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THERAPEUTIC ASSESSMENT OF PANCHAVALKAL KWATHA ADMINISTERED VIA AVAGAHA SWEDANA IN PARIKARTIKA (FISSURE-IN-ANO): A PROSPECTIVE OPEN-LABEL TRIAL

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ABSTRACT

Background and Rationale: Among anorectal ailments presenting to surgical units, fissure-in-ano occupies a clinically demanding position, constituting roughly one-tenth to one-sixth of all such referrals.[1] The condition is defined by a longitudinal mucosal breach in the distal anal canal, typically situated at the posterior commissure, and produces intense perineal distress that undermines daily functioning. In classical Ayurvedic scholarship, an almost identical symptom constellation—parikartana-vat vedana (lancinating anal pain), Daha (scorching sensation), and Rakta-srava (anorectal haemorrhage)—is codified under the designation Parikartika, a Guda Roga documented across the Brihatrayee.[2,3,4] Panchavalkal Kwatha, a decoction derived from the cortex of five botanically allied trees, enjoys explicit textual endorsement in Bhavaprakasha as a Parikartika-specific therapeutic, underpinned by Vrana Ropana and Shothahara pharmacodynamic activities.[5] **Aim:** To determine the clinical benefit and safety profile of Panchavalkal Kwatha delivered as Avagaha Swedana in patients with Parikartika (acute fissure-in-ano). **Methodology:** An open-label, single-arm, prospective trial was conducted at GACH, Patna. Thirty patients (20–60 years) were treated with Panchavalkal Kwatha Avagaha Swedana twice daily for 60 days. Five outcome domains were tracked at weekly intervals using ordinal grading scales. The

Student paired t-test was applied for statistical inference. **Key Findings:** All five parameters showed highly significant improvement ($p < 0.001$): pain 92.98%, bleeding 90.00%, pruritus 90.32%, burning sensation 90.38%, and wound healing 78.18%. Complete cure was achieved in 33.33% of participants; 30.00% showed marked improvement. No adverse events were recorded. **Conclusion:** Avagaha Swedana with Panchavalkal Kwatha is a well-tolerated, cost-effective, and clinically meaningful non-invasive remedy for acute Parikartika warranting wider adoption in Ayurvedic anorectal practice.

KEYWORDS: Parikartika, anal fissure, Panchavalkal Kwatha, Avagaha Swedana, Shalya Tantra, Vrana Ropana, herbal decoction, anorectal disease.

1. INTRODUCTION

Anorectal morbidity represents a substantial yet frequently underreported surgical burden across Indian healthcare settings. Within this spectrum, fissure-in-ano stands out for the disproportionate suffering it inflicts relative to the size of the lesion.[1] It is characterised by a tear propagating along the squamous epithelium of the anal canal below the dentate line, most commonly at the posterior commissure, a predilection attributed to the relative avascularity of this quadrant, the elliptical anal lumen, and the diverging architecture of external sphincter fibres.[1] Cardinal manifestations include sharp defecatory pain, haematochezia, and a burning after-sensation persisting for up to two hours post-defecation—features that impinge substantially on nutritional intake, sleep quality, and occupational productivity.

Contemporary therapeutic algorithms stratify management by acuity. Acute presentations are addressed conservatively through stool-bulking agents, topical anaesthetics, warm sitz baths, and pharmacological agents such as diltiazem or glyceryl trinitrate (GTN) cream. Chronic fissures refractory to pharmacotherapy frequently requires lateral internal sphincterotomy (LIS) or botulinum toxin injection. While LIS achieves high short-term cure rates, it carries a 5–8% risk of permanent faecal incontinence, particularly in females and multiparous women.[1] Botulinum toxin, though reversible, carries recurrence rates approximating 40–50% at one year, warranting exploration of complementary treatment paradigms.

The Ayurvedic Brihatrayee—comprising Charaka Samhita, Sushruta Samhita, and Ashtanga Hridayam—documents a condition designated Parikartika whose clinical portrait maps closely onto fissure-in-ano.[2,3,4] The term derives from the Sanskrit root parikartana, signifying circumferential cutting or sawing pain, capturing the lancinating quality of anal

fissure with remarkable precision. Parikartika is not classified as an autonomous disease in classical Ayurvedic nosology; rather, it surfaces as a symptomatic accompaniment to Arsha, Grahani, Atisara, and Udavarta, or as a Vyapada following errant Virechana or Basti Karma.[2,3,4] The underlying doshic disturbance involves concurrent Vata and Pitta vitiation: Vata-mediated sphincteric hypertonicity causes mucosal ischaemia, while Pitta-mediated inflammation produces burning and haemorrhage.

Panchavalkal—literally 'five barks'—comprises the dried cortex of Vata (*Ficus benghalensis* Linn.), Udumbara (*Ficus glomerata Roxb.*), Ashwattha (*Ficus religiosa* Linn.), Parisha (*Thespesia populnea* Linn.), and Plaksha (*Ficus infectoria Roxb.*).[6] Its preparation as Kwatha following the Sharangadhara Samhita protocol—one part coarse drug powder decocted with sixteen parts water to one-eighth volume—concentrates a complex phytochemical matrix of hydrolysable tannins, terpenoids, flavone glycosides, phytosterols, alkaloids, and saponins.[5,6] This matrix collectively mediates Stambhana (haemostasis), Vrana Ropana (tissue regeneration), Shothahara (anti-inflammation), and Krimighna (antimicrobial action)—a pharmacological portfolio addressing every pathophysiological element of anal fissure.[7,8,9,10,11] Bhavaprakasha explicitly endorses Panchavalkal Kwatha in Parikartika Chikitsa.[5]

Avagaha Swedana is a Swedana sub-type wherein the affected region is immersed in warm medicated liquid. In anorectal practice, it combines the tissue-relaxing effects of moist heat—reducing internal anal sphincter (IAS) tone and augmenting mucosal perfusion—with direct topical delivery of phytoconstituents.[5] The combined hydrothermal and pharmacological action parallels the rationale behind warm sitz baths in modern conservative management. Despite this compelling evidence base, peer-reviewed clinical validation of Panchavalkal Kwatha Avagaha Swedana specifically in Parikartika has remained sparse.[1] The present investigation was designed to address this gap.

2. MATERIALS AND METHODS

2.1 Study Design, Setting, and Ethics

This investigation was structured as an open-label, single-group, prospective interventional trial within the Department of Shalya Tantra, Govt. Ayurvedic College and Hospital (GACH), Patna, Bihar, India, across academic session 2022–2025. Ethical clearance was granted by the Institutional Ethics Committee (IEC Ref.: GAC/IEC/SHALYA/07). The trial was prospectively registered with the Clinical Trials Registry–India (CTRI/2025/03/081616;

Acknowledgement: REF/2025/01/097338). All procedural conduct adhered to the revised ICMR National Ethical Guidelines for Biomedical and Health Research (2017) and the Declaration of Helsinki.

2.2 Recruitment and Sample

Patients presenting to the OPD and IPD of GACH, Patna, with clinically confirmed Parikartika were screened sequentially. Those satisfying all eligibility criteria were enrolled after written informed consent. Thirty participants completed the full treatment course and constitute the analysis population.

2.3 Eligibility Criteria

Inclusion: Adults aged 20–60 years of either sex presenting with Parikartika as per classical Ayurvedic signs and symptoms corroborated by modern proctological examination were eligible, irrespective of socioeconomic status or habitat.

Exclusion: Patients were excluded for seropositivity (HIV, HCV, HBsAg), diabetes mellitus, chronic fissure-in-ano with sentinel tag or Grade IV sphincter spasm, or secondary fissure attributable to Crohn's disease, ulcerative colitis, anorectal tuberculosis, or anorectal malignancy.

2.4 Preparation of Panchavalkal Kwatha

All raw plant materials were sourced from the Post-Graduate Pharmacy, GACH, Patna, and botanically authenticated. Equal parts of the dried bark of each constituent species were reduced to Yavakuta Churna (coarse powder) and boiled with sixteen times their weight in water until volume contracted to one-eighth—the Ashtamsha Kwatha method stipulated in Sharangadhara Samhita (Madhyamakhanda 2:1).[5] Fresh decoction was prepared for each treatment session, strained, and tempered to a therapeutically warm temperature before use.

2.5 Intervention Protocol

Participants underwent Avagaha Swedana by sitting in a hip-bath tub containing Panchavalkal Kwatha, ensuring full immersion of the perianal region for the session duration. This was administered twice daily (morning and evening) throughout the 60-day treatment period.[5] Concurrent Pathya-Apathya counselling included adequate fluid intake (2–3 litres/day), fibre-rich diet, avoidance of pungent and processed foods, and regularisation of defecation timing.

2.6 Outcome Parameters and Grading Instrument

Clinical assessments were conducted at baseline and weekly thereafter. Inpatients were monitored daily; outpatients attended weekly review clinics. Haematological profiles were obtained at enrolment and on treatment completion. Five parameters were graded on validated ordinal scales.

Pain: Grade 0: No pain, Grade I: Negligible or tolerable pain, no medication required, Grade II: Localized tolerable pain relieved by hot sitz bath, Grade III: Pain requiring oral analgesics on SOS basis, Grade IV: Pain requiring regular oral analgesics.

Bleeding: Grade 0: Negligible bleeding, Grade I: Streak-wise bleeding noticed over stool or rarely on fissure, Grade II: Drop-wise bleeding (0–10 drops) during or after defecation, Grade III: Drop-wise bleeding (10–20 drops) during or after defecation, Grade IV: Profuse drop-wise or stream-wise bleeding (>20 drops) with each defecation.

Itching: Grade 0: No itching, Grade I: Occasional itching, Grade II: Frequent itching, Grade III: Continuous itching.

Burning Sensation: Grade 0: No burning sensation, Grade I: Burning sensation noticed only on interrogation, Grade II: Burning during and after defecation, relieved without medication, Grade III: Persistent burning sensation throughout the day interfering with routine activities.

Healing of Parikartika: Grade 0: Completely healed wound with healthy scar, Grade I: Clean wound without slough or discharge, Grade II: Partially healed wound with healthy granulation tissue, Grade III: Wound with discharge.

2.7 Statistical Methods

Demographic data were summarised as frequencies and proportions. Symptom scores were expressed as mean ± SD and SE. Pre- and post-treatment score differences were tested using the Student paired t-test; $p < 0.05$ was considered significant and $p < 0.001$ highly significant. Percentage change in mean score quantified clinical effect size.

3. RESULTS

3.1 Baseline Characteristics of the Study Cohort

Thirty patients completed the treatment course and were included in the final analysis (Table 1). Nearly 83.33% were aged 20–40 years, reflecting the known preponderance of fissure-in-ano in economically active adults.[1] Male patients outnumbered females (76.67% vs. 23.33%), consistent with published epidemiological data from anorectal disease registries.[1] Irregular bowel habits were present in 90.00% of participants, and 46.67% habitually consumed spicy food—both recognised precipitants of Pitta aggravation and constipation-induced anal mucosal trauma.[2,3] Pitta-Kaphaja Prakruti predominated (53.33%), supporting the classical postulate that Pitta-dominant constitutions are predisposed to inflammatory anorectal conditions.[2]

Table 1: Baseline Demographic and Constitutional Profile (n = 30)

Parameter	Subgroup	Frequency n (%)
Age group (years)	20–30	13 (43.33)
	31–40	12 (40.00)
	41–60	05 (16.67)
Sex	Male	23 (76.67)
	Female	07 (23.33)
Habitat	Rural	16 (53.33)
	Urban	14 (46.67)
Bowel regularity	Regular	03 (10.00)
	Irregular	27 (90.00)
Dietary pattern	Spicy	14 (46.67)
	Regular/bland	16 (53.33)
Predominant Prakruti	Pitta-Kaphaja	16 (53.33)
	Vata-Pittaja	11 (36.67)
	Kapha-Vataja	03 (10.00)
Socioeconomic class	Middle	19 (63.33)
	Lower	09 (30.00)
	Upper	02 (06.67)

3.2 Pre-Treatment Symptom Distribution

At enrolment, Grade 2 pain (Localized tolerable pain relieved by hot sitz bath) was the most prevalent presentation (57.14%), while Grade 3 Pain requiring oral analgesics on SOS basis was present in 25.00% of subjects. Rectal bleeding was predominantly Grade 2 (46.42%). Itching was Grade 1 (occasional) in the majority (53.57%). Burning sensation was Grade 2 (Burning during and after defecation, relieved without medication) in 78.57% of recruits. Healing grading placed 46.42% at Grade 2 (Tenderness with grimace and/or flinch on palpation) and 28.57% at Grade 1(Tenderness on palpation without grimace or flinch), confirming predominantly sub-acute presentations.

3.3 Response to Panchavalkal Kwatha Avagaha Swedana

All five outcome domains demonstrated statistically highly significant improvement ($p < 0.001$) at 60-day follow-up. Mean percent improvements ranged from 78.18% for wound healing to 92.98% for pain relief (Table 2).

Table 2: Quantitative Effect of Panchavalkal Kwatha Avagaha Swedana on Clinical Parameters (n = 30).

Outcome Domain	Mean BT	Mean AT	% Improvement	SD	SE	p Value
Pain	2.03	0.14	92.98	0.68	0.12	<0.001**
Bleeding	1.07	0.10	90.00	0.96	0.18	<0.001**
Itching	1.10	0.10	90.32	0.72	0.13	<0.001**
Burning Sensation	1.85	0.17	90.38	0.72	0.13	<0.001**
Healing	1.96	0.42	78.18	0.63	0.12	<0.001**

*BT = Before Treatment; AT = After Treatment; SD = Standard Deviation; SE = Standard Error; ** = Highly Significant (p < 0.001)*

3.4 Global Therapeutic Outcome

Aggregate outcomes are presented in Table 3. A total responder rate of 83.33% was achieved, with 63.33% of participants attaining cure or marked improvement. Three participants (10.00%) demonstrated no measurable change, possibly attributable to deeper fissure chronicity at enrolment or inadequate dietary adherence. No adverse drug reactions or laboratory abnormalities were recorded at any assessment point.

Table 3: Global Therapeutic Outcome Classification (n = 30)

Outcome Category	No. of Patients	Proportion (%)
Complete Cure	10	33.33
Marked Improvement	09	30.00
Moderate Improvement	06	20.00
No Perceptible Change	03	10.00
Total Responders	25	83.33

4. DISCUSSION

4.1 Re-reading Parikartika Through a Modern Lens

Acharya Dalhana's commentary on Sushruta Samhita frames Parikartika as cutting, circumferential pain in the Guda Pradesha with scorching sensation and haemorrhage—a triad that maps unambiguously onto fissure-in-ano.[3] The classical Samprapti posits concurrent Vata-Pitta vitiation: Apana Vayu drives sphincteric hypertonia and mucosal ischaemia while Pitta generates the inflammatory and bleeding components.[2,3] This narrative finds a direct parallel in the pathophysiological vicious cycle of IAS spasm → mucosal

ischaemia → impaired wound repair that sustains acute fissures toward chronicity.[1] Therapeutic strategies that simultaneously relax the IAS, restore local perfusion, and reduce mucosal inflammation therefore address Parikartika at the level of its Samprapti Ghataka—precisely the pharmacodynamic territory of Panchavalkal Kwatha.[5,7,8]

4.2 Mechanistic Basis of Panchavalkal Kwatha

The five-bark formulation creates a layered pharmacological architecture. Hydrolysable tannins—the dominant phytochemical class across all five species—denature surface proteins at the fissure wound edge, form a haemostatic pellicle, and impede bacterial colonisation, thereby executing simultaneous Vrana Shodhana and Stambhana.[7,11,12] Flavonoid glycosides documented in *Ficus religiosa* and *Ficus benghalensis* inhibit COX-2 and lipoxygenase pathways, reducing prostaglandin E2 and leukotriene B4 synthesis and attenuating the inflammatory oedema that perpetuates sphincteric pain.[8,12] Lupeol and related pentacyclic triterpenes from *Thespesia populnea* exert analgesic effects through central and peripheral mechanisms independently of prostaglandin suppression.[9] Saponin glycosides augment capillary permeability at the wound bed, facilitating leukocyte and fibroblast ingress necessary for orderly granulation.[7,10] Collectively, these mechanisms coordinate haemostasis, antimicrobial prophylaxis, angiogenesis, and re-epithelialisation.

Avagaha Swedana at 40–43°C reliably reduces IAS resting pressure by interrupting the ischaemia–spasm loop demonstrable on anorectal manometry in fissure patients.[1] Enhanced perineal vasodilation under heat increases drug-tissue contact time and promotes deeper penetration of polar tannin-flavonoid fractions into the submucosal microvasculature. In Ayurvedic terms, localised moist heat pacifies Vata (alleviating spasm) while the Sheet virya of the decoction counteracts Pitta (reducing inflammation)—a mechanistic duality validated by the present outcome data.[5]

4.3 Interpretation of Efficacy Data

The 92.98% reduction in pain score achieved without systemic analgesics in the majority of participants reflects convergent analgesic action: IAS relaxation via thermotherapy, anti-inflammatory flavonoids, and lupeol-mediated peripheral analgesia.[7,8,9] Haemorrhage cessation (90.00% improvement) correlates with tannin-mediated haemostasis documented in pharmacological studies of the individual Ficus species.[11,12] Near-equivalent improvements in Itching (90.32%) and burning sensation (90.38%) suggest that perianal neurogenic inflammation was substantially attenuated. Wound healing, at 78.18%, was the most time-

dependent parameter given that complete fissure epithelialisation requires sequential granulation, contraction, and keratinocyte migration.[11]

The demographic pattern—young-to-middle-aged males with irregular bowel habits and Pitta-Kaphaja constitution—mirrors clinical epidemiology of fissure-in-ano across the Bihar region, where dietary practices high in refined grains, legumes, and pungent spices predispose to constipation-induced mucosal trauma.[1,2] The 90.00% literacy rate among participants likely facilitated dietary protocol compliance, potentially inflating response rates relative to a general community sample.

The 10.00% non-responder rate merits acknowledgement. These three patients may represent cases with deeper fibro-muscular involvement approaching chronicity at enrolment, requiring adjunct internal medication—such as Triphala Churna or Haritaki for bowel regulation, or Gandhaka Rasayana for mucosal regeneration—or procedural interventions such as Kshara Karma to supplement external hydrotherapy.[2]

4.4 Situating Findings Within Published Literature

A clinical trial evaluating Panchavalkal Kwatha in fistulotomy wound management reported healing rates of 70.62% with Kwatha irrigation alone and 82.96% with combined Nishadya Taila–Kwatha protocol.[11] An investigation in chronic non-healing ulcers demonstrated that 25% aqueous Panchavalkal Ghanasatva extract outperformed collagenase-based topical therapy in reducing exudate and promoting granulation.[11] Gynaecological studies in Karnini Yonivyapad corroborated anti-inflammatory and mucosal-healing properties of Panchavalkal across epithelial tissues beyond the anorectum.[11] The present 78.18% wound-healing improvement in acute fissure is congruent with these benchmarks and extends Panchavalkal's evidence base to a further Shalya Tantra indication. Compared with topical GTN—which heals 50–80% of acute fissures but causes headache in 20–40% of users—the current formulation achieved comparable healing without any reported adverse events.[1]

4.5 Safety Observations

The complete absence of adverse events across 30 participants over 60 days of twice-daily topical application confirms the favourable safety profile historically attributed to Panchavalkal.[13,14] Haematological indices remained within reference ranges at end-of-trial assessment. The Yavakuta decoction form, by avoiding organic solvent fractionation, preserves the natural buffering of minor phytoconstituents that mitigate irritant potential of

concentrated individual tannins. This tolerability advantage is clinically significant compared with pharmacological alternatives such as calcium channel blockers and botulinum toxin, which carry systemic exposure risks and logistical barriers in peripheral hospital settings.[1]

4.6 Limitations and Future Directions

Several methodological constraints must be acknowledged. The absence of a control or active comparator arm limits causal attribution and prevents equivalence claims relative to conventional therapies. The sample size of 30 does not meet power requirements for a definitive trial. The single-centre design restricts generalisability. Post-treatment follow-up for recurrence assessment was not systematically recorded. Future work should prioritise randomised controlled designs incorporating active comparators (warm saline sitz bath or topical diltiazem), larger samples with formal power calculations, standardised fissure chronicity staging, extended follow-up (≥06 months), and objective anorectal manometry to quantify IAS tone reduction. Combination regimens incorporating internal Ayurvedic medications alongside Avagaha Swedana also warrant prospective exploration.[1,5]

5. CONCLUSION

Panchavalkal Kwatha delivered via Avagaha Swedana twice daily over 60 days produced clinically meaningful and statistically highly significant improvement across all five outcome domains in Parikartika (acute fissure-in-ano). With a total responder rate of 83.33%, a complete cure rate of 33.33%, and an unblemished safety record, this classically grounded intervention offers a viable, inexpensive, and non-invasive treatment option.[2,3,4,5] The study validates the textual Chikitsa recommendation of Bhavaprakasha and lays a foundation for larger controlled investigations to establish Panchavalkal Kwatha Avagaha Swedana as a first-line conservative strategy in Ayurvedic proctological practice.[5]

Declarations

Ethical Clearance: IEC, GACH Patna — Ref. No.: GAC/IEC/SHALYA/07.

Trial Registration: CTRI/2025/03/081616 (04 March 2025); Acknowledgement: REF/2025/01/097338.

Participant Consent: Written informed consent obtained from all participants before enrolment.

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Author Contributions: CP: study conception, patient enrolment, data collection and interpretation, manuscript drafting. DSV: study design, clinical supervision, critical intellectual revision of manuscript.

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