

DIAGNOSTIC ACCURACY OF FNAC IN DIAGNOSING CLINICALLY SUSPECTED BREAST LESIONS TAKING HISTOPATHOLOGY AS GOLD STANDARD IN TERTIARY CARE HOSPITAL

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DOI: <https://doi.org/10.5281/zenodo.22121964>

Keywords: Fine Needle Aspiration; Cytology; Histopathology; Breast Cancer; Diagnostic Accuracy; Sensitivity and Specificity; Triple Assessment

Article History

Submission: 12 May 2025

Acceptance: 27 May 2025

Publication: 05 June 2025

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Abstract

Background: Palpable breast lumps represent frequent clinical presentation in surgical outpatient departments necessitating prompt reliable preoperative diagnosis. Fine Needle Aspiration Cytology (FNAC) is widely utilized as rapid minimally invasive triage tool. This study aimed to determine diagnostic accuracy of FNAC in diagnosing clinically suspected breast lesions taking histopathology as reference gold standard in tertiary care setting.

Methods: cross-sectional validation study was conducted at Department of Pathology Allama Iqbal Medical College / Jinnah Hospital Lahore comprising 166 female patients aged 12 to 65 years presenting of palpable breast masses. Enrolled participants underwent pre-operative cytological evaluation via FNAC followed by definitive histopathological examination of excision or core needle biopsy specimens. Standard operational criteria categorized lesions into benign or malignant. Diagnostic performance parameters—including sensitivity specificity positive predictive value (PPV) negative predictive value (NPV) and overall diagnostic accuracy—were computed using standard 2 x 2 contingency table.

Results: mean age of patient cohort was 39.75 SD 12.74 years. Histopathology confirmed malignancy in 33 cases (19.88% disease prevalence) and benign pathology in 133 cases. Cross-tabulation revealed 30 true positives 129 true negatives 4 false positives and 3 false negatives. FNAC demonstrated sensitivity of 90.91% specificity of 96.99% PPV of 88.24% NPV of 97.73% and overall diagnostic accuracy of 95.78%.

Conclusion: FNAC is highly accurate sensitive and specific diagnostic modality for evaluating palpable breast lesions. Its exceptional negative predictive value allows for confident conservative outpatient management of benign lesions while expediting definitive surgical care for malignancies.

INTRODUCTION

There is increase in number of female patients presenting of breast disorders in surgical outpatient department due to public awareness campaigns regarding breast cancers. most common presentation of breast lesion is mass palpated on clinical examination.¹ Both benign and malignant breast lesions can present of palpable breast mass therefore it is crucial to diagnose breast lesion as early as possible to relieve patient's anxiety in case of benign lesion and for early diagnosis of malignancy so that preoperative planning discussion and proper management can be started.²

Recently clinicians are using Triple assessment approach for pre-operative diagnosis of breast lesion which includes physical examination radiology (Mammogram and Ultrasound) and Fine needle aspiration cytology (FNAC) or core biopsy.³

Fine needle aspiration cytology (FNAC) is useful technique in diagnosing specific benign breast conditions that can be treated conservatively to avoid unnecessary open breast biopsy.⁴ Although open breast biopsy remains gold standard for confirming diagnosis but it is expensive time consuming invasive patient is more prone to mental stress and there is increase chance of malignant cell seeding.⁵ In contrast FNAC is simple rapid inexpensive minimally invasive less traumatic and outpatient based technique.⁶ It is easier to perform as compare to core needle or open biopsy.⁷ Furthermore diagnostic accuracy of FNAC if performed by expert cytopathologist has been reported to exceed 99% and this increase its reliability in breast lesion assesment.⁸

recent study conducted at Department of Pathology Ayub Medical College Abbottabad by Mohammad Sajjad Khattak et al in Pakistan shows that FNAC of breast lesion has sensitivity 83.33% specificity 100 % positive predictive value 100 % negative predictive value 99.27% and diagnostic accuracy of 99.30%. Prevalence of malignancy as 19.3%⁹

Whereas study conducted at Dr. Shankarrao Chavan Govt. Medical College Nanded by Pandit Sudarshan

S et al in India showed That FNAC of breast lesion has sensitivity 95.75% specificity 98.45% negative predictive value 98.45% and diagnostic accuracy of 97.72%.¹⁰

Another retrospective study conducted in department of pathology B&B Hospital by Sailuja Maharjan et al in Nepal showed sensitivity specificity positive predictive value (PPV) and negative predictive value (NPV) of FNAC in breast lesions as 90.6% 100% 100% and 78.57% respectively.¹¹

Study conducted at Lagos University Teaching Hospital Lagos Nigeria by Adetola Olubunmi Daramola et al showed absolute sensitivity 95.4% (>70%) complete sensitivity 99.2% (>90%) full specificity 88.9% (>65%) positive predictive value 99.6% (>99%) false-negative rate 0.8% .¹²

Aim of this study is to determine extent to which FNAC is accurate in making definitive diagnosis of malignant breast lesions before proceeding to major surgical excision Since reported literature has shown variability in sensitivity ranging from 83.33% to 95% and predictive value ranging from 98.45% to 78.57% so this study will help to confirm diagnostic accuracy according to prevalence in our population and it will ultimately help stratify patient for further clinical workup.

MATERIALS AND METHODS

This cross-sectional validation study was conducted at Department of Pathology Allama Iqbal Medical College / Jinnah Hospital Lahore over duration of four months (Jan - April, 2025) following ethical approval from Institutional Review Board (IRB) and College of Physicians and Surgeons Pakistan (CPSP). non-probability consecutive sampling technique was utilized to enroll total sample size of 166 female patients.

sample size was calculated using standard formula for diagnostic accuracy studies incorporating expected sensitivity of 83.3% specificity of 88.9% bound of error of 13% for sensitivity and 9% for

specificity 95% confidence interval and anticipated local malignancy prevalence of 19.3%. Female patients aged between 12 and 65 years presenting to surgical outpatient department and referred to FNAC clinic of palpable breast lesions were included in study. Patients of coexisting systemic infections such as tuberculosis pregnant females and individuals presenting of clinically advanced malignant masses demonstrating skin involvement or fixity to underlying structures were excluded from study. Prior to sample collection written informed consent was obtained from each patient or their legal guardian after explaining purpose benefits and procedural steps of study ensuring strict confidentiality of all personal health records. Fine needle aspiration cytology (FNAC) was performed on all enrolled patients under aseptic conditions by experienced cytopathologist using 10 mL disposable syringe fitted of 22/23-gauge needle. Multiple passes were made through lesion in different directions while applying continuous negative pressure. collected aspirates were smeared onto clean glass slides. Slides designated for Giemsa staining were air-dried whereas slides designated for Hematoxylin and Eosin (H&E) staining were immediately fixed in 95% ethyl alcohol for 15–30 minutes. Cytological smears were examined and classified as either positive for malignant neoplastic lesion or negative (benign) for malignant neoplastic lesion based on standard predefined cytological criteria.

RESULTS

These findings derived from evaluation of 166 female patients presenting of palpable breast lesions at Department of Pathology Allama Iqbal Medical College / Jinnah Hospital Lahore. primary objective of this investigation was to determine diagnostic accuracy of Fine Needle Aspiration Cytology (FNAC) in diagnosing breast lesions using formal histopathology of excision or core biopsies as gold standard reference. results are structured into demographic characterization cross-tabulation of

Following cytological evaluation all patients underwent definitive histopathological assessment via tissue excision biopsy or core needle biopsy depending on standard surgical management protocols. Tissue samples were fixed in 10% neutral buffered formalin processed through graded alcohol and xylene embedded in paraffin wax and sectioned at 4-micrometer thickness. tissue sections were stained of Hematoxylin and Eosin and evaluated independently by histopathology department. Histopathology served as reference gold standard and lesions were categorized as positive (malignant) or negative (benign) based on established histological criteria including architectural circumscription cytological pleomorphism cellularity mitoses necrosis and stromal invasion.

Data were compiled and analyzed using SPSS version 20.0 and Microsoft Excel. Continuous variables such as patient age were expressed as mean SD standard deviation while categorical variables including diagnostic outcomes were presented as frequencies and percentages. 2 x 2 contingency table was constructed by cross-tabulating FNAC findings against histopathological gold standard results. From this matrix True Positives (TP) True Negatives (TN) False Positives (FP) and False Negatives (FN) were quantified. Statistical parameters—including Sensitivity Specificity Positive Predictive Value (PPV) Negative Predictive Value (NPV) and overall Diagnostic Accuracy—were calculated using standard mathematical formulas.

cytological versus histological diagnoses and calculation of standard diagnostic performance indices.

total of 166 female patients completed both cytological sampling via FNAC and subsequent definitive histopathological verification. age of study cohort ranged from 14 to 64 years of overall mean age of 39.75 ± 12.74 years. When stratified by definitive histological diagnosis patients confirmed of malignant lesions demonstrated higher mean age

of 48.18 ± 9.94 years compared to those of benign histopathology whose mean age was 37.66 ± 12.52 years. This distribution aligns of established clinical epidemiological trend wherein risk of malignant neoplastic transformation in breast tissue increases proportionally of advancing age.

Out of total sample size ($N = 166$) histopathological examination—serving as definitive gold standard—identified 33 cases of malignant neoplasms establishing disease prevalence of 19.88% (33/166) within study sample. remaining 133 cases (80.12%) were confirmed to be benign breast lesions. On cytological examination using FNAC 34 cases (20.48%) were reported as positive for malignant neoplastic cells while 132 cases (79.52%) were reported as negative (benign).

Cross-tabulating cytological findings against histopathological diagnoses yielded following standard 2×2 diagnostic contingency categories:

1. **True Positives (TP):** 30 cases were correctly diagnosed as malignant by both FNAC and histopathology.
2. **True Negatives (TN):** 129 cases were correctly identified as benign by both FNAC and histopathology.
3. **False Positives (FP):** 4 cases were categorized as positive for malignancy on FNAC but were subsequently proven to be benign on histopathology (cytological over-diagnosis).
4. **False Negatives (FN):** 3 cases were reported as benign on FNAC but were demonstrated to harbor malignant disease upon histopathological tissue evaluation (cytological under-diagnosis).

Statistical analysis of 2×2 contingency matrix demonstrated strong diagnostic performance for FNAC as primary outpatient diagnostic tool. sensitivity of FNAC was determined to be 90.91% indicating that fine needle aspiration correctly detected over nine out of ten malignant breast lesions. specificity was calculated at 96.99% reflecting exceptional capacity to correctly rule out malignancy

in benign masses and minimizing unnecessary surgical excisions for benign disorders.

Positive Predictive Value (PPV) was 88.24% meaning that cytological report indicating malignancy carries high probability of true tissue malignancy. Negative Predictive Value (NPV) reached 97.73% signifying that negative cytological report provides very high clinical reliability for ruling out breast cancer. overall Diagnostic Accuracy of FNAC across entire cohort was 95.78% correctly categorizing 159 out of 166 total patients.

Comprehensive Analytical Interpretation of Findings

FNAC demonstrated overall diagnostic accuracy of 95.78% of Negative Predictive Value of 97.73% supporting its routine clinical use as effective non-invasive primary triage tool for palpable breast masses.

1. **Clinical Utility in Outpatient Triage:** observed overall accuracy of 95.78% confirms that FNAC is highly effective rapid and economical diagnostic modality for initial breast mass assessment. Its implementation allows tertiary care centers to quickly stratify patients requiring urgent oncological management from those suitable for conservative follow-up.
2. **Reassurance from High Specificity and NPV:** of specificity of 96.99% and NPV of 97.73% benign FNAC diagnosis provides strong clinical confidence. This drastically reduces patient anxiety and prevents unneeded costly and invasive open biopsy procedures in young patients of low suspicion of malignancy.
3. **Management of Discrepant Findings (False Positives and Negatives):** 4 false-positive cases (3.01%) typically arise from cellular atypia occurring in hyperactive benign lesions such as fibroadenomas of hyperplastic changes complex sclerosing lesions or lactating adenomas. Conversely 3 false-negative cases (9.09% of malignant cases) are generally attributable to sampling errors in deep-seated lesions scirrhous tumors of dense desmoplastic stroma or well-

differentiated low-grade carcinomas that mimic benign cytological architectural features.

Triple Assessment Protocol Integration: These false outcomes reinforce principle that FNAC should not operate as standalone diagnostic modality. When

clinical examination radiological imaging (ultrasound/mammography) and FNAC yield conflicting results definitive core needle or excision biopsy remains mandatory under standardized Triple Assessment Protocol

Table 1: Demographic Characteristics and Age Distribution Across Diagnostic Subgroups (N = 166)

Demographic Variable	Entire Cohort (N = 166)	Benign Group (n = 133)	Malignant Group (n = 33)
Mean Age (Years) ± SD	39.75 ± 12.74	37.66 ± 12.52	48.18 ± 9.94
Age Range (Min – Max)	14 – 64 years	14 – 58 years	32 – 64 years
Gender Distribution	100% Female (166)	100% Female (133)	100% Female (33)

Table 2: 2×2 Contingency Cross-Tabulation of FNAC Results Against Histopathology Gold Standard

Cytological Finding (FNAC)	Histopathology Positive (Malignant)	Histopathology Negative (Benign)	Total Cytological Diagnoses
FNAC Positive (Malignant)	30 (True Positive)	4 (False Positive)	34
FNAC Negative (Benign)	3 (False Negative)	129 (True Negative)	132
Total Histological Diagnoses	33	133	166

Table 3: Diagnostic Accuracy Parameters of FNAC in Palpable Breast Lesions

Statistical Parameter	Calculated Value (%)	95% Confidence Interval
Sensitivity	90.91%	75.67% – 98.10%
Specificity	96.99%	92.38% – 99.16%
Positive Predictive Value (PPV)	88.24%	72.55% – 96.70%
Negative Predictive Value (NPV)	97.73%	93.42% – 99.53%
Overall Diagnostic Accuracy	95.78%	91.56% – 98.24%
Disease Prevalence	19.88%	14.11% – 26.81%

DISCUSSION:

Fine Needle Aspiration Cytology (FNAC) continues to serve as indispensable primary diagnostic modality in initial triage of patients presenting of palpable breast masses [1–6]. In tertiary care settings of developing regions where access to automated core needle biopsy equipment stereotactic tissue collection or immediate intraoperative frozen section analysis is often constrained by socioeconomic or logistical factors FNAC offers rapid minimally invasive highly cost-effective and reproducible outpatient solution [3–5–7]. current investigation evaluated diagnostic efficacy of FNAC across 166 female

patients presenting of palpable breast lumps utilizing formal histopathological examination of excision or core needle biopsies as reference gold standard [1–4]. Overall FNAC demonstrated exceptional sensitivity of 90.91% specificity of 96.99% Positive Predictive Value (PPV) of 88.24% Negative Predictive Value (NPV) of 97.73% and overall Diagnostic Accuracy of 95.78%.

demographic analysis of present study revealed mean age of 39.75±12.74 years (range: 14 to 64 years). Patients diagnosed of confirmed malignant histopathology exhibited substantially higher mean age (48.18±9.94 years) compared to those of benign

tissue diagnosis (37.66 ± 12.52 years). This age distribution reflects established epidemiological transition of breast pathology wherein benign lesions such as fibroadenomas and fibrocystic changes predominate in younger pre-menopausal women whereas incidence of infiltrating ductal carcinomas increases sharply after fourth and fifth decades of life. Similar demographic patterns have been documented by Khan et al. [14] who observed mean presentation age of 41.43 ± 13.42 years of benign lesions concentrated in women aged 20–45 years and malignancies peaking between 30 and 55 years. Likewise Panjvani et al. [16] reported high concentration of benign lesions in younger age groups (mean age 32.5 years) and carcinoma predominantly in older cohorts.

In this cohort histopathological prevalence of malignancy was 19.88% (33/166). This finding is consistent of local epidemiological prevalence of 19.3% reported by Khattak et al. [9] at Ayub Medical College Abbottabad as well as 19.2% malignancy prevalence observed by Pathak et al. [15]. consistency of disease prevalence across regional studies underscores validity of sample size calculation and confirms that study cohort accurately reflects clinical population presenting to surgical outpatient departments in South Asia [6–9].

sensitivity of FNAC recorded in this study (90.91%) falls well within reported global literature range of 83.3% to 97.8% [9–12]. observed sensitivity is significantly higher than 83.33% reported by Khattak et al. [9] and 83.3% reported by Suroor et al. [18] while closely mirroring sensitivity of 90.6% reported by Maharjan [11] in Nepal and 91.66% published by Pathak et al. [15]. However slightly higher sensitivities have been documented by Pandit & Dwivedy [10] (95.75%) Daramola et al. [12] (95.4%) and Panjvani et al. [16] (97.82%). high sensitivity achieved in our center can be attributed to standardized aspiration techniques immediate wet-fixation of smears for H&E staining and double-pass sampling performed by experienced cytopathologists.

specificity of FNAC in our series (96.99%) demonstrates remarkable ability of cytological examination to correctly identify benign lesions and avoid false-positive classifications. This value is in alignment of Pandit & Dwivedy [10] (98.45%) and Chauhan et al. [4] (98.2%) while approaching absolute 100% specificity reported in several major series including Khattak et al. [9] Maharjan [11] Panjvani et al. [16] and Pathak et al. [15]. high specificity observed across studies reinforces clinical consensus that definitive malignant FNAC diagnosis when supported by concordant clinical and radiological findings provides sufficient justification for initiating preoperative counseling staging workup and definitive surgical planning without mandatory preliminary core biopsy [1–3].

Positive Predictive Value (PPV) of 88.24% and Negative Predictive Value (NPV) of 97.73% observed in our investigation reflect high clinical utility. High NPV is of paramount clinical significance in high-volume tertiary care centers because it provides physicians of confidence to manage young patients of clinically benign masses conservatively thereby reducing patient distress and alleviating burden on operating rooms. Our NPV of 97.73% compares favorably of 98.45% reported by Pandit & Dwivedy [10] 99.27% by Khattak et al. [9] 97.82% by Panjvani et al. [16] and 98.0% by Pathak et al. [15] while surpassing 78.57% reported by Maharjan [11].

overall Diagnostic Accuracy achieved in this study (95.78%) confirms robustness of FNAC in clinical practice. This is directly comparable to findings of Pandit & Dwivedy [10] (97.72%) Khattak et al. [9] (99.30%) Pathak et al. [15] (98.4%) Panjvani et al. [16] (98.90%) and Siddique et al. [1].

Analysis of Diagnostic Pitfalls: False Positives and False Negatives

Despite its overall diagnostic high fidelity cytological interpretation of breast aspirates is subject to recognized technical and morphological pitfalls that account for false-positive (n=4) and false-negative (n=3) occurrences in our study [2–17].

False Positives (n=4 3.01%): False-positive cytological reports represent critical concern due to risk of psychological trauma and potentially inappropriate radical intervention [2–5]. In our series cytological over-diagnosis occurred primarily in cases of highly cellular fibroadenomas exhibiting epithelial hyperplasia complex sclerosing lesions (radial scars) and lactating adenomas [2]. Hyperactive ductal epithelial cells in young or pregnant/lactating females often display pronounced nuclear enlargement prominent nucleoli and mild dyscohesion which can closely mimic low-grade ductal carcinoma [2–17]. Similar false-positive diagnostic challenges have been highlighted by Saldanha & Kannoli [17] who noted that cohesive sheets showing focal nuclear atypia or stripped bipolar nuclei in hyperplastic fibroadenomas represent single most common cause of cytological over-diagnosis. Adherence to strict cytological criteria—specifically requiring presence of characteristic dual-population naked bipolar myoepithelial nuclei in background—is vital to prevent false-positive calls [17].

False Negatives (n=3 9.09% of malignancies): False-negative interpretations carry grave clinical consequences as delays in diagnosing breast carcinoma permit tumor progression and metastasis. In our study false-negative cases were predominantly associated of small deep-seated palpable lesions scirrhous invasive ductal carcinomas of extensive desmoplastic stroma and lobular carcinomas. Scirrhous carcinomas yield sparsely cellular aspirates

due to dense fibrous stroma often leading to inadequate or hypocellular smears that are mischaracterized as benign [17–19]. Furthermore invasive lobular carcinoma cells are characteristically small uniform and lack overt nuclear pleomorphism frequently masquerading as inflammatory lymphocytes or normal ductal cells [17]. These findings align of Maurya et al. [19] who reported false-negative rate of 5.41% primarily attributed to hypocellularity in dense scirrhous tumors and sampling errors in deep lesions.

presence of false-negative and false-positive cytological results underscores fundamental guideline that FNAC must never be evaluated in isolation [3–7]. Rather FNAC serves as key leg of standardized **Triple Assessment Protocol** which combines detailed clinical breast examination high-resolution bilateral mammography/ultrasound imaging and pathomorphological sampling [1–3–7]. As emphasized by Karim et al. [3] and Ogbuanya et al. [7] complete diagnostic concordance among all three modalities approaches diagnostic accuracy exceeding 99%. When clinical radiological and cytological findings are concordant for benign disease conservative management or clinical follow-up can be safely adopted [3]. Conversely any discordance—such as benign FNAC report in patient of clinically or radiologically suspicious BIRADS-4/5 mass—mandates immediate core needle biopsy or surgical excision to exclude malignancy [2–3].

Comparative Analysis of FNAC Diagnostic Efficacy Across Regional and International Literature

Study Author(s) & Year	Region / Country	Sample Size (N)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
Khattak et al. (2020) [9]	Pakistan	150	83.33%	100.0%	100.0%	99.27%	99.30%
Pandit & Dwivedy (2020) [10]	India	636	95.75%	98.45%	—	98.45%	97.72%
Maharjan (2021) [11]	Nepal	112	90.60%	100.0%	100.0%	78.57%	—

Daramola et al. (2015) [12]	Nigeria	328	95.40%	88.90%	99.60 %	—	—
Panjvani et al. (2013) [16]	India	222	97.82%	100.0%	100.0 %	97.82 %	98.90%
Pathak et al. (2020) [15]	India	125	91.66%	100.0%	100.0 %	98.00 %	98.40%
Suroor et al. (2023) [18]	Iraq	91	83.30%	100.0%	100.0 %	—	90.00%
Usman et al. (2015) [13]	Pakistan	100	95.83%	100.0%	100.0 %	98.00 %	98.00%
Present Study (2026)	Pakistan	166	90.91%	96.99%	88.24 %	97.73 %	95.78%

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