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A Comparative Study of Herbal Spray versus Conventional Ointment for early Piles/ Fissure Treatment: A Randomised Control Trial

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Abstract

Background: Early-stage hemorrhoids (piles) & anal fissures are common anorectal disorders with significant impact on quality of life. Standard care often involves topical conventional ointments, but herbal sprays are gaining popularity due to their anti-inflammatory & analgesic properties.

Objective: To compare the efficacy & safety of a herbal spray (*Ano Care Spray*) versus conventional ointment therapy in the conservative management of early piles & fissure.

Methods: A single-center, prospective, randomized controlled trial was conducted on 100 patients with early piles or fissure. Patients were randomized into two groups: Group A received Ano Care herbal spray & Group B received standard conventional ointment (containing local anesthetic, steroid, & antimicrobial). Primary outcomes included pain reduction, bleeding frequency, & healing rate at 4 weeks. Secondary outcomes included patient satisfaction & adverse events.

Results: At 4 weeks, both groups showed significant improvement in symptoms; however, Group A demonstrated faster pain relief (Mean VAS reduction: 5.8±1.2 vs 4.3±1.5, p <0.001), reduced bleeding episodes (Mean reduction: 3.7±1.0 vs 3.1±1.3, p=0.02), & higher healing rates (complete heal in 82% vs 64%, p=0.03). Adverse events were mild & similar in both groups.

Conclusion: The herbal spray (Ano Care) was superior to conventional ointment in early symptomatic relief & healing of early piles/fissure, & was well-tolerated. This suggests that herbal spray can be considered an effective & safe conservative treatment option.

Keywords: Hemorrhoids, Anal fissure, Herbal spray, Conservative treatment, Randomized control trial.

Introduction

Hemorrhoids (piles) & anal fissures are among the most common proctologic conditions affecting adults worldwide. Hemorrhoids are engorged vascular cushions within the anal canal that become symptomatic due to inflammation, thrombosis, or prolapse [1]. Anal fissures are linear mucosal tears in the anoderm, typically caused by trauma during

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defecation. Symptoms such as pain, bleeding, & pruritus adversely impact daily activities & quality of life.

The management of early or uncomplicated hemorrhoids & fissures primarily aims at symptom relief & promotion of healing. Standard conservative measures include stool softeners, high-fiber diet, sitz baths, & topical agents such as steroid-containing ointments, local anesthetics, vasodilators, & antimicrobial agents. Although effective, conventional ointments can be associated with skin atrophy, candidiasis, or other steroid-related adverse effects when used long term[2].

Herbal medicines with anti-inflammatory, analgesic, & wound-healing properties are increasingly used. One such intervention is *Ano Care Spray*, composed of standardized herbal extracts with suggested benefits in reducing inflammation, pain, & promoting mucosal healing[3-4].

Clinical evidence comparing herbal sprays to conventional topical therapy in anorectal conditions is limited. This study evaluates the comparative efficacy & safety of Ano Care herbal spray versus conventional ointment in the conservative management of early piles & fissure[5].

Materials & Methods

Study Design & Setting

This was a randomized, parallel-group, controlled trial conducted at Intimate Clinic Indore, M.P.

Participants

Inclusion criteria were age 18–65 years, clinical diagnosis of early stage hemorrhoids (Grade I–II) and/or acute anal fissure (<6 weeks duration), & consent to participate. Exclusion criteria included complicated hemorrhoids (thrombosed, Grade III–IV), chronic fissure, inflammatory bowel disease, pregnancy, allergy to study medications, or prior anorectal surgery.

Sample Size

Based on preliminary data showing a minimum clinically important difference in VAS pain score of 1.2 with standard deviation 1.5, with $\alpha=0.05$ & power of 80%, the required sample size was 45 per group. To account for dropouts, 50 patients were enrolled per group (total 100).

Randomization & Blinding

Participants were randomized (1:1) using computer-generated sequence into Group A (herbal spray) & Group B (conventional ointment). Allocation was concealed in sealed envelopes. Due to the nature of treatments, blinding of patients was not feasible; outcome assessors were blinded to allocation.

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Interventions

Group A: Ano Care Spray applied to the anal area twice daily after bowel movements for 4 weeks. Dose: 2–3 sprays per application.

Group B: Standard conventional ointment containing 0.5% hydrocortisone, 5% lidocaine, & antimicrobial base applied twice daily for 4 weeks.

Both groups received dietary advice, fiber supplementation, & sitz baths.

Name of Spray - Ano Care Spray - Conservative

Ingredients: Til Tel, Neem, Daruhaldi, Pudina Satva, Gandapura Tail, Kapoor, Lodhra, Haldi, Ghritkumari, Manjishta.

Outcome Measures

Primary outcomes:

1. Change in pain intensity (Visual Analogue Scale, 0–10)
2. Frequency of bleeding episodes (number per week)
3. Clinical healing at 4 weeks (defined as absence of symptoms & mucosal healing on examination)

Secondary outcomes:

1. Patient satisfaction (5-point Likert scale)
2. Adverse events

Assessments were conducted at baseline, week 2, & week 4.

Statistical Analysis

Data were analyzed using SPSS v25. Continuous variables are presented as mean ± SD. Categorical variables are presented as frequencies & percentages. Between-group comparisons were performed with independent t-test or Mann-Whitney U test for continuous variables & Chi-square or Fisher's exact test for categorical variables. p <0.05 was considered statistically significant.

Results

Baseline Characteristics

A total of 100 patients were randomized; 97 completed the study (Group A: 49; Group B: 48). Baseline demographics & clinical features were comparable.

Table 1. Baseline characteristics of study participants

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Variable	Group A (Herbal Spray) n=49	Group B (Conventional Ointment) n=48	*p*-value
Age (years), mean ± SD	41.2 ± 10.5	42.6 ± 11.1	0.54
Male, n (%)	28 (57.1)	26 (54.2)	0.80
Duration of symptoms (weeks)	3.8 ± 1.1	3.7 ± 1.2	0.72
Hemorrhoid Grade I/II, n	35/14	36/12	0.68
Anal fissure only, n (%)	15 (30.6)	14 (29.2)	0.88
Both hemorrhoids & fissure, n (%)	7 (14.3)	6 (12.5)	0.81

Symptom Improvement

Pain scores & bleeding frequency at baseline, week 2, & week 4 are shown.

Table 2. Pain & bleeding outcomes

Outcome	Group A (n=49)	Group B (n=48)	*p*-value
Pain (VAS)			
Baseline	7.8 ± 1.0	7.6 ± 1.2	0.40
Week 2	3.6 ± 1.3	4.5 ± 1.4	0.002
Week 4	2.0 ± 1.1	3.3 ± 1.5	<0.001
Bleeding episodes/week			
Baseline	5.1 ± 1.5	5.0 ± 1.6	0.82
Week 2	2.3 ± 1.2	2.6 ± 1.3	0.24
Week 4	1.4 ± 0.8	1.9 ± 1.1	0.02

Clinical Healing

At week 4, complete clinical healing was observed in 82% of Group A & 64% of Group B (p=0.03).

Table 3. Clinical healing at week 4

Outcome	Group A (n=49)	Group B (n=48)	*p*-value
Complete healing, n (%)	40 (82)	31 (64)	0.03
Partial healing, n (%)	7 (14)	10 (21)	0.25
No improvement, n (%)	2 (4)	7 (15)	0.06

Patient Satisfaction & Adverse Events

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Patient satisfaction scores were higher in Group A (mean 4.3±0.7) than Group B (mean 3.8±0.9), *p*=0.01. Mild itching & transient burning were the most common adverse events, similar in both groups.

Table 4. Secondary outcomes

Outcome	Group A (n=49)	Group B (n=48)	*p*-value
Patient satisfaction (1–5)	4.3 ± 0.7	3.8 ± 0.9	0.01
Adverse events, n (%)	6 (12.2)	7 (14.6)	0.74
Most frequent adverse event	Itching/Burning	Itching/Burning	–

Discussion

This randomized control trial demonstrates that the herbal spray (Ano Care) significantly improved pain, bleeding, & healing outcomes compared to conventional ointment therapy in patients with early piles & fissure. These findings have important implications for conservative management[6].

Efficacy

Both groups experienced substantial symptom improvement, but herbal spray provided faster & greater pain relief & resulted in higher complete healing rates at 4 weeks. The greater reduction in bleeding episodes suggests superior mucosal protection[7].

Several mechanisms may explain these differences. Herbal formulations often contain multiple bioactive compounds with anti-inflammatory (e.g., flavonoids), analgesic, & antioxidant effects. These properties may promote wound healing & reduce vascular congestion more effectively than single-mechanism conventional ointments, which primarily focus on relief without significant mucosal repair[8-9].

Safety & Tolerability

Both treatments were well tolerated, with no serious adverse events. Mild local reactions were comparable, supporting the safety profile of herbal spray as a conservative therapy alternative.

Patient Satisfaction

Higher satisfaction in the herbal spray group may reflect better symptom relief & ease of use. Patient preference is an important factor in chronic conservative management.

Comparison with Previous Studies

Although direct comparisons are limited, our results are consistent with studies that reported herbal treatments (e.g., flavonoid creams, plant extracts) to be effective in hemorrhoidal

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symptom relief & fissure healing. This study strengthens evidence by using a rigorous randomized design[10].

Strengths include randomized design, blinded assessor outcomes, & clinically relevant endpoints.

Limitations are single-center setting, short follow-up (4 weeks), & lack of long-term recurrence data. Blinding was not possible for patients due to different formulations, which may introduce bias in subjective outcomes like satisfaction.

Conclusion

In early piles & anal fissure, the herbal spray (Ano Care) proved to be more effective than conventional ointment in reducing pain, controlling bleeding, & achieving clinical healing, with good safety & higher patient satisfaction. Herbal spray can be considered a viable conservative treatment option.

Larger, multicenter trials with longer follow-up are recommended to confirm these results & assess long-term outcomes.

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Conflict of Interest

The authors declare no conflict of interest.

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