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Research Article

Clinical Effect of Teucrium polium Extract Ointment on Post Pilonidal Sinus Excision Wound Healing: A Randomized Controlled Trial

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Abstract

Background: Due to the critical importance of post-surgical care for pilonidal sinus wounds, particularly in managing edema, infection, and related complications, it is essential to promote rapid wound healing.

Objectives: This study aimed to evaluate the effect of Teucrium polium extract ointment as a wound repair agent for open pilonidal sinus surgery.

Methods: This randomized double-blind clinical trial was conducted from April 2021 to March 2022. A total of 132 participants admitted to public hospitals in Yasuj with pilonidal sinus disease were randomized into three groups: T. polium ointment, serum, and placebo. The primary outcomes were changes in wound size and wound recovery time after surgery, while secondary outcomes included changes in wound edema and wound exudate.

Results: The results indicated that the mean changes in wound size were statistically significant across all three groups over time ($P < 0.001$). Between-group comparisons showed that from weeks 4 to 8, differences between the three groups were statistically significant ($P < 0.001$). Wound recovery time demonstrated a significant difference between the ointment and serum groups ($P = 0.006$) and between the ointment and placebo groups ($P < 0.001$). Wound edema and exudate improved over time for all three groups ($P < 0.001$), but follow-up results revealed a significant difference among the groups ($P < 0.001$).

Conclusions: Based on the findings of this study and the comparison of the effects of T. polium ointment, it can be concluded that this ointment positively impacts wound healing following pilonidal sinus surgery, enhancing the healing process in both short-term and long-term care.

Keywords: Pilonidal Sinus; Open Wound; Teucrium polium; Wound Healing; Ointment

1. Background

A pilonidal cyst, or pilonidal sinus, is a small skin pocket containing hair, typically located in the lower back. This cyst appears as a small skin opening and often contains twisted hairs or skin debris. Pilonidal disease manifests as an acute abscess or draining sinus near the tailbone at the top of the buttocks (1, 2). Three main factors are considered causes of this condition: (1) A loose hair may become trapped in the crease between the buttocks, particularly in individuals with coarse or stiff hair; (2) a hair follicle in the skin may become irritated or stretched; and (3) the pilonidal cyst may be congenital, present at birth (3, 4).

Two common surgical methods for treating pilonidal sinus include extensive excision with secondary repair and excision with primary repair (5, 6). In both methods, various medicines and ointments are used post-surgery to accelerate wound healing. These include pentoxifylline, prostaglandin E1 and I2, calcium channel blockers like nifedipine, serotonin antagonists, zinc oxide mesh, Lietofix cream, platelet-rich plasma, and hydrocolloid dressings, each with their own limitations (7-9).

Recently, several herbal-origin drugs have been employed in wound healing. For instance, grape seed extract has shown promise in accelerating wound healing (10). An increasing interest in medicinal supplements has

drawn attention to products historically used as wound healers in traditional medicine. One such supplement is Teucrium polium (11).

Teucrium polium has been used in traditional medicine for over 2000 years. It is an herbaceous, perennial, multi-branched plant that grows to a height of 10 to 35 cm and has a cottony white appearance, belonging to the mint family. Unique compounds in T. polium extract include tannins, apigenin, rutin, dimethoxy apigenin, verbascoside, and plepomoside, some of which exhibit anti-inflammatory and antimicrobial effects. In Iran and India, this bitter plant is traditionally used to alleviate heart pain, but its therapeutic effects in treating infections, inflammation, rheumatism, and wound healing have also been substantiated (12).

Given the critical importance of post-surgical care for pilonidal sinus wounds, particularly in managing edema, infection, and related complications, it is essential to accelerate wound healing.

2. Objectives

Additionally, with a growing preference for herbal over chemical medicines, this study aimed to evaluate the efficacy of T. polium extract ointment as a wound repair agent for open pilonidal sinus surgery. Limited research exists on this subject, particularly regarding T. polium, underscoring the significance of this investigation.

3. Methods

3.1. Study Design

This study is a prospective double-blind randomized controlled trial, designed in accordance with the CONSORT guidelines (13). It investigated the treatment effects of T. polium extract ointment on wound healing following open pilonidal sinus surgery. The research population included all patients admitted to public hospitals in Yasuj (Imam Sajjad, Shahid Beheshti, and Jalil) for pilonidal sinus disease and awaiting surgery.

3.2. Outcomes

The primary outcome of the study is the mean differences in wound size and the duration of recovery after surgery. Several secondary outcomes, such as changes in wound edema and wound exudate, were also assessed.

3.3. Sample Size Calculation

To detect changes in wound size and the duration of recovery after surgery, with a 5% error rate, a 95% confidence level, 80% power, a recovery ratio of 75.04% in the intervention and control groups, a 1:1 ratio among the three groups, and a two-tailed test, the estimated sample size was determined to be 44 patients per group. The sample size calculation was performed using G*Power software.

3.4. Preparing Teucrium polium Extract Ointment

Teucrium polium was dried and powdered away from direct sunlight. Ethanol 70% was used for the extraction process. A total of 100 grams of plant powder was soaked in 500 ml of ethanol and kept at room temperature for 48 hours. The filtered extract and the remaining powder were then re-extracted with the same solvent for 24 hours, and the resulting extract was combined with the first. The solvent was evaporated at a temperature of 40°C using a rotary evaporator, and the dried extract was prepared in an incubator set at 37°C. The prepared extract was dissolved in distilled water, and the desired ointment was formulated using 10% Oserin.

3.5. Enrollment Process

From April 2021 to March 2022, all patients admitted to the public hospitals of Yasuj (Imam Sajjad, Shahid Beheshti, and Jalil) due to pilonidal sinus disease and awaiting surgery completed a questionnaire containing demographic data such as age, gender, hairiness, and employment status prior to surgery. After providing informed consent and full agreement to participate in the study, and following the patient's surgery, a second questionnaire containing details of the surgery and the wound healing process was completed by the surgeon.

3.6. Randomization Procedure

In this research, all male and female participants were randomly divided into three groups: Intervention, control, and placebo. Cards labeled A, B, and C were prepared and randomly selected by the patients. Card A corresponded to the intervention group, B to the control group, and C to the placebo group, in which Oserin was used as a placebo. Each participant was given a card with the group code, the date of the follow-up visit, and the researcher's contact number to facilitate reminders. All medical staff, research assistants, nursing staff, and participants were blinded to the randomized allocation.

3.7. Clinical Assessments

In the intervention group, T. polium ointment was applied after washing the wound once daily for two months. In the control group, no ointment was provided. In the placebo group, Oserin ointment was used. Patients were followed up and evaluated by the resident during the first 7 to 10 days for any complications, such as hives or erythema. The patients' reactions to the ointment were recorded, and the general surgeon made decisions based on the type of complication observed. Follow-up evaluations of wound healing in all three groups were conducted weekly for up to eight weeks and again six months later.

3.8. Ethical Considerations

This research adheres to the principles of the Declara-

tion of Helsinki. It has been approved by the Ethics Committee of Yasuj University of Medical Sciences (IR.YUMS.REC.1398.161) with an issuance date of 2020-01-08 and is registered under the research number 960581 in the Research Vice-Chancellor of Yasuj University of Medical Sciences.

The principles of patient information confidentiality were upheld, no costs were imposed on the patients or insurance organizations, and patients were allowed to withdraw from the study at any stage of the research process. Any adverse events were reported to the head of the clinical trial committee and the relevant human research ethics committees.

3.9. Statistical Analysis

Data were analyzed using the intention-to-treat principle with SPSS Statistics 20 software (IBM Corporation). Analysis of demographic and baseline characteristics was conducted for all randomized subjects, and results were reported as percentages, frequencies, means, and standard deviations. Changes in the primary and secondary outcomes were evaluated using chi-square tests, Mann-Whitney U tests (for qualitative and rank variables), and independent t-tests (for quantitative variables). The 95% confidence interval (CI) around the adjusted mean change from baseline was calculated for each treatment group and for the differences between treatment groups.

4. Results

A total of 132 subjects were enrolled in this study and were randomly assigned to three groups: Ointment (n = 44), serum (n = 44), and placebo (Oserin) (n = 44). No statistically significant differences were observed between the three studied groups in terms of demographic characteristics (Table 1).

Table 1. Demographic and Baseline Characteristics (All Randomized Subjects) a

Characteristics	Total	Ointment	Serum	Placebo	P-Value
Age (y)					0.22
< 20	34 (27.6)	9 (20.9)	10 (23.8)	15 (39.5)	
21 - 30	45 (36.6)	15 (34.9)	19 (45.2)	11 (28.9)	
31 - 45	44 (35.8)	19 (44.2)	13 (31.0)	12 (31.6)	
Gender					0.53
Male	107 (81.1)	38 (86.4)	34 (77.3)	35 (79.5)	
Female	25 (18.9)	6 (13.6)	10 (22.7)	9 (20.5)	
Weight (kg)					0.47
< 60	7 (5.3)	1 (2.3)	3 (6.8)	3 (7.0)	
61 - 80	74 (56.5)	30 (68.2)	23 (52.3)	21 (48.8)	
81 - 100	30 (22.9)	6 (13.6)	12 (27.3)	12 (27.9)	
> 100	20 (15.3)	7 (15.9)	6 (13.6)	7 (16.3)	
Height (cm2)					0.27
151 - 160	11 (8.4)	2 (4.5)	7 (15.9)	2 (4.7)	
161 - 170	50 (38.2)	20 (45.5)	16 (36.4)	14 (32.6)	
171 - 180	54 (41.2)	18 (40.9)	14 (31.8)	22 (51.2)	
181 - 190	16 (12.2)	4 (9.1)	7 (15.9)	5 (11.6)	
Occupation					0.17
Unemployed	19 (16.1)	11 (25.6)	5 (12.2)	3 (8.8)	
Employee	24 (20.3)	7 (16.3)	9 (22.0)	8 (23.5)	
Self-employment	45 (38.1)	19 (44.2)	15 (36.6)	11 (32.4)	
Others	30 (25.4)	6 (14.0)	12 (29.3)	12 (35.3)	

[a] Values are expressed as No. (%).

In addition, the clinical history and lifestyle of the patients in each group were determined (Table 2). The results showed no significant difference in driving time (hours) among the three groups: Ointment (25.69 ± 17.78), serum (28.73 ± 18.70), and placebo (25.64 ± 15.25). However, prolonged sitting was not homogeneous across the three groups (P = 0.04), with the ointment group reporting longer sitting times compared to the placebo and serum groups.

Table 2. Lifestyle and Clinical History of Participants in Three Groups a

Characteristics	Total	Ointment	Serum	Placebo	P-Value
Long time sittings					0.047
Yes	104 (80.0)	38 (88.4)	36 (83.7)	30 (62.8)	
No	26 (20.0)	14 (31.8)	7 (16.3)	5 (11.6)	
Exercise					0.51
Yes	42 (32.3)	17 (38.6)	12 (27.3)	13 (31.0)	
No	88 (67.7)	27 (61.4)	32 (72.7)	29 (69.0)	
Long time driving					0.79
Yes	47 (35.6)	17 (38.6)	16 (36.4)	14 (31.8)	
No	85 (64.4)	27 (61.4)	28 (63.6)	30 (68.2)	
Wearing tight clothes					0.67
Yes	67 (50.8)	23 (52.3)	20 (45.5)	24 (54.4)	
No	65 (49.2)	21 (47.7)	24 (54.4)	20 (45.5)	
Number of baths in a week					0.5
Two	7 (5.3)	2 (4.5)	4 (9.3)	1 (2.3)	
Three	80 (61.1)	30 (68.2)	24 (55.8)	26 (59.1)	
Every day	44 (33.6)	12 (27.3)	15 (34.9)	17 (38.6)	
Hypertrichosi					0.93
Yes	89 (67.9)	30 (68.2)	29 (65.9)	30 (69.8)	
No	42 (32.1)	14 (31.8)	15 (34.1)	13 (30.2)	
Family history of pilonidal sinus					0.75
Yes	32 (24.2)	11 (25.0)	9 (20.5)	12 (27.3)	
No	100 (75.8)	33 (75.0)	35 (79.5)	32 (72.7)	
Abnormal bleeding from the wound site					0.48
Yes	34 (26.6)	10 (23.8)	10 (22.7)	14 (33.3)	
No	94 (73.4)	32 (76.2)	34 (77.3)	28 (66.7)	

[a] Values are expressed as No. (%).

4.1. Wound Size

To investigate the healing of the open wound from pilonidal sinus surgery, the wound size over time according to the study groups was measured by assessing the wound volume after the operation for 8 weeks and during a follow-up visit 6 months later. As shown in Table 3, the mean changes in wound size were statistically significant for all three groups over time ($P < 0.001$). Additionally, comparisons between groups indicated that the performance of the ointment, serum, and placebo was similar initially; however, between weeks 4 and 8, the differences among the three groups became statistically significant ($P < 0.001$). After 6 months, no significant differences were observed in wound size among the three groups ($P = 0.78$).

Table 3. The Size of the Wound (cm2) Over Time a

Time	Ointment	Serum	Placebo	P-Value b
After surgery	11.1 ± 3.2	11.1 ± 3.8	10.9 ± 3.2	0.90
After 1 week	11.1 ± 3.2	11.1 ± 3.6	10.8 ± 3.2	0.82
After 2 weeks	7.7 ± 3.0	8.7 ± 3.3	8.4 ± 2.8	0.15
After 3 weeks	7.7 ± 3.0	8.7 ± 3.3	8.4 ± 2.8	0.19
After 4 weeks	4.1 ± 2.9	6.3 ± 3.2	5.7 ± 2.8	0.000
After 5 weeks	4.1 ± 3.0	5.9 ± 3.5	5.7 ± 2.8	< 0.001
After 6 weeks	1.5 ± 2.3	3.0 ± 2.9	3.1 ± 2.3	< 0.000
After 7 weeks	1.5 ± 2.3	2.8 ± 2.9	3.1 ± 2.3	< 0.000
After 8 weeks	0.4 ± 1.1	1.0 ± 1.9	0.90 ± 1.3	0.019
After 6 months	0.05 ± 0.3	0.05 ± 0.2	0.02 ± 0.15	0.78
P-value c	< 0.001	< 0.001	< 0.001	-

[a] Values are expressed as mean ± SD.
[b] Kruskal-Wallis test.
[c] Friedman test.

4.2. Recovery Time of the Wound

The mean recovery time (weeks) in the ointment, serum, and placebo groups was 9.1 ± 6.1, 12.9 ± 8.1, and 14.7 ± 8.2, respectively (Figure 1), with a significant difference in recovery time among the three groups (P < 0.000). Additionally, the results of pairwise group comparisons revealed no significant difference in healing time between the placebo and serum groups (P < 0.101). However, there was a significant difference between the ointment and serum groups (P < 0.006) as well as between the ointment and placebo groups (P < 0.000).

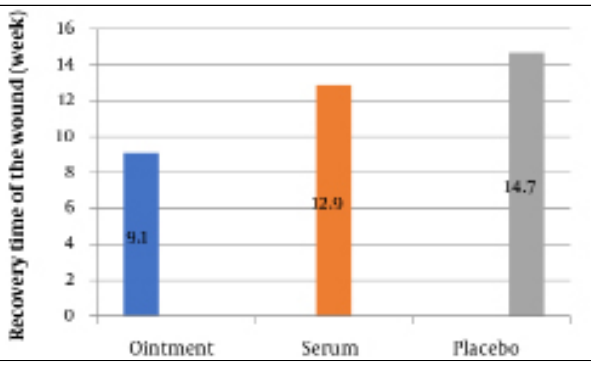

Figure 1. The mean time of wound recovery (weeks) in three groups

As shown in Table 4, 86.4% of the patients in the ointment group recovered within 8 weeks or less, whereas in the other two groups (serum and placebo), more than 30% of the patients required more than 8 weeks or up to six months to recover. Supplementary Figures 1–3 illustrate wound healing progress using placebo, ointment, and serum at different time intervals.

Table 4. Evaluation of the Recovery Time in Three Groups a

Recovery time	Ointment	Serum	Placebo	P-Value
Eight weeks or less	38 (86.4)	29 (65.9)	25 (56.8)	< 0.009
More than 8 weeks	6 (13.6)	15 (34.1)	19 (43.2)	< 0.009

[a] Values are expressed as No. (%).

4.3. The Wound Edema and Exudate

Additionally, wound edema was monitored during patient follow-up after surgery, with results indicating improvement starting from the 4th week. The Q-Cochran test results also demonstrated a significant positive change in wound edema over time for all three groups (P < 0.001). Furthermore, the results showed that wound exudate (often containing electrolytes, proteins, nutrients, digestive enzymes such as matrix metalloproteinase, growth factors, and various immune cells) had almost disappeared by the 6th week. The analysis of changes in wound exudate among different groups during the follow-up period revealed a significant difference over time for all groups (P < 0.001) (Table 5).

Table 5. Evaluation of the Wound Edema and Exudate a

Time	Ointment	Serum	Placebo
After surgery	31 (70.5)	28 (63.6)	29 (65.9)
After 1 week	31 (70.5)	27 (61.4)	29 (65.9)
After 2 weeks	2 (4.5)	4 (9.1)	3 (6.8)
After 3 weeks	2 (4.5)	4 (9.1)	3 (6.8)
After 4 weeks	1 (2.3)	0 (0.0)	0 (0.0)
After 5 weeks	0 (0.0)	0 (0.0)	0 (0.0)
After 6 weeks	0 (0.0)	0 (0.0)	0 (0.0)
After 7 weeks	0 (0.0)	0 (0.0)	0 (0.0)
After 8 weeks	0 (0.0)	0 (0.0)	0 (0.0)
After 6 months	0 (0.0)	2 (4.5)	0 (0.0)
P-value b	< 0.001	< 0.001	< 0.001

[a] Values are expressed as No. (%).
[b] Friedman test.

5. Discussion

The healing effect of T. polium ointment on the open wound from pilonidal sinus surgery, as measured by the wound volume after surgery, demonstrated that changes in wound size were significant across all three groups over time. Additionally, comparisons between groups revealed a significant difference during weeks 4 to 8.

A study evaluating the effect of T. polium ointment on 70 patients with diabetic foot ulcers compared to standard care over 4 weeks found that the initial wound sizes were 3.52 ± 1.47 cm^2 and 1.67 ± 3.21 cm^2 in the T. polium and placebo groups, respectively. After treatment, wound sizes reduced to 0.7 ± 0.19 cm^2 and 1.63 ± 0.72 cm^2, respectively, which was statistically significant. Furthermore, the number of completely healed individuals was significantly higher in the group receiving T. polium ointment alongside standard treatment (14).

Mohammady Rouzbahani et al. conducted a study on 84 women who underwent episiotomy and used 2% T. polium extract ointment twice daily for up to 10 days. Their findings indicated significant improvements in REEDA scoring criteria (redness, ecchymosis, edema, discharge, and convergence of wound edges) on days 5 and 10 (15). Excessive wound exudate or excessive dryness can slow down or disrupt the healing process due to factors such as edema and infection. In our study, wound exudate ceased almost entirely by the 6th week, with significant differences observed between the study groups. Cutting similarly reported improvements in wound exudate from week 4 onwards, with significant changes in wound size correlating with these improvements, aligning with our findings (16).

Regarding recovery time, our results showed that T. polium ointment significantly reduced recovery time compared to the control group, with nearly 90% of patients recovering in less than 8 weeks. Salehi et al. reported that the recovery time for pilonidal sinus surgery wounds treated using a secondary wound recovery technique averaged 78 days in the control group and 61.7 days in the intervention group treated with T. polium honey (1). Similarly, Chabane et al. demonstrated that a 10% T. polium extract ointment accelerated wound healing and reduced oxidative stress (17). Other studies reported average wound recovery times for secondary wound healing methods ranging from 64 to 91 days (18-20). A systematic review on primary wound healing indicated that average recovery times ranged from 13 to 27 days in various studies (21).

Overall, the findings of our study support the effectiveness of T. polium ointment in accelerating wound recovery and improving the healing process after surgery using the secondary wound healing method.

5.1. Conclusions

Besides the proven wound-healing effects of this plant, antimicrobial studies on the use of its extract have also demonstrated its protective and antimicrobial properties. Based on the findings of the present study and the comparison of the effects of T. polium ointment, it can be concluded that the application of T. polium ointment positively influences wound healing following pilonidal sinus surgery. It promotes wound healing in both short- and long-term conditions. To enhance the accuracy and validity of these results and to consider incorporating this drug into treatment protocols, it is recommended that future studies include clinical trials with larger sample sizes.

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