Biomedical Research 2017; 28 (19): 8354-8359 *ISSN 0970-938X*
www.biomedres.info

Feasibility study of large breast benign masses excision with ultrasound-guided Mammotome VABB system.

XiaoHu Sun[1,2,3], Ying Zhao[1,2,3], Bin Zhang[1,2,3], Yue Yu[1,2,3], Xuchen Cao[1,2,3*]

[1]Tianjin Medical University Cancer Institute and Hospital, National Clinical Research Center for Cancer, Tianjin, PR China

[2]Key Laboratory of Cancer Prevention and Therapy, Tianjin, PR China

[3]Key Laboratory of Breast Cancer Prevention and Therapy, Tianjin Medical University, Ministry of Education, Tianjin, PR China

Abstract

Background: This study aimed to investigate the feasibility of large breast benign masses excision with ultrasound-guided Mammotome minimally invasive surgery.
Materials and methods: The clinical data of 1023 patients with breast benign masses in our hospital from December 2013 to December 2015 were collected and analysed. Patients were divided into experimental group with 302 cases (d>2.5 cm) and control group with 721 cases (d ≤ 2.5 cm). All the patients received Mammotome excision, and the treatment effects were followed up. The resection rate, complications and cosmetic effect were compared between the two groups.
Results: All lesions in the two groups were confirmed as benign masses, and the detection rate of residual cancer cells in surgical resection margins was all below 5%, indicating the complete resection rate in two groups was all higher than 95%. No significant difference between the two groups was found in terms of the resection rate. The complication morbidity of pain, hematoma, skin ecchymosis and active bleeding in the experimental group were higher than that in the control group, and the difference was statistically significant (p<0.05). The short-term cosmetic effect was better in the control group than that of the experimental group, and the difference was significant (p=0.029). No significant differences of the long-term cosmetic effect and the subjective evaluation (6 months after the operation) between the two groups were found.
Conclusions: The Mammotome excision of large breast benign masses had many advantages, such as safety, minimally invasive, cosmetic and satisfaction in resection rate, which made the surgical procedure feasible and worth to be recommended.

Keywords: Mammotome excision, Large breast benign mass, Resection rate, Postoperative complication, Cosmetic effect.

Accepted on September 21, 2017

Introduction

As the awareness programs increased, more and more breast lesions have been detected by ultrasound and many other inspections. Most breast lesions were found to be benign. Benign breast mass is a very common disease. With the changes of lifestyle and rhythm of work, the incidence of benign breast lumps is increasing year by year. The clinical manifestations of benign breast tumor are breast swelling and pain, which seriously affect the patients' health and quality of life, and this disease has increased the risk of breast cancer. The incidence of breast cancer in patients with benign breast disease is 2 to 3 times of the normal population.

Surgical treatment is the main treatment method for benign breast masses, however, the curative effect of the traditional surgical resection is not satisfied. It often has large incision(s) and will leave permanent scar(s) on breast skin, thus, it cannot meet the patients' demand for minimizing the cosmetic damage. Mammotome Vacuum-Assisted Breast Biopsy (VABB) systems [1], a new type of vacuum-assisted biopsy devices guided by the iconography, have gradually been applied for the treatment of benign breast lesions. The Mammotome VABB system is mainly used in biopsy of breast lesions [2-6]. Due to its special vacuum suction device and rotary cutting system, most of researchers believed that, for the smaller (d<2.5 cm) benign breast masses, we can use Mammotome VABB system to perform accurate minimally invasive surgery [7-10]. But for larger (d>2.5 cm) breast benign tumor, whether it can be completely excised, postoperative complication rate, cosmetic effect and so on have been the topic of debate and discussion [6,11-13]. Thus, in the present study, we investigated the feasibility of Mammotome

minimally invasive resection in the excision of breast benign tumors with larger diameter (2.5 cm~6.0 cm), and compared with the tumor with smaller diameter.

Materials and Methods

General information

From December 2013 to December 2015, 1023 patients with breast benign tumor were admitted to the Outpatient Department of Tumor Hospital of Tianjin Medical University. All of the patients were voluntarily excised by Mammotome VABB systems. Inclusion criteria: (1) Clinical and imaging (mammary molybdenum target, the ultrasound, nuclear magnetic resonance, etc.) check were in line with the mass of the breast; (2) the examination suggested that the disease was the unilateral or bilateral, the lesion was single or multiple; (3) the examination was considered as a benign mass, the classification of Bi-rads is 3-4 a; (4) the patients without surgical contraindications such as severe organic disease, coagulation disorders, various types of breast hemangioma, built-in breast implants; (5) the patients themselves had the will to complete the operation of outpatient surgery. All of the patients were female, who were between 18 to 60 y old, with an average age of 34. According to the difference of mass diameter, we divided the patients into the experimental group (302 cases, d>2.5 cm) and the control group (721 cases, $d \leq 2.5$ cm). The clinical features of the two groups were approximately similar and comparable. Preoperative routine examinations were performed, such as blood routine, liver and kidney function, infection screening, coagulation routine, blood pressure, electrocardiogram, X-ray chest radiograph, etc., aiming t ruling out the serious damage of heart, lung, liver, kidney.

Instrument and equipment

All of the operations were completed by using Mammotome breast minimally invasive rotary cutting system SCM23 (made up of 8 G, 11 G and 14 G rotary cutting needle, vacuum negative pressure suction pump, controller and related software, etc.) produced by the United States Johnson Medical Equipment Co., Ltd., and using the MyLab70XVG color Doppler ultrasound system which are produced by Yum. Of Italy (the frequency of the breast special high frequency probe is 7-14 MHz and the frequency of the breast specific high frequency volume probe is 4-13 MHz, the length of probe is 5 cm), and can display the Doppler spectrum Color flow at the same time.

Operation methods

Patients should be in supine position, or lie on the side, when necessary. Their affected side arms were abducted, exposing the visual field of operation. In the first place, positioning breast lesions with the aid of ultrasonic probe to ensure the location, size, shape, quantity of the tumor, and marking with a marker pen, which accordingly determined the location and direction of the incision, and whether it was accurate is the key to the success of surgery. Meanwhile, we also considered if the pathological report was malignant, we needed to carry out the opened-surgery incision design again, such as a radical surgery or breast conserving surgery, striving for adopting the "shortest distance" principle. When the local infiltration anesthesia was satisfied, we cut the skin 3-5 mm in the selected position with No.11 flat blade, 8 G rotary cutting needle under the ultrasound guidance and punctured to the bottom of the lump along the path of anesthesia. The mass was determined by ultrasound, and held on to the upper part of the groove of the rotary cutting needle. And then under the guidance of ultrasound, the rotary cutting needle began to rotary cut, repeated several times aiming at the lumps from the bottom of the lumps. During the rotary cutting to larger lumps, the suction of the vacuum negative pressure system should be increased properly, the rotary cutting needle should gradually do the sector, rotation, multi-direction advancing cutting step by step. Making the cutting plane gradually move up from the bottom, distinguishing carefully with the eyes to the specimens which were cut down and finding out the differences between them and normal glands. Until the lesions were completely removed under the ultrasound guidance, which were confirmed no residual and then terminated rotary cutting. After that, in the residual cavity of the operation, multiple point taking samples was carried out once again guided by the type-B ultrasonic on the circumferential resection margin. After the operation, paraffin wax pathology was sent in a separate path. During the whole rotary cutting process, vacuum could be used to aspirate and remove the internal blood until it was confirmed that there is no active bleeding. After the removal of the needle, cohered the incision of skin with a sterile adhesive tape, compressed locally in the cavity for 10 to 15 min, and then compressible bandaged with elastic bandage for 24 to 48 h.

Index

Following indexes were compared between the experimental group and the control group: the operation conditions (the time of the operation, the size of the incision, the time spent in the resection, the cost of treatment); pathological results (the pathological types, the postoperative residual); the postoperative complications (the pain, hematoma, scar skin bruising, active bleeding, infection, skin numbness and recurrence); and the evaluation of the beauty degree of the shape of the breast, and so on.

Statistical methods

All of the data were analysed by SPSS 18.0 statistical software. The technical information were adapted to the test of χ^2, $p<0.05$ was considered as a significant statistical difference.

Results

Comparison between two groups of the operation conditions

The operation conditions of the two groups were shown explicitly in Table 1. In the control group, there was a case of

unilateral multiple patient's whose excision tissues were suspected to be malignant in the surgery, and then it was sent for frozen pathological examination, the results shown that it was an invasive breast cancer, so this case was not included in the statistics.

Table 1. The comparison in the operation conditions of patients of two groups.

Group	The numbers of lump	The average diameter (cm)	The average size of incision (cm)	The average time of removal of a single tumor (min)	The average cost of treatment (Yuan)
The experimental group (n=302)	384	3.30 ± 0.75	0.35 ± 0.05	15.40 ± 5.90	5428.95 ± 572.00
The control group (n=720)	874	1.67 ± 0.65	0.25 ± 0.06	6.10 ± 2.90	4501.37 ± 111.70
P value	N/A	0.023	0.562	0.039	0.036

None of the cases was failed in the operations of the two groups. Between the two groups, there were significant differences in the average diameter of a single tumor, the average time of removal of a single tumor, and the average cost of treatment ($p<0.05$); There was no obvious difference in the average size of incision ($p>0.05$).

Comparison between two groups of pathology

The comparison between the pathological classifications of the two groups was shown in Table 2. Among the 384 lumps in the 302 cases of the experimental group, which included 279 cases of fibroadenoma, 47 cases of intraductal papilloma, 41 cases of phyllodes tumor, 5 cases of hamartoma, 12 cases of cysts; among the 874 lumps in the 720 cases of the control group, which included 499 cases of fibroadenoma, 167 cases of Intraductal papilloma, 111 cases of phyllodes tumor, 17 cases of hamartoma, 80 cases of cysts. According to the pathological data of the two groups, the difference was not statistically significant ($p>0.05$).

Table 2. The comparison of pathological conditions and operation cavity pathological residual rate of two groups.

Group	Fibroadenoma (number/the number of pathological residual)	Papillary epithelioma (number/the number of pathological residual)	Phyllodes tumor (number/the number of pathological residual)	Hamartoma (number/the number of pathological residual)	Cysts (number/the number of pathological residual)	Total	Residual rate (%)
The experimental group (n=302)	279/9	47/4	41/3	5/0	12/0	384/16	4.17%
The control group (n=720)	499/9	167/6	111/4	17-Feb	80/0	874/21	2.40%
P value							0.064

Comments: After the operation, the tumor cells which existed in the multiple points sampling of any one place of residual cavity, having the same pathological type with the primary lesion, were defined as the pathological residues.

The comparison of pathological residual data of the operation cavity: the pathological detection of two groups was shown in Table 2. In the experimental group, 16 cases of pathological residues were detected, and the residual rate was 4.17%; in the control group, 21 cases of pathological residues were detected, and the residual rate was 2.40%. The pathological residual rates of the two groups were all less than 5%, there was no statistical difference ($p=0.064$), namely, the total removal rate was all above 95%.

The comparisons of postoperative complications between the two groups

The postoperative complications of the two groups were shown in Table 3. The follow-up period after the operation was 3-6 months.

During the period of 3-6 months follow-up, none of the patients of two groups was lost to visit. The results suggested that the level of pain of the experimental group was higher than that the control group, there was a significant difference between the two groups ($p<0.05$); the same results were found in the degree of hematoma, skin ecchymosis, active bleeding and bleeding volume and so on. The occurrence rate of hematoma, skin ecchymosis and active bleeding of the experimental group was also higher than that the control group ($p<0.05$). There were no significant differences between the two groups in other observation indexes ($p>0.05$), including infection, skin numbness and the recurrence in the normal position and so on.

The comparison of aesthetic satisfaction rate between two groups after the operation

The postoperative satisfaction of the breast profile was shown in Table 4. We would set 0-3 months and 4-6 months as two stages of short-term and long-term. According to the breast shape, the doctors would make an objective evaluation. While in the 6 months after the operations, the patients would make a subjective evaluation aimed at the shape of breast. The summary of them was shown in the Table 4.

In the short term, the objective rates of perfect and good in the experimental group and the control group were 45% and 93% respectively, there was a significant difference between the two groups ($p<0.05$); In the long term, the objective rates of perfect and good in the experimental group and the control group were 95% and 97% respectively, there was no statistical significance between the two groups ($p>0.05$); the subjective satisfaction rates of the two groups in the 6 months after the operation were all 99%, there was no significant difference ($p>0.05$).

Table 3. The comparisons of postoperative complications of patients in the two groups.

Group	Pain			Hematoma	Skin ecchymosis	Active bleeding	Infections	Skin numbness	Recurrence *in situ*
	0 level	1 level	2-3 level						
The experimental group (n=302)	179/59.27%	115/38.08%	8/2.65%	27/8.94%	53/17.54%	38/12.58%	14/4.64%	31/10.26%	13/4.06%
The control group (n=720)	629/87.36%	77/10.69%	14/1.95%	36/5%	99/13.75%	63/8.75%	15/2.08%	74/10.27%	27/3.75%
P value	0.013			0.018	0.048	0.032	0.217	0.099	0.217

Comments: The standards for dividing the level of pain are shown in here: 0 level: the local pain in the affected side of the breast; 1 level: the overall pain in the affected side of the breast, but it can be endured; 2-3 level: the overall pain in the affected side of the breast, and it cannot be endured.

Table 4. The comparison of aesthetic satisfaction rate of two groups after the operation.

	The short term (3 months after the operation)				The long term (during the months of 4 to 6 after the operation)				The subjective evaluation (6 months after the operation)			
									Scores of 5	Scores of 3 to 4	Scores of 0 to 3	
Group	Perfect	Good	Poor	The rates of perfect and good	Perfect	Good	Poor	The rates of perfect and good	Very satisfied	Satisfied	Not satisfied	The satisfaction rate
The experimental group (n=302)	72	103	209	45%	299	70	15	95%	319	60	5	99%
	18%	27%	55%		77%	18%	5%		83%	16%	1%	
The control group (n=720)	598	219	57	93%	714	138	22	97%	768	98	8	99%
	68%	25%	7%		81%	16%	3%		88%	11%	1%	
P value	0.029				0.248				0.621			

Comments: the standards of the evaluation: Perfect: there was no difference between the affected side of breast after the treatment and the healthy side of breast. Good: there was slight difference between the affected side of breast after the treatment and the healthy side of breast, and there were a few part of deposit of scar and pigment. Poor: there was slight difference between the affected side of breast after the treatment and the healthy side of breast, such as there are depression, asymmetry and so on.

Discussion

Mammotome vacuum-assisted breast biopsy which was assisted by vacuum with the guidance of ultrasound was used to carry out a localized biopsy to suspicious breast lesions in the early stage, but base on the experience of many researches, for smaller lesions, especially for lesions with a diameter less than 2.5 cm, it could have a double effect of biopsy and resection [11]. The wound was so small (about 3 to 5 mm) that it was only the 10 percent of that in the traditional and opened operations [12]. For patients with multiple lesions, in the most of cases, it only needed one wound to solve the problems, the incision was concealed without suture, and there was no scar left after the operation. It is a better surgical method for breast benign tumor [13-15]. But in the clinical practice, most female breast benign tumor are in large masses, and the traditional open surgery will give patients a greater pain and bad appearance [16-18]. Therefore, in the clinic, more and more patients with larger benign tumors are urgent to accept minimally invasive surgery. However, due to the limitations of minimally invasive surgery, some scholars had questioned its application in large tumor resection, and they believed that it was possible to result in the incomplete resection, residual lesions, and the recurrence in the normal position and so on, besides, it would bring significant adverse effects to the shape of breast. Through the method for multiple point biopsy in a residual operation after the resection, this study aimed to evaluate whether minimally invasive resection has the

existence of residual from the point of view of pathology, and through the postoperative followed up after the operations, we also made a statistic and analysis for whether larger tumors would result in the increase of recent complications and the decrease of cosmetic effect.

The results showed that, the rates of complete resection of the two groups were all above 95 percent; there was a certain degree of increase for the incidence of postoperative complications in the experimental group, but all did not cause irreversible damages and deformity of appearance. According to the results of the postoperative followed up after the operations, it could be seen that, in the short term, there was a little difference in the cosmetic effect of breast between the two groups. While in the long term, the objective satisfied rates were all above 95 percent, subjective satisfied rates were all above 99 percent. Therefore, it was considered that using Mammotome minimally invasive rotary cutting surgery to remove large tumors can also obtain the desired results.

When Mammotome vacuum-assisted breast biopsy technique was applied in the clinical application, we should especially pay attention to the following points in the specific operation of the resection to larger breast benign tumors: (1) We should have a sufficient understanding of the Mammotome vacuum-assisted breast biopsy systems, be familiar with the characteristics and performance of each part of it, and be able to operate it skilfully. (2) We should be clearly known that the guidance of ultrasound will run through the entire operation, preoperative positioning, intraoperative guidance, and postoperative observation are required to cooperate with the tacit understanding of the ultrasound. We should master the basic knowledge of ultrasound and have a certain experience in the operation. (3) The choice of the incisions not only meet the following conditions, such as accuracy, concealment and at the same time give attention to multiple lesions, and so on, but also be required to take the condition into account that if the tumor is malignant confirmed by the pathology, it is necessary to carry out the second radical or breast conserving surgery. Thus, the incisions should be done as close as possible to the tumor, making the tumor, the incision and the puncture canal all be in the range of the second surgical excision, for the aim of making the preparation for the second open surgery; if the mass of the patient is multiple, and there is a suspected malignant lesions, the resection of benign lesions should be firstly considered, and finally the suspicious lesions be removed; if the patient has bilateral breast tumor, both surgical instruments should be separated, including the rotary cutting biopsy needle, so as to avoid planting and transferring. (4) In the process of resection, with the aid of ultrasound guidance, scientifically use the vacuum negative pressure suction, adjust the resection angle at any time according to the tumor position, and pay attention to the timely liquidation of the cavity.

From what has been discussed above, when cut off larger breast benign tumor, Mammotome vacuum-assisted breast biopsy has many advantages, such as good resection rates, minimally invasive, safety and good appearance. After the operation, though the incidence rate of complication slightly increased, such as the pain, hematoma, skin ecchymosis, active bleeding, etc., it does not cause irreversible damages. The recovery effect was good in the long term after the operation, and there were no obvious difference in the breast shape and the satisfied rates of patients with small tumors. It is one of the important surgical methods that worth recommending. However, compared with the traditional open surgery, the cost of treatment of Mammotome vacuum-assisted breast biopsy is more expensive. It is currently one of the reasons why it is difficult to carry out in the primary hospital.

Acknowledgements

The present study was financially supported by the Program of Fund for Science and Technology Development of Universities and Colleges of Tianjin (20130120).

Disclosures

All the authors declare that there were not any types of competing interests in current manuscript.

References

1. Parker SH, Stavros AT, Dennis MA. Needle biopsy techniques. Radiol Clin North Am 1995; 33: 1171-1186.
2. 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: 239-246.
3. Meloni GB, Dessole S, Becchere MP, Soro D, Capobianco G. Ultrasound-guided mammotome vacuum biopsy for the diagnosis of impalpable breast lesions. Ultrasound Obstet Gynecol 2001; 18: 520-524.
4. Becette V, Cherel P, Menet E, Yacoub S, Brain E, Hagay C, Guinebretiere JM. Biopsy of breast microcalcifications using an 11-Gauge vacuum-assisted device: roles and challenges for the pathologist. Ann Pathol 2003; 23: 496-507.
5. Sittek H, Kessler M, Untch M, Reiser M. Minimally invasive biopsy and preoperative marking of suspect mammary lesions. Gynakol Geburtshilfliche Rundsch 2004; 44: 69-83.
6. Helbich TH, Matzek W, Fuchsjager MH. Stereotactic and ultrasound-guided breast biopsy. Eur Radiol 2004; 14: 383-393.
7. Yi W, Xu F, Zou Q, Tang Z. Completely removing sditary intraductal papillomas using the Mamnotome system guided by ultrasonography is feasible and safe. World J Surg 2013; 37: 2613-2617.
8. Fine RE, Israel PZ, Walker LC, Corgan KR, Greenwald LV, Berenson JE, Boyd BA, Oliver MK, McClure T, Elberfeld J. A prospective study of the removal rate of imaged breast lesions by an 11-gauge vacuum-assisted biopsy probe system. Am J Surg 2008; 182: 335-340.
9. Chun K, Velanovich V. Patient perceived cosmesis and satisfaction after breast biopsy: comparison of stereotactic

incision, excisional, and wire localized biopsy techniques. Surgery 2002; 131: 497-501.

10. Cassano E, Urban LA, Pizzamiglio M, Abbate F, Maisonneuve P, Renne G, Viale G, Bellomi M. Ultrasound guided vacuum-assisted core breast biopsy: experience with 406 cases. Breast Cancer Res Treat 2007; 102: 103-110.
11. Vargas HI, Agbunag RV, Khaikhali I. State of the art of minimally invasive breast biopsy: principles and practice. Breast Cancer 2000; 7: 370-379.
12. Liberman L. Percutaneous image-guided core breast biopsy. Radiol Clin North Am 2002; 40: 483-500.
13. Sperber F, Blank A, Metser U, Flusser G, Klausner JM. Diagnosis and treatment of breast fibroadenomas by ultrasound-guided vacuum-assisted biopsy. Arch Surg 2003; 138: 796-800.
14. Diebold T, Hahn T, Solbach C, Rody A, Balzer JO, Hansmann ML, Marx A, Viana F, Peters J, Jacobi V, Kaufmann M, Vogl TJ. Evaluation of thestereotactic 8 vacuum assisted breast biopsy in thehistologic evaluation of suspicious mammography findings (BI RADSIV). Invest Radiol 2005; 40: 465-471.
15. Plantade R, Hammou JC, Gerard F, Chanalet I, Aubanel D, David-Bureau M, Scotto A, Fighiera M, Gueret S, Lo Monaco L. Ultrasound guided vacuum-assisted biopsy: review of 382 cases. J Radiol 2005; 86: 1003-1015.
16. Di C, Li Z, Wang H. Experience of minimally invasive operation and traditional operation for benign breast tumor. Guide China Med 2010; 8: 301-302.
17. Si S. Comparative study of minimally invasive operation and traditional operation of breast. Chinese Health Nutr 2009; 18: 96-98.
18. Qu Z, Wang H, Tu W, Wang Q. Comparative study of minimally invasive surgery and traditional surgery in treatment of benign breast tumor. Chinese J Gene Surg 2011; 14: 150-151.

*Correspondence to

Xuchen Cao

Tianjin Medical University Cancer Institute and Hospital

National Clinical Research Center for Cancer

PR China