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Research Progress of Traditional Chinese and Western Medicine in Mastitis During Non-lactation Period

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Abstract: ***Non-lactating mastitis is a group of benign and non-specific inflammatory diseases of unknown etiology that occur in women during the non-lactation period, including mammary ductal ectasia/periductal mastitis, granulomatous lobular mastitis. In recent years, the incidence of this disease has shown a significant upward trend, although it is a group of benign diseases, but it seriously affects the quality of life, causing harm to the physical and mental health of the majority of women, and it is of great research significance to explore the treatment of non-lactating mastitis with traditional Chinese and Western medicine.***

Keywords: Mammary, Non-lactating mastitis**.**

1. Background and Significance of the Study

Acne cradle carbuncle is a chronic benign purulent inflammatory disease of the breast, and its incidence group is mainly concentrated in young and middle-aged women who are not lactating and non-pregnant [1]. In the clinical medical classification system, this disease corresponds to a variety of breast inflammatory diseases diagnosed by Western medicine, mainly including plasma cell mastitis (PCM), breast duct ectasia (MDE), granulomatous lobular mastitis (GLM), subareolar abscess and areolar fistula (Zuska disease) [2-4] and other epidemiological types. Epidemiological data show that the disease has a significant gender distribution characteristics, mainly female patients, and the peak incidence period is 2-5 years postpartum. It is important to note that clinical observation has found that the condition is occasionally found in male patients, but the incidence is significantly lower than that in the female population.

Clinical studies have shown that the pathogenesis of the disease is significantly related to a variety of predisposing factors, including excessive fatigue, abnormal dietary structure, emotional stress, luteal phase of the menstrual cycle, and local mechanical injury of the breast. Of note, congenital or acquired inverted nipples are common in female patients, while a history of chronic smoking exposure is prevalent in male patients. In addition, epidemiological investigations have shown a history of systemic use of psychotropic medications (e.g., antidepressants or antipsychotics) in some cases [5].

The clinical course of comedy cradle carbuncle can be divided into four pathological stages: mass stage, abscess stage, late ulcerative stage, and multimodal coexistence. Epidemiological data show that the incidence of the disease has shown a significant upward trend in recent years [6], accounting for about 4%~5% of benign breast diseases, and about 2%~5% [7] in China. At present, the exact etiological mechanism of the disease has not been fully elucidated, and its clinical characteristics are mainly characterized by prolonged course of disease, significant tendency to relapse, strong tissue destructiveness, and difficult treatment.

2. Overview of Acne Cradle Carbuncles

2.1 Understanding and Research on Acne Cradle Carbuncle in Chinese Medicine

2.1.1 Disease name and history of development

The TCM disease name "acne cradle carbuncle" was first seen in the "Practical Chinese Medicine Surgery" [4] edited by Professor Gu Bohua in 1985, and its name is derived from the powdery residue-like discharge mixed in the pus after the ulceration of the disease, and its morphological characteristics are similar to acne. The name of the disease was later included in the textbook "Surgery of Traditional Chinese Medicine" and is still used today.

The nomenclature of this disease has been studied by doctors in the past dynasties: based on the characteristics of clinical symptoms, there are titles such as "mastoma", "milk flower", "milk string", "milk leakage" and so on; According to the etiology and pathogenesis, there are names such as "milk phlegm" and "milk poison"; If the lesion site is combined with the classification of carbuncle and ulcer diseases, it can be divided into "cradle carbuncle", "cradle carbourne", "breast ulcer", "cradle boil", etc. [8].

In 1958, Professor Gu Bohua first named non-lactating mastitis with fistula formation as "chronic recurrent areolar fistula with nipple intraction" [9]. Professor Lu Deming inherited his academic ideas and believed that the disease was actually a fistula stage manifestation of plasma cell mastitis. After academic evolution, it was finally established as the standard name of "acne cradle carbuncle".

2.1.2 Etiology and pathogenesis

The etiology and pathogenesis of this disease have been systematically discussed in ancient Chinese medicine literature. "Essentials of Surgical Cardiology, Volume 6" [10]

points out: “Those who are not pregnant with a fetus inside and do not have milk outside and produce poison will be coagulated by dampness and heat in the liver and stomach to form milk poison”, which clarifies that the dampness and heat of the liver and stomach are inherent and become toxic over time as an important pathogenesis of this disease. “Treatise on the Origin and Syndrome of Diseases” [11] explains from the meridian theory: “The meridian of Zuyang Ming... Because of labor, the skin is weak, and the wind is evil... Heat in the breast”, revealing the pathological evolution process of the invasion of the surface deficiency and evil → the stagnation of the camp and guard→ the blockage of qi and blood→ and the carbuncle of the breast. According to ancient records, the pathogenesis of this disease can be summarized as two main ways: the invasion of external evils leading to stagnation of camp and health, or the dampness and heat of the liver and stomach stagnation and heat turning into pus.

Modern doctors have further elaborated on this: Professor Chen Hongfeng [12] emphasized the pathogenesis of liver qi stagnation → qi stagnation → blood coagulation mammary congestion → heat accumulation and pus; Professor Yi Weizhen [13] put forward the core pathogenesis theory of phlegm and stasis intertwined, liver, spleen, lung and kidney dysfunction. The exposition of “women’s nipples belong to the liver, and breasts belong to the stomach” in “Danxi Heart Method” has laid the foundation for the theory that breast diseases are related to the liver and stomach meridians. Lou Lihua [14] proposed that although the clinical manifestations can be seen in local redness, swelling, heat and pain, the skin color is mostly transient and not distinct dark red, the lesions are deep, the texture is hard and rigid and difficult to heal, and the course of the disease is prolonged, which is in line with the characteristics of “yin syndrome” in traditional Chinese medicine, and belongs to the evidence of “specimen yang and original yin”. Professor Tang Hanjun [15] believes that the disease is mostly due to liver and spleen disorders, damp heat phlegm and stasis condensation, etc., while Lin Yi [16] believes that the core pathogenesis of this disease lies in the accumulation of foreign bodies and occlusion of the mammary network, which leads to the obstruction of the flow of qi and blood, and the phlegm and stasis are intertwined and condensed into lumps. If it is hot for a long time, and the heat is full of meat rot, it will become carbuncle pus. His theory highlights the key role of “phlegm, stasis and hot knots” in the development of the disease.

This disease has the pathogenic characteristics of the original deficiency standard: congenital nipple indentation causes poor mammary network as the original deficiency; Emotional disorders, impulsive loss and liver depression and stomach fever are the norms. In the early stage of the disease, it was mainly empirical, which was manifested as qi stagnation, phlegm coagulation, blood stasis, and heat and poison. In the later stage, it turned into a love of good and evil, showing a mixture of virtual and real. The basic pathogenesis can be summarized as wood depression, liver depression and stomach fever, and the basis of the pathogenesis lies in insufficient congenital endowment, inverted nipples, and poor mammary circulation [17].

To sum up, the etiology and pathogenesis of this disease can be systematically summarized as follows: the invasion of external evils, congenital insufficiency, emotional disorders, eating disorders and other factors lead to the dysfunction of the lungs, liver, spleen and kidneys, and then produce pathological products such as qi stagnation, phlegm coagulation, blood stasis, heat poisoning, etc., blocking the mammary network, and eventually causing local agglomeration into lumps, and hot flesh rotting into carbuncle pus. Although the disease is located in the breast, it is closely related to the liver, spleen, stomach and Chong Ren two pulses [18], which reflects the overall concept of Chinese medicine and the theoretical characteristics of the theory of viscera meridians.

2.1.3 TCM syndrome type

Chen Hongfeng, editor-in-chief of “Surgery of Traditional Chinese Medicine” [1] divided acne cradle carbuncle into two syndrome types: liver meridian depression and residual toxicity, and the main clinical manifestations of liver meridian heat accumulation syndrome are nipple discharge or pimple indentation with acne-like overflow, breast lumps, redness, swelling and pain, and burning; The main manifestations of residual toxicity are that the abscess is self-ulcerating or not closing for a long time after incision, pus is dripping, and milk leakage is formed, and there are stiff masses or red, swollen and ulcerated locally [19]. However, these two types alone cannot fully summarize the complex clinical manifestations and disease progression of acne cradle carbuncle, and doctors have different views on the clinical syndrome of this disease.

Lu Lixian [20] and other researchers proposed that the disease can be divided into four syndrome types: liver meridian depression and heat pattern, spleen and stomach heat accumulation pattern, kidney meridian deficiency fire pattern and qi and blood weakness pattern. Professor Zhang Huifang [21] divided it into three types: liver qi stagnation type, phlegm-dampness accumulation type, and liver qi stagnation combined with qi stagnation and blood stasis. Professor Guo Yufei [22] proposed a more detailed classification, including five syndrome types: residual poison uncleared syndrome, liver meridian heat accumulation pattern, qi and blood deficiency pattern, spleen and kidney yang deficiency pattern, and rheumatic mixed syndrome. Professor Zhou Yuzhu [23] differentiated the syndrome from the perspective of liver depression, and divided it into six syndrome types: liver depression and stasis obstruction pattern, liver meridian depression and heat pattern, liver depression and phlegm coagulation pattern, liver depression and toxin pattern, liver depression and qi stagnation pattern and liver depression and spleen deficiency pattern. Professor Tang Hanjun [24] summarized the three main syndrome types of liver meridian depression and heat pattern, phlegm stasis coagulation and stagnation pattern and residual poison uncleared pattern. These classification methods reflect the differences in the understanding of the pathogenesis of the disease among different scholars.

2.1.4 Treatment

Treatment principle: Based on the general treatment principle of “elimination, support and supplementation” in TCM surgery, it is advisable to adopt a comprehensive treatment plan of internal and external treatment. At different stages of

disease development, the focus of treatment varies: dissipation in the early stage, toxin in the middle stage, and tonic benefits in the later stage.

Internal treatment: In the early stage of the disease, for the lump formation stage, when the dissipation is the key, the "Outline of the Ulcer Department" clearly points out: "The treatment of ulcers is essential, and those who have not succeeded must seek its elimination, and the treatment is early, although there is a big evidence, it can be dissipated invisibly." In the middle and late stages of the disease, if the abscess has become or has not been closed for a long time after it has been broken, it is advisable to apply the method of going out with poison and tonifying and correcting, as stated in the "Su Wen Commentary": "The flesh likes warmth and hates cold, cold is condensed but not flowing, and warmth is dissipated and walked." "

1) Mass type: This type of treatment is based on dissipation, which can be divided into two methods according to the differentiation of yin and yang, such as clearing heat and reducing swelling and warming yang swelling, and is compatible with treatment methods such as blood circulation and blood stasis, phlegm dissipation, and liver and qi dispelling as appropriate.

a) Impotence type

Clinical manifestations: local swelling is high and prominent, pain is obvious, skin color is reddish or normal, skin temperature is slightly high, tongue coating is thin white or yellow, and the pulse is few and strong.

Treatment: clear away heat and detoxify, reduce swelling and ulceration, invigorate blood and relieve pain

Prescriptions: Xianfang Life Drink, Bupleurum Qinggan Soup, etc. plus or minus [25]

b) Negative syndrome type

Clinical manifestations: the affected area is diffusely swollen, the skin color is as usual, the skin temperature is not high, the mouth is not thirsty, the tongue is pale and pale, and the pulse is heavy or slow.

Treatment: Warm yang replenishes blood, dissipates cold and stagnates

Prescription: Yang and decoction plus minus [26]

2) Abscess type: The basic principle of this type of treatment is to support the poison, which can be divided into three methods: the transmission of pus, the invigorating of qi and the support of poison, and the treatment of warm yang and poison.

a) Empirical type

Syndrome characteristics: the poison is not deficient, the pus is not ripe, or the pus is not smooth after ulceration

Treatment: toxin penetrates pus

Prescription: Diapusan plus or minus [27, 28].

b) Qi deficiency and toxic stagnation type

Syndrome characteristics: the sores are flat and collapsed, difficult to ulcerate and difficult to decay, or the pus is scarce and thin, and the swelling does not disappear

Treatment: Nourishing Qi and Supporting Poison

Formula: Tori Disinfectant Powder plus minus [29]

c) Yang deficiency and toxic stagnation type

Syndrome characteristics: sore-shaped swelling without head, dark and not red, suppuration and sluggishness

Treatment: Wenyang toxin

Prescription: Shengong Neituosan plus or minus

(3) Post-ulcer type: This type of treatment is based on tonic benefits, mainly including invigorating qi and strengthening the spleen, warming yang and reducing swelling, and nourishing qi and blood.

a) Spleen deficiency and dampness type

Syndrome characteristics: pus is thin, the wound is not collected, accompanied by fatigue and sluggishness, and the tongue is pale or greasy

Prescriptions: Shenling Baizhu San, Buzhong Yiqi Soup, Liujunzi Soup, etc. plus or minus [30]

b) Yang deficiency and cold condensation type

Syndrome characteristics: the wound does not heal for a long time, the swelling is flat, the limbs are cold and cold, and the tongue is pale and the pulse is heavy

Prescription: Yanghe decoction, Shengong Neituosan plus or minus [31]

c) Deficiency of qi and blood

Syndrome characteristics: pus is thin and light, the sores are dull, the complexion is yellow, and the body is thin and tired

Prescription: Gui Spleen Soup, Ginseng Yangrong Tang plus or minus [31]

(4) Multi-type coexistence: the main method of treatment of this type is tori suppuration. Although the three manifestations of mass, abscess and ulceration are intertwined with each other, they have their own emphasis at different stages of the course of the disease, and syndrome differentiation and treatment should be carried out in combination with clinical manifestations.

External treatment: As an important part of comprehensive treatment, external treatment of TCM needs to select corresponding interventions according to the different

pathological stages of the disease, and synergize with internal treatment to play a therapeutic role. The specific treatment plan is as follows:

(1) Fire acupuncture

Compared with traditional incision and pus drainage, fire acupuncture has the advantages of less trauma, faster recovery and slight scarring. Its therapeutic mechanism lies in improving local microcirculation, promoting tissue metabolism, accelerating inflammation absorption and wound healing through thermal effect. Clinical observations have shown significant advantages in maintaining the aesthetic integrity of the breast and improving patient satisfaction. Indications include superficial small abscesses, localized abscesses, multiple fistulas, pale wounds, and poor pus drainage [32]. Liu Ying et al. treated 54 patients with fire acupuncture combined with traditional Chinese medicine [33], and the results showed that 31 cases (57.41%) were clinically cured, 21 cases (38.89%) were improved, and 2 cases (3.70%) were not cured. The 6-month follow-up data showed that the recurrence rate was 6.45%.

(2) Topical therapy

External application therapy is to directly apply a traditional Chinese medicine ointment or powder with pharmacological effects to the wound surface, and exert the effect of purulent and decaying, muscle building and sores through transdermal absorption. Professor Liu Lifang [34] clinically used Jiuhua ointment (main effects: blood circulation and blood stasis, removal of saprophytic muscle, swelling and pain relief) to treat the late stage of this disease, and achieved significant clinical efficacy.

(3) Fumigation therapy

Fumigation therapy [35] can be divided into two categories: drug fumigation and steaming:

(1) Fumigation (also known as “smell and inhalation therapy”): the use of volatile components of drugs through the respiratory tract or local action to exert curative effects;

(2) Steaming method: Heating the drug to produce steam to act on the affected area. This therapy has the therapeutic effects of diaphoresis and surface relief, cold and pain relief, blood circulation and circulation.

(4) Other external treatments

Commonly used external treatment methods in clinical practice also include: patch therapy, nipple orthopedics, wound irrigation (drip irrigation), drug twist drainage, saprophytic muscle removal method, gauze drainage, thread tugging therapy, acupuncture pus extraction, cotton pad binding method, pus removal and decay removal method, etc. [36]

2.2 Understanding and Research of Acneiform Mastitis in Western Medicine

2.2.1 Epidemiological Analysis Acneiform mastitis is defined in Western medicine as plasma cell mastitis (PCM) and belongs to the spectrum of non-lactational mastitis. Epidemiological studies show that in recent years, the incidence of granulomatous mastitis (GLM) has shown a significant upward trend, with distinct racial differences.

This condition commonly occurs in women of childbearing age, with clinical observations indicating that the majority of patients are married multiparous women [37]. In terms of body mass index (BMI) distribution, patients with GLM [38] are primarily of normal weight, followed by those who are obese. The occupational distribution indicates a higher incidence among mental laborers, and there is a significant seasonal tendency for onset, with summer being the peak season ($P<0.05$), but no significant correlation with Traditional Chinese Medicine constitution types ($P>0.05$).

In contrast, the proportion of overweight and obese individuals among PCM [39] patients is significantly higher ($P<0.01$). A retrospective study involving 115 patients demonstrated a clear gender inclination in this condition, with a majority being multiparous women. Anatomical distribution studies of the lesions indicate that the outer upper quadrant, inner upper quadrant, and the area of the nipple-areola complex are common sites of occurrence. Pathological typing analysis shows that mammary duct ectasia (MDE) and periductal mastitis [40] (PDM) are the main pathological types.

2.2.2 Etiology and pathology

Comedogenic cradle carbuncle includes plasma cell mastitis (PCM), mammary duct ectasia (MDE), non-puerperal mastitis (NPM), granulomatous mastitis (GLM) in Western medicine. It is thought that the occurrence of this disease is related to inverted or deformed nipples, obesity, smoking, breast trauma, infection, history of breast surgery, oral contraceptives, oral psychotropic drugs, Mycobacterium tuberculosis infection, lactation-induced hypersensitivity or immune reaction, and elevated prolactin.

(1) Bacterial infection

Existing research evidence increasingly supports the role of bacterial infections in the pathogenesis of the disease. Taylor et al. conducted a systematic study on 34 cases of mastitis, and collected a total of 116 clinical specimens for bacterial culture. The results showed that 52 specimens were detected with Corynebacterium infection, of which 20 were corynephilic corynebacterium spp., and 14 specimens were further identified as Corynebacterium kroppenstedtii. Xiaoyan Liu [41] research team used blood plate culture combined with 16S rRNA gene sequencing technology to analyze 190 cases of granulomatous mastitis specimens, and found that 66 cases had bacterial infection, of which 49 cases were isolated Corynebacterium bacteria. Wang Yesheng et al [42]. researchers used the 16S rDNA gene sequence as a molecular marker to perform bacteriological analysis on 12 granulomatous mastitis specimens in South China, and confirmed that 2 cases were infected with Corynebacterium kroppenstedtii. Available data suggest that Corynebacterium kroppenstedtii is significantly associated with granulomatous

mastitis. The above research results provide a new theoretical basis for clinical medical research. The available evidence is sufficient to confirm that bacterial infections, particularly Corynebacterium kroppenstedtii, play an important role in the pathogenesis of granulomatous mastitis. This strain has been successfully isolated and identified in several studies and has been identified as the main causative agent causing the disease [43]. Feng Xinyu [44] used logistic analysis to retrospectively analyze the data of 92 patients with non-lactating mastitis, and found that bacterial infection was a common factor in granulomatous mastitis and plasma cell mastitis.

(2) Autoimmunity

In 1972, Kessler et al. reported for the first time that the histopathological features of granulomatous mastitis (GM) were highly similar to autoimmune diseases such as granulomatous thyroiditis and granulomatous orchitis, and the bacterial culture results were negative, thus suggesting that the disease may belong to the category of autoimmune diseases. In terms of clinical treatment, glucocorticoid is widely used in the treatment of GM due to its significant immunosuppressive effect. The literature has reported that glucocorticoids are 77% effective with monotherapy, compared with only 5% with antibiotics alone. Based on this, Akahane et al. suggested that glucocorticoids should be the first treatment for this disease. Given the widespread use of glucocorticoids in autoimmune diseases and their significant efficacy in the treatment of GM, it is speculated that the pathogenesis of glucocorticoids may be closely related to the autoimmune response.

In terms of clinical manifestations, Adams et al. observed that patients with GM often had erythema in both lower extremities, a systemic manifestation that further supported the hypothesis of autoimmune pathogenesis. Ogura et al. [43] analyzed the GM tissue samples of 2 cases by immunohistochemistry and found that there were a large number of IgG4 plasma cells and CD4/CD8 lymphocyte infiltration in the lesions, and the serum IgG4 level of one patient was significantly increased. Since elevated IgG4 levels are common in autoimmune diseases such as systemic lupus erythematosus and autoimmune pancreatitis, this finding provides more direct evidence for the autoimmune etiology of GM.

2.2.3 Clinical manifestations and diagnostic methods

The clinical manifestations are diverse, including breast lumps, inverted nipples, breast pain, nipple discharge, and skin changes. On the basis of a chronic pathological process, a breast lump can be secondary to acute infection, which can lead to the formation of an abscess. The disease progresses to the terminal stage, and the abscess often causes breast fistulas, sinus tracts, or ulcers after rupture, and the lesions are characterized by long-term non-healing.

Clinical diagnosis requires a combination of physical examination and imaging studies. During the physical examination, the physician evaluates the physical characteristics of the breast lump, such as size, texture, range of motion, and borders, and determines the location and degree of tenderness through palpation, so as to make a preliminary judgment about the condition. Imaging tests mainly use breast ultrasound, mammography and magnetic resonance imaging (MRI). In addition, laboratory tests and pathological examinations also play an important role in the diagnosis of the disease.

2.2.4 Treatment

(1) Non-surgical treatment

Most patients with early-stage non-mammalian mastitis (NPM) respond well to oral glucocorticoid therapy, and the key to its therapeutic effect lies in the reasonable dosage and control of the treatment cycle. Studies by Sakurai K [43] et al. have shown that oral administration of glucocorticoids in the early stage of the disease can effectively stabilize the volume of the lesion and even achieve complete regression of the lesion. For the treatment of acute inflammation in mammary ductal ectasia/periductal mastitis (MDE/PDM), broad-spectrum antibiotics combined with metronidazole can effectively control the inflammatory response. Notably, granulomatous mastitis (GLM) is significantly less sensitive to antibiotic therapy than periductal mastitis.

At present, glucocorticoids combined with methotrexate (MTX) are mainly used in clinical practice, but this regimen may cause significant adverse reactions including osteoporosis, necrosis of the femoral head, immune system dysfunction and endocrine disorders. Immunosuppressant therapy is still in clinical trials, and its efficacy and safety need to be further verified. The existing research data show that tamoxifen can produce significant clinical efficacy in the acute exacerbation of plasma cell mastitis (PCM), but the application of endocrine therapy in non-mammalian mastitis is still limited and needs to be further explored.

Glucocorticoids are still the preferred drug in hormonal therapy for GLM, but there is no uniform standard for their dosing regimens. Recent studies have shown that topical administration of glucocorticoids or intralesional injections can effectively reduce the incidence of systemic adverse reactions (such as weight gain and bone loss) and improve patients' treatment compliance, which may become a promising new treatment strategy for clinical applications [45].

(2) Surgical treatment

Surgical treatment [43] is still an important treatment modality for NPM, but different pathological types and disease stages require differentiated surgical methods:

a) Lumpectomy: suitable for single or multiple localized small masses.

b) Segmentectomy of the gland: suitable for peripheral lesions or residual masses.

c) Puncture aspiration: suitable for single small abscesses.

d) Abscess incision and drainage: suitable for large or multilocular abscesses; Combination antibiotic therapy is

effective in mammary ductal ectasia/periductal mastitis (PDM), but has limited effect on granulomatous mastitis (GLM).

e) Mastectomy: only suitable for complex and refractory cases, and indications need to be strictly evaluated.

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