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Research Article

THE ACCURACY OF THE RESULTS OF BREAST CANCER CLASSIFICATION BY BIRADS METHOD USING ULTRASOUND

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ABSTRACT

Objectives: The purpose of this study was to evaluate the accuracy of the results of BIRADS classification (Grade 3 and Grade 4) using sonography in evaluating the level of malignancy of breast masses and comparing it with pathological outcomes.

Materials and Methods: After obtaining the consent of the Ethics Committee of Mashhad University of Medical Sciences, patients with palpable breast mass who were ultrasound candidates for further examination of the nature of mass were selected. Then, an axilla breast ultrasound was performed by two radiology professors of Mashhad university of medical sciences with at least 10 years of experience in this field. Based on the classification of the American Society for Radiology and the BIRADS system, various degrees of breast masses malignancy were identified. In a group of patients categorized as BIRADS-4 and also in a number of patients classified in the BIRADS-3 that for some reason (such as the patient's request or doctor's opinion), they needed to undergo a biopsy, ultrasound was conducted for patients. The pathologic results were compared with ultrasound reports, and consistency of the results and accuracy of ultrasound were examined with the help of statistical tests. In this study, SPSS software version 16 was used.

This case-series study was performed on 139 patients referred to Imam Reza Hospital, Omid Hospital and some private clinics in Mashhad.

Results: In this study, 139 patients with mean age of 42.4 years were examined and went under core needle biopsy from breast masses. Out of 37 biopsies of lesions with BIRADS-3 in ultrasound, two (5.4%) of the lesions resulted in malignant pathology. Out of 102 biopsies of lesions with BIRADS-4 in ultrasound, 65 (64%) of them resulted in benign pathology. The sensitivity of the BIRADS-3 system for diagnosis of benign breast mass is 94% and its specificity is 64%. The sensitivity of the BIRADS-4 system is 75% for diagnosis of breast cancer while its specificity is 79%.

Conclusion: Our study confirms the consistency between the results obtained from the classification by the BIRADS method with the pathology, and given the relatively high accuracy of this method, radiologic-pathologic consistency can be used to determine how to follow the patients and choose the appropriate treatment.

INTRODUCTION

Breast cancer is the most common type of cancer among women. In the world, after lung and stomach cancers, breast cancer is the third most common cancer (1). Women with positive receptors respond better to hormone therapy, and survival rates increase slowly. Breast cancer is of adenocarcinoma type in most cases (about 95% of cases). In Iran, the prevalence of breast cancer in 35 year-old women and over is 6.6 per thousand, and 12.6% of all cancers in Iran are breast cancer (2, 3). In Iran, breast cancer is the third most common cancer in women after cervix and skin cancers. In the last 50 years, death from breast cancer has remained relatively constant, but between 1980 and 1989 in the United States, death rates from breast cancer have increased by 4% among white women and by 15% among black women, in a way that its incidence rate in 1980 rose from 85 per 100,000 to 105 per 100,000 in 1989. This increase has been seen both in younger and older women, and a part of it is due to increased use of mammogram screening. The recent increase in the incidence, instead of breast cancer death, is likely to be due to early diagnosis of cancer, resulting in higher survival rates (4).

Breast imaging includes ultrasound, mammography and MRI, each of which has its own advantages and disadvantages. Although breast mammography and ultrasound have acceptable

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diagnostic accuracy in diagnosis of benign and malignant lesions in many cases, histological diagnosis of breast cancer is essential before the choice of treatment. Although Fine Needle Aspiration sampling from a lesion in some centers is used as the first biopsy method, this method is not very reliable and, in addition to the probability of sampling error, requires an experienced cytologist in this field. A golden standard method for diagnosis of breast cancer is biopsy through surgery, but this method requires specific and cost-effective measures and is associated with some degrees of morbidity and biopsy through surgery cannot be the first method of selective biopsy. Core Needle Biopsy can eliminate all of these constraints with the help of imaging methods; it can also prevent the formation of scar tissue at the site of the lesion, which may be associated with other problems in later mammography and ultrasound sonography in patients. In the case of non-palpable lesions, if Core Needle Biopsy is performed under the guidance of imaging methods, costs for patients and the incidence of complications are lower, and biopsy is less invasive compared with biopsy during surgery. The success rate of CNB under ultrasound guidance depends on how the biopsy is carried out, the biopsy from the proper site, and the provision of sufficient and proper samples for histological examination. It is clear that if the CNB is not prepared from a suitable site or when a histological sample is prepared, a proper section of the site of the malignant lesions is not given, it will lead to a lack of diagnosis of the cancer, and the histological sample will be reported as a benign lesion.

The aim of this study was to determine the consistency and inconsistency of ultrasound results with pathology in evaluated patients and to evaluate the accuracy of the results of breast cancer classification by BIRADS BIRADS-3 and -4.

METHODOLOGY

This case-series study was performed on 139 patients referred to Imam Reza Hospital, Omid Hospital and some private clinics in Mashhad.

Selection of patients

The referred patients entered the study by easy non-probability sampling method. Patients with palpable breast mass who were candidates for breast ultrasound and were satisfied, entered the study. People with a history of breast cancer, or sampling and breast surgery, were excluded from the study.

Method of study

After obtaining the consent of the Ethics Committee of Mashhad University of Medical Sciences, patients with palpable breast masses who were ultrasound candidates for further examination, were selected based on inclusion criteria. Demographic data of patients including age, height and weight, history of drug use and chronic underlying disease, site of the mass in the examination, and estimated clinical mass and ultrasound were recorded in a researcher-made checklist.

Then, and axilla breast ultrasound was performed by a radiologist with at least 10 years of experience in this field. A print of the ultrasound image was recorded in the patient's records. Based on the classification of the American Society for Radiology and the BIRADS system, various degrees of malignancy were determined, all the ultrasounds in premenopausal women were performed at the days of 8-14 of menstruation. The patients were then referred for sampling. Needle sampling was done. The pathologic results were compared with ultrasound reports, and the consistency of results and accuracy of ultrasound were compared with the help of statistical tests.

RESULTS

In this study, 139 patients with a mean age of 42.4 years were studied. In 67 patients, the right breast, in 68 patients, the left breast, and in 4 patients, both breasts were involved. In 52% of patients, breast mass size was less than 100 square millimeter. The average breast mass size was 154 ± 183 square millimeter. Only 5.4% of patients classified in the BIRADS-3 group were reported as having a malignant pathology. In 35.6% of patients classified in the BIRADS-4 group, the pathology result was reported to be malignant.

In table 1, the prevalence of benign and malignant cases in different groups is given based on the results of pathology in BIRADS-3 and -4 groups.

		BIRADS-3 (%)	BIRADS-4 (%)
Age below 40	Malignant	5	18.5
	Benign	95	80.5
Age above 40	Malignant	7.1	48
	Benign	92.9	52
Mass size less than 100 square mm	Malignant	10	42.1
	Benign	90	57.9
Mass size more than 100 square mm	Malignant	0	25
	Benign	100	75

In some similar articles, the BIRADS-3 and benign pathological sample are considered as positive results, and accordingly, the BIRADS system sensitivity will be as follows.

Table 2 Evaluation of BIRADS-3 sensitivity for breast mass classification

	BIRADS-3	BIRADS except 3
Benign	35	65
Malignant	2	36

The sensitivity of the BIRADS-3 system for diagnosis of benign breast mass is 94% and its specificity is 64%.

Considering BIRADS-4 and the malignant pathologic sample as positive results, the sensitivity of the BIRADS-4 system will be as follows.

Table 3 Evaluation of BIRADS-4 sensitivity for breast mass classification

	BIRADS-4	BIRADS except 4
Malignant	36	11
Benign	12	42

The sensitivity of the BIRADS-4 system for diagnosis of benign breast mass is 75% and its specificity is 79%.

DISCUSSION

In recent years, the needle biopsy under the guidance of imaging techniques has been a great help in detecting breast cancer and differentiating benign and malignant forms of breast masses and making appropriate decisions for lesions with a suspicious or uncertain appearance. The success rate in identifying the nature of breast lesions by CNB depends on the

existence of an appropriate relationship between the radiologist, the pathologist, the surgeon and the oncologist, so that today, it is recommended to investigate the results of CNB by this group and then make a proper decision to follow the patient, perform biopsy again or remove the mass. Since 2003, when ultrasound BIRADS was used, the symptoms of malignant lesions in ultrasound were described and the malignancy rate was determined based on these symptoms. Based on this system, an indication of the biopsy of a breast mass can be identified. In BIRADS-3, the probability of lesion malignancy is 2-3%, and biopsy has indication when the patient or doctor is willing to do biopsy for any reason. In our study, patients with BIRADS-3 were diagnosed due to patient anxiety and the desire to determine the nature of the mass, the physician's tendency to assess the type of mass or the need to determine the nature of the lesion, given that the patient was in the group of patients with a high risk of breast cancer.

BIRADS stands for Breast Imaging-Reporting And Data System. BIRADS is a tool for expressing the quality and risk in breast mammography, ultrasound and MRI.

The breast imaging is applied in two forms of screening and diagnosis. Following the launch of mammography screening in the United States in the 1980s and early 90s, the American Society for Radiology invented the BIRADS. In this system which was first designed to align and store mammogram findings, and then included ultrasound and MRI findings (5-7), the purpose is describing the imaging findings in a way that both the other radiologist and the other breast team members can figure out whether the result of the imaging is normal or requires follow-up or sampling. The division of BIRADS is from 0 to 6. BIRADS-0 means that the radiologist cannot comment on the breast condition with this finding of imaging and needs additional imaging (7). An example is when a mass is found in the mammography, and ultrasound is required to determine whether it is solid or liquid, and the final division depends on the ultrasound response. Or, there is a density increase in mammography and a zoom stereotype is needed. BIRADS-6 is when we know that the patient has cancer and it has been confirmed by needle or surgical sampling and we are imaging. For example, a patient that we know has a cancer and is under the neo-adjuvant chemo therapy and is under imaging to assess the response to treatment. Or when a person is mistakenly sampled without primary imaging evaluation, and pathologic result has proven the cancer. BIRADS-1 means natural imaging (8). In BIRADS-2, there is one finding that we know its source is benign. For example, the presence of calcium deposition in the vascular wall in mammography, the presence of internal mammary lymph nodes in mammography or ultrasound, the presence of simple cysts in ultrasound or MRI do not require follow-up. Unlike the BIRADS-2, in BIRADS-3, we have a findings that is likely to be benign, but we cannot be 100% sure that there is no malignancy. According to the findings of the imaging, it can be said that the imaging finding is likely (98%) benign and for the remaining 2%, the patient goes under short-term follow-up. In BIRADS-4, there is 2-70% of malignancy probability, and therefore, there is a need for sampling to reject the probability of cancer. BIRADS-5 means a suspicion of a malignancy with a probability of more than 70%, meaning that it requires sampling (9). In recent years, in the fourth edition of the BIRADS system, BIRADS-4 has been categorized into four subgroups of 4A, 4B, and 4C according to the risk of malignancy in each subgroup. The probability of malignancy in subgroups 4A, 4B, and 4C are 2-10%, 11-50%, and 51-95%, respectively.

The relationship between the radiologist and the pathologist and the consistency of imaging results with pathology play an important role in assessing the accuracy of the BIRADS classification in distinguishing benign and malignant lesions. The decision to perform a re-biopsy or control of a patient with a short interval depends on the radiology and cytology.

The aim of this study was to determine the consistency and inconsistency of ultrasound results with pathology in patients under study and to evaluate the accuracy of the results of breast cancer classification by BIRADS-3 and -4.

Why in our study of BIRADS-3 lesions, the malignancy was higher and about 5%, maybe due to the novelty of this study type on the adaptation of radiology findings to pathology.

Studies in this field were limited, and therefore, the possibility of comparing the results of our study with several similar studies was not possible. Small number of discordant benign lesions and discordant malignant cases are from our other limitations. As a result, these findings cannot be generalized to larger groups of patients. Undoubtedly, conducting similar studies by examining more patients can help obtaining more complete results.

Another limitation of our study is the lack of follow-up of patients with BIRADS-3 at six-month intervals for any change in the ultrasound image of the lesion, up to a period of 18-24 months from the initial ultrasound. Of course, in a recent study, Johnson et al. showed a significant difference in mass stage and axilla lymph node status in cases where biopsy under ultrasound confirmed the benign lesion, and it is not reported after controlling patients with short intervals in cases where patients referred regularly for follow-up.

In this study, the sensitivity of Breast Cancer Classification by BIRADS method with ultrasound was 97% and its specificity and accuracy were 94% and 87%, respectively. In the study of Hille (2014), the sensitivity, specificity and accuracy of BIRADS were estimated to be 92%, 82% and 87%, respectively (13), which are almost the same as our study.

In a study conducted in 2008 in Germany, it was found that the frequency of malignancy in the group with BIRADS-3 is lower than 2% (14). In our study, the prevalence of malignancy in this group was 5.4%, which is slightly higher than previous studies, which may be due to differences in study groups and mass size.

In previous studies, the likelihood of malignancy in the group with BIRADS-4 was estimated to be between 3% and 94%, which was 18.5% to 42% in the present which is in the same range and is similar to other studies.

Table 4 shows the frequency of malignancy based on the BIRADS class in the results obtained from previous studies.

	BIRADS-3	BIRADS-4
Lorenzen	3.5	71
Liberman	-	34
Mendez	4	15
Orel	2	30

B´erub´e	0	40
Mayi-Tsonga	11	67
Siegmann	6.3	16.7
Median	4	30
Heinig	1.2	17
Present study	5.4	30.3

In the study of Ghare-Khanlu, the average diameter of the mass was 29 mm (10). In our study, the mean largest diameter of the mass was 12 mm, which could be due to differences in sample selection.

A study in China (Li) showed that performing mammography and MRI in patients with BIRADS-3 to -5 does not improve the accuracy of micro-classification lesions (12). But in our study, the accuracy of other diagnostic methods was not studied.

CONCLUSION

Our study suggests good agreement between the results of the classification by BIRADS and pathology. Due to the relatively high accuracy of this method, radiological and pathologic adaptation can be used to determine how to follow up the patients and choose the appropriate treatment methods. On the other hand, although mammography is the golden standard method of breast cancer diagnosis, due to the occurrence of breast cancer in lower ages in recent years and the presence of dense breast tissue in this age, supplementary ultrasound (complementary screening method), especially in the lower age group, will be very effective to increase the diagnostic sensitivity.

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