Effects of cinnamon on perineal pain and healing of episiotomy: a randomized placebo-controlled trial

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BACKGROUND: Analgesic and wound-healing effects of cinnamon, a widely used spice, have been shown in laboratory rats. However, we found no human studies in this area.

OBJECTIVE: The aim of this study was to assess the effect of cinnamon on perineal pain and healing of episiotomy incision.

DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS: In this double-blind, randomized, placebo-controlled trial, 144 postpartum women were allocated into two groups, using stratified block randomization, 1 h after completion of episiotomy repair. They received cinnamon or placebo ointment, 2 mL every 12 h for 10 d.

MAIN OUTCOME MEASURES: Perineal pain and wound healing were assessed using visual analogue scale (0–10) and Redness, Edema, Ecchymosis, Discharge, Approximation scale (0–15), respectively. General linear model was used to compare the groups on the outcomes adjusted for baseline values and stratified factors.

RESULTS: Follow-up rate was 100% up to the 8 h time point in both groups, and 86% (62 of 72) in the cinnamon group and 85% (61 of 72) in the placebo group at day 10–11 after delivery. Pain score in the cinnamon group was significantly lower than that in the placebo group at (±1) h (adjusted difference: –0.6, 95% confidence interval: –1.0 to –0.2) and (±1) h (–0.9, –1.4 to –0.3) after intervention, and on the 10–11th day after delivery (–1.4, –2.0 to –0.7). Also the cinnamon group showed significantly more improvement than the control group in healing score at (±1) h (–0.2, –0.4 to –0.04) and the 10–11th day after delivery (–1.6, –2.0 to –1.1).

CONCLUSION: Cinnamon can be used for reducing perineal pain and improving healing of episiotomy incision.

KEYWORDS: Cinnamomum zeylanicum; episiotomy; postpartum period; pain; wound healing; randomized controlled trial


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1 Introduction

Episiotomy is the most common obstetric intervention in the world. Its prevalence has been reported to be 43% to 100% in primiparous women in Asia and up to 100% in some hospitals of major cities in Iran.

Prevalence of perineal pain in people with episiotomy is about fourfold compared to those with no episiotomy. Perineal pain adversely affects different aspects of women’s life including lactation, child care and daily chores. Postpartum is a sensitive time when mothers must juggle their own recovery while dealing with the needs of their newborns. Effective pain relief is a major aspect of postpartum care that can positively affect women’s life.

There are several common methods used for reducing pain and accelerating the episiotomy-healing process. Nonsteroidal anti-inflammatory drugs are among the typical medications used to reduce episiotomy pain, though they may cause some side effects such as peptic ulcers. Betadine (Iodine) is also commonly used to prevent infection and help with healing of the episiotomy wound. However, various studies show that it has no significant effect on microorganism-reduction. Many women find the current available methods unsatisfactory and are looking for other effective and safe options.

Only a few studies have been conducted on the care of this very common wound. Some studies have examined the effects of herbal remedies such as lavender, olive oil, or curcumin on episiotomy pain and healing. However, definitive effects of these methods have not been verified through clinical trials, and more extensive studies are still required in this area.

Cinnamon is a widely used spice worldwide. It has been found to have numerous properties including anti-inflammatory, antioxidant, and antimicrobial. Analgesic and wound-healing effects of its ethanol extract have been shown in laboratory rats. Also, no significant adverse effects of cinnamon have been found in human studies.

Considering the above-mentioned evidence on the possible efficacy and safety of cinnamon extract, plus the lack of any human studies on its analgesic and healing effects, this study was conducted to determine the effects of a 10-day application of 2% cinnamon extract ointment on episiotomy wound. The primary outcomes involved reducing perineal pain and accelerating healing of the episiotomy wound; secondary outcomes measured consumption of other analgesics, as compared to the placebo group.

2 Materials and methods

2.1 Study design, participants and setting

This study was a randomized, double-blind, placebo-controlled trial. Women aged 18 to 40 years with parity 1–3 who had vaginal birth with episiotomy were included in the study. Exclusion criteria were: being illiterate; having no access to a phone line (for follow-up); use of drugs or psychotropic substances; gestational age of less than 37 or more than 42 weeks; history of chronic physical or mental diseases that may interfere with healing; following a special diet; long-term (over 18 h) rupture of amniotic sac; severe anemia (haemoglobin less than 70 g/L at admission); history of hypersensitivity to certain drugs; extension of episiotomy (tears of grade 3 or 4); and operative delivery.

Recruitment was done at two hospitals affiliated to the Tabriz University of Medical Sciences (Alzahra, Taleghani, Iran), and one hospital affiliated to the Social Security Organization (29 Bahman). The hospitals are the only public maternity facilities in Tabriz and have the highest number of clients for vaginal delivery services among all centers in Tabriz, Iran.

In these hospitals, episiotomy is usually performed in more than 90% of the first vaginal deliveries, and 70% of the second and third deliveries. Episiotomy incision and repair is often done by midwifery students, obstetrics assistants, and senior medical students, and in some cases by employed midwives. Cephalixin (500 mg, oral) is routinely administered four times a day for 6 d after delivery. In all the three medical centers, non-continuous stitches are used to repair episiotomy.

2.2 Allocation and intervention

Allocation sequence was determined by block randomization with block sizes of 4 and 6, and allocation ratio of 1:1 using a computer-generated randomization schedule with stratification for center (three centers) and parity (two strata: first and second or third). Sequentially numbered, opaque, sealed envelopes of the same shape and size containing cinnamon or placebo ointment were used to conceal the allocation and to maintain blinding. Every package contained one 40 g cinnamon or placebo tube with no label on it.

The packages and allocation sequence were prepared by a person who was not involved in the recruitment, data collection and data analysis. Therefore, the investigators and participants were unaware of the type of ointment given to every participant (double blinding).

After obtaining written informed consent from eligible women at the first stage of delivery, the investigator (first author, AM) attended at bedside of every participant to record details of delivery and episiotomy procedure in a checklist. The person in charge of delivery was requested to use no disinfectant on the perineal area. The first part of the questionnaire (socio-demographic and reproductive characteristics) was completed based on the file documentation and interview with the participants. The investigator measured episiotomy incision length using a sterile tool and transferring it onto a ruler. After baseline assessment
of perineal pain and wound-healing which was done about 1 h after completion of the repair, the package containing the ointment was made available to the participant. Participants were taught verbally and were given a written pamphlet on how to take care of the episiotomy incision (including advice on personal hygiene, sexual relationship, and nutrition) and how to use their medication. They were instructed to wash hands and the perineum thoroughly and dry it with a clean tissue every time before using the ointment, then put a length of a finger bone of ointment (approximately 2 cm) on the stitch area after 1–2 min using a sterile pad. This procedure was to be repeated twice daily, at 12-hour intervals (±2 h) for 10 d. To ensure that the participants understood the directions, the first ointment application was carried out by the participant about 1 h after completion of episiotomy repair, in the presence of the investigator.

We also gave the participants 10 mefenamic acid capsules, each 400 mg and a diary to record the ointment use, any analgesics taken and any side events during the 10–11 d after delivery. We asked them to try to take the given capsules for pain relief only if needed. Moreover, they were asked to return to the hospital 10–11 d after delivery for a re-assessment and to deliver the empty tubes of the drugs.

2.3 Ointment preparation

In the Industrial Pharmacy Laboratory of the Tabriz University of Medical Sciences and under direct supervision of the pharmacist from our research team, cinnamon bark was soaked in 70% hydroalcoholic solution and stirred on a shaker for 72 h. After this period, the hydroalcoholic extract was passed through a paper filter. The remaining pulp was shaken again in the hydroalcoholic solution for another 72 h and its hydroalcoholic extract was separated and added to the previous extract. The obtained extract was placed in the rotary evaporator until all the solvents were removed and a dry powder was left.

Dried extract was kept sealed and away from light and humidity until preparation of ointment. To prepare the ointment (2%, w/w), appropriate amounts of extract were levigated with a suitable amount of paraffin. Then, 0.1% (w/w) of methyl paraben and 0.02% (w/w) of propyl paraben were added as preservatives, and stirred. An appropriate amount of eucerin was added, and stirred in a planetary-type stirring device. Next, to homogenize the final weight obtained, a three-cylinder grinding device was used. All of the ointment was passed through this grinder and filled into 40 g tubes using an ointment filling machine under aseptic conditions. The tubes were then packed by a packing machine. Prepared formulations were kept at 5 °C and 40 °C for a period of two months in order to assay their physical stability based on their appearance. After this period, there were not any signs of instabilities such as colour change, phase separation or odour change.

The placebo ointment was also prepared from the same materials except cinnamon extract, and packed into same tubes. The ointments were identical in color, shape and size.

2.4 Outcomes

Primary outcomes of this study were perineal pain intensity score and healing score of episiotomy incision. Perineal pain was recorded before the intervention (1 h after completion of repair), (4±1) h, and (8±1) h after first ointment administration and 10–11 d after delivery, using the visual analogue scale (VAS). Wound-healing was assessed before intervention, at (8±1) h after first ointment administration and 10–11 d after delivery using the Redness, Edema, Ecchymosis, Discharge, Approximation (REEDA) scale. Secondary outcomes were components of REEDA, number of analgesics (mefenamic acid) taken during the 10 d after delivery, resuming normal daily activities within 5 d postpartum, and side events.

VAS is a validated scale length of 10 cm with 0 (no pain) in the one end and 10 (the maximum imaginable pain) on the other end. This scale is widely used in pain-related studies and its validity and reliability have been confirmed[20]. REEDA scale consists of 5 items (redness, edema, ecchymosis, discharge, and approximation). Each item is rated on a scale of zero to three. Sum of the scores (possible score range of 0 to 15) determines the overall healing score; the lesser score, the better healing[21]. Pain intensity was determined by the participants on the relevant ruler and healing status by the investigator through direct observation of episiotomy incision in lithotomy position. Potential side effects of the ointment were investigated twice on the phone over 10 d in addition to assessment at other follow-up visits.

2.5 Sample size and statistical analysis

Considering 5.0 for mean and 1.5 for standard deviation of pain intensity based on results of a study carried out in a similar setting in Iran[11], a two-sided significance level of 0.05, power of 0.80 and a 15% possible dropout rate, the required sample size was calculated to be 71 participants per group to detect at least 20% reduction in mean pain intensity due to the intervention.

Normality of the quantitative variables by the groups was confirmed using skewness and kurtosis. Independent t-test was used for comparison of the baseline scores and general linear model with repeated measures for comparison of the follow-up scores adjusted for the baseline values and stratified factors (hospitals and nulliparity/multiparity). Sidak was used for multiple comparisons of the scores between the groups. Mann-Whitney U test was used for comparing mean rank of the groups in terms of REEDA components. Data analysis was carried out by SPSS for Windows 14.0 (SPSS Inc., Chicago, IL, USA). P values
of less than 0.05 were considered statistically significant.

2.6 Ethical approval

This research project was approved scientifically by the Research Committee of the Tabriz University of Medical Sciences and ethically by the ethic committee of the university (Ethic code: 91157). Also, it was registered in the Iranian registration system with IRTCT201211303706N18 on 13 December 2012 before starting participant recruitment.

3 Results

3.1 Recruitment and follow-up

Participant recruitment was carried out from 20 February to 31 October, 2013 and follow-up ended on 11 November, 2013. A total of 233 patients were initially screened, but 86 were excluded because of ineligibility. Three patients refused to participate due to high work load and inability to use the ointment regularly. Thus, 72 participants were allocated into each group. Follow-up rate was 100% up through the 8-hour mark, and at 10–11 d after delivery was 86% in the cinnamon group and 85% in the placebo group (Figure 1).

3.2 Participant characteristics

More than half (60%) in each group were primiparous. The groups were similar in terms of socio-demographic and reproductive characteristics. Mean age of the participants was (26.4 ± 4.9) years. About one third (35%) reported that their income did not suffice their expenses. A majority of the participants were Azari (89%), housewives (94%), and lived in the city (88%). Mean duration of episiotomy incision repair was (31.1 ± 16.7) min in the cinnamon group and (35.6 ± 18.0) min in the placebo group. Mean interval between episiotomy incision and start of repair was (15.3 ± 6.6) min in the cinnamon group and (17.4 ± 7.2) min in the placebo group (Table 1). Most of participants in both cinnamon (90%) and placebo (80%) groups had used toilet at squatting position.

3.3 Primary outcomes

Mean pain intensity at baseline was 5.0 ± 1.8 in the cinnamon group and 4.6 ± 2.0 in the placebo group. At all three follow-up assessments, intensity of pain in the cinnamon group was significantly lower than that in the placebo group. Adjusted pain score difference (MD) was −0.6 (95% confidence interval (CI): −1.0 to −0.2) at (4±1) h, −0.9 (95% CI: −1.4 to −0.3) at (8±1) h, and −1.4 (95% CI: −2.0 to −0.7) at 10–11 d postpartum (Table 2). Compared to baseline, pain intensity reduction at (4±1) h, (8±1) h, and (10–11) d postpartum was 16%, 26%, and 76% in the cinnamon group and 2%, 4%, and 43% in the placebo group, respectively.

Figure 1 Flowchart of the study
Mean baseline REEDA score was 3.4 ± 1.6 in the cinnamon group and 3.2 ± 1.5 in the placebo group. The score of the cinnamon group was significantly lower than that of the placebo group at both of the follow-up assessments: −0.2 (95% CI: −0.4 to −0.04) at (8±1) h and −1.6 (95% CI: −2.0 to −1.1) on 10–11 d postpartum (Table 2). Compared to baseline, REEDA score reduction was 53% in the cinnamon group and 6% in the placebo group at 10–11 d postpartum.

In the repeated measurement test, both overall pain intensity score (−0.9 (95% CI: −1.36 to −0.53)), and overall healing score (−0.9 (95% CI: −0.6 to −1.16)) after intervention were significantly lower in the cinnamon group as compared to the placebo group (P<0.01) (Figures 2 and 3).

### 3.4 Secondary outcomes
There was no significant difference (P>0.05) between the groups at baseline and the (8±1) h in terms of REEDA components except wound approximation (P=0.02). During 10 d postpartum, in the intervention group vs the placebo group, there was no redness (39% vs 15%), no edema (71% vs 34%), no ecchymosis (95% vs 82%),

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**Table 1** Socio-demographic and reproductive characteristics of the participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Cinnamon group (n=72)</th>
<th>Placebo group (n=72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>27.3±5.1</td>
<td>25.7±4.5</td>
</tr>
<tr>
<td>Education (years)</td>
<td>9.9±3.8</td>
<td>9.4±3.7</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>25.0±3.2</td>
<td>24.6±3.7</td>
</tr>
<tr>
<td>Duration of second stage of labor (min)</td>
<td>39.1±23.3</td>
<td>39.5±26.5</td>
</tr>
<tr>
<td>Duration of third stage of labor (min)</td>
<td>8.2±3.5</td>
<td>9.2±5.1</td>
</tr>
<tr>
<td>Interval between episiotomy incision and start of repair (min)</td>
<td>15.3±6.6</td>
<td>17.4±7.2</td>
</tr>
<tr>
<td>External length of episiotomy (cm)</td>
<td>3.4±0.7</td>
<td>3.4±0.8</td>
</tr>
<tr>
<td>Length of episiotomy repair (min)</td>
<td>31.1±16.7</td>
<td>35.6±18.0</td>
</tr>
<tr>
<td>Weight of newborn (g)</td>
<td>3 164±503</td>
<td>3 294±507</td>
</tr>
<tr>
<td>Neonatal head circumference (cm)</td>
<td>34.6±1.3</td>
<td>34.8±1.3</td>
</tr>
<tr>
<td>Urban resident</td>
<td>62 (86.1%)</td>
<td>64 (88.5%)</td>
</tr>
<tr>
<td>Job (employed)</td>
<td>6 (8.4%)</td>
<td>3 (4.2%)</td>
</tr>
<tr>
<td>Economy status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income upper than spent</td>
<td>2 (2.8%)</td>
<td>6 (8.3%)</td>
</tr>
<tr>
<td>Income equal spent</td>
<td>45 (62.5%)</td>
<td>40 (55.6%)</td>
</tr>
<tr>
<td>Income lower than spent</td>
<td>25 (34.7%)</td>
<td>26 (36.1%)</td>
</tr>
<tr>
<td>Placenta exit (spontaneous)</td>
<td>69 (95.8%)</td>
<td>67 (93.1%)</td>
</tr>
</tbody>
</table>

Data indicate mean ± standard deviation or number (%).

**Table 2** Comparison of pain and healing status between the study groups at different time points

<table>
<thead>
<tr>
<th>Group</th>
<th>Pain (VAS, 0–10)</th>
<th>Healing status (REEDA scale, 0–15)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>(4±1) h after intervention</td>
</tr>
<tr>
<td>Cinnamon</td>
<td>5.0±1.8</td>
<td>4.2±1.6</td>
</tr>
<tr>
<td>Placebo</td>
<td>4.6±2.0</td>
<td>4.5±1.7</td>
</tr>
<tr>
<td>Mean difference (95% CI)</td>
<td>0.5 (−0.1 to 1.1)</td>
<td>−0.6 (−1.0 to −0.2)</td>
</tr>
<tr>
<td>P value</td>
<td>0.12</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Data indicate mean ± standard deviation; number of participants was 72 in each group at baseline, (4±1) h and (8±1) h and 62 in the cinnamon group and 61 in the placebo group at the 10–11 d.

Mean difference for the baseline comparison using independent t-test, adjusted mean difference (adjusted by the baseline values and stratified factors (centers and parity)) for the follow-up comparisons using univariate general linear model.

VAS: visual analogue scale; REEDA: Redness, Edema, Ecchymosis, Discharge, Approximation; CI: confidence interval.
discharge (13% vs 23%) and complete closure (65% vs 39%). Wound-healing scores in the cinnamon group were significantly less than those in the placebo group in 4 of 5 components \( (P<0.01 \text{ for redness and edema}, \ P=0.021 \text{ for ecchymosis}, \text{ and } P=0.003 \text{ for approximation}) \). The difference between groups was not statistically significant \( (P=0.1) \). However, in the placebo group two patients had:

- Serosanguinous discharge (scored 2) and two others had bloody purulent discharge (scored 3), while no one in the cinnamon group had such discharges. Due to existence of significance difference at baseline between the groups in terms of approximation, we also compared change score of this component on day 10–11 (in relation to the baseline), which was also significantly better in the cinnamon group \( (P=0.025) \).

Mean number of mefenamic acid intake over 10–11 d postpartum was 4.2 capsules in the cinnamon group and 4.4 capsules in the placebo group, with no statistically significant difference \( (P=0.8) \). Mean number of other analgesics (diclofenac suppository, acetaminophen codeine, and ibuprofen) in the cinnamon group was 16 and in the placebo group was 18, with no significant difference between the groups \( (P=0.6) \). Seven patients (10%) in the cinnamon group and 15 (21%) in the placebo group had used betadine for washing the perineal area as well.

Forty-six participants (74%) in the cinnamon group and 29 (48%) in the placebo group reported that they had resumed their normal daily activities (household chores, cooking and child care) within 5 d postpartum, and the difference between the groups was statistically significant \( (P=0.003) \).

One patient in the cinnamon group and five in the placebo group had partial dehiscence of episiotomy. None of the patients had dehiscence severe enough to require restoration. Antibiotics were administered for the patients on the 10–11 d visit and these patients were followed up until full recovery. No side effects were reported by the participants in either group.

4 Discussion

Our study results showed that use of cinnamon ointment on episiotomy incision for 10 d reduced intensity of perineal pain and improved healing of the incision with no significant side effects.

According to a review of the literature, this study was the first clinical trial on the anti-inflammatory and analgesic properties of cinnamon for wound-healing in humans. Previous studies on laboratory rats also indicated analgesic and healing properties of cinnamon extract. Some experts believe that cinnamon increases epithelization, reduces oxidative stress and improves wound-healing with its anti-microbial and antioxidant properties.

Based on a review study, cinnamon is recommended for the treatment of many diseases such as diabetes, hypertension, and cardiovascular diseases. Three main compounds in cinnamon include eugenol, cinnamaldehyde, and linalool, which make up about 80% of its composition. Eugenol may affect inflammation through reducing prostaglandin biosynthesis; it also has a numbing effect. Cinnamaldehyde also has anti-inflammatory properties. Linalool’s analgesic
and anti-inflammatory effects work via reducing nitric oxide and activating analgesic pathways of cholinergic and glutamatergic compounds.[25,26,27] Cinnamon extract can also reduce inflammation by its polyphenol compounds.[27]

A 2012 study showed that lavender essence has similar effects on postpartum perineal pain, probably due to the presence of linalool and trephine compounds in lavender, similar to cinnamon compounds.[28] In a study, the positive effect of turmeric ointment was attributed to its curcumin compound.[29] It is believed that this substance asserts its effect through inhibition of cyclooxygenase and reduction of nitric oxide,[29,30] which is similar to linalool’s function in cinnamon.

In the present study, the cinnamon group’s decreases in redness and presence of seroanginous or purulent secretion on the 10th day were probably due to cinnamon’s anti-inflammatory[27] and antimicrobial[14] properties.

Wound dehiscence in the present study (1 case in the cinnamon group and 5 cases in the placebo group) was slightly more common than what is expected based on international references, i.e., 0.1% to 2.1%.[30] However, it was slightly less than what is found in the study conducted in Arak-Iran, in which the wound dehiscence was 3% in the group using a sitz bath of lavender oil and 8% in the group using betadine.[31] A possible reason for this slightly higher dehiscence might be related to insufficient skills of the students who performed most episiotomy procedures in the hospitals. In the present study, repair duration was relatively long (35 min) which is probably accompanied with more manipulation of the incision, and may adversely affect wound healing.

We have no possibility to biopsy for follow-up of the wound due to financial limitations. Although in this study loss to follow-up at the 10th day was relatively high (15%), given that both groups had similar numbers and reasons of withdrawals (even higher frequency of withdrawals in the cinnamon group due to expressing improvement), the loss to follow-up probably has not affected the results in any significant way. Considering lack of previous studies on human wounds, a low dose of cinnamon (2%) was used in the present study.

This is the first human study on the analgesic and healing effects of cinnamon. Similar results have been shown in previous studies on non-human research subjects.[18,22,33] More human studies carried out in other settings would be valuable to confirm these effects on episiotomy and other wounds. This study does not have enough statistical power to identify safety of the intervention, which should be assessed in other trials on higher numbers of participants or in meta-analysis of primary studies. Also, because no particular side effects were reported in this and in other studies with higher doses (3%) on laboratory rats,[18,25] future studies should be conducted with various doses of cinnamon to identify the most effective dose.

5 Conclusion

Results of this study indicate that application of 2% cinnamon ointment on episiotomy incisions has a significant effect in decreasing perineal pain and accelerating healing of the incision.

6 Competing interests

The authors declare that they have no competing interests.

REFERENCES


