

The Effects of Recove Ointment on Wound Healing in Mothers Susceptible to Cesarean Section Infection

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ABSTRACT

Background & aim: Due to the development of major complications after cesarean section (C-section), surgical site infection and delayed wound healing was of great concern to gynecologists since a long time ago. It is especially the case for mothers susceptible to post-cesarean wound infection who need special care. The present study therefore aimed to investigate the effect of Recove ointment on wound healing in women susceptible to C-section wound infection.

Methods: In this triple-blind randomized clinical trial, which was conducted on the women who underwent C-section in Ommolbanin Hospital, Mashhad, in 2019, using a two-group design, a number of 80 eligible women with C-section were assigned into intervention and placebo groups. Intervention group received Recove ointment for a maximum of 10 days. The wound recovery was assessed using Reeda scale before intervention and 3, 5, and 10 days after C-section. Data were analyzed using T test and Mann-Whitey, Chi-square as well as Fisher's exact test.

Results: The score of wound healing was significantly different in intervention and control group 5 days after cesarean section ($P=0.008$). But no significant difference was seen between two groups on days 3 and 10 post cesarean ($P=0.69$). Also there was significant difference between wound healing score before and after intervention in both intervention ($P=0.001$) and placebo groups ($P=0.001$).

Conclusion: Although the effectiveness of the ingredients of Recove ointment was indicated in several studies, this ointment was revealed to be effective for wounds healing just 5 days after cesarean section. Further research with larger sample size is required to investigate the effect of this ointment.

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Introduction

Cesarean section (C-section) is one of the current surgeries (1) that is used when natural delivery is impossible and poses a threat to mother and fetus (2). The complications and mortality following C-section are found to be higher than those of vaginal delivery. Possible C-section risks include infection, bleeding, anesthesia side-effects, and maternal mortality in rare cases (1, 3). The subsequent complications and the cost of care escalate with

the increased rate of C-section endangering maternal and neonatal health (3).

Complications of C-section can impair wound healing, which not only results in pain and discomfort, increased length of initial and hospital stay, or physician visit to secrete and repair the scar and its associated costs, but also interferes with the patient's daily activities and routine life (4-8). Important risk factors for infection and improper surgical wound healing include obesity, hypertensive disorders,

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diabetes, anemia, immunosuppressive drugs, wound hematoma, and treatment with corticosteroids. It should be noted that the risks and complications would be greater along with these factors; therefore, special care is needed in this area (1). In previous studies, the relationship between these risk factors and the increase in surgical wound infection rate has been proved (9).

Skin cleansing with povidone-iodine is one of the hygienic measures for the prevention of surgical site infection (4, 6, 10). However, studies carried out in this respect revealed the negative effects of this antiseptic on wound healing process since an iodine concentration of 1.2 mmol L-1 results in fibroblast cell death and inhibition of lymphocyte function, which in turn disrupts the wound healing process (11). Therefore, skin including abdomen cleansing by Chlorhexidine - alcohol is more widely used (4). Moreover, abdominal skin should be trimmed with scissors as a preparatory measure since razor blade doubles the incidence of wound infection. Additionally, another point worth considering is the specific control of infection by the surgeon and hand hygiene of personnel before, during, and after surgery (4, 12).

In line with the treatment of C-section complications and problems arising from improper wound healing, treatment with chemical drugs produces physical-mental side-effects, impairs emotional relationships and maternal care, disrupts the wound healing process, and imposes high costs on the patients and health care system. Thereby, herbal medicines can be used as a faster and easier alternative treatment (7). Medicinal herbs can be effective in surgical wound healing due to their antioxidant, anti-inflammatory, and antibacterial properties (7, 13). Furthermore, 75-80% of the world population, especially in developing countries, use these herbs for initial healthcare due to cultural factors, better biological adaptability, and their minimal side effects (14).

One of the currently used herbal medicines is Recove ointment, which consists of sesame oil, camphor, and zinc oxide. The use of these three herbal compounds creates a synergistic mechanism and enhances multiple effects, such

as quick relief of pain, irritation, edema, discharge from site of injury, as well as antibacterial effects (15, 16).

Sesame oil has antibacterial, antisecretory, and anti-inflammatory effects due to the high amount of vitamin E, antioxidants, and excessive unsaturated fatty acids, such as Oleic acid. Moreover, it can repair damaged skin cells by increasing blood circulation in the affected area (17-19). In addition, this kind of oil is a major contributor to increased epithelialization, decreased infection, and complete wound healing (20, 21). Camphor in Ricove ointment can relieve itchy and irritated skin and play a role in wound healing and treatment of infections and inflammations due to its antibacterial and antifungal properties (22, 23). Furthermore, it can cause proliferation of primary cutaneous fibroblasts and increased collagen synthesis in the skin. (24)

Another compound is zinc oxide, which has a satisfactory effect on wound healing process by the acceleration of healing and tissue maintenance as a result of elevated re-epithelialization, decreased infection rate, and increased collagen synthesis (25). Furthermore, majority of human and animal studies have confirmed the positive effects of zinc oxide on wound healing. In this regard, the results of a study aiming at oxide-based dressing within 19 days of treatment, revealed 91.7% recovery, compared to 65.9% recovery by standard treatment (26).

In line with the goals of World Health Organization to encourage research in the area of traditional medicines and regarding the absence of any studies on the effect of Recove ointment on healing of C-section wounds, the researcher undertook this study which aimed to determine the effect of Recove ointment on wound healings in mothers prone to C-section infection, referring to Ommolbanin Hospital, Mashhad in 1398.

Materials and Methods

This study was a triple-blinded randomized clinical trial using a two-group design which was performed on a total number of 80 eligible women with C-section hospitalized in women's surgery ward of Ommolbanin Hospital, Mashhad since 6/3/2019 until 10/4/2019. On the onset of the study, the researcher obtained the

approval of Ethics Committee (IR. MUMS. NURSE.REC.1397.065), clinical trial registration (IRCT20181226042134N1), and a written letter from Mashhad University of Medical Sciences

The sample size was calculated based on Cohen's (1987) table in a way that it was significant for both dependent variables of pain and cesarean section with confidence of 95%, power of 80%, and efficiency of 70%. Regarding this, the sample size was calculated as 80 (40 in each group) adjusting for the dropout rate.

The study population was selected by convenience sampling and then randomly assigned to the intervention and placebo groups. Inclusion criteria included: 1) a written consent, 2) a minimum literacy to write and read, 3) a gestational age of 37-42 weeks, 4) non-use of medications effective in wound healing, 5) a low transverse uterine incision and Pfannenstiel skin incision, 6) spinal anesthesia, 7) risk factors for C-section infection (obesity, anemia, diabetes, hypertensive disorder, history of wound hematoma, corticosteroid medication or immunosuppressant), 8) maximal cesarean delivery time of 60 min, 9) no midwifery problems, 10) not more than two C-sections, 11) no history of previous lower abdominal surgery, or 12) injuries concurrent with C-section.

On the other hand, the exclusion criteria entailed: 1) irregular application of ointment not as prescribed, 2) development of puerperal fever, 3) any specific complication while using the ointment, 4) other measures for pain relieve and faster C-sect wound healing, 5) use of specific medications while applying the ointment (e.g., glucocorticoids, anticoagulants, immunosuppressants, broad-spectrum antibiotics, chemotherapy, alcohol and Benzodiazepines), 6) obvious uterine infections, and 7) physician or hospital visit or neonatal hospitalization more than recommended. During the study, 14 subjects were eliminated (one for acute abdominal infection and referral to another hospital for treatment, one due to neonatal hospitalization, two of them for sensitivity to ointment, and 10 participants due to non-cooperation in the study and misuse of the ointment.

Data collection tools included: Selection of study population form (including inclusion and

exclusion criteria); demographic form; individual-pregnancy, and C-section information form; daily use of ointment form; use of antibiotic, iron pill and multivitamin capsule, physical activity and recommended food intake registration form; Reeda wound healing scale; and ointment satisfaction form. The content validity of the researcher-made forms was based on the approval of seven university professors. The Reeda scale is standard and valid with the reliability of $r = 0.9$.

For the conduction of the current study, 40 tubes of Ricove ointment (25gr) were purchased from Tosandarou Company with IRC specification: 1228126376. Moreover, a number of 40 tubes of placebo ointment were provided by the consultant pharmacist. The ointments were coded by the pharmacist in a 25-gram, single-color, plastic container as A or B. At the beginning of the study, the researcher obtained the participants' written consent after a thorough explanation about the nature and method of the research, as well as the intended goals. Eligible patient records were carefully reviewed; thereafter, individual, midwifery, and C-section information were completed. Post-cesarean information, such as duration of operation, type of anesthesia, and time of hospital discharge were then recorded in the related form.

All participants equally received face to face training on personal hygiene, nutrition, physical activity and mobility, and prevention of constipation. This training was provided by the researcher through provision of some pamphlets. Both groups were trained on the application of the ointment. The quantity to be dispensed was 2-3 g of the ointment covering the entire wound 3 times a day, 24 hours after operation for a maximum of 10 days. Thereafter, the ointments were distributed among the study subject. Furthermore, all research participants were provided with checklists in order to record the daily requested information. Distributed checklists included ointment application; use of analgesic and antibiotic medicines, iron tablets and multivitamin capsules; hygiene information; physical activities; and uptake of recommended foods. On days 3, 5, and 10 after C-section, the mothers were reminded to refer to the hospital. During this time, the rate of C-section before and

3,5,10 days after the intervention was assessed in both groups and recorded in the related form. The data were analyzed in SPSS software (version 21). The qualitative data were analyzed using an independent t-test, and Mann-Whitey test. On the other hand, K² test and Fisher's exact test were utilized for the analysis of qualitative data. Eventually, ANOVA was used for analysis of replicated data to control confounding factors.

Results

A number of 80 women with C-section participated in the current study with the mean age of 30.09 years in the intervention group and 29.52 years in control group. Both groups were homogenous in terms of all variables except walking time and use of dairy and proteine. The other information is illustrated in Table 1.

Table 1. Demographic and midwifery information of the women in intervention and control group

variable	Intervention group	group Control	results
	SD±Mean	SD±Mean	
Age (year)	30.09±5.65	29.52±5.65	T=0.42 P=0.65
BMI	26.39±4.6	26.65±5.31	T=0.21 ^b P=82
Number of pregnancies	2.67±0.99	2.09±0.99	Z=0.52 ^a P=0.6
Number of vaginal examinations	2.45±2.98	3.76±6.16	Z=0.27 P=0.78
Caesarean-section duration	33.44±7.66	35.06±10.23	Z=0.68 P=0.49
Number of ointment application (within 10 days)	17.1±3.94	16.39±4.6	Z=0.52 P=0.59
Number of bath taking	4.57±2.27	4.39±2.23	Z=0.49 P=0.62
Walking time	167.12±198.52	253.54±175.07	Z=3.04 P=0.002
Dairy use (within 10 days)	7.18±6.07	4.27±4.03	Z=2.3 P=0.02
Protein use (within 10 days)	6.45±5.59	3.96±4.11	Z=2.44 P=0.01
Number of caesarean sections	1.74±0.44	1.5±0.5	Z=1.96 P=0.05

a: Mann-Whitey test b: independent t-test

Two groups were not different in terms of risk factors (Table 2).

The mean of Reeda scale was the same in both groups before the intervention. In addition, the means of alterations on the third and tenth day of intervention were not significantly different. However, the mean of alteration on the fifth day of intervention was significantly different from that of pre-intervention (Table 3).

The heterogeneous variables of dairy and protein use and walking time were analyzed by covariance analysis, and the variables with $P > 0.2$ were excluded from the model. With maintaining Reeda score before the Intervention ($P < 0.001$) and walking time

($P = 0.49$) on the third day of the intervention, the mean of Reeda scale in intervention group was not significantly different from that of control group ($P = 0.21$). By controlling the pre intervention Reeda score as well as walking time on fifth day, of intervention, the mean of Reeda scale in intervention group was not significantly different from that of control group ($P = 0.7$). Moreover, on the tenth day of intervention, the mean of Reeda scale in intervention group was not significantly different from that of control group ($P = 0.8$) with controlling pre intervention Reeda score ($P = 0.02$) as well as walking time ($P = 0.002$; Table 4).

Table 2. The comparison frequency of participants in terms of risk factors in intervention and control group

variable	Intervention group	Intervention group	Control group	results
		Number (%)	Number (%)	
Anemia	Yes	30(90.9)	28(84.8)	$X^2=0.56^a$
	No	3(9.1)	5(15.2)	$P=0.7$
Obesity	Yes	12(36.4)	10(30.3)	$X^2=0.27^b$
	No	21(63.4)	23(69.7)	$P=0.7$
Hypertensive disorders	Yes	4(12.1)	1(3.0)	$X^2=1.94^a$
	No	29(87.9)	32(97.0)	$P=0.35$
Diabetes	Yes	1(3.0)	4(12.1)	$X^2=1.94^a$
	No	32(97.0)	29(87.9)	$P=0.35$
Ulcer hematoma	Yes	1(3.0)	0(0.0)	$X^2=1.01^a$
	No	32(97.0)	33(100.0)	$P>0.99$
Use of immunosuppressant	Yes	1(3.0)	0(0.0)	$X^2=1.01^a$
	No	32(97.0)	33(100.0)	$P>0.99$

a: Fisher's exact test b: K^2 test**Table 3.** Mean and standard error of Reeda scale in intervention and control groups

Reeda scale	Intervention	Control	Result of Mann-Whitney test
	SD± Mean	SD± Mean	
Before intervention	4.3±1.57	4±1.19	Z=1.13 P=0.25
variations 3 days after the intervention	-0.6±1.56	-0.69±0.98	Z=0.69 P=0.48
variations 5 days after the intervention	-3.54±1.87	-2.57±1.63	Z=2.66 P=0.008
variations 10 days after the intervention	-4.06±1.56	-3±1.22	Z=0.52 P=0.59
Friedman test result	$X^2=86.64$ P<0.001	$X^2=85.13$ P<0.001	

Table 4. Results of covariance analysis of replicated data using Reeda scale in intervention and control groups

Reeda scale	Regression rate	Standard error	results
Mean of Reeda scale on the third day of intervention	-0.37	0.3	t=1.24 P=0.21
Intervention			
Control	Reference	-	-
Reeda score before intervention	0.64	1.01	t=6.01 P=0.001
Walking time	0.001	0.001	t=0.68 P=0.49
Mean of Reeda scale on the fifth day of intervention	-0.67	0.37	T=1.78 P=0.07
Intervention			
Control	reference	-	-
Reeda score before intervention	0.03	0.13	t=2.25 P=0.02
Walking time	0.001	0.001	t=0.68 P=0.49
Mean of Reeda scale on the tenth day of intervention	0.26	0.15	t=1.75 P=0.08
Intervention			
Control	reference	-	-
Reeda score before intervention	0.12	0.05	t=2.32 P=0.02
Walking time	0.001	0	t=3.24 P=0.002

Reeda scale demonstrated a significant difference within each group ($P < 0.001$).

Discussion

In the present study, the group who used Ricove ointment and the other group applying placebo were not significantly different in terms of wound recovery rate. This can be attributed to a difference between previous studies and the current research regarding the nature of wound, as well as the ingredients of this ointment, and days of application. Nonetheless, there was a difference within groups in terms of wound healing. Therefore, no study has yet been performed indicating the effects of ricove ointment on wound recovery. However, some studies which have investigated the effects of the ingredients of this ointment (sesame oil, camphor, and zinc oxide) revealed the positive topical effects of these compounds on different kinds of wounds (15, 16). For instance, sesame oil has antibacterial, anti-secretive, and anti-inflammatory effects due vitamin E, antioxidant, and unsaturated fatty acids, such as Oleic acid (19-17). In addition to anti-inflammatory and anti-pain properties, camphor was found to cause proliferation of primary cutaneous fibroblasts and increased collagen synthesis in human and mouse skin (22-24). Moreover, zinc oxide has a satisfactory effect on wound healing process by accelerating healing and tissue maintenance as a result of elevated re-epithelialization, decreased infection rate, and increased collagen synthesis (25).

In line with the obtained result, Mohammadi tofigh et al. (2014) conducted a clinical trial to investigate the effects of an ointment containing sesame oil, camphor, and honey (i.e., Kimia ointment) on pressure sores in the sacrum, ischium bump or heel of diabetes patients. The study continued for 8 weeks and the patients were assessed meticulously on a weekly basis. The wounds were revealed to recover faster at the end of the trial; moreover, the amount of exudate was lower in the users of the mentioned ointment (27). Although Kimia ointment was similar to Ricove in terms of its ingredients, the results of the mentioned study were not comparable to the results of the present study. In addition, another study was carried out by Majid (2011) to investigate the effects of sesame oil and camphor on burn wound

infection in mice. The wounds were checked on a weekly basis. Finally, from the eight groups, the group using sesame and camphor were revealed to have faster recovery with the mechanism of epithelialization and granulation tissue formation (28).

In addition, Arsalan et al. (2012) performed a study comparing the effect of zinc oxide and silver sulfadiazine on wound healing in rats. The wound healing process was monitored by photo diagnosis and by the burn center surgeon every 3 days. In this 6-week study, the group that used zinc oxide was indicated to have a lower Recovery score and shorter wound healing time (29). However, no significant difference was found between the two groups in the present study. This result can be probably attributed to differences in the nature and type of wound and duration of follow-up. Another study by Pie et al. (2010) on the use of sesame oil in the treatment of wounds in rats showed that, during 11 days of investigation, sesame oil users had a better wound healing and faster collagen synthesis, compared to the standard group (21). In this regard, none of the results of the mentioned study is consistent with the results of the present research.

Obesity and anemia were found to be among the most important risk factors for surgical wound infection and poor surgical wound healing which may increase the consequent risks and complications; therefore, special care is needed in this regard (1). However, the results of the current study showed no significant difference between the intervention and placebo groups regarding C-section wound healing, while the results of another study conducted by Soroush et al. (2008) proved that anemia can impair the wound healing process (9). Furthermore, Palfreeman et al. (2016) indicated that obese people have higher rates of wound complications and mortality. One of these complications is wound infection, which can be due to poor blood circulation and weak immune response at the wound location (30). Limitations of the current study included lack of complete control over personal hygiene and individual differences in terms of tissue type, wound healing quality, nutrition, and mobility. These factors which exert significant effects on wound healing were beyond the researcher's

control. However, the researcher managed to get this situation under control to some extent by the random assignment of participants into two groups of intervention and control and provision of educational pamphlets and face-to-face training.

Conclusion

Recove ointment can be effective in wound healing due to such compounds as sesame oil, camphor, and zinc oxide. However, the present study revealed that this ointment was not effective in C-section wound healing. Therefore, further clinical trials are required to investigate the effect of this ointment on the healing of surgical wounds such as C-section.

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Conflicts of interest

Authors declared no conflicts of interest.

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