

Original Article



The Effects of Ginger (*Zingiber officinale*) Extract Ointment on Pain and Episiotomy Wound Healing in Nulliparous Women: A Randomized Clinical Trial

Fatemeh Cheshfar¹, Soheila Bani^{2*}, Mojgan Mirghafourvand¹, Shirin Hasanpour³, Yousef Javadzadeh⁴

¹Department of Midwifery, Nursing and Midwifery Faculty, Tabriz University of Medical Sciences, Tabriz, Iran

²Physical Medicine and Rehabilitation Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

³Women's Reproductive Health Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

⁴Department of Pharmaceutics, Faculty of Pharmacy, Tabriz University of Medical Sciences, Tabriz, Iran

Article Info

Article History:

Received: October 15, 2022

Accepted: March 12, 2023

e-Published: May 20, 2023

Keywords:

Episiotomy, Wound healing, Pain, Ginger

*Corresponding Author:

Soheila Bani,

Email: Banisoheila@gmail.com

Abstract

Introduction: Episiotomy is a usual midwifery surgery. Iran is a country with an abundant source of medicinal plants. This study aimed to investigate ginger extract ointment's effects on the pain and recovery of episiotomy incisions in nulliparous women.

Methods: This randomized clinical trial was conducted in a public hospital in Iran on 70 nulliparous women with an episiotomy incision. The women were randomly assigned to ginger extract ointment and placebo groups. The primary outcomes included pain and wound healing that were assessed using a visual analog scale (VAS), redness, edema, ecchymosis/bruising, discharge, and an approximation scale (REEDA). The participants were followed up before discharge from the hospital and 5 × 1 and 10 × 1 days after the intervention. The secondary outcome was the number of painkillers used during the study. Data were analyzed by chi-square, independent *t* test, and the Mann-Whitney U via SPSS-13. The significance levels were determined to be $P \leq 0.05$.

Results: There was no significant difference between participants treated with ginger extract ointment and placebo in the pain and wound healing scores before the intervention; 5 × 1 and 10 × 1 days after the intervention. But, the pain intensity decreased, and the recovery speed increased clinically. Also, regarding the secondary outcome of this study, no significant difference between the placebo and intervention groups in the number of painkillers participants took.

Conclusion: The ginger ointment could not significantly improve episiotomy wounds' pain and healing rate, but it was clinically helpful. So more studies with different doses of this ointment are needed.

Introduction

As the most common surgical procedure in midwifery, an episiotomy is a cut (incision) through the area between the vaginal opening and the anus, called the perineum, to make the vaginal opening larger for childbirth.¹ This surgical procedure is more commonly done for Asian women because of having a short perineum that is highly prone to rupture.² It has been reported that the episiotomy rate is less than 30% in Western countries and more than 70% in East Asian countries.³ Like any other surgery, an episiotomy has complications, such as bleeding, infection, pain, inflammation, edema, pain during intercourse, rupture of sutures, and hematoma.⁴ One of the common conditions that women may suffer from during and after pregnancy is the pain caused by tissue damage and inflammation.⁵ Postpartum pain is closely related

to obstetric traumas, especially episiotomy.⁶ A study showed that the perineal pain in women undergoing an episiotomy is usually four times more severe than the pain other women experience. It also reported that the prevalence of postpartum pain was 96.4% and 63% on the first and tenth days after delivery, respectively.⁷ About 12.8% of women claim the chronic pain caused by an episiotomy up to 5 months after delivery.⁸ Wound healing is a process of recovery that begins following any damage to the skin or other tissues.⁹ One of the main objectives of medical sciences is to reduce the duration of wound healing complications. It is essential because a surround-healing process minimizes the risk of wound infections or complications and reduces medical costs.¹⁰ Ginger (*Zingiber officinal*) is an edible plant, spice, and herb that is referred to as "Zanjefil", "Shangwir", or "Zhangvir" in

some ancient Farsi texts. It is a herbaceous perennial with about 70 species native to Southeast Asia that grow annual pseudostems (false stems made of the rolled bases of leaves) about one-meter-tall bearing narrow leaf blades. The inflorescences bear flowers with pale yellow petals with purple edges that arise directly from the rhizome on separate shoots.¹¹ The Food and Drug Administration (FDA) has introduced ginger as a safe medicine.¹²

Ginger contains some active ingredients that exhibit major physiological and pharmacological activities, such as antioxidant, anti-inflammatory, and analgesic activities.¹³ Shogaols and gingerols are two primary biological components of ginger.¹⁴ Ginger also contains anthocyanins, highly potent antioxidants that suppress pain-related pathways by inhibiting cyclooxygenases (COXs) and lipoxygenases (LOXs). These compounds inhibit inflammatory pathways and nitric oxide synthase to exert their analgesic effects.¹⁵ A study showed that Ginger, a healthy and safe herbal medicine with no side effects, can be an excellent alternative to mefenamic acid for mothers who complain of labour pains.¹⁶ A study on the impacts of the nontoxic concentration of ginger extract on wound healing indicated that the cellulose and extract of ginger (*Z. officinale*) are good medicines for wound healing.¹⁷ Medicinal plants and traditional treatments can play a significant role in wound healing. In addition, ginger is an easily accessible plant with numerous beneficial properties. However, few human studies assessed whether oral or topical ginger has a positive effect in reducing pain. And the studies were also on dysmenorrhea, musculoskeletal pain and knee pain, but no human study has been conducted on the effect of ginger on episiotomy pain and recovery. Also, there is some evidence that ginger helps wound healing and inflammation. Continued research is needed to establish a solid evidence base proving its effectiveness in humans. So, this study aimed to investigate the effects of ginger extract ointment on the pain and recovery of episiotomy incisions in nulliparous women.

Materials and Methods

This randomized controlled clinical trial was conducted on 70 nulliparous (After obtaining informed consent (in the postpartum ward of Koohkamri Hospital of Marand, Iran, from August 2020 to December 2020. The Inclusion criteria were: primiparous women, lack of drug and psychotropic addiction (according to the woman and the case file documents), age of the woman in the range of 18-35 years, delivery of live and single fetus, Having a mediolateral episiotomy, no use of particular drugs Such as anti-inflammatory drugs other than acetaminophen and anticoagulants (according to the women), no history of diseases that impair wound healing(such as Systemic diseases, heart, kidney, lung, coagulation disorders, immunodeficiency, connective tissue disorders, diabetes, Anemia, mental illness and hemophilia), not following

a special diet (according to the woman), not having Anemia during pregnancy, no history of prenatal vaginal examinations and manipulations, no large or enlarged episiotomy (length of the repair site 3-5 cm), the desire and possibility of the mother to visit in Koohkamri Hospital on days 5 and 10, no history of reconstructive surgery on the perineum no long-term rupture of the amniotic sac (more than 18 hours), no use of blood pressure medications.

Exclusion criteria include postpartum haemorrhage, topical lidocaine cream use, desmopressin after delivery and unwillingness to continue the partnership. The two research variables, i.e., pain and wound healing, were considered for calculating sample size in G-Power.

Based on the study of Mahmoodi et al and Considering $M_1 = 1.2$ (the mean pain score in the intervention group), $M_2 = 2.2$ (the mean pain score in the control group), $SD_1 = 1.6$, $SD_2 = 1.2$, one-sided $\alpha = 0.05$, and a test power of 90%, the sample size related to "pain" was calculated equal to 32. After assuming an attrition rate of 10%, the final sample size was determined to be 35 in each group. Moreover, considering $M_1 = 1.6$ (the mean wound healing score in the intervention group), $M_2 = 3.0$ (the mean wound healing score in the control group), $SD_1 = 1.3$, $SD_2 = 1.6$, one-sided $\alpha = 0.05$, and a test power of 90%, the sample size related to "wound healing" was calculated equal to 20. After assuming an attrition rate of 10%, the final sample size was determined to be 22 in each group. Since the sample size calculated based on "pain" was more significant, the sample size in each group was finally decided to be 35 (Figure 1).¹⁸ This study was conducted after approval by the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1399.333) and registration on the Iranian Registry of Clinical Trials (Identifier: IRCT20110922007618N9, registered on August 14, 2020). Computer-generated tables performed the randomization process by a third person not involved in the research protocol. The participants were randomly assigned to intervention and control groups at a 1:1 allocation ratio. Details of the allocated groups were recorded on cards contained in sequentially numbered, opaque, sealed envelopes. These were prepared by a third person not involved in the clinical trial phases. Once the participant was eligible for the procedure and completed all baseline assessments, the allocation assignment was revealed by this envelope being opened by the mentioned third person. Neither the participant nor the operator knew the group allocation, both being blinded to the protocol. The participants were selected from the nulliparous women admitted to the postpartum ward 1-2 hours after the delivery with a usual mediolateral episiotomy incision (an incision length of 3-5 cm according to the inclusion criteria). The researcher briefed those who met the inclusion on the research objectives and procedures and then asked those willing to participate in the study to fill out an informed consent form and a demographics form (personal-social information and fertility characteristics).

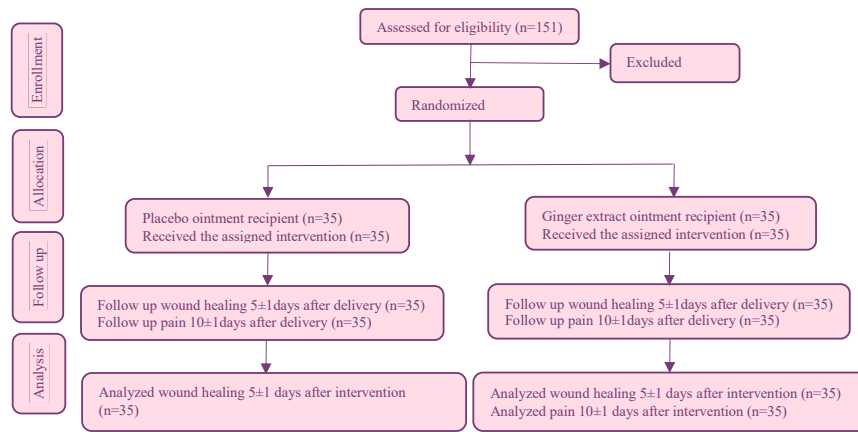


Figure 1. Flowchart of study

After evaluating the pre-intervention severity of pain and wound status using a visual analogue scale (VAS) and the REEDA scale (redness, oedema, ecchymosis, discharge, and approximation), respectively, the participants were assigned to two groups of intervention (ginger extract ointment) and control (placebo ointment) based on a randomized block design with a size of 4 and 6. The utterly identical ointment tubes were placed in opaque numbered envelopes by a person not involved in sampling and data analysis. Each participant who entered the study chose and opened one of the envelopes to be assigned to either the intervention or control groups.

After confirming the identity of the ginger prepared by the herbarium of Tabriz University of Medical Sciences, the extraction of ginger was done using hydroalcoholic solvents (ethanol). The empty metal tubes were first sterilized on dry heat. The ointment base was melted at high temperatures in an ointment-filling machine. Then the temperature was reduced, and the concentrated herbal extract was added to the melted ointment base before it hardened. After stirring the mixture under aseptic conditions, sterile tubes were filled with the ointment and sealed. To prevent possible side effects of Ginger, the most suitable concentration of the ginger extract (0.05%) was determined after reviewing similar papers and eliciting the views and comments of the supervisor and advisors. For placebo ointment, a few drops of ginger extract were added to Vaseline and poured into sterile tubes of the same form, colour, and size. The participants were treated with ginger or placebo extract ointment within 2-10 hours after delivery and 12 hours later. They were also instructed on how to use the ointment at home. Before discharge, form 2 (the number of painkillers taken, if necessary, from the day of intervention to the tenth day after intervention) and the ointment instruction form were given to the participants to fill out at home. They were also provided with the researcher's contact information to report any possible complications or ask questions. The participants were also asked to visit the studied hospital 5 × 1 and 10 × 1 days after the intervention to measure pain severity (by

VAS) and the wound healing status (by REEDA scale). The researcher also contacted the participants to ensure they administered the ointment as instructed. In addition to the person who specified the adornment of participants, only the researcher assistant was aware of the type of medicine prescribed; the researcher, participants, and the data collector and analyzer were unaware of this issue.

Moreover, the participants were provided with twenty 500-mg tablets of acetaminophen and Questionnaire 2 to register the type and number of painkillers taken during the ten days of treatment; they were asked to submit the completed questionnaire and the pocket of tablets to the researcher when they come for a visit on the 10th day. The participants were also instructed on how to administer the ointment. Accordingly, they were expected to wash their hands and the perineum thoroughly and dry them with a clean cloth, then apply a fingertip of the ointment to the sutures and cover the area with a sanitary menstrual pad. They were asked to use the ointment the same way twice a day, with an interval of 12 × 1 hours, for ten days. The researcher also contacted the participants to ensure they administered the ointment as instructed. In case of any side effects (such as allergies and infections) following the use of ointment, the intervention was stopped, and the side effects were recorded in the report. In addition, the participant was referred to a specialist if she reported adverse events. In this study, the primary outcomes were the severity of pain and the wound healing status, whereas the secondary outcome was the number of painkillers each participant took. A VAS was employed to measure the severity of pain. This instrument is a 10-cm ruler graded from 0 (no pain) to 10 (severest pain) in mm. The participants were asked to underline one of the numbers on the ruler to express the severity of pain. This scale has been widely used in other studies to measure pain, and its reliability and validity have been approved.¹⁹ The REEDA scale was also used for measuring the wound healing status. We chose the REDA scale because the studies are valid for measuring wound healing²⁰ (Table 1). The subscales are scored as follows:

Table 1. REEDA* evaluation of postpartum healing

Score	Redness	Oedema	Ecchymosis	Discharge	Approximation
0	No redness	No oedema	No ecchymosis	No discharge	completely closed
1	0.25 cm from the edge of the wound	Less than 1 cm at the perineal incision	About 0.25 cm on both sides and 0.5 cm on one side	serous discharge	3 cm or less
2	0.5 cm from the edge of the wound	2 cm at the perineal incision	About 1 cm on both sides or 2 cm on one side	Purulent serous discharge	Separation of skin and subcutaneous fat layer
3	More than 0.5 from the edge of the wound	More than 2 cm at the perineal incision	More than 2 cm on both sides and 3 cm on one side	Purulent bloody discharge	Separation of subcutaneous and Facia

Total score: Healed: 0, moderately healed: 1-5, mildly healed: 6-10, Not healed: 11-15

* The five subscales of this tool are redness, oedema, ecchymosis, discharge, and approximation.

The collected data were statistically analyzed by descriptive statistics (mean, standard deviation, frequency, ratios) and inferential statistics, including the chi-square test, the independent *t* test, and the Mann-Whitney U test (in the case of the non-normal distribution of data) in SPSS-13. The normality distribution of data was determined using the Kolmogorov-Smirnov test. All calculations were performed based on the intention to treat. All statistical tests' confidence and significance levels were determined to be 95% and $P \leq 0.05$, respectively. Seventy nulliparous women participated in this study, and the attrition rate was zero in both groups.

Results

One hundred fifty-one pregnant women were evaluated for eligibility. Sixty-six people did not meet the inclusion criteria. Fifteen people did not want to participate in the study. Seventy pregnant women were randomly divided into two groups of intervention ($n=35$) and placebo ($n=35$). The results showed that there was no significant difference between the two groups in terms of demographic and midwifery variables. The mean (SD) age of participants was 23.54(5.78) years in the placebo group and 24.94 (5.82) years in the intervention group, which indicates no significant difference between the two groups ($P=0.53$). There was also no significant difference between the placebo and intervention groups in other demographic characteristics such as mean (SD) of episiotomy incision(cm) [4 (0.84) cm vs. 3.88 (0.86) cm, $P=0.50$], BMI (kg/m^2), [27.93 (3.48) vs. 27.22 (3.5), $P=0.89$], number of sutures [4.37 (1.35) vs. 4.74 (1.57), $P=0.57$], the first stage of labor [301.7 (129.5) vs. 297.1 (135.1), $P=0.14$], the second stage of labor [37.85 (12.56) vs. 44.14 (13.79), $P=0.9$], the third stage of labor [10.57 (4.96) vs. 14 (7.15), $P=0.081$], and fetal weight [3042.7 (337.5) vs. 3109.1 (517.8), $P=0.06$] (Table 2).

Episiotomy Healing (Primary Outcome)

There was no significant difference between the intervention and control groups in the pre-intervention mean (SD) score of episiotomies wound healing [5.51 (1.52) vs. 5.54 (1.52), $P=0.894$]. In addition, no significant difference was found between the two groups in this regard on the fifth day [3.62 (1.64) vs. 3.40 (1.19), $P=0.69$] and

the tenth day [2.37 (1.35) vs. 2.28 (1.48), $P=0.98$] after the intervention (Table 3). But the average REDA score on the fifth and tenth days after the intervention showed an improvement in recovery compared to the time before the intervention and was better than the control group.

Episiotomy Pain (Primary Outcome)

The pre-intervention mean (SD) pain score was 5.11 (1.64) in the intervention group and 5.11 (1.77) in the placebo group, which shows no significant difference ($P=0.92$). Moreover, there was no significant difference between the two groups in the mean score of pain on the fifth day [2.37 (2.05) vs. 2.14 (1.97), $P=0.57$] and the tenth day (1.34 (1.71) vs. 1.14 (1.88), $P=0.4$) after the intervention (Table 3). However, the average VAS on the 5th and 10th

Table 2. Demographic Characteristics

Variables	Mean (SD)		P
	Placebo (n=35)	Drug (n=35)	
Means			
Age (year)*	23.54 (5.78)	24.94 (5.82)	0.53
Episiotomy incision (cm)*	4 (0.84)	3.88 (0.86)	0.50
BMI (kg/m^2) *	27.93 (3.48)	27.22 (3.51)	0.89
Number of stitches*	4.37 (1.35)	4.74 (1.57)	0.57
Duration of labor (min)*			
First stage	301.7 (129.5)	297.1 (135.1)	0.14
Second stage	37.85 (12.56)	44.14 (13.79)	0.90
Third stage	10.57 (4.96)	14 (7.15)	0.08
Baby weight (g) *	3042.7 (337.5)	3109.1 (517.8)	0.60
Education**			
High school	21 (60)	18 (51.4)	
Diploma	10 (28.6)	11 (31.4)	0.71
University	4 (11.4)	6 (17.1)	
Income**			
Good	0 (0)	1 (2.9)	
Moderate	32 (91.4)	31 (88.6)	6.02
Weak	3 (8.6)	3(8.6)	
Use of antibiotics**			
Yes	14 (40)	13 (37.1)	
No	21 (60)	22 (62.2)	0.80

* Independent sample t-test; ** Chi-square test.

Table 3. Comparison of the two study groups in terms of healing, pain score, and use of acetaminophen before the intervention, fifth and tenth days after the intervention

Group	Placebo	Drug	P*
Healing			
Before the intervention	5.51(1.52)	5.54(1.52)	0.89
Fifth day	3.62(1.64)	3.40(1.19)	0.69
Tenth day	2.37(1.35)	2.28(1.48)	0.98
Pain			
Before the intervention	5.11(1.77)	5.11(1.64)	0.92
Fifth day	2.37(2.05)	2.14(1.97)	0.57
Tenth day	1.34(1.71)	1.14(1.88)	0.40
Acetaminophen	1.97(0.28)	1.91(0.16)	0.30

Data are expressed as mean (SD).

*Mann-Whitney U test.

day after the intervention decreased pain compared to the control group and before the intervention.

Painkillers Consumption (Secondary Outcome)

The results demonstrated no significant difference between the placebo and intervention groups in the number of painkillers participants took ($P=0.30$) (Table 3).

Discussion

Various mechanisms have been mentioned for pain relief by ginger, such as inhibition of prostaglandins through COXs and LOXs pathways, antioxidant activities, inhibition of the NF- κ B transcription factor (Nuclear NF- κ B is the principal regulator of pro-inflammatory gene expression), and acting as a pain receptor agonist. In addition, ginger has excellent inhibitory effects on oxygen-free radicals such as superoxide, hydroxyl radicals, and lipid peroxide. The current study's results indicated no significant difference between the participants treated with ginger extract and placebo ointment in the severity of pain and wound healing status. However, the episiotomy healing on the 5th and 10th day after the intervention was better than before the intervention and the control group. Also, the episiotomy pain after intervention on the 5th and 10th days was lower than before the intervention and the control group. Although there was no study dealing with the effects of ginger ointment on episiotomy wound healing in humans, many studies have reported the analgesic results of this plant on dysmenorrhea and other pains in women. Mozafari et al studied the effects of rhizome capsules (ginger) on postpartum pain in 128 mothers with moderate to severe pain after vaginal delivery.²¹ Participants in group A (placebo) received 500 mg placebo capsules containing pea flour, and those in group B (intervention) received 500 mg Zintoma capsules (ginger rhizome) every 8 hours from two hours after delivery. In the second and third interventions, group A and group B were administered 250 mg placebo capsules and 250 mg Zintoma capsules, respectively. The severity of pain was measured before each intervention and half

an hour, one hour, and two hours after each intervention. The mean pain score was significantly reduced in both groups during the interventions.

In contrast, the severity of pain in the intervention group was significantly lower than in the control group at any time after the intervention. There are differences between the current study and the study conducted by Mozafari et al for example; they treated the participants with an edible ginger medicine with different doses. They employed a numerical rating scale (NRS) to measure the severity of pain. In contrast, in this study, the participants were treated with ginger ointment, and the severity of their pain was measured using VAS. Ozgoli et al compared the effects of Ginger, mefenamic acid, and ibuprofen on pain in women with primary dysmenorrhea.²² They selected 150 university students (aged over 18 years) with primary dysmenorrhea from the dormitories of two universities of medical sciences as the sample. They alternately assigned them to three groups of equal size. Participants in the ginger group received 250 mg capsules containing rhizome powder four times a day for three days from the beginning of the menstrual cycle. Those in other groups received 250 mg mefenamic acid capsules and 400 mg ibuprofen capsules under the same protocol. The verbal multidimensional scoring system was employed to assess the severity of primary dysmenorrhea. The three groups were also compared regarding disease severity, pain relief, and satisfaction with treatment after a menstrual cycle. The severity of dysmenorrhea significantly reduced in all groups after the treatment. There was no significant difference between the three groups in the severity of dysmenorrhea, pain relief, and satisfaction with treatment. They also reported no severe side effects of the treatments.

This research showed that there is no significant difference in the effectiveness of oral ginger with other routes of that's administration. However, they also measured dysmenorrhea pain, which is more severe than any other postpartum pain.

Kravchenko et al investigated ginger ointment's analgesic and anti-inflammatory effects on rats. Inflammation was induced by the sub-plantar injection of 30 μ L of allyl isothiocyanate (AITC) solution in 1, 2-propylene glycol into the plantar fascia (aponeurosis) of the hind limb of rats. The dynamics of inflammatory changes were evacuated before and 1, 2, 3, 4, 6, and 24 hours after the injection to measure the volume and thickness of the affected limb. The analgesic effects of ginger ointment were also measured using the AITC-induced pain model.²³ Their results showed that the 0.025% ginger ointment was most effective in inhibiting the inflammatory process. The most excellent analgesic effects were observed after using the 0.05% ginger ointment 10 minutes before pain induction. They used a combination of ginger ointment and AITC (an anti-inflammatory solution), whereas the participants in this study were treated only with ginger

ointment (containing no anti-inflammatory substance). In addition, Kravchenko et al studied the pharmacological effects of ginger extract on an AITC-induced model. It can be stated that this plant's possible mechanism is the connection between its compounds to TRPA1 and TRPV1 ion channels.²³

Kazerouni et al conducted a review study about the effects of ginger (*Z. officinale*) on skin health status. For this purpose, they selected and reviewed 34 articles on ginger's anti-inflammatory, antioxidant, anti-cancer, and therapeutic effects. Since there is currently insufficient evidence that ginger helps heal wounds, inflammation, aging, and cancer, there is a need for more substantial evidence to prove the positive effects of this plant on humans. Natural ginger exhibits restorative and antioxidant/anti-inflammatory properties and does not irritate the skin when applied to scratches or ulcers. Therefore, it can be used as a topical medicine to improve skin repair.²⁴

Jamaluddin et al investigated the effects of ginger extract ointment on the wound healing rate and the wound morphological change in the brown rat (*Rattus norvegicus*). To this end, they selected 24 brown rats as subjects. They assigned them to four groups: two intervention groups (10% and 20% ginger extract ointments), a negative control group (no treatment), and a positive control group (Oxyfresh Soothing Pet Gel®). After making an incision on the back of the subjects, the 14-day treatment (administration of ointments twice a day) began. Their results demonstrated a difference between the negative control, positive control, and intervention groups regarding wound surface size. The results also showed that the 10% ginger extract ointment was more effective in accelerating wound healing.²⁵ They tested 10% and 20% ginger ointment on animal subjects, whereas 0.05% ginger ointment was used to treat participants in this study.

The Studies on the effect of ginger on pain relief and wound healing are minimal. Therefore, there is a need for ongoing studies to achieve more vital pieces of evidence proving the effectiveness of ginger in humans. In recent years, people have shown a greater tendency to use herbal and complementary medicine to treat various diseases. Ineffectiveness of chemical drugs and the unavailability of experienced physicians, on the one hand, and the preparation and availability of complementary therapies and their few side effects and noninvasive nature, on the other hand, are the main reasons why patients are more willing to choose complementary treatment. Studies have shown that complementary medicine is practiced in most countries worldwide in different ways, such as massage therapy, touch therapy, and aromatherapy.

Moreover, 85% of gynecologists and midwives argue that complementary medicine practices can improve the quality of life of people. Although complementary medicine can be used in all fields, it is more commonly

and widely employed in oncology, senior care, and midwifery for women.²⁶ According to the comparison of the current study with previous studies, the reason for the non-significance of ginger ointment with a placebo can be related to the pharmaceutical form, drug dose, number of participants, and the study tool. This study investigated the therapeutic effects of 0.05% ginger ointment. However, since a few studies have dealt with the therapeutic value of ginger as well as its drug interactions and possible side effects, there is a need for further studies to determine the best form, concentration, and administration time of this plant to achieve the best therapeutic results.

Limitations and Strengths

In the present study, it was assumed that the participants used the ointments correctly. Because it was out of the researchers' ability to monitor how the participants used the ointment, among this study's strengths is observing all clinical trial principles, including allocation randomization and allocation concealment.

Conclusion

Although the results of this study, the effect of ginger (0.05% ginger ointment) on pain intensity and episiotomy healing were not statistically significant, clinically, it showed a slight improvement in pain intensity and wound healing up to 10 days after the intervention. It seems that more extended studies with different doses of this ointment are needed before coming to a definitive conclusion.

Acknowledgments

The authors would like to thank the officials of Ayatollah Hojjat Koohkamri hospital of Marand, participants, professors, and anyone who helped us in this research project.

Authors' Contribution

Conceptualization: Fatemeh Cheshfar, Soheila Bani, Mojgan Mirghafourvand, Shirin Hasanpour.

Data curation: Fatemeh Cheshfar, Soheila Bani.

Formal analysis: Fatemeh Cheshfar, Soheila Bani, Mojgan Mirghafourvand

Funding acquisition: Yousef Javadzadeh

Investigation: Fatemeh Cheshfar.

Methodology: Fatemeh Cheshfar, Soheila Bani, Mojgan Mirghafourvand, Shirin Hasanpour.

Research Highlights

What is the current knowledge?

Ginger contains some antioxidant, anti-inflammatory, and analgesic activities.

What is new here?

This study was conducted for the first time on the effect of ginger on episiotomy pain and healing in humans. Although it was not statistically significant compared to the control group, a decrease in pain intensity and an acceleration in wound healing were observed clinically up to 10 days after the intervention.

Project administration: Yousef Javadzadeh, Soheila Bani.

Software: Soheila Bani, Mojgan Mirghafourvand.

Supervision: Fatemeh Cheshfar, Soheila Bani, Mojgan Mirghafourvand, Shirin Hasanpour.

Validation: Mojgan Mirghafourvand, Shirin Hasanpour.

Visualization: Fatemeh Cheshfar, Soheila Bani, Mojgan Mirghafourvand, Shirin Hasanpour.

Writing—original draft: Fatemeh Cheshfar, Soheila Bani, Mojgan Mirghafourvand, Shirin Hasanpour, Yousef Javadzadeh.

Writing—review & editing: Fatemeh Cheshfar, Soheila Bani, Mojgan Mirghafourvand, Shirin Hasanpour, Yousef Javadzadeh.

Competing Interests

The authors declare that they have no competing interests.

Data Availability Statement

The datasets are available from the corresponding author on reasonable request.

Ethical Approval

All participants were informed about the study, and written informed consent was obtained from them (Consent to participate was obtained from the parents/guardians of participants under 16 years old). The Ethics Committee of Tabriz University of Medical Sciences confirmed the study (ethical code: IR.TBZMED.REC.1399.333).

Funding

The project was financed by Tabriz University of Medical Sciences (Grant No. 65157). The funding was spent on sampling and conducting the study.

References

- Frigerio M, Mastrolia SA, Spelzini F, Manodoro S, Yohay D, Weintraub AY. Long-term effects of episiotomy on urinary incontinence and pelvic organ prolapse: a systematic review. *Arch Gynecol Obstet*. 2019; 299(2): 317-25. doi: [10.1007/s00404-018-5009-9](https://doi.org/10.1007/s00404-018-5009-9)
- Yang J, Bai H. Knowledge, attitude and experience of episiotomy practice among obstetricians and midwives: a cross-sectional study from China. *BMJ Open*. 2021; 11(4): e043596. doi: [10.1136/bmjopen-2020-043596](https://doi.org/10.1136/bmjopen-2020-043596)
- Clesse C, Lighezzolo-Alnot J, Hamlin S, De Lavergne S, Scheffler M. [The practice of episiotomy in France 10 years after the recommendations of CNGOF: what inventory?]. *Gynecol Obstet Fertil*. 2016; 44(4): 232-8. doi: [10.1016/j.gyobfe.2016.02.011](https://doi.org/10.1016/j.gyobfe.2016.02.011)
- Ghulmiyyah L, Sinno S, Mirza F, Finianos E, Nassar AH. Episiotomy: history, present and future - a review. *J Matern Fetal Neonatal Med*. 2022; 35(7): 1386-91. doi: [10.1080/14767058.2020.1755647](https://doi.org/10.1080/14767058.2020.1755647)
- Gün İ, Doğan B, Özdamar Ö. Long- and short-term complications of episiotomy. *Turk J Obstet Gynecol*. 2016; 13(3): 144-8. doi: [10.4274/tjod.00087](https://doi.org/10.4274/tjod.00087)
- Ostrzenski A. A novel obstetrical surgical intervention - new episiotomy: case series study. *Eur J Obstet Gynecol Reprod Biol*. 2023; 282: 55-60. doi: [10.1016/j.ejogrb.2022.12.029](https://doi.org/10.1016/j.ejogrb.2022.12.029)
- Harasai P, Pattanapanyasat N. Efficacy of a single dose administration of ibuprofen and acetaminophen in comparison with acetaminophen for the relief of perineal pain after childbirth: a randomized controlled trial. *Thai J Obstet Gynaecol*. 2020; 28(1): 24-33. doi: [10.14456/tjog.2020.4](https://doi.org/10.14456/tjog.2020.4)
- Cardaillac C, Ploteau S, Le Thuaut A, Dochez V, Winer N, Ducarme G. Ropivacaine 75 mg versus placebo in perineal infiltration for analgesic efficacy at mid- and long-term for episiotomy repair in postpartum women - the ROPISIO study: a two-center, randomized, double-blind, placebo-controlled trials. *Trials*. 2020; 21(1): 522. doi: [10.1186/s13063-020-04423-x](https://doi.org/10.1186/s13063-020-04423-x)
- Turmo M, Echevarria M, Rubio P, Almeida C. Development of chronic pain after episiotomy. *Rev Esp Anestesiol Reanim*. 2015; 62(8): 436-42. doi: [10.1016/j.redar.2014.10.008](https://doi.org/10.1016/j.redar.2014.10.008)
- Téot L, Mustoe TA, Middelkoop E, Gauglitz GG. *Textbook on Scar Management: State of the Art Management and Emerging Technologies*. Springer; 2020.
- Ashrafi A, Rezaei A, Sohrabi-Haghdost I, Mohajeri D, Mehdineghad B, Ashrafi I, et al. Histometric and histopathologic evaluation of the effects of *Equistum arvense* herbal extract versus zinc oxide in rabbit skin wound healing model. *Vet Clin Pathol*. 2010; 4(2): 843-53. [Persian].
- Cheema HS, Singh MP. The use of medicinal plants in digestive system related disorders—a systematic review. *J Ayurvedic Herb Med*. 2021; 7(3): 182-7. doi: [10.31254/jahm.2021.7303](https://doi.org/10.31254/jahm.2021.7303)
- Kiyama R. Nutritional implications of ginger: chemistry, biological activities and signaling pathways. *J Nutr Biochem*. 2020; 86: 108486. doi: [10.1016/j.jnutbio.2020.108486](https://doi.org/10.1016/j.jnutbio.2020.108486)
- Li X, Ao M, Zhang C, Fan S, Chen Z, Yu L. *Zingiberis Rhizoma Recens*: a review of its traditional uses, phytochemistry, pharmacology, and toxicology. *Evid Based Complement Alternat Med*. 2021; 2021: 6668990. doi: [10.1155/2021/6668990](https://doi.org/10.1155/2021/6668990)
- Ali BH, Blunden G, Tanira MO, Nemmar A. Some phytochemical, pharmacological and toxicological properties of ginger (*Zingiber officinale* Roscoe): a review of recent research. *Food Chem Toxicol*. 2008; 46(2): 409-20. doi: [10.1016/j.fct.2007.09.085](https://doi.org/10.1016/j.fct.2007.09.085)
- Ravindran P, Babu KN. *Ginger: The Genus Zingiber*. CRC Press; 2016.
- Pourali P, Yahyaei B. The healing property of a bioactive wound dressing prepared by the combination of bacterial cellulose (BC) and *Zingiber officinale* root aqueous extract in rats. *3 Biotech*. 2019; 9(2): 59. doi: [10.1007/s13205-019-1588-9](https://doi.org/10.1007/s13205-019-1588-9)
- Mahmoodi P, Farhadian M, Solaimany Nazar AR, Noroozi A. Interaction between diazinon and nitrate pollutant through membrane technology. *J Appl Res Water Wastewater*. 2014; 1(1): 18-25.
- Escalona-Marfil C, Coda A, Ruiz-Moreno J, Riu-Gispert LM, Gironès X. Validation of an electronic visual analog scale mHealth tool for acute pain assessment: prospective cross-sectional study. *J Med Internet Res*. 2020; 22(2): e13468. doi: [10.2196/13468](https://doi.org/10.2196/13468)
- Alvarenga MB, Francisco AA, de Oliveira SM, da Silva FM, Shimoda GT, Damiani LP. Episiotomy healing assessment: redness, oedema, ecchymosis, discharge, approximation (REEDA) scale reliability. *Rev Lat Am Enfermagem*. 2015; 23(1): 162-8. doi: [10.1590/0104-1169.3633.2538](https://doi.org/10.1590/0104-1169.3633.2538)
- Mozaferi S, Esmaili S, Momenyan S, Zadeh Modarres S, Ozgoli G. Effect of *Zingiber officinale* Roscoe rhizome (ginger) capsule on postpartum pain: double-blind randomized clinical trial. *J Res Med Sci*. 2021; 26: 105. doi: [10.4103/jrms.JRMS_544_20](https://doi.org/10.4103/jrms.JRMS_544_20)
- Ozgoli G, Goli M, Moattar F. Comparison of effects of ginger, mefenamic acid, and ibuprofen on pain in women with primary dysmenorrhea. *J Altern Complement Med*. 2009; 15(2): 129-32. doi: [10.1089/acm.2008.0311](https://doi.org/10.1089/acm.2008.0311)
- Kravchenko I, Eberle L, Nesterkina M, Kobernik A. Anti-inflammatory and analgesic activity of ointment based on dense ginger extract (*Zingiber officinale*). *J Herbmед Pharmacol*. 2019; 8(2): 126-32. doi: [10.15171/jhp.2019.20](https://doi.org/10.15171/jhp.2019.20)
- Kazerouni A, Kazerouni O, Pazyar N. Effects of ginger (*Zingiber officinale*) on skin conditions: a non quantitative review article. *J Turk Acad Dermatol*. 2013; 7(2): 1372r2. doi: [10.6003/jtad.1372r2](https://doi.org/10.6003/jtad.1372r2)
- Jamaluddin AW, Lestari A, Monica WO. Effectiveness of ginger ointment (*Zingiber officinale* Roscoe) on incision wound healing in white rats (*Rattus norvegicus*). *J Indones Vet Res*. 2021; 5(1): 20-6. doi: [10.20956/jrvi.v5i1.13060](https://doi.org/10.20956/jrvi.v5i1.13060)
- Naidu S, Wilkinson JM, Simpson MD. Attitudes of Australian pharmacists toward complementary and alternative medicines. *Ann Pharmacother*. 2005; 39(9): 1456-61. doi: [10.1345/aph.1G089](https://doi.org/10.1345/aph.1G089)