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Safety and Efficacy of Vacuum-Assisted Breast Biopsies under Ultrasound and Stereotactic Guidance

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Abstract

Purpose To evaluate the safety and efficacy of vacuum-assisted breast biopsy (VABB) under ultrasound and stereotactic guidance.

Methods This institutionally approved retrospective analysis comprised 60 females who underwent VABB under ultrasound and stereotactic guidance. Technical success and adverse events were analyzed as per the Society of Interventional Radiology standards. Pain score was recorded as per the visual analog scale.

Results Technical success was 100% with high specificity (100%), sensitivity (96%), negative predictive value 97%, and accuracy of 98%. Ductal carcinoma in situ underestimation rate was 4%. No major complications were encountered, and minor complication of postprocedural hematoma did not require intervention. Procedure was well tolerated with majority patients experiencing mild pain.

Conclusion VABB under ultrasound and stereotactic guidance is a safe and effective method for sampling breast abnormalities.

Keywords
- breast
- intervention
- biopsy
- vacuum-assisted biopsy

Introduction

Breast cancer incidence has progressively increased over the years, becoming the leading cause of cancer in females worldwide.[1] Breast abnormalities are currently being assessed using the “triple test,” a comprehensive approach encompassing clinical breast examination, imaging, and histopathological correlation. Despite a multipronged approach of various breast imaging modalities, lesions deemed as indeterminate or suspicious will still require a histological correlation, thereby rendering surgical excision as the gold standard for breast abnormalities. However, the associated

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cost, psychological burden, and duration of hospital stay for open surgical biopsies are high. As a result, since decades, less invasive alternative techniques such as "core needle biopsy" (CNB) whether image guided or nonguided, has been incorporated into standard evaluation of breast lesions requiring histological evaluation.[2–6] CNB may be plagued by histologic underestimation and false-negative diagnoses, especially in smaller and complex lesions.[7–9] These caveats are further reinforced by the need for larger tissue volume imperative for complete histopathological assessment, including analysis of molecular subtype, tumor grade, receptor status, and genetic profile to guide further management. As redressal, vacuum-assisted breast biopsy (VABB), a form of CNB powered by vacuum suction, allowing contiguous retrieval of larger core samples, without the need for needle reinsertion with a collateral benefit of vacuum evacuation of postbiopsy blood products was developed.[10–12] First introduced in 1995, VABB has been accepted as an alternative method to CNB to diagnose breast lesions with high sensitivity and specificity.[13–16] Hematoma formation is the most commonly associated complication with this sampling technique.[17]

This study is a retrospective analysis of all consecutive, VABBs from March 2021 to February 2022 at a tertiary cancer care center to evaluate safety and efficacy of this sampling technique with respect to needle gauge and guiding modality.

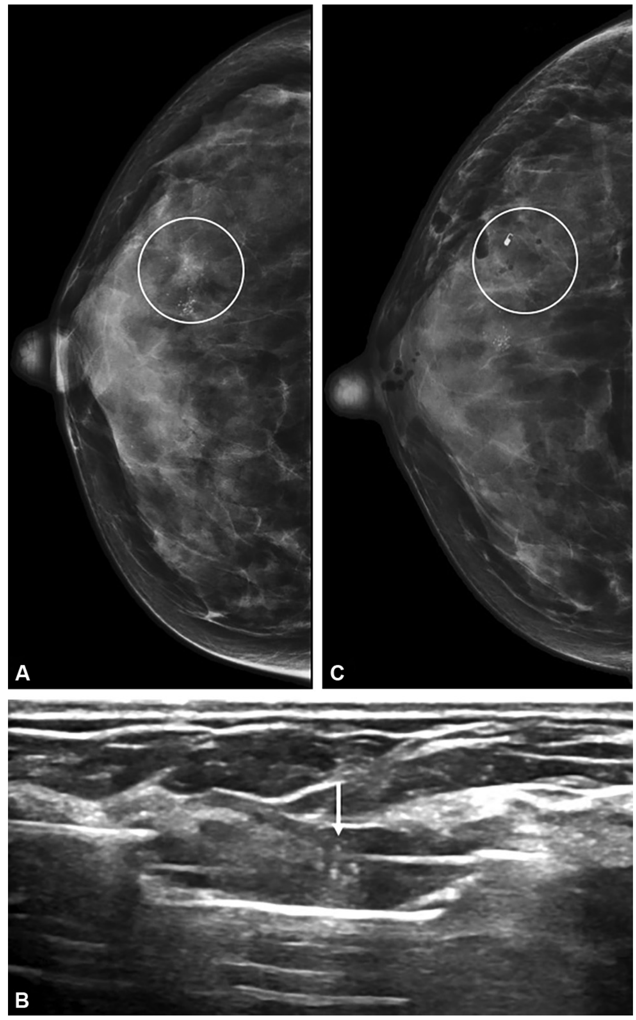

Fig. 1 A 46-year-old woman with a history of nipple discharge from right breast underwent mammography. (**A**) Craniocaudal (CC) view showed regional distribution of amorphous calcification with associated density. Targeted ultrasound revealed an ill-defined hypoechoic lesion with multiple echogenic foci representative of microcalcifications (not shown). (**B**) Ultrasound image showing microcalcification (arrow) within the needle trough. (**C**) CC view showing post-VABB changes and clip marker in situ. Histopathology revealed fibrocystic change, apocrine metaplasia, duct hyperplasia without atypia, and microcalcifications. Patient is on routine surveillance.

Materials and Methods

Ethics Committee approval of a retrospective study with waiver of consent was granted by the Institutional Review Board. Patient demographics and lesion data are shown in ►**Table 1**.

Patient Selection

The morphology of the findings during mammography (MG) and/or ultrasonography (US) were interpreted and categorized as per the American College of Radiology Breast Imaging Reporting and Data System (ACR BI-RADS) version 5.0.[18] According to standard lexicon recommendations, biopsy was considered for all categories 4 and 5 lesions, while for category 3 lesions, biopsy was performed at the discretion of the referring physician. Subcentimeter-sized lesions and those with a complex morphology (aggregation of ducts; initial nonrepresentative or discordant previous biopsy) were planned for VABB. The decision of US versus stereotactic (MG) guidance was case specific, considering the lesion's size, microcalcifications, and location in the breast. If a lesion was detected by both MG and US, then, for noncalcific lesions, ultrasound VABB (U-VABB) was preferred due to greater flexibility in needle placement, maneuvering, and visibility of the procedure performed. For lesions containing microcalcifications, and visible on US, the latter was still preferred for sampling a sonographically visible (possibly invasive) component followed by specimen mammogram (►**Fig. 1**). MG-only-detected suspicious microcalcifications, asymmetry, and architectural distortion were targeted by stereotactic VABB (S-VABB). None of the patients were on

Table 1 Demographic and lesion data

Patients	60
Age (y), mean (range)	47 (22–70)
Gender	Female ($n = 60$)
Location in breast	
Upper outer	24
Upper inner	11
Central, diffuse	13, 3
Lower outer	7
Lower inner	2

anticoagulants/antiplatelets and none of the patients were sedated. Patient demographics and lesion distribution are summarized in ►**Table 1**.

Equipment

US was performed using a linear transducer (LA3–16A) (EVO RS80; Samsung Healthcare, Seoul, South Korea), and MG was performed on Senographe Pristina (GE Healthcare, Milwaukee, Wisconsin, United States) with an integrated stereotaxy facility. 10G and 7G vacuum-assisted needle probes compatible with its dedicated vacuum device were used (EnCor Aspire; BARD, Murray Hill, New Jersey, United States) for performing the biopsies. Written informed consent was obtained from all patients.

Procedure

Patients were placed in the supine position for U-VABB, while for S-VABB, patients were comfortably seated upright. Biopsy track and skin was infiltrated with 2% lidocaine creating a wheal, followed by instillation of lidocaine–adrenaline (1:200,000) along the track and surrounding the lesion to minimize bleeding.

In U-VABB, needle probe was positioned either juxta-superior/inferior or within the lesion depending on its proximity to chest wall or skin, and its size, such that the needle trough is epicentered along the lesion (►**Fig. 2**).

In S-VABB, needle position was confirmed before sample retrieval by acquiring an additional set of paired images after needle insertion, followed by sample acquisition. For lesions with microcalcifications, specimen radiographs were acquired before concluding the procedure to confirm their presence (►**Fig. 3**).

Localizing marker (clip) was placed at the biopsy site in cases of near-complete excision or in cases where the target was a single group of microcalcifications.

Post-VABB, cold compression was applied longitudinally encompassing the site of incision, trajectory, and the lesion for ∼10 to 15 minutes until no oozing was observed, followed by antiseptic dressing, hematoma volume assessment, and application of an elastic compression bandage around the chest. Postprocedure hematoma volume was measured on US immediately postbiopsy (day 0), after 24 hours (day 1), and on the 7th to 10th day. Complications were categorized according to the "Society of Interventional Radiology" (SIR) adverse event classification system.[19] No literature could be found on volume of hematoma considered as significant in breast, and so for the purpose of this study, postprocedure hematoma volume of more than 20 mL was defined as significant. All patients were contacted via telephone on day 3 to inquire about local site discomfort, ooze, purulent discharge, and fever.

Analysis

Diagnostic yield (DY) was analyzed as per the SIR standards[20] where DY is defined as percentage of biopsies that result in a diagnosis. Histopathology of the final surgical specimen or biopsy sample in that order of preference was considered as the gold standard. Safety was evaluated by recording the "SIR-classified" complications as minor (A, B) or major (C, D, E, F).[19] Pain level was recorded using the visual analog scale

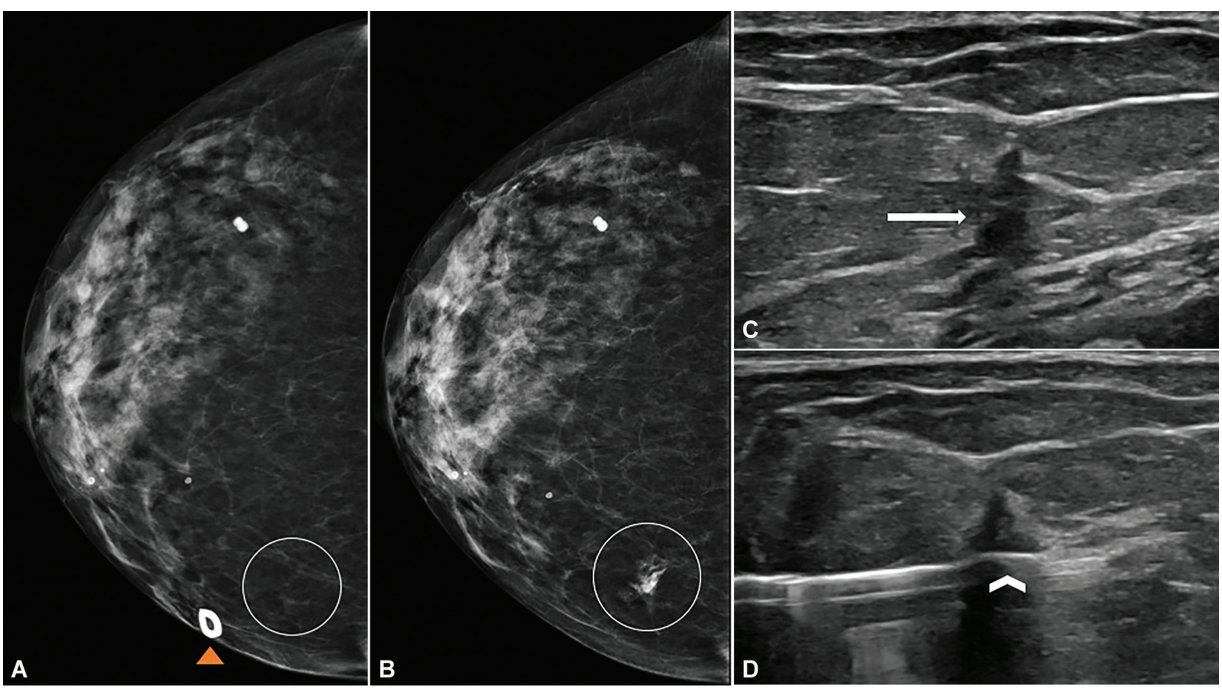

Fig. 2 A 72-year-old woman, treated case of triple negative breast cancer 20 years ago, on routine follow-up. Mammography (MG) showed a faint new density in the inner aspect. A small 5-mm irregular hypoechoic lesion was seen on ultrasonography (US), and confirmed to represent the corresponding MG-detected lesion with a mammogram after placement of a (**A**) skin marker (triangle) and intralesional contrast instillation (**B**). US images showing (**C**) hypoechoic lesion (arrow) and the (**D**) needle along its inferior aspect (arrow head). Histopathology revealed invasive ductal carcinoma.

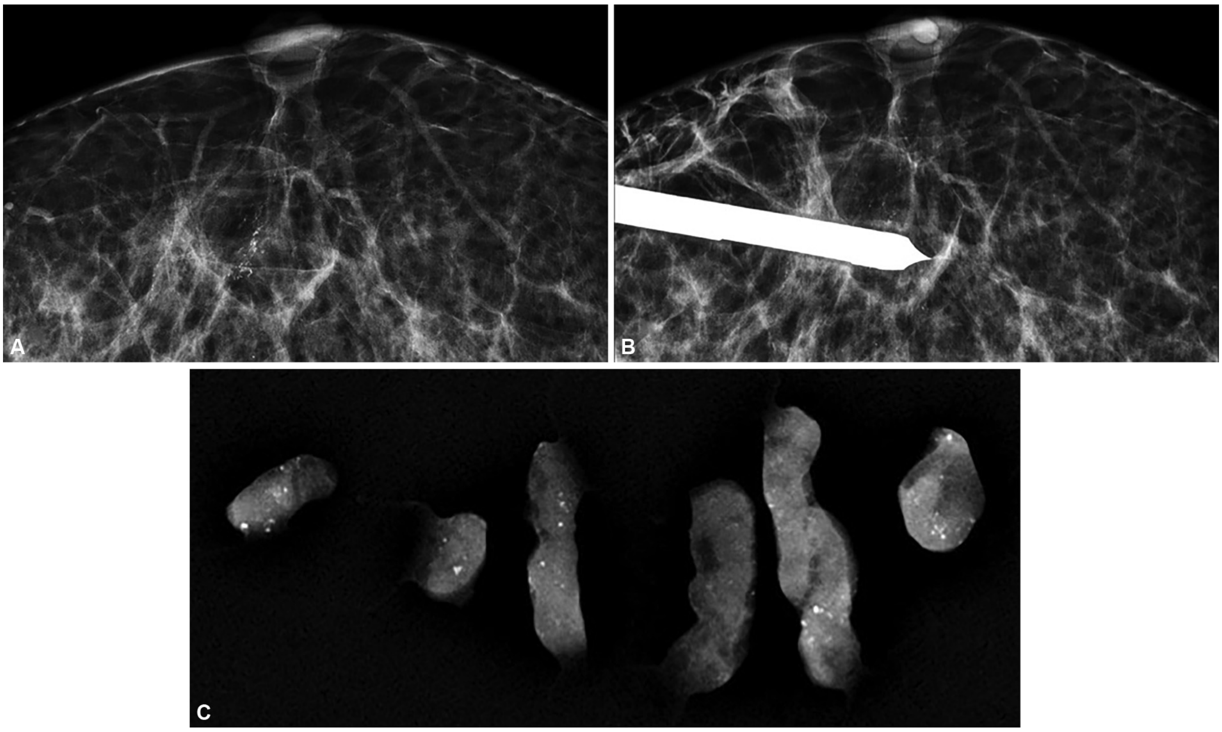

Fig. 3 A 45-year-old woman with a family history of breast cancer underwent screening mammography. (**A**) Biopsy planning craniocaudal view of left breast showed pleomorphic calcification in segmental distribution. (**B**) Needle at target site. (**C**) Specimen radiograph confirming microcalcification in biopsy cores. Histopathology revealed ductal carcinoma in situ, which was further confirmed on subsequent surgery.

(VAS) ranging from 0 (no pain) to 10 (worst pain experienced). Histologic underestimation was considered when "ductal carcinoma in situ" (DCIS) on VABB was upgraded to invasive carcinoma on surgical excision. Statistical analysis for postprocedure hematoma volume and its association with needle gauge (10G vs. 7G) or guiding modality (US vs. MG) was performed using the Mann–Whitney's *U* test and the results were considered statistically significant for p-value < 0.05. Statistical analysis was performed using SPSS (the Statistical Package for Social Sciences), IBM Corp, released 2012, IBM SPSS Statistics for Windows, Version 21.0. Armonk, New York, United States: IBM Corp, and RStudio, version 1.1463, RStudio Inc.

Results

Results are summarized in ►**Table 2**. Sixty patients underwent VABB between March 2021 and February 2022, of which one was a therapeutic excision ($n = 1$) on the patient's request (►**Fig. 4**) and the rest ($n = 59$) were diagnostic. ►**Table 3** gives an overview of lesions categorized as per ACR BI-RADS and their percentage of malignancy on histopathology, with most lesions classified as ACR BI-RADS category 4. Histopathology reports of all patients confirmed 100% DY with one case of underestimation (4%) where U-VABB yielded DCIS; however, invasive ductal carcinoma was found on surgery. In terms of safety, no major complications, requiring hospital stay or intervention were encountered. Minor complication of postprocedural hematoma not requiring nominal therapy or intervention was observed in 42 cases, while 18 patients showed no measurable hematoma immediately after the procedure or on subsequent follow-up imaging. Average postprocedure hematoma volume on day 0 was ~1.8 mL (0.6–2.5) in S-VABB, 2 mL (1–3) in U-VABB, 1.6 mL (0.9–3) with 10G needle, and 2 mL (1.3–3) with 7G needle (►**Figs. 5** and **6**). Of the 42 cases, hematoma volumes were nonmeasurable by day 7 in 31 cases, and there was no significant correlation between postprocedure hematoma volume and needle gauge ($p = 0.2$) or imaging guiding modality ($p = 0.4$). Procedure was well tolerated with most patients (62%) experiencing only mild pain (►**Table 4**).

Table 2 Results

Variable	Value	95% confidence interval
Accuracy	98.3%	91.06–99.96%
Sensitivity	96%	79.65–99.90%
Specificity	100%	90–100%
Negative predictive value	97%	83.7–99.6%

Discussion

The current study affirms the high accuracy of VABB, particularly in small and indeterminate lesions, with high specificity of 100%, sensitivity of 96%, negative predictive value

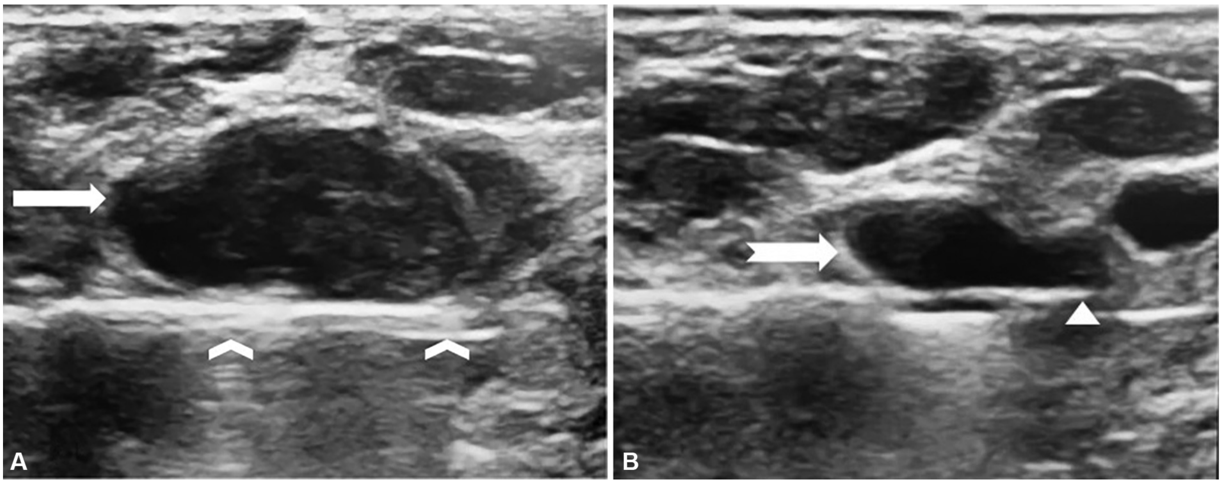

Fig. 4 A 42-year-old woman with clinically palpable right breast lump. Ultrasonography revealed a well-defined oval hypoechoic mass (solid arrow). Vacuum-assisted breast biopsy (VABB) was performed with intent of excision. (**A**) VABB needle probe is seen along the inferior aspect of the mass (arrowheads). (**B**) Gradual decrease in lesion size (split-end arrow) with visible cutting edge (triangle). Histopathology confirmed cellular fibroadenoma. Patient is on follow-up.

Table 3 Lesion characteristics

ACR BI-RADS category	No. of VABB (%) malignant	
3	1 (2)	Nil
4a	27 (45)	6/27 (22%)
4b	16 (27)	7/16 (44%)
4c	11 (18)	8/11 (73%)
5	5 (8)	4/5 (80%)
Biopsy histology		
Benign	35 (58)	
Malignant	25 (42)	
Underestimation (%)	4%	

Abbreviations: ACR BI-RADS, American College of Radiology Breast Imaging Reporting and Data System; VABB, vacuum-assisted breast biopsy.

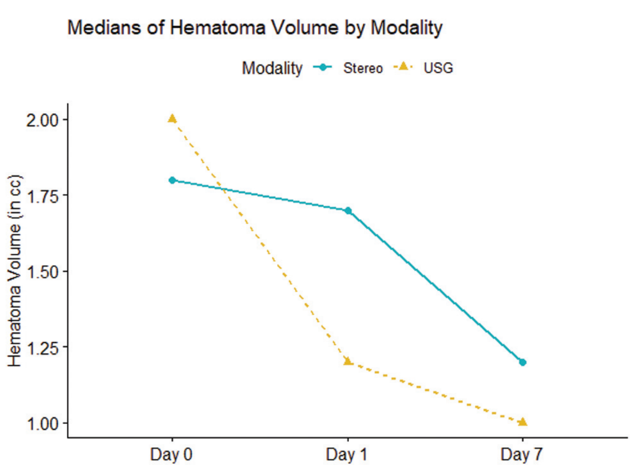

Fig. 5 Evolution of hematoma in relation to vacuum-assisted breast biopsy guiding modality (stereotactic guided vs. ultrasound guided).

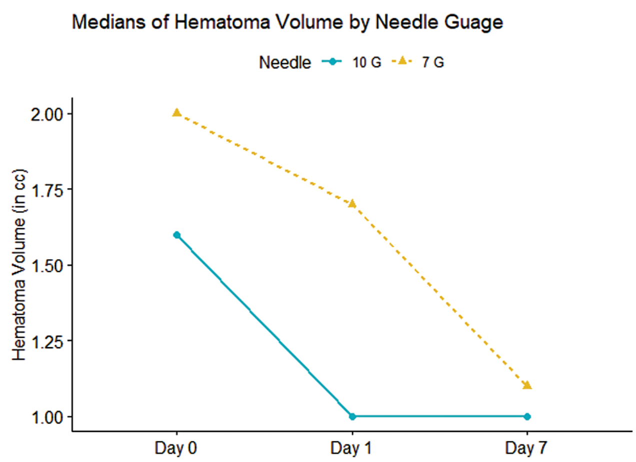

Fig. 6 Evolution of hematoma in relation to vacuum-assisted breast biopsy needle gauge (10G vs. 7G).

Table 4 Pain scores using the visual analog scale

Pain score	Number of VABB (%)
Mild (1–3)	37 (62)
Moderate (4–6)	21 (35)
Severe (7–9)	2 (3)
No pain, worst pain experienced	0

Abbreviation: VABB, vacuum-assisted breast biopsy.

(NPV) of 97%, and accuracy of 98%. These results are in line with meta-analysis by Yu et al[13] estimating specificity of 100% and sensitivity of 98% including larger studies like those by Penco et al ($n = 4,086$) (sensitivity = 99.7–100%)[14] and Kettritz et al ($n = 2,874$) (sensitivity, NPV > 99%).[15]

The DCIS underestimation rate of VABB (4%) in this study was lower than that seen in previous studies such as Tsai et al

(16.7%), Penco et al (17.9%), Cassano et al (16.7%), and Suh et al (16.1%) and the published underestimation rates of CNB (20–55%),[8,14–16,21–23] thus reiterating the benefits of VABB over CNB. VABB successfully addressed all cases of repeat biopsies initially sampled using a 14G CNB automated gun and two cases of CNB underestimation; hence, our findings are in tandem with existing literature suggesting lower sampling error and underestimation in VABB.

VABB specimen histopathology revealed 42% lesions as malignant, and 58% as benign, in concordance with published literature reflecting appropriate patient selection as per BI-RADS categorization[14,15,24–27]; 63% of patients in this study had lesions measuring <10 mm which was comparable to study cohorts of Kettritz et al (58%) and Penco et al (46%) conforming to appropriate patient selection for VABB.

No major complications were encountered in this study which is similar to findings of various previous studies.[28–31] Like Park and Hong, the most commonly associated adverse event was found to be hematoma formation, which was manageable by manual compression and with all except one case having postprocedural hematoma volume <5 mL, which also regressed by the seventh day.[32] Simon et al reported prolonged post-VABB bleeding (>10 minutes) in 7% of patients and vasovagal response in 1% of the procedures,[33] Johnson et al[34] reported infections requiring intervention in 2% cases and Kettritz et al reported complications in 1.4% procedures including hematomas >4 cm ($n = 25$), persistent bleeding ($n = 4$), vasovagal episodes ($n = 5$), seizure ($n = 1$), and inflammation ($n = 5$).[15] One of the reasons for smaller hematoma volumes observed could be meticulous avoidance of traversing vessels by Doppler evaluation of skin site entry, trajectory, up to the lesion, on U-VABB, and repositioning or rolling of breast in case of overlapping coursing vessels in S-VABB. No statistically significant association between complications and needle gauge or guiding modality was observed in this study, similar to findings published by Burbank et al. Alike Bohan et al's experience (55%), most patients in this study reported mild pain (62%).[35] Mean pain score was 3 which was close to findings of Seely et al (3.1), pointing to the good overall tolerance of VABB.[36]

Retrospective design of this study, small sample size, and limited follow-up are limitations of this study. However, VABB holds maximum potential in carefully selected breast lesions considering the balance between associated cost (higher than CNB) and clinical impact.

Conclusion

VABB is a promising means of targeting indeterminate or suspicious findings on MG and ultrasound, and VABB, performed with adequate quality assurance, is safe and efficacious. Side effects are minimal and hematoma formation is unrelated to gauge of needle and imaging modality of guidance.

Ethical Approval
This was an ethics approved study for analysis but being retrospective, formal consent was not required.

Funding
None.

Conflict of Interest
None declared.

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