

The impact of calendula ointment on cesarean wound healing: A randomized controlled clinical trial

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ABSTRACT

Background: Cesarean is one of the most common surgical interventions. Wound complications are one of the most common morbidities following cesarean section. Calendula promotes wound healing and might be effective in shortening the duration of wound healing. Limited researches have been done regarding the healing of this plant as the effect of this ointment on cesarean wound healing has not been studied. Therefore, the purpose of this study was to examine the impact of calendula on cesarean wound healing in primiparous females. **Methods:** This clinical trial involves 72 qualified primiparous females with surgical childbirth admitted in the Akbar-Abadi Educational Hospital. They were randomly categorized into two groups of experimental ($n = 1$) and control ($n = 2$) groups. The females in experimental group used calendula ointment every 12 h and the control group used hospital routine for 10 days. Wound healing was assessed on the 3rd, 6th, 9th days postcesarean using the REEDA scale (REEDA stands for redness, edema, ecchymosis, discharge, and approximation), which had criteria including redness, edema, ecchymosis, discharge, and approximation. The data were collected by demographic questionnaire and redness, edema were used Chi-square test and independent T-test for data analysis. **Results:** Seventy-two females were included in the study. Thirty-six cases in the drug group and 36 cases in control group were studied. The age of patients in the two groups did not differ significantly ($27/17 \pm 4/72$, $28/97 \pm 4/99$ years, respectively; $P = 0/276$). Moreover, there was no significant difference between studied groups regarding the education level of patients and their husbands, the mother's job and the economic situation. **Conclusion:** According to the results, using calendula ointment considerably increases the speed of cesarean wound healing so it can be used for quickening the cesarean healing.

Keywords: Calendula ointment, surgical intervention, wound healing

Introduction

Cesarean is one of the most important gynecology surgeries,^[1] and one of the most common surgical interventions.^[2] As like as labor tremendous impact on maternal mental health and their family members.^[3] Nowadays, Due to increased maternal age at first pregnancy, number of pregnancies, electronic fetal monitoring, improving the socioeconomic situation and increasing cases of

complaints of obstetricians and obstetrics in recent decades, demand of perform cesarean delivery has increased.^[4] World Health Organization announced that acceptable rate of cesarean section in the entire world was 10–15%.^[5] But its prevalence has increased in most countries in the recent years.^[6] Its prevalence in Brazil 80%, Turkey 50.4%, Mexico 45.2%, Italy 36.1%,^[7] and in the United States of America 32.2%. Cesarean section rate in Iran in 2014, have been reported 52%.^[8] In 2014, Argentina, Brazil, Iran, and Mexico had the highest frequency of cesarean delivery in the world.^[9] Infection of the wound, hematoma, serosa, and

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wound opening are among the most common complications of cesarean section, resulting in hospitalization of the mother, her repeated referral to doctor for wound drainage and debridement, treatment of the wound for the second time, and a great economic burden imposed on the family.^[10,11] Thus, wound healing after surgery care is the main goal. Healing of the wound consists of coordinated mending responses that begin after the surgical operations or traumas and leads to reconstruction of the tissue.^[12] Topical treatments are not commonly used for cesarean section wound healing, oral antibiotics are often recommended.^[13] Today, the increase in bacterial resistance to antibiotics and heavy costs of medical care has led to more attention to traditional treatments.^[14] At now, the researchers pay attention to using cheap, effective, proper methods, which are accessible in health centers apart from hospitals and meanwhile, being acceptable by postpartum females.^[15]

Many studies examine the treatment of infected wounds, so there was a few evidence about the effects of topical treatments for wound healing after surgery.^[16] Increased interest in complementary medicine use has led to more attention to product that has long been used in traditional medicine as healing wounds.^[17] In this regard, complementary medicine including traditional and herbal medicine, homeopathy, and aromatherapy solutions has special place in promoting the care quality after delivery. Nowadays, using nontraditional or comprehensive treatment methods are increasing and according to WHO, herbal medicine is part of the complementary medicine that is accepted by many people of the society and 40% of common drugs are derived from plants and natural resources.^[18] *Calendula officinalis* or marigold is a reputed medicinal plant with ornamental properties.^[19] This plant has anti-inflammatory and anti-inflammation properties, antiviral, antimicrobial and antifungal activity, anticancer, antioxidant, and healing function.^[20,21] And the years before the 12th century in Europe as the first topical anti-inflammatory drug are used.^[22] Flavonoids and saponins in calendula prevents from releasing of harmful and histamine enzymes that cause sensitivity and inflammation and heal the redness and pain, and inhibits plasma discretion to the tissues by decreasing the capillary permeability. Meanwhile, it reduces the immigration of white blood cells to inflamed area. Its anti-inflammatory effects are due to triterpenoids.^[23] In addition, reduces the white blood cell migration to inflamed area.^[24] Calendula helps in the process of epithelial reconstruction of surgical wounds and accelerates the wound healing process. In this regard, Lavagna *et al.* (2001) in a clinical study demonstrated that oily extract of *Hypericum perforatum* promotes healing of surgical wound from childbirth with cesarean section.^[25] In addition, results the study of aimed to determine the effectiveness of dressing with aloe vera gel in healing of cesarean wound indicates that the aloe vera gel on wound healing has been going cesarean section. As cesarean sections and its complications is high in Iran and as no research has been done regarding the studying of the impact of calendula on cesarean wound healing. Then, the current study was done in order to determine the effect of calendula ointment on cesarean wound healing compared to

routine of hospital (normal saline) up but also, can offer the more effective, less costly, and available treatment to deal with this problem to females.^[26]

Materials and Methods

Approved by Medical Research Ethics Committee of Iran University of Medical Sciences and record the number (IRCT201507252248N18) in IRCT, from October to December 2015 was conducted in the Akbar-Abadi Educational Hospital. Considering $\alpha = 0.05$ and power = 80%, a 72-subject sample size was determined for the study (36 subjects in each group). The inclusion criteria of the study were age range 20–35 years, term pregnancy (37–42 weeks), education level at least 5th grade class of primary school, not having the history of more than two cesarean sections, and being willing to participate in the study, insensitivity to special drugs in past, lack of preterm rupture of membrane for more than 18 h, body mass index (BMI) >35, Pfannenstiel skin incision, lack of abnormal vaginal bleeding, and received same and routine antibiotics. To prepare the marigold ointment were used hydroalcoholic extract 2% based on the standard rate of flavonoids. And were used at its base compounds such as oils, Avsvyn, and other necessary additives. Ointments were prepared by Barij Essence Pharmaceutical companies and were packaged in tubes 30 g. At first, the participants were provided with enough information about the study procedure and objectives, benefits, nature, and duration of the study. They also signed written informed consents after being ascertained about the confidentiality of their information. They were also ensured that they could withdraw from the study whenever they desired.

By using a table of random numbers, the 70 subjects were randomly allocated to one of two treatment groups. Some variables before intervention controlled and recorded include: duration of labor and membrane rupture, dilatation of cervix at time of cesarean delivery, postoperative hematocrit, operative time, and birth weight. A primary assessment for determining the healing was done immediately before intervention with REEDA (redness, edema, ecchymosis, drainage, and approximation) that was graded for color paper tape by the researcher and at the same time explained for one of the related samples that will stay with her during the study. Thus, the paper tape was perpendicularly on cesarean incision so that the midpoint of the labeled tape was adapted on the middle cesarean section.

Then size of each of the criteria on the basis of in the color spectrum the paper tape in 3rd and 6th day after the intervention to be recorded in the form of reporting. Calculates a score for each criterion after submitting the form reporting will be done by the researcher. Then to ensure that related samples learning, they asked to practice for once under the supervision of researchers. After assessing topical wound healing and pain cesarean section, the researchers rubbed ointment top of wrist for 15 min to detect any complications such as inflammation, itching, etc. The mother has demined to first wash their hand, then rub the ointment over

the sutures twice a day (12 ± 2 h) for 10 days. The control group remained without any intervention postoperatively. In order to blind the study, the second step of assessing the cesarean wound healing was done 10 days after intervention by the trained researcher assistant in the hospital clinic and were registered in appraisal form of REEDA scale. Each characteristic is scaled from 0 to 3, and the ratings for the five characteristics are added to obtain the score. A total score range from 0 to 15 and score of 0 reflects normal skin. The exclusion criteria of the study were nonaccurate use of calendula ointment, sensitivity to desired ointment, nonwillingness to continuing the participation in the study, smoking and diseases or drugs that may affect wound healing, any infection or bleeding is the wound that requires medical intervention. All the study data were analyzed using the SPSS statistical software (version 20) SPSS 20 (Chicago, IL, USA). Chi-square test and independent T-test were used in order to compare the distribution of the qualitative and quantitative demographic variables, respectively. Independent T-test was also used to compare the REEDA scores.

Results

Seventy-two females were included in the study. Thirty-six cases in the drug group and 36 cases in control group were studied.

The age of patients in the two groups did not differ significantly ($27/17 \pm 4/72$, $28/97 \pm 4/99$ years, respectively; $P = 0/276$). Moreover, there was no significant difference between studied groups regarding the education level of patients and their husbands, the mother's job, and the economic situation [Table 1].

A lower score was observed on the 3rd, 6th, and 9th day postpartum in total and five criteria of the REEDA scale including redness, edema, discharge, ecchymosis, and approximation of the wound edges in the treatment group [Table 2].

Overall, statistically significant difference in wound healing was observed between treatment group with control groups (P -value $< 001/0$) [Table 2].

A total of 63.9% in the treatment group on 3rd day and the rest of the patients on 6th day postpartum, The wound was completely improved [Table 3].

Discussion

According to the study calendula ointment compared to standard care, cesarean wound healed on days 3, 6, and 9 after surgery is significantly accelerated. Up to now, multiple number of studies have been conducted on cesarean wound healer. However, none of these studies has investigated the effect of this ointment on abdominal surgery wound healing. The results of the present study regarding the effect of marigold ointment on the wound healing cesarean section showed that the mean cesarean section wound healed 3 days after treatment (4 days after cesarean) in

Table 1: Distribution of frequency of individual specifications of the researched units

Individual specifications	Group		P
	Drug	Control	
Mother's age	27.17±4.72	28.97±4.99	0.276
Mother's level of education (%)			
Elementary and guidance school	8 (22.2)	14 (38.9)	0.250
High school and diploma	23 (63.9)	14 (38.9)	
University	5 (13.9)	8 (22.2)	
Mother's occupation status (%)			
Housewife	32 (88.9)	30 (83.3)	0.382
Occupied	4 (11.1)	6 (16.7)	
Spouse's level of education (%)			0.364
Elementary and guidance school	16 (44.4)	13 (36.1)	
High school and diploma	16 (44.4)	20 (55.6)	
University	4 (11.1)	3 (8.3)	
Spouse's occupation status (%)			
Free	1 (2.8)	1 (2.8)	0.738
Employee	5 (13.9)	9 (25.0)	
Worker	30 (83.3)	26 (72.2)	

Table 2: Comparison of the mean scores of cesarean wound healing in calendula and control groups

	Group (mean±SD)	
	Calendula	Control
REEDA scale 3 days postintervention	0.42±0.60	8.14±2.24
REEDA scale 6 days postintervention	0.00±0.00	2.98±4.86
REEDA scale 9 days postintervention	0.00±0.00	2.71±3.00
Results of the ANOVA	$P<0.001$, $F=41.810$	

REEDA: redness, edema, ecchymosis, drainage, and approximation; SD: standard deviation

Table 3: Group wound healing score in calendula and control group

Group wound healing score	Calendula	Control
0	23 (63/9%)	0/0 (0%)
1-5	13 (36/1)	4 (11/1)
6-10	0/0 (0%)	28 (77/8%)
11-14	0/0 (0%)	4 (11/1)
Total	36 (100%)	36 (100%)
Mean±SD	0/42±0/60	8/14±2/24
Results of the ANOVA	$F=490/187$, $P<001/$	

marigold (0.42 ± 0.60) less the control group (8.14 ± 2.24), respectively. The results Molazem *et al.* aimed to investigate the effect of aloe vera gel on wound healing Cesarean section revealed a significant difference between aloe vera and control groups regarding REEDA score after 24 h ($P = 0.003$).¹²⁷ Moreover, Jahdi *et al.*, conducted a research to study the effect of calendula ointment on perineal healing after episiotomy and the results indicated that the mean grade of wound healing of samples who used calendula ointment 5 days after episiotomy were lower than control group ($P < 0.001$). Although the effect of this drug has been investigated on wound healing episiotomy but is consistent with the study. The findings in this study regarding the effect of calendula ointment on the wound

healing cesarean section shows that the mean score between the two groups after the intervention was 6 days (7 days after surgery) was statistically significant difference ($00/0 \pm 00/0$, $98/2 \pm 86/4$) (P value < 0.001). In this respect, the results of Nikpoor *et al.* suggest an effect of honey gel on wound healing cesarean section in general and only the difference between this study in connection reviews five cases with wound healing redness, bruising, discharge, swelling, and continuity of the edges of the wound showed no difference statistically significant continuity and wound exudates.^[14] The results obtained in this study regarding the effect of marigold ointment on the wound healing cesarean section shows that the mean score between the two groups ($00/0 \pm 00/0$) and control ($71/2 \pm 00/3$) 9 days after treatment (10 days after surgery) was statistically significant difference (P value < 0.001). The results 14 days after surgery was consistent Nikpoor *et al.* ($P < 0/001$), but the Molazem *et al.* score REEDA 8 days after surgery in aloe vera 0.49 ± 0.11 and 0.99 in the control group ± 0.29 that did not show a statistically significant difference ($P = 0.283$). Moreover, the results Samadi and colleagues to investigate hypericum ointment on the wound healing cesarean section indicated significant differences in wound healing between the experimental and control groups did not exist ($P = 03/0$) due to the inconsistency of the results of the present study, usage, dosage, and timing of herbal drug.

Conclusion

The present study showed that calendula ointment was effective in cesarean wound healing. According to the findings of this study, dermal application of calendula ointment did not have any side effects and it could consequently be used as an adjunctive treatment to the standard treatments of cesarean wound.

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Conflicts of interest

There are no conflicts of interest.

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