Standardised Flavonoid Ointment from *Nigella sativa* L. for Postpartum Maternal Perineal Wound Care in Central Kalimantan, Indonesia

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Abstract

Background: Perineal wounds remain a postpartum issue, particularly in Central Kalimantan, Indonesia. Prior research showed that approximately 31.7% of perineal wounds remained unhealed by the seventh day, highlighting the need for additional natural and herbal treatments to accelerate healing and prevent complications. Black cumin (*Nigella sativa* L.) is a medicinal herb rich in flavonoids, which have been scientifically proven to enhance the wound healing process.
Objective: To analyse the effects of flavonoids from *Nigella sativa* (NS) on second-degree perineal wound healing in postpartum women in Central Kalimantan.

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Methods: A single-blind randomised controlled trial involving 81 participants divided into three groups (15% NS ointment, 10% Povidone-iodine (PI) ointment, and a placebo) was conducted. Each group had 27 participants, and ointments were applied twice daily for seven days. Wound healing was assessed using the redness, oedema (edema), ecchymosis, discharge, and approximation (REEDA) scale on the first, third, and seventh days, and data were analysed using IBM SPSS Statistics v27.
Results: NS extract contained 5.253 mg quercetin equivalent (QE)/g flavonoids and exhibited strong antioxidant activity (IC_{50}=19.709 ppm). Significant differences were observed in wound healing among the three treatments ($p \leq 0.001$). Cohen's d showed a large effect (0.8) for NS vs. PI and a very large effect (1.44) for NS vs. the placebo. Wound healing improvements were 96.3% (NS), 81.5% (PI), and 55.6% (placebo).
Conclusion: The 15% NS ointment, which is standardised with flavonoids, significantly accelerated perineal wound healing in postpartum women. These findings suggest that this agent may serve as an alternative or complementary treatment to PI, particularly in areas with limited medical access; however, further research is needed to explore its long-term effects, optimal dosage, and potential side effects.

Keywords: *Nigella sativa* L.; black cumin; flavonoids; perineal wound; postpartum

Introduction

Perineal lacerations are common during vaginal delivery. In the United States, approximately 85% of women experience perineal trauma during childbirth, with at least 70% requiring suturing (Opondo et al. 2023). Complications owing to perineal wounds, such as wound dehiscence with high incidence, range from 0.21% to 24.6%, and are generally associated with infection occurring in 0.1%–23.6% of women (Jones et al. 2019). The majority of postpartum women with perineal wounds experienced second-degree perineal tears, resulting in increased morbidity as wound healing and the restoration of normal perineal function were delayed (Wiseman et al. 2019). Similarly, a study in Palangka Raya City, Central Kalimantan, Indonesia, found that in 2021, 31.7% of 60 postpartum women with second-degree perineal suture wounds were categorised as not healed using the REEDA scale on the seventh day (Yuniarti et al. 2021). These findings underscore the global concern regarding delayed perineal wound healing and highlights the need for effective interventions to improve recovery outcomes.

Postpartum perineal wound complications affect up to 25% of patients; proper management, including timely follow-up, wound care, analgesia, and antibiotics, is crucial for optimal recovery (Saad and Painter 2023). Increasing concerns about antimicrobial resistance and the side effects of conventional treatments make it essential for health professionals and policymakers to focus efforts on better infection prevention practices to reduce preventable maternal morbidity causes in the postpartum period

(Woodd et al. 2019). Resistance and drug side effects not only pose health risks but also increase treatment costs due to the need for managing complications. Therefore, alternative approaches serve as practical and economical solutions to address these issues.

Natural resources such as herbs have the potential to act as companions or substitutes for drugs (Guo et al. 2024). A randomised controlled trial (RCT) herbal study on the effect of Olea ointment only reduced post-episiotomy pain in primiparous women (Jafarzadeh-Kenarsari et al. 2019). Another RCT comparing the effect of green tea ointment and placebo in perineal wound healing after five and 10 days, showed no statistically significant differences between the treatments (Kazemi et al. 2021). Although studies on these alternative approaches show promise, there is still a lack of high-quality research on the most effective herbal options for managing perineal injuries beyond the acute postpartum period (White and Atchan 2022).

Nigella sativa L. (NS), or black cumin, is known to have antioxidant, anti-inflammatory, and antibacterial properties that can contribute to wound healing (Alabdullah, Kara, and Shehada 2023; Almuhayawi 2023). The presence of bioactive compounds in the NS extract has potential applications in wound healing (Alodhaibi et al. 2022; Palanisamy et al. 2023). NS contains flavonoids, with the total flavonoid content ranging from 1.17% to 1.72% (Kurkin et al. 2024). Flavonoids, known for their antimicrobial and antioxidant properties, play a crucial role in healing postpartum perineal wounds (Astri et al. 2023; Fitriani, Noor, and Widiati 2023; Indayani and Juliyanti 2023). The therapeutic potential of flavonoids in NS has been demonstrated in several studies, suggesting their efficacy in promoting wound healing (Fazil and Nikhat 2020). Despite this, the development of standardised formulations to deliver these bioactive compounds reliably and consistently remains limited (Hwang, Cartron, and Khachemoune 2021).

Significance of the Study

The goal of this study was to harness the therapeutic properties of flavonoids in a topical form that can support wound healing, reduce inflammation, and enhance maternal recovery during the postpartum period (Hartinah et al. 2021). By ensuring a standardised concentration of flavonoids in the ointment, this research aimed to provide a consistent and effective natural treatment option for women during these crucial stages of life. Through this study, we aimed to address the growing need for safe and effective natural interventions in maternal health care while contributing to the scientific understanding of NS's medicinal potential.

Objectives of the Study

This study aimed to analyse the effect of a standard flavonoid ointment derived from NS to treat postpartum perineal wounds in women in Central Kalimantan.

Methodology

Study Design and Location

This study was conducted at the Pahandut Community Health Centre of Palangka Raya City, Central Kalimantan, Indonesia. We used a randomised controlled trial with a single-blind control group design. REEDA score data were collected at three time points: 6–12 hours postpartum (pretest), on the third day postpartum (post-test 1), and on the seventh day postpartum (post-test 2) at the Community Health Centre and the patients' homes throughout July to December 2023.

Materials

The raw material used in this study (NS) belongs to the Ranunculaceae family. We obtained it from a local shop in Semarang that imports NS from India. This is supported by studies on ethnobotany, phytochemistry, antimicrobial pharmacology, and toxicology of NS, which show that India is the largest producer and exporter of NS globally (Hossain et al. 2021). The authenticity of NS seeds was determined, and quantitative analysis to determine the total flavonoid and phenol levels using the high-performance liquid chromatography method was carried out at the Tawangmangu Research and Development Centre for Medicinal Plants and Traditional Medicine (B2P2TOOT).

Extraction was carried out in the chemistry laboratory at Semarang State University (UNNES) and dried in the oven at 60°C; the clean and dry NS was then ground with a blender. One kilogram of crushed black cumin seeds was soaked in 96% ethanol at a ratio of 1:10 and macerated three times for 24 h. The extract was then filtered and concentrated using a rotary evaporator. The yield of the thick extract obtained was expressed as %, and calculated by dividing the weight of the obtained extract (extract weight) by the weight of the raw simplicia material (simplicia weight). The result is then multiplied by 100% to express the yield as a percentage (Cyuzuzo et al. 2021). The resultant yield was 152 g (15.2%).

Phytochemical screening of the NS extract was conducted to identify chemical compounds, including flavonoids, tannins (phenolic group), saponins, steroids, alkaloids, and terpenoids. Measurement of antioxidant activity were performed using the DPPH method via a UV-VIS spectrophotometer at a wavelength of 517 nm (Lestari, Supandi, and Nusafitri 2021). The IC_{50} value category indicates antioxidant strength, namely very strong (<50), strong (50–100), medium (100–150), weak (150–200), and very weak (>200) (Jumina et al. 2019). Macerated extraction is preferred for preparing NS seed extracts because it is a simple and cost-effective way to obtain thermolabile drugs (Shafodino, Lusilao, and Mwapagha 2022; Shikwambi, Onywera, and Mwapagha 2021).

The formulation of the ointment was prepared at the UNNES Pharmacy Laboratory. The ointment used in this study contained a 96% ethanol extract of NS combined with

a hydrocarbon base. The base composition included 10% liquid paraffin (emollient), 0.02% paraben (preservative), 0.18% methylparaben (preservative), and white petrolatum (Vaseline®) as the base, all packaged in 20 g containers. The placebo formulation used the same ingredients, excluding the NS extract.

The 15% NS ointment and placebo were evaluated for their organoleptic characteristics (form, colour, odour, texture, and homogeneity), pH and consistency, as per Sheskey et al. (2020). A balanced pH prevents dryness or irritation (Nopal, Abdullah, and Wahab 2021). Higher extract concentrations increase viscosity, reducing spreadability, whereas strong adhesion aids drug absorption (Siemiradzka, Dolinska, and Ryszka 2020). Optimising the natural ointment base is crucial.

Sample Size Determination and Sampling Procedures

The sample size was calculated using the one-way hypothesis test formula against the mean of two independent populations for the numerical scale dependent variable with a type I error of 5% for the one-way hypothesis ($Z1-\alpha=1.645$) and a type II error of 20% ($Z1-\beta=0.842$), as described by Lwanga and Lemeshow (1991). The optimal sample size per group, including an additional 20% margin to account for possible dropouts, was 27 participants (or a total of 81 participants).

The study participants were selected based on inclusion and exclusion criteria. They were recruited through the community health centres where they had given birth and were approached for participation through direct interviews. The participants met the inclusion criteria, namely primiparas and multiparas with ruptured perineal wounds or grade II episiotomies, and did not experience any birth complications. Ethical approval and informed consent were obtained in accordance with applicable research guidelines.

A consecutive sampling method was used; random allocation was performed using computer-generated random numbers. These numbers were kept in a sealed envelope and distributed to the eligible subjects who agreed to participate in this study until the required number of subjects was reached, similar to the procedure described by Sastroasmoro and Ismael (2014) and Lim and In (2019). Subjects were selected randomly and were divided into three equal groups of 27 study subjects each: the control groups received perineal wound treatment using 10% PI ointment or placebo, and the treatment group received 15% NS ointment (see procedure outline in the Consolidated Standards of Reporting Trials (CONSORT) diagram, Figure 1).

Data Collection and Measurements

The NS ointment was applied twice a day (morning and evening after bathing). Perineal wound healing was assessed using the REEDA tool (i.e., according to redness, oedema (edema), ecchymosis, discharge, and approximation). Wound assessments were performed on the first, third, and seventh days of postpartum using a PVC ruler, with one ruler assigned to each respondent. The ruler was disinfected after each assessment.

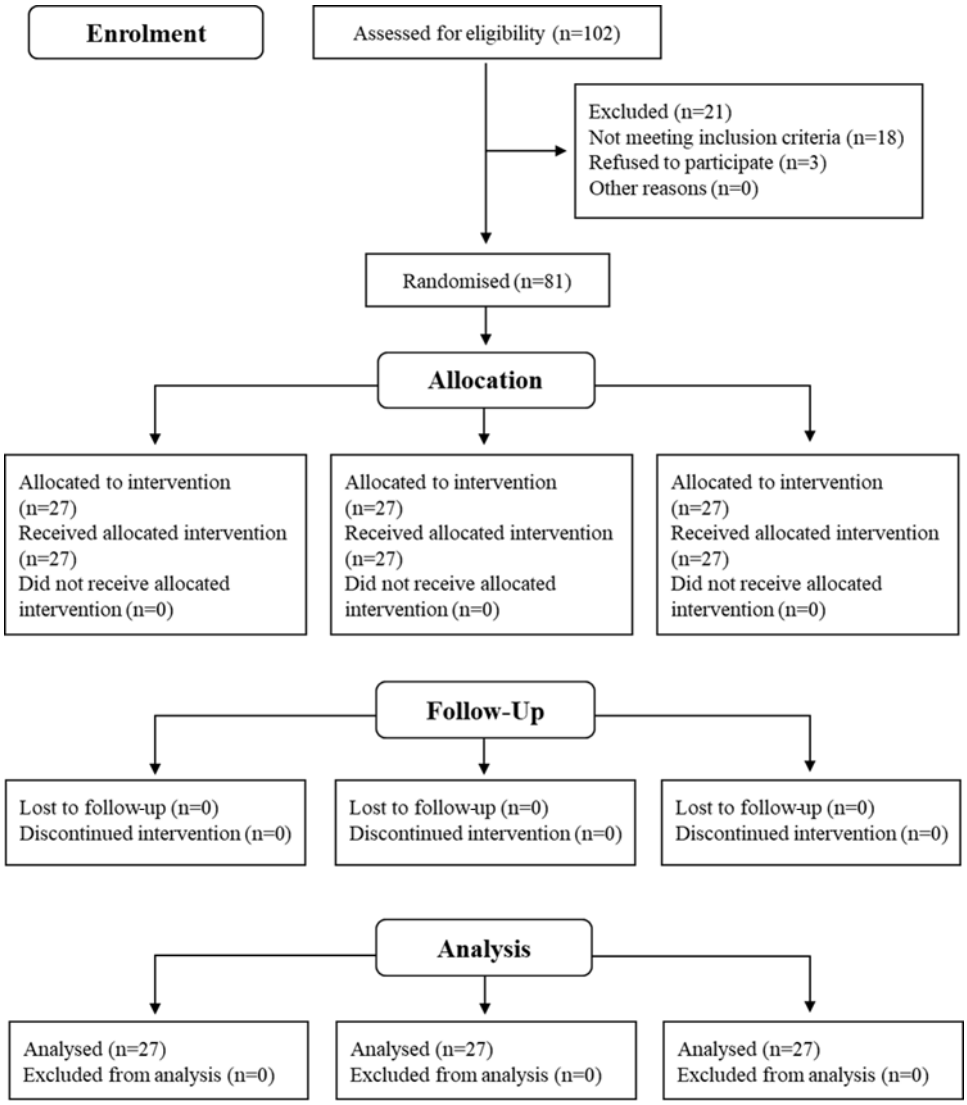

Figure 1: CONSORT diagram.

The REEDA scale is a tool for assessing perineal healing, and was primarily developed by Davidson in 1974. The REEDA scale has been widely used in recent studies to evaluate perineal wound healing, such as in a study examining the effect of ginger on the healing of postpartum women's perineal wounds (Cheshfar et al. 2023). Each item uses a score range of 0–3; perineal wounds are given a score for each item according to the description, which are then summed to get a total score with a value range of 0–15. Higher numbers indicate more significant tissue damage in the wound (Pebolo, Judith, and Dan 2020).

Before commencing this study, we performed an inter-rater reliability test on the REEDA tool, which is utilised to evaluate perineal wound healing in postpartum women who have sustained second-degree perineal lacerations. Researchers and trained midwives assessed the wounds on postpartum days 1, 3, and 7. To determine the consistency of the measurements obtained with the REEDA scale, we used Cohen's kappa coefficient test.

To maintain blinding in the study, the control ointment was created to mimic the texture and packaging of the NS ointment. However, a two-layer sealed container was used to address the odour's challenges. Wound healing evaluators were blinded to the treatment groups to minimise bias, and they wore masks to block any faint scent. The application process was standardised, with all subjects receiving the same home-use instructions. Details regarding ointment characteristics were limited to reduce the potential for subjective bias. Before the intervention, all study subjects received analgesic drugs, antibiotics, and counselling from midwives regarding daily care for perineal suture wounds.

Data Analysis

The collected data were checked and entered in Microsoft Excel, and then exported to IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp. 2020). Data normality was assessed using the Shapiro–Wilk test. Analysis of variance (ANOVA) for age and postpartum perineal wound healing delta (the value was obtained from the post-test 2 minus the pre-test) was performed, followed by an unpaired t-test with LSD correction for post hoc analysis. The chi-square test was applied to the parity and suture technique data, while Fisher's exact test was used to evaluate the injury types. The Kruskal–Wallis test, with subsequent Mann–Whitney U tests, was used to assess differences in postpartum perineal wound healing from the pretest to the post-test, among the three groups. Additionally, the Friedman test was used to analyse differences in perineal wound measurements over time. The effect size was calculated using Cohen's d, with the results indicating a small effect (0.2), medium effect (0.5), large effect (0.8), or very large effect (>1.0).

Ethical Considerations

This research was registered with the health research ethics committee, Faculty of Medicine, Diponegoro University (No.85/EC/KEPK/FK-UNDIP/III/2023). All respondents who participated in this research provided their informed consent.

Results

Sociodemographic Characteristics of Study Participants

The result showed a significant difference in the parity variable and there was a difference in age between groups ($p<0.05$; Table 1). Most participants were high school-

educated, housewives, primiparous, and in the age range of 15–43 years. Most study participants experienced ruptured injuries and received continuous stitches.

Phytochemical and Antioxidant Tests and Evaluation of the Ointment Extract

The phytochemical test results of the NS ethanol extract confirmed the presence of flavonoids, phenols (tannins), saponins, alkaloids, and terpenoids (Table 2). The results of the UV-VIS spectrophotometer test for NS extract showed very strong antioxidant activity (Table 2).

The hydrocarbon-based 15% NS ointment was suitable for postpartum perineal wounds and had good homogeneity, skin-compatible pH (5), strong adhesion, and effective spreadability. The brown colour and black cumin odour confirmed its formulation (Table 3).

Table 1: Sociodemographic characteristics of study participants.

Characteristics	**15% *Nigella sativa* L.**	**10% Povidone Iodine**	**Placebo**	**P-value**
Age; Mean (SD)	24.67 (6.60)	23.89 (4.48)	28.11 (6.04)	0.023*
Education; n (%)				0.561
≤High school	21 (78)	21 (78)	18 (67)	
>High school	6 (22)	6 (22)	9 (33)	
Job; n (%)				0.333
Housewife	19 (70)	16 (59)	21 (78)	
Work from home	8 (30)	11 (41)	6 (22)	
Parity; n (%)				0.001*
Primipara	19 (70)	24 (89)	11 (41)	
Multipara	8 (30)	3 (11)	16 (59)	
Suture technique; n (%)				0.520
Continuous	13 (48)	16 (59)	17 (63)	
Non-continuous	14 (52)	11 (41)	10 (37)	
Type of injury; n (%)				1.000
Rupture	24 (89)	23 (85)	24 (89)	
Episiotomy	3 (11)	4 (15)	3 (11)	

Note: *significant at $p<0.05$.

Table 2: Phytochemical and antioxidant test results of NS extract. Plus (+) and negative (-) signs indicate the presence and absence, respectively, of each chemical compound in NS.

Chemical compound	Results
Flavonoids	+
Tannins (phenolic group)	+
Saponins	+
Steroids	-
Alkaloids	+
Terpenoids	+
Total flavonoids	5.253 mg QE/g extract
Total phenols	0.282 mg GAE/g extract
IC_{50} value	19.709 ppm

Note**:** The mg QE/g extract refers to milligrams of quercetin equivalent per gram of extract, and mg GAE/g extract refers to milligrams of gallic acid equivalent per gram of extract. The antioxidant activity is expressed in ppm (parts per million).

Table 3**:** Evaluation of the properties of 15% NS ointment and placebo.

Type of Test	Placebo	NS 15% Ointment
Form	Semisolid	Semisolid
Colour	White	Brown
Odour	Odourless	Typical cumin smell
Feeling	Sticky	Sticky
Homogeneity	Homogeneous	Homogeneous
pH	5	5
Load spreading capacity (250 g)	5.44 cm	5.16 cm
Sticking power	5 s	9 s

Note: Load spreading capacity refers to the diameter (in cm) of the ointment spread under a 250 g load. Sticking power measures the time (in seconds) that the ointment adheres to the skin before detaching.

Postpartum Perineal Wound Healing

Statistical analysis using the independent-samples Kruskal–Wallis test revealed significant differences in the perineal wound healing outcomes on day three (post-test 1) and day seven (post-test 2; Table 4). The one-way ANOVA test indicated a significant difference in the delta of perineal wound healing. Additionally, Friedman's test showed significant differences ($p<0.001$) across all three groups (NS, PI, placebo). The mean delta exhibited the greatest reduction in inflammatory markers in the NS group, followed by the povidone-iodine (PI) and placebo groups (Table 4).

Cohen's d test, used to analyse the magnitude of the effect on perineal wound healing between research groups, demonstrated that the 15% NS ointment had a significantly greater effect on wound healing compared to the 10% PI ointment, and an even more substantial effect compared to the placebo, highlighting its strong potential in promoting perineal tissue recovery (Table 5). The delta REEDA score was more negative in the NS 15% ointment group than in the other groups (Figure 2). These findings suggest that postpartum women who received the NS 15% ointment experienced the most significant reduction in inflammation signs, with an average delta of −4.3±1.81 (SD).

Figure 3 illustrates the proportion of perineal wound healing status among participants among the three treatment groups (NS, PI, and placebo). The y-axis represents the percentage of study subjects, and the x-axis represents the treatment groups. The NS group exhibited the highest proportion of improved cases, with 26 study subjects (96.3%) showing wound improvement, followed by the PI group with 22 (81.5%), and the placebo group with 15 (55.6%). Conversely, the percentage of non-improved cases was highest in the placebo group with 12 (44.4%), and lowest in the NS group with one study subject (3.7%).

Table 4: Comparison of postpartum perineal wound healing among treatments.

Measurement Time	15% *Nigella sativa* L.		10% Povidone Iodine		Placebo		P-value
	Mean (SD)	Median (min-max)	Mean (SD)	Median (min-max)	Mean (SD)	Median (min-max)	
Pre-test	6.04 (1.37)	6 (4–9)	6.04 (1.85)	6 (3–10)	6.04 (1.32)	6 (4–8)	0.937
Post-test 1	5.15 (2.13)	5 (2–11)	6.67 (2.27)	6 (3–11)	7.30 (2.20)	7 (4–12)	0.001*
Post-test 2	1.74 (1.70)	1 (0–5)	3.33 (2.25)	3 (0–7)	5.07 (2.95)	4 (1–12)	<0.001*
Delta	-4.30 (1.81)	-4 (-8–0)	-2.70 (2.30)	-3 (-7–3)	0.96 (2.72)	-1 (-7–5)	<0.001*

Note: *significant at p≤0.001.

Table 5: Analysis of comparison groups for postpartum perineal wound healing.

Comparison	Post-Hoc Post-Test 1	Post-Hoc Post-Test 2	Pos-Hoc Delta	Effect size Cohen's d
NS vs. PI	0.008*	0.009*	0.013*	0.8
NS vs. Placebo	< 0.001*	< 0.001*	< 0.001*	1.44
PI vs. Placebo	0.282	0.036*	0.007*	0.69

Note: *significant at p<0.05.

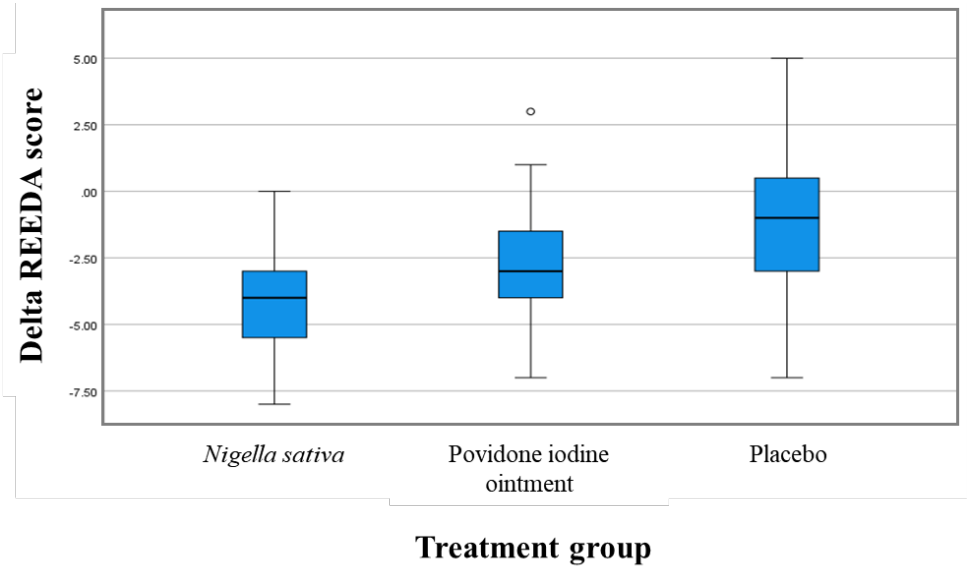

Figure 2: Box plot diagram of perineal wound healing assessment results. Error bars indicate 1 SD.

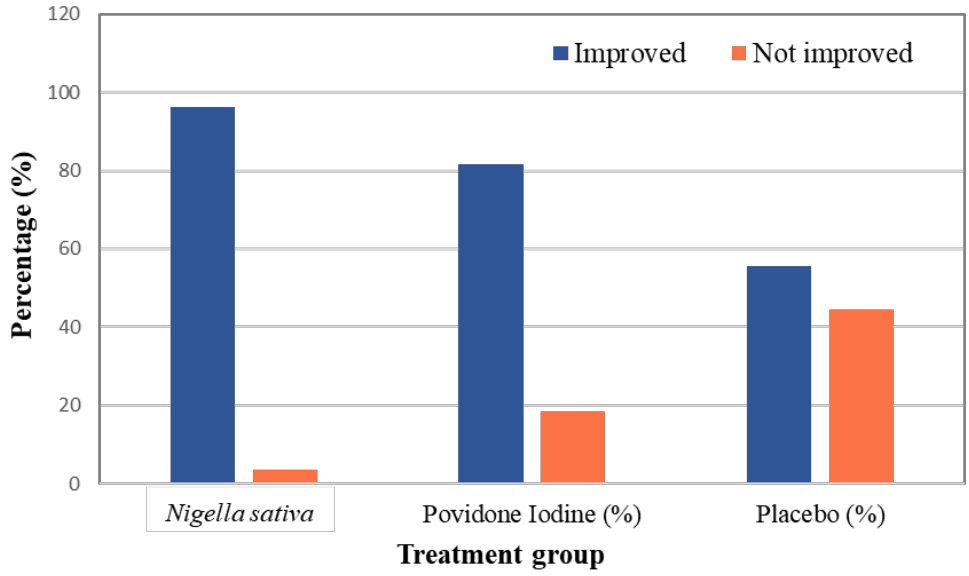

Figure 3: Perineal wound healing status among patients by treatment group.

Wound healing outcomes on day seven post-treatment indicated the significant effect of the NS ointment (Figure 4). Perineal wounds treated with 15% NS demonstrated remarkable healing with reduced inflammation, while wounds treated with 10% PI

showed moderate healing but noticeable irritation. Placebo-treated wounds exhibited minimal healing, further underscoring the efficacy of NS.

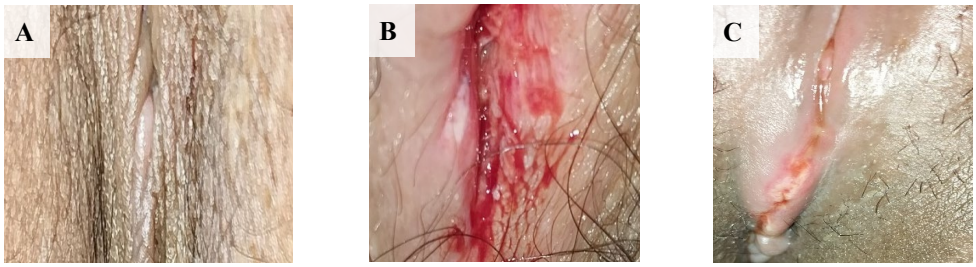

Figure 4: Perineal wounds at the seventh day post-treatment: A) perineal wound treated with 15% NS; B) wound treated with 10% PI; and C) a placebo-treated wound.

Discussion

In this study, a 15% NS extract ointment with a hydrocarbon base was prepared and tested for its effectiveness. Based on previous studies, this base possesses occlusive (water-resistant) properties that are known to provide protection to the wound and last longer compared to other bases (Nopal, Abdullah, and Wahab 2021). Moreover, research has shown that NS extract contains beneficial components such as flavonoids, phenols, saponins, alkaloids, and thymoquinone, which are included in the terpenoid group (Bashir et al. 2023). Consequently, NS extract has various medicinal uses, including wound healing (Elgohary, Al Jaouni, and Selim 2018; Fazil and Nikhat 2020), owing to its antibacterial, anti-inflammatory, and antioxidant properties (Almuhayawi 2023). For example, when formulated into ointments or creams, the NS extract exhibits antibacterial properties against pathogens such as *Staphylococcus aureus* and *E. coli* (Zaid, Hanafi, and Haris 2021). An experimental study of 60 wound infection samples showed that the NS extract had a significant antibacterial effect against wound infections caused by *Staphylococcus aureus* (Babu et al. 2023). Research on tooth extraction wounds showed much faster wound healing with a 12% NS extract concentration than the control group (Dalimunte, Hanafiah, and Rusdy 2020). Our results support these and other findings, showing that 15% NS ointments significantly improved the rate of wound healing when compared to the 10% povidone-iodine ointment and placebo, suggesting that NS ointment may offer advantages over conventional treatments.

The bioactive compounds in NS, i.e., flavonoids, phenols, saponins, tannins, terpenoids, and alkaloids, have potential for therapeutic wound care applications (Alodhaibi et al. 2022; Palanisamy et al. 2023). Our study shows that these compounds play a crucial role in the healing of postpartum perineal wounds. The phytochemical findings in our study are supported by research conducted in 2021, which demonstrated that NS, similarly macerated in 96% ethanol at a one-to-five ratio for three days, tested positive for the same compounds (Cyuzuzo et al. 2021). These compounds, which are also found in plants such as betel leaves and binahong, are known for their antimicrobial and

antioxidant properties that help wound recovery (Astri et al. 2023; Fitriani, Noor, and Widiati 2023; Indayani and Juliyanti 2023). A study on the healing of perineal wounds of 40 participants who were given red betel extract ointment showed significant differences in results on the seventh day compared with conventional care (Astri et al. 2023). The flavonoids in red betel and binahong extracts act as antibiotics and have anti-inflammatory, analgesic, and antioxidant properties. Phenols, saponins, and tannins reduce inflammation and fight infection (Astri et al. 2023). Terpenoids and alkaloids also play a crucial role in accelerating wound healing by increasing collagen production and supporting enzymatic activity, which is important for tissue repair. The combined effects of these bioactive compounds make plant-based medicine an effective alternative for improving perineal wound healing in postpartum women (Astri et al. 2023; Fitriani, Noor, and Widiati 2023; Indayani and Juliyanti 2023). Research showed that NS oil was more effective than Eugenol in accelerating soft tissue healing and reducing inflammation in patients with dry sockets and was statistically significant on the seventh day post-treatment. (Alabdullah, Kara, and Shehada 2023). The bioactive compounds naturally present in the NS extract offers a natural and practical approach to enhancing perineal wound healing in postpartum women, providing a safe alternative to pharmacological interventions.

The novelty of our research lies in the use of specific herbs in the ointment formulations. Numerous studies have investigated the treatment of perineal wounds in postpartum women, including clinical trials assessing the efficacy of various ointments such as Olea ointment (Torkashvand et al. 2021), 2% *Teucrium polium* ointment (Rouzbahani et al. 2021), and green tea ointment (Kazemi et al. 2021). While the wound-healing properties of NS have been previously studied, no research has specifically formulated and evaluated a 15% NS extract hydrocarbon-based ointment for perineal wound healing in postpartum women. This distinction highlights the unique contribution of the present study.

The total flavonoid content in NS extract was standardised to 5.253 mg of quercetin equivalent (QE) per gram of extract. These flavonoid levels were higher than those reported in other studies. For instance, a study of the wound healing activity of purslane herb showed that the total flavonoid content in purslane varieties A and C was 0.55±0.02 (SD) and 1.58±0.02 (SD) mg QE/g, respectively (Budiawan et al. 2023). Furthermore, another study reported the total flavonoid content of NS from the West Dembia district to be 0.764±0.001 (SD) mg QE/g (Tibebe et al. 2024). Consistently maintaining the flavonoid concentration of an ointment ensures stable levels of active compounds in each batch, which contributes to the antioxidant, anti-inflammatory, and wound-healing properties (Aslam et al. 2018; Carvalho et al. 2021), as noted in our study.

Our study revealed statistically significant differences in age and parity among the treatment groups ($p<0.05$). Most participants were high school-educated primipara housewives aged 15–43 years old, with an average age of 25.56±6.00 (SD). In support of this, another study reported a mean age of postpartum women as 24.18±4.70 (SD)

years (Sultana et al. 2022), and most participants were primipara (Arendsen et al. 2021). Parity also affects perineal wound healing, and age is significantly associated with postpartum care (Prince et al. 2023). Although we did not control for demographic characteristics, the introduction of potential confounding factors highlights the importance of such demographic factors in perineal wound healing. Future research should control these variables to better assess treatment effects on recovery.

Nigella sativa ointment is a safe and effective alternative for healing perineal wounds, with no reported adverse side effects in this study. The adhesion of NS-based formulations is crucial for proper drug delivery; studies have investigated various factors influencing transdermal delivery. Optimal formulations show promising results in wound closure and skin infection treatment, with some formulations showing faster healing than conventional treatments (Haq and Michniak-Kohn 2018). These findings suggest that ointments containing NS have the potential to be effective topical treatments. This treatment can be recommended as a complement to standard interventions, such as povidone-iodine, and supports the advancement of herbal-based wound care products. The integration of NS into perineal care protocols can potentially improve postnatal care, especially in resource-limited settings.

Limitations

This study has several limitations. It was conducted in a single region, limiting generalisations of the results. Furthermore, the seven-day monitoring period left the long-term effects of NS extract unknown. The single-blind design may also introduce bias. Finally, uncontrolled factors such as diet could influence wound healing.

Conclusion

The standardised flavonoid content in NS extract provides a consistent therapeutic effect, significantly improving perineal wound healing in postpartum women. The 15% NS ointment formulated in this study showed a significant positive effect compared to PI and an even greater effect compared to the placebo; these findings suggest its potential as an alternative or supplementary treatment to postpartum care. However, further research is necessary to determine the long-term safety of this treatment, its optimal dosage, and its broader applications. Additionally, it is important to consider other factors that may influence wound healing, such as diet, while employing a blinded study design.

Conflict of Interest

The authors declare that this research is not associated with commercial product sales or financial interests that would be considered a potential conflict of interest.

Author's Declaration

The authors declare that the work presented in this article is original, and the authors take all responsibility for claims related to the contents of this article.

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