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Original Research Article

Ultrasound Guided Vacuum Assisted Excision of Fibroadenoma Breast – A Scarless Technique Initial Experience

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Abstract

Aim: The aim of the present 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.

Methods: The prospective study was done in department of Interventional radiology from December 2022 to November 2023. 8 patients with 12 Fibroadenoma (4 patient's single lesion, 4 patients-2 Lesions) were included in the study. Patients were followed up at 1, 6 & 12 months.

Results: The mean age of the patients was 27.5 years. Hematoma formation was not statistically significant related to size of lesion. The correlation between hematoma developments was clinically significantly related to occurrence of pain intra- procedural, although there was not significant difference between hematoma and post-procedural pain statistically.

Conclusion: 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

Introduction

Fibroadenomas (FAs) represent the most common benign breast tumor discovered in 67 to 94% of all breast biopsies in women under the age of 20 and is identified in 10% of all women in their lifetimes [1,2] These are increasingly being detected in the older age group as more and more women are subjected to screening mammography. However, even after appropriate counselling about the innocuous nature of these lesions, many opt for their removal as these are important sources of anxiety and psychological concern to patients. In one study by Greenberg et al, it was reported that between 25 and 75% of patients opt for excisional biopsy over observation when offered a choice. [3] FAs can be removed by open surgery and is one of the popular options even today. However, it is associated with certain disadvantages like high costs due to the need for anesthesia and operating room set-up and inadequate cosmesis due to the surgical scar. To overcome these shortcomings of open surgery, there is a need to look into minimally invasive options for removal of FAs.

Vacuum-assisted breast biopsies (VABB) were being performed and preferred over core-needle biopsies for diagnostic purposes, but it was only with the availability of the 8G needles that a larger volume of tissue could be removed with ease and this led to the extension of the VABB technology for complete excision of benign lesions. [4,5] In 2002, the U.S. Food and Drug Administration (FDA)

approved the use of VABB for therapeutic excision of benign breast lesions. VABB has gained worldwide acceptance and is now considered a safe and effective alternative to open surgery by both the clinicians and the patients given its comparable efficacy in complete lesion removal, better cosmesis, and day-care procedure. [6,7]

While fibroadenomas are nowadays removed by open surgery [8], surgical excision not only presents procedural, organizational, and economic disadvantages, but also entails a common risk of aesthetic damage due to surgical scarring. [9] Thus, the progressive implementation of less costly and less invasive techniques yielding better cosmetic results has been advocated by several groups. [9] In particular, image-guided minimally invasive techniques have achieved encouraging results with potentially low costs and low complication rates for the treatment of benign breast lesions and, in selected cases, even of early-stage breast cancer; these techniques offer several advantages over traditional surgical excision, including smaller incisions and reduced scarring. [10] One of these options is represented by vacuum-assisted excision (VAE), a technique in which a biopsy device that includes a cutting needle and a vacuum suction system is used to target the whole lesion with the goal of complete removal; if this cannot be pursued it is considered appropriate to remove a sample of comparable volume/weight to a diagnostic surgical excision (33 cores with a 9G needle), representing approximately 4 g of tissue. [11]

The aim of the present 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.

Materials and Methods

The prospective study was done in department of Interventional radiology from December 2022 to November 2023. 8 patients with 12 Fibroadenoma (4 patient's single lesion, 4 patients-2 Lesions) were included in the study. Patients were followed up at 1, 6 & 12 months. An Encor Enspire vacuum-assisted biopsy system was used to excise the FA in all cases under USG Guidance. A 10G probe was used for lesions less than 2 cm and a 7G probe was used for lesions more than 2 cm. In patients with multiple FAs, the size of the probe was decided based on the size of the largest lesion to be excised

Inclusion Criteria

Patients with biopsy proven FA less than 4 cm in size who opted for removal were included in the study.

Exclusion Criteria

1. FA > 4 cm,
2. Imaging and histopathology (HPE) suggestive of phyllodes tumor.,
3. Any high risks like atypical ductal hyperplasia, atypia/malignant HPE
4. Not amenable for at least 2 follow ups

US examination before treatment

Ultrasound exams were performed by Siemens ACUSON NX3 ultra- sound machine with a 7.5 MHz linear array probe.

Before the biopsy procedures, a careful breast ultra-sound 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.

Excisional Biopsy Procedure

The probe was introduced into the breast through an about 5-mm skin incision, and then probe approached to lesion under real-time ultra- sound 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 tis- sue was extracted by rotating probe. The completion of lesion excision was determined by real-time ultra-sound 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.

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 devia- tion, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data.

Results

Table 1: Correlation of hematoma formation and size of lesions

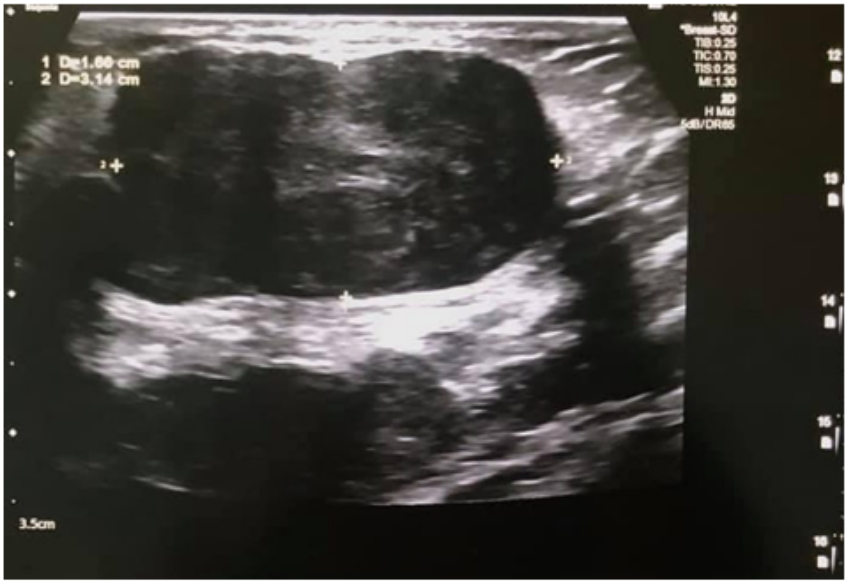
	Hematoma		P Value
	Yes	No	
Size	18.24	22.58	0.185

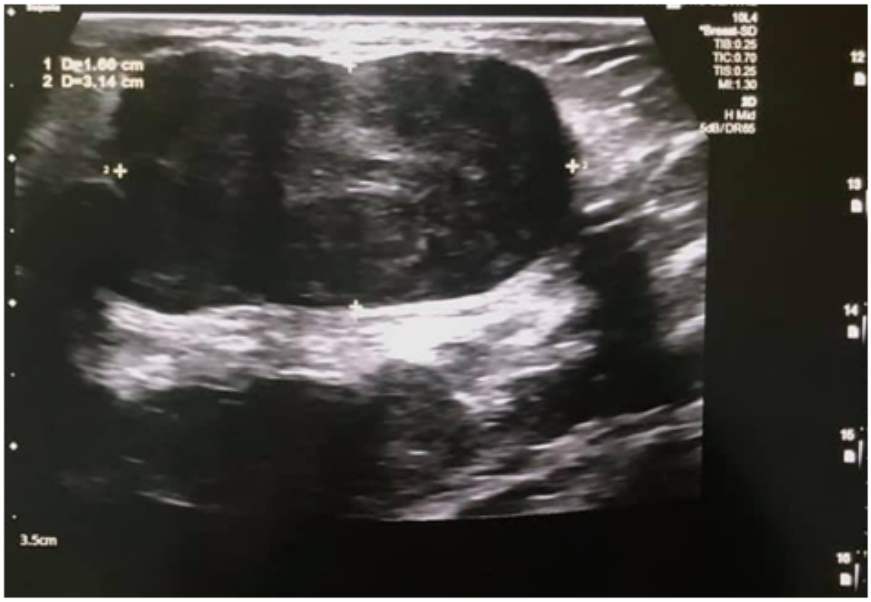
The mean age of the patients was 27.5 years. Hematoma formation was not statistically significant related to size of lesion.

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

	Ecchymosis and hematoma		P Value
	N	N	
Pain during procedure			0.044
No	0	1	
Mild	2	3	
Moderate	1	1	
Pain after procedure			0.178
No pain	1	1	
Mild	1	1	
Moderate	1	1	
Severe	1	1	

The correlation between hematoma developments was clinically significantly related to occurrence of pain intra-procedural, although there was not significant difference between hematoma and post-procedural pain statistically.


1 Dg1.60 cm
2 D=3.14 cm
3.5cm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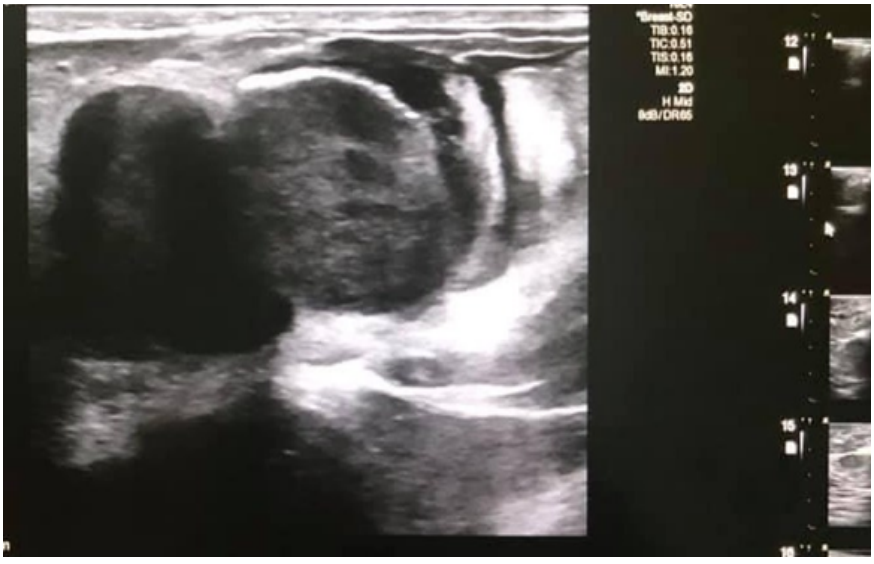

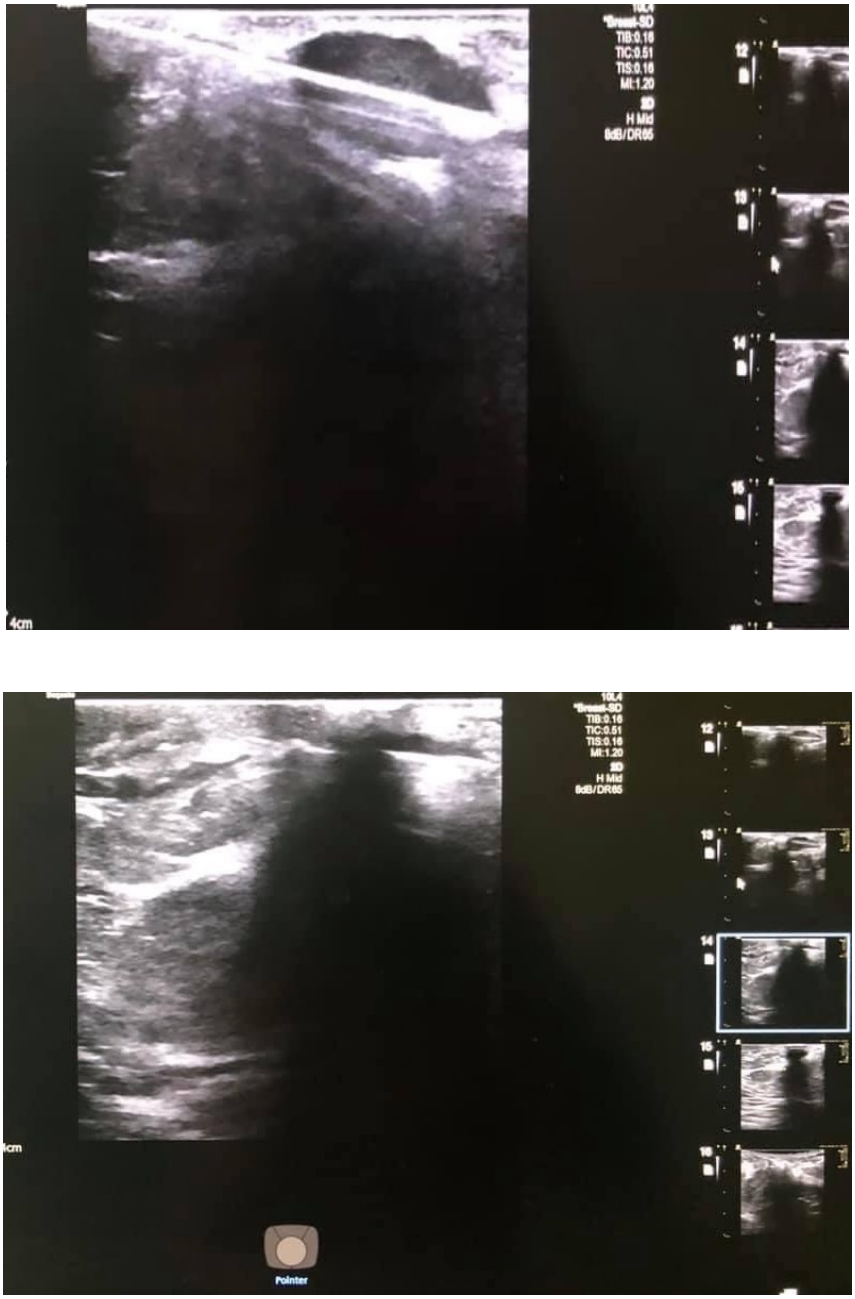

Figure: a. USG image showing wider than taller fibroadenoma b. Local anesthesia being injected around the lesion with hydrodissection c & d Encor Probe in situ in the lesion and lesion being excised

Discussion

The management of most fibroadenomas is usually conservative and, currently, excision is only indicated for fibroadenomas larger than 3 cm in diameter, for fibroadenomas with increasing size over time, and for multiple or bilateral fibroadenomas. [12,13] However, some women do not feel comfortable with observation because of psychological and cosmetic reasons, or because fibroadenomas may sometime cause pain or physical discomfort due to the presence of a palpable lump. [13] Therefore, as much as 75% of these patients come to prefer excision rather than long-term observation of their fibroadenoma. [8,9]

FA is the most common benign breast tumor and usually occurs in women less than 30 years of age. The natural history of FA is variable and some of them may regress with infarction resulting in calcification and hyalinization. [14] FAs have meager malignant potential and hence conservative treatment by observation and periodic follow-up is the norm. The accepted criteria for excision include a size greater than 2 to 3 cm, symptomatic tumors, or when the diagnosis is in question such as with the imaging findings of vascularity or irregular borders on ultrasound. Also, some authors recommend the removal of the lesion if there is a documented increase in size by ultrasound measurements or clinical examination raises the potential for an

alternative diagnosis. [14] Though surgical excision is the most popular option practiced widely, alternative methods like VAEB and cryoablation are reported to have very good results. [15] The mean age of the patients was 27.5 years. Hematoma formation was not statistically significant related to size of lesion. The correlation between hematoma developments was clinically significantly related to occurrence of pain intra- procedural, although there was not significant difference between hematoma and post-procedural pain statistically.

The use of VAE for the excision of benign breast lesions has been approved in the United Kingdom by the National Institute of Care and Excellence in 2006, having already obtained an approval in the US by the Food and Drug Administration in 2002 and a subsequent recommendation by the American Society of Breast Surgeons in 2008. [10,13] The use of VAE has become increasingly popular in recent years due to its advantages: first, it is much less invasive than traditional surgical techniques, resulting in less pain, less scarring, shorter procedure times, fewer side effects, and shorter recovery times for the patient; second, because of its wider availability and favourable cost–benefit profile. [8-10]

Conclusion

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.

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