Annual trends of ultrasonography-guided 14-gauge core-needle biopsy for breast lesions

Inha Jung

Department of Medicine

The Graduate School, Yonsei University

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Directed by Professor Eun-Kyung Kim

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This certifies that the Doctoral Dissertation of Inha Jung is approved.

Thesis Supervisor : Eun-Kyung Kim

Thesis Committee Member#1 : Jung Hyun Yoon

Thesis Committee Member#2 : Kyunghwa Han

Thesis Committee Member#3: Jeong Seon Park

Thesis Committee Member#4: Hyeon Chang Kim

The Graduate School
Yonsei University

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ABSTRACT

Annual trends of ultrasonography-guided 14-gauge core-needle biopsy for breast lesions

Inha Jung

Department of Medicine
The Graduate School, Yonsei University

(Directed by Professor Eun-Kyung Kim)

Objectives: To examine time trends in ultrasonography (US)-guided 14-gauge core needle biopsy (CNB) for breast lesions based on the lesion size, Breast Imaging-Reporting and Data System (BI-RADS) category, and pathologic findings.

Methods: We retrospectively reviewed consecutive US-guided 14-gauge CNBs performed from January 2005 to December 2016 at our institution. Proven malignancies, male patients, and lesions with non-diagnostic pathologic results were excluded; finally, a total of 22,297 breast lesions were included. The total number of biopsies, tumor size (≤ 10 mm to > 40 mm), BI-RADS category (1 to 5), and pathologic findings (benign, high risk, ductal carcinoma in situ [DCIS], invasive cancer) were examined annually, and the malignancy rate was analyzed based on the BI-RADS category.

Results: Both the total number of US scans and US-guided CNBs increased while the proportion of US-guided CNBs to the total number of US scans decreased significantly. The number of biopsies classified based on the tumor size, BI-RADS category, and pathologic findings all increased over time, except for BI-RADS categories 1 or 2 and category 3 (beta = -0.051, 95% confidence interval [CI]: -0.103, 0.002 and beta = -0.022, 95% CI: -0.031, 0.012, respectively). Both the unadjusted and

adjusted total malignancy rates and the DCIS rate increased significantly over time. BI-RADS categories 4a, 4b, and 4c showed a significant increasing trend in the total malignancy rate ($p = 0.020$, $p < 0.001$, and $p = 0.002$, respectively) and DCIS rate ($p < 0.001$, $p = 0.001$, and $p = 0.046$, respectively).

Conclusion: The malignancy rate in the results of US-guided 14-gauge CNB for breast lesions increased as the total number of biopsies increased from 2005 to 2016. This trend persisted after adjusting for the BI-RADS category.

Key words : breast cancer, ultrasonography, image-guided biopsy, trends

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I. INTRODUCTION

Imaging-guided core-needle biopsy (CNB) is considered the gold standard diagnostic modality for breast lesions and a reliable alternative to surgical excisional biopsy [1-5]. Many studies have reported that percutaneous ultrasonography (US)-guided CNB has several advantages over stereotactic or surgical biopsy. It is less invasive, less expensive, and faster to perform; further, it can be performed in real time while still allowing accurate assessments without exposure to ionizing radiation [4,6,7]. Many studies also have proven that US-guided 14-gauge CNB provides optimal diagnostic information for breast lesions with low false-negative rates and accuracy comparable to that of surgical biopsy [3,5,6,8]. Furthermore, the number of breast imaging studies utilizing screening mammography and US has increased, resulting in increased lesion detection and biopsy recommendation. Therefore, US-guided CNB has been increasingly performed since its introduction. However, its subsequent utilization has led to concerns about an unnecessary increase in the number of biopsies associated with benign biopsy results.

In the United States, more than 1 million breast biopsies are performed annually, and approximately 80% of cases are benign [9,10]. However, data are limited on which lesions have been increasingly biopsied over time. US-guided CNB would be cost-ineffective and would be of clinical insignificance if the

increasing number of biopsies does not lead to increased breast cancer detection. With the number of total biopsies increasing over time, the malignancy rate in the results of CNB must be kept constant or increase in order to ensure that unnecessary biopsies are not performed.

The purpose of this study was to examine annual trends in breast lesion characteristics (e.g., lesion size, the Breast Imaging-Reporting and Data System [BI-RADS] category established by the American College of Radiology, and pathologic findings) and the malignancy rate based on a large series of US-guided CNB over a 12-year study period.

II. MATERIALS AND METHODS

1. Study population

This study was conducted with the approval of the Institutional Review Board, and the requirement for informed consent was waived.

From January 2005 to December 2016, 22,667 consecutive US-guided 14-gauge CNBs for breast lesions from 211,986 breast US procedures were performed at our institution. We retrospectively reviewed the biopsy results to analyze the annual trends in US-guided CNB. Proven malignancies assessed as BI-RADS category 6 lesions (n = 282), male patients (n = 62), and lesions with non-diagnostic pathologic results (e.g., adipose tissue only or cell paucity) (n = 26) were excluded from this study. Finally, a total of 22,297 breast masses of 17,241 patients (mean age, 45.65 ± 11.61 years, range, 11 to 92 years) were included in this study.

2. Biopsy procedure

US-guided 14-gauge CNB was performed using the free-hand technique and a high-resolution US unit with 5-15-MHz linear transducers (HDI 5000 or 3000 or iU22, Philips' Advanced Technology Laboratories, Bothell, WA, USA; or LOGIQ 9 or LOGIQ E9, GE Healthcare, Milwaukee, WI, USA). Each procedure was performed with the patient in the supine position under local anesthesia. A 14-gauge automated core biopsy needle with a spring-loaded biopsy gun (Promac 2.2L, Manan Medical Products,

Northbrook, IL, USA), a 14-gauge Tru-Cut needle with a 22-mm throw (SACN biopsy needle; Medical Device Technologies, Gainesville, FL, USA), or a 14-gauge dual-action semiautomatic core biopsy needle with a 22-mm throw (Stericut with a coaxial needle, TSK Laboratory, Tochigi, Japan) was used. All biopsies were performed by one of 42 radiologists with less than 2 years of experience who was in fellowship training, or by one of six radiologists with 2 or more years of clinical experience who was a specialist in breast imaging and biopsies. At least four or five core samples per lesion were routinely obtained.

3. Data analysis

The radiological and pathologic findings of US-guided 14-gauge CNB were obtained from medical records. Breast lesions were classified based on the lesion size, BI-RADS category on US, and pathologic results of CNB. Each variable was categorized as follows: lesion size as less than 10 mm, 10–20 mm, 20–30 mm, 30–40 mm, or more than 40 mm; BI-RADS category on US (category 1 to 5); pathologic results of CNB as benign (neither malignant nor high-risk), high-risk (e.g., atypia, including atypical ductal hyperplasia, lobular neoplasia, radial sclerosing lesions, and possible phyllodes tumors), or malignant (e.g., ductal carcinoma in situ [DCIS] and invasive cancer). The malignancy rates for DCIS and invasive cancer were calculated as proportions among all biopsied breast masses of DCIS and invasive cancer, respectively, diagnosed using US-guided 14-gauge CNB. The total malignancy rate was calculated as the total proportion of both DCIS and invasive cancer among all biopsied cases.

To assess overall trends over time in CNB based on the lesion size, BI-RADS category, and pathologic results, the Mantel-Haenszel chi-square test and Poisson regression analysis were performed. The Cochran-Armitage test was performed for trends in the malignancy rate and the Cochran-Mantel-Haenszel test was performed to adjust variables. A generalized linear model with an identity link for normal distribution was used to calculate the odds ratio (OR) for associations between the calendar

year and each variable. OR was interpreted as the number of times each indicator increased each year. Analyses were performed with a computerized statistic program (SAS, version 9.4 or SPSS, version 23.0), and a *p*-value of less than 0.05 was considered statistically significant.

III. RESULTS

1. Time trends in CNB based on the lesion size, BI-RADS category, and pathology

Both the total number of US scans and US-guided CNBs increased significantly during the study period while the proportion of US-guided CNBs to the total number of US scans decreased (beta = -0.049, 95% CI: -0.053, -0.045, $p < 0.001$) (Table 1). Table 2 shows distributions of US-guided 14-gauge CNB based on the lesion size and BI-RADS category. Table 3 shows the distribution of US-guided 14-gauge CNB based on the pathologic results.

Table 1. Distribution of US-guided 14-gauge core-needle biopsy and total ultrasonography, 2005-2016

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total	Beta (95% CI)	*p* value
No. of US-guided core-needle biopsies[1]	1294	1504	1377	1639	1975	2080	1938	2019	1972	2111	2334	2054	22297	0.043 (0.038, 0.046)	<0.001
(%)	(16.57)	(14.14)	(11.51)	(12.30)	(11.50)	(11.65)	(10.12)	(9.70)	(9.02)	(9.43)	(10.28)	(7.93)		-0.049 (-0.053, -0.045)	<0.001
No. of total breast US examinations	7808	10635	11963	13766	17171	17859	19151	20808	21854	22377	22698	25896	211986	0.087 (0.086, 0.089)	<0.001

[1]Percentage of total core-needle biopsies performed among total USs is in parentheses.

CI = confidence interval; US = ultrasonography.

Table 2. Distribution of US-guided 14-gauge core-needle biopsy according to the lesion size and BI-RADS category

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total	Beta (95% CI)	*p* value
Size (mm)															
≤10	575 (44.44)	698 (46.41)	682 (49.53)	959 (58.51)	989 (50.08)	1043 (50.14)	997 (51.44)	1057 (52.35)	1000 (50.71)	979 (46.38)	1125 (48.2)	828 (40.31)	10932 (49.03)	0.035 (0.029, 0.04)	<0.001
10 to ≤20	466 (36.01)	502 (33.38)	452 (32.82)	451 (27.52)	688 (34.84)	699 (33.61)	614 (31.68)	638 (31.6)	654 (33.16)	715 (33.87)	779 (33.38)	734 (35.74)	7392 (33.15)	0.046 (0.039, 0.053)	<0.001
20 to ≤30	159 (12.29)	196 (13.03)	150 (10.89)	129 (7.87)	196 (9.92)	203 (9.76)	203 (10.47)	194 (9.61)	188 (9.53)	254 (12.03)	252 (10.8)	285 (13.88)	2409 (10.80)	0.051 (0.039, 0.063)	<0.001
30 to ≤40	44 (3.4)	63 (4.19)	64 (4.65)	63 (3.84)	69 (3.49)	64 (3.08)	70 (3.61)	69 (3.42)	61 (3.09)	89 (4.22)	80 (3.43)	98 (4.77)	834 (3.74)	0.046 (0.027, 0.066)	<0.001
> 40	50 (3.86)	45 (2.99)	29 (2.11)	37 (2.26)	33 (1.67)	71 (3.41)	54 (2.79)	61 (3.02)	69 (3.5)	74 (3.51)	98 (4.2)	109 (5.31)	730 (3.27)	0.098 (0.076, 0.12)	<0.001
BI-RADS category															
1 or 2	6 (0.46)	17 (1.13)	10 (0.73)	9 (0.55)	8 (0.41)	11 (0.53)	21 (1.08)	15 (0.74)	9 (0.46)	5 (0.24)	4 (0.17)	4 (0.19)	119 (0.53)	-0.051 (-0.103, 0.002)	0.058
3	346 (26.74)	310 (20.61)	285 (20.7)	237 (14.46)	338 (17.11)	360 (17.31)	401 (20.69)	347 (17.19)	318 (16.13)	306 (14.5)	264 (11.31)	156 (7.59)	3668 (16.45)	-0.022 (-0.031, -0.012)	<0.001
4a	608 (46.99)	725 (48.2)	711 (51.63)	1004 (61.26)	1211 (61.32)	1254 (60.29)	1100 (56.76)	1229 (60.87)	1238 (62.78)	1274 (60.35)	1472 (63.07)	1222 (59.49)	13048 (58.52)	0.06 (0.055, 0.065)	<0.001
4b	42 (3.25)	78 (5.19)	90 (6.54)	100 (6.1)	117 (5.92)	124 (5.96)	72 (3.72)	79 (3.91)	84 (4.26)	116 (5.5)	141 (6.04)	160 (7.79)	1203 (5.40)	0.063 (0.047, 0.08)	<0.001
4c	113 (8.73)	130 (8.64)	102 (7.41)	93 (5.67)	102 (5.16)	130 (6.25)	117 (6.04)	99 (4.9)	97 (4.92)	132 (6.25)	182 (7.8)	223 (10.86)	1520 (6.82)	0.052 (0.038, 0.067)	<0.001

5	179 (13.83)	244 (16.22)	179 (13)	196 (11.96)	199 (10.08)	201 (9.66)	227 (11.71)	250 (12.38)	226 (11.46)	278 (13.17)	271 (11.61)	289 (14.07)	2739 (12.28)	0.038 (0.027, 0.049)	<0.001

Values are presented as numbers of core-needle biopsies with percentages in parenthesis.

BI-RADS, Breast Imaging-Reporting and Data System; CI = confidence interval; US = ultrasonography.

Table 3. Distribution of US-guided 14-gauge core-needle biopsy according to the pathologic results

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total	Beta (95% CI)	*p* value
Pathologic results															
Benign	941 (72.72)	1063 (70.68)	1013 (73.57)	1250 (76.27)	1513 (76.61)	1575 (75.72)	1468 (75.75)	1497 (74.15)	1467 (74.39)	1469 (69.59)	1619 (69.37)	1320 (64.26)	16195 (72.63)	0.035 (0.03, 0.039)	<0.001
High risk	37 (2.86)	30 (1.99)	26 (1.89)	45 (2.75)	74 (3.75)	64 (3.08)	52 (2.68)	57 (2.82)	81 (4.11)	111 (5.26)	111 (4.76)	108 (5.26)	796 (3.57)	0.121 (0.1, 0.142)	<0.001
Total Malignancy	316 (24.42)	411 (27.33)	338 (24.55)	344 (20.99)	388 (19.65)	441 (21.2)	418 (21.57)	465 (23.03)	424 (21.5)	531 (25.15)	604 (25.88)	626 (30.48)	5306 (23.80)	0.057 (0.049, 0.065)	<0.001
DCIS	35 (2.7)	44 (2.93)	33 (2.4)	47 (2.87)	49 (2.48)	62 (2.98)	57 (2.94)	62 (3.07)	69 (3.5)	94 (4.45)	101 (4.33)	98 (4.77)	751 (3.37)	0.102 (0.08, 0.123)	<0.001
Invasive cancer	281 (21.72)	367 (24.4)	305 (22.15)	297 (18.12)	339 (17.16)	379 (18.22)	361 (18.63)	403 (19.96)	355 (18)	437 (20.7)	503 (21.55)	528 (25.71)	4555 (20.43)	0.049 (0.041, 0.058)	<0.001

Values are presented as numbers of core-needle biopsies with percentages in parenthesis.

CI = confidence interval; DCIS = ductal carcinoma *in situ*; US = ultrasonography.

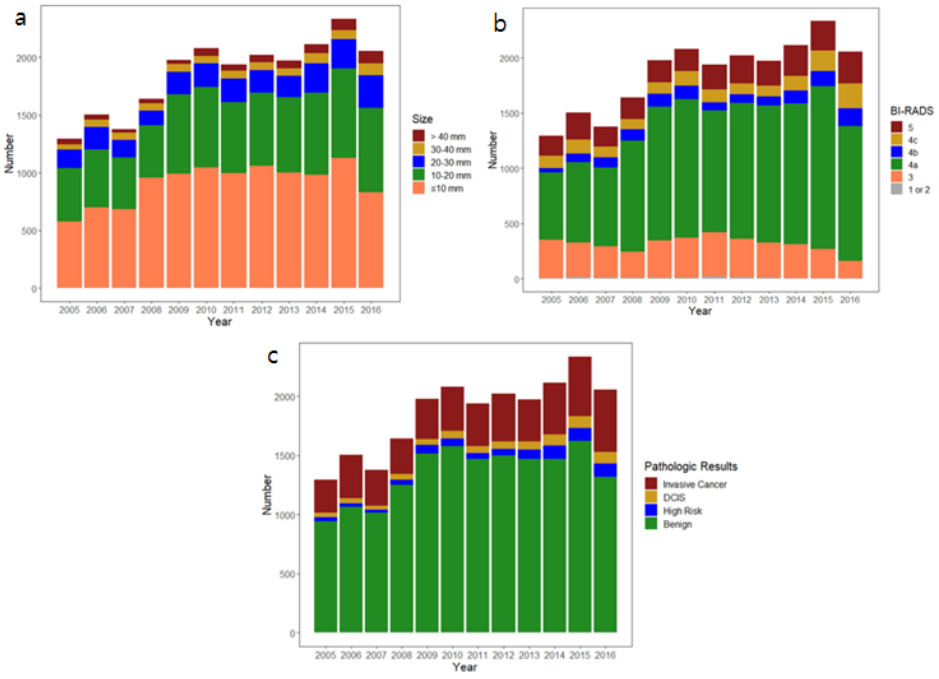

Figure 1. Distribution of US-guided 14-gauge core-needle biopsies based on the lesion size (a), Breast Imaging-Reporting and Data System category (b), and pathologic results (c) from 2005 to 2016. BI-RADS = Breast Imaging-Reporting and Data System; DCIS = ductal carcinoma *in situ*; US = ultrasonography.

Figure 1 illustrates distributions US-guided 14-gauge CNB based on the lesion size, BI-RADS category, and pathologic results. With the Poisson regression analysis, we found statistically significant trends in all variables ($p < 0.001$, respectively), except for BI-RADS categories 1 and 2. BI-RADS category 3 lesions showed a statistically significant decreasing trend of 0.979 times per year (95% CI: 0.970, 0.988; $p < 0.001$). The number of BI-RADS category 1 or 2 lesions also decreased to 0.951 times per year without statistical significance (95% CI: 0.902, 1.002; $p = 0.058$), and the rest of the variables showed an increasing trend over time. Among all biopsied cases, the proportion of high-risk and DCIS lesions increased while the proportion of benign lesions decreased over time (Figure 2).

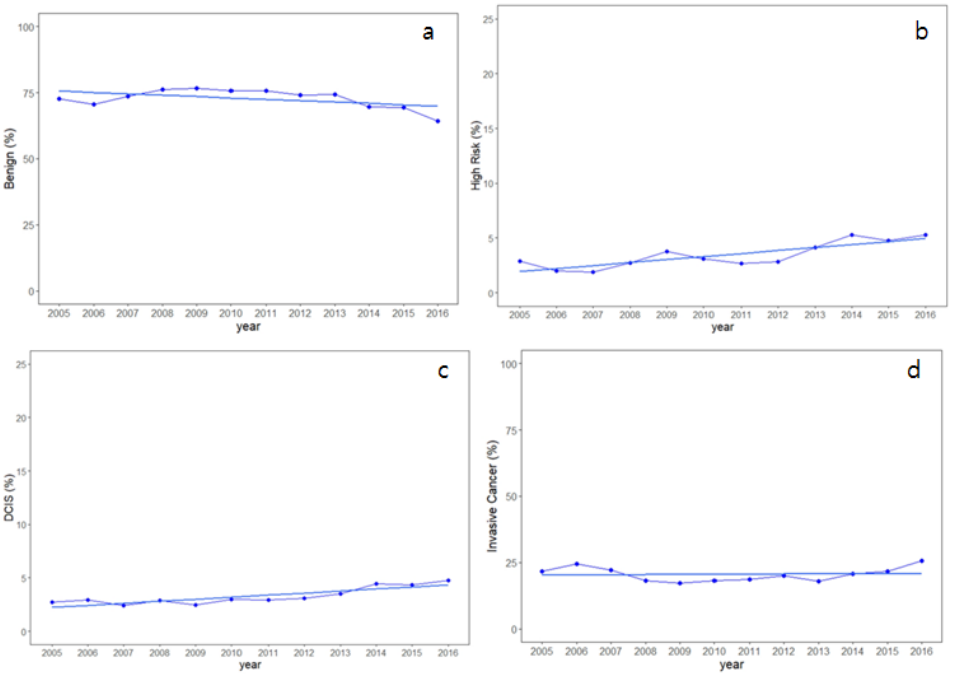

Figure 2. Line plot and trend line for the proportion of pathologic results. Linear line (estimated by linear regression) show a significant decrease in the proportion of benign (a) lesions and significant increase in proportions of high-risk (b) and DCIS (c) lesions over time but no significant trend in the proportion of invasive cancer (d) lesions. DCIS = ductal carcinoma *in situ.*

2. Unadjusted and adjusted time trends of the malignancy rate

For the malignancy rate, the unadjusted results showed significantly increasing trends in rates of total malignancy ($p < 0.001$), DCIS ($p < 0.001$), and invasive cancer ($p = 0.039$). After adjusting for the BI-RADS category, the increasing trends in rates of total malignancy ($p < 0.001$) and DCIS ($p < 0.003$) remained significant, but the rate of invasive cancer did not show a statistically significant increasing trend ($p = 0.215$). Figure 3 shows the time trend line (by linear regression) in the rate of total malignancy based on the BI-RADS category. The increasing trends in the malignancy rate were

statistically significant in BI-RADS categories 4a ($p < 0.001$), 4b ($p = 0.001$), and 4c ($p = 0.046$) for DCIS, BI-RADS category 4b ($p = 0.024$) for invasive cancer, and BI-RADS categories 4a ($p = 0.020$), 4b ($p < 0.001$), and 4c ($p = 0.002$) for total malignancy (Table 4).

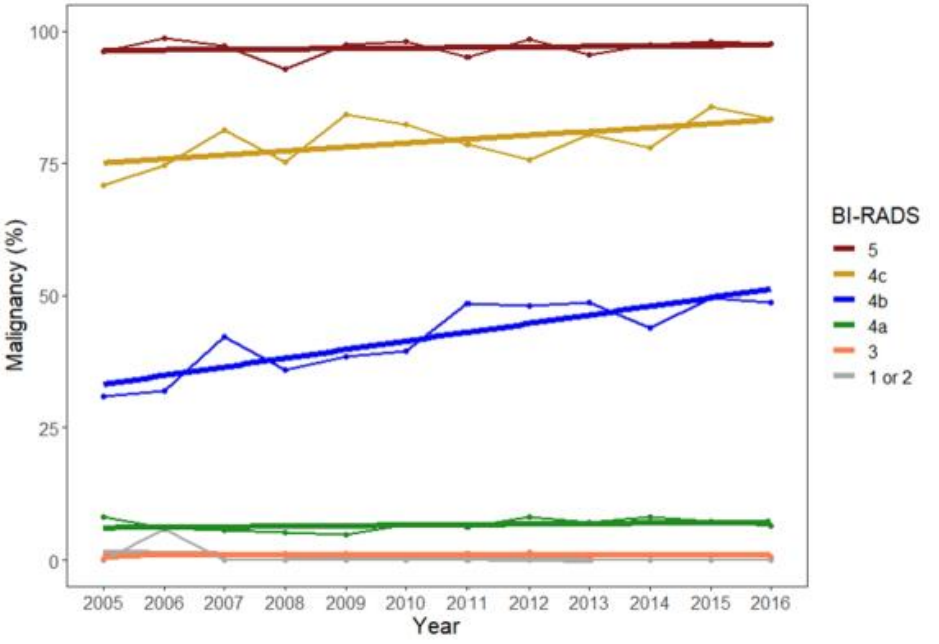

Figure 3. Line plot and trend line for the total malignancy based on the BI-RADS category. Linear line (estimated by linear regression) show that the total malignancy rates increased significantly over time in BI-RADS categories 4a ($p = 0.020$), 4b ($p < 0.001$), and 4c ($p = 0.002$) but not in BI-RADS category 3 ($p = 0.324$) or 5 ($p = 0.175$). BI-RADS = Breast Imaging-Reporting and Data System.

Table 4. Malignancy rate according to the BI-RADS category

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total	*p* value
BI-RADS 3														
DCIS	1 (0.29)	0 (0)	1 (0.35)	2 (0.84)	1 (0.3)	1 (0.28)	1 (0.25)	2 (0.58)	0 (0)	2 (0.65)	2 (0.76)	0 (0)	13 (0.35)	0.280
Invasive cancer	0 (0)	3 (0.97)	2 (0.7)	1 (0.42)	3 (0.89)	3 (0.83)	4 (1)	3 (0.86)	2 (0.63)	1 (0.33)	1 (0.38)	1 (0.64)	24 (0.65)	0.446
Total Malignancy	1 (0.29)	3 (0.97)	3 (1.05)	3 (1.27)	4 (1.18)	4 (1.11)	5 (1.25)	5 (1.44)	2 (0.63)	3 (0.98)	3 (1.14)	1 (0.64)	37 (1.01)	0.324
BI-RADS 4a														
DCIS	16 (2.63)	13 (1.79)	8 (1.13)	10 (1)	13 (1.07)	21 (1.67)	12 (1.09)	24 (1.95)	28 (2.26)	40 (3.14)	35 (2.38)	37 (3.03)	257 (1.97)	<0.001
Invasive cancer	34 (5.59)	31 (4.28)	32 (4.5)	43 (4.28)	46 (3.8)	63 (5.02)	58 (5.27)	77 (6.27)	59 (4.77)	63 (4.95)	74 (5.03)	42 (3.44)	622 (4.77)	0.446
Total Malignancy	50 (8.22)	44 (6.07)	40 (5.63)	53 (5.28)	59 (4.87)	84 (6.7)	70 (6.36)	101 (8.22)	87 (7.03)	103 (8.08)	109 (7.4)	79 (6.46)	879 (6.74)	0.020
BI-RADS 4b														
DCIS	3 (7.14)	1 (1.28)	5 (5.56)	6 (6)	8 (6.84)	12 (9.68)	8 (11.11)	6 (7.59)	5 (5.95)	12 (10.34)	17 (12.06)	19 (11.88)	102 (8.48)	0.001
Invasive cancer	10 (23.81)	24 (30.77)	33 (36.67)	30 (30)	37 (31.62)	37 (29.84)	27 (37.5)	32 (40.51)	36 (42.86)	39 (33.62)	53 (37.59)	59 (36.88)	417 (34.66)	0.024
Total Malignancy	13 (30.95)	25 (32.05)	38 (42.22)	36 (36)	45 (38.46)	49 (39.52)	35 (48.61)	38 (48.1)	41 (48.81)	51 (43.97)	70 (49.65)	78 (48.75)	519 (43.14)	<0.001
BI-RADS 4c														
DCIS	4 (3.54)	15 (11.54)	12 (11.76)	11 (11.83)	8 (7.84)	14 (10.77)	14 (11.97)	12 (12.12)	11 (11.34)	22 (16.67)	24 (13.19)	22 (9.87)	169 (11.12)	0.046
Invasive cancer	76 (67.26)	82 (63.08)	71 (69.61)	59 (63.44)	78 (76.47)	93 (71.54)	78 (66.67)	63 (63.64)	67 (69.07)	81 (61.36)	132 (72.53)	164 (73.54)	1044 (68.68)	0.193
Total Malignancy	80 (70.8)	97 (74.62)	83 (81.37)	70 (75.27)	86 (84.31)	107 (82.31)	92 (78.63)	75 (75.76)	78 (80.41)	103 (78.03)	156 (85.71)	186 (83.41)	1213 (79.80)	0.002
BI-RADS 5														
DCIS	11 (6.15)	15 (6.15)	7 (3.91)	18 (9.18)	19 (9.55)	14 (6.97)	22 (9.69)	18 (7.2)	25 (11.06)	18 (6.47)	23 (8.49)	20 (6.92)	210 (7.67)	0.156
Invasive cancer	161 (89.94)	226 (92.62)	167 (93.3)	164 (83.67)	175 (87.94)	183 (91.04)	194 (85.46)	228 (91.2)	191 (84.51)	253 (91.01)	243 (89.67)	262 (90.66)	2447 (89.34)	0.361
Total Malignancy	172 (96.09)	241 (98.77)	174 (97.21)	182 (92.86)	194 (97.49)	197 (98.01)	216 (95.15)	246 (98.4)	216 (95.58)	271 (97.48)	266 (98.15)	282 (97.58)	2657 (97.01)	0.175

Values are presented as numbers of malignant results with percentages in parenthesis.

There was one case of breast cancer being assigned BI-RADS category 1 or 2 during the 12-year study period.

BI-RADS = Breast Imaging-Reporting and Data System; DCIS = ductal carcinoma *in situ*.

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IV. DISCUSSION

Our results show that in a large series (n = 22,297) of US-guided CNBs for breast lesions, the overall number of both US scans and US-guided CNBs increased from 2005 to 2016. The increase in the total number of US scans performed may partly contribute to the increase in the number of biopsies; however, the proportion of US-guided CNBs among the total number of US scans decreased over time. One possible reason for this proportional decrease is revisions made to BI-RADS during the study period. The 5th edition of BI-RADS released in 2013 had several changes in the US section to include newer technology, such as elastography, and some additional descriptors in its lexicon [11,12]. There were several studies in which additional sonoelastography led to downgrading of BI-RADS 4a masses, potentially reducing the number of unnecessary biopsies [13-15]. In our study, the decreasing rate of biopsies over time might be partly attributed to efforts made to reduce the number of unnecessary biopsies with various novel techniques, such as elastography.

Our analysis revealed that only BI-RADS category 3 lesions decreased significantly over time in terms of both the total number and percentage (26.74% in 2005 to 7.59% in 2016) among the total biopsied lesions. The total malignancy rate among BI-RADS category 3 lesions remained at approximately 1% throughout the study period. This observation is encouraging as otherwise there might have been more unnecessary patient cost and anxiety caused by biopsy because of the high rate of benign lesions in the biopsy results for BI-RADS category 3 lesions. One possible explanation for this may be the efforts to downgrade BI-RADS category 3 lesions by radiologists at our institution. Since March 2010, we have trained our radiologists to downgrade certain lesions found using supplemental screening US to BI-RADS category 2 in efforts to reduce the false-positive rate [16]. In a previous study, the downgrade criteria reduced the BI-RADS category 3 rate from 28.3% to 12.6% without loss of cancer detection, and the biopsy rate also decreased significantly over 3 years. Despite using different inclusion criteria in the two studies, our results showed that the decrease in the BI-RADS category 3 rate was most prominent and

persistent from 2011 to 2016, which fit the timeframe in which the downgrade criteria were first incorporated into the clinical practice at our institution.

The total malignancy rate in the results of US-guided CNB slightly increased over time with statistical significance, and this trend persisted after adjusting for the BI-RADS category. These results were consistent with our initial assumption that the malignancy rate in the results of CNB should be constant or increase in order to ensure that unnecessary biopsies were not performed. Among cases of total malignancy, the rate of DCIS showed an increasing trend during our study period. This observation can be attributed to the widespread use of screening mammography, which reveals clinically occult pre-invasive disease, and advances of other diagnostic imaging modalities, such as US and magnetic resonance imaging [17-19]. In addition, improved resolution and technique have enabled visualization of microcalcifications on US, thus increasing the detection rate of DCIS using US-guided biopsy, which was formerly diagnosed using stereotactic-guided biopsy [20-22].

When lesions were classified based on the BI-RADS category, the total malignancy rates of BI-RADS category 4a, 4b, and 4c lesions showed slightly increasing trends over time. Because BI-RADS category 4 on US indicates a lesion suspected with malignancy for which biopsy is recommended, the aforementioned result may correlate with decreased false-positive results in the US findings of breast lesions. Our results showed that the malignancy rate based on the BI-RADS category generally matched the stratification of positive predictive values for each BI-RADS category during the past 12 years, with an exception in year 2008 (92.86% in BI-RADS 5). BI-RADS suggests a positive predictive value of less than 2%, 3%–10%, 11%–50%, more than 95% for categories 3, 4a, 4b, 4c, and 5, respectively [11].

In 2005, a community population-based trend study was performed on the frequency and malignancy rate of breast biopsies, similar to our study [23]. However, many subjects of this past study underwent surgical biopsies, which are no longer recommended as the initial diagnostic approach [24]. In addition, unlike our study, there was no BI-RADS classification for US lesions, which is

now used in clinical practice. Thus, our study better reflects the latest clinical management approaches chosen for breast lesions compared with the previous study. Another recent study described time trends in minimally invasive breast biopsy for 9 years [25]; however, this study primarily analyzed geographic/ethnic variations in breast biopsy and did not assess malignancy rates relating to unnecessary biopsies and cost-ineffectiveness in the clinical practice, while our study focused on the malignancy rate of breast biopsies.

Our study has a few limitations. First, this study was retrospectively conducted at a single tertiary hospital; therefore, its results cannot be generalized immediately to other populations. Further multicenter studies are required before our results can be applied to general clinical circumstances. Second, there was no standard diagnostic reference, such as surgical excision or follow-up data, to confirm the pathologic results of CNB. However, US-guided 14-gauge CNB is a reliable diagnostic modality that allows accurate assessments [4,6,7]. A previous study at our institution showed reliable sensitivity (95.4%) and no false-positive results for US-guided CNB from 2005 to 2012 [8]. Third, we did not classify US-guided CNB based on the indication of biopsy (e.g., screening or diagnostic clinical setting), which would potentially affect trends. in larger changes for breast biopsy in the future and further study is needed.

V. CONCLUSION

In conclusion, w we found an overall slightly increasing trend in the malignancy rate in the results of US-guided 14-gauge CNB for breast lesions and an increase in the total number of biopsies performed from 2005 to 2016. This trend persisted after adjusting for the BI-RADS category. We could also observe the efforts made to avoid unnecessary biopsies during the 12-year study period with a large population at a single institution.

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ABSTRACT(IN KOREAN)

유방 병변의 초음파 유도 14 게이지 중심 바늘 생검의 연간 경향

<지도교수 김은경>

연세대학교 대학원 의학과

정 인 하

목적: 유방 병변의 초음파 유도 14 게이지 중심 바늘 생검의 연간 경향을 병변의 크기, Breast Imaging-Reporting and Data System (BI-RADS) 범주, 병리 결과에 따라 알아보고자 하였다.

방법: 2005년 1월부터 2016년 12월까지 본 기관에서 시행한 초음파 유도 14 게이지 중심 바늘 생검을 후향적으로 검토하였다. 증명된 악성 병변, 남자 환자, 진단적이지 않은 병리 결과는 제외하였고, 최종적으로 총 22,297건의 유방 생검 병변이 연구에 포함되었다. 생검의 총 건수, 병변의 크기, BI-RADS 범주, 병리 결과를 연도별로 분류하였고, 악성률을 BI-RADS 범주에 따라 분석하였다.

결과: 총 초음파 건수와 총 초음파 유도 중심 바늘 생검 건수 모두 시간에 따라 유의하게 증가하였고, 초음파 유도 중심 바늘 생검이 총 초음파 건수에서 차지하는 비율은 유의하게 감소하였다. 초음파 유도 중심 바늘 생검의 모든 변수들은 증가하는 경향을 보였고, 예외적으로 BI-RADS 범주 1 또는 2 (베타값 = -0.051, 95% 신뢰구간: -0.103, 0.002)와 BI-RADS 범주 3 (베타값 = -0.022, 95% 신뢰구간: -0.031, 0.012) 은 감소하였다. BI-RADS 범주에 대해 보정하기 전과 보정한 후 모두 총 악성률과 관상피내암의 악성률은 시간이 지남에 따라 유의하게 증가하였다. BI-RADS 범주 4a, 4b, 4c 병변은 총 악성률 (p = 0.020, p < 0.001, p = 0.002) 과 관상피내암의

악성률 ($p < 0.001$, $p = 0.001$, $p = 0.046$) 에서 유의하게 증가하는 경향을 보였다.

결론: 2005년부터 2016년까지 유방 병변에 대한 초음파 유도 14 게이지 중심 바늘 생검의 총 건수가 증가함에 따라 악성률도 증가하였다. 이러한 경향은 BI-RADS 범주에 대해 보정한 후에도 유의하였다.

핵심되는 말 : 유방암, 초음파, 영상 유도 생검, 경향

PUBLICATION LIST

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