

An Investigation into the Effect of Alpha Ointment (Fundermol) On Perineal Pain Relief Following Episiotomy in Nulliparous Women

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ARTICLE INFO	ABSTRACT
<p><i>Article type:</i> Original article</p> <hr/> <p><i>Article History:</i> Received: 08-Dec -2016 Accepted: 21-Feb -2017</p> <hr/> <p><i>Key words:</i> Alpha ointment Episiotomy Intensity of episiotomy pain</p>	<p>Background & aim: Pain is the most common complaint of mothers after episiotomy. Various medications are used for the alleviation of this pain. The aim of this study was to evaluate the effect of alpha ointment on the relief of pain caused by episiotomy.</p> <p>Methods: This double-blind clinical trial was conducted on 70 primiparous women in Ommolbanin Hospital in Mashhad, Iran. The participants were divided into two groups of control and intervention. The intervention group received one fingertip unit of Alpha ointment following washing the wound with normal saline and drying, 48 hour after delivery, once a day, until the tenth day. The control group received a placebo in the same manner. Pain intensity was evaluated using the shortened form of McGill Pain Questionnaire on the first, fifth, and tenth days post-delivery. Data analysis was carried out in SPSS (version 16) using the Mann-Whitney U test, t-test, Chi-square test, and Fisher's exact test.</p> <p>Results: There was no statistically significant difference between the two groups in terms of the mean pain score on the first, fifth, and tenth days of the study ($P=0.73$, $P=0.098$, and $P=0.464$, respectively).</p> <p>Conclusion: As the finding of the present study showed, Alpha ointment had no effect on the perineal pain after episiotomy.</p>

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Introduction

Episiotomy means cutting the surface skin and muscles of the vaginal wall. This surgical incision is carried out on the perineum tissue in the second stage of labor to widen the vaginal opening during delivery (1). The main reason for using episiotomy is to reduce severe injuries in vagina and perineum, alleviate pressure on the fetal head, and speed up the process of delivery when fetus is under distress (1). One of the reasons for the popularity of episiotomy is that this direct surgical cut, which is easy to repair, is a good alternation for the rough tears, created in the absence of episiotomy (2).

Despite numerous benefits, episiotomy can lead to the emergence of such complications as infection, inflammation, and painful intercourse, out of which the perineal pain is the most common one (3). The perineal pain leads to mother's avoidance and fear of excretion, which in turn results in constipation, urinary retention, and complications, such as bleeding after delivery. Many patients state that the pain in the episiotomy area is much more severe than that of delivery, and that they mainly think that if they sit down or move, the sutures might be opened (3). Perineal pain resulting from episiotomy has always been a stressful problem

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for nulliparous women, which exerts a negative effect on their performance and first experience of becoming mother (4).

The frequencies of the perineal pain has been reported to be 96.4%, 64%, and 25% on the first, second, fortieth days post-delivery (5). The consequences of perineal pain include insomnia, fatigue, disturbance, anxiety, lack of attention to health education provided by caregivers, delay in joining the mother to her neonate (even sometimes prevention of emotional relationship between the mother and neonate), maternal immobility, formation of a sense of inability to look after the newborn, improper placement during breast-feeding, and in severe cases, deep vein thrombosis (1).

The pain may be affected by several factors, including breast feeding, epidural anesthesia, duration of the second stage of labor, degree of perineal laceration, kind of suturing, and type of delivery (6).

Many measures have been recommended to reduce perineal pain, such as observing the perineal hygiene, keeping the wound dry, and using various pharmacological and non-pharmacological treatments (7). Non-pharmacological treatments in this regard include cryotherapy, laser therapy, electrical stimulation, acupuncture, and pelvic floor exercises (7-12).

Furthermore, the pharmacological treatments to alleviate perineal pain are acetaminophen, mefenamic acid, lidocaine gel, and sodium diclofenac suppository. The herbal remedies for the management of this pain include olive, lavender, Aloe vera, chamomile, marigold, and cinnamon (13). The normal way of pain relief involves using non-steroidal anti-inflammatory oral medications (5).

Despite the large number of clinical trials and empirical evidence regarding this issue, the use of pharmacological treatments for the mitigation of perineal pain can cause some side effects, including constipation, digestive problems, risk of drug transfer into breastmilk, and possible neonatal side effects (1). Therefore, the use of an effective method with minimum side effects, which is available and acceptable by the women giving birth, is currently considered by the researchers.

In a study conducted by Golmakani, turmeric had no effect on the perineal pain after

episiotomy (14). Aghdampour demonstrated the effectiveness of Aloe vera on episiotomy pain (15). In a study performed by Golozar, the oral usage of bromelain reduced pain just 24 h after episiotomy; nonetheless, it failed to reduce the postpartum pain on the 7th and 14th days (16). Among the studies examining the effects of herbal medicines on wound healing and episiotomy pain based on the mean score of pain recovery, the use of lavender, olive, turmeric, Aloe vera, and cryotherapy were reported as the most effective methods in wound healing and alleviation of episiotomy pain (13).

Considering the increasing trend of using herbal medicines in the world, special attention has been paid to these herbs in this domain. According to the World Health Organization, 25% of the commonly used medicines are of herbal origin, and in 74% of these medicines, the traditional effect have been transmitted from their past (17). Given the effectiveness of Alpha herbal ointment on pain and the increased tendency to use herbal medicines, the current study aimed to determine the effect of Alpha ointment on episiotomy pain among the primiparous women.

Fundermol is a purely herbal agent, the ingredients of which are domestically produced. It is known as 30-gram ointment under the commercial name of Alpha ointment. This medication is covered by the national insurance and presented in all pharmacies. The active ingredient of this ointment is Lawsone (2-hydroxy-1, 4-naphthoquinone), which is obtained from hinna or *Lawsonia inermis* (18, 19). The ingredients of this medication includes Lawsone from henna (active ingredient), honey (Medicine based), flavonoids, polyunsaturated fatty acids, and curcumin (*Curcuma longa*) (20).

Alpha ointment stimulates epithelialization (density of the affected area) and angiogenesis in the affected area; furthermore, it increases the elasticity of the tissue during its restoration process. Moreover, this agent exerts its restorative effects through reducing inflammation or swelling and preventing the spread of infection (21). According to the manufacturer, this ointment has anti-inflammatory and soothing properties in addition to the antibacterial and restorative effects (22).

In a study titled "Comparison of healing time

of the 2nd degree burn wounds with two dressing methods of fundermol herbal ointment and 1% silver sulfadiazine cream", Daryabeigi (2011) showed that Alpha ointment was more effective than sulfadiazine ointment in the alleviation of pain (23).

Beeswax is used as the basis for the Alpha ointment. It contains various compounds, such as flavonoids. This substance has estrogenic and antibacterial effects on animal systems. Beeswax affects membrane permeability and reduces the free radical formation. The anti-inflammatory effect of this substance results from the inhibition of inflammatory mediators, such as prostaglandins. Furthermore, this substance is used as a local anesthetic due its sedative effect, which is comparable to that of cocaine (24). Beeswax entails a substance called Propolis, which has an anti-inflammatory effect comparable to that of diclofenac (20).

Given the physiological, psychological, and socio-economic effects of episiotomy on the women, attempts to reduce maternal pain should be considered at the heart of postpartum care (25-26). Alpha ointment is an inexpensive medicine produced in Iran, the impact of which on the acceleration of wound healing and reduction of pain has been demonstrated in numerous studies (27).

To the best of our knowledge, there is no study investigating the impact of Alpha ointment on the pain experienced by primiparous women after episiotomy. Regarding this and given the importance of returning mothers to their daily activities quickly, the present study aimed to examine the effect of Alpha ointment (fundermol) on the severity of pain after episiotomy among the primiparous women.

Materials and Methods

This parallel clinical trial was conducted on 70 primiparous women referring to Ommolbanin Hospital in Mashhad, Iran, for normal delivery within February to September of 2016. Since similar studies were not found during the research, the sample size was selected according to a study performed by Heidari et al. at the University of Boroujen, Chaharmahal and Bakhtiari Province, Iran (2014) that compared the healing time of second-degree burns using herbal fundermol (Alpha ointment) and silver

sulfadiazine 1% (19).

In the mentioned study, the mean healing time in the Alpha ointment and sulfadiazine ointment 1% groups (at least 30 cases in each group) were 8.1 ± 4.4 and 207.2 ± 9.5 days, respectively, that was calculated with 95% confidence coefficient and 80% power. In the present study, considering 15% sample loss in each group, the sample size was determined as 35 subjects per group (i.e., 70 cases in total).

After obtaining written consent and controlling the inclusion and exclusion criteria, the study population was selected. Subsequently, the participants were assigned into two groups of intervention and control using the simple random sampling method by throwing coins. The research approval was obtained from the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran, and the research was registered in the registry of Iranian clinical trials. The placebo ointment was prepared by a pharmacist, and Alfa and placebo ointments were named as A and B, respectively.

The inclusion criteria were: 1) term pregnancy, 2) nulliparity, 3) age range of 18-35 years, 4) lack of any acute and chronic diseases, 5) normal body mass index, 6) no prolonged labor, 7) lack of chronic constipation, 8) insensitivity to herbal medicines, 9) no history of active skin disease, 10) no history of disruptive disease in wound healing, 11) non-consumption of any disruptive medicine in wound healing, 12) absence of symptomatic infection in the vagina and vulva (e.g., infectious discharge, itching, burning), and 13) no lesions in anus, vulva, and perineum at the time of hospital stay.

On the other hand, the exclusion criteria included: 1) too much manipulation in the perineum during delivery, 2) assisted delivery (i.e., forceps and vacuum), 3) extension of the incision area into tear grades 3 and 4, 4) existence of tear, except for episiotomy tear, 5) neonatal admission to the Neonatal Intensive Care Unit, 6) abnormal vaginal bleeding, 7) hematoma formation in the perineum, 8) intercourse till the end of the study, 9) manual removal of placenta, 10) elongation of the first, second, and third stages of labor (i.e., more than 14, 2, and 1 h, respectively), 11) irregular use of the ointment, and 12) puerperal fever.

The data were collected through using the McGill Pain Questionnaire, an information form covering such data as the stages of labor and episiotomy, and a form for keeping daily information regarding the consumption of painkillers and antibiotics as well as taking care of hygiene and nutrition, the content validity of which was confirmed. The validity of the shortened format of the McGill Pain Questionnaire was approved by Khosravi in 2012 (28). This questionnaire consists of three parts.

The first part consists of 15 verbal descriptors each of which has a specific rank (i.e., 0=no pain, 1=mild, 2=moderate, 3=severe) divided into two main groups (i.e., sensual, emotional). The second part involves the visual scale of pain with a score range of 0-10. Additionally, the third part contains the current pain intensity as determined in a range (i.e., 0=no pain, 1=mild, 2=annoying, 3=painful, 4=horrible, and 5=excruciating).

The total score of the patient's pain is obtained by summing up the total score of all collections in different aspects of pain. The reliability of the McGill questionnaire was calculated by Khosravi et al. (2013) in all areas, rendering a Cronbach's alpha coefficient of over 0.8 (4). In the present study, the reliability of the pain interference questionnaire was evaluated using physical and psychological activities with an equal assessment method ($\alpha=0.95$).

The participants and researcher were not aware of the medications available in the coded tubes. The researcher was present at mothers' bedside since the beginning of their admission to the maternity department to record personal information, progress of delivery, information about the infant, size of episiotomy incision, type of thread, as well as number and depth of sutures. After episiotomy, the participants were provided with essential recommendations for caring the wound, such as drying and cleaning, health advice, regular consumption of antibiotics and painkillers as prescribed by doctor, and nutrition.

The coded ointment tubes were given to the participants. The subjects were taught to use one fingertip unit of the ointment after washing and drying the perineum to cover the entire surface of the wound 48 h post-delivery once a

day until the tenth day. On the first, fifth, and tenth days after delivery, the perineal pain was evaluated in the lithotomy position using the McGill's shortened questionnaire.

The mothers were informed about the time and date of the next appointment and provided with the researcher's phone number. They were recommended to first contact the researcher in case of any problems. The data were analyzed using Mann-Whitney U test, t-test, Fisher's exact test, and Chi-square test in SPSS (version 16). P-value less than 0.05 was considered statistically significant.

Results

The study population consisted of 76 primiparous women, who were eligible for the research. During the study, six subjects were excluded from the research due to such reasons as the non-use of the ointment on a regular basis, lack of referral, non-cooperation, and neonatal admission due to jaundice. Finally, the study was continued with 70 patients (i.e., 35 cases in each group).

The two groups had no significant difference regarding the length of the second stage of labor, number of vaginal examinations, length of skin incision from fourchette to the end of cutting, cutting length of mucosa, deepest area of skin incision, and number of sutures ($P>0.05$) (Table 1).

Prior to the intervention, no significant statistical difference was found between the Alpha ointment and placebo groups ($P=0.204$). However, there was a significant difference in the mean pain scores of the two groups on the first, fifth, and tenth days post-delivery ($P=0.046$, $P=0.01$, and $P=0.024$, respectively). On the other hand, there was no significant difference between the two groups in terms of the mean score of pain in none of the study days (Table 2).

The variables related to reaction or skin sensitivity (e.g., itching, redness, burning, skin spots) were also investigated. No case was diagnosed with allergy symptoms; therefore, alpha ointment resulted in no skin allergy in the participants.

Table 1. Comparison of the two groups in terms of some variables based on mean, standard deviation, median, and interquartile domain

Variable Name	Group		Test result (Mann-Whitney U test)
	Alpha Ointment	Placebo	
Duration of the second stage of labor (min)	61±36.8	34.3 ±54.1	Z=-0.826 P=0.409
Number of vaginal examinations in the second stage of labor	2 (0.923)	2 (0.877)	Z=-1.268 P=0.205
Length of skin incision from fourchette to the end of cutting (cm)	4±0.9	4±0.94	Z=-0.106 P=0.915
Mucosa cutting length (cm)	4.7±0.957	4.28±1.01	Z=-1.789 P=0.074
Deepest area of cut (cm)	2.5±0.683	2.5±0.683	Z=-0.512 P=0.609
Number of sutures	5 (1.03)	6 (0.85)	Z=-1.617 P=0.106

Table 2. Comparison of the two study groups in terms of pain score before the intervention and on the first, fifth, and tenth days after childbirth

Group	Medicine	Placebo	Significance level
Time	SD ± Mean	SD ± Mean	(t-test)
Before the intervention	8.917±3.194	9.08±3.27	P=0.883
First day	7.54±2.196	8.045±3.8	P=0.73
Fifth day	6±2.74	7.54±3.8	P=0.098
Tenth day	4.228±2.36	4.68±2.8	P=0.464

Discussion

The comparison of the difference between the mean scores of perineal pain on the 5th and 10th days of the postpartum period in the two groups of alpha ointment and placebo showed that the pain scores reduced from 8.9 to 4.2 and from 9.08 to 6.6 in the intervention and control groups, respectively, within ten days. Nonetheless, there was no significant difference between the two groups regarding the pain reduction (Table 2). So far, there has been no study investigating the impact of Alpha ointment on the intensity of perineal pain after episiotomy. There are some studies comparing the alleviation of pain in some wounds, such as burning.

In a comparative study examining the impact of silver sulfadiazine ointment 1% and Alpha ointment on pain relief among the patients suffering from second-degree burn, Heidari (2013) demonstrated that Alpha ointment was more effective in pain mitigation than silver sulfadiazine 1%. Therefore, they concluded Alpha ointment as a proper substitute to reduce the pain in the patients suffering from burn. In addition, they stated that the analgesic effects of

fundermol (Alpha ointment) is due to beeswax, which is one of the components of this medicine (19). The results of the mentioned study are inconsistent with those of the present study.

Beeswax is used as the basis for the Alpha ointment (24).

Beeswax contains a substance called Propolis, which has anti-inflammatory effects comparable to that of diclofenac (20). Propolis is a resinous substance that is collected by bees from the buds or other parts of the plants. This substance is known for its biological, antibacterial, antifungal, and healing properties. Its antifungal activity has been confirmed in numerous studies (29). Propolis is known for being a disinfectant and is an effective factor in preventing the spread of disease in the hive (29).

Roghani (2012) conducted a study titled "The investigation of analgesic effect of curcumin (turmeric effective substance) on diabetic rats and the evaluation of the role of lipid peroxidation". Roghani concluded that the prescription of curcumin for reducing pain in

both acute and chronic phases of formalin test was effective in diabetic rats and increased the thermal pain threshold. In the mentioned study, it was stated that this beneficial effects were partly applied by lipid peroxidation (30).

Golmakani et al. (2008) assessed the effect of turmeric ointment on the wound healing of episiotomy in nulliparous women. They reported no significant difference between the intervention and control groups in terms of pain intensity (14). In a study carried out by Chipodiora et al., curcumin was reported to be effective in the pain alleviation (31). In addition, Nesa et al. (2014) confirmed the analgesic and anti-inflammatory effects of hinna in this regard (32).

In the current study, despite the lower mean score of pain in the Alpha ointment group, compared to the placebo group, there was no significant difference between the two groups in terms of the pain after episiotomy. Therefore, alpha ointment was concluded to be ineffective in reducing episiotomy pain despite containing beeswax, curcumin, and hinna (all of which reduce pain and inflammation).

In the present study, variables related to the reaction or skin sensitivity (e.g., itching, redness, burning, and skin spots) were investigated, and no participant showed signs of allergy. Our findings are in line with those obtained by Ansari (27), and the Alpha ointment resulted in no skin sensitivity in any of the studies. In a study titled "Effect of alpha ointment (fundermol) on episiotomy wound healing in primiparous women", Navinejad et al. (2017) showed that Alpha ointment had no effect on wound healing (33).

The limitations of the present study included the inability to control the individual differences in the samples regarding the type of perineal tissue, power of wound healing, nutrition status, level of individuals' health, and rate of physical mobility in each person, which are effective in wound healing process. However, attempts were made to control these issues by providing equal education with the purpose of reducing the effective factors and random selection of the individuals.

Conclusion

As the findings of the present study

indicated, there was no significant difference between the two groups in terms of the mean score of pain. Therefore, it could be concluded that Alpha ointment did not alleviate the perineal pain following episiotomy. Regarding this, it is recommended to conduct further studies on open sores using the animal models.

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Conflicts of interest

The authors declare no conflicts of interest.

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