Clinic efficacy and safety of ultrasound-guided Mammotome-assisted surgery for patients with breast benign tumors

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Abstract. – **OBJECTIVE:** The aim of this study was to assess the efficacy of ultrasound-guided Mammotome-assisted resection *vs.* conventional open surgery for benign breast tumors.

PATIENTS AND METHODS: From July 2019 to December 2020, 134 suitable patients with benign breast cancers treated at our institution (Breast Surgery Department) were recruited and randomly allocated (1:1) to receive either Mammotome-assisted tumor excision (observation group) or open surgery (control group). The primary endpoint was clinical effectiveness, with surgical outcomes, complications, and satisfaction as secondary endpoints.

RESULTS: Mammotome-assisted surgery resulted in shorter operative time, scar length, and postoperative healing time and less intraoperative bleeding volume vs. open surgery (p<0.001). Mammotome-assisted surgery was associated with a significantly higher clinical efficacy vs. open surgery (p<0.05). Patients receiving Mammotome-assisted surgery had a lower incidence of complications vs. those given open surgery (p<0.05). A significantly higher satisfaction was observed in patients given Mammotome-assisted surgery vs. open surgery (p<0.05).

CONCLUSIONS: In comparison to standard open surgery, ultrasound-guided Mammotome-assisted surgery provides a viable alternative for breast benign tumor removal with superior efficacy, shorter operating time, less trauma, higher safety, fewer complications, and higher patient satisfaction.

Key Words:

Ultrasound guidance, Mammotome, Conventional open surgery, Breast benign tumor, Satisfaction.

Introduction

Currently, breast cancer is the most prevalent cancer and the 5th deadliest cancer among women. Breast benign tumor is a common disease prevalent in young women¹. It includes breast fibroadenoma,

breast fat necrosis, and breast hyperplasia². Most lumps are round or ovoid painless masses with clear borders, and small nodular surfaces with a fine touch, some of which are obviously lobulated, mostly painless, and small in size but fastgrowing^{3,4}. Breast cancer is a systemic illness in terms of etiology, and increased levels of endogenous estrogens contribute to the development of breast cancer, which is encouraged by the receptor signaling pathway and estrogen metabolite toxicity. In vivo, estrogen travels through a catechol metabolic route that involves the detoxification of catechol metabolites^{5,6}. Estrone or estradiol is converted to 2-hydroxycatechol estrogen or 4-hydroxycatechol estrogen catalyzed by cytochrome P450 enzymes, which form unstable adducts with adenine and guanine in DNA, causing depurination and mutation7. The cyclic redox events observed during estrogen metabolism create cascades of oxygen radicals, which contributes to lipid and DNA oxidative damage. Research⁸ has confirmed that estrogen metabolites exhibit genotoxic, mutagenic, transformative, and direct tumorigenic potential, thereby eliciting oncogenesis.

Previous research9 suggests a significant increase in the incidence of breast tumor disease in women in recent years. The incidence of breast cancer in Chinese women is increasing at an average annual rate of 8.76%. In clinical practice, pharmacological treatment is used to inhibit the growth of the mass, and surgical treatment involves the complete removal of the mass to achieve a radical cure. However, variations in efficacy and safety exist in surgical procedures, resulting in different implications for the prognosis¹⁰. The traditional Chinese medicine (TCM) treatment for breast cancer mostly involves draining the liver and Qi and activating blood circulation to remove blood stasis. Adjuvant TCM therapy and radio-chemotherapy can reduce the incidence of adverse effects and recurrence rates and improve the quality of life of patients¹¹. Commonly used TCM formulas include Chaihu Guizhi Decoction, Tiaogan Yangxue Decoction, and Huangqi Guizhi Wuwu Decoction. In response to this molecular mechanism, the traditional Chinese medicine (TCM) Liangxue Shugan formula can significantly alleviate symptoms, relieve adverse effects, reduce hormone levels, and prevent the increase of endometrial thickness in breast cancer patients^{12,13}.

Traditional surgical mastectomy is exceedingly intrusive and prone to complications, which heavily compromises postoperative recovery. Minimally invasive surgery with considerable advantages such as precise localization and minimal problems is increasingly employed in surgical therapy¹⁴. Ultrasound-guided Mammotome-assisted surgery¹⁵ is a minimally invasive procedure that perforates a small hole of about 3 mm in a concealed place such as the axilla or areola and rapidly locates the location of the mass under ultrasound guidance, followed by accurate excision of the lump¹⁶. This technique is less invasive and less painful, with a short hospital stay, high satisfaction, and robust postoperative recovery, resulting in improved quality of life of patients and low risks of postoperative complications^{17,18}. The present study was conducted to assess the efficacy of ultrasound-guided Mammotome-assisted resection vs. conventional open surgery in the treatment of breast benign tumors.

Patients and Methods

Baseline Data

From July 2019 to December 2020, 134 suitable patients with benign breast cancers treated at our hospital (Breast Surgery Department) were recruited and randomly allocated (1:1) to one of two groups: observation or control. All eligible patients provided written informed consent prior to recruitment. The study protocol has been approved by the hospital Ethics Committee (Ethics number: SG-YET20190514). All procedures complied with the Declaration of Helsinki's ethical guidelines for clinical research. The patient characteristics of the two groups were comparable (p>0.05) (Table I).

Inclusion and Exclusion Criteria

Inclusion criteria¹⁹: ① patients were diagnosed with breast benign tumors as per the clinical diagnostic criteria of the International Federation of Obstetrics and Gynecology; ② the masses were

graded as grade II-IVb by Breast Imaging Reporting and Data System (BI-RADS); ③ patients and their families were aware of the study and voluntarily signed the consent form.

Exclusion criteria²⁰: ① patients with breast cancer or unclear diagnosis; ② with coagulation dysfunctions; ③ with relevant surgical contraindications.

Treatment Methods

The control group received traditional open surgery. The lump resection was performed with the patient lying supine. A well-defined peritoneal mass was excised, whereas an indistinctly defined peritoneal mass was excised with the gland, followed by hemostasis, coagulation, and anti-infection therapy. Following removal, the tumor was submitted for histological investigation.

The observation group was given ultrasound-guided Mammotome-assisted surgerv²¹. After routine disinfection and draping, a Mammotome device (Johnson & Johnson, New Brunswick, NJ, USA) was used to determine the incision and operation path according to the location and size of the mass under ultrasound guidance. Local infiltration anesthesia was performed under the mass by ultrasound guidance at about 2-3 cm from the mass. In the event of a near-skin or near-vascular mass, a certain amount of anesthetic was administered over and around the mass to avoid pain from skin or vascular injury during excision. A 2-3 mm incision was made at the anesthesia site, and the resection blade was inserted along the anesthesia path to the deep side of the breast lump through ultrasound guidance, followed by the adjustment of the blade to a proper position, and then the mass was excised and removed strip by strip under real-time ultrasound monitoring until the complete excision of the lesion. After resection, any bleeding was aspirated using vacuum suction, and pressure was applied to stop bleeding for 3-5 min. If there was no blood retention, the puncture site was glued using sterile adhesive paper and wrapped with pressure using a Mammotome special bandage for 48 h²².

TCM adjuvant therapy

All patients received 1 dose of Liangxue Shugan granules (30 g of Arnebiae Radix, 10 g of Bupleuri Radix, 15 g of Paeoniae Radix Alba, 15 g of Ginseng, 10 g of Atractylodis Macrocephalae Rhizoma, 9 g of Chuanxiong Rhizoma, 9 g of Rehmanniae Radix, 30 g of wheat and 18 g of Jujube were added for anxious and depressed patients) twice daily. The duration of treatment was 3 months.

Table I. Comparison of baseline data.

Groups	n	Mean age (x±s)	Mean diameter (x±s)	Unilateral lesions [n (%)]	Bilateral lesions [n (%)]
Observation group	67	29.84±5.36	1.53±0.39	29 (43.28)	38 (56.72)
Control group	67	30.27 ± 4.98	1.62 ± 0.54	31 (46.27)	36 (53.73)
t/χ^2	-	0.481	1.106	0.121	0.121
<i>p</i> -value	-	0.631	0.271	0.728	0.728

Clinical Endpoints

- (1) The operative time, intraoperative bleeding, scar length, and postoperative healing time of the two groups were recorded.
- (2) The treatment efficacy was evaluated according to the clinical symptoms and divided into markedly effective, effective, and ineffective. Markedly effective: clinical symptoms disappeared after treatment. Effective: clinical symptoms were improved after treatment. Ineffective: No improvement was observed in clinical symptoms. Total efficacy=(markedly effective cases+effective cases)/total cases*100 %.
- (3) The patients' complications, including postoperative pain, local hematoma, subcutaneous bruising, and postoperative infection, were recorded to calculate the total incidence.
- (4) Our hospital's patient satisfaction questionnaire assessed patient satisfaction in both groups, with four degrees of satisfaction: extremely satisfied, satisfied, less happy, and dissatisfied. Total satisfaction=(highly satisfied cases+satisfied cases)/total number of cases*100%.

Statistical Analysis

SPSS 22.0 (IBM Corp., Armonk, NY, USA) was used for data analyses, and GraphPad Prism 8 (GraphPad Software Inc., San Diego, CA, USA) was used for image rendering. The measurement data were expressed as ($\overline{x}\pm s$) and processed using the *t*-test. The count data were expressed as the number of cases (rate) and analyzed using the Chi-square test. Differences were considered statistically significant at p < 0.05.

Results

Surgical Outcomes

Mammotome-assisted surgery resulted in shorter operative time, scar length, and postoperative healing time and less intraoperative bleeding volume (17.28 \pm 5.17 min, 2.25 \pm 0.71 mm, 3.17 \pm 2.14 d and 3.21 \pm 1.12 ml) *vs.* open surgery (31.46 \pm 9.85 min, 25.15 \pm 8.51 mm, 6.35 \pm 3.02 d and 10.54 \pm 3.85 ml) (p<0.001) (Table II).

Clinical Efficacy

There were 31 (46.27%) cases of markedly effective, 34 (50.74%) cases of effective, and 2 (2.99%) cases of ineffective in the observation group, with a total efficacy of 97.01%. There were 21 (31.34%) cases of markedly effective, 33 (49.25%) cases of effective, and 13 (19.40%) cases of ineffective in the control group, with a total efficacy of 80.59%. Mammotome-assisted surgery was associated with a significantly higher clinical efficacy vs. open surgery (χ^2 =9.083, p=0.001) (Table III).

Complications

There were 1 (1.49%) case of postoperative pain and 1 (1.49%) case of subcutaneous bruising in the observation group, with an incidence of complications of 2.98%. There were 5 (7.46%) cases of postoperative pain, 4 (5.97%) cases of local hematoma, 2 (2.98%) cases of subcutaneous bruising, and 1 (1.49%) case of postoperative infection, with an incidence of complications of 19.40%. Mammotome-assisted surgery showed a lower incidence of complications vs. open surgery (χ^2 =8.465, p=0.001) (Table IV).

Table II. Comparison of surgical outcomes ($\bar{x}\pm s$).

Groups	n	Operative time (min)	Intraoperative bleeding (ml)	Scar length (mm)	Postoperative healing time (d)
Observation group	67	17.28±5.17	3.21±1.12	2.25±0.71	3.17±2.14
Control group	67	31.46 ± 9.85	10.54±3.85	25.15±8.51	6.35 ± 3.02
<i>t</i> -value	-	10.434	14.964	21.950	7.032
<i>p</i> -value	-	< 0.001	< 0.001	< 0.001	< 0.001

Table III. Comparison of clinical efficacy [n (%)].

Groups	n	Markedly effective	Effective	Ineffective	Total efficacy
Observation group Control group χ^2 p-value	67 67 -	31 (46.27) 21 (31.34) 9.083 0.003	34 (50.74) 33 (49.25)	2 (2.99) 13 (19.40)	65 (97.01) 54 (80.59)

Table IV. Comparison of complications [n (%)].

Groups	n	Postoperative pain	Local hematoma	Subcutaneous bruising	Postoperative infection	Total incidence
Observation group Control group χ^2 p -value	67 67 -	1 (1.49) 5 (7.46) 8.465 0.001	0 (0.00) 4 (5.97)	1 (1.49) 2 (2.98)	0 (0.00) 1 (1.49)	2 (2.98) 12 (17.91)

Satisfaction

In the observation group, there were 29 (43.28%) cases of highly satisfied, 35 (52.24%) cases of satisfied, 2 (2.98%) cases of less satisfied, and 1 (1.49%) case of dissatisfied, with a satisfaction rate of 95.52%. In the control group, 17 (25.37%) cases of highly satisfied, 34 (50.74%) cases of satisfied, 11 (16.42%) cases of less satisfied, and 5 (7.46%) cases of dissatisfied, with a satisfaction rate of 76.12%. A significantly higher satisfaction was observed in patients given Mammotome-assisted surgery vs. open surgery (p<0.05) (Figure 1).

Discussion

The causes of benign breast lumps are mostly related to environmental factors, lifestyle changes, endocrine hormone disorders, and other factors. Most current theories consider benign

breast masses as an abnormal proliferation of tissue cells, with fibroadenoma and lipoma of the breast being the more common types²³. The disease causes functional impairment and has negative implications for the psychological well-being of patients²⁴. Currently, the prevailing treatment modalities are surgery and endocrine therapy, but they are associated with serious adverse effects^{25,26}. Liver stagnation and Qi stagnation are the most common TCM evidence of breast cancer²⁷, so treatment is mostly based on draining the liver and Qi, detoxifying, and dispersing nodules.

At the current stage, breast benign tumor is mostly treated clinically by surgical resection^{28,29}. Open surgery is associated with trauma and significant hemorrhage in patients, and improper surgical procedures may lead to poor postoperative recovery and compromised quality of life for patients^{30,31}. The ultrasound-guided Mammotome device³² allows minimally invasive excision of breast lesions and provides a viable alternative for early

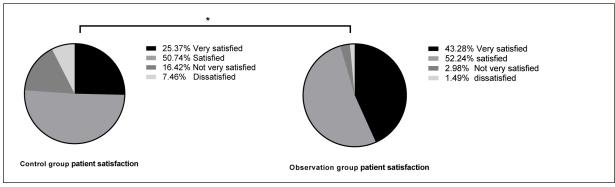


Figure 1. Comparison of satisfaction. *indicates a statistically significant difference (p<0.05) in inter-group comparison.

detection and diagnosis of breast cancer^{33,34}. Breast cancer patients fear serious consequences to their lives after surgical removal of the breast or chest³⁵. Aside from physical trauma, patients experience negative emotions such as depression and anxiety.

Mammotome-assisted surgery has also reported promising efficacy and high safety³⁶. According to the theoretical foundation of breast-conserving surgery³⁷, the minimally invasive, aesthetically pleasing, and abundantly accessible Mammotome-assisted surgery has great potential in achieving the surgical standard required for breast-conserving surgery; however, clinical data are still needed to clarify whether it achieves complete tumor resection and the presence of needle tract metastases. Compared to conventional open surgery, Mammotome-assisted surgery is less effective for Ki-67 positive, human epidermal growth factor receptor 2 (HER2), and lymph node metastasis breast cancers, which are also independent risk factors for compromised survival and the occurrence of residual tumors in the residual luminal margin after surgery. The tumor diameter has been identified as the most important factor influencing tumor residual after Mammotome surgery, in which the residual rate of lesions ≤ 20 mm in diameter is $\leq 5\%$, and the residual rate gradually increases with the increase of mass diameter^{38,39}. Because the Mammotome method involves needle biopsies, tumor cell spread by needle tract implantation is a major issue in clinical practice. Previous research⁴⁰ found that, whereas needle biopsy increased the risk of needle tract metastases, it did not provoke local recurrence. However, Mammotome surgery avoids repeated multiple punctures with a lower risk of needle tract implant metastasis⁴¹. Currently, Mammotome-assisted surgery is more accurate than previous mastectomies, less painful, requires no sutures, and is highly beneficial to postoperative recovery.

In the present study, Mammotome-assisted surgery was associated with significantly higher clinical efficacy and resulted in shorter operative time, scar length, and postoperative healing time and less intraoperative bleeding volume vs. open surgery, indicating that ultrasound-guided Mammotome-assisted surgery features better treatment efficacy benefits than traditional open surgery treatment, which may be attributed to the minimal invasiveness of the Mammotome device. The results were also consistent with previous research results found in the literature. The reason may be that the Mammotome system in Mammotome-assisted surgery facilitates the detection

and diagnosis of breast cancer by performing repeated incisions on suspicious lesions of the breast to obtain histological specimens of the breast. This minimally invasive procedure has only minimal incisions, with high safety, minimal tissue trauma, reduced local bleeding, good recovery, and low risks of infection and subcutaneous hematoma. Moreover, patients receiving Mammotome-assisted surgery showed a lower incidence of complications vs. those given open surgery, which may be ascribed to the smaller trauma, less bleeding, and accurate complete excision of the lump to lower the risk of postoperative complications. In addition, the minimal invasiveness of the Mammotome procedure also resulted in significantly higher patient satisfaction (95.52 %) vs. open surgery (76.12 %). In the present study, after the administration of the Liangxue Shugan granules, the patients' symptoms were relieved, and postoperative dysphoria and pain were significantly reduced, which may be associated with the effect of the decoction to detoxify the liver. nourish the blood, and soften the liver. However, insomnia in some patients showed no improvement, which requires further exploration.

According to medical literature⁴², the internal cause of breast cancer is a deficiency of positive energy, while the external cause is the invasion of the six desires, disorders of emotion, and diet. In addition, the disease is closely associated with the kidney, liver, and spleen⁴³. Chemoradiotherapy will cause further damage to Qi and blood, dysfunction of internal organs, and damage to kidney Qi, manifesting as irritability and depression, hot flashes, and night sweats. Liangxue Shugan granules are mainly composed of Shengdi, Chaihu, Baizhu, and Chuanxiong. The combination of all the drugs in the formula has the effect of nourishing Yin and dipping fire, benefiting Qi and dispersing nodules.

The advantage of the present study is that ultrasound Mammotome-assisted surgery clearly shows the location, size, shape, and number of masses to clarify the relationship between the masses and the vascular involvement of the surrounding tissues and effectively reduce intraoperative bleeding. Mammotome-assisted surgery has a small surgical incision, avoids large incisions of the skin, subcutaneous tissue, and normal glands, causes less damage to the tissue, significantly reduces the risk of infection and postoperative complications, promotes patient recovery, and facilitates prognosis^{9,10}. In addition, patients in this study received Liangxue Shugan granules postoperatively to potentiate the efficacy of the treatment.

Conclusions

In comparison to standard open surgery, ultrasound-guided Mammotome-assisted surgery provides a feasible therapeutic option for breast benign tumor removal with superior efficacy, shorter operating time, less trauma, higher safety, fewer problems, and higher patient satisfaction. Longterm effectiveness, disease-free survival, and other critical markers still require large-sample multicenter investigations. To get further clinical data, prospective research with a large sample obtained from several sites will be done in the future.

Data Availability

All data generated or analyzed during this study are included in this published article.

Conflict of Interest

The authors declare no competing financial interests.

Authors' Contributions

Donghua Chang and Yile Shu drafted and revised the manuscript. Donghua Chang and Yile Shu Mu were in charge of data collection. All the authors have read and agreed to the final version of the manuscript.

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Informed Consent

All eligible patients provided written informed consent prior to recruitment.

Ethics Approval

The study protocol has been approved by the hospital Ethics Committee (Ethics number: SG-YET20190514). All procedures complied with the Declaration of Helsinki's ethical guidelines for clinical research.

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