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ORIGINAL ARTICLE

The value of stereotactic vacuum assisted breast biopsy in the investigation of microcalcifications. A six-year experience with 853 patients

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Summary

Purpose: *Vacuum Assisted Breast Biopsy (VABB) is a minimal invasive technique, in the diagnostic approach for non palpable lesions. The aim of this study was to evaluate the efficacy and accuracy of VABB in the investigation of breast microcalcifications, a significant mammographic sign of early breast cancer. The rate of histological underestimation and the false negative rate were assessed based on the follow up data and the histological examination of the surgical specimens.*

Methods: *From January 2005 to November 2011, 853 women with mammographically detected microcalcifications, classified as BI-RADS 3-5, were referred to our Breast Unit for evaluation. During this 6-year period, 825 vacuum-assisted breast biopsies were performed, while 28 women (3.3%) were not submitted to VABB due to superficial location of microcalcifications.*

Results: *VABB histology revealed 594 benign (69.6%), 66 high risk (7.7%) and 164 malignant (19.2%) lesions. Twenty-nine cases were classified as non diagnostic, as in one case (0.1%) the sample of the biopsy was maladjusted and not suitable to undergo histopathological examination due to mechanical alterations and in 28 (3.3%) cases microcalcifications were located in proximity to the skin and open surgical excision was performed. The overall documented underestimation rate was 4.6%, the false negative rate was 2.4%. The sensitivity of the method was 98.2%, specificity 100%, positive predictive value 100% and negative predictive value 97.6%.*

Conclusions: *VABB is a safe and accurate method for the evaluation of suspicious microcalcifications and diagnosis of early breast cancer.*

Key words: *BI-RADS 3, breast biopsy, early breast cancer, mammotome, microcalcifications, vacuum assisted breast biopsy*

Introduction

Microcalcifications play a crucial role in early breast cancer diagnosis, the second leading cause of cancer death among women. Approximately 50% of non-palpable breast cancers are detected by mammography, exclusively by microcalcifications patterns. Moreover, 80-90% of ductal carcinoma *in situ* (DCIS) lesions present with microcalcifications only, without any accompanying mass lesions [1,2].

The Breast Imaging Reporting and Data System (BI-RADS) offers a standardized common language to determine the level of suspicion and recommended follow-up for patients with mammographic findings in cases of non palpable abnormalities [3,4].

Currently, the diagnostic approach for this category of patients is worldwide achieved with the use of VABB, a modern tool which functions

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under stereotactic, ultrasound or MRI guidance. A clear indication to prefer stereotactic guidance is when the target is non palpable microcalcifications [5]. The tool for VABB is called Mammotome and has been available in our Breast Unit since 2004.

The aim of the present study was to evaluate the efficacy and accuracy of VABB in non palpable lesions, as well as to report the complications of this method.

Methods

For publication of the findings of this study permission was obtained from the local institutional review board and all patients provided oral informed consent.

The current study included 853 patients with non palpable mammographically detected microcalcifications, who were referred to our Breast Unit from January 2005 to November 2011. During this 6-year period, 825 vacuum-assisted breast biopsies were performed, while 28 patients (3.3%) were not submitted to VABB due to superficial location of microcalcifications.

VABBs were performed by Mammotome (Mammotome, Ethicon Endo-Surgery, USA) under stereotactic guidance on the digital prone table (Mammotest, Fischer Imaging, Denver, CO, USA), using 11-gauge Mammotome probe with local anesthesia.

All the VABBs were performed by five surgeons, and two radiologists assisted with targeting. The mammographic findings were categorized by the one of two radiologists of our Unit as: 178 cases (20.9%) as most likely benign 'BI-RADS 3', 344 cases (40.3%) as low suspicion for malignancy 'BI-RADS 4A', 274 cases (32.1%) as moderate suspicion for malignancy 'BI-RADS 4B', 49 cases (5.7%) as high suspicion for malignancy 'BI-RADS 4C' and 8 cases (0.9%) as highly suggestive for malignancy 'BI-RADS 5' .

Although, a follow-up examination is generally recommended for BI-RADS 3, since there is a 0.5-2.0% possibility of malignancy [6], the 170 cases of our study underwent biopsy either because of positive family or personal history of breast cancer or patient's will in order to minimize their anxiety. Moreover, patients with poor compliance for follow up or planning pregnancy or breast plastic surgery [7], were also submitted to VABB.

Until November 2006, 266 patients were randomly allocated into two groups. The first group included 133 women who underwent the standard protocol and according to the consensus meeting in Norderstedt [8], 24 cores were obtained. In order to achieve this, we used 1 offset-main target and 1 or 2 additional offsets in the hypothetical center of microcalcifications. Twelve cores were excised from each offset [12x (2 or 3) = 24-36]. The second group with 133 women underwent the extended protocol in which 1 offset-main target and 7 additional offsets were retrieved. Similarly, 12 cores were excised per offset [12x8=96]. From November 2006, the vast majority of our patients were submitted to the extended protocol as we had demonstrated the optimal results of this alternative approach [9]. Before the completion of the procedure, a radiopaque clip was inserted into the biopsy cavity and a final mammogram confirmed the complete removal of microcalcifications.

Histology of samples was performed by a specialized pathologist on breast. Histopathologic diagnoses were categorized as benign, high risk and malignant. High risk lesions included atypical ductal hyperplasia (ADH) and atypical lobular hyperplasia (ALH). Malignant lesions included DCIS, lobular carcinoma *in situ* (LCIS), microinvasive carcinoma, invasive ductal carcinoma (IDC), invasive lobular carcinoma (ILC) and mucinous carcinoma. Most benign lesions were referred for clinical follow up and mammographic surveillance at 6 months and every 1-2 years thereafter. All patients with papillary, mucocele-like, radial scar, sclerosing adenosis, high risk and malignant lesions, underwent surgical excision (289 cases).

The rate of histological underestimation and the false negative rate were assessed based on the follow up data and the histological examination of the surgical specimens. Underestimation was defined as an ADH or ALH lesion of the VABB that was upgraded to *in situ* or invasive carcinoma after surgical excision and a DCIS or LCIS lesion of the VABB that was upgraded to invasive carcinoma after the surgical excision. Overall underestimation rate was calculated by the benign, high risk or *in situ* lesions of the VABB that were upgraded.

Statistics

Descriptive statistics and more specifically univariate data analysis were used. Data were presented as frequencies and percent distributions, as well as rates and ratios.

Data analysis was performed using the Statistical Package for Social Sciences (version 20.0) software (SPSS Inc., Chicago, IL, USA).

Results

A total of 825 consecutively performed VABBs were included in our study. The mean age of patients was 52 years (range 31-84) and the mean follow-up was 45 months (range 24-60). According to our results (Tables 1,2), there were 594 benign (69.6%), 66 high risk (7.7%) and 164 malignant (19.2%) lesions. Twenty-nine cases were classified as non diagnostic as the biopsy was technically successful in 824 (96.6%) of 853 patients. From the non-diagnostic cases, in one case

Table 1. Histologic VABB findings in correlation to BI-RADS

BI-RADS	VABB Histology										
	Benign	ADH	ALH	DCIS	Microinvasive	LCIS	IDC	ILC	Mucinous carcinoma	Non-diagnostic	Total
3	153	12	1	3	0	0	1	0	0	8	178
4A	258	9	14	37	4	3	7	1	1	10	344
4B	166	10	16	48	3	6	15	0	1	9	274
4C	16	0	4	15	4	0	8	0	0	2	49
5	1	0	0	1	2	1	3	0	0	0	8
Total	594	31	35	104	13	10	34	1	2	29	853

For abbreviations see text

Table 2. Histologic VABB findings in 853 patients

	Disease	Number	Percent
Benign	Fibrocystic disease	138	16.2
	Fibroadenoma	48	5.6
	Atrophy	55	6.4
	Papilloma	33	3.9
	Ductasia	38	4.5
	Apocrine metaplasia	9	1.1
	Fat necrosis	7	0.8
	Mastitis	19	2.2
	Radial scar	3	0.4
	Sclerosing adenosis	11	1.3
	Monckeberg sclerosis	2	0.2
	Mucocele	12	1.4
	Postradiation/Chemotherapy lesion	5	0.6
	Simple duct hyperplasia	18	2.1
	Coexistence of benign and malignant disease	196	22.9
High-risk	ADH	31	3.6
	ALH	35	4.1
Malignant	DCIS grade I	40	4.7
	DCIS grade II	21	2.5
	DCIS grade III	43	5.0
	Microinvasive	13	1.5
	LCIS	10	1.2
	IDC	34	0.4

(0.1%) the sample of the biopsy was maladjusted and not suitable to undergo histopathological examination due to mechanical alterations and in 28 cases microcalcifications were located in proximity to the skin and open surgical excision was performed.

In 808 cases only a single round of tissue collection was needed, while 17 patients (2%) required a second targeting and aspiration in order to excise all microcalcifications. Moreover, in 64 patients (7.75%) we used double target, as a second group of microcalcifications on the same breast was present.

The 594 benign lesions encompassed 16 groups of histological diagnosis and in one group were patients found to have more than one benign diseases (Table 2). The 33 cases (3.9 %) of papillary lesion, 12 cases (1.4%) of mucocele-like lesion, 3 cases (0.4%) of radial scar and 11 cases (1.3%) of sclerosing adenosis were subjected to surgical excision after hook wire localization. None of these cases was proved to obscure malignancy.

Of the 66 high risk lesions, 31 cases (3.6%) were ADH and 35 (4.1%) ALH (Table 2). All of these patients underwent open surgery for wider local excision. The underestimation rate was 4.54%, as one case of ADH was upgraded to DCIS and two cases of ALH to LCIS (Table 3).

The 164 malignant lesions, included 104 cases (12.2%) of DCIS, 13 cases (1.5%) of microinvasive carcinoma, 10 cases (1.2%) of LCIS, 34 cases (4%) of IDC, 1 case (0.1%) of ILC and 2 cases (0.2%) of mucinous carcinoma (Table 2). The underestimation rate for *in situ* carcinoma was 7.01% as 8 cases were upgraded to IDC after hook wire localization and open surgery. In none of the other categories, discordance was noted (Table 3).

The overall documented underestimation rate was 4.6% (11/239). The false negative rate was 2.4% (3/125) as the 3 aforementioned high risk cases were diagnosed as malignant in final histology. The sensitivity of the method was 98.2%, specificity 100%, positive predictive value 100% and negative predictive value 97.6%.

Complications were encountered in 76 cases corresponding to 9.2% of the total VABBs. In 35 cases (4.25%) a small hematoma (<2cm) was formatted, 29 cases (3.5%) experienced moderate bleeding and in additional 2 cases (0.25%) more severe bleeding was noted, requiring admission to our hospital for 24 hrs and transfusion of one unit of red blood cells. Finally, 10 patients (1.2%) experienced vasovagal symptoms.

Table 3. Association of VABB histology with final outcome

VABB histology				*Surgical histology*				*Underestimation rate (%)*	
		ADH	*ALH*	*DCIS*	*LCIS*	*IC*			
Benign	59	59	0	0	0	0	0	0	
ADH	31	0	30	0	1	0	0	3.22	4.54
ALH	35	0	0	33	0	2	0	6.06	
DCIS	104	0	0	0	96	0	8	7.69	7.01
LCIS	10	0	0	0	0	10	0	0	
IC	50	0	0	0	0	0	50	-	

For abbreviations see text

Discussion

Non palpable lesions of the breast constitute the 'Achilles heel' of the triple assessment for the diagnosis of breast cancer, as the clinical examination is not feasible. For these cases, mammography and biopsy are the assessments remained. The widespread use of mammography, as a breast cancer screening tool, has increased the detection of suspicious non palpable lesions [10]. Microcalcifications, representing one of the most frequent - and sometimes the sole - malignant mammographic findings, play a crucial role in early breast cancer diagnosis. Therefore, non palpable lesions with microcalcifications found in mammography should be urgently evaluated.

The classification of microcalcifications found in mammography is based on BI-RADS, a lexicon proposed by the American College of Radiology including five categories followed by proceeding proposals. More specifically, for BI-RADS category 1 (negative mammogram) and category 2 (benign findings) an annual follow up is recommended. For BI-RADS category 3 (probably benign) a 6-month follow-up for the breast in question, with 1-, 2- and 3-year follow-up for both breasts, is recommended, while for lesions assigned as BI-RADS category 4 (suspicious) and category 5 (highly suggestive of malignancy) a biopsy is suggested [11].

However, there is controversy over how to treat a suspicious benign lesion. Until today all the available methods can discriminate between benign and malignant breast lesions with 95% accuracy. This means, it may be efficient to monitor these lesions for 1 to 3 years with the risk for the patient to neglect follow up visits and return later with advanced disease. Nevertheless, some patients may seek multiple medical opinions because of doubt. Inconclusive radiological or clinical reports as well as positive family history of cancer contribute to aggravating stressful factors. Therefore, a selective histological diagnosis is justified in order to eliminate the risk of misdiagnosis even for lesion classified as rather benign, i.e. BI-RADS 3.

It is worth noticing that the role of Dynamic Contrast-Enhanced Magnetic Resonance Imaging (DCE-MRI) in the differential diagnosis of microcalcifications still remains unclear with some studies indicating that DCE-MRI is an accurate tool in this field [12] and others suggesting lack of credibility [13]. Thus, there is no imaging modality that can render invasive techniques redundant.

In the 1980s fine needle aspiration cytology (FNA) was a widespread painless technique, as part of the evaluation process for breast lesions [10]. However, its current use has been limited as it is an operator-depended process with high rates of insufficient specimen aspirations for non palpable lesions (range 0-38%) [14]. The inability of FNA to differentiate between DCIS and IDC leads to a 9% overestimation of cases with DCIS [10]. Moreover, the difference in the treatment of DCIS and IDC, with respect to the axilla, makes this a serious clinical concern. These facts imply that FNA is inappropriate for the evaluation of microcalcifications.

Until a few years ago, hook wire localization biopsy was the gold standard for obtaining histological evaluation of such cases [15]. However, the heterogeneous nature of most lesions poses a problem for core biopsies, as the reported underestimation rate for ADH ranges from 18 to 88% [16] and the percentage of non diagnostic samples can be as high as 5-10% [17]. It is notable that up to 37% of the cases with DCIS diagnosed through ultrasound-guided core needle biopsy and 8% after needle localization breast biopsy, proved to be invasive carcinoma after surgical excision [18]. As mentioned above, in regards to the axilla, it is crucial the differential diagnosis between DCIS and IDC.

The innovative Mammotome VABB system, introduced by Burbank and Parker in 1996 [19], is a milestone event in the application of mini-

Table 4. Comparison of VABB studies' results

Study, first author		*Patients, Lesions*	*Follow up, mean*	*Needle (gauge)*	*Core samples, mean*	*Underestimation rate for ADH %*	*Underestimation rate for DCIS %*	*Overall underestimation rate %*	*False negative rate %*	*Sensitivity %*	*Specificity %*	*PPV %*	*NPV %*	*Complications %*
Atasoy et al. 2015 [23]	Prospective	63 patients, 66 lesions	22.7 months	10	8	0	25	20	0	NA	NA	NA	NA	NA
Ohsumi et al. 2014 [22]	Prospective	488 patients, 506 lesions (455 microcalcifications)	33 months	11	8	≥30	28	15.9	2.8	NA	NA	NA	NA	5.1
Pan et al. 2014 [24]	Retrospective	3985 patients, 5232 lesions	NA	8	8,2	0	0	0	NA	100	NA	NA	NA	NA
Imschweiler et al. 2014 [25]	Retrospective comparative (MRI vs stereotactic vs us guidance)	9213 lesions	NA	11	NA	19 vs 9 vs 0.2	NA	NA	3 vs 1 vs 0.4	79.7 vs 91.5 vs 95.7	92.2 vs 81.9 vs 91.7	96.5 vs 92.2 vs 95.7	62.7 vs 80.5 vs 91.7	6 (8 vs 6 vs 4)
Lee et al 2013 [26]	Retrospective comparative	208 patients, 210 lesions	340 days	11 (120 lesions) vs 8 (90 lesions)	17.5 vs 9.6	6.25 vs 9.09	0	NA	NA	NA	NA	NA	NA	1.4
Povoski et al. 2011 [27]	Retrospective comparative	1443 patients	24.5 months	8 VABB vs 14 CNB	6	NA	NA	NA	0 vs 2.1	NA	NA	NA	NA	11.9 vs 12.3
Eby et al. 2009 [28]	Retrospective comparative	991 lesions	NA	11 vs 9	10.5 vs 9.9	20.4 vs 21.6	NA	NA	NA	NA	NA	NA	NA	NA
Kettritz et al. 2004 [29]	Retrospective	2874 patients	25 months	11	NA	24	12	NA	NA	99	NA	NA	99	1.4
Pfarl et al. 2002 [30]	Retrospective	318 patients, 318 lesions	NA	11	15-20	35.3	12.1	NA	3.3	NA	NA	NA	NA	NA
Our study	Prospective	825 patients, 889 lesions	45 months	11	96	3.22	7.69	4.6	2.4	97.6	100	100	99.54	9.2

NA: non available. For other abbreviations see text mally invasive techniques in breast surgery. The more sophisticated sampling technology of VABB allows reliable diagnosis of suspicious non palpable lesions while causing less patient discomfort and entailing lower costs for public health services [20].

The main disadvantage of VABB is underestimation. Reported rates range between 10-35.3% for ADH and 4.8-35% for DCIS. As displayed in Table 4, our results, in comparison to the literature, outcompete in terms of underestimation, as the underestimation rate of ADH was 3.22% and of DCIS was 7.69%. The lower underestimation can be accredited to the precise targeting and the larger tissue volume excised, as most patients underwent the extended protocol with 96 cores per lesion, suggesting that the excision of more cores increases the accuracy of the method [21,22]. The false negative rate in the present study is comparable to that previously reported.

The main drawback of this research was the formation of hematoma or bleeding from the cavity of the excised lesion. We encountered this complication in 8% of our patients - despite the 10 min post-procedural compression - which is greater than the frequency of other authors (range 0.9-3.8%) [22,29]. This fact can also be attributed at the more extensive tissue retrieval. Finally, a limitation in the use of VABB is when microcalcifications are under the skin, due to the risk of removing healthy tissue with cosmetic complications. These patients should undergo wire localization and excisional biopsy.

Conclusions

Based on the results of our study, the use of VABB is a reliable and safe method for the diagnosis of non palpable radiologically suspicious microcalcifications. The benefits for the patient are clear, as she avoids an unnecessary surgery, the associated risks and cosmetic implications in the case of benign lesion, while a patient with a malignant lesion will undergo a tailored surgery.

Conflict of interests

The authors declare no confict of interests.

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