# US-guided 14-gauge Core Needle Biopsy: Comparsion Between Underestimated and Accurately Diagnosed Breast Cancer

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Directed by Professor Eun Ju Son

The Master's Thesis submitted to the Department of Medicine, the Graduate School of Yonsei University in partial fulfillment of the requirements for the degree of Master of Medical Science

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ABSTRACT

# US-guided 14-gauge Core Needle Biopsy: Comparison between Underestimated and Accurately Diagnosed Breast Cancer

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**Purpose**: The purpose of this study was to evaluate imaging features of breast cancer which was underestimated on ultrasound (US)-guided 14-gauge (14G) core needle biopsy (CNB) and analyze the clinical differences between the underestimated breast cancer and accurately diagnosed breast cancer.

**Materials and Methods**: From Jan. 2007 to Dec. 2009, 1898 cases of US-guided 14G CNB were performed in our institute. 514 cases underwent operation after CNB. Among them, 248 cases proved to be cancer by surgical pathology. We retrospectively reviewed the lesions that were CNB results and categorized benign, high risk lesions and breast cancer. The clinical and imaging features such as mammographic and US findings were compared between underestimated breast cancer and accurately diagnosed breast cancer.

**Results**: Of 248 cases of cancer, underestimation occurred in 18 lesions (7.2%). Among the 18 underestimated breast cancer, the CNB results were: atypical ductal hyperplasia (ADH) (n=7) and ductal carcinoma in situ (DCIS) (n=11)

which were invasive ductal carcinoma (IDC) (n=2) or DCIS (n=5) and IDC in final pathology. Among the 186 accurately diagnosed breast cancer, the CNB results were: IDC (n=157) and DCIS (n=29). In comparison of underestimated and accurately diagnosed breast cancer, there was no statistical significance in presence of symptom, past history and patient's age. However, BI-RADS category, margin of mass on mammography and US, and orientation of lesion on US revealed statistically significant difference. ($p < .05$).

**Conclusion:** The underestimation rate of US-guided 14G CNB was 7.2%. Compared with correctly diagnosed breast cancer, relatively lower BI-RADS category on underestimated breast cancer was noted and margin and orientation of lesion showed significantly different values between two groups.

Key words : breast cancer, underestimation, core needle biopsy

# US-guided 14-gauge Core Needle Biopsy: Comparsion between Underestimated and Accurately Diagnosed Breast Cancer

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## I. INTRODUCTION

Since the early 1990s, percutaneous image-guided core needle biopsy (CNB) has been a widely used technique for evaluating breast abnormalities as a less invasive and inexpensive modality.[1] This technique is now accepted as a reliable and accurate tool to diagnosis of both benign and malignant diseases of the breast.[2-4] However, the CNB finding of atypical ductal hyperplasia (ADH) is less reliable owing to histologic underestimation of malignancy, that is, upgrade of the result to ductal carcinoma in situ (DCIS) or invasive ductal carcinoma (IDC) at surgical excision. The rate of underestimation of ADH has been reported to be 11–75% for 14-gauge (14G) CNB.[5,6] Therefore, there seems to be a consensus on the need for surgical excision when ADH is diagnosed at CNB.[7] And DCIS underestimation occurs when a lesion yields DCIS at percutaneous breast needle biopsy and IDC at surgery.[8] DCIS underestimation is probably due to sampling error in a lesion that contains both DCIS and IDC. Previous reports have suggested underestimation rates ranging from 11% to 75% for ADH and the underestimation rates of DCIS were from 15% to 35% by using various CNB methods.[4,9-14] There were several studies about correlation

with underestimation rate and clinical condition or radiologic findings such as US or mammogram finding. And there were only few reports about the comparisons between the underestimated breast cancer and accurately diagnosed breast cancer in 11-gauge vacuum assisted biopsy.[15] So when pathologic result revealed breast cancer with Ultrasound (US) -guided 14G CNB, our investigation was undertaken to compare the clinical and radiologic features between the underestimated breast cancer and accurately diagnosed breast cancer.

The purpose of our study was to determine the rate of underestimation of US-guided 14G CNB, to reveal the US and mammographic features of breast cancer which was underestimated on US-guided CNB, and to compare clinical and radiologic findings between underestimated breast cancer and accurately diagnosed breast cancer.

## II. MATERIALS AND METHODS

### 1. Study Population

Our institutional review board approved this retrospective observational study, and informed consent was not required from patients. Informed consent for all percutaneous biopsy procedures was obtained from all patients prior to biopsy. Between January 2007 and December 2009, percutaneous US-guided 14G CNB was performed on 1898 consecutive breast lesions at our institution. Among them, 248 cases were proved to be breast cancer. So we categorized as underestimated breast cancer including indication of cases about CNB proven ADH and CNB proven DCIS with final diagnosed IDC and accurately breast diagnosed cancer including with CNB proven IDC and CNB proven DCIS with final diagnosed also DCIS.

US were available in all patients with US guided CNB and Mammograms of 12 of the 18 patients in underestimated breast cancer group and 149 of the 186

patients in accurately diagnosed breast cancer group were available.

2. Imaging and Biopsy Technique

Breast US was performed with high resolution US unit with 7.5 or 12-MHz linear array transducers (ATL HDI 5000 or IU-22, Philips-Advanced Technology Laboratories, Bothell, WA, USA). The mammography was done with GE Senographe 2000D (GE Medical Systems, Milwaukee, WI, USA). US-guided CNBs were performed using a free-hand technique with a 14G semi-automated CNB (Stericut, TSK, Japan). US and biopsies were performed by one of three radiologists with fellowship training (n=1) or experienced radiologist in breast imaging and biopsy (n=2, each were 10 and 6 years of experiences). According to our standard protocol, five or six core samples were obtained, and the appearance of the formalin-fixed core samples were examined during the procedure to confirm that the targeted lesion was sampled adequately. Prior to biopsy, mammographic and US findings were categorized according to BI-RADS, and the data were entered into a database using a computerized spreadsheet (Excel, Microsoft, Redmond, WA). The CNB results were divided into malignant, high-risk, and benign according to the pathologic report. We recommended definitive treatment for malignant lesions and advised surgical excision for high-risk lesions.

3. Imaging Review and Analysis

After review of the surgical and CNB histologic findings, we categorized as accurately diagnosed breast cancer or underestimated breast cancer and the rate of underestimation was assessed. For each lesion, medical records, image findings of mammograms and US also were reviewed, and clinical and radiologic variables were coded.

The collected clinical variables were as follows: age, personal history of breast cancer, and associated symptoms. For collection of radiologic variables, each

image was reviewed retrospectively by two radiologists (H.N.K and E.J.S) with consensus. The following US features were determined according to the terminology of the American College of Radiology BI-RADS lexicon[16]: size, location, shape, orientation, depth, margin, echogenicity, calcification and multiplicity. Mammographic visibility of the lesion pattern (focal asymmetry, asymmetry and mass) and lesion type (mass shape, margin, density and calcification shape and distribution) were evaluated. The prospectively assigned mammographic and US BI-RADS categories were documented. We have subclassified category 4 into categories 4a, 4b, and 4c.

4. Data Analysis

Retrospectively, pathologic results on CNB were breast cancer or high-risk lesions or benign lesions. Among the CNB proven high-risk lesions, pathologic results were categorized ADH and other high-risk. CNB proven breast cancer were divided IDC and DCIS cases. So we categorized as underestimated breast cancer including indication of cases about CNB proven ADH and CNB proven DCIS with final diagnosed IDC and accurately breast diagnosed cancer including with CNB proven IDC and CNB proven DCIS with final diagnosed also DCIS.

The underestimated and the accurately diagnosed breast cancer were compared in terms of mammographic and US features, the size of lesion (as measured on the longest sonographic diameter), and tumor location and patient's age, symptom and history. Data were analyzed using the Chi-square test for nonparametric variables and the t-test for parametric variables. Statistical significance was indicated by a *p*-value less than 0.05. All data was processed with commercially available software using the SYSTAT, version 5.2, statistical package (Systat, Evanston, IL).

## III. RESULTS

Retrospectively, pathologic results on CNB were breast cancer in 197 cases, high-risk lesions in 22 cases, and benign in 29 cases (which were false negative results were excluded in this study). Among the CNB proven high-risk lesions, pathologic result revealed ADH (n=7) and other high-risk lesions (such as papillary lesion with atypia or phyllodes tumor or lobular neoplasm, which were potentially malignant lesion, but also debates for aspect of definition of underestimated cancer and also excluded on this study, n=15). Among the CNB proven breast cancer, IDC (n=157) and DCIS (n=40) were reported. Surgically pathologic results of All CNB proven DCIS cases were IDC (n=11) and DCIS, itself (n=29). So we included indication of cases about CNB proven ADH (n=7), CNB proven DCIS (n=40) or IDC (n=157) and categorized as underestimated breast cancer including 7 cases with CNB proved ADH and 11 cases with CNB proven DCIS with final diagnosed IDC or DCIS (total n=18) and accurately breast diagnosed cancer including 157 cases with CNB proven IDC and 29 cases with CNB proven DCIS with final diagnosed also DCIS (total n=186) (Fig. 1).

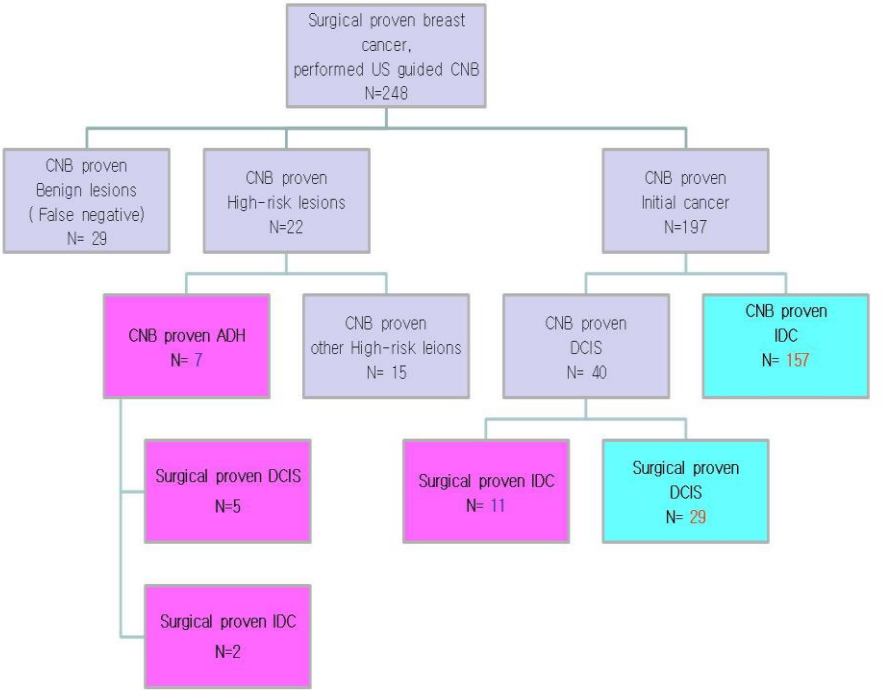


**Figure 1**. Pathologic results of US-guided 14-gauge core needle biopsy

Of 248 cases of cancer, underestimation occurred in 18 lesions at percutaneous US-guided 14G CNB (7.2%). Our study showed that ADH underestimation rate and DCIS underestimation rate of 53.8% (7 of 13 lesions) and 27.5% (11 of 40 lesions). Among the 18 underestimated breast cancer, the CNB results were ADH (n=7) and DCIS (n=11) which were breast cancer and upgrade to IDC in final pathology.

The analysis of clinical variables is summarized in Table 1.

**Table 1.** Comparision of underestimated and accurately diagnosed breast cancer : clinical variables

| Variable | Underestimated breast cacner (n=18) | Accurately diagnosed breast cancer (n=186) | p-value |
|---|---|---|---|
| **Age** | | | 0.53 |
| 30-50 | 11 | 103 | |
| 51-70 | 7 | 83 | |
| **Past history** | | | 0.57 |
| No | 15 | 169 | |
| Breast cancer | 1 | 10 | |
| Benign breast mass | 2 | 7 | |
| **Associated symptom** | | | 0.31 |
| Palpable | 10 | 95 | |
| Nipple discharge | 3 | 6 | |
| Pain | 1 | 13 | |
| No | 4 | 68 | |
| Axillary mass | 0 | 4 | |

The mean age of the patients was 46.1 ± 14.5 years (range, 21–77 years), 50.6 years for patients with underestimated breast cancer and 49.1 years for those with accurately diagnosed breast cancer ($p$ =0.53). One patient (6%) among the underestimated cancer group and 10 patients (5%) among the accurately diagnosed breast cancer group had a personal history of cancer of the contralateral breast (p= 0.57).

In terms of associated symptoms, there was no statistically significant differences were found in between underestimated and accurately diagnosed group.

The analysis of mammographic findings is summarized in Table 2.

**Table 2.** Comparison of underestimated and accurately diagnosed breast cancer: mammographic findings

| Variable | | Underestimated Breast cancer (n=12) | Accurately diagnosed breast cancer (n=149) | p-value |
|---|---|---|---|---|
| **Category** | | | | 0.01 |
| **0/1/2/3** | | 4/1/0/1 | 22/0/0/0 | |
| **4a/b/c** | | 0/2/0 | 0/15/17 | |
| **5** | | 4 | 95 | |
| **Focal asymmetry** | | 2 | 15 | 0.72 |
| **Asymmetry** | | 0 | 1 | |
| **Mass** | | 6 | 126 | |
| **Shape** | Round | 3 | 21 | 0.55 |
| | Oval | 0 | 2 | |
| | Lobular | 0 | 7 | |
| | Irregular | 3 | 96 | |
| **Margin** | Circumscribed | 1 | 7 | 0.01 |
| | Microlobulated | 2 | 5 | |
| | Obscured | 1 | 3 | |
| | Lobular | 0 | 19 | |
| | Indistinct | 0 | 0 | |
| | Spiculated | 2 | 92 | |
| **Density** | High | 6 | 124 | 0.33 |
| | Iso | 0 | 2 | |
| | Low | 0 | 0 | |
| **Calcification** | Yes | 7 | 67 | 0.36 |
| | No | 5 | 82 | |
| **Shape** | Pleomorphic | 6 | 65 | 0.16 |
| | Amorphous | 1 | 2 | |
| **Distribution** | Clustered | 3 | 51 | 0.13 |
| | Linear | 0 | 0 | |
| | Segmental | 3 | 16 | |
| | Diffuse | 1 | 0 | |

Mammograms of 12 of the 18 patients in underestimated breast cancer group and 149 of the 186 patients in accurately diagnosed breast cancer group were available. All lesions were classified as BI-RADS category. Relatively high

BI-RADS categories was noted in accurately diagnosed breast cancer (for example, category 5 in underestimated breast cancer, 33.3%, and in accurately diagnosed breast cancer, 63.7% on mammogram) (p=0.01). Margin of mass on mammography revealed statistically significant difference between two groups (p=0.01). Underestimation rate for microlobulated and obscured margin were in 28.5 % (2/7) and 25% (1/4) on mammogram (p=0.01). There was no statistically significant difference in asymmetricity, shape and density of mass, presence of calcifications, shape and distribution of calcifications in between underestimation and accurately diagnosed group. Our result also showed that the underestimation rate for calcifications was 9.4 % (7/74) on mammogram without statistically significant difference between two groups (p=0.36).

Table 3 summarizes the US features of all lesions according to BI-RADS descriptions.

**Table 3.** Comparison of underestimated and accurately diagnosed breast cancer: US findings

| Variable | | Underestimated Breast cancer (n=18) | Accurately diagnosed breast cancer (n=186) | p-value |
|---|---|---|---|---|
| **Category** | | | | 0.01 |
| **4a/b/c** | | 7/8/1 | 12/19/25 | |
| **5** | | 2 | 130 | |
| **6** | | 0 | 0 | |
| **Size** | <10 | 4 | 24 | 0.49 |
| | ≥10 | 14 | 162 | |
| **Location** | Right | 11 | 88 | 0.46 |
| | Left | 7 | 98 | |
| **Shape** | Oval | 2 | 21 | 0.35 |
| | Round | 4 | 29 | |
| | Irregular | 12 | 136 | |
| **Orientation** | Parallel | 15 | 71 | 0.01 |
| | Non-parallel | 3 | 115 | |
| **Depth** | Superficial | 5 | 19 | 0.43 |
| | Mid | 12 | 145 | |
| | Deep | 1 | 22 | |
| **Margin** | Circumscribed | 2 | 14 | 0.01 |
| | Indistinct | 5 | 9 | |
| | Angular | 3 | 0 | |
| | Microlobulated | 8 | 51 | |
| | Spiculated | 0 | 112 | |
| **Echogenicity** | Anechoic | 0 | 0 | 0.67 |
| | Hyperechoic | 0 | 8 | |
| | Complex | 1 | 19 | |
| | Hypoechoic | 11 | 158 | |
| | Isoechoic | 6 | 1 | |
| **Calcification** | No | 13 | 151 | 0.93 |
| | Micocalcification | 3 | 35 | |
| | Macrocalcification | 2 | 0 | |
| **Multiplicity** | No | 8 | 137 | 0.52 |
| | Yes | 10 | 49 | |

The mean diameter of the lesions measured at sonography was 31.9 ± 9.2 mm (range, 5–100 mm), 37.5 mm for underestimated breast cancer and 20.0 mm for accurately diagnosed breast cancer. Larger than 10mm lesions were 77.7% in underestimaged breast cancer and 87% in accurately diagnosed breast cancer ($p < .05$). Relatively high BI-RADS categories was revealed in accurately diagnosed breast cancer (for example, category 5 in underestimated breast cancer, 11.1% and in accurately diagnosed breast cancer, 69.8% on US) ($p=0.01$). Margin and orientation of mass on US and revealed statistically significant difference between two groups ($p=0.01$). In underestimated breast cancer, fifteen of the all lesions (83%) showed parallel orientation and two circumscribed lesions and sixteen cases show not circumscribed lesions (5 indistinct, 3 angular, 8 microlobulated and no spiculated). Underestimation rate for microlobulated and obscured margin were in 13.5% (8/59) and 35.7% (5/14) on US ($p=0.01$).There was no statistically significant difference in location and depth of the lesions and shape, echogenicity, combined calcifications and multiplicity on sonography in between underestimation and accurately diagnosed group. Our result also showed that the underestimation rate for calcifications was 12.5% (5/40) on US without statistically significant difference between two groups ($p=0.36$).

## IV. DISCUSSION

For the diagnosis of breast masses visible with sonography, US guided 14G CNB is often the procedure of choice because of its reliability and advantages over stereotactic biopsy and surgical biopsy.[17-19] Underestimation at CNB often results in the need for additional surgery. Histologically, underestimation of ADH can be explained by the inherent ambiguity of ADH. ADH has been variably defined as a lesion that has some but not all of the cytologic features of DCIS and as a lesion that has all of the cytologic features of DCIS but lacks the

extent of involvement required to meet the strict criteria for DCIS.[6] Other investigators have found rates of underestimation ranging from from 0% to 75% for ADH and 0-50% for DCIS (Table 4).

**Table4.** Comparison of investigations of large-core needle biopsy in underestimation of atypical ductal hyperplasia or ductal carcinoma in situ

| Researchers | Underestimation of ADH (%) | Researchers | Underestimation of DCIS (%) |
|---|---|---|---|
| Stereotactic, 14-gauge automated large-core needle biopsy | | | |
| Meyer et al. [4] | 56 | Won et al. [12] | 35 |
| Philopotts et al. [20] | 20 | Jackman et al. [21] | 15 |
| Jackman et al. [21] | 58 | Liberman et al. [27] | 33 |
| Lin et al. [22] | 11 | Burbank [31] | 16 |
| Stolier [23] | 37.5 | Meyer et al. [9] | 50 |
| Jackman et al. [24] | 48 | Liberman et al. [34] | 20 |
| Moore et al. [25] | 33 | Jackman et al. [10] | 19 |
| Gadzala et al. [26] | 47 | | |
| Liberman et al. [27] | 75 | | |
| US-guided, 14-gauge automated large-core needle biopsy | | | |
| Darling et al. [6] | 50 | Londero et al. [35] | 41.5 |
| Mainiero et al.[28] | 33 | Lee et al. [36] | 42 |
| Crystal et al. [29] | 33 | King et al.[37]* | 26 |
| Cho et al. [30] | 58 | Dillon et al. [38]* | 42 |
| Stereotactic, 14-gauge directional vacuum-assisted large-core needle biopsy | | | |
| Meyer et al. [4] | 38 | Burbank [31] | 0 |
| Stolier at al. [23] | 37.5 | | |
| Jackman et al. [24] | 18 | | |
| Burbank [31] | 0 | | |
| Stereotactic, 11-gauge directional vacuum-assisted large-core needle biopsy | | | |
| Brem et al. [32] | 25 | Won et al. [12] | 15 |
| Meyer et al. [4] | 11 | Meyer et al. [4] | 4 |
| Philopotts et al. [20] | 26.7 | Liberman et al. [33] | 5 |
| Liberman et al. [33] | 10 | Liberman et al. [39] | 0 |

*Biopsy methods of these studied were US-guided or stereotactic 14-gauge automated large-core needle biopsy.

*ADH= atypical ductal hyperplasia, DCIS= ductal carcinoma in situ

The rate of underestimation of ADH has been reported to be 33-62 % for US guided 14G CNB.[6,28-30] And previously reported underestimations range from 26 to 42% for DCIS diagnosed using US guided 14G automated CNB.[38-41] These findings show similar results in our study with ADH underestimation rate of 53.8% (7 of 13 lesions) and DCIS underestimation rate of 40.7% (11 of 27 lesions ). Our results showed no significant difference in the sizes, clinical variables such as patient's age, past history and associated symptom between the underestimated and accurately diagnosed breast cancer. So underestimation rate using US-guided CNB is not related with clinical condition.

One report showed that almost all (93%) underestimated cases were those presenting mammographically as calcifications. Of ADH lesions that proved to be carcinoma at excision[15], Liberman et al.[40] also found a significantly higher percentage of calcifications than masses. But our study suggested that the underestimation rate for calcifications were 9.4 % (7/74) on mammogram and 12.5% (5/40) on US without statistically significant difference between two groups (p=0.36), even though we performed US-guided CNB and excluded only calcification lesions without mass on this study.

Margin of mass and orientation revealed statistically significant difference in comparison between underestimated and accurately diagnosed breast cancer. For example, underestimation rate for microlobulated, obscured margin were in 28.5 % (2/7), 25% (1/4) on mammogram (p=0.01) and in 13.5% (8/59), 35.7% (5/14) on US (p=0.01). More interesting point was underestimation rate for parallel mass was in 17.4% (15/86) and non-parallel mass was in 2.5% (3/115) on US. These radiologic findings affect results of BI-RADS category in two groups. Relatively lower BI-RADS category on underestimated breast cancer, compared with correctly diagnosed breast cancer. It means relatively low suspicious finding on US and mammogram affected pathologic finding of

inherent ambiguity of ADH or DCIS which is lack of stromal invasion area.[6]

Our study had several limitations. First, this analysis was limited by the small number of patients in underestimated breast cancer. Second, the retrospective nature of the analysis was could be limitation in this study. Third, other borderline or high risk lesions such as papillary lesion with atypia or phyllodes tumor or lobular neoplasm were excluded at underestimated breast cancer group without any explanation or definite evidence. These entities should be considered further investigation. Finally, there might have been selection bias because only surgically excised lesions were included.

## V. CONCLUSION

We concluded that the underestimation rate of US-guided 14G CNB was 7.2%. Relatively lower BI-RADS category on underestimated breast cancer, compared with accurately diagnosed breast cancer was noted and margin of mass and orientation revealed statistically significant difference in comparison between underestimated breast cancer and accurately diagnosed breast cancer.

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ABSTRACT(IN KOREAN)

# 초음파 유도 하 14 게이지 중심부바늘생검으로 진단된 과소평가된 유방암과 정확히 진단된 유방암의 비교와 고찰

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## Ⅰ. 서론

영상유도하의 조직생검은 광범위하게 사용되는 유용한 방법이다. 하지만 과소평가되는 병변의 여부가 여전히 문제가 되고 있다. 본 연구의 목적은 초음파 유도 하 14 게이지 중심부바늘생검을 통해 과소평가된 유방암의 사례의 영상학적 소견을 분석해보고, 임상적으로 또는 영상의학적 측면에서 과소평가된 유방암과 정확히 진단된 유방암을 비교 연구하여 과소평가되는 유방암의 예측하고자 한다

## Ⅱ. 재료 및 방법

2007년도 3월부터 2009년도 12월까지 총 1898개의 초음파 유도 하 14 게이지 중심부바늘생검술을 시행하였다. 그 중에 생검술후에 514 개의 병변이 수술을 시행하였다. 그 중, 248 개 병변이 수술로 유방암으로 진단되었다. 중심부바늘생검술에 의한 결과는 암으로 이거나 고위험병변 또는 양성병변 으로 나누었다. 그래서, 임상적 또는 초음파 와 유방촬영술에서 보이는 영상의학적 소견을 통해 과소평가된 유방암과 정확히 진단된 유방암을 비교 평가하였다.

## III. 결과

중심부바늘생검술로 진단된 248개의 유방암중에, 18개가 과소평가되었다(7.2%). 18개의 과소평가된 유방암중에, 7개의 비정형적 유관 증식증과 11개의 관내상피암이 수술로 5개의 관내상피암과 13개의 침윤성 유방암으로 확진되었다. 186개의 정확히 진단된 유방암중에는, 29개의 관내상피암과 157개의 침윤성 유방암으로 진단되었다. 과소평가된 유방암 그룹과 정확히 진단된 유방암을 비교해보았을때, 환자의 과거력, 나이 와 동반된 증상에서는 통계학적으로 유의한 차이를 보이지 않았다. 하지만 Breast Imaging Reporting and Data system (BI-RADS) 분류, 초음파 와 유방촬영술에서 보이는 병변의 경계와 초음파 상 보이는 병변의 방향성이 통계학적으로 유의한 차이를 보였다 ($p<0.05$)

## IV.결론

초음파 유도 하 14 게이지 중심부바늘생검술에 의한 과소평가률은 7.2%로 보고되었다. 과소평가된 유방암과 정확히 진단된 유방암을 비교 평가하였을때, Breast Imaging Reporting and Data system (BI-RADS) 분류, 초음파 와 유방촬영술에서 보이는 병변의 경계와

초음파 상 보이는 병변의 방향성이 통계학적으로 유의한 차이를 보였다.

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핵심되는 말: 유방암, 과소평가, 중심부바늘생검