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

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Research Article

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Abstract

**Background:** An episiotomy is a common midwifery surgery that may cause severe pain and discomfort for mothers. Iran is a country with an abundant source of medicinal plants. This study hence aimed to investigate the effects of ginger (*Zingiber officinale*) extract ointment on the inflammation, pain, and recovery of an episiotomy incision in order to improve the quality of midwifery care in nulliparous women.

**Method:** This triple-blind randomized clinical trial was conducted in a public hospital of Marand, Iran, on 70 nulliparous women with a mediolateral episiotomy incision. Those who met the inclusion criteria were randomly assigned to two groups of ginger extract ointment and placebo ointment at a 1:1 allocation ratio. The REEDA (redness, edema, ecchymosis, discharge, and approximation) scale and a Visual Analogue Scale (VAS) were employed to measure the episiotomy healing rate and the mean severity of pain, respectively, before discharge and 5±1 and 10±1 days after the intervention. The collected data were statistically analyzed by the chi-square test, the independent t-test, and the Mann-Whitney U test (in the case of non-normal distribution of data) in SPSS-18. The confidence level and the significance level in all statistical tests were determined to be 90% and $p \leq 0.05$, respectively.

**Results:** There was no significant difference between participants treated with ginger extract ointment and those treated with placebo ointment in the wound healing score before the intervention ($p=0.894$), 5±1 days after the intervention ($p=0.695$), and 10±1 days after the intervention ($p=0.986$). There was also no significant difference between the two groups in the mean severity of pain before the intervention ($p=0.924$), 5±1 days after the intervention ($p=0.576$), and 10±1 days after the intervention ($p=0.400$).

**Conclusion:** The study findings revealed that the 200 mg dose of ginger ointment could not significantly improve the pain and increase the healing rate of episiotomy wounds 5 and 10 days after the intervention. It seems that more and longer studies with different doses of this ointment are needed before coming to a definitive conclusion about its effects.

**Trial Registration:** IRCT Registration Number: IRCT20110922007618N9, registered on August 14, 2020 (IR.TBZMED.REC.1399.333)

Background

As the most common surgical procedure in midwifery, an episiotomy is a cut (incision) through the area between the vaginal opening and the anus, which is called the perineum, in order 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 rate of episiotomy is less than 30% in Western countries and more than 70% in East Asian countries [3]. Some advantages of an episiotomy include the easier healing of a straight and regular incision than an irregular one, shorter duration of the second stage of labor, and prevention of fetal brain damage due to the reduced pressure on the fetal head in the pelvic floor [5]. Similar to any other surgery, an episiotomy has
its own complications such as bleeding, infection, pain, inflammation, edema, and pain during intercourse, rupture of sutures, and hematoma [6].

One of the common conditions that women may suffer from during and after pregnancy is the pain caused by tissue damage and inflammation [7]. Postpartum pain is closely related to obstetric traumas, especially an episiotomy [8]. The results of a study showed that the perineal pain in women undergoing an episiotomy is usually four times severer 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 [9]. About 12.8% of women claim the chronic pain caused by an episiotomy up to 5 months after delivery [10].

Wound healing is a process of recovery that begins following any damage to the skin or other tissues [11]. One of the main objectives of medical sciences is to reduce the duration and complication of wound healing. It is of special importance because a shorter wound healing process minimizes the risk of wound infections or complications and also reduces medical costs [12].

Ginger (*Zingiber officinalis*) is an edible plant, spice, and herb that is referred to as “Zanjefil”, “Shangwir”, or “Zhangvir” in some ancient Farsi texts. It is an 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 having pale yellow petals with purple edges, and arise directly from the rhizome on separate shoots [13]. The Food and Drug Administration (FDA) has introduced ginger as a safe medicine [14]. Ginger contains some active ingredients that exhibit major physiological and pharmacological activities such as antioxidant, anti-inflammatory, and analgesic activities [15]. Shogaols and gingerols are two major biological components of ginger [16]. Ginger also contains anthocyanins, which are highly potent antioxidants that can suppress pain-related pathways by inhibiting cyclooxygenases (COXs) and lipoxygenases (LOXs). These compounds inhibit inflammatory pathways and then nitric oxide synthase to exert their analgesic effects [17]. A study showed that ginger, as a healthy and safe herbal medicine with no side effects, can be a good alternative to mefenamic acid for mothers who complain of labor pains [18]. In a study about the effects of the nontoxic concentration of ginger extract on wound healing, the results indicated that the cellulose and extract of ginger (*Zingiber officinale*) are good medicines for wound healing [19].

Medicinal plants and traditional medicine can play a major role in wound healing. In addition, ginger is an easily accessible plant with numerous beneficial properties. Since few studies have dealt with the restorative effects of this plant on humans, this study hence aims to investigate the effects of ginger extract ointment on the pain and recovery of episiotomy incisions in nulliparous women.

**Method**

**Research design and participants**
This randomized controlled clinical trial was conducted on 70 nulliparous in the postpartum ward of Ayatollah Hojjat Kookhakamri Hospital of Marand, Iran. Inclusion criteria include: 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, no use of special drugs ( Such as anti-inflammatory drugs other than acetaminophen and anticoagulants (according to the patient), no history of diseases that impair wound healing such as systemic, heart, kidney, lung, coagulation disorders, immunodeficiency, connective tissue disorders, diabetes Anemia, mental illness, 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 3–4 cm), the desire and possibility of the mother to Hojjat Kookhakamri Hospital on days 5 and 10, no history of reconstructive surgery on the vagina and midline Two-way (according to the woman), no long-term rupture of the amniotic sac (more than 18 hours), no use of blood pressure medications (mothers with high blood pressure and preeclampsia).

Exclusion criteria include: postpartum hemorrhage, use of topical lidocaine cream, use of mepressin.

The two research variables, i.e. pain and wound healing, were taken into account for the calculation of sample size in G-Power. 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 pain score in the intervention group), $M_2 = 3.0$ (the mean pain 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 larger, the sample size in each group was finally decided to be 35.

**Sampling and randomization**

This study was conducted after approval by the Ethics Committee of Tabriz University of Medical Sciences and registration on the Iranian Registry of Clinical Trials. The participants were selected through purposive sampling and then they were randomly assigned to intervention and control groups at a 1:1 allocation ratio. The participants were selected from among the nulliparous women who were admitted to the postpartum ward 1–2 hours after the delivery with a normal mediolateral episiotomy incision (an incision length of 3–4 cm according to the inclusion criteria). The researcher briefed those who met the inclusion on the research objectives and procedures and then asked those who were willing to participate in the study to fill out an informed consent form and a demographics form (personal-social information and fertility characteristics). After evaluating the pre-intervention severity of pain and wound status using VAS and the REEDA scale, 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. For the concealment of allocation, the completely identical tubes of ointment were placed in
opaque numbered envelopes by a person who was 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 group or the control group.

**Intervention**

After purchasing ginger and approving its identity by the Herbarium of Faculty of Pharmacy, Tabriz University, ginger extraction was performed using hydro alcoholic (ethanol) solvents. To prepare sterile ointment, 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 hardens. After stirring the mixture under aseptic conditions, sterile tubes were filled with the ointment, and then they were 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. To prepare the placebo ointment, a few drops of ginger extract were added to Vaseline and poured into sterile tubes of the same form, color, and size. The participants were treated with ginger extract ointment or placebo ointment within 2–10 hours after delivery and 12 hours later. They were also instructed 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 their possible questions.

The participants were also asked to visit the studied hospital 5 ± 1 and 10 ± 1 days after the intervention for the measurement of pain severity (by VAS) and the wound healing status (by REEDA scale). The researcher also contacted the participants during this time to ensure that they were administering 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 completely 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 10 days of treatment; they were asked to submit the completed questionnaire and the pocket of tablets to the researcher when they come for visit on the 10th day. The participants were also instructed how to administer the ointment. Accordingly, they were expected to first wash the hands and the perineum thoroughly and dry them with a clean piece of cloth and then apply a fingertip of the ointment to the sutures and cover the area with a clean menstrual pad. They were asked to use the ointment in the same way twice a day, with an interval of 12 ± 1 hours, for 10 days. The researcher also contacted the participants during this time to ensure that they were administering 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, primary outcomes were the severity of pain and the wound healing status, whereas the secondary outcome was the number of painkillers taken by each participant.
Data collection tools

A Visual Analogue Scale (VAS) was employed to measure the severity of pain. This instrument is actually 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 their severity of pain. This scale has been widely used in other studies for the measurement of pain and its reliability and validity have been approved (29).

The REEDA scale was also used for measuring the wound healing status. The five subscales of this tool are redness, edema, ecchymosis, discharge, and approximation. We chose REDA scale because the studies shown are valid for measuring wound healing (30).

The subscales are scored as follows:

Redness: 0: no redness, 1: 0.25 cm from the edge of the wound, 2: 0.5 cm from the edge of the wound, and 3: more than 0.5 from the edge of the wound.

Edema: 0: no edema, 1: less than 1 cm at the perineal incision, 2: 2 cm at the perineal incision, and 3: more than 2 cm at the perineal incision.

Ecchymosis: 0: no ecchymosis, 1: about 0.25 cm on both sides and 0.5 cm on one side, 2: about 1 cm on both sides or 2 cm on one side, and 3: more than 2 cm on both sides or 3 cm on one side.

Discharge: 0: no discharge, 1: serous discharge, 2: purulent serous discharge, and 3: purulent bloody discharge.

Approximation: 0: completely closed, 1: 3 cm or less, 2: separation of skin and subcutaneous fat layer, and 3: separation of subcutaneous and Facia.

Data analysis

The collected data were statistically analyzed by descriptive statistics (mean, standard deviation, frequency, ratios, and graphs) and also the chi-square test, the independent t-test, and the Mann-Whitney U test (in the case of non-normal distribution of data) in SPSS-18. The normal distribution of data was tested by the Kolmogorov-Smirnov test, and all calculations were performed based on ITT (Intention to Treat). The confidence level and the significance level in all statistical tests were determined to be 90% and \( p \leq 0.05 \), respectively. A total of 70 nulliparous women participated in this study, and the attrition rate was zero in both groups.

Results

The present study started in January 2020 and ended in September 2021. 151 pregnant women were evaluated for eligibility. 66 people did not meet the inclusion criteria. 15 people did not want to participate in the study. 70 pregnant women were randomly divided into two groups of intervention (\( n = 35 \)) and placebo (\( n = 35 \)). Figure 1. The results showed that there was no significant difference between the two groups in terms of demographic and midwifery variables. The mean age of participants was \( 23.54 \pm 5.78 \)
years in the placebo group and $24.94 \pm 5.82$ years in the intervention group, which indicates no significant
difference between the two groups ($p = 0.536$). There was also no significant difference between the
placebo and intervention groups in other demographic characteristics such as episiotomy incision ($4 \pm
0.84$ vs. $3.88 \pm 0.86$, $p = 0.502$), BMI ($27.93 \pm 3.48$ vs. $27.22 \pm 3.5$, $p = 0.899$), number of sutures ($4.37
\pm 1.35$ vs. $4.74 \pm 1.57$, $p = 0.579$), the first stage of labor ($301.7 \pm 129.5$ vs. $297.1 \pm 135.1$, $p = 0.147$),
the second stage of labor ($37.85 \pm 12.56$ vs. $44.14 \pm 13.79$, $p = 0.9$), the third stage of labor ($10.57 \pm 4.96$ vs.
$14 \pm 7.15$, $p = 0.081$), and fetal weight ($3042.7 \pm 337.5$ vs. $3109.1 \pm 517.8$, $p = 0.06$) (Table 1).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Placebo (N = 35)</th>
<th>Drug (N = 35)</th>
<th>Test statistics</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Means</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (year)</td>
<td>$23.54 \pm 5.78$</td>
<td>$24.94 \pm 5.82$</td>
<td>.388</td>
<td>.536</td>
</tr>
<tr>
<td>Episiotomy incision</td>
<td>$4 \pm .84$</td>
<td>$3.88 \pm .866$</td>
<td>.455</td>
<td>.502</td>
</tr>
<tr>
<td>BMI</td>
<td>$27.93 \pm 3.48$</td>
<td>$27.22 \pm 3.51$</td>
<td>.016</td>
<td>.899</td>
</tr>
<tr>
<td>Number of stitches</td>
<td>$4.37 \pm 1.35$</td>
<td>$4.74 \pm 1.57$</td>
<td>.312</td>
<td>.579</td>
</tr>
<tr>
<td><strong>Duration of labor (min)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First stage</td>
<td>$301.7 \pm 129.5$</td>
<td>$297.1 \pm 135.1$</td>
<td>2.14</td>
<td>.147</td>
</tr>
<tr>
<td>Second stage</td>
<td>$37.85 \pm 12.56$</td>
<td>$44.14 \pm 13.79$</td>
<td>.016</td>
<td>.9</td>
</tr>
<tr>
<td>Third stage</td>
<td>$10.57 \pm 4.96$</td>
<td>$14 \pm 7.15$</td>
<td>3.129</td>
<td>.081</td>
</tr>
<tr>
<td><strong>Baby weight (gr)</strong></td>
<td>$3042.7 \pm 337.5$</td>
<td>$3109.1 \pm 517.8$</td>
<td>3.49</td>
<td>.06</td>
</tr>
<tr>
<td><strong>Frequency (percentage)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>high school</td>
<td>21(60)</td>
<td>18(51.4)</td>
<td>.715</td>
<td>.717</td>
</tr>
<tr>
<td>Diploma</td>
<td>10(28.6)</td>
<td>11(31.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University</td>
<td>4(11.4)</td>
<td>6(17.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>3(8.6)</td>
<td>3(8.6)</td>
<td>1.01</td>
<td>.602</td>
</tr>
<tr>
<td>Moderate</td>
<td>32(91.4)</td>
<td>31(88.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weak</td>
<td>0</td>
<td>1(2.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of antibiotic**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14(40)</td>
<td>13(37.1)</td>
<td>.06</td>
<td>.806</td>
</tr>
<tr>
<td>No</td>
<td>21(60)</td>
<td>22(62.2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Independent sample t-test, ** chi square test
Episiotomy healing (primary outcome)

There was no significant difference between the intervention and control groups in the pre-intervention mean score of episiotomy 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 (3.4 ± 1.64 vs. 3.62 ± 1.19, p = 0.695) and the tenth day (2.37 ± 1.35 vs. 2.28 ± 1.48, p = 0.986) after the intervention (Table 2).

Table 2
Comparison of the two study groups in terms of healing, pain score and use of acetaminophen before the intervention, fifth, and fifteenth days after childbirth

<table>
<thead>
<tr>
<th>Group</th>
<th>Placebo</th>
<th>Drug</th>
<th>Statistical test</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healing* Before the intervention</td>
<td>5.51 ± 1.52</td>
<td>5.54 ± 1.52</td>
<td>-.133</td>
<td>.894</td>
</tr>
<tr>
<td>Fifth day</td>
<td>3.4 ± 1.64</td>
<td>3.62 ± 1.19</td>
<td>-.392</td>
<td>.695</td>
</tr>
<tr>
<td>Fifteenth day</td>
<td>2.37 ± 1.35</td>
<td>2.28 ± 1.48</td>
<td>-.018</td>
<td>.986</td>
</tr>
<tr>
<td>Pain* Before the intervention</td>
<td>5.11 ± 1.77</td>
<td>5.11 ± 1.64</td>
<td>-.095</td>
<td>.924</td>
</tr>
<tr>
<td>Fifth day</td>
<td>2.37 ± 2.05</td>
<td>2.14 ± 1.97</td>
<td>-.559</td>
<td>.576</td>
</tr>
<tr>
<td>Fifteenth day</td>
<td>1.34 ± 1.71</td>
<td>1.14 ± 1.88</td>
<td>-.842</td>
<td>.4</td>
</tr>
<tr>
<td>Acetaminophen*</td>
<td>1.91 ± .284</td>
<td>1.97 ± .169</td>
<td>-.1.02</td>
<td>.307</td>
</tr>
</tbody>
</table>

*Mann Whitney u test (mean ± SD)

Episiotomy pain (primary outcome)

The pre-intervention mean score of pain was 5.11 ± 1.77 in the intervention group and 5.11 ± 1.64 in the placebo group, which shows no significant difference (p = 0.924). 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 = 0.576) and the tenth day (2.37 ± 1.35 vs. 1.14 ± 1.88, p = 0.4) after the intervention (Table 2).

Painkillers consumption (secondary outcome)

The results demonstrated that there was no significant difference between the placebo and intervention groups in the number of painkillers taken by participants (p = 0.307) (Table 2).

Discussion

Ginger uses several mechanisms to relieve pain, such as inhibition of prostaglandins through COXs and LOXs pathways, antioxidant activities, inhibition of the nf-kB transcription factor, and acting as a pain...
receptor agonist [20]. Moreover, the great inhibitory effects of ginger on oxygen free radicals, such as superoxide, hydroxyl radicals, and lipid peroxide, result in its high level of antioxidant activity. Although some studies have reported the effects of ginger on growth factors, it has been shown that synthetic gingerols (the main ingredient of ginger extract), phenyl alkanol analogs, and the aqueous extract of ginger can inhibit platelet serotonin secretion resulting from the accumulation of arachidonic acid in human blood, improve local blood circulation, and, thereby, greatly accelerate the wound healing process [21].

The results of this study indicated that there was no significant difference between the participants treated with ginger extract ointment and placebo ointment in the severity of pain and wound healing status. However, participants in the intervention group took fewer painkillers than those in the control group did.

Although there was no study dealing with the effects of ginger ointment on episiotomy wound healing in humans, many studies have reported the analgesic effects of this plant on dysmenorrhea and other pains in women. Mozaffari et al. studied the effects of rhizome capsules (ginger) on postpartum pain in 128 mothers with moderate to severe pain after vaginal delivery. 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 score of pain significantly reduced in both groups during the interventions, whereas the severity of pain in the intervention group was significantly lower than the control group at any time after the intervention [22]. There are differences between this study and the study conducted by Mozaffari et al.; for example, they treated the participants with an edible ginger medicine and employed a numerical rating scale (NRS) to measure the severity of pain, whereas the participants were treated with ginger ointment and the severity of their pain was measured using VAS in this study.

Ozgoli et al. compared the effects of ginger, mefenamic acid, and ibuprofen on pain in women with primary dysmenorrhea. They selected 150 university students (aged over 18 years) with primary dysmenorrhea from the dormitories of two universities of medical sciences as the sample and 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, and those in other groups received 250-mg mefenamic acid capsules and 400-mg ibuprofen capsules under the same protocol. The Verbal Multidimensional Scoring System (VMDS) was employed to assess the severity of primary dysmenorrhea. The three groups were also compared in terms of the severity of disease, pain relief, and satisfaction with treatment after a menstrual cycle. The severity of dysmenorrhea significantly reduced in all groups after the treatment, and there was no significant difference between the three groups in the severity of dysmenorrhea, pain relief, and satisfaction with treatment (p > 0.05). They also reported no severe side effects of the treatments [23].
Although they administered ginger to participants orally, they found no significant difference between this method and other methods of administration in terms of effectiveness. However, they also measured dysmenorrhea pain, which is severer than any other postpartum pain.

Kravchenko et al. investigated the analgesic and anti-inflammatory effects of ginger ointment on rats. Inflammation was induced by the sub-plantar injection of 30 µl 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 was 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. Their results showed that the 0.025% ginger ointment was most effective in inhibiting the inflammatory process and the greatest analgesic effects were observed after using the 0.05% ginger ointment 10 minutes before pain induction [24]. 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 hence stated that a possible mechanism of this plant is the connection between its compounds to TRPA1 and TRPV1 ion channels.

Kazerouni et al. conducted a review study about the effects of ginger (*Zingiber officinale*) on skin health status. For this purpose, they selected and reviewed 34 articles on the anti-inflammatory, antioxidant, anti-cancer, and restorative effects of ginger. Since there is currently insufficient evidence that ginger helps heal wounds, inflammation, aging, and cancer, there is a need for stronger 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 it is applied to scratches or ulcers. Therefore, it can be used as a topical medicine to improve skin repair [25].

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 and 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 that there was a difference between the negative control group, the positive control group, and intervention groups in terms of the wound surface size. The results also showed that the 10% ginger extract ointment was more effective in accelerating the wound healing process [26]. They tested 10% and 20% ginger ointment on animal subjects, whereas the 0.05% ginger ointment was used for the treatment of participants in this study.

Most studies in this field have focused on animals and a few experimental studies have been conducted on humans. Therefore, there is a need for continuous studies to achieve stronger pieces of evidence proving the effectiveness of ginger in humans. People have shown a greater tendency to use herbal medicines and complementary medicine for the treatment of a variety of diseases in recent years.
Ineffectiveness of chemical drugs and 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 therapy. Studies have shown that complementary medicine is practiced in most countries around the world 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, geriatric care, and midwifery for women [27, 28]. 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, how to use the ointment of participants were assumed to be correct as their validation was beyond the researchers’ ability. Among the strengths of this study are observing all principles of clinical trials, including allocation randomization and allocation concealment.

**Conclusion**

The study findings indicated that there was no significant difference between the intervention group (0.05% ginger ointment) and the control group (placebo ointment) in the pain and wound healing status up to 10 days after delivery. It seems that more and longer studies with different doses of this ointment are needed before coming to a definitive conclusion.

**Abbreviations**

REEDA  
redness, edema, ecchymosis, discharge, and approximation

VAS  
Visual Analogue Scale

AITC  
allyl isothiocyanate.

**Declarations**

**Ethics approval and consent to participate**

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

Consent for publication

Not applicable.

Availability of data and materials

Data and materials of this study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

FCh implemented the study and was responsible for data collection and wrote the first draft of the manuscript. SB and MM contributed in the study design and data analysis, assisted in the preparation of the final version of the manuscript, SH Assisted in writing and editing the article. YJ Prepared medicines and placebo and the authors read and approved the final version of the manuscript.

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References


Figures
151 pregnant women were evaluated for eligibility. 66 people did not meet the inclusion criteria. 15 people did not want to participate in the study. 70 pregnant women were randomly divided into two groups of intervention (n=35) and placebo (n=35).

**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.