

Type of the Paper (Article)

Evaluation of core-needle biopsy in indeterminate breast masses with no significant imaging finding

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Abstract

Introduction: Breast cancer is the most common cause of death due to malignancy among females. Breast ultrasonography plus mammography could enhance the breast cancer detection.

Aim of the study: to assess the value of core biopsy in the early diagnosis of atypia and malignancy in ambiguous breast lesions corresponding to the Breast Imaging Reporting and Data system (BI-RADS) in mammographic findings and complementary breast ultrasonography.

Subjects and Methods: 50 female patients with indeterminate breast lump were recruited. From all patients, an ultrasound-guided core-needle biopsy was taken from breast lesions. The BI-RADS scores in mammography were detected.

Results: All patients had BI-RADS 3 with breast lesions sizes ranged from 14-90 mm in 64% and 14-68 mm in 36% of them. 94% of lesions were benign, 68% were Fibroadenomas, 2% was a fibrocystic disease with ductal hyperplasia with no atypia, 12% were Fibrocystic disease without ductal hyperplasia, and 12% showed periductal mastitis. No upgrades were detected in lumpectomy histopathological analyses for both patients.

Conclusion: Ultrasound-guided core biopsy is necessary for investigating clinically indeterminate breast masses in symptomatizing patients with irrelevant changes in imaging for early detection of malignancy and atypical hyperplastic changes.

Keywords: Breast Cancer; core-needle biopsy; BI-RADS.

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1. Introduction

The most common cause of death due to malignancy among females is breast cancer. It caused 2.1 million new cases (11.59 percent of all cancer patients) and 626,679 cancer-related mortalities (6.6

percent of all cancer-related mortalities) that were reported worldwide in 2018 [1].

Although the majority of palpable breast lumps are benign, no one can guarantee that malignant masses are completely excluded. Breast cancer is

determined to be present in roughly one-third of breast biopsies [2].

Symptomatic breast lesions are usually evaluated by clinical breast examination and mammography [3]. Breast cancer can be found with a clinical breast examination, which is a quick, non-invasive, and affordable method; however, further imaging should be used to improve the ultimate accuracy. Compared to women who receive screening mammography alone, breast ultrasonography plus mammography could enhance the breast cancer detection rate by 4.2 malignancies per 1,000 screened females [4].

Breast masses undergoing mammographic scanning are classified into

six categories according to the Breast Imaging Reporting and Data (BI-RADS) system. The BI-RADS can be summarized as a normal mammogram for BI-RADS 1, a benign breast lesion for BI-RADS 2, an indeterminate benign breast lesion for BI-RADS 3, suspicious malignancy for BI-RADS 4, highly indicative of malignancy for BI-RADS 5, and pathologically established malignancy for BI-RADS 6 [5].

Our research was conducted to assess the value of core biopsy in the early diagnosis of atypia and malignancy in ambiguous breast lesions, corresponding to BI-RADS 3 score in mammographic findings and complementary breast ultrasonography.

2. Subjects and methods

2.1. Subjects

The study was carried out prospectively. On fifty patients satisfying our eligibility criteria who presented with symptomatic indeterminate breast masses chosen according to our selection criteria and underwent an ultrasound-guided core biopsy in the period from January 2021 to March 2022,

Inclusion criteria

All female patients had indeterminate breast lumps, and there were no notable imaging findings. (BI-RADS 3 score in mammography and ultrasonography).

Exclusion criteria

Female patients presented with inflammatory breast masses or different BI-

RADS scores in mammography were excluded.

Ethical Consideration

The regional Ethics Committee of Fayoum University has given its approval to this research, with approval number (80) on: January 10th, 2021. Each participant gave written informed consent before to taking part in the research.

2.2. Methods

An ultrasound-guided core-needle biopsy was taken from breast lesions. Under complete aseptic conditions while the breast is exposed. The breast was prepared with Povidone-iodine 10% antiseptic solution. Sterile drapes were used to assure the complete asepsis. The local infiltrating

anesthesia is 1% lidocaine in a 10:1 ratio. A small skin incision made with a scalpel facilitates the insertion of the needles used for a core needle biopsy. We used disposal semi-automatic 18- & 16-gauge core needles to biopsy masses under real-time ultrasound scanning of the breast mass. The skin incision was covered with sterile gauze only. It spontaneously closes. All participants stayed in the ward for two hours for monitoring of vital signs and biopsy site expanding hematoma. The patient is directed during this time about what to expect, outpatient clinic visit return dates & how and where to get her result.

The first outpatient clinic return was within one week to check the biopsied breast

3. Results

Fifty female patients were clinically examined and had bilateral breast sonography and mammography (mammography was for those above 35 years old). The total number of patients was 50, the median age was 30 years, the mean

for biopsy site infection or hematomas and review the pathology report and the strategy for the further managing.

2.3. Statistical Methods

Microsoft Access was used to double-enter the data after it had been collected and coded to make data processing easier. SPSS software version 18 running on Windows 7 was used for data analysis. For qualitative data, a straightforward descriptive analysis stated as percentages and figures, for parametric quantitative data, arithmetic means as a measure of central tendency, and standard deviations as a measure of dispersion.

age was 31.9 years, and the standard deviation was 10.832 patients (64%) who were under the age of 35, compared to 18 patients (36%) who were over that age (Table 1).

Table 1: Age groups of the study population.

Age (year)	Frequency (n=50)
< 35 years	32 (64%)
35-49 years	14 (28%)
≥ 50 years	4 (8%)

The total number of patients with breast masses categorized as BIRADs was 3. Only one patient (2%) had a first-degree family history of breast malignancy. The 32 patients, younger than 35 years old, had breast lesions ranging between 14 mm (the

smallest) and 90 mm (the largest). The mean size in this age group is 31.7 mm. The 18 patients, older than 35 years, had breast lesions ranging between 14 mm (the smallest) and 68 mm (the largest). The mean size in this age group is 32.2 mm (Table 2).

Table 2: Comparison of mass size to age group.

	Age (year)	Frequency (n=50)	Mass size (mm)	Mean	
II	< 35 years	32 (64%)	14-90	31.8 mm	focal
	>35 years	18 (36%)	14-68	32.2 mm	atypia

patients had undergone an ultrasound-guided core needle biopsy. Clinical core biopsy histological results showed that 47 lesions (94%) were benign lesions, of which 34 lesions (68%) were fibroadenomas, one lesion (2%) was fibrocystic disease with ductal hyperplasia with no atypia, 6 lesions (12%) were fibrocystic disease without ductal hyperplasia, and 6 lesions (12%) showed periductal mastitis. Two lesions (4%) were proliferative breast lesions with

One lesion (2%) was invasive ductal carcinoma grade 2 (Tables 3 &4). The two patients with proliferative breast lesions with focal atypia were 53 and 31 years old, with breast lesion sizes of 15 mm and 25 mm, respectively. The one patient with infiltrating duct carcinoma was 28 years old with a breast lesion size of 33 mm. All three patients mentioned had no family history of breast cancer.

Table 3: Histological results of core biopsy.

Lesion type	Frequency (n=50)
Benign	47 (94%)
Hyperplastic with focal atypia	2 (4%)
Malignant	1 (2%)

Table 4: Histological subtypes of benign masses.

Benign masses type	Frequency (n=50)
Fibroadenoma	34 (68%)
Fibrocystic disease without ductal hyperplasia	6 (12%)
fibrocystic disease with ductal hyperplasia with no atypia	1 (2%)
periductal mastitis	6 (12%)

4. Discussion

In Egypt, breast cancer affects more women than any other type of cancer, accounting for 32% of all newly diagnosed malignancy cases each year, or 157 per 100,000 women [6]. Breast soreness accounts for 18.9% of presenting symptoms, despite the fact that a palpable breast lump is the most common presenting symptom of breast cancer (71.4%). Individuals who visit the breast clinic are usually given a clinical breast examination before proceeding to imaging. According to research, people who have a persistent mass are more likely to request a breast exam than those who have other breast concerns [7].

Breast cancer can be found with a clinical breast examination, which is a straightforward, inexpensive, and non-invasive method. However, auxiliary imaging should be used to improve ultimate accuracy. Compared to women who just have screening mammography, breast ultrasonography and mammography could raise the rate of breast cancer detection by 4.2 cancers per 1,000 screened women [4]. The sensitivity of breast ultrasound is 89% [8], and the total sensitivity of mammography and ultrasound is 96% [9].

The same radiologist performed an ultrasound-guided biopsy of BI-RADs 3 breast lesions on all fifty patients in our research. Ward demonstrated that using imaging-guided sampling boosts diagnostic accuracy [10]. Schoonjans observed that ultrasound-guided needle biopsy has a 99.1% sensitivity for the identification of breast cancer [11].

Using a total of 50 core biopsies collected from ambiguous breast lesions matching to BI-RAD 3, we discovered one instance of malignancy (2%) and two cases of proliferative breast lesions with localized atypia (4%) in our research. Pakdemirli *et al.*, 2020 conducted a retrospective observational study of their practice encompassing 72 patients who had had a clinical needle biopsy to look at clinically palpable breast lesions with normal imaging. One instance was diagnosed with invasive lobular carcinoma, and the other with breast metastatic colorectal cancer. "Any equivocal breast lesions linked with BI-RADs 3 masses should be clinically biopsied, if possible, with a core biopsy," the authors wrote [12]. Park *et al.*, 2008, recommended short-term follow-up as an alternative to immediate biopsy for BI-RAD 3 breast lesions. There were 310 benign lesions and two cancers among the 312 masses biopsied [13]. Sickles' studies additionally included 3184 lesions that had short-term follow-up mammography and were BI-RADS category 3. Cancer was found in 17 (0.5%) of the lesions. These data imply that BIRADS category 3 lesions are almost always benign, and that short-term follow-up mammography allows for the early diagnosis of the rare malignant category 3 lesions [14]. If Sickles were to advocate for a core biopsy of ambiguous, most likely benign breast lesions, it would be reserved for individuals who suffer severe anxiety despite proper information and counseling

or who are unable to provide mammographic follow-up [15].

In our study, the three patients whose biopsies were not benign varied in age (from 28 to 53 years old), and we could not correlate the age of the patients with the predisposition to atypical proliferative lesions or malignancy in their biopsies from vague breast lesions. According to a study by Lee et al., 2018, the cancer yields for women over the age of 60 exceeded the 2% barrier and rose to 4.6% for those between the ages of 80 and 89 [16]. However, Giess *et al.*, 2012, noted that all three of the cancer patients in her series were over 40 years old [17], whereas the study by Panigrahi *et al.*, 2019, included only one cancer patient who was 59 years old and had a BI-RADS 3 finding [18]. While their small size, these numbers suggest that our findings may not apply to older age groups, especially considering our sample's large share of young women (age mean = 31.91). Future studies should compare the malignancy rates in larger numbers of BIRADS-3 palpable

Ethical considerations

The study was approved by the regional Ethics Committee of Fayoum University, with approval number (80) on: January 10th 2021. Each participant gave written informed consent before to taking part in the research

Availability of data and materials

The data sets used and/or analyzed during the current study available from the corresponding author on reasonable request.

lesions in women under 40 to those in women over 40.

The three instances in our research had no family history of breast cancer. This study, however, was unable to show a conclusive link between family history and the incidence of malignancy or an atypical proliferative lesion. since the study was not planned to avoid memory bias, which is formed by lacking medical records of patients' relatives and dependently generated by patients' questionnaire responses (completely subjective). Our study's limitations were a limited sample size and a high percentage of symptomatic patients who arrived at our clinic without being tested.

Conclusion

Ultrasound-guided core biopsy is necessary for investigating clinically indeterminate breast masses in symptomatizing patients with irrelevant changes in imaging for early detection of malignancy and atypical hyperplastic changes.

Patient consent

Informed written consents for participation were taken and signed by the eligible relatives before recruitment and randomization.

Funding: This research is not funded.

Conflicts of Interest: All authors declare no conflict of interest.

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