

Clinical efficacy of the external application of Ji De Sheng She Yao in the treatment of inflammatory breast mass during lactation and the postoperative recovery after minimally invasive surgery

Lei Fang¹, Hong Li² and Wei Xu^{1*}

¹Thyroid Surgery, First people's Hospital of Jining, Jining, China

²The BH Ultrasound Office, First people's Hospital of Jining, Jining, China

Abstract: Aim of present study is to observe and analyze the clinical efficacy of the external application of Ji De Sheng She Yao in the treatment of inflammatory breast mass during lactation and to investigate the postoperative recovery condition after minimally invasive surgery. A total of 160 patients who had been treated at our hospital for inflammatory breast mass during lactation from January 2016 to August 2018 were enrolled as research objects. They were randomized into research group and control group, with 80 patients in each group. The patients in the control group were treated with intravenous administration of cefmetazole as well as traditional excision; while external application of Ji De Sheng She Yao and minimally invasive surgery were applied to patients in the research group. The therapeutic efficacy was compared between both groups. The total therapeutic efficacy of the research group was significantly higher than that of the control group ($p < 0.05$). By comparing the surgical indexes of both groups, the operation time, the volume of intraoperative bleeding, size of incision and healing of incision of the research group were significantly better than those of the control group ($p < 0.05$). Moreover, the research group had better advantages over the control group regarding the time of clinical improvement, complication rate and the satisfaction of cosmetic effects ($p < 0.05$). External application of Ji De Sheng She Yao has therapeutic advantages in the treatment for inflammatory breast mass during lactation, and minimally invasive surgery can significantly improve the therapeutic effects and thus promote recovery.

Keywords: External application of Ji De Sheng She Yao, inflammatory breast mass during lactation, clinical efficacy, minimally invasive surgery, effect on recovery.

INTRODUCTION

Postpartum mastitis often occurs after the first delivery, which is categorized into two types based on the development course of disease: stasis mastitis and suppurative mastitis. The puerperal mastitis, that is, the suppurative infection of the breast during acute mastitis, is mainly seen in primipara, mostly 3-4 weeks after delivery (Yu, *et al.*, 2016; Luo, 2016; Wroblewska *et al.*, 2015). The disease is mainly characterized swelling, heat and pain of the breast, with local lumps or abscess, elevated body temperature and increased white blood cells. Before the formation of abscess, therapies are mainly directed in anti-infection and promotion of the discharge of milk. Once the abscess is formed, it is mainly treated with incision and drainage. The prognosis of this disease is rather good.

In the case of inflammatory breast mass during lactation (shown in fig. 1 below), if part of the mass become soft in a short time, it indicates that an abscess has been formed, and then incision and drainage are needed. The axillary lymph nodes on the affected side are often swollen and the white blood cell count is increased. The clinical manifestations of inflammatory breast mass during lactation are related to its position. When at shallow

position, local redness and swelling can be observed in the early stage, while it is often not obvious when the abscess is at deep position (Moty, *et al.*, 2016; Hazra, *et al.*, 2015), which is mainly presented as local pain and systemic symptoms. Abscess can be single or multiple, can be formed sequentially or simultaneously, can be ruptured spontaneously or discharged through the nipple. Moreover, it can also invade the loose tissue in the posterior space of the breast to form a post-mammary abscess. In this study, we observed and analyzed the clinical efficacy of the external application of Ji De Sheng She Yao in the treatment for inflammatory breast mass during lactation, as well as investigated the postoperative recovery condition after minimally invasive surgery, aiming to provide valuable instructions for practical treatments.

MATERIALS AND METHODS

General data

A total of 160 patients who had been treated at the First people's Hospital of Jining for inflammatory breast mass during lactation from January 2016 to August 2018 were enrolled as research objects. This paper has a rigorous structure and the conclusion has been approved by relevant ethics and relevant departments. All cases were definitely diagnosed as inflammatory breast mass during

*Corresponding author: e-mail: 374636277@qq.com

lactation with relevant clinical examinations (as shown in fig. 2). Those with abnormal liver and kidney functions, abnormal blood results, severe organ diseases, mental disorders and those who were unwilling to participate were excluded. All patients in this study enjoyed the right to know and signed informed consent. All patients were randomized into research group and control group, with 80 patients in each group. Of those, the average age of the patients in the research group was (30.0±2.9) years, ranging from 20 to 40. The average age of the patients in the control group was (32.6±1.8) years, ranging from 21 to 43. There was no significant difference in data between two groups before treatment ($p>0.05$).

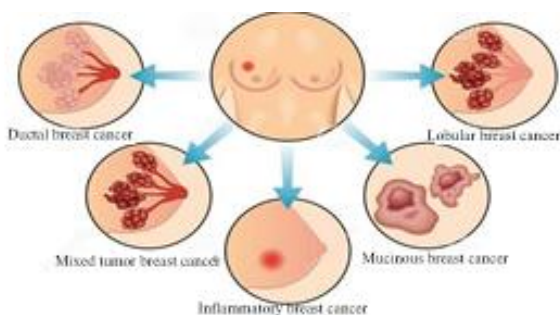


Fig. 1: Inflammatory breast mass during lactation

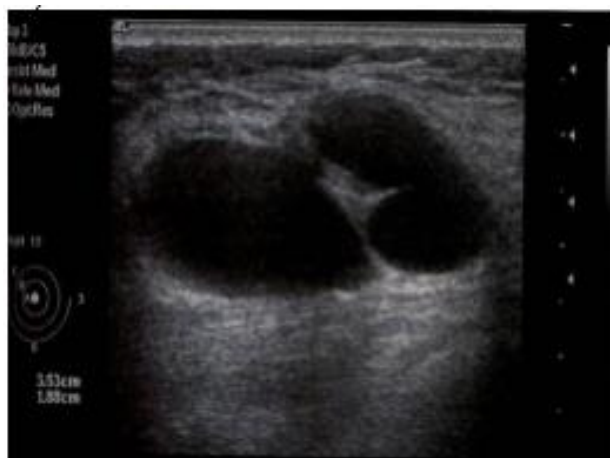


Fig. 2: The imaging figure of inflammatory breast mass during lactation

Methods

Different therapeutic methods were applied for the two groups. The patients in the control group were treated with intravenous administration of cefmetazole as well as traditional excision, while external application of Ji De Sheng She Yao and minimally invasive surgery were applied to patients in the research group.

For the control group, the patients WERE treated with cefmetazole treatment. 2.0g of cefmetazole (Harbin Pharmaceutical Group Pharmaceutical Factory, H20070136) was added in 100mL of normal saline and given via intravenous drip every 12 hours. At the same time, the traditional surgery was carried out. After local

infiltration anesthesia and thoroughly understanding the location of the mass, an incision was made on the surface of the mass. The skin, subcutaneous tissue and breast.



Fig. 3: The ultrasound image of removal process of lesion by a rotary cutting

Tissue were cut orderly to get to the surface of the mass, and sharp separation was carried out along the edge of the mass by an electric knife. Completely remove the mass. After hemostasis of the wound, the incision was carefully and intermittently sutured.

For the research group, the patients were treated with external application of Ji De Sheng She Yao. 15-20 pieces of Ji De Sheng She Yao (Nantong Essence Pharmaceutical Factory, Z32020048, specification 0.4g × 15 pieces × 4 plates) were crushed and mixed thoroughly with vinegar. Then it was applied evenly on the gauze, and externally applied on the patient's affected area, once a day. In addition, the patient underwent minimally invasive resection (American Johnson & Johnson company Mammotome minimally invasive rotary cutting system, model scm 23k). Before surgery, the B-ultrasound examination was performed to strictly define the location, the specific size and number of the mass, which is located on the surface of the breast. The patient's affected breast was fully exposed, and the incision was made at the puncture site after local anesthesia. Under ultrasound guidance, the puncture needle was passed from the posterior space of the breast to the posterior part of the mass. For the reasonable adjustment of the puncture angle, the groove of the rotary needle was aligned with the lump. Part of the mass was adsorbed in the groove, and then the fan-shaped rotary cut was developed. During the implementation of the atherectomy, multiple angles and multiple depths were required until the lumps were completely removed. After resection, we observed whether there are residual lesions, evacuated residual oozing by vacuum, and slowly withdrew the rotary cutter (Jia, *et al.*, 2017). The removal process of lesion by a rotary cutting is shown in fig. 3. Finally, the sterile

incision paper was used to bond the incision, while the local compression was required for several minutes, and the elastic bandage was applied to perform the pressure bandaging.



Fig. 4: Surgical incision and vacuum drainage

Outcome measurements

The following items were observed and compared: 24h postoperative visual analog pain scores, surgical indexes (operation time, the volume of intraoperative bleeding, size of incision and healing of incision), the time of clinical improvement, complication rates (disruption of wound, ecchymosis, hematoma, infection of the wound, etc.) and the satisfaction on cosmetic effects.

STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS21.0. All quantitative data were expressed in the form of mean \pm standard variance (\pm s), and intergroup comparisons were made with t-test. Enumeration data were expressed in the form of natural number (n) + percentage (%), and intergroup comparisons were made with chi-square test. $P < 0.05$ represents the intergroup difference is of statistically significance.

RESULTS

Comparison of the total clinical efficacy between both groups

As shown in table 1, the total clinical efficacy of the research group was significantly higher than that of the control group ($p < 0.05$).

Comparison of the surgical indexes between both groups

As shown in table 2, the operation time, the volume of intraoperative bleeding, size of incision and healing of incision of the research group were significantly better than those of the control group ($p < 0.05$).

Comparison of other indexes between both groups

As shown in table 3, the research group had better advantages over the control group regarding the 24h postoperative visual analog pain scores, the time of clinical improvement, complication rates and the satisfaction on cosmetic effects ($p < 0.05$).

DISCUSSION

Relevant data show that the incidence of benign breast mass can reach 11.3%-26.5% (Ge, et al., 2018), which brings adverse effects on the physical and mental health of patients. More seriously, some benign masses may become malignant, which seriously threatens the lives of patients. In recent years, the number of patients who suffer from inflammatory breast mass during lactation is unceasingly increasing, which makes it essential to take active and effective treatment to control the progress of the disease (Oforikwakye, et al., 2016).

Ji De Sheng She Yao, as a national secret prescription developed by Nantong famous doctor Ji De-sheng, which consists of *Paris polyphylla*, toad skin, centipede and *Euphorbiae humifusae*. Of those, *Paris polyphylla* is bitter and slightly cold, with the functions of clearing away heat and detoxifying, reducing swelling and relieving pain; centipede is Xin Wen, belonging to the liver, has the effect of attacking toxic substances and dispersing, relieving pain; toad skin is warm-natured, belonging to the heart, has the effect of detoxifying, pain relieving and inducing resuscitation; *Euphorbiae humifusae* is mild-natured, belonging to the liver and large intestine, has the effect of clearing away heat and detoxification, draining dampness and anti-icteric, promoting blood circulation and hemostasis, excellent in detoxification (Attari, et al., 2016; Huang, et al., 2014). All of the above together have the function of clearing away heat and detoxifying, anti-inflammatory, swelling and analgesic. Minimally invasive resection is a minimally invasive technique used in the treatment of breast mass in recent years. Compared with traditional surgery, this procedure requires only one little incision to treat multiple lesions, with the advantages of small incision, no scarring, low incidence of postoperative complications and rapid recovery after surgery, etc. This surgery has achieved good clinical results. To effectively improve the surgical results, we should ensure accurate preoperative ultrasound positioning; choose a short channel to puncture, not damage the breast blood vessels, adjust the needle according to the specific position at any time, fix lesions, and follow the principle of "small first, then big" to resect the mass of the tumor; keep the probe under vacuum suction; conduct postoperative anti-infective treatment, change the dressing on time, and reduce the daily drainage volume to 5 ml or less after about 5-7 days. The surgical incision and negative pressure drainage are shown in fig. 4 below.

Table 1: Comparison of the total clinical efficacy between both groups [n (%)]

| Groups | Excellent | Valid | Invalid | Total clinical efficacy |
|-----------------------|-----------|-------|---------|-------------------------|
| Research group (n=80) | 56 | 20 | 4 | 76 (95.00) |
| Control group (n=80) | 30 | 32 | 18 | 62 (77.50) |
| χ^2 | | | | 10.28 |
| p | | | | <0.05 |

Table 2: Comparison of the surgical indexes between both groups ($\bar{x} \pm s$)

| Groups | Operation time (min) | The volume of intraoperative bleeding (ml) | Size of incision (cm) | Healing of incision (d) |
|-----------------------|----------------------|--|-----------------------|-------------------------|
| Research group (n=80) | 15.09±4.57 | 13.28±3.25 | 0.56±0.21 | 3.94±0.67 |
| Control group (n=80) | 32.84±5.09 | 28.99±4.20 | 4.68±0.95 | 7.80±0.59 |
| t | 9.04 | 6.70 | 8.36 | 8.73 |
| p | <0.05 | <0.05 | <0.05 | <0.05 |

Table 3: Comparison of other indexes between both groups ($\bar{x} \pm s$)

| Groups | 24h postoperative visual analog pain scores (point) | The time of clinical improvement (d) | Complication rates (%) | Satisfaction of cosmetic effects (%) |
|-----------------------|---|--------------------------------------|------------------------|--------------------------------------|
| Research group (n=80) | 2.12±0.54 | 2.01±0.38 | 5(6.25) | 78(97.50) |
| Control group (n=80) | 3.63±0.81 | 4.80±0.20 | 18(22.50) | 62(77.50) |
| t | 6.71 | 9.06 | 11.48 | 10.28 |
| p | <0.05 | <0.05 | <0.05 | <0.05 |

The total therapeutic efficacy of the research group was significantly higher than that of the control group ($P < 0.05$). By comparing the surgical indexes of both groups, the operation time, the volume of intraoperative bleeding, size of incision and healing of incision of the research group were significantly better than those of the control group ($p < 0.05$). Moreover, the research group had better advantages over the control group regarding the time of clinical improvement, complication rate and the satisfaction of cosmetic effects ($p < 0.05$). The above results are consistent with relevant researches.

CONCLUSION

To sum up, minimally invasive resection is a safe and reliable surgical procedure for the treatment of inflammatory breast mass during lactation. It can effectively resect the mass, with small incision, less intraoperative blood loss as well as shorter operation time and incision healing time. Also, it can significantly relieve postoperative pain, reduce the incidence of complications and promote postoperative recovery and the satisfaction on cosmetic effects. All the above advantages have made it a preferred surgical method for patients with indications. In addition, external application of Ji De Sheng She Yao can help treat this disease, significantly improve the clinical symptoms and reduce the incidence of complications, bringing satisfactory results. Therefore, it is worthy of clinical popularization. Meanwhile, the sample size of this study is rather small, so a larger amount of researches are needed in the future to more

effectively prove the effectiveness of this regimen and provide valuable evidence for clinical practice. Then, better results could be obtained by external application of Ji De Sheng She Yao and minimally invasive surgery in the treatment of inflammatory breast mass during lactation.

REFERENCES

- Attari Z, Bhandari A, Jagadish PC and Lewis S (2016). Enhanced ex vivo intestinal absorption of olmesartan medoxomil nanosuspension: Preparation by combinative technology. *Saudi Pharm. J.*, **24**(1): 57-63.
- Ge Cx, Li M, Gu El and Sun Xj (2018). Clinical Observation on 82 Cases of Epidemic Mumps Treated by External Application of Ji Desheng Snake Medicine Combined with Xiyanning. *Chinese Journal of Pediatrics*, **14**(02): 42-44.
- Hazra M, Mandal DD, Mandal T, Bhuniya S and Ghosh M (2015). Designing polymeric microparticulate drug delivery system for hydrophobic drug quercetin. *Saudi Pharm. J.*, **23**(4): 429-36.
- Huang QF, Hu JF, Zhai XY, Lv J, Fu Q, Zhang L and Huo YP (2014). Clinical analysis of 95 cases of mastitis lesions treated with Ma Moitong minimally invasive surgery. *Chinese Journal of Breast Diseases* (electronic version), **8**(01): 37-40.
- Jia JF, Chen YF and Li CJ (2017). Observation on the effect of Ji Desheng snake medicine plus nitrofurazone wet compress on local tissue injury induced by

- adriamycin extravasation in rabbits. *Journal of Nursing*, **20**(08): 75-76.
- Luo YQ (2016). Analysis of 46 cases of benign breast mass treated by ultrasound-guided minimally invasive surgery. *Shaanxi Medical Journal*, **45**(05): 576-578.
- Moty SGA, Hussein MA, Aziz SAA and Abousalim MA (2016). Design and synthesis of some substituted thiazolo [3,2-a] pyrimidine derivatives of potential biological activities. *Saudi Pharm. J.*, **24**(2): 119-132.
- Oforikwakye K, Mfofo KA, Kipo SL, Kuntworbe N and Boakyegyasi ME (2016). Development and evaluation of natural gum-based extended release matrix tablets of two model drugs of different water solubilities by direct compression. *Saudi Pharm. J.*, **24**(1): 82-91.
- Wroblewska K, Kucinska M, Murias M and Lulek J (2015). Characterization of new eye drops with choline salicylate and assessment of their irritancy by in vitro short time exposure tests. *Saudi Pharm. J.*, **23**(4): 407-412.
- Yu Q, Feng Y, Ren XC, Zheng J, Lu LM and Dong YH (2016). Study on the relationship between the prevention and treatment of Novi-induced phlebitis and the expression of ICAM-1 and VEGF by external application of Ji Desheng. *Zhejiang Journal of Traditional Chinese Medicine*, **51**(04): 290-292.