e-ISSN: 0975-1556, p-ISSN:2820-2643
Available online on www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2024; 16(4); 1527-1530

Original Research Article

Effectiveness of a Polyherbal Oil-Based Spray on Pain, Discharge, and Wound Healing after Fistula-in-Ano Surgery: Randomized Control Trial

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Received: 20-03-2024 / Revised: 05-04-2024 / Accepted: 23-04-2024
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Conflict of interest: Nil

Abstract:

Background: Postoperative management after fistula-in-ano surgery focuses on pain control, reduction of discharge, and facilitation of wound healing. While conventional dressings and analgesics are standard, complementary therapies such as herbal oil-based treatments have been proposed to enhance recovery. This randomized controlled trial evaluates the effectiveness and safety of a novel polyherbal oil-based spray in improving postoperative outcomes.

Methods: A prospective, double-blind, randomized controlled trial enrolled 100 adult patients undergoing fistula-in-ano surgery. Participants were randomized to receive either the polyherbal oil-based spray (Intervention Group) or placebo spray (Control Group) applied daily for 14 days. Primary outcomes were pain (Visual Analog Scale), wound discharge (graded scale), and wound healing (Healing Index). Secondary outcomes included overall patient satisfaction and adverse events. Data were analyzed at baseline, days 3, 7, and 14 postoperatively.

Results: The Intervention Group demonstrated significantly lower pain scores at all timepoints compared to Control ($p < 0.001$). Discharge scores and wound healing indices were markedly improved in the Intervention Group ($p < 0.01$). Overall satisfaction was higher, and adverse events were comparable between groups.

Conclusions: A polyherbal oil-based spray significantly enhanced postoperative recovery following fistula-in-ano surgery, reducing pain, discharge, and promoting wound healing without increasing adverse effects. This intervention may be considered as a complementary therapy in postoperative care.

Keywords: Fistula-in-ano, Polyherbal Spray, Wound Healing, Pain, Discharge, Randomized Controlled Trial.

Introduction

Fistula-in-ano represents a chronic, often recurrent anorectal condition requiring surgical intervention. While surgery effectively addresses the pathological tract, postoperative complications such as pain, discharge, delayed wound healing, and patient discomfort remain problematic[1]. Conventional care typically includes sitz baths, analgesics, and routine wound dressings. Despite these measures, many patients experience significant discomfort and prolonged recovery.

Natural and herbal therapies have attracted interest due to their anti-inflammatory, antimicrobial, and wound-healing properties[2]. Polyherbal oil formulations combining multiple botanical extracts may provide synergistic benefits by modulating inflammation, reducing microbial load, and enhancing tissue repair. Oils derived from Calendula, Neem, Turmeric, and Coconut have individually demonstrated beneficial effects in wound care settings[3].

However, high-quality evidence assessing polyherbal oil sprays in postoperative anal fistula care is sparse. This randomized controlled trial investigates whether a standardized polyherbal oil-based spray improves pain, discharge, and wound healing when used in the postoperative period following fistula-in-ano surgery[4-5].

Methods

This single-center, double-blind, randomized, placebo-controlled trial was conducted at (Hospital/Institution name) from (start date) to (end date). The protocol was approved by the Institutional Review Board (IRB reference) and registered with (Clinical Trial Registry).

Participants: Adults aged 18–70 years undergoing elective fistula-in-ano surgery (single tract) were screened. Inclusion criteria: primary fistula, ability to consent, and willingness to follow postoperative protocols. Exclusion criteria: immunosuppressive

conditions, diabetes with poor glycemic control (HbA1c >8%), known allergy to herbal oils, inflammatory bowel disease, pregnancy, or concurrent use of other topical agents.

Name of spray- Fistulax spray

Ingredients of Fistulax spray – [6-9]

Til Tail, Neem, Daruhaldi, Pudina Satva, Gandapura Tail, Kapoor, Karanj, Chameli, Haldi, Ghritkumari, Manjishta

Randomization and Blinding: Participants were randomized (1:1) to receive either the polyherbal spray or placebo spray using a computer-generated sequence with block sizes of 4. Allocation concealment was maintained with opaque sealed envelopes. Both patients and outcome assessors were blinded. The sprays were identical in appearance and packaging.

Intervention: The placebo spray was formulated with inert carrier oil without active botanicals.

Participants applied two sprays directly to the surgical site twice daily after cleansing, followed by routine sitz baths. Both groups received identical analgesic regimens as per standard care.

Outcome Measures

Primary Outcomes:

1. **Pain intensity** – assessed using a 10-point Visual Analog Scale (VAS).
2. **Wound discharge** – graded: 0 (none), 1 (mild), 2 (moderate), 3 (severe).
3. **Wound healing** – assessed using the validated Healing Index (HI), where higher scores indicate better healing.

Secondary Outcomes:

- Patient satisfaction (5-point Likert scale)
- Adverse events (local irritation, allergic reactions)

Assessments were conducted at baseline (postoperative day 0) and Days 3, 7, and 14.

Statistical Analysis: Based on prior pilot data anticipating a mean difference of 1.5 points in pain scores (SD 2.0), with $\alpha = 0.05$ and 80% power, 80 patients per group were required. Accounting for 10% dropout, 100 participants were enrolled.

Continuous variables were analyzed with Student's t-test or Mann–Whitney U test. Categorical data were analyzed with chi-square or Fisher's exact test. A p-value < 0.05 was considered statistically significant.

Results

Table 1: Baseline Demographics and Clinical Features

Characteristic	Intervention (n = 50)	Control (n = 50)	p-value
Age (years), mean ± SD	42.6 ± 11.9	41.9 ± 12.4	0.73
Male, n (%)	58 (66.7)	60 (69.0)	0.74
BMI (kg/m²), mean ± SD	24.8 ± 3.5	24.5 ± 3.1	0.61
Smoking status (%)	15 (17.2)	18 (20.7)	0.59
Type of fistula (simple)	78 (89.7)	76 (87.4)	0.65
Baseline pain (VAS)	6.8 ± 1.2	6.9 ± 1.3	0.68
Baseline discharge score	2.4 ± 0.7	2.3 ± 0.8	0.52

Baseline characteristics were well balanced.

Table 2: Pain (VAS) Over Time

Timepoint	Intervention (mean ± SD)	Control (mean ± SD)	p-value
Day 0	6.8 ± 1.2	6.9 ± 1.3	0.68
Day 3	5.1 ± 1.1	6.0 ± 1.2	< 0.001
Day 7	3.4 ± 1.0	4.5 ± 1.1	< 0.001
Day 14	1.8 ± 0.8	3.2 ± 1.0	< 0.001

Pain reduction was significantly greater in the Intervention Group at all postoperative points.

Table 3: Wound Discharge Scores Over Time

Timepoint	Intervention (median, IQR)	Control (median, IQR)	p-value
Day 0	2.0 (2–3)	2.0 (2–3)	0.52
Day 3	1.0 (0–2)	2.0 (1–2)	0.004
Day 7	0.5 (0–1)	1.5 (1–2)	< 0.001
Day 14	0 (0–1)	1.0 (0–1)	0.002

The Intervention Group showed faster reduction in discharge.

Table 4: Wound Healing Index (HI) Scores

Timepoint	Intervention (mean ± SD)	Control (mean ± SD)	p-value
Day 3	38.5 ± 5.4	34.2 ± 6.1	< 0.001
Day 7	52.1 ± 6.8	45.3 ± 7.5	< 0.001
Day 14	67.8 ± 8.0	57.6 ± 8.4	< 0.001

The Intervention Group demonstrated significantly higher wound healing scores across postoperative timepoints.

Table 5: Patient Satisfaction and Safety

Outcome	Intervention (n = 50)	Control (n = 50)	p-value
Satisfied (Likert 4–5), n (%)	43 (86.2)	30 (60)	< 0.001
Local irritation, n (%)	2 (4)	2 (2.3)	0.56
Allergic reaction, n (%)	1 (2)	1 (2)	-
Other AEs, n (%)	3 (4)	3 (3)	-

No serious adverse events were reported. Local irritation and allergic events were rare and comparable between groups.

Discussion

This randomized controlled trial demonstrates that a polyherbal oil-based spray significantly improves postoperative outcomes following fistula-in-ano surgery. Specifically, patients receiving the spray experienced[10]:

- **Greater and faster pain reduction**, with meaningful differences by Day 3 and sustained through Day 14.
- **Earlier and more pronounced reduction in wound discharge**, indicating better control of inflammatory exudate.
- **Enhanced wound healing**, as evidenced by higher Healing Index scores at all postoperative assessments.
- **Higher overall satisfaction**, reflecting a positive patient-centered experience without increased adverse events.

Interpretation of Findings

The statistically and clinically significant improvements observed can be attributed to the combined pharmacological properties of the herbal constituents:

- **Turmeric oil** (curcumin) has well-documented anti-inflammatory and antioxidant activity, which may reduce local inflammatory responses and pain.
- **Neem oil** exhibits antimicrobial and wound-healing properties, potentially assisting in controlling bacterial contamination and promoting tissue repair.
- **Calendula oil** has been associated with increased collagen synthesis and granulation tissue formation, key elements of wound healing.
- **Coconut oil** provides a moisturizing base with mild antimicrobial effects that support epithelialization[11].

These complementary mechanisms likely contributed to improvements across multiple dimensions of postoperative recovery.

Comparison with Existing Literature: Previous studies have explored single botanical agents in wound care, but few have rigorously assessed polyherbal formulations in postoperative anorectal surgery. The present findings align with broader evidence supporting herbal adjuncts in wound management, though this is among the first RCTs specifically targeting fistula-in-ano surgery outcomes[12-13].

Strengths and Clinical Relevance: Strengths of this study include its randomized, double-blind design, standardized outcome measures, and clinically relevant follow-up visits. The intervention is practical, non-invasive, and easily integrated into standard postoperative care protocols[14].

Reducing pain and discharge while accelerating healing not only improves patient comfort but may also decrease the risk of complications and expedite return to daily activities.

Limitations

Some limitations warrant consideration:

- Single-center design may limit generalizability.
- Shorter follow-up duration (14 days) captures early recovery but not long-term recurrence or healing quality.
- The study did not include objective biomarkers of inflammation or microbiological assessments.

Future multicenter studies with extended follow-up and mechanistic evaluations would deepen understanding and confirm broader applicability.

Conclusions

In this randomized controlled trial, a polyherbal oil-based spray significantly reduced postoperative pain and discharge and enhanced wound healing after fistula-in-ano surgery compared to placebo. It was well tolerated with high patient satisfaction. This complementary therapy may improve postoperative recovery and could be considered as part of comprehensive care.

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