

A retrospective study on 221 patients with granulomatous lobular mastitis treated by a combination of traditional Chinese medicine and western medicine



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A retrospective study on 221 patients with granulomatous lobular mastitis treated by a combination of traditional Chinese medicine and western medicine

OBJECTIVE: This study aims to investigate the clinical efficacy and safety of integrative Chinese and Western medicine in the treatment of granulomatous lobular mastitis.

METHODS: In the present study, the clinical data of patients with granulomatous lobular mastitis in our hospital were retrospectively analyzed. According to the treatment regimens, these patients were divided into two groups: observation group (n=92) and control group (n=129). Patients in the observation group were treated with traditional Chinese medicine in combination with the surgical treatment of Western medicine, while the patients in the control group received surgical treatment alone. The main observation indexes included clinical cure rate, mass size, prolactin level and aesthetic evaluation results of the breasts. **Results:** The results revealed that there was no significant correlation between the observation group and control group, in terms of age, prolactin level, and marriage and childbearing history ($P>0.05$). Furthermore, the recurrence rate was lower in the observation group, when compared to the control group, and the difference was statistically significant ($P<0.05$). The aesthetic evaluation was higher in the observation group than in the control group, and the difference was statistically significant ($P<0.05$). However, the difference in the transverse diameter and long diameter of the tumor and clinical cure rate was not statistically significant ($P>0.05$) between the observation group and control group.

CONCLUSION: Compared with the simple surgical treatment of Western medicine, the combination of traditional Chinese medicine and Western medicine in the treatment of granulomatous lobular mastitis can significantly reduce the recurrence rate, and improve the symmetry and beauty of bilateral breasts, which is worthy of clinical application.

KEY WORDS: Granulomatous lobular mastitis, Integrated Chinese and western medicine treatment, Unclog lacteal, Prolactin, Aesthetic evaluation of milk preservation

Introduction

Granulomatous mastitis (GM), which is also known as granulomatous lobular mastitis (GLM), is a rare chronic breast inflammatory disease with unknown etiology^{1,2}. Its

pathological feature is necrotic granulomatous lobular mastitis, which was first proposed by Kessler and Wolloch in 1972⁴. Granulomatous lobular mastitis is a kind of non-mammalian mastitis, which is characterized by sudden mass, no pain, or slight pain, followed by rapid occurrence of redness, swelling, heat and pain, purulence, ulceration, sinus formation and long-lasting course. This disease progresses more rapidly, the course of disease is prolonged, and the treatment lasts longer, which is painful, and may affect the breast shape and lactation function of patients. Furthermore, the prognosis is general^{5,6}. The incidence of this disease has been increasing in recent years due to the change in the fam-

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ily planning policy in China. There is no single classification of this disease in the ancient books of traditional Chinese medicine. Most of these patients are diagnosed with different diseases, according to the individual symptoms. For example, acute mastitis can be diagnosed due to nipple discharge, and mass festers and bursts. Galactorrhoea was named after the abscess, which bursts to form a sinus tract. If there is no other auxiliary examination in the stage of mass formation, this can be easily diagnosed as mammary cancer. In the 1980s, GuBohua, Lu Deming and Tang Hanjun summarized the clinical characteristics of the disease, and named the disease "comedomastitis". They included the disease into the *Practical Surgery of Traditional Chinese Medicine* ⁷ edited by Mr. Gu Bohua for the first time.

The present study aims at retrospectively analyze the clinical data of patients with GLM in our hospital, and observe and explore the clinical efficacy and safety of integrating Chinese and Western medicine for the treatment of GLM. This would provide a theoretical basis for the treatment of GLM with the combination of traditional Chinese medicine and Western medicine.

Materials and Methods

GENERAL DATA DATA

The medical records used in the present study were selected from patients with GLM, who were treated in the Breast Department and General Surgical Ward of Dongzhimen Hospital between September 2017 and May 2019. The *Diagnosis and Treatment Criteria of TCM Syndrome* was referred for the diagnostic criteria. The present study was approved by the Ethics Committee of our hospital, and all patients provided a signed informed consent.

INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria: (1) patients who are definitely diagnosed with GLM; (2) patients who received other traditional Chinese medicine treatments within three months before admission to the hospital; (3) patients >18 years old. Exclusion criteria: (1) patients with severe liver and kidney dysfunction; (2) patients with acute heart failure; (3) patients with severe coagulation dysfunction; (4) pregnant or lactating patients.

THERAPEUTIC METHODS

The observation group adopted the "dredging breast collaterals" as the guideline for the diagnosis and treatment suggested by Shi Xiaoguang, a chief physician of the Breast Department of Dongzhimen Hospital, and the patients were treated with the combination of tradition-

al Chinese medicine and Western medicine. Patients in the control group only received surgical treatment. The details are presented, as follows.

Oral administration of traditional Chinese medicine

The oral administration of traditional Chinese medicine was adopted. If the mass presented with redness, swelling and heat pain, and a sense of volatility, or when there was a liquid dark area or purulent cavity under the indication of ultrasound, the patients were treated with the oral administration of Tounong decoction with addition and subtraction. In addition, on the basis of the traditional Chinese medicine compound, which was mostly based on the dialectical analysis, different kinds of herbal drugs were used with a function of supporting righteousness, removing pus and dredging collaterals, such as malt, Zhejiang shellfish, luffa, corn stigma, beautiful sweetgum fruit and cowherb. The treatment outcomes were achieved by considering that the breast belonged to the Jueyin liver meridian of the foot, plus the use of the messenger drug, bupleurum.

Partial debridement and filling

This is suitable for patients with mass forming pus, accompanied by fluctuation or wound rupture. Local anesthesia with 2% lidocaine was used before debridement, as appropriate. The puncture point was made at the strongest part of fluctuation, in the mass that did not break, but has fluctuation. An incision of approximately 0.5 cm in length was made. The necrotic pus cavity of the gland tissue was fully opened using mosquito forceps. The necrotic tissue, pus, congestion and edema granulation in the breast were removed by forceps. The lactide ethacridine or concentrated Tuo-litounong decoction was used for wet compressing and bandaging, after being fully sterilized and cleaned with the iodophor solution. For the patients with obvious bleeding, the oil gauze strips were filled in on the day of debridement, and taken out on the next day. The dressing was changed according to the above method. The pus was reduced in the affected area. The fresh granulation could be observed. The wound can be pulled using a butterfly tape to facilitate the healing. According to the wound condition, the dressing was changed every 1-3 days.

Surgical treatment:

Most of the incisions were made in the ulceration site of the skin or areola. The main purpose of the operation was to partially resect the mass, explore the mammary ducts on the affected side, remove the diseased local ducts, correct the nipple invagination, and prevent the recur-

rence of the disease. After the surgical resection of local lesions, the shape of the breasts was improved using free gland flap shifting, and a drainage tube was retained to prevent the formation of hydrops. Relative contraindications for the surgical resection: GM patients with acute infection symptoms or patients in the advanced stage of the disease; patients with a wide range of GM lesions (whole breast or 2/3 breast) or a large area of skin lesions, or patients required for mastectomy, according to the general principle; GM patients who are pregnant.

THERAPEUTIC EVALUATION

Cured: The redness, swelling and pain of the breasts disappear; the fistula is healed, with no false healing; the systemic symptoms disappear; there was no purulent cavity and sinus tract found under color Doppler ultrasound. **Improved:** Most of the fistula is healed, or the rigid mass did not disappear; there are still inflammatory lesions or pus cavity detected by color Doppler ultrasound, and the range is less than 30% before treatment. **Not cured:** The above criteria are not met, and even the range of the lesions is expanded ⁸.

STATISTICAL ANALYSIS

In the present study, the SPSS 20.0 statistical software was used to process the data. The measurement data were expressed as mean \pm standard deviation ($\bar{x} \pm SD$). Enumeration data were expressed in percentage (%). *W*-test was used for the normality test. *F*-test was used for the homogeneity test of variances. *T*-test was used for comparisons between two groups. The nonparametric test was used to compare the mean of multiple samples that did not obey the normal distribution, or obeyed the normal distribution, but the variance was uneven. Counting data were used for the chi-square test. $P < 0.05$ was considered statistically significant.

Result

GENERAL DATA

A total of 221 patients were included in the present study. All patients were female, who were within 21-53

years old, with an average age of 31.5 years old. Among these patients, 218 patients had disease onset in non-lactation or pregnancy, while four patients had disease onset in lactation. Furthermore, 221 patients had enlarged breast masses with pain, redness and swelling. Among these patients, 106 patients had suppurative rupture of the breast masses. In addition, 64 of 221 patients had nipple inversion, 12 patients had nipple discharge, and 23 patients had erythema of the lower extremities and joint pain. Moreover, 138 patients had poor outcomes after treatment with antibiotics, while 60 patients were treated with hormones ⁴. A prolactin-related examination was performed for 210 patients. Among these patients, 108 patients had normal prolactin levels, while 101 patients had elevated prolactin levels. All 221 patients received a color Doppler ultrasound examination of the lymph nodes in the mammary gland and drainage areas. Among these patients, 221 patients had masses with unclear boundaries with the surrounding tissues, and rich color blood flow signals. Most of these were considered as inflammation, while some of these were observed to have necrotic fluid sonolucent areas after suppuration. A total of 221 patients underwent core needle biopsy and postoperative pathology, and the results suggested GLM.

COMPARISON OF PROLACTIN LEVEL AND AGE BETWEEN THE TWO GROUPS

There was no significant correlation between the observation group and control group, in terms of age, prolactin level, and marriage and childbearing history ($P > 0.05$). The difference in transverse diameter and long diameter was not statistically significant ($P > 0.05$) between the observation group and control group (Table I).

COMPARISON OF CLINICAL EFFICACY EVALUATION

In the control group, 129 patients were cured and 11 patients had contralateral recurrence, while in the observation group, 92 patients were cured, among which, four patients were cured before the operation and two patients were recurred. The cure rate for both the control group and observation group was 100%. The recurrence rate

TABLE I - Comparison of age, prolactin levels and mass size between the two groups.

Index	Observation group	Control group	P
N	92	129	
Age	31.49 \pm 5.107	31.60 \pm 4.433	0.858
Childbearing history	2.37 \pm 0.549	2.29 \pm 0.491	0.288
Prolactin level	1.66 \pm 0.715	1.58 \pm 0.809	0.422
Transverse diameter	15.41 \pm 4.117	12.12 \pm 4.37	<0.000
Long diameter	11.68 \pm 4.175	8.38 \pm 3.18	<0.000

TABLE II - Comparison of clinical efficacy evaluation between the two groups.

Group	Number of cures	Number of relapses	Total
Observation group	115	14	129
Control group	90	2	92
Total	205	16	221
P	0.00		

was lower in the observation group than in the control group, and the difference was statistically significant ($P < 0.05$, Table II).

AESTHETIC EVALUATION

The present study was summarized following the bilateral breast symmetry project, and according to the Harris

Standard 2001, the evaluation form of breast conserving aesthetics, the viewpoint of breast aesthetics established in the National "10th Five-year" Plan for Science and Technology Research funding Project (2001BA70303 B20), and the experience of clinical treatment (Table III). The results of the present study revealed that the aesthetic evaluation results of the control group and observation group (Table IV). The aesthetic evaluation was higher in the observation group than in the control group, and the difference was statistically significant ($P < 0.05$).

Discussion

The results of the present study revealed that the recurrence rate was lower in the observation group than in the control group, and the difference was statistically significant. The aesthetic evaluation was higher in the treat-

TABLE III - Breast conserving aesthetic evaluation.

Item	Evaluation grade division rules		
	Two points	One point	Zero point
Breast volume symmetry	The affected breast is almost the same size as the healthy side	The size of the affected side is smaller than the healthy side $\leq 1/2$	The size of the affected side is smaller than the healthy side $> 1/2$; the affected side is absent.
Breast height symmetry	The height of the affected side is almost the same as the height of the healthy side	The difference between the affected side and the healthy side is ≤ 2 rib spacing	The difference between the affected side and the healthy side is > 2 rib intervals; the affected side was absent
Breast shape symmetry	The shape of the affected side is almost the same as that of the healthy side	There are sags and bulges in the affected side	The shape of the breast on the affected side is different from that on the healthy side; the breast on the affected side is absent
Nipple areola complex (NAC position symmetry)	NAC position of the affected side is almost the same as that of the healthy side.	The displacement distance of NAC on the affected side is ≤ 3 cm	The displacement distance of NAC in the affected side is > 3 cm; NAC in the affected side was absent
Nipple morphology symmetry	The shape of papilla on the affected side is almost the same as that on the healthy side	Part of the papilla on the affected side is invaginated and / or not consistent with the shape on the opposite side	The papillae of the affected side is completely invaginated; the papillae of the affected side is absent
Nipple morphology symmetry	The size and shape of the papilla on the affected side are almost the same as those on the healthy side	The size difference between the affected side and the healthy side is $\leq 1/2$ and (or) the shape is different	The size difference between the affected side and the healthy side is $> 1/2$; the affected side is absent
Skin color symmetry	The skin color of the affected side is almost the same as that of the healthy side	The skin color of the affected side is reddish and light red	The skin color of the affected side is bright red, purple or even black
Complete symmetry of the skin	Intact skin on the affected side	The volume of skin breaking and incision not healing on the affected side is ≤ 4 cm ²	The volume of skin breaking and incision not healing on the affected side is > 4 cm ²
Texture and elastic symmetry	The texture and elasticity of the affected side were almost the same as those of the healthy side	Lamellae in the operative area of the affected side	The affected side lacks elasticity due to edema and / or fibrosis

TABLE IV - Comparison of aesthetic evaluation results of breast conserving between the two groups.

Index	Observation group	Control group	P
N	92	129	
Aesthetic score of breast conserving	6.53±5.386	8.99±7.767	0.01

ment group than in the control group, and the difference was statistically significant. However, there was no significant difference in age, prolactin level, and marriage and childbearing history between the observation group and control group. The difference in the transverse diameter and long diameter of the tumor and clinical cure rate was not statistically significant between the observation group and control group.

Although the GLM does not have a uniform pathophysiological theory at the Western medicine level ^{9,10}, GLM is mostly caused by the deposited milk in the lobules after abnormal hormones induce milk to secrete into the acinus, and the milk is unable to be normally discharged into the mammary ducts from the lobules of the breasts. Through trauma, emotional stimulation and other reasons, the lipids break through the local ducts, the decomposition products generate an allergic reaction and immune response in the local lobule, and these finally induces granulomatous lobular inflammation ¹¹⁻¹⁴. In contrast, the etiology of traditional Chinese medicine can be deduced as local breast collaterals damage, resulting in the local accumulation of pathological substances and development of the disease.

Therefore, most of the causes of comedomastitis are as follows: (1) Congenital insufficiency, known with nipple inversion, poor circulation of the breast collaterals, qi and blood stasis, and the coagulation into lumps develop to the disease. (2) Bad emotions result in liver qi stagnation, qi and blood obstruction, blood stasis transforming into heat, steaming and rotting, resulting in local abscess formation. (3) Improper lactation, external evil invasion during lactation, improper treatment and mistreatment result in residual evils to stay between the breast collaterals, leading to acute onset after being affected. (4) Trauma, breakage of breast collaterals, stagnation of qi and blood, steaming and rotting result in abscess. The traditional Chinese medicine etiology and pathogenesis of the disease are similar to those of plasma cell mastitis: Both are caused by the deposition of foreign bodies in the breasts. The understanding of the disease in traditional Chinese medicine may also refer to plasma cell mastitis. However, it should be noted that the site of plasma cell mastitis is mostly in the breast collaterals or around the breast collaterals, while the main pathological changes of the GLM are in the local lobular tissue ^{8,15-16}.

Considering that there are various causes of comedomastitis, the major cause almost refers to the pathological changes of breast collaterals. Therefore, in the treatment of comedomastitis through the integration of

Chinese and Western medicine, either traditional Chinese medicine or Western medicine is based on the guidelines of “dredging collaterals”. Furthermore, either of the above four causes resulted from the accumulation of foreign bodies in the breast collaterals. Long-term stasis is the transformation to heat, and subsequently, steaming and rotting, resulting in redness, swelling, heat pain and other pathological manifestations, such as acute mastitis ¹⁷⁻¹⁹. The essence of the above treatment is to circulate the breast collaterals. Regardless of whether it is regulating qi activity, clearing away heat and exorcising evils, or removing lesions by using the existing surgical treatment from the physical level, the thorough debridement after exploration of the breast ducts is essentially the same, and the purpose is to make the breast collaterals unobstructed. After ensuring that the breast collaterals are unobstructed with the use of a variety of treatment methods, the range of the lesion is naturally limited, and the disease would not be recurrent. In addition, from the cause of the disease, it can be deduced how to prevent the disease. That is, in order to inhibit the occurrence of the disease, the first priority is to keep the breast collaterals unobstructed. Therefore, the oral administration of Chinese medicine can disperse the liver and rectify the qi, or tonify the vital qi, thereby making the qi activity smooth, or correcting the nipple inversion using surgical treatment. Both can prevent the recurrence of the disease by keeping the mammary gland unobstructed.

There were still limitations in the present study. First, the present study was a retrospective study, and not a randomized controlled trial, and there was no blinding method established. Therefore, there is still a certain risk of bias in case selection. Second, the present study is a single-center clinical study, and the sample size was small. Thus, it is necessary to further increase the sample size and carry out multicenter clinical research. Finally, the specific mechanism of integrative Chinese and Western medicine in the treatment of GLM remains unclear, and needs to be further studied from the point of view of molecular biology.

Summary: Compared with the simple surgical treatment of Western medicine, the combination of traditional Chinese medicine and Western medicine for the treatment of GLM can significantly reduce the recurrence rate, and improve the symmetry and beauty of bilateral breasts. Therefore, with “dredging collaterals” as the guidelines of diagnosis and treatment, especially which it is mainly based on external treatment and supplemented by internal treatment, this would have some advantages, in terms of preventing recurrence and breast

shape preservation, in the treatment of comedomastitis. However, further research on the treatment of this disease still needs to be conducted due to the lack of detailed pathophysiological support.

Riassunto

Studio finalizzato a valutare l'efficacia clinica e la sicurezza dell'integrazione tra medicina cinese e occidentale nel trattamento della mastite lobulare granulomatosa.

Sono stati analizzati retrospettivamente i dati clinici delle pazienti con mastite lobulare granulomatosa nel nostro ospedale. Le pazienti sono state suddivise in due gruppi secondo il regime di trattamento eseguito: gruppo di osservazione (n = 92) e gruppo di controllo (n = 129). Le pazienti del gruppo di osservazione sono state trattate con la medicina tradizionale cinese in combinazione con il trattamento chirurgico della medicina occidentale, mentre le pazienti del gruppo di controllo hanno ricevuto solo un trattamento chirurgico.

I principali parametri di analisi includevano il tasso di guarigione clinica, la dimensione della massa, il livello di prolattina e i risultati della valutazione estetica del seno. Risultati: i risultati hanno rivelato che non vi era alcuna correlazione significativa tra il gruppo di osservazione e il gruppo di controllo, in termini di età, livello di prolattina e storia matrimoniale e della gravidanza ($P > 0,05$). Inoltre, il tasso di recidiva era più basso nel gruppo di osservazione, rispetto al gruppo di controllo, e la differenza era statisticamente significativa ($P < 0,05$). La valutazione estetica era più alta nel gruppo di osservazione che nel gruppo di controllo e la differenza era statisticamente significativa ($P < 0,05$). Tuttavia, la differenza tra il diametro trasversale e il diametro longitudinale del tumore e il tasso di guarigione clinica non era statisticamente significativa ($P > 0,05$) tra il gruppo di osservazione e il gruppo di controllo.

In conclusione: rispetto al semplice trattamento chirurgico della medicina occidentale, la combinazione della medicina tradizionale cinese e della medicina occidentale nel trattamento della mastite lobulare granulomatosa può ridurre significativamente il tasso di recidiva e migliorare la simmetria e la bellezza del seno bilaterale, che è degno di rilevanza clinica.

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Commento e Commentary

PROF. NICOLA PICARDI

Già Ordinario di Chirurgia Generale

La conoscenza in occidente della erboristeria è un lontano ricordo che risale in Italia addirittura alle competenze della Scuola Medica Salernitana, di derivazione ellenistica, araba e orientale. Lo sviluppo in occidente della moderna medicina e farmacologia e la prevalenza accordata alla chirurgia interventistica hanno oscurato l'interesse per cognizioni ritenute irrimediabilmente superate, e che vengono qui all'improvviso richiamate alla nostra attenzione da riferimenti alla medicina tradizionale cinese.

La globalizzazione ci propone oggi notizie da un mondo culturale da molto tempo trascurato, perché lontano geograficamente e culturalmente, e la conoscenza media in occidente della cultura sanitaria cinese si limita al generico riferimento all'agopuntura e ai meridiani di energia.

Pur senza essere in grado di poter dare un riconoscimento con cognizione di causa al tema di questo studio, con umiltà ci poniamo di fronte a notizie di questo genere che ci giungono dalla civilissima Cina, e ci svelano un mondo di conoscenze che continuano a sfuggire ai nostri concetti di fisiopatologia e di farmacodinamica occidentale. Ci si rende conto che questa conoscenza non modificherà il nostro atteggiamento pragmatico di tipo occidentale, ma la curiosità del medico viene all'improvviso risvegliata da nozioni impreviste.

Prendiamo nota con rispetto di queste osservazioni inaspettate e curiosità dei loro risultati.

* * *

Knowledge in the West of herbal medicine is a distant memory that goes back in Italy even to the skills of the Salerno Medical School, of Hellenistic, Arab and Eastern origin. The development of modern medicine and pharmacology in the West and the prevalence accorded to interventional surgery have obscured the interest in knowledge deemed hopelessly outdated, and which are suddenly called to our attention by references to traditional Chinese medicine.

Globalization today offers us news from a long neglected cultural world, because geographically and culturally distant, and the average knowledge in the West of Chinese health culture is limited to the generic reference to acupuncture and to energy meridians.

Even without being able to give an acknowledgment of the subject of this study based on borrowed knowledge, we humbly face news of this kind that comes to us from civilized China, and reveals a world of knowledge that continues to escape the our concepts of pathophysiology and western pharmacodynamics. We realize that this knowledge will not change our Western-style pragmatic attitude, but the doctor's curiosity is suddenly awakened by unexpected notions.

We respectfully take note of these unexpected observations, and with curiosity of their results.