Original Article

Reconsidering the therapeutic use for vacuum-assisted breast biopsy in breast cancer patients: a retrospective single-center study

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Background: The management of breast cancer has evolved over the last few decades, with needle biopsy interventions now including vacuum-assisted breast biopsy (VABB). Previous studies have examined the utility of VABB for diagnosing breast diseases, although it remains unclear whether VABB is safe and effective for breast cancer. This study evaluated the residual tumor rate and prognosis of breast cancer patients who underwent VABB-based resection.

Methods: This single-center retrospective study evaluated data of 89 Chinese female patients who underwent VABB between January 2011 and December 2018 and had confirmed malignancy on pathological diagnosis. All patients had complete clinical, treatment, and follow-up records. Outcomes were compared according to whether there was residual tumor after the VABB, as well as the time from the VABB to the surgery.

Results: Residual tumor was detected for 62 of the 89 patients (69.6%). When we compared the residual and non-residual groups, we detected significant differences in the ultrasonography-determined diameter (P=0.002) and morphology (P=0.000) of tumor bed after VABB. T classification was also significantly different in the residual and non-residual groups (P=0.001). However, no significant differences were observed when we compared the resected and residual tumors histopathologically (all P>0.05). We did not detect significant differences in disease-free survival (DFS) when we compared the residual and non-residual groups over a median follow-up time of 52.3 months. However, in the residual group, a longer time to surgery after VABB (>31 days) was associated with significantly shorter DFS.

Conclusions: While previous studies have indicated that VABB can be used for early breast cancer, we observed a residual tumor rate of 69.6%, which is consistent with previously reported results. If there is a strong suspicion of breast cancer based on the preoperative examination, the surgeon must be careful to reduce the risk of residual tumor whenever possible, and should also consider performing standard surgery after VABB.

Keywords: Vacuum-assisted breast biopsy (VABB); breast neoplasms; residual tumor; prognosis

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Introduction

Based on the latest data in 2019 (1), breast cancer accounts for approximately 30% of new cancer cases and is the most prevalent malignant tumor in American women. New techniques in medical imaging, which include mammography, ultrasonography (US), and magnetic resonance imaging (MRI), have improved the early diagnosis of breast cancer. Furthermore, these imaging modalities have facilitated imaging-guided breast biopsy, including image-guided fine needle aspiration biopsy (FNAB), core needle biopsy (CNB), vacuum-assisted breast biopsy (VABB), and fine needle localization. Moreover, the concept of minimally invasive surgery has been increasingly applied to breast cancer treatment.

The VABB technique has been widely used for diagnosing breast lesions (2), especially for multiple or non-palpable breast masses and microcalcifications of extreme size (3). In 2002, the US Food and Drug Administration (FDA) approved VABB for the removal of benign lesions, as it is considered safe, provides effective complete excision, and cosmetic benefits (4). Previous studies (3,5) have evaluated the usefulness and safety of VABB; it is believed that VABB could replace FNAB and CNB for the diagnosis of breast disease. In a recent systematic review and meta-analysis of 20,000 people from 36 longitudinal studies (6), the pooled data suggested that VABB with US or mammography could be promising for the diagnosis of breast disease.

The diagnostic usefulness of VABB in breast diseases has been proved over the years (7,8), and is even being explored in breast lesions that cannot be detected by other imaging modalities (9,10). The development of VABB has enabled the excision of benign breast tumors and complete excision is possible without residual tumor tissue (3,6). VABB has proven useful even for phyllodes tumors, which have a tendency of recurrence; using VABB to excise benign phyllodes tumors showed a low recurrence rate of 7.46% during the follow-up period (11). Researchers have also tried to evaluate the use of VABB in breast-conserving surgery (12,13). However, there is little evidence regarding the therapeutic indications for VABB in breast cancer, given the lack of long-term follow-up data.

Therefore, this single-center retrospective study evaluated Chinese breast cancer patients who had undergone VABB. We aimed to evaluate the rate of residual tumor remaining after the VABB procedure, the time to surgery after VABB, and any differences in pathological findings between the excised and residual tumors. We presented the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/tcr-19-2906).

Methods

This study's retrospective protocol was approved by the Peking Union Medical College Hospital Institutional Review Board (S-K930). Following consensus guidelines (8), we confirmed that there were no contraindications to surgery. Only mass lesions that could be positioned by preoperative US-guided VABB were included. A Samsung Medison linear transducer was utilized for the US examination. The Mammotome systems were from Johnson Companies and appropriate types of rotary cutter were selected according to the size of the targeted lesions. The VABB process included routine disinfection, VABB equipment preparation, anesthesia, placement of the rotary cutter and performance of the rotary excision until the operation was completed under US monitoring. At the end of the resection operation, re-examination of the tumor bed under US was also performed to ensure that there was no residual lesion.

We identified 89 Chinese women who underwent VABB between January 2011 and December 2018 and were confirmed as having breast cancer, including *in situ* or invasive malignant lesions. The pathological results of all enrolled patients from the VABB were evaluated by at least two pathologists at our hospital. The pathological diagnostic criteria were based on the World Health Organization Classification of Breast Tumors (14), and molecular classification was based on the St. Gallen Consensus criteria (15). Data that couldn't be classified were recorded as "unknown" in the tables. Patients were excluded if they were pregnant or lactating, had distant metastasis at the initial diagnosis, or had undergone palliative resection or neoadjuvant chemotherapy.

Two ultrasonologists assessed the breast lesion's morphology and blood flow signals. Each patient was provided a personalized surgical plan based on their preference and the National Comprehensive Cancer Network guidelines (16). Postoperative adjuvant chemotherapy, radiotherapy, endocrine therapy, or targeted therapy was provided according to the pathological results from the resected and residual tumors. Targeted therapy mainly referred to adjuvant trastuzumab in the treatment of human epidermal growth factor receptor 2 (Her-2) positive

breast cancer patients.

The enrolled patients were divided into two groups: residual and non-residual. Patients in the residual group had a residual tumor in the postoperative pathology of open surgical excision, whereas no residual tumor was identified in the non-residual group. All patients underwent follow-up using clinical examinations and comprehensive imaging examinations, including US, mammography, computed tomography, and even positron emission tomography if necessary. Because death was a rare outcome in this time frame and it was too short to analyze overall survival, we used disease-free survival (DFS) as the endpoint, defined as the duration from the date of initial diagnosis of breast cancer to the first time of breast cancer-specific recurrence or distant metastasis. Recurrence or distant metastasis during the follow-up period was evaluated using the Kaplan-Meier method. All statistical analyses were performed using IBM SPSS software (version 24.0), with the χ^2 test or Fisher's exact probability text as appropriate. Differences were considered statistically significant at P values of <0.05.

Results

Patient characteristics

Based on the inclusion and exclusion criteria, 89 patients were included, with a mean original lesion size of 1.76±0.90 cm. The mean number of biopsy samples was 8.9±6.6 in our study, since most of the tumors were less than 2 cm in size. The number of samples varied due to the size and shape of different lesions; precise positioning is also an important factor when considering the number of specimens removed. Among the patients, 62 had residual tumors after the VABB (69.6%). The mean patient age was 44.3 years (range: 28–57 years), although no significant inter-group differences were observed in age (*Table 1*). When we compared the groups with and without residual tumor, we failed to detect significant differences in the maximum resected tumor size (1.30±0.42 *vs.* 1.22±0.39 cm, P=0.418), Breast Imaging-Reporting and Data System (BI-RADS) classification (17), histological type, and histological grade. The difference in the breast cancer subtypes may have been related to the unclear immunohistochemical staining results for some patients.

All patients underwent breast US before surgery, which revealed a significant inter-group difference in the tumor bed lesions' maximum diameters (1.76±0.49 *vs.* 1.36±0.68 cm, P=0.002). The US-determined morphology and blood flow signals were also evaluated preoperatively according to the BI-RADS system. All the patients in the residual group had irregularly shaped lesions, while 52.6% of the patients in the non-residual group had irregular morphology. The blood flow signal grades were predominantly grade 0–I in the non-residual group, while approximately one-half of the results were grade II–III in the residual group (P=0.000).

Comparison of treatments and TNM staging between the two groups

The mean time from VABB to surgery was 29.97±11.73 days in all patients. *Table 2* showed that both groups had similar time to surgery after the VABB (31.45±11.61 *vs.* 26.56±11.50 days, P=0.072). There were also no significant differences in surgical technique, chemotherapy, endocrine therapy, radiotherapy, targeted therapy, or breast-conservation rate (40.3% *vs.* 44.4%).

The average maximum diameter of the residual tumors was 0.69 cm (range: 0.1–6 cm). All patients were staged according to the 8th edition of the American Joint Committee on Cancer guidelines (18). The primary tumors in the non-residual group were all <2 cm, while 29% of patients in the residual group had T classifications of T2–3, and this difference was statistically significant (P=0.001). All patients in the non-residual group were considered TNM stage I, while 32.3% of the patients in the residual group were considered stage II–III (P=0.054). We also made subgroup analyses to see how tumor size could influence the rate of total resection of the lesions (*Table 3*). There was a rising residual rate with an increasing tumor size.

Pathological consistency between the resected and residual tumors

Some researchers have expressed concerns regarding the accuracy of preoperative VABB for determining the pathological characteristics of breast diseases (19,20). Therefore, we compared the pathological findings between the excised and residual tumors (*Table 4*). Twenty-nine patients were diagnosed with invasive ductal carcinoma based on the VABB, which was ultimately confirmed by the postoperative pathological diagnosis. In the residual group, comparisons of the histopathological findings between the resected and residual tumors revealed no significant differences (all P>0.05).

Table 1 Baseline characteristics of the 89 patients who underwent vacuum-assisted breast biopsy

Variable	No. (%)		χ^2	P
	Residual group	Non-residual group		
Total	62	27		
Age group (years)			0.059	0.808
≤35	8 (12.9%)	4 (14.8%)		
>35	54 (87.1%)	23 (85.2%)		
BI-RADS classification			1.220	0.921
3	27 (43.5%)	13 (48.1%)		
4	29 (46.8%)	13 (48.1%)		
5	4 (6.5%)	1 (3.7%)		
Unknown	2 (3.2%)	0 (0.0%)		
Maximum size of resected tumors			0.816	0.418
Mean ± SD (cm)	1.30±0.42	1.22±0.39		
Histological type			0.836	0.658
DCIS	11 (17.7%)	7 (25.9%)		
IDC	29 (46.8%)	12 (44.4%)		
DCIS + IDC	22 (35.5%)	8 (29.6%)		
Histological grade			3.774	0.169
I	19 (30.6%)	10 (37.0%)		
II	28 (45.2%)	15 (55.6%)		
III	11 (17.7%)	2 (7.4%)		
Unknown	4 (6.5%)	0 (0.0%)		
Breast subtype			11.324	0.010
Luminal A	24 (38.7%)	17 (63.0%)		
Luminal B	28 (45.2%)	4 (18.5%)		
Her-2	0 (0.0%)	0 (0.0%)		
Triple negative	4 (6.5%)	3 (18.5%)		
Unknown	6 (9.7%)	0 (0.0%)		
Lesion size by US after VABB			3.117	0.002
Mean ± SD (cm)	1.76±0.49	1.36±0.68		
Lesion morphology by US after VABB			38.149	0.000
Regular morphology	0 (0.0%)	14 (51.9%)		
Irregular morphology	62 (100.0%)	13 (48.1%)		
Blood flow signal grade via US after VABB			18.773	0.000
0	25 (40.3%)	21 (77.8%)		
I	8 (12.9%)	6 (22.2%)		
II–III	29 (46.8%)	0 (0.0%)		

SD, standard deviation; IDC, invasive ductal carcinoma; DCIS, ductal carcinoma in situ; Her-2, human epidermal growth factor receptor 2; US, ultrasound; VABB, vacuum-assisted breast biopsy.

Table 2 Treatments for the residual and non-residual groups after vacuum-assisted breast biopsy

Variable	No. (%)		χ^2	P
	Residual group	Non-residual group		
Time to surgery after VABB			1.841	0.072
Mean ± SD (days)	31.45±11.61	26.56±11.50		
Surgery type			0.132	0.717
BCS	25 (40.3%)	12 (44.4%)		
Mastectomy	37 (59.7%)	15 (55.6%)		
Axillary staging methods			3.828	0.147
SLNB	26 (41.9%)	9 (33.3%)		
ALND	36 (58.1%)	18 (66.7%)		
Hormone therapy			3.013	0.083
Yes	58 (93.5%)	22 (81.5%)		
No	4 (6.5%)	5 (18.5%)		
Chemotherapy			3.174	0.075
Yes	26 (41.9%)	6 (22.2%)		
No	36 (58.1%)	21 (77.8%)		
Radiotherapy				
Yes	25 (40.3%)	8 (29.6%)	0.922	0.337
No	37 (59.7%)	19 (70.4%)		
Targeted therapy				
Yes	7 (11.3%)	1 (3.7%)	1.323	0.250
No	55 (88.7%)	26 (96.3%)		
Size of residual tumors			4.466	0.000
Mean ± SD (cm)	0.69±0.81	0±0		
Tumor staging			19.637	0.001
Tis	4 (6.5%)	0 (0.0%)		
T1a	0 (0.0%)	0 (0.0%)		
T1b	2 (3.2%)	7 (25.9%)		
T1c	38 (61.3%)	20 (74.1%)		
T2	17 (27.4%)	0 (0.0%)		
T3	1 (1.6%)	0 (0.0%)		
TNM staging			16.879	0.054
0	7 (11.3%)	0 (0.0%)		
I	35 (56.5%)	27 (100.0%)		
II	12 (19.4%)	0 (0.0%)		
III	8 (12.9%)	0 (0.0%)		

BCS, breast-conserving surgery; SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection; Tis, carcinoma in situ; T1a, tumor size of 0.1–0.5 cm; T1b, tumor size of 0.5–1 cm; T1c, tumor size of 1–20 mm; T2, tumor size of 20–50 mm; T3, tumor size of >50 mm.

Follow-up

All patients had available follow-up data, with a median follow-up time of 52.3 months (range: 8–100 months). Patients were censored on September 30, 2019, at which point all patients in the non-residual group were alive, including 2 patients who had experienced local recurrence. At that same point, some patients in the residual group had experienced local recurrence of breast cancer (3 patients, 4.8%), bone metastasis (1 patient, 1.6%), or lung metastasis (3 patients, 4.8%). When we compared the residual and non-residual groups, we failed to detect significant differences in DFS (log-rank P=0.53) (*Figure 1*).

We also subdivided the residual group according to the time between the VABB and surgery (cut-off: 31 days), and our analyses failed to detect significant differences in tumor classification (P=0.73) or TNM stage (P=0.621). A longer time to surgery was associated with significantly shorter DFS in the residual group (log-rank P=0.009) (*Figure 2*).

Table 3 Subgroup analyses of residual tumor rate based on tumor size

Variable	No. (%)		P
	Residual group	Non-residual group	
Tumor size T (cm)			<0.001
T ≤1	2 (22.2%)	7 (77.8%)	
1< T ≤2	38 (65.5%)	20 (34.5%)	
T >2	17 (100%)	0 (0%)	

Discussion

The VABB device was developed in the 1990s by California radiologist Fred Burbank and medical device engineer Mark Retchard to address the limitations of CNB (21). In 2002, VABB was approved by the US FDA as a diagnostic tool for localized biopsy of breast lesions. The VABB device consists of a rotating cutter head and a vacuum suction system, which provides clear benefits compared with CNB. For example, tissues can be sucked out through the vacuum system, which allows for multiple tissue samples to be obtained without repeated punctures (22). The VABB was originally intended to facilitate a pathological diagnosis,

Table 4 Comparison of pathological findings between the resected and residual tumors

Variable	No. (%)		χ^2	P
	Resected tumors	Residual tumors		
Histological type			1.567	0.457
DCIS	11 (17.7%)	16 (25.8%)		
IDC	29 (46.8%)	29 (46.8%)		
DCIS + IDC	22 (35.5%)	17 (27.4%)		
Histological grade			7.477	0.058
I	19 (30.6%)	15 (24.2%)		
II	28 (45.2%)	40 (64.5%)		
III	11 (17.7%)	7 (11.3%)		
Unknown	4 (6.5%)	0 (0.0%)		
Breast subtype			10.412	0.015
Luminal A	24 (38.7%)	14 (22.6%)		
Luminal B	28 (45.2%)	34 (54.8%)		
Her-2	0 (0.0%)	0 (0.0%)		
Triple negative	4 (6.5%)	0 (0.0%)		
Unknown	6 (9.7%)	14 (22.6%)		

IDC, invasive ductal carcinoma; DCIS, ductal carcinoma in situ; Her-2, human epidermal growth factor receptor 2.

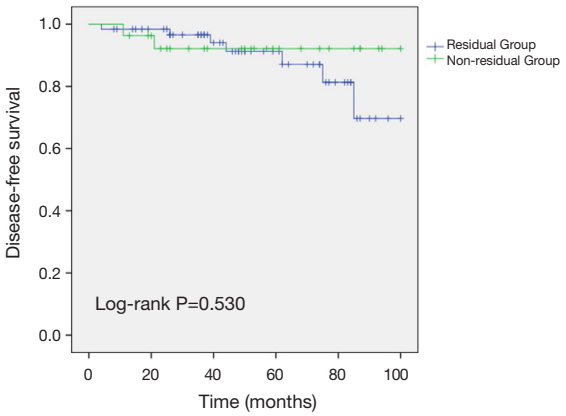

Figure 1 Disease-free survival (DFS) in the residual and non-residual groups.

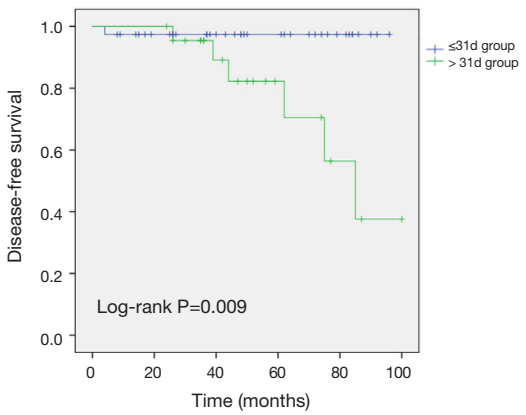

Figure 2 Disease-free survival (DFS) in the residual group according to the time to surgery.

although VABB has been clinically used for complete excision of benign breast tumors (23), especially unilateral or bilateral multiple benign breast lesions, clinically non-palpable breast lesions, or microcalcifications identified using mammography (24,25).

However, the therapeutic value of VABB for breast cancer remains controversial, given the lack of high-quality data, and VABB is not currently recommended for breast cancer excision (3). A retrospective study (26) of 5,232 patients undergoing VABB revealed 61 malignant lesions (44 lesions were carcinoma *in situ* and 17 lesions were invasive carcinomas), and the study showed that VABB provided 100% sensitivity for breast cancer detection. We conclude that VABB could be used for the detection of early breast cancer and as a clinical diagnostic technique. Given that malignant tumors could invade and spread to other parts of the body, they are more likely to be incompletely resected, especially for irregularly shaped tumors that are identified via US before VABB (27). Previous studies (12,28,29) have also suggested that the residual tumor rates for breast cancer were 45.5–67%, which is similar to our rate of 69.6%. Nevertheless, it has been emphasized that maximal tumor control via breast-conserving surgery should be a priority (15), and it is not advisable to avoid radical resection because of the minimal invasiveness or cosmetic benefits of VABB.

The present study revealed that US-based morphology and blood flow signals from before surgery were related to residual tumor. This may be because invasive breast cancer cells can exhibit "burr" or "crab foot" US signs, with rich blood flow around the tumor. Some authors (30) suggests that single tumors with good morphology and benign tendency should be resected first, although the same head should not be used to remove bilateral or multiple lesions, given the possibility of unsuspected breast cancer. Thus US-determined diameter and morphology of tumor bed after VABB may have an indication for surgeons to decide the resection range in open surgery. In addition, the present study revealed inter-group differences in residual tumor diameter and T classification. Since tumor size is an important factor for minimally invasive treatment (31), we have also seen a rising residual rate with an increasing tumor size in this study. This is important because larger tumors (>3 cm) may not be feasibly removed via VABB, given that the rotating cutter head is approximately 2.6 cm (32). If negative margins cannot be confirmed, open surgery should be considered. Some researchers (13) have also tried to combine VABB with endoscopic minimally invasive breast-conserving surgery to improve the cosmetic outcomes, although they acknowledged that >2 cm tumors are not suitable for this technique, which also requires a longer procedure than open surgery.

The follow-up data from this study revealed that the residual tumor group had more recurrences and metastases, which may be related to the ratio of stage II–III patients. Nevertheless, we did not detect significant differences in DFS, given that most patients had early breast cancer (TNM stage 0–I). Thus, we evaluated the relevance of the time from VABB to surgery, and found that longer times were associated with shorter DFS in the residual group. Relative to open surgery under direct vision, the main complications of VABB are pain and ongoing post-procedural bleeding (3).

Furthermore, we speculate that there would be more circulating tumor cells in patients with a long time between VABB and surgery. Liquid biopsy refers to the use of circulating tumor DNA, circulating tumor cells and other non-invasive biomarkers such as long-stranded non-coding RNA, messenger RNA and microRNA, proteins and exons for early diagnosis, prognosis, monitoring clinical progression and treatment response in patients (33). Recent studies have applied liquid biopsy to traditional breast cancer screening for personalized diagnosis and breast cancer management (34); this may be a potentially useful application for identifying breast cancer patients with residual tumors after VABB.

Moreover, VABB is now mainly conducted in the outpatient department in China. Cross-provincial medical treatments could be rather complicated in some cases due to different medical care payment systems. Many patients will have to pay for VABB in the outpatient department at their own expense. We believe that, further selection of proper breast lesions for VABB would be a valid option in order to reduce the excessive operative costs (35,36).

Our study included breast cancer patients with survival data, and we also found an association between the time from VABB to open surgery with DFS in the residual group, which has seldom been provided in previous studies. However, the present study has several limitations. First, it was a retrospective review of a small sample of breast cancer patients who were treated at a single center. Given the small sample size, additional studies are needed to explore potential differences in the molecular subtypes. Second, not all the patients were eligible for or would consent to VABB. Third, the median follow-up time was only 52.3 months and longer follow-up may be needed to detect recurrence and metastasis from early breast cancer. Fourth, because of technical limitations at our center, the subtyping of the cases was imprecise and could not be assigned for approximately 25% of patients. Further studies may be needed to clarify any differences regarding breast cancer subtype.

Conclusions

The present study revealed that VABB was associated with a substantial residual tumor rate in breast cancer cases, and that further extended surgery is always essential. Based on our experience, VABB should not be considered for malignant breast tumors with a diameter of >2 cm or in cases with an anticipated prolonged time to surgery. Nevertheless, given the limited existing data, additional large studies with long follow-ups are needed to clarify the safety and efficacy of VABB for breast cancer. Moreover, it is important to include cost analyses based on the overall economic cost of open surgery.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at http://dx.doi.org/10.21037/tcr-19-2906

Data Sharing Statement: Available at http://dx.doi.org/10.21037/tcr-19-2906

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/tcr-19-2906). 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 protocol was approved by the Peking Union Medical College Hospital Institutional Review Board (No. S-K930). Written informed consent was obtained from the patient for publication of this study and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

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