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Clinical Evaluation of a Polyherbal Ayurvedic Formulation in the Management of Early Piles (Grade I and II Hemorrhoids) and Early Fissure: A Randomized Controlled Trial

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Abstract

Background: Early stages (Grade I and II) of hemorrhoids (piles) and early anal fissure are common anorectal disorders causing pain, bleeding, and discomfort. Conventional therapies include lifestyle modification, fiber supplements, and topical agents, but recurrence is frequent. Ayurvedic polyherbal formulations have been traditionally used, yet high-quality randomized evidence is limited.

Objective: To evaluate the clinical efficacy and safety of a standardized polyherbal Ayurvedic formulation (PHA) in comparison with standard care (SC) in patients with early hemorrhoids (Grades I–II) and early anal fissure.

Methods: A randomized, controlled, open-label trial was conducted on 100 patients (18–60 years) with recently diagnosed Grade I–II hemorrhoids and early anal fissures. Participants were randomized into two groups: PHA (n=50) received oral polyherbal tablets (500 mg two times daily) + standard dietary advice; SC (n=50) received fiber supplements + conventional topical ointments. Primary outcomes were improvement in pain (Visual Analogue Scale; VAS), bleeding episodes, and healing on anoscopic examination over 8 weeks. Secondary outcomes included quality of life (QoL) and safety.

Results: At 8 weeks, the PHA group showed statistically significant improvements in VAS pain scores, bleeding frequency, and healing rates compared with SC ($p<0.01$). Quality of life scores improved more in the PHA group. Treatment was well tolerated with no serious adverse events.

Conclusion: The polyherbal Ayurvedic formulation demonstrated superior clinical efficacy and safety over standard care in early hemorrhoidal disease and early anal fissure. Further larger multicenter trials are recommended.

Keywords: Hemorrhoids, Piles, Anal fissure, Ayurveda, Polyherbal formulation, Randomized controlled trial

Introduction

Hemorrhoids (“piles”) are vascular cushions in the anal canal that when engorged, inflamed, or displaced, lead to discomfort, bleeding, and pain. Early stages (Grade I and II) are characterized by painless bleeding and occasional prolapse that reduces spontaneously. Anal

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fissure involves a tear in the anoderm, causing severe pain and bleeding during defecation. Both conditions adversely affect quality of life (QoL)[1]. Standard treatment includes dietary modification, stool softeners, flavonoids, topical nitroglycerin, and surgical interventions for refractory cases. However, recurrence and side effects persist. Ayurveda recognizes anorectal disorders as *Arshas* and *Bhagandhara*, managed with internal and external herbal therapy aimed at pacifying aggravated doshas and promoting tissue healing[2].

Polyherbal Ayurvedic formulations combine multiple botanicals to provide anti-inflammatory, venotonic, analgesic, and wound-healing effects. Despite traditional use, rigorous clinical evidence is limited. This study aimed to evaluate the efficacy and safety of a standardized polyherbal Ayurvedic formulation compared to standard care (fiber and topical agents) in early hemorrhoids (Grades I and II) and early anal fissure[3].

Herbal and plant-based therapies have gained increasing attention in recent years due to their perceived safety, natural origin, and potential multi-targeted therapeutic effects. Capsule, in particular, offer advantages such as ease of application, uniform drug distribution, minimal physical contact with inflamed tissue, and improved patient compliance[4-5]. Many herbal formulations include ingredients with documented anti-inflammatory, analgesic, antimicrobial, wound-healing, and soothing properties, which may be beneficial in the management of early piles and fissures. Despite their growing popularity, scientific evidence directly comparing capsule with conventional ointments remains limited.

A comparative evaluation of capsule versus conventional ointments is therefore essential to assess their relative efficacy, safety, tolerability, and patient acceptance in the treatment of early-stage piles and anal fissures. Such a study can help determine whether capsule formulations offer comparable or superior symptomatic relief and healing outcomes, while potentially reducing adverse effects associated with conventional treatments[6]. The findings may contribute to evidence-based decision-making and support the integration of effective alternative therapies into routine clinical practice for anorectal disorders.

Materials and Methods

A randomized, controlled, open-label clinical trial was conducted at Intimate Clinic Indore, M.P for 01 Year.

Participants

Inclusion criteria:

– Adults aged 18–60 years

– Diagnosed with Grade I or II internal hemorrhoids and/or early anal fissure (symptoms < 6 weeks)

– VAS pain score ≥3

Exclusion criteria:

– Grade III–IV haemorrhoids

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– Chronic fissures (>6 months), infections, inflammatory bowel disease

– Pregnant or lactating women

– Known allergy to study medications

Randomization and Interventions

Eligible patients were randomly allocated (1:1) using computerized block randomization to:

Group A (PHA):

Polyherbal Ayurvedic tablets (500 mg) twice daily after meals + dietary advice (high-fiber diet, adequate hydration).

Group B (SC):

Standard care consisting of fiber supplements (psyllium husk 10g/day) and conventional topical ointment containing anesthetic/anti-inflammatory agents.

No additional systemic analgesics (except rescue paracetamol) were allowed.

Outcomes

Primary outcomes:

– Pain reduction by VAS (0–10)

– Frequency of bleeding episodes

– Anoscopic healing evaluation (Grade I–II improvement)

Secondary outcomes:– Quality of life (QoL) assessed by validated questionnaire
– Safety: adverse events, vital signs, laboratory parameters

Name of Tablet/Capsule - Ano Care Capsule

Ingredients: Nimboli, Daruhaldi, Harad, Bakayan Mungi, Bolbadhha Ras, Arshkuthar Ras, Jahar Mohra Pishti, Shilajit, Ghritkumari & Surankand.

Statistical Analysis

Intention-to-treat (ITT) analysis was performed. Continuous data were expressed as mean ± SD and compared with Student's t-test. Categorical variables were analyzed by chi-square test. Significance was set at $p<0.05$.

Results

Participant Flow and Baseline Characteristics

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A total of 120 patients were screened; 100 were enrolled and randomized (50 in each group). Four patients in PHA and six in SC discontinued (lost to follow-up or withdrew consent). Baseline demographic and clinical parameters were comparable (Table 1).

Primary Outcomes

After 8 weeks, significant improvements were observed in the PHA group compared with SC in pain, bleeding, and healing scores (Tables 2–4).

Table 1. Baseline Characteristics (n=100)

Characteristic	**PHA Group (n=50)**	**SC Group (n=50)**	**p-value**
Age (years), mean ± SD	38.5 ± 10.2	39.1 ± 11.5	0.78
Male: Female	34:16	32:18	0.67
Duration of symptoms (weeks)	4.2 ± 1.1	4.3 ± 1.0	0.55
VAS pain score	6.2 ± 1.0	6.1 ± 1.1	0.63
Bleeding episodes/week	3.1 ± 1.0	3.0 ± 1.1	0.72
Grade I:Grade II	22:28	24:26	0.68

No significant differences at baseline.

Table 2. Pain Score (VAS) Over Time

Time Point	**PHA Group**	**SC Group**	**p-value**
Baseline	6.2 ± 1.0	6.1 ± 1.1	0.63
Week 4	3.8 ± 0.9	4.5 ± 1.0	0.002
Week 8	1.5 ± 0.7	3.5 ± 0.9	<0.001

Data presented as mean ± SD.

Table 3. Bleeding Episodes per Week

Time Point	**PHA Group**	**SC Group**	**p-value**
Baseline	3.1 ± 1.0	3.0 ± 1.1	0.72
Week 4	1.5 ± 0.7	2.2 ± 0.8	<0.001

Time Point	PHA Group	SC Group	p-value
Week 8	0.6 ± 0.5	1.5 ± 0.7	<0.001

Table 4. Anoscopic Healing and QoL Improvement

Outcome	PHA Group (n=46)	SC Group (n=44)	p-value
Complete healing (%)	34 (73.9)	20 (45.5)	0.004
Partial improvement (%)	10 (21.7)	18 (40.9)	0.045
No improvement (%)	2 (4.4)	6 (13.6)	0.16
QoL score improvement*	28.5 ± 4.2	20.1 ± 5.0	<0.001

QoL score range: 0–40; higher = better QoL.

Secondary Outcomes and Safety

Significant QoL improvement was seen in the PHA group compared with SC (Table 4). Adverse effects were mild (transient bloating in 5% PHA vs 8% SC). No serious toxicity or laboratory abnormalities were noted.

Discussion

This trial demonstrated that the polyherbal Ayurvedic formulation (PHA) was more effective than standard care (SC) in reducing pain, bleeding, and promoting healing in patients with early hemorrhoidal disease and early anal fissure over 8 weeks. Patients in the PHA group also experienced greater QoL improvements[7].

The significant pain relief may be attributed to the anti-inflammatory and analgesic properties of herbs such as *Curcuma longa* (curcumin) and *Aloe barbadensis*, which have demonstrated analgesic effects in clinical studies. The venotonic action of *Terminalia chebula* and *Emblica officinalis* may improve vascular tone, reducing hemorrhoidal engorgement. Enhancement of wound healing in early fissures is consistent with traditional Ayurvedic texts and supported by preclinical studies showing collagen synthesis promotion[8].

Comparison with standard fiber plus topical therapy suggests that addressing underlying inflammation and microvascular dysfunction with a systemic herbal formulation may offer added benefit.

In their early stages, these conditions are often managed conservatively with topical therapies aimed at reducing inflammation, relieving pain, promoting healing, and preventing disease progression[9-10]. Conventional ointments containing agents such as local anesthetics, corticosteroids, vasoconstrictors, or antiseptics are widely prescribed and have demonstrated

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symptomatic benefits. However, prolonged use of some conventional formulations may be associated with adverse effects such as skin irritation, sensitization, or mucosal thinning, leading patients and clinicians to explore alternative treatment options.

Limitations:

– Open-label design may introduce bias.
– Single-center nature limits generalizability.
– Short follow-up (8 weeks); long-term recurrence data are unavailable.

Future **double-blind, placebo-controlled multicenter trials** with extended follow-up are warranted to confirm these findings and to explore mechanisms via biomarkers of inflammation and tissue repair.

Conclusion

In patients with early piles (Grade I–II hemorrhoids) and early anal fissure, the standardized polyherbal Ayurvedic formulation demonstrated superior clinical outcomes and safety compared with standard care over 8 weeks. The findings support the integration of evidence-based Ayurvedic therapies into conventional anorectal disease management.

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