Research Protocol

A Prospective Randomized Controlled Study of the Modified Local Compression Bandaging Method and the Traditional Whole Breast Compression Bandaging Method in Minimally Invasive Breast Surgery

1.Research Background

Due to the relatively large trauma to the breast caused by traditional general anesthesia surgery, long recovery time, high incidence of postoperative complications, and the fear of general anesthesia surgery among patients, the Mammotome minimally invasive rotational resection technique has emerged. The advantages of this minimally invasive breast surgery are quite prominent, mainly manifested as visualization, small incisions, and safety and reliability. Currently, the commonly used bandaging method after minimally invasive breast surgery in clinical practice is the whole breast compression bandaging method. One or two pieces of sterile loose gauze are kneaded into a gauze ball and pressed on the residual cavity. Then, 5 to 8 pieces of loose gauze are continuously used to stack gauze balls within a 5-cm diameter around the wound for bandaging. Finally, an elastic bra is used for compression bandaging for one day. The elastic bra is a special compression elastic bandage for breast surgery, aiming to achieve auxiliary therapeutic effects such as eliminating the cavity and protecting the surgical incision. However, in the process of clinical practice, it has been found that this bandaging method brings great discomfort to patients. It is not only reflected in varying degrees of skin itching on the covered skin, with a relatively high occurrence of local red rashes, but also affects the patients' breathing. The vast majority of patients complain of pain and discomfort due to the tightness on the chest and back, being restless while sitting or lying down. At night, they can only sleep in a semi-sitting position and are largely unable to enter deep sleep, seriously affecting the patients' daily activities and sleep. In order to improve the patients' experience and reduce their discomfort as much as possible, the medical and nursing joint team has explored and modified the compression bandaging method after minimally invasive surgery and found that the local compression bandaging method is more comfortable. That is, one or two pieces of loose gauze are kneaded into a gauze ball to replace multiple gauze balls and placed in the residual cavity. Then, elastic medical adhesive tape is used for local compression and sticking. Finally, a pure cotton clean towel is placed inside the elastic bra and the elastic bra is worn for one day. The results of a pre-experiment with 50 cases show that among the patients using the local compression bandaging method, there is no occurrence of wound hematoma, and their skin itching, chest and back pain, comfort level, and

sleep quality have all been improved. In order to further compare the application effects of the whole breast compression bandaging method and the local compression bandaging method, our research team intends to conduct a controlled study of these two methods.

2. Research Objectives

Research objective: Through a randomized controlled study, compare and study the curative effects of the whole breast bandaging method and the local bandaging method during the perioperative period of minimally invasive breast surgery. Evaluate the impacts of the two bandaging methods on the wound healing status after minimally invasive breast surgery, the incidence of hematoma, the patients' comfort level, and the incidence of patients' pain.

3. Research Design

① Randomized controlled trial. Put the number tags 1 and 2 into two identical envelopes respectively. The number tag 1 represents the whole breast compression bandaging method as the control group, and the number tag 2 represents the local compression bandaging method as the experimental group. The patients included in the study randomly draw an envelope and enter the corresponding group according to the tag they draw. The patients' surgeries are all scheduled during the non-menstrual period. On the first day after the surgery, the patients in both groups fill in the questionnaire QR code. The content of the questionnaire QR code includes general information (including: name, age, underlying diseases, educational background, etc.), pain rating scale, comfort scale, whether there is a hematoma, and a patient satisfaction questionnaire. Use breast color Doppler ultrasound to check the wound healing and hematoma status at 2 weeks and 3 months after the surgery respectively.

② The control group uses the whole breast bandaging method: Knead 1 to 2 pieces of sterile loose gauze into a gauze ball and press it on the residual cavity. Then, continue to use 5 to 8 pieces of loose gauze to stack gauze balls within a 5-cm diameter around the wound for bandaging, and finally use an elastic bra for compression bandaging. The time for compression bandaging with the elastic bra is 24 hours.

③ The experimental group uses the local bandaging method: Knead one or two pieces of loose gauze into a gauze ball to replace multiple gauze balls and place it in the residual cavity. Then, use elastic medical adhesive tape for local compression and sticking. Finally, place a pure cotton clean towel inside the elastic bra and wear the elastic bra for one day.

④ The elastic bras involved above are all purchased by the patients themselves. The elastic bra is a product with a sealed package and can be directly used after being opened according to the instructions. The material of the elastic bra is made of spandex elastic fabric, with a front row of snap

buttons. There is a compression band at the front end of the bra, which adopts a double parallel band design and can adjust the local pressure intensity. The compression band can be pressurized in parallel or crossed. Crossed pressurization can be used for local pressurization to accelerate the repair of the residual cavity. The functions of the elastic bra are: 1. Effectively stop bleeding after surgery and reduce postoperative exudation; 2. Apply scientific multi-point compression to prevent tissue necrosis; 3. Repair the surgical wound and promote wound healing. The wearing method of the elastic bra: After laying out the elastic bra flat, pull the snap buttons to the front of the chest and fasten them. Stick the Velcro of the left and right shoulder straps of the patient. Forcefully press the compression band at the front end on the side with the wound backward and stick it firmly. For the side without the wound, it can be generally stuck. Patients with different chest circumferences and weights choose different models of elastic bras, M size (45-55 kg) and L size (55-65 kg).

⑤ This study is carried out by the minimally invasive team led by Provide Health Care of provide. The team consists of 1 chief physician and 4 nurses, and the postoperative bandaging of the minimally invasive wound and the inspection of the bandaging effect are completed under the guidance and assistance of Surgeon .

4.Research Subjects

Patients scheduled to undergo ultrasound-guided minimally invasive rotational resection of the breast.

Inclusion Criteria:

① Age between 18 and 70 years old;

② The ultrasound report shows category or category 4A;

③ Patients without allergy to medical adhesive tape;

④ Patients without hematopoietic system diseases such as bleeding tendency and coagulation dysfunction;

⑤ Willingly participate in the investigation and study;

⑥ No fever and no infection found during the admission physical examination.

Exclusion Criteria:

① Patients with malignant breast tumors;

② Patients with mental illnesses;

③ Patients who do not meet the indications for minimally invasive

surgery according to the examination results.

5. Research Endpoints

1. Primary research endpoint: The incidence of hematoma in patients. 2. Secondary research endpoints: The patients' comfort level, the incidence of pain, the satisfaction with medical treatment, medical adhesive-related skin damage, and safety.

6. Research Risks

Both groups of patients may experience subcutaneous hematoma, itching, pain, poor breathing, etc. If any damage related to the study occurs, it will be handled in accordance with relevant national laws and regulations.

7. Definitions of Research Endpoints and Related Outcome Judgments

① Comfort level: Comfort scale: Use the Kolcaba General Comfort Questionnaire (GCQ) to evaluate the patients' comfort level, including four dimensions of physiology, psychology, spirit, social culture, and environment, with a total of 28 items. The higher the score, the more comfortable the patient is.

② Incidence of hematoma in both groups: Postoperative hematoma is commonly seen within 24 hours after the surgery, often manifested as a local hard mass in the residual cavity, ecchymosis under the skin, and the patient complains of severe pain and a feeling of swelling.

③ Incidence of pain in both groups: Defined as the comparison of the pain of the wound from skin incision to the first day after the surgery and 2 weeks after the surgery.

④ Patient satisfaction: A survey of all patients on our medical staff, the ward environment, and the overall medical experience from admission to discharge.

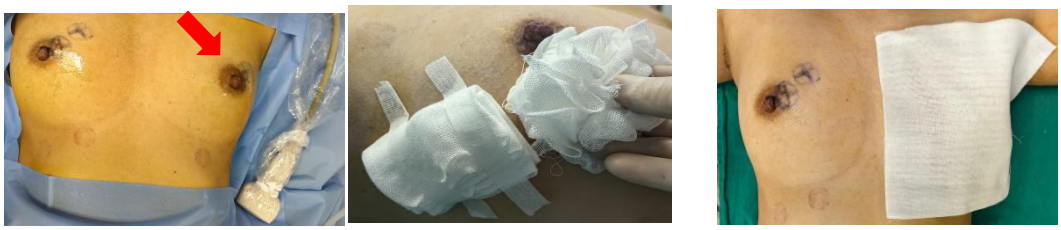
⑤ Medical adhesive-related skin damage: Observation of related skin damage caused during the period from fixing the gauze with anti-allergic medical elastic adhesive tape on the patient to removing the tape one day later, such as mechanical damage, contact dermatitis, local skin allergy,

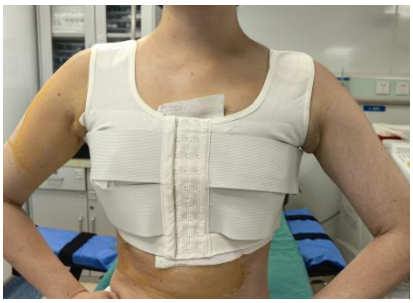
tension injury, and epidermal exfoliation injury.

8、Standard Operating Procedure (SOP) for the Surgical Operation

1.Preoperative Ultrasound Localization

A **B** **C**

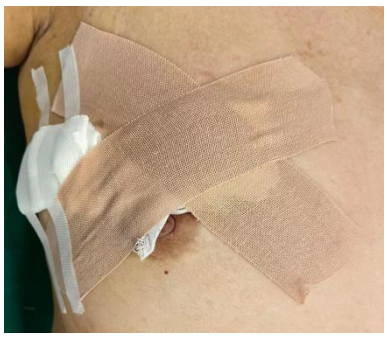


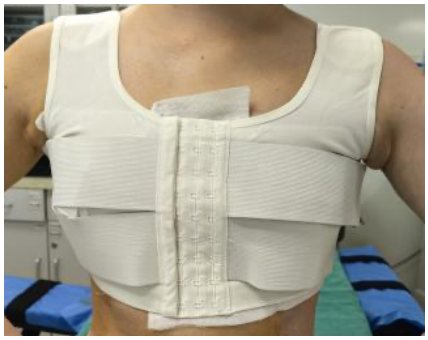


D

Picture1. Traditional Whole Breast Compression Bandaging Method

A: Locate the position of the mass before the operation (as indicated by the red arrow), and resect the mass under the guidance of color Doppler ultrasound; B: After the mass is resected, perform bandaging. Place several loose gauze balls at the position of the residual cavity for local compression; C: Cover the residual cavity and the incision with a sterile cotton pad; D: Finally, put on an elastic bra for compression bandaging.





Ⅰ Ⅱ

Picture2：the Modified Local Compression Bandaging Method

Ⅰ ：The intraoperative operation method remains unchanged. The postoperative bandaging technique is improved. Ⅱ：finally, just wear an elastic bra.

9. Sample Size Estimation

The evaluation items of this study include the patients' general information: two dimensions of age and chest circumference size, four dimensions of the patients' comfort level, one dimension of the incidence of patients' hematoma, one dimension of the incidence of pain, one dimension of the satisfaction with medical treatment, one dimension of medical adhesive-related skin damage, and three dimensions of safety, totaling 13 items. According to the formula, the number of samples N = the number of variables × 20 × (1 + 20%) = 13 × 20 × (1 + 20%), and the actual sample size is 312 people.

10. Statistical Analysis

① Use the SPSS 25.0 software for statistical analysis. All statistical tests are two-sided tests, with $\alpha = 0.05$, and a P value less than 0.05 is considered statistically significant.

② Use percentages, means ± standard deviations to describe the patients' general information.

③ Use rates, frequencies, and percentages to describe the incidences, and use means ± standard deviations to describe the scores of each dimension of the comfort level, the incidence of hematoma, the incidence of pain, the satisfaction with medical treatment, medical adhesive-related skin damage, and safety.

④ Use t-tests or regression analysis to study the impact of the patients' general information on the symptoms.

XI. Data Management

All clinical pathological data are consistent with the clinical records. A Case Report Form (CRF) will be established for each patient.