

Research Article

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The effect of portulaca oleracea capsules on hemorrhage volume and postpartum pain: Clinical trial study

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Keywords: postpartum hemorrhage; postpartum pain; portulaca oleracea; alternative medicine.**Abstract**

Background: Postpartum affects the well-being of mothers. Examining the approaches that could reduce the maternal side effects such as pain and bleeding, are among the top research priorities in midwifery. The present research aims to determine the effects of Portulaca Oleracea capsules on hemorrhage volume and postpartum pain.

Methods: The double-blind clinical trial- after receiving permission from the Ethics Committee- targeted 106 women. The qualified mothers were classified into two groups using Sealed Envelope sample size. In both groups after taking Mefenamic acid as a routine treatment, the interventions were done. One group took Portulaca Oleracea capsules and the other group received placebo drugs that were similar in smell, color, and taste. In the interventional group, Portulaca Oleracea capsules were prescribed two times a day in the twelve-hour interval, after taking Mefenamic acid. In the control group, the placebo capsules were prescribed at the same intervals. To measure the amount of hemorrhage after delivery, pads were used after each intervention to determine differences in pads weighed. The IBM SPSS for Windows, version 16 was used for statistical analysis. Data analyzed by descriptive and analytic statistics Mann Whitney tests, and Generalized Estimating Equation (GEE). The level of significance was considered 0.05.

Results: The average rate of pain intensity after the first intervention in the interventional group was 4.82 ± 1.11 and in the placebo group was 5.22 ± 1.09 ($p=0.037$). After the second intervention was 3.74 ± 0.91 in the intervention group and 4.79 ± 0.97 in the placebo group ($p<0.001$). The average hemorrhage volume after the second intervention was 28.33 ± 6.67 in the interventional group and 35.96 ± 7.59 ($p<0.001$) in the placebo group.

Conclusion: Portulaca Oleracea capsules were effective in reducing the amount of postpartum pain and hemorrhage and can be used as herbal medicine to decrease postpartum pain and hemorrhage.

Introduction

Postpartum hemorrhage is one of the important causes of mortality in mothers all over the world [13]. In 529000 pregnancies, 25-30% are linked to postpartum hemorrhage [8]. Hemorrhage is the cause of more than 17% of 4200 maternal mortalities in the U.S. and developed countries [16]. Losing 500 ccs of blood or more after the delivery is considered postpartum hemorrhage [14]. If the bleeding is in the first 24 hours after delivery it is early bleeding. Bleeding after 24 hours to 6 weeks is late bleeding [5]. After delivery, the uterus is contracted by massaging and injecting the uterotonic drugs [24]. Pains usually last 2-3 days after labor. The maximum pain occurs on the first day of labor and is reduced gradually [6]. To reduce post-pain, non-pharmaceutical methods including supporting actions - abdominal and uterine massage, homeopathy are utilized. Furthermore, chemical anti-inflammatory and oxytocin drugs are used to relieve pain and hemorrhage [10]. Chemical hemorrhage drugs have side effects, namely nausea, vomit, diarrhea, arrhythmia, hypotension, stomach ache, gastrointestinal bleeding, confusion, vertigo, dizziness, drowsiness, convulsion, and deep coma, which increases the interest in herbal medicine [12]. The effect of herbal medicine such as fennel, ginger, and dill seed has been studied in the reduction of hemorrhage and postpartum pain.

Portulaca Oleracea is a traditional medicine used since a long time ago [25]. Portulaca Oleracea (Latin: porortulaca Oleracea) is in the Portulacaceae family. It is also known as bakhleh, farfakh, and china in Persian and Arabic [22]. Since a long time ago, Egyptian and English physicians used it to treat headaches, earache, menstruation, immune system problems, muscular pain, rheumatoid arthritis, coughs, UTI, bladder stones, urinary retention, and fever. It has anti-pain, anti-oxidant, and anti-anxiety benefits and is also used for psychological disorders such as schizophrenia [11]. So far, there has not been a report on the toxicity of Portulaca Oleracea [2].

Effective materials are omega3, omega6, exilic acid, oxalic acid, kinamic acid, maleic acid, alpha-linolenic acid, linoleic acid, and gamma-linoleic acid. Omega3 participates in the cell membrane, cyclooxygenase 2, and lipoxigenase 5 paths and leads to stopping production of thromboxane and prostaglandin series 2 and locotrienes series 4. Instead, cause the production of thromboxane and prostaglandin series 3 via cyclooxygenase 2 and locotrienes 5. Also reduce the perceived pain by increasing the threshold of neurons and [15]. Omega 6 fatty acids change into semi-hormonal materials of prostaglandin, thromboxane, and prostacyclin. It could curb hemorrhage by anti-inflammatory reactions. Omega 6 enhances red cell adhesion and causes blood clots [19]. 10% ethanol extract of Portulaca Oleracea (with a dosage of 400 mg per kg in rat) affects the opioid receptors in the central and environmental nerve system [20].

Mirzaei N [17] found that the Portulaca Oleracea capsules which were prescribed with an interval of 8 hours for three days were effective in curing menorrhagia and have anti-inflammatory and anti-prostaglandin effects. Regarding the high prevalence of postpartum pain and hemorrhage, side effects of non-steroidal anti-inflammatory drugs, and lack of sufficient studies about Portulaca Oleracea effects on postpartum pain and hemorrhage, the present study was done by revealing the effects of

the Portulaca Oleracea capsules on bleeding volume and intensity of postpartum pain.

Methods

Trials

The clinical trial double-blind study was conducted after registration in Iran clinical trial website (No. IRCT 201804280394554) and receiving the ethics code IR.IUMS.FMD.REC1396.9411373009. After approval permission from the Iran University of Medical Sciences and Shahid Akbar Abadi Hospital, sampling started in April 2018 until late Nov 2018. 106 pregnant women, who were fully aware of the intervention process and the sign was written consent, and giving natural birth in Shahid Akbari Educational Center were classified into two simple random groups A and B using Sealed Envelope sample size.

Participants

Inclusion criteria were vaginal delivery, Single pregnancy, nulliparous, postpartum normal bleeding, postpartum pain according to VAS (4-7 average pain and 8-10 severe pain), ability to use oral medication, no record of physical and psychological disease, no allergy to herbal medicine, BMI under 35, non-smokers and no need to postpartum surgery. Exclusion criteria were surgery or taking anesthesia after delivery, medicinal side effects, or needing the stronger drug than typical drugs during the investigation.

Sample size

The sample size considering $\alpha = 0.05$ and $\beta = 0.2$ and probably of 10% sample loss were calculated 106 members which divided to two 53 members.

Intervention

Both groups received capsules, 30 minutes after taking Mefenamic acid. Visual Analog Scale (VAS) was measured after every intervention. The bleeding volume was measured after each intervention by placing the pads on a digital scale (an error rate of 1 gram).

Portulaca Oleracea 500 mg approved by Food and Drug Organization and registration number of 2668 and code IRC: 9466292276785580. It is prescribed twice a day in the interventional group, half an hour after taking Mefenamic acid with an interval of 12 hours. In the control group, the placebo capsules which were similar to Portulaca Oleracea in shape, color, and smell prescribed twice a day half an hour after taking Mefenamic acid. The intensity of postpartum pain was measured by a pain rating scale ranging from 0 to 10 (4-7 average pain and 8-10 intense pain) according to the visual analog scale. After each intervention, patients were asked to rate the pain, the intensity of the pain was measured using a pain rating scale. To measure the hemorrhage after every immediate intervention, the pads were weighed using a digital scale. Finally, the amount of increase in the weight of the pad, which is, the amount of hemorrhage, was recorded. Before urinating, the patient received a uterine massage and the tampon was inserted in the patient's vagina gradually. After taking it out, it was weighed by the digital scale to determine bleeding during the urine.

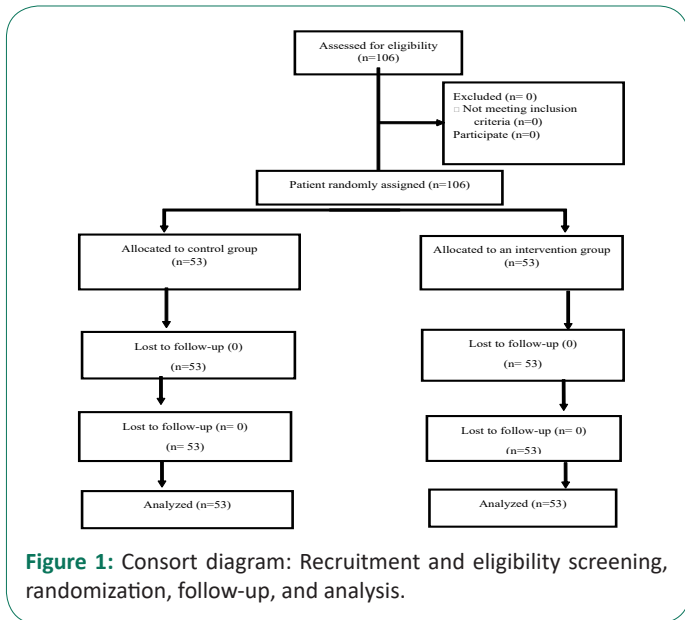


Figure 1: Consort diagram: Recruitment and eligibility screening, randomization, follow-up, and analysis.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta} \right) (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

$$n = \frac{4.5(19.55^2 + 14.37^2)}{(120 - 105)^2} = 53$$

Instruments

1) Demographic information was asked before the intervention, by using self-reports and mothers' medical records. This form includes questions related to age, weight, education, occupation, husbands' education, and occupation, records of using herbal medicine, exercise during pregnancy, episiotomy, and neonate gender and weight.

2) The intensity of pain measured following every intervention by using VAS. The validity of a visual pain questionnaire was confirmed by Gharloghi et al. (2013) and Chihan et al. (2013) (Chia, CF et al. 2013). The reliability was confirmed with a Cronbach alpha of 0.862 (Gharloghi et al., 2013).

3) To measure the hemorrhage volume pads were weighted. One gram increase in the weight of the pad was regarded as one cc of blood.

Statistical methods

Chi 2, Shapiro-Wilk test, U Mann Whitney, and Generalized Estimating Equations (GEE) SPSS version 16 were applied to the analysis. $p < 0.05$ was considered statistically significant.

Results

Data analysis was done on all 106 participants. Two groups were homogenous regarding all demographic variables had no significant differences (Table 1). Hemorrhage (normal postpartum hemorrhage ≥ 500 ccs) and postpartum pain (based on VAS ranging from 4-7 –average pain– and 8-10– intense pain) were homogenous in both groups. Among demographic variables, except mother's age and weight, the rest of the variables were not normal (Shapiro-Wilk tests). U Mann Whitney test indicates, there is a statistical difference ($p < 0.05$) between the intervention and the placebo groups. Generalized Estimating Equation (GEE) was utilized to find the amount of drug effects and demographic variables on the samples. Average pain inten-

sity before and after each intervention showed in Table 2 which had significant results except before the first intervention. The difference between pain intensity before and after the intervention was taken to determine the effects of the drugs on pain intensity (Table 3).

Table 4 indicates the average hemorrhage volume in the intervention group was noticeably lower than the placebo group. Average hemorrhage volume after the first and the second interventions in the intervention group and the placebo group was significant ($p < 0.001$). GEE model represents the effect of various factors. In all surveyed variables only the intervention group and the duration of intervention were affected pain intensity and hemorrhage volume (Table 5).

Table 1: Demographics characteristics of the intervention and the control groups.

P-value	Intervention group Mean \pm SD		Placebo group Mean \pm SD		Demographics characteristics	
0.423	25.5 \pm 6.63		52.27 \pm 6.53		Mother's age	
0.100	72.52 \pm 14.39		76.72 \pm 14.15		Mother's weight	
P-value	Intervention		Placebo			
	%	N	%	N		
0.31	39.6	21	30.2	16	Girl neonate	
	60.4	32	69.8	37	Boyneonate	
0.946	81.1	43	90.6	48	Yes	Episiotomy
	18.9	10	9.4	5	No	
0.367	24.5	13	20.9	11	2.5~3 Kg	Neo-nate's weight
	73.6	39	75.5	40	3~4 Kg	
	1.9	1	3.6	2	>4 Kg	

Table 2: Comparing average intensity postpartum pain in the intervention and the control groups.

Intensity postpartum pain	Intervention	Placebo	P-value
Before the first intervention	5.88 \pm 1.51	5.82 \pm 1.4	0.559
After the first intervention	4.82 \pm 1.11	5.22 \pm 1.09	0.037
Before the second intervention	4.92 \pm 1.13	5.11 \pm 1.08	0.001
After the second intervention	3.74 \pm 0.91	4.70 \pm 0.97	0.001

Table 3: Comparing mean differences in pain intensity before and after each intervention in both intervention and placebo groups.

P-value	Intervention	Placebo	The Difference in pain intensity before and after each intervention
$P < 0/001$	1/04 \pm 0/69	0/59 \pm 0/55	The first intervention
$P < 0.001$	1/17 \pm 0/62	0/35 \pm 0/46	The second intervention

Table 4: Comparing average hemorrhage volume in the intervention and the control groups.

Hemorrhage volume	Intervention	Placebo	P – value
The first intervention	78.79 ± 18.47	112.92 ± 25.07	P <0.001
The second intervention	28.33 ± 6.67	35.96 ± 7.59	P<0.001

Table 5: GEE test results on pain intensity and Hemorrhage volume.

Model	Variable	Rate	P-value	Error	B
Pain intensity	Group	Intervention	<0.001	0.011	679/0-
		Placebo	considered as base		
	Time	Primary intervention	<0.001	0.07	053/
		Secondary intervention	considered as base		
Hemorrhage volume	Group	intervention	<0.001	2.14	-21/51
		Placebo	considered as base		
	Time	Primary intervention	<0.001	2.65	63.83
		Secondary intervention	considered as base		

Discussion

Considering the importance of postpartum hemorrhage in the prevention of maternal mortality, the present study aims to clarify the effect of the *Portulaca Oleracea* capsules on hemorrhage volume and postpartum pain. There was a significant statistical difference between the average postpartum pain and hemorrhage volume in interventional and placebo groups. As a result, taking the *Portulaca Oleracea* capsules in postpartum was effective in reducing postpartum pain and hemorrhage volume.

U Mann Whitney test showed, decreased average pain intensity ($P=0.014$, $P<0.001$) and hemorrhage volume ($P<0.001$, $P<0.001$) after both interventions in comparison to the placebos. Due to the effects of *Portulaca Oleracea* on the cell membrane, production of PG2 inhibits and pain perception is reduced in patients [15]. The pain threshold had a significant increase after injection of average and high dosage of *Portulaca Oleracea*, in Syrian mice compared to the control group ($p<0.005$ and $p<0.009$) [1], which is in line with the findings of the present study. Rao's study about the anti-pain effects of *Portulaca Oleracea* on arthritis concludes that the presence of compounds such as flavonoid, tannin, and saponin in *Portulaca Oleracea* is the reason for pain relief [21]. Furthermore, *Portulaca Oleracea* is known as a harmless plant and it was confirmed that *Portulaca Oleracea* extract up to 2 g/kg is not toxic. The palliative, anti-inflammatory, and anti-pain effects of *Portulaca Oleracea* are a result of α -Tocopherol and antioxidant [7,18]. Compared effects of *Portulaca Oleracea* creams and lanolin on nipple fissure. The results verify the effects of *Portulaca Oleracea* cream on reducing nipple fissure pain was better than lanolin. Regarding the anti-pain effectiveness of *Portulaca Oleracea*, it is consonant with the present study.

Omega 6 by converting to prostaglandin, thromboxane, and prostacyclin increases anti-inflammatory reactions and enhances red cell adhesion which makes blood clots and stops the hemorrhage. The mechanism for reducing hemorrhage of *Portulaca Oleracea* is regarded as omega6. The average hemorrhage at 12 and 24 hours after labor in *Portulaca Oleracea* and placebo groups had a significant decrease ($p<0.001$ and $p<0.001$) [19,17]. Probed the effects of *Portulaca Oleracea* on menstruation menorrhagia. One and two months after the intervention, average hemorrhage in the *Portulaca Oleracea* group had a significant decrease compared to before the intervention. *Portulaca Oleracea* decreases the amount of hemorrhage and number of menstrual bleeding days by anti-inflammatory and anti-prostaglandin effects. *Portulaca Oleracea* plant is a rich anti-oxidant and contains noleic acid, exilic acid, phenolic Vanilic acid, noradrenaline, Glutathione, Gama acid linoleic, and minerals. Effects of *Portulaca Oleracea* on abnormal uterus hemorrhage on 10 pre-menopause women showed that *Portulaca Oleracea* improved menorrhagia ($p=0.001$) [23]. Which is also in agreement with the findings of the present study.

Limitations and delimitations

There was a limitation in collecting hemorrhage while urinating. To measure the amount of blood while urinating, tampons were placed in the vagina to stop the loss of hemorrhage and were taken out after urinating and weighed.

Conclusion

Portulaca Oleracea could be a simple and cheap supplemental drug suggested to midwives, gynecologists, and mothers in postpartum pain and hemorrhage.

Declarations

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Publication ethics: All standards of ethics were observed in writing and conducting the research.

Conflict of interest: The authors report no conflict of interest.

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