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Original article

Contribution of Fine-Needle Aspiration Cytology and Ultrasonography Versus Histopathology in Diagnosing Breast Lumps

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Abstract
Breast carcinoma remains a significant global health concern for women. Accurate diagnosis of breast cancer relies on a thorough clinical history and examination, along with the rational use of imaging techniques and tissue diagnosis. The study analyzed the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of fine-needle aspiration cytology (FNAC) and ultrasonography (USG) compared to histopathology at Tobruk Medical Center (TMC), Tobruk, Libya. Records of all patients who presented to the general surgery department with a clinically suspicious breast lump or mass between 2014 and 2017 were reviewed. FNAC and histopathology reports were retrieved from the Department of Pathology at TMC. The study retrospectively reviewed FNAC and USG reports for 42 patients, and the results were compared with histopathological diagnoses. The sensitivity, specificity, PPV, and NPV of FNAC for diagnosing malignant breast lesions were 86%, 80%, 96.9%, and 44.4%, respectively. For USG, the sensitivity and PPV were 87.9% and 96.7%, respectively. Specificity and NPV for USG could not be determined due to the lack of true-negative cases. Indeterminate results were more frequent with USG than with FNAC (19% vs. 2.38%, respectively). In summary, FNAC and USG are best used in combination, as both techniques showed high PPV in the diagnosis of breast malignancy.
Keywords. Fine Needle Aspiration Cytology, Ultrasonography, Breast Lumps.

Introduction

Breast carcinoma is the most common site-specific cancer in women and the leading cause of carcinoma death in women aged from 20 to 59 years [1], with more than 1,000,000 cases occurring worldwide annually. A lump in the breast, whether benign or malignant, results in anxiety for the patient, her family, and the surgeon. Hence, a quick diagnosis of a breast lump is essential. Evaluation of breast lumps involves the rational use of a detailed history, clinical examination, imaging modalities, and tissue diagnosis. Although the final diagnosis requires histopathological examination of the excised tissue, routine excision of all breast lumps would not be rational, as up to 80% of lumps are benign [2]. Thus, there is a need for less invasive and cost-effective method(s) of diagnosis that avoid painful and invasive surgical biopsy. The modality should also be acceptable to the patient, accurate, easy to apply, reproducible, and must not require too many preparations [2]. The incisional or excisional biopsy is a well-accepted diagnostic method for breast lumps, but both procedures are traumatic and require operating theatre facilities [3].

Fine-needle aspiration (FNA) has become a routine part of the physical diagnosis of breast masses. It can be done with a 22-gauge needle, an appropriate-size syringe, and an alcohol preparation pad. The main utility of FNAC is differentiation of solid from cystic masses, but it may be done whenever a new dominant, unexplained mass is found in the breast [4]. There are many advantages of FNAC, as it avoids hospital admission, saves on preliminary biopsy, saves on frozen section, and allows patients to know the type of operation required beforehand. The patient's acceptance is high, as it gives a rapid diagnosis and can be carried out in outpatient services. Apart from mild bruising, no complications have been encountered. The false negative rate of FNAC for breast carcinoma is 0-10 %. The correct diagnosis by FNAC can be achieved in 80-95 % of cases [3].

Technical problems--such as limited cellularity, excessive air drying, and/or artifactual mechanical disaggregation--can potentially limit the interpretation and contribute to false-negative or false-positive diagnoses of malignancy, respectively [5]. However, FNAC results should always be correlated with clinical impression. Ultrasonography is an important method for resolving equivocal mammographic findings, defining cystic lesions, and demonstrating the echogenic qualities of solid abnormalities. It is also used to guide FNA, core needle biopsy, and needle localization of breast lesions [1]. Its findings are highly reproducible, and it has a high patient acceptance rate [1]. USG also has many advantages as it is non-invasive, painless, easily available, and harmless. Its main disadvantage is that it is operator dependent [6] and does not reliably detect lesions less than 1cm in diameter.

Methods

Records of all patients who presented to the general surgical department at TMC, with a clinically suspicious breast lump or mass between 2014 and 2017 were reviewed. The FNAC and histopathology reports were retrieved from the Department of Pathology at TMC. We retrospectively reviewed the FNA and USG reports of 42 patients, and the results were compared with histopathological diagnosis. Variables used in this study were age and the size of the lump. Aspiration was performed using a disposable 23-gauge needle and a 20cc syringe. Papanicolaou (PAP) and May-Grünwald-Giemsa (MGG) staining were performed on cytology smears.

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Haematoxylin and Eosin (H&E) staining was done on tissue specimens obtained from subsequent excisional biopsies to assess the histopathological features. Regarding diagnosis, FNAC outcomes were reported using the standard NHSBSP criteria (National Health Service Breast Screening Programme), and data were classified as malignant, benign, or indeterminate. Ultrasonography was done at the Department of Radiology, TMC, using a 7.5-MHz probe, and data were categorized according to the BI-RADS system.
ACR BI-RADS–US describes 7 assessment categories, as follows:
Category 0: Incomplete, Need Additional Imaging Evaluation and/or Prior Images for Comparison
Category 1: Negative
Category 2: Benign
Category 3: Probably Benign
Category 4: Suspicious. This category is reserved for findings that do not have the classic appearance of malignancy but are sufficiently suspicious to justify a recommendation for biopsy [10].
Category 5: Highly Suggestive of Malignancy
Category 6: Known Biopsy-Proven Malignancy [1].
Data were analyzed using SPSS (the Statistical Package for the Social Sciences).

Results

All 42 patients underwent FNA in the pathology department, and ultrasonography in the Radiology department, followed by definitive excisional biopsy in the General surgical department at TMC. All excised specimens were subjected to histopathological examination. The demographic profile is shown in (Table 1, Figure 1; the ages ranged from 23 to 85 years (Mean: 50.98 years). The highest rate (38%) was in the 46_55 years age group.

Table 1. Demographic profile of the 42 patients

Age (years)	***NO. of patient***	**%**
16 – 25	1	2.4%
26 – 35	3	7.14%
36 – 45	11	26.2%
46 – 55	16	38%
<56 YEARS	11	26.2%
Total	42	100%

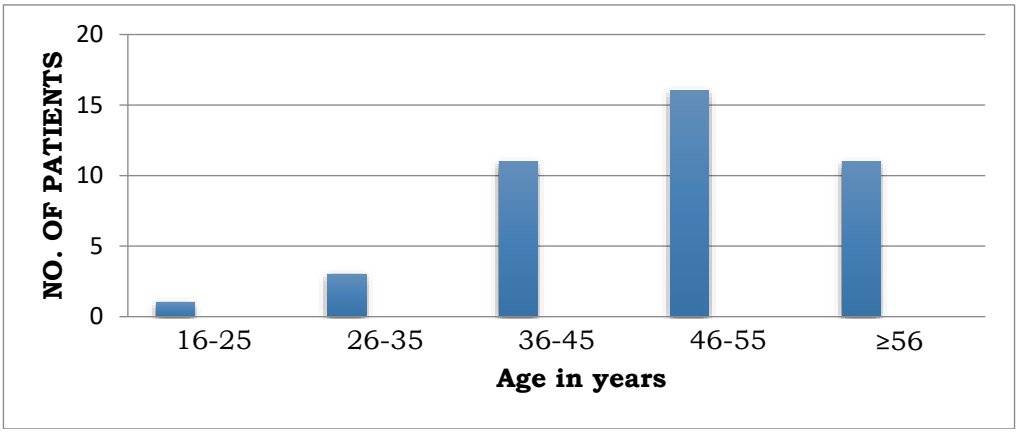

Figure 1. Demographic profile of the 42 patients.

Malignant and benign breast lump sizes

(defined by ultrasonography, Maximum dimension in cm) The highest percentage of lumps were (2-< 3cm) in size (45.2%).

Table 2. Malignant and benign breast lump sizes

Size of lump	***Benign***		***Malignant***		***Total***	
	No.	%	No.	%	No.	%
≤1 cm	0	0	0	0	0	0
1-<2cm	0	0	3	8	3	7
2-<3cm	2	.476	17	46	19	45.2
3-<4cm	2	.476	8	21.6	10	23.8
≥4cm	1	2.38	9	24.3	10	23.8
Total	5	12	37	88	42	100

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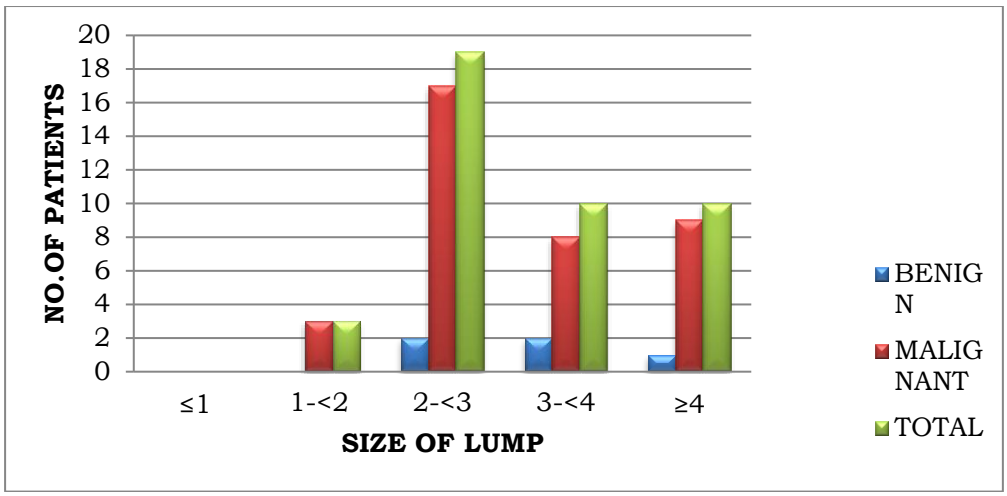

Figure 2. Breast lump size is defined by ultrasonography.

The final histopathological results of the 42 examined lumps are shown in (Table/Fig 3). Of the total 42 breast lumps, 5 (12%) were reported as benign, and 37 (88%) as malignant. Malignant lumps were highest in the 46-55 years age group (14 cases; 33.3% of the 42 patients).

Table3. Histopathology Results

Age group	***Malignant***		***Benign***		***Total***	
	No.	%	No.	%	No.	%
16-25	0	0	1	20	1	2.4
26-35	3	8	0	0	3	7.1
36-45	10	27	1	20	11	26.2
46-55	14	37.8	2	40	16	38.1
≥56	10	27	1	20	11	26.2
Total	37	88	5	12	42	100

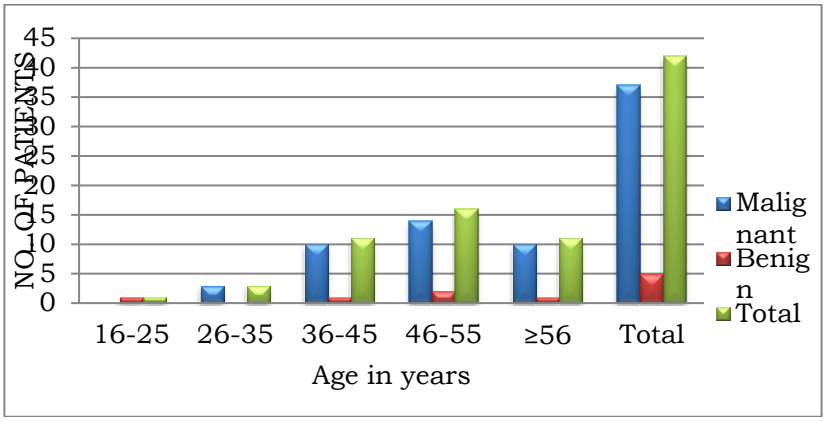

Figure 3. Histopathology Results

Table 4. Histopathology Results (Pathological Types) of 42 breast lumps.

Pathological type	***≤ 34 years of age***		***≥ 35 years***		***Total***	
	No.	%	No.	%	No.	%
Benign proliferative disease.	1	25%	0	0	1	2.4%
Fibrocystic disease.	0	0	4	10.5%	4	9.5%
DCIS.	1	25%	3	7.8%	4	9.5%
IDC	2	50%	28	73.7%	30	71.4%
IMC	0	0	1	2.6%	1	2.4%
Undifferentiated carcinoma	0	0	2	5.3%	2	4.8%
TOTAL	4	9.5%	38	90.5%	42	100%

The highest rate was for invasive ductal carcinoma (IDC): 30 lumps (71.4%) [Figure-4]. Four (9.5%) were Ductal carcinoma in situ. Four (9.5%) were fibrocystic disease. Two cases were reported as undifferentiated carcinoma, one as Squamous cell carcinoma, and one as mucoid adenocarcinoma. FNAC result: Of the total 42 breast lumps examined, 9 (21.4%) were reported as benign,32 (76.2%) as malignant, and 1 (2.38%) as

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Indeterminate, as shown in Table 5/Fig 5. The final histopathology result for the indeterminate case was invasive ductal carcinoma. An indeterminate report means the patient should undergo further workup, such as core needle biopsy or excisional biopsy.

Table5. Results of FNAC.

Age group	***Malignant***		***Benign***		***Indeterminate***		***Total***	
	No.	%	No.	%	No.	**%**	No.	**%**
16-25	1	3.12	0	0	0	0	1	2.38
26-35	0	0	2	22.2	1	100	3	7.1
36-45	8	25	3	33.3	0	0	11	26.2
46-55	13	40.6	3	33.3	0	0	16	38.1
≥ 56 years	10	23.8	1	11.1	0	0	11	26.2
Total	32	76.2	9	21.4	1	2.38	42	100

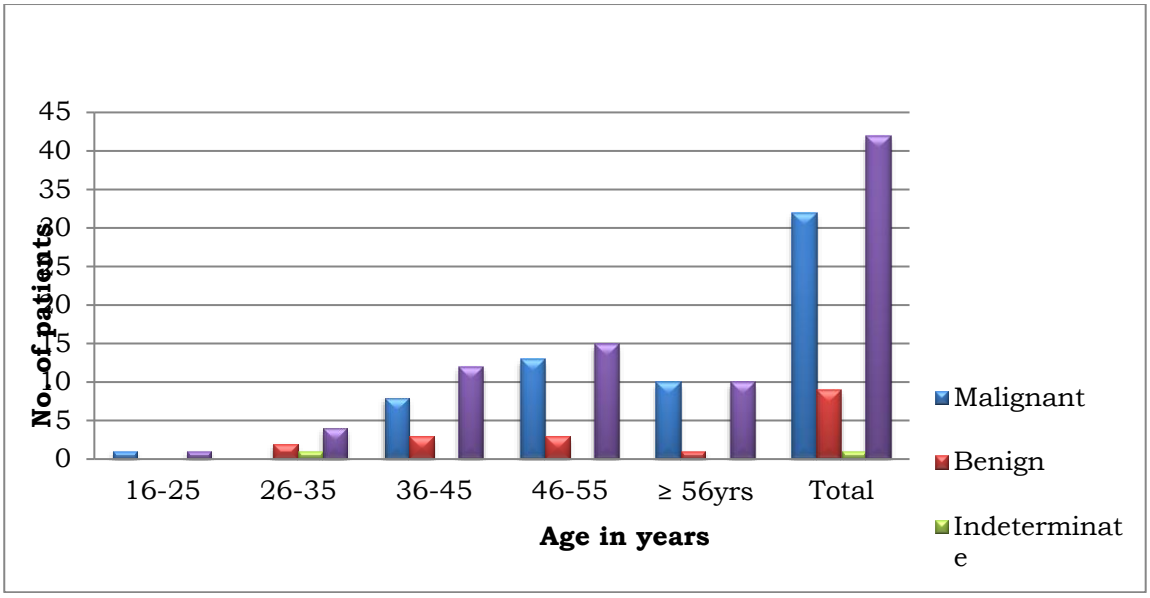

Figure 4. Result of FNAC

Table 6. FNAC vs. HPE Results (Histopathology as Gold Standard).

FNAC	***Histopathology***					
	Malignant		***Benign***		***Total***	
	No.	%	No.	%	NO.	%
Malignant	31	86.1	1	20	32	78
Benign	5	13.9	4	80	9	22
Total	36	87.8	5	12.2	41	100

The indeterminate result (1 case) was excluded.

After comparing FNAC with the final histopathological result (Table 6), we found 31 true positives, 4 true negatives, 1 false positive, and 5 false negative reports. Of the 5 patients where FNAC did not match histopathology, three showed fibrocystic disease with atypical hyperplasia, and 2 patients showed benign proliferative breast disease on FNAC; all showed invasive ductal carcinoma on histopathology. The patient with the false positive result showed malignant cells on FNAC but had fibroadenoma on histopathology.

USG Result for 42 breast lumps

Results were categorized according to the BI-RAD system, taking age into account (≤ 34 years and ≥ 35 years).

Table 7. USG Result for 42 breast lumps,

USG result	***Malignant***		***Benign***		***Indeterminate***		***Total***	
	No.	%	No.	%	No.	%	No.	%
≤ 34 years	2	6.7	1	25	1	12.5	4	9.5
≥ 35 years	28	93.3	3	75	7	87.5	38	90.5
Total	30	71.4	4	9.5	8	19	42	100

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Of the total 42 breast lumps examined, 8 (19%) lumps were reported as Indeterminate (BIRAD 0). 4 (9.5%) as benign (BIRAD 2), and 30 (71.4%) as suspicious malignant (BIRAD 4).

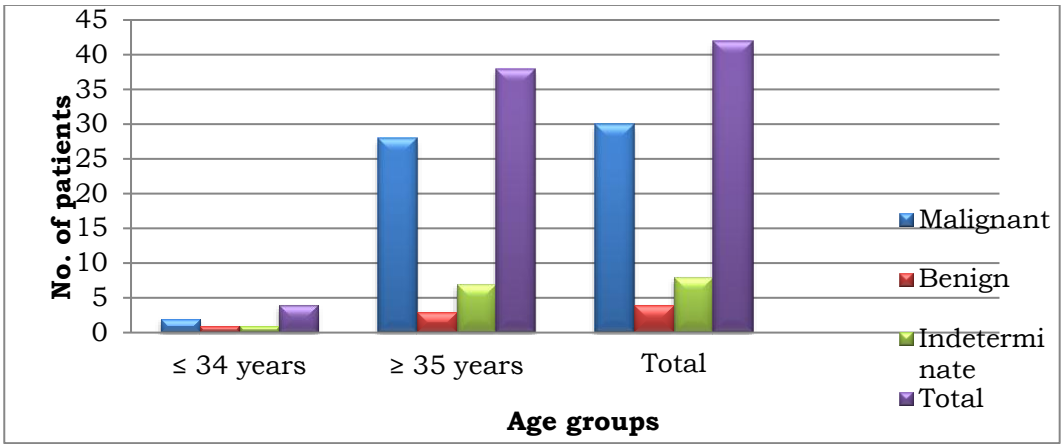

Figure 5. Result of ultrasonography.

Table 8. USG versus HPE result (34 patients; 8 indeterminate cases excluded.

USG		***Histopathology***					
		Malignant		**Benign**		**Total**	
		No.	%	No.	%	No.	%
≤ 34 years	Malignant	2	66.6	0	0	2	66.6
	Benign	1	33.3	0	0	1	33.3
	Total	3	7.1	0	0	3	8.8
≥ 35 years	Malignant	27	90	1	__	27	79.4
	Benign	3	10	0	0	3	8.8
	Total	30	88.2	1	__	30	88.2
USG result Overall	Malignant	29	87.9	1	__	30	88.2
	Benign	4	12.1	0	0	4	11.8
	Total	33	97	1	__	34	100

USG reports were analyzed by age group (≤ 34 years and ≥ 35 years), as shown in (Table 8), due to differences in USG performance related to breast density in these groups. Sensitivity of USG was higher for patients ≥ 35 years than for the younger patients (66.7% vs. 90%), positive predictive value was 100% for both groups. There was 1 patient with a false positive result and no true negative result, so the specificity and negative predictive value for ultrasonography could not be calculated.

Table 9. Comparison of FNAC and USG in diagnosing Malignant Breast Lumps.

	FNAC	**USG (overall)**
Sensitivity	86%	87.9%
Specificity	80%	__
Predictive value of positive result (malignant lesions)	96.9%	96.7%
Predictive value of negative result (benign lesions)	44.4%	__

The sensitivity of USG was slightly higher than that of FNAC (87.9% vs. 86%). However, the indeterminate rate was higher with USG (19% vs.2.38% respectively).

Discussion

A triple assessment consisting of clinical examination, mammography or USG, and FNAC or core needle biopsy is considered the gold standard in making a definitive diagnosis of breast lumps [25]. Palpable breast masses are a common problem in female patients. Diagnostic delays in breast cancer occur due to a generally low index of suspicion. The traditional diagnostic method of breast masses is excisional biopsy, which gives a precise diagnosis. Core-needle biopsy is definitely a robust and reliable diagnostic modality, but it carries disadvantages in terms of a longer turnaround due to the tissue processing time and patient

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discomfort during the procedure. FNAC has some advantages over core-needle biopsy: it uses a smaller needle, reducing the risk of hematoma and other rare complications, such as pneumothorax, and the delay until the date of the final diagnosis was shorter in the group with a cytological diagnosis positive for malignancy. This study aimed to assess the accuracy and reliability of FNAC and USG in diagnosing breast lumps, which could help us proceed towards definitive excisional surgery. In our study, the age ranged from 23 to 85 years (mean: 50.98 years). Peak incidence occurred in the 5th decade (46-55 years): 14 cases (37.8%) were diagnosed with breast cancer on histopathology, followed by 10 patients (27%) in the 36-45 years group. We found 10 cases (27%) more than 56 years and 3 cases (3%) in the 26-35 years group. Forty-six percent (17 cases) presented to the hospital with the lump size had already reached 2-<3cm (corresponding to T2 Stage).

Eight cases (21.6%) had a lump size of 3-<4 cm (also T2 Stage). Nine cases (24.3%) had a lump size more than 4 cm (T2-T3 Stages). Higher stage at presentation has a direct influence on the prognosis of the disease. The most common pathology was invasive ductal carcinoma (IDC): 30 cases (71.4%), which is in agreement with previous studies [1,11], which reported the incidence of IDC between 70-80%. Of these 28 cases were in patients more than 35 years, and 2 were in patients less than 35 years. The second most common pathology was ANDI (5 cases;11.9%), followed by DCIS (4 cases;9.5%). Our results are in agreement with previous studies [25,26], which reported the sensitivity of FNAC ranges from 80% to 98%, and specificity up to 100% [26]. USG sensitivity ranges from 67%-97% with specificity around 100% [26]. FNAC sensitivity in our study was 86%, suggesting that about 14 of 100 having malignant lumps may be missed; this may depend on the experience and skill of the aspirator.

False positives of FNAC were less common than false negative results. In our study, the negative predictive value of FNAC was 44.4%, which means that the patient still has 66.6% chance of malignancy despite a negative result. This indicates that the negative FNAC result does not rule out malignancy, so additional investigations should be considered. Among the reported cases, the common lesion causing false negatives was atypical ductal hyperplasia. Reasons for false negative results include small or deep lumps, acellular aspirates from very hard lumps, hemorrhagic aspirates from vascular lumps, cystic lump aspirates, or sampling error. Sampling error can be minimized by proper localization and aspiration technique performed by an experienced cytologist. However, 96.9% positive predictive value means that a positive (malignant) FNAC result carries only 3.1% chance of a benign lesion; thus, the positive report of FNAC should be considered confirmatory. The sensitivity of USG for diagnosis of malignant breast lesions was 87.5%, suggesting that about 12.5 of 100 malignant cases would be missed. Thus, additional investigation is needed for benign USG reports. The positive predictive value was 96.7%; a malignant report can be considered confirmatory. Specificity and negative predictive value of USG could not be calculated due to no true negatives. USG sensitivity was slightly higher than that of FNAC (87.9% vs. 86%). These results suggest USG may be better than FNAC for ruling out the possibility of malignancy. However, the indeterminate rate was higher with USG (19% vs 2.38%).

Four breast masses were missed by USG (False negatives). In the eight cases with indeterminate USG reports, (one patient was aged ≤34 years, while the remaining seven patients were aged ≥35 years); FNAC correctly diagnosed five of these indeterminate cases; In the other 3, FNAC incorrectly diagnosed ANDI with atypical hyperplasia (histopathology showed malignancy). One indeterminate FNAC case was correctly diagnosed as malignant by USG. An additional important finding is that when we consider younger patients (≤ 34 years; 3 cases), 2 were correctly diagnosed by USG; 1 case was a false negative result. When considering patients (≥35 years; 30 cases), malignancy was missed in only 3 cases. Patient age affects USG accuracy, with generally higher accuracy in older patients [26]. Our study did not confirm this due to the small number of cases, fewer than 35 years. There are certain strong points in our study; First, Histopathology was used as the gold standard, which has been accepted internationally. Secondly, both diagnostic tools (FNAC and USG) were tested in the same study population. Limitations in our study are a small sample size, a small number of cases that proved benign on histopathology, as non-suspicious lumps are usually assessed on an outpatient basis, and the indeterminate cases were excluded from the sensitivity/ specificity calculation. The effectiveness of these diagnostic modalities depends on the experience and availability of tools, patient age, and the clinician's suspicion of the nature of the mass. Thus, both diagnostic tools should be considered complementary. Physicians should use their clinical findings and experience as the basis for choosing one or both.

Conclusion

Carcinoma breast continues to be a major threat to women's health worldwide. Diagnosis of breast cancer requires thorough clinical history and examination, along with the rational use of imaging modalities and tissue diagnosis. Breast ultrasound is an inexpensive, accessible, accurate, and dynamic tool for diagnosing breast lumps. However, it is operator-dependent and should be performed by an experienced radiologist. Considering patient comfort, lack of need for anesthesia, rapid analysis and reporting, reduced cost, and relatively fewer false positives, FNAC is an ideal initial diagnostic modality in breast lumps. FNAC and USG should be considered complementary; both techniques demonstrated high positive predictive value in diagnosing breast malignancy. Their sensitivity and positive predictive values were 86% and 96.9% for FNAC,

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and 87.5% and96.7% for USG, respectively. However, an excisional biopsy is needed for definitive histopathology before proceeding to definitive surgery.

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Ethical Approval
Ethical approval for this retrospective study was obtained from [University of Tobruk] Ethics Committee (No: [NBC:009.H.25.49], Date: [11/Sep/2025]. Informed consent was waived due to the retrospective design.

Conflicts of Interest
The author declares no conflicts of interest.

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