Benign papilloma of the breast at US-guided directional vacuum-assisted removal: can replace the surgical excision?

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Purpose

The management of papillary lesions diagnosed as benign at core-needle biopsy has been controversial [1-14]. Several investigators recommend surgical excision even when papillary lesions are benign at core-needle biopsy because 10-21% of those lesions were upgraded to atypical ductal hyperplasia (ADH) and ductal carcinoma in situ (DCIS) when re-assessed after excision [6, 10, 11]. However, these studies used stereotactic guidance or US-guided automated core biopsy with 14-gauge or smaller needles.

More recently, few studies have been suggested that US-guided directional vacuum-assisted removal (US-DVAR) of benign papillomas for diagnostic or therapeutic reasons is a satisfactory alternative to surgery, with 0% false negative biopsy results [15-17]. But, the number of cases in their studies was small.

Thus, the purpose of this study is to evaluate the follow-up results from a larger study population and to assess the value of US-DVAR in diagnosis and management of benign papillomas of the breast.
Methods and Materials

Patients

Between October 2004 and December 2009, 1,250 consecutive percutaneous, ultrasound-guided vacuum-assisted biopsies of breast lesions were performed at our institution.

Of these 1,250 lesions, 155 nonmalignant papillary lesions were diagnosed in 140 patients. In 3 of 155 biopsies, the purpose was not removal but sampling of the lesions that were sonographically visible microcalcifications (n=1) or heterogeneous areas (n=2). The remaining 152 procedures for 152 lesions were prospectively intended to remove the sonographically visible mass. Of the 152 nonmalignant papillary lesions that were diagnosed at US-guided vacuum-assisted removal, one lesion with focal atypia was excluded. The other 151 lesions were diagnosed as histologically benign papillomas without atypia. Of the 151 lesions, 34 lesions were excluded because there was no subsequent surgical excision or imaging follow-up after US-DVAR. The remaining 117 lesions in 104 patients that were diagnosed as benign papilloma at US-DVAR made up the study population. The mean patient age was 44 years (range, 16-74 years).

Eighty of the 117 lesions were detected on screening mammography or US; the remaining 37 presented with symptoms such as a nipple discharge (n=32), a lump (n=4), and a pain (n=1).

Prior to DVAR, US-guided 14-gauge core needle biopsy were performed for 89 of the 117 lesions. Of the 89 lesions, 81 had been diagnosed as benign papilloma and 8 had been diagnosed as other benign lesions; adenosis (n=3), fibrocystic disease (n=2), sclerosing adenosis (n=1), radial scar (n=1) and usual ductal hyperplasia (n=1).

Imaging evaluation

Bilateral mammography was performed with dedicated equipment.

Galactography was performed for the work-up of pathological nipple discharge.

Ultrasonography was performed using high-resolution ultrasonography units with 10- or 12-MHz linear array transducers.

Prior to 14-gauge automated core-needle biopsy or directional vacuum-assisted removal, lesions were assigned to final assessment categories of the Breast Imaging Reporting and Data System (BI-RADS) [18].
DVAR procedure

After administration of local anesthetic, the 8-gauge probe (for lesions 1.0-3.0 cm in the greatest dimension) or an 11-gauge probe (for lesions 1.0 cm or less in the greatest dimension) was inserted into the breast through a small skin incision. The probe was guided into biopsy position under direct US visualization. Multiple core samples were taken until the mass was completely removed, determined with real-time sonography of the biopsy site. Sonographic imaging data were collected immediately after biopsy demonstrated the procedural feasibility of complete lesion removal. The DVAR procedure was performed by three board-certified radiologists with 10, 5 and 2 years of experience in breast imaging. The completeness of mass removal was recorded as "yes" or "no" for each patient, immediately after the procedure.

Follow-up

All 117 lesions underwent imaging follow-up for an average of 17 months (range, 6-69 months). On US follow-up, mild distortion at the site of DVAR was considered to be a post-DVAR change, while space-occupying lesion was considered to be a residual. With respect to the follow-up exams, patients were advised to undergo 6- and 12-month follow-up sonography and 12-month follow-up mammography with annual mammographic and sonographic evaluations thereafter.

Outcome analysis

The clinical, pathologic and imaging findings from the 104 patients, including subsequent excisions and follow-up imaging studies, were reviewed. Data were entered into a computerized spreadsheet. With respect to follow-up data, the radiologist evaluated whether there was histologic upgrade at follow-up and whether follow-up imaging demonstrated residual lesions.

Upgrade rate

An "upgrade" in diagnosis was recorded when a patient had at least one benign lesion at DVAR, classified as ADH, DCIS, or invasive carcinoma at surgical excision or follow-up, or one atypical lesion at DVAR, classified as DCIS or invasive carcinoma at surgery or follow-up. The upgrade rate was determined by dividing the number of cases with upgrade in diagnosis by the total number of DVAR performed.

Exact confidence intervals were calculated according to the formula given by Berry [19].
Results

All the 117 lesions were diagnosed at US-DVAR as histologically benign papilloma with no evidence of atypia or malignancy. At 14G core-needle biopsy before DVAR, 81 lesions had been diagnosed as benign papilloma and 8 had been diagnosed as nonpapillary benign lesions.

A mammography was performed in 86 cases. Sixty five (75.6 %) cases had a negative finding, 12 (14.0 %) had a mass (Fig. 1a), and 9 (10.4 %) had a focal asymmetry. A galactography was performed in 24 lesions. Thirteen lesions (54.2 %) showed abnormal galactogram such as duct ectasia (n=1, 4.2 %), intraductal filling defect (n=9, 37.5 %) or ductal cut-off (n=3, 12.5 %) (Fig. 1b). Ten lesions (41.6 %) showed negative finding. In the remaining one (4.2 %), reading was not possible due to the presence of extravasation. Sonographic findings were a hypoechoic solid mass in 70 lesions (59.8 %) (Figs. 2a, 3a, 4a and 5b) and mass within a dilated duct in 47 lesions (40.2 %) (Fig. 1c). There were no cases in which histological and imaging findings were considered discordant. At sonography, the mean lesion size was 9.0 mm (range, 4-22 mm).

Final assessments of 117 lesions based on combined mammographic, galactographic and sonographic findings are shown in Table 1.

Table 1: Final assessment of 117 benign papillomas before US-DVAR

<table>
<thead>
<tr>
<th>Final assessment</th>
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<tr>
<td>Category 3</td>
<td>7</td>
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<tr>
<td>Category 4a</td>
<td>109</td>
</tr>
<tr>
<td>Category 4b</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>117</td>
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</table>

US-DVAR, ultrasound-guided directional vacuum-assisted removal

DVAR procedure

An 11-gauge directional vacuum biopsy device was used for 88 lesions, and an 8-gauge was used for the remaining 29 lesions. Fourteen core samples were obtained on average per lesion (range, 4-45). For all patients, the completeness of mass removal was recorded as "yes." Three patients developed post-procedural hematomas (ranging in size from 1.0-1.9 cm) (Fig. 3c), which did not require treatment. There were no serious short-term complications, such as postprocedural bleeding or skin tear requiring a second procedure.
Follow-up

Of the 117 lesions that underwent imaging follow-up, 113 (96.6 \%) showed no sonographically visible residual lesions (Figs. 1f, 2c, 2d and 3d), while 4 (3.4 \%) showed residual lesions on the first follow-up US (4-15 months) (Fig. 4c and 5e). Table 2 lists the details of each of the four cases that showed residual lesions. One of the 4 residual lesions was surgically excised and was confirmed to be benign papilloma. The other one residual lesion was diagnosed as benign papilloma at repeat US-DVAR (Fig. 4d). The remaining 2 residual lesions showed no interval change in size on serial follow-up sonography (12 and 28 months) since the residual lesions were detected on sonography (Fig. 5e).

Table 2: Details of the four residual papillomas

<table>
<thead>
<tr>
<th>Case</th>
<th>Re-presentation</th>
<th>Time after DVAR (months)</th>
<th>Size of original lesion (mm)</th>
<th>Size of residual lesion (mm)</th>
<th>Probe size (gauge)</th>
<th>Number of cores</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Ultrasonographic</td>
<td>4</td>
<td>10</td>
<td>4</td>
<td>11</td>
<td>NA</td>
</tr>
<tr>
<td>19</td>
<td>Ultrasonographic</td>
<td>11</td>
<td>9</td>
<td>5</td>
<td>11</td>
<td>NA</td>
</tr>
<tr>
<td>107</td>
<td>Ultrasonographic</td>
<td>10</td>
<td>11</td>
<td>13</td>
<td>11</td>
<td>20</td>
</tr>
<tr>
<td>114</td>
<td>Ultrasonographic</td>
<td>15</td>
<td>10</td>
<td>19</td>
<td>8</td>
<td>11</td>
</tr>
</tbody>
</table>

DVAR, directional vacuum-assisted removal; NA, not available

The upgrade rate in DVAR of benign papillomas was 0 \% (95 \% confidence interval, 0-10 \%).

At the initial visits after US-DVAR, the symptoms had disappeared in all patients. And no patients later experienced symptom recurrence over the mean follow-up of 17 months (range 6-69 months).

In terms of symptom elimination, US-DVAR eliminated the symptom in all 37 symptomatic cases. Of the 32 patients with abnormal nipple discharge, no case showed a persisting symptom or symptom recurrence over the follow-up period.
Fig. 0: A 42-year-old woman with bloody nipple discharge. The mammogram (a) showed an 1.0-cm circumscribed oval isodense mass (arrow) in the inner portion of the right breast. The galactography (b) showed a dilated duct with filling defect at the corresponding portion. A 1.0-cm partially ill-defined oval hypoechoic mass with adjacent ductal dilatation was noted at the corresponding portion on a transverse sonogram (c). This lesion was classified as BI-RADS category 4a and diagnosed at 14G needle biopsy as benign papilloma. DVAR of the lesion was performed using an 8-gauge probe (d, arrows indicate the opened notch for capture of directional vacuum-associated biopsy probe). The pathology was benign papilloma. Post-DVAR sonogram (e) ensured that the lesion was completely removed. A 6-month follow-up sonogram (f) showed mild distortion (arrow) at the site of DVAR, considered to be a post-DVAR change.
**Fig. 0:** A 40-year-old woman with screening sonogram for dense breast on mammogram. The mammogram showed negative findings (not shown). The sonogram (a) showed a 1.1-cm partially ill-defined, irregular hypoechoic mass in the outer portion of her right breast, which was classified as BI-RADS category 4a. The 14G core biopsy and the subsequent DVAR yielded a benign papilloma. Post-DVAR sonogram (b) ensured that the lesion was completely removed. One-year follow-up sonogram (c) showed mild distortion (arrows) at the site of DVAR, considered to be a post-DVAR change. At 3-year follow-up sonogram (d), the distortion had faded (arrows).

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Fig. 0: A 49-year-old woman with screening sonogram for dense breast on mammogram. The mammogram showed negative findings (not shown). The sonogram (a) showed a 0.7-cm ill-defined irregular hypoechoic mass in the outer portion of the right breast, which was classified as BI-RADS category 4b. The 14G core biopsy yielded a benign papilloma. DVAR of the lesion was performed using an 11-gauge probe (b). The final pathology was also benign papilloma. Post-DVAR sonogram (c) showed small hypoechoic lesion (arrow) at the site of DVAR, considered to be a hematoma. A 6-month follow-up sonogram (d) showed mild distortion (arrow) at the site of DVAR, considered to be a post-DVAR change.

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Fig. 0: A 40-year-old woman with left nipple discharge. The sonogram (a) showed a 1.0-cm sized partially ill-defined oval hypoechoic mass in the left subareolar region, which was classified as BI-RADS category 4a. The 14G core biopsy and DVAR yielded a benign papilloma. DVAR of the lesion was performed using an 11-gauge probe. Post-DVAR sonogram (b) ensured that the lesion was completely removed. 4-month follow-up sonogram (c) after DVAR showed a 0.4-cm irregular hypoechoic mass at the site of DVAR, which was diagnosed as a benign papilloma at the 14G core biopsy. The repeat DVAR (d) was performed and the sonogram obtained immediately after the DVAR showed no evidence of residual lesion (e). The final pathology was also a benign papilloma.

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Fig. 0: A 49-year-old woman with bloody nipple discharge. The previous screening sonogram (a) that was performed one and a half years ago showed a 0.6-cm sized circumscribed oval hypoechoic mass in the upper outer quadrant of her right breast, interpreted as BI-RADS category 3. On the next sonogram (b) for the work-up of bloody nipple discharge, the mass showed an increase in size, measuring 0.9 cm in the greatest dimension and was categorized as category 4a. The 14G core biopsy and DVAR (c) yielded a benign papilloma. DVAR of the lesion was performed using an 11-gauge probe. Post-DVAR sonogram (d) ensured that the lesion was completely removed. 11-month follow-up sonogram (e) after DVAR showed a 0.5-cm mass at the site of DVAR, which was considered residual. This lesion did not undergo any biopsy, DVAR, or surgical excision but underwent imaging follow-up and showed no interval change in size on 28-month follow-up sonogram (f) since the lesion was detected on sonogram (e).

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Conclusion

Our results show that 96.6 % (113 of 117) of benign papillomas were removed successfully by DVAR on follow-up imaging and no histologic upgrade was found on subsequent excision in 2 patients with residual lesions. An US-guided DVAR may be a valuable alternative to surgical excision in accurate diagnosis and management of benign papilloma of the breast. Longer follow-up results are required to confirm this conclusion.
References
