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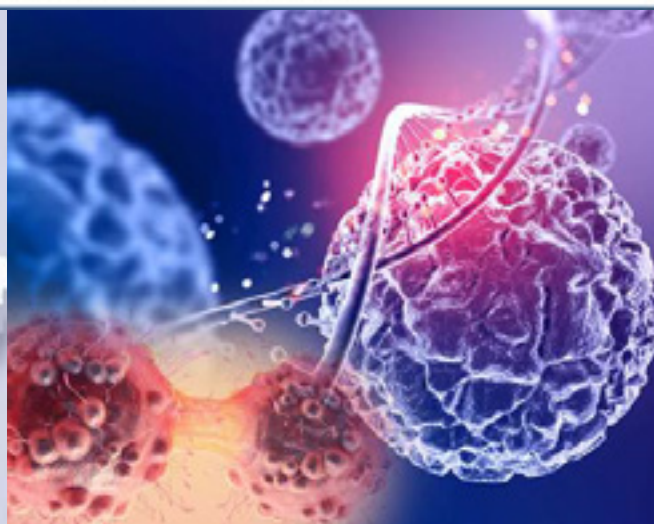


**RC70**  
United for a  
healthier  
future

70th session of the Regional  
Committee for the Eastern  
Mediterranean

Cairo, Egypt 9–12 October 2023

Theme: "Moving forward towards a healthier future in the Eastern Mediterranean Region:  
Promoting, protecting and delivering health for all by all"



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## Original Article

# Outcomes of Vacuum–Assisted Breast Biopsy for Management of Benign Breast Masses

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## Abstract

**Introduction :** The triple assessment, which combines a clinical examination, radiological imaging, and pathology, is used to assess the breast mass. The open excision of the suspicious lesion is the gold standard for breast biopsy techniques. However, because an excisional biopsy always results in a scar, many surgeons are considering less invasive, alternative methods due to the cost and morbidity of this operation. Image–guided percutaneous core–needle biopsy has recently gained popularity in identifying palpable and non–palpable breast lesions. Vacuum– assisted breast biopsy (VABB) was created to address some of these limitations of core–needle biopsy.

**Methodology:** We performed a retrospective review of 38 patients who underwent VABB. To Report the recurrence one–year post–VABB for management of benign breast masses and To evaluate patient–reported cosmetic satisfaction using the cosmetic scale.

**Results:** The mean age of the study participants was about 30.34 ( $\pm 10.11$ ) years. The average size of breast masses was 1.23 ( $\pm 0.83$ ) cm. The recurrence rate was 13.16%, confirmed by follow up ultrasound and all these patients

underwent excisional biopsy. There were significant differences in breast mass recurrence rate by the side affected. Recurrence was more likely in right–sided breast masses ( $P=0.048$ ). In our study, no significant relationships between the occurrence of complications following surgery and patients ‘demographics and mass features and no infection were reported. The hematoma was reported in 2 patients 5.26 %, Mild induration at the site of surgery 2 patients 5.26 %, Small contusion at the site of surgery in one patient 2.63 % and no other complication was reported. The patient’s cosmetic satisfaction using the cosmetic scale from 1–5, 1: not satisfied, 2: low satisfaction, 3: mild satisfaction, 4: moderate satisfaction, 5: completely satisfied, The mean cosmetic score was 4.03.

**Conclusion:** Our study concluded that VABB is reliable for removing small benign breast masses with a satisfying cosmetic outcome & low recurrence rate, and fewer complications.

**Keywords:** Benign Breast disease, Breast biopsy and Fibroadenoma.

## Introduction

One in eight women in Western nations may experience breast cancer at some point in their lives, and roughly 60% will experience benign breast disease.<sup>(1)</sup> Fibroadenoma and fibrocystic disease are the most prevalent benign breast disorders. Today, a combination of three tests—clinical examination, radiological imaging (mammography, ultrasonography), and pathology—known as the triple assessment test—is utilized to reliably diagnose all palpable breast masses. The majority of breast cancers are now diagnosed nonoperatively. Together, they provide

99% sensitivity. The triple assessment is only considered negative if all three of its components are negative for malignancy. It is positive if any one of the three components is positive.<sup>(2)</sup>

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Open excision of the suspicious lesion is the gold standard for breast biopsy methods. Excisional biopsies, however, always result in scarring. Numerous surgeons are considering less invasive, alternative techniques due to the expense and morbidity of this procedure (3, 4). Minimally invasive biopsies aim to lessen the side effects without compromising accuracy or cost-effectiveness. A less invasive, more affordable alternative called fine-needle aspiration (FNA) biopsy has been recommended and used at various institutions. The false negative rate for FNAC is high, ranging from 1.2 to 10.6%. (5) also, it was reported a false rate of up to 40% in some studies; for this reason, this approach has not been widely used. (6, 7). This percentage is frequently associated with insufficient information from cytological samples to diagnose. Non-diagnostic outcomes result in unwarranted delays in diagnosis, the requirement for more biopsies, and higher costs. Non-diagnostic outcomes result in unwarranted delays in diagnosis, the requirement for more biopsies, and higher costs.

To identify palpable and non-palpable breast lesions, image-guided percutaneous core-needle biopsy has lately gained popularity. At the end of 1995, vacuum assisted breast biopsy (VABB) was created to address some of these limitations of core-needle biopsy<sup>(8)</sup>.

With the help of Ultrasonography, VABB enables the operator to get enough samples with a single insertion to provide a more precise diagnosis and can help in entirely eliminating the lesion.<sup>(9, 10)</sup>

Complete lesion excision using VABB has the advantages of decreasing or eliminating sample error, histological underestimation, imaging-histological discordance, re-biopsy rate, and subsequent growth on follow-up. Numerous studies have been carried out to remove benign tumors with a curative goal due to advancements in VABB tools and techniques<sup>(11, 12)</sup>.

VABB is a large-size core biopsy that is performed by rotating cutter and suction. Without removing the needle from the biopsy site, each specimen core is moved to the specimen port for collection. The needle shaft can be turned in order to take multiple biopsies. There are also large needle sizes of 11G and 8G available. Because of this, lesions smaller than 2 cm in size can be entirely removed piecemeal using a 3 mm incision without the need for sutures to close it. It can be carried out either with stereotactic guidance for microcalcification<sup>(13)</sup> or with ultrasonic guidance for mass lesions<sup>(9)</sup>. The diagnostic accuracy of VAB is very high<sup>(14-16)</sup>

The percentage of false negatives was about 2%. Microcalcification had a high degree of diagnostic accuracy, and compared to core biopsy, its histological

underestimation rates for atypical ductal hyperplasia (ADH) and ductal carcinoma in situ (DCIS) were much lower<sup>(11, 12)</sup>.

**Objective:** To Report the recurrence 1-year post vacuum-assisted breast biopsy for management of benign breast masses. To evaluate patient-reported cosmetic satisfaction using the cosmetic scale. Analyze the findings for possible trends. Build a base for further studies relating the use of vacuum-assisted breast biopsy for management of benign breast masses. Compare our findings with local and international studies on this subject.

## Patients and Methods

In a retrospective cross-sectional study, Data was collected from all patients who presented with breast mass to the surgical clinic at the Specialized Medical Center Private Hospital, Riyadh-KSA. Between the period of June 2012 to July 2017. Permission taken from the hospital administration to allow the researchers to revise the patients' medical records archived in a specified hospital center system (doctor/idoc). Patients were chosen based on the following criteria: The inclusion criteria: 1. Patient with Breast mass who undergoes VABB as diagnostic and therapeutic procedures. 2. Limited study to the lesion size is 2 cm in the longitudinal axis. 3. Patients of all ages, sex, and medical comorbidities included. Exclusion criteria: 1. Breast cancer (confirmed by histopathology) Demographic data: Age and Gender. 2. Family History of malignancies 3. Lesion size and location 4. Histopathology 5. Recurrence 6. Complication 7. Cosmetic satisfaction by cosmetic scale to assess patient satisfaction 8. Follow up post VABB. All this information was retrieved from patients' medical records.

## Statistical analysis

The collected data were described in terms of mean  $\pm$  Standard Deviation (SD) and range regarding numerical data, and frequency and percentage regarding categorical data. The Fisher Exact Test (FET) was used to compare categorical data. The distribution of numerical data was examined using the Skewness and Kurtosis normality test. The Mann-Whitney (MW) test and the Kruskal Wallis (KW) test were used to detect differences between two and more than two groups of non-parametric numerical data, respectively. The Spearman correlation coefficient ( $\rho$ ) was used to test for the correlation between cosmetic satisfaction score and age of participants and lesion size. A two-sided P-value  $<0.05$  was considered statistically significant. All statistical analysis was carried out using STATA/SE version 11.2 for Windows (STATA Corporation, College Station, Texas).

Variable (no.=38)		No.	%
Age (years)	<35	27	71.05
	≥35	11	28.95
	Mean ± SD; (range)	30.34±10.11; (17–66)	
Family history	Negative	36	94.74
	Positive	2	5.26
Breast	Left	21	55.26
	Right	16	42.11
	Bilateral	1	2.63
Lesion size (cm)*	Mean ± SD; (range)	1.23±0.83; (0.13–2.8)	
Histopathology	Fibroadenoma	34	89.47
	Fibrocystic disease	3	7.89
	Tubular adenoma	1	2.63
Complications	No	33	86.84
	Hematoma	2	5.26
	Mild induration at the site of surgery	2	5.26
	Small contusion at the site of surgery	1	2.63
Cosmetic score	Mean ± SD; (range)	4.03±0.85; (2–5)	
Recurrence	No	33	86.84
	Yes	5	13.16

**Table 1:** Relationship between the occurrence of complications and patients' characteristics and lesion features  
\*n.=39 as one patient with bilateral lesions

SD: Standard Deviation

## Result

The study recruited 38 female patients presented with benign breast mass. Their ages ranged between 17 and 66 years with an average of 30.34 ( $\pm 10.11$ ) years. Only 5.26% had a positive family history of breast mass. The size of breast masses ranged between 0.13 and 2.8 cm with an average of 1.23 ( $\pm 0.83$ ) cm. Recurrence rate was 13.16% (Table 1).

Table 2 shows no significant relationships between the occurrence of complications following surgery and patients' demographics and mass features.

Table 3 shows cosmetic satisfaction scores were more likely lower in patients with positive family history of breast mass compared to those with negative family history ( $3.0 \pm 0$  vs.  $4.08 \pm 0.84$ ;  $P=0.04$ ). the occurrence of complications was associated with lower cosmetic satisfaction scores ( $P=0.007$ ).

There was a significant negative correlation between the lesion size and cosmetic scores ( $\rho = -0.34$ ;  $P=0.035$ ) as demonstrated in Figure 1.

There were significant differences in breast mass recurrence rate by the side affected (Table 4). Recurrence was more likely in right-sided breast masses ( $P=0.048$ ).

Demographics and lesion characteristics of the studied patients

\*n.=6 as one patient had bilateral lesions

SD: Standard Deviation

FET: Fisher Exact Test

P: Probability

MW: Mann–Whitney test

Variable	Complications				Test	P	
	No (no.=33)		Yes (no.=5)				
	No.	%	No.	%			
Age (years)	<35	24	72.73	3	60.00	FET	0.615
	≥35	9	27.27	2	40.00		
	Mean ± SD; (range)	30.76±10.37; (17–66)		27.6±8.62; (20–37)		MW=0.30	0.76
Family history	Negative	31	93.94	5	100.00	FET	1.00
	Positive	2	6.06	0	0.00		
Breast	Left	18	54.55	3	60.00	FET	1.00
	Right	14	42.42	2	40.00		
	Bilateral	1	3.03	0	0.00		
Lesion size (cm)	Mean ± SD; (range)	1.14±0.79; (0.13–2.36) *		1.64±0.94; (0.21–2.8)		MW=1.17	0.24
Histopathology	Fibroadenoma	29	87.88	5	100.00	FET	1.00
	Fibrocystic disease	3	9.09	0	0.00		
	Tubular adenoma	1	3.03	0	0.00		
Recurrence	No	30	90.91	3	60.00	FET	0.12
	Yes	3	9.09	2	40.00		

**Table 2:** Relationship between the occurrence of complications and patients’ characteristics and lesion features

## Discussion:

Currently, a wide variety of management techniques for breast masses have been described.

Percutaneous breast biopsy aims to accurately diagnose tissue in a safe manner. However, there are concern over the expenses, the efficiency of the various operations, and the comfort of the patients or the operators. VAB provides an excellent balance between all of these needs for breast biopsy. The cancer detection rate, histological underestimations, and calcification retrieval failure are all indicators of how accurate a biopsy procedure is. We regularly utilize a 7–gauge to 11–gauge needle and avoid using 14–gauge VAB needles because a false negative rate is correlated with needle gauge <sup>(17)</sup>

According to Jackman <sup>(18)</sup> et al. using a 14–gauge needle resulted in a false negative diagnosis of stereotactic VAB in 4.4% of instances while using an 11–gauge needle resulted in 0.45% of cases. The reported cancer miss rate for an 11–gauge VAB is between 0–3.3% <sup>(7, 10)</sup>, which is consistently lower than the 4% recorded for a 14–gauge core biopsy and comparable to the 2.5% reported for a needle localized breast biopsy <sup>(11, 19)</sup>.

The study recruited 38 female patients presented with benign breast mass. Their ages ranged between 17 and 66 years with an average of 30.34 (±10.11) years.

The mean age of the study participants was about 30.34 (±10.11) years. with about 71.05 % of them aged less than 35 years. This finding was comparable with Maleeha Ajmal; Kelly Van Fossen. <sup>(19)</sup> where they reported that A breast fibro adenoma. It commonly occurs in women between the age of 14 to 35 years.

Only 5.26% had positive family history of breast mass. No genetics factors are known to alter the risk of fibro–

adenoma. However, a family history of breast cancer in first–degree relatives were reported by some investigators to be.

related with increased risk of developing these tumors <sup>(20)</sup>

The size of breast masses ranged between 0.13 and 2.8 cm with an average of 1.23 (±0.83) cm.

Mass lesions less than 2 cm in size can be completely removed by VAB under ultrasound guidance <sup>[14, 21–22]</sup>. complete removal was achieved in 71–99% of the reported series.

A 97% of women showed immediate full elimination of the imaging mass. Repeat sonography revealed that 73% of the women for whose data were available at 6 months following biopsy remained lacking sonographic evidence of the first detected tumor. However, during the 6–month follow–up sonography, 27% still had a mass <sup>(20)</sup>.

Variable		Cosmetic score			Test	P
		No	Mean $\pm$ SD	range		
Age (years)	<35	27	4 $\pm$ 0.88	2–5	MW=0.14	0.89
	$\geq$ 35	11	4.09 $\pm$ 0.83	3–5		
Family history	Negative	36	4.08 $\pm$ 0.84	2–5	MW=2.01	<b>0.04</b>
	Positive	2	3 $\pm$ 0	3		
Breast	Left	21	3.90 $\pm$ 0.83	2–5	KW=1.20	0.55
	Right	16	4.19 $\pm$ 0.91	2–5		
	Bilateral	1	4 $\pm$ 0	4		
Histopathology	Fibroadenoma	34	3.97 $\pm$ 0.87	2–5	KW=1.84	0.40
	Fibrocystic disease	3	4.33 $\pm$ 0.58	4–5		
	Tubular adenoma	1	5 $\pm$ 0	5		
Complications	No	33	4.21 $\pm$ 0.65	3–5	MW=2.68	<b>0.007</b>
	Yes	5	2.8 $\pm$ 1.09	2–4		
Recurrence	No	33	4.15 $\pm$ 0.75	2–5	MW=1.94	0.052
	Yes	5	3.2 $\pm$ 1.09	2–4		

**Table 3:** Variations in cosmetic score by patients' characteristics and lesion features

\*n.=34 as one patient had bilateral lesions

SD: Standard Deviation

P: Probability

MW: Mann–Whitney test

KW: Kruskal Wallis test

No.=38	Cosmetic score		Age (years)		Lesion size (cm)	
	Rho	P	Rho	P	Rho	P
Cosmetic score	1.00					
Age (years)	0.07	0.67	1.00			
Lesion size (cm)	–0.34	<b>0.035</b>	–0.14	0.41	1.00	

**Table 4:** Correlations between cosmetic score and patient age and lesion size

In our study the Recurrence rate was 13.16%, confirmed by follow up ultrasound and all these patients underwent excisional biopsy. There were significant differences in breast mass recurrence rate by the side affected (Table 4). Recurrence was more likely in right–sided breast masses (P=0.048).

Although the majority of studies claim success rates of 75–100%, the rate of initial complete removal of a lesion successfully varies greatly from 22 to 100%. 62–98% of follow–ups without recurrence.<sup>(20–23)</sup>

These discrepancies may be partially explained by the use of various gauged devices (ranging from 8 to 14 gauge), various techniques for determining the extent of removal (including clinical, radiographic, and histological procedures), and the variety of histological lesions examined.

The use of image guided VAB to remove benign breast tumors like fibroadenomas has received support from the National Health Service in the United Kingdom .

Since true ultrasound can guarantee the visualization of a lesion's total eradication, this is typically done under its guidance. Lesions under 2.0 cm can be totally excised, according to Sperber et al<sup>(24)</sup>, and lesions under 1.5 cm can be entirely excised according to Baez et al<sup>(25)</sup>. Regarding safety concerns, VAB is thought to have an extremely low complication rate. Although bruising following a biopsy or even a blood draw with a needle is frequent, severe hematomas needing surgical intervention following a VAB are uncommon. Less than 1% of VAB were found to have large hematomas, according to Parker et al.<sup>(9)</sup>, and none of them necessitated surgical treatment.

A 25 out of 2,874 patients (less than 1%), according to

Variable	Breast mass recurrence				Test	P	
	No (no.=33)		Yes (no.=5)				
	No.	%	No.	%			
Age (years)	<35	22	66.67	5	100.00	FET	0.29
	≥35	11	33.33	0	0.00		
	Mean ± SD; (range)	31.39±10.26; (17–66)		23.4±5.81; (17–32)		MW=1.90	0.057
Family history	Negative	31	93.94	5	100.00	FET	1.00
	Positive	2	6.06	0	0.00		
Breast	Left	20	60.61	1	20.00	FET	<b>0.048</b>
	Right	13	39.39	3	60.00		
	Bilateral	0	0.00	1	20.00		
Lesion size (cm)	Mean ± SD; (range)	1.13±0.80; (0.13–2.8)		1.70±0.83; (0.26–2.34)*		MW=1.64	0.10
Histopathology	Fibroadenoma	29	87.88	5	100.0	FET	1.00
	Fibrocystic disease	3	9.09	0	0.00		
	Tubular adenoma	1	3.03	0	0.00		

**Table 5:** Relationship between breast mass recurrence and patients’ characteristics and lesion features

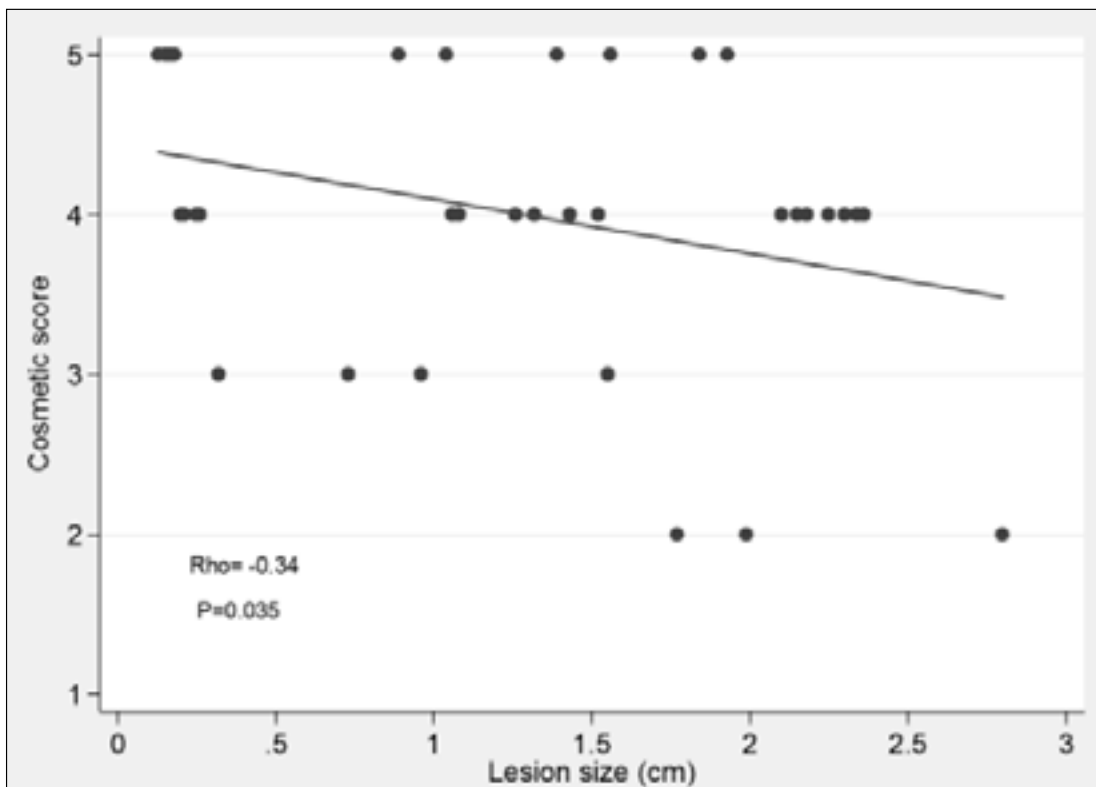
\*n.=6 as one patient had bilateral lesions

SD: Standard Deviation

FET: Fisher Exact Test

P: Probability

MW: Mann–Whitney test



**Figure 1** scatter graph showing correlation between cosmetic scores and lesion size.

Rho: Spearman correlation coefficient

P: Probability



Kettritz et al.<sup>(26)</sup>, showed hematoma formation.

In our investigation, only a mild hematoma (5.26%) that was treated conservatively was seen.

After VAB, infection is uncommon. Less than 0.10% of patients experience infection and need antibiotic therapy, according to Parker et al.<sup>(9)</sup>. According to Kettritz et al. (26), 0.17% of patients experienced mastitis that required antibiotic treatment.

## Results:

In our study no infection was reported.

In our study no significant relationships between the occurrence of complications following surgery and patients' demographics and mass features.

Hematoma was reported in 2 patients 5.26 %, Mild induration at the site of surgery 2 patients 5.26 %, Small contusion at the site of surgery in one patient 2.63 %.

And no other complication was reported.

The patient cosmetic satisfaction using the cosmetic scale from 1–5,

1: not satisfied, 2: low satisfaction, 3: mild satisfaction, 4: moderate satisfaction, 5: completely satisfied

The mean cosmetic score was 4.03.

Table 3 shows cosmetic satisfaction scores were more likely lower in patients with positive family history of breast mass compared to those with negative family history ( $3.0 \pm 0$  vs.  $4.08 \pm 0.84$ ;  $P=0.04$ ). the occurrence of complications was associated with lower cosmetic satisfaction scores ( $P=0.007$ ).

There was a significant negative correlation between the lesion size and cosmetic scores ( $\rho = -0.34$ ;  $P=0.035$ ) as demonstrated in Figure 1.

## limitation:

Insufficient sample size for statistical measurement.

Lack of previous studies in the research area.

## Acknowledgment:

Thanks to Dr. Hanaa E. Bayomy from Department of Family & Community Medicine, Faculty of Medicine, Northern Border University for her help for the statistical analysis.

## Statement conflict of Interest:

No conflict of interest to disclose.

## Ethics approval and consent to participate:

It has been approved by Specialized Medical Center committee

## Conclusion:

Vacuum assisted breast biopsy is reliable for the removal of small benign breast masses less than 2 cm with a satisfying cosmetic outcome in the majority of the patients & low recurrence rate and less complications

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