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Full Length Research Paper

Evaluation on pathologic status of the residual lesions after ultrasound- guided, 8-gauge vacuum-assisted mammotome® system biopsy for nonpalpable malignant breast lesions and its influencing factors

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The vacuum-assisted Mammotome® system is now considered highly accurate for ultrasound-guided diagnostic biopsy and selective excision of suspicious breast lesions. Our goal is to evaluate the residual lesions pathologic status after ultrasound-guided, 8-gauge vacuum-assisted mammotome® system biopsy for nonpalpable malignant breast lesions, and to explore its influencing factors. A total of 281 patients with nonpalpable breast lesions underwent ultrasound-guided, 8-gauge mammotome® biopsy from August 2005 to February 2009, of whom 56 with malignant lesion received subsequent surgery. Multiple variables, including patient demographics, characteristics of the breast lesion (based on ultrasound and mammography), procedural and histopathological features were evaluated. A total of 56 (19.9%) of 281 lesions were diagnosed as pathological breast cancer by mammotome® excisional biopsy. 100% of all lesions were accurately diagnosed by ultrasound-guided mammotome® biopsy, and no further ultrasonographic evidence of lesions were noted among the 193 patients of benign pathologies that were compliant with follow-up. Of the 56 malignant cases, 41 (73%) lesions were completely excised (based on pathology), and the incidence rate of negative surgical margin was 93% during the subsequent breast-conserving surgery. There were significant correlations between the original ultrasound breast lesion size and shape with successful complete excision of nonpalpable lesion by the ultrasound-guided, 8-gauge mammotome® biopsy procedure. The ultrasound-guided, 8-gauge mammotome® breast biopsy system is highly accurate and successful for excisional biopsy of nonpalpable suspicious breast lesions. This procedure should be routinely applied in the treatment of patients with nonpalpable suspicious breast lesions.

Key words: Breast malignant lesion, ultrasound-guided, vacuum-assisted mammotome®, excisional biopsy.

INTRODUCTION

With the wide application of mammography and high-frequency ultrasound in screening of breast cancer, the detection rate of nonpalpable early-stage breast cancer is increasing higher and higher. Previous diagnosis of nonpalpable breast cancer was based on core needle biopsy guided by mammography and/or high-frequency ultrasound (Fuhrman et al., 1998; Verkooijen et al., 2000) but unfortunately, it is often associated with a high false

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negative rate and pathological underestimation rate (Staren and O'Neill, 1999; Smith et al., 2001). In recent years, vacuum assisted mammotome® biopsy technique has been developing rapidly. Breast tissue samples give different orientations depending on how they are obtained; from only one skin incision, with a large sample volume, it is widely used in minimally invasive diagnosis of breast cancer (Brem et al., 2001; Parker et al., 2001). This technology, the mammotome® breast biopsy system, was first utilized in stereotactic (mammographically-guided) applications (Burbank et al., 1996) and was thereafter, soon adapted for ultrasound-guided applications (Parker et al., 1996). Since that time, multiple reports have been published using ultrasound-guided mammotome® system in diagnosis of breast cancer. Furthermore, some physicians recommend that the 8-gauge Mammotome® system is the desired and optimal method both for accurate diagnosis of any suspicious ultrasound breast lesions and for complete excision (based on ultrasound) of appropriately selected presumed benign ultrasound lesions (Parker et al., 2001; Burak et al., 2000; Liberman et al., 1999; Simon et al., 2000; Inui et al., 2008). However, no single report has comprehensively outlined the evaluation of the residual lesions status (based on pathology) for nonpalpable malignant breast lesions after mammotome® system biopsy. The present study was carried out to evaluate the residual lesions status (based on pathology) after the ultrasound-guided, 8-gauge vacuum-assisted mammotome® biopsy system for nonpalpable suspicious breast lesions and the multivariate analysis of its influencing factors.

PATIENTS AND METHODS

The results of ultrasound (US)-guided mammotome® biopsy for 281 nonpalpable suspicious breast lesions treated at the Second People's Hospital of Shenzhen in a 4-year period were retrospectively reviewed from May 2005 to March 2009. The average age for these patients was 42 years. High frequency ultrasound and /or mammography screening were performed before mammotome® procedure. There were 139 patients with breast mass, 64 patients with mass and microcalcifications and 78 patients with breast calcifications alone. Sizes of these lesions ranged from 4 to 15 mm in diameter; the diameter of all calcifications was less than 1 mm, and the calcifications were present as two particles or a cluster of multiple particles. All the lesions evaluated by the 8-gauge mammotome® breast biopsy system were sonographically visible and were classified as BI-RADS (American College of Radiology Breast Imaging Reporting and Data System) category 3, 4, or 5. No suspicious axillary lymph node was detected by palpation and ultrasonography in all patients.

Color Doppler ultrasound apparatus has a 10 to 13 MHz broad and linear array probe (DU-8, Esaote, Italy); vaccum-assisted mammotome® biopsy system with an 8-gauge needle, a vacuum aspiration pump and a controller (Johnson and Johnson, USA). Ultrasound-guided mamotome® biopsy was performed in the 281 patients. After locally anesthetized with 10 to 20 ml, 1% lidocaine accompanied with epinephrine require a 22 G long needle layer by layer around needle tract and lesions, and position of the suspicious lesion. Then the needle was removed and the 8-gauge mammotome® needle was inserted toward the lesion along the tract of an acupuncture needle. The mammotome® blade flute was located behind the lesions and the lesions were excised in sector and cone shapes (Figure 1). All procedures were monitored by real-time ultrasound. The lesions were rotarly excised for multiple times, and were removed as completely as possible, with no further evidence of lesions detected sonographically. Normal breast tissues (based on ultrasound) around the lesions were also excised with an excision range exceeding cancer margin by 10 mm during these mammotome® procedures. The number of samples obtained was dependent on the size and the position of the needle relative to the lesions.

Patients whose lesions proved to be benign were asked to undergo US every 3 months post surgery; all the patients with premalignant or malignant pathology underwent subsequent surgery (partial mastectomy, simple mastectomy or modified radical mastectomy). Sentinel node biopsy (SLB) was performed during the subsequent surgery for pathological evaluation. We used a technique with methylene blue dye for sentinel lymphatic mapping (Simmons et al., 2003), and axillary lymph node dissection was performed if sentinel node had positive pathologically results.

The software program SPSS 13.0 for Windows (SPSS, Inc., Chicago, Illinois) was used for all statistical analyses. Continuous variables were expressed as mean ± SD and the differences between means were evaluated by using Student's t-test. For univariate comparisons of categorical variables, either Pearson chi-square test or Fisher exact test was utilized when appropriate. Multivariate logistic regression analysis was performed in appropriately selected situations on all variables with a univariate P-value of 0.05 or less, in order to assess for the determination of possible independent predictors. All reported univariate P-values were two-sided and determined to be 0.05 or less were considered to be significant.

RESULTS

Pathological evaluation of the 281 patients by mammotome® biopsy showed 225 cases (80.1%) of benign lesions (BI-RADS category3,4), including 92 fibroadenomas, 109 fibrocystic changes, 15 papillomas and 5 atypical ductal hyperplasia (ADH). 56 of the 281 lesions (19.9%) were proved malignant (BIRAD Scategory 3-5), including 36 ductal carcinomas in situ (DCIS), 4 extensive intraductal components (EIC), 14 invasive ductal carcinoma and 2 invasive lobular carcinoma(ILC). Duration of the Mammotome® procedure was 14 to 23 min (mean 18 min); amount of samples taken per patient was 15 to 28 core needles respectively (mean 23). No residual lesion was detected by high frequency ultrasound after mammotome® biopsy. Size of the biopsy cavity was 15×16×20 to 20×22×25 mm (mean18×20×23 mm) (Figures 2 - 4). No severe complication and re-biopsy was noted in the study. All of the 56 patients with malignant pathology and 9 ADH patients underwent subsequent surgery (partial mastectomy or simple mastectomy). Of the 216 benign lesion patients being asked to undergo US post surgery, 193 (89%) patients were compliant and returned for the interval follow-up breast US at a median time of 16 months (ranges from 3 to 42), and with no residual ultrasound lesion visible, while 23 (11%) were noncompliant and did not return for interval follow-up.

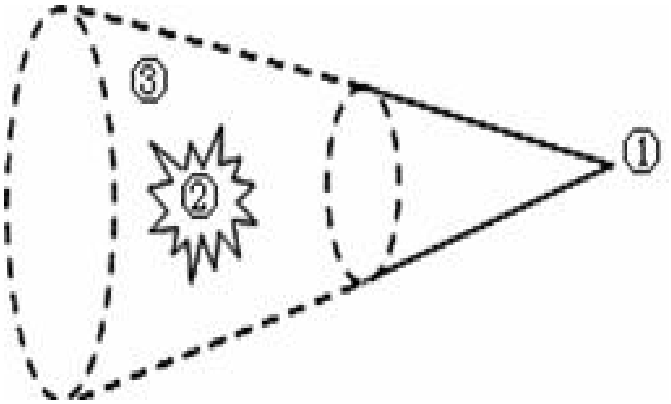

Figure 1. Schematic diagram of Mammotome® excision in fan and cone shape. □ acupuncture point; □ primary lesion; □ excision range.

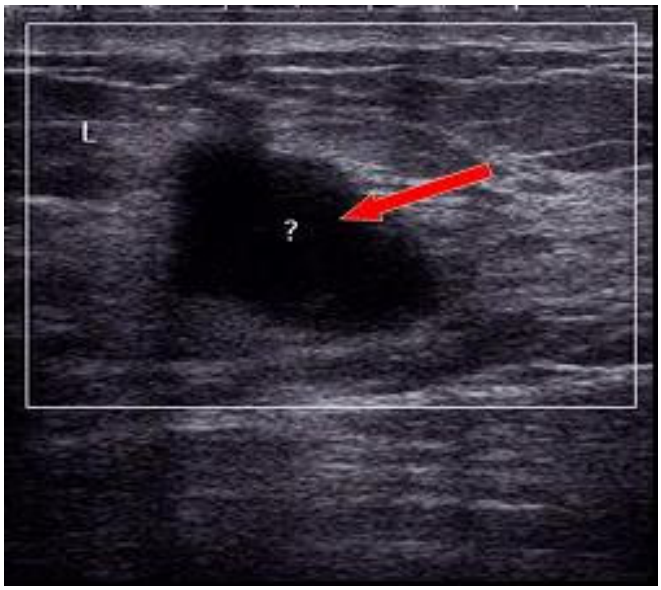

Figure 3. The Mammotome® biopsy cavity of original lesion is clearly detected by 13 MHz ultrasound transducer.

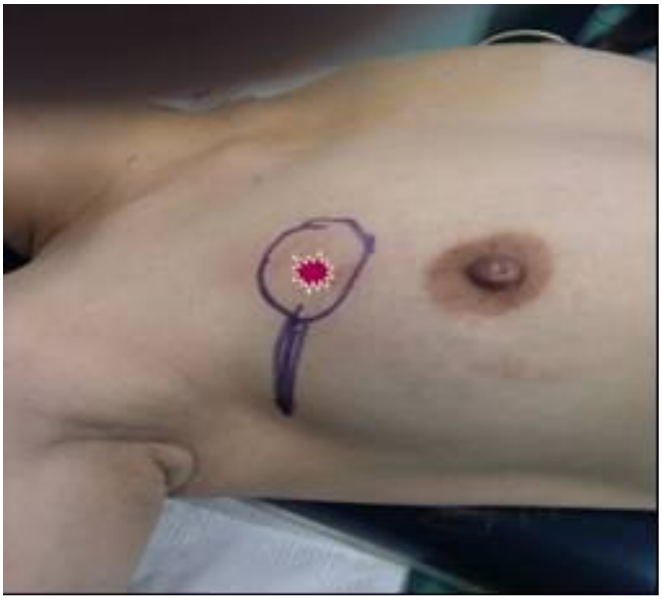

Figure 2. The original ultrasound breast lesion with microcalcification.

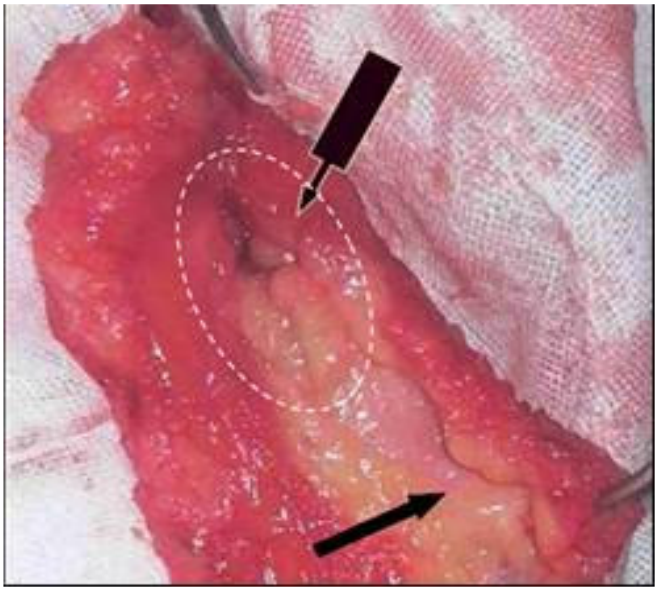

Figure 4. Breast sample collected from subsequent surgery. The Mammotome® biopsy cavity of original lesion; The Mammotome® acupuncture tract.

For all the 9 ADH patients, no evidence of residual lesion was noted from the examination of subsequent surgical specimens. Among the 56 malignant cases, no evidence of pathological residual lesion was noted from the examination of subsequent surgical specimens in 41 patients (no-residual lesions group), and pathological residual lesion was found in subsequent surgical specimens for 15 patients (residual lesions group), including 11 patients with negative surgical margins and 4 EIC patients with positive surgical margins undergoing partial excision. A positive surgical margin was still found in the 4 EIC patients after re-excision, and then simple mastectomy was performed. Therefore, 52 of 56 (93%) underwent subsequent successful breast conservation therapy. The pathological examinations of subsequent surgical specimens were all in accordance with that from the mammotome® biopsy in these 65 patients (56 malignant cases and 9 ADH cases). Sentinel lymph node was positive only in one invasive ductal carcinoma patient. Then, level I~II axillary lymph node dissection was performed, including 15 level I lymph nodes and 4 level II lymph nodes, and no evidence of cancer

metastasis was found.

Patient demographics and characteristics of the original breast lesions seen on the pre-mammotome® procedure ultrasound are shown in Table 1. The average age for the no-residual lesion and residual lesion groups were 42.6 ± 5.1 years (ranges from 27 to 53 years) and 41.5 ± 5.2 years (ranges from 34 to 53 years) respectively, there were no significant differences between the two groups ($P = 0.456$). The average size of the lesion was 9.2 ± 2.9 mm (ranges from 4 to 15mm) and 12.6 ± 1.9 mm (ranges from 9 to 15 mm) respectively. Numbers of the patients with no-residual lesion and residual lesion were 26 and 15 respectively, 12 of which have lesions more than 10 mm in diameter. Numbers of the patients for no-residual lesions group and residual lesions group where lesion shape was regular were 21 (51.2%) and 3 (20.0%), and 20 cases and 12 cases(80.0%) for irregular shape lesions respectively. And the median size of the original ultrasound breast lesion significantly correlated with whether a residual lesion, with smaller such original ultrasound breast lesions being seen in the group having no residual lesion and with larger such original ultrasound breast lesions being seen in the group have a residual lesion. (P = 0.004). The patients with no-residual lesion had a significantly smaller original breast lesion size based on the pre-mammotome® procedure ultrasound findings ($P < 0.0001$) and had a predilection toward regular shape of the breast lesion ($P = 0.037$). Whereas patients with residual lesion had a significantly larger original breast lesion size ($P < 0.0001$), and had a predilection toward irregular shape of the breast lesion ($P = 0.037$). There were 19 patients with breast mass, 22 patients with crocalcifications (including 11 patients with mass and microcalcifications and 11 patients with breast calcifications) in no-residual group, and there were 3 patients with breast mass, 12 patients with crocalcifications (including 7 patients with mass and microcalcifications and 5 patients with breast calcifications) in the residual group. Those patients with breast calcification lesions (which included only calcifications and mass with calcifications) had a predilection toward residual lesion group, but were not significantly different between the two groups ($P = 0.074$). The average number of mammotome® cores removed per patient was 20.2 ± 3.6 and 23.4 ± 3.4 core needle samples for no-residual lesions group and residual lesions group respectively, and that of the residual lesions group was more than no-residual lesions group ($P = 0.004$).

As shown in Table 1 for the non-residual lesion group 7, 26 and 8 of 41 breast lesions (17.1, 63.4 and 19.5%) were classified as BI-RADS (American College of Radiology Breast Imaging Reporting and Data System) category 3, 4 or 5 (based on pre-mammotome® procedure ultrasound), respectively; these consisted of 34 DCIS and 0 EIC, 5 IDC, and 2 ILC. For the residual lesions group 0, 5 and 10 of 15 breast lesions (0.0, 33.3 and 66.7%) were classified as BI-RADS category 3, 4 or 5 respectively; these consisted of 2 DCIS and 4 EIC, 9 IDC, and 0 ILC. Patients in which the lesion appeared to be completely excised during mammotome® core acquisition (no residual lesion group) had a predilection toward BI-RADS category 3 and 4 classification of the breast lesion ($P = 0.003$) and the final histopathology more frequently rendered DCIS and ILC diagnosis ($P < 0.0001$). Whereas patients in which there were residual lesions (residual lesion group) during mammotome® core acquisition had a predilection toward BI-RADS category 4 and 5 classification of the breast lesion ($P = 0.003$) and the final histopathology was more frequently rendered IDC and EIC diagnosis ($P < 0.0001$).

Variable influencing whether an evidence of residual lesion is noted from examination of subsequent surgical specimens are shown in Table 2. A multivariate analysis using logistic regression showed a significant original ultrasound breast lesion size and shape correlation with whether the lesion could be completely excised during mammotome® core acquisition. The lesions with smaller size (10 mm in diameter) ($P = 0.007$) and regular ($P = 0.040$) would be more easy to be completely excised during the ultrasound- guided, 8-gauge mammotome® procedure.

DISCUSSION

The early diagnosis of clinical nonpalpable suspicious breast lesions is difficult, and previous operative excisioned biopsy is blind and invasive. Over the last 15 years, percutaneous imaging-guided minimally invasive breast biopsy has become widely adopted for the diagnostic evaluation of nonpalpable suspicious breast lesions, and it is now routinely considered a standard of care by those physicians involved in breast- specific health care (Burak et al., 2004). Mammography and/or ultrasound-guided fine needle aspiration biopsy (FNAB) and large-core needle biopsy (LCNB) are widely used for the diagnosis of nonpalpable breast lesions. However, the efficacy of the diagnosis has been questioned because of the relatively high percentage of false-negative rate and pathological underestimation rate (Fuhrman et al., 1998; Verkooijen et al., 2000; Staren and O'Neill, 1999; Smith et al., 2001). Vacuum-assisted mammotome® biopsy is an ideal diagnostic technique for the treatment of nonpalpable breast lesions (Chen et al., 2003), due to the large sample volume and lower underestimation and false-negative results, as well as the complete removal of suspicious breast lesions (Parker et al., 2001; Burak et al., 2000; Liberman et al., 1999; Simon et al., 2000; Inui et al., 2008). Breast calcifications were mainly detected by mammography, but nowadays microcalcifications can be detected by ultrasonography with the improvement of ultrasound apparatus and application of high-frequency probe (Chen et al., 2000). Kasumi (1993) found that ultrasound could detect a micro particle with a diameter

Table 1. Patient demographics characteristics of the original breast lesions seen on the pre-mammotome® procedure ultrasound and sample number of breast lesions of mammotome® biopsy comparing residual and no-residual lesions.

Factors	No.	Residual lesions (n = 15)	No residual lesions (n = 41)	*p*-value
Age(yrs)(mean+SD)	56	41.5±5.2	42.6±5.1	0.456
Lesion size(mm)(mean+SD)	56	12.6±1.9	9.2±2.9	<0.0001
Lesion size (mm)				0.004
□10	29	3(20%)	26(63.4%)	
>10	27	12(80%)	15(36.6%)	
Lesion shape				0.037
Regular	24	3 (20.0%)	21(51.2%)	
Irregular	32	12 (80.0%)	20(48.8%)	
Visible lesion on pre-procedural Mammogram also				0.864
Yes	35	10(66.7%)	25(61.0%)	
No	11	3(20.0%)	8(19.5%)	
mammogram not done	10	2(13.3%)	8(19.5%)	
Calcifications*				0.074
Yes	34	12 (80.0%)	22(53.7%)	
No	22	3(20.0%)	19(46.3%)	
BI-RADS # classification of ultrasound				0.003
Category 3	7	0(0.0%)	7(17.1%)	
Category 4	31	5(33.3%)	26(63.4%)	
Category 5	18	10(66.7%)	8(19.5)	
Sample number	56	23.4±3.4	20.2±3.6	0.004
Pathology**				<0.0001
DCIS	36	2(13.3%)	34(82.9%)	
EIC	4	4(26.7%)	0(0.0%)	
IDC	14	9(60.0%)	5(12.2%)	
ILC	2	0(0.0%)	2(4.9%)	
Lesion shape				0.037
Regular	24	3 (20.0%)	21(51.2%)	
Irregular	32	12 (80.0%)	20(48.8%)	
Visible lesion on pre-procedural Mammogram also				0.864
Yes	35	10(66.7%)	25(61.0%)	
No	11	3(20.0%)	8(19.5%)	

Calcifications*: calcification alone and mass with calcification; BI-RADS #: breast imaging reporting and data system; pathology**: DCIS, ductal carcinoma in situ; EIC, extensive intraductual component; IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma.

Table 2. Variable influencing the evidence of residual lesion are noted from examination of subsequent surgical specimens.

Factor	Odds ratio for residual lesions	(95% C.I.)	*p*
Lesion size (mm) (>10/□10)	7.75	1.761-34.48	0.007
Lesion shape (irregular/ regular)	4.88	1.07-22.22	0.040

of 110 µm under a low-echo background. Ultrasonographically guided excision of microcalcifications in breast had also been reported. The 8-guage mammotome® biopsy was performed in 281 patients with clinically nonpalpable mass and/or calcifications guided by high-frequency ultrasound in the present study, with a successful rate of 100%, and no evidence of residual lesions was seen on post-mammotome® procedure ultrasound. The size of nonpalpable lesion was usually very small, and the size was 4 to 15 mm in the present study. The suspicious lesion was completely removed at the same time of mammotome® biopsy, therefore the sample volume was large enough, and false-negative rate and pathological underestimation rate were reduced. Likewise, the location was exact and lesion removal was complete and effective because all procedures were performed visibly under on-going real-time guide of high-frequency ultrasound. Many women with high-risk lesions such as those of BI-RADS category >3 who undergo biopsy prefer complete removal rather than follow-up at regular intervals. The 8-gauge mammotome® procedure will satisfy the requirement for complete removal. In the present study, 100% of all ultrasound lesions were accurately diagnosed by the ultrasound-guided 8-gauge mammotome® biopsy procedure, demonstrating no apparent false-negative results and no evidence of residual ultrasound lesions among the 193 patients that were compliant with follow-up at a current median interval follow-up duration of 16 months (ranges from 3 to 42). Anxiety of the high-risk patients was avoided. Therefore, we agree with Povoski et al. (2007) and recommend complete removal if possible by sonographic evidence of small appropriately selected presumed benign lesions during mammotome® procedure.

It was demonstrated that the ratio of negative margin was higher when performing breast-conserving surgery after core needle biopsy was done to confirm the diagnosis (Yim et al., 1996). Mammotome biopsy was even more accurate than core needle biopsy with adequate sample volume as well as reduced false-negative results and underestimation (Meyer et al., 1997; Liberman et al., 1995).

In the study of Cangiarella (2000), 11 (69%) patients performed breast conserving cancer surgery and was demonstrated to have a negative margin out of 16 cases with early-stage breast cancer following mammotome® biopsy. In the current study, we excised normal breast tissue 10 mm around the original lesion and found that the original lesion was completely removed in 41 patients (73%) during the subsequent surgery (based on pathology). Regionally residual lesion was detected in 11 patients but the surgical margin was negative. Thus the total negative rate of surgical margin was as high as 93%. This figure of a nearly 93% negative rate of surgical margin (based on pathology) exceeds the 73% success of complete excision previously reported by Fine et al. (2003). The margin was positive in only 4 patients with EIC, and remained positive after re-excision during subsequent surgery. Pathological evaluation by mammotome biopsy in the 56 breast cancer patients and 9 atypical ductal hyperplasia patients were in accordance with that by the subsequent surgery. In the current study, 100% of all ultrasound lesions were accurately diagnosed by the ultrasound-guided, 8-gauge mammotome® biopsy technique, demonstrating no apparent false-negative results and no underestimates of the disease. The absence of underestimation and high diagnostic rate was similar to the regard of Parker et al. (2001), which might attribute to the complete removal of primary lesion and surrounding tissues, as well as adequate sample volume. Therefore, we recommend completely possible removal of the sonographic evidence of small nonpalpable suspicious breast lesions which can reduce sampling error, false-negative diagnosis and re-biopsy. Mammotome® biopsy might not be able to reflect the condition of axillary lymph nodes. But metastasis to lymph node seldom occurs in patients with early-stage breast cancer. Axillary sentinel node was positive in only 3 patients with invasive duct carcinoma and no evidence of other metastasis lymph nodes were noted from examination of subsequent axillary lymph node dissection specimens.

Negative margin was crucial for success of breast-conserving surgery. However, the definition of negative margin distance had not reached a consensus until now. One well accepted standard of breast-conserving surgery in clinical practice is at least a 2 mm tumor-free margin under microscopy in order to excise breast tissue 10 mm around the original lesion. Burak et al. (2000) found that tumor-free margin was present in 73.6% of 89 DCIS patients undergoing mammotome® biopsy. Parker et al. (2001) suggests that 9 core samples can entirely remove a breast mass <1.5 cm and Liberman et al. (1999) reported that infiltrating ductal carcinoma may be completely excised if 14 or more core samples are obtained. The present study demonstrated that the ultrasound-guided, 8-guage mammotome® biopsy could completely remove a lesion with a diameter of 10 mm. Negative margin rate of the following breast-conserving surgery was as high as 93% when excising surrounding breast tissues for more than 10 mm. In the current study, those patients with no residual lesions during mammotome® procedure had a predilection toward BI-RADS category 3 and 4 classification of the breast lesion ($P = 0.003$) and the final histopathology more frequently rendered DCIS and ILC diagnosis ($P < 0.0001$) (Table 1). Povoski et al. (2007) recommended limiting attempts at complete excision to that of such breast lesions which approximate a prolate ellipsoid (that is, cigar-shaped) or a scalene ellipsoid (that is, three unequal dimensions) and to that of such breast lesions that have a maximum lesion length of 25 mm and maximum lesion width of 15 mm. In a similar regard, multivariate analysis using logistic

regression showed a significant original ultrasound breast lesion size and shape correlation with whether the lesion can be completely removed by mammotome® biopsy. The lesions with smaller size (□10 mm in diameter) (P = 0.007) and regular shape (P = 0.040) would be more easy to be completely removed during mammotome® core acquisition in the current study (Table 2). In the current study, the average number of tissue samples per lesion for residual lesions group (23.4 ± 3.4) was more than that for no-residual lesions group (20.2 ± 3.6) (P = 0.004), which suggest that despite the more average numbers of the excised lesions during mammotome® procedure, it is difficult to completely remove lesions with bigger sizes and irregular shapes. Patients with breast calcification lesions had a predilection toward residual lesion groups, but this was not significantly different between the two groups (P = 0.074) which might be due to the small number of patients in the study. EIC was accepted as a high-risk factor of regional recurrence of breast cancer. The optimal treatment for confirmed or suspicious EIC was to enlarge the excision range (Wazer et al., 1999). The study also implicates that the surgical margin after enlarging the excision range remained positive in 4 EIC patients, thus simple mastectomy was performed.

The 8-gauge mammotome® system allows for more rapid and larger volume tissue acquisition, resulting in more representative tissue sampling. Thus, the ultrasound-guided, 8-gauge vacuum-assisted mammotome® system should be considered highly accurate for diagnostic biopsy of nonpalpable suspicious breast lesions and is successful for complete removal of small size (□10 mm in diameter) and regular shape nonpalpable suspicious breast lesions. In the present study, we tried to develop a minimally invasive surgery for patients with breast cancer which should be safe, effective and in accordance with medical principles.

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