# ORIGINAL ARTICLE

# The Effect of Malva Sylvestris Cream on Episiotomy Pain and Healing: A Randomized Controlled Clinical Trial

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### **ABSTRACT**

**Background:** Episiotomy is one of the common procedures during childbirth in Iran, which causes pain, discomfort, and scar in the perineum. This study aimed to pursue the effect of Malva Sylvestris cream on episiotomy pain and healing.

Methods: This study was a double-blinded randomized-controlled clinical trial that was conducted from April to December 2021 at the Sina hospital in Ahvaz, Iran. Sixty women were selected and randomly assigned to control and intervention groups using block randomization. The main outcomes included pain assessment and episiotomy wound healing that are assessed by the Visual analog scale (VAS), and perineal healing scale included redness, edema, ecchymosis/bruising, discharge, approximation (REEDA). The cream was used twice a day for up to 14 days. The participants were followed on the first, seventh, and fourteenth days postpartum. Independent T-test, Mann-Whitney, and Chi-square, and Generalized Estimating Equations (GEE) model were used by SPSS software version 22 for data analysis. Statistically significant level was considered less than 0.05.

**Results:** There were no significant statistical differences between the two groups in demographic characteristics (P>0.05). No significant statistical differences were found in both groups in terms of perineal healing (B=-0.05; P=0.89) and pain scores (B=0.15; P=0.56). However, the chance of external dysuria in the intervention group decreased by 77% (P=0.01).

**Conclusion:** Despite showing the positive effect of Malva Sylvestris extract on wound healing in animal and in-vitro studies, this clinical study failed to show the positive effect of this extract on wound healing and pain relief of episiotomy. However, future clinical trials are needed to substantiate the above findings. **Trial Registration Number:** IRCT20190826044621N1.

Keywords: Episiotomy, Malva, Pain, Wound healing

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### INTRODUCTION

Episiotomy is a common procedure in labor on the perineum that is performed with scissors and can prevent potentially dangerous grade 3 and 4 perineal rupture during labor. However, the American College of Obstetricians and Gynecologists and the International Federation of Gynecology and Obstetrics recommend limited use of episiotomy, only if indicated. This procedure is commonly performed in Iran, especially in nulliparous women. In a study in Iran, the prevalence of episiotomy was reported about 41.5%. However, the World Health Organization does not recommends routine or liberal use of episiotomy.

Pain is a common problem of episiotomy. The prevalence of postpartum perineal pain on the first day after delivery is estimated at 88.2% and at the end of the first week after birth at 62.3%.6 In a qualitative study on women's experiences of episiotomy, their perceptions of episiotomy pain and discomfort varied, with some reporting mild, some severe, and some unbearable. In some women, the pain lasted for months. Women reported suture problems with tight sutures, suture stimulation, or wound incisions.<sup>7</sup> Perineal injuries that do not heal well can have some impact on women's health, motherinfant relationships, and family relationships.8 Effective pain relief during the postpartum period could have a definitely positive effect on women's quality of life.9

Many herbs have been used to accelerate wound healing and reduce perineal pain, such as Aloe Vera, calendula, cinnamon, chamomile, lavender, and so on. 9-13 One of these Iranian herbal plants is Malva Sylvestris that is known as a Panirak. In traditional medicine, Malva Sylvestris is used to treat gastrointestinal disorders, skin diseases, menstrual cramps, urinary disorders, respiratory and oral diseases. The anti-inflammatory effects of Malva Sylvestris are related to inhibition of prostaglandin and thromboxane A2 activity. This property is present in the flower and leaf extracts of this plant. 14

In addition, Malva Sylvestris has antimicrobial activity.<sup>15</sup> In the laboratory culture medium, Malva Sylvestris is effective against microorganisms such as Staphylococcus Aureus, Corynebacterium, Pseudomonas Aeruginosa, Candida Albicans, and Klebsiella Pneumoniae and prevents their growth.<sup>16, 17</sup> This plant is effective in the wound healing process in rats.<sup>18</sup> To the best of our knowledge, in human studies, the effect of Malva on wounds has not been investigated so far, and all studies have been done on animals.

Considering the anti-inflammatory and antimicrobial effect of Malva Sylvestris, as well as the high prevalence of episiotomy and pain in Iran, we decided to investigate the effect of Malva Sylvestris cream on episiotomy healing and pain.

# **MATERIAL AND METHODS**

A double-blinded randomized controlled clinical trial was performed on sixty primiparous and multiparous women who met the inclusion criteria and referred to Sina hospital in Ahvaz, Iran from April to December 2021. Sina Hospital is a second-level educational-medical hospital affiliated to Ahvaz University of Medical Sciences. The birth statistics in this hospital in 2021 were 4496 births per year, of which 64.45% (2898 births) were vaginal births (almost 230 vaginal childbirth per month). The percentage of using episiotomy in this hospital is reported as 37.66%. In this hospital, diclofenac suppositories and ibuprofen tablets are used for pain relief after childbirth.

Due to the lack of similar studies in this field, a pilot study was conducted to determine the sample size. After taking 10 samples in both intervention and placebo groups, we found that the mean score and standard deviation of the main variable Visual Analogue Scale (VAS) in the placebo groups were 1.4 and 1.57; in the intervention groups, they were 0.20 and 0.63 at time points 1 and 14 days after childbirth, respectively. Based on this pilot study, 30 participants were selected in each group with a 95% confidence interval

and a power of 95%.

$$n = \frac{(s_1^2 + s_2^2) \left(z_{1 - \frac{\alpha}{2}} + z_{1 - \beta}\right)^2}{(\overline{x}_1 - \overline{x}_2)^2} =$$

$$\frac{(1.57^2 + 0.63^2)(1.96 + 1.64)^2}{(1.4 - 0.20)^2} = 25$$

In this equation,  $S_1$ =1.57,  $S_2$ =0.63,  $X_1$ =1.4,  $X_2$ =0.20,  $z_{1-\frac{\alpha}{2}}$  = 1.96, and  $z_{1-\beta}$  = 1.64.

By considering a 20% probability of dropout, the total number of individuals in each sample group was calculated to be 30.

The inclusion criteria were the primiparous or multiparous women with single pregnancy, cephalic presentation, normal maternal body mass index between 19.5 and 24.9, full-term gestational age (37-41 weeks), uncomplicated delivery, lack of labor dystocia due to 'the powers' (uterus), 'the passenger' (fetus), and 'the parts' (pelvis) factors, no use of instrumental delivery, mediolateral episiotomy, no 3rd or 4th degree perineal tear, normal infant weight, lack of any medical or surgical illness in mother and infant, and willingness to cooperate. Exclusion criteria were the participants' withdrawal during the study, severe postpartum hemorrhage, any skin lesion or infection in the perineal area or occurrence of any side effect during the intervention, and use of other herbal or medical drugs to heal the episiotomy during the intervention. All participants were carefully assessed through a complete history and examination to ensure that the participants' inclusion and exclusion criteria were met.

After receiving approval from the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences and preparing the cream, the researcher and her assistant were present in the maternity ward of Sina hospital, and immediately after delivery, they took a history of postpartum women. If the inclusion criteria were met, after obtaining written informed consents, we enrolled the participants in the study. It should be noted that childbirth process was managed by the hospital staff.

Ninety-eight women who delivered in Sina Hospital in Ahvaz were examined for eligibility to take part in the study, of which 18 mothers did not meet the inclusion criteria, and 20 mothers did not tend to participate in the study. Sixty primiparous and multiparous women who underwent mediolateral episiotomy were selected and randomly assigned in a 1:1 ratio of the placebo and intervention groups by block randomization with 15 equal-sized blocks (4 subjects). Randomization was performed using the codes generated by Epi Info software, version 6 (Epi Info<sup>TM</sup>, Centers for 131 Disease Control and Prevention, Atlanta, Georgia, USA). The generated codes were 60 that were randomly assigned to the patients. There was no attrition in any of the groups and statistical analysis was performed on 60 participants. The flowchart for the study is presented in Figure 1.

Each serial number was placed in an opaque sealed envelope, and the participants who signed the consent form were assigned an envelope indicating which participant should be received which a certain cream. Random allocation and allocation concealment were conducted by a person who was not involved in the sampling and data collection.

All the individuals involved in this study (researchers, research assistants, mothers, and statistician except pharmacists) were blinded to the allocated treatment group. In order to conceal the medication allocation, we prepared the creams in tubes of the same color and shape, and coded by the pharmacist. After allocation, the necessary training on perineal hygiene was provided for the groups, and they were asked to rub the medicine on the repaired site of episiotomy twice a day at morning/night (every 12 hours) after rinsing the perineum with water and mild soap and continue this work for up to 14 days. During this time, the researchers followed the mothers by phone to check the proper use of medicine or the occurrence of complications every two days. Then, on the first, seventh, and fourteenth days of postpartum, the

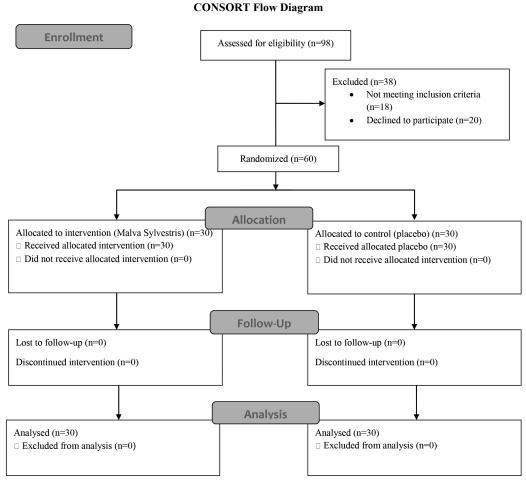


Figure 1: CONSORT diagram of the participants of the study.

women were examined in lithotomy position in the obstetrics clinic of Sina hospitals, and the episiotomy wound healing and pain intensity were evaluated using the episiotomy healing assessment scale: Redness, Oedema, Ecchymosis, Discharge, Approximation (REEDA) and the VAS score by the assistant researchers.

To collect the data, socio-demographic and childbirth characteristics, VAS score, and REEDA scale were used. Socio-demographic and childbirth characteristics were about age, weight, education, job, financial situation, gravida, parity, gestational age, weight of infant, first dilatation, length between rupture of membrane to delivery, the length of the first, second and third stage of labor, number of vaginal exams, time for repair of episiotomy, number of suture packets used, use of lidocaine, and birth attendant.

The VAS score first was used by Hayes and

Patterson in 1921.<sup>19</sup> VAS consists of a straight line with endpoints scored from zero to 10 ("It does not hurt at all" and "the pain is as severe as it can be"). The patient was asked to mark her level of pain on the line between the two endpoints based on her perception of pain intensity.<sup>20</sup> Reliability and validity of VAS score were reported (ICC=0.99<sup>21</sup> and Spearman's r coefficient=0.818,<sup>22</sup> respectively). In Iran, the reliability of this scale with a correlation coefficient of 0.77 has also been confirmed in the study of Rezvani et al (2012).<sup>23</sup>-

In order to assess the reliability of the VAS scale in this study, we checked the episiotomy wound healing twice, first by the assistant researcher and then by a gynecologist on the pilot samples (20 participants). Afterwards, the findings were compared and their consistency was verified based on the total score of each outcome. The intraclass correlation coefficient

(ICC) value of agreement between the two evaluators was 0.96, which showed a high level of agreement between the two evaluators.

The REEDA scale is a tool used for measuring perineal healing following tear during labor, first by Davidson and then by Carey. 24, 25 This scale includes five items in the perineal healing process that include Redness, Edema, Ecchymosis, Discharge, and Approximation. Each item gets a scores between zero and three, and the total score is between zero to 15. Total higher score shows weaker perineal healing. This criterion was used to evaluate the improvement of perineal trauma after childbirth. The reliability of this criterion has been confirmed in the study of Alvarenga et al. (2015) by determining the agreement between the observers.<sup>26</sup> In Iran, reliability and validity of REEDA scale were confirmed by Pazandeh et al. To assess its reliability, they used the method of measuring among the observers. Reliability of REEDA scale was 0.89.27

In the present study, the reliability of the REEDA scale (agreement between the two evaluators) was 0.81 that was calculated by intraclass correlation coefficient (ICC) on the pilot samples. The result showed a high level of agreement between the two evaluators.

Primary outcomes of this study were perineal healing and pain relief of episiotomy after using the herbal cream. Secondary outcomes of this study were pain and irritation during urination and defecation, the number of pain relief pills consumption; that the observer asked the participants and recorded their responses in the questionnaire.

Side effects of cream such as irritation, itching, and infection were assessed by the observer through examination and recorded in the questionnaire as yes/no. If there was any side effect, we consulted with the gynecologist for discontinuing the intervention.

Aerial parts of the Malva Sylvestris were prepared from the local herbal market of Ahvaz city, Iran, and identified by one of the pharmacognosy specialists of the Medicinal Plants Research Center of Ahvaz Jundishapur University of Medical Sciences.

Extraction was performed by maceration with 70° ethanol solvent for 72 hours. The extract was then filtered using filter paper (Whatman no.1). The filtered solution was concentrated in a rotary apparatus (vacuum distillation) and dried under sterile conditions in a vacuum oven. The dried extract was collected in a dark container and stored in the refrigerator until the formulation was prepared. All the steps of preparing the products were performed under the lab hood and in the aseptic condition to reduce the chance of contamination. Formulation A consisted of 10% dried M. Sylvestris extract in Eucrine: cold cream (25:45) base, 0.020 g of methylparaben, and 0.18 g of propylparaben as a preservative.

Formulation B (placebo) included the base used in the cream without the extract. Purple food color was used in the placebo cream to maintain the blinding conditions. The products were filled and labeled in similar 30g tubes, and the tubes were differentiated using the codes unknown to participants and researchers.

In this study, to examine demographic variables, we used descriptive statistics including frequency distribution, and mean and standard deviation. Shapiro-Wilk test was used to evaluate the normality of the data. To compare the homogeneity of demographic characteristics between the study groups in baseline, we used independent T-test, Mann-Whitney, and Chi-square test. Also, the Generalized Estimating Equations (GEE) model was used to compare the average VAS score and REEDA at three time points. Because the response variables were repeated measures and were not normally distributed, GEE model was used. A p value less than 0.05 was considered as the significant level. SPSS software version 22 was used for data analysis.

Written and verbal consent was obtained from the individuals after we explained the aim of the study. Mothers were assured that they could withdraw from the study at any

time during the study without aftermaths. The researcher emphasized that all participants should report any adverse effect by telephone. Ethical approval for this study was obtained from the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (Ref. No: IR.AJUMS.REC.1398.137).

### **RESULTS**

The mean age of the participants was 26.8±9.3 years, and the mean gestational age was 39.01±1.17. Most of the participants were housewives with university education [15 (50.0%) versus 12 (40.0%)]. There were no statistical differences between the two groups. According to Mann-Whitney test, there was no difference between the two groups in the

variables of age, weight, gravidity, and parity (P>0.05). Based on the independent t-test results, there was no statistically significant difference in the length of the first, second and third stages of labor, rupture of membranes to birth, frequency of vaginal examinations, number of suture pocket, and lidocaine consumption (P>0.05). Some of the other demographic and obstetric characteristics are shown in Table 1. Also, the mean and standard deviation of the scores of VAS and REEDA variables are shown in Table 2 in three periods of time: days 1, 7, and 14.

The results of the GEE model in Table 3 show that the intervention has no statistically significant relationship with better wound healing. In other words, the results show that the mean score of REEDA is not statistically different in terms of the two

**Table 1:** Demographic and childbirth characteristics of the participants

	Placebo (N=30)	Intervention (N=30)	P value
	Mean±SD	Mean±SD	
	27.83±12.34	$25.77 \pm 6.26$	*0.76
Weight (kg)		70.86±14.51	*0.67
Gestational age (week)		$39.20 \pm 1.21$	**0.13
	3303.33±497.22	3348.33±422.93	**0.73
First dilatation (cm)		$3.86\pm2.20$	**0.93
Length between ROMa to delivery (min)		188.26±261.62	**0.80
Length of the first stage of labor (min)		$315.16\pm250.92$	**0.44
Length of the second stage of labor (min)		33.76±20.46	**0.42
Length of the third stage of labor (min)		$8.80 \pm 8.45$	**0.74
Number of vaginal exams		10.76±6.01	**0.16
Time for repair of episiotomy (min)		17.16±6.39	**0.38
Number of suture packets used		$1.83\pm0.53$	**0.15
Use of lidocaine (ml)		8.33±2.73	**0.86
	N (%)	N (%)	
1	15(50%)	12(40%)	***0.43
≥2	15(50%)	18(60%)	
1	14(46.70%)	7(23.30%)	***0.05
≥2	16(53.30%)	23(76.70%)	
Primary or Guidance school	9 (30%)	12 (40%)	***0.68
High school or diploma	6 (20%)	6 (20%)	
University	15 (50%)	12 (40%)	
House wife	28 (93.30%)	29 (96.70%)	***> 0.99
Employed	2 (6.70%)	1 (3.30%)	
Low	10 (33.30%)	8 (26.70%)	***0.57
Medium	20 (66.70%)	22 (73.30%)	
High	-	-	
	14 (46.70%)	16 (53.30%)	***0.60
Midwifery Student	8 (26.7%)	10 (33.3%)	***0.28
Midwife	22 (73.3%)	20 (66.7%)	
	Ma to delivery (min) age of labor (min) stage of labor (min) age of labor (min) age of labor (min) cams disiotomy (min) ckets used  1 ≥2 1 ≥2 Primary or Guidance school High school or diploma University House wife Employed Low Medium High  Midwifery Student	Mean±SD         27.83±12.34         76.53±27.16         38.83±1.14         3303.33±497.22         5.76±10.34         Ma to delivery (min)       167.66±196.08         age of labor (min)       279.00±245.61         stage of labor (min)       33.66±35.62         age of labor (min)       9.36±7.94         xams       8.63±4.43         isiotomy (min)       18.50±6.58         Ekets used       1.63±0.61         N (%)       1         1       15(50%)         ≥2       15(50%)         1       14(46.70%)         ≥2       16(53.30%)         Primary or Guidance school       9 (30%)         High school or diploma       6 (20%)         University       15 (50%)         House wife       28 (93.30%)         Employed       2 (6.70%)         Low       10 (33.30%)         Medium       20 (66.70%)         High       -         Midwifery Student       8 (26.7%)	Mean±SD         Mean±SD           27.83±12.34         25.77±6.26           76.53±27.16         70.86±14.51           38.83±1.14         39.20±1.21           3303.33±497.22         3348.33±422.93           5.76±10.34         3.86±2.20           A* to delivery (min)         167.66±196.08         188.26±261.62           age of labor (min)         279.00±245.61         315.16±250.92           stage of labor (min)         33.66±35.62         33.76±20.46           age of labor (min)         9.36±7.94         8.80±8.45           sams         8.63±4.43         10.76±6.01           sisiotomy (min)         18.50±6.58         17.16±6.39           skets used         1.63±0.61         1.83±0.53           8.66±3.45         8.33±2.73           N (%)         N (%)           1         15(50%)         12(40%)           ≥2         15(50%)         12(40%)           ≥2         16(53.30%)         23(76.70%)           Primary or Guidance school         9 (30%)         12 (40%)           High school or diploma         6 (20%)         6 (20%)           University         15 (50%)         12 (40%)           House wife         28 (93.30%)         29 (96.70%)

<sup>\*</sup> Mann-Whitney U test; \*\* Independent t-test; \*\*\* chi square test, a:rupture of membrane

 Table 2: Mean of Visual Analogue Scale and Redness, Oedema, Ecchymosis, Discharge, Approximation scale

variables in the intervention and placebo groups

Variable	Time	Group	Mean±SD	Minimum	Maximum
REEDA <sup>a</sup>	First day	Intervention	3.30±3.48	0	11
		Placebo	$3.27 \pm 3.84$	0	11
REEDA	Seventh day	Intervention	1.37±1.69	0	5
		Placebo	1.30±1.26	0	5
REEDA	Fourteenth day	Intervention	$0.03 \pm 0.18$	0	1
		Placebo	$0.30 \pm 0.65$	0	3
VAS <sup>b</sup>	First day	Intervention	5.27±2.03	2	10
		Placebo	$4.83\pm2.07$	1	10
VAS	Seventh day	Intervention	1.57±1.72	0	6
		Placebo	$1.43 \pm 1.04$	0	5
VAS	Fourteenth day	Intervention	0.13±0.35	0	1
		Placebo	$0.23 \pm 0.50$	0	2

a: Redness, Oedema, Ecchymosis, Discharge, Approximation; b: Visual Analogue Scale

**Table 3:** Results of Generalized Estimating Equations model in examining the trend of changes in variables of Redness, Oedema, Ecchymosis, Discharge, Approximation scale and Visual Analogue Scale in terms of group and time

Variable	Group/Time	В	SE	Wald Chi-Square	P value
REEDA <sup>a</sup>	Placebo (Baseline)	-	-	-	-
	Intervention	-0.05	0.42	0.01	0.89
	First day (Baseline)	-	-	-	-
	Seventh day	-1.95	0.34	31.92	< 0.001
	Fourteenth day	-3.11	0.45	46.12	< 0.001
VAS <sup>b</sup>	Placebo (Baseline)	-	-	-	-
	Intervention	0.15	0.27	0.32	0.56
	First day (Baseline)	-	-	-	-
	Seventh day	-3.55	0.23	237.72	< 0.001
	Fourteenth day	-4.86	0.25	356.85	< 0.001

<sup>&</sup>lt;sup>a</sup>: Redness, Oedema, Ecchymosis, Discharge, Approximation; <sup>b</sup>: Visual Analogue Scale

groups (intervention and placebo), and the intervention had no effect on the mean score of REEDA (P=0.89). However, the trend of changes in the mean REEDA score over time was significant and decreasing, which indicates wound healing over time.

Furthermore, the results showed that the intervention had no statistically significant relationship with pain reduction. In other words, the mean score of VAS according to the two groups under study (intervention and placebo), is not statistically different and the intervention had no effect on the mean score of VAS (P=0.56). However, the trend of changes in the mean VAS score over time has been significant and decreasing and the pain decreases over time (Table 3).

The results of shown in Table 4 also

showed that the intervention significantly reduces the chance of urinary irritation. In other words, the chance of urinary irritation in the intervention group decreased by 77% (P=0.01). However, the intervention did not have a statistically significant effect on the pain during defecation (P=0.19) and the number of analgesic pills taken (P=0.19). Also, this drug did not have any specific side effects on the intervention group, and there was no statistically significant difference between the placebo and intervention groups (P=0.32).

### DISCUSSION

The results of the present study did not show the usefulness of the extract of Malva Sylvestris on

Table 4: Results of Generalized Estimating Equations model in examining the trend of changes in secondary

outcomes in terms of group and time

Variable	Group/Time	В	SE	Wald Chi-Square	OR	P value
	Placebo (Baseline)	-	_	=	-	-
Urinary Irritation	Intervention	-1.47	0.59	6.02	0.23	0.01
	First day (Baseline)	-	-	-	-	-
	Seventh day	-3.53	0.54	42.63	0.02	< 0.001
	Fourteenth day	-5.57	0.81	46.86	0.004	< 0.001
Defecation Pain	Placebo (Baseline)	-	-	-	-	-
	Intervention	-0.70	0.54	1.69	0.49	0.19
	First day (Baseline)	-	-	-	-	-
	Seventh day	-1.51	0.41	13.77	0.22	< 0.001
	Fourteenth day	-3.58	1.00	12.90	0.02	< 0.001
Number of	Placebo (Baseline)	-	-	-	-	-
analgesic pills	Intervention	-0.12	0.09	1.66	-	0.19
taken	First day (Baseline)	-	-	-	-	-
	Seventh day	-1.35	0.13	99.93	-	< 0.001
	Fourteenth day	-1.70	0.11	223.26	-	< 0.001
Cream Side	Placebo (Baseline)	-	-	-	-	-
Effect	Intervention	0.92	0.92	1.00	2.50	0.32
	First day (Baseline)	-	-	-	-	-
	Seventh day	0.31	0.54	0.33	1.36	0.56
	Fourteenth day	0.00	0.87	0.00	1.00	>0.99

wound healing and pain score of episiotomy of postpartum mothers. After the intervention, the mean score of pain and wound healing did not significantly differ from that of the placebo group.

In line with the results of the present study, a study investigated the effect of Malva Sylvestris L. on treating the palatal mucosal ulcers in rats. The result showed that Malva Sylvestris L. extract could not improve the wound healing of the palatal mucosa.<sup>28</sup>

However, laboratory studies have proven the anti-inflammatory activity of Malva Sylvestris and attributed this effect to the presence of malvidin 3-glucoside in the leaves of this plant. The antibacterial and antiviral activity of this plant has been observed against many pathogens.<sup>29, 30</sup> Also, in animal studies, this plant, due to its hydroalcoholic extract, has increased the rate of skin wound contraction and reduced the duration of the healing process; moreover, due to its collagen, it increased the ability of wound edges to join each other.<sup>29, 31</sup> In wounds of diabetic mice, the extract of this plant had a positive effect on the healing of diabetic wounds as an anti-inflammatory-antimicrobial dressing.31 However, the present study did not reveal any significant effect of this cream on wound healing and reducing maternal pain. In order to justify the lack of effect of Malva in the present study compared to rat studies, it is possible to point out the type of wound. In animal studies, the effect of Malva on open wounds has been investigated, while in the present study, the effect of Malva after wound closure was assessed.

Overall, the organized wound healing stages included four processes: homeostasis, inflammation, proliferation, and maturation.<sup>15</sup> Clinical studies have shown that adequate moisture in wound sites accelerates re-epithelialization.<sup>32, 33</sup> On the other hand, excessive fluid in the wound bed can disrupt the wound healing process and make it chronic. Excess moisture penetrates the skin around the wound and causes maceration in the tissue around the wound. If the fluid is not controlled, wound healing is impaired, which leads to an increase in the wound size and intensification of pain.34 Therefore, the fluid level in wounds should be carefully balanced to prevent the accumulation of excessive moisture (in which maceration occurs and leads to tissue damage) or excessive dryness

(which delays the epithelialization process and slows down the healing process).<sup>35</sup>

On the other hand, wound fluid contains endogenous protein-degrading enzymes that are irritating and damage the intact skin.<sup>36</sup> Since Malva is a hydrophilic plant and causes the heat of tissue nanofibers to increase at the wound surface,<sup>31</sup> the presence of excess moisture in this area may be effective in causing moisture-associated skin damage.

Furthermore, the relationship between wound healing and pain is well known. The faster the wound heals, the faster the pain heals.<sup>37</sup> In the present study, Malva did not affect the severity of pain or the duration of pain at the episiotomy site, which is due to the lack of effect of this cream on the healing of the wound in this area. However, consistent with the present results, a previous study showed that Malva could not have clear analgesic effects in the acute phase of inflammation, but it was effective in reducing pain in the chronic phase of inflammation.<sup>38</sup>

In the current study, there was no infection or wound opening in the episiotomy site in both groups. Also, the dysuria rate in the intervention group were statistically lower than the placebo group. In this regard, the result of one study showed that Malva could reduce urinary irritation after radiotherapy.<sup>39</sup> The results of another study listed one of the effects of the aqueous or hydroalcoholic extract of Malva Sylvestris on the skin, increasing the elasticity or structural integrity of the skin, and the tissue of the urogenital system, which can reduce the burning sensation during urination. This is consistent with the results of the present study.<sup>40</sup>

Also, in the present study, there were no side effects in the groups. In this regard, another research that used the Malva for prevention of proctitis in patients with prostate cancer showed no severe side effect.<sup>41</sup>

The limitation of this study was that only the aerial parts of the Malva sylvestris were used to make this cream. Adding the leaf extract of Malva Sylvestris might affect its medicinal properties. However, the present study, in to

the best of our knowledgeable, is the first study on the effect of Malva Sylvestris on episiotomy pain and healing. Randomized allocation and the use of a placebo group for reducing the risk of bias are the other strengths of this study.

### Conclusion

According to the findings of this study, Malva Sylvestris is not effective in episiotomy wound healing and reducing the perineal pain in postpartum women. Given that this study was the first clinical study of the effect of this herbal medicine on the wounds of the vagina and perineum, and probably due to the very humid and hot environment in this area, this cream did not have a positive effect on wound healing or mean pain score in women who had undergone episiotomies. Other studies are recommended to confirm the findings of this study.

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