

## Original Paper

# Effectiveness of *Onosma dichroanthum* Boiss Combined Ointment on Episiotomy Healing and Pain in Primiparous Women: A Randomized, Clinical Trial



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## ABSTRACT

**Introduction:** Incomplete wound healing or episiotomy pain can cause short-term or long-term physical, psychological, and sexual complications for women.

**Objective:** This study aimed to assess the efficacy of *Onosma dichroanthum* Boiss combined (ODBC) ointment on episiotomy healing and pain relief in primiparous women.

**Materials and Methods:** A double-blind, randomized clinical trial was conducted on 190 primiparous women in a therapeutic education center in Karaj City, Iran, from December 2022 to March 2023. Eligible women were randomly assigned to either the intervention or control group using the block randomization method (95 participants in each group). The intervention group applied 2 g of ODBC ointment every 8 hours, starting 4 hours and continuing until 10 days post-delivery. Equally, the control group received a placebo following the same schedule. Study data were collected at 4 time points using the Redness, Edema, Ecchymosis, Discharge, Approximation (REEDA) and Visual Analog Scale (VAS) tools. The data were analyzed using the chi-squared, independent t, Mann-Whitney, and Friedman tests.

**Results:** Before the intervention, both groups exhibited homogeneity in demographic and gestational characteristics such as age, Body Mass Index (BMI), Job, level of education, gestational age, number of pregnancies, and birth weight. The Mean±SD age and BMI in the intervention and control groups were 27±5.7 and 27.28±4.69 years, as well as 23.59±4.68 and 24.02±4.83 kg/m<sup>2</sup>, respectively. Four hours after the intervention, a statistically significant difference between the two groups was observed in pain ( $P=0.01$ , 6.09±2.02 to 4.77±1.85) and healing scores ( $P=0.01$ , 2.75±0.43 to 2.41±0.49). A significant difference in changes in pain score and healing was observed in the intervention group at 4 time points: before the intervention, 4 hours, 5 days, and 10 days after the intervention ( $P=0.001$ ). In contrast, no statistically significant change was seen in the control group.

**Conclusion:** Based on the results, it succinctly communicates the positive impact of ODBC ointment on the healing process of the episiotomy wound and the reduction of pain intensity in that area, which can be noticed in episiotomy wound care.

## Keywords:

Episiotomy, Pain, Wound healing, Medicinal plant

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## Highlights

- In Iran, various plants have been traditionally used to heal episiotomy wounds. However, the effectiveness of *Onosma dichroanthum* Boiss combined ointment for healing and reducing episiotomy pain in primiparous women is being studied for the first time.
- Using an ointment containing *O. dichroanthum* Boiss (ODB) root extract, beeswax, and olive oil positively impacted the healing process of the episiotomy wound and effectively reduced pain intensity in that area.
- Using herbal plants in Iran is widely accepted because some are good alternatives to synthetic medicines.

## Plain Language Summary

Episiotomy, if not performed at the appropriate time or if it incompletely heals, can lead to weakening or damage of the pelvic floor muscles, resulting in short-term or long-term complications such as urinary incontinence, gas, or stool issues. As a result, promoting perineal healing is essential to maintain pelvic floor strength, tissue continuity, and uniformity, thereby preventing episiotomy-related complications. In our study, *O. dichroanthum* Boiss combined ointment effectiveness was seen, reducing pain and improving healing. *O. dichroanthum* Boiss is rich in alkannin/shikonin (A/S), where in shikonin demonstrates potent anti-inflammatory properties along with antimicrobial, antitumor, and anticancer properties.

## Introduction

**E**pisiotomy is performed to facilitate efficient delivery, minimize severe injuries to the vagina and perineum, alleviate pressure on the cervix, and accelerate the delivery process in challenging circumstances [1, 2]. Despite the World Health Organization's (WHO) recommendation to limit episiotomies in complicated vaginal deliveries, such as breech births, shoulder dystocia, instrumental delivery, fetal distress, and in women with female genital circumcision [2], the rates of episiotomy have remained high in developing countries [3-5]. The prevalence of episiotomy is estimated to be 50% in America, 31% in China, and 41.5% in Iran [4, 6].

The pelvic floor muscles and fascia provide critical support to prevent sagging of pelvic organs, supporting the proper function of the vagina, bladder, uterus, and rectum. Mis-timed episiotomy or incomplete healing can weaken or damage these muscles, resulting in short-term or long-term complications such as urinary incontinence, gas, or stool issues. Therefore, promoting perineal healing is crucial to uphold pelvic floor strength, tissue continuity, and uniformity to avert episiotomy-related complications [7].

Pain or incomplete healing of the episiotomy wound can instill fear in mothers about vaginal delivery and lead to a preference for cesarean sections. This pain

and incomplete healing can disrupt a mother's peace, hinder her enjoyment of childbirth, make her feel inadequate in caring for her baby and performing daily activities, and contribute to diminished sexual performance in the postpartum period [8-10].

The management of postpartum pain resulting from episiotomy and tears can involve various treatments such as using Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), intravenous and epidural narcotics, local anesthetic sprays, as well as other measures like hot or cold-water basins, ultrasonic waves, exercise therapy, massage, acupuncture, distraction, hypnotism, relaxation, and herbal treatment [11, 12]. The use of medicinal plants as remedies and dietary supplements to enhance overall health and medical treatment has garnered considerable attention [12-14]. Herbal medicine, a subset of complementary medicine, has been part of Iran's long history of using medicinal plants [15, 16]. Various plants in Iran, including frankincense [17], green tea [18], *Myrtus communis* [19], *Pistacia atlantica* [20], Aloe vera [21], honey, olive, and curcumin [22], have been utilized to heal episiotomy wounds. Additionally, the root of the *Onosma dichroanthum* Boiss (ODB) plant, known for its anti-inflammatory and wound-healing properties due to its alkannin/shikonin (A/S) content, has traditionally been used to treat burn wounds [23-28]. Numerous studies have demonstrated the positive effects of ODB, particularly in pain reduction and wound

healing for surgical wounds such as those from hemorrhoidectomy. ODB is one of the herbal medicines used in ointments, often combined with olive oil and beeswax for enhanced efficacy. Its properties, including disinfectant, antibacterial, antioxidant, anti-inflammatory, and wound-healing effects, make this herbal medicine native to Iran notable [27-37]. However, there is a lack of studies in Iran investigating the effectiveness of ODB Combined (ODBC) ointment in treating episiotomy wounds. Therefore, this study aims to assess the efficacy of ODBC ointment in healing and managing episiotomy pain intensity in primiparous women.

## Materials and Methods

This double-blind, placebo-controlled clinical trial study was conducted on 190 eligible women in a therapeutic education center in Karaj City, Iran, from December 2022 to March 2023. According to Lavaf et al. study [36], the trial was designed to have 190 patients (95 in each group) using G\*Power software (USA), considering 90% power, significance level ( $\alpha$ ) of 0.05, effect size ( $d$ ) of 0.5, two-sided, allocation ratio ( $N2/N1$ ) of 1 and 10% loss to follow up. The inclusion criteria were Iranian primiparous women aged 18 to 35 years, with mediolateral episiotomy, gestational age  $\geq 37$  weeks, no history of taking psychotropic or narcotic drugs, no alcohol addiction, no instrumental delivery such as forceps or a ventouse suction cup, no vulvovaginal inflammation or infection, no gestational or overt diabetes, without rupture of the membrane for more than 18 hours, and singleton pregnancy. The exclusion criterion was sensitivity to ointment.

For allocation concealment, the medications and placebos were put in sealed opaque envelopes sequentially. Randomized and prepared envelopes were done by someone not involved in sampling and data analysis. In the present study, observers and participants were blinded.

The intervention group received the leading ointment containing ODBC root extract, beeswax, and olive oil. This ointment is produced by [Sanable Darou Herbal Pharmaceutical Company](#) under the brand name ODBC with registration number SMMP80102011 and a standard hologram. This combined ointment is distributed in official pharmacies all over Iran and is used to heal diabetic foot ulcers.

After getting the approval of the Ethics Committee of [Alborz University of Medical Sciences](#) and registering the study on the [Iranian Registry of Clinical Trials \(IRCT\)](#) website, eligible participants entered the study volun-

tarily after the researcher explained the study's objectives and obtained their written consent. The researcher completed the demographic and gestational characteristics based on the participants' medical records. They were assigned to the intervention and control groups based on block randomization using Random Allocation Software (RAS).

In the intervention group, the initial intervention was conducted by a trained midwife, starting 4 hours post-delivery, once every eight hours (three times a day), and continuing until 10 days post-delivery in the Postpartum Department. The procedure involved cleansing the episiotomy wound with physiological saline. Subsequently, the wound was dried using sterile gauze. Following this, ODBC ointment was applied to the episiotomy area using sterile gloves, with a dosage equivalent to the size of an adult's knuckle (5 mm or 2 g) every 8 hours. Finally, the treated area was covered with sterile gauze. Then, participants used sanitary pads to remove secretions after delivery. In the hospital, participants were taught how to use the ointment after discharge. Because the wound is close to the urethra or anus, mothers were asked to dry the area with a hair dryer after urinating or defecating, use sterile gauze and a new sanitary pad, and continue applying the ointment.

The placebo ointment was prepared by a fellow pharmacist at the Pharmacy Faculty of [Alborz University of Medical Sciences](#). The ointment in the intervention group comprised starch devoid of active ingredients and side effects [36]. It was formulated to possess characteristics such as essence, color, consistency, and weight closely resembling the original ointment. In the control group, placebo ointment was used the same way as in the intervention group. It should be noted that no ointment is routinely used for episiotomy repair. The participants of the two groups were given a checklist to indicate complications or other cases and the frequency of ointment use. The participants were contacted once a day to report their adherence to the use of the ointment or the presence of complications from the use of the ointment and the irregular use of antibiotics or NSAIDs. Five participants in the intervention group and four in the control group lost to follow-up (Figure 1). The participants visited the clinic on the fifth and tenth day after delivery. The intensity of pain and healing was recorded by two observers who were not members of the research team and had received the necessary training (two experienced midwives) in the women's clinic affiliated in Educational Therapeutic Hospital. The agreement between the two observers was measured by the kappa index ( $\kappa=0.8$ ).

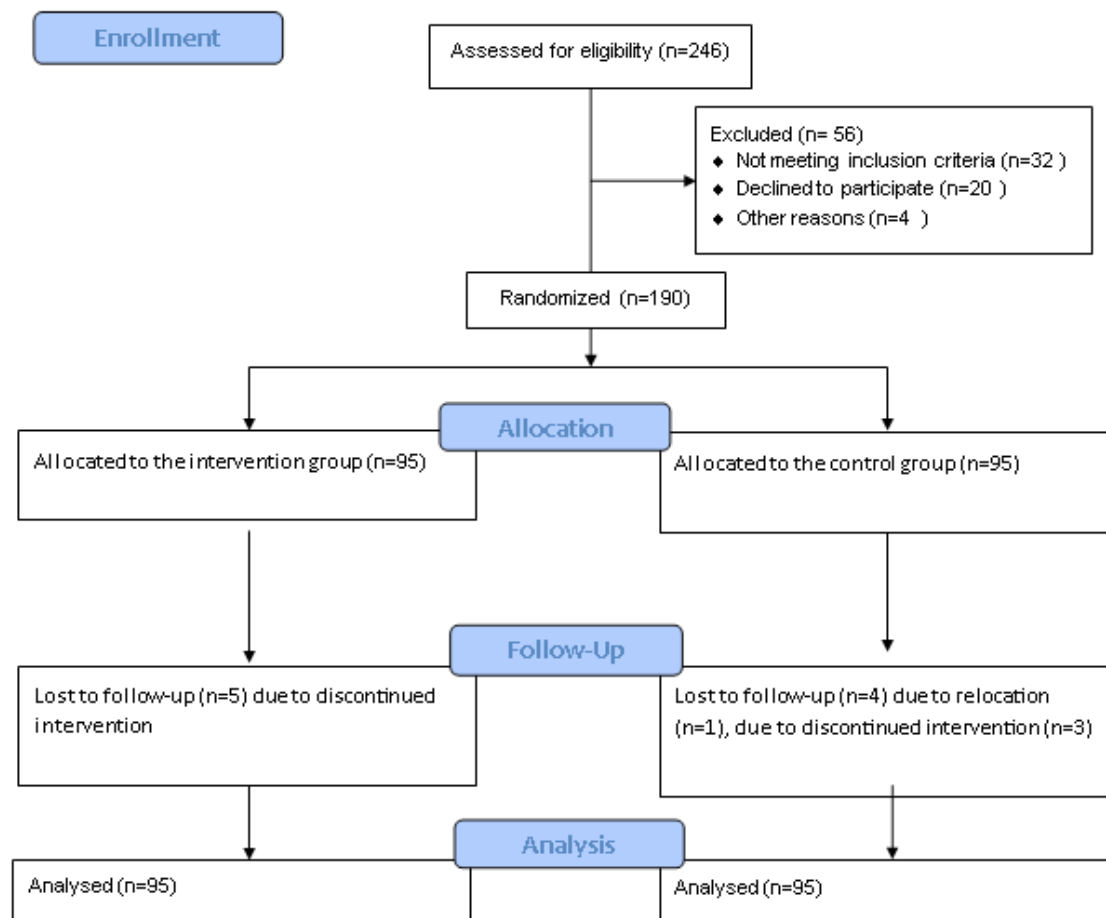


Figure 1. CONSORT diagram of study

Data were collected using demographics, gestational characteristics, and irregular use of antibiotics and NSAIDs during the study and the Redness, Edema, Ecchymosis, Discharge, Approximation (REEDA) checklist and Visual Analog Scale (VAS).

The REEDA scale is a tool that assesses the inflammatory process and tissue healing in the perineal trauma through the evaluation of five items of healing: Redness (hyperemia), edema, ecchymosis, discharge, and approximation of the wound edges (coaptation). For each assessed item, a score ranging from 0 to 3 can be assigned by the health care provider. A higher score indicates a greater level of tissue trauma. The maximum value of 15 means the worst perineum healing outcome [30]. The REEDA scale is a tool for assessing perineal healing primarily developed by Davidson [31]. In Iran, this scale has been confirmed and also its validity and reliability [33]. This scale has been used in many Iranian studies [32, 33]. Episiotomy pain status was assessed using a standardized VAS. This tool measures

the pain score from 0 (no pain) to 10 (the most pain amount) [32, 34].

The study data were collected from two groups across 4 time points: Before the intervention (baseline), 4 hours, 5 days, and 10 days after the intervention. In this double-blind study, primiparous mothers and research assistants were blinded to allocating intervention and control group participants. The chi-square test was used for qualitative variables. Statistical results from the quantitative data were presented with Mean±SD. The Kolmogorov-Smirnov test assessed data normality. The Mann-Whitney and Friedman nonparametric tests were used for variables with non-normal distribution. An independent parametric t-test was used for variables with the normal distribution. The significance level was set at less than 0.05. Missing data management was done using Generalized Estimating Equations (GEE) and random assumption. Statistical analyses were done with SPSS software, version 21 (IBM Corporation, USA).

## Results

This study analyzed the demographic characteristics and other variables of 190 participants, with 95 participants in each group.

The intervention and control groups were homogeneous regarding maternal age, Body Mass Index (BMI), gestational age, number of pregnancies, birth weight, episiotomy incision size, number of pads used for bleeding, baseline pain, and healing scores. Variables of maternal age, body mass index, gestational age, number of pregnancies, birth weight, episiotomy incision size, and number of pads used for bleeding had normal distribution. Baseline pain and healing scores had a non-normal distribution (Table 1).

The chi-square test results showed no statistically significant differences between the two groups regarding socioeconomic status, occupation, and education level (Table 2).

Based on the Mann-Whitney test, there was a statistically significant ( $P=0.001$ ) difference between the two groups in the score of pain and healing 4 hours after the intervention compared to before the intervention (Table 3).

In the intervention group, the results of the Friedman test showed a trend of statistically significant changes in the mean score of pain and healing at 4 time points: Before the intervention, 4 hours, 5 days, and 10 days after the intervention ( $P=0.001$ ). No statistically significant difference was observed in the control group (Table 4).

In Figure 2, on the horizontal axis, number 1 represents before the intervention, number 2 represents 4 hours, number 3 represents 5 days after, and number 4 represents 10 days after the intervention and the mean pain scores are on the vertical axis. In Figure 3, on the horizontal axis, number 1 represents before the intervention, number 2 represents 4 hours, number 3 represents 5 days after, and number 4 represents 10 days after the intervention and the mean healing scores are on the vertical axis.

The results of the independent t-test showed that there is no statistically significant difference between the two groups in the mean number of days of NSAIDs and irregular antibiotic use (Table 5).

## Discussion

In our study, pain and healing were homogeneous in the two groups before the intervention. Four hours after the intervention, a decrease in pain score and healing was observed in the intervention group. In the intervention group, the trend of changes in pain score and healing significantly differed at four time points: Before the intervention, 4 hours, 5 days, and 10 days after the intervention. The decrease in the mean pain score and enhancement in healing indicate that ODBC has lessened pain intensity and promoted healing within the intervention group. These changes were not observed in the control group.

**Table 1.** Comparing quantitative demographics and gestational characteristics in two groups

Variables	Mean±SD		P
	Intervention Group (n=95)	Control Group (n=95)	
Maternal age (y)	27±5.7	27.28±4.69	0.68*
BMI (kg/m <sup>2</sup> )	23.59±4.68	24.02±4.83	0.16*
Gestational age (W)	39.21±0.94	39.17±0.96	0.76*
Number of pregnancies	1.92±0.14	2.04±0.202	0.40*
Birth weight (g)	3351.58±331.2	3315.26±238.625	0.42*
Episiotomy incision size (cm)	2.36±33.36	2.46±35.36	0.23*
Number of pads used for bleeding	5.36±23.27	5.21±28.64	0.34*
Baseline pain score	6.09±2.02	6.07±1.93	0.98**
Baseline healing score	2.75±0.43	2.74±0.44	0.86**

\*The independent t-test, \*\*The Mann-Whitney test.

**Table 2.** Comparing qualitative demographic characteristics in two groups

Variables	No. (%)		P*
	Intervention (n=95)	Control (n=95)	
Socio economic status	Poor	14(14.7)	0.87
	Moderate	70(73.7)	
	Good	11(11.6)	
Job	Housewife	79(83.2)	0.67
	Laborer	8(8.4)	
	Employee	8(8.4)	
Level of education	Middle school	11(11.64)	0.74
	High school	28(29.5)	
	Diploma	40(42.1)	
	Academic	16(16.8)	

\*Chi-square test.

The evaluation of the effect of quantity and quality of secondary active ingredients in the roots of ODB plant showed that the total amount of flavonoids in the roots is higher than the phenolic compounds, and they practically lack anthocyanins. Its high level of flavonoid as an anti-inflammatory, antioxidant, disinfectant, anti-pathogen, and free radical inhibitor indicates that it can prevent and treat infectious, cardiovascular, and cancer diseases [38, 39]. A study has been conducted in Iran to determine the effect of ODB root on stomach cancer. Since the root of ODB is used as an antiseptic and anti-inflammatory to healing wounds, their purpose was to investigate the cytotoxic and anticancer effects of ODB in laboratory conditions. Three periods (24, 48, and 72 hours) were used to treat gastric cancer and normal fibroblast cell lines L-929. An incubation time of 48 hours with 64 µg/mL showed the best effect on

the cancer cell line, while it was safe for the standard cell line. The results showed that ODB root extract has a cytotoxic and safe impact on gastric cancer cell lines and normal cells in 48-hour treatment periods. So, it can be an effective anticancer agent (stomach cancer) [35]. In another study, the anti-inflammatory effect of ODB was investigated using ODB ointment to prevent phlebitis caused by venous catheter placement. Their study showed a decrease in the incidence of phlebitis in the first 12 hours in the intervention group compared to the control group [40, 41]. In our study, the significant difference obtained between the two groups, which shows the improvement of healing and the reduction of pain in the episiotomy area in the intervention group, is attributed to the antimicrobial and anti-inflammatory properties of ODB, which results from the migration of leukocytes to the wound area. It prevents and inhibits

**Table 3.** Comparing pain and healing before and 4 hours after the intervention in two groups

Variables	Time Point	Mean±SD		P*
		Intervention	Control	
Pain	Before	6.09±2.02	6.07±1.93	0.98
	After	4.77±1.85	5.05±1.47	0.001
Healing	Before	2.75±0.43	2.74±0.44	0.86
	After	2.41±0.49	2.69±0.46)	0.001

\*Mann-Whitney test.



**Table 4.** Comparing the changes in pain and healing before the intervention, 4 hours, 5 days, and 10 days after the intervention

Variables	Time Point	Mean±SD	P*	Mean±SD	P*
		Intervention Group		Control Group	
Pain	Before	6.09±2.02	0.001	6.07±1.93	0.07
	4 hours after	4.77±1.85		5.05±1.47	
	5 days after	2.31±1.64		5±1.47	
	10 days after	1.09±1.86		4.63±1.81	
Healing	Before	2.75±0.43	0.001	2.74±0.44	0.06
	4 hours after	2.41±0.49		2.69±0.46	
	5 days after	0.56±0.74		1.85±0.79	
	10 days after	0.09±0.29		1.45±0.43	

\*Friedman test

inflammatory substances or reduces the mediating factors of inflammation. This effect is similar to Rosemary cream, which is used to heal the episiotomy wound and has improved the process of episiotomy healing during the first 10 days after delivery in the intervention group.

Regarding olive oil as one of the ingredients of this ointment, a study single-blind clinical trial was conducted to investigate the effect of olive oil sitting bath on the healing of perineal wounds after delivery on 60 eligible mothers who had an episiotomy or first or second-grade episiotomy. Data were collected using demographic information, the REEDA tool, and VAS before the intervention, 2 hours later, 5 days, and 10 days after. The results demonstrated the effect of olive oil sitting bath between the two groups 5 days and 10 days after the intervention, but 2 hours after the intervention, no statistically significant difference was found between the two groups [37].

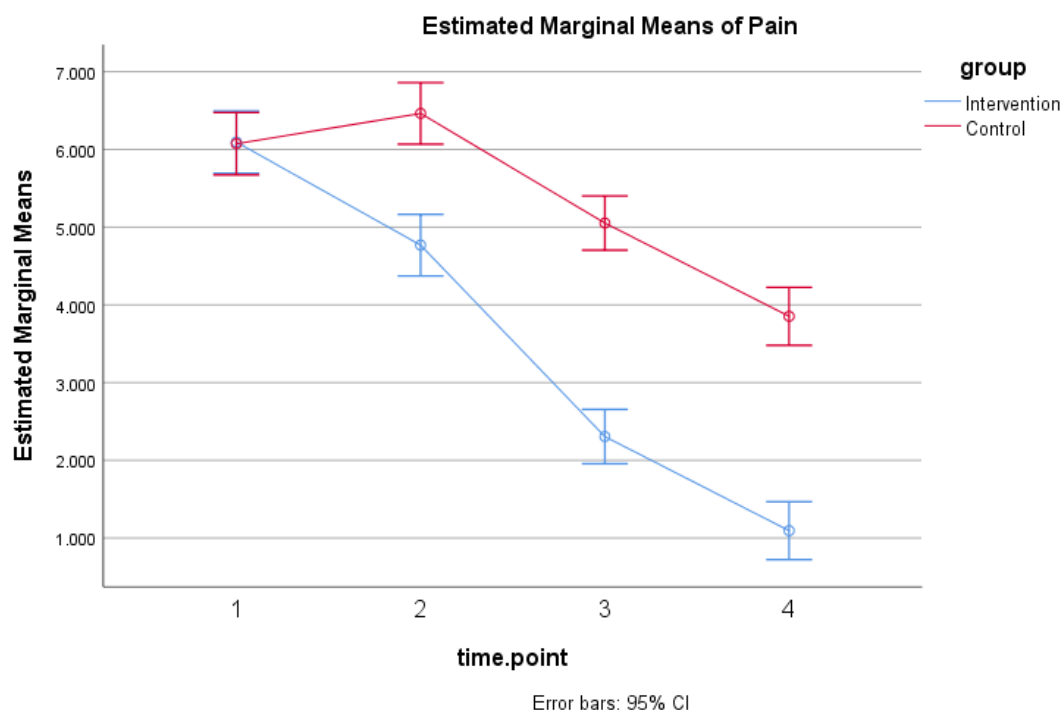
Another component of ODBC ointment was beeswax. There are many studies on the use of honey in healing wounds. The acidic pH of honey, between 3.2 and 4.5, causes the healing of wounds. In addition, the sugar nat-

urally present in honey causes water to be drawn out of the damaged tissues based on the mechanism of the osmotic effect. Therefore, the swelling decreases. It increases lymph flow to heal the wound. Sugar also draws water out of bacterial cells, which can prevent them from multiplying. Healing wounds with honey due to its antibacterial effect so that honey kills the bacteria that normally reside in the wound. Bacteria such as methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant *Enterococci* exist in wounds [36]. In another study, using honey cream or curcumin alone did not reduce the pain intensity, but their combinations (ODB, honey, and curcumin) reduced the pain intensity [22]. In a study where honey was combined with sesame oil and camphor, it positively affected the healing process of pressure ulcers in diabetic people [25]. In another study, ODBC ointment (Sanable Darou) was used with the aim of its effect on wound healing and pain decrease after hemorrhoidectomy. The results demonstrated that pain after hemorrhoidectomy at 4 time points (4, 12, 24 hours, and 7 days) after surgery with ODBC ointment with a dose of 2 g every 8 hours in the intervention group compared to the placebo group has reduced the intensity of pain and burning in the surgical wound.

**Table 5.** Comparing the number of days of irregular NSAIDs and antibiotics use during the study

Time	Mean±SD		P*
	Intervention Group	Control Group	
Number of days of irregular NSAID use	4.45±0.69	4.44±0.89	0.5
Number of days of irregular antibiotic use	2.55±0.39	2.53±0.84	0.67

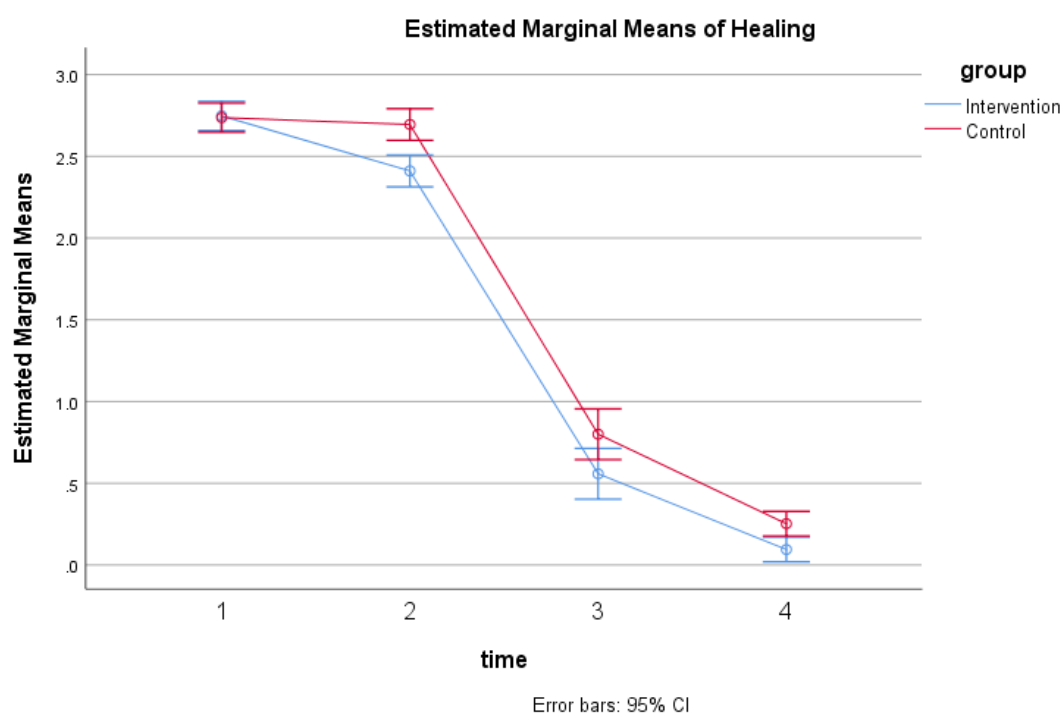
\*Independent t-test



**Figure 2.** The changes in the mean pain score in study groups

The rapid action of ODBC ointment is attributed to its potent anti-inflammatory properties. Our study observed a decrease in pain and enhancement in healing within the intervention group after 4 hours, at 5 days, and 10 days

post-intervention, compared to the placebo group [42]. Our study observed a reduction in pain and improvement in healing within the intervention group at 4 hours, 5 days, and 10 days following the intervention.



**Figure 3.** The changes in healing mean score in study groups



In episiotomy or hemorrhoidectomy wounds where the wound is close to the urethra and anus, pain relief reduces constipation and urinary retention. Aloe vera is one of the other plants that have anti-inflammatory effects, such as ODB. Beta-sitosterol, as one of the components of aloe vera, increases the expression of the vascular endothelial growth factor and its receptor in the wound site, increasing angiogenesis and better healing of damaged tissues. On the other hand, vitamins E and C in Aloe vera affect the wound-healing process by increasing collagen production as an anti-inflammatory [43]. A study utilized Aloe vera to reduce inflammation and alleviate pain following hemorrhoidectomy surgical wounds. The study findings positively impacted wound healing and pain relief within the intervention group [44]. The analgesic effects of ODB are not yet known. In other words, compounds that are effective on pain receptors have not been found at the root of ODB. Hence, the analgesic effects of ODB have a secondary mechanism. Increased tissue perfusion and blood supply reduce pain by accelerating wound healing and healing with anti-inflammatory effects [45].

One of the limitations of our study was assessing participants' adherence to medication usage, which was addressed by implementing a checklist and conducting follow-up phone calls with the researcher. The large sample and double-blind, placebo-controlled clinical trial design are strengths of our study.

Using an ointment containing ODB root extract, beeswax, and olive oil positively impacted the healing process of the episiotomy wound and effectively reduced pain intensity in that area. Given the significance of minimizing both short-term and long-term complications stemming from incomplete wound healing, along with the absence of adverse effects associated with this treatment, as well as the potential for cost reduction and the growing acceptance of herbal medicine, this approach may be considered as a viable alternative for reducing pain intensity and promoting the wound healing process.

## Ethical Considerations

### Compliance with ethical guidelines

This study was approved by the Ethics Committee of Alborz University of Medical Sciences, Karaj, Iran (Code: ABZUMS.REC.1396.213). The study was registered by the Iranian Registry of Clinical Trials (IRCT), Tehran, Iran (Code: IRCT20180110038302N2). Written informed consent was obtained from all the participants.

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This study was sponsored by the Research Deputy Chancellor of Alborz University of Medical Sciences, Karaj, Iran.

## Authors' contributions

Study design: Kourosh Kabir and Mansoureh Yazdkhasti; Data analysis: Kourosh Kabir; Data collection: Shekoufee Tourkashvand; Data management: Zahra Mehdizadeh Tourzani; Supervision: Mansoureh Yazdkhasti; writing the original draft Zahra Mehdizadeh Tourzani and Shekoufee Tourkashvand; Review and editing: Kourosh Kabir and Mansoureh Yazdkhasti.

## Conflict of interest

The authors declared no conflict of interest.

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