Original Article

Comparing the Effects of Hot Compress and Hot Ginger Compress on Pain Associated with Breast Engorgement

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Background: Breast engorgement (BE) is a physiologic condition in the postpartum period characterized by painful swelling of the breasts. BE-associated pain is the second main cause of exclusive breastfeeding failure in the early weeks of childbirth. Objectives: This study aimed to compare the effects of hot compress and hot ginger compress on BE-associated pain. Methods: This randomized clinical trial was conducted in 2018 on 76 breastfeeding women with BE conveniently recruited from Imam Reza hospital, Mashhad, Iran, Participants were randomly allocated to a control group to receive hot compress (n = 38) and an intervention group to receive hot ginger compress (n = 38). Study intervention was implemented in both groups thrice daily for 2 consecutive days. A Visual Analog scale was used for the assessment of BE-associated pain before and after the study intervention. Data were analyzed using the Mann-Whitney U, the independent-samples t, the Wilcoxon, and the Chi-square tests as well as the analysis of covariance. Results: The mean score of BE-associated pain in the right and the left breasts significantly reduced by, respectively, 6.25 ± 1.76 and 6.06 ± 1.76 points in the intervention group (P < 0.05) and by 3.21 ± 1.02 and 3.48 ± 1.21 points in the control group (P > 0.05). The decreases in the mean scores of the right and the left BE-associated pain in the intervention group were significantly greater than the control group (P < 0.05). Conclusion: Hot ginger compress is more effective than hot compress in reducing BE-associated pain

Keywords: Breast engorgement, Ginger, Hot compress, Pain

among breastfeeding women.

Introduction

Breast milk is the best food for new-borns. [1] However, exclusive breastfeeding is sometimes interrupted due to the factors such as nipple fissure, mastitis, and pain associated with breast engorgement (BE). BE is one of the most common problems among breastfeeding women. [2] In BE, breasts are overfilled with milk and become heavy, swollen, and painful. [3] The prevalence of BE is 20%–70%. [4]

BE-associated pain is the second main cause of failure in exclusive breastfeeding in the 1st week after delivery. Its most basic mechanisms are increased vascularization

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of the breast, milk accumulation in the breast, breast vascular hypertension, and inadequate breast lymphatic drainage. [5] BE-associated pain can lead to breastfeeding problems, inadequate milk production, and reduced tendency for breastfeeding. It inhibits the production

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of oxytocin and other hormones contributing to milk production and thereby, reduces milk production and flow from the alveoli to the nipple. [5,6] Severe BE-associated pain also results in emotional distress, impaired mother-infant relationships, and increased risk of postpartum depression. [7] Consequently, it can make some women avoid breastfeeding and opt for simpler feeding methods such as bottle-feeding. [8] These problems in the period of infancy, i.e., when new-borns are at high risk for neonatal mortality, have turned BE-associated pain into an important health problem. [5]

Many different pharmacological and nonpharmacological strategies have so far been recommended for managing BE-associated pain. Pharmacological strategies have different side effects and women are concerned with their negative effects on their new-borns.[9] Therefore, nonpharmacological strategies have attracted considerable attention in recent years. These strategies include frequent breastfeeding, hot compress before breastfeeding, cold therapy, spa shower, [5] cabbage compress, [10] acupressure, [11] Gua Sha, [12] and medicinal plants such as cabbage, peppermint, sage, and hollyhock. However, previous studies reported contradictory results about the effects of these strategies, and there is no conclusive evidence regarding their effectiveness.^[13] For example, a study reported cold compress more effective than fomentation in reducing BE-associated pain.[14] Another study found that warm and cold compresses were more effective than acupressure in the management of BE but reported that the use of warm compress to the engorged breasts may be harmful because heat increases blood circulation.[9]

Ginger is a medicinal plant with the potential effects on BE. It has been used in the Chinese traditional medicine from 25 centuries ago[15] and has been introduced by the United States Food and Drug Administration as a safe medicinal plant.[16] Previous studies reported the analgesic and the anti-inflammatory effects of ginger.[17,18] Ginger exerts its analgesic and anti-inflammatory effects through inhibiting cyclooxygenase and lipoxygenase pathways and preventing the metabolism of arachidonic acid.[19] A study in Thailand showed that compared with nonsteroidal anti-inflammatory drugs, ginger produced better analgesic and anti-inflammatory effects. [20] Ginger is also topically used for managing mastitis^[21] and breast fissure, [22] but there is limited information about its systemic effects on BE-associated pain. Therefore, more studies are needed to provide more conclusive evidence about the effects of ginger on BE-associated pain.

Objectives

This study aimed to compare the effects of hot compress and hot ginger compress on BE-associated pain.

Methods

Study design and participants

This clinical trial study was conducted in 2018, in Imam Reza hospital, Mashhad, Iran. Participants were breastfeeding women with BE hospitalized in the obstetric ward of the study setting during the 2nd to 5th day after delivery or referred to the study setting due to problems in breastfeeding. They were recruited to the study through the convenience sampling. Inclusion criteria were BE-associated pain with a pain intensity score of 2 or more for the standard BE checklist,[12] receiving no lactation suppressants or topical herbal remedies, no high-risk condition in the recent pregnancy or delivery, a new-born with a birth weight of 2500 g or more, and no history of breast surgery or serious physical or mental health problems such as cardiovascular, renal, or respiratory diseases, hypertension, hepatitis, or diabetes mellitus. The exclusion criteria were sensitivity to ginger, increased body temperature to more than 38°C after starting the intervention, development of mastitis or breast abscess, and using analgesics during the study. Participants were allocated to a hot compress (or control) group and a hot ginger compress (or intervention) group through stratified randomization with a block size of 2. Type of delivery (normal or cesarean section) was considered as the stratum for randomization. Randomization was performed using the SPSS software version 22 (SPSS, Inc. Chicago, Illinois, USA).

As there was no similar study respecting the effects of hot ginger compress on BE-associated pain, sample size was calculated using the Cohen's sample size calculation method. With an effect size of 0.7, a power of 0.8, a confidence level of 0.95, and a probable attrition rate of 25%, sample size was determined to be forty per group [Figure 1].

Data collection instruments

Data collection instruments were a demographic questionnaire, an obstetric data sheet, and the BE checklist. The checklist contained three items on BE-associated inflammation, tension, and pain. The inflammation item was scored from zero ("No redness") to 4 ("Glowing redness throughout the breast"), the tension item was scored from zero ("Completely loose and soft tissue") to 5 ("Painful and tense tissue"), and the pain item was scored using a Visual Analog Scale from zero ("No pain") to 10 ("Severest possible pain"). The total score of the checklist was 0–19. Previous

$$n = \frac{2(Z_{1-\alpha/2} + Z_{1-\beta})^2}{f^2} = \frac{2(1.96 + 0.84)^2}{0.70^2} = 32$$

Figure 1: Sample size calculation

studies reported the acceptable validity and reliability of the checklist. [12,24] Another study also confirmed the acceptable reliability of the checklist with an inter-rater agreement coefficient of 0.8. [25] The validity of the checklist was also confirmed by ten instructors of Mashhad University of Medical Sciences, Mashhad, Iran.

Intervention

Study intervention was hot compress for participants in the control group and hot ginger compress for participants in the intervention group. In the control group, hot compress was applied to the breast for 30 min before breastfeeding. The temperature of the compress was 43°C-46°C and was maintained at this temperature throughout the intervention through placing the compress in hot water every 2 min. In the intervention group, ten grams of ginger powder was placed in 100 ml of hot water for 10 min and then, multi-layered gauzes (10 cm × 10 cm) were soaked in the water and placed on either or both engorged breasts for 30 min before breastfeeding. [9,26] Ginger plant roots used in the present study were approved by Mashhad Faculty of Pharmacy, Mashhad, Iran (with the herbarium code of FUMH-E 1004) and were dried using a dryer at a temperature of 60°C for 24 h. Drying was done for weight stabilization. Then, dried ginger roots were powdered using a grinder and were disinfected through ultraviolet radiation for 30 min. Participants applied the first round of hot compress under the supervision of the first author in the study setting. Participants in both groups were personally instructed about applying compress at home and were asked to apply it thrice daily for 2 consecutive days. They were also provided with both verbal and written instructions about proper breastfeeding and hand hygiene before applying compress and were asked to perform breastfeeding at their new-born's request by both breasts every 2-3 h for 10-15 min. Frequent breastfeeding is a nonpharmacological strategy for BE management. They were also provided with the opportunity to call the first author of the study in case of any problem or question during the study intervention. Finally, they were asked to refer to the study setting 10-24 h after the last session of the intervention for the posttest assessment of BE. BE assessment was performed both before and after the intervention.

Ethical considerations

This study has the approval of the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (IR.MUMS.REC.1397.008) and was registered in the Iranian Registry of Clinical Trials (code: IRCT20180508039585N1). Study instruments were all anonymous, and participants were ensured that their data would be kept confidential and they could withdraw

from the study at will. All of them signed the written informed consent form of the study.

Data analysis

Data were analyzed using the SPSS software version 22 (SPSS, Inc. Chicago, Illinois, USA). Normality was assessed using the Kolmogorov–Smirnov test. Two variables (namely the number of births and Newborn's age) had non-normal distribution. Data were analyzed using the Mann–Whitney U, the independent-samples t, the Wilcoxon, and the Chi-square tests. The analysis of covariance was also used to determine the effects of the study intervention on BE-associated pain adjusted for the effects of potential confounders, namely pretest mean score of BE-associated pain and new-born's age. The level of significance was set at < 0.05.

RESULTS

Eighty breastfeeding women with BE were recruited to the study. Two participants from each group were excluded due to nonadherence to the study intervention and hence, 76 participants (38 in each group) completed the study [Figure 2]. Age mean was 28.76 ± 6.23 years in the intervention group and 28.55 ± 6.41 in the control group. Most participants in both groups reported that their income was insufficient. There were no significant differences between the groups in terms of participants' age, educational level, family income, type of delivery, previous history of breastfeeding, number of childbirths, and their new-borns' weight (P > 0.05); however, newborn's age in the control group was significantly greater than the control group [P < 0.001; Table 1].

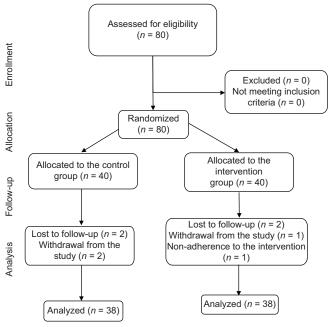


Figure 2: The consort flow diagram of the study

The results of the Mann-Whitney U-test showed that there was no significant between-group difference respecting the pretest mean score of BE-associated pain (P > 0.05). Within-group comparisons using the Wilcoxon test revealed that in the intervention group, the mean score of BE-associated pain in the right and the left breasts significantly reduced by 6.25 ± 1.76 and 6.06 ± 1.76 points, respectively (P < 0.05). Similarly in the control group, the mean score of BE-associated pain in the right and the left breasts significantly reduced by 3.21 ± 1.02 and 3.48 ± 1.21 points, respectively (P < 0.05). Between-group comparisons revealed that the decreases in the mean scores of BE-associated pain in the right and the left breasts in the intervention group were significantly greater than the control group [P < 0.05; Table 2].

As the between-group difference respecting new-born's age was statistically significant, the analysis of covariance was used to adjust the confounding effects of new-born's age as well as the pretest mean score

of BE-associated pain. The results showed that when adjusted for the confounding effects of new-born's age and the pretest mean score of BE-associated pain, the posttest mean score of BE-associated pain in the intervention group was significantly less than the control group [P < 0.001; Table 3].

DISCUSSION

The findings showed that both hot compress and hot ginger compress were effective in significantly reducing BE-associated pain, though the effects of hot ginger compress were significantly greater than the effects of hot compress. Similarly, a former study reported the greater effectiveness of herbal compresses (containing dried parts of herbs such as ginger, acacia, citrus, and camphor) in reducing BE-associated pain compared with hot compress.^[27] Ginger contains active compounds such as gingerols and shogaol which have analgesic effects and can reduce pain and inflammation.^[28-30] These compounds are fat-soluble, and hence, can be absorbed

Table 1: Participants' demographic and clinical characteristics						
Characteristics	Gro	P				
	Intervention	Control				
Age (years)	28.76 ± 6.23	28.55 ± 6.41	0.885 ^b			
Educational level						
Elementary	11 (28.9)	11 (28.9)	0.849°			
Guidance school	6 (15.8)	4 (10.5)				
High school	17 (44.7)	17 (44.7)				
University	4 (10.5)	6 (15.8)				
Family income						
Insufficient	24 (63.2)	23 (60.5)	0.813c			
Sufficient	14 (36.8)	15 (39.5)				
Type of delivery						
Normal delivery	19 (50.0)	18 (47.4)	0.818^{c}			
Cesarean section	19 (50.0)	20 (52.6)				
Previous history of breastfeeding ^d						
Yes	24 (92.3)	26 (100.0)	0.490°			
No	2 (7.7)	0 (0.0)				
Number of childbirths	2.16 ± 1.20	2.16 ± 1.01	0.719^{d}			
Newborn's weight after delivery (g)	3236.11 ± 313.28	3236.84 ± 441.52	0.535^{b}			
Newborn's age (days)	3.32 ± 0.78	2.32 ± 1.12	<0.001 ^d			

^aData presented as mean \pm SD or n (%), ^bThe results of the independent-sample t-test, ^cThe results of the Chi-square test, ^dThe results of the Mann–Whitney U-test, ^dThose without children were not considered. SD: Standard deviation

Table 2: Within-and between-group comparisons respecting the mean score of BE-associated pain ^a						
	Right breast		Pc	P ^c Left breast		P ^c
	Intervention	Control		Intervention	Control	
Time						
Before	6.97 ± 1.87	6.76 ± 1.77	0.608	7.09 ± 1.79	6.90 ± 1.57	0.714
After	0.72 ± 1.11	3.55 ± 1.37	< 0.001	1.03 ± 1.18	3.41 ± 1.30	0.001
Pretest-posttest mean difference	-6.25 ± 1.76	-3.21 ± 1.02	< 0.001	-6.06 ± 1.76	-3.48 ± 1.21	0.001
P^{b}	0.001	0.001		0.001	0.001	

^aData presented as mean ± SD, ^bThe results of the Wilcoxon test, ^cThe results of the Mann–Whitney test. SD: Standard deviation

Table 3: The results of the analysis of covariance for between-group comparisons respecting breast engorgement-					
associated pain adjusted for potential cofounders					

Variables		Right brea	st			Left breas	t	
	В	Standard error	t	P	B	Standard error	t	P
Intervention group	-3.06	0.264	-11.61	0.001	-2.66	0.288	-9.24	0.001
Control group	0				0			
Pretest pain score	0.409	0.066	6.16	0.001	0.351	0.082	4.29	0.001
Newborn's age	0.169	0.124	1.36	0.178	0.297	0.140	2.12	0.038

through the skin and provide pain relief. Studies into the effects of other medicinal plants also reported their effectiveness in significantly reducing BE-associated pain. For instance, a study found that curcumin cream applied thrice daily for 3 days was effective in significantly reducing pain, tension, and erythema among breastfeeding women without any significant side effects.^[21] Curcumin belongs to the ginger family, and therefore, the results of that study are in line with our results.

Although there are few studies into the effects of ginger on BE-associated pain, there are studies into its effects on muscular pain. For instance, a comparative study into the effects of hot herbal compress (containing ginger, curcumin, citratus, and acacia), hot compress, and diclofenac (an anti-inflammatory drug) found that all these interventions were effective in reducing muscular pain. That study suggested that hot herbal compress has the potential effects on pain and quality of life.[20] Conventionally, anti-inflammatory drugs are considered as the best choice for managing pain and inflammation. However, these drugs have significant cardiovascular, gastrointestinal, metabolic, and cerebral adverse effects for breastfeeding women, while herbal compresses have no significant adverse effects on breastfeeding.^[27]

Our findings also showed the effectiveness of both hot compress and hot ginger compress in significantly reducing BE-associated pain. In line with this finding, a review study suggested that hot compress can reduce breast temperature, engorgement, and pain within 30 min after its application. [3] Ginger hot compress enhances the flow of oxygen and nutrients to the tissues and facilitates the recovery of injured tissues. Heat also produces analgesic effects through stimulating the sensory receptors of the skin and reducing pain signal transmission to the brain.[31] Accordingly, hot ginger compress can produce better anti-inflammatory and analgesic effects compared with simple hot compress. Another study reported that compared with hot and cold compresses, the combination of hollyhock leaf compress and hot and cold compresses was more effective in reducing BE-associated pain. [9] The

consistency between our findings and the findings of that study is due to the fact that both ginger and hollyhock have antibacterial and anti-inflammatory effects.

The strengths of this study were its two-group design and the assessment of two different methods on BE-associated pain in both breasts. On the other hand, one of the study limitations was that we assigned the responsibility of compress application at home to participants in order not to disturb their privacy and comfort during the study intervention. We also could not assess BE-associated pain after each round of the intervention. Moreover, due to the distinct color and smell of ginger, blinding was impossible. Future studies are recommended to compare the effects of ginger and other conventional therapies on BE-associated pain using blinded designs.

CONCLUSION

Hot ginger compress is more effective than hot compress in reducing BE-associated pain among breastfeeding women. Therefore, ginger hot compress can be used to improve the quality of postpartum care and outcomes and help women succeed in breastfeeding. Health-care providers, particularly nurses and midwives, should be provided with educations about complementary therapies for BE management, including the safe and easily applicable therapy of ginger hot compress.

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Conflicts of interest

There are no conflicts of interest.

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