Original Article

The Effect of Olea Ointment on Post-Episiotomy Pain Severity in Primiparous Women: A Paralleled Randomized Controlled Clinical Trial

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Abstract

Background: Episiotomy is the most commonly performed surgical procedure during delivery, and its associated pain is a major problem in obstetrics. This study aimed to determine the effect of Olea ointment on the severity of post-episiotomy pain in primiparous women. **Materials and Methods:** This paralleled randomized controlled clinical trial was performed on 73 primiparous women in Al-Zahra hospital in Rasht, Iran in 2017-2018. Women were randomly allocated into intervention (n = 39) and control (n = 34) groups. The first intervention was performed 4 h after the episiotomy. This continued every 8 h for 10 days. The pain intensity of episiotomy was assessed by the Visual Analogue Scale (VAS) before intervention, 2 and 24 h after the beginning of intervention, and 5 and 10 days after childbirth. Descriptive and inferential statistics (Mann-Whitney, Fisher exact test, Independent t-test, Friedman test, and Chi-square) were performed for statistical analysis. **Results:** There were no significant differences among two groups in terms of demographic and obstetrics characteristics. The severity of pain in intervention and control group before the intervention was not statistically significant, but the variable depicted a meaningful difference between the groups 2 h after the intervention (U = 483.50, p = 0.021), 24 h after the intervention (U = 489.50, p = 0.019), as well as the 5th day (U = 112.50, p < 0.001) and 10th day postpartum (U = 136.50, p < 0.001). **Conclusions:** Based on the findings, Olea ointment could be used effectively for reducing of episiotomy pain. Similar studies are recommended.

Keywords: *Episiotomy, Iran, Olea, pain, postpartum period*

Introduction

Episiotomy is defined as perineal incisions in the second stage of labor which is performed for facilitation and shortening of the duration of the second stage of delivery, preventing possible damages to perineum, and pelvic organs, sexual dysfunctions, and severe perineal tears.[1-6] In fact, episiotomy is counted as the second most common surgical experiment during delivery after cutting down of the umbilical cord.[7]

Episiotomy is of different prevalence rates in different countries, under 10% in countries such as Sweden and Denmark, more than 50% in countries such as Netherlands and Portugal,[8] and 100% in the Asian country (Taiwan).[4] According to some studies, the second stage of delivery is longer in Asian women, and thus, perineal tears occur with a greater frequency.[9,10] Even though no exact statistics is available on prevalence of episiotomy in Iran, its distribution is assessed by cross-sectional studies as 88.32% in Mashhad, and 97.3% in Tehran.[11]

The benefits of episiotomy is still subject to doubt.[2-4] Thus, as recommended by World Health Organization (WHO), episiotomy should be reduced to 10%,[12] and its application should be limited to high-risk cases.[2]

Many women suffer from short-term side-effects of episiotomy, and more than 20% of women experience its long-term side-effects.[13] Perineal pain is the most common complication in episiotomy, and it ranges from 96.4% on the first 24 h after the labor to 63% on the second day and 25% at the end of puerperium.[10] This pain can be accompanied by some morbidities and causes trouble in sitting, breastfeeding, and formation of relationship between mother and infant.[4,5] Thus, relieving the perineal pain is of great importance and, to this end, non-medical methods as well as medical

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therapies such as application of lidocaine, phenytoin, normal saline, and iodine, and also oral medications or herbal remedies such as olives, honey, saffron, turmeric, cinnamon, spring flowers, chamomile, aloe vera, bromillin, and lavender can be employed.[10,14,15] Sesame oil also has at least seven pain-relieving substances.[16]

Olea ointment is an herbal ointment that is a combination of honey (33.4%), olive oil (33.3%), and sesame oil (33.3%). This ointment prevents infection, and by reducing the pain and inflammation, the healing process accelerates the formation of new tissue and facilitates the debridement of the necrotic tissue.[17] For instance, a study showed that the extra virgin olive oil has been effective in the treatment of primary dysmenorrhea.[18] Also, another study showed that the use of honey cream has not been associated with the reduction of pain in the episiotomy region.[19]

The findings of the studies on herbal medicine are contradictory, and confirmation of the therapeutic effects of herbs requires more laboratory studies and clinical trials. Considering the importance of the reduction of pain and faster return of the mothers to daily activities, the researchers aimed to determine the effect of Olea ointment on the severity of episiotomy pain in primiparous women.

Materials and Methods

This paralleled randomized clinical trial was performed on primiparous women attending Al-Zahra hospital in Rasht (North of Iran), who had normal vaginal delivery with episiotomy. IRCT code number was 2017020332374N1. The sample size was obtained by reference to Jahdi *et al*. study,[20] by a statistical formula with a 95% confidence interval and a 90% test power as at least 36 individuals in each group. Taking into account 15% drop-out, 41 women were considered in each group. Thus, 82 primiparous women were selected in LDR ward (labour-delivery room) by convenient sampling and randomly allocated into intervention (n = 41) and control (n = 41) groups (by simple random sampling method and selecting cards A or B, representing intervention and control groups respectively). A total of four individuals were excluded from the study due to the opening of the wound and five patients for not referring back to the hospital; two of them were in the Olea intervening group (one due to not referring and one due to wound opening) and seven people in control group (four due to not referring and three due to wound opening). At the end of the intervention, the intervention and control groups consisted of 39 and 34 participants, respectively [Figure 1]. Sampling was conducted between December 2017 and May 2018. The inclusion criteria were Iranian ethnicity, being primiparous and aged 18-35 years old, ability to read and write, willingness to participate, live term singleton pregnancy with cephalic presentation and mediolateral episiotomy without laceration, lack of infection, and visible lesions in the perineum, and constipation, no prolonged premature rupture of the membrane, the first, second, and third stage of labor less than 14 h, 2 h, and half an hour,

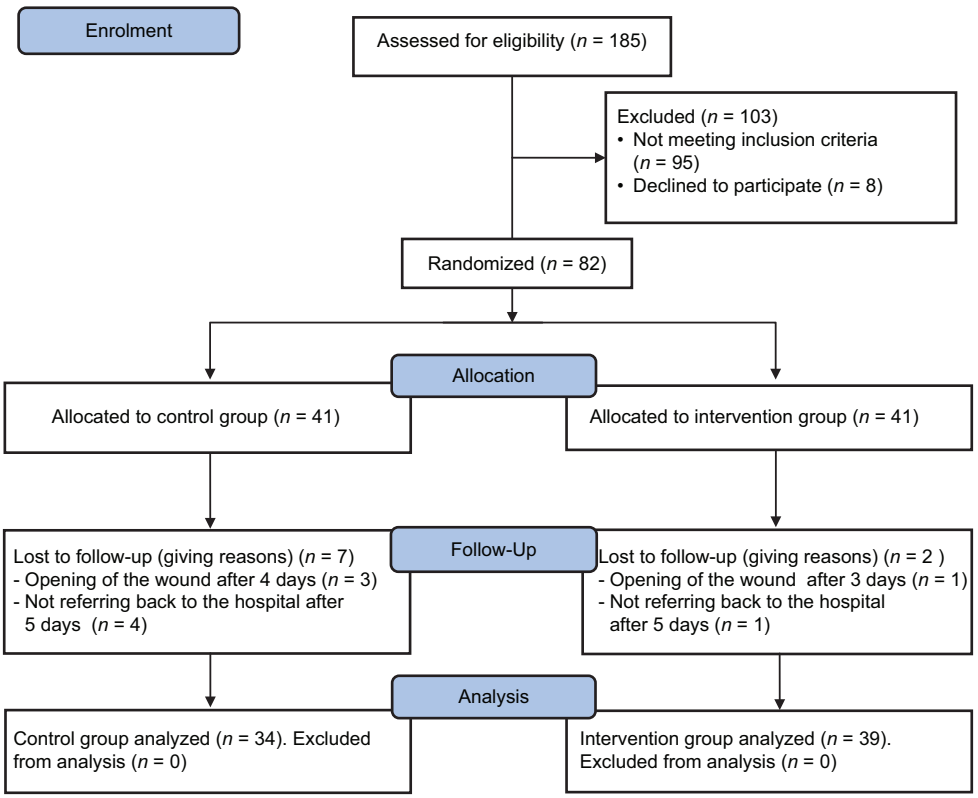

Figure 1: Consort diagram

respectively, the absence of manual removal of placenta, the absence of postpartum hemorrhage, lack of perineal hematoma, and the new-born weight between 2,500 and 4,000 g. The exclusion criteria included unwillingness to continue participating in the study, use of other remedies affecting wound healing during the study, inappropriate use of the drug (more than 2 days), being allergic to Olea ointment, no referral to the hospital on the 5th and 10th days after childbirth, sexual intercourse in the first 5 days after childbirth, and resectioning of the perineum after repair of episiotomy.

Data collection scales included: 1. Demographic information form (age, education, occupation, economic status). 2. Obstetrics and delivery information form (gestational age, the number of pregnancies, the number of abortions, the gender and weight of new-borns, new-born's circumference of head and duration of the first, second, and third stages of labor). 3. The Visual Analogue Scale (VAS), which is a 10-cm paper ruler ranging from 0 to 10 where 0 indicates lack of pain, scores 1-3 indicate mild pain, scores 4-6 indicate moderate pain, and 7-10 indicate severe pain symptoms. VAS is a standard tool and its validity and reliability have been confirmed (correlation = 0.71-0.78, the intra-class coefficient = 0.95, and concurrent validity, $r > 0.8$; $p < 0.01$) in various studies.[20-23] Data were collected through interviews, patients' files, and study, observation, and examination which were directly conducted by the researchers. Education was provided on the perineal and suture care, personal health, nutrition, and physical activity in face-to-face method and with pamphlets, alike for both groups. Before intervention, the pain intensity of the episiotomy was measured and recorded for each group based on the VAS.

Olea ointment was ordered in 30-g tubes containing equal ratios of olive oil, sesame oil, and honey from Farateb Yazd Company in Iran and were delivered by post. The first intervention was performed 4 h after the episiotomy. The samples of intervening group were asked to place a specific amount of Olea ointment (one-third of a finger) on the sutures after washing and drying the perineum area, covering it, and using a clean sanitary pad after 1-2 min. This procedure was continued every 8 h for 10 days after childbirth. It should be noted that the first intervention was carried out by the researchers and the subsequent interventions by the trained mothers. Also, the subjects in the intervention group were emphasized to use a physiologic serum (2 times a day for 10 days) to wash the perineal area along with the use of Olea ointment at home. The control group received only physiologic serum twice a day until the 10th day after delivery. We used a bottle of normal saline 0.9%, 1000cc, and a tube of Olea ointment containing 30 g effective materials for each person in intervention group. Also, we used a bottle of normal saline 0.9%, 1000cc for each participant in control group. The severity of the pain was measured and recorded by the researchers 2 h after the first intervention, 24 h after the first intervention, then, on days 5 and 10 after delivery, and if the wound was not repaired, on the 14th day after the delivery. It should be noted that we checked women by phone to assure they used the drug properly and regularly. The patients were also asked to contact the researchers if any problems and complications would occur.

After data collection, statistical analysis was performed by SPSS version 16 (SPSS, Inc Sep 13, 2007); then descriptive statistics (quantitative variables were described by mean and standard deviation and qualitative variables with percentages and numbers), and inferential statistics (Mann-Whitney, Fisher exact test, Independent *t*-test, Friedman test, and Chi-square) were performed. To check the effect of time and compare the values, obtained over the 5 recorded times, since our variable was to be rated, we used the Friedman test separately in each group. In cases in which the data had no normal distribution, nonparametric statistical tests were used to analyse the data. A significance level of 0.05 was considered for all tests.

Ethical considerations

The study was approved in the Ethics Committee of Guilan University of Medical Sciences (IR.GUMS.REC.1396.191), Rasht, Iran, and also, it was registered at the Iranian Centre for Clinical Trials. All participants in this study were selected after obtaining their written informed consents, explaining the study objectives, as well as assuring the confidentiality of their research data.

Results

The demographic and obstetrics characteristics of the subjects were presented in Tables 1 and 2. There were no significant differences among the control and intervention groups in terms of other demographic characteristics ($p > 0.005$), except for the length of the first stage of labor ($Z = -2.81$, $p = 0.005$). Mann-Whitney test was used to compare the groups in terms of the pain severity scores before and after the intervention. The results presented in Table 3 show that the severity of pain in two groups of Olea ointment and physiologic serum before the intervention was not statistically significant ($p = 0.667$), but the variable depicted a meaningful difference between the two groups 2 h after the intervention ($U = 483.50$, $p = 0.021$), 24 h after the intervention ($U = 489.50$, $p = 0.019$), as well as on the 5th day ($U = 112.50$, $p < 0.001$) and 10th day postpartum ($U = 136.5$, $p < 0.001$). Effect of group was statistically significant, indicating that the odds of feeling mild pain would be higher [exp (0.62) = 1.87] among women who received Olea ointmant, compared to these who received physiologic serum. Effects of time and length of the first stage of labor were not statistically significant [Table 4]. In other words, administration of Olea ointment decreased the episiotomy pain severity.

Table 1: Qualitative demographic information and obstetrics characteristics of the study subjects in two groups

Variables	Properties	Olea ointment *N* (%)	Physiologic serum *N* (%)	Tests Chi-square		
				χ^2	df	*p*
Age	20-25	19 (48.72)	10 (29.41)	3.52	2	0.172
	26-30	10 (25.64)	15 (44.12)			
	31-35	10 (25.64)	9 (26.47)			
					Fisher's Exact Test	
Education	Primary school	6 (15.38)	3 (8.82)		1.29	0.770
	Elementary school	10 (25.64)	7 (20.59)			
	High school	17 (43.60)	17 (50.00)			
	University	6 (15.38)	7 (20.59)			
					Fisher's Exact Test	
Job	Housewife	31 (79.49)	29 (85.30)		0.51	0.902
	Home employed	3 (7.69)	2 (5.88)			
	Working outside the home	5 (12.82)	3 (8.82)			
					Fisher's Exact Test	
Economic Condition	Weak	6 (15.38)	3 (8.82)		1.46	0.555
	Moderate	26 (66.67)	27 (79.41)			
	Good	7 (17.95)	4 (11.76)			
					Chi-square	
Fetal sex	Female	21 (53.85)	16 (47.06)	0.33	1	0.642
	Male	18 (46.15)	18 (52.94)			

Table 2: Quantitative demographic information and obstetrics characteristics of the study subjects in two groups

Variables	Olea Ointment Mean (SD)	Physiologic serum Mean (SD)	Tests Mann-whitney	
			U	*p*
Gestational Age	39.08 (0.84)	39.21 (0.88)	588.50	0.381
			Fisher's Exact Test	*p*
Gravida				
One	39 (100.00)	32 (94.12)		0.213
Two	0 (0.00)	2 (5.88)		
			Fisher's Exact Test	*p*
Abortion				
Zero	39 (100.00)	33 (97.10)		
One	0 (0.00)	1 (2.90)		0.466
			Mann-whitney	
			U	*p*
Duration of the first stage of labor (h)	3.98 (1.23)	3.29 (0.42)	410	0.005*
Duration of the second stage of labor (min)	1.00 (0.44)	0.91 (0.29)	534.50	0.148
Duration of the third stage of labor (min)	0.07 (0.03)	0.07 (0.03)	638.50	0.745
Newborn's head circumference	34.91 (0.84)	35.34 (1.13)	528	0.118
			Independent *t*-student	
			t	df	*p*
Newborn's Weight	3375.13 (353.72)	3328.82 (278.78)	0.61	71	0.541

*Statistically significant in confidence level α=0.05

Discussion

The present study was the first randomized controlled clinical trial in an Iranian context aiming to determine the effect of Olea ointment on the severity of pain after episiotomy in primiparous women. Based on the results obtained by this study, Olea ointment was effective in reducing pain at 2 h and 24 h after the beginning of intervention, as well as on the days 5 and 10 after delivery. A study found that when olive oil sitz bath was used in perineal injury after delivery, there was a significant difference between the intervention and control groups regarding the intensity of pain on the 5th and 10th day after delivery ($p < 0.05$), and olive oil was effective in

Table 3: Comparison of pain severity scores before and after the intervention in two groups

Time	Olea Ointment Mean (SD)	Physiologic serum Mean (SD)	Tests Mann-Whitney	
			U	*p*
Before intervention	2.33 (0.48)	2.26 (0.58)	630.50	0.667
2 h after intervention	2.08 (0.53)	2.38 (0.60)	483.50	0.021
24 h after intervention	1.92 (0.58)	2.82 (3.42)	489.50	0.019
5 days after delivery	1.03 (0.16)	1.97 (0.52)	112.50	<0.001
10 days after delivery	1.00 (0.0001)	1.79 (0.41)	136.50	<0.001

Table 4: The results of Generalized Estimating Equations (GEE) tests to assess the effects of groups, time, and demographic variables on pain severity

Parameter	Parameter estimate	Standard error	95% confidence interval		*p*
Pain					
Low	−2.17	0.67	−3.49	−0.85	0.001
Moderate	−0.72	0.58	−1.87	0.41	0.212
Group					
Olea ointment	0.62	0.3	0.02	1.22	0.042
Physiologic serum	ref	-	-	-	-
Time	0.078	0.09	−0.11	0.27	0.430
Length of the first stage of labor	−0.01	0.13	−0.26	0.24	0.939

reducing the pain.[24] The results of another study aiming at "comparing the effect of pure and gross honey on the severity of primary dysmenorrhea, the amount, duration and interval between two menstrual cycles in female students with primary dysmenorrhea" showed that the consumption of pure honey has resulted in a significant reduction in the severity of pain and the amount of menstrual bleeding in women with primary dysmenorrhea ($p = 0.002$).[25] According to a study aiming at "assessing the effect of back massage with sesame oil on the pain and length of delivery in primiparous women," massage with sesame oil resulted in pain reduction at all stages of labor, especially the third stage ($p < 0.001$).[16] It seems that fatty acids in sesame oil increase analgesia by decreasing neurotransmission, and by inhibiting the prostaglandin synthesise E2 enzyme, it increases the threshold for pain perception.[26] Olea ointment is a mixture of olive oil, honey, and sesame oil. So, it contains the useful effects of each of these substances[17] and can be helpful to decrease pain severity; however, in a study aiming at "comparing the effect of olive oil, aloe vera extract, and breast milk on healing of breast fissure in lactating mothers," olive oil, aloe vera extract, and breast milk decreased pain severity and breast fissure in mothers. But, the aloe vera extract was more effective than olive oil and breast milk.[27] According to a study aiming at "comparing the effect of honey and mefenamic acid on severe pain in women with primary dysmenorrhea," there was no significant difference between the severity of pain in the first and second months of treatment, and mefenamic acid and honey had similar effects on reducing the pain in women with primary dysmenorrhea.[28] Also, based on the results of a study aiming at "comparing the effect of honey cream and Phenytoin cream on the pain severity of episiotomy in nulliparous women" in a double-blind, triplicate clinical trial, the severity of pain on the 7th and 14th days postpartum were not significantly different in the three groups.[19] The possible reason for that was consumption of pain killers for 14 days after delivery by most of the subjects of the study in all 3 groups.

In the present study, opening of the episiotomy wound occurred in three participants of the control group, whereas this occurrence was observed in one participant of the intervention group. This may be due to the possible effect of Olea ointment on episiotomy wound healing. However, further similar studies in this area are recommended with the use of placebo.

When interpreting the results of the present study, a few weaknesses and limitations need to be considered. Lack of using the placebo in the control group might be considered as a weakness because the observed effect of Olea ointment may be unreal, and replication of similar studies with placebo is recommended. Given that the threshold for pain tolerance varies from person to person due to individual and social differences, pain intensity may be less or more than the true extent, and this is one of the limitations of the present study. Lack of complete blindness of the all researchers and study subjects was the other limitation of the present study although the statistical analyst did not know the type of treatment received by the groups.

Conclusion

Based on the findings of this study, the use of Olea ointment has been associated with the reduction of episiotomy pain. Therefore, more clinical trials are needed to support our findings. The findings of this study could encourage and stimulate researchers to design and conduct similar clinical trials with the use of Olea ointment on a wider scale.

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Conflict of interest

There are no conflicts of interest.

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