

# Is 9-G DBT-Guided Vacuum-Assisted Breast Biopsy Sufficient to Completely Remove T1 Breast Cancers (below 20 mm)? Analysis of 146 Patients with Histology as Reference Standard

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## Key Points

- In our study, we reevaluated the degree of therapeutic efficacy of the stereotaxic vacuum-assisted breast biopsy (VABB) technique when the pathologically confirmed findings, according to recent literature are small breast cancers (T1N0M0) lesions.
- Our study confirms the efficacy of VABB in true radical excision of small breast cancers, compared to the gold standard of postsurgical histology.
- DBT-guided 9-G VABB is highly effective in the complete removal of breast cancer if the lesion has a diameter <10 mm.

## Keywords

Stereotaxic techniques · Biopsy · Mammography · Breast cancer

## Abstract

**Objectives:** Vacuum-assisted breast biopsy (VABB) is a safe procedure comparable to surgical biopsy for the characterization of distortions, microcalcifications, and mass lesions. Vacuum-assisted excision of T1 breast tumors could be on potential management in alternative to surgery. The primary objective of this work was to assess the therapeutic success of the stereotaxic vacuum breast biopsy in small breast cancer (T1N0M0) lesions excision. **Methods:** From our electronic database, all the vacuum breast biopsies performed from January 1, 2015, to December 1, 2019, have been retrospectively reevaluated.  $N = 2,200$  cases were identified and  $n = 145$  ensured “mammographic complete removal” at the end of vacuum-assisted excision treatment and were considered

for analysis. Surgical gold standard was used. **Results:**  $N = 143$  procedures were successfully completed with complete removal of mammographic calcifications. The mean size of the lesions completely excised with VABB was  $8.9 \pm 3.6$  mm (range, 3–23 mm). Lesions below 10 mm were  $n = 118$  and lesion with diameter >10 mm were  $n = 28$ .  $N = 3/146$  cases (4.4%), relapses were observed in follow-up (at 12–24 up to a maximum of 60 months): the mean size of relapsed lesions completely excised was  $3.6 \pm 2.1$  mm (range, 2–6 mm). No relapse before 12 months were observed. The mean size of the lesions in these patients with relapse at the time of the first VABB procedures was  $13 \pm 6.5$  mm (range, 7–12 mm).  $N = 117/118$  (99%) lesions excised using VABB without relapse after 1 year of follow-up had a diameter below 10 mm. **Conclusions:** Vacuum breast biopsy could safely remove small breast cancers (T1N0M0) with few relapses.

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Published by S. Karger AG, Basel

## Introduction

Stereotactic vacuum-assisted breast biopsy (VABB) is considered a safe procedure, comparable to surgical biopsy for characterization of microcalcification distortions and mass lesions [1, 2]. The confidence rate of biopsy specimens acquired via VABB is increasing, with low rates of false-negative results. For 15 years, VABB has been one of the most effective methods in the histological diagnosis of breast cancer [3–6]. VABB can be used not only in stereotaxis (Mammography or DBT-guided) but also under ultrasound guidance and through MRI-guided technique. Percutaneous excision of microcalcifications is often achieved by the VABB-assisted technique when such lesions are around 1 cm or less [7, 8]. Several studies demonstrated a potential-evolving role for the use of vacuum-assisted excision in the management of pathologically diagnosed B3 lesions (heterogeneous group of lesions of uncertain malignant potential of the breast with an overall risk for malignancy of 8.9%–35.1% after total resection) which might include lesions such as radial scars, papillary lesions without atypia, mucinous lesions, and some atypical epithelial hyperplasias as ADH and FEA [9–12]. T1N0M0 breast neoplastic lesions are usually described as “Small Cancers of Breast” (BCS). BCS are early-stage tumors, measuring less than 2 cm [13]. Treatment for these cancers consists of complete surgical removal of the lesion. Small tumors carry good prognosis with cancer-specific survival rates after 5–10 years as high as 90% or 95% [13–15]. The primary goal of this work is to reevaluate the degree of therapeutic success rate of the 9-G DBT-guided stereotactic VABB technique when the BCS measured <2 cm.

## Materials and Methods

### *Stereotactic VABB Technique*

VABB is a well-established technique for diagnostic work up of suspicious microcalcifications of the breast. VABBs were performed by 3 radiologists with 15, 12, and 11 years of experience in breast imaging field. The procedure was performed with a DBT-guided stereotactic VABB system (Selenia Dimensions system's Genius™ 3D Mammography™; Hologic, Bedford, MA, USA), with the patient being in a sitting position although less comfortable than the supine position [16]. The entry approach was chosen to ensure the shortest possible distance between the skin and the target lesion.

The breast is positioned and flattened by a fenestrated compressor and after a standard projection is performed. If the lesion is inside the fenestrated part of the compressor, acquisitions are performed using tomosynthesis. For the present study, we included patients evaluated with 9-G needle VABB. Using a 9 or 8-G needle, sample size is approximately three times the amount collected by an 11-G needle, and it can be used to resect breast lesions with a therapeutic intent [17]. Sampling is performed with a 360° rotation and uses a 9-G (Eviva® Breast Biopsy System; Cradle: 20 mm; Hologic) needle. Normally about 12 samples are obtained, in

order to obtain the maximum diagnostic performance for the suspected lesion; depending on the size of the lesion, it is possible to proportionally opt for an increase in sampling. Through this procedure it is not necessary to remove the needle from the breast after obtaining each sample, thus being a less bloody technique than non-vacuum-assisted techniques (Fig. 1). The tissue sample is aspirated into a chamber where it is collected in a small container basket. Radiographs of the extracted specimens are always acquired (Hologic Lorad Selenia Digital Mammo Unit; Hologic). If the control radiograph of the samples shows the presence of the lesion in the material taken during the biopsy, mammography, and ultrasound examinations are required to demonstrate completed excision or any residual post-VABB lesions. Finally, after the sample harvest, images then are acquired to document the final position of the biopsy needle.

At the end of the sampling, the operator releases a titanium radiopaque marker (Atec TriMark; Hologic, Indianapolis, IN, USA). Two radiographic projections must be acquired: one performed cranium caudal and one lateral at 90° (ML) in order to document the positioning of the clip. At the end of the procedure, pressure is applied for 10 min along the path of the needle (Fig. 2). All surgeries were performed by our dedicated breast surgery team (6 operators with an average experience of 25 years), as well as the pathological evaluation was carried out by 2 specialists with, respectively, 30 and 25 years of experience.

### *Patient Selection*

Inclusion criteria:

- Presence of clustered microcalcifications considered indeterminate or suspicious, distortions, and mass lesions (BI-RADS 4a-b-c, and 5) at mammography and not palpable or visible by ultrasound.

Exclusion criteria:

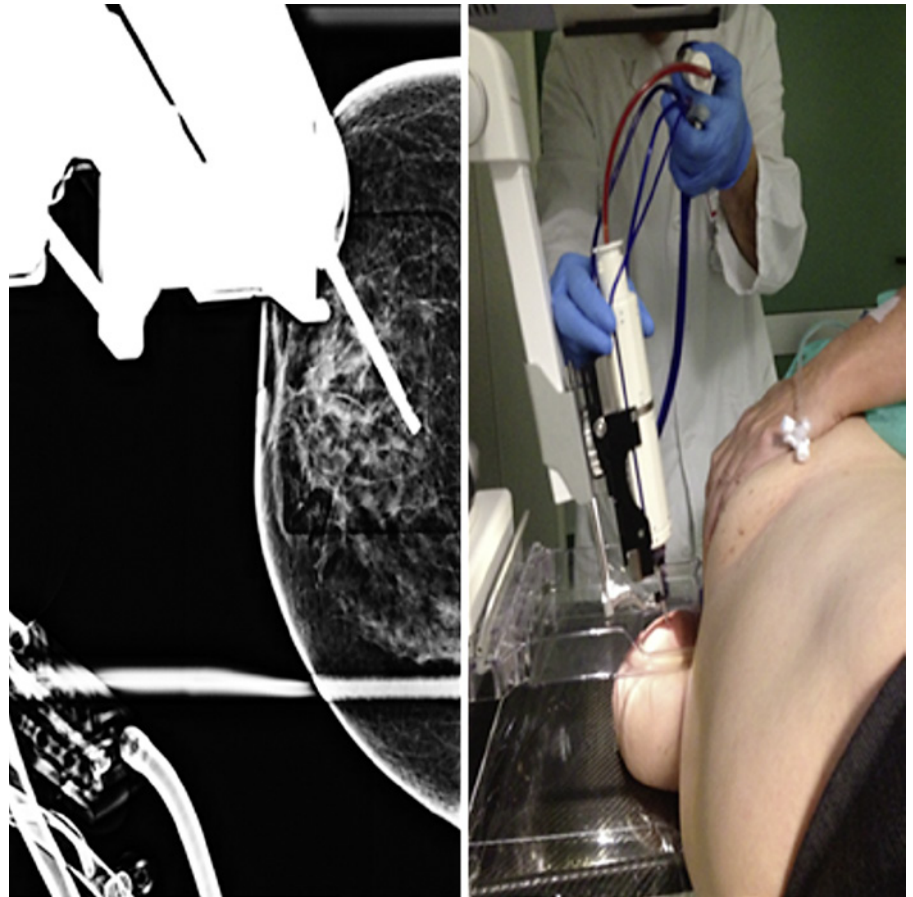
- All patients who did not perform all imaging, biopsy, surgical, and pathological evaluations at our center (150 cases) were excluded from our study.

### *Post Biopsy Management of Patients*

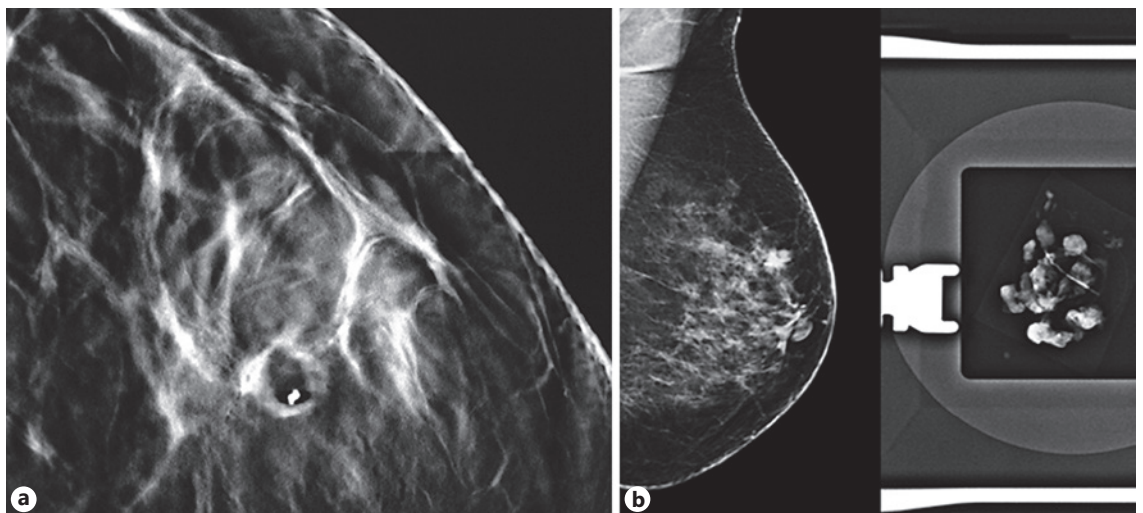
All patients included in the study were reevaluated over time, with follow-up starting from 12 months on an annual basis, up to a maximum of 60 months; specifically, the patients stratified by follow-up are distributed as follows: 41 (60 months), 32 (48 months), 40 (36 months), 20 (24 months), and 12 (18 months). All patients who did not continue the periodic checkups at our facility were excluded from the series and not included in this study. In the absence of a new microcalcification cluster or other suspicious lesions detected during these checks, the patients returned to the conventional screening program.

### *Data Acquisition*

From our electronic database (Estensa Ebit Esaote Italy), all VABB investigations performed with stereotactic guidance from January 1, 2015, to December 1, 2019, were reevaluated retrospectively, for a total number of 2,200 procedures. All patients included in the study are from a normal screening population (with a mean age of 53 years). Among these 2,200 cases, 145 were selected in which complete removal of the pathological finding was confirmed mammographically at the end of the VABB, confirmed by the surgical piece used as gold standard [7]. All cases of discrepancy between the histological result and the BI-RADS category of mammography were reevaluated by the radiologist and the pathologist (dedicated in breast care with 25 years of experience) in agreement to define the causes of inconsistency. If the discrepancy was not resolved, such cases were excluded from the study (60 cases). Postsurgical histopathology was the gold



**Fig. 1.** Biopsy sampling using the VABB system.



**Fig. 2. a** Post-VABB MLO projection. **b** Radiogram of the biopsy frustules.

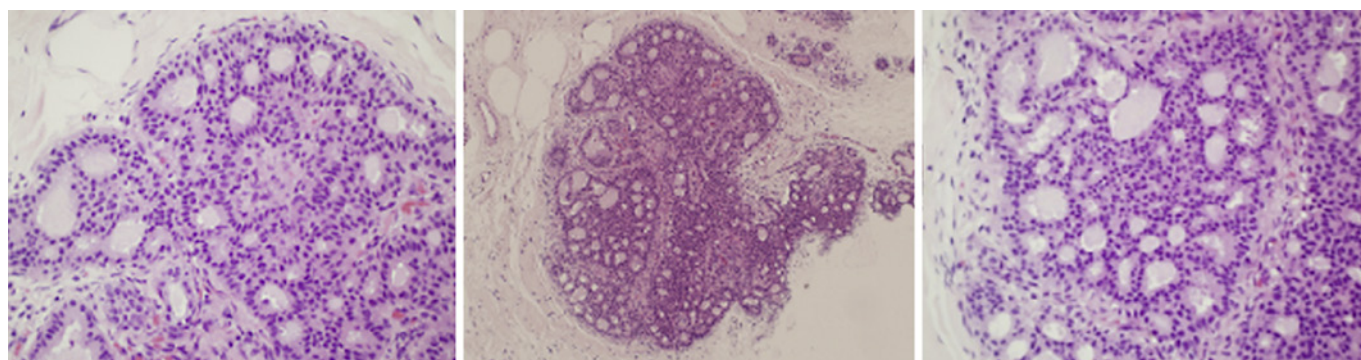
standard. One of the inclusion criteria was the histopathological evaluation of the definitive surgical piece demonstrated complete removal of breast cancer; in our case series, there was no histopathological update after surgery. Descriptive statistical analysis was done. Statistical analysis was performed using commercially available software (SAS, version 9.1.3; SAS Institute, Cary, NC, USA).

## Results

The mean age of the patients was 55 years (age range 35–88 years).  $N = 143$  procedures were successfully completed with complete removal of mammographic calcifications. No clinically significant bleeding or major pa-

**Table 1.** Final histology of the excised lesions

Anatomo-pathological classification	<i>n</i>	Average diameter	Type of lesion	Relapse	Histotype relapse
B3a	67	12	45 microcalcifications 7 masses 14 distortions		2 sclerosing papillary lesions with FEA
B3b	31	9	24 microcalcifications 5 masses 2 distortions	2	0
B4	3	8	3 microcalcifications 0 masses 0 distortion	0	0
B5a	34	9	31 microcalcifications 2 masses 1 distortion	1	1 DCIS
B5b	6	7	3 microcalcifications 2 masses 1 distortion	0	0
B5c	5	9	5 microcalcifications 0 masses 0 distortion	0	0



**Fig. 3.** Outbreaks of low-grade ductal carcinoma in situ (G1) with a prevalent cribriform pattern, characterized by rounded, uniform nuclei, with regular chromatin pattern, and with inapparent nucleoli. Mitotic figures are rare. Absent necrosis.

tient discomfort was recorded. The mean size of the lesions completely excised with VABB was  $8.9 \pm 3.6$  mm (range, 3–23 mm). Lesions below 10 mm were  $n = 118$  and lesion with diameter >10 mm were  $n = 28$ .

$N = 3/146$  cases (4.4%), relapses were observed in follow-up (at 12–24 up to a maximum of 60 months): the mean size of relapsed lesions completely excised was  $3.6 \pm 2.1$  mm (range, 2–6 mm). No relapse before 12 months were observed.

The mean size of the lesions in these patients with relapse at the time of the first VABB procedures was  $13 \pm 6.5$  mm (range, 7–12 mm): 1 with only microcalcification 1 with microcalcification and a small nodule, and 1 with a nodule.  $N = 117/118$  (99%) lesions excised using VABB without relapse after 1 year of follow-up had a diameter below 10 mm.  $N = 26/28$  (93%) lesions excised using VABB without relapse after 1 year of follow-up had a di-

ameter >10 mm. No malignancy (invasive cancers) resulted from the histologic analysis of the relapsed lesions: two relapses resulted to be sclerosing papillary lesions, and 1 case resulted not be a ductal carcinoma in situ (Table 1; Fig. 3).

### Discussion

Stereotaxic VABB is increasingly considered a safe and comparable procedure to surgical biopsy for the study of distortions, microcalcifications, and mass lesions [1–3, 18, 19]. Our study compared DBT-guided 9-G VABB with the gold standard of postsurgical histology to remove small breast cancers. The main result of this study is that it was possible to obtain a complete removal of the lesion in 117/118 (99%) cases with lesion diameter <10

mm with no relapse at 12–60 months of follow-up. In addition, when lesion diameter was higher than 10 mm,  $n = 2/28$  (7%) lesions relapsed after 12–60 months of follow-up. Therefore, on the base of the results of this study, we can affirm that DBT-guided 9-G VABB is highly effective in complete removal of breast cancer if the lesion has a diameter <10 mm. VABB treatment with complete biop- tical excision of the specimen proved at the control mam- mogram allows only a small enlargement of the surgical bed to remove the clip thus reducing bleeding. In addi- tion, DBT-guided 9-G VABB could reduce costs of the entire procedure. Indeed, Alonso-Bartolome et al. [20] in the analysis of the financial outlays of VABB procedure pointed out that the costs associated with VABB systems are 82% lower than a surgical biopsy and that the time spent by the patient was 71% less with VABB than with surgery. VABB cost analyses need to be considered in the context of the overall economic costs related to any po- tential reduction in the need for open surgical procedures [11]. The main limitations of this study were as follows: it represented the experience of a single academic institu- tion, the sample size is relatively small, there are few re- lapses, and no surgery control group, for ethical reasons. A further recognized limitation of the VABB technique is its therapeutic approach in the presence of classic lobular tumors, regardless of whether they are lobular carcino- mas in situ or atypical lobular hyperplasia, both often characterized by a multicentric and multifocal pattern. We acknowledge that a potential selection bias could be present when selecting patients for VABB.

## Conclusion

DBT-guided 9-G VABB is highly effective in the com- plete removal of breast cancer if the lesion has a diameter <10 mm. DBT-guided 9-G VABB could have an impor- tant role in the management of T1 breast tumors.

## References

- 1 Pfarl G, Helbich TH, Riedl CC, Wagner T, Gnant M, Rudas M, et al. Stereotactic 11-gauge vacuum-assisted breast biopsy: a validation study. *AJR Am J Roentgenol*. 2002; 179:1503–7.
- 2 Sigal-Zafrani B, Muller K, El Khoury C, Va- rountas PC, Buron C, Vincent-Salomon A, et al. Vacuum-assisted large-core needle biopsy (VLNB) improves the management of pa- tients with breast microcalcifications: analysis of 1009 cases. *Eur J Surg Oncol*. 2008;34:377– 81.
- 3 Burbank F, Parker SH, Fogarty TJ. Stereotac- tic breast biopsy: improved tissue harvesting with the Mammotome. *Am Surg*. 1996;62: 738–44.
- 4 Liberman L, Smolkin JH, Dershaw DD, Mor- ris EA, Abramson AF, Rosen PP. Calcification retrieval at stereotactic, 11-gauge, directional, vacuum-assisted breast biopsy. *Radiology*. 1998;208:251–60.
- 5 Meyer JE, Smith DN, Di Piro PJ, Denison CM, Frenna TH, Harvey SC, et al. Stereotactic breast biopsy of clustered microcalcifications with a directional vacuum-assisted device. *Radiology*. 1997;204:575–6.
- 6 Jackman RJ, Burbank F, Parker SH, Evans WP 3rd, Lechner MC, Richardson TR, et al. Atyp- ical ductal hyperplasia diagnosed at stereotac- tic breast biopsy: improved reliability with a 14-gauge directional vacuum biopsy. *Radiol- ogy*. 1997;204:485–8.
- 7 Penco S, Rizzo S, Bozzini AC, Latronico A, Menna S, Cassano E, et al. Stereotactic vacu- um-assisted breast biopsy is not a therapeutic procedure even when all mammographically found calcifications are removed: analysis of 4,086 procedures. *AJR Am J Roentgenol*. 2010;195(5):1255–60.
- 8 Kettritz U, Rotter K, Schreer I, Murauer M, Schulz-Wendtland R, Peter D, et al. Stereotac- tic vacuum assisted breast biopsy in 2874 pa- tients: a multicenter study. *Cancer*. 2004;100: 245–51.
- 9 Tennant SL, Evans A, Hamilton LJ, James J, Lee AH, Hodi Z, et al. Vacuum-assisted exci- sion of breast lesions of uncertain malignant potential (B3): an alternative to surgery in se- lected cases. *Breast*. 2008;17:546–9.

## Statement of Ethics

This research has been carried out in accordance with the stan- dards set out in the Declaration of Helsinki for experiments involv- ing humans. This retrospective study was approved by the Ethics Committee of the Hospital IRCCS Ospedale Policlinico San Mar- tino (CER REG 16/2021 11176). All subjects (or their parents or guardians) have given their written informed consent.

## Conflict of Interest Statement

The authors have no personal, financial, or institutional inter- est with regard to the authorship and/or publication of this manu- script.

## Funding Sources

This research did not receive any specific grant from funding agencies.

## Author Contributions

Guarantor of integrity of the entire study: Alberto Stefano Ta- gliafico. Study concepts and design: Alessandro Garlaschi and Al- berto Tagliafico. Literature research: Alessandro Garlaschi. Clini- cal studies: Alessandro Garlaschi, Irene Valente, Nicole Brunetti, Sara De Giorgis, Barbara Massa, Massimo Calabrese, and Alberto Stefano Tagliafico. Experimental studies/data analysis: Alberto Stefano Tagliafico. Statistical analysis: Alberto Stefano Tagliafico. Manuscript preparation: Alessandro Garlaschi and Alberto Stefa- no Tagliafico. Manuscript editing: all authors.

## Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the correspond- ing author.

- 10 Rakha EA, Lee AH, Jenkins JA, Murphy AE, Hamilton LJ, Ellis IO. Characterization and outcome of breast needle core biopsy diagnoses of lesions of uncertain malignant potential (B3) in abnormalities detected by mammographic screening. *Int J Cancer*. 2011;129(6):1417–24.
- 11 Bennett IC, Saboo A. The evolving role of vacuum assisted biopsy of the breast: a progression from fine-needle aspiration biopsy. *World J Surg*. 2019;43(4):1054–61.
- 12 Bianchi S, Caini S, Renne G, Cassano E, Ambrogetti D, Cattani MG, et al. Positive predictive value for malignancy on surgical excision of breast lesions of uncertain malignant potential (B3) diagnosed by stereotactic vacuum-assisted needle core biopsy (VANCB): a large multi-institutional study in Italy. *Breast*. 2011;20(3):264–70.
- 13 Houvenaeghel G, Goncalves A, Classe JM, Garbay JR, Giard S, Charytensky H, et al. Characteristics and clinical outcome of T1 breast cancer: a multicenter retrospective cohort study. *Ann Oncol*. 2014;25(3):623–8.
- 14 Lee AK, Loda M, Mackarem G, Bosari S, DeLellis RA, Heatley GJ, et al. Lymph node negative invasive breast carcinoma 1 centimeter or less in size (T1a,bNOMO): clinicopathologic features and outcome. *Cancer*. 1997;79:761–71.
- 15 Leitner SP, Swern AS, Weinberger D, Duncan LJ, Hutter RV. Predictors of recurrence for patients with small (one centimeter or less) localized breast cancer (T1a,b N0 M0). *Cancer*. 1995;76:2266–74.
- 16 Tagliafico A, Gristina L, Bignotti B, Valdora F, Tosto S, Calabrese M. Effects on short-term quality of life of vacuum-assisted breast biopsy: comparison between digital breast tomosynthesis and digital mammography. *Br J Radiol*. 2015;88(1056):20150593.
- 17 Villa A, Chiesa F, Massa T, Friedman D, Canavese G, Baccini P, et al. Flat epithelial atypia: comparison between 9-gauge and 11-gauge devices. *Clin Breast Cancer*. 2013 Dec;13(6):450–4.
- 18 Rageth CJ, O'Flynn EAM, Pinker K, Kubik-Huch RA, Munding A, Decker T, et al. Second International Consensus Conference on lesions of uncertain malignant potential in the breast (B3 lesions). *Breast Cancer Res Treat*. 2019;174(2):279–96.
- 19 Mariscotti G, Durando M, Ruggirello I, Belli P, Caumo F, Nori J, et al. Lesions of uncertain malignant potential of the breast (B3) on vacuum-assisted biopsy for microcalcifications: predictors of malignancy. *Eur J Radiol*. 2020 Sep;130:109194.
- 20 Alonso-Bartolomé P, Vega-Bolivar A, Torres-Tabanera M, Ortega E, Acebal-Blanco M, et al. Sonographically guided 11-G directional vacuum-assisted breast biopsy as an alternative to surgical excision: utility and cost study in probably benign lesions. *Acta Radiol*. 2004;45:390–6.