Original Research Article

Comparative Evaluation of FNAC and USG Breast with Core Needle Biopsy in the Diagnosis of Malignant Breast Lesions: A Prospective Observational Study

Dr. Swani Bhagat[1], Dr. Sheema Sheikh[2], Dr. Atul Choudhary[3]

[1]MBBS, MD Pathology Government Medical College, Srinagar
[2]Professor, Department of Pathology, Government Medical College, Srinagar
[3]MBBS, MD Medicine ASCOMS, Jammu

Corresponding Author: Dr Swani Bhagat

ABSTRACT

Background: There is no doubt that breast cancer is the most frequently diagnosed life-threatening cancer in women and a significant cause of cancer death among women in both developing and developed nations. Using breast imaging-reporting and data system (BI-RADS) classification and breast core needle biopsy (CNB) results, we compared the diagnostic efficacy of FNAC and ultrasonography breast in separating malignant from benign breast masses.
Methods: After getting the approval from the Institutional Ethical Committee, the present prospective cross-sectional study was conducted in the Department of Pathology, Government Medical College, Srinagar (tertiary care hospital), Kashmir, India over a period of 2 years (July 2019 to June 2021).
Results: With a mean age of (45.4±13.4) years, the age incidence among the 108 individuals ranged from 22 to 85 years, with the most common age group for breast lumps to occur being (30-39) years. Both FNAC and USG breast were compared to CNB (gold standard), they both had sensitivity and specificity values of (94.57%, 100%) and (95%, 50%), respectively.
Conclusion: When FNAC and USG breast were compared to CNB, the gold standard test, FNAC was found to be more reliable and accurate for the identification of malignant breast lesions. However, when these two tests were utilised in tandem, a better outcome and diagnosis could be achieved.

Keywords: Ultrasonography, FNAC, Core needle biopsy, Breast malignancy

INTRODUCTION

Breast cancer refers to cancers originating from breast tissue, most commonly from the inner lining of milk ducts or the lobules that supply the ducts with milk. There is no doubt that breast cancer is the most frequently diagnosed life-threatening cancer in women and a significant cause of cancer death among women in both developing and developed nations.[1,2] All regions of India have experienced an increase in the yearly incidence of breast cancer of 0.5-2 percent, with the younger age groups (45 years) experiencing the greatest increase.[3] Breast cancer is believed to be the second most prevalent cancer in Kashmir (16.8%), only second to colorectal cancer in women.[4] It can strike at any age, but is uncommon in people under the age of 25 and above the age of 80, with the peak incidence occurring between the ages of 45 and 60. In comparison to men, women experience breast cancer more than 200 times more frequently.[5]A thorough history, clinical breast examination, imaging techniques, and tissue diagnosis should all be used to

evaluate breast masses. Even if the final diagnosis is determined by a histological study of the removed tissue, routine breast lump excision would be illogical because up to 80% of lumps are benign.[6]

The primary way used to reduce mortality is early diagnosis, with conventional mammography and breast ultrasonography being the most popular techniques. To prevent surgical overtreatment of breast lesions with questionable radiological characteristics, pathologic examination is crucial. The most popular methods for material sampling are core biopsy (CNB) and fine needle aspiration cytology (FNAC).[7] More than ten years ago, emphasis was placed on the pre-operative diagnosis in the assessment of breast lesions by using triple assessment, which entails multidisciplinary cooperation between radiologist, surgeon, and pathologist. In this context, the American College of Radiology developed a standardized format and terminology known as the breast imaging-reporting and data system (BI-RADS). The most crucial section of an imaging report is the BI-RADS. In this system, every report must begin with an explanation of the breast's general make-up. The higher number in BI-seven RADS's categories, which range from 0 to 6, indicates the presence of malignancy.[8,9] Particularly in our area, there is little comprehensive research on the accuracy of FNAC and ultrasonography and their BI-RADS categorization in separating malignant from benign breast masses. We therefore sought to explore the efficacy of FNAC, USG and the associated BI-RADS ratings based on pathology results in the diagnosis of breast cancer.

MATERIAL AND METHODS
After getting the approval from the Institutional Ethical Committee, the present prospective cross-sectional study was conducted in the Department of Pathology, Government Medical College, Srinagar (tertiary care hospital), Kashmir, India over a period of 2 years (July 2019 to June 2021).

The total number of cases with breast lesions including the CNB, excisional biopsy, lumpectomy and MRM were 515 out of which 108 cases of the breast lesions who came to us as core needle biopsy (CNB) were included in our study as per the laid down criteria:

Inclusion Criteria
1. Patients suspicious of breast carcinomas on USG breast and clinically.
2. Patients having unsatisfactory FNAC reports and advised for core needle biopsy.

Exclusion Criteria
1. Benign breast lesions.
2. History of bleeding diathesis
3. History of allergic reaction to lignocaine
4. Recurrent/ histopathologically known cases of carcinoma breast.

The clinical history and the findings of physical examination of the patients were recorded. The results of the three major investigations i.e., the ultrasonography which was represented in the form of BI-RADS score, Fine Needle Aspiration Cytology (FNAC) and Core Needle Biopsy (CNBC) were obtained and studied in detail. The findings of these three investigations were compared keeping core needle biopsy as the gold standard. The results were subjected to statistical analysis and following observations were made:

RESULTS
With a mean age of (45.4±13.4) years, the age incidence among the 108 individuals ranged from 22 to 85 years, with the most common age group for breast lumps to occur being (30-39) years. Specifically for the patients with benign breast lesions, the age of patients ranged from (23-59) years with the most affected individuals being fewer than 30 years old. And for the patients with malignant lesions, the age of patients ranged from (25-85) with the most affected age group being (30-39) years old. Out of 108 studied patients, only (2.78%)

individuals were men compared to (97.22%) females. Evidently, out of 108 patients, 60 (55.56%) had lesions on their right sided breast while as 47 (43.52%) patients had lesions on their left breast. However, one of the patients (0.93%) had bilateral breast involvement. The upper outer quadrant (UOQ) of the breast was most frequently affected by breast lesions. Out of 108 individuals, 54 (50%) had a lesion in the UOQ, 24 (22.22%) in the UIQ, 15 (13.89%) in the LIQ, 10 (9.56%) in the LOQ, and only 5 (4.63%) had a lesion in the central quadrant. Patients with breast lesions underwent ultrasound breast imaging (USG).

Table 1: BI-RADS Scoring of the Breast Lesions

BI-RADS Category	Freq.	Percent
Probably benign (BI-RADS-3)	9	8.34
Suspicious (BI-RADS-4)	70	64.81
Highly suggestive of malignancy (BI-RADS-5)	29	26.85
Total	108	100.00

The USG results of the lesions were graded using the BI-RADS scoring system, which identified 9 instances (8.33%) as Probably Benign (BIRADS 3), 70 cases (64.81%) as Suspicious (BIRADS 4), and 29 cases (26.85%) as highly suggestive of malignancy (BI-RADS 5).

Table 2: Calculation of Sensitivity and Specificity of USG(BI-RADS)

BI-RADS Category	Sensitivity	Specificity	Correctly Classified
≥ Probably benign (BI-RADS-3)	100.00%	0.00%	92.59%
≥ Suspicious (BI-RADS- 4)	95.00%	50.00%	91.67%
≥ Highly suggestive of malignancy (BI-RADS- 5)	29.00%	100.00%	34.26%

Lesions made with BI-RADS-3 were 100% sensitive but 0% specific, while as lesions made with BI-RADS-4 were 95% sensitive and 50% specific. Only 29% of BI-RADS-5 lesions were sensitive, but were 100% specific.

Table 3: Tabulation of FNAC diagnosis of the breast lesions

FNAC Diagnosis	Freq.	Percent
Benign	13	13.00
Suspicious	8	8.00
Malignant	79	79.00
Total	100	100

A fine needle aspiration cytology was performed on all 108 individuals, of them 78 (72.22%) had ductal carcinoma, followed by 6 individuals (5.54%) with mature adipose tissue, three patients (2.77%) with suspicious of malignancy, three patients (2.77%) with atypical ductal cells, two patients (1.85%) with abscess, two patients (1.85%) with fibrocystic disease, one patient (0.93%) each with amorphous debris, apocrine adenosis, fibroadenoma with atypia, and several other breast lesions. The diagnosis of the FNAC findings was categorized into four categories i.e. benign, malignant, suspicious of malignancy, and inconclusive. Out of 108 patients 13 were diagnosed as benign, 79 were diagnosed as Malignant, 8 were diagnosed as suspicious of malignancy and 8 as Inconclusive. However, inconclusive category was excluded from the analysis i.e. 8 out of 108 patients were excluded as these were non-contributory to the study. Most of the patients were diagnosed as malignant on FNAC.

Table 4: Calculation of Sensitivity and Specificity of FNAC

FNAC diagnosis	Sensitivity	Specificity	Correctly Classified
≥ Benign	100.00%	0.00%	92.00%
≥ Suspicious	94.57%	100.00%	95.00%
≥ malignancy	85.87%	100.00%	87.00%

The (sensitivity and specificity) of benign, suspicious and malignant cases on FNAC was respectively (100% and 0.00%), (94.57% and 100%) and (85.87% and 100%). The area under ROC curve was 0.9728 with CI 0.950-0.996. Out of 108 patients 81 (75%) were diagnosed with invasive ductal carcinoma (IDC), 11 patients (10.19%) as Invasive Lobular carcinoma (ILC), 3 patients (2.78%) as DCIS, another 3 patients (2.78%) as tubular carcinoma, 2 patients (1.85%) with mastitis and 1 patient (0.93%) each with adenomyoepithelioma, adenosis, benign phyllodes, fibroadenoma and other breast lesions.

Table 5: Tabulation of CNB diagnosis of the breast lesions

HPE Diagnosis	Freq.	Percent
Benign	8	7.41
Malignant	100	92.59
Total	108	100.00

CNB (HPE) investigation revealed that out of 108 patients, 8 (7.41%) had benign breast lesions and 100 (92.59%) patients had malignant lesion which was considered as final diagnosis of breast lesions.

Table 6: Correlation of BI-RADS and CNB(HPE) diagnosis			
BI-RADS Category	CNB Diagnosis		Total
	Malignant	Benign	
Highly suggestive of Malignancy (5)	29	0	29
Suspicious (4)	66	4	70
Probably benign (3)	5	4	9
Total	100	8	108

Out of 9 benign cases (BI-RADS-3), 5 (55.5%) were found to be malignant on CNB, while 4 (44.4%) were found to be benign. Similarly, out of 70 cases (BI-RADS-4), 66 (94.28%) were found to be malignant on CNB, while 4 (5.72%) were found to be benign. Finally, all 29 cases (BI-RADS-5) were found to be malignant (100%) on CNB.

Table 7: Correlation of FNAC and CNB Diagnosis			
FNAC Diagnosis	CNB DIAGNOSIS		Total
	Malignant	Benign	
Malignant	79	0	79
Suspicious	8	0	8
Benign	5	8	13
Total	92	8	100

All the 79 patients with malignant status on FNAC were also diagnosed as malignant with (100%) agreement on CNB. However, out of 13 benign cases on FNAC, only 8(61.5%) were diagnosed as benign and 5(38.5%) as malignant on CNB. All the 8 patients with suspicious FNAC diagnosis were tuned out to be malignant on CNB. With the p-value of 0.0132, the area under ROC curve for FNAC and BI-RADS was (0.9728, 95% CI: 0.94954-0.99612) and (0.80, 95% CI: 0.67578-0.93835) respectively

DISCUSSION
In the present study on 108 individuals with palpable lump in the breast, visited a surgical OPD where a thorough clinical and physical examination was performed and an ultrasonographic examination was done. According to the BI-RADS system of scoring, the lesion on ultrasonography was divided into six categories: 0, 1, 2, and 6. Category 6 was removed from the study since it was known from a biopsy to be malignant, whereas categories 0 and 1 had almost no chance of being cancerous. Our study focused on BI-RADS categories 3, 4, and 5, where the likelihood of cancer ranges from 0% to 95%. Following ultrasonographic evaluation, the patients underwent FNAC in the pathology department. Following the receipt of informed permission, the procedure was performed. After interpreting the FNAC findings patients were advised for a core needle biopsy of the breast lump for the final confirmation of the diagnosis. The age of studied patients was ranging from 22 years to 85 years with a mean age of (45.4±13.4) years, which is comparable to the results of previous studies.[10-12] Consistent with our study, Teck-Meng T et al47 in their study on 388 patients reported the age distribution of their patients was ranging from 22 to 86 years with an average age of 54 years.[10] Baloo M. Set al in their study reported the age range of such patients as (28-86) years with an average age of 51 years.[11] Similarly, Saha A et al reported that the age distribution of their patients was from 26-75 years, with an average age of 47.4 years, which is much similar to our study.[12] Breast carcinoma in men is a rare neoplastic disorder, making up less than 1% of all breast carcinomas.[13] In line with Saha A et al. (2% - Male and 98% - Female), and Rocha PD et al. (3.35% - Male and 96.65% - Female), our studied population was made up of 2.78% men and 97.22% women.[12, 14] Of all 108 patients, 55.56% patients had their lesions in the Right sided breast and 43.52% in Left sided breast which was in concordance with Saha A et al (52%- Right and 48%- Left).[12] However; contrary to our study, Risaldar AA et al and Takhellambam YS et al reported the predominance of left sided lesions in their patients.[15,16] Around 50% of the 108 patients had a lesion in the upper outer quadrant (UOQ), which is consistent with findings from other studies

like Saha A et al, who reported that 50% of patients had a lump in the upper outer quadrant, and A Aljajarrah et al, who reported that breast carcinoma most frequently affected the upper outer quadrant (UOQ) of the breast (53.4%).[12,17] The upper outside quadrant of the breast had the highest prevalence of lesions (45.2%), according to Rocha P D et al.[14]

Since its introduction in 1993, the BIRAD mammography reporting system has grown to be a crucial diagnostic tool for determining the likelihood of breast cancer.[18]In our investigation, BI-RADS-3 was reported for 9 patients (8.33%), BI-RADS-4 for 70 patients (64.81%), and BI-RADS-5 for 29 patients (26.85%). Six of the nine cases with a probable benign outcome (BI-RADS-3) were listed on FNAC as benign. On CNB, 4 of these 6 cases were determined to be benign, while the other 2 were determined to be malignant. Out of 108 patients who underwent FNAC examination as part of our study, 79 were classified as malignant, 13 as benign, 8 as suspected of malignancy, and 8 as inconclusive. Out of the 13 benign cases, 8 were confirmed benign, and 5 were classified as malignant on CNB. All of the malignant cases on FNAC were diagnosed as malignant on CNB. On CNB, all of the suspect and ambiguous cases from FNAC were classified as malignant. Accordingly, the FNAC's sensitivity and specificity for cases of malignancy, benignity, and suspicion were, respectively, (85.87% and 100%), (100% and 0.00%), and (94.57% and 100%). Eliminating the study's ambiguous findings and presuming that suspicious cytologic findings represented breast cancer, FNA detected cancer with a sensitivity of 94.57% and a specificity of 100%, which was consistent with a study by Risaldar A. A et al. in which FNAC had a sensitivity of 91.66% and a specificity of 100%.[15]Similar kind of findings were made by Ballo M.S. et al, who discovered that FNAC has a sensitivity of 97.5% and a specificity of 100%.[11] According to Bukhari, M.H. et al study, FNAC has a sensitivity of 80% and a specificity of 99%.[19] In their investigation, Yumjaobabu S T et al observed a sensitivity of 90.48% and a specificity of 100%.[20] In their investigation, Collaço, L.M. et al. found that FNAC has a 92.1% sensitivity and a 98.6% specificity.[21] Following the discovery of a palpable or radiologic abnormality of the breast, core needle biopsy is firmly established as the gold standard for tissue acquisition for pathologic examination. Most core needle biopsy samples are quickly identified as the pathologic correlate of a palpable or image-detected mass, such as fibroadenoma or invasive ductal carcinoma, or lesions associated with micro-calcifications, such as ductal carcinoma in situ (DCIS), sclerosing adenosis, etc. [22] Trucut biopsies can be carried out either subcutaneously or with the aid of an MRI or ultrasound. Patients can begin receiving neo-adjuvant chemotherapy after receiving a trucut biopsy evaluation without undergoing a mastectomy or excisional biopsy.[23]

The USG and FNAC findings' final diagnosis was supported by CNB in our investigation. ILC (10%), DCIS (2.77%), tubular CA (2.77%), malignant phyllodes (0.92%), and medullary CA (0.92%) were the next most frequent findings among all the malignant cases reported on CNB, with IDC accounting for 75% of all cases. The most frequent discovery in the benign group was mastitis (1.85%), which was followed by adenomyoepithelioma (0.92%), adenosis (0.92%), and other conditions. These results were in line with a research by Ballo MS et al., which had 124 patients who underwent concurrent FNAC and CNB procedures and had the malignancy confirmed by the latter.[11]They reported the most common malignancy found was IDC, followed by ILC.[11] Our study's findings indicate that FNAC and USG breast both have a high degree of diagnostic accuracy for finding breast cancers; however FNAC is still more trustworthy and accurate than USG breast. This is evident with the p-value of 0.0132, the area under ROC curve for FNAC and BI-RADS was (0.9728, 95% CI: 0.94954-

0.99612) and (0.80, 95% CI: 0.67578-0.93835) respectively. The test's efficacy is determined by how closely the significant value of diagnostic accuracy is to one, which ranges from 0.5 to 1. Values at 95% confidence interval (CI) ranged from 0.67578 to 0.93835 for USG and 0.94954 to 0.99612 for FNAC. For the test to be accurate, the p-value must be less than 0.05, and it turned out to be 0.0132, which is significant. Our research was consistent with that of Liew, P. L. et al, who performed FNAC on 400 patients and classified them into four categories using the quick stain method: inadequate, benign, atypical, suspicious, and malignant.[24] The subsequent alcohol-fixed Papanicolaou-stained slides, mammography, ultrasonography, and histopathological results were all associated with all of these cytological diagnoses. All of these cytological diagnoses were linked to later alcohol-fixed Papanicolaou-stained slides, mammographic, ultrasonographic, and histopathological findings. They reported that the ROC area for FNAC was 0.713, CI-95%, ranging from (0.686-0.740), p-value<0.001 and for USG the ROC area was 0.849, CI-95%, ranging from (0.774-0.924), P<0.001. This indicated that both FNAC and USG breast have good diagnostic accuracy but that, in their study, USG was more accurate than FNAC in the diagnosis of malignant breast lesions.

CONCLUSION

The present study revealed that for the preoperative pathological diagnosis of breast cancer in a developing country like ours, FNAC is an efficient, less complex, affordable, reliable, and relevant approach. Both the USG and the FNAC tests used to diagnose the malignant breast lumps have good sensitivity with a high degree of reliability, and the surgeons should take a positive (malignant) result from either test seriously. However, when both FNAC and USG breast were compared to CNB (gold standard), they both had sensitivity and specificity values of (94.57%, 100%) and

(95%, 50%), respectively. In conclusion, when FNAC and USG breast were compared to CNB, the gold standard test, FNAC was found to be more reliable and accurate for the identification of malignant breast lesions. However, when these two tests were utilised in tandem, a better outcome and diagnosis could be achieved.

REFERENCES

1. Walker RA, Hanby A, Pinder SE, Thomas J, Ellis IO (2012) Current issues in diagnostic breast pathology. *J Clin Pathol* 65: 771-785. [Crossref]
2. Bao J, Yu KD, Jiang YZ, Shao ZM, Di GH. The effect of laterality and primary tumor site on cancer-specific mortality in breast cancer: a SEER population-based study. PLoS One. 2014 Apr 16;9(4):e94815. doi: 10.1371/journal.pone.0094815. PMID: 24740002; PMCID: PMC3989248.
3. Chatterjee S, Levine PH, Senapati SN, Samanta DR, Panigrahi P (2019) Cancer Patterns in Odisha - An Important Mining State in India. Int J Cancer Clin Res 6:126. doi.org/10.23937/2378-3419/1410126
4. Qureshi MA, Salim SM1, Masood MA, Qureshi U, Ain Q, Jan Y et al. Epidemiology of cancers in Kashmir, India: an analysis of hospital data. Advances in Preventive Medicine Volume 2016; Article ID 189761
5. Ellis I.O, Lee. A.H.S, Pinder.S.E, Fletcher. C.D.M, et al. Diagnostic Histopathology of Tumors, volume 2, Fourth edition, Tumors of the breast, 2013, Elsevier, page 1081.
6. Malvia S, Bagadi SA, Dubey US, Saxena S. Epidemiology of breast cancer in Indian women. Asia Pac J ClinOncol 2017 Aug; 13(4): 289-295.
7. Capalbo E, Sajadidehkordi F, Colombi C, Ticha V, Moretti A, Peli M, Cosentino M, Lovisatti M, Berti E, Cariati M. Revaluation of breast cytology with pathologist on-site of lesions with suspicious sonographic

features. Eur J Radiol. 2013 Sep;82(9): 1410-5.

8. Spak DA, Plaxco JS, Santiago L, Dryden MJ, Dogan BE. BI-RADS® fifth edition: A summary of changes. Diagn Interv Imaging. 2017;98:179–90. [PubMed] [Google Scholar]

9. Bartolotta TV, Orlando AAM, Di Vittorio ML, et al. S-Detect characterization of focal solid breast lesions: a prospective analysis of inter-reader agreement for US BI-RADS descriptors. J Ultrasound. 2021;24:143–50. [PMC free article] [PubMed] [Google Scholar]

10. Tham TM, Iyengar KR, Taib NA, Yip CH. Fine needle aspiration biopsy, core needle biopsy or excision biopsy to diagnose breast cancer - which is the ideal method? Asian Pac J Cancer Prev. 2009 Jan-Mar;10(1):155-8. PMID: 19469645.

11. Ballo MS, Sneige N. Can core needle biopsy replace fine-needle aspiration cytology in the diagnosis of palpable breast carcinoma. A comparative study of 124 women. Cancer. 1996 Aug 15;78(4):773-7.

12. Saha A, Mukhopadhaye M, Das C Sarhar K et al. FNAC versus core needle biopsy: a comparative study in evaluation of palpable breast lesions. Indian Journal of Clinical and Diagnostic Research 2016 Feb; Vol. 10(2): EC05- EC08

13. Hoda SA, Brosi E, Koerner FC, Rosen PP. Rosen's Breast Pathology, 4th edition. Philadelphia, USA: Lippincot Williams & Wilkins; 2014

14. Rocha PD, Nadkarni NS, Menezes S. Fine Needle Aspiration Biopsy of Breast Lesions and Histopathologic Correlation. Acta Cytologica. 1997;41(3):705–12.

15. Risaldar AA, Begum Z, Alvi U. Correlation of FNAC with Histopathology of breast lesions. IP J Diagn Pathol Oncol 2020;5(4):375-380.

16. Takhellambam YS, Lourembam SS, Sapam OS, Kshetrimayum RS, Ningthoujam BS, Khan T. Comparison of ultrasonography and fine needle aspiration cytology in the diagnosis of malignant breast lesions. J Clin Diagn Res. 2013 Dec;7(12):2847-50.

17. Aljarrah A and Miller WR Trends in the distribution of breast cancer over time in the south of Scotland and review of the literature Ecancermedical science. 2014; 8:439

18. Richie AJ, Mellonie P. Radiological and Cytological Correlation of Breast Lesions with Histopathological Findings in a Tertiary Care Hospital in Costal Karnataka. Int J Contemp Med Res [IJCMR]. 2019;6(2):B1–4

19. Bukhari M.H, Akhtar. Z, Comparison of Accuracy of Diagnostic Modalities for Evaluation of Breast Cancer with Review of Literature. Diagnostic cytopathology 2009. 37. 416-24.

20. Yumjaobabu S T, Sunil S l, Opendro S S,Raju S, Bhubon S, TouSif K, Comparison of ultrasonography and fine needle aspiration cytology in the diagnosis of malignant breast lesions. Journal of clinical and diagnostic research, vol-7(12):2847-2850,2013

21. Collaço, L.M, Lima. R.S, Werner B, Torres L.F.B, Value of Fine Needle Aspiration in the Diagnosis of Breast Lesions. Volume 43, Number 4/July–August 1999.

22. Collins LC. Precision pathology as applied to breast core needle biopsy evaluation: implications for management. Mod Pathol. 2021 Jan; 34(Suppl 1):48-61.

23. Aebi S, Davidson T, Gruber G, Castiglione M; ESMO Guidelines Working Group. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol.2010;21 Suppl 5:v9-14

24. Pinder SE, Elston CW, Ellis IO. The role of pre-operative diagnosis in breast cancer. Histopathology. 1996 Jun;28(6):563-6.

******