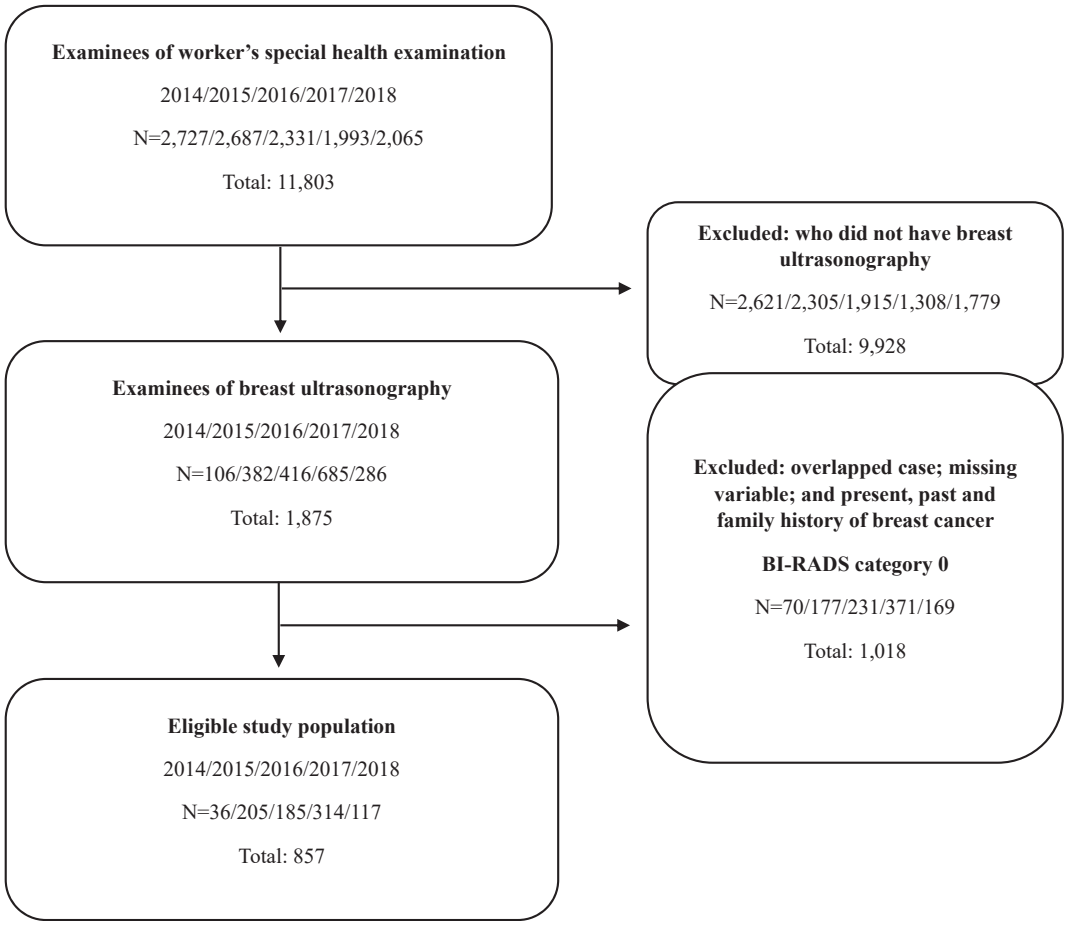

Fig. 1. Flow chart of the selection of participants.

2.3. Breast cancer symptom questionnaire

During the night worker's special health examination, women completed a breast cancer questionnaire and had a one-to-one interview with a doctor. The breast cancer questionnaire used in the night worker's special health examination comprised three items. Among those, the first and third items determine whether the participant had early and recent examinations for breast cancer and were excluded from the analyses because they were deemed unrelated to this study. The participants' response to the second item asking about the symptoms was used in the analysis. The question and answers to the second item are shown in the following context.

(Question) Please check all of your current symptoms.

(Answer).

1. I can feel a lump (mass) in my breast.
2. I have secretions from my nipples.
3. My nipples are broken or sunk.
4. I have no symptoms.

In this study, checking items 1, 2, and 3 were categorized as having symptoms.

2.4. Categorization of breast ultrasonography results

Breast ultrasonography was performed by an experienced specialist using RS80A (Samsung Medison Co., Ltd., Seoul, Korea). The results were shown by applying the American College of Radiology-BI-RADS [12]. The assessment categories of BI-RADS are shown in the following context. In this study, category 4 and higher were categorized as suspected malignancy and were analyzed.

BI-RADS assessment categories

0: Incomplete.
1: Negative.
2: Benign.
3: Probably benign.
4: Suspicious.
5: Highly suggestive of malignancy.
6: Known biopsy − proven malignancy.

2.5. Data analysis

To examine the differences in the sociodemographic and occupational characteristics of participants based on symptoms, chi-square test and t-test were performed. To see the difference in symptoms between BI-RADS category groups, the BI-RADS category group was divided into two cases, 1/2/3/4 and 1~3/4, and analyzed by chi-square test. Variables that showed significant results in the univariate logistic regression and categorization based on the symptoms on the breast cancer symptom questionnaire were used as independent variables. Meanwhile categorization in accordance with the breast ultrasonography results (higher/lower than category 4) was used as a dependent variable to perform the multiple logistic regression analysis. For sensitivity, the percentage of participants with a BI-RADS category of 4 or higher in accordance with the breast ultrasonography whose answer to the questionnaire was 1, 2, or 3 was obtained. For specificity, the percentage of participants with a BI-RADS category of 1, 2, or 3 in accordance with the breast ultrasonography whose answer to the questionnaire was 4 was calculated. The positive predictive value (PPV) and negative predictive value (NPV) were calculated using the following formulas:

$$\text{PPV} = \text{Sensitivity} \times \text{prevalence}/[(\text{sensitivity} \times \text{prevalence}) + (1-\text{specificity}) \times (1-\text{prevalence})]$$

$$\text{NPV} = \text{Specificity} \times (1-\text{prevalence})/[\text{prevalence} \times (1-\text{sensitivity}) + \text{specificity} \times (1-\text{prevalence})]$$

The confidence interval (CI) was calculated using the exact Clopper−Pearson confidence interval method.

All data were analyzed using SPSS for windows, version 25.0 (SPSS Inc., Chicago, IL, USA).

This study was approved by the institutional Review Board of Samsung Changwon Hospital (SCMC 2020-03-007). The study was conducted in accordance with the tenets of the Declaration of Helsinki and its revisions.

3. Results

3.1. General characteristics of the participants

The results of analyzing the differences in the general and occupational characteristics of the participants according to the symptom assessed in the breast cancer questionnaire are shown in Table 1. Among the 857 participants, 751 responded that they had no symptoms, whereas 106 responded that they developed symptoms related to high levels of triglycerides ($p = 0.002$). Moreover, significant differences were observed between the two groups in terms of in smoking status ($p = 0.037$). By contrast, no significant differences in age, systolic BP, diastolic BP, height, weight, body mass index, HbA1c (%), total cholesterol, HDL cholesterol, LDL cholesterol, AST, ALT, r-GTP, alcohol, and exercise were observed between the two groups. For occupational characteristics, no significant differences were observed in shift work tenure and working hours per week between the two groups.

3.2. Distribution of breast ultrasonography category by symptom existence

Table 2 shows the distribution difference of BI-RADS category in accordance with symptom existence using two methods: In one method, the participants were categorized into each of the 1/2/3/4 categories; in the second method, the participants were categorized into either category 1−3 or category 4. There were statistically significant differences in the distribution of BI-RADS categories between the symptomatic group and asymptomatic group ($p = 0.033$). However, no significant differences were found when the analysis was performed by categorizing the participants into BI-RADS category 4 and BI-RADS category lower than 4 ($p = 0.576$).

3.3. Relationship with the results of breast ultrasonography

In the univariate logistic regression analysis, age and shift work tenure significantly increased the risk of diagnosis with BI-RADS category 4 or above, but symptom existence had no statistically significant impact (Table 3). Adjusted odds ratio (OR) showed no significant differences between age and symptoms checked, and significant OR increase was only observed if the shift work tenure was 15 years or longer.

3.4. Validity of the breast cancer symptom questionnaire

The breast cancer symptom questionnaire had a sensitivity of 16.3% (95% CI: 4.4%−42.3%) (Table 4); specificity of 87.7% (95% CI: 85.3%−89.8%), which was relatively high; PPV of 2.8% (95% CI: 0.7%−8.7%), which was very low; and NPV of 98.0% (95% CI: 96.6%-98.8%), which was high.

Table 1
General and occupational characteristics of the participants in accordance with symptom checked in breast cancer questionnaire

Variables		Total (n = 857)	Symptom checked		*p*-value
			No (n = 751)	Yes (n = 106)	
Age (years)*		28.2 ± 4.2	28.2 ± 4.2	28.2 ± 4.4	0.972
Systolic Blood Pressure (mmHg)		110.4 ± 9.8	110.6 ± 9.9	108.7 ± 9.5	0.054
Diastolic Blood Pressure (mmHg)		67.3 ± 8.3	67.5 ± 8.3	66 ± 8	0.077
Height (cm)		161.5 ± 5.1	161.5 ± 5.1	162 ± 5.7	0.399
Weight (kg)		56.8 ± 9.9	56.9 ± 10	56.1 ± 9.8	0.444
BMI (kg/m^2)		21.7 ± 3.6	21.8 ± 3.5	21.1 ± 3.9	0.072
HbA1c (%)		5.3 ± 0.4	5.3 ± 0.4	5.2 ± 0.3	0.243
Total cholesterol (mg/dL)		176.7 ± 29.2	177.4 ± 29	172 ± 30.1	0.079
HDL cholesterol (mg/dL)		69.4 ± 15.5	69.2 ± 15.5	70.6 ± 15.6	0.392
LDL cholesterol (mg/dL)		104.1 ± 27.7	104.7 ± 27.6	100.3 ± 28.8	0.127
Triglyceride (mg/dL)		73.6 ± 38.7	74.7 ± 40.2	65.6 ± 25	0.002§
AST (IU/L)		18 ± 9.5	18.1 ± 9.8	17.6 ± 7	0.657
ALT (IU/L)		15.2 ± 11.1	15.3 ± 11.4	14.7 ± 8.6	0.644
r-GTP (IU/L)		14.9 ± 17	15.1 ± 18	13.3 ± 6.7	0.326
Alcohol†	Adequate Overdrink	681 (79.5%) 176 (20.5%)	599 (79.8%) 152 (20.2%)	82 (77.4%) 24 (22.6%)	0.567
Exercise‡	None Adequate	244 (28.5%) 613 (71.5%)	208 (27.7%) 543 (72.3%)	36 (34.0%) 70 (66.0%)	0.181
Smoking	None Ex-smoker Smoker	773 (90.2%) 21 (2.5%) 63 (7.4%)	683 (90.9%) 18 (2.4%) 50 (6.7%)	90 (84.9%) 3 (2.8%) 13 (12.3%)	0.037§
Shift work tenure (years)	≤9 10–14 ≥15	432 (50.4%) 339 (39.6%) 86 (10.0%)	378 (50.3%) 295 (39.3%) 78 (10.4%)	54 (50.9%) 44 (41.5%) 8 (7.5%)	0.617
Working hours per week (hours/week)	≤40 41–51 52–59 ≥60	378 (44.1%) 386 (45.0%) 79 (9.2%) 14 (1.6%)	333 (44.3%) 338 (45.0%) 68 (9.1%) 12 (1.6%)	45 (42.5%) 48 (45.3%) 11 (10.4%) 2 (1.9%)	0.638

* Continuous variables are expressed as mean ± SD, whereas categorical variables are expressed as numbers (%).
† Overdrink = consume alcohol at least once a week; adequate = consume alcohol less than once a week.
‡ Adequate = exercise three times or more per week; none = exercise less than three times per week.
§ $p < 0.05$.

Table 2
Differences in BI-RADS category between groups who responded that they had symptoms in the breast cancer questionnaire

BI-RADS category	Total (n = 857)		Symptom checked				*p*-value
			No (n = 751)		Yes (n = 106)		
	N	%	N	%	N	%	
1	462	53.9%	419	55.8%	43	40.6%	0.033*
2	156	18.2%	132	17.6%	24	22.6%	
3	221	25.8%	185	24.6%	36	34.0%	
4	18	2.1%	15	2.0%	3	2.8%	
1~3	839	97.9%	736	98.0%	103	97.2%	0.576
4	18	2.1%	15	2.0%	3	2.8%	

BI-RADS, Breast Imaging Reporting and Database System.
* $p < 0.05$.

Table 3
ORs for BI-RADS category 4 in accordance with symptom checked in the breast cancer questionnaire

Variables		Crude OR	95% CI	Adjusted OR*	95% CI
Age (years)		1.19	1.06–1.34	1.01	0.80–1.27
Shift work tenure (years)	<9	1.00		1.00	
	10–14	6.54	1.42–30.03	6.27	0.93–42.41
	≥15	16.13	3.20–81.32	15.24	1.04–222.85
Symptom checked	No	1.00		1.00	
	Yes	1.43	0.41–5.02	1.54	0.43–5.51

BI-RADS, Breast Imaging Reporting and Database System; CI, confidence interval; OR, odds ratio.
* Adjusted for age, shift work tenure, and symptom checked.

4. Discussion

This study investigated the validity of the breast cancer symptom questionnaire conducted during the night worker's special health examination for young women and its relationship with the breast ultrasonography results. The results showed no statistically significant difference in the frequency and risk of diagnosis of BI-RADS category 4 between the symptoms checked on the questionnaire. The only statistically significant variable was the shift work tenure. There was a positive relationship between increasing years of shift work tenure and increasing OR. However, after adjusting for other variables, shift work tenure only showed statistical significance if the shift work tenure was 15 years or greater, and no significant results were identified if the shift work tenure was below 15 years (Table 3). There are limitations on this result. Only a minority of female employees had more than 20 years of work experience owing to the relatively short shift work tenure, given that the participants of this study were young female adults in their 20s and 30s. However, this result is in line with the findings of previous large-scale cohort studies conducted in nurses, which reported that the incidence rate of breast cancer significantly increased only if nurses worked night shifts for 2–30 years or longer [13,14], and a Swedish cohort study that found a significant increase in the hazard ratio of breast cancer in the group of people who worked night shifts for 21 years or longer [15].

However, a statistical significance could not be found between the responses to the breast cancer symptom questionnaire and the suspected malignancy in accordance with the breast ultrasonography results. Furthermore, the sensitivity of the breast cancer

Table 4
Validity of breast cancer questionnaire

	Value	95% CI
Sensitivity	16.7%	4.4%–42.3%
Specificity	87.7%	85.3%–89.8%
PPV*	2.8%	0.7%–8.7%
NPV	98.0%	96.6%–98.8%

* PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval.

symptom questionnaire was 16.7% (95% CI: 4.4%–42.3%), and its PPV was 2.8% (95% CI: 0.7%–8.7%), indicating that it is not suitable screening test for cancer. There may be a number of reasons why the findings of this study indicate that the breast cancer symptom questionnaire has a low sensitivity and PPV.

First of all, the participants of this study were young women in their 20s and 30s. As they are not in the age group in which breast cancer is prevalent (40s), they do not usually perform breast self-examination for early detection of breast cancer or could not perceive the symptoms as they have relatively low interest. In accordance with the results of a study in Korea, only 17.8%–20% of the employed women in their 20s and 30s performed self-examination for breast cancer [16]. Although not shown in the results, only 2.8% of the participants of this study regularly performed early examinations for breast cancer, including self-examination. In this case, the breast cancer symptom questionnaire had a low sensitivity probably because it does not include assessment of symptoms. However, suspected malignancy results were coincidentally found on breast ultrasonography. Furthermore, young women may experience various biological changes in the breasts due to menstrual cycle, pregnancy, birth, and breastfeeding. Symptoms can be more difficult to detect because of the high breast density associated with the development of mammary glands.

The breast cancer symptom questionnaire showed low PPV because the participants' responses to the questionnaire item asking about the symptoms were categorized into lump/secretion/broken and that these symptoms can be observed not only among individuals with breast cancers, but also among those with other benign breast diseases and systemic diseases. In particular, for a lump, which is the most common symptom, 90% of all newly observed breast lumps in pre-menopausal young women are benign lesions, such as fibroadenoma [17]. Although not shown in the results, 43.4% (46) of the 106 respondents in this study who responded that they had symptoms in the breast cancer symptom questionnaire reported a lump. Among those, 2 of 46 (4.3%) respondents had suspected malignancy, whereas 29 (63.0%) had benign nodes or cysts. Therefore, a response to the breast cancer symptom questionnaire that cannot be differentiated from breast diseases with much higher prevalence rates among young women would have a lower PPV.

In the worker's special health examinations, women who worked night shifts for 5 years or more or are 35 years old or older who have suspected symptoms of breast cancer based on the results of the interview and consultation during the preliminary health examinations conducted among night shift workers underwent mammograms in accordance with the protocol. Among those, women who may be or are pregnant underwent breast ultrasonography after the preliminary examination [18]. Here, suspected symptoms of breast cancer refer to the participants' response to the breast cancer symptom questionnaire in this study. Based on this, the doctor determines whether a breast ultrasonography should be performed or not. However, from the results of this study, the sensitivity and PPV of the breast cancer symptom questionnaire are low. Thus, there may be problems with identifying the need for additional examinations.

The number of female workers who underwent night worker's special health examination in Korea was 315,267 as of 2018 [19]. Performing mammography or breast ultrasonography on this large number of people could be undesirable from the cost-benefit perspective. Furthermore, mammography is not recommended in women who are younger than 40 years old owing to concerns with radiation exposure. In accordance with the Korean Society for Breast Cancer, clinical examinations carried out by a doctor should be performed every 2 years after the age of 35 [20]. Clinical examination by a doctor is an examination method that can substantially supplement the limitations of mammograms. However, this requires visual and touch-based examinations by a doctor and cannot be easily performed in a worker's special health examination. Therefore, doctor's interview and questionnaire survey, which are currently used, may be a practical method of screening for breast cancer among night shift workers.

However, the results of this study showed that the current questionnaire has low sensitivity and PPV. Thus, considerations about its usefulness are necessary. As a solution, more efforts should be made to increase the recognition of symptoms through active education and advertisement on how to perform self-examination for early breast cancer detection among young female workers, proper categorization of high-risk group by identifying other known risk factors for breast cancer including shift work tenure rather than the use of current symptom-based self-questionnaires, and modification the protocol in special health examination for night workers, i.e., implementing additional examination regardless of symptoms. Furthermore, policy support that enables active mammography or breast ultrasonography for night workers categorized into the high-risk group may be necessary.

There are several limitations to this study. First, there may be problems with the reliability of the results of the breast ultrasonography, which was used as an index of suspected malignancy in this study. Breast ultrasonography may show different results depending on the experiences and the knowledge of the examiner. However, in this study, the breast ultrasonography was performed by an experienced specialist. Thus, the problem with reliability can be considered relatively low.

Problems with BI-RADS category 4 diagnosis, which was used as an index of suspected malignancy in this study, can also be considered a limitation of this study. The BI-RADS category 4 can be divided into three subcategories (4a, 4b, and 4c) depending on the level of suspected malignancy since 2013 [12]. In accordance with a South Korean study, the PPV of BI-RADS category 4 for breast cancer was 18.9%. When this category was further divided into subcategories 4a, 4b, and 4c, PPVs were 8.9%, 47.9%, and 82.0%, respectively [21]. Although not indicated in the results, 17 of 18 participants with BI-RADS category 4 were in category 4a, whereas one was in category 4c. Because the confirmation of breast cancer could not be followed up, whether they actually were diagnosed with breast cancer could not be identified. Because 4a had a low PPV, the number of patients who were actually diagnosed with breast cancer is thought to be lower than 18. Therefore, if breast cancer diagnosis is considered to be the outcome, the sensitivity and PPV of the results may be lower. However, the purpose of a health examination is to identify patients who require additional detailed diagnosis rather than identifying their final diagnosis; it was thought that it would not be inappropriate to select category 4, which requires additional examination owing to suspected malignancy.

Mammography is selected over breast ultrasonography as an examination for breast cancer and is considered as the most effective single screening test for breast cancer [20]. Breast ultrasonography is often performed if clinical examinations and mammograms

show abnormal findings. Therefore, the use of breast ultrasonography as a single screening test remains controversial. However, regular mammograms are not recommended for people aged younger than 40 years owing to concerns with radiation exposure. Furthermore, unlike breast ultrasonography, mammograms involve the application of excessive pressure to the breasts, which can cause pain and discomfort. Thus, compliance to screening tests is reduced among young women. In particular, results of previous studies showed that young women, who are the main participants of this study, have relatively dense mammary glands, which make it difficult to perform an accurate diagnosis using mammograms alone; hence, ultrasonography may be more useful [22,23]. However, breast ultrasonography is thought to be an inappropriate test for screening breast cancer in young working women.

In this study, breast ultrasound was performed by the examinee's choice. Therefore, a person who has an interest and concern for breast cancer in general can choose a breast ultrasound examination more. In this situation, selection bias may be a concern.

In this study, the 95% CI of sensitivity was wide, ranging from 4.2 to 42.3%. This is presumed to be due to the very small number of individuals in this study, who were BI-RADS category 4 or higher, in 18 individuals. This seems to be a questionable accuracy in the estimation of sensitivity, but it seems reasonable to interpret it as still showing low sensitivity.

This study was conducted in female night shift workers in one electronic manufacturing company. Thus, there are limitations in generalizing the results of this study to all female night workers. The level of breast cancer health education and recognition in this workplace may differ from that in other workplaces. This can affect the participants' responses to the breast cancer symptom questionnaire and thus the sensitivity of the questionnaire.

Despite many limitations, this study is significant in that it is the first Korean study to investigate the validity of the breast cancer symptom questionnaire used during the night worker's special health examinations. In the future, large-scale, multicenter cohort studies should be conducted to supplement the limitations of this study. Moreover, more efficient and accurate methods should be developed to screen for breast cancer among female night shift workers.

5. Conclusion

The results showed that the sensitivity and PPV of the breast cancer symptom questionnaire were low, suggesting that it is not suitable for screening breast cancer. Active training and improvement of awareness for breast cancer screening and continued attention and consideration for efficient and accurate screening should be conducted in the future.

Conflicts of interest

The author declares that there are no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.shaw.2020.04.008.

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