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Mammotome® and EnCor®: comparison of two systems for stereotactic vacuum-assisted core biopsy in the characterisation of suspicious mammographic microcalcifications alone

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Abstract
Purpose The authors sought to compare the diagnostic performance of the Mammotome® and EnCor® vacuum-assisted breast biopsy (VABB) systems in the assessment of suspicious mammographic microcalcifications.
Materials and methods Between January 2011 and July 2012, a total of 169 VABB were performed by stereotactic guidance on a prone table. The Mammotome® 11G (S1) or EnCor® 10G (S2) probes were used randomly. Sampling time and the number of frustules collected were considered; sensitivity, specificity, diagnostic accuracy, positive and negative predictive value (PPV, NPV) of both procedures were evaluated, considering the final histological examination as reference (B1, B3, B5 lesions underwent surgical excision; B2 lesion were considered confirmed after a negative follow-up of at least 1 year).
Results There were no statistically significant differences between the two groups of patients according to the number of procedures (S1 82/169; S2 87/169), average age, BIRADS category (4a, b), and average size of the lesions. The two systems did not differ statistically for correlation with the final histology (S1 k = 0.94 ± 0.06; S2 k = 0.92 ± 0.08) and underestimation of B3 lesions or in situ (S1 4.5 %; S2 4.3 %). Sensitivity, specificity, PPV, NPV, diagnostic accuracy of S1 and S2 were also not statistically different. The systems differed only in sampling time (S1 80; S2 63 s), but not in total procedure time.
Conclusions Our study confirms the effectiveness of VABB in the assessment of microcalcifications and highlights the lack of significant differences between the two systems in terms of diagnostic performance.

Keywords Breast cancer · Vacuum-assisted core biopsy · Microcalcifications

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Introduction

It is widely recognised that the development of systems for minimally invasive needle biopsy (Tru-Cut needle biopsy and vacuum-assisted breast biopsy, VABB) has increased the diagnostic accuracy of percutaneous needle biopsies. In particular, the introduction of VABB systems into clinical practice has allowed researchers to reduce the amount of surgical biopsies performed for diagnostic purposes, so reducing the associated costs [1]. The major advantage of VABB is the chance to withdraw a number of samples sufficient for an accurate diagnosis with a single insertion of the needle and even, in some cases, to completely remove the lesion. VABB also removes a greater amount of material, thus reducing the likelihood of preoperative underestimation, as well as the need to repeat the procedure due to the inadequacy of sampled tissue [2]. The VABB systems (gauge 7–11) can be used with stereotactic guidance (either using upright devices or prone table systems), ultrasound or

magnetic resonance. According to the European Guidelines [3, 4] they can be considered the method of choice for sampling nonpalpable lesions, such as:

- groups of microcalcifications with indistinct morphology, for which the removal of a greater volume of tissue for accurate histological evaluation is required;
- groups of microcalcifications distributed in small clusters, difficult to sample (<5 mm);
- groups of microcalcifications suspected of malignancy, to increase the chances of detecting invasive foci;
- discordant results (B1, B3, or B4) after needle biopsy using 14G conventional core biopsy;
- architectural distortion;
- diagnostic excision of papillary lesions after core biopsy.

The effectiveness and accuracy of a VABB system is generally evaluated in the literature by using parameters such as the percentages of underestimation of proliferative risk lesions, classified as B3 (most frequently atypical ductal hyperplasia (ADH) versus ductal carcinoma in situ) and the underestimation of malignant lesions in situ, usually ductal carcinoma in situ (DCIS) versus infiltrating malignant lesions [5].

There are various VABB systems on the market (Suros®, Vacora®, Mammotome®, EnCor®) which have in common the use of forced aspiration and the option of using large-calibre needles (14–7G) [6].

The different systems are divided mainly into open or closed, depending on whether the tissue sampling is performed manually or automatically. In this study, we compared two VABB devices, one open with manual sampling Mammotome® (Devicor Medical Products, Inc., Cincinnati, Ohio, USA) and one closed with automated sampling (EnCor®, SenoRx, Aliso Viejo, CA) to evaluate their diagnostic performances.

Materials and methods

Study design

Between January 2011 and July 2012, we compared two different VABB systems. Over this period, 169 consecutive VABB procedures were performed in all cases with the aim of evaluating areas of suspicious mammographic microcalcifications not associated with other signs (asymmetric densities, structural distortions masses or opacities). All the areas of microcalcifications were classified BIRADS 4 and divided into subcategories 4a, b and c [7]. All procedures were performed using a Fischer stereotactic prone table (Fischer Medical Technologies, USA) with Mammotome probes®, 11G (Mammotome®, Devicor Medical Products, Inc., Cincinnati, Ohio, USA) or EnCor® 10G (EnCor®, SenoRx, Aliso Viejo, CA).

The patients were divided into two groups according to the device used for each procedure. The choice of which needle biopsy system to use was made randomly. In the period under consideration, we performed a weekly session by VABB needle biopsy system, alternating between the two sampling systems at our disposal. All patients had previously undergone digital mammography in two standard projections (cranio-caudal and medio-lateral oblique). The digital mammographic devices used were Lorad Selenia and Selenia Dimensions Lorad (Hologic, Bedford, MA, USA). In all cases, a complementary ultrasound examination was performed.

All VABB procedures were performed after obtaining the informed consent of the patient.

Biopsy technique

A stereotactic digital Mammotest Fischer prone table was used (Fischer Medical Technologies, USA) connected to a computer equipped with Mammovision software.

The initial localisation phase is the same for both procedures. Evaluation of the lesion is made with a radiographic scout view at 0° and then subsequently two stereotactic projections at +15° and −15° are run.

After selecting the type of biopsy needle system to use and the relative calibre of needle, the software follows stereotactic principles and transmits the numerical values that govern the placement and depth of the needle into the lesion to the device command unit, where the probe is to be installed.

Local anaesthesia is performed with 1 % lidocaine (10 mL), followed by two stereotactic projections at +15° and −15° to confirm the correct target.

If, after the injection, the target is not correct, it is re-centred. The next step is the insertion of the needle. In the case of the Mammotome® probe it is necessary to make a 4–5-mm-long incision with a scalpel. This procedure is not necessary with the EnCor® probe (10 gauge G, with a standard chamber biopsy opening of 19 mm), equipped with a tri-concave tip.

Subsequently two stereotactic pre-fire projections are performed to verify the correct distance between the needle tip and the lesion, and then two post-fire projections to check that the target is at the centre of the biopsy needle chamber. The sampling phase comes next, during which the breast tissue is excised by a rotating blade, in conjunction with forced aspiration, and placed in the sample chamber.

With the Mammotome® probe the position of the camera is controlled manually and the samples must be removed individually by the operator (open system) and placed on

an appropriate support such as absorbent paper and adequately irrigated with physiological saline solution.

The EnCor® is an automatic sampling system with preprogrammed probe, the number and location of the samples are all that is needed before starting. An option can be selected that allows you to reduce the opening of the biopsy needle chamber, which is useful for superficial lesions. This is not available with the Mammotome® system that we used (our model of Original Mammotome® ST, calibre 11G, came with the opening of the biopsy needle chamber at 20 mm), which provides the alternative of a small reducer to place above the biopsy needle chamber before the procedure. The needle picks up the EnCor® frustules that are expelled into a separate chamber, from which they are extracted at the end of the sampling (closed system). After six withdrawals, the collected material is removed and replaced. With this system it is not possible to determine the exact order in which the various cores were collected. The system is supplied with a cleaning function to cleanse the chamber with saline solution.

For both procedures, when used for the characterisation of microcalcifications, mammograms are performed with direct radiological magnification of the cores to assess the presence of microcalcifications in the tissue samples. All cores are then placed in a container with 10 % formalin, the samples containing microcalcifications being marked with Indian ink.

At the end of both procedures it is possible to position a marker consisting of a nonmagnetic metal clip that identifies the site of the needle biopsy.

At about 2 weeks after the procedure, all patients underwent mammographic evaluation of the correct positioning of the clip and the possible presence of residual microcalcifications.

Interpretation of results

According to the European Guidelines, the microhistological examinations of the samples obtained by VABB were classified into five categories: B1 = normal, B2 = benign, B3 = lesion of uncertain significance, B4 = suspected malignancy, B5 = malignant [8].

The lesions classified as benign (B2) were monitored with follow-up mammograms at 6–12 months.

For all lesions classified as B1–B3, diagnostic surgical biopsy after multidisciplinary consultation was advised. The lesions classified as B4 or B5 underwent surgical excision.

Definitive histological examination was considered the gold standard for the comparison of results and the diagnostic performance of the VABB probes. In cases of B4 or B5 lesions completely removed by VABB and no longer histologically present we proceeded to the pathological evaluation of the samples collected by needle biopsy for appropriate cancer treatment. For both systems we evaluated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), diagnostic accuracy, sampling time and the number of cores taken.

Statistical analysis

The continuous variables, expressed as averages with standard deviation, were analysed with Student's *t* test and the nonparametric Mann–Whitney test. The category variables were instead compared by contingency tables analysed with the Chi square test and with 2 × 2 tables using the Yates or Fischer correction. The concordance between the results of the microhistological examination and the definitive histological examination was calculated using Cohen's coefficient.

Results

The radiological characteristics of the lesions in the two groups of patients divided according to the device used for the VABB procedure (Mammotome® or EnCor®) were comparable (Table 1) with no statistically significant differences.

The average time taken for the removal of 6 cores was respectively 63 s with probe EnCor® vs. 80 s with Mammotome® probe, with a statistically significant difference ($p < 0.01$). The overall duration of the procedures was not

Table 1 Characteristics of the two study groups

	EnCor	Mammotome	*p* value	Overall procedures
Number of procedures	82	87		169
Patient age (mean ± standard deviation)	52.72 ± 9.52	53.88 ± 9.74	0.46	53.34 ± 9.63
Lesion size (mm) (mean ± standard deviation)	8.24 ± 4.71	8.84 ± 5.86	0.44	8.58 ± 5.38
Microcalcifications as only mammographic sign	82	87	0.98	169
Lesion BIRADS classification				
R4a	90.24 % (74/82)	90.80 % (79/87)	0.58	90.53 % (153/169)
R4b	9.76 % (8/82)	9.19 % (8/87)		9.47 % (16/169)
R4c	0	0	–	0

Table 2 Comparison between the two different devices considering procedure time and sampling

	EnCor ($N = 82$)	Mammotome ($N = 87$)	p value
Number of samples taken (mean ± standard deviation)	9.73 ± 2.12	9.68 ± 2.25	0.88
Time to sample 6 specimens (sec) (mean ± standard deviation)	63 ± 9.52	80 ± 12.21	<0.01
Total duration of the procedure (min) (mean ± standard deviation)	54 ± 12	55 ± 15	0.55

Table 3 Results of the microhistological examination on the vacuum-assisted breast biopsy specimens

	EnCor	Mammotome
B1	1.22 % (1/82)	0 % (0/87)
B2	69.51 % (57/82)	62.07 % (54/87)
B3	14.63 % (12/82)	17.24 % (15/87)
B4	0.00 % (0/82)	0.00 % (0/87)
B5	14.63 % (12/82)	20.69 % (18/87)
B5a	9.76 % (8/82)	20.69 % (18/87)
B5b	2.44 % (2/82)	0.00 % (0/87)
B5c	2.44 % (2/82)	0.00 % (0/87)

statistically significantly different between the two systems. On average 9.73 (range 6–18) cores were collected with the EnCor® system and 9.68 (range 6–18) cores with the Mammotome® system (Table 2), with no statistically significant differences between the two systems.

Also with regard to the results of the microhistological VABB samples obtained with the two systems, there were no statistically significant differences, as summarised in Table 3 (Figs. 1, 2, 3, 4).

With the Mammotome probe, in no case did the sample prove inconclusive. With the probe EnCor one case (1.22 %) was classified B1 after the microhistology examination (Table 3). In this case, the procedure was interrupted due to major bleeding. In the 6 cores taken no microcalcifications were present. After surgical excision biopsy, the lesion proved to be benign on histological examination.

The only complication observed was the formation of haematoma at the site of collection. In particular, during the check performed 2 weeks after the procedure, we found four blood collections after biopsy with the EnCor probe and three with the Mammotome probe (for both systems, the collections had ultrasound dimensions between 1 and 2 cm).

The lesions classified as B2, with follow-up mammography performed for at least 1 year, were negative in all cases.

All VABB with microhistological results classified as B3 received surgical biopsy after multidisciplinary discussion in the course of diagnostic-therapeutic consultations at the Breast Unit. All VABB with microhistology results of B5 (no case was classified B4) were sent to surgery.

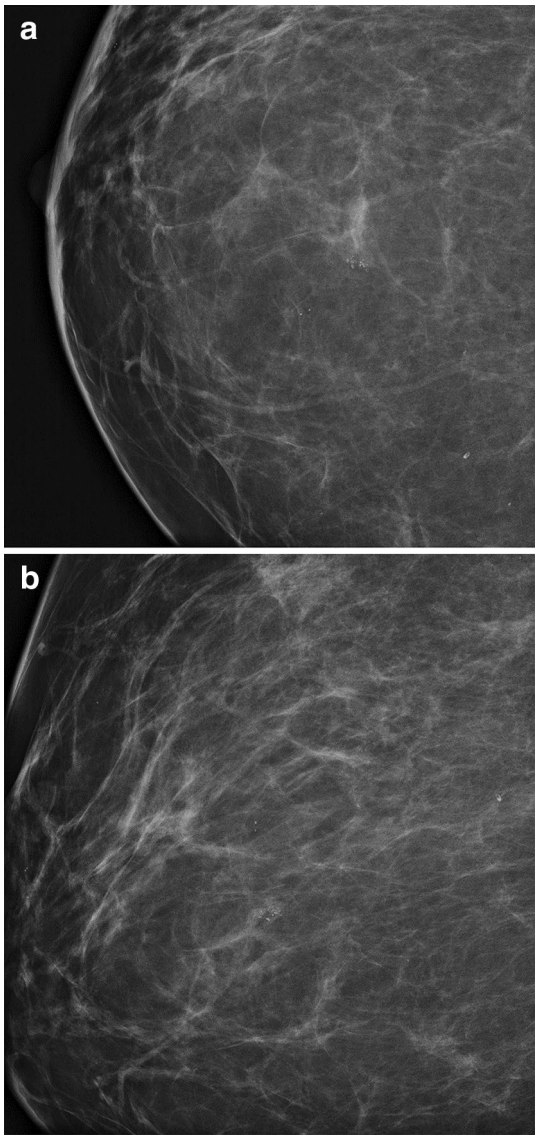

Fig. 1 Magnification views of a 5-mm cluster of heterogeneous and polymorphous microcalcifications classified as BIRADS 4b, which underwent Mammotome® vacuum-assisted biopsy

In four cases of malignant lesions in situ complete excision was achieved of the area of microcalcifications with the Mammotome® probe: at final histology, in two cases (average size 10.5 mm) there were no malignant cells in the surgical specimen, in the other two cases (average size 11 mm) a complex sclerosing lesion with foci of

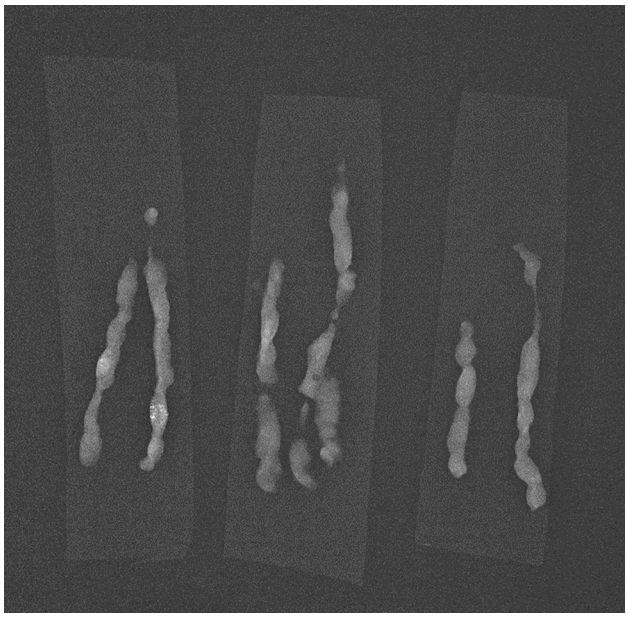

Fig. 2 Magnification view of breast tissue specimens removed by Mammotome® in the same case of Fig. 1: the microhistological finding was B5b (infiltrating lobular carcinoma), confirmed at the final histological examination

atypical ductal hyperplasia (DIN1B) and flat epithelial atypia (DIN1A) were present. With the EnCor® probe two areas of microcalcifications were totally excised: one area (diameter 7 mm) was classified as B3 at microhistological examination and on final pathology no residual lesion was found; similarly, the other totally excised area of microcalcifications (diameter 10 mm) was classified as B5a at microhistological examination and on final histology no residual in situ or invasive carcinoma was found (Tables 4, 5). The correlation between the microhistology outcome and the definitive histology expressed by Cohen's coefficient was equivalent for both probes: 0.92 ± 0.08 (95 % CI 0.75–1) for the EnCor system (Table 6) and 0.94 ± 0.06 (95 % CI 0.82–1) for the Mammotome system (Table 7), with no statistically significant differences between the two.

With regard to the underestimation of the lesions of uncertain biological potential (B3) or in situ (B5a) for both systems the shortcoming was broadly equivalent: using the EnCor® probe in 1/22 cases (4.5 %) and in 1/23 cases (4.3 %) with Mammotome®.

With EnCor, no B3 lesion was underestimated, but one case diagnosed as B5a (DCIS with papillary aspects) proved to be an infiltrating tubular carcinoma with papillomas and columnar cell modifications, at final histological examination.

With Mammotome, no B5a was later identified as an infiltrating lesion but one case diagnosed as B3 (radial scar) at final histological examination proved to be a low-grade DCIS (DIN1C) arising in radial scar.

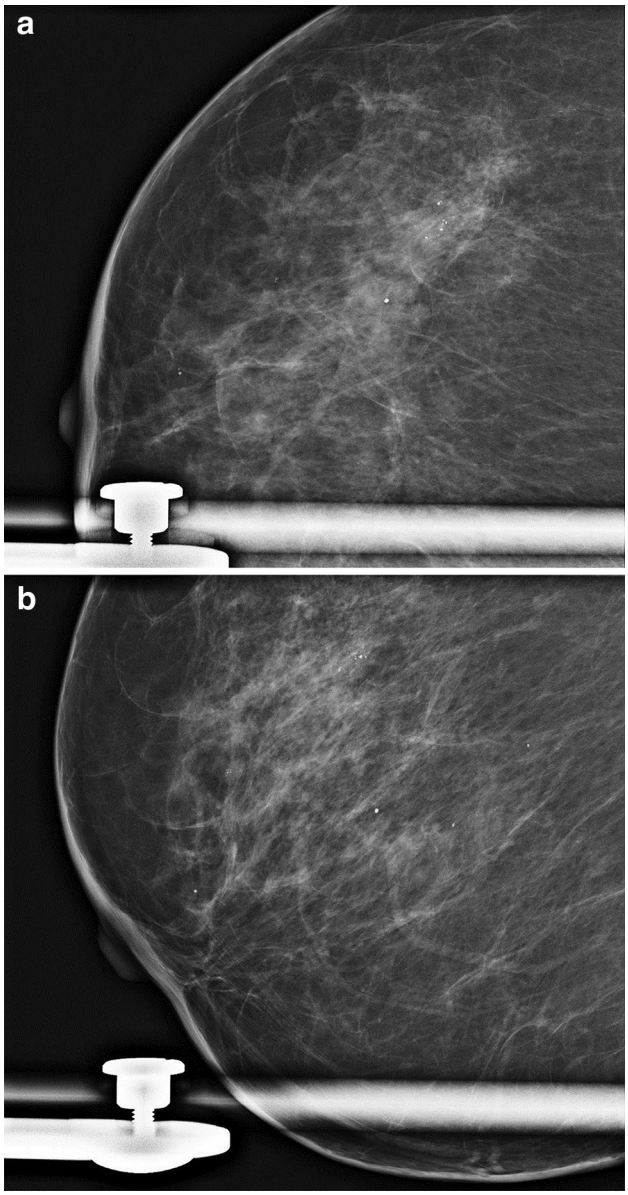

Fig. 3 Magnification views of a 7-mm cluster of microcalcifications with predominantly granular morphology and ductal distribution, classified as BIRADS 4b, which underwent EnCor® vacuum-assisted biopsy

Regarding the diagnostic performance of the two probes (Table 8) the values obtained in terms of sensitivity, specificity, PPV, NPV and accuracy were compared using the Chi square test with Yates correction and were not statistically different.

Discussion

In this series, the Mammotome® and EnCor® VABB systems achieved equivalent results with regard to their

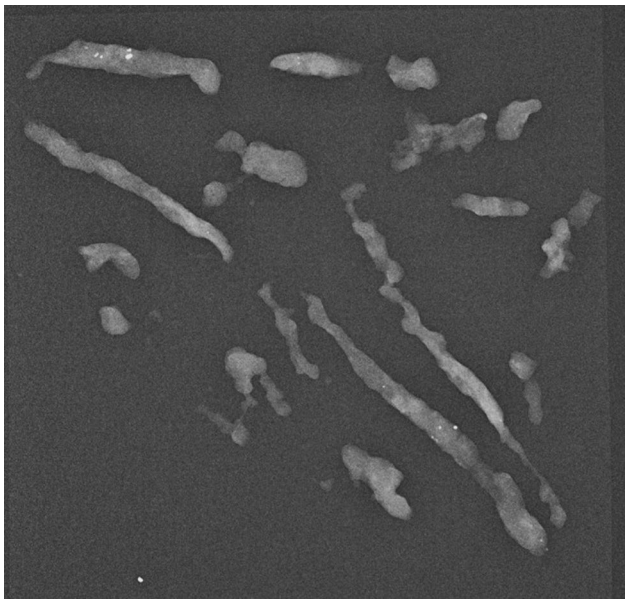

Fig. 4 Magnification view of breast tissue specimens removed by EnCor® in the same case of Fig. 3: the microhistological finding was ductal cribriform carcinoma in situ (B5a); at the final histological examination there was columnar hyperplasia without atypia and no residual carcinoma

Table 4 Vacuum-assisted biopsy-proven B3 lesions: comparison with final histological examination

Final histological examination	EnCor ($N = 12$)	Mammotome ($N = 15$)	p value
DIN1A	4	7	0.76
DIN1B	6	–	NA
DIN1C		1[b]	NA
DIN1A + DIN1B	1	1	NA
Radial scar	–	4	NA
Sclerosing papillomas	–	2	NA
Complete excision	1[a]	–	NA

DIN 1A flat epithelial atypia, *DIN 1B* atypical ductal hyperplasia, *DIN 1C* low-grade ductal carcinoma in situ (grade 1), *NA* not applicable

[a] Normal breast parenchyma

[b] Underestimation of radial scar on VAAB

performance in terms of sensitivity, specificity and diagnostic accuracy. The effectiveness of the Mammotome® system has been demonstrated in a large number of studies in the literature [1, 5, 9], while for the EnCor® system, more recently introduced in interventional breast imaging, experience is more limited [10].

Our data support the validity of the EnCor® system for the assessment of areas of suspicious microcalcifications, as comparable to the Mammotome® system.

The two systems used in this study differ in the size of the probe needle, with the EnCor® using the larger (10G)

Table 5 Vacuum-assisted biopsy-proven B5 lesions: comparison with final histological examination

Final histological examination	EnCor $N = 12$	Mammotome $N = 18$	p value
DIN1C	1	2	0.71
DIN2	3	4	0.79
DIN3	4	8	0.82
IDC + DIN3	1	–	NA
Invasive tubular carcinoma + DIN1B	1[a]	–	NA
ILC + LIN2	1	–	NA
Complete excision	1[b]	4[c]	NA

DIN 1C grade 1 ductal carcinoma in situ, *DIN 2* grade 2 ductal carcinoma in situ, *DIN 3* grade 3 ductal carcinoma in situ, *IDC* invasive ductal carcinoma, *ILC* invasive lobular carcinoma, *LIN2* lobular carcinoma in situ, classic type, *NA* not applicable

[a] Case of VABB underestimation (biopsy-proven ductal carcinoma in situ)

[b] Normal breast parenchyma with no residual ductal carcinoma in situ

[c] 1 Case DIN1A (flat epithelial atypia), 1 case DIN1B (atypical ductal hyperplasia), 2 cases normal breast parenchyma without residual carcinoma

needle compared to the Mammotome® (11G). This difference in size, a single value in the Gauge scale, did not lead to superior performance as also observed by Lourenco et al. [11]. Significantly better performances were observed when greater calibre differences were considered, as in the study by Venkataraman et al. [12], who compared 8G vs. 11G needles.

Both systems allow complete excision of microcalcifications in some cases, although the objective of VABB is exclusively diagnostic. The complete excision of microcalcifications is not to be considered an advantage compared to other techniques for percutaneous VABB needle biopsies since the goal is not therapeutic [13]. In this regard, a reduction of the underestimation of malignancy with an increase of the diagnostic accuracy of the procedure was observed in the case of a complete excision of the lesions [14].

Both VABB system results are highly sensitive and specific in the assessment of suspicious microcalcifications with values similar to those obtained in the study of Zuiani et al. [15] (sensitivity 98.7 %, specificity 83.7 %). Our study differs as regard to the prediction of positivity which it assesses as lower. This difference was caused in our series by the fact that most of the lesions classified as B3 were not malignant upon surgical verification. This could be mostly due to the type of mammographic alterations we selected to undergo to VABB procedures. Most of the cases had been classified as BIRADS 4a, in a few cases 4b and in no case 4c. The subdivision of the class BIRADS 4 into subcategories, introduced in the fourth edition [7], improves the accuracy in the classification of

Table 6 Correlation between the microhistological results by EnCor system and the final histological examination

EnCor	B1*	B2*	B3*	B5a*	B5b*	B5c*
Non-operated patients	0	57	0	0	0	0
Histological examination: benign	1	0	12	0	0	0
Histological examination: DCIS	0	0	0	7	0	2
Histological examination: IC	0	0	0	1	2	0
Total	1	57	12	8	2	2

The grey cells report the data used to calculate the Cohen's kappa coefficient of agreement [k = 0.92 ± 0.08; CI 95 % (confidence interval) 0.75–1]

DCIS ductal carcinoma in situ, *IC* invasive carcinoma

[A] According to the European Guidelines [8]

Table 7 Correlation between the microhistological results by Mammotome system and the final histological examination

MAMMOTOME	B1	B2	B3	B5a	B5b	B5c
Non-operated patients	0	54	0	0	0	0
Histological examination: benign	0	0	14	0	0	0
Histological examination: DCIS	0	0	1	18	0	0
Histological examination: IC	0	0	0	0	0	0
Total	0	54	15	18	0	0

The grey cells report the data used to calculate the Cohen's kappa coefficient of agreement [k = 0.94 ± 0.06; CI 95 % (confidence interval) 0.82–1]

DCIS ductal carcinoma in situ cancer, *IC* invasive carcinoma

Table 8 Comparison of the diagnostic performance of the two systems, considering B3 lesions as a positive prediction of cancer

	EnCor		Mammotome		*p* value
	%	Lower–Upper 95 % CIs	%	Lower–Upper 95 % CIs	
SN	100	(75.75–100)	100	(83.18–100)	NA
SP	82.86	(72.38–89.91)	79.41	(68.36–87.32)	0.76
PPV	50	(31.43–68.57)	57.58	(40.81–72.76)	0.77
NPV	100	(93.79–100)	100	(93.36–100)	NA
AC	85.37	(76.14–91.43)	83.91	(74.78–90.17)	0.96

SN sensitivity, *SP* specificity, *PPV* positive predictive value, *NPV* negative predictive value, *AC* diagnostic accuracy, *CI* confidence interval, *NA* not applicable

the likelihood of malignancy [16], but with regard to less suspicious lesions, such as those classifiable as 4a, mammographic abnormalities classified as BIRADS 3 could be included in this group due to their greater variability and lesser concordance among observers as shown in previous studies [17, 18]. Consequently, the malignancy associated with lesions classified as B3 may be more variable and tends to be lower. Taking into account these variables, the technical characteristics of the VABB system used do not seem to have the potential to increase the PPV.

The strength of the VABB systems lies, however, in their high predictive value for the absence of malignancy (VPN). In this study and in our previous wider experience [1] in no case of VABB microhistological findings classified as benign did we later find the onset of a malignant lesion in the VABB sampling site, in agreement with other studies [8, 13, 19, 20].

A second advantage of using VABB systems compared to core biopsy with conventional semiautomatic systems is the reduction of the underestimation of lesions of uncertain biological potential or malignant in situ lesions. Both VABB systems used give very accurate results in our series

and the underestimation of these types of lesions was inferior to other studies with respect to which it is probably not comparable due to the small sample size. As regards the processing time, the use of a closed system with automated VABB sampling compared to an open one with manual sampling resulted in a significant reduction only of the time taken to sample the cores (calculated on an average of at least 6 cores). The overall duration of the procedures (positioning of the patient, pre- and post-fire checks, etc.) did not reveal statistically significant variations (Table 2). Finally, both systems are highly effective in terms of technical success of the procedure, of almost 100 %. A failure occurred only in one case with the EnCor® probe. However, this finding cannot be attributed to the system used, since failure rates between 0 and 5 % with Mammotome® system in previous studies have been described [21–23].

Conclusions

Our study highlights the lack of statistically significant differences between the EnCor® system and the Mammotome® system for the variables we considered; for this reason, even considering the relatively modest number of patients, the EnCor® system can be considered by no means inferior when compared with the Mammotome® procedures under stereotactic guidance.

Our data also confirm the effectiveness of the VABB procedures in the assessment of suspicious microcalcifications as a single mammographic sign for the purposes of proper planning of surgical treatment.

Conflict of interest The authors declare no conflict of interest.

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