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Original Article

Visual inspection results of ultrasound guided biopsy specimens and compared with open biopsy pathologic in patients with breast lesions

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Abstract: Background: Core needle biopsy (CNB) method is a common method and a gold standard for the diagnosis of breast lesions. The purpose of this study was to compare the results of visual inspection of ultrasound guided biopsy specimens with pathologic outcomes in patients with breast lesions. Methods: This cross-sectional descriptive was conducted on 600 patients with breast lesions who were candidates for ultrasonography with CNB were entered into the study. Then, patients underwent sonography with needle biopsy, in a sample taken by The radiologist classifies the breast mass according to its consistency and shape based on observation to the malignant or benign, as well as the Breast Imaging Reporting and Data System or Mass BIRADs. visual inspection results were compared with the CNB pathology of patients. Results: In this study, the sensitivity and specificity of the lesion were 97.48% and 94.10%, respectively, and positive and negative predictive values of this test were 85.64% and 99.05%, respectively. Conclusion: Given that the sensitivity and specificity of the biopsy lesions to detect the type of mass was higher than the pathology of the sample, it can be ensured that the biopsy of breast lesions, especially in sizes less than 10 mm in time Increased the biopsy and reduced the number of cores taken from the lesion.

Keywords: Observation, needle biopsy, breast lesion, pathology

Introduction

Breast cancer after lung cancer The most common type of malignancy, the most common cancer in women, is the first cause of female mortality in the third to fifth decades, and the second cause of mortality in women. The incidence of this cancer is also progressing [1]. The prevalence of this cancer in the whole world is about 25.5% of all cancers, and its incidence is 1384155 cases per year [2]. It is the most common cancer in Southeast Asia, the most common cancer in eastern Asia after gastric cancer and the most common cancer in South Asia after cervical cancer, as well as in the eastern Mediterranean, the fourth leading cause of mortality, and in Iran it is similar to the Mediterranean [3]. Breast cancer in young women occurs in Iran a decade earlier than in advanced countries, and is diagnosed at advanced stages of the disease. Also, breast cancer in Iran has grown dramatically over the last four decades, as it has become the most common cancer among women today [4]. Factors conducive to breast cancer include factors such as age, especially over age 50, family history, diet, obesity, alcohol, reproductive and hormonal factors, history of cancer, menarche age, and menopause [5]. Breast cancer is divided into two types of invasive and non-invasive, or two types of ductal and lobular, most of which are ductal and invasive [6]. Today, for the diagnosis of breast cancer, specific biotype (ER) subunits, progesterone receptor (PR) receptor and human epidemic growth factor (HER2) receptor are used routinely to examine the types of breast cancer that are used with core samples Are prepared in CNB, and also play a major role in the development of optimal therapeutic strategies for the treatment of patients with breast tumors [7, 8]. Routine diagnosis of the disease is based on clinical signs, Para clinical findings and imaging. Imaging is performed on the basis of follow-up and patient require-

ments, so that initially imaging such as mammography and ultrasound is performed and If you suspect malignancy, invasive diagnostic methods such as core needle biopsy (CNB), fine needle aspiration [9], (VAB) vacuum assisted biopsy or open biopsy are used. In these two methods, the needle sampling, FNA and CNB, have high sensitivity and high sensitivity with ultrasound guidance (if visible in ultrasound), and CNB has a higher sensitivity to FNA for diagnosis, CNB is also the most commonly used diagnostic method for diagnosis of breast cancer [10]. Given the high prevalence of breast cancer in terms of mortality and malignancy, we need to look for solutions for early detection, rapid and convenient, and available. After screening and finding a lesion in the breast, we must understand the type of lesion and the degree of malignancy of the lesion. There are different methods of biopsy to do this, but there must be a method that is both affordable and available and has fewer side effects than other methods. It also has a high sensitivity and high false negative effect. One of Core Needle Biopsy's strategies is ultrasound. During several years of performing CNB with ultrasound examination of breast masses by experienced radiologists, we found that through visual inspection, samples taken according to specimen characteristics such as consistency, color and content can be high percentages The pathological findings of lesions were detected before the microscopic examination of the masses. According to these findings, the aim of this study was to examine the specificity of samples obtained by CNB with ultrasound guide and by examining the color, consistency and contents of the samples. To this end, the results were classified into benign and malignant groups (as Probable). After examining the pathology response and comparing the results, we examined the accuracy of the core specimens.

Materials and methods

In this cross-sectional descriptive study, 600 patients with suspected breast lesions who had undergone CNB undergoing ultrasound examination at Tehran in 2018 and 2019, according to entry and exit criteria, entered the study. The protocol of this study was approved by Research Committee of Yazd University of Medical Sciences with the code of IR.SSU.MED.REC.1393.590. Patients were also sampled easily and at least 5 nuclei of each lesion were taken with a needle g = 16 trucut. Inclusion criteria included breast women with Breast Imaging Reporting and Data System or BIRADs between 2 and 5 who referred to Imaging Center of Imam-Khomeini of Tehran, Iran, who had ultrasound guidance for CNB needles biopsy. Exclusion criteria included the patient's lack of cooperation in conducting the tests or the inadequacy of the sample for pathology or the failure of the pathologic response. The method for collecting information was that the mass was detected by touch or observation in the imaging (through screening, or self-examination, and referenced by a specialist physician, etc.). And classified according to the BIRADS classification accepted by the American College of Radiology. Based on this system, BIRADS scoring is used for imaging such as mammography, so B 0 (zero), inadequate study, B1 means negative study (no lesion was observed), B2 is benign lesions, B3 is the observed lesion Less than 2% is likely to be malignant, B4 means that the lesions seen are between 2% -95% malignant (10-2 a = 4, 10-60% b = 4, 60-95% c = 4) and B5 is more There is a 95% chance of malignancy [11]. Simultaneously with the biopsy and observation of specimen, CNB was divided into benign (possibly benign), and malignant (possibly malignant), color, consistency and content. Also, visual inspection was performed on the basis of BIRADS criteria for patients according to visual inspection by a radiologist performing CNB. The above results correlated with the pathologic response and the accuracy of the classification was determined based on visual inspection. Patients were examined by a radiologist at the Imaging Center and pathologist in the field of CNB with sonography. Patient characteristics and diagnostic results were considered in the form. Samples collected by experienced pathologists in breast diseases were studied. The criteria for visual classification were based on the consistency of the sample, color and content, in that the malignant samples of B5 were rigid and dyed and sometimes contained calcification, benign samples at B2, soft consistency and creamy color, B4a, more firmness, B4b consistency Relatively hard and B4c were highly suspected of malignancy. Registration data and finally, the comparison of visual inspection reports of CNB samples with ultrasound exami-

Table 1. Clinical information of patients in two groups

Variables		The benign group based on observation	Malignant group based on observation	*P*-value
Number		419	181	-
Age (years)	(Mean ± SD)	46.68 ± 13.01	47.29 ± 13.13	0.67
Side	Right	(49.2%) 206	(39.2%) 71	0.07
	Left	(43%) 180	(50.3%) 91	
	Both	(7.9%) 33	(10.5%) 19	
Place the mass	right Upper quadrant	(56.8%) 238	(64.6%) 117	0.34
	Left Upper quadrant	(21.2%) 89	(18.2%) 33	
	Right Lower quadrant	(11.7%) 49	(8.8%) 16	
	Left Lower quadrant	(10.3%) 43	(8.3%) 15	

nations with pathologic results was compared. The tools needed to conduct this study were files and documents available at the Center for Neonatal Neurosurgery Center and the pathological centers visited by the patients. The data of this study included patients' age, location of mass, visual acuity determined according to BIRADS criteria by visual inspection of CNB, benign and malignant type based on visual inspection and pathologic response. They entered the checklist and then entered SPSS version 24 and the tests used in this study, Independent t-test and Chi-Square were used to compare benign and malignant groups. Also, qualitative data were presented as numbers or percentages, and quantitative data were presented as mean and standard deviation. It should be noted that $P < 0.05$ The title was considered as a meaningful relationship.

Results

In this study, out of a total of 600 breast lesions, 419 cases were assigned to benign and 181 patients in the malignant group, based on visual inspection. The mean age of patients in benign and malignant groups was 13.01 ± 46.68 and 47.29 ± 13.13 years, respectively. There was no significant difference between the two groups based on age ($P = 0.67$). 49.2% of the case group had benign mass in the right breast and 50.3% of the cases of the malignant mass in the left breast, and the location of the mass was 56.8% in benign and 64.6% in the malignant group in the upper and right quadrant, but there was no significant difference between the two groups based on the involved breasts ($P = 0.07$) and breast mass ($P = 0.34$). Other patient information based on age, and location of the mass is summarized in **Table 1**.

In the visual inspection, according to the above criteria, B 2-4c was classified in benign and B5 in the malignant group. Therefore, the incidence of cases based on BIRADs in the benign group was 52.5% in 2BIRADs, 9.5% in 3 = BIRADs, 30.5% in a4BIRADs = 6% in b4BIRADs, and 1.4% in c4BIRADs =, as well as in the malignant group of all 5 BIRADs =. There were significant differences between the two groups based on BIRADs ($P = 0.00$).

Of the pathologically reported samples, only 6 cases of benign protozoa were not matched with visual inspection, in which 2 cases of Mucinous carcinoma, 2 cases of Phyllodes tumor and 2 other cases of Invasive ductal carcinoma were reported in the pathology. Also, 24 cases of malignant neoplasms did not match the pathology response, with 4 (2.2%) Complex fibro-adenoma, 4 cases (2.2%) of granuloma mastitis, 6 cases (3.3%), ductal hyperplasia, 8 (4.4%) Epithelial hyperplasia and 2 cases (1.1%) Intra ductal papilloma were reported in pathology. Therefore, the sensitivity and specificity characteristics of the malignancy were 96.32% and 94.51%, respectively, as well as positive and negative predictive values of 86.74% and 98.57%, respectively (pathologic information and BIRADs of patients are completely in the **Table 2** is summarized). Also, the distribution of patient pathological findings based on their BIRADS is summarized in **Table 3**.

Discussion

According to the results of our study, the sensitivity and specificity of the examination of the visual inspection based on consistency and the form of the sample based on its observation to

Table 2. Pathology and visual inspection of patients in two groups

Variables		The benign group based on observation	Malignant group based on observation	*P*-value
visual inspection	2	(52.5%) 220	(0%) 0	0.00
	3	(9.5%) 40	(0%) 0	
	4 a	(30.5%) 128	(0%) 0	
	4 b	(6%) 25	(0%) 0	
	4 c	(1.4%) 6	(0%) 0	
	5	(0%) 0	(100%) 181	
Results Pathology Samples	Fibro adenoma	(29.8%) 125	(0%) 0	0.00
	Complex fibro adenoma	(9.8%) 41	(2.2%) 4	
	Fibrocystic change	(18.1%) 76	(0%) 0	
	Sclerosis adenoma	(3.8%) 16	(0%) 0	
	Granuloma mastitis	(2.6%) 11	(2.2%) 4	
	Tubular adenoma	(0.7%) 3	(0%) 0	
	Florid ductal hyperplasia	(0.5%) 2	(0%) 0	
	Keratin plaque	(0.5%) 2	(0%) 0	
	Mucinous carcinoma	(0.5%) 2	(1.1%) 2	
	Lactating adenoma	(0.5%) 2	(0%) 0	
	Phyllodes tumor	(0.5%) 2	(1.1%) 2	
	Atypical ductal hyperplasia	(0.5%) 2	(0%) 0	
	Ductal Hyperplasia	(2.9%) 12	(3.3%) 6	
	Proliferative Fibrocystic Disease	(24.3%) 102	(0%) 0	
	Epithelial hyperplasia	(1.4%) 6	(4.4%) 8	
	Intra ductal papilloma	(0.5%) 2	(1.1%) 2	
	Juvenile papilloma	(0.5%) 2	(0%) 0	
	Radial scar	(0.7%) 3	(0%) 0	
	Fat necrosis	(1%) 4	(0%) 0	
	Atypical adenoma	(0.2%) 1	(0%) 0	
	Lymph nodes	(0.2%) 1	(0%) 0	
	Invasive ductal carcinoma	(0.5%) 2	(73.5%) 133	
	Invasive lobular carcinoma	(0%) 0	(5.5%) 10	
	In situ ductal carcinoma	(0%) 0	(1.1%) 2	
	Invasive lobular and ductal carcinoma	(0%) 0	(3.3%) 6	
	Tubular carcinoma	(0%) 0	(1.1) 2	

determine benign or malignant lesion was high compared to the pathological response, so that the test sensitivity or the ability of the test to diagnose the patient's cases, 96.32%, and the test's ability to determine the cases was 94.51%. Therefore, the visual inspection seems to be helpful with observation of the sample to determine the type of mass in cases where the patient has the malignant malformation problem of the sample, as well as the accuracy of the visual inspection by looking at the sample. The false negative results (6 cases) were very low and 2 of these 6 cases were mucinous carcinoma that inherently have soft and gelatinous consistency, and its incidence is very low compared to Invasive ductal carcinoma. In some cases, they were examined in the B5 of visual inspection and reported in benign pathology including complex fibro-adenoma, granulomastitis, and ductal hyperplasia, which can produce tense constipation. The last point is that in non-b5 cases in ophthalmic specimens, with a high percentage of certainty, malignancy can be ruled out, and especially in benign b2 benign of visual inspection, with a high percentage of patient confidence in pathological benignity. It should be noted that 110 visual inspections were diagnosed with fibro-adenoma among visual inspections (in BIRADs = 2), and in response to pathology, 73 of them were fibro-adenoma. Also, 13 of the BIRADs = 2 samples with visual inspection were diagnosed with

Table 3. Frequency distribution of patient pathological findings based on visual inspection of patients

Pathology	B2	B3	4a	4b	4c	B5
Fibro adenoma	80	12	23	10	0	0
Complex fibro adenoma	30	0	8	0	3	4
Fibrocystic change	76	0	0	0	0	0
Sclerosis adenoma	10	2	4	0	0	0
Granuloma mastitis	4	4	0	3	0	4
Tubular adenoma	2	0	1	0	0	0
Florid ductal hyperplasia	2	0	0	0	0	0
Keratin plaque	2	0	0	0	0	0
Mucinous carcinoma	2	0	0	0	0	2
Lactating adenoma	2	0	0	0	0	0
Phyllodes tumor	2	0	0	0	0	2
Atypical ductal hyperplasia	2	0	0	0	0	0
Ductal Hyperplasia	6	2	4	0	0	6
Proliferative Fibrocystic Disease	0	14	74	11	3	0
Epithelial hyperplasia	0	4	2	0	0	8
Intra ductal papilloma	0	2	0	0	0	2
Juvenile papilloma	.	0	2	0	0	0
Radial scar	.	0	3	0	0	0
Fat necrosis	.	0	4	0	0	0
Atypical adenoma	.	0	1	0	0	0
Lymph nodes	.	0	1	0	0	0
Invasive ductal carcinoma	.	0	1	1	0	133
Invasive lobular carcinoma	.	0	0	0	0	10
In situ ductal carcinoma	.	0	0	0	0	2
Invasive lobular and ductal carcinoma	.	0	0	0	0	6
Tubular carcinoma	.	0	0	0	0	2

fibrotic changes, of which seven were in response to fibrosis pathology. In a similar study by Radhakrishna [12], CNB outcomes were based on visual inspection or gross pathology in 467 samples with BIRADS 3 to 5, based on the results of this study, out of 437 patients who were symptomatic, 30 were unusual. The positive predictive value for lesions with B5 for malignancy was 93.25%, and the negative predictive value for lesions with B3 was 98.4%, as well as false negative 0.85%. The conclusion of this study was that the positive and negative predictive values for CNB in lesions with BIRADS between 3 and 5 are very high. Where there is no difference between clinical findings, radiology and pathology, surgery can be done in benign lesions. While in poorer countries, FNA was still a valuable way of detecting palpable and impenetrable lesions, and CNB has the most accurate and optimal diagnostic information. In a study by Dzierzanowski [13], it was concluded that the identification of Ductal carcinoma in situ or DCIS in relation to invasive cancer is important in the case of core (CB) sampling. Awareness of DCIS in CBS with invasive cancer may be helpful to the surgeon in planning gross marginalization in lumpectomy. In a study by Apple [14] who reviewed and compared microscopic and gross pathology reports on breast cancer, the sample size included 91 excisional biopsies and concluded that the Gross report was uneven according to the final microscopic presentation and suggested that Microscopy pathology should be used to detect lesions. To provide the result of our study, we need to other similar in the higher sample size [15].

Conclusion

According to our previous studies and the results of our study, CNB is a useful method for diagnosis of breast lesions and is highly accurate. Also, according to our study, visual inspection was also a useful method with low sensitivity and high specificity and false negative, but according to That the CNB pathology response is reported relatively late and at this time interval for patients with stress and discomfort to be malignant or benign, it seems that visual inspection using a CNB-tested lesion is a useful method for assurance Giving patients benign cases, Also, visual inspection should consider the physician's experience in this regard. Also, due to the high sensitivity and specificity of the visual inspection, it can be ensured that the biopsy of the breast lesions is accurate and reduce the number of CNBs taken from the lesions and give the patient a relative assurance of benign injury before the Get Out of anxiety. In the end, in order to confirm our

study results, we need more studies in higher sample sizes.

Disclosure of conflict of interest

None.

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