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Original Article

The clinical value of surgery combined with modified Shengyang Yiwei decoction and Yanghe decoction in treating refractory plasma cell mastitis

Meili Zhang[1], Linhai Li[3], Fang Li[2]

Departments of [1]Function Examination, [2]Radiotherapy, Jiaozhou People's Hospital, Jiaozhou, Shandong Province, China; [3]Qingdao Zhanshan Sanatorium, Qingdao, Shandong Province, China

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Abstract: Objective: To analyze the clinical value of surgery combined with modified Shengyang Yiwei decoction and Yanghe decoction in the treatment of refractory plasma cell mastitis. Methods: Ninety-two patients with refractory plasma cell mastitis were selected and randomly divided into a control group (46 cases, treated with surgery) and a study group (46 cases, treated with modified Shengyang Yiwei decoction and Yanghe decoction on the basis of the control group). The clinical efficacy, traditional Chinese medicine (TCM) symptom score, treatment duration, recurrence rate, and quality of life were compared. Results: The total effective rate in the study group was significantly higher than it was in the control group (P<0.01). The TCM symptom score in the study group was significantly lower than it was in the control group (P<0.001). The treatment duration in the study group was significantly shorter than it was in the control group (P<0.001). The recurrence rate in the study group was significantly lower than the rate in the control group (P<0.05). The quality of life in the study group was significantly higher than it was in the control group (P<0.01). Conclusion: The combination of Shengyang Yiwei decoction and Yanghe decoction and surgery has a significant effect in the treatment of refractory plasma cell mastitis, and significantly reduces the clinical symptoms, shortens the treatment duration and lowers the recurrence rate.

Keywords: Surgery, Shengyang Yiwei decoction and Yanghe decoction, refractory plasma cell mastitis, quality of life

Introduction

Plasma cell mastitis, also called "mammary duct ectasia" in clinical practice, is commonly seen in the breast-feeding population with the pathological features of duct ectasia and plasma cell infiltration, and the clinical symptoms of abscess, discharge and mass [1]. According to some incomplete statistics, the incidence of plasma cell mastitis has increased yearly in recent years, accounting for 1.4-5.4% of all benign breast diseases [2]. Surgery is the main method for the treatment of this disease, which can quickly relieve patients' pain in a short period of time but with a poor prognosis. At present, the clinical treatment for plasma cell mastitis has gradually shifted from simple internal or external treatment to comprehensive treatment [3, 4].

Plasma cell mastitis belongs to "acute mastitis" in traditional Chinese medicine (TCM) which believes that the disease is located in the breast and closely related to liver, spleen, and stomach, Chong and Ren. An interior deficiency of vital *qi* is the root of plasma cell mastitis, and *yang* weakness, cold coagulation, and toxin stagnation, Chong and Ren disorders, emotional internal injuries, improper diet and overstrain, and liver *qi* stagnation are important elements of the pathogenesis. At the beginning of the disease, vital *qi* is vigorous and struggles with the pathogenic factors, so there are more excessive syndromes, and later vital *qi* is depleted or accompanied by a prevailing of the pathogenic factors, so there are more *yin* syndromes. Therefore, the treatment is mainly based on warming *yang* and dispersing mass, dispersing stagnated liver *qi*, nourishing *qi*, and

harmonizing *yin* [5]. Shengyang Yiwei decoction and Yanghe decoction is made with *Cinnamomum cassia*, *Radix rehmanniae preparata*, Herba schizonepetae, *Codonopsis pilosula*, *Ligusticum wallichii*, *Astragalus membranaceus*, *Glycyrrhiza uralensis*, *Angelica pubescens*, *Fructus Aurantii*, and *Rhizoma Zingiberis*. Now it has been widely used in the treatment of breast diseases such as mastitis, breast mass, nipple discharge, and has achieved some success [6]. At present, the clinical application of the combination of surgery and Shengyang Yiwei decoction and Yanghe decoction in the treatment of refractory plasma cell mastitis is rarely reported. On this basis, 92 patients with refractory plasma cell mastitis admitted to Jiaozhou People's Hospital from August 2016 to August 2018 were selected as our study cohort, with the aim of providing a scientific and safe treatment method for this disease.

Materials and methods

Baseline information

The study was approved by the Jiaozhou People's Hospital Ethics Committee. Ninety-two patients with refractory plasma cell mastitis admitted to Jiaozhou People's Hospital from August 2016 to August 2018 were enrolled in this study and randomly divided into a control group and a study group, with 46 cases in each group.

The patients in the study group were 25 to 70 years old with an average age of (47.4±3.1) years, the course of the disease ranged from 3 to 18 months with an average course of (15.52±2.14) months, and the patients' body weight ranged from 44 to 68 kg with an average weight of (56.25±5.14) kg. There were 12 patients with nipple deformity, 26 with abscess induration, 38 with a childbearing history, 37 with a breastfeeding history, and 18 with an abortion history.

Meanwhile, the patients in the control group were 26 to 68 years old with an average age of (48.3±3.3) years, the course of the disease ranged from 4 to 17 months with an average course of (15.49±2.11) months, and the patients' body weight ranged from 45 to 67 kg with an average weight of (56.37±5.07) kg. There were 14 patients with nipple deformity, 25 with abscess induration, 39 with a childbearing history, 38 with a breastfeeding history, and 20 with an abortion history.

Inclusion criteria: patients meeting the diagnostic criteria of refractory plasma cell mastitis presented at the 2012 China Nursing Association National Conference on Nursing in the Operating Room, "Diagnosis and treatment of plasma cell mastitis", and diagnosed using cytological smears of puncture fluid [7]. All the patients signed an informed consent form. The criteria also included patients who were conscious and who had normal cognition, and first-episode patients.

Exclusion criteria: patients who received relevant treatment before the study. Patients with impaired kidney and liver function. Patients with heart failure, malignant tumors, and respiratory failure. Patients with complications such as metabolic and endocrine diseases. Patients with electrolyte and water metabolism disorders. Patients with mental illness or depression. Patients with contraindications to drug use. All nursing, pregnant women. Patients with complications of other breast diseases.

Methods

Drugs and medical devices: cefoxitin sodium (Shanghai New Asia Pharmaceutical Co., Ltd., specification: 1.0 g), cefuroxime injection (Glaxo Smith Kline S. p. A, specification: 0.75 g), The Mammotome System (Shenzhen DRMT Trading Co., Ltd.).

Control group: all subjects were treated with cefoxitin sodium and cefuroxime injections for 7 consecutive days before surgery until their condition stabilized. The pathological type and location of the focus were determined and a targeted treatment was made according to the specific condition. For patients with redness, swelling, heat, and pain: incision and drainage was carried out after local infiltration anesthesia, while the focus was directly removed for some patients. Regular dressing changes were made after surgery, and the wound was rinsed with hydrogen peroxide 1-2 times during the dressing changes. Meanwhile, anti-anaerobic agents, quinolones, and cephalosporins were administered, and we kept the incisions clean and dry. For patients with breast masses: the resection range was determined according to the size of the mass. Nipple lesions were cor-

rected in time, and for those with a large range, gland flap migration was carried out.

Study Group: on the basis of the control group, Shengyang Yiwei decoction and Yanghe decoction (the dosage of the drug was modified with the severity) were given: 15 g *Cinnamomum cassia*, 15 g *Radix rehmanniae preparata*, 9 g *Herba schizonepetae*, 15 g *Codonopsis pilosula*, 15 g *Ligusticum wallichii*, 30 g *Astragalus membranaceus*, 6 g *Glycyrrhiza uralensis*, 6 g *Angelica pubescens*, 9 g *Fructus aurantii* and 3 g *Rhizoma zingiberis*. The decoctions were mixed with water for each oral dose, and taken in the mornings and evenings for 1 month.

Observation indicators

Clinical efficacy: markedly effective: the fistula healed well, and the masses disappeared. Effective: the fistula was basically healed, and the masses significantly reduced. Ineffective: the fistula did not heal, and the masses did not change significantly or worsen. Total effective rate = markedly effective cases and effective cases/total cases [7, 8].

TCM symptom score: the symptoms of fistula, abscess, mass, swelling and pain of all the subjects were evaluated before and at 3 months after the treatment and scored 0 (no symptoms), 2 (mild symptoms, no impact on life), 4 (obvious symptoms, impact on life), 6 (severe symptoms, serious impact on life). The lower the score, the milder the symptoms [9].

Treatment duration: the average treatment duration of all subjects, from admission to discharge, was recorded.

Recurrence rate: all the subjects were followed up for 3 months to determine whether there was any recurrence. The appearance of pain, swelling, mass tenderness, surface redness and swelling, and fever indicated a recurrence of the refractory plasma cell mastitis.

Quality of life: the quality of life scale proposed by the World Health Organization (WHO) was used to assess the quality of life of all the subjects before and at 3 months after the treatment, including the reliance on medical means, positive feelings, sex life, pain, daily living activities, and overall health. The higher the score, the higher the quality of life [10, 11].

Statistical methods

SPSS 24.0 software was used to process the data. The measurement data (TCM symptom score, treatment duration, and quality of life) were expressed as $\bar{x} \pm s$. Independent *t*-tests were used for the group comparisons, and paired *t*-tests were used for the self-comparisons before and after treatment. Counting data (clinical efficacy, recurrence rate) expressed in [n (%)] were mainly tested using χ^2 tests. $P< 0.05$ was considered a statistically significant difference.

Results

Comparison of the baseline data between the two groups

There were no statistical differences in the baseline data in terms of the course of the disease, age, weight, nipple deformity, abscess induration, childbearing history, breastfeeding history, or abortion history ($P>0.05$). See **Table 1**.

Comparison of the clinical efficacy between the two groups

The total clinical effective rates in the study group and the control group were 95.65% and 73.91%, respectively, showing that the study group was significantly higher than the control group ($P<0.01$). See **Table 2** and **Figure 1**.

Comparison of the TCM symptom scores between the two groups

There was no statistical difference between the two groups before the treatment ($P>0.05$). However, after the treatment, the scores in the two groups were significantly lower than they were before the treatment, and the study group was significantly lower than the control group ($P<0.001$). See **Table 3**.

Comparison of the treatment duration between the two groups

Hospital stay: the study group stayed (9.25± 1.16) days and the control group stayed (14.25±2.61) days, indicating that the study

Table 1. Comparison of the baseline data in the two groups

Group	Study group (n = 46)	Control group (n = 46)	t	P
Average course of disease (months)	15.52±2.14	15.49±2.11	0.0677	0.9462
Average age (years)	47.4±3.1	48.3±3.3	1.219	0.226
Average weight (kg)	56.25±5.14	56.37±5.07	0.1127	0.9105
Nipple deformity			0.1991	0.6554
Yes	12	14		
No	34	32		
Abscess induration			0.04	0.8339
Yes	26	25		
No	20	21		
Childbearing history			0.0797	0.7778
Yes	38	39		
No	8	7		
Breastfeeding history			0.0722	0.7882
Yes	37	38		
No	9	8		
Abortion history			0.1793	0.6719
Yes	18	20		
No	28	26		

Table 2. Comparison of the clinical efficacy in the two groups (n, %)

Group	Markedly effective	Effective	Ineffective	Total effective rate
Study group (n = 46)	18 (39.13)	26 (56.52)	2 (4.35)	44 (95.65)
Control group (n = 46)	11 (23.91)	23 (50.00)	12 (26.09)	34 (73.91)
χ^2				8.4249
P				0.0037

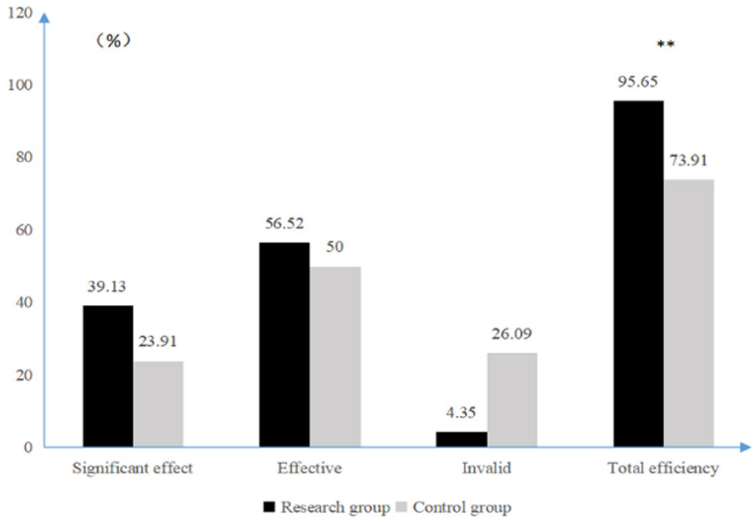

Figure 1. Comparison of clinical efficacy between the two groups. **P<0.01.

group's stays were significantly shorter than the control group's (P<0.001). See **Table 4**.

Comparison of the recurrence rate between the two groups

Recurrence rate: the study group had a significantly lower recurrence rate than the control group (P<0.05). See **Table 5**.

Comparison of the quality of life between the two groups

Quality of life scores: there was no statistical difference between the two groups before treatment (P>0.05). After the treatment, the scores in the two groups were significantly lower than they were before the treatment, and the study group's scores were significantly lower than the control group's (P<0.01). See **Table 6**.

Discussion

The pathogenesis of plasma cell mastitis is still clinically unclear. But it is generally believed that its occurrence is closely related to abnormal hormone stimulation and duct block-

Table 3. Comparison of the TCM symptom scores between the two groups ($\bar{x}$ ± sd)

Group	Fistula	Abscess	Mass	Swelling and pain
Study group (n = 46)				
Before treatment	3.25±0.37	3.11±0.41	3.28±0.51	3.27±0.49
3 months after treatment	0.95±0.05	1.01±0.11	0.98±0.09	1.06±0.13
t	41.7807	33.5522	30.1216	29.5669
P	0.0000	0.0000	0.0000	0.0000
Control group (n = 46)				
Before treatment	3.26±0.27	3.13±0.39	3.27±0.49	3.28±0.44
3 months after treatment	2.25±0.31***	2.16±0.15***	2.41±0.38***	2.34±0.28***
t	16.6631	15.7445	9.4065	12.2243
P	0.0000	0.0000	0.0000	0.0000

Note: TCM, traditional Chinese medicine; ***refers to the comparison between the two groups after treatment, P<0.001.

Table 4. Comparison of the treatment durations in the two groups ($\bar{x}$ ± sd)

Group	Treatment duration
Study group (n = 46)	9.25±1.16
Control group (n = 46)	14.25±2.61
χ^2	11.8731
P	0.0000

Table 5. Comparison of the recurrence rates in the two groups

Group	Recurrence case (n)	Recurrence rate (%)
Study group (n = 46)	2	4.35
Control group (n = 46)	10	21.74
χ^2		6.1333
P		0.0133

age, and bacteria breeding in the catheter increases the secondary infection rate and aggravates the disease [12, 13]. Ductal epithelial dysplasia is the main clinical feature in the early stage of plasma cell mastitis. With the aggravation of the disease, the diameter of the duct lumen increases continuously, secretion increases significantly, and the lymph is infiltrated. When the duct wall becomes fibrotic or thickened, the fat around the duct will gradually necrotize [14, 15]. Surgery is currently a common clinical treatment for plasma cell mastitis and can effectively remove the focus. However, it is traumatic and has a serious adverse effect on the breast appearance, with a high recurrence rate and poor disease control [16, 17].

Plasma cell mastitis is a form of acute mastitis and is also called comedomastitis in TCM. Due to liver *qi* stagnation, *qi* stagnation and blood stasis, nutrient-blood insufficiency and pathogens accumulation, the wound develops ulceration, abscesses, ulcers, and fistulas [18, 19]. Some scholars believe that acute mastitis is caused by the disorder of Chong and Ren, excessive emotions, emotional disorder, congenital deficiency, and exogenous wind cold dampness evil [20]. Therefore, the treatment for this disease is to warm and regulate the *qi* and blood, raise yang to strengthen the stomach, nourishing *qi* and blood [21]. Plasma cell mastitis attacks acutely in a short period of time with obvious positive manifestations, followed by swelling without pain or redness, secretions as white as bean curd residue, and with a long course of disease.

All the subjects in this study were also had different degrees of pain, swelling, mass tenderness, surface redness and swelling, fever, and other symptoms. Combined with the *yin-yang* dialectics in TCM surgery, plasma cell mastitis is mainly characterized by *yin* syndrome, therefore, it's treated with Shengyang Yiwei decoction and Yanghe decoction in order to stimulate the body's *yang qi* and remove cold coagulation. The *Cinnamon cassia* used in the decoction has the function of warming meridians; *Fru-ctus aurantii* removes phlegm, relieves stagnant *qi*, and improves local blood circulation; *Radix rehmanniae preparata* replenishes lean and marrow, tonifying the blood and nourishing the *yin*; *Herba schizonepetae* and *Angelica pubescens* relieve the exterior and dispersing wind; *Angelicae pubescentis* and *Ligusticum wallichii* promote blood circulation, relieving pain and accelerating symptom regre-

Table 6. Comparison of the quality of life scores in the two groups ($\bar{x}$ ± sd)

Group	Sex life	Positive feelings	Reliance on medical means	Pain	Daily living activities	Overall health
Study group (n = 46)						
Before treatment	52.26±5.14	53.16±4.55	55.16±6.08	54.16±5.64	52.62±4.16	53.66±5.31
3 months after treatment	89.26±7.14	88.26±6.16	84.26±5.14	86.25±6.17	87.62±8.88	85.95±6.37
t	28.5241	31.0856	24.7899	26.0362	24.2075	26.4081
P	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
Control group (n = 46)						
Before treatment	53.06±5.21	53.06±5.14	54.92±6.11	55.16±6.25	53.02±4.21	53.16±6.52
3 months after treatment	68.25±3.62***	69.25±4.15**	68.26±5.14**	68.25±6.21**	66.28±4.62**	67.16±5.14**
t	16.2391	16.6216	11.3315	10.0766	14.3883	11.4368
P	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

Note: comparison between the two groups after treatment, **P<0.01, ***P<0.001.

ssion; *Astragalus membranaceus* induces diuresis, expelling toxins, discharging pus, and invigorating *qi* for strengthening superficies; *Codonopsis pilosula* enriches blood and invigorates *qi* and can be used for treating fatigue and lung and spleen *qi* deficiency. Modern medicine believes that Shengyang Yiwei decoction and Yanghe decoction plays an important role in blood vessel dilation, local blood circulation improvement, a reduction of the release of inflammatory factors, and a promotion of the regression of symptoms such as redness, swelling, and fistula [22].

The results of this study showed that the total clinical effective rate in the study group was significantly higher than the rate in the control group, and the TCM symptom score was significantly lower than it was in the control group. The TCM decoction has the advantages of easy operation, non-invasiveness, and a remarkable effect, so it is easy for the patients to accept it. Moreover, its mild nature and taste does not cause any distinct toxic side effects, and it is safer, so there were no adverse reactions caused by the drugs used in this study. Therefore, the combined treatment of Shengyang Yiwei decoction and Yanghe decoction with surgery has further consolidated the surgical effect, and can rapidly improve the patient's condition and promote the body's recovery in a short period of time. As a result, this study showed that the treatment duration in the study group was significantly shorter than it was in the control group. As the saying goes, Western medicine treats symptoms and traditional Chinese medicine treats root causes. First, TCM emphasizes and attaches importance to vital *qi* of the human body, believing that diseases are caused by pathogenic factors that can be dispelled by vital *qi*. Secondly, TCM also emphasizes that the human body is an organic whole. If the five zang-organs and six fu-organs coordinate with each other, and the meridians and *qi* and blood are unobstructed, people will not get sick, so the diagnosis and treatment are based on an overall analysis of the illness and the patient's condition. Therefore, this study showed that the recurrence rate in the study group was significantly lower than it was in the control group. The significant reduction of the recurrence rate greatly decreased the treatment times and improved the prognoses. This study also showed that the quality of life in the study group was significantly higher than it was in the control group. In the study of Chai Yu et al., the total effective rate of 60 subjects treated with surgery combined with modified Shengyang Yiwei decoction and Yanghe decoction was 100.00%, indicating the combined therapy is effective and reliable in the treatment of refractory plasma cell mastitis and can be used as an ideal treatment method [23].

The deficiency of this article is the short research time and the small sample size, which affects the generality and universality of the results. Therefore, it is still necessary to further expand the sample research capacity and prolong the research time to better evaluate the clinical efficacy of surgery combined with Shengyang Yiwei decoction and Yanghe decoction in the treatment of refractory plasma cell mastitis.

To sum up, surgery combined with Shengyang Yiwei decoction and Yanghe decoction can effectively reduce the recurrence rate and improve the prognosis and quality of life with significant short-term and long-term effects in patients with refractory plasma cell mastitis, which is worthy of clinical promotion.

Disclosure of conflict of interest

None.

Address correspondence to: Fang Li, Department of Radiotherapy, Jiaozhou People's Hospital, No. 88 Guangzhou North Road, Jiaozhou 266300, Shandong Province, China. Tel: +86-0532-5865-6291; Fax: +86-0532-58656291; E-mail: lifang-1fa7@163.com

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