Clinical Observation on the Efficacy of External Application of Rutong San for Stagnation-stage Mastitis (Post-print)

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Date: 2022-08-17T00:00:00+00:00

Abstract

Objective To investigate the clinical efficacy of external application of Rutong San for mastitis in the stagnation stage. Methods Sixty patients with mastitis in the stagnation stage admitted from May 2021 to January 2022 were selected and randomly divided into an observation group and a control group, with 30 cases in each group. The control group received manual milk expression therapy alone, while the observation group received external application of Rutong San in addition to the control group treatment. Clinical efficacy was compared between the two groups. Results The effective rate in the observation group was 96.67% (29/30), which was higher than the 83.33% (25/30) in the control group, and the difference was statistically significant ($P < 0.05$). Conclusion Manual milk expression combined with external application of Rutong San helps alleviate discomfort symptoms in patients with mastitis in the stagnation stage.

Full Text

Clinical Observation on the Effect of External Application of Rutong Powder in the Treatment of Acute Mastitis at Stagnation Stage

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Abstract

Objective: To investigate the clinical efficacy of external application of Rutong powder in treating stagnation-stage mastitis.
Methods: A total of [number] patients with stagnation-stage mastitis treated

at the breast surgery outpatient clinic of Dongfang Hospital, Beijing University of Chinese Medicine between [start date] and [end date] were selected and randomly divided into an observation group and a control group, with [number] cases in each group. The control group received manual milk expression therapy alone, while the observation group received additional intervention with external application of Rutong powder on top of the control group treatment. Clinical efficacy was compared between the two groups.
Results: The effective rate in the observation group was [percentage]%, which was significantly higher than [percentage]% in the control group ($P < 0.05$).
Conclusion: Combined manual milk expression and external application of Rutong powder helps relieve symptoms and discomfort in patients with stagnation-stage mastitis, demonstrating superior therapeutic effects.

Keywords: acute mastitis; manual milk expression; Rutong powder; Chinese herbal medicine external application; Traditional Chinese Medicine nursing

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Introduction

Acute mastitis falls under the category of "mastitis"(乳痈) in Traditional Chinese Medicine (TCM). With continuous improvement in living standards, the incidence of acute mastitis has shown an upward trend. The condition progresses rapidly and easily leads to suppuration, making early treatment particularly crucial. While antibiotics represent the mainstay of conventional treatment for acute mastitis, they can interfere with breastfeeding and suffer from poor patient compliance. External application of Chinese herbal medicine can effectively promote drug absorption, shorten disease course, and is characterized by low cost and minimal adverse reactions, making it more readily acceptable to patients [1-2]. This study primarily investigated the clinical efficacy of Rutong powder external application in treating patients with stagnation-stage mastitis.

1. Materials and Methods

1.1 Study Participants Patients with mastitis who visited the breast surgery outpatient clinic of Dongfang Hospital, Beijing University of Chinese Medicine between [month/year] and [month/year] were selected as study subjects.

Inclusion Criteria:
1. Met both Western medicine diagnostic criteria and TCM diagnostic criteria.
- *Western medicine criteria:* Referenced *Practical Mastology* [3]: occurred during postpartum lactation period; breast pain and swelling with palpable hard masses; body temperature ≥ 38.5°C in the absence of other infections; localized erythema of the breast with or without increased skin temperature; elevated total white blood cell count or neutrophils; inflammatory manifestations.
- *TCM criteria:* Referenced *Guiding Principles for Clinical Research of New Chinese Medicines* [4]: painful masses within the breast, non-red or slightly red skin, poor milk drainage, possible nipple fissures or erosion; when suppurating,

breast pain and swelling worsen, masses soften with a fluctuant sensation; after rupture or incision and drainage, pain and swelling reduce; if pus drainage is inadequate, pain and swelling persist; most patients are lactating women, particularly primipara within one month postpartum.
2. Typical breast pain symptoms with poor milk drainage.
3. No abscess formation indicated by breast ultrasound.
4. Voluntary participation with signed informed consent.

Exclusion Criteria:
1. Severe breast deformity.
2. Breast masses or established abscess.
3. Non-lactating mastitis patients.
4. Patients using other mastitis medications.
5. Patients allergic to experimental drugs or TCM external applications.
6. Patients with psychiatric skin diseases.

1.2 Grouping A total of [number] patients were randomly divided into a control group and an observation group, with 30 cases in each group. The control group had ages ranging from [age] to [age] years, while the observation group ranged from [age] to [age] years. Comparison of general data between the two groups showed no statistically significant differences ($P > 0.05$), indicating comparability.

1.3 Interventions **Control Group:** Received manual milk expression therapy alone.
Observation Group: Received manual milk expression therapy plus external application of Rutong powder.

Manual Milk Expression Procedure:
After verifying medical orders and assessing the patient, the affected breast was identified according to physician instructions and the procedure was explained to the patient. Manual milk expression is generally unsuitable for patients with breast abscess or rupture, as severe local inflammatory reactions and improper technique may lead to inflammation spread. However, since milk production is continuous and inadequate drainage of non-breastfed breasts leads to milk stasis, causing breast pain and severe physiological and psychological harm that further exacerbates the condition [5]. After preparing all necessary items, patients were escorted to the TCM treatment room where a nursing pad was placed on the bed and body temperature was measured. Patients were assisted into a proper position with both breasts exposed, ensuring privacy protection and warmth. Breast palpation was performed before the procedure.

Acupoint Opening: Using thumb and index finger pressure, the acupoints "Rugen (ST18), Tanzhong (CV17), Ruzhong (ST17), Yingchuang (ST16), and Qimen (LR14)" were massaged for 2 minutes each, with pressure sufficient to produce slight soreness. This achieves the effects of soothing liver qi, dispersing

masses and relieving pain, clearing yang heat toxins, unblocking breast collaterals and qi-blood, promoting qi circulation and depression relief, and facilitating milk drainage.

Breast Lubrication: The nipple was gently squeezed and stimulated. Thumb and index finger were placed at the areolar margin, gently pressed downward on the milk sinuses, and lifted upward to express milk for breast skin lubrication. Milk stasis around the areola was drained first, then the thenar eminence and hypothenar eminence were used to massage along the mammary duct direction from the breast root toward the nipple, generating propulsive force to empty accumulated milk. Patient feedback on pain was monitored to adjust pressure accordingly. Massage should begin from non-lesion areas of the breast [6], continuing until accumulated milk was drained, glands became uniformly soft, and pain was significantly relieved.

Post-procedure: Patients were assisted in wiping expressed milk from the skin and dressing. Post-treatment temperature was remeasured and recorded. Treatment duration for a single breast was 15-20 minutes.

Rutong Powder External Application:
Based on the control group treatment, the observation group received Rutong powder external application.

Basic Formula: Rutong powder consists of dandelion 30g, Poria 15g, liquidambaris fructus 15g, licorice slices 6g, vinegar-processed green tangerine peel 10g, and bran-fried atractylodes rhizome 10g.

Application Method: The powder was mixed with green tea water into a paste and applied evenly to the affected breast area, with coverage slightly exceeding the lesion border and a thickness of 2-3mm. Application time was 20-30 minutes per session, achieving local detumescence and fever reduction through topical medication.

Nursing Care: Before application, patients were asked about Chinese medicine allergy history. The mechanism of action, operation method, and precautions were explained to obtain patient cooperation. The painful area was cleaned with warm water first, then the paste mixed with green tea water was applied. Patient reactions were closely monitored to prevent complications. If skin itching, redness, or other reactions occurred, application time could be shortened.

1.4 Evaluation Criteria Clinical efficacy was evaluated based on symptom improvement and classified as cured, markedly effective, effective, or ineffective. Effective rate = (cured cases + markedly effective cases + effective cases) / total cases $\times$ 100%.

1.5 Statistical Methods SPSS software was used for statistical analysis. Count data were expressed as rates (%) and compared using ^{2} test. Test level $\alpha = 0.05$.

2. Results

The effective rate in the observation group was 93.3% (28/30), significantly higher than 73.3% (22/30) in the control group ($P < 0.05$). The difference was statistically significant.

Comparison of Treatment Efficacy Between Two Groups [n (%)]

Discussion

According to the natural disease progression, acute mastitis is divided into three stages: stagnation stage, suppuration stage, and post-rupture stage. The stagnation stage represents the critical period for treatment [7]; if not treated promptly, it may induce breast abscess formation and cause mammary tissue damage. Acute mastitis belongs to the TCM category of "mastitis" (乳痈). As recorded in *Zhouhou Beiji Fang* (Handbook of Prescriptions for Emergencies): "When milk cannot be discharged, internal accumulation is called jealous milk," indicating that milk stasis induces mastitis. *Waike Fengshi Jinxiang Milu Jingyi* (Essential Records of Feng' s Secret Brocade Bag for External Medicine) elaborates on the etiology and pathogenesis: "Mothers who nurse their children without proper care, with anger and resentment causing reversal, depression causing obstruction, and rich, roasted foods causing fermentation, lead to non-circulation of Jueyin qi, thus orifices cannot communicate and milk cannot discharge; Yangming blood heat boils, thus heat predominance transforms into pus." Therefore, TCM believes external causes include postpartum breastfeeding with nipple damage allowing pathogenic wind-toxins to enter collaterals; internal causes include non-circulation of Jueyin qi and steaming heat in Yangming meridian, with liver depression and stomach heat mutually influencing each other, inducing milk stasis and breast collateral obstruction with qi-blood stagnation.

Chen Shigong recorded in *Waike Zhengzong* (Orthodox Manual of External Medicine): "Depression and worry injure the liver, liver qi stagnation leads to swelling," indicating that liver depression, qi stagnation, and meridian obstruction are key to pattern differentiation in stagnation-type acute mastitis. In treatment, Western medicine considers lactation-stage stagnation-type acute mastitis as the early inflammatory phase of acute mastitis, emphasizing early milk drainage and avoiding excessive cold or cool medicinals. Once milk flow is unobstructed, inflammation resolves and masses dissipate. Manual milk expression can effectively unblock mammary ducts, allowing accumulated milk to discharge and preventing suppuration [8]. This study' s results demonstrate that syndrome-differentiated external application of Chinese medicine combined with relevant nursing interventions can effectively relieve redness, swelling, and pain in stagnation-type acute mastitis patients, consistent with domestic research findings [9-10] showing that Chinese medicine paste application effectively alleviates acute mastitis symptoms. External application of Chinese medicine is part of TCM nursing technology, offering advantages of individualized treatment and nursing, syndrome-based medication and care, effective pain relief

without dependence or withdrawal reactions, reflecting the strengths of TCM nursing and warranting clinical promotion.

Conflict of Interest Statement: The authors declare no conflicts of interest.

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Note: Figure translations are in progress. See original paper for figures.