

# Assessment of the accordance between sonography and mammography reports with pathology report based on sonographic guided core needle biopsy in diagnosis of breast masses

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**Background:** Screening programs for the early diagnosis of breast cancer lead to perform several biopsies in order to determine the breast abnormalities found in sonography and mammography. According to gradually replacement of core needle biopsy instead of more invasive methods like open surgical biopsy, it seems necessary to study the concordance between biopsy results and non-invasive diagnostic methods in order to clarify ambiguous results and confirm the reliability of non-invasive methods.

**Objective:** The objective of this study was to match the sonography and mammography reports with core needle biopsy in patients referred to Sahand core needle biopsy center.

**Materials and methods:** This prospective cross-sectional study was performed on 240 patients referred to Sahand Center with sonography or mammography reports or by a surgeon for core needle biopsy. All the patients were examined by a gynecologist assistant and were asked about demographic information and their recent diseases. The matched sonography or mammography cases with pathology reports and positive predictive value based on comparison between them and pathology report were determined as standard diagnostic criteria. Then, data were statistically analyzed by SPSS v.21 software.

**Results:** In this study, there was no statistically significant difference between sonography or mammography and pathology reports for categorizing patients in two distinct malignant and benign groups ( $p > 0.05$ ). There was also no difference observed in two age groups ( $p > 0.05$ ). In both sonography and mammography groups, the sensitivity and specificity were 60.32% and 92.96%, respectively. Moreover, the positive and negative predictive values of sonography and mammography were the same in both methods and were 70.37% and 86.56%, respectively.

**Conclusion:** According to the significant concordance between sonography and mammography with core needle biopsy, these non-invasive methods can be helpful in diagnosing malignant lesions and differentiating them from benign lesions; they are also affordable and available. The attention to underlying variables such as age, can improve sensitivity and specificity of non-invasive methods in comparison to invasive diagnostic methods.g.

**Keywords:** Breast cancer, Sonography, Mammography, Core needle biopsy

*Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.*

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## Introduction

Breast cancer is one of the most common malignancies of women in all over the world and in Iran <sup>[1]</sup>. According to the Iran cancer center reports in 2009, there were 7582 cases with breast cancer which 51% of them were diagnosed before 50 years old <sup>[2]</sup>. Khadivi et al. reported the age of breast cancer incidence in Iran 10 years lower than western countries <sup>[3]</sup>. Based on Harirchi et al. report, compared to other countries, there is a high frequency of cancer diagnosis of advanced levels in Iran <sup>[4]</sup>.

Breast cancer is one of the most important and vital cancers leads to mortality in women. Early diagnosis leads to improvement in treatment and survival <sup>[5]</sup>. One of the most important factors in survival is the stage in which cancer is diagnosed. Moreover, tumor

size, its extension and existence of lymphadenopathy while diagnosis, have a significant effect on selecting the type of surgery and additional treatment. Considering that most of the breast lesions are benign and in consequence most of benign breast lesions have no risks of malignancy, it is in high importance to assess the lesions carefully before the surgery [6].

It is necessary to be able to diagnose the cancer in primary stages and before metastasis begins [7]. The gold standard method of diagnosis is pathologic assessment but it is invasive and a physician prefers to perform non-invasive techniques in primary stages. Therefore, there is always tends to improve diagnostic methods of breast cancer which can help patients in early diagnosis and early treatment by using medical imaging techniques. There is no screening method with 100% sensitivity and specificity and there is always a gap between these two in all screening methods. It means that, there would be a decrease in specificity whenever the sensitivity is high [8]. Thus, physicians are interested in non-invasive methods for diagnosis, among which sonography and mammography, commonly used imaging techniques in gynecology, can help a physician diagnose and treat breast lesions [9]. Recommendation of breast imaging depends on several factors including, age, history of breast feeding, parity, breast problems, symptoms and examination findings [10].

Mammography, one of the most common non-invasive methods in breast assessment, has a diagnostic value in both screening and discovering new cases of the disease. It is also noteworthy that mammography has a low resolution in women younger than 30 years old due to a dense stroma and epithelium. The adipose tissue absorbs low levels of ultrasound and leads to a better contrast of lesions in elder patients [11]. Thus, other non-invasive method in breast assessment, especially in dense breasts, is sonography. Sonography is also valuable in assessment of doubtful mammography results [9,12].

It is noted that sonography is safer than mammography. The sensitivity of sonography is higher than mammography according to the age groups. However, specificity of mammography is higher in women older than 50 years old. Considering the breast density, sonography has more sensitivity and mammography has more specificity. About 20% of undiagnosed breast cancer with mammography is diagnosed with sonography [13,14].

There are few studies about assessment of less invasive methods of breast cancer diagnosis. Yumjal et al. study, comparing sonography with FNAC in diagnosis of breast malignancy, showed that FNAC has 100% specificity in diagnosis of breast malignancies otherwise sonography seems to be more sensitive than FNAC [15]. However, these methods necessitate the assessment and systemic studies in order to determine their diagnostic value according to the current medical status in the country. In fact, mammography screening programs, for early diagnosis of breast cancer, lead to perform several biopsies in order to determine breast abnormalities found in sonography or mammography. According to gradually replacement of core needle biopsy instead of more invasive methods like open surgical biopsy, it seems necessary to assess the concordance between biopsy results and non-invasive diagnostic methods in order to clarify ambiguous results, replace these non-invasive methods and confirm the reliability of these methods [16]. Thus, the aim of this study was to investigate the reliability of sonography and mammography reports compared to core needle biopsy reports in patients referred to Sahand core needle biopsy center and suggest a suitable non-invasive method for diagnosis of breast lesions.

## Materials and Methods

### Studied population

This cross sectional descriptive study was approved by Guilan University of medical sciences Ethics Committee (code: IR.GUMS.REC.1394.297) and performed on 240 patients referred to Sahand radiology center for core needle biopsy.

### Data collection

Patient's demographic information (age, BMI, marital status) and their data of disease (nipple discharge, mass sensibility, mastalgia, location of mass, side of involvement, sonography status, mammographic status and pathology report) were recorded. Then, biopsy procedure was performed using a whole-automatic BARD 14 gauge toggled needle. After that, obtained samples were sent for pathologic evaluation, then patients were followed up for pathology, sonography and mammography results which performed afterwards.

The sonography and mammography results were divided into 2 groups: The first group with high probability of benignity composed of BIRADS 3, 4<sub>A</sub>, 4<sub>B</sub> and the second group with high probability of malignancy composed of BIRADS 4<sub>C</sub>, 5, 6. Pathology results were divided into a benign group (B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub>) and a malignant group (B<sub>4</sub>, B<sub>5</sub>).

### Statistical analysis

After completing the check list, in order to assess the presence or absence of a significant difference between sonography and mammography results with pathology reports (as null hypothesis), McNemar statistical test by SPSS version 21 software was used. P-value less than 0.05 was considered as significant. McNemar's test investigates paired-samples with dichotomous variables (which were the results of sonography with pathology and mammography with pathology in this study). Moreover, sensitivity, specificity, positive predictive value and negative predictive value of sonography and mammography were determined regarding their pathology result as a diagnostic standard.

For calculating the sensitivity, specificity, positive and negative predictive values, pathology results used as a gold standard. Sensitivity defined as cases diagnosed malignant by both sonography and pathology results divided by overall cases diagnosed malignant by both methods in addition to cases diagnosed benign by sonography but malignant by pathology and the resultant multiplied by a hundred. Specificity defined as cases diagnosed benign by both sonography and pathology results divided by overall cases diagnosed benign by both methods in addition to cases diagnosed malignant by sonography but benign by pathology and the resultant multiplied by a hundred. Positive predictive value defined as cases diagnosed malignant by both sonography and pathology results divided by overall cases diagnosed malignant by sonography and multiplied by a hundred. Negative predictive value defined as "cases diagnosed benign by both sonography and pathology results divided by overall cases diagnosed benign by sonography and multiplied by a hundred". Same methods used for calculating sensitivity, specificity, positive and negative predictive values for mammography.

## Results

Demographic information of all 240 participants is listed in Table 1. No history of breast cancer was noted in patients. Sonography

and mammography results were completely in concordance with each other. The frequency distributions of breast disorders are noted in Table 2.

Table 3 demonstrates the complete concordance, but not significant differences, between sonography and mammography with pathology results ( $p>0.05$ ). Specificity of both sonography and mammography in malignant breast masses detection was 90.57%. Sensitivity, positive and negative predictive values, according to two age ranges ( $\leq 30$  and  $>30$  years old) in all patients, are listed in Table 4.

**Table 1**  
Distribution of patient's demographic variables.

Demographic item		Value (percentages)
Age	$\leq 30$ year	18 (7.5)
	$> 30$ year	222(92.5)
Marriage status	Single- widow- Divorced	46 (19.2)
	Married	194 (80.8)
BMI	$\leq 30$	156 (65)
	$> 30$	(53) 48
Oligomenorrhea	Yes	16 (6.7)
	No	224 (93.3)
Family history of breast cancer	Yes	24 (10)
	No	216 (90)
Family history of other cancers	Yes	59 (24.6)
	No	181 (75.4)
History of other cancers	Yes	3 (1.3)
	No	237 (98.7)
Smoking	Yes	10 (4.2)
	No	230 (95.8)
Alcohol consumption	Yes	2 (0.8)
	No	238 (99.2)
Fertility	Menopause	53 (22.1)
	Fertile	187 (77.9)

**Table 2**  
The frequency of breast disorders

Item	Value (percentages)
A history of breast trauma (yes)	7 (2.9)
Nipple discharge (yes)	26 (10.8)
Sensible breast mass (yes)	90 (37.5)
Mastalgia (yes)	82 (34.2)
Breast deformity (yes)	20 (8.3)
<b>Mass Side of Involvement</b>	
Right	147 (61.3)
Left	93 (38.8)
<b>Sonography Results</b>	
Benign (BIRADS 3, 4A, 4B)	186 (77.5)
Malignant (BIRADS 4C, 5, 6)	54 (22.5)
<b>Mammography Result</b>	
Benign (BIRADS 3, 4A, 4B)	186 (77.5)
Malignant (BIRADS 4C, 5, 6)	54 (22.5)
<b>Biopsy results</b>	
Benign (B1,B2,B3)	177 (73.8)
Malignant (B4,B5)	63 (26.3)

**Table 3**  
Comparing Sonography and mammography with pathology in categorizing patients with breast mass.

Sonography and mammography		Pathology		p-value
		Strongly suggestive of benign	Strongly suggestive malignancy	
All patients	Highly malignant	16 (6.67)	38 (15.83)	0.212
	Highly benign	161 (67.08)	25 (10.42)	
Age $\leq 30$ year	Highly malignant	1 (5.55)	0	0.999
	Highly benign	17 (94.45)	0	
Age $>30$ year	Highly malignant	15 (6.76)	38 (17.12)	0.155
	Highly benign	144 (64.86)	25 (11.26)	

**Table 4**  
Sensitivity, positive and negative predictive values according to age range ( $<30$  &  $>30$  years old).

	Sensitivity	Specificity	*P.P.V	**N.P.V
All patients	60.32%	92.96%	70.37%	86.56%
Age $\leq 30$ year	-	94.45%	0	100%
Age $> 30$ year	60.32%	90.57%	71.70%	85.21%
*Positive predictive value				
**Negative predictive value				

## Discussion

Non-invasive methods are most noticeable methods in diagnosis of breast masses. Applying these methods into clinical routines are challengeable due to their different sensitivities and specificities noted in several studies [17,18]. These differences are so important, specially sonography, and mammography which has high sensitivity (55%-90%) in diagnosing malignant breast tumors, because they are dependent on radiologists' ability [19,20].

In our study, there was no significant difference between sonography, mammography and pathology reports in categorizing patients in two malignant and benign groups. Significant difference was observed in each age groups. The results, represents coordination between two radiologic and biopsy diagnostic methods in categorizing the patients. It is necessary to pay attention to sample size in order to determine statistical differences. Larger sample size leads to higher diagnosis, even with negligible differences. Also, in terms of BMI, smoking, previous medical history and familial history of breast cancer or other cancers, categorized in low risk group.

As stated above, there was no statistical difference between invasive and non- invasive methods in categorizing patients. In our study, sonography and mammography sensitivity and specificity were 60.32% and 92.96%, respectively. Moreover, positive and negative predictive value of both imaging methods were 70.37% and 86.56%, respectively. According to the positive predictive value of more than 70% and negative predictive value of more than 85%, the results of non-invasive methods (sonography and mammography) can be clinically reliable. Also, in addition to sonography and mammography results, other characteristics should be considered in order to decide clinically. Although, in comparison with more than 30 years old group, higher sonography specificity observed in less than 30 years old group which is not reliable due to small sample size.

In this study, most of the patients were more than 30 years old and just 7.5% of patients were less than 30 years old. Patients were analyzed statistically based on their age groups separately, in order to achieve a suitable interpretation of obtained data. It is noteworthy that none of less than 30 years old patients had a malignant lesion in pathologic sample while malignancy is reported in one case of sonography and one case of mammography. Thus, according to our study, the usage of these tests is not very practical due to low malignancy rates in less than 30 years old group. However, small sample size in this age group would be a challenge in decision of this case. In assessment of more than 30 years old patients, the sensitivity and specificity of sonography and mammography were 60.32% and 90.57%, respectively. The sensitivity was in concordance with previous studies while specificity differs from those studies [11,17-20].

This difference can be due to participants' age and sample size. The specificity of sonography and mammography as non-invasive radiological diagnostic tools was 45% in Akbari et al. [21] study. In Haghighatkhah et al. [22] study the specificity of sonography and mammography were 55.3 and 50.7, respectively, that was different from our study. In the study of Akbari et al. [21], patients younger than 30 years old were excluded and the others were divided into two groups; younger and older than 50 years old. Their findings showed an increase in the level of specificity in mammography from 48% in <50 years old group to 67% in >50 years old group. In Haghighatkhah et al. study, there was a statistically significant difference between sensitivity and specificity with age [22]. Moreover, in Sirus et al. [11] study in Isfahan, the specificity was 97% for sonography and 98% for mammography which were in concordance with our findings. All the patients were older than 32 years old in Sirus et al. study.

We should note that in applying a diagnostic test of malignant lesions, it is better to have a high and acceptable level of sensitivity while the obtained sensitivity for sonography and mammography was 60% in our study which was not so high. In the other words, these two tests reported 40% of malignancies as benign lesions; this can delay the diagnosis of malignant lesions and ultimately cause complications in treatment. It was also noted in other studies and applying precise non-invasive methods were recommended [23,24]. Nowadays, sonography and mammography is yet of the best and most important screening tests in diagnosis of benign and malignant breast lesions due to their availability and affordability in comparison with invasive methods such as needle biopsy or core biopsy.

In the similar study conducted by Haghighatkhah et al. [22], non-invasive radiological diagnostic reports (sonography and mammography) were compared with pathologic reports of invasive methods (needle biopsy and surgery), indicating the suitable sensitivity and specificity of non-invasive diagnostic methods in concordance with our study. In another similar study, performed by Naghizadeh et al. [23], non-invasive imaging methods as an effective effort besides precise physical examination were recommended for patients with breast pain. The diagnostic value of these non-invasive imaging assessments was so high that negative sonography and mammographic results were so reliable and there was no need for invasive interventions such as needle biopsy. High sonography and mammography specificity in our study verify their result.

Suitable sensitivity and specificity of non-invasive diagnostic imaging methods in Sirous et al. [11] study were assessed in comparison with invasive diagnostic method of FNA that were in concordance

with our study. The researchers recommended these methods as non-invasive diagnostic tools in breast masses screening. Farokh et al. [24] demonstrated that radiologic non-invasive diagnostic methods (sonography and mammography) can be valuable even in diagnosis the volume and size of breast lesions similar to invasive methods.

Considering patient's age as an underlying variable in assessment the results of non-invasive diagnostic tools, was noteworthy in our study. In this study, 30 years of age in considered as cut off point, where 50 years of age was set as cut-off point in several studies [21]. According to the results, it seems that considering the age of individuals referring to sonography and mammography, can be a suitable guide in reliance of physicians to sonography and mammography results. In an extent that the higher age yields the higher reliance. Moreover, in several studies, other factors such as BMI and tumor size were also took into account because large tumors may decrease the accuracy of non-invasive tools in diagnosis of malignant lesions [24].

According to the results, applying sonography and mammography as non-invasive tests can be helpful in diagnosis of malignant lesions and differentiation of benign lesions. Considering underlying variables such as age, may improve and increase the sensitivity and specificity of non-invasive methods in comparison with invasive diagnostic methods.

According to the significant concordance between core needle biopsy with sonography and mammography these non-invasive methods can have an important role in diagnosis of breast lesions as an affordable, easy and available method. So, these methods can lead to a suitable approach to breast lesions, even though the value of these results was higher in more than 30 years old group and according to the sample size of less than 30 years old group, the obtained results cannot be utilized in the group of patients with less than 30 years of age.

## Conclusion

It is important that other factors including epidemiology of the disease, acceptability of diagnostic method by patient, costs of diagnostic methods and their availability to be noticed in interpretation of the results. Moreover, sonography and mammography results should be interpret besides other factors such as age, symptoms, previous medical history and familial medical history.

It is recommended to perform a multicentric study for increasing sample size and assessment of invasive methods concordance in less than 30 years old group because of low malignancy rate and the value of diagnosis and treatment in early ages. It is recommended to perform a similar study to ours in 2 or more hospitals all over the country in order to demolish the probable epidemiological, economic, social and ethical intervening factors.

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## Conflict of Interest

The authors declare that they have no conflicts of interest.

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