The influence of preoperative biopsy on the surgical method in breast cancer patients: a single-center experience of 3,966 cases in China

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Background: The National Surgical Adjuvant Breast and Bowel Project (NSABP) B32 trial reported that the detection rate of sentinel lymph nodes by core needle biopsy (CNB) is higher than that by segmental resection. However, there are few reports regarding the detection rate of sentinel lymph nodes by vacuum-assisted breast biopsy (VABB). Therefore, we analyzed the impact of preoperative biopsy methods on the surgical modes of 3,966 patients with breast cancer in our center.
Methods: In total, 3,966 female breast cancer patients [clinical tumor node metastasis (TNM) stage I–III] were enrolled in this study. Preoperative pathological diagnosis methods included fine needle aspiration (FNA) biopsy, CNB, excision biopsy, and VABB. According to the time of diagnosis. The data were analysis by chi square test, variance analysis and the Kaplan-Meier time series in SPSS 22.0.
Results: There was a decrease in the number of patients that underwent excision biopsy (7.3% to 2.7%) and intraoperative freezing (89.4% to 28.9%) over time, while CNB exhibited an increasing trend (1.6% to 55.3%). The positive rates of VABB, CNB, excision biopsy, and FNA were 99.5%, 97.1%, 97.9%, and 82.2%, respectively, and the false negative rates were 0%, 1.8%, 0.34%, and 8.9%, respectively. The overall breast-conserving rate was 36.7%, while the breast-conserving rate for VABB was 57.1%. The axillary sentinel lymph node biopsy rate of cN0 patients was 48.3%, and the intraoperative frozen group (36.7%) and excision biopsy group (39.5%) were lower than the CNB (57.1%) and VABB (77.9%) groups. Until December 2019, there were 350 cases with tumor recurrence or metastasis. The methods of biopsy were not correlated to the cumulative survival time.
Conclusions: Changes to the diagnosis and treatment of breast cancer has a profound impact on the method of tumor biopsy. VABB biopsy offers advantages such as accurate diagnosis, a greater volume of tissue taken at one time, minimally invasive and repeatable, and does not affect the surgical approach and prognosis of patients. It will gradually become the primary method of preoperative pathological evaluation of breast cancer.

Keywords: Breast cancer; core needle biopsy (CNB); excision; vacuum-assisted breast biopsy (VABB); overall survival

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Introduction

Breast cancer is the most common malignancy in women. With the progress of research, the methods of tumor treatment have become increasingly standardized. Individualized treatment, such as breast-conserving surgery, axillary sentinel lymph node biopsy, and new adjuvant therapy, as well as patient participation in the treatment decision, requires more precise preoperative tumor biopsy. The traditional methods of preoperative tumor biopsy, including resection biopsy, core needle biopsy (CNB), or fine needle aspiration (FNA) biopsy, have been shown to be safe and have no impact on the prognosis of patients (1-4). With the development of biopsy diagnosis technology and the increased popularity of the newly developed vacuum-assisted breast biopsy (VABB) such as Mammotome biopsy (Devicor® Medical Products, USA) and Cassi biopsy (Scion Medical Technologies, USA), these methods will play an increasingly important role in the diagnosis of breast cancer. However, there is no long-term research reporting on whether this novel biopsy mode is consistent with the traditional biopsy methods in terms of its surgical procedure and impact on the prognosis of breast cancer patients. This study reviewed the breast cancer biopsy data in our center for 20 years, summarized the differences between the novel preoperative biopsy VABB approach and the traditional biopsy techniques, and discussed its influence on treatment decisions and prognosis.

We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/gs-21-7).

Methods

From January 1998 to May 2019, a total of 5,109 newly treated breast cancer patients were admitted to our center. The exclusion criteria flow chart is shown in *Figure 1*. There were 3,966 cases with tumor node metastasis (TNM) stage I–III female breast cancer patients undergoing radical surgery for the first time. Preoperative pathological diagnosis methods included FNA, CNB, excision biopsy, VABB, and Cassi biopsy. If the pathological diagnosis of the biopsy was clinically suspicious, the tumor could not be confirmed by puncture, and the patient refuses biopsy, further resection biopsy and intraoperative frozen section was performed. According to the biopsy results, breast cancer can be divided into the following: confirmed breast cancer, undetermined diagnosis (including suspicious tumors, atypical hyperplasia, undetermined diagnosis such as undetermined papillary tumors or only a small amount of dysplasia), false negative puncture sample, or frozen section without tumor tissue. The diagnosis was reconfirmed by freezing. Resected specimens from other hospitals were reconfirmed by the pathology department in our hospital.

Statistical analysis

SPSS 22.0 software (IBM, USA) was used for statistical analysis. The chi square test and variance analysis were used to compare the different characteristics between all the groups. The Kaplan-Meier time series test was used to analyze survival time of different biopsy groups. Log rank was used to compare the survival time, and $P<0.05$ was considered as the statistically significant standard.

This study was approved by Medical Ethics Committee of Sir Run Run Shaw Hospital (Approval NO: 2020-618-01). All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). Individual consent for this retrospective analysis was waived.

Results

There were 3,966 cases analyzed in this study, including eight cases of simultaneous bilateral cancer and nine cases of isochronous bilateral cancer. Ninety-four cases were associated with other malignant tumors, including 44 cases of thyroid cancer, 27 cases of lung cancer, nine cases of colorectal cancer, three cases of ovarian cancer, three cases of more than three primary cancers, and eight cases of other malignant tumors. The median age of included patients was 51 years (range, 21–89 years). Notably, there were 2,071 cases with breast tumors on the left side and 1,895 cases with breast tumors on the right side. Furthermore, there were 2,073 premenopausal cases, 1,811 menopausal cases, and 82 cases of unknown menstrual state.

According to the time of diagnosis, the results can be divided into five periods: 1998 to 2002, 2003 to 2007, 2008 to 2012, 2013 to 2017, and 2018 to May 2019. *Table 1* shows the development of tumor biopsy methods among these five time periods. Over time, there was a decrease in local resection (7.3% to 2.7%) and intraoperative frozen section (89.4% to 28.9%), while CNB diagnosis increased every year (1.6% to 55.3%). In 2009, the proportion of breast cancer diagnosed by VABB increased from 0.3% to 13.0%,

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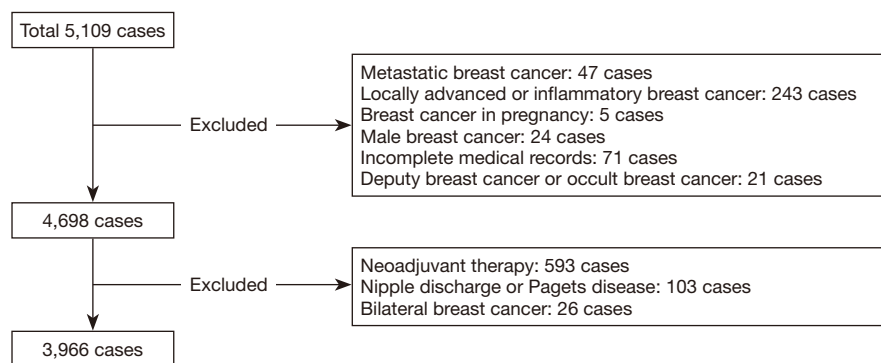
Figure 1 The flow chart for exclusion criteria of 5,109 newly treated breast cancer patients. There were 3,966 cases with TNM stage I–III female breast cancer patients were included in this study.

Table 1 Development of preoperative tumor biopsy techniques in five time periods

Characteristics and biopsy techniques	CNB	Intraoperative frozen resection	Local resection	VABB	FNA	Total	P value
Median age	52	50	45.5	48	51		
Cases	1,815	1,747	170	189	45	3,966	
Development of preoperative biopsy techniques in five time periods							<0.001
1998–2002	2 (1.6)	110 (89.4)	9 (7.3)	0	2 (1.6)	123	
2003–2007	64 (19.4)	226 (68.5)	21 (6.4)	1 (0.3)	18 (5.5)	330	
2008–2012	228 (31.9)	419 (58.6)	51 (7.1)	6 (0.8)	11 (1.5)	715	
2013–2017	1,043 (53.9)	742 (38.4)	66 (3.4)	70 (3.6)	13 (0.7)	1,934	
2018–2019	478 (55.3)	250 (28.9)	23 (2.7)	112 (13.0)	1 (0.1)	864	
Diagnostic efficiency of different biopsy							<0.001
Confirmed diagnosis	1,762 (97.1)	1,711 (97.9)	170	188 (99.5)	37 (82.2)	3,868	
Unconfirmed diagnosis	20 (1.1)	30 (1.7)	0	1 (0.5)	4 (8.9)	55	
False negative	33 (1.8)	6 (0.3)	0	0	4 (8.9)	43	
Tumor biopsy influence on surgical approach							<0.001
Mastectomy							
Yes	1,115	1,177	99	81	36	2,508	
No	700	570	71	108	9	1,458	
Sentinel lymph node biopsy *n=3,598							
Yes	934 (57.1)	585 (36.8)	60 (39.5)	145 (77.9)	15 (45.4)	1,739 (48.3)	
No	703	1,005	92	41	18	1,859	

Data are n or n (%). *, cN0 or cN1 but FNA negative. VABB, vacuum-assisted breast biopsy; FNA, fine needle aspiration; CNB, core needle biopsy; SLNB, sentinel lymph node biopsy.
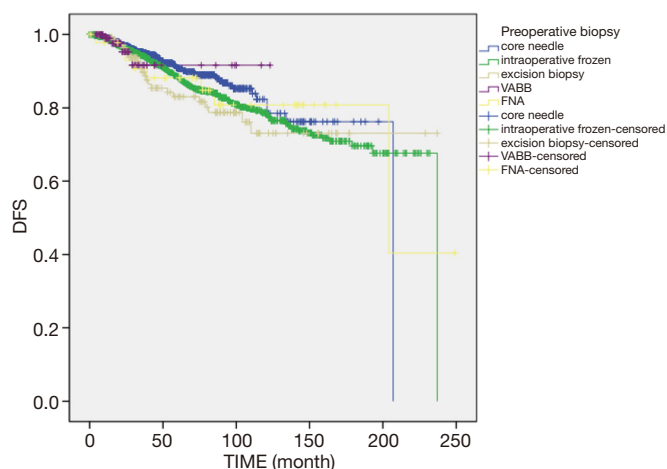
Figure 2 The biopsy method and the disease-free survival time. The 1-, 3-, 5-, 7-, 10-, 15-year tumor free survival was 98.8%, 94.3%, 89.2%, 85.6%, 79.9% and 71.8% respectively. Log rank survival analysis showed that tumor biopsy is not correlated with tumor free survival (χ^2=2.668, P=0.102). CNB, core needle biopsy; VABB, vacuum-assisted breast biopsy; FNA, fine needle aspiration.

and the difference was statistically significant (χ^2=606.479, P=0.000, *Table 1*).

The final pathological diagnosis rate of five preoperative biopsy methods is shown in *Table 1*. The diagnosis rate of VABB was 99.5% (188/189), CNB was 97.1% (1,762/1,815), local resection was 97.9% (1,711/1,747), and FNA was 82.2% (37/45), while the false negative of these methods was as follows: 1.8% (33/1,815), 0.34% (6/1,747), 0% (0/170) and 8.9% (4/45), respectively, and the difference was statistically significant (χ^2=72.423, P=0.000). It is suggested that VABB is the most effective method for the preoperative diagnosis of breast cancer, and CNB can replace local resection biopsy. In the ductal carcinoma *in situ* (DCIS) group, the false negative rates of CNB and local resection biopsy were 5.1% (5/99) and 2.3% (5/219), respectively, while the ratio of tumors that could not be confirmed in the CNB group was 8.1% (8/99), and was 9.1% (20/219) in the local resection biopsy group (χ^2=24.792, P=0.002). For invasive cancers, the false negative rate of the CNB and local resection biopsy groups was 1.3% (21/1,593) and 0% (0/1,351), respectively, and the ratio of tumors that could not be confirmed in these groups was 0.3% (5/1,593) and 0.4% (6/1,351), respectively (χ^2=66.853, P=0.000). Moreover, in the T1 group (tumor ≤2 cm), the false negative rates of CNB, local resection biopsy, and FNA were 2.3% (21/924), 0.3% (3/1,057), and 9.1% (2/22),

respectively, and the undetermined rates of tumor pathology were 1.3% (12/924), 1.8% (19/1,057), and 13.6% (3/22), respectively (χ^2=56.936, P=0.000)

In this study, the overall breast-conserving rate was 36.7%. The correlation between tumor biopsy and the breast-conserving rate is shown in *Table 1*. The breast-conserving rate of breast cancer confirmed by VABB was 57.1% (108/189), including 134 cases of incidental breast cancer [54.5% (73/134) of breast conserving rate] and 55 cases of breast cancer confirmed by VABB biopsy (63.6% of breast conserving rate). The breast-conserving rate in the local resection group was 41.7%, which was higher than the overall breast-conserving rate. It has been suggested that VABB and preoperative local tumor resection do not affect breast-conserving surgery. The immediate breast reconstruction rate in 69 patients who underwent mastectomy was 2.8%. The reconstruction rate in the VABB group 11.1% (9/81) was the highest, the FNA group was 0%, and the CNB group was 3.5% (*Table 1*).

The results showed that 3,600 cases of axillary cN0 or cN1 were preoperatively evaluated, however no lymph node metastasis was confirmed by FNA biopsy. 1,739 cases (48.3%, 1,739/3,600) of axillary sentinel lymph node biopsy were performed. The rate of sentinel lymph node biopsy in the frozen (36.7%) and the local resection (39.5%) groups was lower than that in the CNB (57.1%) and VABB (77.9%) groups. The successful rate of sentinel lymph node biopsy was 75.2% (1,307/1,739), which was not affected by the biopsy method (*Table 1*). The sentinel lymph node metastasis rate was 21.2% (368/1,739) in patients with cN0 or cN1 (negative axillary puncture).

Until December 2019, there were 350 cases of tumor recurrence or metastasis, 149 cases of death, and 47 cases that were loss to follow-up. The end points of the study were tumor recurrence, death due to other diseases, or recurrent breast cancer of the contralateral breast. The 1-, 3-, 5-, 7-, 10-, and 15-year tumor-free survival was 98.8%, 94.3%, 89.2%, 85.6%, 79.9%, and 71.8%, respectively. Log rank survival analysis showed that tumor biopsy was not correlated with tumor-free survival (χ^2=2.668, P=0.102) (*Figure 2*). The cumulative survival time was calculated based on the patient's death. The total 1-, 3-, 5-, 7-, 10-, and 15-year cumulative survival times were 99.9%, 98.2%, 96.0%, 93.4%, 90.2%, and 83.6%, respectively. There was no correlation between the biopsy method and the cumulative survival time (χ^2=0.364, P=0.546) (*Figure 3*).
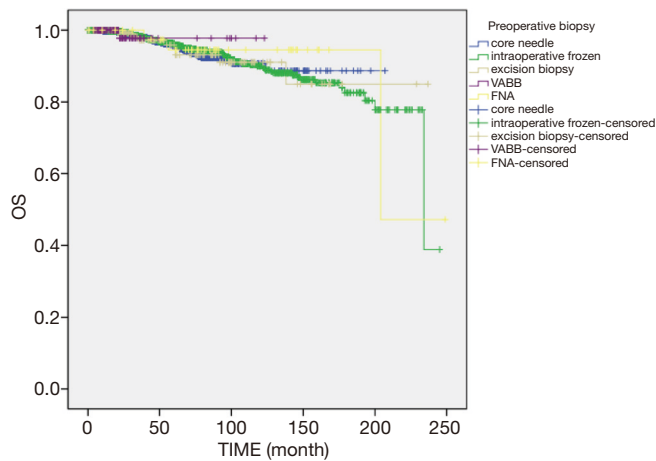
Figure 3 The biopsy method and the Overall survival time. The total 1-, 3-, 5-, 7-, 10-, 15-year cumulative survival time was 99.9%, 98.2%, 96.0%, 93.4%, 90.2% and 83.6% respectively. There was no correlation between the biopsy method and the cumulative survival time (χ^2=0.364, P=0.546). CNB, core needle biopsy; VABB, vacuum-assisted breast biopsy; FNA, fine needle aspiration.

Discussion

The purpose of this study was to review and analyze the preoperative biopsy data of breast cancer patients in our center from the past 20 years, and to observe the changes in preoperative pathological diagnosis modes for these patients. We also sought to examine the influence of VABB on treatment and prognosis. Previously, tumor resection biopsy (including intraoperative frozen section) was the main preoperative pathological diagnosis method for breast cancer. With the development of imaging and pathology, especially the understanding of molecular diagnosis of breast cancer, breast-conserving surgery, sentinel lymph node biopsy, axillary-conserving surgery, and new adjuvant treatment were carried out individually.

The proportion of tumor resection as a breast cancer diagnostic method has exhibited a decreasing trend over time, and is only used as a secondary option when CNB results are uncertain or inconsistent with imaging results (5). Technically, tumor resection biopsy is not a biopsy, but a partial mastectomy. After local tumor resection or intraoperative frozen section, the abnormal drainage of breast lymph nodes, together with the concerns of patients and doctors, led to a decrease in the rate of axillary sentinel lymph node biopsy. According to the data from our center, tumor resection biopsy (including intraoperative frozen

section) has decreased from 96.7% (119/123) before 2002 to 31.6% (273/864) after 2018. Axillary sentinel lymph node biopsy in the CNB (57.1%) or VABB (77.9%) groups was significantly higher compared to the tumor resection biopsy and intraoperative frozen group (39.5% and 36.8%, respectively). However, by using the double method tracing, some studies have reported that the successful rate of sentinel lymph node biopsy is 96% and the false negative rate is 10%, while in the preoperative biopsy group, the successful rate of sentinel lymph node biopsy is 95% and the false negative rate is 5.6%. It is believed that sentinel lymph node biopsy after breast tumor resection and biopsy is safe and feasible, but the false negative rate is slightly higher than that of the biopsy group (6). Puncture cytology can provide rapid confirmation of malignant diagnosis, and has been used as an early alternative to tumor resection and biopsy. However, the diagnostic performance of FNA varies according to the experience of operators and cell pathologists, and FNA shows a higher rate of non-diagnostic samples and false negative results (usually greater than 15%) compared to CNB, where false negative results are usually less than 5% (7,8). In 522 cases of breast cancer, FNA had a sensitivity of 68% and a specificity of 99.6%, while CNB had a sensitivity of 90% and a specificity of 98.8% (9).

In a meta-analysis, FNA was reported to have a sensitivity of 74% and a specificity of 96%, while ultrasound (US) or stereotactically guided CNB showed 87% sensitivity and 98% specificity (10). The results showed that FNA had a higher false negative rates and uncertainty (8.9%), while in DCIS cases, the false negative rates were 5.1% and 2.3%, respectively, and the pathological uncertainty rates were 8.1% and 9.1%, respectively. However, in invasive breast cancer, the false negative and uncertainty rates were very low for both groups. The false negative rates of CNB, local resection biopsy, and FNA were 2.3%, 0.3%, and 9.1%, respectively, and the rate of pathological uncertainty of these three biopsy methods was 1.3%, 1.8%, and 13.6%, respectively. It is suggested that the false negative of CNB is due to the inaccurate location of the focus, the insufficient amount of tissue obtained, and the puncture technique of the operator.

VABB technology was introduced into China in 1998, and the Food and Drug Administration (FDA) approved the complete resection of lesions in 2004. Since then, an increasing number of benign diseases indicated by imaging adopt minimally invasive circumcision instead of open breast segmental resection, resulting in a greater number

of incidental cancer cases of "benign" breast diseases (BI-RADS, Breast Imaging Reporting and Data System less than 4a) (11-15). VABB has been utilized in our hospital since 2009. The prevalence of incidental breast cancer detected by VABB ranged from 0.3% in the initial stage to 13.3% in the past 2 years. Furthermore, it has been reported that the learning curve time of VABB (4 weeks) is shorter than that of CNB (12 weeks) (16), and that there is a greater amount of tissue removed. Also, US-guided localization surgery is more suitable for *in situ* cancers, invasive cancers which need neoadjuvant therapy and more accurate evaluation of neoadjuvant therapy response (17-21). Compared to the negative predictive value and false negative rate of open surgical biopsy (99.61% and 4.76%), the negative predictive value of VABB was 99.77% and the false negative rate was 0.96% (22). These results demonstrated that VABB under the guidance of US exhibited the same diagnostic coincidence rate as that of segmental resection. There were no false negatives in 44 cases of carcinoma *in situ* and 110 cases of lesions less than 2 cm. After extended resection of the tumor in one case of uncertain pathology, intraoperative freezing was also unclear, and was then confirmed by immunohistochemistry. At the same time, VABB had a higher breast-conserving rate (57.1% *vs.* 41.8%) and sentinel lymph node biopsy rate (77.9% *vs.* 39.5%) compared to tumor resection. Recently, we also compared the medical economics of VABB and CNB, which differed from the previous literature (23), and showed that the overall medical costs of the VABB group were lower than those of the CNB group (24).

At present, whether percutaneous tumor biopsy will cause tumor cells to be implanted in soft tissue or skin around the tumor remains debatable (1-3,25-29). Previous studies have reported that the positive rate of cytological examination of CNB syringe lavage fluid can reach 65% (25), and pathological examination shows that the tumor implantation rate in the syringe can reach 50% (26). Other studies have reported that the prognosis of patients that undergo biopsy is significantly lower than that of patients with tumor resection (27). Diaz *et al.* reported that 32% of resected specimens were implanted in the needle channel, with 21.6% in 1–2 nests and 10.8% in multiple nests, while the tumor implantation rate in the CNB group was significantly higher than that of the VABB group (37% *vs.* 23%, P<0.05) (28). Uematsu *et al.* reported that the positive rate of VABB was 33%, and was 69% in CNB (29). The follow-up study showed that the tumor implantation

rate decreased gradually over time. The time from biopsy to tumor resection was less than 15 days, and the tumor cell implantation rate was 42%, while the rate decreased to 15% when the interval was more than 28 days. It has been suggested that the cells implanted in the needle canal cannot survive for a long time (28). There were no reports of needle implantation in Michalopoulos *et al.*'s study (30). Thurfjell *et al.* reported 303 cases of clinically untouchable breast cancer, with a median follow-up time of 5.4 years and a local recurrence rate of 11%. No radiotherapy was one of the causes of high recurrence (31), and the recurrence rate of radiotherapy was 3% lower compared that with no radiotherapy (32). Also, the local recurrence rate was less than 4% when only extended local resection was performed without radiotherapy (32). More clinical studies have shown that biopsy is not correlated to the local recurrence rate and overall survival. Therefore, preoperative biopsy is recommended as the standard technique for the preoperative diagnosis of breast cancer (4,33). According to the long-term follow-up prognosis data in this group, the preoperative biopsy mode had no effect on the prognosis of tumor-free and total survival time.

Conclusions

In summary, changes to the diagnosis and treatment of breast cancer have profoundly influenced and altered the methods of tumor biopsy. A more precise preoperative tumor biopsy mode was needed for comprehensive evaluation of patient information, especially pathological and molecular data, patients' participation in the whole treatment process, minimally invasive and sufficient tissue acquisition of the biopsy approach, and the repeatability of the biopsy. VABB biopsy will gradually become the main method of preoperative pathological evaluation of breast cancer. The overall success rate, sensitivity, and specificity of FNA, CNB, and VABB were not analyzed in this study. Due to the high overall success rate, multi-factor analysis was not conducted to identify the confounding factors of false negatives.

Acknowledgments

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Footnote

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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. This study was approved by Medical Ethics Committee of Sir Run Run Shaw Hospital, Comment (approval No. 2020-618-01). All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). Individual consent for this retrospective analysis was waived.

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