Clinical experience with a second-generation vacuum-assisted breast biopsy (VABB) device under stereotactic guidance

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Purpose

Stereotactic breast biopsy has rapidly gained acceptance as a safe and accurate alternative to surgical biopsy for preoperative histopathologic diagnosis [1] for non-palpable mammographic breast lesions, which are not visible on ultrasound.

Initially performed with 14 gauge automated needles, it is now increasingly performed with vacuum assisted breast biopsy (VABB) device.

The advantages of VABB include improved retrieval of microcalcifications, ability to obtain contiguous samples with a single probe insertion, lower re-biopsy rates and fewer histological underestimations from atypical ductal hyperplasia (ADH) to ductal carcinoma in situ (DCIS) or DCIS to invasive carcinoma [2-7].

Accurate percutaneous diagnosis of benign breast disease can avoid unnecessary surgical biopsy and, on the other hand, accurate preoperative diagnosis of malignancy can decrease the number of operations needed for removal and treatment of a lesion [2, 6-9].

Nowadays, there are a variety of available VAB devices, each with different strengths and weaknesses [10].

Since 2011, The EnCor Breast Biopsy System, manufactured by SenoRX, Bard Biopsy Systems, has been introduced in our Institution. This system (with a wide variety of needle sizes available: 7 G, 10 G and 12 G) is a single-insertion device with directional sampling capability. The tissue samples are automatically delivered to a closed collection chamber [10, 11]. Besides, the EnCor employs an oscillating cutter, which functions in a scissor-like fashion. The oscillating cutting mechanism offers the ability to alter the size of the sampling aperture, which is advantageous in superficial lesions. Use of the oscillating cutter mechanism allows the speed at which the cutter courses through the tissue to be varied, according to the tissue density. This increases the duration of vacuum assistance when sampling dense breast tissue [11].

The purpose of our study was to report our initial clinical experience with this second-generation 10G vacuum-assisted device for stereotactic breast biopsy and to investigate its diagnostic accuracy.

Methods and Materials

We did a retrospective analysis of 82 consecutive stereotactic VABB using EnCor device, performed between January 2011 and July 2012.
**Guided Biopsy Procedure**

All biopsies were performed on a dedicated digital prone stereotactic biopsy table (Fischer Imaging, Denver, CO, USA) by two experienced radiologists in breast imaging, with a previous experience with stereotactic guided vacuum-assisted biopsy.

Informed consent for each biopsy was obtained.

Standard sterile skin preparation was used. Local anesthesia was administered with 10 ml lidocaine. After calculating the exact localization of the suspect lesion the needle was advanced to the target lesion. The needle position was checked by pre- and post-fire stereotactic views in plus 15° and minus 15° projection (Fig.1-2). Any changes in targeting were made appropriately and reconfirmed by imaging before sampling the lesion. The center of the lesion was targeted in most cases. With calcifications that were greater than 1 cm in distribution, the most suspicious area was targeted for biopsy. Then, the tissue was extracted.

Once tissue acquisition was complete, a radio opaque tissue marker clip was deployed at the biopsy site. A post biopsy image was obtained with the patient still on the biopsy table to confirm clip placement (Fig.3).

The wound was manually compressed for few minutes, sealed with sterile strips and a compression bandage.

All patients underwent a post-interventional mammography after 15 days to confirm the position of the tissue marker and to evaluate possible complications.

**Tissue Sampling**

The EnCor device has a needle with a tri-concave tip (no skin incision was necessary) and an inner retractable cutting blade. The needle is 10G, with a 19-mm biopsy aperture. This aperture can be directed to any 360-degree position for sampling. The device has directional capability so that sampling can be preferentially directed toward the lesion. Multiple samples were obtained for pathological analysis. A specimen radiograph was obtained if the target was microcalcifications, for adequacy of sampling. More samples were obtained if felt necessary by the radiologist.

The system is equipped with a collection basket for the harvested tissue and with a lavage function to flush the biopsy cavity with NaCl solution 0.9%. After six biopsy runs, the collecting vessel is removed and a new basket is positioning to complete the sampling.

All core needle biopsies were placed into 10% neutral buffered formalin immediately after the procedure and submitted to pathology.

Histo-pathological evaluation was performed by dedicated breast pathologists.
**Post biopsy management**

Imaging and pathology were reviewed and discussed in a weekly multidisciplinary conference.

Surgical excision was recommended for all cases of malignancy, high risk pathology (lesions with uncertain biological potential, B3 [12]), or discordant lesions.

A 6-month follow-up examination was recommended for all benign concordant lesions.

**Data analysis**

VABB mammographic indications (mammographic features, BIRADS classification and size of target lesions), number of cores taken, sampling time (duration of procedure was measured as the time taken for tissue removal from the first to the last tissue sample) and hematoma formation at 2 week follow-up were evaluated.

Final outcome was histological diagnosis at surgery or mammographic follow-up.

**Images for this section:**

**Fig. 1:** Pre-fire stereotactic views to check EnCor Breast Biopsy System position on target microcalcifications.
Fig. 2: Post-fire stereotactic views to check VABB position on target microcalcifications before sampling.
Fig. 3: Post biopsy image obtained with the patient still on the biopsy table, to confirm the radio opaque tissue marker clip at the biopsy site.
Results

We performed 82 biopsies in 81 patients (mean age 54.4 years, range 38-79)

97.5% (80/82) of all procedures were performed for suspicious microcalcifications and 2.5% (2/82) for microcalcifications associated with mass/architectural distortion. BIRADS classification of target lesion is reported in table 1.

Table 1.

<table>
<thead>
<tr>
<th>BIRADS classification</th>
<th>n° of lesions (%)</th>
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<tr>
<td>R3</td>
<td>0 (0%)</td>
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<tr>
<td>R4a</td>
<td>74/82 (90.2%)</td>
</tr>
<tr>
<td>R4b</td>
<td>8/82 (9.8%)</td>
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Mean lesion size was 8.3 ± 4.9 mm (range 3-30 mm).

Mean sampling time for six specimens was 90 seconds and mean duration to complete sampling procedure was 170 seconds.

Mean number of cores taken was 10 (range 6-12).

Histologic results (table 2) yielded malignancy (DCIS or invasive cancer) in 12/82 (14.6%) lesions, which were confirmed after surgical excision. Only 2/82 cases of B5c were downgraded to DCIS at definitive histological examination.

Lesions with uncertain biological potential (B3) were 12/82 (14.6%) of which 7/12 were ADH; at definitive histological examination, there were no cases upgraded to DCIS or invasive carcinoma.

69.5% (57/82) of VABB were benign lesions, which undergone at least 6 months follow-up (range 6-24 months).

Failure to retrieve calcifications occurred in 1/82 procedure, subsequently found to be benign on diagnostic excision.

Table 2.

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<th>Pathology on VABB</th>
<th>n° (%)</th>
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<td>B1[^12]</td>
<td>1/82 (1.3%)</td>
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Minor complications, such as hematoma, happened in 24.4% (20/82) of patients.

**Conclusion**

Despite limitations of an initial retrospective experience, EnCor breast biopsy device showed comparable results to those previously reported for other stereotactic guided vacuum-assisted technologies.

In literature, VABB histological underestimation has been reported with ADH in 10-27% and DCIS in 5-21% [13-17] of cases. Even if we have a small number of cases, in our series we have not VABB histological underestimation. However, we have less than 2-year follow-up for the benign lesions.

Time efficiency as well as capacity and accuracy of this system could be taken into account for a wider clinical employment.

**References**


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