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Original Article

Ultrasound-guided vacuum-assisted breast biopsy using Mammotome biopsy system for detection of breast cancer: results from two high volume hospitals

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Abstract: Ultrasound-guided vacuum-assisted breast biopsy (VABB) has been recently regarded as a feasible, effective, minimally invasive and safe method for removal of benign breast lesions without serious complications. The frequency of detection of noninvasive malignant breast lesions by ultrasound-guided VABB is increasing. The aim of this study was to evaluate the role of the ultrasound-guided VABB using Mammotome biopsy system in the early detection of breast cancer. Retrospective review between January 2008 to March 2013 the First Affiliated Hospital, Zhejiang University School of Medicine and Taizhou Hospital, Wenzhou Medical College. From January 2008 to March 2013, a total of 5232 ultrasound-guided VABB procedures were performed in 3985 patients whose mean ages were 36.3 years (range: 16-73). The histological results of 5232 ultrasound-guided VABB were retrospectively reviewed. Ultrasonography follow-up was performed at 3 to 6 month intervals in order to assess recurrence. Two hundred twenty three high risk lesions (comprising 59 papilloma, 57 papillomatosis, and 107 atypical hyperplasia) and 61 malignant lesions (comprising 23 ductal carcinoma in situ, 21 lobular carcinoma in situ, 12 infiltrating ductal carcinoma, and 5 infiltrating mucinous carcinoma) were identified. Sensitivity (100%) and diagnostic accuracy (100%) regarding the detection of malignancy were excellent for ultrasound-guided VABB using Mammotome biopsy system. Our results indicate that ultrasound-guided VABB using Mammotome biopsy system is an accurate technique for the sampling, diagnosis, and early detection of breast cancer. It is recommended that the Mammotome biopsy system could be as the method of choice for detecting nonpalpable early breast cancer.

Keywords: Vacuum-assisted biopsy, breast cancer, early diagnosis, ultrasound guidance, Mammotome biopsy

Introduction

Throughout the last two decades the interest in early detection of breast cancer has increased steadily. Various breast cancer screening programs have been established worldwide. In this process the number of suspicious findings on mammography that are non-palpable and non-detectable with ultrasound has risen steadily. The most common way to confirm dignity of non-palpable and sonographically-occult suspicious findings on mammography is minimally invasive breast biopsy. Minimally invasive breast biopsy has proved to be an important technique in the diagnosis of breast cancer. Pathologists, radiologists, and surgeons have used a variety of biopsy techniques over the past 30 years. Each of these techniques varies in relation to the degree of invasion, ease of performance, and accuracy [1, 2].

With the development of minimally invasive breast biopsy systems such as fine-needle aspiration cytology, core needle biopsy, and vacuum-assisted biopsy, the diagnostic accuracy of breast lesions has been greatly improved [3]. Ultrasound-guided vacuum-assisted breast biopsy (VABB) has been widely adopted by surgeons as an alternative to the more invasive open surgical biopsy. This technique can be

performed rapidly in the outpatient setting, is easy to master, and is inexpensive when compared with open surgery. In cases of malignancy, a definitive diagnosis before operation results in fewer required surgical procedures [4].

However, the relative accuracy of ultrasound-guided VABB techniques is still an open question. Although there is extensive literature on stereotactic VABB, the ultrasound-guided VABB literature is limited. It is known that ultrasound-guided VABB techniques are more accurate than other biopsy techniques under stereotactic guidance. It does not follow necessarily that this is also true under ultrasound guidance, because the types of lesions seen sonographically are mass lesions, as opposed to calcified lesions, which are more frequently seen on mammogram [5].

Introduced in the late 1990s [6], the Mammotome biopsy system (Johnson & Johnson Corp., Ethicon Endo-Surgery, Cincinnati, OH, USA), an ultrasound-guided vacuum-assisted breast biopsy (VABB) system, has been suggested as a new strategy for breast diagnosis. With the help of ultrasound-guided VABB using Mammotome biopsy system, benign breast lesions can be excised, including surrounding normal tissue in a minimally invasive way; complete excision, without residual tissues is possible in most cases [7], which greatly prompted the complete excision of breast lesions in our daily practices.

The aim of this study was to evaluate the role of the ultrasound-guided VABB using Mammotome biopsy system (Johnson & Johnson Corp., Ethicon Endo-Surgery, Cincinnati, OH, USA) in the early detection of breast cancer.

Patients and methods

Patients

This study is approved by Institutional Review Boards in the First Affiliated Hospital, Zhejiang University School of Medicine and Taizhou Hospital, Wenzhou Medical College. In the period from January 2008 to March 2013, in the Department of Breast Surgery, the First Affiliated Hospital, Zhejiang University School of Medicine and Department of Surgical Oncology, Taizhou Hospital, Wenzhou Medical College, a total of 5232 ultrasound-guided VABB using Mammotome biopsy system (Johnson & Johnson Corp., Ethicon Endo-Surgery, Cincinnati, OH, USA) were performed in 3985 patients. All patients had a previously performed breast ultrasound, and those over the age of 35 years, mammography. The parameters analyzed included size of the lesion as shown in the mammogram or ultrasonogram, a peripheral or central location, or a lump detected in a physical examination. Clinical data including the Breast Imaging Reporting and Data System (BI-RADS) category for the lesions were also recorded [8]. None of the patients had discharge from the nipple. Considering the cost of the performance of ultrasound-guided VABB using Mammotome biopsy system was not accepted widely in China, a therapeutic strategy was formulated. Namely, the ultrasound-guided VABB procedures were always managed for the patients whose lesion(s) was (were) probably benign and equal or less than four in BI-RADS category. On the other hand, mere biopsy was allowed in suspicious malignancy cases (five in BI-RADS category) if the patient desired. In all cases, preoperative core-needle gun biopsy was not performed prior to ultrasound-guided VABB. Ultrasound-guided VABB was performed mostly in patients who were expected to have a difficult follow-up for lesions 3 cm or smaller according to the BI-RADS category 3 or 4 on ultrasonography, who planned to be pregnant, who felt extremely uneasy from their lesions, whose lesions enlarged during follow-up, and who complained of pains or symptoms. Additionally, this was performed in some patients who refused to undergo excision, though their lesions were larger than 3 cm, because they were concerned about breast scars. The patients who did not provide informed consent, allergic to the local anesthetic and active chest skin infections on the breast were disqualified from biopsy.

Surgical procedure

Before the ultrasound-guided VABB procedure, blood group and coagulation parameter examinations were evaluated. All the procedures were performed by two skilled surgeons and two ultrasound radiologists with experience by using the 8-gauge Mammotome biopsy system (Johnson & Johnson; Ethicon Endo-Surgery, Cincinnati, OH). Terason T3000 ultrasound system (Terason Division; Teratech Corporation; Burlington, MA) with high-resolution linear array

Table 1. Patients' features and lesion characteristics

Parameter		Patients (n=202)	%
Patient's age (years)	<35	78	38.6
	≥35	124	61.4
BI-RADS category	Category 4	150	74.3
	Category 5	52	25.7
Recurrence	Local recurrence	0	0
	New lesions	0	0
Parameter		Lesions (n=284)	%
Lesions location in the inner breast	Right breast	131	46.1
	Left breast	153	53.9
	Upper external quadrant	131	46.1
	Upper internal quadrant	57	20.1
	Lower external quadrant	88	31.0
	Lower internal quadrant	8	2.8
Size of the lesions	<15 mm	207	72.9
	>15 mm	77	27.1
Lesion characteristic	Non-palpable lesion	243	85.6
	Palpable lesion	41	14.4
	Single lesion	160	56.3
	Multiple lesions	124	43.7
	Right lateral lesion	112	39.4
	Left lateral lesion	84	29.6
	Bilateral lesions	88	31.0
	Solid	214	75.4
	Cystic or mixed	70	24.6

transducers (12L5A, 5-12 MHz) was used to offer real-time ultrasound guidance.

Patients were kept in supine position with the ipsilateral arm raised above the head and with operational area sterilized and draped. An ultrasonic assessment was performed again before the procedure. After local anesthetic consisting of 1% lidocaine containing a 1:100,000 mixture of epinephrine was applied, a 3-5-mm skin incision was made, which serves as the access for the 8-gauge probe. Under real-time ultrasound guidance, the probe was positioned beneath the lesion. To make localization accurate, the target lesion was rescanned longitudinally and transversely according to the probe. The needle was rotated at an angle of 45 degrees, to both sides, during the procedure, in order to completely excise the hypoechoic lesion on intraoperative ultrasonography and until normal fat tissue was verified grossly on core pieces. Multiple cores in different directions, as many as needed, were taken sequentially, also under ultrasound guidance. Postprocedure sonography evaluation was made to confirm complete excision. For hemostasis, direct compression was applied for 5 to 10 minutes immediately following the procedure; an elastic bandage was attached, and the patient took bed rest for 6 hours.

A frozen section of the resected specimen was examined intraoperatively for pathological confirmation. Tissue specimens were preserved in 10% formaldehyde solution and sent for histopathologic evaluation to the Department of Pathology. Whenever possible, a malignant lesion was treated by breast conserving tumorectomy followed by adjuvant radiotherapy and systemic therapy if indicated. Otherwise, the patient could go back to daily life the day after the procedure. The follow-up was carried out with ultrasonography and mammography, at intervals of 3 to 6 months, in order to identify recurrences.

Results

A total of 5,232 consecutive 8-gauge ultrasound-guided VABB procedures were per-

Table 2. Histopathologic characteristics (n=284)

Histopathological diagnosis	Types	Frozen section	Hematoxylin and eosin staining	Sensitivity (%)
		Lesions (n/%)	Lesions (n/%)	
High-risk	Papilloma	59/20.8	59/20.8	100
	Papillomatosis	57/20.1	57/20.1	100
	Atypical lobular hyperplasia	85/29.9	85/29.9	100
	Atypical ductal hyperplasia	22/7.7	22/7.7	100
	Total	223/78.5	223/78.5	100
Malignant	Ductal carcinoma in situ	23/8.1	23/8.1	100
	Lobular carcinoma in situ	21/7.4	21/7.4	100
	Infiltrating ductal carcinoma	12/4.2	12/4.2	100
	Infiltrating mucinous carcinoma	5/1.8	5/1.8	100
	Total	61/21.5	61/21.5	100

VABB, ultrasound-guided vacuum-assisted breast biopsy.

formed for 3,985 patients, whose mean age was 36.3 years (range: 16-73). Parameters of high risk and malignant lesions such as location in the inner breast, size of the lesion seen by ultrasonography and mammography, lesion characteristics, and data system for ultrasound category were presented in **Table 1**. A hundred and fifty patients (74.3%) were assessed by ultrasound to be BI-RADS category 4, and 52 (25.7%) category 5. Mean number of cores removed in the procedure was 8.2 (range: 3-32). The average number of lesions was 1.32 (range: 1-12) in the patients with high risk and malignant lesions. The size of the biopsy lesions ranged between 6 and 59 mm (average, 14.8 mm). 207 (72.9%) lesions were <15 mm, 77 (27.1%) lesions were >15 mm (**Table 1**). Multiple lesions, either lateral or bilateral, were detected in 43.7% of them. And 31.0% of the patients harbored bilateral lesions (**Table 1**). Over half (46.1%) of the lesions were localized in the upper external quadrant (**Table 1**).

In 202 patients with 284 lesions, the histopathologic diagnosis revealed that 223 (159 patients) high risk lesions (comprising 59 papilloma, 57 papillomatosis, and 107 atypical hyperplasia) and 61 (43 patients) malignant lesions (comprising 23 ductal carcinoma in situ, 21 lobular carcinoma in situ, 12 infiltrating ductal carcinoma, and 5 infiltrating mucinous carcinoma) (**Table 2**). Sensitivity (100%) and diagnostic accuracy (100%) regarding the detection of malignancy were excellent for ultrasound-guided VABB using Mammotome biopsy system. The mean follow-up period was 25.8 months (range, 1-63 months). No patients were identified to have recurrence (local recurrence or new lesion).

Discussion

The development of minimally invasive techniques, including VABB, made it an interesting alternative to open surgical biopsy in the diagnosis and treatment of focal lesions of the breast [9-11]. It is well tolerated by patients, is efficient, and is associated with a low number of complications. Its accuracy ranges between 98% and 100% [3] and is comparable to that of open surgical biopsy.

Breast carcinoma in China is the most common malignant tumor in female patients. The growing awareness of patients, fear of cancer, progress in imaging diagnostics, and relatively high availability of ultrasound examinations require effective verification of nodular breast lesions. Differential diagnostics of small, nonpalpable lesions suspected of malignancy is especially difficult. Until recently, the golden standard in such cases was open surgical biopsy. However, the possible complications, the duration of the procedure, costs, possible scarring, and breast deformations tend to seek less invasive and cheaper methods. In the past 10 years, minimally invasive breast biopsy system has gotten great development. As a kind of minimally invasive method, VABB has been shown to be safe and effective for the definitive diagnosis and treatment of benign breast lesions [8]. VABB is a minimally invasive procedure that can remove

lesions under ultrasonography guidance, without re-aim or re-insertion. It has many advantages over surgical excision, including good cosmetic results, minimal complications, patient convenience, and satisfaction. Initially, VABB was used for biopsy; later, with advancements in the understanding of the technique, it was used in attempts to excise lesions suspected to be benign tumors, such as fibroadenoma, fibrocystic lesions, adenosis, and papilloma [8].

Mammotome biopsy system (Johnson & Johnson Corp., Ethicon Endo-Surgery, Cincinnati, OH, USA), is a minimally invasive surgical technique that was introduced by Burbank et al. in 1996 [12], successfully marketed by Ethicon Endo-Surgery and approved to remove image evidence by US Food and Drugs Administration in 2004. The Mammotome biopsy system has been accepted as the standard of breast biopsy because it offered a new choice to eradicate these lesions by a minimal invasive approach. The Mammotome biopsy system procedure becomes an effective and safe therapeutic management when the targeted lesion is completely excised [13-16]. It could carry out the biopsy in a visible and reliable way because of stereotactic, ultrasound, and magnetic resonance guidance. Its probe could obtain much larger volume sample, resulting in high accuracy and specificity in pathologic diagnosis [3, 13, 17-20]. Worthwhile, its cosmetic outcome could satisfactorily match the requisite of breast surgery and the patient's acceptance. Therefore, Mammotome biopsy system procedure was highly recommended and was applied increasingly in the treatment of benign breast lesions [14, 15, 20-23]. Ultrasound guidance is applied more wildly at present because of its convenience [14, 15, 20-23].

Originally, this ingenious invention of the Mammotome biopsy system was approved for breast biopsy [20]. Later, ultrasonography was used to offer real time guidance and considerable progress was made by high-resolution linear transducer. In the practice of Mammotome biopsy system, complete excision was achieved and therapeutic management toward benign breast disease was carried out incidentally [16]. Increasing numbers of surgeons attempted similar therapeutic outcomes thereafter [14, 20, 21, 23-25]. When 8-gauge probe was applied, larger volume sampling and excision was possible [24]. As a result of the potential of complete excision, both biopsy and treatment for benign breast lesions was facilitated. Our clinical experience confirmed the 8-gauge probe was apt for the firm breast tissue because of its sharp scalpel point and especially for the complete removal of benign lesions under ultrasound guidance [24]. Considering its powerful capability to obtain sample and therapeutic notion, the 8-gauge probe was used from stem to stem in our series.

In the present study, a total of 223 (159 patients) high risk lesions and 61 (43 patients) malignant lesions were incidentally encountered and revealed in our series. Fortunately, most of them were early breast cancers (**Table 2**). More accurate histologic diagnoses can be made when a larger volume of tissue is available for examination. A diagnosis of high risk breast lesion, such as atypical ductal hyperplasia, stereotactic core biopsy warrants surgical excision of the atypical area because over 50% of these lesions harbor carcinoma at the time of surgical excision. In our study, all the lesions that were diagnosed as high risk breast lesions on ultrasound-guided VABB using Mammotome biopsy system have had the diagnosis confirmed at the time of surgical excision, which indicates an early diagnosis for our patients. It was reported that VABB was shown to reduce the false negative rate for carcinoma to 18% [26]. This rate is higher than in the current study, where all the cases diagnosed with ductal carcinoma in situ, lobular carcinoma in situ, infiltrating ductal carcinoma or infiltrating mucinous carcinoma on ultrasound-guided VABB using Mammotome biopsy system had the same diagnosis confirmed at surgical excision. None of our patients that were diagnosed to have ductal carcinoma in situ on VABB had any invasive component at surgical excision. This finding is superior to that reported with stereotactic core needle biopsy in other studies, where 16-31% of the biopsies reported to have ductal carcinoma in situ contained an invasive component at surgical excision [26-29]. We consider that the high accuracy rate in the histologic diagnosis of ultrasound-guided VABB using Mammotome biopsy system is related to the large volume of tissue obtained in each biopsy and the serial sectioning of each specimen on different levels.

It is worth noting that the ultrasound-guided VABB procedure cannot replace surgery for

breast cancer completely at present, although the malignant lesion can be completely excised. Although the standard procedure after diagnosis of malignant breast lesions by VABB is still controversial, routine surgical excision of malignant breast lesions is our recommendation. In this study, all the 43 patients with 61 malignant lesions were treated by breast conserving tumorectomy followed by adjuvant radiotherapy and systemic therapy if indicated. There is a common trend in the literature toward routine surgical excision of high risk breast lesions, such as papilloma, papillomatosis, and atypical hyperplasia detected by VABB to ensure adequate staging [30-37]. However, some authors still disagree because of the many cases of unnecessary removal of these lesions [38-40]. For these lesions, we considered that subsequent surgery is not mandatory but intensive clinical and radiologic supervision is necessary.

Conclusion

In summary, sensitivity (100%) and diagnostic accuracy (100%) regarding the detection of malignancy were excellent for ultrasound-guided VABB using Mammotome biopsy system. As its high sensitivity and accuracy for the detection of malignant breast lesions, we recommend the Mammotome system as the method of choice for detecting nonpalpable early breast cancer.

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Disclosure of conflict of interest

The authors report no conflicts of interest in this work.

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