Benign Papillomas Diagnosed on Large-gauge Vacuum-Assisted Core Needle Biopsy which Span <1.5 cm Do Not Need Surgical Excision

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Abstract: The objective of our study is to determine if a carefully selected subset of benign breast papillomas (size ≤1.5 cm) can be safely followed by imaging surveillance instead of immediate surgical excision. Over a 6½-year period, 86 breast lesions were diagnosed as a benign papilloma (BP) utilizing an 11- or 8-gauge vacuum-assisted core needle biopsy (VACNB) device. In general, it was our intent to remove as much of the radiologically evident lesion as possible. These 86 lesions underwent ≥2 years of imaging surveillance, without surgical excision following initial detection. With ≥2 years of radiologic follow-up, none of the 86 BPs demonstrated imaging findings that necessitated repeat biopsy or surgical excision. Benign breast papillomas ≤1.5 cm that are biopsied using an 11- or 8-gauge VACNB device with intent to remove as much of the radiologically evident lesion as possible are safe to undergo serial imaging surveillance rather than immediate surgical excision.

Key Words: benign papilloma, intraductal papilloma, papilloma excision

A papillary lesion of the breast is a general descriptor for a continuum of benign to malignant lesions, which include benign papillomas (BP), papillomatosis and sclerosing papillomas, atypical papillomas, micropapillary ductal carcinoma in situ (DCIS), and papillary breast carcinoma or invasive ductal carcinoma (IDC) (1,2). Papillary breast carcinoma itself accounts for only about 2% of all breast cancers (3). Despite this distinct terminological continuum of papillary lesions, it can be difficult to differentiate borderline lesions (i.e., atypical papilloma versus papillary carcinoma) on the basis of histopathologic features. In the past, this challenge has made certain difficult cases arbitrarily subjective for the interpreting pathologist (2,4).

The difficulties in management and disposition of papillary breast lesions begin with the physician who performs the biopsy. Sampling error leading to a false-negative result is often cited as the foremost reason to excise all papillary lesions diagnosed by fine-needle aspiration (FNA) and smaller gauge core needle biopsy (CNB). These sampling methods may miss areas of atypia or small malignant foci (3,5–9). Pathologic distinction may remain difficult even with biopsy of the entire lesion, particularly when the lesion is not reviewed by a pathologist subspecialized in breast disorders (1,2,10).

More recently, studies have suggested that surgical excision may not be necessary for accurate diagnosis of benign papillary lesions sampled by larger (11- or 8-gauge) VACNB devices and confirmed as benign by surgical excision (3,11), 2-year imaging follow-up, or a combination of both (12,13).

In our study, the reliability of imaging surveillance for BPs ≤1.5 cm initially sampled with an 11- or 8-gauge VACNB device was retrospectively assessed over a 6½-year period at our institution. BPs greater than 1.4 cm tend to be malignant more often than those which were smaller (1); and no papillary lesion we assessed (whether by mammography, ultrasound, or
final pathology) was >1.5 cm. In general, it is our practice to remove as much of the radiologically evident lesion as possible (whether calcifications and/or a mass with stereotactic technique, or a mass with ultrasound-guided biopsy technique). Of note, a predecessor study at our institution by Sohn et al. (14) retrospectively assessed the upgrade rate of papillary breast lesions sampled by 14- or 11-gauge biopsies from January 1994 to December 2005. Sohn et al. found that only two lesions initially designated as BP (1.1%) were upgraded (to carcinoma) following surgical excision.

**MATERIALS AND METHODS**

**Subjects**

We reviewed all BPs at our institution from January 2003 to June 2009. January 2003 was designated as our starting point because this is when we began more routine use of our 8-gauge VACNB biopsy device. June 2009 was designated as the end point to give ≥2 years for possible follow-up imaging surveillance (assuming patients would return as scheduled). This end point was additionally chosen because 2 years is the time interval used to more closely follow a probably benign finding until it can be reduced from a Breast Imaging-Reporting and Data System (BI-RADS) 3 to BI-RADS 2. During this time, 4293 CNBs were performed.

For inclusion into the study, all papillary lesions were confirmed as a BP following initial sampling by an 11- or 8-gauge VACNB intended to remove as much as possible of the sonographically visible lesion or stereotactically visible calcifications. On average, visible lesional removal required four samples with an 8-g VACNB device, and six to seven with an 11-g VACNB device. These BP then demonstrated benign radiographic findings for at least 2 years on follow-up mammograms, without change necessitating repeat biopsy or surgical excision. In most cases, follow-up consisted of mammograms every 6 months for 2 years, and then annually thereafter.

One hundred and fifty-two papillary lesions were identified by an 11- or 8-gauge VACNB. Of these, 11 papillary lesions (7.1%) were associated with atypia (PA) and 12 (7.7%) with malignancy (PM). These 23 PAs and PMs were excluded because it is standard of care to recommend surgical removal for all PAs and PMs. Ten BPs were surgically excised after VACNB due to patient preference, and were therefore excluded from the study (even though these 10 were confirmed as BPs following surgery). Finally, one papilloma was excluded because it was initially designated a BI-RADS five lesion, requiring surgical excision. The surgical specimen revealed a final diagnosis of a BP. Fifteen BPs have not yet completed 2 years of imaging follow-up (either due to patient noncompliance; or because the patient has not yet completed a follow-up mammogram at least 2 years from the excision date). These 15 have therefore been excluded. In addition, 17 have been lost to follow-up prior to 2 years of imaging follow-up, mostly due to patient relocation. Thus, these 17 have also been excluded.

Eighty-six BPs (in 84 women; two women had multiple BPs) remained following the aforementioned exclusions. The average age of the patient at the time of biopsy was 54 years 6 months (range of 32.9–83.1). The average length of radiographic follow-up (from initial biopsy to the most recent examination reconfirming a benign appearance) is 4 years 10 months (range of 2–8.83 years), with 41/86 lesions above this average length of follow-up time.

Overall, only 45 of 86 BPs were initially radiologically evident by mammography as a mass/focal asymmetry with (8) or without (37) suspicious microcalcifications. The remaining 41 BPs were incidentally discovered in the management of suspicious microcalcifications (29), bloody nipple discharge (5), a palpable abnormality (5), or on the preoperative MRI of a contralateral breast cancer (2).

**Management and Follow-up**

Thirty-seven BPs were initially discovered on mammography as a mass or focal asymmetry without associated calcifications. All 37 of the BPs were next imaged with ultrasound, which redemonstrated the mammographically evident mass in 35 of 37. These 35 BPs were biopsied with ultrasound guidance. The other two BPs not visualized by ultrasound underwent biopsy with stereotactic guidance.

Eight BPs were initially discovered on mammography as a mass/focal asymmetry with associated microcalcifications. All eight were next imaged with ultrasound, which redemonstrated the mass in seven of the eight. Five of the eight underwent stereotactic biopsy (including the one BP, which did not show an associated mass on ultrasound). The other three BPs were biopsied with ultrasound guidance because the sonographic mass was more obvious than the mammographic calcifications.
Twenty-nine BPs were initially discovered on mammography as microcalcifications without an associated mass or asymmetry. Because there was no associated mass or asymmetry, and because 0 of the 29 patients reported a palpable lesion, ultrasound was not performed. All 29 underwent stereotactic 11- or 8-g VACNB.

Five BPs were initially discovered on ultrasound as part of the management for a clinically palpable mass. Five other BPs were first discovered on US (2) or MRI (3) as part of the management for bloody nipple discharge. All 10 of these BPs underwent ultrasound-guided VACNB. We generally evaluate bloody nipple discharge with MRI and mammography—often with additional MR-directed (or 2nd-look) ultrasound when appropriate. The three BPs associated with bloody nipple discharge [initially discovered on MRI] were subsequently confirmed on a MR-directed ultrasound exam prior to ultrasound-guided VACNB.

Two BPs were initially discovered as small masses on preoperative MRI in the management of a contralateral breast cancer. They were subsequently confirmed on MR-directed ultrasound. Next, they underwent ultrasound-guided VACNB and were confirmed as BPs. To date, both remain unchanged in their mammographic appearance.

When the BPs of this study were biopsied with ultrasound guidance (and the percentage removed was included in the postprocedure report by the radiologist), no less than 75% and no more than 90% of the radiographically evident lesion was reportedly removed. Often because of location (retroareolar, within a dilated duct) and/or clinical history (bloody nipple discharge), we had a high degree of suspicion before the biopsy that the mass may be a BP.

However, when the BPs of this study were biopsied with stereotactic guidance for a cluster of suspicious microcalcification, we often did not suspect that the suspicious microcalcifications were possibly caused by a BP prior to biopsy. Therefore, when stereotactic biopsy of suspicious grouped or clustered calcifications is performed, it is our practice to remove most (>75%) to all of the radiographically evident calcifications. However, we do not routinely report a percentage or estimation of calcifications removed. Nor do we reposition the stereotactic biopsy needle unless absolutely necessary (for reasons beyond the scope of this paper) if calcifications are adequately obtained within the biopsy specimen on specimen mammography.

After each biopsy (ultrasound-guided or stereotactic), a clip is placed, and a postprocedure mammogram is obtained. We do not routinely review biopsy margins with pathology. Instead, follow-up mammograms are obtained every 6 months for 2 years, and annually thereafter.

Mammographic images of a BP, and its typical appearance on multiple follow-up images, have been included below (Fig. 1). There is no growth/development of a new mass or suspicious calcifications or a mass at or adjacent to the biopsy site.

**Figure 1.** Initial (left), 6-month follow-up (middle), and 3-year follow-up (right) craniocaudal views of the left breast demonstrate a nonspecific mass (white circle) in the upper outer quadrant of the left breast (bracketed by the black oil pencil). The mass on the initial mammogram was excised and a clip was placed. The mammographic appearance remained benign without development of suspicious calcifications or a mass at or adjacent to the biopsy site.
Procedure

An 8- or 11-gauge VACNB device (Mammotome; Ethicon Endo-Surgery, Cincinnati, OH) was used for both ultrasound-guided and stereotactic biopsies. Preference was given to the 8-gauge biopsy device with intent to remove as much of the lesional calcifications (stereotactic approach) or mass (ultrasound or stereotactic approach) as possible. An 8-gauge needle was also preferred when possible to retrieve a larger histologic sample per core, and for more complete sampling of the lesion. Exceptions to our preference for the 8-gauge system were made in the following instances: 1—the lesion was too close to the skin surface; 2—compression was not adequate for stereotactic technique leading to a negative stroke margin; or 3—color Doppler demonstrated abundant vascularity or a large vessel adjacent to the lesion (to mitigate the risk of a hematoma).

RESULTS

To date, 0 of the 86 BPs that have undergone at least 2 years of benign mammographic follow-up have demonstrated change on imaging that would necessitate repeat biopsy or surgical excision. We did encounter one case of interest where the patient underwent a mastectomy for DCIS in a different quadrant from a BP identified 4 years earlier in the same breast. The clip of that BP was 5.0 cm from the...
closest margin of the intermediate-grade DCIS on final pathology, and no atypia or malignancy was identified at or adjacent to the clip.

The average size of the 86 BPs (when reported) was 7.5 mm ($n = 49$; range of 3–15 mm). The average number of cores was 6.6 (range: 2–18) for 11-gauge biopsies, and 4.33 (range: 1–8) for 8-gauge biopsies. Forty-four biopsies (51.2%) were performed with an 11 gauge device; 27 by US-guidance and 17 by stereotactic technique. Forty-two (48.8%) biopsies were performed with an 8 gauge device; 26 by US-guidance and 16 by stereotactic technique. Fifty-six papillomas were located in the left breast and 30 in the right breast.

**DISCUSSION**

Because many papillary lesions are undetected [as a discrete mass] on mammography, differentiation by imaging alone has previously proven unreliable (15); however, a newer study notes that certain sonographic features suggest benignity. Benign papillary lesions tend to demonstrate homogeneous echotexture, in contrast to malignant or high-risk lesions, which often demonstrate mixed or complex cystic echogenicity. In addition, benign papillary lesions were more often well-circumscribed when compared with malignant equivalents. Finally, no benign papillary lesion demonstrated angular margins or spiculation (3).

Multiple additional confounding variables must be considered. It has been postulated that papillomas may be a precursor of papillary carcinoma; or that they may degenerate into a malignant lesion over time (1,10,14,16). Also, a carcinoma in situ [PM] diagnosed by CNB may be upgraded to invasive cancer when the entire lesion is examined (17–20). These observations, however, were based on results from smaller gauge core biopsy without vacuum assistance; and without [expressed] intent to remove as much of the radiographically evident lesion as possible. It is indeed known that CNB without vacuum assistance has been associated with significantly higher false-negative rates and histologic upgrade than biopsies performed with vacuum assistance. The aforementioned studies are also reporting the upgrade rate of PA and PM, which we always recommend for surgical excision and have therefore excluded from our study. Moreover, more recent studies suggest that histologic upgrade from lesional undersampling is not as prevalent with VACNB as previously suggested (13).

A recent study by Chang et al. correlates the size of a benign papillary lesion with its potential for histologic upgrade to carcinoma. As may be expected, malignancies tended to be larger (average of 1.4) than benign lesions (average of 0.9 cm) (1). However, we did not have a benign papillary lesion greater than 1.5 cm in our sample group, and the average size of papillary lesions in our study was around 7.5 mm.

As recently as 2008, the surgical literature reported that all papillomas require surgical excision regardless of radiologic–pathologic correlation when utilizing a 14-gauge CNB technique (21). In that same year, a similar conclusion was suggested by Shin et al.
Regardless of the somewhat inconsistent nature of recommended follow-up for benign papillary lesions, it is the accepted standard of care to excise all papillomas with any degree of atypia or malignancy (14,22,23). Chang et al. affirmed that surgical excision is required for accurate diagnosis of papillary lesions sampled by CNB (1); however, a more recent paper by the same author suggests that surgical excision may not be necessary when these lesions are sampled by an 11-gauge US-guided VACNB device (11). A recent article by Kim et al. also challenges the recommendation for surgical excision, as this study demonstrated a 0% upgrade rate to carcinoma in 54 BPs initially biopsied by an 11- or 8-gauge VACNB technique. Kim et al. has also followed a large number of initially BPs that were not immediately excised and remained radiographically benign without changes necessitating surgical excision (13).

Some studies have reported that BPs demonstrating radiologic–pathologic concordance can be safely observed with mammographic follow-up (22,24,25). In 2008, Kim et al. reported that surgical excision is not necessary for accurate diagnosis in a series of 39 papillary lesions removed by 11- or 8-gauge US-guided vacuum-assisted technique (12).

What is becoming clear is that sampling error is significantly reduced with increased core needle gauge size (11–13), vacuum assistance (3), and intent to percutaneously remove most or all of the visualized lesion (12). Furthermore, the use of an 8-gauge VACNB to achieve lesion removal appears to circumvent the need for subsequent excision (12), particularly when the lesion demonstrates benign findings on follow-up for ≥2 years (22) (Table 1).

A few limitations of our study merit consideration. The sample size was affected by 17 patients who were lost to follow-up (usually due to patient relocation). A second limitation is lack of definitive radiologic–pathologic correlation, as none of the 86 BPs included in the study has undergone surgical excision for histologic confirmation. Indeed, BPs subjected to surgical excision could have represented a control group for the study, allowing for true statistical analysis of BPs diagnosed by VACNB at our institution. However, because 24 months of serial imaging is required to reassign a BI-RADS 3 (probably benign) lesion to BI-RADS 2 (benign), it is unlikely that a surgically excised control group would change the management or categorization of these lesions as the average follow-up time of the BPs we reviewed is 58 months. Finally, even though the 86 BPs in this study are the largest current [reported] group of BPs followed exclusively by imaging, an even greater number of BPs would have allowed for greater levels of assurance.

Our data suggest that at 2 years post biopsy, there is no difference in the outcome of BPs initially biopsied by a large-gauge VACNB and closely followed by imaging surveillance, versus those which are immediately surgically excised. Therefore, BPs less than 1.5 cm, biopsied by 11- or 8-g CNB, using vacuum assistance, with intent to remove as much of the radiographically-evident lesion as possible, do not require immediate surgical excision if instead followed by short-interval imaging surveillance. The radiographic follow-up of BPs should, therefore, be a focus of future interest as the cost, risk, and morbidity of surgical excision can potentially be avoided.

**LEARNING POINTS**

1. All papillary lesions with atypia and malignancy should undergo surgical excision.

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**Table 1. Summary of Recent Studies on Management of Papillary Breast Lesions**

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of papillary lesions upgraded after surgical excision</th>
<th>Conclusion</th>
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<tbody>
<tr>
<td>Kim et al. (13)</td>
<td>14 g – 12 of 157 (7.6%)</td>
<td>Surgical excision may not be mandatory for benign papillary lesions removed by US-guided VACNB</td>
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<td>11 and 8 g – 0 of 54 (0%)</td>
<td>Surgical excision is required for accurate diagnosis of benign papillomas removed by CNB</td>
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<td>Chang et al. (1)</td>
<td>14 g – 8 of 54 (14.8%)</td>
<td>Surgical excision may not be required for benign papillomas removed by 11-gauge US-guided VACNB</td>
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<tr>
<td></td>
<td>11 g – 0 of 10</td>
<td>Surgical excision should be performed for accurate diagnosis of papillary lesions</td>
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<tr>
<td>Shin et al. (3)</td>
<td>11 and 8 g – 3 of 49 to atypical (6.1%), 0 to malignancy</td>
<td>Surgical excision may not be required for benign papillomas removed by 11-gauge US-guided VACNB</td>
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<tr>
<td></td>
<td>11 and 8 g – 2 of 15 (13.3%) to atypical, and 2 to malignancy</td>
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<tr>
<td>Kim et al. (12)</td>
<td>11 g – 0 of 29 (0%)</td>
<td>Surgical excision may not be required for benign papillary lesions excised by US-guided directional vacuum-assisted removal</td>
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<td></td>
<td>8 g – 0 of 10 (0%)</td>
<td>Mammographic follow-up is reasonable for a benign papilloma diagnosed at core biopsy based on an infrequent (3%) association of this lesion with cancer</td>
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<tr>
<td>Sydnor (22)</td>
<td>14 and 11 g – 1 of 38 (2.6%)</td>
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2 Papillary lesions eligible for mammographic follow-up (instead of surgical excision) include those which meet all of the following criteria:

- a papillary lesion less than 1.5 cm on initial radiographic imaging (measured if visualized as a mass on mammogram or ultrasound);
- biopsied by a large-gauge (11 or 8 g), vacuum-assisted, core needle biopsy device; and
- confirmed as a BP by pathology.

3 Typically, follow-up should include a mammogram every 6 months for the first 2 years, and annually thereafter.

4 Any concerning mammographic change (increasing calcifications or new/recurrent mass at the site of the biopsy clip) should prompt a full re-assessment and discussion of surgical excision even if a repeat biopsy is benign.

5 When following over 86 BPs with the criteria from learning points 1–3, 0 of the 86 BPs have demonstrated any change necessitating repeat biopsy or surgical excision with an average of 58 months of benign imaging follow-up.

CONFLICTS OF INTEREST

None.

REFERENCES


