Validity of Ultrasound Guided FNAB for the Diagnosis of Breast Carcinoma
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ABSTRACT

Background: A number of biopsy techniques have been utilized to procure tissue samples from suspected malignant masses of breast. The availability and cost of these techniques varies but they are all associated with significant local trauma. Among them, the fine needle aspiration biopsy is a time-tested low-cost diagnostic test that has been in use for decades.

Objective: This study was conducted with an aim to establish the sensitivity, specificity, positive predictive value and negative predictive value of ultrasound-guided fine needle aspiration biopsy (FNAB) for diagnosis of malignancies of breast.

Materials & Methods: This descriptive cross-sectional study was conducted at Radiology Department, in alliance with the departments of Surgery and Pathology (outdoor patient and indoor patient) Ayub Teaching Hospital, Abbottabad from 1st May 2019 to 31 December 2019. Initially sixty patients were recruited however histopathology of ten patients were not available so they were excluded from final results. Data was collected from 50 females with suspected breast malignancy. The biopsy of breast mass using fine needle aspiration technique under ultrasound guidance was performed on each member of the cohort of fifty patient. To validate the result, each member underwent surgical biopsy (incisional/excisional) thereafter. The results of FNAB was compared with the histopathology reports to determine accuracy of FNAB.

Results: USG-FNAB was able to correctly diagnose 49 cases in 50 patients with an accuracy of 98%. 25 cases were declared as malignant while 25 cases were categorized as benign lesion. Out of the 25 negative cases, on histopathology 24 cases were correctly diagnosed while 1 case was false negative, on histopathology it proved to be invasive papillary carcinoma.

Conclusion: that FNAB is a key preliminary test for the diagnosis of the breast lumps, and when done under ultrasound guidance, the results show a significant correlation with the final histopathology report.

Keywords: Biopsy, Carcinoma, Histopathology, Fibroadenoma

INTRODUCTION

The fine needle aspiration biopsy (FNAB) is an economical, less invasive technique with negligible complications and its contraindications are almost non-existent.¹ Currently, the FNAB is suggested in patients with a suspicious (category IV) and highly suspicious (category V) breast mass according to the Breast Imaging Reporting and Data System (BI-RADS).² Additionally, breast ultrasound can be employed for the diagnosis of breast malignancies and has been interventional breast ultrasound is now becoming an accepted diagnostic modality among surgeons and radiologists.³ Biopsies of palpable masses under the guidance of ultrasound are generally more accurate than the palpatory method and ultrasound-guided biopsies are known to offer significant advantage over other stereo-tactic techniques.¹,⁴

Two mechanisms have been suggested whereby

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Techniques include the tru-cut needle and its later core needle version, image-guided “advance breast biopsy instrumentation (ABBI)”, vacuum assisted biopsy (VAB) devices such as the mammotome and minimally invasive breast biopsy. All these The main objective of all these biopsy techniques is to help obtain sufficient tissue sample for diagnosis with minimal possible entry wound. Keeping their limited availability and cost aside, these techniques are known to be associated with significant trauma. Thus it is important to agree upon a least invasive, cost-effective and least traumatic method of obtaining tissue sample for establishing pre-operative diagnosis which as as accurate as the open surgical biopsy of breast masses.

The main aim of this study was to demonstrate the sensitivity, specificity, positive predictive value and negative predictive value of ultrasound-guided fine needle aspiration biopsy (FNAB) for detection of malignancies of breast. The findings of FNAB were correlated with histopathology results (taken as gold standard for the purpose of this study). The results of study were assessed statistically and compared with several previous studies in terms of outcome. On the basis of results, conclusion were derived about the validity of Ultrasound guided FNAB in the diagnosis of breast malignancies.

MATERIAL AND METHODS
This study was descriptive cross-sectional, conducted at Radiology Department, in alliance with the departments of Surgery and Pathology (outdoor patient and indoor patient) Ayub Teaching Hospital, Abbottabad from 1st May 2019 to 31 December 2019. During the study period a total of 50 patients with suspected breast malignancies were studied. Purposive (non-probability) sampling technique was used to recruit patients into the study. TOSHIBA, Xario 100 with medium / high frequency range of probes was used for the purpose of ultrasound guidance during the needle aspiration biopsy procedure. 50 female patients presenting with palpable lump/thickening in breast or the lump found on imaging (ultrasound/mammography) were included in this study, according to inclusion & exclusion criteria. After history taking / initial physical examination and assessment by surgeon/gynecologist, these patients were referred to our department. We included only those patients in our study that subsequently underwent tissue sampling. The inclusion criteria involved all female patients with sonographically visible solid breast lump who were candidates of an open surgical biopsy (incisional / excisional) on the assessment of clinical and imaging findings, irrespective of the result of ultrasound guided FNAB. Women who had previously been diagnosed definitely of breast carcinoma, with mastitis, those who were not undergoing surgery for the breast mass and those who failed to give consent were excluded from the study. Study was started after taking permission from hospital ethical committee. Patients were selected from surgical out-patient and inpatient departments according to inclusion criteria. Confounding variables were controlled by adhering to the exclusion criteria. Bias was controlled by performing procedure in the presence of another senior radiologist. Brief history was taken and the breast was palpated carefully to identify the lump. Pre-FNAB sonogram was done to locate the lump and see whether it is solid or cystic. Skin overlying the lump was cleaned with spirit. The ultrasound probe was also cleaned with spirit and betadine solution for 10 minutes. The ultrasound probe of 7.5 MHZ was placed perpendicular to the skin and lump was brought in the central field of view. The 20ml plastic syringe with mounted 20G spinal needle inserted obliquely from one end of the transducer within the scan plane. Strenuous suction was applied and thorough sampling of the lesion was obtained by to and fro and fan like movements of needle under continuous real time monitoring. The suction was released before the needle is withdrawn. The aspirate was expelled immediately on glass slides and was dipped into the alcohol for fixation of cells. The slide was labeled showing name and patient control number and then was sent to pathology department for cytological examination. Results of cytological examination were collected from pathology department and were entered on Perfroma and were compared with the histopathology report of breast tissue after surgery. The data was entered and analyzed on SPSS version 10. 2 X 2 tables were used to calculate test performance characteristic of the Ultrasound guided FNAB.

RESULTS
Presenting mean age of the patients is 38.14±14.47 years (age range: 15-69). The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic efficacy for Ultrasound guided FNAB is determined by the following standard formulas. (Table-1)
Initially 60 patients were inducted in the study, however histopathology report of 10 patients is not available, and so only 50 patients are available for statistical analysis. USG-FNAB is able to correctly diagnose 49 cases in 50 patients with an accuracy of 98%. 25 cases are declared as malignant while 25 cases are categorized as benign lesion. Out of the 25 negative cases on histopathology, 24 cases are correctly diagnosed as true negative while 01 case is false negative, on histopathology it is proved to be invasive papillary carcinoma. Out of 25 malignant cases, 24 are infiltrating/ invasive ductal carcinoma and one invasive papillary carcinoma. The one false negative case is partly solid and partly cystic. It contained a variety of changes in it, ranging from cystic changes in ducts, apocrine metaplasia, atypical ductal metaplasia and ductal carcinoma in situ. Out of 25 benign lesions on FNAB, 13 are fibroadenoma, 4 are fibrofatty change, 5 are fibrocystic change, 1 tubular adenoma and 1 virginal hypertrophy. Maximum number of women with malignant disease fell in the age group 4150 years.

Figure-1: Fibroadenoma

Figure-2: Deep seated small lesion proved fibroadenoma

**DISCUSSION**

A palpable breast mass is a usually encountered diagnostic problem for general practitioner and surgeons. Confirmation of the diagnosis of breast cancer requires trucut needle biopsy or open biopsy followed by mastectomy for surgical management. On the other hand, the diagnosis can be established by frozen section, followed immediately by mastectomy. This approach is troublesome for the patient who is unsure about the outcome of result whether they awake from anesthesia with one breast or two. So the need of day is to establish a rapid method for conclusive diagnosis of breast lesions at outpatient department. This method must be definitive, imitable and tolerable to the patient and easily applicable in a crowded Outpatient Clinic without too much preparation or expensive apparatus. In this context, FNAC is a cost effective, less traumatic and fast procedure that can be achieved.

**TABLE No.1: Comparison of Ultrasound Guided FNAB Results with Final Diagnosis**

| POST SURGICAL HISTOPATHOLOGY | Malignant | Benign |
|-----------------------------|-----------|--------|
| TRUE POSITIVE               | 25        | 0      |
| FALSE NEGATIVE              | 1         | 24     |
| **TOTAL**                   | **26**    | **24** |

**TABLE No.2: Sensitivity, Specificity, Predictive Values and overall Accuracy of US Guided FNAB**

| Sensitivity | Specificity | PPV | NPV | Accuracy |
|-------------|-------------|-----|-----|----------|
| 96.15%      | 100%        | 100%| 96% | 98%      |

NPV= Negative predictive value. PPV=Positive predictive value.

Sensitivity = TP / TP + FN X 100 = 25 / 26 x 100 = 96.15%
Specificity = TN / TN + FP X 100 = 24 / 24 x 100 = 100%
Positive Predictive Value = TP/TP+ FP X 100=25/25x100 = 100%
Negative Predictive Value = TN/TN+ FN X 100 =24/25x100 = 96%
Diagnostic efficacy = TP+TN / TP+ TN +FP+FN X 100 = 98%.
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In Outpatient clinics. It has high acceptance rate by both clinicians and patients and can be used for evaluation of multiple breast nodule. FNAB is a well-grounded procedure to determine the nature of a breast lesion and can fulfill the above mentioned criteria. In our study 60 patients are included who are referred from surgical units, after taking informed consent. 50 patients are analyzed statistically on account of availability of histopathology reports. All these 50 members of this study cohort underwent Ultrasound Guided Fine Needle Aspiration Biopsy of the breast lump and subsequently followed by surgical biopsy. The FNAB results are compared with the histopathology results to find the accuracy of FNAB as compared to open biopsy. Patients are selected regardless of their occupation, financial status or religion. Each participant included in this study was an admitted case and underwent a surgical procedure, which varied from excisional/incisional biopsy to a modified radical mastectomy.

Fifty out of total 60 female selected for this study are in the age ranges from fifteen years to sixty-nine years with an average of thirty-eight and a half years. Ten patients with malignant disease are in the forty to fifty year group, six patients found in the thirty one to forty-year age group and six patients in fifty-one to sixty-year age group. No patient under the age of twenty-three was found with malignant tumour. Benign masses of breasts, however, are observed in patients of all ages, particularly amongst younger age patients. The largest numbers of participants with benign masses fell in the age group of twenty-one to thirty years.

In another study done by Khan S, the age distribution for fibroadenoma was 20-40 years, breast abscess at 15-40 years, ANDI (aberration of normal development and Involution) at 18-40 years and for gynecomastia age range was 10-19 and 50-59 years, whereas malignant lesions of breast was commonly found in the age range of forties and fifties. Similar age distribution patterns noted in other studies done by Stephen MI et al and Panjvani SI et al.

The breast lump in this study is commonly found in upper outer quadrant, (twenty one Patients). Nine patients have lump in upper inner quadrant, eleven have lump in lower outer quadrant, two in lower inner quadrant and seven in retroareolar region. This is comparable to the study by Hussain, which also found maximum number of breast lumps in upper outer quadrant.

The commonest pathology found in our patients among benign pathologies are fibroadenoma in thirteen patients. Fibrocystic disease is noted in five patients and four patient show Fibrofatty changes. The malignant lumps are found in twenty-six patients. In the study done by S khan et al the commonest lesions of the breast were benign breast disease, found in 93.2% whereas malignant lesions were infrequent only 6.8%. Among benign breast diseases, the fibroadenoma was the commonest (32.57%), second commonly found benign lesion was breast abscess (24.19%) followed by ANDI (Aberration of Normal Development and Involution) which was 16.63% and only 11.34% of them were gynecomastia. In his study, malignant lesions were 6.80%. Similar findings were noted in studies of Yusuf I et al and Stephen MI et al.

As we have already mentioned, the main objective of our study is to find the diagnostic relationship between fine needle aspiration biopsy and the histopathology of the breast lump. In other words, how reliable and accurate is FNAB in detecting breast diseases which can assist the treating doctor to take an informed decision about the surgical options. The apparent advantages of FNAB are fast and cheap, out-patient's procedure, not requiring anesthesia, and imitability without much discomfort to the patient. However sometimes complications do occur, which include post procedure pain or the formation of a hematoma and later on infection or rare chance of tumor seeding along the tract of needle. However, the needles used now a days are of good quality so this complication is even less likely. Few limitations of FNAB are also present, in terms of its inconclusiveness if the aspirate is not enough, either due to interventionist lacking experience or inconspicuous or deeply seated lesion. Different needle maneuvers may be needed in some patients and it can be difficult to diagnose unusual tumors. Another limitation is inability to, classify and grade the tumor as it is cytological study. If the aspirate is from the necrotic component of tumour then diagnosis might be out of question.

There are some apparent advantages of FNAB (aside from the general ones) in relation to breast pathologies. Amongst such benefits include lower number of false positives results for discrimination between benign and malignant masses and use of
FNAB as a therapeutic procedure of simple breast cysts. Moreover, quite often the malignancy related to the recurrence of carcinoma can be detected. Risks, on the other hand, include observance of false positive result in cases of atypical epithelial hyperplasia, atypia of ductal epithelium in a cyst and papillary lesions.

A small or complex proliferative lesions or tumors with large necrotic components can give false negative results. Malignant tumour with low grade potential also carry a risk of false negative result. However, in one of the study, Muhammad E et al' found that in comparison to the core biopsy, FNAC from palpable breast lesions tend to present higher NPV( negative predictive value) for diagnosing malignant lesion and recurrent local disease (88% for FNAC and 70% for core biopsy).

Using the statistical concept of Sensitivity to establish the accuracy of the positive results, if the results from FNAB is positive, it would indicate that disease is present. In contrast, the Specificity refers to the accuracy of the negative results. In this study, since all the patients came with a prior presentation of breast mass, Specificity, in relation to correct identification of disease free patients, cannot be measured. Given the structure of this study and the patients chosen, and since the Specificity of FNAB as a whole, cannot be determined, we look at Specificity of FNAB as a diagnostic test for malignant lesions. In other words, our results demonstrate the Specificity of FNAB as test for the diagnosis of carcinoma in a breast lesion.

The Positive Predictive Value of a procedure reflects the probability of having a disease when the results of such procedure comes positive for the underlying disease of interest. The Negative Predictive Value, reflects the probability of not having a disease when the results of such procedure for the underlying disease of interest comes negative. Given that there are no true negatives in our study, it is not possible to calculate the Negative Predictive Value. Similar to the treatment for the Specificity, we have calculated the Negative Predictive Value of FNAB in the presence of breast lesions.

In our study, there were 25 true positives i.e. positive for malignancy, one false negative, 24 true negatives i.e., negative for malignancy and no false positives. The Sensitivity and Positive Predictive Value of FNAB for this study is calculated as 96.2% and 100%, respectively.

Specificity and the Negative Predictive Value for malignancy are calculated as 100% and 96%, respectively.

The value of Sensitivity of FNAB in our study i.e. 96% is comparable to that in other similar studies. An absolute value of 93.5% is obtained in the study by Muhammad E et al.' for FNAC and 86.1% for core trucut needle biopsy. In another study Madubogwu CI' who subclassify the breast lesions on FNAC and histopathology, showed the sensitivity for FNAC was 90%. However, Alatise' et al., in Ibadan and Yusuf I et al. recorded lower sensitivity than that obtained in our study. These values of our study are still much higher than >60% for specificity and > 80% for sensitivity recommended by NHSBSP of Britain. The UK NHSBSP suggested a minimum threshold for breast cytology performance as thus: Absolute sensitivity >60%, complete sensitivity >80%, full specificity >55%, PPV >98%, FNR <6% and FPR <1%.

For comparison of the results of the Positive and Negative Predictive Value, we find that Obaseki DE et al.', in his study of 103 patients determined the positive predictive value for malignancies 100% with a false positive rate of 0%. In a larger study of 1,162 patients done by Yusuf I et al.' on correlation of FNAC and histopathology reports, Positive Predictive Value was determined at 97.7% and Negative Predictive Value at 90.8%.

In the light of above mentioned discussion, it is evident that results of our study are compare favourably with those of previous studies reported in the literature. However, there is some variability in the values in some of the studies, we feel that the most probable reason is related to use of ultrasound guidance for FNAB which has resulted in reduction of insufficient aspirates and hence improved the diagnostic yield. Houssami N, et al. stated in his study that absolute sensitivity (proportion of all cancers with c5 category cytology) is higher for US guided FNAB than for freehand FNAB, this is mainly due to difference in insufficient aspirates. US guided FNAB resulted in 13.6% less insufficient aspirates than free hand FNAB.

CONCLUSION
We conclude that FNAB from breast lump serves as a simple, rapid, cost effective and accurate early diagnostic investigation before surgical management. Diagnosis of breast lesion using FNAB should be practiced as a routine procedure.
in our center as there is a high degree of correlation with histopathologic findings. In the presence of budget constraints and personnel shortage, hospitals are required to demonstrate even great cost-effectiveness in the diagnosis of breast lesions. It is an accurate method to differentiate between benign and malignant breast lesions. The triple diagnostic approach which include use of FNAB together with clinical and mammographic findings can decrease the possibility of over-diagnosis or under-diagnosis.

REFERENCES

1. Houssami N, Ciato S, Ambrogetti D, Catarzi S, Risso G, Bonardi R. FlorenceSydney Breast Biopsy Study: sensitivity of ultrasound-guided versus freehand fine needle biopsy of palpable breast cancer. Breast Cancer Res Treat 2005;89:55-9.

2. Kluttig A, Trocchi P, Heinig A, Holzhausen HJ, Taeger C, Hauptmann S, et al. Reliability and validity of needle biopsy evaluation of breast abnormalities using the B-categorization design and objectives of the Diagnosis Optimisation Study (DIOS). BMC Cancer 2007; 7: 100-05.

3. Mesurrolle B, Bining JH, El Khoury M, Barhdadi A, Kao E. Contribution of Tissue Harmonic Imaging and Frequency Compound Imaging in Interventional Breast Sonography. J Ultrasound Med 2006;25:845-55.

4. Dillon MF, Hill AD, Quinn CM, O’Doherty A, McDermott EW, O’Higgins N. The Accuracy of Ultrasound, Stereotactic, and Clinical Core Biopsies in the Diagnosis of Breast Cancer, With an Analysis of False-Negative Cases. Ann Surg 2005;242:701-7.

5. Aziz M, Ahmad N, Zahid J, Faizullah, Aziz M. Comparison of FNAC and open biopsy in palpable breast lump. J Coll Physicians Surg Pak 2004;14:654-6.

6. Ahmed I, Nazir R, Chaudhary MY, Kundi S. Triple assessment of breast lump. J Coll Physicians Surg Pak 2007;17:535-8.

7. Muhammad E, Roshdi A, Osman S. Validity of fine needle aspiration cytology in diagnosis of breast lumps in upper Egypt. Egypt J. Med. Lab. Sci., Mar. 2012; 21(1):69-81.

8. Khan S, Kapoor AK, Khan IU, Shrestha GB, Singh P. Prospective Study of Pattern of Breast Diseases at Nepalgunj Medical College (NGMC), Nepal. Kathmandu Univ Med J (KUMJ). Apr-Jun 2003;1(2):95-100.

9. Stephen MI, daye SF, Raphael S, palpable breast masses in a tertiary institution of South Nigeria; fine needle aspiration cytology versus histopathology: A correlation of diagnostic accuracy. Niger J Clin Res 2018;7:43-7.

10. Panjvani S, Parikh BJ, Parikh SB, Chaudhari BR, Pate KK, Gupta GS et al. Utility of fine needle aspiration cytology in the evaluation of breast lesion. J Clin Diagn Res. 2013 Dec; 7(12): 2777-2779.

11. Hussain MT. Comparison of fine needle aspiration cytology with excision biopsy of breast lump. J Coll Physicians and Surg Pak 2005;15:211-4.

12. Yusuf I, Atanda AT. Validity of fine needle aspiration cytology of the palpable breast lesions: A teaching hospital experience. Niger J Basic Clin Sci 2014;11:36-40.

13. Madubogwu CI, Ukah CO, Anyanwu SNC, Chianakwana GU, Onyiaorah IV and Anyiam DCD Subclassification of breast masses by fine needle aspiration cytology. Eur J Breast Health. 2017 Oct; 13(4): 194-199.

14. Alatise OI, Lawal OO, Olasode OO, Adesukanami. Breast fine needle aspiration cytology in a Nigerian tertiary hospital. East central Afr J 2006;12:126-32.

15. Non-operative diagnostic sub-group of the National Co-ordinating Group for Breast Screening Pathology. Jun, 2001. Guidelines for non-operative diagnostic procedures and reporting in breast cancer screening; pp. 1822. NHSBSP-Publication No. 50. [Google Scholar]

16. Obaseki DE, Olu-Eddo AN, Ogunbiyi JO. Diagnostic accuracy of fine needle aspiration cytology of palpable breast masses in Benin City, Nigeria. West Afr J Med 2010;29:259-62.