



# The Effects of Alpha<sup>®</sup> Ointment (Containing Natural Henna) and Betadine<sup>®</sup> Solution on Episiotomy Healing in Primiparous Women: A Randomized Controlled Trial

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## Abstract

**Background:** Episiotomy is one of the most common surgical procedures in obstetrics performed in the second stage of labor.

**Objectives:** This study was conducted to compare the effects of Alpha<sup>®</sup> Ointment in comparison with Betadine<sup>®</sup> solution on episiotomy healing process.

**Methods:** The present single-blind clinical trial was conducted on 128 eligible women admitted to a university affiliated hospital in Karaj, Iran, in 2015. The subjects were divided into a case group (getting an Alpha<sup>®</sup> Ointment plus a sitz bath with Betadine<sup>®</sup> solution) and a control group (getting a sitz bath with Betadine<sup>®</sup> solution). After delivery, the mothers applied 2 g of Alpha<sup>®</sup> Ointment on their episiotomy site three times a day. The REEDA scale was used to assess the wound healing process, and the intensity of pain was assessed by measuring pain in the first 24 hours as well as the third and seventh day after delivery.

**Results:** In the first 24 hours after delivery, the two groups were not significantly different in terms of their repair score ( $P = 0.27$ ), however, the mean REEDA score was  $0.25 \pm 0.53$  on the third day and  $0.203 \pm 0.47$  on the seventh day in the case group, while in the control group, it was  $1.32 \pm 1.4$  and  $0.92 \pm 1.17$ , suggesting a significant difference between the groups ( $P < 0.001$ ).

**Conclusions:** Alpha<sup>®</sup> Ointment is more effective than Betadine<sup>®</sup> solution for episiotomy wound healing and pain reduction and can, therefore, be regarded as an appropriate medication for episiotomy wound healing.

**Keywords:** Alpha, Betadine, Episiotomy, Fundermol, Healing, Henna, Lawsonia plant, Ointment, Sitz bath

## 1. Background

Episiotomy is one of the most common surgical procedures in obstetrics performed in the second stage of labor to widen the pelvic outlet and facilitate the delivery process and consists of a pudendal incision (1). This technique is mainly used to reduce severe injuries to the vagina and perineum, and to remove pressure on the baby's head and help speed up delivery when the fetus is in distress (2). The prevalence of episiotomy varies from 8% in the Netherlands, 20% in the UK, and 50% in the US (3, 4). There is no accurate information about the prevalence of episiotomy in Iran; however, according to studies, it varies from 70.6% in Tabriz to 97.3% in Tehran (5). Like any other surgical procedure, the episiotomy can be associated with short-term

or long-term complications such as pain, infection, painful intercourse, bleeding, and the need for a re-repair. The episiotomy incision is made at a site that increases the risk of wound infection with vaginal and rectal bacteria; therefore, any delays in wound repair increases the risk of infection. One of the concerns in cases of infection is incision site rupture (6).

Although most of the noted complications are not life-threatening, they can affect women's lives and daily activities. In addition, the pain caused by episiotomy has adverse effects on the women's sexual activities up (7, 8). Researchers have therefore made significant efforts to find proper methods and treatments for reducing the risk of infection and shortening the course of treatment for patients. One of the available treatments is the use of topi-

cal antimicrobial agents that effectively reduce the rate of infection. Betadine® (Povidon Iodine) solution is widely used after episiotomy repair due to its disinfecting properties on surgical incisions and sitz baths with Betadine® three times a day is routinely recommended to patients (9); however, studies have shown that the antibacterial effect of Betadine® in contact with tissues is not precise and should be further examined (10-13).

Fundermol is a repair Ointment with the brand name Alpha®, which is produced by the RejuderM- Group, is purely herbal, and has the active ingredient Lawson (2-hydroxy-1,4-Naphthoquinone), which is extracted from *Lawsonia inermis* (Henna). Lawson is one of the derivatives of quinones that increases the oxygen affinity of the red blood cells and strengthens the red blood cell membrane. Other reasons for the effectiveness of this plant in healing skin wounds include glycosides, which inhibit macrophage activity and thus, inhibit the production of inflammatory chemical mediators and ultimately reduce inflammation, as well as alkaloids, which have powerful physiological effects (14).

Beeswax is the base ingredient of this medication. Wax has different compounds, including flavonoids, which have a high chemical activity. The properties of wax include estrogenic effects, antibacterial effects, membrane permeability, anti-inflammatory effects (as a result of inhibiting inflammatory mediators such as prostaglandins), analgesic effects, and local anesthetic effects (15). The results of in vitro studies show that Alpha® Ointment is more effective than silver sulfadiazine 1% in the treatment of burn wounds, the control of infection and pain relief at the site of the burn injury, reduces the chances of burn scars due to not needing debridement, and is cost-effective (15, 16). Given that most of the studies conducted on the effect of Alpha® Ointment have been in vitro and have revealed the effectiveness of this Ointment on burn wound repair, and since no studies have yet evaluated the effectiveness of this Ointment on episiotomy wound repair, the present study was conducted to investigate the effects of Alpha® Ointment (Containing Natural Henna) and Betadine® solution on the process of episiotomy wound repair in primiparous women.

## 2. Methods

### 2.1. Study Design

A single-blind placebo clinical trial was conducted in 2015 at Bahonar Teaching Hospital, which is affiliated with Alborz University of Medical Sciences in Alborz province of Iran (Figure 1). The participants were selected from the

primiparous women admitted to the maternity ward at Bahonar teaching hospital based on the study inclusion criteria.

### 2.2. The Inclusion Criteria

Iranian nationality, reading and writing literacy, BMI of 19.8 to 26 kg/m<sup>2</sup>, no prolonged rupture of membrane (exceeding 18 hours), duration of the first stage of labor less than 14 hours and duration of the second stage of labor less than two hours, anterior cephalic presentation, birth weight of 400 to 2500 g, vaginal delivery with episiotomy and without additional grade 3 or 4 ruptures or the use of assistive tools, episiotomy repair using chromic catgut 0 and 00 through an identical method, episiotomy repair time less than 25 minutes, duration of the third stage of labor less than one hour, lack of obstetric complications such as eclampsia, pre-eclampsia, or gestational diabetes, lack of past or present history of cardiovascular, liver or kidney diseases, blood coagulation disorders, anemia, constipation and hemorrhoids, no history of anticoagulant, antidepressant, or anticonvulsant, and alcohol, drug, and cigarette use and no active skin disease (allergic disorders, symptomatic vicinities, wounds at the site or skin allergies).

### 2.3. The Exclusion Criteria

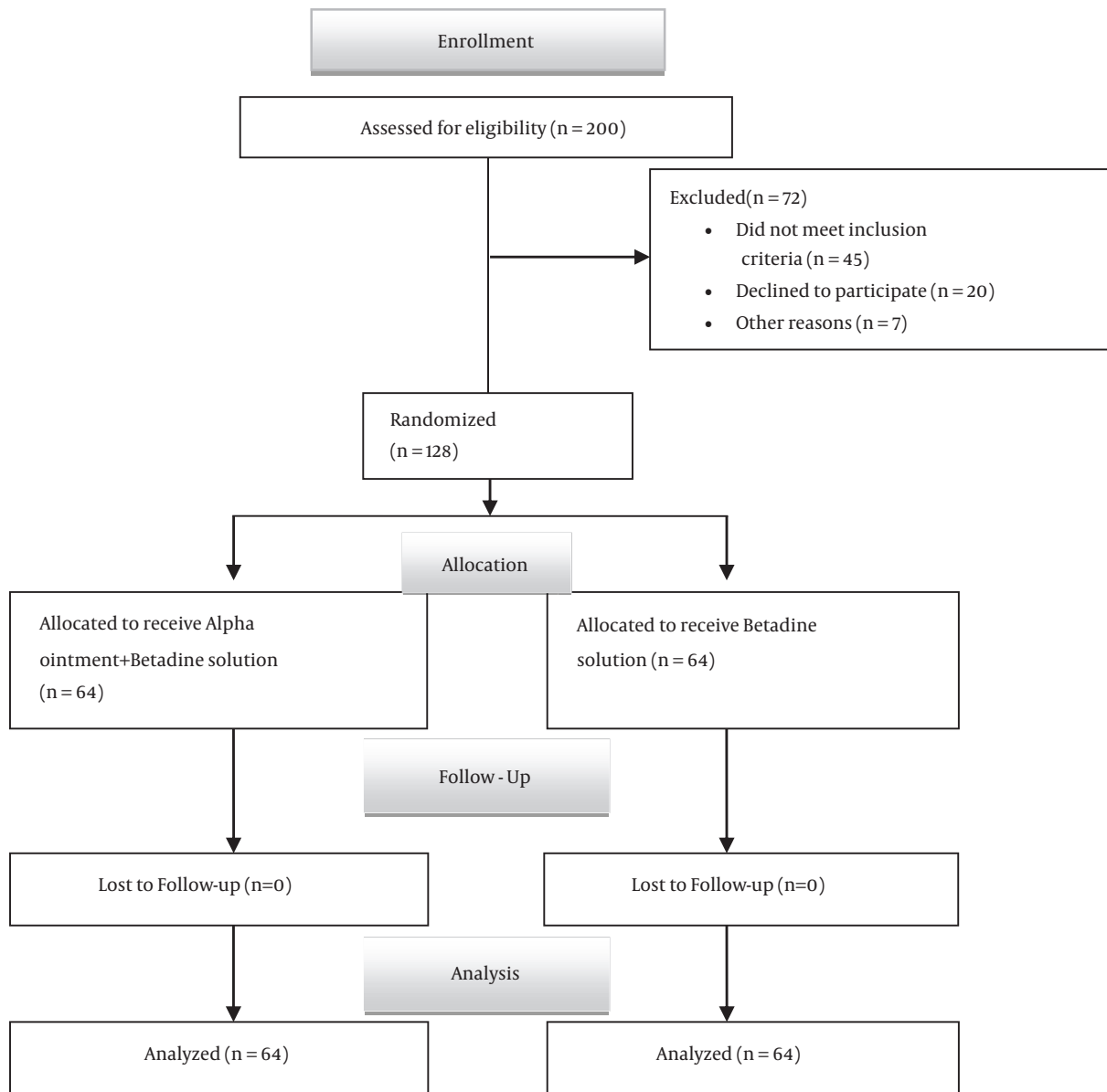
Women that were not willing to continue participation in the study or had abnormal bleeding or a hematoma after their delivery were excluded from the study. They were also excluded from the study if they failed to give their consent for trial participation in personal follow-ups.

### 2.4. Samples

The sample size was calculated as 64 per group in accordance with the results of previous studies conducted in Iran and using the formula for testing differences between means with  $\alpha = 0.05$ , a confidence interval of 95%, and a statistical power of 80%

### 2.5. Preparation of Ointment

The Alpha® Ointment is a combination of Lawson (natural Henna) and unsaturated fatty acids. Lawson is the main component of Alpha® Ointment extracted from *Lawsonia inermis*. The Alpha® Development Company prepared it in packages of 30 g.



**Figure 1.** Flow of participants through the study (CONSORT format)

## 2.6. Data and Measures

Data were collected using two instruments; first, a researcher-made checklist inquiring about participants' demographic details, including personal and obstetric details, with an item assessing personal satisfaction with the method of repair used, i.e., Alpha<sup>®</sup> Ointment/Betadine<sup>®</sup> solution, which ranged in response from 'very satisfied' to 'completely unsatisfied'; this form was completed during labor and after delivery; second, the REEDA scale for grading episiotomy wound repair, and third, the McGill Pain In-

dex.

The REEDA scale consists of five items including redness, edema, ecchymosed, discharge, and approximation, each of which receives a score from 0 (indicating no trauma) to 3 (indicating the most trauma); the total score ranges from 0 to 15. The lower is the total score obtained on this scale; the more effective has been the process of wound repair. The international scale has had its validity and reliability confirmed in several domestic and foreign studies (4, 5), for example, Yashari confirmed its content

validity with the approval of 40 physicians and nurses and confirmed its reliability with a Cronbach's Alpha<sup>®</sup> of 0.9 (5).

The McGill pain index rates pain from zero to 10. A score of zero indicates 'no pain' and 10 indicates 'maximum pain'. The reliability of this index has also been confirmed in Iran with a correlation coefficient of 0.88 (4).

The REEDA scale and the McGill Pain Index were completed in the first 24 hours and third and seventh days after delivery.

### 2.7. Procedures

The present single-blind clinical trial was conducted in 2015 at Bahonar teaching hospital in Alborz province of Iran. First, permission was obtained from the research council and the ethics committee of Alborz University of Medical Sciences as well as from the presidents of the university, the hospital, and the maternity ward manager. The researchers visited the hospital's delivery room for sampling and identified eligible mothers and divided them into a case and a control group using random allocation software.

All the samples were similar concerning the type of episiotomy, method of wound repair, type of thread used, and the amount of anesthetic administered before and after episiotomy; in all the cases, two colleagues were responsible for performing the delivery and repairing the episiotomy.

All the participants had adequate information regarding the Ointment and Betadine<sup>®</sup> solution used and had submitted their written consent before entering the study. The same type of antibiotic (intravenous Cefazolin 2 g) was used after delivery in both groups.

After repairing the episiotomy, all the mothers in both groups received the same training about perineal hygiene and getting a sitz bath with Betadine<sup>®</sup> solution three times a day, according to the national protocol. In addition to the sitz bath with Betadine<sup>®</sup>, the case group also received training on applying Alpha<sup>®</sup> Ointment, about the size of a knuckle (2 g), on the episiotomy site three times a day (with intervals of at least five hours) after washing and drying the perineum and to wait ten minutes after each application for the Ointment to be absorbed before covering the wound with sterile gauze to avoid contact with their underwear or pad. Both the cases and the controls were prescribed Mefenamic acid capsules (250 mg) to take every eight hours for pain relief. The data analyzer was unaware of the type of the groups, and the study was therefore one-blind.

For follow-up purposes, green cards were distributed among the case group and yellow cards among the control

group. In addition, they were asked to present to the maternity ward of Bahonar teaching hospital in the first 24 hours (before discharge) and the third and seventh days after their delivery. The green and yellow cards were used to distinguish between the study samples and also served as a reminder to present to the hospital; their dates of presenting to the hospital were recorded.

A colleague of the project assessed episiotomy wound healing in the subjects using the REEDA scale in a lithotomic position and assessed the intensity of pain using the McGill Pain Index in lying and sitting positions in the first 24 hours after delivery (before discharge) and on the third and seventh days after delivery. The researchers had given training to the project colleague on how to use the tools. This colleague was blinded to the study groupings and did not know the color of the cards; thus, the research is therefore considered a single-blind study.

The researcher recorded the subjects' phone numbers and contacted them every day to inform about the proper method of administering the medications and remind them of the time of presenting to the hospital.

The project was approved on June 17, 2015, in a meeting of the ethics committee of Alborz University of Medical Sciences and Health Services under the code abzums.rec1394.19 and was recorded at the Iranian registry of clinical trials under the code IRCT2015071523230N1.

### 2.8. Statistical Analysis

The data obtained were analyzed in IBM SPSS statistics for Windows, version 19.0 (IBM Corp., Armonk, N.Y., USA) using the independent t-test and Mann-Whitney's test. The  $P$  value  $< 0.05$  was considered as a significant difference in this study.

## 3. Results

A total of 128 primiparous women were divided into two groups of 64; the case group getting Alpha<sup>®</sup> Ointment plus a sitz bath with Betadine<sup>®</sup> solution and a control getting only a sitz bath with Betadine<sup>®</sup>. The Kolmogorov-Smirnov test evaluated the normality of the variables and the two groups were found to have no significant differences between them in terms of mean age, BMI, gestational age, birth weight, level of education, mother's employment status, the condition of the membrane, and were matching in these variables (Table 1).

According to the findings, the mean pain score, as determined by the McGill pain index, differed significantly between the groups in the first 24 hours after delivery ( $P = 0.01$ ) and was higher in the control group than in the case group. The groups also differed significantly concerning

**Table 1.** Comparing Some Individual Social Characteristics of Research Units in the Two Groups

Variable	Groups <sup>a</sup>		P Value
	Case <sup>b</sup>	Control <sup>c</sup>	
Level of education	63.38	65.52	0.72
Mother's employment status	62.2	66.90	0.11
Socio-economic status	62.70	67.26	0.32
Status membrane in admission	63.64	66.34	0.70
Gestational age according LMP	38.80 ± 1.01	39.1 ± 1.16	0.29

Abbreviation: LMP, Last Menstrual Period.

<sup>a</sup>Values are expressed as Mean ± SD or Mean rank.<sup>b</sup>Case: using Alpha<sup>®</sup> Ointment.<sup>c</sup>Control: using Betadine.

their rate of satisfaction with the treatment received ( $P = 0.02$ ); thus, the mean rate of satisfaction was higher in the case group than in the control group. Nevertheless, there were no significant differences between the two groups in terms of the intensity of pain ( $P = 0.11$ ), the repair score ( $P = 0.27$ ), redness ( $P = 0.13$ ), edema ( $P = 0.49$ ), ecchymosed ( $P = 0.61$ ), discharge ( $P = 1.000$ ), and approximation ( $P = 1.000$ ) in the first 24 hours after delivery (Table 2).

According to the results obtained on the third day after delivery, the two groups differed significantly concerning the mean score of pain as determined by the McGill Pain Index, the repair score, the mean intensity of pain, approximation, redness, and discharge ( $P < 0.001$ ). The mean score and rate of these variables were higher in the control group than in the cases. The two groups also differed significantly regarding their rate of satisfaction ( $P < 0.001$ ) and the case group had a higher rate of satisfaction than the control group. Nevertheless, there were no significant differences between the two groups concerning ecchymosis ( $P = 0.61$ ) and edema ( $P = 0.53$ ) (Table 2).

The results of evaluating the groups on the seventh day after delivery showed significant differences between the two groups in terms of the mean pain score, repair score, intensity of pain, redness, and discharge ( $P = 0.001$ ,  $P < 0.001$ ), as the mean score and rate of these variables were higher in the control group than in the cases. On the seventh day after delivery, there was a significant difference between the groups regarding approximation ( $P = 0.002$ ), as the rate of wound closure was higher in the case group than in the control group. The rate of satisfaction was also significantly different between the groups on the seventh day ( $P < 0.001$ ) and the case group enjoyed a higher rate of satisfaction than the control group. Nevertheless, there were no significant differences between the two groups concerning ecchymosed ( $P = 1.00$ ) and edema ( $P = 1.00$ ) (Table 2).

**Table 2.** Comparing Pain, Repair Score and Intensity of Pain in Two Groups<sup>a</sup>

Variable/Flowing After Delivery	Case	Control	P Value
<b>Pain score</b>			
The first 24 hours	4.48 ± 1.33	5.1 ± 1.6	0.01
The third day	2.76 ± 1.19	3.6 ± 1.6	0.00
The seventh day	2.9 ± 1.27	1.59 ± 1.04	0.00
<b>Repair score</b>			
The first 24 hours	0.37 ± 0.76	0.52 ± 0.75	0.27
The third day	1.32 ± 1.4	0.25 ± 0.53	0.00
The seventh day	0.203 ± 0.47	0.93 ± 1.17	0.00
<b>Intensity of pain</b>			
The first 24 hours	60.95	68.99	0.11
The third day	53	76.82	0.00
The seventh day	55.52	74.34	0.00
<b>Redness</b>			
The first 24 hours	61.50	68.45	0.13
The third day	56.95	78.92	0.00
The seventh day	60	69.92	0.001
<b>Edema</b>			
The first 24 hours	63.12	66.58	0.49
The third day	63.59	66.39	0.53
The seventh day	65.01	64.99	1
<b>Ecchymosed</b>			
The first 24 hours	65.52	64.49	0.61
The third day	65.52	64.49	0.61
The seventh day	64.50	65.49	1
<b>Discharge</b>			
The first 24 hours	65.01	64.99	1
The third day	53.31	76.51	0.00
The seventh day	57.62	72.37	0.00
<b>Approximation</b>			
The first 24 hours	65.1	64.99	1
The third day	55	76.51	0.00
The seventh day	57.1	72.75	0.002
<b>Satisfaction</b>			
The first 24 hours	70.95	58.05	0.02
The third day	71.23	56.65	0.001
The seventh day	73.49	56.64	0.00

<sup>a</sup>Values are expressed as mean ± SD or mean rank.

#### 4. Discussion

Comparing the effects of Alpha<sup>®</sup> Ointment and sitz bath with Betadine<sup>®</sup> solution on episiotomy wound heal-



ing on three different follow-up occasions after delivery, it was shown that the pain score was lower in the cases than in the controls on all the follow-up occasions, while the pain intensity score and repair score were lower in the cases only on the third and seventh days after delivery, suggesting that the use of Alpha<sup>®</sup> Ointment is significantly effective on pain reduction and wound healing. Shiravi et al. (2011), examined the effects of Henna leaf extract on skin wound repair in rats and found the mean duration of complete wound repair to be lower in the case group than in the other groups (14). Habbal et al. (2005) examined the antimicrobial activity of Henna and found that Henna products have anti-inflammatory effects on bacteria (17). Alpha<sup>®</sup> Ointment is also derived from this plant and has similar properties. Several studies have examined the effect of this Ointment on the repair process of burn wounds and have unanimously confirmed its positive effects (18, 19). Hosseini et al. (2007), carried out a comparative study of the anti-inflammatory effects of Alpha<sup>®</sup> Ointment and reported the Ointment to effectively stop the growth of bacteria and improve wound healing since it can penetrate into the wound and exerts its antimicrobial effects. This Ointment affects tissue epithelialization indirectly by increasing local blood circulation and protecting the hair follicles and is therefore effective in the treatment of wounds (16). As noted, beeswax is the base of this Ointment; honey has long been used as a treatment for repairing wounds (6, 20). Honey appears to affect keratinocyte and fibroblast activities as well as the endothelial cell response (21). The results of a study by Lavaf et al. (2015), showed that Ointments of honey and phenytoin are both effective on episiotomy wound healing; however, the study found honey cream to be more effective than phenytoin cream and the placebo (22).

The evaluation of the five criteria of the REEDA scale in the present study showed that redness and discharge were higher in the controls than in the cases on the third and seventh days after delivery. Pain, warmth, redness, swelling, and loss of function are local symptoms of inflammation, and inflammation is the body's immune defense response to tissue injury or destruction (23). Alpha<sup>®</sup> Ointment reduces inflammation through the anti-inflammatory properties caused by the presence of glycoside, which inhibit macrophage activity and thus, also inhibit the production of inflammatory chemical mediators (14). Azhari et al. examined the effect of chamomile cream on episiotomy wound healing and found that the redness score was 2-5 times higher in the control group than in the case group on the seventh and fourteenth days after delivery. Chamomile appears to have similar anti-inflammatory effects as Alpha<sup>®</sup> Ointment (24).

Wound healing or repair has different stages, includ-

ing inflammation, proliferation, and remodeling, each of which are composed of other stages and some of which overlap and are not easily distinguishable from one another. Given the long tradition of herbal medicine in the history of healing and the re-emerging attention of physicians and researchers to the use of these substances due to their many benefits, finding effective alternatives for chemical medications in the wound repair process appears essential.

Despite the researchers' efforts to provide similar training to both groups and to match the subjects through random selection, the present study has limitations, including the impossibility of having full control over participants' health status, physical activity, and nutritional status, which may have influenced their wound healing process, and the subjects' different pain thresholds due to personal, cultural, and economic differences, which may have resulted in an over-reported or underreported intensity of pain. The strengths of the study include using the same delivery personnel for all the women and the similar number and type of threads used in the two groups.

#### 4.1. Conclusion

The present findings showed that Alpha<sup>®</sup> Ointment is more effective in episiotomy wound repair and pain relief than the national protocol of Betadine<sup>®</sup> solution; due to advantages such as shortening the wound repair and tissue damage healing processes, reducing mobility limitations, reducing treatment costs, and easy accessibility in addition to using pharmaceutical raw materials that are locally produced in Iran, Alpha<sup>®</sup> Ointment can serve as an effective medication for the treatment of episiotomy wounds. The introduction of these medications to medical personnel, especially physicians and midwives, who have an essential role in the treatment and care of women after delivery, will result in shorter wound repair processes, lower intensities of pain, and reduced costs following episiotomy wound infections.

#### 4.2. Limitation

Although we tried to control the factors affecting wound healing by providing the same training and random allocation, it was impossible to control the nutritional status, level of health of individuals, and the amount of physical activity per person that is effective in wound healing; these are the limitations of this research.

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