Section: Pathology

Original Research Article

A PROSPECTIVE STUDY EVALUATING THE DIAGNOSTIC ACCURACY OF FNAC IN PALPABLE BREAST LUMPS IN WOMEN UNDER 40 YEARS OF AGE

Shivee Singh Dhaketa[1], G. Pavan Kumar[2], Prakhar Garg[3]

[1]Specialist, Esic Hospital & Medical College, Indore, Madhya Pradesh, India
[2]Assistant Professor, Indore, Madhya Pradesh, India
[3]Senior Resident, ESIC medical College, Indore, Madhya Pradesh, India

Received : 02/06/2025
Received in revised form : 16/07/2025
Accepted : 05/08/2025

Keywords:
FNAC, breast lump, diagnostic accuracy, histopathology, young women.

Corresponding Author:
Dr. Prakhar Garg,
Email: prakhargargps@gmail.com

DOI: 10.47009/jamp.2025.7.4.173

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (4); 920-924

ABSTRACT

Background: Palpable breast lumps are a common clinical presentation in women under 40 years of age. Although most are benign, distinguishing them from malignant lesions is essential for early intervention. Fine-needle aspiration cytology (FNAC) has emerged as a quick, cost-effective, and minimally invasive diagnostic tool, particularly in resource-constrained settings. Evaluating its diagnostic accuracy in younger women is crucial to guide appropriate clinical decision-making. The aim is to assess the diagnostic accuracy of fine-needle aspiration cytology (FNAC) in evaluating palpable breast lumps in women under 40 years of age, using histopathology as the gold standard. **Materials and Methods:** This prospective observational study was conducted at a tertiary care hospital and included 70 female patients aged 15 to 40 years presenting with palpable breast lumps. Each patient underwent clinical evaluation, FNAC, and subsequent histopathological confirmation through either excisional or core needle biopsy. FNAC findings were categorized as benign, suspicious, malignant, or inadequate. Diagnostic performance was assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy using SPSS version 26.0. **Result:** The majority of patients were aged 26–30 years (28.57%). FNAC reported 71.43% lesions as benign, 14.29% as malignant, 8.57% as suspicious, and 5.71% as inadequate. Histopathology confirmed 74.29% benign and 25.71% malignant lesions. Correlation between FNAC and histopathology was statistically significant ($p = 0.0004$). After excluding inadequate samples, FNAC demonstrated a sensitivity of 93.75%, specificity of 96.00%, PPV of 88.24%, NPV of 97.96%, and overall diagnostic accuracy of 95.00% ($p < 0.001$). **Conclusion:** FNAC is a reliable, accurate, and minimally invasive diagnostic tool for evaluating palpable breast lumps in women under 40 years of age. It effectively differentiates benign from malignant lesions and plays a pivotal role in early diagnosis and clinical management. Histopathology remains essential for confirmation, especially in cases with suspicious or inadequate cytology.

INTRODUCTION

Breast health is an essential component of women's overall well-being, particularly in the younger population where the majority of breast conditions tend to be benign but can cause considerable anxiety. In India, breast cancer has emerged as the most common cancer among women, overtaking cervical cancer in urban areas. Alarming trends in incidence and mortality have been noted not only in metropolitan centers but also in semi-urban and rural settings, highlighting a growing public health concern that requires early and efficient diagnostic approaches.[1] Although the peak incidence of breast cancer typically occurs in women over 40, a significant number of cases are being reported in younger women under 40 years of age.[2] These cases often present unique diagnostic challenges due to dense breast tissue, overlapping clinical features with benign conditions, and hormonal influences that can mimic malignancy on physical examination.

Fine-needle aspiration cytology (FNAC) has been widely accepted as a minimally invasive, cost-effective, and rapid diagnostic method for evaluating palpable breast lumps. Particularly in low-resource settings, FNAC plays a crucial role in the initial

ISSN (O): 2687-5365; ISSN (P): 2753-6556

triaging of patients and aids in early decision-making. It offers the advantage of being outpatient-based, requiring minimal equipment, and producing results within a short turnaround time. In women under 40, where breast lumps are predominantly benign, FNAC serves as a vital tool to differentiate between non-neoplastic and neoplastic lesions, thus preventing unnecessary surgeries and reducing patient burden.[3] Despite its widespread use, questions remain about its accuracy and reliability, especially in comparison with core needle biopsy or histopathology.

The anatomical and physiological differences in the breast tissue of younger women complicate the diagnostic process. Hormonal influences lead to increased glandular density and cyclical changes, often resulting in fibroadenomas and other benign proliferative disorders. These conditions can clinically resemble malignancies and require cytological confirmation to avoid over-treatment.[4] Moreover, due to societal awareness and breast health education, women in their 20s and 30s are now more likely to present early for medical evaluation of breast lumps, necessitating a reliable, accessible, and accurate diagnostic method.[5]

Breast cancer, although less common in younger age groups, tends to be more aggressive and presents with poorer prognostic factors when it does occur in this population. Delayed diagnosis in such cases can lead to rapid disease progression and lower survival rates. FNAC, by facilitating early and accurate diagnosis, contributes significantly to improved clinical outcomes. However, the success of FNAC is dependent on the expertise of the cytologist, adequacy of the aspirated material, and correlation with clinical and imaging findings.[6] As part of the "triple assessment" approach — which includes clinical examination, imaging, and cytology/biopsy — FNAC plays a central role, particularly in palpable lesions.

The limitation of FNAC lies in its inability to provide architectural patterns, which are often crucial for certain diagnoses like in-situ carcinomas or complex benign lesions. While core needle biopsy is often considered more definitive, especially in ambiguous or radiologically suspicious cases, FNAC remains valuable due to its speed and simplicity.[7] Moreover, in high-volume outpatient settings or in developing regions where histopathology and advanced imaging may not be readily available, FNAC serves as the frontline diagnostic tool. When interpreted by experienced professionals and correlated clinically, FNAC demonstrates high sensitivity and specificity in identifying both benign and malignant breast lesions.

In India, with a vast and diverse female population and increasing cancer burden, the role of FNAC in early breast cancer detection cannot be overstated.[8] National screening programs are still in the nascent stages, and most patients present with palpable lumps rather than being detected through routine imaging. This makes FNAC all the more relevant as it provides an opportunity for quick evaluation, categorization, and guidance for further intervention. Additionally, FNAC provides psychological relief to patients, especially when a benign diagnosis is rapidly confirmed.

A major advantage of FNAC is its ability to stratify lesions based on cellular morphology into benign, suspicious, malignant, or inadequate categories. This categorization allows clinicians to decide which patients require surgical excision, close monitoring, or further diagnostic workup.[9] In cases where FNAC yields indeterminate or non-diagnostic results, subsequent biopsy or imaging can be planned, thus avoiding both over-treatment and under-treatment. With appropriate training and quality assurance, the diagnostic utility of FNAC can be enhanced even further, making it a cornerstone of breast lump evaluation protocols.[10]

MATERIALS AND METHODS

This prospective observational study was conducted at a tertiary care hospital, after obtaining approval from the Institutional Ethics Committee. Informed written consent was obtained from all participants prior to enrollment in the study. The study included a total of 70 female patients under the age of 40 years who presented with clinically palpable breast lumps. Only women aged between 15 to 40 years were considered eligible. Exclusion criteria included women over 40 years of age, those with non-palpable lumps detected on imaging, patients with a history of recurrent breast lumps or prior breast surgery, and those who declined to undergo fine-needle aspiration cytology (FNAC) or histopathological confirmation.

Each patient underwent a thorough clinical evaluation, which included detailed history taking and physical examination of the breast lump. Characteristics such as lump size, consistency, tenderness, mobility, and the presence or absence of axillary lymphadenopathy were recorded. Additional information such as reproductive and menstrual history was also noted as part of the clinical profile.

FNAC was performed using a 22–24 gauge needle attached to a 10 mL disposable syringe. The procedure was carried out by an experienced pathologist using standard aseptic precautions. Multiple passes were taken when necessary to ensure adequate sampling. The aspirated material was expelled onto glass slides, air-dried or fixed in 95% ethanol, and stained using Giemsa and Papanicolaou stains. Cytological interpretation was categorized into four diagnostic groups: benign, suspicious, malignant, and inadequate/non-diagnostic.

All patients subsequently underwent either excisional biopsy or core needle biopsy, and the collected tissue specimens were sent for histopathological examination. Histopathological analysis served as the gold standard for diagnosis and allowed for the final classification of the breast lesions as benign or malignant.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

The data collected from clinical, cytological, and histopathological evaluations were compiled and analyzed using the Statistical Package for the Social Sciences (SPSS) version 26.0. The diagnostic efficacy of FNAC was determined by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy. A 2×2 contingency table was used to compare FNAC findings with the corresponding histopathological outcomes. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Age-wise Distribution of Patients [Table 1]

The age distribution of the 70 female patients included in the study revealed that the majority of patients were in the 26–30 years age group, accounting for 28.57% (n = 20). This was followed closely by the 21–25 years group, which comprised 25.71% (n = 18) of the total study population. The 31–35 year group contributed 17.14% (n = 12), while both the 15–20 years and 36–40 years categories accounted for 14.29% each (n = 10 each). These findings suggest that breast lumps are more frequently evaluated in women between 21 to 30 years, highlighting this age range as a period of higher clinical presentation and possibly greater health-seeking behavior in younger women.

Distribution of FNAC Diagnoses [Table 2]

Fine-needle aspiration cytology (FNAC) findings demonstrated that benign lesions were the most common, comprising 71.43% (n = 50) of cases. Atypical or suspicious cytological features were noted in 8.57% (n = 6), while malignant lesions constituted 14.29% (n = 10). Notably, inadequate or non-diagnostic samples were observed in 5.71% (n = 4), emphasizing the importance of technical skill and sampling adequacy. The predominance of benign FNAC findings aligns with existing literature, reflecting the higher frequency of benign breast diseases in women under 40.

Histopathological Diagnosis (Gold Standard) [Table 3]

Histopathological evaluation, which served as the gold standard, confirmed that benign lesions were present in 74.29% (n = 52) of patients, whereas malignant lesions were identified in 25.71% (n = 18). The slightly higher proportion of benign cases compared to FNAC reinforces the reliability of cytology in ruling out malignancy but also underlines the importance of confirmatory histopathology, especially in suspicious or inadequate samples.

Correlation Between FNAC and Histopathology [Table 4]

A comparative analysis between FNAC results and histopathological findings showed a high degree of correlation. Among the 50 cases diagnosed as benign by FNAC, 48 were confirmed benign and 2 were malignant on histology, indicating two false negatives. For the 6 suspicious cases, 2 turned out to be benign and 4 were malignant, showing that the suspicious category requires careful follow-up and biopsy confirmation. All 10 cases diagnosed as malignant on FNAC were confirmed malignant on histopathology, with no false positives in the malignant category. Among the 4 inadequate FNAC cases, histology revealed 2 benign and 2 malignant lesions, highlighting the diagnostic risk in non-conclusive cytology. The Chi-square test yielded a p-value of 0.0004, indicating a statistically significant association between FNAC results and histopathological outcomes. This suggests that FNAC is a reliable screening tool, especially when samples are adequate and diagnostic.

Diagnostic Accuracy of FNAC [Table 5]

After excluding the 4 inadequate samples, the diagnostic performance of FNAC was robust. The sensitivity, which reflects the ability of FNAC to correctly identify malignant lesions, was 93.75%, while the specificity, or the ability to correctly identify benign lesions, was 96.00%. The positive predictive value (PPV) was 88.24%, meaning that 88.24% of those diagnosed as malignant by FNAC were actually malignant on histopathology. The negative predictive value (NPV) stood at a high 97.96%, indicating strong reliability in ruling out malignancy when FNAC is benign. The overall diagnostic accuracy of FNAC was calculated at 95.00%, and the p-value was <0.001, underscoring that these results are statistically significant. These findings reaffirm that FNAC is an effective, minimally invasive, and accurate tool for the preliminary diagnosis of palpable breast lumps in women under 40 years of age.

Table 1: Age-wise Distribution of Patients (n = 70)

Age Group (Years)	Number of Patients	Percentage (%)
15–20	10	14.29%
21–25	18	25.71%
26–30	20	28.57%
31–35	12	17.14%
36–40	10	14.29%
Total	70	100.00%

Table 2: Distribution of FNAC Diagnoses (n = 70)

FNAC Category	Number of Cases	Percentage (%)
Benign	50	71.43%
Suspicious (Atypia)	6	8.57%
Malignant	10	14.29%

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Inadequate/Non-diagnostic	4	5.71%
Total	70	100.00%

Table 3: Histopathological Diagnosis (Gold Standard) (n = 70)

Histopathology Diagnosis	Number of Cases	Percentage (%)
Benign	52	74.29%
Malignant	18	25.71%
Total	70	100.00%

Table 4: Correlation Between FNAC and Histopathology

FNAC Diagnosis	Histopathology Benign	Histopathology Malignant	Total
Benign	48	2	50
Suspicious	2	4	6
Malignant	0	10	10
Inadequate	2	2	4
Total	52	18	70

p-value = 0.0004 (Chi-square test — statistically significant association between FNAC and histopathology)

Table 5: Diagnostic Accuracy of FNAC (Excluding Inadequate Cases)

Parameter	Value (%)
Sensitivity	93.75%
Specificity	96.00%
Positive Predictive Value	88.24%
Negative Predictive Value	97.96%
Diagnostic Accuracy	95.00%
p-value	<0.001

DISCUSSION

In the current study, the majority of breast lump cases were observed in women aged 26–30 years (28.57%), followed by the 21–25 age group (25.71%). These findings reinforce the observation that younger women—especially those in their reproductive years—are more likely to present with palpable breast masses. Similar age patterns have been documented in the literature. Pradhan et al,[11] (2024) and Tripathi et al,[12] (2022) noted a peak incidence of breast lumps in women aged 20–35 years, indicating that this demographic is both biologically and behaviorally predisposed to present early for breast lump evaluation. Kaleemuddin et al,[13] (2016) also reported the most cases in the 21–30 age bracket. The overlap across studies suggests a universal trend, potentially driven by greater awareness and health-seeking behavior in younger populations, combined with benign proliferative conditions that are hormonally influenced.

In our study, benign lesions were the most frequent finding on FNAC (71.43%), while malignant lesions accounted for 14.29%, and suspicious/atypical lesions for 8.57%. A small proportion (5.71%) were inadequate for diagnosis. These results align with those of Mitra and Dey (2016),[14] who reported a predominance of benign lesions in young women presenting with breast lumps. Vyas and Rai (2018),[15] similarly found over 70% of FNAC samples to be benign, indicating that most breast lumps in this population are non-malignant. However, the malignant rate of 14.29% in the current study is slightly higher than some reports—for instance, Pandey et al,[16] (2017) documented only 9.8% malignancies on FNAC. This difference could stem from variations in referral patterns, population characteristics, or cytopathological interpretation standards. Moreover, Verma et al,[17] (2021) emphasized that the rate of inadequate samples can be mitigated with proper technique and operator expertise, echoing our findings that inadequate sampling carries diagnostic uncertainty.

Histopathological analysis confirmed 74.29% benign and 25.71% malignant lesions in our study, underscoring its critical role as the gold standard. The slightly higher detection of malignancy on histopathology compared to FNAC highlights the occasional limitations of cytological methods. Shah et al,[18] (2020) and Garg et al,[19] (2007) noted similar trends, where FNAC underestimated malignant potential in a subset of cases that histopathology later confirmed. For instance, Garg et al,[19] (2007) reported 22% malignant lesions on histopathology, despite a lower initial impression from FNAC. The convergence of our results with these studies confirms the indispensable role of histopathology in suspicious or borderline cases and in those with inadequate FNAC samples.

Out of 50 cases diagnosed as benign on FNAC, 48 were truly benign, and 2 were false negatives, later confirmed malignant on histopathology. Among 6 suspicious cases, 4 were malignant, and 2 were benign, confirming the ambiguous nature of this category. All 10 malignant cases on FNAC were confirmed malignant, resulting in no false positives. The 4 inadequate FNAC samples had mixed outcomes—2 benign and 2 malignant—on histopathology. These findings resulted in a statistically significant correlation ($p = 0.0004$), reaffirming the diagnostic utility of FNAC. Similar levels of concordance have been reported in prior comparative studies. Willems et al,[20] (2012) and Verma et al,[17] (2021) highlighted that FNAC shows

ISSN (O): 2687-5365; ISSN (P): 2753-6556

strong concordance with histopathology when samples are adequate. The two false negatives observed in our study are consistent with the findings of Mitra and Dey (2016),[14] who also observed misclassification in benign-appearing aspirates. This supports the recommendation that all suspicious or atypical lesions, even if initially benign, require histological confirmation for accurate diagnosis.

Excluding the 4 inadequate samples, FNAC demonstrated high diagnostic efficacy in this study with a sensitivity of 93.75%, specificity of 96.00%, positive predictive value (PPV) of 88.24%, and negative predictive value (NPV) of 97.96%. The overall accuracy was 95.00%, with a p-value < 0.001, indicating statistical significance. These metrics are consistent with those reported by Kaleemuddin et al. (2016),[13] who observed an FNAC sensitivity of 92% and specificity of 98%. Likewise, Tripathi et al,[12] (2022) reported an FNAC accuracy of 94.5%, closely mirroring our results. The slight variation in PPV and NPV across studies is often due to differences in case selection, sample size, and operator experience. Pandey et al,[16] (2017) and Pradhan et al,[11] (2024) also supported FNAC as a reliable diagnostic tool, especially for triaging palpable breast lumps, citing similarly high diagnostic indices. Compared to core needle biopsy, which offers architectural detail, FNAC continues to be a preferable first-line investigation due to its simplicity, low cost, and quick turnaround, particularly in developing countries (Willems et al. 2012),[20] (Verma et al. 2021).[17]

CONCLUSION

Fine-needle aspiration cytology (FNAC) proves to be a highly accurate, minimally invasive, and cost-effective diagnostic tool for evaluating palpable breast lumps in women under 40 years of age. With high sensitivity, specificity, and strong correlation with histopathological findings, FNAC effectively aids in distinguishing benign from malignant lesions. It plays a vital role in early diagnosis, triaging, and guiding further management. However, histopathological confirmation remains essential in suspicious or inadequate cases to ensure diagnostic precision.

REFERENCES

1. Statistical analysis of breast cancer in India. Biospectrum India. 2019. Available from: https://www.biospectrumindia.com/views/21/15300/statistical-analysis-of-breast-cancer-in-india.html
2. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2021;71(3):209–49. doi:10.3322/caac.21660.
3. Beiki O, Hall P, Ekbom A, Moradi T. Breast cancer incidence and case fatality among 4.7 million women in relation to social and ethnic background: a population-based cohort study. Breast Cancer Res. 2012;14(1):R5. doi:10.1186/bcr3086. Available from: https://breast-cancer-research.biomedcentral.com/track/pdf/10.1186/bcr3086.pdf
4. Dikshit R, Gupta PC, Ramasundarahettige C, Gajalakshmi V, Aleksandrowicz L, Badwe R, et al. Cancer mortality in India: a nationally representative survey. Lancet. 2012;379(9828):1807–16. doi:10.1016/S0140-6736(12)60358-4.
5. Mathur P, Sathishkumar K, Chaturvedi M, Balasubramanian S, Santa Kumar D, Das P, et al. Cancer statistics, 2020: report from National Cancer Registry Programme, India. JCO Glob Oncol. 2020;6:1063–75. doi:10.1200/GO.20.00122.
6. Kharkwal S, Sameer S, Mukherjee A. Triple test in carcinoma breast. J Clin Diagn Res. 2014;8(5):OC09–11. doi:10.7860/JCDR/2014/9237.4971.
7. Watkins EJ. Overview of breast cancer. JAAPA. 2019;32(10):13–7. doi:10.1097/01.JAA.0000580524.95733.3d.
8. Sathishkumar K, Chaturvedi M, Das P, Stephen S, Mathur P. Cancer incidence estimates for 2022 & projection for 2025: result from National Cancer Registry Programme, India. Indian J Med Res. 2022;156(5&6):598–607. doi:10.4103/ijmr.ijmr_1821_22.
9. Guray M, Sahin AA. Benign breast diseases: classification, diagnosis, and management. Oncologist. 2006;11(5):435–49. doi:10.1634/theoncologist.11-5-435.
10. Mannello F, Tonti GA. Benign breast diseases: classification, diagnosis, and management. Oncologist. 2006;11(10):1132–4; author reply 1134. doi:10.1634/theoncologist.11-10-1132.
11. Pradhan M, Mandal A, Biswas BK, Sinha SK, Maity S. The role of fine-needle aspiration cytology in the evaluation of breast lumps. Cureus. 2024;16(10):e70748. doi:10.7759/cureus.70748.
12. Tripathi K, Yadav R, Maurya SK. A comparative study between fine-needle aspiration cytology and core needle biopsy in diagnosing clinically palpable breast lumps. Cureus. 2022;14(8):e27709. doi:10.7759/cureus.27709.
13. Kaleemuddin A, Suresh K, Reddy M, Nightingale F. A prospective study of the palpable lesions of the breast and the role of FNAC in these lesions with available histopathology methods. Trop J Pathol Microbiol. 2016;2(3):192–200. doi:10.17511/jopm.2016.i03.19.
14. Mitra S, Dey P. Fine-needle aspiration and core biopsy in the diagnosis of breast lesions: a comparison and review of the literature. Cytojournal. 2016;13:18. doi:10.4103/1742-6413.189637.
15. Vyas A, Rai NN. A study of role of FNAC in palpable breast lump. J Mahatma Gandhi Univ Med Sci Tech. 2018;3(1):1–6.
16. Pandey A, Mishra K, Singh Gaur B, Singh R. The diagnostic utility of FNAC in palpable lesions of breast at a tertiary care centre. Int J Med Res Rev. 2017;5(3):338–45. Available from: https://ijmrr.medresearch.in/index.php/ijmrr/article/view/844
17. Verma P, Sharma R, Sharma N, Gulati A, Parashar A, Kaundal A. Fine-needle aspiration cytology versus core-needle biopsy for breast lesions: a dilemma of superiority between the two. Acta Cytol. 2021;65(5):411–6. doi:10.1159/000517005.
18. Shah S, Suthar N, Gohil V, Patel J, Sachdev R. Prospective comparative study between fine needle aspiration cytology and core needle biopsy in diagnosis of palpable breast lumps. Eur J Mol Clin Med. 2020;7(7):4479–83. Available from: https://ejmcm.com/pdf_12141_7f79c4078d14d97fc5aa2ec7e852e3f1.html
19. Garg S, Mohan H, Bal A, Attri AK, Kochhar S. A comparative analysis of core needle biopsy and fine-needle aspiration cytology in the evaluation of palpable and mammographically detected suspicious breast lesions. Diagn Cytopathol. 2007;35(11):681–9. doi:10.1002/dc.20721.
20. Willems SM, van Deurzen CH, van Diest PJ. Diagnosis of breast lesions: fine-needle aspiration cytology or core needle biopsy? A review. J Clin Pathol. 2012;65(4):287–92. doi:10.1136/jclinpath-2011-200410.

ISSN (O): 2687-5365; ISSN (P): 2753-6556