The effect of *Quercus infectoria* pair cream on the severity of episiotomy pain in nulliparous women

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**Implication for health policy/practice/research/medical education:**
Methanol extract of *Quercus infectoria* pair reduces episiotomy pain in nulliparous women activity and might be used as episiotomy pain therapy for prevention of nulliparous women mainly caused by drugs.


**Introduction**

Episiotomy is a surgical incision in the perineal area that helps facilitate the birth of a baby by enlarging the vaginal entrance during the second stage of labor (1), and is one of the most common midwifery interventions (2). The World Health Organization recommends a 10% prevalence for episiotomy operations (3). In line with this trend, the prevalence of episiotomy decreased from 60.9% to 24.5% in the United States between 1979 and 2004. (4). The prevalence of episiotomy varies from 9.7% in Sweden to about 100% in Taiwan (5). In Asian women, due to their short and rigid perineal structure, they are at higher risk for injuries to the lower part of the area during childbirth (6), so that the prevalence of episiotomy in Oman and Saudi Arabia is 66% and 20%, respectively (7). Although it is not possible to access accurate statistics on the prevalence of episiotomy in Iran, high birth rates can raise the possibility of a high prevalence of episiotomy. The prevalence of episiotomy has been reported to be 88.32% in Mashhad and 80% in Hamedan (8). Complications of perineal injuries associated with childbirth are one of the most important health issues.
Because episiotomy requires suturing, it can cause complications such as pain, bleeding, and infection during intercourse and, in the long term, urinary incontinence (9). Perineal pain is the earliest complication of episiotomy, the prevalence of which is 96.4% and 12% in the world according to the visual analogue scale of pain on the 1st and 90th days after delivery, respectively. 89.7% of postpartum women reported varying degrees of perineal pain, including 53% mild pain, 33% moderate pain, and 3.7% severe pain. Delayed damage to the perineum increases the severity of pain in the area (10). Perineal pain can affect the physical, mental and social aspects of women’s health. It can also disrupt the process of breastfeeding, family life, and sex (11).

Therapeutic approaches to relieve perineal pain in the postpartum period include a variety of pharmacological (including oral and local anesthesia) and non-pharmacological methods such as the use of ice-cold bath/ice packs (12).

Oak (Quercus infectoria), lavender, turmeric, Aloe vera, pineapple and marigold are currently used to reduce perineal pain due to episiotomy (8). The 21st century is the century of return to nature; plants are being increasingly used during this century (13). There are reports of the use of herbal remedies for pain control that, despite the lack of scientific evidence, explanation of the use of these herbal remedies for pain relief has been reported. Using safe methods during breastfeeding is of benefit to women who have undergone episiotomy. The Quercus infectoria (oak tree) has greenish-gray leaves with hairy branches and oval fruits that weigh about 15 to 20 g and is encapsulated in a cup. The oak pair is a thin shell surrounding the main fruit and contains substantial amounts of tannins (14). Tannins are the major polyphenolic groups playing various biological and medicinal roles, including antioxidant, anticancer, anti-inflammatory, antibacterial, antimutation, and cardioprotective activities. Oak pair also has high levels of phenol and flavonoid compounds. Flavonoids have biological properties with possible therapeutic effects, such as antihepatoxic, antitumor, antimicrobial, antioxidant, anti-allergic, anti-inflammatory, and analgesic activities. Tannins cover a wide range of biological and pharmacological activities, including antibacterial, anti-inflammatory, anti-mutational, and cardioprotective properties (15).

In a study conducted by Jahanshahi et al (16) on the effect of oak and lemongrass combination on the control of minor aphthous ulcers of the oral mucosa, promising results regarding the effectiveness of the plant combination were reported, with a relative improvement of 86.6% in the treated group (16). The present study was performed to investigate the effect of oak pair on episiotomy pain intensity.

Materials and Methods
This study was a double-blind clinical trial conducted from August to December 2018 to investigate the effect of oak pair cream on the severity of episiotomy pain in 120 eligible nulliparous women referred to Asali Charity Obstetrics and Gynecology Hospital, Khorramabad. After approval by the ethics committee of Shahid Beheshti School of Nursing and Midwifery in Tehran, this research project was carried out. Given 95% confidence interval, test power 80% and average effect size 0.5 and expected correlation of 0.7 in repetition of measurements, and given 3 intervals, the minimum sample size in each group was determined to be 36 people. Given the potential dropouts, the sample size in each group was finally decided to be 40 samples. Therefore a total of 120 samples were enrolled in this study. The process of comparing the effect of oak cream, placebo, and routine care on episiotomy wound healing in nulliparous women referred to Asali Charity Hospital in Khorramabad is presented in Figure 1.

The data collection tool in this study was a personal information checklist, including demographic characteristics, midwifery, and childbirth conditions. The content validity method was used to determine the validity of this form. The developed questionnaire was distributed among 10 faculty members, obstetricians and gynecologists and, after retrieving their opinions and making final corrections, it was used. Pain intensity was also measured using a visual numerical pain scale, which is a ten-centimeter ruler and was rated from zero (painless) to 10 (maximum pain). Rahu et al reviewed the validity of this tool and considered it to be a valid tool (17). Chuang et al reviewed its reliability, and its interclass correlation reported to be 95 (18). Also, its validity and reliability have been confirmed by Kotfis et al (19).

Women fulfilling the following inclusion criteria were enrolled: nulliparous women aged 18-35 years, no drug addiction, body mass index 19.8-30 (kg/m²), gestational age 37-42 weeks, living single fetus with a head display, infant weight between 4000-2500 g, vaginal delivery with medial-lateral episiotomy without other ruptures in the perineal area, delivery without assistive devices, lack of episiotomy progression to grade 3 and 4 rupture, no pregnancy complications (preeclampsia and gestational diabetes), no rupture of the bladder for more than 24 hours, no severe anemia (hemoglobin less than 7), no current or history of diseases that interfere with wound healing, no use of drugs effective in wound healing such as corticosteroids administered during the study period, no history of allergy to herbal medicines, no financial problems, and family conflicts.

Exclusion criteria included lack of referral on appointed days, no use of creams regularly and according to instructions, having an allergic reaction to oak cream, hospitalization of the infant during the study, the need to repair the perineal area, severe bleeding in the first 24 hours postpartum, fever and postpartum infection, severe postpartum constipation, or having sex in the first 10 days after delivery.

After obtaining permission from the hospital officials
and obtaining informed written consent from the sample of research units, if they fulfilled the inclusion criteria, after filling out the relevant questionnaires, entered the study and then were assigned to the studied groups using random blocks. All samples were similar in terms of episiotomy (middle-lateral), wound healing method, and the type of suture used. Health and nutritional recommendations and how to use normal saline were given to all three groups. For the convenience of research samples, an irrigator (for easy washing with normal saline serum) was provided to each sample. In the groups that received the drug code A or B, the method of applying the cream was taught face to face. The participants were asked to wash the perineal area with normal saline and clean the area, apply the cream in a 2 cm length twice a day for 10 days at the episiotomy site, and after 2 minutes, use a clean sanitary pad.

To prepare oak pair cream, after being purchased from a medicinal plants market in Khorramabad and identified and approved by the pharmacist, the oak pairs were pulverized with an electric mill and extracted with methanol (macerationx3). The resulting extract was concentrated, and after removing the solvent, the resulting extract was mixed with 2% of the cream base and filled in 60 g tubes in a sterile manner. The placebo was filled with the base cream without any drug in 60 g tubes, the same as the drug and was given to the researcher in coded form (A and B) without any information, and the samples were completely blind of which group they belonged to. Only the pharmacist knew about the contents of the creams.

Before the intervention, all three groups underwent a baseline assessment of the pain intensity of the episiotomy site, and subsequent follow-ups were performed 24 hours after delivery on days 5 and 10 (for those who referred to a gynecologist for postpartum care).

After collecting the data and entering them in SPSS statistical software (version 21), the results of qualitative data were reported as number (percentage) and qualitative data as mean ± standard deviation. The chi-square test was used to analyze the data if qualitative variables were compared between the groups, and the Kruskal-Wallis test was used to compare rank variables and quantitative data for which the assumption of normality was not true. One-way analysis of variance was used to compare the means between groups. In order to compare the changes in mean pain intensity at different times within groups and between groups, a repeated measures analysis of variance (ANOVA) test was used. The probability value (P value) less than 0.05 was considered significant.

Results
This study was performed on 120 nulliparous women in Asali Hospital in Khorramabad. Three persons were excluded due to non-referral (One in each group). Finally, the data of 117 enrolled people were analyzed.

Three groups of this study were evaluated in terms of demographic characteristics, including age, body mass index, education, occupation (Table 1), as well as delivery information, including baby weight, around the baby’s head, length of first, second, and third stages of delivery, use of painkillers, episiotomy size, and episiotomy repair time (Table 2). None of the parameters was statistically significant between groups.
### Table 1. Frequency distribution of research units according to personal characteristics and midwifery information

<table>
<thead>
<tr>
<th>Variables</th>
<th>Levels</th>
<th>Normal saline group No. (%)</th>
<th>Placebo group No. (%)</th>
<th>Oak pair group No. (%)</th>
<th>Statistical test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mother’s education</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Primary</td>
<td>11 (37.9%)</td>
<td>8 (27.6%)</td>
<td>10 (34.5%)</td>
<td>Chi-square</td>
<td>0.72</td>
</tr>
<tr>
<td></td>
<td>Intermediate</td>
<td>13 (35.1%)</td>
<td>14 (37.8%)</td>
<td>10 (27%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High school</td>
<td>14 (29.2%)</td>
<td>16 (33.3%)</td>
<td>18 (37.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>College</td>
<td>0 (0%)</td>
<td>1 (23.3%)</td>
<td>2 (66.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Spouse education</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Primary</td>
<td>7 (35%)</td>
<td>5 (25%)</td>
<td>8 (40%)</td>
<td>Chi-square</td>
<td>0.74</td>
</tr>
<tr>
<td></td>
<td>Intermediate</td>
<td>15 (34.9%)</td>
<td>14 (32.6%)</td>
<td>14 (32.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High school</td>
<td>15 (29.4%)</td>
<td>20 (39.2%)</td>
<td>16 (31.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>College</td>
<td>1 (33.3%)</td>
<td>0 (0%)</td>
<td>2 (66.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mother’s job</strong></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Housewife</td>
<td>38 (32.5%)</td>
<td>38 (34.2%)</td>
<td>38 (33.3%)</td>
<td>Chi-square</td>
<td>0.42</td>
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<tr>
<td></td>
<td>Manual worker</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
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<tr>
<td></td>
<td>Employee</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Free</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Spouse job</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Unemployed</td>
<td>2 (66.7%)</td>
<td>1 (33.3%)</td>
<td>0 (0%)</td>
<td>Chi-square</td>
<td>0.38</td>
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<tr>
<td></td>
<td>Farmer-worker</td>
<td>23 (34.8%)</td>
<td>24 (36.4%)</td>
<td>19 (28.8%)</td>
<td></td>
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<tr>
<td></td>
<td>Employee</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Free job</td>
<td>1 (27.7%)</td>
<td>14 (29.8%)</td>
<td>20 (42.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of household members</strong></td>
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<td></td>
<td></td>
<td>Kruskal-Wallis</td>
<td>0.23</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>32 (35.6%)</td>
<td>31 (34.4%)</td>
<td>27 (30%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>4 (21.1%)</td>
<td>6 (31.6%)</td>
<td>9 (47.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>2 (28.6%)</td>
<td>(28.6%)</td>
<td>3 (43.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age (y)</strong></td>
<td></td>
<td>21.76±2.70</td>
<td>22.58±3.93</td>
<td>21.85±3.30</td>
<td>One-way ANOVA</td>
<td>0.49</td>
</tr>
<tr>
<td><em><em>BMI</em> (kg/m^2)</em>*</td>
<td></td>
<td>25.17±2.38</td>
<td>24.98±2.43</td>
<td>24.77±2.15</td>
<td>One-way ANOVA</td>
<td>0.68</td>
</tr>
<tr>
<td><strong>Housing status</strong></td>
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<td></td>
<td></td>
<td></td>
<td>Chi-square</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Personal</td>
<td>4 (13.3%)</td>
<td>1 (50%)</td>
<td>11 (36.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rental mortgage</td>
<td>23 (35.9%)</td>
<td>5 (21.7%)</td>
<td>22 (34.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Live with relatives</td>
<td>11 (47.8%)</td>
<td>19 (29.7%)</td>
<td>7 (30.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Income</strong></td>
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<td></td>
<td></td>
<td></td>
<td>Kruskal-Wallis</td>
<td>0.40</td>
</tr>
<tr>
<td></td>
<td>&lt;1 million</td>
<td>2 (66.7%)</td>
<td>1 (33.3%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-1.5 million</td>
<td>14 (38.9%)</td>
<td>13 (36.1%)</td>
<td>9 (25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.5-2 million</td>
<td>13 (22.8%)</td>
<td>20 (35.1%)</td>
<td>24 (42.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;2 million</td>
<td>9 (42.9%)</td>
<td>5 (23.8%)</td>
<td>7 (33.3%)</td>
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</tr>
</tbody>
</table>

* Data are shown as mean ± SD.

Analysis of pain intensity before intervention showed no significant difference between the mean pain intensity of the three groups ($P = 0.20$). However, there was a significant decrease in the mean pain intensity score of the oak pair receiving group over time ($P<0.001$). Similarly, there was a significant decrease in the mean score of women's pain intensity over time between placebo and normal saline groups ($P<0.001$). There was no significant difference in the pain reduction changes between the two groups receiving placebo and normal saline ($P>0.05$). Pain intensity was assessed before the intervention and then 1, 5, and 10 days after delivery. There was no statistically significant difference in pain intensity scores between the three groups of oak pair, placebo, and normal saline before the intervention ($P=0.20$). The severity of pain on days 1, 5, and 10 after the intervention showed a significant difference between the three groups ($P<0.001$) (Table 3).

### Discussion

The present study, which was performed as a double-blind clinical trial study, showed that oak pair cream was effective in reducing perineal pain on days 1, 5, and 10 after the intervention. Inflammation is followed by any tissue damage with an unpleasant sensation of pain. There are many anti-inflammatory compounds, one of the most well-known of which is flavonoids (19). Flavonoids are able to cross the blood-brain barrier and, through mechanisms such as affecting receptors (GABA), opioids, and adrenoceptors, are able to inhibit the enzymes that contribute to inflammation and pain and produce an analgesic effect.

Flavonoids interact with cyclooxygenase to exert their analgesic and anti-inflammatory effects. These compounds can also have analgesic and anti-inflammatory effects by inhibiting the mechanism of inhibition of prostaglandin...
E2 and proinflammatory cytokines such as interleukin 1B and tumor necrosis factor α (20). Another mechanism for the analgesic and anti-inflammatory effects of flavonoids is the activation of GABA and opioid receptors (20).

Antioxidant compounds such as phenols increase the size of collagen in the wound healing area and stimulate angiogenesis, proliferation, and differentiation of keratinocytes in the wound site and cause wound healing (21). Researchers also confirmed accelerating wound healing using *Quercus infectoria* species due to increased levels of antioxidant enzymes. A study showed that aqueous extract of oak pair, compared to silver sulfadiazine, healed burn wounds in male mice in a shorter time (22). In agreement with this study, the oak pairs have wound-healing properties and, therefore, might reduce pain (22).

In addition, in a study, coriander gum smoke had no significant effect on improving episiotomy pain. Coriander, like oak, contains flavonoid compounds that are expected to have analgesic effects. The reason for the difference between the results of the present study and the study of Modi et al can be attributed to the difference between the route of drug administration and the dose used in the two studies. It seems that in topical use, the drug is in contact with the affected area for a longer time and has more functional power (23). In a study aimed at evaluating the combined ointment of chamomile and marigold on the episiotomy pain intensity of nulliparous women and comparing the pain intensity before the intervention, and on days 1, 5, 10 after intervention, the mean pain intensity in the intervention group was significantly lower. This might be explained by the presence of flavonoid compounds that can improve pain by inhibiting the release of harmful histamines and enzymes. The effect of St. John’s Wort cream was also studied on perineal pain after episiotomy in nulliparous women using the visual pain scale to measure pain before the intervention, 12 hours, and 5 and 10 days after delivery, which showed a significant decrease in mean pain intensity. This effect has been attributed to its biological compounds such as flavonoids and tannins (24, 25). The presence of these compounds in oak can be predicted by its exerting analgesic effect through a similar process. Medicinal plants due to their active ingredients and antioxidant activities have beneficial effects on human health and have a substantial role in the treatment of diseases (26-39).

**Conclusion**

Oak pair can affect the severity of perineal pain after episiotomy and reduce perineal pain. Since this study is the first clinical trial to investigate the effect of oak pair on pain relief, it seems that more trials with higher sample sizes are needed to arrive at a more reliable conclusion.

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we would like to thank the hospital administration, the staff of the delivery unit and all the participants for their cooperation.

**Authors’ contributions**
RS and FN conceptualized the research and prepared the draft of manuscript; MB and FM reviewed the literature and analyzed the data; RS, FN, FM, and MB prepared the draft. All authors read and approved the final report.

**Conflict of interests**
The authors declare no conflict of interest.

**Ethical considerations**
The studies were conducted according to protocols approved by institutional ethical committee with the ethics code IR.SBMU.PHN.M.1396, 849. This article is a part of the dissertation of Shahid Beheshti University of Medical Sciences, which has been registered.

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