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ULTRASOUND GUIDED THERAPEUTIC EXCISIONAL VACUUM ASSISTED BIOPSY IN FIBROADENOMA (BIRAD3 LESIONS)

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ABSTRACT

Background: Ultrasound-guided, vacuum-assisted excision can play an efficient role in the diagnosis of benign breast lesions and is a safe and successful alternative treatment of fibroadenomas. Although the breast fibroadenoma is a common benign breast tumor, the treatment and follow-up of these lesions is still debatable. Ultrasound guided therapeutic excisional vacuum assisted biopsy has a well-documented role in the diagnosis of breast lesions, may provide an option for the definitive treatment of breast fibroadenomas. **Objective:** To evaluate ultrasound-guided, vacuum-assisted excision as an alternative approach in the diagnosis of radiologically benign breast lesions. **Methods:** This prospective study evaluated breast lesions excised using vacuum-assisted biopsy between April -October 2025 at Al Jumhori Teaching hospital/ radiology department. Patients with proven diagnosis of fibroadenoma were included in the study. All patients have been subjected to breast ultrasound examination. **Results:** Thirteen patients developed hematomas during Ultrasound guided therapeutic excisional vacuum assisted biopsy but none needed surgical intervention, while twelve patients pass with no significant hematomas, with 100% cure rate. None of the patients experienced significant enough pain to require the cessation of the procedure, although 22 (88%) patients reported mild pain and moderate pain (12%) during procedure. At the two-week control, 3 (12%) patients reported taking paracetamol for mild pain. In ten of them (40%) the pain was strong enough to interfere with sleep. **Conclusion:** Vacuum assisted Ultrasound-guided biopsy allows real-time imaging, could be performed without breast compression, and is the preferred method if the lesion is detectable with ultrasound.

KEYWORD: Breast fibroadenomas, Ultrasound, Vacuum assisted excisional biopsy.

1- INTRODUCTION

Breast fibroadenoma is the most frequent benign breast tumor, especially in women in their second and third decades of life.[1] Early and precise diagnosis is critical to avoiding complications like perforation, abscess formation, and peritonitis, which are associated with higher morbidity and longer hospital stays It accounts for a large proportion of palpable breast lumps and is a common reason for breast imaging and biopsy.[2]

Although fibroadenomas are benign tumors with a very low malignant potential, their identification frequently causes significant worry for patients and may lead to further diagnostic investigations or surgical intervention.[3]

Modern breast imaging tools, notably ultrasonography, have made it much easier to detect and characterize breast lesions. The Breast Imaging Reporting and Data System (BI-RADS) classification offers a standardized framework for reporting breast imaging results. Lesions classified as BI-RADS 3 are most likely benign, with a malignancy risk of less than 2%, and are often handled with short-interval imaging follow-up rather than prompt intervention. However, some patients desire a clear diagnosis or excision owing to ongoing worry, increased lesion size, or cosmetic issues.[4,5]

Historically, symptomatic or expanding fibroadenomas were treated with surgical excision. Although surgery is beneficial, it has some disadvantages, including the necessity for general anesthesia, surgical scars, higher expenses, and the possibility of a cosmetic deformity of the breast. These restrictions have generated interest in minimally invasive procedures that allow for precise diagnosis and therapy while sparing breast tissue.[6]

Vacuum-assisted biopsy (VAB) is a minimally invasive procedure that can remove larger tissue samples than traditional core needle biopsy. When conducted under ultrasound guidance, VAB allows for real-time viewing of the lesion and exact excision with minimum harm to the surrounding tissues. Ultrasound-guided vacuum-assisted biopsy, which was originally created as a diagnostic tool, is now widely utilized for the therapeutic excision of benign breast lesions, notably fibroadenomas.[7]

Several studies have shown that ultrasound-guided vacuum-assisted excision is a safer and more successful alternative to surgical treatment for small benign breast lesions. High rates of total lesion excision have been recorded, with few complications such as moderate discomfort or small hematoma formation, and great cosmetic results. Furthermore, the treatment can be conducted in an outpatient setting using local anesthesia, which increases patient satisfaction while decreasing healthcare expenditures.[8,10]

In developing countries, such as Iraq, the use of minimally invasive breast procedures remains limited as compared to surgical techniques. In Mosul, where breast imaging services are expanding and ultrasound is widely available, ultrasound-guided vacuum-assisted biopsy may be a viable option for the treatment of BI-RADS 3 fibroadenomas. This method may eliminate unnecessary surgery, shorten hospital stays, and improve cosmetic outcomes while retaining diagnostic accuracy.[11] As a result, the aim of this study is to assess the efficacy, safety, and clinical results of ultrasound-guided therapeutic excisional vacuum-assisted biopsy in the treatment of fibroadenomas classified as BI-RADS 3 lesions in Mosul, Iraq.

2. PATIENTS AND METHODS

This prospective study evaluated breast lesions excised using vacuum-assisted biopsy between April -October 2025 at Al Jumhori Teaching hospital/ radiology department. Ethical approval was taken from the Directorate of Health in Nineveh Governorate. An informed consent form was obtained from 25 cases ultrasound-guided VABB using biopsy system. All patients had a previously performed breast ultrasound.

The parameters which included in the study were the size of the lesion as shown in the mammogram or ultrasonogram, a peripheral or central location, or a lump detected in a physical examination. Clinical data including the Breast Imaging Reporting and Data System (BI-RADS) category for the lesions were also recorded. None of the patients had discharge from the nipple. A therapeutic strategy was formulated. Namely, the ultrasound-guided VABB procedures were always managed for the patients whose lesion(s) was (were) probably benign and equal or less than three in BI-RADS category. Ultrasound-guided VABB was performed mostly in patients who were expected to have a difficult follow-up for lesions 3 cm or smaller according to the BI-RADS category 3 on ultrasonography, who planned to be pregnant, who felt extremely uneasy from their lesions, whose lesions enlarged during follow-up, and who complained of pains or symptoms. Additionally, this was performed in some patients who refused to undergo excision. Patients who did not provide informed consent, allergic to the local anesthetic and active chest skin infections on the breast were disqualified from biopsy.

Patients were kept in supine position with the ipsilateral arm raised above the head and with operational area sterilized and draped. An ultrasonic assessment was performed again before the procedure. After local anesthetic consisting of 1% lidocaine containing a 1:100,000 mixture of epinephrine was applied, a 3-5-mm skin incision was made, which serves as the access for the 8-gauge probe. Under real-time ultrasound guidance, the probe was positioned beneath the lesion. To make localization accurate, the target lesion was rescanned longitudinally and transversely according to the probe.

The needle was rotated at an angle of 45 degrees, to both sides, during the procedure, in order to completely excise the hypoechoic lesion on intraoperative ultrasonography and until normal fat tissue was verified grossly on core pieces. Multiple cores in different directions, as many as needed, were taken sequentially, also under ultrasound guidance. Post procedure sonography evaluation was made to confirm complete excision. For hemostasis, direct compression was applied for 5 to 10 minutes immediately following the procedure; an elastic bandage was attached and the patient took bed rest for 6 hours. Tissue specimens were preserved in 10% formaldehyde solution and sent to Department of pathology for histopathologic evaluation. The patient could go back to his normal daily life one day post the procedure. The follow-up was carried out with ultrasonography and mammography, at intervals of 3 to 6 months, in order to identify recurrences.

Data analysis will be performed using statistical software (SPSS version 31). Descriptive statistics were used to summarize patient and outcome characteristics. Chi square test was used for categorical data comparison, P value was considered significant if its less than 0.05.

3. RESULTS

A total 25 patients with breast fibroadenoma were included in this study. The mean age was 36.24±11.21 years with range of 21-51 years. Of them 13 (52%)

patients were aged more than 35 years and 12 (48%) patients were aged less than 35 years. As shown in figure 1.

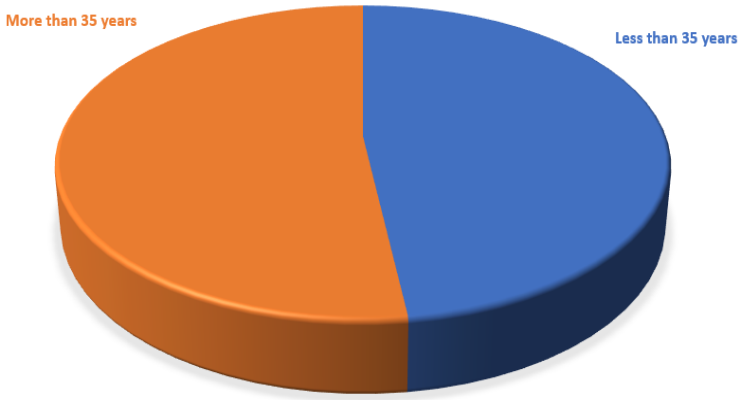

Figure 1: Distribution of the study patients according to their age.

Table 1 shows distribution of the study patients according to their laterality and number of fibroadenoma. The majority of patients had unilateral breast fibroadenoma in 22 (88%) and single lesion in 19/22 (86.4%).

Table 1: Distribution of the study patients according to their laterality and number of fibroadenoma.

Side	No.	%
Bilateral	3	12.0%
Unilateral	22	88.0%
Single	*19/22*	*86.4%*
Two	*3/22*	*13.6%*
Total	25	100.0%

Table 2 shows distribution of the study patients according to the size of fibroadenoma. 13 (52%) patients had breast fibroadenoma of more than 300 mm versus 12 (48%) patients had breast fibroadenoma of less than 300 mm.

Table 2: Distribution of the study patients according to their size of fibroadenoma.

Lesion (mm)	No.	%
≤300 mm	12	48.0%
>300 mm	13	52.0%
Total	25	100.0%
Range (Mean ±SD)	148.5-588 (324.42±152.48)	

Among 25 patients included in the study, 23 (92%) complete the follow up visits and only 2 (8%) patients loss the follow up visiting. Moreover, all of the study patients were cured. On the other hand, hematoma was occurred in 13 (52%) patients, as shown in table 3.

Table 3: Distribution of the study patients according to their post ultrasound-guided VABB hematoma formation.

Hematoma	No.	%
Hematoma	13	52.0%
No hematoma	12	48.0%
Total	25	100.0%

Table 4 shows distribution of the study patients according to their pain during ultrasound-guided VABB. It's evident that 22 (88%) patients had mild pain, 3 (12%) patients had moderate pain.

Table 4: Distribution of the study patients according to their pain during ultrasound-guided VABB.

Pain During procedure	No.	%
No pain	0	0.0%
Mild	22	88.0%
Moderate	3	12.0%
Total	25	100.0%

Table 5 shows distribution of the study patients according to their pain at 2 weeks after ultrasound-guided VABB. It's evident that 3 (12%) patients had mild pain, 10 (40%) patients had moderate pain.

Table 5: Distribution of the study patients according to their pain at 2 weeks after ultrasound-guided VABB.

Pain after 2 wks procedure	No.	%
No pain	12	48.0%
Mild	3	12.0%
Moderate	10	40.0%
Total	25	100.0%

Table 6 shows comparison between patients' pain during and 2 weeks after ultrasound-guided VABB. Statistically significant difference between patients' pain, in other word, the pain was significantly subsided after 2 weeks of procedure.

Table 6: Comparison between patients' pain during and 2 weeks after ultrasound-guided VABB.

Pain	During procedure	After 2 wks procedure	x2	p-value
No pain	0 (0%)	12 (48%)	30.209	<0.001**
Mild	22 (88%)	3 (12%)		
Moderate	3 (12%)	10 (40%)		
Total	25 (100%)	25 (100%)		

4. DISCUSSION

Fibroadenoma is the most common benign breast tumor in young and middle-aged women, and it usually manifests as a palpable breast lump discovered clinically or during imaging tests. With the widespread use of breast ultrasonography, an increasing number of likely benign lesions classified as BI-RADS 3 are discovered. Although these lesions have a very minimal risk of cancer, many patients' desire removal due to worry, gradual growth, or cosmetic concerns. In recent years, ultrasound-guided vacuum-assisted breast biopsy has developed as a minimally invasive alternative to surgical excision for benign breast lesions, offering both diagnostic and therapeutic benefits while achieving great cosmetic results.[12,14]

In the current study, the mean age of the patients was 36.24 ± 11.21 years, with a range of 21-51 years. Approximately half of the patients were over 35 years old. This finding is consistent with previous study results showing that fibroadenomas are more prevalent during the second and fourth decades of life. Park et al. found that patients undergoing ultrasound-guided VABB for benign breast lesions had an average age of 34.6 years, which is consistent with the current findings.[15] Similarly, Wang et al. found that fibroadenomas treated with vacuum-assisted excision were more common in women aged 20 to 40.[16]

In terms of lesion characteristics, the majority of patients in the current study had unilateral fibroadenoma (88%), with the majority of lesions being single (86.4%), which is consistent with fibroadenoma's typical clinical presentation as a solitary unilateral mass. Previous study had found that solitary fibroadenomas are more prevalent

than numerous lesions, while multiple fibroadenomas can occur in up to 15-20% of individuals.[17]

In regard to lesion size, nearly half of the lesions in the current study measured more than 300 mm, with the remainder measuring less than 300 mm. Vacuum-assisted excision is particularly useful for small to medium sized benign breast lesions. According to a recent systematic analysis, ultrasound-guided vacuum-assisted excision had a full removal rate of over 90% for fibroadenomas smaller than 3 cm.[18]

A notable finding of the current study is the high treatment success rate, since all patients were successfully treated and 92% completed follow-up, with just a small percentage missing. This provides support to the efficacy of ultrasound-guided VABB as a treatment for benign breast lesions. Similar results were reported in a multicenter trial by Li et al., who found a full excision rate of 94-98% for fibroadenomas treated with ultrasound-guided VABB, with a very low recurrence rate during follow-up.[19]

The current study found that post-procedural complications were mainly minimal. Hematoma formation occurred in 52% of patients, making it the most common event linked with VABB. However, in most situations, post-procedural hematomas are minor, self-limiting, and disappear on their own without further intervention. Previous studies found that hematoma rates ranged from 10% to 60%, depending on lesion size, device gauge, and operator expertise.[20] The substantially higher prevalence found in this study could be attributed to the short sample size or lesion characteristics. Nonetheless, no major problems, such as infection or excessive bleeding, were recorded, indicating the procedure's general safety.

Pain assessment in this study found that 88% of patients experienced mild pain throughout the treatment, with just 12% reporting considerable pain, indicating that the procedure was well tolerated under local anesthesia. These findings are consistent with those published by Huang et al., who discovered that the majority of patients having ultrasound-guided VABB had no discomfort during the treatment.[21]

Interestingly, pain levels dropped dramatically during the follow-up. Two weeks following the surgery, the level of pain had greatly decreased, and statistical analysis revealed a significant difference between pain levels during the procedure and during follow-up. This suggests that post-procedural discomfort is transient and generally improves with time. Earlier study found that most patients recover quickly with minimal residual pain after vacuum-assisted excision.[22]

Despite the study's useful findings, a few limitations should be noted. First, the sample size was limited (25 patients), which may restrict the data' generalizability and statistical power to detect rare problems or outcomes. Second, the study was carried out at a single Mosul center, which may not accurately reflect the general population or healthcare practices in other regions. Third, while the majority of patients completed follow-up, a small number (8%) were lost to follow-up, which may have an impact on long-term outcomes and recurrence rates. Furthermore, the follow-up period was brief, limiting the ability to assess long-term recurrence or delayed sequelae following ultrasound-guided vacuum-assisted breast biopsy. Finally, because the study focused mostly on BI-RADS 3 fibroadenomas, the results may not be immediately relevant to other breast tumors with different BI-RADS categories or larger tumor sizes. Future studies using larger multicenter cohorts and longer follow-up periods are needed to confirm the safety, effectiveness, and long-term effects of ultrasound-guided vacuum-assisted excision for benign breast lesions.

5- CONCLUSION

Ultrasound-guided vacuum-assisted breast biopsy is a safe and effective minimally invasive procedure for removing fibroadenomas classified as BI-RADS 3 lesions. This study found a high success rate for lesion excision with low complications and good patient tolerance. Most patients felt relatively mild pain during the surgery, and post-procedural discomfort subsided within two weeks. Although hematoma formation was seen in certain cases, it was usually moderate and self-limiting. These findings support the use of ultrasound-guided VABB as a viable alternative to traditional surgical excision, with benefits such as reduced invasiveness, improved cosmetic outcomes, and a faster recovery period.

Based on these findings, ultrasound-guided VABB should be considered as a preferred treatment option for appropriately selected patients with fibroadenoma, particularly BI-RADS 3 tumors. The wider use of this technique in breast imaging centers may reduce unnecessary surgical procedures and increase patient satisfaction. More multicenter trials with larger sample sizes and longer follow-up periods are needed to demonstrate the long-term efficacy and recurrence rates of this technique.

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