

COMPARISON OF THE EFFECTS OF CALENDULA OFFICINALIS OINTMENT AND TURMERIC OINTMENT ON IMPROVEMENT OF EPISIOTOMY WOUND IN PRIMIPAROUS WOMEN

Masumeh Kaviani¹, Elahe Mahmoudi^{2*}, Sara Azima¹, Masoumeh Emamghoreishi³, Nasrin Asadi⁴, Sezaneh Haghpanah⁵

1.Department Of Midwifery, School Of Nursing And Midwifery, Shiraz University Of Medical Sciences, Shiraz, Iran

2.Student Research Committe, Shiraz University Of Medical Sciences, Shiraz. Iran.

3.Maternal-Fetal Medicine Research Center, Shiraz University Of Medical Science, Shiraz, Iran

4.Department Of Pharmacology, School Of Medicine, Shiraz University Of Medical Sciences, Shiraz, Iran

5.Department Of Biostatistics And Hematology Research Center, Shiraz University Of Medical Sciences, Shiraz, Iran

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ABSTRACT

Background and Objectives: Episiotomy is among the common obstetric surgeries with complications, such as inflammation, edema, rupture expansion, and perineal pain. The present study aimed to investigate the effects of calendula officinalis ointment and turmeric ointment on episiotomy wound healing in primiparous women.

Methods: This double-blind randomized clinical trial was conducted on 90 primiparous women divided into calendula officinalis ointment, turmeric ointment, and placebo groups each containing 30 women. After delivery, the mothers were required to apply the prescribed ointments to the suture area every 8 hours for 10 days. The study data were collected using Reeda scale. Healing of episiotomy wound was assessed before and 3, 7, 10 and 14 days after the intervention. Then, the data were analyzed using the SPSS statistical software, version 17.

Results: The mean scores of wound healing were lower in calendula officinalis ointment and turmeric ointment groups compared to the placebo group. Additionally, a significant difference was found between the calendula officinalis ointment and turmeric ointment groups on days 3, 7, and 10 after delivery ($p=0.008$, $p=0.0012$, and $p=0.0098$, respectively). Accordingly, wound healing was more significant in the calendula officinalis ointment group.

Conclusion: Calendula officinalis ointment and turmeric ointment were both effective in healing of episiotomy wound, but calendula officinalis ointment was more efficient in this regard.

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Introduction

Episiotomy is defined as incision of the perineum at the second stage of delivery for widening the pelvic outlet and preventing delay in fetal head delivery (1). In this context, perineal inflammation should be taken into account because this area cannot be observed by mothers and, consequently, secretions, inflammation, and infection can result in maternal complications (2).

Nowadays, complementary methods, such as medicinal plants, have attracted much attention in midwifery. In other words, herbal complementary medicine is being used to decrease delivery complications (3). *Calendula officinalis* and turmeric are among the medicinal plants that are widely applied in gynecology and obstetrics.

Calendula officinalis has anti-inflammatory, antiviral, antimicrobial, antifungal, anticancer, antioxidant, and healing properties (4). However, a limited number of studies have been conducted on the effect of this plant on healing of episiotomy wound, which necessitates further investigations in this area. Turmeric is also one of the ancient medicinal plants (5). The crude extract of turmeric stem contains nearly 60-70% curcumin (6), which possesses anti-inflammatory, antibacterial, and antiviral properties (6, 7).

Generally, delay in wound healing increases the risk of infection and negative anatomic effects. Infection can in turn lead to dangerous complications and even death, eventually affecting the mother's physical and mental health. It can also have an impact on the mother's life quality, infant care, and relationship with her husband and other family members (8, 9). In order to enhance the mother's quality of life after delivery through treatment methods with the least side effects, the researcher in the present study aimed to compare the effects of *calendula officinalis* ointment and turmeric ointment on healing of episiotomy wound in primiparous women.

Materials and Methods

This double-blind randomized clinical trial was conducted on 90 primiparous women referring to delivery wards of the selected hospitals of Shiraz University of Medical Sciences, Shiraz, Iran. This study lasted for 4 months from the beginning of July to the end of October 2015. Based on the studies by Golmakani et al. (8) and Jahdi et al. (10), considering $SD = 1.39$, $\alpha = 0.05$, and power = 80%, and using the following formula, a 69-subject sample size was determined for the study (23 subjects in each group). Yet, considering the loss rate of 20%, the number of subjects was increased to 30 in each group.

$$N = \frac{2(z1 - \frac{\alpha}{2} + z1 - \beta)^2 \sigma^2}{(\mu2 - \mu1)^2}$$

The study participants were selected through simple purposive sampling. The inclusion criteria of the study were willingness to cooperate; being primiparous; gestational age of 37-42 weeks; natural vaginal delivery with mediolateral episiotomy; singleton pregnancy; Body Mass Index (BMI) < 30 kg/m² before pregnancy; not having the history of reconstructive surgery on the vagina and perineum; not using wound healing medications; not having specific disorders such as anemia, cardiovascular disease, diabetes, immune disorders, hepatic disorders, depression, coagulation disorders, preeclampsia, and infectious diseases; and lack of episiotomy expansion. On the other hand, the exclusion criteria of the study were unwillingness to cooperate, manual removal of placenta, abnormal vaginal bleeding after delivery, hematoma formation, postpartum fever and shivering (fever ≥ 38 °C), perineal manipulation after delivery, infection at the episiotomy area, using other creams or ointments, and incidence of allergic reactions.

Before delivery, the participants were divided into *calendula officinalis* ointment, turmeric ointment, and placebo groups through permuted block randomization. Then, the data were collected using demographic information form, maternal-infantile questionnaire, and Reeda scale. Reeda scale was used to evaluate wound healing. This scale contains 5 dimensions, namely redness (hyperanemia), edema, ecchymosis, discharge, and approximation of wound edges (coaptation), each receiving 0-3 scores. Thus, the total score of the scale could range from 0 to 15. In the Reeda scale, lower scores represent better wound healing. Reeda is an international scale whose reliability and validity have been confirmed in many researches. In Iran, the validity and inter-rater reliability of Reeda scale were approved by Pazandeh (11).

In this study, the researchers made use of *calendula officinalis* ointment containing 90% hydroalcoholic extract of *calendula officinalis* and 10% petroleum jelly, and turmeric ointment (*curcuma longa*) containing 90% hydroalcoholic extract of turmeric and 10% petroleum jelly made by Sohajisa Company, Iran. Additionally, the placebo was made using petroleum jelly in the form of a sterile ointment in 5 gr tubes under the supervision of a pharmacologist in the School of Medicine. It should be noted that the placebo was prepared in similar packages to those of other medicines. Also, a drop of turmeric extract was added to *calendula officinalis* ointment and placebo to obtain similar colors.

All the study participants underwent mediolateral episiotomy. Then, the mucosa, submucosa, and muscle layers were sutured by "0" thread and the skin was repaired using "2/0" chromic catgut by a midwife. In order to blind the research, we coded the tubes containing the medicines and placebo by a pharmacologist. After that, the method of using the medications was taught to the participants. In doing so, after washing the episiotomy area with water, the researcher applied the intended ointment using single-use syringes and gloves. Then, the mothers were required to apply 1 gr of the ointment every 8 hours for 10 days. It should also be noted that all the participants received the same training regarding the wound care. Wound healing was evaluated before and 3, 7, 10 and 14 days after the intervention.

Ethical considerations

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences (IR.SUMS.REC.1394.40) and registered in the Iranian Registry of Clinical Trials (IRCT2015072023265N1). Besides, written informed consents for taking part in the study were obtained from all the participants.

Results

This study was conducted on 90 primiparous women referring to delivery wards of the selected hospitals of Shiraz University of Medical Sciences in 2015. The results showed no significant difference among the participants regarding demographic and obstetric characteristics (Table 1).

Comparison of the scores of Reeda scale indicated a significant difference among the three groups on days 3, 7, 10, and 14 postpartum. Based on the results of Dunnett's t-test, calendula officinalis ointment and turmeric ointment groups were significantly different on days 3, 7, and 10 postpartum ($p=0.008$, $p<0.001$, and $p<0.001$, respectively). However, no significant difference was observed between the two groups on day 14 ($p=0.5$). Moreover, the results revealed a significant difference between the calendula officinalis ointment and placebo groups at all-time points after delivery. On the other hand, the difference between the turmeric ointment and placebo groups was significant on days 10 and 14 ($p=0.007$ and $p<0.001$, respectively), but not on days 3 and 7 after delivery ($p=0.35$ and $p=0.15$, respectively) (Table 2).

Discussion

This study aimed to compare the effects of calendula officinalis ointment and turmeric ointment on healing of episiotomy wound in primiparous women. The results demonstrated that episiotomy wound healing was significantly better in the calendula officinalis ointment group compared to the placebo group. In the same line, Jahdi et al. revealed that topical application of calendula officinalis ointment was effective in healing of episiotomy wound (10). Calendula officinalis has been reported to be effective in healing of other types of wounds, as well. For instance, Buzzi et al. (2016) investigated the impact of topical application of calendula officinalis extract on treatment of diabetic foot ulcers and showed that the wounds were completely healed in 54%, 68%, and 78% of the patients 11, 20, and 30 weeks after the treatment, respectively. Additionally, the average duration of wound healing was 15.5 ± 6.7 weeks, which represents the quick process of wound healing after treatment with calendula officinalis extract (12).

Another research (2013) assessed the effect of calendula officinalis mouthwash on prevention of oral mucositis and indicated a significant difference between the calendula officinalis and placebo groups at the end of the second, third, and sixth weeks. These results indicated quick re-epithelialization of the mouth tissue in the calendula officinalis group (13).

Moreover, Duran et al. (2004) evaluated the impact of calendula officinalis on epithelialization of the venous leg ulcers. The results showed 7 patients in the intervention group and 4 patients in the control group with complete epithelialization after the third week. Thus, calendula officinalis resulted in healing of the wounds by causing progress in epithelialization (14). These results were in agreement with those of the current study.

Our study findings showed that turmeric ointment quickened the process of wound healing, as well. Similarly, Mahmoudi et al. (2015) stated that topical application of turmeric cream was effective in healing of cesarean wound (15). Another study performed in 2015 assessed the impact of topical application of turmeric on superficial burns. Based on the results, 52% of the participants in the turmeric group compared to 16% of those in the control group showed complete wound healing without any infections on the third day after the treatment. These values were respectively obtained as 85% and 34% on day 11. Hence, turmeric quickened the process of wound healing with good epithelialization (16), which is consistent with the results of the present study.

Due to its impact on stimulation of granulation and increase of glycoproteins and collagen, calendula officinalis quickens the process of wound healing (17). Indeed, since calendula officinalis contains flavonoids with antioxidant properties, it may be effective in healing of episiotomy wound by neutralizing oxygen free radicals (18). On the other hand, evidence has indicated that curcumin, as the active ingredient of turmeric, can result in healing of superficial wounds. In fact, curcumin can quicken the normal process of wound healing by transfer of inflammatory cells and presentation of fibroblasts and collagen (19). It should be noted that none of the participants showed allergic reactions to the ointments used in the present study.

One of the limitations of our study was individual differences regarding perineum tissue, wound healing capacity, and extent of mobility, which are highly effective in the process of wound healing.

Conclusion

The results of this study indicated that calendula officinalis ointment and turmeric ointment were both effective in healing of episiotomy wound, but calendula officinalis ointment was more influential. Generally, midwives play a critical role in care, training, and treatment of women all through their lives, particularly after delivery. Considering the fact that no specific side effects were detected after utilization of calendula officinalis ointment and turmeric ointment in the current study, they can be employed as appropriate, inexpensive, and safe methods for obstetric cares after delivery. Yet, further studies with larger sample sizes and longer follow-up periods are required to be conducted on the issue.

Table 1. Comparison of the three groups regarding demographic, obstetric, infantile, and postpartum characteristics

| Groups Variables | Calendula officinalis ointment | Turmeric ointment | Placebo | P- value |
|--|--------------------------------------|----------------------|----------------|--------------------|
| Age | 25.30±5.11 | 23.33±4.68 | 22.50±4.07 | 0.06 ^a |
| BMI | 22.32±3.69 | 22.93±2.98 | 21.79±3.47 | 0.44 ^a |
| Gestational age | 39.20±1.61 | 39.70±1.44 | 38.97±1.33 | 0.15 ^a |
| Episiotomy length | 3.83±0.87 | 3.52±0.77 | 3.63±0.93 | 0.36 ^a |
| Duration of the first stage of delivery (min) | 398.33±123.21 | 409.17±118.49 | 426.00±123.83 | 0.68 ^a |
| Duration of the second stage of delivery (min) | 42.52±22.88 | 50.83±24.29 | 38.50±25.50 | 0.14 ^a |
| Duration of the third stage of delivery (min) | 6.83±2.78 | 6.50±2.98 | 6.33±2.25 | 0.77 ^a |
| Number of superficial sutures | 4.87±1.11 | 4.93±0.87 | 4.83±1.02 | 0.93 ^a |
| Infant's weight (gr) | 3237.33±381.58 | 3170.67±374.64 | 3120.33±348.79 | 0.47 ^a |
| Infant's head circumference (cm) | 34.67±1.23 | 34.65±1.69 | 34.75±1.51 | 0.96 ^a |
| Time of beginning of daily activities after delivery | 5.63±1.43 | 5.67±1.32 | 5.57±1.47 | 0.96 ^a |
| Education leve (diploma) | 10 (33.3%) | 13 (43.3%) | 9 (30.0%) | 0.11 ^b |
| Occupation (homemaker) | 27 (90%) | 28 (93.3%) | 28 (93.3%) | 0.989 ^c |
| Breastfeeding in sitting position | 18 (60%) | 19 (63.3%) | 22 (73.3%) | 0.74 ^b |

Mean + SD for quantitative and percent for qualitative variables. ^a: one-way ANOVA, ^b: chi-square test, ^c: Fisher's exact test.

Table 2. Comparison of the three groups regarding the mean scores of Reeda scale

| Group | Calendula officinalis ointment | Turmeric ointment | Placebo | P-value |
|-------------------------|--------------------------------------|----------------------|-------------|---------|
| Reeda score | Mean ± SD | Mean ± SD | Mean ± SD | |
| Before the intervention | 3.03± 0.183 | 3± 0 | 3± 0 | 0.368 |
| Day 3 | 1.4± _0.724 | 1.83± 0.699 | 1.97± 0.89 | 0.01* |
| Day 7 | 0.5± 0.63 | 1.07± _0.691 | 1.37± 0.89 | <0.001* |
| Day 10 | 0.1± 0.305 | 0.43± 0.504 | 0.97± 0.85 | <0.001* |
| Day 14 | 0 | 0 | 0.47± 0.507 | <0.001* |

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