

# Vacuum-assisted breast biopsy in nonpalpable solid breast lesions without microcalcifications: the Greek experience

George Zografos, Flora Zagouri, Theodoros N. Sergentanis, Afroditi Nonni, Dimitra Koulocheri, Dimitrios Dardamanis, Vassiliki Oikonomou, Panagiotis Giannopoulos, Ilias Kouerinis, Christos Tsigris, John Bramis

## PURPOSE

To present the initial Greek experience with vacuum-assisted breast biopsy (VABB) in the diagnosis of nonpalpable solid mammographic lesions without microcalcifications.

## MATERIALS AND METHODS

We performed 83 VABB procedures (using a Fischer table and 11-gauge Mammotome probes) in an 18-month period on women with nonpalpable solid breast tumors. We performed VABB procedures on women with breast imaging reporting and data system (BI-RADS) categories 3 and 4. VABB procedures excised more than 24 cores.

## RESULTS

Eighty-three women with nonpalpable lesions identified on mammography were evaluated; 42.2% were BI-RADS category 3, and 57.8% were BI-RADS 4. Of all solid tumors excised, 83.1% were benign, 3.6% were precursor lesions, and 13.3% of the lesions were malignant. No underestimation occurred. Clinically important hematoma developed in 4.8% of cases.

## CONCLUSION

VABB is an effective method for the diagnosis of nonpalpable solid lesions because of the lack of underestimation, although it is technically more difficult to focus on lesions without microcalcifications than those with microcalcifications on the Fischer table.

**Key words:** • vacuum-assisted breast biopsy  
• Mammotome • non-palpable solid lesions

**E**valuation of women with an abnormal mammography result is a common problem, since even high-quality mammography facilities generally interpret 5% to 10% of all screening examinations as abnormal (1, 2). The most common mammographic abnormalities found on screening examinations, requiring further evaluation are masses and calcifications. Approximately 90% of women with abnormal results do not have breast cancer (3, 4); therefore, safe and efficient evaluation is crucial.

The American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) recommends one of five assessments for the interpretation of a mammographic screening examination (5). Annual follow-up is recommended for lesions classified as BI-RADS category 1 (negative mammogram) or 2 (benign findings). A 6-month follow-up for the breast in question has been recommended for lesions belonging to BI-RADS category 3 (probably benign); biopsy is suggested for those classified as category 4 (suspicious) or category 5 (highly suggestive of malignancy) (6, 7). Some BI-RADS category 3 lesions are biopsied if requested by the patient or referring physician (5–7).

In early detection of breast cancer, newly introduced techniques, such as Advanced Breast Biopsy Instrumentation (ABBI) System (8), and vacuum-assisted breast biopsy (VABB) are becoming increasingly common. VABB provides a minimally invasive, faster, less expensive, and less painful method for sampling nonpalpable abnormalities seen on mammograms (9). The method has proven to be very useful, especially in the evaluation of microcalcifications (10, 11).

In the international literature on VABB, there are fewer studies examining VABB in tumors without microcalcifications than those with microcalcifications. In addition, there are reservations regarding possible histologic underestimation of nonpalpable tumors using VABB.

The aim of this study is to present the Greek experience of VABB in the management of BI-RADS 3/BI-RADS 4 non-palpable breast solid tumors without mammographic microcalcifications.

## Materials and methods

We present the Greek experience since our breast unit is the only center equipped with a VABB (Mammotome) device and a Fischer table (Mammotest, Fischer Imaging, Denver, Colorado, USA). The material of this study consists of 83 procedures performed from January 2004 to June 2006 in our unit on women with a median age of 53 years (range, 37–76; mean  $\pm$  SD, 53.7  $\pm$  9.14), for nonpalpable solid breast lesions without microcalcifications.

Within this period, 348 women with nonpalpable mammographic findings successfully underwent VABB; of these, 83 (23.9%) were performed for mammographic solid tumor without microcalcifications (le-

From the Department of Radiology (G.Z. ✉ gzograf@med.uoa.gr, F.Z., T.N.S., A.N., D.K., D.D., V.O., P.G., I.K., J.B.), University of Athens Hippokratia Hospital, Breast Unit, Athens, Greece; and Department of Surgery (C.T.), University of Athens Laiko Hospital, Athens, Greece.

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sions with microcalcifications: 69.5%, asymmetric density: 6.6%).

Before VABB, all patients were evaluated by one of the two radiologists assigned to the breast imaging section, and all films were reviewed. A BI-RADS category was assigned before VABB, using the interpretation provided by the first institutional radiologist who assessed the films. Because of the broad spectrum and correspondingly wide range of malignancy pertaining to the BI-RADS 4 category, this group was subdivided into group 4A (low suspicion for malignancy), 4B (intermediate suspicion for malignancy), and 4C (moderate concern, but not classic for malignancy).

For lesions categorized as BIRADS 3, follow-up was generally recommended. However, VABB was performed in the cases where family history was strongly positive or when the patient and referring physician expressed particular concern. In such cases, VABB was performed to avoid an open biopsy. In our unit, most of the BI-RADS category 5 cases are directly submitted for surgical biopsy in view of the great likelihood of cancer. Additionally, curative surgery may be performed during a single procedure if a malignant lesion is identified on frozen sections.

During this period, VABB was performed by 5 surgeons. A radiologist was present to assist in the targeting. All women were informed about the procedure by the surgeon performing the intervention. VABB was performed on digital prone table using 11-gauge vacuum probes, under local anesthesia. The examination proceeded according to a standardized protocol for quality control. A mammogram following VABB confirmed the excision of the suspicious lesion, showing cavitation in the suspicious area. In all cases, we attempted to obtain 24 or more cores. Cases with a preinvasive or malignant diagnosis underwent surgery, and the underestimation rates were calculated. All patients underwent one face mammographic view 6 months after VABB on the affected breast.

The association between BI-RADS classification and the pathological types was studied. Statistical analysis was performed with the use of STATA 8.0 statistical software. Permission has been obtained from the local institutional review board for publication of the findings summarized in this study.

## Results

A total of 83 women with nonpalpable solid tumors had VABB. Thirty-five of these 83 (42.2%) had a radiological classification of BI-RADS 3, and 48 (57.8%) were classified as BI-RADS 4. Of the 83 tumors evaluated, irrespective of BI-RADS classification, 69 (83.1%) were benign, 3 were preinvasive, and 11 were malignant (Table).

The benign diagnoses were fibrocystic changes (23/69, 33.3% of all benign lesions), fibroadenomas (18/69, 26.1%), sclerosing adenoses (8/69), adenoses (8/69), papillomas (4/69), hemangiomas (2/69), ductal ectasia (2/69), epitheliosis with atypia (2/69), lobular hyperplasia (1/69), and lipogranuloma (1/69).

As the BI-RADS classification indicated increasing severity, there was a statistically significant increase in the probability of malignancy ( $P = 0.004$ , malignancy vs. all other diagnoses; Fisher exact test).

As mentioned above, in 11 out of 83 cases (13.3%), irrespectively to their BI-RADS classification, a malignancy was found and 3.6% of the biopsies (3 out of 83) were precursor lesions (two cases of atypical ductal hyperplasia and one case of lobular carcinoma in situ [LCIS]). Ductal invasive carcinoma was identified in 10 of 11 malignant cases (90.9%). Moreover, one case of non-Hodgkin lymphoma was identified (9.1%), to which a BI-RADS 4B was assigned. After the comparison with the pathological diagnosis after surgery with hook-wire localization, it became

apparent that no underestimation was present.

The mean age of women diagnosed with malignancy was  $58.09 \pm 11.43$  years, while those with the rest of diagnoses were  $53.01 \pm 8.63$  years old. The preoperative diagnosis of malignancy was more frequent as the age of the patient increased, but this trend is of marginal statistical significance, probably due to the relatively small sample size ( $P = 0.093$ , logistic regression).

Clinically significant hematoma developed in 4 of 83 patients (4.8%), none of whom required surgical intervention. There was no statistically significant association of hematoma formation with BI-RADS classification or with patient age. In 2 of 85 procedures (2.4%), VABB was not performed, as the solid tumor was too close to the examination plate. These tumors were subsequently excised by open surgery with hook-wire localization. There was no statistically significant association with the BI-RADS classification or patient age.

## Discussion

The use of the VABB device on the Fischer table is an effective method for the preoperative diagnosis of breast cancer (10), with very satisfactory sensitivity, specificity, and positive and negative prognostic values (9, 12). Many studies have focused on the role of VABB in the assessment of lesions with microcalcifications (13). In parallel, recently published papers have evaluated the role of VABB in the final

**Table.** Non palpable mammographic solid lesions: radiological and pathological correlations

	Pathological diagnosis			Total
	Benign	Precursor lesion	Malignant	
BI-RADS 3 95% CI	33 (94.3%)	0	2 (5.7%) 0.7%-19.2%	35
BI-RADS 4A 95% CI	23 (88.5%)	1 (3.8%)	2 (7.7%) 0.9%-25.1%	26
BI-RADS 4B 95% CI	13 (65%)	2 (10%)	5 (25%) 8.7%-49.1%	20
BI-RADS 4C One-sided, 97.5% CI	0	0	2 (100%) 15.8%-100%	2
Total	69	3	11	83

BI-RADS: breast imaging reporting and data system

histological diagnosis and the management of lesions without microcalcifications (14), as well as other conditions, such as single duct nipple discharge (15). In line with these studies, which broadened the spectrum of conditions where VABB may be useful, we conducted the present nested retrospective study focusing on lesions without microcalcifications.

A crucial factor underlying the importance of studies focusing on this type of lesion is the greater reservation regarding VABB for lesions without microcalcifications than those with microcalcifications. According to our experience, the reasons for such caution in regard to the role of VABB vis-à-vis nonpalpable solid tumors lacking microcalcifications, may include the following:

1. Focusing nonpalpable mammographic solid tumors on VABB is more difficult than focusing calcifications. Due to resonance limitations, the digital views taken from the Fischer table have limited clarity compared with the conventional mammogram.
2. Because of hematoma developing quickly after biopsy of solid tumors, the efficacy of the biopsy cannot be precisely estimated. The six-month mammogram should be performed, in which the hematoma will be disappeared, for the evaluation of the biopsy. In our experience, on the contrary, in the biopsy of calcifications, the x-ray evaluation of the specimen is a very accurate and precise method, irrespective of hematoma development.

Despite the above difficulties, according both to our results and the literature (14), nonpalpable solid lesions without microcalcifications can be evaluated effectively by VABB. Furthermore, VABB provides adequate tissue for histological diagnosis (10). It is worth mentioning that more than 24 cores are excised in our material in order to minimize the underestimation rate of atypical ductal hyperplasia (ADH), lobular neoplasia, and ductal carcinoma in situ (DCIS) (16–18).

In our study, 86.7% of women with a nonpalpable solid tumor did not have breast cancer. VABB was an alternative to unnecessary open surgical procedures. It should be also stressed that our study is free from underestima-

tion, possibly due to the great number of cores excised. This is of importance, since underestimation has been reported up to 50% (19).

Our findings are in accordance with the BI-RADS classification, as 5.7% of the BI-RADS 3 lesions, 7.7% of BI-RADS 4A solid tumors, 25% of BI-RADS 4B specimens, and all BI-RADS 4C lesions were found to be malignant. Along with the BI-RADS subgroups, the aforementioned percentages of preoperative cancer diagnosis exhibit an increasing trend; as expected, the positive association between BI-RADS classification and the occurrence of cancer is statistically significant.

The frequency of cancer in BI-RADS 3 lesions ranges from 0.5% to 2% in the literature (5); however, in our sample, the observed frequency of malignancies was 5.7%. Given the confidence intervals of the proportion (Table), this discrepancy is not statistically significant and should be attributed to the relatively small size of the sample.

Five percent of lesions characterized as BI-RADS 4B were atypical ductal hyperplasias. The relatively low percentage of ADH in nonpalpable solid tumors of our sample seems quite surprising. The low incidence of ADH is probably a result of the type of mammographic lesion (the solid tumor) (20) and to the lack of underestimation in our material.

As expected, most VABB procedures were performed on BI-RADS category 4 patients, as this is the most common indication for the procedure (11, 13, 14). Biopsy results for category 3 patients are usually benign; VABB is usually performed when the patient is extremely anxious, has a strong family history, or there is a concern about adequate follow-up (21). The percentage of BI-RADS 3 biopsies performed is higher in our series for two reasons: we are the only referral center in Greece to which patients with a higher risk or positive family history are sent from other centers, and women and/or their referring physicians persisted on VABB.

For the interpretation of the latter, the management scheme of women with BI-RADS 3 findings should be kept in mind. A repeated diagnostic evaluation of the breast is suggested in 6 months to determine if the lesion is truly benign (5, 22, 23). Lesions that have progressed generally require im-

mediate evaluation, whereas those that remain stable are most frequently benign. Women with stable lesions are usually evaluated at an additional 6-month interval and, if the lesion has still not progressed, the woman can resume a regular screening interval (5, 24). Despite our information policies, the notion of repeated examinations after six months and the reevaluation of the finding frequently evoked a great deal of anxiety and depression in women, leading them to request VABB.

The complications and limitations of the method seem to be acceptable. In our population, VABB has proven to be well tolerated by the patients, with a minimal degree of complications. All the patients completed the procedure. Clinically significant hematoma developed in only 4.8% of our cases, none of whom required either hospitalization or surgical intervention. This percentage is consistent with other series in Southern Europe (25). The failure rate was comparable to other studies, and was caused by the solid tumor being too close to the examination plate, thereby necessitating excision by open biopsy (26).

In conclusion, nonpalpable solid mammographic tumors can be biopsied effectively and safely by the VABB device on the Fischer table, minimizing indication for open surgery. Lack of underestimation is a major advantage of the method. The use of wider needles (8G) could expand the indications for the intramammary solid tumors and improve the specificity and sensitivity of the method.

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