



Efficacy and safety of percutaneous ultrasound–guided vacuum–assisted excision for the treatment of clinical benign breast lesions larger than 3 cm: a retrospective cohort study

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Background: Breast ultrasound-guided vacuum-assisted excision (US-VAE) has become a scarless solution for the removal of benign breast lesions. This procedure is now favored by more and more female patients for its satisfactory cosmetic outcome and few postoperative complications. However, controversy have been raised regarding its efficacy and safety in treating larger benign breast lesions. This study aimed to evaluate whether US-VAE is sufficient for the treatment of clinical benign breast lesions larger than 3 cm and to investigate the lesion features that affect the complete excision rate and hematoma occurrence rate.

Methods: From January 2018 to July 2021, a total of 1,812 lesions in 1,367 patients underwent US-VAE at the Chinese People's Liberation Army General Hospital. A total of 89 benign breast lesions in 87 patients enrolled in this retrospective cohort study. The baseline clinical characteristics and ultrasonographic features of the lesions were recorded. Patients were followed up by US to record if there are any serious issues and the occurrence of hematoma and the recurrence of the lesions within 3 days and 6–12 months later, then at 1-year intervals. Lesions were classified to analyze the possible factors associated with complete excision rate and hematoma occurrence rate.

Results: The mean age was 35.9±9.5 years (range, 18–54 years), and the median maximum size of benign breast lesions was 3.5 cm (range, 3.1–5.0 cm). The complete excision rate was 91.0% (81/89). Histopathology ($P=0.002$) and vascularity ($P=0.032$) of lesions showed statistically significant differences in groups with or without recurrent lesions. A total of 17 cases (17/89, 19.1%) presented with hematoma after the procedure. The maximum lesion size in patients with hematoma was significantly larger than that in those without hematoma ($P<0.001$).

Conclusions: US-VAE is an effective and safe alternative method for the treatment of benign breast lesions larger than 3 cm, especially for fibroadenoma, adenosis, hamartoma. For benign phyllodes tumors and intraductal papillomas larger than 3 cm and lesions with hypervascularity, the possibility of recurrence after US-VAE should be noted. The size of lesions needs to be considered when evaluating the occurrence of hematoma after US-VAE.

Keywords: Ultrasound-guided vacuum-assisted excision (US-VAE); benign breast lesions; complete excision rate; hematoma occurrence rate

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Introduction

Benign breast lesions, rather than malignancies, are frequently detected in women worldwide (1,2). Currently, women worldwide have an increased awareness of breast health, and thus the rate of newly detected benign breast lesions is increasing. Although the possibility of benign breast lesions turning into malignant lesions is low, active therapy may be recommended when the patient's age, family history, presence of symptoms, and psychological condition are considered (3,4). The conventional treatment for benign breast lesions is close surveillance or open resection. As a traditional treatment method, open surgery has the disadvantage of being traumatically invasive, and scar tissue is likely to develop after the treatment (5). In recent years, breast ultrasound (US)-guided vacuum-assisted excision (US-VAE), a minimally invasive procedure, has become a scarless solution for the removal of breast lesions (6,7). In order to circumvent the potential of benign breast lesions to grow larger or become cancerous, US-VAE is now favored by more and more female patients for its satisfactory cosmetic outcome and few postoperative complications (8,9).

However, the complete resection rate of VAE during follow-up had a wide range. It is reported that the probability of residual lesions is positively correlated with the tumor size and the possibility of residual lesions is greater in

patients with large size breast lesions (10). Thus, US-VAE is generally not recommended by the Chinese Society of Breast Surgery for lesions size larger than 3 cm (10,11). To date, most studies have focused on the US-VAE treatment of benign breast lesions ≤ 3 cm, and there have been no systematic trials on the US-VAE treatment of benign breast lesions larger than 3 cm, particularly on their complete excision and the occurrence of hematoma. Therefore, the purpose of this study was to investigate whether US-VAE is sufficient for the treatment of clinical benign breast lesions larger than 3 cm. We present the following article in accordance with the STROBE reporting checklist (available at <https://atm.amegroups.com/article/view/10.21037/atm-22-5829/rc>).

Methods

Study design and patients

This retrospective cohort study included female patients with benign breast lesions larger than 3 cm removed by US-VAE at the Department of Ultrasound of Chinese PLA General Hospital from January 2018 to July 2021. The retrospective nature of the study predetermines the sample size. The clinical data and ultrasonography were extracted from the database. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Medical Ethics Committee of Chinese PLA General Hospital (No. S2021-684-01). This study was conducted retrospectively, and the need for individual consent was waived.

The inclusion criteria of this study were as follows: (I) single or multiple benign breast lesions larger than 3 cm on sonography; (II) lesions that are Breast Imaging Reporting and Data System (BI-RADS) category 2 or 3, or benign breast lesions confirmed by core needle biopsy; (III) patients who were willing to have the lesions removed by US-VAE. The exclusion criteria were as follows: (I) benign breast lesions ≤ 3 cm on sonography; (II) malignant breast lesions; (III) patients who were allergic to anesthetics; (IV) patients with coagulation disorders; (V) patients with infection in the excision site; (VI) patients without detailed clinical information; (VII) patients who were pregnant, lactating, or menstruating.

US scanning

Before US-VAE, a radiologist specializing in breast US and

Highlight box

Key findings

- Ultrasound-guided vacuum-assisted excision (US-VAE) is an effective and safe alternative method for the treatment of benign breast lesions larger than 3 cm with the complete excision rate of 91.0% (81/89).

What is known and what is new?

- US-VAE is a safe, alternative treatment for patients with benign breast lesions with surgical indications
- The size of lesions should be considered when assess the possibility of the occurrence of hematoma after US-VAE procedure. Benign breast lesions with larger maximum size have higher chances of hematoma occurrence after US-VAE procedure. The complete excision rate of US-VAE was affected by histopathology and vascularity of lesions. For benign phyllodes tumors and intraductal papillomas larger than 3 cm and lesions with hypervascularity, the possibility of recurrence after US-VAE should be noted.

What is the implication, and what should change now?

- US-VAE is an effective and safe alternative method for the treatment of benign breast lesions larger than 3 cm, especially for fibroadenoma, adenosis, hamartoma.

interventional US performed a thorough breast scan using Acuson Sequoia 512 ultrasound system (Acuson, Mountain View, CA, USA) with a 15L8 w linear array transducer. When the lesion was detected, sonography features, including margin, internal echogenicity, blood flow signal, and BI-RADS category were recorded. Then, the insertion site and procedure route were determined based on the location and orientation of the lesion.

US-VAE procedure

A total of 10 mL 1% lidocaine was injected into the cutaneous layer, the estimated incision route, and the space around the lesion. More lidocaine was injected to increase the safe distance if the lesion was beneath the skin or adjacent to pectoralis major. The 7-gauge EnCor[®] system (SenoRX, Irvine, CA, USA) was used for US-VAE procedure. The interventional radiologist (ZLW) with more than 10 years of experience of US-VAE performed all the procedures. Under the guidance of US, the needle was inserted into the lesion or close to the lesion via a small incision. Multiple lesion tissues were automatically transported into a collection basket by EnCor[®] system. The lesion excision was finished when no residual tissue could be identified on US. Manual compression to the excision site was performed for about 15 minutes when the incisions were finished. Then, the radiologist performed a repeat US again to ensure that there was no residual lesion or obvious hematoma. The excision site was covered with an elastic bandage for 24–48 hours. The collected tissues were sent to the department of pathology for pathological examination.

Follow-up

The patients were required to have the first follow-up within 3 days after the procedure to assess if they were experiencing any serious issues. Subsequently, the follow-up US scans were performed 6–12 months later, then at 1-year intervals. The follow-ups focused on the recovery of hematoma and the recurrence of the lesion. Newly detected lesions in the region of the excision site on US were identified as recurrent lesions. A hematoma was defined as a non-echoic area larger than 1 cm at the incision site on the follow-up US scans.

Statistical analysis

The software SPSS 21.0 (IBM Corp., Armonk, NY, USA)

was used for data analysis. Mean \pm standard deviation (SD) or median with range was used for continuous data. Analysis of variance (ANOVA) was used if data from 2 different groups were confirmed as having normal distribution and homogeneity of variance, and Mann–Whitney U test was used if not. Numerable variables are presented as frequencies and percentages and were analyzed using the chi-square test or Fisher exact test. A two-sided P value <0.05 was considered a statistically significant difference.

Results

Characteristics of the patients and lesions

From January 2018 to July 2021, a total of 1,812 lesions in 1,367 patients were subjected to US-VAE. A total of 101 lesions in 98 consecutive patients who underwent US-VAE for benign breast lesions larger than 3 cm were enrolled. 9 lesions in 8 patients were lost to follow-up, and 3 cases in 3 patients were excluded because of malignant lesions. Finally, 89 benign breast lesions with confirmed histopathology in 87 patients were included in the final analysis (*Figure 1*). All patients were female. The mean age was 35.9 ± 9.5 years (range, 18–54 years). The median maximum size of benign breast lesions was 3.5 cm (range, 3.1–5.0 cm). The BI-RADS category was 3 in 81 cases (91.0%) and 4 in 8 cases (9.0%).

The histopathological results showed that among the benign breast lesions in the 89 cases, 58.4% were fibroadenoma (52/89), 18.0% were adenosis in (16/89), 14.6% were hamartoma (13/89), and other lesion types included intraductal papilloma, benign phyllodes tumor in 9.0% (8/89). The detailed baseline information is shown in *Table 1*.

Complete excision rate

The median follow-up duration was 24 months (range, 12–41 months). In 89 cases, 8 cases (8/89, 9.0%) were identified as having recurrent lesions during follow-up, among which 4 cases had fibroadenoma, 3 cases had intraductal papilloma, and 1 case had phyllodes. The complete excision rate was 91.0% (81/89). The features of recurrent and complete excised lesions are summarized in *Table 2*. Location, maximum size, BI-RADS category, palpation, margin, echo pattern, calcification of lesions, and age of patients did not have significant statistical differences in each group. Histopathology ($P=0.002$) and vascularity

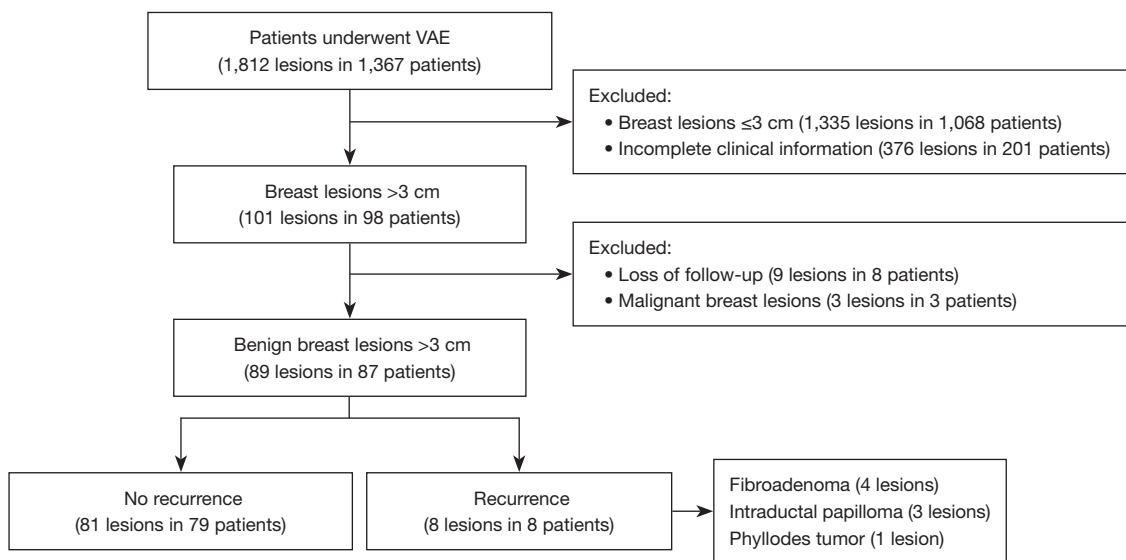


Figure 1 Flow diagram of included patients. VAE, vacuum-assisted excision.

Table 1 Characteristics of patients undergoing VAE for benign breast lesions >3 cm

Characteristics	Value
Total lesions (N)	89
Age (year)*	35.9±9.5
Size (cm) [#]	3.5 [3.1–5.0]
Follow-up duration (month) [#]	24 [12–41]
Histopathology, n (%)	
Fibroadenoma	52 (58.4)
Adenosis	16 (18.0)
Hamartoma	13 (14.6)
Phyllodes	3 (3.4)
Intraductal papilloma	5 (5.6)
BI-RADS, n (%)	
3	81 (91.0)
4a	8 (9.0)

*, mean ± standard deviation; [#], median with range. BI-RADS, breast imaging reporting and data system; VAE, vacuum-assisted excision.

($P=0.032$) of lesions showed significant statistical differences in each subgroup.

Hematoma

During follow-up, 17 cases (17/89, 19.1%) presented with hematoma and 72 cases presented without hematoma (72/89, 81.9%). The size of hematoma ranged from 1.0 to 5.9 cm (*Figure 2*). All the hematomas had disappeared by the 12 months follow-up. The features of cases with or without hematoma are summarized in *Table 3*. Median maximum lesion size was significantly larger in patients with hematoma compared with those without hematoma (3.9 *vs.* 3.4 cm, $P<0.001$). Lesion location, BI-RADS category, histopathology, palpation, margin, echo pattern, calcification, vascularity of lesions, and age of patients were not statistically different in subgroups with or without hematoma.

Other complications

The other complications, including pain and ecchymosis,

Table 2 Features of lesions in groups with recurrent lesions and complete excision lesions

Lesion features	Recurrent lesions (n=8)	Complete excision lesions (n=81)	P value
Age (years)			0.160
Mean \pm SD	40.4 \pm 7.2	35.4 \pm 9.6	
Range	31–54	18–54	
Maximum size (cm)			0.799
Median	3.8	3.5	
Range	3.1–4.4	3.1–5.0	
Breast, n (%)			0.838
Right	3 (37.5)	39 (48.1)	
Left	5 (62.5)	42 (51.9)	
Lesion location, n (%)			0.551
UIQ	2 (25.0)	11 (13.6)	
UOQ	5 (62.5)	44 (54.3)	
LOQ	0 (0.0)	13 (16.0)	
LIQ	0 (0.0)	7 (8.6)	
Subareolar	1 (12.5)	6 (7.4)	
BI-RADS category, n (%)			0.545
3	7 (87.5)	74 (91.4)	
4a	1 (12.5)	7 (8.6)	
Histopathology*, n (%)			0.002
Intraductal papilloma and phyllodes tumor	4 (50.0)	4 (4.9)	
Others	4 (50.0)	77 (95.1)	
Palpation, n (%)			1
Yes	7 (87.5)	64 (79.0)	
No	1 (12.5)	17 (21.0)	
Margin, n (%)			1
Distinct	7 (87.5)	72 (88.9)	
Indistinct	1 (12.5)	9 (11.1)	
Echo pattern, n (%)			0.631
Hypoechoic	7 (87.5)	72 (88.9)	
Isoechoic	0 (0.0)	4 (4.9)	
Heterogeneous	1 (12.5)	5 (6.2)	
Calcification, n (%)			1
Present	0 (0.0)	2 (2.5)	
Absent	8 (100.0)	79 (97.5)	
Vascularity*, n (%)			0.032
Hypervascular	7 (87.5)	30 (37.0)	
Hypovascular	1 (12.5)	31 (38.3)	
Avascular	0 (0.0)	20 (24.7)	

*, statistical significance. SD, standard deviation; UIQ, upper inner quadrant; UOQ, upper outer quadrant; LOQ, lower outer quadrant; LIQ, lower inner quadrant; BI-RADS, breast imaging reporting and data system.

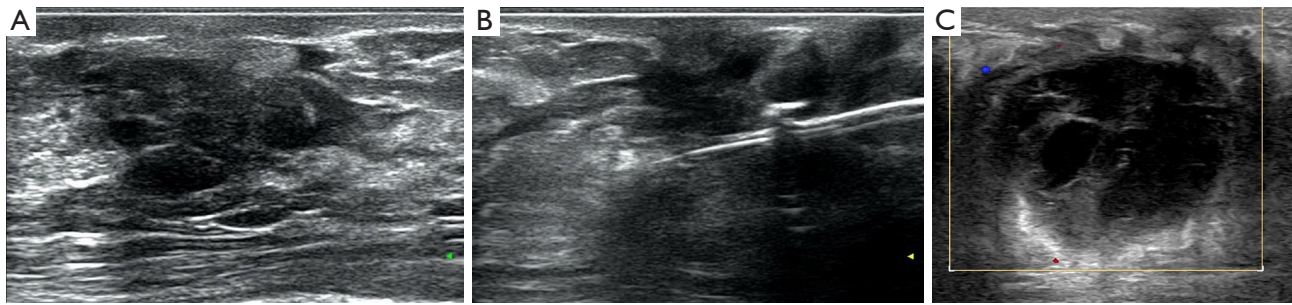


Figure 2 US-VAE for benign breast lesions larger than 3 cm. (A) A 36-year-old female with fibroadenoma of right breast. Ultrasonography shows a regular distinct and hypoechoic lesion in the right breast with a maximum size larger than 3 cm; (B) ultrasonography shows the incision needle in the lesion; (C) hematoma at the incision site after VAE. US-VAE, ultrasound-guided vacuum-assisted excision; VAE, vacuum-assisted excision. (Green and yellow arrowheads indicate the focal position of ultrasound imaging).

were also recorded. A total of 19 patients (19/87, 21.84%) experienced pain within 5 days after the procedure. Ecchymosis was observed in 4 patients (5/87, 5.74%) and it was relieved gradually within weeks. No infection and other severe complications were found in all patients.

Discussion

This study included 89 benign breast lesions in 87 patients to evaluate the efficacy of US-VAE for the treatment of benign breast lesions larger than 3 cm. As far as we can see, this is the first study to focus on whether US-VAE is sufficient for the treatment of clinical benign breast lesions larger than 3 cm. US-VAE is a safe, alternative treatment for patients with benign breast lesions with surgical indications (12). However, the complete resection rate of VAE at 6–12 months had a wide range: from 38% to 100% (13). It is reported that the probability of residual lesions is positively correlated with the tumor size (14–16). Therefore, US-VAE was not recommended for benign breast lesions larger than 3 cm due to its higher possibility of residual lesions. Park *et al.* (16) and Bennett *et al.* (17) reported that the complete excision rate of US-VAE was 94.4% for lesions with an average size of 1.24 cm and 94.8% for lesions with an average size of 1.06 cm. However, this study found that the complete excision rate was 91.0% for benign breast lesions larger than 3 cm, which was similar to the 93.7% reported for benign breast lesions with mean diameter of 1.25 ± 0.70 cm in our previous research (18). Moreover, this study included a case with the maximum size of 5.0 cm, and no recurrence was observed during the 18 months of follow-up after US-VAE procedure. It has been reported that radiologists initially required a level

of experience accumulated through treating 11 cases to demonstrate a complete excision rate higher than 80%, and 18 cases to achieve long-term adequate effectiveness experience (13). The high complete excision rate in this study is probably due to the accumulation of radiologist's experience in dealing with large benign breast lesions. Furthermore, with advancement of US-VAE systems and operation techniques, the complete excision rate could be improved over time.

A total of 8 patients were found to have recurrent lesions in the procedure site in this study. Recurrent lesions were observed in cases with phyllodes, intraductal papilloma, and fibroadenoma. This study found that histopathology of lesions had significant difference in groups with or without recurrent lesions. Histopathology needs to be considered when evaluating the possibility of recurrence in patients with large benign breast lesions.

Only 4 cases in 52 cases with fibroadenoma in our study had recurrent lesions after US-VAE, which indicates that US-VAE is a good alternative treatment for patients with fibroadenoma larger than 3 cm. Fibroadenoma is one of the most common lesions in benign breast lesions (10). Considering that the size of the fibroadenoma in our study was larger than 3 cm, the complete excision rate is relatively acceptable. No patients with adenosis and hamartoma were identified with recurrent lesions in our study. Breast adenosis, which is normally not considered a premalignant lesion, is histological hyperplasia that involves the glandular component of the breast. However, it has been considered to be associated with breast cancer, especially for sclerosing and microglandular adenosis (19). Thus, the excision of adenosis is essential for those patients. Hamartoma is composed of normal distorted tissue, which contributes

Table 3 Features of lesions in groups with and without hematoma

Lesion features	Hematoma (n=17)	No hematoma (n=72)	P value
Age (years)			
Mean ± SD	39.3±10.9	34.1±9.6	0.06
Range	18–54	16–50	
Maximum size (cm)			
Median	3.9	3.4	<0.001
Range	3.1–5.0	3.1–4.9	
Breast, n (%)			1
Right	8 (47.1%)	34 (47.2%)	
Left	9 (52.9%)	38 (52.8%)	
Lesion location, n (%)			0.353
UIQ	1 (5.9%)	12 (16.7%)	
UOQ	9 (52.9%)	40 (55.6%)	
LOQ	2 (11.8%)	11 (15.3%)	
LIQ	3 (17.6%)	4 (5.6%)	
Subareolar	2 (11.8%)	5 (6.9%)	
BI-RADS category, n (%)			0.063
3	13 (76.5%)	68 (94.4%)	
4a	4 (23.5%)	4 (5.6%)	
Histopathology, n (%)			1
Intraductal papilloma and phyllodes tumor	2 (11.8%)	6 (8.3%)	
Others	15 (88.2%)	66 (91.7%)	
Palpation, n (%)			1
Yes	14 (82.4%)	57 (79.2%)	
No	3 (17.6%)	15 (20.8%)	
Margin, n (%)			0.093
Distinct	13 (76.5%)	66 (91.7%)	
Indistinct	4 (23.5%)	6 (8.3%)	
Echo pattern, n (%)			0.333
Hypoechoic	14 (82.4%)	65 (90.3%)	
Isoechoic	1 (5.9%)	3 (4.2%)	
Heterogeneous	2 (11.8%)	4 (5.6%)	
Calcification, n (%)			0.347
Present	1 (5.9%)	1 (1.4%)	
Absent	16 (94.1%)	71 (98.6%)	
Vascularity, n (%)			0.319
Hypervascular	5 (29.4%)	32 (44.4%)	
Hypovascular	6 (35.3)	26 (36.1%)	
Avascular	6 (35.3)	14 (19.4%)	

*, statistical significance. SD, standard deviation; UIQ, upper inner quadrant; UOQ, upper outer quadrant; LOQ, lower outer quadrant; LIQ, lower inner quadrant; BI-RADS, breast imaging reporting and data system.

to its low recurrence compared with other benign breast lesions. Therefore, the lesion size for US-VAE may be more flexible for hamartoma. Hu *et al.* (20) also reported that the complete excision rate for the treatment hamartoma is 96.8% (30/31) and believed that US-VAE is an alternative treatment to open surgery, especially for large mammary hamartoma. In this study, we found that US-VAE could treat fibroadenoma, adenosis, and hamartoma with great efficacy, which indicates that US-VAE is an alternative treatment to open surgery.

In our study, intraductal papilloma and benign phyllodes were related with recurrence in patients treated by US-VAE. We found that 1 in 3 cases with benign phyllodes and 3 in 5 cases with intraductal papilloma had recurrent lesion after US-VAE. Phyllodes tumors are uncommon fibroepithelial lesions accounting for about 1% of all breast lesions. Park *et al.* (21) reported that the local recurrence rate was 7.5% for benign phyllodes treated with US-VAE, and lesions larger than 3.0 cm are not recommended for US-VAE. As for intraductal papilloma, it has also been reported that US-VAE is an effective method for the treatment of benign breast intraductal papilloma and can serve as an alternative to open surgery (22,23). The recurrent rate of US-VAE for benign intraductal papilloma has also been reported to be affected by lesion size (24). Our group previously reported that the recurrence rate of lesions less than 1 cm was significantly lower than that of lesions 1 cm or larger (25). In this study, we also observed a high recurrence rate in large phyllodes and intraductal papilloma. Thus, US-VAE is not preferred for patients with large benign phyllodes and intraductal papilloma. However, the number of cases of hamartoma, adenosis, phyllodes, and intraductal papilloma we included in this study was relatively small; the results should be interpreted with caution.

In previous studies, the vascularity of lesions was not found to be significant different (25,26). However, this study found that lesions with hypervascularity tend to have a higher recurrence rate. It could be possible that breast lesions with hypervascularity may be prone to hemorrhage during the US-VAE procedure, and thus tiny residuals might not be detected by US. Therefore, it is also pivotal to evaluate the vascularity of breast lesions before US-VAE to assess the possibility of residuals.

None of the patients in our study experienced any severe complications. Hematoma is the most frequent complication after US-VAE of breast lesions, with occurrence ranging from 8% to 27% (27-29). The occurrence of hematoma in benign breast lesions larger than 3 cm was 19.1% in

our study. Yom *et al.* (30) reported that the incidence of hematoma was more likely to increase at age <35 years. However, blood coagulation enhances with age, which makes intraoperative hemorrhage more likely to coagulate into hematoma (31,32). This might explain why age was not significantly different between groups with or without hematoma in this study.

Several studies have suggested that the size of the lesion influences subsequent hematoma formation (13,33). We also observed that an increase in lesion size was associated with a higher risk of hematoma. Median maximum lesion size was significantly larger in patients with hematoma (3.9 cm) compared with patients without hematoma (3.4 cm) in our study. During the US-VAE procedure, a larger lesion size indicates a larger residual cavity, which may increase the possibility of hematoma formation. For patients with large benign breast lesions, the probability of hematoma occurrence should be noted in advance. Adrenaline and hemocoagulase can be injected into the cavity to reduce hematoma formation if bleeding is detected (34). Besides, for large lesions, extension of bandage time should be performed after US-VAE to reduce the occurrence of hematoma (3,34).

This study provides evidence against the clinical practice guidelines that US-VAE is not recommended to treat benign breast lesions larger than 3 cm. To our knowledge, this is the first study to focus on the US-VAE treatment of benign breast lesions larger than 3 cm. This study had a few limitations. Firstly, the number of recurrent cases in our study was small. We should not neglect the inadequate statistical power of the analyses on the factors associated with recurrent lesions and hematoma. So, the interpretation of the results should be made with caution. Secondly, any new masses in the region of the excision site were classified as recurrent lesions without histopathological confirmation. Thus, multicenter studies on US-VAE for benign breast lesions larger than 3 cm may be needed in further studies. Studies with histopathological characteristics of recurrent lesions are needed to obtain a more robust conclusion.

Conclusions

US-VAE is an effective and safe alternative method for the treatment of benign breast lesions larger than 3 cm, especially for fibroadenoma, adenosis, hamartoma. The complete excision rate of US-VAE is affected by histopathology and vascularity of lesions. For benign phyllodes tumors and intraductal papillomas larger than

3 cm and lesions with hypervascularity, the possibility of recurrence after US-VAE should be noted. The size of lesions should be considered when assessing the possibility of the occurrence of hematoma after a US-VAE procedure. Benign breast lesions with a larger maximum size have a higher risk of hematoma occurrence after the US-VAE procedure.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://atm.amegroups.com/article/view/10.21037/atm-22-5829/rc>

Data Sharing Statement: Available at <https://atm.amegroups.com/article/view/10.21037/atm-22-5829/dss>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://atm.amegroups.com/article/view/10.21037/atm-22-5829/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Medical Ethics Committee of Chinese PLA General Hospital (No. S2021-684-01). This study was conducted retrospectively, and the need for individual consent was waived.

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References

1. Lakoma A, Kim ES. Minimally invasive surgical management of benign breast lesions. *Gland Surg* 2014;3:142-8.
2. Posso M, Alcántara R, Vázquez I, et al. Mammographic features of benign breast lesions and risk of subsequent breast cancer in women attending breast cancer screening. *Eur Radiol* 2022;32:621-9.
3. Jiang Y, Lan H, Ye Q, et al. Mammotome® biopsy system for the resection of breast lesions: Clinical experience in two high-volume teaching hospitals. *Exp Ther Med* 2013;6:759-64.
4. Orr B, Kelley JL 3rd. Benign Breast Diseases: Evaluation and Management. *Clin Obstet Gynecol* 2016;59:710-26.
5. Zhang J, Li H, Lin L, et al. Ultrasound-guided microwave ablation for multiple benign breast lesions: A prospective study. *J Obstet Gynaecol Res* 2021;47:3362-9.
6. Yao F, Li J, Wan Y, et al. Sonographically guided vacuum-assisted breast biopsy for complete excision of presumed benign breast lesions. *J Ultrasound Med* 2012;31:1951-7.
7. Rupa R, Kushvaha S. Vacuum-Assisted Excision, Scarless Solution for Fibroadenoma Breast-A Single-Center Experience. *Indian J Radiol Imaging* 2021;31:844-9.
8. Ding Y, Cao L, Chen J, et al. Serial image changes in ultrasonography after the excision of benign breast lesions by mammotome® biopsy system. *Saudi J Biol Sci* 2019;26:178-82.
9. van de Voort EMF, Klem TMAL, Struik GM, et al. Patient reported cosmetic outcome after vacuum assisted excision of benign breast lesions: a cross-sectional study. *Br J Radiol* 2020;93:20190994.
10. Peng Y, Xie F, Zhao Y, et al. Clinical practice guideline for breast fibroadenoma: Chinese Society of Breast Surgery (CSBrS) practice guideline 2021. *Chin Med J (Engl)* 2021;134:1014-6.
11. Fan ZM, Wang JD, Hua B, et al. Expert consensus and operation guidelines for ultrasound-guided vacuum-assisted breast biopsy surgery (2017). *Chin J Pract Surg* 2018;37:1374-6.
12. Bick U, Trimboli RM, Athanasiou A, et al. Image-guided breast biopsy and localisation: recommendations for information to women and referring physicians by the European Society of Breast Imaging. *Insights Imaging* 2020;11:12.

13. Salazar JP, Miranda I, de Torres J, et al. Percutaneous ultrasound-guided vacuum-assisted excision of benign breast lesions: A learning curve to assess outcomes. *Br J Radiol* 2019;92:20180626.
14. Bennett IC, Saboo A. The Evolving Role of Vacuum Assisted Biopsy of the Breast: A Progression from Fine-Needle Aspiration Biopsy. *World J Surg* 2019;43:1054-61.
15. Bozzini A, Cassano E, Raciti D, et al. Analysis of Efficacy and Accuracy of 2 Vacuum-Assisted Breast Biopsy Devices: Mammotome and Elite. *Clin Breast Cancer* 2018;18:e1277-82.
16. Park HL, Kim KY, Park JS, et al. Clinicopathological Analysis of Ultrasound-guided Vacuum-assisted Breast Biopsy for the Diagnosis and Treatment of Breast Disease. *Anticancer Res* 2018;38:2455-62.
17. Bennett I, de Viana D, Law M, et al. Surgeon-Performed Vacuum-Assisted Biopsy of the Breast: Results from a Multicentre Australian Study. *World J Surg* 2020;44:819-24.
18. Wang ZL, Liu G, Li JL, et al. Sonographically guided percutaneous excision of clinically benign breast masses. *J Clin Ultrasound* 2011;39:1-5.
19. Ozturk E, Yucesoy C, Onal B, et al. Mammographic and Ultrasonographic Findings of Different Breast Adenosis Lesions. *J Belg Soc Radiol* 2015;99:21-7.
20. Hu H, Zhang M, Liu Y, et al. Mammary hamartoma: is ultrasound-guided vacuum-assisted breast biopsy sufficient for its treatment? *Gland Surg* 2020;9:1278-85.
21. Park HL, Pyo YC, Kim KY, et al. Recurrence Rates and Characteristics of Phyllodes Tumors Diagnosed by Ultrasound-guided Vacuum-assisted Breast Biopsy (VABB). *Anticancer Res* 2018;38:5481-7.
22. Björnström M, Niinikoski L, Meretoja TJ, et al. Comparison of vacuum-assisted excision (VAE) and breast lesion excision system (BLES) in the treatment of intraductal papillomas. *Eur J Surg Oncol* 2022;48:67-72.
23. Maxwell AJ. Ultrasound-guided vacuum-assisted excision of breast papillomas: review of 6-years experience. *Clin Radiol* 2009;64:801-6.
24. Ko KH, Jung HK, Youk JH, et al. Potential application of ultrasound-guided vacuum-assisted excision (US-VAE) for well-selected intraductal papillomas of the breast: single-institutional experiences. *Ann Surg Oncol* 2012;19:908-13.
25. Wang ZL, Liu G, He Y, et al. Ultrasound-guided 7-gauge vacuum-assisted core biopsy: Could it be sufficient for the diagnosis and treatment of intraductal papilloma? *Breast J* 2019;25:807-12.
26. Daya D, Trus T, D'Souza TJ, et al. Hamartoma of the breast, an underrecognized breast lesion. A clinicopathologic and radiographic study of 25 cases. *Am J Clin Pathol* 1995;103:685-9.
27. Slanetz PJ, Wu SP, Mendel JB. Percutaneous excision: a viable alternative to manage benign breast lesions. *Can Assoc Radiol J* 2011;62:265-71.
28. Berná-Serna JD, Guzmán-Aroca F, Berná-Mestre JD, et al. A new method for the prevention of skin laceration during vacuum-assisted breast biopsy. *Br J Radiol* 2017;90:20160866.
29. Ding B, Chen D, Li X, et al. Meta analysis of efficacy and safety between Mammotome vacuum-assisted breast biopsy and open excision for benign breast tumor. *Gland Surg* 2013;2:69-79.
30. Yom CK, Moon BI, Choe KJ, et al. Long-term results after excision of breast mass using a vacuum-assisted biopsy device. *ANZ J Surg* 2009;79:794-8.
31. Lowe GD, Drummond MM, Forbes CD, et al. The effects of age and cigarette-smoking on blood and plasma viscosity in men. *Scott Med J* 1980;25:13-7.
32. Hahr JY. Physiology of aging. *Med Hypotheses* 2019;123:83-5.
33. Guzmán-Aroca F, Berná-Serna JD, García-Ortega AA, et al. A New Management Technique for Symptomatic Haematomas Following Therapeutic Vacuum-Assisted Biopsy. *J Clin Med* 2019;8:1493.
34. Zheng J, Cai S, Song H, et al. Prediction of postoperative hematoma occurrence after ultrasound-guided vacuum-assisted breast biopsy in minimally invasive surgery for percutaneous removal of benign breast lesions. *Gland Surg* 2020;9:1346-53.

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