

ORIGINAL ARTICLE

Role of directional vacuum assisted breast biopsy in previously equivocal biopsies for breast masses suspicious for malignancy

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Abstract

Among percutaneous biopsy techniques, the vacuum assisted breast biopsy (VAB) obtains large tissue samples to alleviate some of the limitations associated with conventional percutaneous biopsy techniques. We aimed to determine the efficacy of VAB in previous equivocal biopsies using the mammotome device. *Materials and Methods:* A prospective non-randomized efficacy study was planned and executed on 43 patients (42 women, 1 man) whose previous FNAC and/or CNB of breast masses yielded inconclusive results or were suspicious for cancer. *Results:* VAB revealed malignancy in 31 (72%) of the 43 patients. Among them, 23 were diagnosed as infiltrative ductal carcinoma (IDC) on VAB, 20 underwent surgery and the final histopathological diagnosis was the same in 19 of them. One patient showed ductal carcinoma-in-situ (DCIS) only in the surgical specimen. Other malignancies included infiltrating lobular carcinoma (ILC) in 5 patients and one each of DCIS, non- Hodgkin lymphoma (NHL) and metastasis from lung cancer. Benign lesions were detected in 12 (28%) patients. These included 8 fibroadenomas, 2 fibrocystic disease and 1 each of mastitis and breast abscess. Four patients with fibroadenoma underwent surgical excision.

Keywords: vacuum assisted breast biopsy, breast cancer, mammotome, mammogram, BIRADS, stereotactic biopsy

INTRODUCTION

Breast cancer is the most common cancer in woman and is the leading cause of death from cancer. It accounts for 32% of all cancers in women and is responsible for 19% of cancer-related deaths in woman.¹ Early detection of breast cancer improves the chance of cure and thereby saves lives. It is always desirable to have a definitive pre-operative diagnosis to permit the physicians and patients to discuss and explain the available treatment options, risks, follow-up and post-operative treatment to the patient. It also helps the surgeon to plan the type and extent of the surgery or start neoadjuvant chemotherapy in cases of locally advanced breast cancer.

The diagnosis of breast cancer is normally based on microscopical analyses of percutaneous biopsies using fine needle aspiration cytology (FNAC) or core needle biopsy (CNB). Small

imaging detected cancers require imaging guidance to perform FNAC or CNB. Among percutaneous biopsy techniques, vacuum assisted breast biopsy (VAB) obtains large tissue samples to alleviate some of the limitations associated with conventional percutaneous biopsy techniques. It allows faster acquisition of contiguous, multiple cores with a single needle insertion. A 10-fold greater tissue volume is obtained per core with VAB compared with core needle biopsy. VAB can be used under stereotactic, ultrasound or MRI guidance. Large samples make VAB almost equivalent to surgical biopsies. VAB is an accurate and reliable technique to obtain histological diagnosis of malignant or benign breast lesions and assists therapeutic decisions. We aimed to determine the efficacy of VAB in patients with previous equivocal biopsies using a mammotome device.

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MATERIALS AND METHODS

A prospective non randomized efficacy study was planned and executed to evaluate the efficacy of vacuum-assisted large core breast biopsy using mammotome device. Forty-three patients presented over a period of three years to the Surgical Oncology or General Surgery outpatient departments at the All India Institute of Medical Sciences, New Delhi, India. A thorough clinical history including present, past and relevant family history was taken. Details of clinical examination, imaging findings and number and results of previous FNAC and/or CNB of the breast were noted. All but one of the 43 patients was female. The median age was 48 years (range 22-73 years).

Study design

Of the 43 patients, mammographic BIRADS categories were assigned to 36 abnormalities as per ACR guidelines.² A mass was found in 35 patients and asymmetric density with calcification was found in only 1 patient. Four patients demonstrated dense breasts on mammography and another 3 patients did not have mammography. USG features were used to assign BIRADS categories to these seven patients using breast ultrasound BIRADS.² USG revealed masses in 41 of the 43 patients; 40 masses were solid and only one mass had both solid and cystic components. In 1 patient with calcifications with asymmetric density on mammography, USG did not reveal any definite abnormality. In another patient, with a small non-palpable mass seen on mammography, the mass was not accurately delineated on USG. Two patients had multiple additional sub-centimeter BIRADS category 3 masses on mammography and USG. Of the 36 lesions seen on mammography, 21 were in right breast and 15 were in left breast. Eighteen of these abnormalities were located in upper outer quadrant of the breasts. We preferred USG guidance for VAB whenever possible and 40 (93%) of the 43 patients underwent VAB under USG guidance. Broad band multi-frequency probe was used and all procedures were performed on the same USG unit (Envisor HD, Philips Medical Systems, Bothell, WA, USA). In 3 (7%) patients, 1 with calcifications only and 2 patients in whom USG did not satisfactorily demonstrate the lesions, VAB was performed under stereotactic guidance. An add-on erect stereotactic biopsy device with digital spot imaging (Opdim, Philips Medical Systems, The

Netherlands) attached to the mammography unit (Mammo-diagnost, Philips Medical Systems, The Netherlands) was used for this purpose. All VABs were performed with Mammotome (Ethicon Endo surgery, Cincinnati, Ohio, USA) directional vacuum assisted breast biopsy device.

Indications for Vacuum assisted breast biopsy (VAB)

Indications for VAB were variable in our study. All previous procedures were inadequate or inconclusive in 12 patients. In another 17 patients, at least 1 of the previous procedures was reported suspicious for malignancy. In 5 patients, VAB was done because previous results were benign but discordant with imaging. VAB was performed in 9 patients because of concerns from patients or clinicians. This included 8 patients with BIRADS 3 category masses and 1 patient with BIRADS 4 category mass with benign previous diagnosis.

USG guided VAB

The procedures were performed with a 11G handheld vacuum probe. The vacuum probe was introduced in its positioning mode with closed sample notch after giving incision. Then, the mammotome device was switched to sample mode of operations which retracts the cannula and exposes the sample notch. The tissue is sucked in the notch with vacuum and by pressing the forward button; the rotating head of the cannula is advanced which cuts and encloses the sample within the notch. By pressing the reverse button of the probe, second channel of vacuum is activated. This retracts the cannula and sample is delivered outside the breast in proximal part of the probe. An assistant then carefully puts the samples in a specimen bottle containing 10% formalin solution. All movements of the probes are observed under real time USG. The procedure is repeated for subsequent samples.

Stereotactic VAB

Stereotactic VAB was also performed with 11G stereotactic probe. It needs to be fixed to the stereotactic device before the procedure and is operated with a remote control. The patient is positioned in the stereotactic device in a comfortable sitting position and a pair of stereo images (10° right and left oblique positions of mammography tube) is obtained. At the workstation, the centre of the mass is marked as the target on both the digital stereo images

thus obtained. X-Y-Z co-ordinates depicted are transmitted to the stereotactic device and the needle holder is positioned. After the skin incision, the probe is advanced in the lesion in positioning mode. The rest of the procedure is similar to the USG guide procedure. For each subsequent sample, the probe is rotated at various positions to cover 360°. We attempted to obtain 10 cores whenever feasible. Specimen radiography of harvested cores was performed after two stereotactic VABs and it showed calcifications in the specimen.

Statistical analysis

Outcome of the objective of the study as mentioned above is categorical in nature that places the suspected cases in two categories, i.e. confirmed or remains negative. Statistical analysis for this purpose is descriptive statistics which is represented by number or percentage. MS-Excel was used for the analysis.

RESULTS

In this study, malignancy was diagnosed on VAB in 31 (72%) patients and various benign conditions were diagnosed in 12 (28%) patients.

Results of VAB according to BIRADS categories
Among BI-RAD categories, 8 masses were

diagnosed as BI-RADS 3 and all of them were benign on VAB. 15 patients had BI-RADS 4 category lesions; 11 of them were malignant and 4 were benign. All 20 BIRADS category 5 lesions were malignant on VAB (Fig. 1).

Correlation of results of previous biopsies and VAB

Majority of patients had cancers on VAB when previous FNAC/ CNB results were inconclusive (10 of 12) and suspicious (16 of 17). All 5 patients with previous benign diagnoses but highly suspicious imaging findings had cancers. Similarly, all 9 patients with previous benign diagnoses which were compatible with imaging proved benign on VAB. The outcomes of VAB correlated against indications for VAB are given in Table 1.

Malignant lesions on VAB

The majority of cancers diagnosed were infiltrating ductal carcinoma and this diagnosis was made on VAB in 23 of the 31 cancers diagnosed (Fig. 2). Other malignancies included infiltrating lobular carcinoma (ILC) in 5 patients and one each of ductal carcinoma in situ (DCIS), non Hodgkin lymphoma (NHL) and metastasis from lung cancer (Fig. 3). In 4 patients with locally advanced breast cancer (T4)

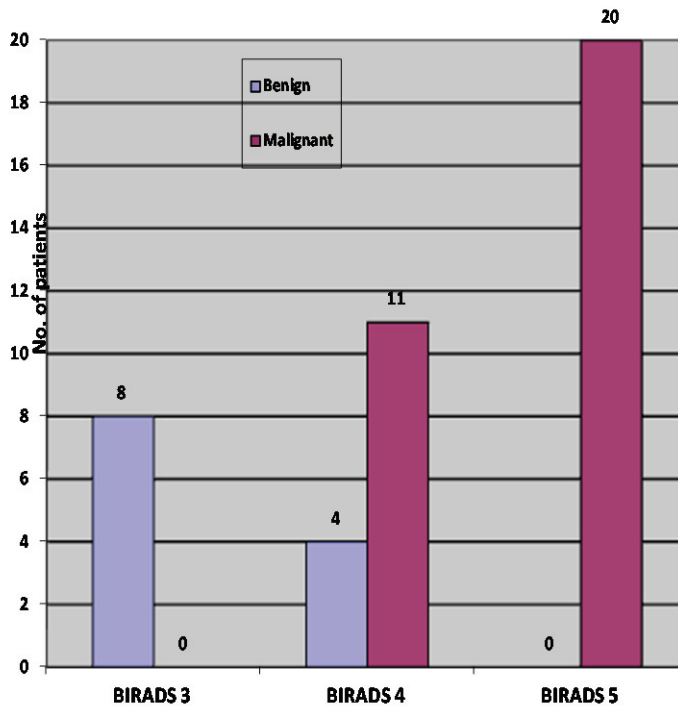


TABLE 1: Correlation of results of previous biopsy and VAB

Previous FNAC/ CNB	Number of VABs	Benign on VAB	Malignant on VAB
Inadequate/ inconclusive	12	2 (16.7%)	10 (83.3%)
Suspicious	17	1 (5.9%)	16 (94.1%)
Discordant benign	5	0 (0%)	5 (100%)
Concordant benign	9	9 (100%)	0 (0%)

and two patients with T2 tumours, VAB cores were also subjected to immunohistochemistry for evaluation of the hormonal receptor status (oestrogen and progesterone receptors) and

Her 2 neu receptor status. This information was important for chemo/hormone therapy decisions.

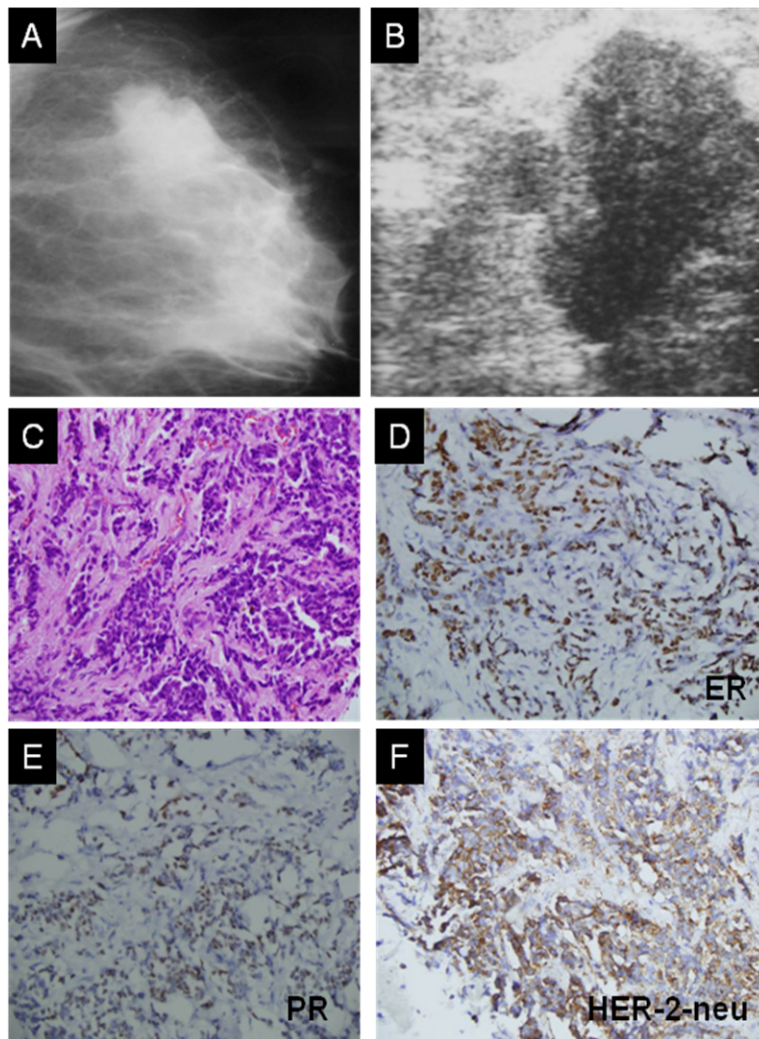


FIG. 2: (A) Mammogram of the left breast (MLO view) showed an irregular, high density mass with indistinct margins in the upper outer quadrant. (B) USG showed an oval, hypoechoic mass with angulated margins which is taller than wide. Previous FNAC was suspicious. Histopathological examination of VAB (C) showed sheets of infiltrating ductal carcinoma (H&E X 100) and on immunohistochemistry the tumour cells were positive for (D) ER, (E) PR and (F) HER-2-neu receptors.

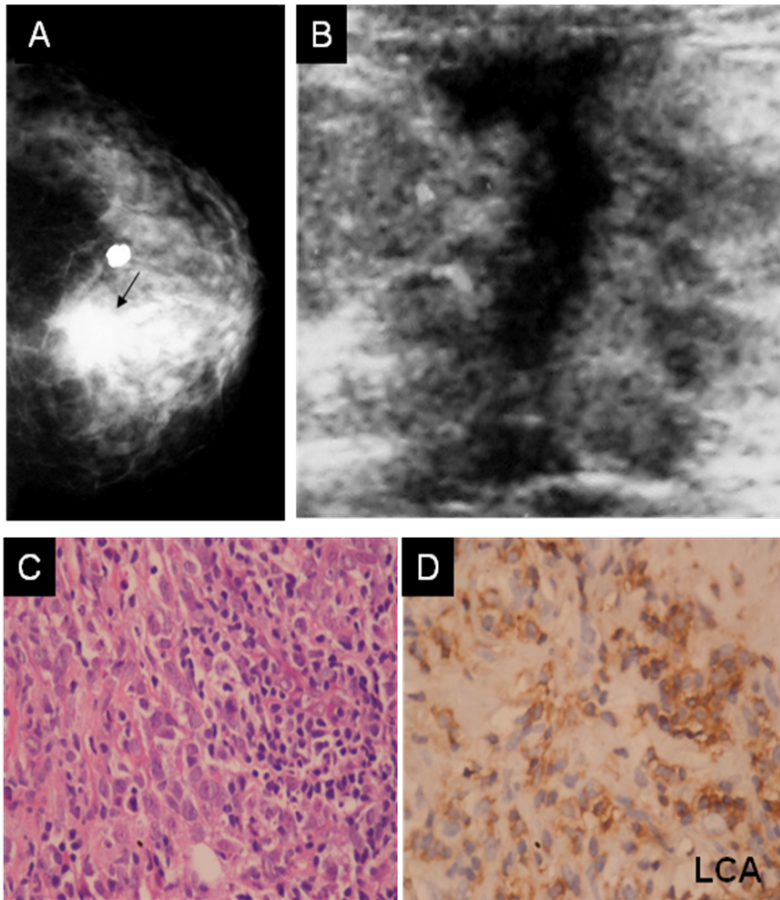


FIG. 3: (A) Mammogram of left breast (CC view) showed a high density, irregular mass with indistinct margins (arrow). Adjacent coarse benign calcification is also seen. (B) USG showed a hypoechoic mass with indistinct margins which is taller than wide. Previous FNAC was suspicious. Histopathological examination of VAB (C) shows atypical lymphoid cells (H&E X 400) and on immunohistochemistry, the tumour cells stained positive for (D) leukocyte common antigen (LCA) suggestive of non Hodgkin lymphoma (NHL).

Final diagnosis

Out of 23 patients with IDC, 20 were operated (19 immediately after completion of preoperative investigations and metastatic work-up and one after neoadjuvant chemotherapy) and the final histopathological diagnosis was the same in 19 of them. One patient showed DCIS only in the surgical specimen. On retrospective review, the VAB histopathology showed the presence of a very small focus of invasive cancer. It was probably completely removed during VAB of this small mass which measured only 7 mm on mammography.

Surgical confirmation was not available in 3 patients who were diagnosed to have IDC on VAB. All of them had locally advanced breast cancer and were referred for neo-adjuvant chemotherapy.

5 patients were diagnosed with invasive lobular carcinoma (ILC) on VAB. Four of them were operated and the diagnosis of ILC was confirmed. One patient refused surgery and opted for alternative treatment. She was lost to follow up subsequently.

There was one case of B-cell NHL diagnosed on VAB. She was an elderly woman who had a past history of lymphoma and had undergone mastectomy of the right breast for lymphoma. She underwent lumpectomy followed by chemotherapy this time.

One patient was diagnosed to have DCIS. Another patient with non-small cell carcinoma of the lung was diagnosed with metastasis in breast on VAB.

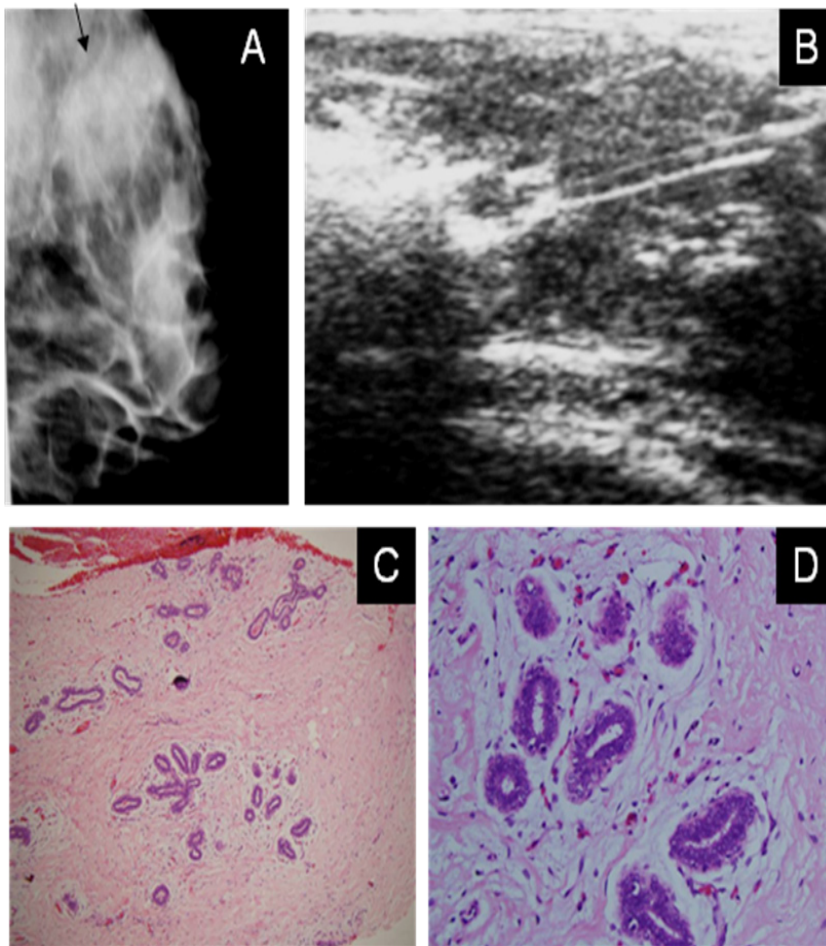


FIG. 4: (A) Mammogram of left breast (MLO view) showed a low density mass with obscured margins in the upper outer quadrant (arrow). (B) USG shows a hypoechoic oval mass with indistinct margins and the 11G VAB probe is seen within the mass. Histopathological examination (C) shows glands with apocrine changes and interlobular (H&E X 100), and (D) intralobular fibrosis suggestive of fibrocystic changes (H&E X 400).

Benign lesions on VAB

In this study, 12 benign cases were detected. This included 8 fibroadenomas, 2 cases of fibrocystic disease and 1 each case of mastitis and breast abscess (Fig. 4). Four patients with fibroadenomas underwent surgical excision. Surgical excision confirmed the VAB diagnosis of fibroadenomas in all of them. One patient with breast abscess was also operated and the drainage of pus confirmed the diagnosis of abscess. Seven other patients with benign masses as diagnosed on VAB were advised for clinical and sonographic follow up. Clinical follow-up was available in 6 of the 7 patients for a mean period of 11.7 months (range 6-18 months). There was no evidence of malignancy in these patients. One patient was lost to follow-up.

Confirmation of VAB diagnoses

Of 43 VAB, subsequent confirmation of VAB diagnoses was available in 37 patients (31 with surgical excision and 6 with follow up). Surgical confirmation or adequate follow-up was not available in the remaining 6 patients. One patient of invasive cancer on VAB had in-situ cancer on surgical histopathology. The final diagnosis of 37 patients is given below in Table 2.

There was no case of false negative or false positive diagnoses on VAB in 37 patients in whom the final diagnosis was available i.e. sensitivity, specificity, PPV and NPV of VAB were all 100% in our study. Hence, no further statistical analysis was undertaken.

TABLE 2: Final diagnosis in 37 patients

VAB diagnosis	No. of patients	Surgical confirmation	Follow up confirmation	No surgical/follow up confirmation
Malignant	31	26 [#]	-	5
Benign	12	5	6	1
Total	43	31	6	6

includes one case of VAB overestimation

DISCUSSION

We performed VAB in 43 patients to evaluate this concept of the VAB as an alternative to surgical biopsy in patients with previously inconclusive, suspicious or discordant percutaneous FNAC or CNB results.

All but 1 of our 43 patients were symptomatic and 40 (93%) of these had clinically palpable masses. Four patients had locally advanced (T4) tumours. Mean size of the masses was large, 2.9 cm (range 0.7-6 cm) in our study. Perez Fuentes *et al* however, had 27.3% of their patients with palpable lesions.³

The indications for rebiopsy in our patients are compared with similar data available in few previous studies. Imaging histological discordance is a major indication for rebiopsy in these studies, as reported by Philpotts *et al* who retrospectively compared the rate of repeat biopsy after stereotactic core needle biopsy of the breast.⁴ Rebiopsy after VAB was required in 9% (32 of 354) cases which is lower than the rebiopsy rate of 14.9% (88 of 592) after 14G needle biopsies.

The majority of our patients were in the highly suspicious (BIRADS 5) category. This selection bias is reflected when we compared our data with some other studies. Ketritz *et al* classified malignant lesions as suspicious or highly suggestive of malignancy in 63%.⁵ The frequency of malignancy in BI-RADS categories 3, 4 and 5 was 19%, 35% and 100% respectively.

The mixed use of sonography and stereotaxy has also been reported by several authors.^{4, 6-9} Philpotts *et al* compared VAB under USG and stereotactic guidance and found that there was no significant difference between these two techniques in terms of results (benign Vs malignant), complication rates, histological underestimation, missed cancers and the need for a second biopsy.^{4, 8} In our study however, most

of the patients had palpable and large masses which were suitable for USG guidance.

We performed stereotactic VAB in 3 cases; one with calcifications only. In one case USG did not demonstrate the mass and in another USG could demonstrate a small 0.7 mm mass on mammography but stereotactic guidance was considered more suitable. Meloni *et al* have reported a success rate of about 80% with stereotactic VABs performed using add on unit.¹⁰

In major studies, the reported average number of cores per VAB procedure range from 5.8 to 26.^{3, 8, 9, 11-16} Lomoschitz *et al* prospectively studied the influence of number of specimens on diagnostic accuracy.¹⁷ Up to 12 specimens were necessary to yield correct diagnosis in 96% of patients with masses and 92% of patients with microcalcifications. In our study, the average number of cores per VAB procedure was 8 (range 5-10). We attempted to obtain 10 cores whenever feasible and this was achieved in 9 patients.

We performed specimen radiography of harvested cores after two stereotactic VABs using the same mammographic unit and it showed calcifications in the specimen. High calcification retrieval rate of 99% was also reported by Cangiarella *et al* and there was no missed cancer in these patients.¹⁸

In this study, malignancy was diagnosed on VAB in 31 (72%) patients and various benign conditions were diagnosed in 12 (28%) patients. A study by Nakano *et al* reported similar findings and cancers were found in the majority of them.¹⁹

12 benign cases were detected in our study. Peres Funtez *et al* followed 42 benign lesions on VAB for a mean of 11.3 months (range 4-24 months) and Plantade *et al* followed 308 benign lesions for a mean of 20 months (range 1-43 months).^{3, 13} As in our study, no missed cancer was reported in these studies.

VAB cores were especially suitable for immunohistochemical analysis for oestrogen, progesterone and Her 2 neu receptor analysis. Histopathological and receptor status analysis was one of the major indications for VAB after diagnostic FNAC.¹⁹

The false negative rate of VAB is significantly lower than that of CNB or FNAC. In a retrospective comparative analysis of missed cancers, Shah *et al* found that miss rates for CNB and VAB were 22.2% and 3.3 %, while Cho *et al* reported it to be 3% and 1% respectively.^{20, 21}

In a meta-analysis of the data from major published studies, Hoorntje *et al* retrospectively found that underestimation rates for VAB of 16% is significantly lower than the underestimation rate of 40% for CNB.²² We did not have any case of histological underestimation on VAB in our patients.

False positives are known with FNACs but these are extremely rare with core biopsy.²³ Simon *et al* had reported two cases of overestimation in their series of 71 VABs.¹²

Imaging-histological discordance is more common with BIRADS 5 lesions and cancers are also more commonly detected in the same BIRADS category on rebiopsy.⁶ Imaging-histological discordance on percutaneous core biopsy of breast, CNB or VAB has been reported to occur in 1-6% of biopsies. On surgical biopsy, cancer is found in 0-64% of such lesions.^{4,14,15,17-19} Philpotts *et al* reported significantly reduced rates of imaging-histological discordance with VAB (0.8%) than with CNB (3.4%), while another study found no significant difference between CNB and VAB in terms of discordance and rebiopsy rates.^{4, 8}

We did not have any case of imaging-histological discordance with VAB diagnosis. Kim *et al* reported similar finding.²⁴ Pfarl *et al* reported a false negative rate of 3.3% (7 of 214) on VAB in pathologically proven cases of breast cancer.²⁵

Most investigators who reported complete removal of imaging evidence of the lesion with VAB have attempted it on small masses with a mean diameter of 1 to 1.5 cm and the success rate was 72.5 to 97%.^{11,13,26,27} Complete removal eliminated underestimation or false negatives in many studies.^{11,13,27,28} However, Liberman *et al* found that complete removal only lowers the frequency of discordant results and does not offer significant advantage in terms of underestimation or rebiopsy rates.¹⁵ The lesions in our study were large in size and we did not attempt their

complete removal. Up to 3-cm size masses can be removed with high patient satisfaction rates.^{7,29,30}

Nakamura *et al* reported VAB with the lateral approach and noted that it is possible to use 11G probes if the breast is thin (minimum thickness was 10 mm) with only polyethylene foam.³¹ This advantage is very important in stereotactic biopsy, especially in Japan.

Several studies have reported VAB to be a highly cost-effective alternative to the surgical biopsy as it spared surgery in 71% to 95% patients.^{3,13,30,32} In our hospital, however, VAB is an expensive technique. Soo *et al* also found it to be 1.22 times costlier than CNB.³³

In summary, VAB is a well established technique which harvests a large number of thick and contiguous cores with single needle insertion, thereby increasing the diagnostic yield.

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This was approved by the AIIMS Institutional ethical committee as an MD (Radiodiagnosis) dissertation study.

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