Review Article

Intraductal papillomas of the breast

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Abstract: Papillary lesions of the breast are classified as benign or malignant. Making a definitive diagnosis for a papillary lesion based on a core needle biopsy remains a challenge for pathologists. Intraductal papillomas are a common benign lesion of the breast with variable presentations. They may be identified with or without atypia and may present with or without symptoms, often identified on breast imaging. Patients with intraductal papillomas with atypia should be referred for surgical excision due to the higher rate of upstaging to malignancy and they should also be referred for high risk assessment for possible chemoprevention. Unlike intraductal papillomas with atypia, there is no consensus for the management of intraductal papillomas without atypia and the management of intraductal papillomas without atypia has been controversial. Retrospective studies for intraductal papillomas without atypia have shown upstaging rates to carcinoma ranging from 0–33%. Excision can be considered for those patients presenting with symptoms such as palpable masses, nipple discharge or larger masses greater than 1 cm. Surgical excision is not indicated for asymptomatic intraductal papillomas without atypia where there is pathologic-radiographic concordance based on the prospective TBCRC 034 trial. The objective of this article is to review the current literature with series published over the last 5 years regarding intraductal papillomas with and without atypia and to summarize their management.

Keywords: Intraductal; papilloma; breast; atypia; upstaging; carcinoma

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Introduction

Papillary lesions of the breast were described as early as 1905 by J. Collins Warren (1). He described papillary lesions as benign or malignant. The distinction between the two can be a challenge to pathologists. Haagensen and colleagues described benign intraductal papillomas (IPs) as proliferations of duct epithelium which project outward into a dilated lumen (2) (*Figures 1*,*2*). They can have variable presentations depending upon their location in the breast, central versus peripheral. IPs are common breast lesions, however, historically the management of IPs has been controversial. This article will review the current literature with series published over the last 5 years regarding IPs with and without atypia and to summarize their management.

Presentation

IPs can occur in women of all ages. With modern breast screening, asymptomatic IPs present as imaging findings on screening mammograms, ultrasounds or breast MRIs (3). Asymptomatic IPs are typically peripheral in location, present as calcifications or densities on mammograms or MRIs (*Figures 3*,*4*,*5*) and can have a higher association with malignancy (2,4).

Symptomatic IPs typically occur in the large central

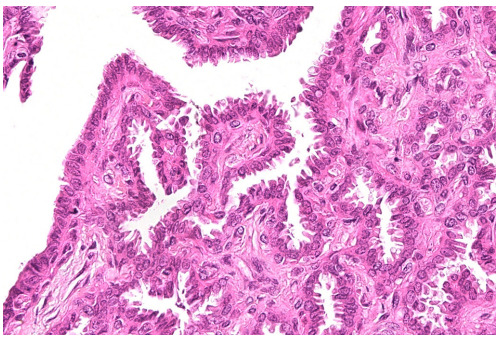

Figure 1 Duct epithelium of a benign intraductal papilloma (HE stain, magnification ×80).

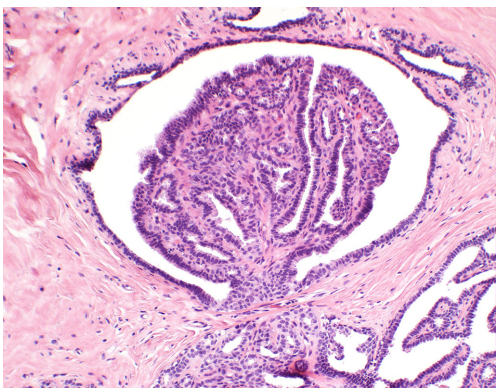

Figure 2 Benign intraductal papilloma seen within a breast duct (HE stain, magnification ×40).

ducts of the breast so they often present with serous or bloody nipple discharge (*Figure 6*). They can also present as palpable masses on clinical breast exam. They are typically solitary and tend to have a lower risk of carcinoma (2). Ultrasound usually demonstrates a solid intraductal mass (*Figure 7*) while mammographic findings can suggest a mass, density, or calcifications (3,5-7).

The diagnosis of papillary lesions provides a challenge to pathologists. The presence or absence of a myoepithelial cell layer in the papillary component of the lesion is the most important feature that helps differentiate a benign papilloma from a papillary carcinoma (8). IPs are typically diagnosed by stereotactic, ultrasound- or MRI-guided core needle biopsy (CNB) (9-11) or vacuum-assisted biopsy (12,13). Although minimally invasive techniques have become the gold standard in evaluating breast lesions, the findings can prove to be challenging to pathologists when trying to distinguish between benign and malignant lesions (12,14-16). Under

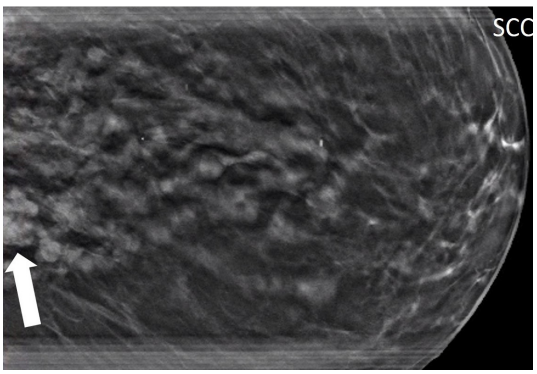

Figure 3 Intraductal papilloma seen on a breast screening mammogram presenting as a mass lesion (the arrow indicates the mass).

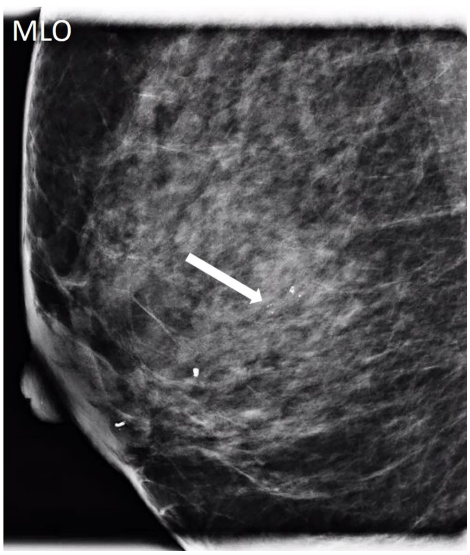

Figure 4 Intraductal papilloma seen on breast screening mammogram presenting as calcifications (the arrow indicates the calcifications).

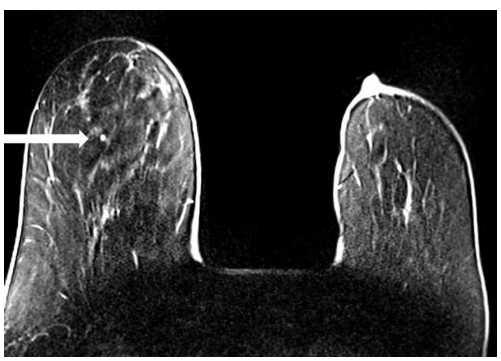

Figure 5 Intraductal papilloma seen on breast screening MRI presenting as a mass (the arrow indicates the mass).

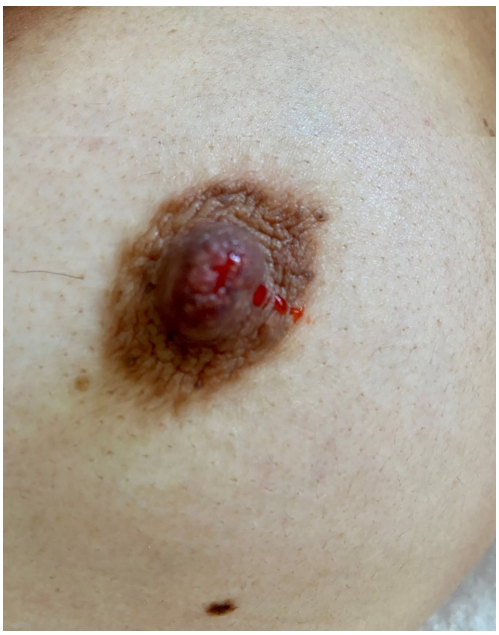

Figure 6 Bloody nipple discharge on clinical breast exam.

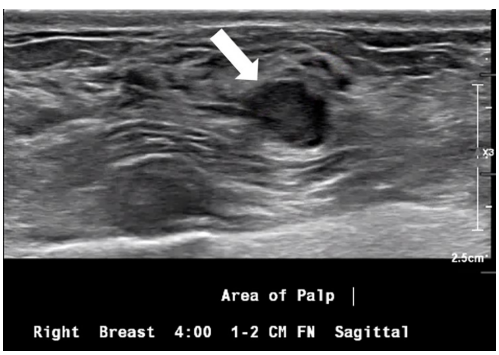

Figure 7 Intraductal papilloma seen on diagnostic breast ultrasound presenting as an intraductal mass (the arrow indicates the mass).

sampling or sampling error can also lead to false negative rates after CNB therefore a sufficient amount of core samples is critical (17). The management of IPs, therefore, is dependent upon on the presence or absence of atypia and also on pathologic-radiologic concordance, the determination that clinical, imaging, and pathologic findings that are all in agreement (15).

Management

Intraductal papillomas with atypia

The general consensus for IPs with atypia diagnosed on CNB remains surgical excision to exclude malignancy. Upstaging rates to ductal carcinoma in situ or invasive carcinoma can range up to 77% (14,18-20).

Nakhlis and colleagues conducted a study in 2015 identifying 97 patients diagnosed with IPs on CNB; 52 IPs with atypia were identified and the remainder without atypia. Patient who had concomitant diagnoses of atypical ductal hyperplasia, ductal carcinoma in situ (DCIS) or symptomatic nipple discharge were excluded from the study. All 97 patient underwent surgical excisions. Upstaging to carcinoma, all of which were DCIS, were found in 11 of 52 IPs with atypia for an upstage rate of 21% (21).

Hong *et al*. evaluated 592 papillary lesions diagnosed on CNB. 363 surgical excisions were performed and of those, 41 were IPs with atypia. Synchronous carcinomas and BIRADS 6 lesions were excluded. They found that 11 IPs with atypia were upstaged to carcinoma for an upgrade rate of 26.8%. Age >54, size >1 cm on ultrasound and a mammographic density were found to be statistically significant for upstaging to carcinoma. A trend was also seen in symptomatic patients with nipple discharge or palpable masses, however the trends were not statistically significant (16).

Armes *et al*. conducted a study in Australia evaluating 114 IPs diagnosed on CNB. A total of 103 excisions were performed for 36 IPs with atypia and 67 IPs without atypia. They divided the lesions into 2 groups: lesions associated with microcalcifications and lesions other than microcalcifications. In evaluating the IPs with atypia, malignancy was found in 1 of 8 (12.5%) lesions with microcalcifications whereas 25 of 28 (89%) lesions other than microcalcifications were upstaged to carcinoma for an overall upstage of 72%. They noted that pathologic-radiologic concordance through multidisciplinary review was important (14).

In 2018, Forester and colleagues performed a meta-analysis of high-risk lesions and reviewed 11 studies evaluating IPs with atypia. 91 malignancies were found in 298 lesions yielding a 31% upstaging rate to carcinoma (22). Similarly in 2013, Wen *et al*. conducted a meta-analysis of 34 studies in which a papillary lesion with atypia was diagnosed on CNB and found an upgrade rate to malignancy of 36.9% (23).

Kupsik, Perez and Bargaje identified 123 papillary lesions in their 2019 study. They evaluated patients diagnosed with papillary lesions on CNB and excluded any synchronous DCIS. These were divided into papillary lesions/papillomas, papillary lesion with hyperplasia and papillary

lesion with atypia and 105 lesions underwent surgical excision within 6 months after diagnosis. They identified 47 IPs with atypia and 13 were upstaged to carcinoma for an upstage of 28%. They found that atypia in papillary lesions was the most significant contributor to the risk of upstaging to malignancy. They noted that atypical lesions demonstrated a higher likelihood of upstaging based on BI-RADS classification. Race, age, size of tumor and other radiographic features were not associated with an increased risk for upstaging to malignancy (18).

Finally, Liu *et al*. conducted a retrospective study in 2019 with the largest number of excisions discussed in this manuscript, excluding meta-analyses, for IPs with atypia. Out of 317 patients identified as having papillary lesions after CNB, 92 papillary lesions with atypia were identified, excluding 19 with atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH) or flat epithelial hyperplasia (FEA). 71 patients were upstaged to carcinoma for an upstage rate of 77%. They found that older patient age, larger lesion size >1 cm, and presence of atypia were factors associated with a higher risk of malignancy. They recommended excision for IPs with atypia and pathologic-radiologic discordance.

Based on these studies, we recommend surgical excision for IPs with atypia.

Intraductal papillomas without atypia

Making a definitive diagnosis for a papillary lesion based on a CNB remains a challenge for pathologists (15). Retrospective studies for IPs without atypia have shown upstaging rates to carcinoma ranging from 0–33% (24). Unlike IPs with atypia, for which the consensus is to undergo surgical excision due to higher rates of upstaging to carcinoma, there is no consensus for the management of IPs without atypia. Some studies have suggested a greater size, peripheral lesions, palpable masses, and lesions diagnosed in older patients carry a higher risk of upgrade (4,25-27). Until recently, it was a common recommendation for patients with IPs without atypia to undergo routine surgical excision. More recent studies are now suggesting otherwise.

In 2018, Ahn and colleagues evaluated 520 benign papillomas diagnosed on CNB. 452 were IPs without atypia; 250 of these lesions were excised within 6 months after diagnosis and 17 lesions were upstaged to carcinoma for a 6.8% upstaging rate. Multivariate analysis revealed that bloody nipple discharge, size on imaging ≥1.5 cm, BI-RADS ≥4b (which implies discordance), peripheral location >3 cm from the nipple and palpability were independent predictors of malignancy (28).

Chen *et al*. conducted a retrospective review in 2019 of 324 patients diagnosed with papillary lesions after CNB. Papillomas without atypia were found in 332 lesions, of which 265 underwent excisional biopsy. The upgrade to carcinoma was found in 6 patients for an upstage rate of 2.2%. Peripheral lesions in postmenopausal or older (P=0.001) patients showed significantly higher upgrade rates (29).

In 2019, Choi *et al*. reported on 500 patients diagnosed with IPs without atypia on CNB. 203 patients underwent surgical excision, 233 underwent ultrasound-guided directional vacuum-assisted removal (DVAR) with 8- and 11-gauge needles, depending on the size of the lesion, and 61 patients had no intervention but were followed with ultrasound for at least 2 years. Of the 206 patients who underwent surgical excision, DCIS was found in 4 patients for an upstage rate of 1.9%. In the DVAR group, 5 of 233 patients were upstaged to carcinoma for a rate of 2.1%, 4 being DCIS and 1 invasive ductal carcinoma. None of the 61 patients with no intervention were diagnosed with carcinoma during the time of the study and mean follow up of 43 months (30).

In their 2019 study, Liu and colleagues identified 317 papillary neoplasms after CNB that underwent surgical excision. 206 papillary lesions were identified with no atypia. Initially 7 patients were upstaged to malignancy for a rate of 3.4% however after a second pathology review, 2 cases were identified with no atypia after excluding the others with atypia for an upstage rate of 1%. They suggested serial imaging follow up for lesions less than 1 cm with no histological atypia and recommended attention to the size of the lesion identified (20).

Kuehner *et al*. identified 407 patients in a retrospective study presenting with a palpable mass diagnosed with IP without atypia on CNB. 327 patients underwent surgical excision, 61 patients underwent surveillance imaging, and 19 patients had no surgery nor imaging surveillance. Among the 327 women with surgical excision, 11 (3.4%) had in situ cancer and 8 (2.4%) had invasive cancer for an overall upstage rate of 5%. An upgrade to an in situ cancer or invasive cancer was more common among women with a lesion greater than 1 cm, a palpable breast mass, age >50 years, or if the lesion was >5 cm from the nipple, findings also supported by other studies (19-21,31,32). No

Table 1 Intraductal papillomas with atypia (14,16,18,20-22)

Study, year	Study design	Excisions (n)	Upgraded to carcinoma
Nakhlis, 2015 (21)	Retrospective	52	11 (21%)
Hong, 2016 (16)	Retrospective	41	11 (27%)
Armes, 2017 (14)	Retrospective	36	26 (72%)
Forester, 2018 (22)	Meta-analysis	298	91 (31%)
Kupsik, 2019 (18)	Retrospective	47	13 (28%)
Liu, 2019 (20)	Retrospective	111	76 (68%)

Table 2 Intraductal papillomas without atypia (20,26,28-30,33)

Study, year	Study design	Excisions (n)	Upgraded to carcinoma
Ahn, 2018 (28)	Retrospective	250	17 (7%)
Choi, 2019 (30)	Retrospective	206	4 (2%)
Liu, 2019 (20)	Retrospective	206	2 (1%)
Chen, 2019 (29)	Retrospective	265	6 (2%)
Kuehner, 2019 (26)	Retrospective	327	19 (5%)
Nakhlis, 2020 (33)	Prospective	116	2 (1.7%)

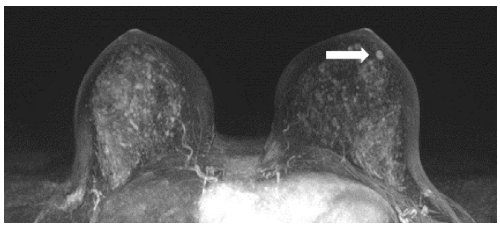

Figure 8 Sclerosing papilloma seen on screening breast MRI presenting as a well-defined mass (the arrow indicates the mass).

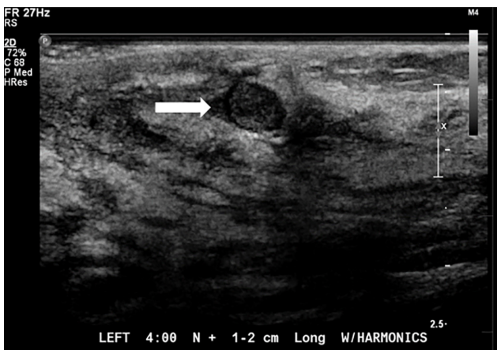

Figure 9 Sclerosing papilloma seen on a diagnostic breast ultrasound presenting as a well-defined mass (the arrow indicates the mass).

cancers were diagnosed in 61 women followed by imaging surveillance followed for 2 years (26).

It must be noted that the majority of studies reported in the literature today are retrospective in nature which can lead to biases, however, the TBCRC 034 registry study done by Nakhlis *et al.* was a prospective multi-institutional registry to study the upgrade rate of IPs without atypia in a prospective manner, the first of its kind (33).

Intraductal papillomas with atypia and without atypia are summarized in *Tables 1,2*.

One hundred and sixteen patients were identified prospectively in the TBCRC 034 registry and consented to surgical excision after excluding discordant cases, BI-RADS >4, and those with concurrent lesions already requiring excision such as ADH or atypia. Masses or distortion were the most common imaging finding on mammogram in 77 patients, while mammographic calcifications were found in 25 patients. On MRI, 10 patients presented with masses and 4 patients with non-mass enhancement. Pathology review at the local institution upgraded 2 of 116 cases for an upstaging rate of 1.7%, both of which were DCIS. Both upgrades were diagnosed in patients on screening mammogram and MRI in masses less than 1cm in size. Interestingly, upon central pathology review of the slides in both upstaged cases, the central pathologist deemed both lesions represented ADH only and not DCIS. It was noted that in 1 of the 2 centrally reviewed cases, not all of the slides were available for central review so the highest possible rate of upstage could be 1.2% (33).

Lastly, it must be stressed that radiologic-pathologic concordance is critical when making recommendations for IPs without atypia (9,11,12,15,26,31). Some studies have reported concordance (16,31,33) whereas others have not (14,30,34). Sclerosing papillomas are well-defined solid masses on imaging (*Figures 8,9*) with a dominant sclerosed architecture, not to be confused with complex sclerosing lesions, which often appear as spiculated or stellate lesions on imaging (35). Pathologically they usually have wider, more collagenous fibrovascular cores (36). If a sclerosed papilloma is diagnosed on core needle biopsy and are found to be concordant with imaging, they do not require excision. When a lesion seen on imaging appears suspicious for carcinoma but CNB or VAB yields benign results, excision should be performed based on discordance.

Clinical scenarios

Scenario 1

A 53-year-old patient presents with an asymptomatic ovoid 1cm mammographic density diagnosed on a routine screening mammogram (*Figure 3*). Diagnostic imaging on ultrasound confirms a 0.7 cm intraductal lesion most consistent with an intraductal papilloma (*Figure 7*). Ultrasound guided core needle biopsy reveals an intraductal papilloma with no atypia which is deemed to be concordant by the radiologist. No surgical excision is recommended.

Scenario 2

A 64-year-old patient presents with a 2-month history of unilateral bloody nipple discharge (*Figure 6*). On clinical breast exam, she has reproducible bloody discharge emanating from a central duct with a 1.5 cm periareolar mass that can be appreciated near the areolar edge at 6:00. Mammogram revealed no abnormal findings but correlative ultrasound reveals a 1.5 cm intraductal mass (*Figure 7*). Ultrasound guided core needle biopsy reveals an intraductal papilloma with no atypia. Surgical excision is recommended given the patient's presentation of nipple discharge with a palpable mass. Surgical pathology confirmed a 1.8 cm intraductal papilloma with no atypia. If the pathology would have revealed atypia, the patient would have been referred to the high-risk clinic for assessment and possible chemoprevention.

Scenario 3

A 71-year-old patient undergoes a routine screening mammogram which reveals a 5 mm grouping of calcifications in the retroareolar breast (*Figure 4*) confirmed on diagnostic mammogram. Stereotactic core needle biopsy reveals an intraductal papilloma with no atypia which is found to be concordant by the radiologist. No surgical excision is recommended.

Conclusion

To summarize, IPs with atypia should be excised due to the higher rate of upstaging to malignancy. Patients with IPs with atypia should also be referred for high risk assessment for possible chemoprevention. Surgical excision is not indicated for asymptomatic IPs without atypia where there is pathologic-radiographic concordance based on the prospective TBCRC 034 trial (33). Excision can be considered for those patients presenting with symptoms such as palpable masses, nipple discharge or larger masses greater than 1 cm.

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Footnote

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