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RESEARCH

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Adding merits of vacuum assisted biopsy in diagnosis and management of indeterminate breast micro-calcifications

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Abstract

Background Stereotactic guided biopsies have become the sampling method of choice in diagnosis of non-palpable breast microcalcifications which directly impact patients' management plans and consequently morbidity and mortality.

Purpose The purpose is to compare the diagnostic accuracy of VAB and CNB in diagnosis of indeterminate breast microcalcifications and subsequent management of cases of indeterminate breast micro-calcifications.

Methods Retrospective review of stereotactic CNB and VAB was done, pathological data were classified as benign, high risk and malignant lesions and compared with gold standard surgical specimen. The influence on patients' surgical planning was depicted.

Results A total of 268 lesions were included in our study divided as 136 lesions that underwent VAB and 132 lesions that underwent CNB, for the VAB group the overall PPV was 100% (96–100% CI) and NPV was 95.8% (90–98% CI) with overall diagnostic accuracy of 97% (92–99% CI), while for the CNB group the PPV was 100% (95–100% CI) and NPV was 80.2% (74.2–85% CI) with overall diagnostic accuracy of 84.8% (77–90% CI). 4/136 VAB lesions did not match the surgical specimen malignant diagnosis this could be explained by their mean diameter of 9.725 ± 1.8 cm and 3.172 ± 1.84 cm which was found statistically significant *P* value of less than 0.0001. The percentage of re-operation in VAB group was 2.9% while in CNB group was 7.5%.

Conclusions VAB is a superior diagnostic tool over CNB in diagnosis of indeterminate breast microcalcifications and reducing the percentage of re-operations which directly impacts the patient's morbidity. Moreover, it can replace surgery in cases of benign lesions and totally resected high risk lesions especially when operations are contraindicated or refused by the patient, yet with strict follow up.

Keywords Vacuum assisted biopsy, Core needle biopsy, Breast micro-calcifications

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Background

Breast cancer is the most common cancer and the fifth cause of death from cancer in women, mammographically detectable lesions are those lesions that may be occult both clinically and/or sono-graphically such as; micro-calcifications. The gold standard for diagnosis of such lesions is wire localization and excision [1].

Micro-calcifications may be the key or even sole mammographic finding to suspect malignant breast neoplasia. Yet, diagnosis of breast micro-calcifications may be problematic as different management courses are set upon the pre-operative pathological diagnosis so accurate pre-operative diagnosis is a must [2, 3].

Stereotactic guided biopsies have been one of the minimally invasive initial procedures to diagnose micro-calcifications and therefore; guiding further management plans [4].

Stereotactic guided biopsies are either core or vacuum assisted, conventional core biopsies uses automated or semi-automated needles for the procedure while VAB uses special needles and special device, the first VAB device was manufactured by Johnson and Johnson on 1995 [5].

There are several variations in results and outcome of both procedures which directly affect the patients' management and rate of re-operation with reports suggesting that VAB is superior to CNB in terms of matching the pathological diagnosis with the gold standard surgical specimen [5, 13].

Methods

Patients

Our institutional review board approved this retrospective study.

Image analysis was done in a retrospective fashion by two radiologists with above 10 years of experience in breast imaging. Each reader was blinded to the lesion's definitive pathological reports.

A retrospective review of the database of all 268 female patients with microcalcifications at our institution which were further subdivided into two major groups and a third subsidiary group.

First major group included 136 patients who underwent VAB (vacuum assisted biopsy) alone while the second major group included 132 patients and the third subsidiary group included 27 patients from both major groups who have performed both VAB and CNB (core needle biopsy).

All patients underwent an initial sono-mammographic assessment where all suspicious micro-calcifications were classified as BI-RADS 4b (52%) or 4c (48%).

Patients' management was discussed in multidisciplinary meetings where clinical and imaging findings were evaluated, and a consensus decision was taken to perform VAB and/or CNB in selected cases for histopathological assessment.

Data collection of 268 patients included: histology of the biopsy in either CNB or VAB or both as well as the gold standard surgical specimen, distribution and morphology of micro-calcifications, clinical information regarding age at diagnosis, oral contraceptive usage history, personal and family history of breast cancer.

Lesions were considered benign if pathologically proven on one occasion with VAB, at least two occasions of CNB followed by at least 2 year stationary course of follow up, running stationary course on follow up for at least 2 years with no biopsy taken (based on multidisciplinary team (MDT) decision) or confirmed with surgical excision.

Image guided biopsies

Patients were referred to stereotactic tru-cut or vacuum-assisted biopsy (VAB) by trained breast imagers, both procedures using dedicated GE, Pristina, Serena.

All CNB and VAB procedures were performed by two professional radiologists with experience above 10 years in breast imaging and biopsy.

Stereotactic biopsy procedures were performed on a dedicated digital stereotactic table (GE) with the patient sitting. Sampling of the lesions was performed using a vacuum-assisted EnCore Enspire Breast Biopsy System (BARD) with 10-gauge needles. Biopsy specimens from patients with calcifications were routinely examined by specimen mammography.

Tru-cut biopsies were performed with the patient lying sitting using a 14-gauge needle.

A clip was left to mark the site of biopsy except for those marked with residual micro-calcifications.

Out of the 268 patients, 136 patients underwent stereotactic guided VAB and 132 patients underwent CNB.

The outcome of each lesion was determined using the subsequent surgical excision and/or follow-up as a gold standard.

Surgical intervention was done in 203 out of 268 patients (75.7%) when:

- Needle biopsy is not concordant with imaging: pathology does not explain radiographic findings.
- Needle biopsy findings show atypia or Lobular carcinoma in situ (LCIS) and there is a concern for missed cancer in the adjacent tissue.
- Upon patient's request to alleviate psychological stress.

Surgical excisional biopsy was omitted in cases with concordance between imaging and histological findings, with no atypia, or because of the patient's choice, who decided against surgical excision or biopsy performing only follow-up.

Range of pathologies is shown in Table 1.

Statistical analysis

Data analysis was performed with commercially available software (IBM SPSS Statistics for Windows version 24.0.2), data were summarized using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency and percentage for categorical data.

The mean values of the true positive or true negative results group and the false negative group were compared, using *t* test. Sensitivity, specificity, and likelihood ratios were calculated at different cut-off values with a 95% confidence interval. *P* values ≤ 0.05 were considered statistically significant. Statistical evaluation was performed with the Chi-squared and the Fisher exact test for categorical variables.

Table 1 The range of pathologies in the study

Pathology	Number of cases	Percentage
Fibroadenosis	66	24.62%
Fibrocystic changes	34	12.6%
Intra-ductal small papilloma	4	1.49%
PASH	9	3.35%
Sclerosing adenosis	17	6.34%
UDH	37	13.8%
Fibroadenoma	2	0.74%
Apocrine hyperplasia	1	0.37%
ADH	23	8.58%
Columnar cell with atypia	1	0.37%
Radial scar	1	0.37%
Flat epithelial atypia	2	0.74%
DCIS	53	19.7%
LCIS	3	1.11%
Invasive ductal Carcinoma	11	4.1%
Invasive lobular Carcinoma	2	0.74%
Invasive tubular carcinoma	1	0.37%
Invasive Mucinous carcinoma	1	0.37%
Total	268	100%

Percentages of lesions upgraded from malignant to benign as well as re-operation were calculated in each group separately and comparison was done between different groups

PASH, pseudoangiomatous stromal hyperplasia; UDH, usual ductal hyperplasia; ADH, atypical ductal hyperplasia; DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ

Results

The ages of the VAB group ranged from 22 to 79 years with the mean age 50.12 ± 9.74 years while the ages of the Tru-cut group ranged from 25 to 74 years with the mean age 50.48 ± 10.02 years (Fig. 1).

Table 1 demonstrates the range of pathologies in the study.

VAB group

The overall specificity, sensitivity and diagnostic accuracy of VAB in diagnosis of breast micro-calcifications was 100%, 90.70% and 97.06% respectively (Figs. 2, 3, 4).

The overall PPV for the VAB group was 100% (96–100% CI) and NPV was 95.8% (90–98% CI) with overall diagnostic accuracy of 97% (92–99% CI).

Only 4 out of 136 VAB lesions did not match the surgical specimen malignant diagnosis; this could be explained by their mean diameter of 9.725 ± 1.8 cm and 3.172 ± 1.84 cm which was found to have a statistically significant *P* value of less than 0.0001.

Consequently the percentage of re-operation in the VAB group was 2.9% (Fig. 1).

CNB group

The overall CNB specificity, sensitivity and diagnostic accuracy of CNB in diagnosis of breast micro-calcifications was 100%, 60.78% and 84.85% respectively.

While for the CNB group the PPV was 100% (95–100% CI) and NPV was 80.2% (74.2–85% CI) with overall diagnostic accuracy of 84.8% (77–90% CI).

The CNB group showed that the percentage of non-matching cases was 16%, while the percentage of re-operation was 7.5%.

Third subsidiary group

As for the third subsidiary group of patients who underwent both VAB and CNB 20/27 (74.1%) patients

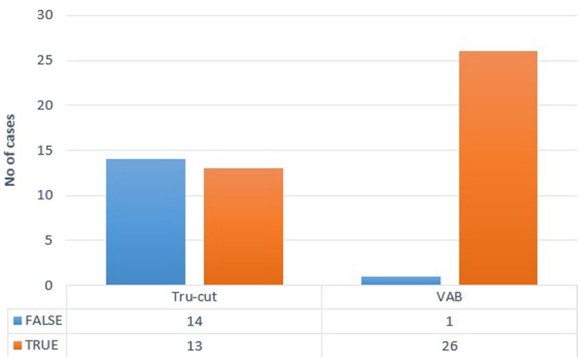

Fig. 1 Matching and non matching cases of VAB and CNB in third subsidiary group

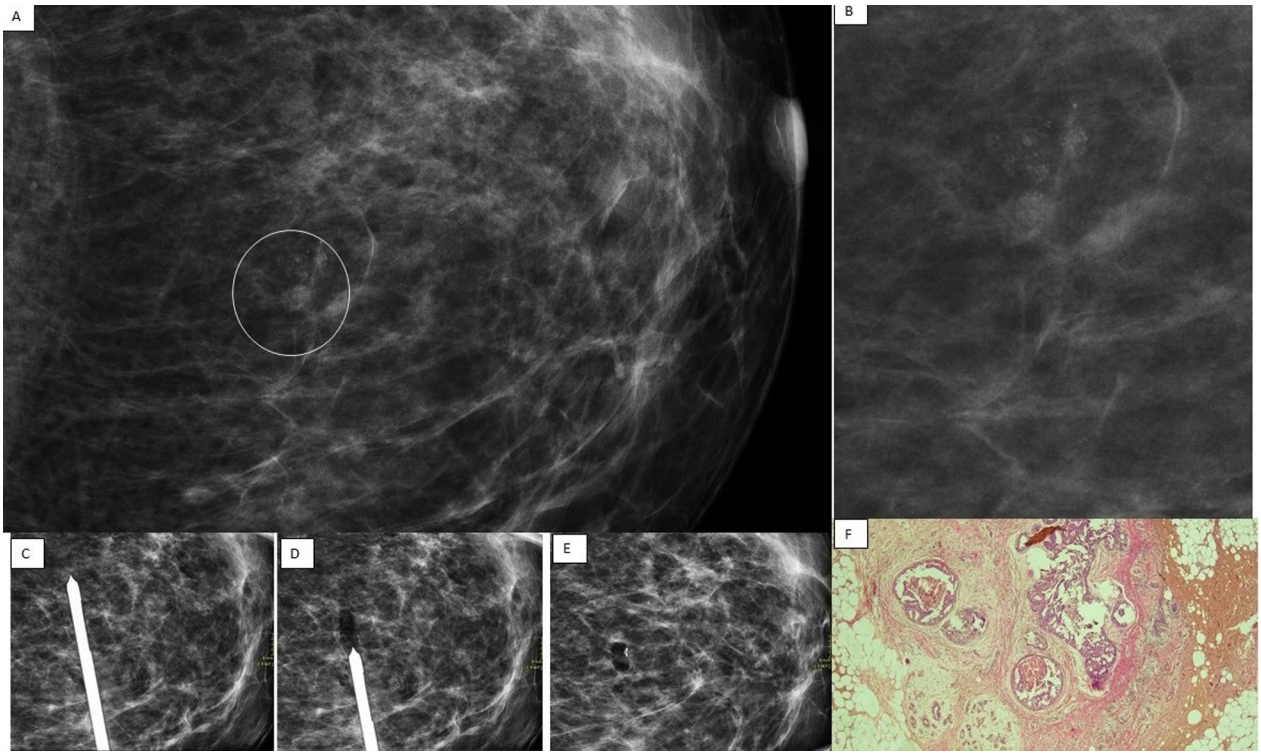

Fig. 2 48 year-old patient with positive family history (mother) showing **A** CC view, **B** Magnified view, **C** left LIQ magnified view, left breast lower inner quadrant (red circles) in (**A**) and (**B**) suspicious amorphous grouped micro-calcifications, **C**, **D** she went on to have VAB, **E** a clip was inserted at site of biopsy. **F** Pathological assessment revealed DCIS (Hematoxylin & Eosin, ×100), so the patient went on to have wire localization and excision which confirmed the diagnosis with negative safety margin, no re-operation

underwent surgery while 7/27 (25.9%) have sufficed for follow up (Figs. 5, 6).

The VAB subgroup in such subsidiary group showed 96.3% matching cases while the CNB group had 48.1% matching cases only, VAB upgraded 13/27 benign and high risk lesions proven via tru-cut core biopsy into malignant categories.

Discussion

One of the common forms of radiological presentations of breast cancer is micro-calcifications which are only detectable on mammography, hence the concept of stereotactic guided biopsies have emerged [1].

Stereotactic guided biopsies utilize the mammogram device via special equipment to localize and sample the targeted micro-calcifications to help in diagnosis and guide further management plans [4].

Our study divided the patients into two main groups and one subgroup according to the modality of sampling into; those who underwent VAB only, those who underwent CNB only and those who underwent both procedures sampled from the latter two groups.

The study included 268 lesions which was non-congruent with Lacambra et al., who had 464 lesions as well as Huang et al., which had 335 patients, the lesions, in our study, were divided into 136 lesions who underwent VAB and 132 lesions who underwent CNB [6, 7].

The VAB group did not match the population of Sadighi et al., which had 258 lesions and Atasoy et al., which had 66 lesions as well as Tsai et al., which included 769 lesions, Huang et al., which had 64 lesions and Lucioni et al., which had 1250 lesions, yet it was comparable with Alexander et al., which had 132 lesions and Huang et al., which had 117 lesions, thus predicting possible variance in results compared with other studies [4, 7–12].

The CNB group was in disagreement with Huang et al., which had 218 lesions and Lacambra et al., who had 285 lesions, both studies performed direct comparison with another subset of patients who underwent VAB [6, 7].

In our study we deemed the benignity of lesions via either pathological specimen or follow up for 24 months which disagreed with Esen et al., who settled for only 12 months of follow up, thus we more confidently assured the benignity of lesions via 2 year follow up [13].

About 63% of micro-calcifications in our study have had a final pathological diagnosis within benign entities, the most common morphology of these micro-calcifications was Coarse heterogeneous (51%) followed by

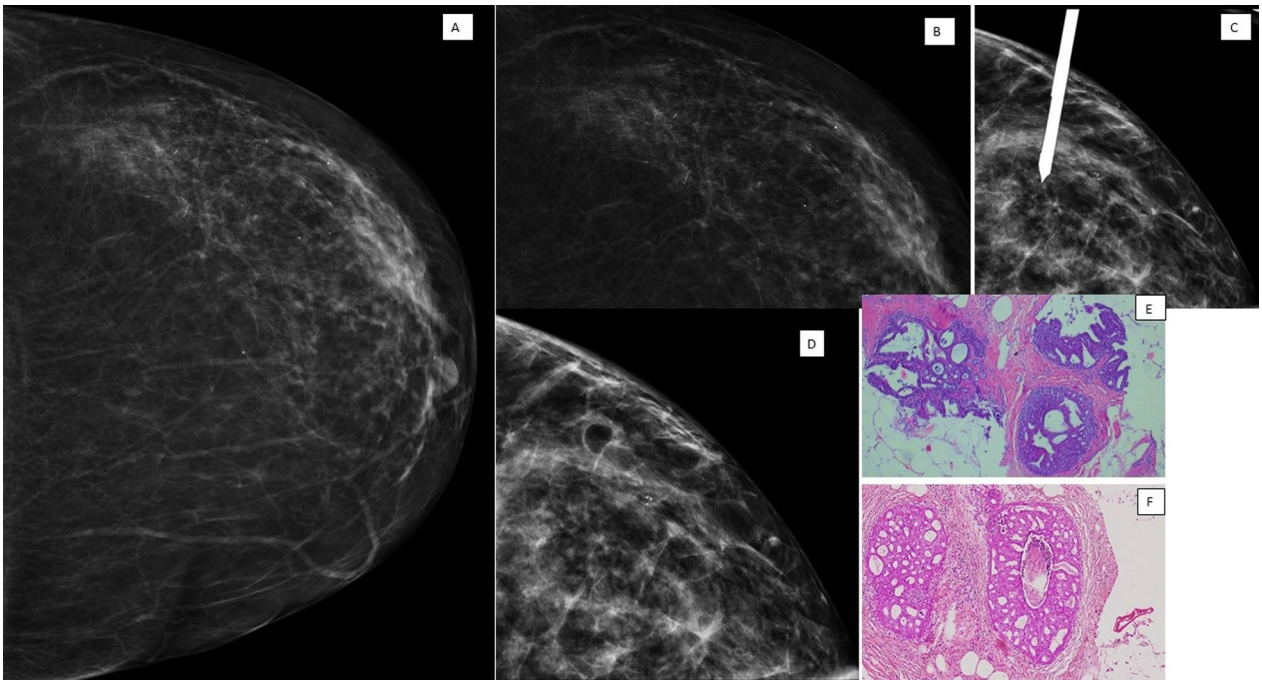

Fig. 3 38 year-old patient with positive family history (mother and sister), showing **A** CC view **B** magnification of the UOQ **C** left UOQ magnified view for VAB procedure, left breast upper outer quadrant (red circles) in (**A**) and (**B**) suspicious segmental pleomorphic micro-calcifications, **C** SVAB was done, **D** the site of biopsy is marked by residual micro-calcifications, its largest diameter measured 51 mm, **E** pathological assessment of VAB specimen revealed Atypical ductal hyperplasia/atypical intraductal proliferation (ADH) (Hematoxylin&Eosin ×200), **F** wire localization and excision was done which upgraded the lesion to DCIS (Hematoxylin&Eosin × 200) and subsequent re-operation was done (skin sparing mastectomy)

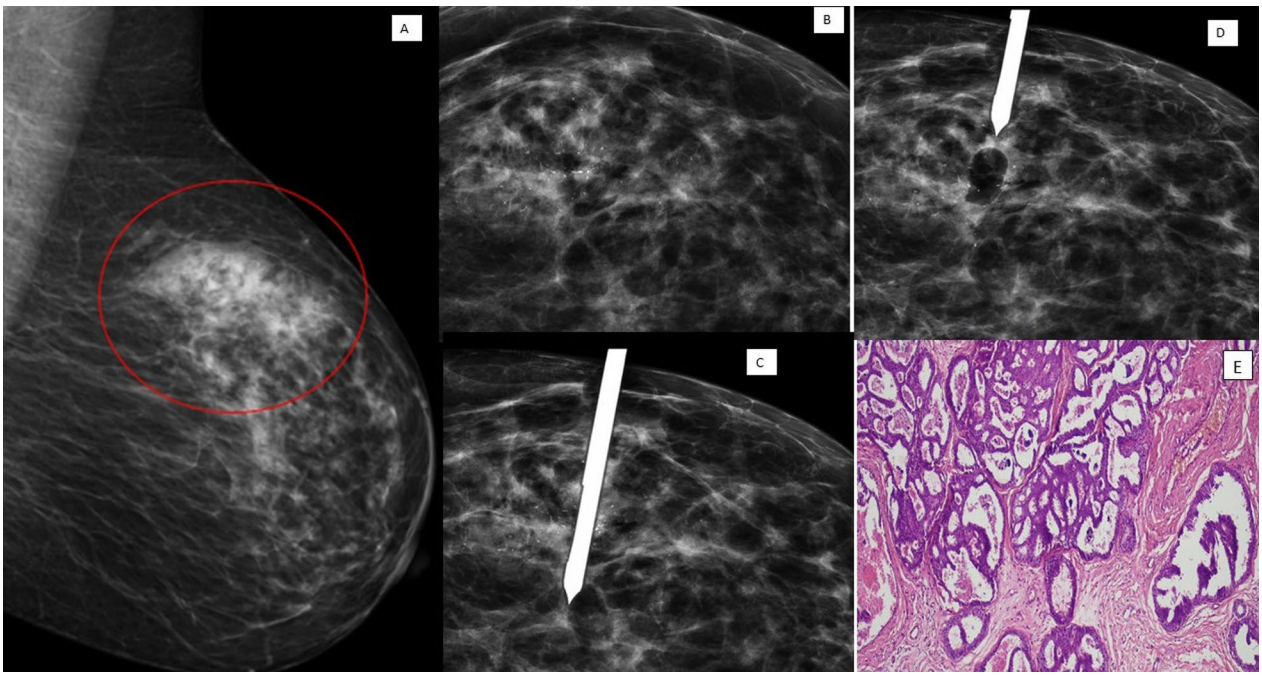

Fig. 4 54 year old with negative family history, showing **A** MLO view **B** left UOQ magnified view, left breast upper outer quadrant (red circles) in (**A**) suspicious pleomorphic ductal micro-calcifications overlying an area of focal asymmetry, **C** she went on to have VAB, **D** biopsy site was marked by residual micro-calcifications. **E** Pathological assessment revealed DCIS (Hematoxylin&Eosin × 200), so the patient went on to simple mastectomy and sentinel lymph node biopsy which confirmed the diagnosis with negative safety margin, no re-operation was done

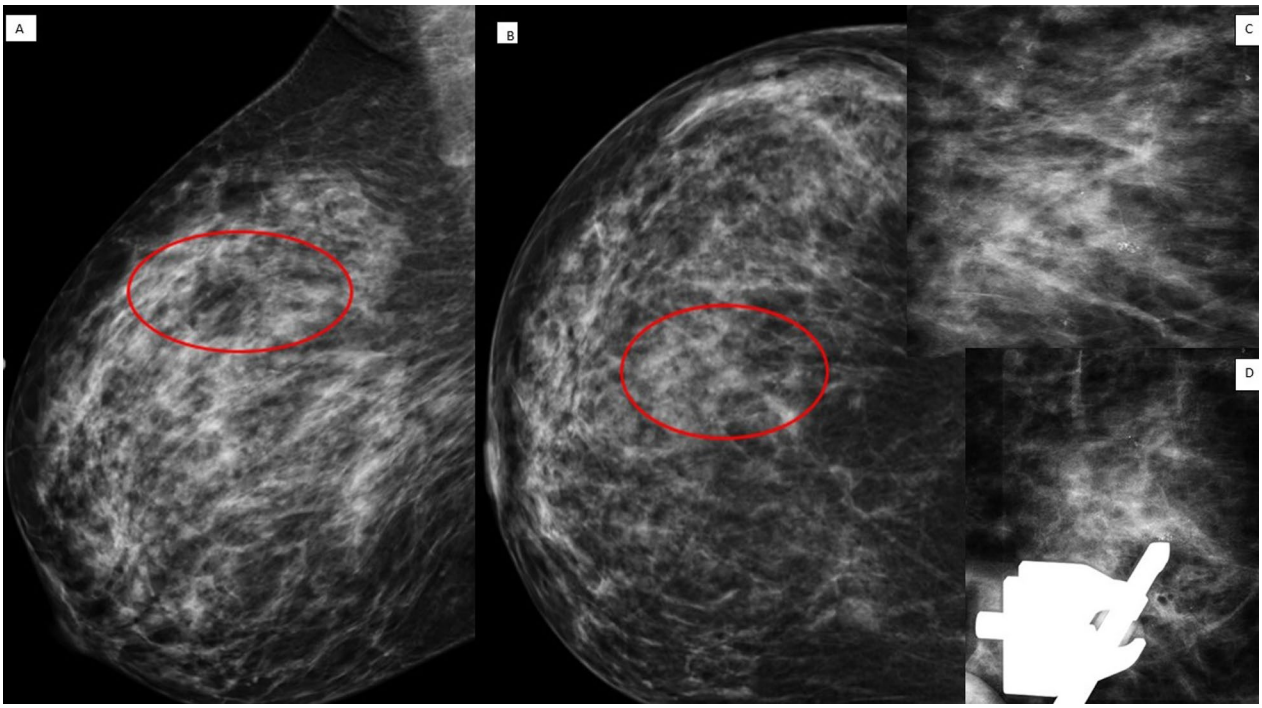

Fig. 5 52 year old with positive family history (sister), showing **A** MLO view **B** CC view **C** right UOQ magnified view, right breast upper outer quadrant (red circles) in (**A**) and (**B**) suspicious grouped coarse heterogeneous micro-calcifications, **D** she went on to have VAB, **E** biopsy site was marked by residual micro-calcifications. Pathological assessment revealed DCIS, so the patient went on to wire localization and excision which confirmed the diagnosis, no re-operation was done

amorphous (20%), while the most common distribution was regional (47%) followed by grouped (36%).

While about 10% were diagnosed as high risk lesions that showed fine pleomorphic (65%) and amorphous (30%) as the most common morphology while grouped (40%) and regional (33%) were the most common distributions.

On the other hand, about 26.5% have had a final malignant pathological diagnosis where fine linear and fine linear branching (59%) followed by fine pleomorphic (27%) were the most common morphological features, while linear (59%) and segmental (35%) were the most common distributions.

The most common overall pathological entity was benign (63.4%) followed by malignant lesions (26.4%) and high-risk lesions (10.2%), findings were consistent with Alexander et al.,, Sadighi et al.,, Grimm et al.,, Huang et al., and Lacambra et al., with comparable malignant to benign lesions' ratios which is probably attributed to the same method of random sampling [6–8, 12, 14].

The most common benign and overall pathological diagnosis was fibroadenosis followed by fibrocystic changes which agreed with several studies such as Grimm et al.,, Huang et al.,, Lacambra et al., and Kettritz et al., While it was inconsistent with Sadighi et al., and Alexander et al., which had such incidences reversed yet with only a slight discordance thus the overall results matched that described in literature.

The most common malignant pathological diagnosis in our study for all groups was DCIS which was in agreement with Alexander et al., Sadighi et al., Grimm et al., and Kettritz et al. [6–8, 12, 14, 15], where of micro-calcifications being the most common mammographic presentation of DCIS, while DCIS is also the most common malignancy depicted in suspicious micro-calcifications [6, 14].

The most common high risk lesion was ADH (8.5%) which was congruent with Alexander et al.,, Atasoy et al.,, Huang et al., and Lacambra et al., as well as Bianchi et al., and Rakha et al. [6, 7, 9, 12, 16, 17].

Only few studies performed simultaneous separate group comparisons of VAB versus CNB as regards to their accuracy, sensitivity and specificity in diagnosis of breast micro-calcifications, nonetheless, fewer studies had the same group of patients undergo both interventional modalities.

Lacambra et al., And Huang et al., are the two main studies that have directly compared VAB and CNB yielding better sensitivity, PPV, NPV and accuracy of

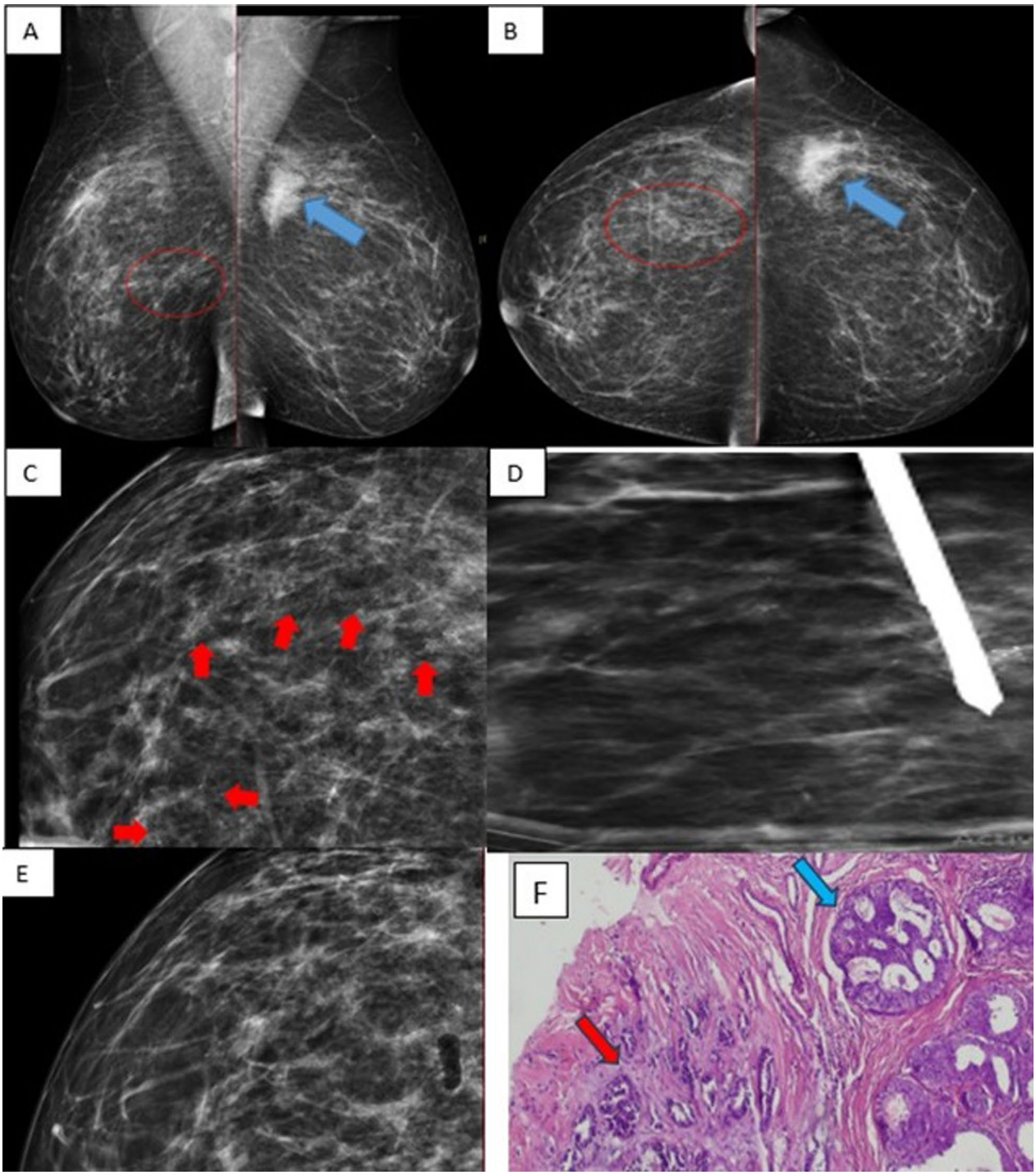

Fig. 6 38 year-old patient with positive family history (mother), **A** MLO view **B** CC view **C** right UOQ magnified view, patient presented with left breast UOQ pathologically proven invasive duct carcinoma (blue arrows in (**A**) and (**B**)), she presented with right breast UOQ segmental pleomorphic suspicious micro-calcifications, red circles in (**A**) and (**B**) and red arrows in (**C**), she went on to have VAB (**D**) and (**E**) with the site marked by residual calcifications, which yielded (**F**) invasive duct carcinoma (Red arrow) with Major DCIS component (Blue arrow) (Hematoxylin&Eosin ×200), a finding which was confirmed on surgical specimen

VAB over CNB which matched with our study and is detailed as follows [6, 7].

In our study, for the VAB group, only 4/136 cases did not match the surgical pathology, the true negative percentage was 68.4%, true positive percentage was 28.7% while the false negative percentage was only 2.9%, estimated PPV is 100% (96–100% CI) and NPV was 95.88% (90–98% CI).

While the CNB groups had less accurate matching with surgical specimens as follows, 21/132 (15.9%) cases that did match the surgical specimens, the true negative percentage was 61.4%, true positive percentage was 23.5% while the false negative percentage was 15.2%, estimated PPV is 100% (96–100% CI) and NPV was 80.20% (74–85% CI).

On the other hand for the VAB group the estimated sensitivity was 90.7% (77.86–97.41% CI) while the specificity for the VAB group was 100% (96.11–100% CI) and the diagnostic accuracy is 97.06% (92.64–99.19% CI). Malignant lesion underestimation rate was 2.9%.

The CNB group had an estimated sensitivity of 60.78% (46–74% CI) while the specificity for the VAB group was 100% (95–100% CI) and the diagnostic accuracy was 84.85% (77–90% CI). Malignant lesion underestimation rate was 15.9%.

The VAB group sensitivity, specificity, NPV and PPV were comparable with Safioleas et al., and Lacambra et al.,, yet there was slight discordance regarding the sensitivity and NPV, where the sensitivity on our study was 90.7% and NPV was 95.8% while Safioleas et al., had 98.2% and 97% and Lacambra et al., had 100% and 100% respectively, this could be explained by the false negative results of VAB in larger lesions yet the two studies did not mention the lesions' sizes [6, 18].

On the other hand, we had nine cases which were upgraded from insitu to invasive pathological status, this is explained as follows.

First group of false negative results (n = 4) had a mean of largest diameter of (9.72 ± 1.80) while the true positive group (n = 132) had a mean of largest diameter of (3.06 ± 1.76), a finding which was found statistically significant via student *t* test (*P* value < 0.0001), thus providing possible explanation for such discrepancy.

The above noted discrepancy was analyzed on basis of its size where we postulated that larger lesions, as described by Cheng et al., could increase the rate of miss-sampling of serious pathologies within a single lesion rendering targeted biopsy of only a small part of such larger lesions not as accurate as sampling a smaller one [19].

Furthermore, it focuses on the importance of inclusion of initial micro-calcifications size and surface area calculation which may also help in surgical management and reduction of rate of recurrence as well as yielding sufficient post-operative margin status for DCIS cases, this was initially proposed by Cheng et al. [19].

The overall malignant lesion underestimation rate was 2.9% for the VAB group which was in disagreement with Alexander et al., (10.3%), Jackman et al., (13%), Venkataraman et al., (12.2%) as well as Heller et al., (1.2%) yet it was comparable with Rochat et al., (1.4%) [12, 20–23].

Such discrepancies could be explained as follows; Alexander et al., and Venkataraman et al., expressed the underestimation rate of DCIS diagnosis only while Jackman et al., expressed high risk lesion underestimation rate yet Rochat et al., and Heller et al., represented the overall malignant lesion underestimation rate [12, 20–23].

On the contrary, CNB had much higher malignant lesion underestimation rate of 15.9% which was much more than that of VAB group 2.9%, reflecting the direct impact of using VAB for initial assessment of suspicious microcalcifications.

While the DCIS underestimation rate for our study was 5.8%, a value that is lower than Alexander et al., (10.3%) and Venkataraman et al., (12.2%), however, none of the aforementioned studies stated the relation of the lesions' initial mammographic size to its final pathological diagnosis which may be a deterministic factor for the variance of underestimation rates [12, 21].

Out of the four mismatched cases on the VAB group we had three cases that underwent wider local excision and only one case went on to have mastectomy, while out of the twenty one cases on the CNB group, thus increasing the patient's morbidity and possible rate of recurrence which concurred with the description of Cheng et al. [19].

While the CNB group 21/132 lesions did not match the surgical pathology, the true negative percentage was 61.4%, and true positive percentage was 23.5% while the false negative percentage was 15.2%, estimated PPV is 100% and NPV is 80.20%.

Moreover, direct comparison was done on 27 patients from both groups who underwent both VAB and CNB where the estimated malignant lesion underestimation rate was 3.7% for VAB patients while it was 51.8% for the CNB patients.

Such immense discrepancy in underestimation rates in the aforementioned subgroup is augmented by the fact that patients in this subgroup have had initial CNB which yielded insufficient benign results (non-compatible with mammographic criteria and risk factors) which warranted further assessment by VAB, rather than localization and excision, guided by the patients' and surgeons' aim of conservation.

However, such non-random sampling confirmed the superiority of VAB over CNB in diagnosis of suspicious breast microcalcifications and further confirming the results of the forenoted two main groups.

We can conclude that the introduction of VAB as an initial procedure could obviate the need for further localization and surgical excision in cases of benign lesions, it may be also indicated in some high risk lesions where total excision of small lesions is feasible or patients do not consent to surgery, yet these patients should be projected to prolonged and strict follow up intervals, further researches are needed to confirm and lay down proper guidelines for such proposition.

One pitfall of our study was that the sample size of each separate group and subgroups were relatively small which might not reflect the entire population raising the importance of future more expanded researches.

Another pitfall was the inclusion of a subgroup that included patients who underwent both VAB and CNB, this formed a sort of selection bias in this subgroup as discussed before.

Conclusions

VAB is a better diagnostic tool than CNB for breast micro-calcifications with less frequency of re-operations which decreases patients' morbidity, Moreover, VAB could null the need for surgical excision of pathologically proven small sized benign lesions which may also decrease patients' morbidity, yet further studies are needed to confirm the usefulness of VAB in this entity and detect proper lesions' size cut-off points for this aim.

Abbreviations

VAB	Vacuum-assisted biopsy
CNB	Core needle biopsy
PASH	Pseudo-angiomatous stromal hyperplasia
ADH	Atypical ductal hyperplasia
UDH	Usual ductal hyperplasia
DCIS	Ductal carcinoma in situ
BI-RADS	Breast Imaging-Reporting and Data System
LCIS	Lobular Carcinoma in situ
PPV	Positive predictive value
NPV	Negative predictive value

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Author contributions

MM wrote the manuscript. AM is responsible for correspondence to journal. MG and MM collected patient data and was responsible for image processing and collection of patient's images. OM, GM & AM participated in the design of the study and performed the statistical analysis. MH and OM conceived of the study and participated in its design and coordination, and was responsible for the review of the draft from a clinical point of view. All authors have read and approved the manuscript.

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Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board (IRB) of the National Cancer Institute, Cairo University with ethical committee approval number 2110-308-048 dated 12.October.2021 and IRB number IRB00004025. Informed written consent was taken from all subjects.

Consent for publication

All patients included in this research gave written informed consent to publish the data contained within this study.

Competing interests

No financial or non-financial competing interests.

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