A comparative study on ultrasound-guided elite, Mammotome, and core needle biopsy for diagnosing malignant breast masses

Shi-Fang Zou¹, Lin Tao², Zhen-Chu Feng³, Ji-Yan Wang¹, Lin Liu¹, Wen-Long Liang¹, Jie-Na Liu¹, Dan-Dan Xu¹, Jia-Yan Lin¹, Jian-Guo Zhang¹, Xi Chen¹

¹The 8th Ward of General Surgery, The Second Affiliated Hospital of Harbin Medical University, Harbin, China
²Department of Ultrasound, The Second Affiliated Hospital of Harbin Medical University, Harbin, China

Submitted: 30 January 2019; Accepted: 6 April 2019
Online publication: 22 August 2019
Arch Med Sci 2022; 18 (2): 422–431
DOI: https://doi.org/10.5114/aoms.2019.87096
Copyright © 2019 Termedia & Banach

Abstract

Introduction: The present study aims to clarify the advantages and disadvantages of elite biopsy, to provide a reference for selecting the puncture method.

Material and methods: A total of 802 patients with a BI-RADS grade ≥ 4, as evaluated by the molybdenum target, and measurable lesions revealed by colour Doppler ultrasound, who were admitted at our department from January 2017 to January 2018, were enrolled in the present study. These patients were randomly divided into three groups: elite, Mammotome and core needle biopsy groups. The pathological underestimation rate, diagnostic accordance rate, haematoma incidence rate, and costs of these three biopsy methods were compared.

Results: The difference in diagnostic accordance rates between the elite biopsy group and core needle biopsy group was statistically significant (98.9% vs. 94.7%, p = 0.003), as well as between the Mammotome biopsy group and core needle biopsy group (99.6% vs. 94.7%, p < 0.001). The difference in pathological underestimation rates between the elite biopsy group and core needle biopsy group was statistically significant (7.2% vs. 37.3%, p < 0.001), as well as between the Mammotome biopsy group and core needle biopsy group (1.6% vs. 7.2%, p < 0.001). The difference between the Mammotome biopsy group and elite biopsy group was not statistically significant. The incidence of haematoma in the Mammotome, elite, and core needle groups was 15.9%, 13%, and 21.7%, respectively (13% vs. 21.7%, p = 0.021).

Conclusions: Elite biopsy has a low rate of pathological underestimation and low incidence of haematoma, can improve the breast conserving rate, and has an affordable cost. As a biopsy method with high accuracy, safety, and economy, elite biopsy can be widely used in clinics.

Key words: elite biopsy, Mammotome biopsy, core needle biopsy, breast masses, diagnosis.

Introduction

Breast cancer is the most common malignant tumour with the highest incidence in women, and its incidence is gradually increasing [1]. Although the precise treatment of breast cancer is presently being pursued, precise
treatment remains inseparable from accurate preoperative diagnosis. The breast biopsy methods in the 2018 National Comprehensive Cancer Network (NCCN) guidelines include fine-needle aspiration (FNA) biopsy, core needle biopsy, excisional biopsy, and vacuum-assisted biopsy [2].

Core needle biopsy is easy to operate and cheap. However, it can easily lead to acquiring inadequate samples and has a high pathological underestimation rate [3, 4]. Furthermore, repeated puncture leads to haematoma.

Vacuum-assisted Mammotome biopsy can obtain sufficient samples without repeated puncture. Hence, the diagnostic accuracy is high [5, 6]. However, it requires expensive special equipment (vacuum pumps, operating handles, etc.), and this technology also has a high incidence of haematoma [7].

In 2012, a wireless vacuum-assisted biopsy device was invented. Bagnera et al. [8] first confirmed the safety, convenience, and ease of operation of an elite biopsy device. Subsequently, Choi et al. [9] confirmed that the biopsy method has a high accuracy.

The elite biopsy system is a special vacuum-assisted, minimally invasive breast biopsy tool developed on the basis of a Mammotome minimally invasive rotary cutting system. This device is portable, does not need to be connected to a power supply, and is a special negative pressure device and special machine. The sampling can begin after self-examination on the basis of properly installing the biopsy needle and operating handle. Sufficient samples can be obtained with only one puncture. Furthermore, the accuracy of elite biopsy is high (95–97.6%) [10, 11]. The elite biopsy device has high accuracy and is convenient to operate. However, the clinical application of elite biopsy is rare. Hence, in order to further explore the elite biopsy method, the investigators designed the present test to compare the advantages and disadvantages of the three biopsy methods.

Material and methods

Age of subjects and experimental design

A total of 802 eligible patients, who were admitted to our department from January 2017 to January 2018, were enrolled in the present study. These lesions were measured by colour Doppler ultrasonography before the operation, regardless of the age and size of the masses. All patients were assessed by imaging. The diagnosis of BI-RADS by the age and size of the masses. All patients were assigned to the core needle biopsy group, while 270 patients were assigned to the core needle biopsy group. The age of patients in the study groups ranged from 20 to 85 years old, and the diameter of the lesion ranged from 0.68 to 6.0 cm under colour Doppler ultrasound. Standard treatment was performed after biopsy. The preoperative biopsy and postoperative pathology of each patient were compared, and the pathological underestimation rate and diagnostic coincidence rate of these three biopsy methods were calculated. The number of patients with haematoma after biopsy was counted, and the incidence of haematoma in these three groups was calculated. The cost was evaluated based on the standard of our hospital, and the costs of these three biopsy methods were roughly calculated (Figure 1, Table I).

Major instruments

The ultrasound machine was a colour ultrasound diagnostic apparatus (LOGIQ BOOK XP, GE, USA), with a probe frequency of 11 MHz. The Mammotome biopsy system was purchased from Devicor Medical (USA), which included a vacuum suction pump, an operating handle, and a disposable 8 G biopsy rotary cutting (probe) needle head (the external diameter was 4.3 mm). The elite biopsy system was purchased from Devicor Medical (USA), which included an operating handle and a disposable 10 G biopsy rotary cutting (probe) needle head (the external diameter was 3.4 mm). The tissue biopsy needle was a disposable 14 G automatic biopsy needle (the external diameter was 2.1 mm) (CareFusion, USA) (Figure 2).

Operation methods

Mammotome biopsy

Patients were laid in the supine position, routine disinfection was performed, and surgical drapes were placed. The locations of the lesions were determined by ultrasound. The biopsy points were selected according to the requirements of the breast conserving surgery. It should be considered that the biopsy point and biopsy needle track should be removed as much as possible during the operation. Patients were treated with a mixture of 0.16% lidocaine and a small amount of epinephrine hydrochloride for local infiltration anaesthesia. Anaesthetics were injected into the posterior or breast space and the surrounding area of the

Arch Med Sci 2, 1st March / 2022

423
A total of 802 patients were enrolled in the present study

**Figure 1.** The flow chart of the study

**Table I.** The basic characteristics of the three groups

| Item                                      | Mammothome biopsy group (n = 257) | Elite biopsy group (n = 269) | Core needle biopsy group (n = 276) |
|-------------------------------------------|-----------------------------------|-------------------------------|----------------------------------|
| The size of tumour, n (%):                |                                   |                               |                                  |
| ≤ 2 cm                                    | 129 (50.2)                        | 134 (49.8)                    | 139 (50.4)                       |
| 2 < D ≤ 5 cm                              | 118 (46.0)                        | 126 (46.8)                    | 128 (46.4)                       |
| > 5 cm                                    | 10 (3.8)                          | 9 (3.4)                       | 9 (3.2)                          |
| Age [years], median                       | 53 ±9.1                           | 54 ±9.5                       | 54 ±9.3                          |
| Puncture for the first time, n (%):       |                                   |                               |                                  |
| Yes*                                      | 255 (99.2)                        | 267 (99.3)                    | 273 (98.9)                       |
| No                                        | 0 (0.8)                           | 2 (0.7)                       | 3 (1.1)                          |
| Enlarged lymph nodes in the axilla, n (%):|                                   |                               |                                  |
| Yes                                       | 92 (35.8)                         | 96 (35.7)                     | 99 (35.9)                        |
| No                                        | 165 (64.2)                        | 173 (64.3)                    | 177 (64.1)                       |
| Colour Doppler ultrasound BI-RADS grade, n (%): |   |                               |                                  |
| Grade 3*                                   | 16 (6.2)                          | 17 (6.3)                      | 17 (6.2)                         |
| Grade 4A                                   | 35 (13.6)                         | 37 (13.8)                     | 38 (13.8)                        |
| Grade 4B                                  | 40 (15.6)                         | 42 (15.6)                     | 43 (15.6)                        |
| Grade 4C                                  | 87 (33.9)                         | 91 (33.8)                     | 94 (34.0)                        |
| Grade 5                                   | 79 (30.7)                         | 82 (30.5)                     | 84 (30.4)                        |
| Pathology results, n (%):                 |                                   |                               |                                  |
| Invasive carcinoma                        | 193 (75.1)                        | 196 (72.9)                    | 183 (66.3)                       |
| DCIS                                      | 15 (5.8)                          | 14 (5.2)                      | 8 (2.9)                          |
| Non-malignant diseases*                   | 48 (18.7)                         | 50 (18.6)                     | 48 (17.4)                        |
| Malignant tumor*                          | 1 (0.4)                           | 3 (1.1)                       | 9 (3.3)                          |
| Undetermined                              | 0 (0.4)                           | 1 (0.4)                       | 1 (0.3)                          |

*Most of them are patients undergoing neoadjuvant therapy. The diagnosis of BI-RADS by molybdenum target was grade 4 or higher. Including the cases diagnosed as invasive carcinoma with intraductal carcinoma and intraductal carcinoma with microinvasion. Including all benign diseases and atypical hyperplasia. The biopsy was diagnosed as malignant tumour. However, the type was undetermined. Undiagnosed cases. DCIS – ductal carcinoma in situ.
mass, in order to separate the pectoral muscles and reduce secondary damage. A Mammotome rotary cutting machine was checked and connected, and an incision of approximately 3-mm length was made at the appropriate position. The Mammotome rotary cutting knife head was inserted into the centre of the mass through the incision under the guidance of ultrasound, and the gland tissues were cut in a rotary way under ultrasound monitoring. An appropriate amount of tissue was obtained, and the rotary cutting step was ended. The biopsy tissue was fixed with 10% formalin for routine pathological examination. The surface of the wound was covered with sterile dressing and compressed for 15–30 min. Then, the compression bandage with elastic dressing was given for 48 h.

**Elite biopsy group**

The operation process was the same as that for the Mammotome biopsy.

**Core needle biopsy**

Routine disinfection was performed and surgical drapes were placed in the operation scope. The biopsy point was selected, and the infiltration anaesthesia of the skin and surrounding area of the mass was performed. Real-time monitoring was performed with a probe to optimise the location of the biopsy guide line and biopsy site. Then, the probe was fixed, and the biopsy needle was placed in the lesion position. Afterwards, the biopsy gun was initiated, and the biopsy needle was quickly pulled out after hearing the gunshot. The tissues in the needle groove were pushed out. This procedure was repeated to obtain the appropriate amount of tissues. Then, the specimens were fixed and patients were bandaged (Figure 3).

**Evaluation criteria**

Paraffin section pathological diagnosis was performed on both the biopsy and operation samples of the same patient. Haematoxylin and eosin (H&E) staining was performed. These paraffin sections were observed by two veteran physicians in the Department of Pathology, and their matching conclusion was regarded as the diagnosis. The diagnostic result of the surgical pathology was regarded as the gold standard. In the present study, the underestimation rate was defined as the percentage of the number of patients with benign or undetermined biopsy pathology but with malignant post-operative pathology (ductal carcinoma in situ (DCIS), invasive carcinoma, other malignant tumours), plus the number of patients with DCIS biopsy pathology but with invasive carcinoma post-operative pathology, which accounted for the total number of patients with non-invasive carcinoma or malignant tumour biopsy pathology. The diagnostic accordance rate was defined as the percentage of the number of patients with benign and malignant biopsy pathology, which was consistent with the post-operative pathology, and this accounted for the number of patients without undetermined biopsy pathology. The incidence of haematoma was defined as the percentage of the number of patients with haematomas, which accounted for the total number of patients in the present study.

**Statistical analysis**

Data were statistically analysed using SPSS 19.0 software. Count data were expressed in percentage (%) and compared using the $\chi^2$-test. If the theoretical frequency is between 1 and 5, the continuity correction result was used. If the theoretical frequency is less than 1, the Fisher exact probability test result was used. On the basis of the results of the $\chi^2$ test, the Bonferroni correction method was used to correct the results of multiple tests after the pairwise comparison. $P < 0.05$ was considered statistically significant.

**Results**

**Pathological underestimation rate and diagnostic accordance rate**

There were 257 patients in the Mammotome biopsy group. Among these patients, the biopsy
diagnosis revealed that 193 patients had invasive carcinoma, 1 patient had a malignant tumour, 15 patients had DCIS, and 48 patients had non-malignant diseases (one of these patients was diagnosed with malignancy after the operation). The diagnostic accordance rate between the biopsy pathology and post-operative pathology was 99.6%, and the pathological underestimation rate was 1.6% (1/63).

There were 269 patients in the elite biopsy group. Among these patients, the biopsy diagnosis revealed that in total, 196 patients had invasive carcinoma, 3 patients had malignant tumours, 1 patient had lymphoma, 14 patients had DCIS (one of them was diagnosed with invasive carcinoma after the operation), 5 patients could not be diagnosed (two of them were diagnosed with breast cancer after the operation), 48 patients had non-malignant diseases (5 of them were diagnosed with breast cancer after the operation), and 37 patients had malignant tumours. The diagnostic accordance rate between the biopsy pathology and post-operative pathology was 98.9% (261/264), and the pathological underestimation rate was 7.2% (5/69).

There were 276 patients in the core needle biopsy group. Among these patients, the biopsy diagnosis revealed that 183 patients had invasive carcinomas, 8 patients had DCIS (all of them were diagnosed with invasive carcinoma after the operation), 27 patients could not be diagnosed (18 of them were diagnosed with breast cancer after the operation), 48 patients had non-malignant diseases (5 of them were diagnosed with breast cancer after the operation), 9 patients had malignant tumours, and 1 patient had lymphoma. The diagnostic accordance rate between the biopsy pathology and post-operative pathology was 94.7% (236/249), and the pathological underestimation rate was 37.3% (31/83).

There were differences in overall comparison in terms of diagnostic accordance rates and pathological underestimation rates among the three groups ($p < 0.001$). The diagnostic accordance rates of the elite biopsy group (98.9%) were significantly higher than those of the core needle biopsy group (94.7%), and the difference was statistically significant ($p = 0.003$). The diagnostic accordance rates of the Mammotome biopsy group (99.6%) was significantly higher than that of the core needle biopsy group (94.7%), and the difference was statistically significant ($p < 0.001$). The difference in diagnostic accordance rates between the Mammotome biopsy group and elite biopsy group was not statistically significant ($p = 1.905$). The pathological underestimation rates of the elite biopsy group (7.2%) was significantly lower than that of the core needle biopsy group (37.3%), and the difference was statistically significant ($p < 0.001$). The pathological underestimation rates of the Mammotome biopsy group (1.6%) was significant.
ly lower than that of the core needle biopsy group (37.3%), and the difference was statistically significant ($p < 0.0001$). The difference in pathological underestimation rates between the Mammotome biopsy group and the elite biopsy group was not statistically significant ($p = 0.762$, Table I).

In subgroups, different colour Doppler ultrasound BI-RADS grade had different results. In respect of diagnostic accordance rates, only grade 4B was statistically significant as a whole ($p = 0.002$). In the subsequent pairwise comparison, the diagnostic accordance rate of the elite biopsy group was significantly higher than that of the core needle biopsy group, and the difference was statistically significant ($p = 0.006$). The diagnostic accordance rate of the Mammotome biopsy group was significantly higher than that of the core needle biopsy group, and the difference was statistically significant ($p = 0.048$). The difference in diagnostic accordance rates between the Mammotome biopsy group and the elite biopsy group was not statistically significant. In respect of pathological underestimation rates, grades 4B, 4C, and 5 were statistically significant as a whole ($p < 0.001$). In subsequent pairwise comparison of grade 4B, the rate of the elite biopsy group was significantly lower than that of the core needle biopsy group, and the difference was statistically significant ($p = 0.024$). The rate of the Mammotome biopsy group was significantly lower than that of the core needle biopsy group, and the difference was statistically significant ($p < 0.001$). In following pairwise comparison of grade 4C, the rate of the elite biopsy group was significantly lower than that of the core needle biopsy group, and the difference was statistically significant ($p = 0.006$). The rate of the Mammotome biopsy group was significantly lower than that of the core needle biopsy group, and the difference was statistically significant ($p < 0.001$). In following pairwise comparison of grade 5, the rate of the elite biopsy group was significantly lower than that of the core needle biopsy group, and the difference was statistically significant ($p < 0.001$). The rates between the Mammotome biopsy group and elite biopsy group were not statistically significant in these three subgroups (Table III).

In the subgroup of the size of the mass it was significant only in $2 < D \leq 5$ cm about diagnostic accordance rate (Mammotome: 99.2%, elite: 99.2%, core needle: 93.0%, $p = 0.004$). However, there was no statistical difference between any two groups. There was significance in $\leq 2$ cm ($p = 0.002$) and $2 < D \leq 5$ cm ($p < 0.001$) in terms of pathological underestimation rates. In subsequent pairwise comparison, the rate of the Mammotome

| Table II. Comparison of biopsy and postoperative pathology |
|-----------------|-----------------|-----------------|-----------------|
|                  | Non-malignant diseases | Underdiagnosed | Undetermined | Intraductal carcinoma | Underestimation rate (%) |
|                  | Biopsy (n) | Underestimation cases (n) | Biopsy (n) | Underestimation cases (n) | Biopsy (n) | Underestimation cases (n) |
| Mammotome biopsy group | 48 | 15 | 0 | 99.6 | 1.6 |
| Elite biopsy group | 50 | 14 | 1 | 98.9 | 7.2 |
| Core needle biopsy group | 48 | 8 | 8 | 94.7 | 37.3 |
| P-value | - | - | - | 0.0004 | 0.0001 |

The underestimation of intraductal carcinoma including the cases diagnosed as invasive carcinoma with intraductal carcinoma and intraductal carcinomas with micropinvasion.
biopsy group was lower than that of the core needle biopsy group in ≤ 2 cm (0.0 vs. 23.5), and the difference was statistically significant (p = 0.003). In 2 < D ≤ 5 cm, the differences of Mammotome vs. core needle (4.3 vs. 6.3) and elite vs. core needle (8.3 vs. 6.3) were significant (p < 0.001).

The incidence of haematoma

The case data were reviewed. There were 257 patients in the Mammotome biopsy group. Among these patients, haematoma occurred in 41 patients after the operation, and the incidence of haematoma was 15.9%. Furthermore, there were 269 patients in the elite biopsy group. Among these patients, haematoma occurred in 35 patients after the operation, and the incidence of haematoma was 13.0%. There were 276 patients in the core needle biopsy group. Among these patients, haematoma occurred in 60 patients after the operation, and the incidence of haematoma was 21.7%. There were differences in overall comparison among the three groups (p < 0.001). The incidence of haematoma in the elite biopsy group was lower than that in the core needle biopsy group, and the difference was statistically significant (p = 0.021). Nonetheless, the difference between the Mammotome biopsy group and core needle biopsy group was not statistically significant (p = 0.267), as was the case between the Mammotome biopsy group and elite biopsy group (p = 1.000, Table IV).

In the experiment, a small number of people gave up breast-conserving surgery because of the haematoma. A total of 16 patients gave up breast-conserving due to severe haematoma. The statistical results revealed that in the core needle biopsy group 10 patients gave up breast conserving, and the breast conserving rate was reduced by 4.4%. In the Mammotome biopsy group, 6 patients gave up breast-conserving due to haematoma, and the breast conserving rate was reduced by 2.8%. In the elite biopsy group, none of the patients gave up breast-conserving due to haematoma. Concerning patients resigned from BCT due to an extensive haematoma, there were differences in overall comparison among the three groups (p = 0.007). However, in pairings, only the difference between the elite biopsy group and core needle biopsy group was statistically significant (p = 0.012). The p-value between the Mammotome biopsy group and core needle biopsy group was 1.000. The p-value between the Mammotome biopsy group and elite needle biopsy group was 0.105.

Cost

With our hospital’s fee standard as a reference, the cost of a Mammotome biopsy is approximately 7500 yuan, the cost of an elite biopsy is approx-

---

**Table III.** The colour Doppler ultrasound BI-RADS grade of three groups

| Rate                        | Mammotome biopsy group (%) | Elite biopsy group (%) | Core needle biopsy group (%) | P-value |
|-----------------------------|----------------------------|------------------------|------------------------------|---------|
| Diagnostic accordance rate: |                            |                        |                              |         |
| Grade 4A                    | 97.1                       | 97.0                   | 93.3                         | 0.1391  |
| Grade 4B                    | 100                        | 97.6                   | 82.1                         | < 0.001 |
| Grade 4C                    | 100                        | 98.9                   | 97.6                         | 0.1071  |
| Grade 5                     | 100                        | 100                    | 97.5                         | 0.1111  |
| Pathological underestimation rate: |                        |                        |                              |         |
| Grade 4A                    | 2.9                        | 6.5                    | 15.4                         | 0.1942  |
| Grade 4B                    | 0                          | 10.0                   | 47.6                         | < 0.001 |
| Grade 4C                    | 0                          | 6.7                    | 58.8                         | < 0.001 |
| Grade 5                     | 0                          | 0                      | 100                          | < 0.001 |

**Table IV.** The comparison of three groups after puncture

| Treatment                  | Mammotome biopsy group, n (%) | Elite biopsy group, n (%) | Core needle biopsy group, n (%) | P-value |
|----------------------------|-------------------------------|---------------------------|-------------------------------|---------|
| Neoadjuvant therapy        | 45 (17.5)                     | 47 (17.5)                 | 49 (17.7)                     | 0.9956  |
| Breast-conserving operation | 38 (17.9)                     | 47 (21.2)                 | 35 (15.4)                     | 0.285   |
| Mastectomy                 | 177 (64.6)                    | 175 (61.3)                | 192 (66.9)                    |         |
| Haematoma                  | 41 (15.9)                     | 35 (13.0)                 | 60 (21.7)                     | 0.0219  |

*Some patients gave up breast-conserving due to the severe haematoma. The breast-conserving rate here is the data after removing the cases of giving up breast-conserving therapy.*
There is no significant difference in pathological underestimation rate than core needle biopsy. Our experimental results show that elite biopsy has a higher pathological accuracy rate and low-pathological underestimation rate are closely correlated with the formulation of the treatment plan and prognosis of patients. Therefore, high diagnostic accuracy rate and low pathological underestimation rate are the first choice. If the biopsy diagnosis is DCIS or DCIS with a small amount of invasive carcinoma, perhaps surgical therapy is the first choice. Therefore, high diagnostic accordance rate and low pathological underestimation rate are closely correlated with the formulation of the treatment plan and prognosis of patients. Our experimental results show that elite biopsy has a higher pathological accuracy rate and lower underestimation rate than core needle biopsy. There is no significant difference in pathological accuracy rate and underestimation rate between the Mammotome and elite biopsy group, as other experimental studies have revealed [11, 19]. It is safe to operate without special equipment, it is easy and simple to operate, and is not limited by the environment. The Mammotome’s line-piping system limits the needle insertion direction, needle insertion depth, and rotation direction to a certain extent, and has certain requirements for the operation site. Hence, elite biopsy has obvious advantages over Mammotome biopsy.

The biopsy results of different BI-RADS grades revealed that the difference in the diagnostic accordance rate of BI-RADS grade was statistically significant only in grade 4B among the three groups. In subsequent pairwise comparison, the difference between Mammotome biopsy and core needle biopsy, elite and core needle biopsy were significant. Regardless of BI-RADS result, the rate of the elite biopsy group was significantly lower than that of the core needle biopsy group. The longitudinal comparison revealed that in our experiments there was no significant correlation between the BI-RADS grade and the accuracy of diagnosis and the rate of pathological underestimation. The study revealed that the accuracy of core needle biopsy increased with the increase in BI-RADS grade, but the difference was not statistically significant [20]. The BI-RADS is an index to assess the risk of breast cancer. Its height only represents the probability of breast cancer. Whether the accuracy of diagnosis and the rate of pathological underestimation are correlated to BI-RADS grade or not is worthy of further exploration. Hence, no matter the rating, we can choose the elite biopsy first. In view of the fact of the high diagnostic accordance rate of the three biopsy methods, and taking into account the cost, core needle biopsy can be considered for grade 4C and 5 masses.

Determining from the results of our experiments, the accuracy of the biopsy is not correlated to the size of the mass. Although some of the positive results were obtained in our experiment, there was no corresponding clinical significance. According to the ease of operation, a large mass is easier to operate than a small one. This difference is more pronounced in the core needle biopsy. For the incidence of haematoma, vacuum-assisted biopsy does not require repeated needle insertion, which reduces tissue secondary damage, and the incidence of haematoma is lower than that of core needle biopsy. The external diameter of the Mammotome biopsy needle is 4.3 mm, while the exter-
nal diameter of the elite biopsy needle is 3.4 mm. The external diameter of the Mammotome biopsy needle is larger than that of the elite biopsy needle, which leads to more gland destruction during biopsy to the glands. In fact, the incidence of haematoma was statistically significant in only the elite group compared with core needle biopsy. The incidence of haematoma of the elite biopsy group was lower than that of the core needle biopsy group. In deciding the surgical method before the operation, there is a need to comprehensively evaluate the size of the mass, the size of the breast, and the ratio of the mass to the breast, and there is also a need to evaluate the operability of the breast-conserving surgery and the accuracy of the surgical margin selection. Severe haematomata can lead to unclear margins of the mass, which affects the judgment of the surgical margin. For patients with severe haematoma after biopsy, the incidence of false negativity is increased in breast-conserving surgical margins. Therefore, taking into account operation safety, in the preoperative formulation of surgical strategies, some of the patients gave up breast conserving because of the haematoma. The decreased rate of breast conserving in the elite group was significantly lower than that in the core needle biopsy group. This approach can improve the breast conserving rate. Related experimental studies have revealed that breast-conserving patients have better functional status and fewer symptoms than those with mastectomy [21]. The loss of breast has a major effect on patient’s identity and mental health. Patients who underwent breast-conserving therapy (BCT) reported better body shape. The results of the experiment showed that the approach of operation had little effect on the quality of life. After all, there are too many factors related to quality of life [22]. But the investigator wonders whether breast-preservation has a certain effect on quality of life [22].

In conclusion, as a new method of breast biopsy, elite biopsy has a high diagnostic accuracy rate and a low pathological underestimation rate, and the incidence of haematoma after biopsy is low. Furthermore, this approach can improve the breast conserving rate, and has an affordable price. As an economical biopsy method with high accuracy and safety, elite biopsy can be widely used in clinics.

Acknowledgments

Shi-Fang Zou and Lin Tao contributed equally to this study.

Conflict of interest

The authors declare no conflict of interest.

References

1. India State-Level Disease Burden Initiative Cancer Collaborators. The burden of cancers and their variations across the states of India: the Global Burden of Disease Study 1990-2016. Lancet Oncol 2018; 19: 1289-306.
2. National Comprehensive Cancer Network. NCCN Guidelines – Breast Cancer. Available from: https://www.nccn.org/
3. Łukasiewicz E, Ziemiecka A, Jakubowski W, Vojnovic I, Boguckowska M, Dobruch-Solczak K. Fine-needle versus core-needle biopsy – which one to choose in preoperative assessment of focal lesions in the breasts? Literature review. J Ultrasound 2017; 17: 267-74.
4. Brennan ME, Turner RM, Ciatto S, et al. Ductal carcinoma in situ at core-needle biopsy: meta-analysis of underestimation and predictors of invasive breast cancer. Radiology 2011; 260: 119-28.
5. Huang XC, Hu XH, Wang XR, et al. A comparison of diagnostic performance of vacuum-assisted biopsy and core needle biopsy for breast microlcalfication: a systematic review and meta-analysis. IR J Med Sci 2018; 187: 999-1008.
6. Pan S, Liu W, Jin K, Liu Y, Zhou Y. Ultrasound-guided vacuum-assisted breast biopsy using Mammotome biopsy system for detection of breast cancer: results from two high volume hospitals. Int J Clin Exp Med 2014; 7: 239-46.
7. Kibil W, Hodorowicz-Zaniewska D, Kulig J. Mammotome biopsy under ultrasound control in the diagnostics and treatment of nodular breast lesions – own experience. Pol Przegl Chir 2012; 84: 242-6.
8. Bagnara S, Patania S, Milanesio L, Gatti G, Orlassino R. New wireless handheld ultrasound-guided vacuum-assisted breast biopsy (VABB) devices: an important innovation in breast diagnosis. Open J Radiol 2013; 3: 174-9.
9. Choi ER, Han BK, Ko ES, et al. Initial experience with a wireless ultrasound-guided vacuum-assisted breast biopsy device. PLoS One 2015; 10: e0144046.
10. Ma SH, Ling FH, Cui SE, Li XW, Huang ZH. Application of ultrasound-guided mmammotome elite biopsy system in preoperative diagnosis of breast cancer [Article in Chinese]. Modern Diagnosis and Treatment 2017; 28: 1448-50.
11. Bozzi A, Cassano E, Racti D, et al. Analysis of efficacy and accuracy of 2 vacuum-assisted breast biopsy devices: mammotome and elite. Clin Breast Cancer 2018; 18: e1277-82.
12. Mocian F, Georgescu R, Coroș ME, et al. The revisited role of ultrasound guided core needle biopsy in the breast cancer diagnosis. Chirurgia (Bucur) 2018; 113: 244-52.
13. Koskela A, Berg M, Sudah M, et al. Learning curve for add-on stereotactic core needle breast biopsy. Acta Radiol 2006; 47: 454-60.
14. Ciatto S, Houssami N, Ambrogetti D, et al. Accuracy and underestimation of malignancy of breast core needle biopsy: the Florence experience of over 4000 consecutive biopsies. Breast Cancer Res Treat 2007; 101: 291-7.
15. Schizas N, Lazopoulos A, Krimiotis D, et al. Beware of hemopneumothorax following core needle breast biopsy. Respir Med Case Rep 2018; 25: 49-51.
16. Park HS, Jeon CW. Learning curve for breast mass excision using a vacuum-assisted biopsy system. Minim Invasive Ther Allied Technol 2014; 23: 235-40.
17. Nakano S, Imwari Y, Mibu A, Otsuka M, Ohnuma T. Differentiating vacuum-assisted breast biopsy from core needle biopsy: Is it necessary? Br J Radiol 2018; 91: 20180250.
18. Fishman JE, Milikowski C, Ramsinghani R, Velasquez MV, Aviram G. US-guided core-needle biopsy of the breast:
how many specimens are necessary? Radiology 2003; 226: 779-82.
19. Seo J, Kim SM, Jang M, et al. Ultrasound-guided cable-free 13-gauge vacuum-assisted biopsy of non-mass breast lesions. PLoS One 2017; 12: e0179182.
20. Wang JX, Cao XC. Diagnostic value of ultrasound-guided biopsy for BI-RADS grade 4A to 4C breast masses [Article in Chinese]. Chin J Clin Oncol 2017; 44: 83-6.
21. Acil H, Cavdar I. Comparison of quality of life of Turkish breast cancer patients receiving breast conserving surgery or modified radical mastectomy. Asian Pac J Cancer Prev 2014; 15: 5377-81.
22. Tsai HY, Kuo RN, Chung KP. Quality of life of breast cancer survivors following breast-conserving therapy versus mastectomy: a multicenter study in Taiwan. Jpn J Clin Oncol 2017; 47: 909-18.