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Ultrasound-guided vacuum-assisted excision biopsy in breast fibroadenomas: an Egyptian center experience

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Abstract

Background: Benign breast tumors although classified as benign lesions but excising them remain a troublesome problem. Surgical excision for benign breast lesions frightens most of female population suffering from such a problem, which created an urgency to search for a safe and effective alternative. My aim was to assess the efficacy of vacuum-assisted biopsy (VAB) excision system for the removal of benign breast lesions in terms of complete excision rate and incidence of complications.

Results: Twenty-three female patients with 29 twenty-nine lesions were included in our study. Mean age was 33 years (19–52 years). The incidence of complete excision was 100% in follow-up with 3 drop outs. The largest diameter of the tumors ranged from 1.2 to 3.3 cm. Rate of occurrence of complications in form of intra-procedural pain, 69% of our patients experienced mild intra-procedural pain with visual analog pain scale (VAS) score (1–3).21% experienced moderate pain with VAS score (4–6).8% experienced no pain. Patients who developed post procedural ecchymosis were 17% while hematoma group of patients were 10% of total number of patients.

Conclusions: The study showed that the use of vacuum-assisted biopsy excision system could provide a safe method for complete excision of fibroadenomas, with low rate of complications as incomplete excision, pain, and hematoma formation.

Keywords: Vacuum-assisted biopsy, Breast fibroadenoma excision, Benign breast lesions

Background

Vacuum-assisted breast biopsy (VABB) has proved to be among the most efficient means of obtaining tissue, guided by ultrasound, stereotactic techniques, or MRI [1].

Lately, a growing interest has been placed on the application of ultrasound-guided vacuum-assisted techniques. Long-term follow-up of ultrasound-guided vacuum-assisted systems excisions has proved that it is comparable to conventional methods [2]. Hematoma remains the main complication after minimally invasive procedures, which is involved in limiting the utility of ultrasound-guided vacuum-assisted systems in benign breast mass [3]. However, no solid explanation justifies the mechanism of occurrence of hematoma induced by vacuum-assisted systems [4].

The aim of our study was to assess the efficacy of vacuum-assisted biopsy (VAB) excision system for the removal of benign breast lesions in terms of complete excision rate and incidence of complications in our Ain Shams breast interventional radiology unit.

Methods

Informed consent was obtained from all patients, and the study was approved by our local ethical Committee. Written informed consent was obtained from every patient at enrollment.

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Patients

From June 2017 to February 2018, 23 female patients underwent percutaneous excision of breast fibroadenoma with vacuum-assisted system under the guidance of ultrasound after obtaining ethical committee approval and consent from all patients.

Inclusion criteria

Age of the patients was 19–52 years.
The lesions were categorized BIRADs 3 lesions as determined by ultrasound imaging according to the American College of Radiology Breast Imaging Reporting and Data System (ACR BI-RADS).

Exclusion criteria

Lesions higher grade than BIRAD 3(BIRAD 4 and 5) according to ACR BI-RADS.
The lesion was confirmed malignant previously.
Patients with breast implants.
Patients with abnormal coagulation profile.
Patients who had been on antiplatelet or anticoagulants for a long time.

US examination before treatment

Ultrasound exams were performed by Logic P5 ultrasound machine (GE—General Electric Healthcare—USA) with a 7.5 MHz linear array probe.

Before the biopsy procedures, a careful breast ultrasound examination for all lesions was performed to determine the largest diameter and direction of the lesions, then to determine insertion site for the probe.

The approach to the lesion from the insertion site was along the long axis of the lesion.

Anesthesia

10 ml 1% lidocaine was injected to the cutaneous layer, and then injected around the mass and along the estimated course of the probe with a 10-ml injection syringe. For masses, adjacent to the pectoralis major muscle or masses just beneath the skin, lidocaine was administered between the structures and masses to artificially increase the distance for needle passage and to increase safety, as illustrated in Fig. 1a, b.

Excisional biopsy procedure

As shown in Fig. 2a–d the probe was introduced into the breast through an about 5-mm skin incision, and then probe approached to lesion under real-time ultrasound visualization guidance. For avoiding damage to surrounding vessels and masses located near the lesions, probe was injected into the bottom or the side of lesion, and tubular sampling groove was pointed to lesions. The specimens were automatically sucked into tubular sampling groove through negative pressure. To remove the lesions completely, angle of probe was adjusted and sufficient surrounding normal breast tissue was extracted by rotating probe. The completion of lesion excision was determined by real-time ultrasound guidance. After blood was removed by vacuum-assisted hand-held device Encore ultra-breast biopsy system, manual compression to the skin incision site of lesions was performed for approximately 10–15 min to stop bleeding, followed by ice packs for 15–20 min. No residual lesions and obvious blood were existed after an ultrasound examination, and then skin incision was covered with steri-strips then covered with sterile elastic bandage for 24–48 h. The pathological diagnosis was made according to postoperative paraffin pathological examination.

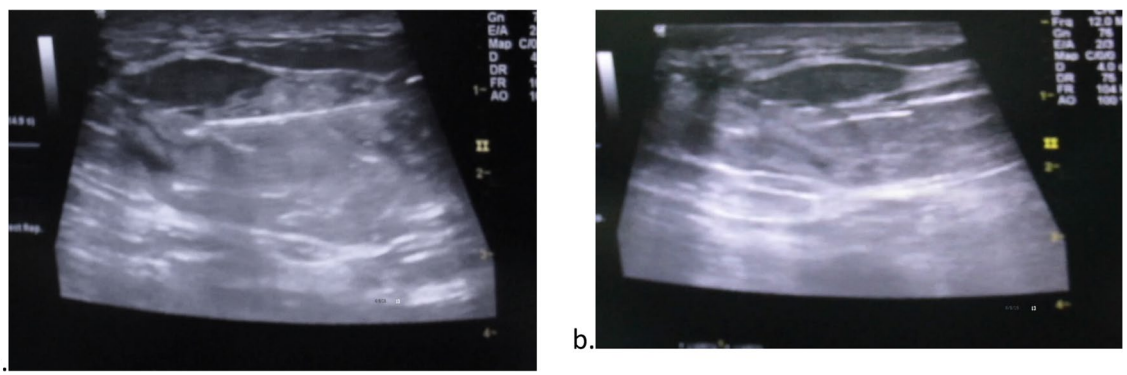

Fig. 1 **a**, **b** Local anesthetic injection around the lesion and along course of needle

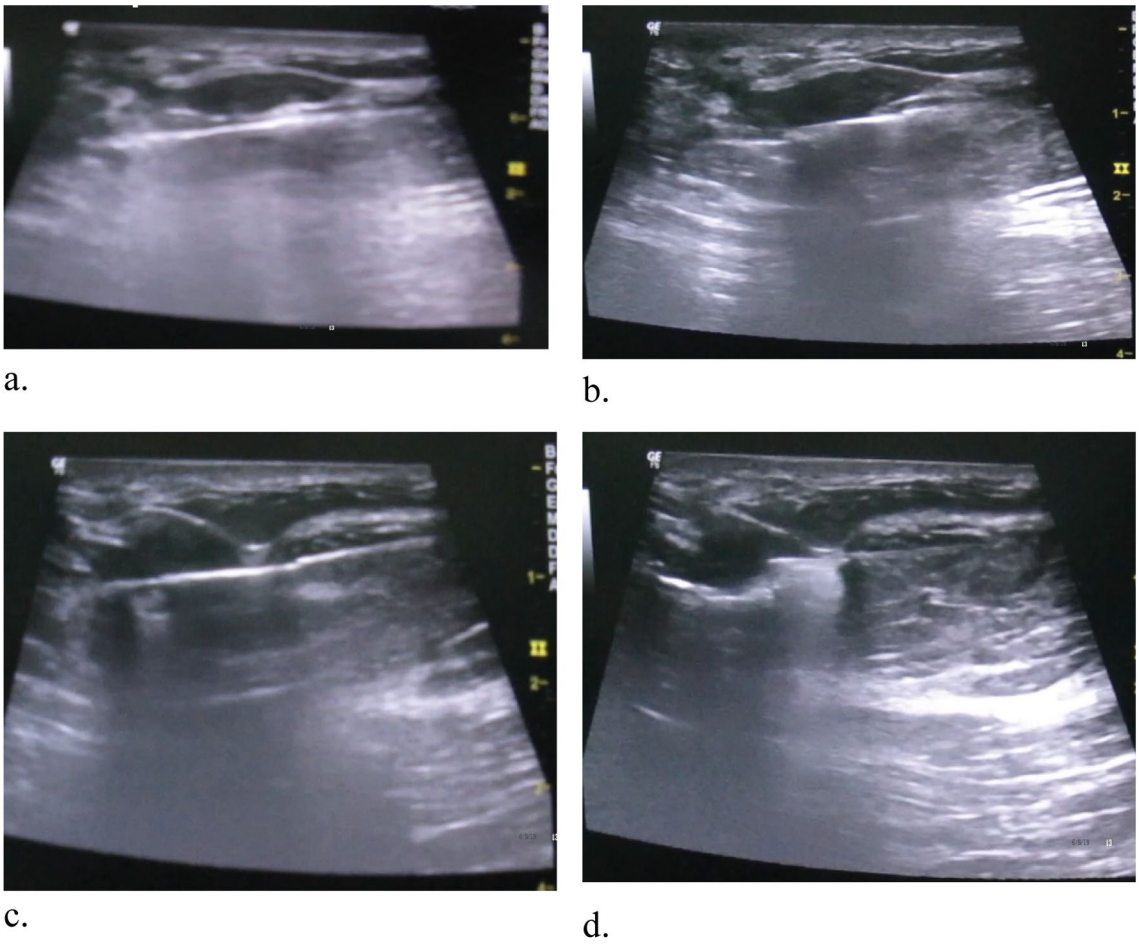

Fig. 2 **a**–**d** The process of VAB excision system suction of fibroadenoma

Follow-up visits

After 24–48 h of the procedure, patients were required to have the first follow-up visit with ultrasound examination to assess the extent of hematoma development which a case is illustrated in Figs. 3 and 4. Thereafter, follow-up visits were done at 1, 3, and 6 months after the procedure with ultrasound examination.

Primary outcomes and secondary outcomes

The potential variables included nodule size, number of nodules, postoperative hematoma formation rate and intra and postoperative pain.

Measurement of pain

Immediately after the biopsy, women were interviewed on their discomfort during the procedure. For the quantification of the pain experienced by a patient during biopsy, a visual analogue scale (VAS) illustrated in Fig. 5 was used. Pain was defined as a score on the eleven-point scale (0–10). A rating of zero indicated "no pain", while a rating of ten meant "extreme, worst possible pain". VAS scores (1–3) were defined as "mild", (4–6) as "moderate", and (7–9) as "severe" pain. Women were asked to indicate on the scale the maximum pain they experienced during the whole procedure.

Only the breast pain was considered. Neither neck and shoulder pain related to the body position nor the anxiety and emotional discomfort was assessed.

Statistical analysis

Data was coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) version 25. Data was summarized using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data.

Comparisons between quantitative variables were done using the non-parametric Mann–Whitney test. For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when

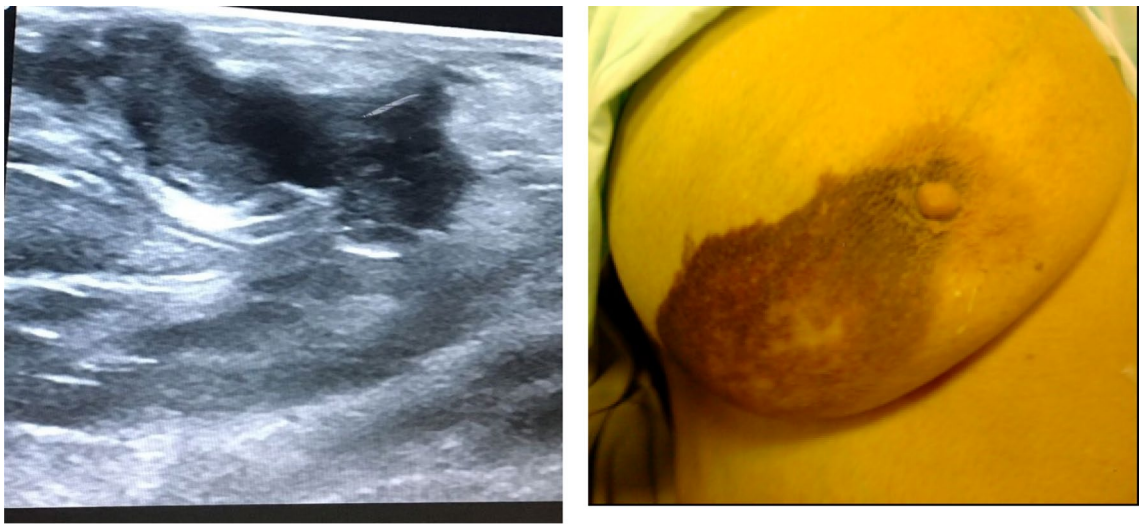

Fig. 3 **a**, **b** Breast hematoma evident in ultrasound and clinical examination

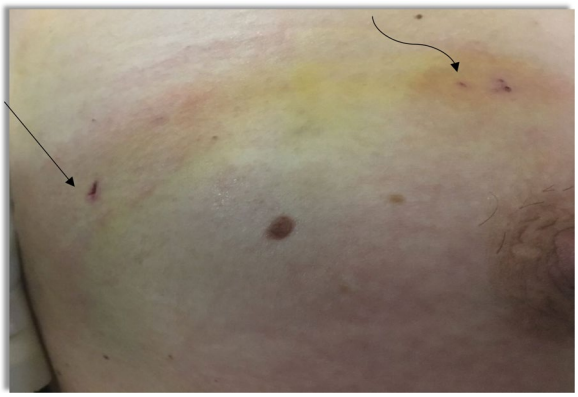

Fig. 4 Shows straight line showing site of entrance of needle and curved connector showing ecchymosis

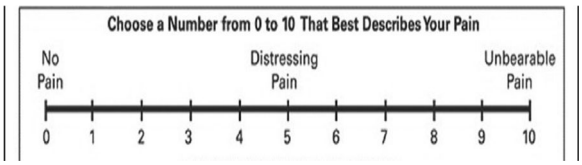

Fig. 5 Visual analogue scale: shows grades of pain from 0 = No pain to 10 = unbearable pain

the expected frequency is less than 5. Correlations between quantitative variables were done using Spearman correlation coefficient. *P* values less than 0.05 were considered as statistically significant.

Results

Twenty-three female patients with 29 twenty-nine lesions were included in our study. Three patients had bilateral lesions and three patients had two lesions on the same side.

Mean age was 33 years (19–52 years). The incidence of complete excision was 100% in follow-up with 3 drop outs.

The largest diameter of the tumors ranged from 1.2 to 3.3 cm.

Intra-procedural and post procedural pain score was assessed via visual analogue scale.

Rate of occurrence of complications in form of intra-procedural pain, 69% of our patients experienced mild intra-procedural pain with VAS score (1–3).

21% experienced moderate pain with VAS score (4–6). 8% experienced no pain or just discomfort.

For post procedural pain, 70% of the patients needed no analgesics post-procedural. 30% had mild to moderate post procedural pain (VAS score 1–6).

Only one patient experienced severe post procedural pain (VAS score 7–10).

The incidence of post procedural pain had significant correlation to hematoma development.

Incidence of post procedural ecchymosis and hematoma was 27%.

Patients who developed post procedural ecchymosis were 17% while hematoma group of patients were 10% of total number of patients.

Their occurrence was statistically significant in patients who experienced pain during the procedure. Hematoma formation was not statistically significantly related to size of lesion which is shown in Table 1.

Table 1 Correlation of hematoma formation and size of lesions

	Hematoma		
	Yes	No	*P* value
	Mean	Mean	
Size	19.22	21.60	*0.199

Its occurrence was statistically significant in patients who experienced pain during the procedure

Hematoma formation was not statistically significantly related to size of lesion (*P* value < 0.005 considered significant)

* *P* value > 0.005 denotes non-significance

Table 2 Correlation between occurrence of hematoma & ecchymosis and pain experienced during and after procedure

	Ecchymosis and hematoma				
	Yes		No		P value
	Count	%	Count	%	
Pain during procedure					
No	0	0.0	8	40.0	*0.049
Mild	6	66.7	10	50.0	
Moderate	3	33.3	2	10.0	
Pain after procedure					
No pain	5	55.6	17	85.0	0.193
Mild	1	11.1	1	5.0	
Moderate	2	22.2	2	10.0	
Severe	1	11.1	0	0.0	

The correlation between hematoma development was clinically significantly related to occurrence of pain intra-procedural, although there was not significant difference between hematoma and post-procedural pain, which may be attributed to that most hematomas were small in size and we allowed our patients to take post-procedural mild analgesics as paracetamol

* *P* value < 0.005 denoted statistical significance

The correlation between hematoma development was clinically significantly related to occurrence of pain intra-procedural, although there was not significant difference between hematoma and post-procedural pain statistically explained in Table 2, which may be attributed to that most hematomas were small in size and we allowed our patients to take post-procedural mild analgesics as paracetamol.

Discussion

Minimally invasive breast biopsy system took the diagnosis and treatment of benign breast diseases to another level.

Notably, the previous studies have confirmed that ultrasound-guided vacuum-assisted system is an effective, safe method with satisfactory cosmetic outcomes for removal of benign breast lesions. However, Potential failures of ultrasound-guided vacuum-assisted system were mainly due to complications after operation, which limit its widespread application in managing breast diseases. And the major complication of the procedure was hematoma occurrence.

Our 100% excision rate by the Encore was nearly proven previously by Zhi Li Wang and colleagues when they compared the 3 vacuum-assisted devices in breast masses excision and mentioned that the overall complete excision rate of vacuum-assisted excision was 94.8% (932/983 cases) [5].

As regards the incidence of complications, our study showed that patients who developed post procedural ecchymosis were 17% while hematoma group of patients were 10% of total number of patients. In the same study by Zhi Li Wang, 9.4% (92/983) cases had hematoma after the procedure. Hematoma was much more in EnCor and Mammotome groups than in Vacora group [5].

The discomfort experienced by the patient during biopsy is influenced by many variables. A lot of factors significantly associated with the patient's comfort have been reported as follows: type of breast tissue, depth of biopsy, number of samples, type of device, size of needle used, underlying histology of the lesion, type of guidance, physician performing the procedure, and the duration of biopsy [6–10].

B. Szynglarewicz et al. indicate that VA biopsy with hand-held device is more comfortable for women, probably because of contiguous collection of tissue without removing the needle, despite its larger size (11-G vs 14-G). They suggested that the pain experienced during biopsy is mostly influenced by the type of tissue collection rather than by the needle size. This concept is supported by the comparison of 11-gauge and 8-gauge needles used for VA biopsy in a group of 128 females. No significant differences were found with regard to the perception of pain [11].

This supports the findings of our study that 69% 0f our patients experienced mild intra-procedural pain with VAS score (1–3), 21% experienced moderate pain with VAS score (4–6), while only 8% experienced no pain or just discomfort. 70% of the patients needed no analgesics post-procedural. 30% had mild to moderate post procedural pain which indicated non-opoid analgesics. only one patient experienced severe post procedural pain. The incidence of post procedural pain had significant correlation to hematoma development.

Limitations

Our main limitation was that it is a single center study and we recommend a larger number of patients as a continuum.

Conclusions

Our study showed that the use of vacuum-assisted biopsy excision system could provide a safe method for complete excision of fibroadenomas, with low rate of complications as incomplete excision, pain, and hematoma formation.

Abbreviations

VAB: Vacuum-assisted biopsy; VAS: Visual analog pain scale; VABB: Vacuum-assisted breast biopsy; ACR BI-RADS: American College of Radiology Breast Imaging Reporting and Data System; SPSS: Statistical Package for the Social Sciences.

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Author contributions

Not applicable as single author study.

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This study had no funding from any resource.

Availability of data and materials

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

Declarations

Ethics approval and consent to participate

This study received an institutional approval by Ain Shams Faculty of medicine (Radiology section) Research Ethics Committee without a reference number. All patients included in this study gave written informed consent to participate in this research.

Consent for publication

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

Competing interests

The author declare that he has no competing interests.

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