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The Effect of Apricot Kernel Oil Cream on Post-episiotomy Pain Intensity in Primiparous Women: A Triple-Blind Randomized Controlled Trial

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ABSTRACT

Background & aim: Episiotomy pain in the first days after birth can affect the mother's quality of life, mental health, and interaction with and care of the newborn. According to the evidence, apricot kernel oil, through anti-inflammatory properties and phenolic compounds, could reduce pain. This study was performed to assess the effect of apricot kernel oil cream on post-episiotomy pain intensity in primiparous women.

Methods: This triple-blind randomized clinical trial was conducted on 70 primiparous women visiting a teaching hospital in Mashhad, Iran. Participants were randomly assigned to intervention and placebo groups using permuted block randomization. The intervention started 2 hours after episiotomy repair by applying two cm of cream (medication or placebo) on the episiotomy site and was repeated every 12 hours for 10 days. Pain intensity was assssed by McGill's questionnaire before intervention, in the first 24 hours after delivery, on the fifth day, and on the 10th day after delivery. Data were analyzed with SPSS (version 21) using Chi-square, Fisher exact test, t-test, and Mann-Whitney.

Results: The mean total pain score had no significant difference between the two groups on the first day following intervention (P=0.58). But on the fifth (P=0.015) and 10th day postintervention (P<0.01), there was a significant difference between the two groups, i. e. the mean total pain score in the intervention group was 12.24±3.56 and 5.17±2.01 and in the placebo group was 15.57±5.76, and 8.47±3.91, respectively.

Conclusion: Based on the results, apricot kernel oil could be suggested as an topical complementary medication for episiotomy wound pain relief. Larger studies recommended to measure drug's efficacy and safety before its routine prescription.

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Introduction

Episiotomy is a surgical cut made in the perineum during the late second stage of labor (1-2). It was introduced as a clinical practice in the 18th century (3-4). Episiotomy is done to expand the outlet of the vulva (2), facilitate the delivery process, prevent fetal damage, and shorten the second stage of labor (5). Episiotomy is commonly indicated in cases such as first delivery, hard perineum, large fetus, facial presentation, breech or shoulder dystocia, and instrumental delivery and unreliable fetal heart rate pattern (1).

Prevalence of episiotomy is different in Sweden 7.9%, in China 3.52%, and in Nigeria

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1.62%. The rate of episiotomy is high in Asian women compared to other races (6). In Iran, there are no exact statistics on the rate of episiotomies, but it is probably high due to the high number of births (7). Bakhal et al(2022). reported the prevalence of episiotomy in Iran as 41.5% (8). Another study reported that the rate of episiotomy in Iranian primiparous women 88.7% which is higher than in other parts of the world (9).

Episiotomy has complications such as perineal rupture, perineal pain, hematoma, wound infection and subsequently dyspareunia (10). The most common complication of episiotomy is perineal pain (11). Based on the results of a study, perineal pain related to episiotomy interferes with women's daily activities, and also causes interruption of communication between mother and baby and interferes with breastfeeding (12). Perineal pain that continues after birth may cause long-term effects such as sexual and pelvic dysfunction (13). Therefore, quick and complete repair of episiotomy is of great importance (7).

Different methods of pain relief include: Topical analgesics and cooling treatments that often is used in combination (14). Some medication that relieve perineal pain include acetaminophen, mefenamic acid, epidural analgesia, lidocaine gel, and diclofenac suppositories (1). These drugs have side effects such as allergies and digestive complications and even drug resistance (15).

The use of traditional medicine in reproductive-age women is increasing due to better cultural acceptance, more compatibility with the individual's body and fewer side effects (16). To reduce the pain of the episiotomy wound, herbs are recommended, such as lavender (17), cinnamon (18), Myrtus communis (19) and frankincense (20). In the meantime, apricot with the scientific name Pernus Armeniaca is a fruit that is available and can be cultivated in favorable places in most countries (21). The apricot kernel contains a lot of oil (about 50 to 60 percent) (22). Studies have shown that sweet apricot kernel oil has antioxidant, antimicrobial, and anti-apoptotic properties (23-24). The apricot kernel contains a substance called polyphenol, which destroys free radicals and contains large amounts of vitamins D, A, K, and E, which are the main source of protection against free radicals and can be effective for treating skin disorders. Also, the highest percentage of inhibition of lipid peroxidation (69%) and total phenolic content (7.9±0.2 µg/ml) is found in the methanolic extract of licorice seeds, which are also effective in reducing pain (25). Apricot oil also effectively reduces pain due to its anti-inflammatory carotenoids (26-27). In 2018, Karaboga et al. studied the digestive protective effect of apricot kernel oil on gastric mucosa damage caused by ethanol in rats. They found that apricot kernel oil protects rat gastric mucosa from ethanol-induced damage with anti-inflammatory, anti-oxidative, and anti-apoptotic effects may be useful for treating and reducing the severity of stomach ulcers (23). In 2014, Minaiyan et al. investigated the effect of apricot kernel oil and extract on rat ulcerative colitis. According to their results, apricot kernel extract (with or without oil) can be introduced for further clinical studies as a complementary medicine for inflammatory bowel disorder (24).

Based on the previous studies, the toxicity of apricot kernels is related to amygdalin, which is not present in sweet apricot kernels and is related to bitter kernels. Therefore, due to abundance and accessability of apricot fruit, and the lack of existing research on apricot kernel oil for episiotomy pain relief, this research was conducted to assess the effect of topical cream containing apricot kernel oil on the pain intensity of episiotomy wound.

Materials and Methods

This study was a triple-blind randomized placebo-controlled clinical trial, which was conducted on 70 eligible women who referred to one training Hospital in Mashhad, Iran, from July 2023 to October 2023. It was registered in the Iranian Registry of Clinical Trials (IRCT) under the code of IRCT20230501058041N.

The sample size was determined based on the results of study by Mirzaee et al. (2019), considering the error of 5% and the power of 80 (19). The percentage was determined using the formula of the average of two independent communities, with a minimum sample size of 32 people in each group. According to the nature of interventional studies and probability of dropping about 20%, final sample size of 38

mothers in each group was determined. Finally, data analysis was done on 35 number in each research groups (Figure 1).

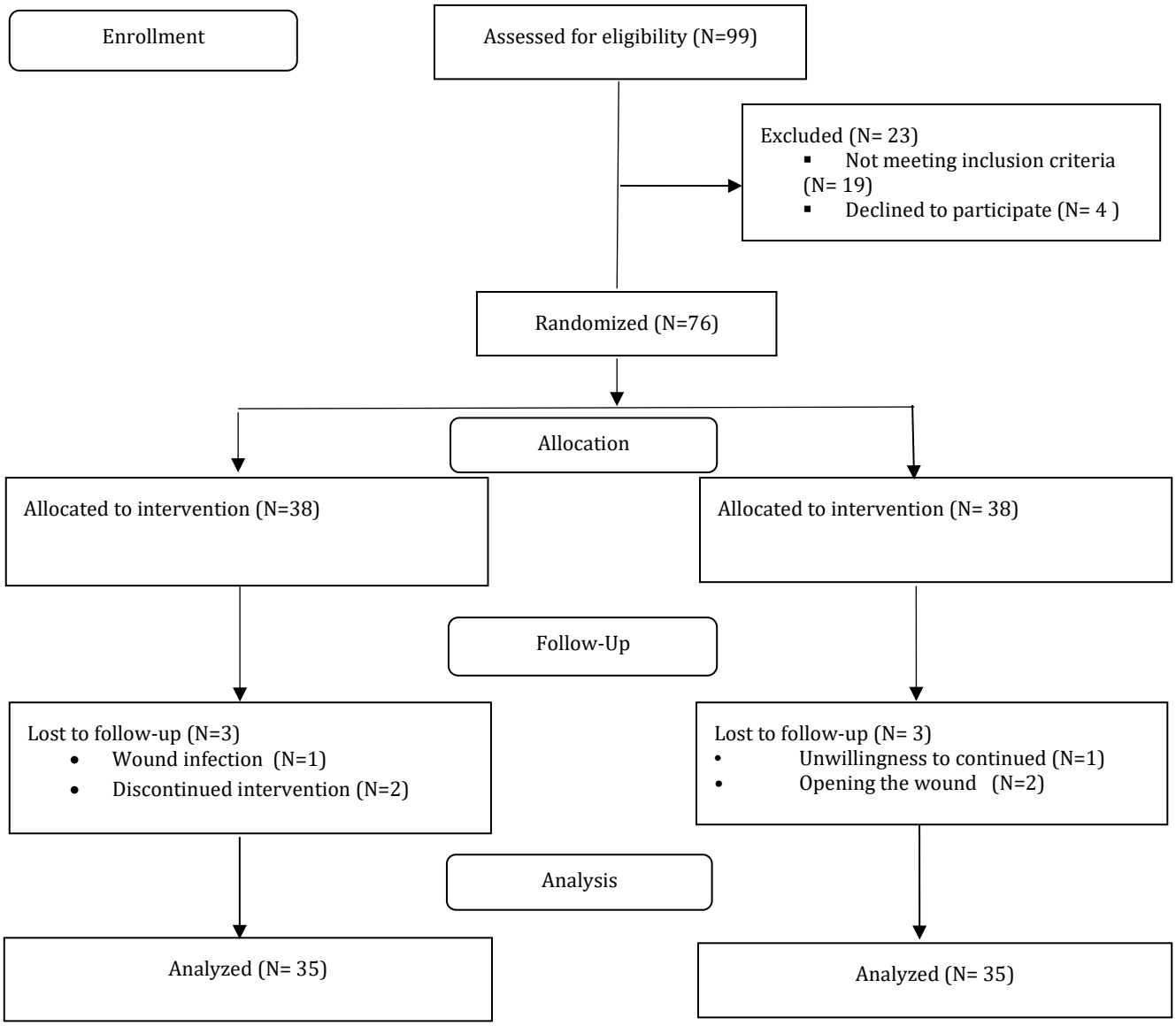

Figure 1. CONSORT Flowchart of the study

Inclusion criteria were**:** being primiparous women, within the age range of 18 to 35 years and BMI 19.8 to 30 kg/m^2, literate, with gestational age of 37 to 42 weeks and singleton fetus as well as having no history of allergy or sensitivity to topical medications in the past, not using medications for wound healing (glucocorticoids and anticoagulants), as well as immunosuppressive drugs, broad-spectrum antibiotics, and chemotherapy, no drug addiction, no diabetes, no rupture of amniotic sac for more than 18 hours, , no history of surgery or visible lesions in the perineum.

Exclusion criteria included postpartum hemorrhage, irregular use of cream, allergy, wound infection, new trauma, no return for follow-up, disease requiring antibiotic

prescription, unwillingness to continue the research, sexual intercourse in the first ten days, re-manipulation after episiotomy repair, 3rd and 4th-degree perineal tear, postpartum fever, instrumental vaginal delivery, removal of the placenta by hand, presence of hematoma in the episiotomy area, duration of first stage of labor more than 14 hours, duration of second stage of labor more than 2 hours and third stage of more than one hour, and hospitalization of baby in hospital.

To prepare apricot kernel oil cream, first apricot kernels were purchased, and then oil extraction was done with a cold press machine in Burta's workshop under the supervision of a researcher. After that, the concentration of the oil was determined by the pharmacist and mixed into the base cream (cold cream), then filled in 30 gr tubes by the researcher in the Faculty of Pharmacy. The intervention group used 10% apricot kernel oil cream containing 10 gr of apricot kernel oil that its concentration was determined based on the study of Mehrizi et al (2015) (28) made according to the opinion of pharmacy professors. The frequency of cream application, twice a day, was established in accordance with the recommendation of the pharmaceutical expert and derived from the research conducted by Ghaderbasti et al. (2022) (28).

The cold cream contained cetostearyl alcohol, petroleum gel, glycerin, Mineral oil, preservatives, and antioxidants that were neutral and ineffective substances prepared by Farabi Pharmaceutical and Health Company. The placebo was made by filling 30 gr tubes with cold cream, which was supervised by the pharmacist and the researcher.

All participants who met the inclusion criteria entered the study in the active phase of labor. The subjects were randomly assigned to the intervention and placebo groups using permutation blocks. The sequence of random allocation of people was done using Random Allocation Software and the block size was four. Also, to hide the allocation, closed doors envelopes were used and according to the order of arrival of the participants, the envelopes were opened in order and the assigned group was revealed. The drug and placebo were blinded by the pharmacist, and the researcher and the participants did not know the contents of the package. The statistical consultant was also blinded in this study. Drug and placebo were prepared in 30 gr containers at the same shape and color and labeled A & B by pharmacist consultant. So that, 35 participants in each group randomly received cream A or B. Adherence to health and nutritional tips after delivery was taught to all participants based on the protocol of the Ministry of Health and Medical Education. The questionnaire related to personal information and current pregnancy was completed for the participants by the researcher. The care provided during labor was also recorded in the birth information checklist. After the birth of newborn and before the episiotomy wound repair, the depth and length of the incision were measured using a sterile swab, which recorded by the researcher after matching with a ruler. In both groups, the repair method was the same and the repair was performed by the staff midwife). For episiotomy repair, 0 and 2/0 chromic Cutgut was used under sterile conditions. After the episiotomy repair, wound care was taught to the participants by the researcher, then intervention (drug or placebo) was given based on the relevant codes. The first topical application of the cream was performed two hours after the completion of the episiotomy repair and after washing the perineum with normal saline then 2 cm of the desired cream prescribed. All mothers were instructed to use the cream every 12 hours during 10 days after delivery.

The pain intensity of all participants were measured before the intervention as baseline, 24 hours after delivery, fifth day and 10th day after delivery. During this period, the researcher contacted with mothers by phone and followed them. It was worth noting that the participants entered the study in the active phase of labor and the minimum time required for the skin sensitivity test of the desired cream was 24 hours, and participants were not available before the active phase. In case of any abnormal findings after using the cream, the researcher was contacted. According to the opinion of the pharmacist consultant, in case of any allergy, or non-consecutive use of the cream by the participant for 4 or 6 occasions, the participant was excluded from the study. Also, if any

analgesia was used to relieve pain, the type and number and the mother's purpose for using that (e.g relieve pain in other parts of the body), by relevant questions and information were recorded. The daily information questionnair completed by own particioants.

The research tools including demographic and midwifery questionnaire, McGill pain assessment questionnaire, analgesic and antibiotic use registration form, drug side effects form, and satisfaction with drug use in 4 follow-up sessions were completed by the researcher before the intervention, 24 hours after delivery, the fifth day and in the 10th day after delivery. The validity of the forms was determined by content validity method . VAS is a validated scale length of 10 cm with 0 (no pain) in the one end and 10 (maximum imaginable pain) on the other end. This scale is widely used in pain-related studies and its validity and reliability have been confirmed (29). The McGill pain questionnaire consists of three parts. The first part of the verbal description includes two main domains (sensory and emotional) and each description has a specific rating in the range (no pain = 0, mild = 1, moderate = 2, severe = 3). It ranges from 0 to 3. The second part is the visual pain scale, which is used for the subjective estimation of pain. It is comprised of a 10-point numerical scale, with zero representing no pain and 10 representing the worst degree of pain.

Scores 1, 2, and 3 indicate mild pain, while scores 4, 5, and 6 moderate pain, and scores 7, 8, and 9 severe pain; finally, a score of 10 indicates the worst untolerable pain. The third part includes the intensity of pain at the moment, which is in the range (0 = no pain, 1 = mild, 2 = uncomfortable, 3 = excruciating, 4 = terrible, 5 = excruciating). The total of the patient's pain scores is equal to the total score obtained from all sets in different dimensions of pain. Rezvani (2013) confirmed the validity of this tool in chronic back pain sufferers (30). In this research, the validity of this tool it was confirmed by content validity. The reliability of this tool was confirmed by the internal consistency method (Cronbach's alpha) r=.91.

Data was analyzed using SPSS software (version 21). Smirnov's Kolmograph test was used to check the normality of the distribution of the variables. Chi-square and Fisher tests were used for qualitative variables. Also, the Independent t-test was used to examine quantitative variables with normal distribution and the Mann-Whitney test was used for non-normal distribution. $P<0.05$ were considered statistically significant.

Results

The mean age of the mothers in the intervention group was 20.77±2.31 years and in the placebo group was 21.43±3.99 years; the difference between the two groups was not statistically significant (P=0.799).

The mean gestational age in the intervention group was 39.11 ± 0.80 weeks and in the placebo group was 38.97 ± 0.82 weeks, the difference between the two groups was not statistically significant (P=0.462). The demographic as well as neonatal and onstetric data of the participants in the two groups are presented in Tables 1 and 2.

About 97% of mothers in both groups used painkillers in the first week after delivery, and the mean number of days of using painkillers was 2.66±0.97 days in the drug group and 3.62±0.92 days in the placebo group; the significant difference was observed between the two groups (P=0.001). In order to adjust the effect of heterogeneity in the two groups, the covariance test was used, which according to the results did not affect on the total score of pain intensity on the fifth and tenth day after delivery.

Accoding to the results there was no significant difference between the two groups in pain quality scores (P=0.06), visual scale score (P=0.2), pain intensity (P=0.291) and McGill's total pain intensity score (P=0.5) before the intervention.

Also there was no significant difference between the two groups in pain quality scores (P=0.099), visual scale score (P=0.069), pain intensity (P=0.600) and McGill's total pain intensity score (P=0.58)on the first day. But on the fifth (P=0.01) and tenth days (P<0.001), pain quality scores showed a significant difference between the two groups.

Table 1. Demographic characteristics of participants in the two groups

Variable	Drug N (%)	Placebo N (%)	P-Value
Age	20.77±2.31	21.43±3.99	** P=0.799
Gestational age	39.11 ± 0.80	38.97 ± 0.82	** P=0.462
Education			
Primary	12 (34.3)	6 (17/1)	*
High school	26(74.2)	15(42.8)	P=0.72
Diploma	2(5.7)	7(20.0)	EFT=7/923
Academic	1(2.9)	0(0.0)	
Job			*
Housekeeper	34(97.1)	35(100.0)	P>0.999
Student	1(2.9)	0(0.0)	EFT=-
Income			*
Less than sufficient	7(20. 0)	6 (17. 1)	P=0.141
sufficient	24(68.6)	29(82.9)	EFT=4.283
More than sufficient	4(11.4)	0(0.0)	

*Fisher's test **Man-Whitney test

Table 2. Neonatal and obstetric data of the participants in the two groups

Variable	Drug	Placebo	P-Value
	Mean± S.D Median (first quartile, third quartile)	Mean± S.D Median (first quartile, third quartile)	
Neonate's weight (gr)	3150.57±344.44 3170(2950-3365)	3114.29±313.82 3180(2890-3250)	** P=0.526
Neonate's height (cm)	51.71±1.71 52(51-53)	52.10±1.81 52(50-53)	** P=0.202
Head circumference (cm)	34.61±1.32 35(34-35.50)	34.29±1.13 52(50-53)	** P=0.442
Cutting length (mm)	18.51±3.90 17(13-20)	17.21±3.70 18(14-20)	** P=0.521
Number of cutgut used	1.20±0.41 1(1-1)	1.29±0.52 1(1-2)	** P=0.535
Number of days of analgesic	2.66±0.97 3(2-3)	3.62±0.92 4(3-4)	** P=0.001

**Man-Whitney test

Also there was a significant difference between the two groups in visual scale scores on the fifth (P=0.01) and tenth days (P<0.001). However there was no significant difference between the two groups in pain intensity on the fifth day (P=0.100) and on the tenth day (P=0.788).

Based on the result, a significant difference was found between the two groups in McGill's total pain intensity score on days 5 (P=0.01) and 10 after delivery (P<0.001) (Table 3).

Table 4 shows the comparison of pain scores on follow-up days.In this table, the difference in the mean pain scores in all three parts of the questionnaire before the intervention is presented alongside the follow-up days.

It should be mentioned that among the sensory and emotional components of the McGill pain quality questionnaire, shooting and burning were the most common symptoms on the fifth and tenth days.

Table 3. Mean difference of pain quality score, visual scale and total pain intensity score in two drug and placebo groups

Variable	Drug	Placebo	P-Value
	Mean ±S.D Median (first quartile, third quartile)	Mean± S.D Median (first quartile, third quartile)	
Pain quality score on the fifth day	6.31±2.82	8.57±4.21	* P=0.010
Pain quality score on the 10th day	2.29±1.34 2(1-3)	4.29±2.60 4(3-6)	** P<0.001
Visual scale score on the fifth day	4.59±1.43 4(4-5)	5.37±1.46 5(4-6)	** P=0.014
Visual scale score on the 10th day	1.91±0.98 2(1-3)	3.24±1.46 3(2-4)	** P<0.001
McGill's total pain intensity score on the fifth day	12.24±3.56 13(9-14)	15.57±5.76 13(12-20)	** P=0.015
McGill's total pain intensity score on the 10th day	5.17±2.01	8.47±3.91	* P<0.001

*T-test; **Man-Whitney test

Table 4. Mean difference of pain quality score, visual scale and total pain intensity score on follow-up days in two drug and placebo groups

Variable	Drug	placebo	P-Value
	Mean± S.D Median (first quartile, third quartile)	Mean± S.D Median (first quartile, third quartile)	
Pain quality score			
Difference between the baseline and the first day	4.24±1.86 2(5-1)	7.83±3.63 5(0-9)	** P=0.001
Difference between the baseline and the fifth day	8.43±5.79	7.18±2.74	* P=0.001
Difference between the baseline and the tenth day	12.46±6.07	7.03±6.20	* P<0.001
Comparing the visual scale score			
Difference between the baseline and the first day	2.01±0.26 0(1-2)	2.13±1.10 2(3-0)	** P=0.003
Difference between the baseline and the fifth day	2.57±1.69	2.71±0.21	* P=0.034
Difference between the baseline and the tenth day	4.36±2.47 4(3-6)	2.45±2.34 3(1-4)	** P=0.009
Comparing the McGill total pain intensity score			
Difference between the baseline and the first day	2.57±1.86	10.16±5.19	* P=0.001
Difference between the baseline and the fifth day	10.74±8.35	9.77±3.10	* P=0.001
Difference between the baseline and tenth day	17.81±8.49	10.20±8.32	* P<0.001

*T-test **Man-Whitney test

In this study, 6 mothers in apricot group and 9 mothers in the placebo group had mild burning after usage the cream, researchers considered that mild burning in both groups may be attributed to the base cream and didn't exclud from the analysis. Only two mothers from the intervention group complained of severe burning while taking the cream, which led to not continuing the treatment.

Discussion

The purpose of this study was to assess the effect of topical cream of apricot kernel oil on pain intensity of episiotomy in primiparous women. According to the results of the McGill scale, there was no statistically significant difference in the two groups before the intervention and on the first day, which may be due to the injection of lidocaine in the two groups. However, there was a significant difference between the two groups on the fifth and tenth days, so that the apricot kernel oil group experienced less perineal pain than the placebo group on days 5 and 10. Today, various studies have been conducted on episiotomy pain, but so far no animal or human study has been published to examine the effect of apricot kernel oil on pain reduction. Therefore, in order to review and compare of result, herbs with similar compounds to apricot kernel oil were discussed.

The analgesic effects of apricot kernel oil can be attributed to polyphenol agent and also a large amount of vitamins D, A, K, and E, which these ingredients play the main protection against free radicals. In addition, there is the highest percentage of inhibition of lipid peroxidation (69%) and total phenolic content (7.9±0.2 µg/ml) sweet kernel in the methanolic extract, which are also effective in reducing pain (25). Karaboga et al. (2018) in their study on the digestive protective effect of apricot kernel oil on ethanol-induced gastric mucosal damage in rats found that apricot kernel oil with anti-inflammatory, anti-oxidative and anti-apoptotic effects protects rat gastric mucosa from ethanol-induced damage (23). This result is consistent with the present study in terms of the mechanism of effect. Moreover, Minaiyan et al. (2014) investigated the effect of apricot kernel extract and oil on ulcerative colitis in rats. Apricot kernel extract, with its high tendency to clear free radicals, can stabilize the cell membrane and prevent the oxidation of membrane lipids (24). The mechanism of the effect is similar to the current research.

Mirzaee et al. (2019) investigated the effect of the Myrtus Communis on the intensity of episiotomy pain. Reduction of perineal pain was significant on days 5 and 10, the mechanism of which was attributed to the inhibition of prostaglandins and cyclooxygenase by flavonoid compounds (19). Since flavonoids are the most common group of polyphenolic compounds in the human diet, it is consistent with theresults of the present study in terms of mechanism. In the study of Davami et al. (2017) who investigated the effect of combined ointment of chamomile and marigold on episiotomy pain on the fifth and tenth day after delivery, perineal pain reduction was reported and the mechanism of pain reduction is due to the effect of flavonoids. Flavonoids are one of the inhibitors of nitric oxide synthesizing enzymes (31). Therefore, reducing the amount of nitric oxide causes pain-relieving effects, which is also consistent with the present study in terms of the effective pain-reducing substance. In the clinical trial of Sheikhan et al. (2012) who examined the lavender oil on episiotomy pain, a significant difference in pain reduction was reported from the fifth day after delivery. Lavender plant reduces pain with an anti-inflammatory mechanism (32). Considering the anti-inflammatory properties of apricot kernel oil, the pain reduction mechanism of apricot kernel oil can be justified.

Cheshmfar et al. (2023) investigated the effect of ginger ointment on the severity of episiotomy pain. Ginger contains anthocyanins, a very strong antioxidant, which inhibits pain-related pathways by inhibiting cyclooxygenases and lipoxygenases. In addition, these compounds inhibit inflammatory pathways and nitric oxide synthase. Despite this mechanism, the use of ginger did not show a significant difference in pain reduction on the fifth and tenth days after delivery (33). Therefore, even though the findings of their study are not correspond with the present study, the possible mechanisms in reducing pain are similar.

Overall, the results of this study showed the positive effect of apricot kernel oil on pain in episiotomy wounds, but the present study is the first study conducted regarding this issue on humans, which is one of the strengths of this study, so, it is recommended to conduct the next studies with a larger sample size.

One of the limitations of this study was that all of birth were not performed by a midwife. The study attempted to control intervening variables to some extent by the presence of researcher at all stages of labor.Other limitations of the study

were the loss of samples due to the infant's hospitalization or participant's unwillingness to stay in the study.

Conclusion

The findings of the present study indicated that the use of apricot kernel oil cream can play a beneficial role in reducing post-episiotomy pain in postpartum women. Apricot kernel oil cream, as a natural and low-cost topical intervention, may provide a practical and easily applicable option for pain management in routine postpartum care. Its use could potentially reduce the need for pharmacological analgesics and contribute to improved maternal comfort and recovery during the early postpartum period. Therefore, incorporating this intervention into postpartum care protocols may be beneficial for healthcare providers. Future research with larger sample size, longer follow-up periods, and more robust methodology is recommended to confirm the effectiveness, safety, and long-term benefits of apricot kernel oil cream in post-episiotomy care.

Declarations

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Conflicts of interest

The authors declared no conflicts of interest.

Ethical approval

This study was conducted on human samples based on the regulations and guidelines of the Declaration of Helsinki. The research protocol was approved by the research ethics committee. Written informed consent was taken from all participants before starting the study, and the objectives and methods of the study was fully explained. All participants were assured of the confidentiality of the data and the right of withdrawing the study at each stage they wish.

Code of Ethics

This research project was approved by the Research Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (IR.MUMS.NURSE.REC.1402.032).

Use of Artificial Intelligence (AI)

We have not used any AI tools or technologies to prepare this manuscript

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Authors' contribution

NKK, MF, HR and JJ designed the study. NKK collected data. NKK and JJ analyzed and interpreted the data. NKK drafted and MF revised the manuscript, critically. All authors read and approved the fnal manuscript and agreed to be accountable for all aspects of the work.

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