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Histopathological Upgrade in Papillary Breast Lesions Diagnosed on Core Needle Biopsy: Predictors and Clinical Implications from a Tertiary-Care Cohort

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ABSTRACT

Background: Papillary breast lesions encompass a heterogeneous spectrum, and core needle biopsy (CNB) may underestimate in situ or invasive malignancy. We evaluated malignant upgrade and preoperative factors associated with upgrade after surgical excision.

Methods: This retrospective cohort study identified 298 patient records with papillary breast lesions. A total of 14 patients were excluded: eight who lacked a preceding CNB, five who did not undergo subsequent surgical excision, and one whose index papillary diagnosis and surgery both occurred before the January 2019–December 2025 study period. This left 284 patients for analysis. Malignant upgrade was defined as ductal carcinoma in situ or invasive malignancy on excision after a benign or atypical papillary lesion on CNB; atypical ductal hyperplasia alone was not considered malignant upgrade. Firth-penalized logistic regression was used to obtain adjusted estimates because a highly predictive atypia variable was present.

Results: Malignant upgrade occurred in 137 of 284 patients (48.2%). Upgrade was observed in 130 of 150 lesions with atypia (86.7%) and 7 of 134 lesions without atypia (5.2%). In adjusted analysis (n = 273 complete cases), atypia on CNB was the strongest independent predictor (adjusted odds ratio [aOR] 71.49, 95% CI 25.96–196.84; $P < .001$). Increasing age (aOR 1.04 per year, 95% CI 1.01–1.07; $P = .02$) and manual rather than ultrasound-guided core biopsy (aOR 5.01, 95% CI 1.46–17.20; $P = .010$) also remained associated with malignant upgrade. Ultrasound lesion size, palpability, peripheral location, and BI-RADS ≥4 were not independently associated with malignant upgrade after adjustment.

Conclusion: Atypia on CNB was associated with a very high probability of malignant upgrade and supports surgical excision. The low upgrade rate among lesions without atypia is hypothesis-generating but cannot establish the safety of surveillance because only surgically excised lesions were analyzed.

INTRODUCTION

Papillary breast lesions (PBLs) are a heterogeneous group characterized by fibrovascular cores lined by epithelial cells, with variable preservation of the myoepithelial layer. They range from benign intraductal papilloma and papilloma with atypical epithelial proliferation to ductal carcinoma in situ (DCIS), encapsulated papillary carcinoma, solid papillary carcinoma, and invasive papillary carcinoma.[1]

Core needle biopsy is commonly used for diagnosis, but sampling limitations and the pathological complexity of papillary proliferations may lead to underestimation of malignancy.[1,2] Published malignant upgrade rates vary according to the presence of atypia, radiology–pathology concordance, biopsy technique, sampling adequacy, and selection for excision.[2–6]

Therefore, we evaluated the malignant upgrade rate among papillary lesions diagnosed on CNB and subsequently excised, and examined preoperative clinical, radiological, and biopsy-related factors associated with upgrade. We additionally distinguished synchronous bilateral malignancy managed during the index definitive surgical episode from a new breast cancer diagnosed after completion of index treatment.

METHODS

Study design and setting

This retrospective cohort study was conducted at Liaquat National Hospital and Medical College,

Karachi, Pakistan, and included patients evaluated between January 2019 and December 2025. Reporting was reviewed against the STROBE checklist for cohort studies.[7]

Study population and selection

Female patients aged 18–85 years with a papillary breast lesion, with or without atypia, diagnosed on CNB and subsequently managed by surgical excision were eligible. The following patients were excluded from the primary upgrade analysis: those without a preceding CNB, those who did not undergo excision, those with a previous breast malignancy, and those without an assessable final excision diagnosis.

A total of 298 patient records were identified. Eight patients were excluded because they underwent a surgical diagnostic procedure without a preceding CNB, leaving 290 patients with a papillary lesion diagnosed on CNB. The institutional practice was to recommend surgical excision for all CNB-diagnosed papillary lesions, irrespective of whether atypia was present. Of these 290 patients, 285 (98.3%) underwent excision; the remaining five (1.7%) did not undergo excision and therefore had no final excision histopathology. One additional patient was excluded because her index papillary diagnosis and surgery occurred in December 2017, before the prespecified January 2019–December 2025 study period. Therefore, the final analytical cohort comprised 284 patients. Further definitive surgical management, when required, was determined by the excision histopathology.

Sample size and sampling

The sample size was calculated using the WHO sample-size calculator, assuming an expected upgrade rate of 29.6%, 95% confidence level, and 6% absolute precision, giving a minimum required sample of 223. The expected rate was taken from Park *et al.*[8], who reported an overall diagnostic upgrade rate of 29.6% (50/169). Their definition included upgrade to high-risk lesions as well as malignancy; the malignant upgrade rate in that study was 16.6%. Thus, using the 29.6% estimate yielded the larger, more conservative sample-size requirement. Consecutive eligible patients were included, and the final analytical cohort of 284 exceeded the calculated minimum. The higher malignant upgrade rate observed in our cohort likely reflects the high proportion of lesions with atypia and restriction to surgically excised cases.

Core biopsy and pathological assessment

The initial diagnosis was established by either ultrasound-guided or manually performed core needle biopsy. Ultrasound-guided biopsies were performed using an 18-gauge semiautomatic core needle, with four to five cores obtained to ensure adequate sampling. Manually performed freehand biopsies were used for palpable lesions and employed a 14-gauge Tru-Cut needle, again with four to five cores obtained for adequacy. Vacuum-assisted biopsy was not used because this facility was not available at the institution. The biopsy method was analysed as a preoperative procedural variable.

Core biopsy and excision specimens were reported by pathologists with substantial breast-pathology experience using the WHO Classification of Breast Tumors, 5th edition (2019).[9] Diagnostically difficult cases were discussed with pathologist colleagues to reach a consensus. In accordance with the WHO criteria, invasive papillary carcinoma was defined as an invasive mammary carcinoma with predominantly papillary morphology (> 90%) and an infiltrative growth pattern; invasive breast carcinoma of no special type containing more limited papillary areas was reported as invasive breast carcinoma with papillary features. When required, p63 and alpha-smooth muscle actin were used to assess the myoepithelial layer. Additional immunohistochemistry was selected according to the differential diagnosis and included synaptophysin, estrogen receptor, and Ki-67; oestrogen receptor, p63, and CK5/6 were used when evaluating atypical epithelial proliferations.

Variables and operational definitions

Age was analyzed as a continuous variable. Menopausal status was recorded as premenopausal or postmenopausal. Clinical presentation was represented by separate binary variables for lump, pain, nipple discharge, bloody discharge, and serous discharge; these symptom variables were not mutually exclusive. Palpability was recorded independently on clinical examination. Lesion size was recorded in centimetres, with ultrasound size used in prediction modeling because it was available before surgery. Final pathological size was not considered a preoperative predictor.

Lesions within 2 cm of the nipple were classified as central and those beyond 2 cm as peripheral. Multiplicity, laterality, BI-RADS category, family history, and biopsy approach were abstracted from clinical and radiological records. BI-RADS 4 without a documented subcategory was retained as a separate recorded category and was not assumed to represent 4A, 4B, or 4C.

Atypia on CNB referred to a low-grade atypical epithelial proliferation/atypical ductal hyperplasia involving a papillary lesion and measuring <3 mm. Larger low-grade atypical proliferations were classified as ductal carcinoma in situ according to WHO criteria. Oestrogen receptor, p63, and CK5/6 were used when required to support the distinction.

Detailed operational definitions and coding conventions for all study variables are provided in Supplementary Table S1.

Outcome definitions

The primary outcome was malignant histopathological upgrade, defined as DCIS or invasive malignancy in the excision specimen after a benign papillary lesion or papillary lesion with atypia on CNB. ADH identified on excision was not classified as malignant upgrade and is reported separately. Secondary outcomes were preoperative factors associated with malignant upgrade and new breast cancer occurrence after

completion of index treatment among patients with available follow-up data. A contralateral cancer diagnosed and managed during the same definitive surgical episode was classified as synchronous bilateral disease rather than a subsequent event.

Statistical analysis

Continuous variables were assessed for normality using the Shapiro–Wilk test. Because age and lesion-size distributions departed from normality, groups were compared with the Mann–Whitney U test and summarized using medians and interquartile ranges; means and standard deviations are also provided for comparability. Categorical variables were summarized as frequencies and percentages and compared using the chi-square test or Fisher's exact test where expected cell counts were small. Symptom indicators were analyzed as separate, potentially overlapping binary variables, and their results were interpreted as exploratory because of multiple comparisons.

Univariable Firth-penalized logistic regression was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs). A prespecified multivariable Firth model included age, ultrasound lesion size, palpability, central versus peripheral location, biopsy approach, atypia on CNB, and BI-RADS ≥4. Firth-penalization was selected because atypia was a very strong predictor and produced sparse outcome cells, for which ordinary maximum-likelihood estimates may be unstable.[10] Menopausal status was not included with age in the primary adjusted model to limit collinearity. Only preoperative variables were included. Complete-case analysis was used for the adjusted model, with the analytical denominator reported. Two-sided $P < .05$ was considered statistically significant.

Synchronous contralateral malignancies and subsequent breast cancers were summarized descriptively. No true subsequent breast cancer was identified in the eligible cohort; therefore, no between-group inferential comparison of subsequent-cancer risk was performed. Statistical analyses were performed using IBM SPSS Statistics version 27 for data summaries and independent verification using Firth-penalized logistic regression.

Ethical considerations

The study was approved by the Institutional Review Board of Liaquat National Hospital and Medical College (Approval No. 1247-2025-LNH-ERC). Informed consent was waived because of the retrospective design, and patient confidentiality was maintained.

RESULTS

Study population and upgrade rate

Of 298 records identified, eight were excluded because there was no preceding CNB, five because surgical excision was not performed, and one because the index papillary diagnosis and surgery predated the study period, leaving 284 patients for analysis (Figure 1). Malignant upgrade occurred in 137 patients (48.2%). The rate was 86.7% (130/150) among lesions with atypia on CNB and 5.2% (7/134) among lesions without atypia.

Age, clinical lump size, and ultrasound lesion size were non-normally distributed (all Shapiro–Wilk $P < .01$). Upgraded lesions occurred in older patients and had larger clinical and ultrasound measurements on unadjusted comparison. Palpability, peripheral location, postmenopausal status, manual core biopsy, higher BI-RADS category, and atypia were also associated with upgrade in unadjusted analyses. Multiplicity and family history were not associated with malignant upgrade.

Synchronous bilateral and subsequent breast cancers

Dates of surgery and last documented contact were available for all 284 eligible patients. Four apparent date-entry errors were checked against the source records and corrected. The median documented follow-up was 4.5 months (IQR 1.3–15.2 months; range 2 days–76.5 months). Subsequent-cancer outcome status was recorded for 277 patients and was coded as unavailable in seven patients. Nine patients had a synchronous contralateral malignancy diagnosed and managed during the same definitive surgical episode. One of these patients had invasive carcinoma involving both breasts and is presented in Table 3 as "bilateral invasive carcinomas." The remaining eight patients are classified in Table 3 according to the final excision diagnosis of the index papillary lesion. The only record containing a later ipsilateral breast cancer was excluded because its index papillary diagnosis and surgery occurred in December 2017, before the prespecified study period. Consequently, no true subsequent breast cancer was identified in the eligible cohort, and no comparative-risk analysis was performed.

DISCUSSION

This surgically selected tertiary-care cohort had an overall malignant upgrade rate of 48.2%, higher than that reported in many published series.[2,3,11] The rate differed markedly by CNB atypia: 86.7% among lesions with atypia compared with 5.2% among lesions without atypia. The high overall rate should therefore not be interpreted as the risk among all papillary lesions encountered in practice; it reflects the case mix and the restriction to patients selected for excision.[8,11]

Atypia remained the dominant predictor after adjustment, with an adjusted OR of 71.49, consistent with previous studies demonstrating substantially higher malignant upgrade in atypical papillary lesions.[3,4,11] Firth-penalized logistic regression provided finite estimates despite sparse outcome cells and avoided the instability that may occur with ordinary maximum-likelihood estimation when predictors are strongly predictive.[10] These results support excision when atypia is identified on CNB.

Older age and manual rather than ultrasound-guided core biopsy also remained independently associated with upgrade. Age, lesion size, peripheral location, and biopsy-related sampling factors have been examined as predictors in previous studies.[2,6,8] The

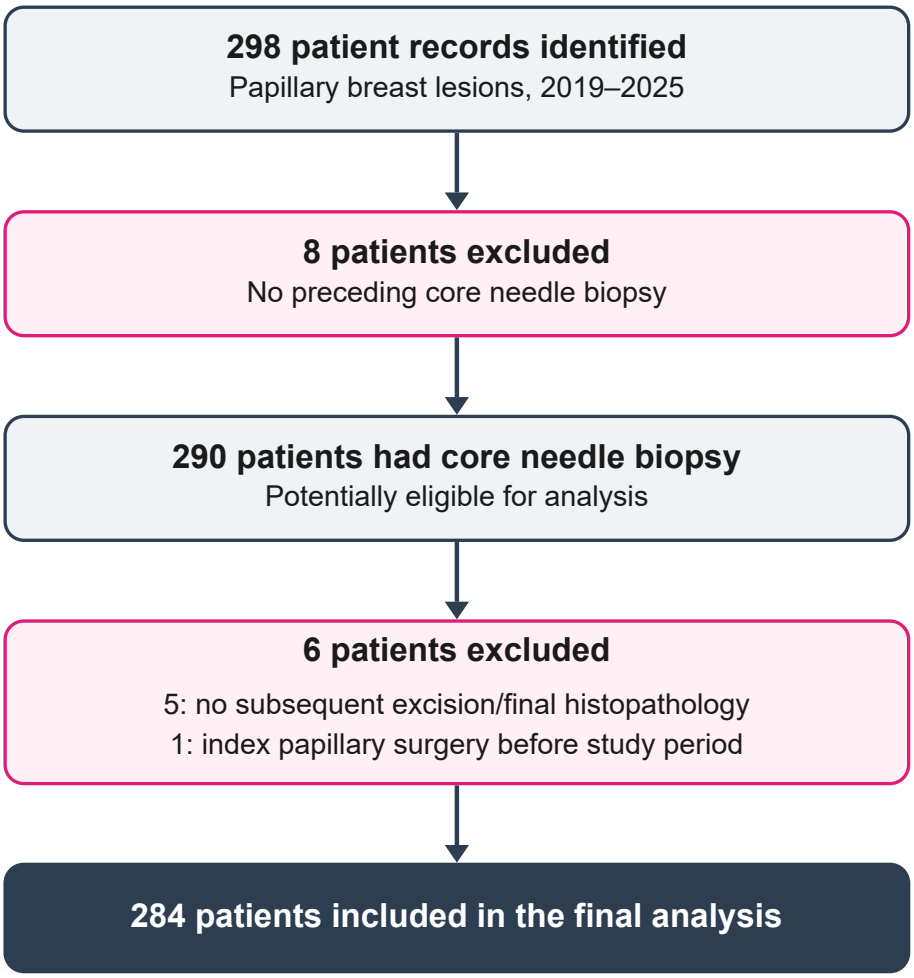


Figure 1. STROBE Flow Diagram Showing Selection of Patients for the Final Analysis

Table 1. Clinical characteristics of the 284 surgically excised papillary breast lesions according to malignant upgrade status

Variable	Upgrade (n = 137)	No upgrade (n = 147)	*P* value
Age, years, median (IQR)	62.0 (53.5–69.0)	46.0 (39.0–58.0)	<.001
Clinical lump size, cm, median (IQR)	3.0 (2.0–5.0); n = 124	1.5 (0.6–2.6); n = 96	<.001
Ultrasound size, cm, median (IQR)	2.7 (1.2–5.0); n = 135	0.7 (0.5–1.5); n = 141	<.001
Palpable lesion	116 (84.7)	58 (39.5)	<.001
Peripheral location	83 (60.6)	51 (34.7)	<.001
Multiple lesions	3 (2.2)	5 (3.4)	.72
Family history present	10 (7.3)	20 (13.6)	.08
Postmenopausal	118 (86.1)	78 (53.1)	<.001

Values are n (%) unless otherwise specified. IQR denotes interquartile range. Denominators are shown where data were missing. Mann–Whitney U test was used for continuous variables; chi-square or Fisher's exact test was used for categorical variables.

biopsy association should be interpreted cautiously: it may reflect differences in lesion palpability, imaging selection, needle placement, number of cores, or sampling adequacy rather than an intrinsic causal effect of the biopsy approach.[4,12]

Although lesion size, palpability, peripheral location, postmenopausal status, and higher BI-RADS category were associated with upgrade in unadjusted comparisons, ultrasound size, palpability, peripheral location, and BI-RADS ≥4 did not remain significant in the adjusted model. Imaging–pathology concordance remains clinically important, but thresholds such as age >50 years, lesion size >2 cm, and BI-RADS ≥4B should not be presented as a validated clinical prediction rule based on these data.[5,8]

The 5.2% malignant upgrade rate among lesions

Table 2. Preoperative imaging, biopsy, and CNB findings according to malignant upgrade status

Variable/category	Upgrade (n = 137)	No upgrade (n = 147)	*P* value
BI-RADS 0	8 (5.8)	22 (15.0)	.001[a]
BI-RADS 2	1 (0.7)	2 (1.4)	
BI-RADS 3	8 (5.8)	19 (12.9)	
BI-RADS 4, not subcategorized	100 (73.0)	82 (55.8)	
BI-RADS 4A	8 (5.8)	20 (13.6)	
BI-RADS 4B	5 (3.6)	2 (1.4)	
BI-RADS 4C	6 (4.4)	0	
BI-RADS 5	1 (0.7)	0	
Ultrasound-guided core biopsy	37 (27.0)	114 (77.6)	<.001
Manual core biopsy	100 (73.0)	33 (22.4)	
CNB with atypia	130 (94.9)	20 (13.6)	<.001
CNB without atypia[b]	7 (5.1)	127 (86.4)	

[a]The *P* value refers to the overall comparison across BI-RADS categories. [b]The CNB without atypia category includes four lesions recorded as intraductal papilloma without a separate atypia designation. BI-RADS denotes Breast Imaging Reporting and Data System, and CNB denotes core needle biopsy.

Table 3. Final excision diagnosis according to atypia status on core needle biopsy

Final excision diagnosis	CNB without atypia (n = 134)	CNB with atypia (n = 150)	Total (n = 284)
Atypical ductal hyperplasia	3	0	3
Benign breast tissue	4	1	5
Benign breast tissue with adenosis	3	0	3
Intraductal papilloma	116	18	134
Intraductal papilloma with ADH	1	1	2
DCIS	1	29	30
Papillary DCIS	0	12	12
Intraductal papilloma with DCIS	1	0	1
Encapsulated papillary carcinoma, no invasion	1	12	13
Encapsulated papillary carcinoma with DCIS	0	1	1
Encapsulated papillary carcinoma with invasion	0	11	11
Solid papillary carcinoma, no invasion	1	32	33
Solid papillary carcinoma with invasion	1	4	5
Invasive papillary carcinoma	1	9	10
Invasive carcinoma NST	1	17	18
Invasive carcinoma with papillary differentiation	0	1	1
Bilateral invasive carcinomas[a]	0	1	1
Malignant phyllodes tumor[b]	0	1	1

ADH, DCIS, and NST denote atypical ductal hyperplasia, ductal carcinoma in situ, and no special type, respectively. [a]One patient had invasive carcinoma involving both breasts. This patient was one of the nine patients with a synchronous contralateral malignancy; the remaining eight patients are classified according to the final excision diagnosis of the index papillary lesion. [b]The diagnosis of malignant phyllodes tumor was re-reviewed and confirmed by the reporting pathologist. The initial core contained papillary and leaf-like areas; because malignant phyllodes tumors are heterogeneous, the sampled stromal component may initially have been misinterpreted as a papillary lesion.

Table 4. Univariable and multivariable Firth-penalized logistic regression for malignant upgrade

Predictor	Unadjusted OR (95% CI)	*P* value	Adjusted OR (95% CI)	*P* value
Age, per year	1.07 (1.05–1.09)	<.001	1.04 (1.01–1.07)	.02
Ultrasound size, per cm	1.98 (1.63–2.42)	<.001	1.10 (0.78–1.55)	.60
Palpable lesion	8.29 (4.70–14.63)	<.001	1.03 (0.32–3.33)	.96
Peripheral location	2.87 (1.77–4.65)	<.001	1.01 (0.40–2.55)	.98
Manual core biopsy	9.16 (5.34–15.71)	<.001	5.01 (1.46–17.20)	.010
Atypia on CNB	108.22 (45.14–259.46)	<.001	71.49 (25.96–196.84)	<.001
BI-RADS ≥4	2.87 (1.55–5.32)	.001	1.76 (0.59–5.27)	.31

Adjusted analysis used complete cases (n = 273). Only variables available before surgery were included. Firth-penalization was used because of sparse cells and the strong atypia effect.

without atypia is clinically relevant but does not establish the safety of imaging surveillance. During the study period, surgical excision was routinely recommended for all CNB-diagnosed papillary lesions irrespective of atypia; therefore, the cohort did not include a standardized imaging-surveillance comparison group. Radiology–pathology concordance, biopsy sampling adequacy, and prospective follow-up would be required to define a reliably low-risk surveillance group.[5,12,13]

The nine contralateral malignancies were synchronous and should not be interpreted as follow-up events. The one record containing an ipsilateral invasive breast carcinoma NST after prior excision of an intraductal papilloma was excluded because the index papillary diagnosis and surgery occurred before the study period. No true subsequent breast cancer was therefore identified in the eligible cohort. Given the short median follow-up, seven unavailable outcome entries, and non-standardized surveillance, no meaningful inference about subsequent-cancer risk can be made.

Strengths and limitations

Strengths include the relatively large cohort, detailed clinical and imaging variables, separate reporting according to atypia on CNB, and bias-reduced multivariable modeling. Definitive excision histopathology was available for 285 of 290 CNB-diagnosed patients (98.3%); after exclusion of one patient whose index surgery predated the study period, 284 were eligible for analysis, enabling near-complete ascertainment of malignant upgrade. Limitations include the retrospective single-center design, referral bias, and the absence of a non-operative surveillance comparison group. Because surgical excision was routinely recommended irrespective of atypia, the study cannot determine the safety of selective imaging surveillance, and its findings may not be directly generalizable to centers following selective excision policies. Other limitations include missing covariate data requiring complete-case regression (273/284), short and non-standardized follow-up, seven unavailable subsequent-cancer outcome entries, absence of vacuum-assisted biopsy, and incomplete documentation of radiology–pathology discordance. Pathological classification may have varied over the seven-year study interval; however, the WHO 5th edition was used, diagnostically difficult cases were discussed among experienced pathologists, and the malignant phyllodes tumor was retrospectively re-reviewed and confirmed. The high proportion of lesions with atypia, together with potential differences in diagnostic thresholds and sampling practices, may further limit generalizability.

Clinical implications

Papillary lesions with atypia on CNB should generally undergo surgical excision. For lesions without atypia, the low observed upgrade rate supports further investigation of selective surveillance but does not, by itself, justify a definitive surveillance recommendation.

CONCLUSION

Atypia on CNB was the strongest independent predictor of malignant upgrade in surgically excised papillary breast lesions. The findings support excision for lesions with atypia. For lesions without atypia, surveillance remains a hypothesis-generating option requiring radiology–pathology concordance, adequate sampling, and prospective outcome validation.

ETHICAL CONSIDERATIONS

This study was approved by the Institutional Review Board (IRB), and all procedures were conducted in accordance with the relevant guidelines of Liaquat National Hospital & Medical College, Karachi, Pakistan (Approval No.: 1247-2025-LNH-ERC).

DATA AVAILABILITY

The data are not publicly available due to patient confidentiality and institutional restrictions but are available from the corresponding author on reasonable request.

CONFLICT OF INTERESTS

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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AI DISCLOSURE

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AUTHOR CONTRIBUTIONS

MKL: Conceptualization, Methodology, Data curation, Formal analysis, Writing – original draft. RS: Supervision, Validation, Writing – review & editing.

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