Clinical therapeutic evaluation of vacuum sealing drainage and precise ultrasound-guided debridement in the treatment of non-lactational mastitis

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Abstract. The aim of the present study was to compare the efficacy of vacuum sealing drainage (VSD) and precise ultrasound-guided debridement in the treatment of non-lactational mastitis and to determine the optimal surgical treatment. A set of 60 cases diagnosed with non-lactational mastitis who had received surgical treatment at the Department of Thoracic and Breast Surgery of Xiamen Hospital of Traditional Chinese Medicine (Xiamen, China) between July 2017 and June 2019 were included. According to the surgical method, 30 patients were assigned to the VSD group and 30 patients were assigned to the precise ultrasound-guided debridement group. The clinicopathological data of the two groups were compared. The overall rates of recurrence and new incidence were 6.8 and 8.5%, respectively. The mean total disease course was 5.3 months and all of the patients were cured after treatment. Except for the hospitalization time and post-operative pain scores, the clinicopathological data between the two groups were similar. The hospitalization time in the VSD group was significantly longer than that in the precise ultrasound-guided debridement group. Pain scores on the first and third days after the operation in the precise ultrasound-guided debridement group were significantly higher than those in the VSD group (P=0.008 and 0.001, respectively). In conclusion, the efficacies of VSD and precise ultrasound-guided debridement for the treatment of non-lactational mastitis were generally both satisfactory without significant differences. Of note, the former is suitable for patients with inverted nipples and obvious skin ulcerations, while the latter is mainly suitable for patients with abscesses, small surgical incisions and those who require short hospital stays.

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Introduction

Non-lactational mastitis refers to a group of nonspecific inflammatory diseases with unknown pathogeneses, which mainly occur in females during non-breastfeeding periods. The pathological types include mammary duct ectasia (MDE)/periduct mastitis (PDM) and granulomatous lobular mastitis (GLM) (1). Typical clinical symptoms are lacking and at times, the only symptom may be a breast lump without any obvious inflammatory signs, making it difficult to distinguish the disease from breast cancer (2). Abscess, sinus or ulcer formation are frequent and the condition is unlikely to be cured by conventional antibiotics. As the surgical methods are not uniform in consensus, it is difficult for surgeons to make clinical decisions when patients require surgical intervention (3-5). Certain patients lose their breasts due to having non-lactational mastitis, which seriously affects their physical and mental health. At present, surgery is the most common and effective method for non-lactational mastitis (3,6). However, the current conventional surgical treatment, particularly for abscess incision drainage, has several disadvantages, including a long time interval over which the patient requires dressing changes, nonhealing wounds, obvious breast deformation, high recurrence rate and poor efficacy. Simple lumpectomy is suitable for patients with localized lesions, but the disease easily recurs (7). However, total mastectomy causes patients to lose their breasts and there are still cases of residual skin ulceration after the operation. Therefore, surgical treatment is still the focus and challenge of current research.

Vacuum sealing drainage (VSD) technology refers to the debridement of lesions, the placement of medical sponge parceling drainage tubes into the lacuna, the sealing of wounds with a semipermeable membrane and the connection of the drainage tube to a device for negative pressure drainage. This technology may intermittently or continuously generate a pressure lower than atmospheric pressure at the wound surface and promote wound healing through a series of physiological mechanisms (8). VSD may be applied to various types of wounds, including infected wounds, skin graft wounds and wounds without skin or soft tissue (9,10). This technique has outstanding advantages in clinical application, e.g. it is easy to operate, is able to avoid cross-infection and accurately observe the amount and character of drainage, and it may relieve wound

pain and significantly shorten the treatment time (11-13). VSD is rarely reported for the treatment of non-lactational mastitis and no prospective or controlled trials have been performed to confirm the short-term and long-term efficacies of VSD in the treatment of non-lactational mastitis.

Precise ultrasound-guided debridement refers to the intraoperative use of ultrasound to locate the scope and depth of lesions, and instruments such as probes and spatulas are employed to remove pus and necrosis, as well as to clear the sinus tract. Compared with traditional debridement, this technology has numerous advantages, such as its accuracy, small incision and thorough debridement. To the best of our knowledge, there are currently no research studies on the use of this technology in the treatment of non-lactational mastitis or comparisons with VSD in terms of clinical efficacy. At our department, VSD and precise ultrasound-guided debridement are both used to treat non-lactational mastitis, with satisfactory clinical efficacies. However, due to a lack of sufficient clinical data and objective research to discuss the indications for the two treatment methods, it is still in the exploratory stage. In the present study, the efficacies of VSD and precise ultrasound-guided debridement in the treatment of non-lactational mastitis were analyzed and the advantages and disadvantages were compared to identify the optimal surgical treatment for non-lactational mastitis.

Materials and methods

Subjects. A total of 60 patients diagnosed with non-lactational mastitis who received surgical treatment at the Department of Thoracic and Breast Surgery of Xiamen Hospital of Traditional Chinese Medicine (Xiamen, China) between July 2017 and June 2019 were included.

The adjustable negative pressure drainage device (SAC-A3-D2; Sacco Medical Technology Co., Ltd.) consisted of four parts: i) An adsorption sponge; ii) a semipermeable membrane; iii) a sucking disc and pipeline; and iv) a negative pressure device. A negative pressure of 140-150 mmHg was maintained.

The pathologic types included MDE/PDM and GLM. According to the diagnostic criteria reported in literatures (14-17), the following diagnostic criteria were applied (all cases were in accordance with the following two points): i) Clinical symptoms of breast mass, with or without an inverted nipple, nipple discharge and breast pain; an abscess may occur when the acute infection is secondary to the disease; end-stage abscesses may be divided into fistulas, sinus tracts or ulcers of the breast skin and they require a long time period to heal because of recurrent chronic inflammation; ii) Histopathological features: Hollow-needle puncture biopsy was used to obtain specimens; microscopically, for MDE/PDM, the breast duct is highly dilated and the lumen is filled with pink granular thick material; infiltrating lymphocytes, plasma cells and neutrophils are present around the dilated duct. The main features of GLMs are non-caseous granulomas centered on lobular units of the mammary gland and they are multifocal and unequal in size, with or without micro-abscesses (1). Recurrence was defined as follows: Recurrence at the primary site after the primary disease has been cured for a period of time. The definition of new incidence was as follows: After the disappearance or stabilization of the original lesion, new lesions appear in other parts of the ipsilateral breast or in the contralateral breast under certain conditions, not caused by any direct spread of the original lesion. Clinical cure was defined as disappearance of systemic symptoms, clinically untouchable primary inflammatory lesions and healing of ulcers or wounds. Exclusion criteria were as follows: i) Pregnant and breast feeding patients, ii) patients with acute infectious mastitis and iii) patients with malignant breast tumors.

Preoperative preparation. All patients were examined by color doppler ultrasound before the operation to determine the location, breadth and depth of lesions, and to mark the skin to avoid any omission during the operation. In patients with skin tension caused by abscess, a cut should be performed to discharge pus. The pus and secretions of skin ulceration were subjected to bacterial culture and drug sensitivity tests. Operation style was selected on an individual basis after the surgeon clarified the advantages and disadvantages of each surgery. A total of 30 patients received VSD and the other 30 patients received precise ultrasound-guided debridement. Full anesthesia was applied in the two groups before surgery. Patients were put in the supine position with abduction of upper limbs.

VSD. Representative images of the procedure are presented in Fig. 1 (8,18). Stage I operation: The location and size of the incision were selected according to the location, scope and skin condition of the lesion. On the basis of ensuring that the lesions were cleared to the greatest extent, the surgical incision was inconspicuous as much as possible for example incision around the areola and was approximately 3-4 cm in length, as showed in Fig. 1D. For those cases with skin ulcerations, the skin incision was extended directly and was at least 2 cm away from the nipple to avoid nipple ischemia and necrosis caused by subsequent compression of the sucking disc on the nipple. For patients with multiple abscesses, intraoperative ultrasound was used to open each abscess cavity to facilitate drainage, and to remove pus and necrotic tissue. In cases of combined inverted nipples or abscesses involving the large lacteal duct, the large lacteal duct was disconnected intraoperatively and the nipple was reconstructed with purse-string sutures behind the nipple. For subcutaneous abscesses, the subcutaneous necrotic tissue was scraped off with a spatula; chronic fistulas and sinus tracts were resected intraoperatively as much as possible. The wound was washed repeatedly with hydrogen peroxide (3%), dilute iodine and normal saline. The pus was extracted and sent for bacterial culture.

Placement of negative pressure drainage: After the surgical wound was fully hemostatic, the size and shape of the wound were initially estimated and a medical sponge was cut to fit the size and shape of the wound to avoid the formation of a remnant cavity (Fig. 1C). After the medical sponge was placed, the whole wound was sealed with a medical semipermeable membrane, with the coverage exceeding the scope of the wound (Fig. 1E). If there was a large extent of exudation at the site of the skin laceration, gauze was used to cover the wound first and subsequently, the membrane was applied. The connecting sucking disc was placed on the surface of the wound and connected to the negative pressure

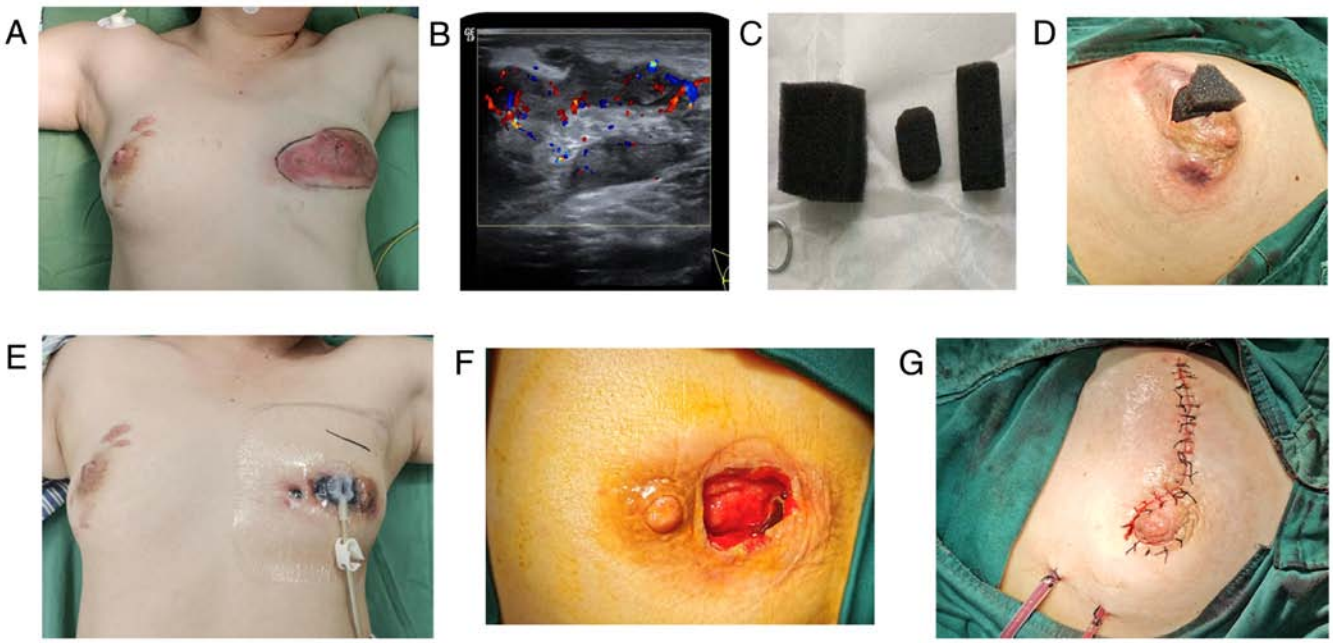

Figure 1. Representative images of VSD (all images were obtained from the same patients whose age was 33 years). (A) The lesion invaded each quadrant of the breast preoperatively. (B) Color ultrasound examination revealing abscesses and sinus tracts. (C) The medical sponge was cut to fit the size and shape of the wound. (D) After debridement, the medical sponges were placed to fill the cavity. (E) The wound was sealed with semi-permeable membrane and sucking disc was connected to a negative pressure device. (F) After VSD, the cavity diminished and the granulation tissue was fresh. (G) The wound was sutured and drainage tubes were placed. VSD, vacuum sealing drainage.

device. A continuous negative pressure of 140-150 mmHg was maintained. During the treatment, obstruction of the negative pressure drainage tube was avoided, the amount and characteristics of the drainage fluid were observed and the negative pressure drainage material was replaced once a week. Traditional Chinese Medicine, such as Tounong Powder (19), was administered according to the symptoms.

Stage II operation for wound repair: The granulation after vacuum drainage was evaluated over 3 weeks. If the granulation tissue was fresh, the drainage fluid was clear and the purulent fluid was small, a second-stage operation was performed. The material was removed during the operation and the purulent cavity was cleaned and explored again (Fig. 1F). If there was still a fistula or sinus tract, it was removed. If the wound was too large to suture directly, the mammary gland flap was transferred to fill the defect area and a drainage tube was then placed.

Precise ultrasound-guided debridement. Representative images of the procedure are presented in Fig. 2. The procedure of the surgery was similar to that of minimally invasive rotary cutting surgery as previously reported (20). During the operation, the breadth and depth of the abscess were located by color Doppler ultrasound. The incision was made as small as possible, approximately 1-2 cm long, as showed in Fig. 2B. Under the guidance of color Doppler ultrasound, a probe was used to explore the purulent cavity and the necrotic tissue was scraped off with a spatula (Fig. 2B and C). Multiple incisions were made for those cases with multiple sinuses or a long distance from the purulent cavity. During the operation, purulent fluid was extracted for bacterial culture. After debridement, the wound was washed repeatedly with hydrogen peroxide, dilute iodophor and normal saline. Vaseline gauze was placed in the sinus or pus cavity (Fig. 2E), which was covered with imbricated triangular gauze after surgery (Fig. 2F). Subsequently, elastic bandages were applied under pressure to cover the wound (Fig. 2G). For patients with excessive bleeding during the operation, the bandage was maintained for 2 days and the dressing was changed on the second day after the operation. The dressing was changed every day or every 2 days according to the exudation situation. Gauze was placed for drainage each time. After there was no purulent exudation, the gauze strip was removed and the wound was closed with elastic bandages and gauze under pressure. Prior to and after the operation, all patients were treated with Traditional Chinese Medicine (19).

Post-operation and follow-up. After operation, dressing were changed every day in the first week, and after that period, a compression bandage was applied to reduce the abscess cavity of breast. Pain numerical score (NRS) (21) was used to evaluate the level of pain of the wound on the first, third, and fifth days after operation. Patient follow-ups were performed via outpatient appointment or telephone until the diseases were cured. During follow-up, outcomes such as recurrent, new incidence, and clinical cure were evaluated and recorded, as defined at the 'subjects' section.

Statistical analysis. All data were statistically processed with the SPSS 18.0 statistical software package (SPSS, Inc.). Continuous variables were expressed as the mean ± SD after the testing of the normal distribution and compared using unpaired t-tests. Count data were expressed as n (%) and compared by Chi-square tests. $P<0.05$ was considered to indicate a statistically significant difference. Mann-Whitney U tests were used to compare the postoperative pain scores.

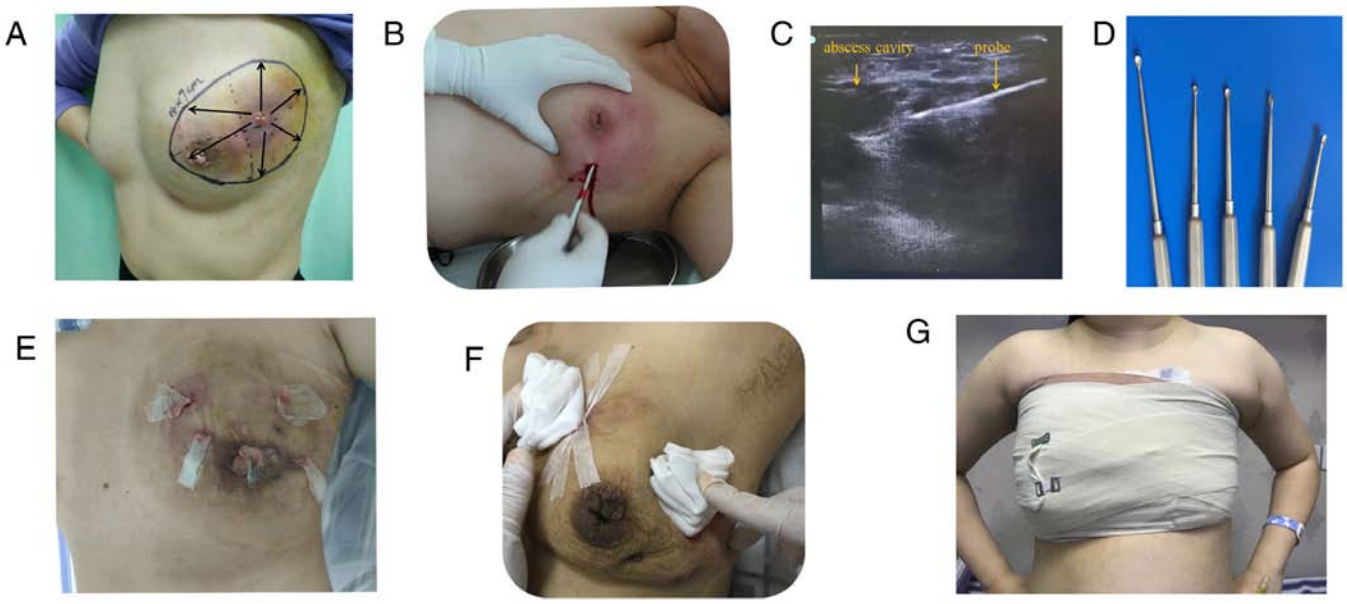

Figure 2. Representative images of precise ultrasound-guided debridement (the images were obtained from 4 patients whose ages ranged from 26 to 35 years). (A) The lesion was marked on the skin prior to the operation. (B) During the operation, a probe was used to explore the purulent cavity and the necrotic tissue was scraped off with a spatula. (C) Color ultrasound located the lesion intraoperatively. (D) Various spatulas. (E) Vaseline gauzes were placed for drainage. (F) The wound was covered with triangular gauze. (G) Elastic bandages were applied under pressure to bandage the breast.

Results

General information. All patients were female. One patent was lost to the follow-up in the precise ultrasound-guided debridement group. The average age at onset in the entire cohort was 31.1 years (23-44 years), there was no significant age different between groups and the average preoperative disease course was 2.7 months and the average time from delivery to onset was 2.8 years. Except for one case of positive pus culture (*Corynebacterium minimus*), the remainder of cases was negative. A total of 18.6% (11/59) of the patients had inverted nipples. The follow-up rate was 98.3% (59/60), the average follow-up time was 16.9 months, the total recurrence rate was 6.8% (4/59), the total new incidence rate was 8.5% (5/59) and the average disease course was 5.3 months. All patients were cured after the operation, as shown in Table I.

Comparison of efficacy. The clinicopathological data of the two groups were compared (Table I). Except for the hospitalization time and postoperative pain score, the clinicopathological data of the VSD group and precise ultrasound-guided debridement group were similar, with no significant differences. The hospitalization time in the VSD group was significantly longer than that in the other group (24.80±3.32 vs. 8.62±3.80 days, P<0.001). The pain scores on the first and third days after the operation in the precise ultrasound-guided debridement group were significantly higher than those in the VSD group (P=0.008 and 0.001, respectively), while the pain scores on the fifth day after the operation were similar between the two groups. There was no significant difference in the recurrence rate, new incidence rate, disease course after the operation or total disease course between the two groups.

Representative case. The patient was 33 years old, had 2 pregnancies and 2 births and was 3 years postpartum. She had left breast non-lactational mastitis 3 months previously and the mass disappeared after taking Traditional Chinese Medicine and applying Traditional Chinese Medicine ointment externally for 1 month. The right breast mass accompanied by pain and skin ulceration occurred for 2 weeks. No significant relief was achieved after treatment with Traditional Chinese Medicine or incision and drainage. The right nipple was indicated to be inverted. The right breast was obviously larger than the left breast. The size of the mass was ~10x8 cm in the upper and lower quadrants of the right breast. The skin surface was ulcerated and purulent, with unclear boundaries and poor mobility. The puncture pathology indicated 'GLM' and no bacterial growth was detected in the pus culture. After admission, 'right mammary abscess debridement + VSD drainage + inverted nipple correction' was performed. After negative pressure drainage for 21 days, granulation was fresh without obvious pus exudation, so VSD equipment was removed, debridement and suture were performed and a rubber drainage tube was placed. Prior to and after the operation, the patient was treated with Traditional Chinese Medicine. The drainage tube was removed 2 weeks after the operation, the wound healed and the mass subsided. At four months after this, a mass was observed again at the periphery of the primary lesion with skin redness and ulceration. The biopsy again indicated 'GLM'. After 2 months of incision, drainage and treatment with Traditional Chinese Medicine, the abscess still repeatedly recurred. Subsequently, precise ultrasound-guided debridement surgery was performed. After 2 months of conventional dressing change and treatment with Traditional Chinese Medicine (19), the lesion had healed and the mass had subsided.

Discussion

In recent years, the incidence rate of non-lactation mastitis has been obviously increasing, particularly in coastal cities (5).

Table I. Comparison of clinicopathological data between the two groups.

Item	VSD group, n=30	Precise ultrasound-guided debridement, group n=29	P-value
Age (years)	31.90±1.85	30.24±4.50	0.177
Time from morbidity to surgery (months)	3.02±3.26	2.36±2.25	0.369
Time from last birth to morbidity (years)	2.85±1.48	2.74±1.16	0.748
Location			0.992
Left	16	15	
Right	13	13	
Bilateral	1	1	
Inverted nipple			0.287
Yes	4	7	
No	26	23	
Birth history			0.513
Yes	28	28	
No	2	1	
Maximum diameter of lesion (cm)	9.83±3.78	9.00±4.09	0.419
Skin ulceration			0.937
Yes	22	21	
No	8	8	
Pathology			0.233
MDE/PDE	8	12	
GLM	22	17	
Blood loss (ml)	64±33.38	76.9±41.93	0.196
Hospitalization time (days)	24.80±3.32	8.62±3.80	<0.001
Recurrence			0.681
Yes	2 (6.7)	2 (6.9)	
No	28 (93.3)	27 (93.1)	
New incidence			0.516
Yes	3 (10)	2 (6.9)	
No	27 (90)	27 (93.1)	
Postoperative pain score (0-10)			
Day 1	2.33±0.71	3.10±1.08	0.008
Day 3	1.57±0.68	2.14±0.52	0.001
Day 5	0.93±0.58	0.79±0.49	0.348
Cure rate (%)	100 (30/30)	100 (29/29)	
Postoperative disease course (months)	2.97±1.49	2.40±0.93	0.084
Total disease course (months)	5.98±3.69	4.75±2.50	0.141

Values are expressed as the mean ± standard deviation or n (%). VSD, vacuum sealing drainage; MDE/PDE, mammary duct ectasia/periduct mastitis; GLM, granulomatous lobular mastitis.

To date, the pathogenesis of the disease has remained elusive (2,22,23). It is characterized by various types, a long disease course and a high recurrence rate, particularly for refractory non-lactational mastitis, which is a focus and challenge in the clinic (24). At present, there are various treatment methods for this disease. Traditional Chinese Medicine emphasizes the concept of combining overall and local syndrome differentiation, combining internal and external treatment and treating both the symptoms and root causes. Internal and external treatment methods are mostly used and external treatment methods are also diversified. To date, Western medicine has not formulated any systematic treatment standard. The common treatment methods include surgical treatment, hormone therapy, immunosuppressive therapy, antibiotic therapy (including antimycobacterial drug therapy) and expectant therapy (3). Among them, surgery is the preferred treatment. At present, there are various surgical methods used at home and abroad, including lumpectomy,

incision and drainage, segmental resection, simple mastectomy and subcutaneous mastectomy (4,5). However, there is no unified surgical method. For simple lump-type non-lactational mastitis, Traditional Chinese Medicine plus external therapy has been adopted in our department. For refractory non-lactation mastitis, particularly for cases of multiple abscesses or sinuses, VSD or precise ultrasound-guided debridement combined with Traditional Chinese Medicine has been adopted for treatment. The purpose of the present study was to compare the short-term and long-term effects of the two surgical methods, to explore their clinical application value and to provide an optimal treatment for refractory non-lactational mastitis.

Classic inflammatory lesions require long-term dressing changes after incision and pus discharge (6). When dressings are changed, patients suffer from intense pain. Open wounds are prone to secondary bacterial infections and require a long time to heal. Compared with traditional dressing changes, VSD is able to shorten the time required for wound healing (25) and markedly reduces the level of pain (26). The surgeon is able to trim the medical sponge according to the size and shape of the purulent cavity to make it fit into the cavity. After surgery, the sponge may be adjusted according to the specific situation of the wound and it may also be washed. It may not only ensure the timely removal of necrotic tissue and exudate, but also promote the growth of granulation and accelerate wound repair (9,25,27). During precise ultrasound-guided debridement, it is easy to determine the location, scope and depth of the lesions, which makes it convenient to detect and deal with purulent cavities or sinuses of various sizes by using color ultrasound, thereby avoiding missing any lesions. This technology has the advantages of accurate location, limited trauma and sufficient debridement. Comparing the clinical data of the two groups of the present study indicated that the hospitalization time in the VSD group was longer and the hospitalization costs were higher due to the high cost of consumables, but the postoperative pain score in this group was significantly lower. In the VSD group, the incision was larger and it was possible to excise the sinus simultaneously, trim the skin lesion and correct the inverted nipple. The amount of intraoperative bleeding in the precise ultrasound-guided debridement group was slightly higher than that in the VSD group but the difference was not statistically significant. The reason was that the surgical wound was small, it was not possible to achieve accurate hemostasis during the operation and the dressing required to be changed more frequently after the operation. In addition, the pus and necrotic tissue required to be cleared manually during dressing changes, leading to a significantly higher pain score on the first and third days after the operation than in the VSD group. Therefore, VSD technology is suitable for patients with multiple abscesses, sinus tracts, inverted nipples or obvious skin ulcerations, while precise ultrasound-guided debridement is more suitable for patients with abscesses or patients who require small incisions, short hospitalization times and low hospitalization costs. As reported in the literature, the course of GLM may be as long as 10-22 months (28,29), but the average disease course in the present study was only 5.3 months (1.25-19 months). This suggests that surgery with VSD and precise ultrasound-guided debridement may be able to markedly shorten the disease course of non-lactational mastitis. The total recurrence rate was 6.8% (4/59), which was lower than that reported in the literature (30). Non-lactational mastitis is complex. As for refractory non-lactational mastitis, VSD or precise ultrasound-guided debridement combined with Traditional Chinese Medicine may achieve satisfactory clinical effects, avoiding total mastectomy. Of note, the VSD is suitable for patients with inverted nipples and obvious skin ulcerations, while the precise ultrasound-guided debridement is mainly suitable for patients with abscesses, small surgical incisions and those who require short hospital stays.

However, a limitation of the present study is the low number of patients enrolled. Including more participants may help to confirm the findings of the present study. However, the follow-up rate was 98% in total, the quality and reliability of the data was good despite small sample size. As another limitation of the present study, other diagnostic information (such as blood tests and more detailed clinical stages of the disease) was not available; however, future studies may be able to include such additional parameters. Furthermore, the present study was a clinical study lacking any mechanistic analysis of the two techniques from a pathophysiological perspective. In addition, traditional incision and drainage is a therapeutic option for the disease (6), the present study lacked a control group subjected to the traditional incision and drainage and the length of the follow-up time was not sufficient. These points will be addressed in future studies.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

RC and JC designed the study. RC, JC, AP, LY and RZ performed the trial and collected the clinical data. RC analyzed and interpreted the data. All authors wrote the manuscript and revised it for important intellectual content. RC and JC checked and approved the authenticity of the raw data. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

The present study was approved by the Ethics Committee on Scientific Research of Xiamen Hospital of Traditional Chinese Medicine (Xiamen, China). Written informed consent was acquired from all patients.

Patient consent for publication

The patients provided written informed consent for the publication of their data and images.

Competing interests

The authors declare that they have no competing interests.

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