Vacuum assisted biopsy under ultrasound guidance: results from a multicentric study of 650 lesions

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Résumé
Place des macrobiopsies mammaires assistées par le vide sous guidage échographique : étude multi-centrique de 650 lésions

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Objectif. Les auteurs, sur la base d’une étude rétrospective multicentrique, exposent la technique de macrobiopsies avec aspiration par le vide sous guidage échographique et la situent par rapport aux autres techniques diagnostiques classiquement reconnues.


Résultat. Cent soixante dix-neuf lésions malignes et quatre cent soixante et onze lésions bénignes ont été découvertes. La taille moyenne des lésions était de 9 mm. Trois cancers (1,7 %) ont été diagnostiqués pour des lésions probablement bénignes et 18 cas de lésions probablement malignes (27 %) correspondaient à une pathologie inflammatoire. 4 cas (2,8 %) ont été sous estimés en rapport avec la chirurgie : 2 cas d’HCA (hyperplasie canalaire atypique) versus CCIS (carcinome canalaire in situ) et 3 cas de CCIS versus CCI (carcinome canalaire infiltrant). Grâce à cette technique, une chirurgie a pu être évitée chez 71 % des femmes qui présentaient une anomalie indeterminée ou probablement maligne. La spécificité reste bonne avec aucun cancer dépisté dans la surveillance des lésions bénignes.

Conclusion. La macrobiopsie sous guidage échographique est une technique récente, sans grande contrainte et peu invasive sous réserve d’une période d’apprentissage. L’importance du matériel recueilli à chaque procédure nous a permis d’obtenir un diagnostic fiable dans les petites lésions, les lésions complexes ou indéterminées, ou certaines lésions à risque (papillome). Cette technique nous paraît donc indiquée dans ces cas de figures où les autres techniques de prélèvements peuvent être prises en défaut et où la biopsie chirurgicale reste la règle.

Mots-clés : Macrobiose par aspiration. Échographie. Pathologie mammaire.

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Vacuum assisted biopsy under ultrasound guidance is a fairly recent technique by which a larger biopsy specimen is obtained under real time imaging. We present a retrospective review of results using this technique in a multicenter setting. The feasibility criteria, indications and role of this technique for imaging and management of breast disorders are reviewed.

Materials and Methods
Between May 2000 and December 2004, a total of 650 vacuum assisted biopsies under US guidance were performed on 644 patients in 3 centers using a single technical protocol. The Mammmotome HH (Breast Care, Ethicon, Surgery*) unit was used, initially with the 11 gauge probe then with either the 11 gauge or the 8 gauge probe after the latter became commercially available. All included patients presented a problematic breast lesion at US that could not be assessed or resolved using other available imaging techniques.
All patients were evaluated at a breast care center and/or their chart was reviewed at a multi-disciplinary breast care center conference. The following patient data were recorded: past medical history, age, imaging characteristics of lesions including size and US imaging features. Verbal and written information was provided to patients with regards to the procedure and potential peri-procedural risks and complications.

All biopsies were performed as outpatient procedures in the US department under local anesthesia with the patients supine. Local compression with a cold compress was applied after the procedure and patients were discharged home with a compressive bandage to be kept in place for 24-48 hours.

The examinations were performed using either a Toshiba Power 6000 (15 MHz), General Electric (9-11 MHz) or Philips (5-12 MHz) US unit. A clip was placed at the site of biopsy in selected patients based on the extent of resection, suspicion of malignancy, and anticipated difficulties of post-procedure localization of the biopsy and lesion site. Biplane mammograms were obtained after clip placement.

We have elected to use the classification proposed by Stavros et al. (1) in 1995 as opposed to the ACR classification (2) because the former is only based on US imaging features and allows separation of suspicious lesions into indeterminate lesions with low risk of malignancy and probably malignant lesions with high risk of malignancy. This classification defines sonographic criteria for benign and malignant lesions. A lesion is considered “probably benign” when it shows none of the malignant features and at least two of the benign features. If two benign features are not present, the lesion is classified as “indeterminate”. When one malignant feature is present, the lesion is considered “probably malignant”. To remain consistent, we have continued using this classification. After review of all data, some lesions could be upstaged.

We have first evaluated the feasibility of the macrobiopsy technique to determine the level of difficulty. To reduce the operator dependent effect, we have used a strict methodology including only moderate sized lesions (+/-1cm), avoiding difficult lesion location, and favoring ACR3 lesions to limit the risk of discordance between imaging and histological data. This phase of the study included about 30 cases per team and provided a learning curve.

In a second phase, we have proposed macrobiopsy as opposed to surgical biopsy for patients where microbiopsy was unsuccessful due to technical difficulties or lack of concordance between imaging and histological results. From a total of 165 lesions 6 mm or less in diameter, microbiopsy was non-contributive in 3 out of 4 cases and more extended biopsy was deemed necessary to achieve an accurate diagnosis.

Follow-up at 7 days was obtained in all cases at which time the presence of complication was recorded. Histological diagnosis was verified using concordance between imaging and histology, and post-surgical diagnosis when surgery was performed.

For benign cases, clinical, mammographic and sonographic follow-up was obtained at 6 and 12 months.

### Results

A total of 650 lesions were biopsied using vacuum assisted biopsy under ultrasound guidance. In 6 cases, 2 separate lesions were biopsied during a single session. The mean age of patients was 47 years (range: 19 to 83). Mean lesion size was 9 mm (4 to 38 mm) and 68% of nodular lesions measured between 6 and 10 mm. Mean procedure time was 30 minutes. Macrobiopsy was possible in all cases. Patient tolerance was excellent: only a single procedure was interrupted secondary to pain early on during the study. The number of core samples ranged between 4 and 32 (m=16.5) with a weight between 65 and 300 mg with the 8 G system.

Hematoma was the most frequent complication: 5% of cases early on (100 first cases), currently less than 2% for the last 300 cases. They were always less than 3 cm in size and surgical management was never required. A single case of cutaneous injury was recorded in a patient with hard and mobile subcutaneous nodule. A single case of hemotorax was noted in a patient with smaller breast and deeply located lesion of the inner upper quadrant.

A clip was left at the site of macrobiopsy in 17 patients in order to facilitate eventual lesion localization should surgery be required. Clip positioning is more accurate here when compared to stereotactic procedures with compressed breast tissue where the clip may migrate away from the delivery site once compression is released. On the other hand, in two patients with large post biopsy resection cavities, the clip was evacuated at the time of probe removal.

Results from correlation between histological diagnosis (benign/malignant) and US findings using the Stavros classification are summarized in Table I. Benign lesions are summarized in Table II. Inflammatory lesions were rarely classified as benign prior to biopsy and accounted for 27% of lesions classified as probably malignant prior to biopsy. Fibroadenomas were classified as indeterminate (91 cases) or probably benign (88 cases). Atypical ductal hyperplasia was present in 3 of 25 cases of biopsied peripheral papillomas (12%).

Table III is a summary of malignant lesions. Invasive ductal carcinoma, invasive lobular carcinoma and DCIS corresponded to 68%, 13% and 19% of biopsied carcinomas respectively. Malignant lesions had imaging features of probably malignant or malignant lesions in 76% of cases. Surgery was avoided in 88% of women with indeterminate lesions and 44% of...

### Table I

<table>
<thead>
<tr>
<th>Classification</th>
<th>Stavros US classification and rate of malignancy.</th>
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<tbody>
<tr>
<td></td>
<td>All lesions</td>
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<tr>
<td>Probably benign</td>
<td>152</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>285</td>
</tr>
<tr>
<td>Probably malignant</td>
<td>181</td>
</tr>
<tr>
<td>Malignant</td>
<td>42</td>
</tr>
<tr>
<td>Total</td>
<td>650</td>
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women with probably malignant lesions. From the 152 patients who underwent surgery, 5 cases (2.8%) were upstaged based on surgical results when compared to biopsy results: surgical biopsy showed DCIS instead of atypical ductal hyperplasia in 2 cases and invasive ductal carcinoma instead of DCIS in 3 cases.

Discussion

Vacuum assisted biopsy under ultrasound guidance allows removal of a larger volume of breast tissue. This technique now is a standard procedure available to interventional breast radiologists. Specific technical difficulties related to the procedure introduce some operator dependent limitations. We believe that these limitations can be overcome by using a strict methodology and allowing a learning curve on easier lesions. The latter probably explains the relatively larger number of benign lesions early on during our work. This is similar to other reports from the literature.

The mean procedure time for the radiologist is 30 minutes. The post-mammotome time required to review biopsy results, occasionally discuss the case in a multidisciplinary meeting, and provide follow-up to the patient and referring physician must also be accounted for.

In our patient population, biopsy could be performed in all cases, and added expertise is useful in more challenging situations: dense breast tissue, smaller breasts (<2cm thick), and specific lesion locations (prepectoralis, axillary, and inframammary crease). These locations may be limitations to microbiopsy, especially prepectoralis lesions where needle throw may cause chest wall injuries. Macrobiopsy would seem appropriate in such cases.

Because of the low rate of complications, macrobiopsy could be used as an alternative to surgery for complete removal of selected benign lesions (11). Larger gauge systems (8 gauge) facilitate lesion resection by reducing the number of required biopsy steps and overall procedure length.

Once familiar with the technique, we were able to consider using this technique for ACR4 lesions (2) corresponding to indeterminate and probably malignant lesions (1). Based on our experience, the indications for vacuum assisted biopsy under ultrasound guidance are similar to those for vacuum assisted biopsy under stereotactic guidance: inadequate microbiopsy. Under US guidance, the rate of false negative result ranges between 8 and 15% in the literature (3). Two main categories of failure exist: those related to technical considerations such as smaller breast and suboptimal lesion location that can be minimized with increased experience and those related to discordance between histological and imaging findings related to lesion size, histological type of the lesion (diffuse and ill-defined), of presence of fibrosis or inflammation (peritumoral or related to proliferative mastopathy). In such cases, a large biopsy sample is required to achieve a confident diagnosis.

In our series and in the literature (3-9) most biopsied nodules were less than 1 cm in size. The number of lesions <6mm in size is increasing. The number of smaller lesions detectable with current US units is increasing and such small lesions may not be suitable for FNA.

Based on experience, it appears that the rate of malignancy decreases as lesion size decreases for lesions classified as probably malignant. This may be explained by difficulties in defining reliable US criteria in such small lesions (8).

Macrobiopsy was performed for smaller lesions because of the unreliable nature of US, either primarily when FNA was deemed not possible or after FNA when results were inconsistent with imaging findings or when a sampling error was suspected (fig. 1). Macrobiopsy with complete lesion resection could accurately diagnose benign and malignant lesions.

Data from the literature confirm that small lesions may pose diagnostic challenges (8). The type of biopsy (FNA versus macrobiopsy) must be based on the radiologist’s experience, and evaluated in terms of concordance with clinical and imaging findings.

Larger indeterminate and probably malignant lesions are handled similarly when

### Table II

<table>
<thead>
<tr>
<th>Stavros Classification</th>
<th>Fibroadenoma</th>
<th>Papilloma</th>
<th>Phyllodes tumor</th>
<th>Inflammatory lesions</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probably benign</td>
<td>88</td>
<td>10</td>
<td>1</td>
<td>1</td>
<td>40</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>91</td>
<td>12</td>
<td>0</td>
<td>19</td>
<td>145</td>
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<tr>
<td>Probably malignant</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>18</td>
<td>41</td>
</tr>
</tbody>
</table>

Others: Fibrocystic disease, sclerosing adenosis, angiolipoma, radial scar…

### Table III

<table>
<thead>
<tr>
<th>Stavros Classification</th>
<th>DCIS grade I</th>
<th>IDC Grade I</th>
<th>IDC Grade II</th>
<th>IDC grade III</th>
<th>ILC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indeterminate</td>
<td>18</td>
<td>8</td>
<td>7</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Probably malignant</td>
<td>13</td>
<td>23</td>
<td>29</td>
<td>17</td>
<td>11</td>
</tr>
<tr>
<td>Malignant</td>
<td>2</td>
<td>8</td>
<td>13</td>
<td>11</td>
<td>4</td>
</tr>
</tbody>
</table>

DCIS: Invasive ductal carcinoma; ILC: invasive lobular carcinoma.
biopsy results are discordant (fig. 2), or when the complex US features of the lesion cannot validate the results at FNA (10, 11) (fig. 3). These lesions seem ideal for extended macrobiopsy similar to surgical biopsy (10). The 8G probe is valuable because it allows faster removal of larger lesions with fewer biopsy samples. This technique has enabled us to confidently diagnose several benign inflammatory lesions and lesions of fibrocystic disease when clinical and imaging findings were suspicious. A total of 27.5% of lesions in our study were malignant. This is comparable to results reported by Stavros (750 nodules) at Amelia Island in 2001 and to results from other series in the literature (3-9). A total of 18.5% were DCIS, a lesion frequently under-diagnosed at FNA. The specificity for “probably benign” lesions was high, with only 2% of cancers in our series, fairly similar to the results reported by Stavros (1). Our number of core samples remains significantly higher than in the series by Philpotts (m=5.8). Our experience is different since their rate of immediate recommendation for repeat biopsy was 17% (4). This suggests that the size of the biopsy specimen was insufficient. The mean number of core samples in their series was 5.8 versus 16.5 in our series (similar gauge). The rate of under-diagnosis was 0.75% (5/650) ; only lesions classified as “probably malignant” and “malignant” were involved. These false negative results did not affect patient outcome.

Macrobiopsy for nodules classified as “malignant” is part of a management strategy (one-step surgery) and is performed only if diagnostic FNA does not seem technically possible or reliable. In a subgroup of surgical candidates with indeterminate and probably malignant lesions, US guided macrobiopsy was successful as an alternative to diagnostic surgery in 71% of cases. Surgery was avoided in 88% of patients with “indeterminate” lesion and 44% of patients with “probably malignant” lesion. This impact on surgical management is similar to the impact of stereotactic guided macrobiopsy (12). Based on the available follow-up, no false negative result has occurred. The absence of malignancy during follow-up of patients with benign findings at macrobiopsy confirms that the larger size of the biopsy sample provides a positive predictive value of 100% for benign lesions. We believe that this is a significant benefit of this technique because it avoids the pitfalls of FNA and provides an alternative to diagnostic surgical biopsy.

A specific indication is the benign papilloma diagnosed on FNA. The FNA sample allows diagnosis of the papilloma but does not provide enough information to exclude an accompanying borderline lesion or DCIS, requiring surgical biopsy. Mammotome biopsy, because of its larger volume, allows accurate evaluation of the surrounding breast tissue, similar to a surgical biopsy. Some authors already use this approach clinically (11).

**Conclusion**

Our results, along with results from other authors, support the addition of this technique in the routine practice of interventional breast imaging. The technique used (microbiopsy/macrobiopsy) for the diagnosis of breast lesions requires that the US imaging features, size and malignant potential be carefully assessed. Microbiopsy remains the standard approach for suspected malignant lesions but the results must be correlated to other data since a false negative FNA.
may be more dangerous than not performing FNA at all.

For other cases, the respective role of macrobiopsy and microbiopsy must be assessed on a case by case review based on local expertise (8). The volume of tissue re-equired to ensure accurate diagnosis should be considered during this selection process. The use of this technique for complete lesion removal (3-9) may be considered in specific circumstances and only in experienced hands.

References