

DIAGNOSTIC ACCURACY AND HISTOPATHOLOGICAL CORRELATION OF IMPRINT CYTOLOGY IN ULTRASOUND-GUIDED BREAST CORE NEEDLE BIOPSY SPECIMENS: A FIVE-YEAR RETROSPECTIVE STUDY

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ABSTRACT

Background: Imprint cytology is a rapid, simple, and inexpensive adjunct to ultrasound-guided core needle biopsy for the preliminary evaluation of breast lesions. This study evaluated the cytohistological correlation and diagnostic accuracy of imprint cytology using histopathology as the reference standard. **Materials and Methods:** A retrospective observational study was conducted in the Department of Pathology over a five-year period (January 2021–December 2025). **IEC Number:** ECR/641/INST/MH/2014 -RR17.A total of 215 ultrasound-guided breast core needle biopsy specimens with corresponding imprint cytology and histopathological diagnoses were included. Imprint cytology findings were categorized as benign, malignant, suspicious, or inadequate and correlated with the final histopathological diagnosis. Diagnostic performance was assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall diagnostic accuracy, and cytohistological concordance. **Results:** Histopathology confirmed 126 (58.6%) malignant and 89 (41.4%) benign lesions. Imprint cytology diagnosed 101 (47.0%) malignant, 96 (44.7%) benign, 11 (5.1%) suspicious, and 7 (3.3%) inadequate cases. Overall cytohistological concordance was observed in 203 of 215 cases (94.4%), with discordance in 12 (5.6%) cases, predominantly due to false-negative results associated with low cellularity, sampling error, and presence of well-differentiated tumors. Excluding suspicious and inadequate smears, imprint cytology demonstrated a sensitivity of 89.3%, specificity of 98.8%, positive predictive value of 99.0%, negative predictive value of 87.5%, and overall diagnostic accuracy of 93.4%. **Conclusion:** Imprint cytology is a reliable adjunctive technique for the rapid evaluation of ultrasound-guided breast core needle biopsy specimens. Its high specificity, excellent cytohistological concordance, and diagnostic accuracy make it valuable for early clinical decision-making and assessment of specimen adequacy. However, histopathological examination remains the gold standard, particularly in lesions with equivocal or discordant cytological findings.

INTRODUCTION

Breast cancer is the most common malignancy among women worldwide and represents a

biologically heterogeneous disease with diverse molecular and histopathological characteristics that influence prognosis and treatment, which has emphasized the importance of obtaining an accurate

tissue diagnosis before initiating definitive management.^[1]

Image-guided core needle biopsy has become the standard diagnostic procedure for evaluating suspicious breast lesions because it provides adequate tissue for histopathological assessment while being minimally invasive and highly accurate. Histopathological processing requires several hours to days before a definitive diagnosis becomes available, creating a need for rapid adjunctive diagnostic techniques for various reasons.^[2]

Imprint cytology (touch imprint cytology) is a simple, rapid, and cost-effective method in which freshly obtained core biopsy specimens are gently touched onto glass slides to obtain cellular material for immediate cytological examination without compromising the tissue required for histopathology. Several studies have demonstrated that imprint cytology provides high diagnostic accuracy and serves as a valuable adjunct for rapid preliminary diagnosis, assessment of specimen adequacy, and early clinical decision-making in breast lesions.^[3-6] Immediate evaluation of biopsy adequacy using imprint cytology also reduces inadequate sampling and the need for repeat biopsy procedures, thereby improving diagnostic efficiency.^[7]

Furthermore, good cytohistological correlation has been consistently reported between imprint cytology and final histopathological diagnosis, supporting its reliability as an adjunctive diagnostic tool in breast pathology.^[8]

Despite these advantages, the routine use of imprint cytology in ultrasound-guided breast core needle biopsy remains variable across institutions, and long-term data evaluating its diagnostic performance in routine practice are limited. Assessing the cytohistological concordance and diagnostic accuracy of imprint cytology over an extended period can provide important evidence regarding its clinical utility and reliability. Therefore, the present retrospective study was undertaken to evaluate the cytohistological correlation and diagnostic accuracy of imprint cytology in ultrasound-guided breast biopsy specimens received in the Department of Pathology over a five-year period (January 2021 to December 2025), using the final histopathological diagnosis as the reference standard.

MATERIALS AND METHODS

Study Design: This retrospective observational diagnostic accuracy study was conducted to evaluate the cytohistological correlation and diagnostic performance of imprint cytology in ultrasound-guided breast core needle biopsy specimens by comparing cytological findings with the corresponding histopathological diagnosis.

Study Setting: The study was carried out in the Department of Pathology, RK Damani Medical College, ShriRamchandra Institute of Medical Sciences & Dr. Hedgewar Hospital, Chhatrapati

Sambhajanagar. Data were retrieved from the departmental archives, pathology records, and laboratory information system.

Study Duration:

The study included all eligible cases received over a five-year period from January 2021 to December 2025.

Study Population: The study population comprised patients who underwent ultrasound-guided core needle biopsy of breast lesions and for whom both imprint cytology smears and corresponding histopathological specimens were available for evaluation.

Sample Size: All consecutive eligible cases fulfilling the inclusion criteria during the study period were included. A total of 215 ultrasound-guided breast biopsy specimens were analyzed.

Inclusion Criteria

- Ultrasound-guided breast core needle biopsy specimens received between January 2021 and December 2025.
- Cases with corresponding imprint cytology smears and definitive histopathological diagnosis.

Exclusion Criteria

- Cases with incomplete records or without corresponding histopathological diagnosis, precluding cytohistological correlation.

Study Procedure

Patient demographic and clinical information, including age, sex, clinical presentation, and radiological findings, were retrieved from hospital records. Ultrasound-guided core needle biopsies had been performed by experienced radiologists using standard image-guided technique.^[1,2]

Immediately after obtaining the core biopsy specimen, fresh tissue cores were gently touched or rolled over clean glass slides without excessive pressure to prepare imprint smears while preserving tissue architecture for histopathological examination. The prepared smears were air-dried and/or alcohol-fixed according to the departmental protocol and stained using May-Grünwald-Giemsa (MGG) and Papanicolaou stain, wherever applicable. The stained smears were examined by consultant cytopathologists and categorized as benign, suspicious for malignancy, malignant, or inadequate based on established cytomorphological criteria.^[3,4]

Following imprint preparation, the biopsy cores were immediately fixed in 10% neutral buffered formalin, processed routinely, embedded in paraffin, sectioned at 3–5 µm, and stained with hematoxylin and eosin (H&E). Histopathological examination was performed by experienced histopathologists according to standard diagnostic criteria and as the reference (gold) standard for final diagnosis.^[1,5]

The imprint cytology findings were subsequently compared with the corresponding histopathological diagnosis to determine cytohistological concordance. Discordant cases were reviewed to identify possible causes such as sampling error, low cellularity,

technical limitations, or interpretative difficulties. Previous studies have demonstrated that imprint cytology is an effective adjunct for rapid assessment of specimen adequacy and preliminary diagnosis without compromising histopathological evaluation.^[3,8]

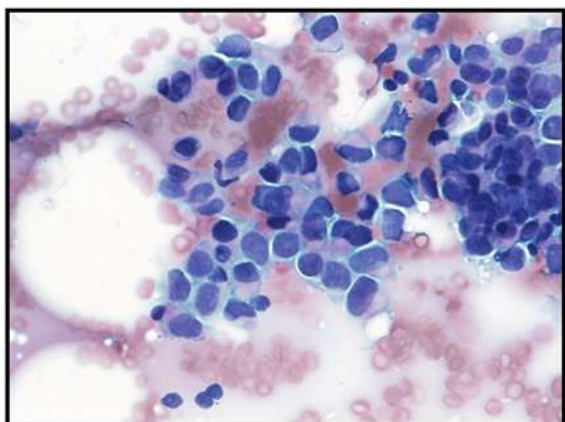


Figure 1: Tissue imprint cytology: Papanicolaou stain, 400x: Malignant cells with high N:C ratio, pleomorphic, hyperchromatic nuclei and occasional nucleolus. This case was reported as Malignant lesion on cytology. On histopathology, it turned out be invasive ductal carcinoma

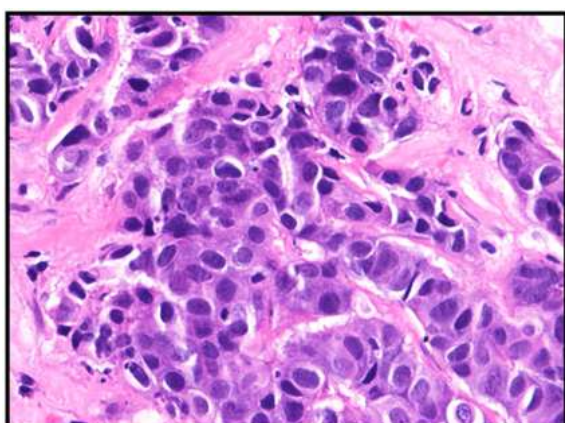


Figure 2: Histopathology: H&E, 400x: Invasive ductal carcinoma. Malignant cells with large, pleomorphic nuclei arranged in trabeculae and sheets

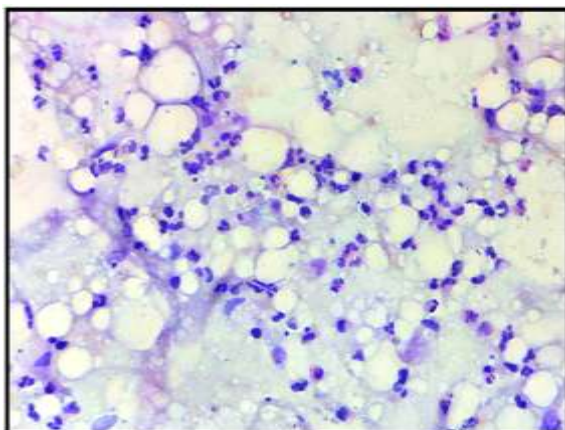


Figure 3: Tissue Imprint Cytology: Papanicolaou stain, 400x: Benign. Neutrophil aggregates

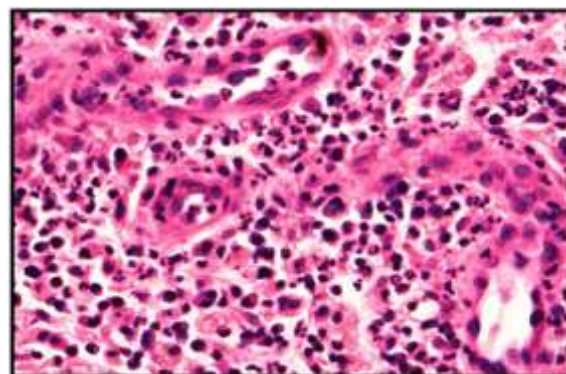


Figure 4: Histopathology: H&E, 400x: Breast parenchyma with dense inflammatory infiltrate with predominant neutrophils

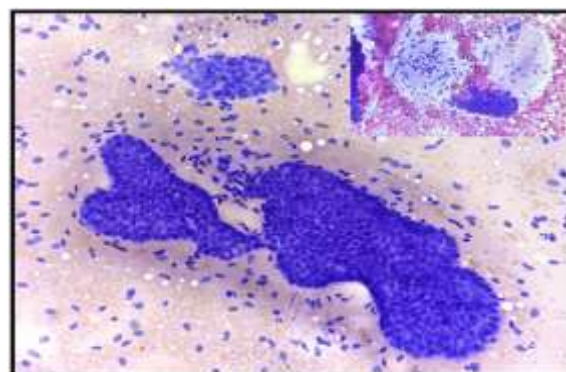


Figure 5: Tissue Imprint Cytology: Papanicolaou stain, 400x: Benign. Fibroadenoma. Biphasic population of epithelial cells and stromal fragment (inset)

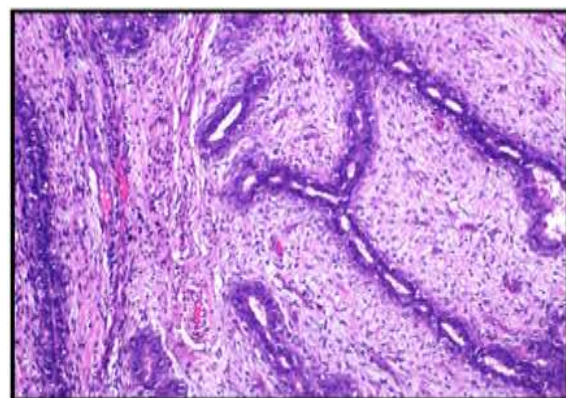


Figure 6: Histopathology: H&E, 400x. Fibroadenoma. Histopathological examination shows biphasic tumour

Outcome Measures

The primary outcome measures were:

- Cytohistological concordance rate.
- Sensitivity.
- Specificity.
- Positive predictive value (PPV).
- Negative predictive value (NPV).
- Overall diagnostic accuracy.
- False-positive and false-negative rates.

Data Collection

Relevant demographic, clinical, radiological, cytological, and histopathological data were extracted from pathology records using a structured

data collection proforma and entered into a Microsoft Excel spreadsheet for analysis.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized as mean $\pm$ standard deviation (SD). Cytohistological agreement was assessed using Cohen's kappa (κ) coefficient. Diagnostic indices, including sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy, were calculated using histopathological diagnosis as the gold standard. A 95% confidence interval (CI) was calculated where appropriate, and a p-value <0.05 was considered statistically significant.

Ethical Considerations

IEC Number: ECR/641/INST/MH/2014 -RR17

The study protocol was approved by the Institutional Ethics Committee before commencement. As this was a retrospective record-based study, informed consent was waived. Patient confidentiality was maintained by anonymizing all identifying information, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

RESULTS

A total of 215 ultrasound-guided breast core needle biopsy specimens were included in the study. Histopathological examination confirmed 126 (58.6%) malignant and 89 (41.4%) benign lesions. Imprint cytology diagnosed 101 (47.0%) malignant, 96 (44.7%) benign, 11 (5.1%) suspicious, and 7 (3.3%) inadequate cases.

Table 1: Distribution of imprint cytology and histopathological diagnosis (n = 215)

Parameter	Number (%)
Histopathology	
Benign	89 (41.4%)
Malignant	126 (58.6%)
Imprint cytology	
Benign	96 (44.7%)
Malignant	101 (47%)
Suspicious	11 (5.1%)
Inadequate	7 (3.3%)

Histopathology identified a higher proportion of malignant lesions than benign lesions. Definitive imprint cytology yielded adequate diagnostic

material in the majority of cases, while only 3.3% of smears were inadequate.

Table 2: Cytohistological correlation of definitive imprint cytology diagnoses (Suspicious and inadequate cases excluded; n = 197)

Imprint cytology	Histopathology Benign	Histopathology Malignant	Total
Benign	84	12	96
Malignant	1	100	101
Total	85	112	197

Among the definitive cytological diagnoses, 184 of 197 cases (93.4%) showed agreement with histopathology. One benign lesion was overcalled as

malignant (false positive), whereas twelve malignant lesions were reported as benign (false negatives).

Table 3: Diagnostic performance of imprint cytology

Parameter	Value (%)
Sensitivity	89.3
Specificity	98.8
Positive Predictive Value (PPV)	99.0
Negative Predictive Value (NPV)	87.5
Overall Diagnostic Accuracy	93.4

Imprint cytology demonstrated high specificity (98.8%) and an excellent positive predictive value (99.0%), indicating that a cytological diagnosis of malignancy was highly reliable. The sensitivity of 89.3% reflects a small number of false-negative cases, while the overall diagnostic accuracy of 93.4% confirms that imprint cytology is a dependable adjunctive technique for evaluating ultrasound-guided breast core biopsy specimens.

Concordance and Discordance

Overall, 203 of 215 cases (94.4%) showed cytohistological concordance, whereas 12 cases (5.6%) were discordant.

The observed discordant cases were predominantly false-negative results. Likely causes included:

- Low cellularity or inadequate transfer of tumor cells to the imprint smear.
- Sampling error, particularly in small or heterogeneous lesions.

- Well-differentiated or low-grade carcinomas with minimal cytological atypia.
- Lobular carcinomas and sclerotic lesions, which are known to yield relatively paucicellular smears.
- Technical factors during smear preparation and staining.

These findings highlight that although imprint cytology provides rapid and highly specific preliminary diagnosis, it cannot replace histopathological examination. Histopathology remains the gold standard, particularly in cases with suspicious imaging findings or discordant clinical and cytological features. The principal limitation of imprint cytology is its potential for false-negative diagnoses, especially in hypocellular lesions and tumors with subtle cytomorphological features. Routine cytohistological correlation therefore remains essential to ensure accurate diagnosis and appropriate patient management.

DISCUSSION

The present study evaluated the cytohistological correlation and diagnostic accuracy of imprint cytology in ultrasound-guided breast core needle biopsy specimens over a five-year period. Imprint cytology demonstrated excellent diagnostic performance with an overall diagnostic accuracy of 93.4%, sensitivity of 89.3%, specificity of 98.8%, positive predictive value of 99.0%, and negative predictive value of 87.5%. The overall cytohistological concordance was 94.4%, indicating that imprint cytology is a reliable adjunct to histopathological evaluation.

Rosa et al. reviewed the role of touch imprint cytology in breast core needle biopsy specimens and reported that the technique provides high sensitivity and specificity while allowing rapid assessment of specimen adequacy without compromising tissue for histopathological examination. The high diagnostic accuracy and concordance observed in the present study are consistent with their findings, reaffirming that imprint cytology is a valuable adjunctive diagnostic tool in routine breast pathology practice.^[9] The College of American Pathologists (CAP) recommends histopathological examination as the reference standard for diagnosing breast lesions and emphasizes the importance of correlating pathological findings with clinical and radiological features to ensure diagnostic accuracy.^[10] Similarly, in the present study, all imprint cytology findings were compared with the final histopathological diagnosis, which served as the gold standard for evaluating diagnostic performance.

The National Comprehensive Cancer Network (NCCN) guidelines continue to recommend image-guided core needle biopsy as the preferred diagnostic procedure for suspicious breast lesions because of its high diagnostic reliability and ability to provide sufficient tissue for histological and biomarker

evaluation.^[11] Our findings support these recommendations, demonstrating that imprint cytology can provide an accurate preliminary diagnosis while preserving tissue for definitive histopathological assessment.

The consensus guideline of the American Society of Breast Surgeons highlights that image-guided breast biopsy should be integrated with radiological and pathological correlation to minimize diagnostic errors and improve patient management.^[12] The excellent cytohistological concordance observed in the present study reflects the effectiveness of such a multidisciplinary diagnostic approach and supports the use of imprint cytology as an adjunct during image-guided breast biopsy.

Willems et al. discussed the strengths and limitations of cytological techniques used alongside core needle biopsy and reported that false-negative diagnoses may occur because of sampling error, low cellularity, well-differentiated tumors, or specific histological subtypes such as invasive lobular carcinoma.^[13] Similar observations were made in the present study, where most discordant cases were false-negative results. These discordances were likely attributable to hypocellular smears, limited transfer of tumor cells, technical factors during smear preparation, and subtle cytomorphological features of low-grade malignancies.

Rakha et al. emphasized that contemporary breast pathology requires accurate histopathological reporting supported by clinicoradiological correlation and standardized diagnostic criteria.^[14] Although imprint cytology provides rapid preliminary information, it cannot replace histopathological examination, particularly for tumor typing, grading, receptor evaluation, and assessment of prognostic parameters. The findings of the present study further reinforce the complementary role of imprint cytology rather than its use as an independent diagnostic modality.

The European Society of Breast Cancer Specialists (EUSOMA) recommends strict quality assurance measures and multidisciplinary correlation in breast cancer diagnosis to reduce diagnostic discrepancies and optimize patient care.^[15] The high concordance rate observed in this study demonstrates that adherence to standardized pathological evaluation and close clinicoradiological correlation contributes significantly to maintaining diagnostic quality in breast biopsy practice.

Baloch and LiVolsi reported that imprint cytology is a rapid, inexpensive, and highly specific diagnostic technique but cautioned that occasional false-negative results are unavoidable because of inadequate cellularity, technical limitations, and interpretative challenges.^[16] The present study showed similar findings, with a small proportion of discordant cases attributable mainly to false-negative diagnoses. Therefore, while imprint cytology is extremely useful for rapid intra-laboratory assessment and evaluation of specimen adequacy,

final patient management should always be based on histopathological diagnosis.

Table 4: Comparison of the Present Study with Previous Studies

Study	Year	Sensitivity (%)	Specificity (%)	Accuracy (%)
Green et al. ^[17]	2001	92.3	98.0	96.2
Klevesath et al. ^[18]	2005	96.2	100.0	96.7
Kulkarni et al. ^[19]	2009	97.7	94.2	95.5
Masood et al. ^[20]	2011	95.0	96.0	95.0
Kashiwagi et al. ^[3]	2013	100.0	99.6	99.8
Kehl et al. ^[21]	2014	99.0	100.0	99.0
Sivaprasad et al. ^[22]	2017	91.3	87.5	90.7
Modi & Rajyaguru. ^[23]	2022	93.55	94.74	94.0
Vaithi et al. ^[6]	2022	91.6	100.0	95.0
Boler et al. ^[24]	2024	86.05	97.22	90.0
Present study	2026	89.3	98.8	93.4

The present study showed good diagnostic performance, with 89.3% sensitivity, 98.8% specificity, and 93.4% accuracy, comparable to previous studies. The high specificity indicates that imprint cytology is a reliable adjunct to histopathological diagnosis.

Overall, the present study demonstrates that imprint cytology is a simple, rapid, and highly accurate adjunctive technique for ultrasound-guided breast core needle biopsy specimens. Its excellent cytohistological concordance and high specificity make it a valuable tool for early diagnostic assessment; however, histopathological examination remains indispensable for definitive diagnosis and comprehensive characterization of breast lesions.

CONCLUSION

Imprint cytology demonstrated excellent cytohistological correlation with final histopathological diagnosis in ultrasound-guided breast core needle biopsy specimens. The technique provided rapid and reliable preliminary diagnosis with high concordance and minimal inadequate smears. Although histopathology remains the gold standard, imprint cytology serves as a valuable adjunct by facilitating early assessment of specimen adequacy and timely clinical decision-making. Routine incorporation of imprint cytology into the evaluation of ultrasound-guided breast biopsies can enhance diagnostic efficiency, particularly in resource-limited settings, while maintaining high diagnostic accuracy.

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