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The Effect of Raspberry Ointment on Episiotomy Wound Healing and Pain Relief in Primiparous Women: A Double-blind Randomized Clinical Trial

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ABSTRACT

Background & aim: Episiotomy is linked to increased perineal pain and wound healing problems during postpartum. Rising drug resistance is driving a growing trend toward herbal remedies as a possible substitute for wound healing and pain management. This study explored the effect of raspberry ointment on episiotomy wound healing and pain relief in primiparous women.

Methods: This double-blind randomized clinical trial included 66 primiparous women giving birth in one Public Teaching Hospital in Shushtar, Southwest Iran. Participants were randomly assigned to either a control group, which received a placebo, or an intervention group, applying raspberry ointment topically to their episiotomy wounds twice daily for two weeks. Wound healing was assessed with the REEDA (Redness, Edema, Ecchymosis, Discharge, Approximation) scale and pain severity was measured using the Visual Analog Scale (VAS), both pre-intervention and on days 7, 10, and 14 post-delivery. Statistical analysis was done using independent t-test, Friedman test, GEE, Mann-Whitney U test and Chi-square in SPSS version 22.

Results: The results of REEDA were significantly different in the two groups on the 7th, 10th, and 14th days ($P= 0.003$, $P < 0.001$, $P < 0.001$). Also, there was a significant difference between the two study groups in terms of their VAS score on the 10th and 14th days ($P <0.004$, $P = 0.001$).

Conclusion: Raspberry ointment could accelerate the episiotomy wound healing process and alleviate associated pain.

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Introduction

Episiotomy is a popular surgical incision on the muscles of the perineum during vaginal delivery, which is performed to prevent tearing of the perineum and to facilitate and accelerate delivery (1). Despite the World Health Organization's recommendation to reduce episiotomy rates to 10% for natural births, this procedure is still performed on 30-50% of women (2). A study in Iran has reported an episiotomy rate of 41.5% (3). While an episiotomy can facilitate a faster delivery and reduce the risk of perineal tears, it is associated with pain, discomfort, and delayed recovery. Episiotomy wounds can also increase the risk of infection, dyspareunia, and fecal and urinary incontinence (4-5).

There are several interventions to relieve pain in the perineum, heal the wound, and reduce

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edema and redness (6-7). While pharmacological treatments are often prescribed for these conditions, non-pharmacological interventions are becoming more popular due to their fewer side effects and possibly greater effectiveness (8, 9). Natural remedies have been suggested as an alternative treatment option for the healing of perineal ulcers and pain relief. Herbs such as Silybum marianum, green tea, Malva Sylvestris Cream, etc. have been used for episiotomy wound healing and pain relief (10-12).

Raspberry leaves have long been used for medicinal purposes, especially in Europe and North America (13-14). In Iran, Raspberries are grown in Gilan, Mazandaran, Gorgan, Azerbaijan, Khorasan, Lorestan, and Kohgluye & Boyer Ahmad provinces (15). Previous studies have shown that ellagic acid, salicylic acid, superoxide dismutase, polysaccharides, anthocyanins, flavonoids, vitamins, and other active ingredients in raspberry extract have strong antioxidant and antibacterial effects and can enhance cell proliferation, which effectively shrinks the wound area (16-17). Also, it has been shown that raspberry leaf extract has antimicrobial activity against a wide range of microorganisms including Streptococcus pyogenes, Staphylococcus aureus, and Escherichia coli (18). The research conducted by Lu et al. demonstrated that both raspberry extract and ellagic acid exhibit similar antioxidant capabilities and comparably encourage cell proliferation. In an experiment involving mice, raspberry extract significantly decreased the size of the wound area (16). The findings of the study conducted by Zomorrodi et al. indicated that the topical application of raspberry extract facilitates wound healing in diabetic rats by stimulating collagen synthesis, promoting faster wound contraction, and enhancing angiogenesis (15).

Given the potential side effects of chemical drugs, medicinal plants offer a promising alternative for wound healing. This preference stems from the minimal side effects and cost-effectiveness exhibited by medicinal plants. It is important to note, however, that using of plants for medicinal purposes necessitates the presence of clinical evidence. Primiparous women were specifically selected as the study population due to their substantially higher exposure to episiotomy compared to multiparous women. An Indian trial reported episiotomy rates of 93.3% in primiparous versus 30.2% in multiparous women undergoing vaginal birth (19). Similarly, a large Brazilian study found that primiparous women are approximately three times more likely to undergo episiotomy than women with prior vaginal deliveries, with multiparity conferring a 55% reduced probability of the procedure (20). A risk-modeling study also found primiparity independently predicts poor perineal wound healing (21).

To the best of our knowledge, this is the first double-blind randomized clinical trial to evaluate the efficacy of raspberry ointment on episiotomy wound healing in a human population. Therefore, this study aims to explore the effects of raspberry ointment on the episiotomy wound healing and pain relief wounds in primiparous women.

Materials and Methods

The current study was a randomized, double-blind clinical trial,which was registered in the Iranian Registry of Clinical Trials (Ref. ID: IRCT 20181007041267 N1). The study took place at one Public Teaching Hospital in Shushtar, Southwest Iran, from May 2021 to August 2022. The participants of this study included the primiparous women referring to hospital, who were assigned to the intervention or control groups using permuted block randomization.

Based on the outcome of the study (pain intensity score of both groups at the end of the study) and prior research (22), assuming s1=0.5, s2=1.17, α=0.05, β = 0.20 and d = 0.65, and using the mean comparison formula, the sample size for each group was initially determined to be 30 women. Adjusting for a 10% dropout rate, each group's final sample size was 33 individuals, totaling 66 participants.

Inclusion criteria were: Iranian ethnicity and residency in Shushtar City, primiparity, age of 18-35, literacy, full-term singleton pregnancy with head presentation, birthweight of 2500-4000 grams, BMI of 19.8-29.9, no medications affecting wound healing, no interfering diseases, intact amniotic sac for at least 18 hours, no history of postpartum bleeding, manual placental removal, perineal hematoma or re-manipulation, severe cystocele or rectocele, prior vaginal or mesenteric surgery, perineal rupture (grades 3-

4), precipitous labor as well as no neonatal hospitalization or anomalies.

The exclusion criteria were: any disorders affecting labor progress or second stage >2 hours, abnormal vaginal bleeding, curettage within 24 hours post-delivery, puerperal fever, episiotomy infection, re-stitching of the episiotomy, use of wound-healing medications during the study, improper ointment application, and allergy to ointment.

The participants were chosen deliberately based on specific inclusion and exclusion criteria. For this research, Rand List software was utilized to divide the participants into two groups: an intervention group consisting of 33 individuals who received raspberry ointment, and a control group consisting of 33 individuals who received a placebo. To ensure unbiased results, both the participants and the researcher were blinded throughout the study.

A statistician performed random allocation using permuted block randomization with blocks of 6, implemented through random allocation software.

To ensure allocation concealment, a random sequence was generated and corresponding envelopes prepared. Each envelope contained a card with a random sequence number. This process was conducted by someone not involved in sampling to minimize bias. The envelopes were sequentially numbered to maintain sequence integrity and sealed. The sealed envelopes were then collected and stored in a designated box. During recruitment, eligible participants were enrolled sequentially. An envelope was randomly selected and opened to reveal the assigned group. This method ensured random allocation and unbiased assignment, strengthening the preciseness of study.

To ensure blinding, identical tubes were used, and drugs were labeled with generic codes 1 and 2. Only the pharmacist knew the specific drug in each tube. Neither the participants nor the researcher were aware of the type of drug in the tubes with codes 1 and 2 until completion of data analysis.

The primary outcomes of this study were the assessment of episiotomy wound healing using the REEDA scale and the evaluation of pain intensity using the Visual Analog Scale (VAS).

Data collection included a demographic questionnaire (including data related to age, educational level of the participant and her husband, monthly income, and housing status), an obstetric questionnaire (including data pertaining to gestational age, birthweight, pregnancy control in health centers, intended pregnancy, and restroom use), and a form of the side effects of drugs and analgesics. The content and face validity of all these three tools were evaluated and confirmed.

The main scale used for assessing tissue healing in the wound area was REEDA. It includes the following items: Redness, Edema, Ecchymosis, Discharge, and Approximation. Each variable was scored on a 4-point Likert scale from 0 to 3, with 0 indicating the absence and 3 indicating the highest presence. The content validity of the REEDA tool has been established in study by Yashariporefter obtaining approval from 40 medical professionals. Its reliability has been verified by achieving a Cronbach's alpha of 0.9 (7).

To measure pain intensity, the Visual Analogue Scale (VAS) was used . On this scale, scores from 0-3 indicate mild pain, 4-7 represent moderate pain, and 8-10 show severe pain. Vardanjani et al. (2010) and Sabzaligol et al. (2014) assessed and validated the reliability and validity of this instrument (23-24). VAS is considered one of the most reliable pain measurement scale (7).

Raspberry fruits were sourced from Guilan province and identified botanically at the Faculty of Pharmacy, Shahid Beheshti University, Tehran, Iran. They were then extracted with 70% ethanol using the soaking method (X3). After the solvents were distilled, the resulting extract was mixed with the ointment base. Finally, the ointment made with a dose of 2% was placed in empty tubes. The placebo was prepared in the pharmacognosy laboratory at the Faculty of Pharmacy of fthe same University.

First, the drug was piloted on five volunteers, and after ensuring that no side effects occurred, in the main sampling stage, the coded package of medications was randomly given to the participants, while the research team was blind. Participants in both groups were provided with instructional pamphlets detailing the correct management of their incision and sutures.

After washing and drying the perineum, the participants were asked to put a fingertip of the ointment on the sutured area to cover it, and after 1-2 minutes, to use a clean sanitary napkin. They were supposed to perform the same action twice a day: in the morning and at night before going to bed until the fourteenth day after post-partum. Under the supervision of the researcher in the hospital, the patients were administered the initial dose of the drug within the first 24 hours following a minimum of 2 hours of episiotomy repair. The participants were free to use 250 mg of mefenamic acid capsules in case they needed pain relief. The mothers were asked to contact the researcher in case of experiencing any of the following problems or complications: fever and chills, allergy to the cream, discharge from the wound, severe pain in the perineal area, excessive swelling of the perineal area, and any burning, itching, stiffness, and dryness in the wound area. This was done to enable the timely implementation of necessary interventions and to allow the researcher to document any complications in the adverse event form based on the participant's responses. All participants were given a card containing the following information: the code of the intervention or control group, the date of next appointment, and the researcher's phone number. In order to check the status of episiotomy recovery, the researcher contacted the mothers on days 6, 9 and 13, reminding them to refer to the Postpartum unit at hospital to attend their appointment. The assessment of episiotomy recovery was conducted utilizing the REEDA scale and the Visual Analog Scale (VAS), which is scored from 0 to 10, on the 7th, 10th, and 14th days post-delivery.

Data analysis was performed using SPSS version 22. Normality of continuous variables was assessed using the Shapiro-Wilk test. For between-group comparisons at each time point:

Independent t-test was used for normally distributed variables (e.g., age, BMI, gestational age).

Mann-Whitney U test was applied for non-normally distributed variables (e.g., VAS and REEDA scores). Chi-square test was employed to compare categorical variables (e.g., education level, occupation). For within-group comparisons across the four measurement time points (1st, 7th, 10th, and 14th days), the Friedman test was used due to the repeated-measures design. To evaluate the overall effect of the intervention on longitudinal outcomes while adjusting for potential confounders (e.g., baseline differences in education level), Generalized Estimating Equations (GEE) with an exchangeable correlation structure were applied. A P-value < 0.05 was considered statistically significant.

Results

Initially, 84 primiparous women were assessed for eligibility. Of these, 18 were excluded (8 did not meet the inclusion criteria and 10 declined to participate). The remaining 66 eligible women were randomly allocated to the raspberry ointment group (n=33) or placebo group (n=33). During the intervention period, 6 participants in the raspberry group discontinued the study (4 discontinued the intervention and 2 were lost to follow-up due to immigration). Consequently, data from 60 participants (raspberry group n=27; placebo group n=33) were included in the final analysis (Figure 1).

Table 1. Sociodemographic and obstetric data for women in the two groups

Variable	Intervention Group (N=27)	Control Group (N= 33)	Statistical	P-Value
Quantitative variables, Mean (SD)				
Age	24.85 (5.68)	27.33 (5.15)	3.14	0.082*
BMI	25.81 (3.43)	25.91 (3.92)	0.011	0.917*
Gestational age based on sonography	38.62(0.92)	38.69 (0.80)	0.366	0.714*
Birth weight (gr)	3342.22 (325.95)	3241.81 (479.80)	0.857	0.358*
Qualitative variables, N (%)				
Gravid				
1	23 (83.34)	27 (81.81)	0.121	0.728**
2	4 (16.66)	6 (18.18)		

Variable	Intervention Group (N=27)	Control Group (N= 33)	Statistical	P-Value
Perineal outcome				
Minor perineal trauma	2 (7.40)	3 (9.09)		
First–degree tear	12 (44.44)	9 (27.28)	1.930	0.381**
Second–degree tear	13 (48.14)	21 (63.63)		
Educational level				
High school	7 (25.92)	(54.54) 18		
Diploma	11 (40.74)	12 (36.36)	7.357	0.025**
College	9 (33.33)	3 (9.09)		
Occupation				
Employed	6 (22.22)	2 (33.30)	1.264	0.261**
Housewife	21(77.78)	31 (93.93)		

*Independent t-test or Mann-Whitney test, **Chi-square test

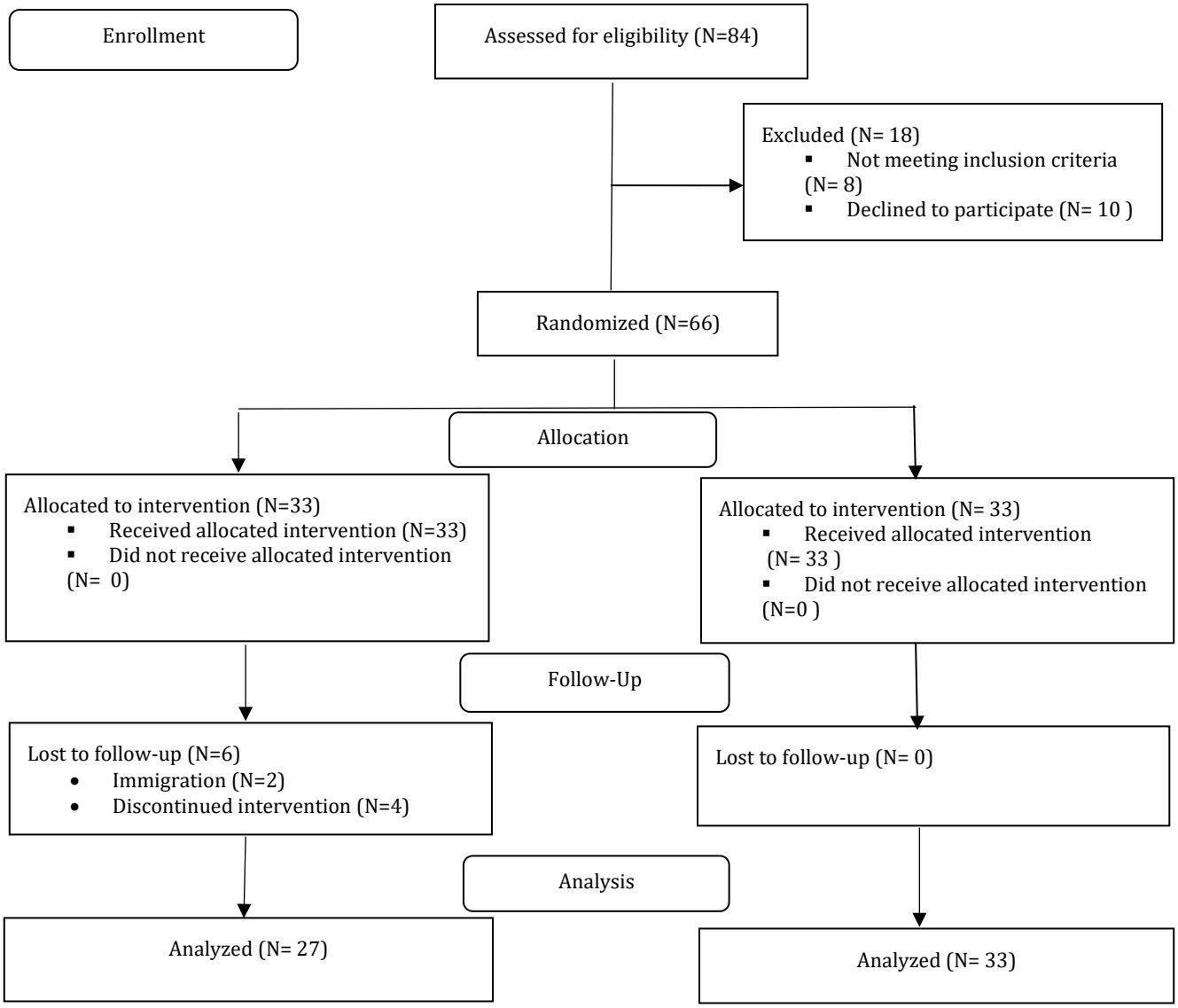

Figure 1. CONSORT Flowchart of the study

Most of the individuals in the intervention (n = 11; 40.807%) and the control group (n = 18; 54.54%) had high school education (P= 0.025). Most of the women in the intervention group (n = 21; 77.78 %), and the control care group (n = 31; 93.93%) were housewives (P =0.261). Table 1 provides demographic and obstetric characteristics.

There was no significant difference between the two study groups in terms of their VAS score on the first and seventh days (P = 0.079, P = 0.837). However, on the 10th and 14th days, there was a significant difference between the investigated groups (P < 0.004, P = 0.001). The VAS score in the intervention group had a greater reduction during the initial and final days of the study compared with the control group (P<0.001). Over time, the VAS score decreased in both groups (P<0.001) (Table 2, Figure 2).

Table 2. Comparison of pain severity scores based on VAS before and after intervention in the two groups at different time points

Time of measurment	Intervention Group (N=27)	Control group (N= 33)	Difference between groups	P-Value Mann-Whitney
1st	5.88 (0.32)	5.78 (0.34)	0.10 (0.49)	0.837
7th	4.29(0.31)	5.09(0.30)	0.79 (0.43)	0.079
10th	2.92 (0.22)	4.24 (0.28)	1.31 (0.36)	0.001
14th	1.70 (0.14)	3.09 (0.27)	1.38 (0.30)	< 0.001
Difference between 1 st and 14th	4.18 (1.27)	2.69 (1.10)	1.14 (0.30)	< 0.001
P-Value Friedman	< 0.001	<0.001	<0.001	

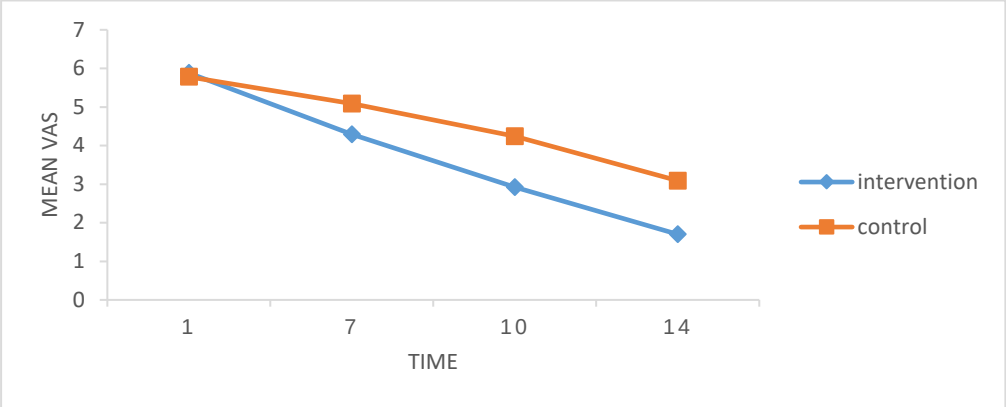

Figure 2. Comparison of the VAS score at different time points in the two groups

Overall, the results of REEDA were not significantly different in the two groups on the first day (P = 0.46). However, on the 7th, 10th, and 14th days, there was a significant difference between the investigated groups (P = 0.003, P < 0.001, P < 0.001). In general, the REEDA score in the intervention group had a greater decrease during the initial and final days of the study, compared with the control group (P < 0.001). Over time, the REEDA index decreased in both groups (P < 0.001) (Table 3, Figure 3).

Tabel 3. Comparison of Mean (SD) REEDA scale scores between the raspberry ointment and placebo groups at different time points

Parameter	REEDA Scale			P-Value Mann-Whitney
	Intervention Group (N=27)	Control group (N= 33)	Difference between groups	
Redness				
1 st	1.81(0.15)	2.06 (0.11)	-0.24 (0.19)	0.207
7th	1.44(0.17)	1.72 (0.12)	-0.28 (0.21)	0.190
10th	0.85 (0.12)	1.45 (0.14)	-0.60 (0.18)	0.003
14th	0.55 (0.09)	1.03 (0.11)	-0.47 (0.15)	0.004
Difference between 1st and 14th	1.25 (0.81)	1.03 (0.76)	0.22 (0.20)	0.268
	P-Value		**< 0.001**	
Edema				
1 st	2.14 (0.13)	2.12(0.11)	0.02 (0.17)	0.026
7th	1.14 (0.14)	1.72 (0.13)	-0.57 (0.20)	0.006
10th	0.85 (0.12)	1.24(0.14)	-.039 (0.19)	0.055
14th	0.40 (0.09)	0.78 (0.09)	-.038 (0.13)	0.007
Difference between 1st and 14th	1.74 (0.94)	1.33 (0.64)	0.40 (.20)	0.029
	P-Value		**< 0.001**	
Bruising				
1 st	1.51 (0.80)	1.66 (0.88)	-0.14 (0.22)	0.505
7th	1.03 (0.97)	1.51 (0.79)	-0.47 (0.22)	0.041
10th	0.51 (0.70)	1.15 (0.71)	-0.63 (0.18)	0.001
14th	0.03 (0.19)	0.72 (0.67)	-0.69 (0.13)	< 0.001
Difference between 1st and 14th	1.48 (0.80)	0.93 (0.86)	0.54 (0.21)	0.015
	P-Value		**< 0.001**	
Discharge				
1 st	1.14 (0.94)	1.21 (1.05)	-0.06 (0.26)	0.808
7th	0.92 (0.72)	0.96 (0.88)	-0.04 (0.21)	0.837
10th	0.44 (0.50)	0.69 (0.76)	-0.25 (0.17)	0.149
14th	0.00 (0.00)	0.33 (0.47)	-0.33 (0.09)	0.001
Difference between 1st and 14th	1.14 (0.94)	0.87 (0.96)	0.26 (0.24)	0.282
	P-Value		**< 0.001**	
The distance between the two edges of the wound				
1 st	1.81 (0.92)	1.78 (1.02)	0.02 (0.25)	0.916
7 th	1.25 (1.12)	1.33 (1.02)	-0.07 (0.27)	0.791
10 th	0.81(0.78)	0.93 (0.89)	-0.12 (0.22)	0.575
14 th	0.22 (0.42)	0.48 (0.75)	-0.26 (0.16)	0.113
Difference between 1st and 14th	1.59 (0.79)	1.30 (0.95)	0.28 (0.22)	0.213
	P-Value		**< 0.001**	
Total score				
1 st	8.48 (1.74)	8.75 (1.11)	-.27 (0.37)	0.460
7 th	5.62 (1.86)	7.06 (1.65)	-1.43 (0.45)	0.003
10 th	3.33 (1.44)	5.51 (1.76)	-2.18 (0.42)	< 0.001
14 th	1.18 (1.03)	3.42 (1.47)	2.23 (0.33)	< 0.001
Difference between 1st and 14th	7.29 (1.77)	5.33 (1.02)	1.96 (0.36)	< 0.001
	P-Value		**< 0.001**	

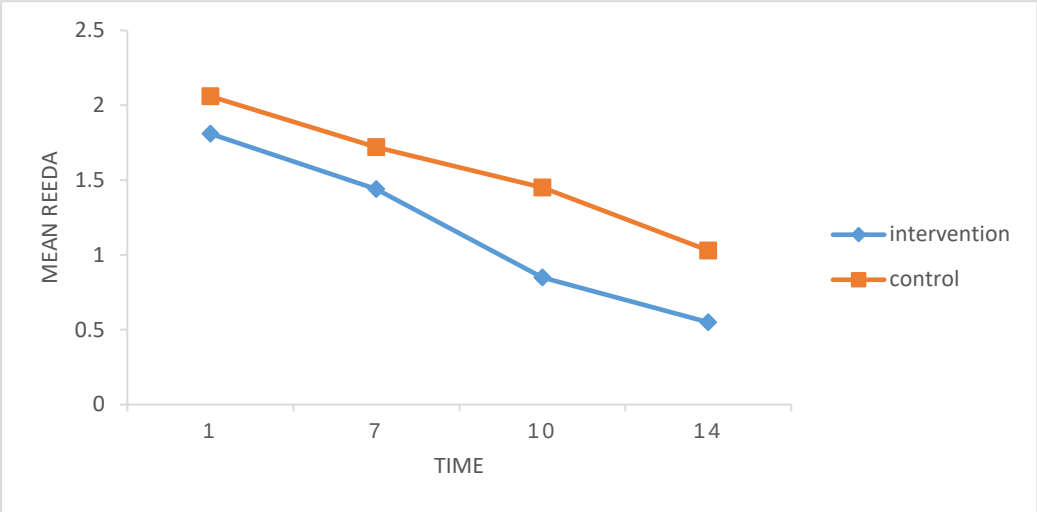

Figure 3. Comparison of the REEDA score at different time points in the two groups

Regarding side effects, the results showed that one woman in the intervention group (3.7%) and one in the control group (3.03%) reported a burning sensation. Both of them recovered spontaneously after 6-7 hours, which is not statistically significant according to the independent t-test and indicates that the raspberry ointment was without complications.

Discussion

The study aimed to evaluate the effects of raspberry ointment on the healing of episiotomy incisions in primiparous women.

This randomized controlled trial demonstrates that topical raspberry (Rubus fruticosus) ointment significantly accelerates episiotomy wound healing and reduces perineal pain in primiparous women from day 10 onward. Notably, no significant differences were observed between groups during the first week, suggesting that raspberry's therapeutic effects manifest during the proliferative phase of wound healing rather than the initial inflammatory phase. The delayed onset of significant between-group differences (days 10–14) aligns with the physiological timeline of the proliferative phase of wound healing, during which collagen synthesis and angiogenesis predominate (25-26). This temporal pattern is consistent with the mechanism of polyphenolic compounds—particularly ellagic acid and anthocyanins abundant in raspberry—which enhance wound healing by upregulating TGF-β1-mediated collagen deposition and VEGF-driven angiogenesis, processes that reach their peak activity after day 7 (27-28).

To our knowledge, this study represents the first randomized controlled trial evaluating raspberry ointment for episiotomy wound healing in humans. While preclinical evidence from diabetic rat models demonstrated that topical Rubus fruticosus extract accelerates wound contraction and enhances collagen deposition in cutaneous wounds (29), our study provides the first clinical validation of these effects in postpartum women undergoing episiotomy repair. our findings bridge the translational gap between animal studies and clinical application in postpartum women.

This addresses a critical evidence gap in herbal interventions for episiotomy care. A 2020 Iranian systematic review of 28 clinical trials identified 19 different medicinal plants used for episiotomy wound healing; however, the authors emphasized that most studies suffered from small sample sizes and methodological limitations, precluding firm clinical recommendations (13). Similarly, a comprehensive review noted that over 60% of existing trials focused on only four plants (aloe vera, lavender, turmeric, and green tea), with limited evidence for other botanical candidates

(30). While recent systematic reviews have confirmed the efficacy of established agents such as lavender (31), green tea (10), Silybum marianum (32), and Malva sylvestris (11), raspberry (Rubus fruticosus) remains unexplored in human episiotomy trials. Our study therefore expands the repertoire of clinically validated herbal options for postpartum perineal care.

The observed reduction in REEDA components (redness, edema, ecchymosis, and discharge) from day 10 aligns with the documented anti-inflammatory properties of ellagic acid—the primary bioactive compound in raspberry—which suppresses COX-2 expression (33), and inhibits nitric oxide production in activated macrophages (34). These mechanisms likely contribute to the attenuation of local perineal inflammation observed in our intervention group. Importantly, the absence of significant differences in wound edge approximation between groups likely reflects the standardized surgical technique applied uniformly to all participants, rather than a limitation of the intervention itself (35-36). Our findings should be contextualized within the expanding evidence base for herbal interventions in perineal care. Recent systematic reviews confirm that topical herbal preparations significantly improve episiotomy wound healing and reduce pain intensity compared to placebo or standard car (31). Individual randomized trials have demonstrated robust efficacy for specific botanicals: Silybum marianum ointment (2%) significantly accelerated episiotomy wound healing and reduced pain intensity by approximately 40% on day 10 (32).

Similarly, green tea ointment (1%) significantly improved REEDA scores and reduced pain on days 5 and 10 postpartum ($P < 0.001$)(10). Although direct head-to-head comparison with these agents was beyond our study scope, raspberry's comparable efficacy profile and favorable safety data position it as a promising addition to the repertoire of evidence-based herbal options for midwifery practice.

The strengths of the study include its randomized controlled trial design and double-blind methodology, both of which reduce bias. Also, evaluating multiple outcomes like wound healing and pain, provides a comprehensive understanding of intervention effects.

Several limitations warrant acknowledgment. First, the absence of prior human trials on raspberry for episiotomy precluded direct comparison with similar interventions. Second, blinding could not be maintained during telephone follow-ups on days 7, 10, and 14, potentially introducing measurement bias. Third, the single-center design limits generalizability to diverse healthcare settings. Nevertheless, these constraints also underscore the novelty of our work as the inaugural clinical trial in this domain.

Future research should prioritize head-to-head comparisons between raspberry and established herbal agents (e.g., green tea, Silybum marianum) in multicenter trials with larger samples. Investigation of optimal concentrations (1% vs. 2% vs. 5%) and assessment of long-term outcomes-including dyspareunia and pelvic floor dysfunction at 6–12 weeks postpartum—would further inform clinical implementation.

Conclusion

This study demonstrates that topical raspberry ointment may enhance episiotomy wound healing and reduce perineal pain in primiparous women. As the first randomized controlled trial evaluating Rubus fruticosus for episiotomy care in humans, our findings introduce a novel herbal option to the limited repertoire of evidence-based non-pharmacological interventions for postpartum perineal recovery. Raspberry ointment offers a safe, affordable, and culturally acceptable adjunctive therapy that midwives can readily integrate into routine postpartum care. Given the high episiotomy rates among primiparous women—particularly in resource-limited settings—this intervention may reduce dependence on systemic analgesics while supporting early recovery. We recommend that maternity care providers consider raspberry ointment as part of standardized perineal wound management protocols, coupled with patient education on proper application.

Future multicenter trials with larger samples should investigate optimal concentrations, compare raspberry with other herbal agents, and assess long-term outcomes such as dyspareunia

and pelvic floor function to establish evidence-based clinical guidelines.

Declarations

Acknowledgements

We extend our gratitude to all the women who took part in this study.

Conflicts of interest

The authors declared no conflicts of interest.

Ethical approval

The ethical considerations that were taken into account involved informing the participants about the research process and its timing, the nature of the intervention, obtaining written consent, maintaining the confidentiality of the sessions, and allowing the participants to withdraw from the study at any point during the research.

Code of Ethics

The study received approval from the ethics committee of Shushtar University of Medical Sciences (Ref. ID: IR.SHOUSHTAR.REC.1397.003).

Use of Artificial Intelligence (AI)

The authors declare that AI tools (Grammarly) were used solely to assist with language refinement and clarity; all study design, data analysis, interpretation, and conclusions were performed by the authors.

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Authors' contribution

All authors significantly contributed to the conception, design, data collection, analysis, and interpretation of the results. Furthermore, all authors reviewed and approved the manuscript prior to its submission.

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