Ultrasound-guided vacuum-assisted breast biopsy: Use at the European Institute of Oncology in 2010

F. Abbate^{a,*}, E. Cassano^a, S. Menna^a, G. Viale^{b,c}

^a Department of Breast Radiology, European Institute of Oncology, Milan, Italy

^b Department of Pathology and Laboratory Medicine, European Institute of Oncology, Milan, Italy

^c School of Medicine, University of Milan, Italy

KEYWORDS

Breast;
Histology biopsy;
Ultrasonography;
Mammotome;
Surgical biopsy.

Abstract Vacuum-assisted breast biopsy (VABB), which plays a fundamental role in the preoperative assessment of microcalcifications, can also be used (with ultrasound guidance) to obtain histology samples of breast lesions that are visible on ultrasonography. It is particularly useful when the lesion diameter is less than 1 cm. This technique has been used in our institute since 1998, and in this report we analyze our experience with it in 2010. This analysis shows that VABB is a safe, effective procedure that can markedly reduce the need for surgical biopsy.

Sommario La biopsia vacuum assistita che riveste già un ruolo fondamentale nell'analisi preoperatoria delle microcalcificazioni, viene utilizzata con successo anche con guida ecografica per la valutazione microistologica di lesioni mammarie eco visibili, soprattutto se di piccole dimensioni, cioè al di sotto del centimetro. Nel nostro istituto viene utilizzata ormai dal 1998. Riportiamo i dati dell'anno precedentemente trascorso.

Secondo la nostra esperienza risulta essere una procedura molto sicura ed efficace per ridurre drasticamente le biopsie chirurgiche diagnostiche.

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Introduction

With increasing frequency, modern methods for the diagnosis of breast lesions (mammography, sonography, MRI) are revealing small, nonpalpable lesions that are nonetheless suspicious and require further work-up to determine

their true nature. This has led to the development of a number of noninvasive biopsy techniques [1–5] in an attempt to reduce the need for diagnostic surgical biopsies and provide less invasive support for treatment planning [6]. Several less invasive alternatives have been introduced, which frequently (though not always) allow pre-surgical differentiation between benign and malignant lesions. They include fine needle aspiration cytology (FNAC) [1,2] and percutaneous biopsy performed with an automated or semiautomated, spring-loaded system (CB-Tru Cut) [3] or a directional vacuum-assisted biopsy system (VABB-Mammotome) [9–12]. In our institute, the latter

* Corresponding author. Breast Imaging Unit, Department of Radiology, European Institute of Oncology, Via Ripamonti 435, 20141 Milan, Italy.

E-mail address: francesca.abbate@ieo.it (F. Abbate).

method is used in selected cases, i.e., lesions with initial needle aspirate findings classified C1 or C3 according to international guidelines [7,8] or, as the first-line diagnostic approach for small lesions (approximately 5 mm in diameter), which are associated with a substantial risk of false negative findings and samples that are not large enough for diagnosis. This report describes our experience during the year 2010, which confirms the efficacy of this procedure.

Materials and methods

We examined the European Institute of Oncology's (EIO) database to identify all patients who underwent ultrasound (US)-guided VABB (Mammotome) in 2010. VABB was performed with a hand-held mammotome probe (Ethicon Endosurgery, Cincinnati, Ohio, USA), an ultrasound scanner equipped with a 14-8-MHz transducer (Technos MPX, Genoa, Italy), and an 11-gauge needle. The procedure included the following steps:

- Sonographic identification of the lesion (BI-RADS assessment and, when necessary, color-Doppler examination to locate blood vessels whose puncture might cause significant hematomas)
- Local anesthesia (10cc of 2% carbocaine)
- Skin incision (approximately 3 mm wide) with a scalpel blade
- US-guided placement of the Mammotome probe at the level of the target lesion
- Lesion sampling
- Optional post-procedural placement of a localizing marker clip (if the post-biopsy assessment indicates that the entire lesion has been removed)
- Two orthogonal projections to confirm the exact location of the clip
- Compression and dressing of the wound

The entire VABB procedure lasts from 20 to 40 min.

After a lesion has been subjected to ultrasound-guided VABB with FNAC, our diagnostic algorithm provides for the following actions:

- Lesions classified as B1: repeat VABB or surgery
- B2 lesions: follow-up based on radiological findings
- B3 lesions: surgery
- B4 lesions: surgery
- B5 lesions: surgery

Ultrasound-guided vacuum-assisted biopsy has been used in our institute since 1998.

Results

Review of the database entries for the year 2010 (1 January – 31 December) revealed that 140 patients underwent US-guided VABB (Mammotome), and 141 diagnostically adequate biopsies were collected.

The mean age of the patients was 48 years (range 22–85). One hundred five (75%) of the patients had previously undergone fine needle aspiration cytology, which

revealed C1 lesions in 13 cases, C2 in 16 cases, C3 in 71, and 5 lesions that were C4.

In the other 36, the initial diagnostic work-up had been based on histology.

Most of the lesions were nodules; the other 16 were areas of increased density.

The sizes of the lesions sampled are reported in Table 1. The mean diameter was 10.4 mm (range 4 mm–40 mm).

An 11-gauge needle was used for all biopsies.

The mean number of specimens collected per patient was 13.6 (range 4–28).

In 83 cases (58.9%), the entire lesion was removed; removal was partial in 46 (32.6%).

Thirty-four patients experienced early complications, which consisted in hematomas in 12 cases, venous bleeding in 19, and incorrect placement of the localizing clip in 3.

Table 1 shows the characteristics of the lesions successfully sampled with VABB (with collection of adequate specimens). The pathological findings are shown in Table 2. VABB identified 26/141 (18.4%) lesions as malignant and 115/141 (81.6%) as benign.

Table 1 Characteristics of cases with adequate vacuum-assisted breast biopsy specimens ($n = 141$).

Lesion diameter (mm)		
Range	4–40	
Mean	10.4	
Morphology on US ($n = 141$)		%
Nodule	125	88.7
Density	16	11.3
BI-RADS on US ($n = 141$)		%
2	1	0.7
3	52	36.9
4	85	60.3
5	3	2.1
Mammographic findings ($n = 141$)		%
Architectural distortion	6	4.3
Opacity	26	18.4
Microcalcifications	4	2.8
Opacity + Microcalcifications	3	2.1
Negative	60	42.6
Not available	42	29.8
Early complications ($N = 141$)		%
None	107	75.9
Hematoma	12	8.5
Venous bleeding	19	13.5
Incorrectly positioned clip	3	2.1
Cytology ($n = 141$)		%
Yes	105	74.5
No	36	25.5
Cytological class (105)		%
C1	13	12.4
C2	16	15.2
C3	71	67.6
C4	5	4.8
Complete removal of lesion ($N = 141$)		%
Yes	83	58.9
No	46	32.6
Not specified	12	8.5

Table 2 Histological diagnosis based on mammotome findings (141).

Histotype	141	%
nonproliferative fibrocystic disease	1	0.7
proliferative fibrocystic disease	41	29.1
with ductal hyperplasia		
atypical ductal hyperplasia	1	0.7
atypical lobular hyperplasia	6	4.3
fibroadenoma	31	22.0
LCIS	2	1.4
DCIS	4	2.8
infiltrating ductal carcinoma	16	11.4
infiltrating tubular carcinoma	2	1.4
infiltrating lobular carcinoma	3	2.1
infiltrating mucinous carcinoma	1	0.7
phylloid tumor	1	0.7
other	25	17.8
inflammation	4	2.8
adenosis	3	2.1

The surgical histology findings are shown in Table 3: in 29/141(20.6%) cases surgery was performed, and in the other 112/141 (79.4%) there was no intervention.

Twenty-five of the 29 women who were operated on were positive.

The sensitivity was 96.2% and the specificity 99.1%.

In 1 case, the stage of the lesion was underestimated, i.e., a DCIS that proved to be an invasive carcinoma, and the lesion was not completely removed.

There were no cases of false negativity (although this finding may reflect the fact that follow-up was very brief).

Discussion

Ultrasound-guided FNAC is known to be a simple, economical procedure [1–3], which in expert hands can furnish good results, and it can still be regarded as the first-line diagnostic procedure for most sonographically visualized breast lesions [1]. Nonetheless, when it yields nondiagnostic or ambiguous results, other procedures are indicated.

The diagnostic algorithm proposed on the basis of our experience is as follows:

- C1: repeat FNAC (depending on the radiological findings); if the second specimen is also C1, we review

Table 3 Diagnosis based on surgical histology (141).

Histotype	141	%
infiltrating ductal carcinoma	14	9.9
infiltrating lobular carcinoma	2	1.4
infiltrating cribriform carcinoma	1	0.7
negative	2	1.4
DCIS	4	2.9
mixed infiltrating carcinoma (ductal + lobular)	2	1.4
infiltrating tubular carcinoma	2	1.4
LCIS	2	1.4
not done/results not available yet	112	79.5

imaging findings (ultrasound, mammography) to decide whether the lesion requires later evaluation, VABB, or an excisional biopsy.

- C2: regular re-assessment
- C3: US-guided VABB
- C4: Excisional biopsy
- C5: Excisional biopsy

Among the possible results of an US-guided FNAC, category C3 is the one with the broadest range of choices for continuation of the diagnostic work-up. In fact, the significance of C3 lesions is uncertain: they are probably benign but present certain forms of atypia. They are supposed to have a low positive predictive value (around 20%), but some investigators have reported much higher values (40%–65%) [2,7–9]. In the past, most of these lesions were subjected to excisional biopsies, but today percutaneous biopsy methods offer low-cost, noninvasive alternatives with high diagnostic accuracy.

In some cases, C4 and C5 lesions may also be candidates for VABB or presurgical Tru cut CB, e.g., when it is important to know the hormone receptor status of a tumor before surgery or with an eye to neoadjuvant chemotherapy.

The VABB procedure used in this study is in line with that described by other authors [6,10–12,24]; post-VABB hematomas occurred in 12/141(8.5%), an incidence rate similar to that reported by others [13].

The VABB procedure is mainly diagnostic rather than therapeutic so we did not always attempt to remove the entire lesion. Certain investigators maintain that this can be done and that it facilitates diagnosis and increases certainty during the follow-up, particularly in the assessment of atypical ductal hyperplasia [14,15].

At the end of the procedure (when necessary) a nonmagnetic, titanium clip is inserted to mark the site of the VABB; we do not use the “gel marker clip” proposed by other authors [16].

VABB identified 26/141 lesions as malignant (18.4%); surgery was performed on 28, in this experience VABB proved to be a conclusive method that could be used to avoid surgical biopsy [17]. Other authors reported 95% sensitivity and 98% specificity, probably reflecting the fact that in this case the US-guided VABB was used as a first-line examination for sonographically visualized lesions [13].

Our diagnostic algorithm calls for the following after ultrasound-guided VABB:

- B1: Repeat VABB or perform excisional biopsy or reassess after 6 months (depending on imaging findings)
- B2: Reassess after 6 or 12 months, or perform excisional biopsy (depending on imaging findings)
- B3: Excisional biopsy
- B4: Surgery
- B5: Surgery

It is important to assess VABB results in light of imaging findings. In this series of patients, the assigned BI-RADS category displayed a PPV that was largely confirmed by the results of VABB and surgical findings. The PPV of the BR3 lesions was slightly higher than those of the guidelines, but the problem of correct use of this category, or of its correct

PVV, is well-known, and it is even more evident for BR3 lesions (microcalcifications) subjected to stereotaxic VABB [11,18,19].

In general, the VABB results obtained by our group seem to be consistent with those in the literature although no one has specifically assessed the impact of ultrasound-guided VABB in the evaluation of lesions classified C3 on the basis of ultrasound-guided FNAC.

Thus far our follow-up has not revealed any cases of false negativity. Our experience suggests that follow-up at 6 months or 1 year (depending on VABB and sonographic findings) is indicated to exclude false negative results. During the follow-up examination, the site of the biopsy and/or any remaining lesional tissue should be identified (with or without the aid of the clip). It is important to remember that clips can become displaced and provide incorrect information on the site of the VABB. Complications of this type have been reported, especially after stereotaxic VABB [25]. In contrast to the reports of other authors [26], we did not find that VABB interferes with subsequent mammographic or sonographic assessments of the breast. This represents an additional advantage of VABB over excisional biopsy, which can leave scars that are difficult to interpret during subsequent studies.

VABB clearly proved to be an excellent alternative to surgical excisional biopsy, as previously stressed by other authors in the assessment of lesions that seem to be benign on the basis of imaging and/or FNAC findings [4,5,14]. Although complete removal of the lesion is feasible, we feel that US-guided VABB is and should remain an essentially diagnostic procedure, which can be combined with surgery, when necessary [20].

CB-Tru Cut represents an alternative to VABB for the evaluation of lesions that appear to be benign on the basis of imaging or FNAC findings (C3 lesions in particular). On the basis of data in the literature, the choice between VABB and CB-Tru Cut is not clear-cut. Some authors feel that VABB is superior, but others find no real difference between the two methods [21–23]. In our opinion, US-guided VABB has certain features that make it superior to CB-Tru Cut. They include:

- In the evaluation of small lesions (approx. diameter 5–10 mm), the use of Tru Cut CB carries a moderate risk of inadequate sampling.
- With VABB, contiguous samples can be collected without multiple needle insertions, and this increases the likelihood of adequate results even when the needle tip is not right in the middle of the target.
- For ultrasound-guided specimen collection, VABB allows more precise control of the position of the probe, without the excursion that occurs with CB-Tru Cut. This feature reduces the risk of injury to the chest wall during biopsy of deep lesions.
- The larger-gauge needle (11G vs 14G) allows one to obtain larger tissue cores that are more likely to be suitable for pathological assessment.

Ultrasound-guided VABB can be considered a second-line study performed in specialized centers; it appears to be an effective strategy in terms of diagnostic accuracy and costs in light of the improved diagnostic process [3].

Conclusions

Ultrasound-guided VABB can provide accurate characterization of breast lesions classified C1 or C3 on the basis of ultrasound-guided FNAC. The low rate of malignancy observed in the present series indicates that surgical excisional biopsy can probably be avoided in most cases.

It is important to recall that VABB findings should be evaluated in light of clinical data/history and imaging findings (sonography, mammography) to identify those lesions that require surgical intervention (even when the VABB results are not clearly indicative of malignancy). For most lesions with VABB results suggestive of malignancy, the role of surgery exclusively therapeutic: it is rarely used to confirm VABB findings and/or obtain additional information on the lesion. Follow-up is indispensable to identify patients with VABB and/or other diagnostic findings that are false negatives.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Appendix. Supplementary data

Supplementary data related to this article can be found online at [doi:10.1016/j.jus.2011.10.003](https://doi.org/10.1016/j.jus.2011.10.003).

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