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Research Article

A Five-step Systematic Therapy for Treating Plugged Ducts and Mastitis in Breastfeeding Women: A Case–Control Study

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ABSTRACT

Purpose: This study aimed to describe the clinical response to five-step systematic therapy (FSST) in the management of plugged ducts and mastitis. FSST was a comprehensive milk stasis dredging treatment, which contained five steps to make the milk out of the plugged duct.

Methods: This retrospective study included 922 breastfeeding women, 714 with plugged ducts, and 208 with mastitis who received FSST from June to September 2017. The breast pain score, swelling degree, and range of breast induration were recorded pre-FSST and post-FSST.

Results: After a single FSST, pain score and swelling degree were significantly improved (both $p < .001$) in all cases. After FSST, the mean breast pain relief score was 1.69 ± 0.70, whereas the mean swelling fade away degree was 1.61 ± 0.62. In the subgroup analysis, pain score and swelling degree were significantly improved (both $p < .001$) in the plugged ducts group and the mastitis group. The score of pain relief in the plugged ducts group was less than that in the mastitis group (1.63 ± 0.68 vs. 1.91 ± 0.70, $t = 5.30$; $p < .001$), whereas improvement of swelling fade away was greater in the plugged ducts group than the mastitis group (1.65 ± 0.64 vs. 1.48 ± 0.56, $t = 3.49$; $p = .001$). The composition ratio of changes in induration range between the two groups was statistically different (Pearson $\chi^2 = 137.87$, $p < .001$), of which more obvious improvement in the plugged ducts group than the mastitis group ($\chi^2 = 25.65$, $p < .001$).

Conclusion: FSST can relieve pain, reduce breast swelling and range of induration, and for plugged ducts or mastitis varied degree differently.

Introduction

Because of the benefits to both infants and mothers, breastfeeding is recommended by the World Health Organization (WHO) [1–4]. Furthermore, exclusive breastfeeding is recommended for infants from birth to 6 months [5]. Inflammatory breast diseases, such as plugged ducts and acute mastitis, are common conditions that afflict women during lactation, causing breast pain and discomfort. Studies have shown that breast inflammation during lactation is one of the most important iatrogenic causes of weaning [6,7]. Therefore, the efficient management of plugged ducts and acute mastitis during lactation is key to ensure successful breastfeeding [8].

According to WHO guidelines, plugged ducts and mastitis are different stages of breast inflammation during lactation caused by the blockage of lactiferous ducts as the initial factor [9]. There is no clear boundary between the two conditions, but mastitis is accompanied by more serious local and/or systemic inflammation manifestation. Significant fever, especially when associated with breast erythema and systemic symptoms such as myalgias, suggests the diagnosis of mastitis [10,11]. Both conditions may develop into a mammary abscess if they are not treated promptly and properly [12]. As such, effective treatment of plugged ducts and acute mastitis is particularly important in the management of lactation. The common pathogenesis of both plugged ducts and acute mastitis is inefficient milk emptying. It has been reported that

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timely and effective breast emptying is important to prevent and manage plugged ducts and acute mastitis [8,9].

A number of measures to stimulate efficient breast emptying have been explored, including massage, milk expression, breast pumping, cold and hot compression, acupuncture, auricular therapy, Gua-Sha therapy, ultrasonic treatment, and laser therapy [13–21]. When a single measure proves effective, combination of multiple measures should yield better results. Based on the aforementioned information, we combined five measures and developed a therapy called five-step systematic therapy (FSST). The Breast Surgery Department of our hospital has been performing FSST for patients with inflammatory conditions during lactation since 2015. Until now, more than 10,000 patients received this therapy and achieved good results. We found the symptoms improvement of the patients varied by different inflammatory stages. Commonly used evaluation indicators include ratings of pain, swelling, and hardness [7,22]. The purpose of this study was to describe the clinical response of lactating women with plugged ducts and/or acute mastitis treated with FSST from June to September 2017.

Methods

Study design

This study was a retrospective analysis of lactating women with plugged ducts and acute mastitis women treated with FSST. Case–control study was performed to observed the differences in clinical response between plugged ducts and acute mastitis after a single FSST.

Setting and sample

This study was performed at Guangzhou Women and Children's Medical Center, the largest Women and Children specialized hospital in south China. This hospital is a third-level Grade A hospital, which is the first public hospital certified by the Joint Commission International (JCI) in China. All pregnant women receive breastfeeding education according to the Chinese Baby-Friendly Hospital Standards.

The study included a convenience sample of all lactating women who received FSST from June to September 2017. The symptoms of lactating women with plugged ducts and/or acute mastitis did not relieve after frequently breastfeeding for 48 hours. These women who were referred to our department and received FSST were brought into our analysis. Exclusion criteria were patients who received FSST for other reasons, for example, hypogalactia or breast abscess. Patients who did not complete treatment were also excluded. In fact, all patients should be evaluated and prescribed by a breast specialist before treatment. Suspected benign or malignant tumor excluded from this study should enter the corresponding treatment process.

During the study period, 1,078 patients completed FSST. Of these, 156 (14.5%) were excluded: 100 patients with hypogalactia and 56 with breast abscesses. A total of 922 patients met the criteria and were included in this study and were divided into plugged ducts group (PDG; n = 714) and mastitis group (MG; n = 208).

Ethical consideration

The study was approved by the Ethics Committee of G Medical Center (Approval no. [2020] 30501). Because of the retrospective nature of the study, the requirement of informed patient consent was waived.

Measurements

Five-step systematic therapy

FSST is performed by breast specialist outpatient nurses. The five steps of FSST are as follows.

1) Laser therapy [19,20]. With the patient in the sitting position, the breast skin is fully exposed and irradiated by a SUNDOM-300 IB/233 LCD-type semiconductor laser therapy unit (Beijing SUNDOM Medical Equipment Co. Ltd., China). This semiconductor laser instrument adopts multiwavelength composite output (650/810 mm). According to the instruction of the machine, the composite wavelength laser has the characteristics of noninjury and strong penetration, which can induce the local biological stimulation effect manifested in local blood circulation promotion, tissue edema reduction, inflammatory relief, and analgesic effects. The procedure of laser therapy is 1200 milliwatts of power for 10 minutes, irradiation area of 8800 mm^2, and irradiation distance of 10–15 cm. If both breasts are affected, both should be irradiated at the same time. The nipple/areola is covered with gauze during irradiation.
2) Electric breast pumping [7–9]. A Medela Swing medical breast pump (Medela AG, Switzerland) is used for bilateral breast pumping. Beginning at zero, the negative pressure increases until the patient's maximum discomfort level is reached. Pumping is continued for 10–15 minutes. The medical-grade pump is more efficient and provides better pumping effect.
3) Breast massage [13,16,18,22]. Breast massage is to better promote the discharge of milk stasis, especially when breast pumping still cannot empty the breast. Patients are placed in the supine position with two dry towels under their body. After the comprehensive evaluation of both breasts, the massage is started from the contralateral breast. The root of the nipple is softly massaged for 30 seconds for the milk ejection reflex. The areola is pressed from different directions to open the milk ducts. The breast is pushed and kneaded from the base toward the areola to excrete the milk, and then the nipple and areola are squeezed again to discharge the milk. Hard knots are gently massaged with the thumb or hypothenar muscles until softened. Unilateral breast massage is performed for no more than 15 minutes.
4) Cold wet compress [14,18]. Gauze soaked in a 33% magnesium sulfate solution is applied to both sides of the breast for 10–15 minutes. According to the drug instruction, the external application of 33% magnesium sulfate, which is a hypertonic solution at room temperature, has the effect of cold and wet compress that can reduce swelling and relieve pain after milk discharge confirmed by previous studies.
5) Patient education [8,9,14]. Patients are given individualized guidance for breastfeeding based on their existing problems. Latch-on and breastfeeding position are the most common problem that the breastfeeding mother faced. Tell the mothers how to latch on the nipple–areolar complex to form a long teat, but not only the nipple tip. Teach the mothers to choose a suitable position when feeding. The position of mother semi-reclining and infant semiprone is helpful, especially for a mother who has had a cesarean delivery. Use reverse pressure softening if the areola is edematous. It is very important to insist on breastfeeding. More frequent feeding is helpful to promote milk excretion. The benefits of breastfeeding are reinforced, and they are encouraged to increase their self-confidence for breastfeeding.

According to the work rationale of each step, comprehensive schemes such as FSST can promote milk excretion, reduce tissue

edema, and relieve pain. Individualized guidance can better maintain the therapeutic effect in the out-of-hospital period.

Outcome measures

Pain score, degree of breast swelling, and range of induration were recorded before and after treatment by the breast specialist outpatient nurses who were trained to make sure to keep the measurement consistency. Pain was graded on a numerical rating scale: 0 points for no pain; 1–3 points for mild pain, 4–6 points for moderate pain, and 7–10 points for severe pain. The pain score before treatment minus that after treatment was defined as the pain relief score; the higher the score, the greater the pain relief.

The degree of swelling was assessed using the scale developed by Humenick et al [23]. The scale is as follows: 1°, the breast is soft, no changes; 2°, slight breast swelling; 3°, breast swelling is present, no pain (0 points); 4°, breast distension, mild pain (1-3 points); 5°, breast distension, moderate pain (4–6 points); and 6°, the breast is very swollen, and there is severe pain (7–10 points). Swelling degree was recorded before and after treatment. The swelling degree before treatment minus that after treatment was defined as the swelling fade away degree; the higher the score, the greater the improvement.

The range of induration was recorded before and after treatment. The changes in the range of induration were recorded by modified quantitative grades [22]. The grades are as follows: disappearance (2): the range of the hard lump was reduced by more than 80% after treatment; reduction (1): the range was reduced by 10–80% after treatment; no change (0): the range was between −10% and 10% after treatment; aggravation (−1): the range increased by more than 10% after treatment. The higher the score, the greater the improvement.

Data collection

Data were collected from June to September 2017 by the breast specialist outpatient nurses who performed the treatments. To ensure the accuracy and consistency of the data collection process, a training session was provided to all the breast specialist outpatient nurses involved in this study. Patient demographic information and the time of onset of the condition were recorded before treatment, and pain score, swelling degree, and range of induration were recorded before and after treatment. The data of each patient were recorded separately in an individual form. Data were entered periodically into IBM Statistical Package for the Social Sciences 22.0 (SPSS) software for subsequent analysis (IBM Corp., Armonk, NY, USA).

Data analysis

Descriptive statistics, including median, range, and frequency, were calculated. Items were first summed to create a score for age, onset time, pain level, swelling degree, and changes in the range of induration. Single sample *t* test, two independent samples test, and Pearson Chi-square test were used to assess the variables. For all analyses, a value of $p < .050$ was considered to indicate statistical significance.

Results

Patient basic information

The mean age of all patients was 30.37 ± 3.88 years. The oldest patient was 43 years, and the youngest was 17 years. The most common onset time of all patients was during the first to the third month postpartum, accounting for 41.6%, and the incidence rate within the third month postpartum was as high as 80.7%. According to PDG and MG, the characteristics of the two groups are summarized in Table 1.

Pain

The overall mean pain score before treatment was 3.79 ± 1.54, with a maximum of 7 and a minimum of 0. The mean pain score pre-FSST in the PDG was 3.22 ± 1.23, with a maximum of 7 and a minimum of 0. In the MG, the mean pain score pre-FSST was 5.73 ± 0.72, with a maximum of 7 and a minimum of 4. The pain score pre-FSST of the MG was higher than that of the PDG, and the difference was statistically significant ($t = 28.13$, $p < .001$).

The overall mean breast pain relief score was 1.69 ± 0.70. All patients had statistically significant difference in pain relief score after treatment ($t = 73.54$, $p < .001$). In the PDG, the mean pain relief score was 1.63 ± 0.68, with a maximum pain relief score of 4. No patient experienced pain aggravation after treatment, but some patients did not experience pain relief. In the MG, the mean pain relief score was 1.91 ± 0.70, and the maximum pain relief score was 3. One patient experienced the aggravation of pain after the treatment, with a score of −1. There was a statistically significant difference in pain relief score between the two groups ($t = 5.30$, $p < .001$), with greater pain relief in the MG (Figure 1).

Swelling

The mean swelling degree of all patients before treatment was 3.85 ± 1.21, with a maximum of 6 and a minimum of 1. The mean swelling degree pre-FSST in the PDG was 3.48 ± 1.07, with a maximum of 6 and a minimum of 1. The mean swelling degree pre-FSST in the MG was 5.15 ± 0.59, with a maximum of 6 and a minimum of 4. The swelling degree pre-FSST of the MG was higher than that of the PDG, and the difference between the two groups was statistically significant ($t = 21.66$, $p < .001$).

In the whole population, the mean swelling fade away degree was 1.61 ± 0.62. All patients had a statistically significant difference in swelling fade away degree after treatment ($t = 78.46$, $p < .001$). In the PDG, the mean swelling fade away degree was 1.65 ± 0.64, with a maximum of 3 and with a minimum of 0. In the MG, the mean swelling fade away degree was 1.48 ± 0.56, with a maximum of 3 and with a minimum of 0. There was a statistically significant difference in the swelling fade away degree between the two

Table 1 *Clinical Characteristics of PDG and MG (N = 922).*

Group	No.	Age (years)	Onset time		
			Within the first month, *n* (%)	During the first to third month, *n* (%)	Beyond the third month, *n* (%)
PDG	714	30.38 ± 3.89	300 (42.0)	277 (38.8)	137 (19.2)
MG	208	30.35 ± 3.83	60 (28.9)	107 (51.4)	41 (19.7)
Test value		$t = 0.11$	Pearson $\chi^2 = 13.37$		
p value		$p = .909$	$p = .001$		

Note. MG = mastitis group; PDG = plugged ducts group.

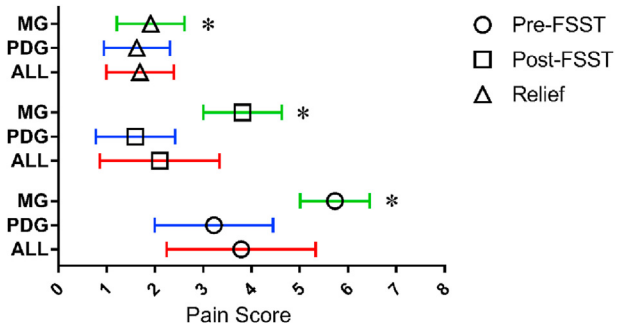

Figure 1. Separated symbols plots of pain scores in ALL, PDG, and MG.
Note. FSST = five-step systematic therapy; MG = mastitis group; PDG = plugged ducts group. *Compared with PDG, pain score in MG was statistically different in subgroup ($p < .050$).

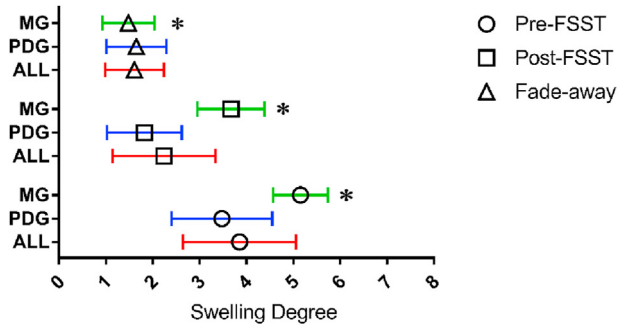

Figure 2. Separated symbols plots of swelling degree in ALL, PDG, and MG.
Note. FSST = 5-step systematic therapy; MG = mastitis group; PDG = plugged ducts group. *Compared with PDG, swelling degree in MG was statistically different in subgroup ($p < .050$).

groups ($t = 3.49$, $p = .001$), with the swelling fade away greater in patients with plugged ducts (Figure 2).

Range of breast induration

All breast induration in all patients could be evaluated. Based on the scoring system, in the overall population, the frequency of a score of 2 (disappearance) was 31.7% (292/922), 1 (reduction) was 63.9% (589/922), 0 (no change) was 4.4% (41/922), and −1 (aggravation) was 0 (0/922). Change score of induration range in PDG and MG could be seen in Table 2. The effective rate of treatment (the frequency of 1 and 2) was 97.5% in the PDG, whereas 88.9% in the MG. According to the effective rate, the range of breast induration was improved more obviously in the PDG than the MG ($\chi^2 = 25.65$, $p < .001$).

Table 2 *Change Score of Induration Range in PDG and MG (N = 922).*

Group	No.	Change score of induration range		
		0, *n* (%)	1, *n* (%)	2, *n* (%)
PDG	714	18 (2.5)	404 (56.6)	292 (40.9)
MG	208	23 (11.1)	185 (88.9)	0 (0)
Test value		Pearson $\chi^2 = 137.87$		
p value		$p < .001$		

Note. MG = mastitis group; PDG = plugged ducts group.

Discussion

Plugged ducts, acute mastitis, and mammary abscesses are collectively called inflammatory breast diseases during lactation. Plugged ducts often occur 2–3 weeks after delivery [24] because of injury to the nipple, ineffective milk removal, poor breastfeeding technique, irregular lactation, superficial pressure on the breast, and an overabundant milk supply [9,25]. Because of the delayed resolution, plugged ducts may lead to more severe symptoms, such as mastitis and mammary abscess [24]. Acute mastitis can happen at any time during lactation, but mostly seen in the first 6 weeks postpartum [8,26]. Whatever plugged ducts or mastitis, the discomfort and pain can affect the mother's confidence in breastfeeding, cause anxiety, and can lead to early weaning [6]. In our study, plugged ducts occurred more frequently within the first month of postpartum, whereas mastitis occurred in the first to the third month of postpartum. No matter the onset time of plugged ducts or mastitis was similar in the previous study.

Plugged ducts and mastitis can be effectively relieved with enough breast emptying. A baby feeding is the most effective way to empty the breast. However, because of the separation of maternal and infant diseases, nipple injury, congenital malformation, or the blocked milk tube hard to be recanalized by infant sucking, some mothers must seek medical help. Our hospital developed a comprehensive milk stasis treatment called FSST, which can effectively increase stasis milk excretion to relieve the symptoms of patients with plugged ducts and mastitis. Previous studies have used similar comprehensive treatments and obtained similar positive results [27].

In our study, the symptoms of the patients, including pain and swelling, were significantly improved after receiving FSST, which to some extent indicated that the FSST scheme had certain curative effects on these patients. Previous studies had shown that the clinical symptoms at different stages of lactation could be effectively alleviated after treatment [28]. Laser therapy adopted composite output (650/810 mm) could relieve pain and reduce tissue edema. According to the instruction of the machine and the results of the previous study, the composite wavelength laser was the golden wavelength of the human body, which can stimulate the biological effect of anti-inflammation and detumescence at the irradiated site [20]. The laser treatment had the characteristics of high efficiency, noninjury, and safety, as long as it worked in the recommended irradiation mode. No adverse effects caused by laser treatment had been seen in our hospital in clinical practice. The second and third steps were to directly promote milk excretion through different ways, whereas the excretion of stasis milk removed the cause of disease and significantly improved the symptoms such as pain, swelling, and induration formation caused by it. The fourth step was through the hyperosmotic liquid cold compress so that breast swelling and pain might further relief. External application of 33% magnesium sulfate solution was safe because of minimal absorption on intact skin and limited duration. Magnesium poisoning caused by topical magnesium sulfate had not been reported before. But there were no prior data to show whether the clinical response on different symptoms varied at different stages after effective treatment. We focused on the clinical response to FSST on patients with plugged ducts and those with mastitis, and an interesting phenomenon was found. FSST provided better pain relief in the MG, whereas breast swelling fade away and reduction of hard lumps were greater in the PDG. Breast swelling fade away and hard lumps reduction both reflected the objective situation of the disease change, indicating the degree of milk excretion, the results of both should be consistent, and statistical analysis also supported this conclusion. In theory, the breast swelling fade away, and the lumps reduction was better in the PDG, suggesting greater pain relief, but the opposite was observed. There may be two reasons for this finding. The pretreatment pain score of the MG was higher than that of the PDG. The higher the score, the more obvious it falls. Patients had a strong feeling about the

improvement of pain. Second, breast pain is not only caused by the mechanical expansion of milk ducts caused by plugged ducts but also by an increase in inflammatory factors, such as prostaglandins, bradykinin, and substance P [29]. In animal studies, extracellular matrix (ECM) increases during the mastitis stage, and the increased ECM such as prostaglandins can cause more serious pain [30,31]. Human study has shown there are considerable differences in the concentrations of many components of human milk before and after breast massage [32]. FSST can stimulate stasis milk excretion, and milk excretion may affect the concentration of ECM. We hypothesized that pain relief in mastitis after FSST is, on the one hand, because of the physical effect of stasis milk excretion and, on the other hand, because of the chemical effect of milk excretion causing a decrease in the concentration of pain-related factors. Further research is needed to confirm the hypothesis. Changes in induration range could be observed that the lumps could vanish completely in quite a number of patients in PDG (40.9%) after treatment, but none of the patients in MG.

Since 2015, more than 10,000 patients have been treated with FSST at our hospital. FSST was simple and easy to implement and could be applied in the clinical treatment of lactating women with plugged ducts and/or mastitis. Because of the variation of clinical response at different stages, therapeutic scheme required optimization to achieve the best effect, such as more times FSST, medicine, and so on. The detailed operation steps of FSST could refer to the introduction mentioned previously. Breast massage techniques needed to be practiced to find effective drainage skills and needed to be individualized because of the variation of strength tolerance for different patients. Our goal was not to completely clear the breast induration in one FSST, and the scheme was not just a step as breast massage. The specialist nurses had played an important role in this treatment process. Higher requirements were put forward for the nurses. They not only needed to master the process of FSST but also master the professional knowledge of breast and breastfeeding. They needed to have knowledge of the breast anatomy to dredge along the direction of the plugged duct to the nipple because the induration was drained rather than crushed. Breast massage step is needed to avoid violence. Meanwhile, they needed to master rich professional knowledge of breastfeeding to give the individualized guidance to the patients according to the different breastfeeding problems. At the end of each treatment, the efficacy should be evaluated by the nurses, and the cases with poor effect should be referred to the clinician again to exclude the tumor or abscess. The safety and effectiveness of FSST were based on the cooperation of medical and nursing care. Professional guidance, adequate evaluation, and multidisciplinary collaboration were essential to carry out this treatment program.

There are some shortcomings in the study. FSST is a complex therapeutic protocol, and the most effective scheme should be explored. In addition, the difference of clinical response to FSST between the two groups is still in observation research. There is lack of pathophysiological evidence, such as the hypothesis that treatment can reduce the concentration of pain-related factors in ECM, and the analysis of milk is still to be further studied in the next stage.

Conclusion

FSST relieved breast pain and reduced breast swelling and range of induration. An interesting phenomenon was found that clinical response was different between the two groups. However, the FSST scheme requires optimization, and the mechanisms of difference in clinical response need to be further studied.

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Conflict of interest

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