

## Comparison of the Effects of Purslane and Alcea Ointment on Episiotomy Wound Pain and Healing: A Clinical Trial Study

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### **ABSTRACT:**

**Introduction:** Perineal pain can reduce the mother's quality of life and change the mother's attitude towards her baby. Delayed wound healing can lead to poor anatomical outcomes, increase the risk of infection, reduce breastfeeding success, and ultimately lead to serious complications and even death. The goal of the study was to investigate the effects of topical purslane and hollyhock on episiotomy wound. **Methods:** This is a three-group randomized controlled clinical trial conducted on 90 women. The samples were allocated by simple random sampling method (drawing lots) in three groups (purslane, hollyhock, placebo). After teaching people how to wash and dry the perineal area, the intervention was carried out using 2% purslane ointment and 2% hollyhock ointment in the experimental group, and mothers were asked to apply an FTU of the ointment on the stitched area once a day. A total of 2% vitamin A ointment was used in the relevant part of the placebo group. All three groups received the intervention at baseline, on days 5 and 10 after delivery. Pain intensity and wound healing were recorded at baseline, on days 5 and 10 after delivery. Data analysis was carried out using one-way analysis of variance (ANOVA), Kruskal-Wallis and chi-square tests in SPSS ver. 16 and P-value<0.05 was considered as the significance level. **Results:** The mean age of the participants was 23.44±2.15 years. There was no significant difference between the groups in terms of pain intensity (p=0.26) and wound healing 24 hours after the intervention (p=0.20), but there was a significant difference between them 5 days for pain intensity (p=0.001) and wound healing (p=0.38) and 10 days for pain intensity (p=0.001) and wound healing (p=0.003) after the intervention. The pain intensity was lower (p<0.001) and wound healing was better (p=0.003) in the purslane and hollyhock groups than the placebo group. **Conclusion:** Purslane and hollyhock ointments are effective on pain intensity and wound healing and reduce the consumption of oral painkillers.

**Keywords:** purslane ointment, hollyhock ointment, episiotomy, pain, wound

### **INTRODUCTION:**

Episiotomy is a surgical incision that is made by the treatment team during the vaginal opening and perineum in the second stage of labour to facilitate childbirth. [1] The prevalence of episiotomy varies across countries [3], with 60% reported in Jordan (4) and 85% in Australia (5). An episiotomy may lead to perineal pain (7).

Perineal pain can reduce the mother's quality of life and change the mother's attitude towards her baby (10). There are various methods to reduce pain intensity and improve wound healing, including cold compresses (12), acupuncture (13), laser therapy (14), lavender scent (15), pelvic floor muscle exercises, epidural anaesthesia, as well as taking drugs such as acetaminophen, mefenamic

acid, diclofenac sodium suppositories (16). However, many drugs that are used for this purpose, especially narcotics and nonsteroidal anti-inflammatory drugs (NSAIDs), are associated with side effects such as nausea, itching, and gastrointestinal bleeding (17, 18). Herbal products are one of the most basic methods of treating diseases and relieving pain (19). Purslane is one of the well-known herbs in traditional medicine. The leaves and seeds of this herb are used to prepare food, and its poultice is used locally to relieve pain and inflammation (19). Purslane (*Portulaca oleracea*) has anti-inflammatory, analgesic, antiseptic, antifungal and bacteriostatic effects and accelerates wound healing by increasing collagen synthesis and angiogenesis (17, 20). Purslane exerts its analgesic effect through the opioid pathway and postsynaptic adrenoceptors (19). Various studies have reported its functions.[19,21-24] Furthermore, hollyhock is also recommended to relieve pain and treat swelling, especially in the genital area. Local use of hollyhock roots, which belong to the Malvaceae family and are often known as hollyhock, is recommended for the treatment of redness of the suprapubic area and breasts (27). Considering the high prevalence of episiotomy pain and absence of any treatment, the goal of this study was to investigate the effects of topical purslane and hollyhock on episiotomy wound.

## **METHODS:**

### **Design, participants and data collection:**

This is a randomized controlled clinical trial and its study population includes all women admitted to a tertiary center. The protocol was approved by the institutional research council (IR.GMU.REC.1398.065) and registered in the Iranian Registry of Clinical Trials (IRCT20190315043059N2).

Inclusion criteria included term pregnancy (37-42 weeks), singleton pregnancy, age 18-35 years, primiparous, and consent to participate in the study. Exclusion criteria included special diet, special disease (anaemia, cardiovascular, autoimmune, and liver diseases, diabetes, depression), smoking, alcohol consumption, drug use, Body mass index (BMI)  $\text{kg/m}^2 < 29$ , hematoma, infection, failure to progress during labour and delivery (prolongation of the stages of childbirth and dystocia), the need for neonatal resuscitation, extension of episiotomy, excessive bleeding after delivery, use of vacuum and re-manipulation of the perineum.

The sample size was calculated as 26 people for each group using G-power software, taking into account a 95% confidence interval the rest power=80% and the effect size=0.8, which was obtained based on the related study. Then, eligible people were selected from the research population by simple random sampling

(drawing samples from the lots stored in the bins). Necessary information, as well as information sheets (containing health recommendations, type of nutrition, researcher's phone number, fifth and tenth-day follow-up reminder, referral location and a table marking the days of medication use), was provided to the mothers through face-to-face training. To blind the samples and the researchers, the ointments were presented in containers with the same colour and shape.

To prepare the ointment, purslane and hollyhock herbs were collected from the fields around Mashhad and their identity was confirmed by the herbarium of the Mashhad Faculty of Pharmacy. After being cleaned and washed, the aerial parts of both herbs were placed in a dryer at a temperature of 40°C for two days. A total of 300 grams of ground purslane powder was poured into a cartouche and extracted with 70% alcohol by soaking. After removing the solvent, the concentrated extract was prepared in the Pharmacology Laboratory of the Faculty of Medicine. A total of 1 gram of concentrated extract was obtained from every 10 grams of herb powder. The purslane ointment (2%) was prepared from the combination of a specified amount of purslane extract and cold cream (USP). The above steps have also been performed for the hollyhock herb. To start the intervention, 2% purslane, 2% hollyhock and 2% vitamin A(as placebo) ointments were used for the intervention and placebo groups. Mothers of both groups were asked to put ointment (one fingertip unit (FTU)) on the stitched area once a day after washing and drying the perineum. The episiotomy healing rate was measured using the healing control form Redness, Oedema, Ecchymosis, Discharge, Approximation (REEDA Scale) in five parts including oedema, redness, approximation, discharge, and ecchymosis. Each option is assigned a score from 0 to 3 and the total score of the options is 0 to 15. The lower scores show a higher healing rate. This is an international scale and its validity and reliability have been confirmed in several articles (28). It was carried out within 24 hours after delivery. Then, the researcher reminded them how to take the medicine, when to return to the clinic on days 5 and 10 after delivery and to bring the medicine registration sheet during a phone call. On days 5 and 10, the rate of wound healing was again measured and recorded.

The pain intensity was also measured using a visual analogue scale (VAS). A 10-cm rule is used where 0, 1-3, 4-7 and 8-10 indicate no pain, mild pain, moderate pain and severe pain, respectively. The pain intensity was determined before delivery, 24 hours after delivery, and on days 5 and 10 after delivery. To determine the pain score using VAS, the researcher placed a ruler in front of the mother and asked her to mark her pain intensity. The number 10 is the most severe pain and 0 is the least pain. The distance between the onset of no pain

and this point marked by the patient was measured and recorded by the researcher. (Figure 1)

The collected data was entered into SPSS software. Then, the normality of the distribution of the variables was checked using the Kolmogorov-Smirnov test, and according to the results, parametric and non-parametric

statistical tests were used. Data analysis was carried out using chi-square, t-test, Mann-Whitney, and repeated measurement ANOVA tests in SPSS ver. 16 software. Besides, all necessary ethical considerations have been taken into consideration in the present study.

## RESULTS:

In the present research, 90 patients were analyzed. The results showed that the mean age of the participants was  $23.44 \pm 2.15$  years (Table 1).

**Table 1: Demographic characteristics of participants**

<b>Groups</b> <b>Variables</b>	Purslane	Hollyhock	Placebo	P value
Age (year)	22.87±2.47	23.83 ± 1.95	23.63 ± 1.96	<b>P=0.18</b>
Temperature (°C)	36.10±0.20	37.50 ± 0.10	37.60 ± 0.24	P=0.20
Systolic blood pressure (mmHg)	113.10±67.74	112.7±33.63	114.8 ± 17.52	P=0.72
Diastolic blood pressure(mmhg)	71.6 ±33.42	70.5 ±33.86	73.7 ± 67.06	P=0.12
Hemoglobin (g/dl)	12.1 ± 33.09	12.1 ± 23.19	12.1 ±17.02	P=0.84
Child rank	0.2 ± 40.93	0.2 ± 33.96	0.2 ± 10.80	P=0.40
BMI (kg/m2)	25.1 ± 04.63	24.1 ± 71.90	25.1 ±0.67	P=0.40
Gestational age(week)	38.1 ± 43.30	38.1 ± 23.10	38.1 ± 37.19	P=0.87
Birth weight (kg)	3.3± 12	3.3± 21.65	3.3± 22.13	P=0.42
Head circumference (cm)	33± 87.82	33.1 ± 97	34 ± 13.73	P=0.40
Length of hospital stay (day)	12.2 ± 63.57	13.2 ± 0.51	13.3 ± 97.10	P=0.15
Duration of the first stage of labour (hour)	7.2 ± 63.51	8.2 ± 61.54	8.2 ± 23.52	P=0.32
Duration of the second stage of labour (hour)	36.11 ± 98.33	37.11 ± 65.24	37.11 ± 65.24	P=0.32
Duration of the third stage of labour (hour)	10.3 ± 58.66	11.2 ± 31.73	9.4 ± 56.13	P=0.32
Baseline pain intensity (score)	3.1 ± 79.06	3.98 ± 0.78	4.1 ± 20.04	p=0.26

**Table 2: Comparison of the mean pain severity and wound healing on days 5 and 10 after the intervention in three groups**

<b>Groups</b>	Purslane	Hollyhock	Placebo	P value
<b>Variables</b>				
Pain level 5 days after the intervention	2.47±0.67	3.29±0.64	4.13±1.02	<b>P=0.01</b>
Pain level 10 days after the intervention	1.38±0.41	2.34±0.50	3.41±0.86	<b>P=0.01</b>
Wound healing 5 days after the intervention	1.93±0.94	2.13±1.00	2.53±0.81	p=0.038
Wound healing 10 days after the intervention	1.33±0.71	1.23±0.56	1.76±0.62	p=0.003

**Table 3. Repeated Measures ANOVA for T1, T2, and T3 for pain severity**

<b>Groups</b>	<b>Pain severity</b>			<b>P value</b>
	<b>Tests</b>	<b>Mean</b>	<b>Se</b>	
Purslane	T1 T2	0.694*	0.040	0.001
	T1 T3	1.616*	0.065	0.001
	T2 T3	0.921*	0.42	0.001
Hollyhock	T1 T2	0.656*	0.087	0.001
	T1 T3	1.451*	0.27	0.001
	T2 T3	0.876*	0.024	0.001
Placebo	T1 T2	0.651*	0.075	0.1
	T1 T3	0.657*	0.48	0.1
	T2 T3	0.751*	0.067	0.1

\* The mean difference is significant at the .05 level.

The results showed a significant difference between the three groups in terms of pain on days 5 and 10 after the intervention (p<0.001). The results also revealed a significant difference between the three groups in terms of wound healing on day-5 (p=0.038) and -10 (p=0.003) after the intervention (Table 2).

Repeated measures ANOVA showed that the baseline pain intensity did not differ in the three groups, but there

was a significant difference between the groups after the intervention in this regard (Table 3). Tukey's post-hoc test showed that the difference is significant difference between three groups in terms of pain reduction. The results also showed that both purslane and hollyhock are significantly different from the placebo, and purslane is significantly better (Table 3). Also, the pain intensity in

all three groups was significantly different over time  $p=0.001$  (Table 3).

The results also showed a significant difference between the three groups in terms of the average wound size ( $p=0.017$ ). Pairwise comparisons showed that the average wound size in the hollyhock extract group was 0.36 cm less than the placebo group ( $p=0.048$ ). The average wound size in the purslane extract group was also 0.31 cm less than the placebo group, although this difference was not significant ( $p=0.089$ ). The baseline wound size was small in all three groups. But the average wound size on days 5 and 10 after delivery was 1.44 cm, and 0.69 larger than the baseline size, respectively ( $p < 0.001$ ). The average wound size in the second measurement was 0.76 higher than the third measurement  $p < 0.001$ . (Figure 2)

## **DISCUSSION:**

Purslane ointment was found to be effective on pain and episiotomy wound healing. The results of the present study showed that the average baseline pain score was  $4.20 \pm 1.04$  and  $3.79 \pm 1.06$  in the placebo and the purslane groups, respectively. Furthermore, the average VAS on day 5 after the intervention was  $4.13 \pm 1.02$  and  $2.47 \pm 0.67$  ( $p=...?$ ) in the placebo and purslane groups, respectively, and on day 10 after the intervention was  $3.41 \pm 0.86$  and  $1.38 \pm 0.41$ , respectively. Various studies have determined the effect of purslane on pain. In a study on the effects of purslane and mefenamic acid capsules on menstrual menorrhagia, purslane and mefenamic acid capsules reduce menorrhagia and the subsequent pain (32), which is consistent with the results of the present study. Also, similar results were obtained in other studies. Another study showed that aloe vera gel and purslane cream, Calendite-E Cream and curcumin can have beneficial effects in improving nipples (37), which was consistent with the results of the present study.

The results of the present study showed that the average baseline VAS was  $4.20 \pm 1.04$  and  $3.98 \pm 0.78$  in the placebo and hollyhock groups, respectively. Also, the average pain scores on (day-5) and (day-10) after the intervention in the placebo and hollyhock groups were  $4.13 \pm 1.02$  (day-5),  $3.29 \pm 0.64$  (day-10), and  $3.41 \pm 0.86$  (day-5),  $2.34 \pm 0.50$  (day-10), respectively, which indicates the average moderate to low pain score in the intervention group. Various studies have determined the effect of alcea on the pain intensity. [34,35] Furthermore, a study showed that the mucositis severity and the average oral pain in the hollyhock was lower than the control group (38).

Regarding the effect of purslane ointment on episiotomy wound healing in each of the intervention and placebo groups, the results of the present study showed that the average baseline wound healing score in the placebo and

purslane groups was  $0.76 \pm 0.72$ , and  $0.86 \pm 0.77$ , respectively. The average wound healing scores on days 5 and 10 days after the intervention in the placebo and purslane groups were  $2.53 \pm 0.81$ ,  $1.93 \pm 0.94$  and  $1.76 \pm 0.62$ ,  $1.33 \pm 0.71$ , respectively, which indicates the average moderate to low score for wound healing in the intervention group. In a comparative study of the treatment of breast fissure with purslane cream and lanolin on the level of breastfeeding self-efficacy compared to lanolin, purslane cream accelerates the healing process of breast fissure and then increases the breastfeeding self-efficacy score (36).

Regarding the effect of the hollyhock ointment on episiotomy wound healing in each of the intervention and placebo groups, the results of the study showed that the average baseline wound healing score in the placebo and hollyhock groups was  $0.76 \pm 0.72$ , and  $0.63 \pm 0.66$ , respectively. Also, the same score on days 5 and 10 after the intervention in the placebo and hollyhock groups was  $2.53 \pm 0.81$ ,  $2.13 \pm 1$  and  $1.76 \pm 0.62$ ,  $1.23 \pm 0.56$ , respectively, which indicates the average moderate to low wound healing score and better wound healing in the intervention group. The results also showed that hollyhock has a significant effect on wound healing. There have been various studies on the effect of hollyhock on wound healing. A study of the sexual performance of postmenopausal women found that hollyhock has a beneficial effect on the sexual performance of postmenopausal women (26).

Unlike drug treatments, complementary treatments possess economical advantage, without any serious complications and drug interactions in most cases. Moreover, they are simple to perform and are well accepted by the patient.

The most important limitation of the study was the low sample size of study. Another limitation was that it was only performed in one center, which cannot generalize the results.

## **CONCLUSION:**

The results of the present study showed that purslane ointment outperformed hollyhock in improving pain intensity, and also that hollyhock ointment outperformed purslane ointment in improving wound healing. The use of complementary treatments such as purslane and hollyhock ointments is part of the professional goals of nurses.

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