

AN EXPLORATORY STUDY TO EVALUATE THE EFFICACY OF KADALI (MUSA PARADISIACA) PRATISARNEEYA KSHAR APPLICATION IN THE MANAGEMENT OF 2nd INTERNAL HAEMORRHOIDS

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ABSTRACT

Background: Haemorrhoids (Arsha) are counted among the Ashtamahagada by Acharya Sushruta and remain one of the most common anorectal disorders seen in surgical practice. Conventional haemorrhoidectomy is effective but carries the burden of hospitalisation, anaesthesia and post-operative pain, prompting continued interest in gentler, para-surgical alternatives. Kshara Karma — the application of a caustic alkali to the pile mass — was regarded by Sushruta as the foremost of these alternatives, and Kadali (Musa paradisiaca, the banana plant) is one of the classical Kshara-yielding drugs described for this purpose. **Objective:** To evaluate the efficacy and safety of topically applied Kadali Tikshna Pratisarneeya Kshara in the management of second-degree internal haemorrhoids. **Methods:** Thirty patients of second-degree internal haemorrhoids, aged 16–70 years, were enrolled in this single-arm, open-label, prospective exploratory study at the Post Graduate Institute of Ayurveda, Jodhpur. Kadali Kshara,

prepared by the classical Sushrutokta method and confirmed to have a pH greater than 12, was applied to each pile mass at the 3, 7 and 11 o'clock positions, one quadrant per sitting, seven days apart. Bleeding, itching, colour of the pile mass and prolapse were scored on a 0–3 grading scale at baseline, Day 7, Day 14, Day 21 and a follow-up assessment, and analysed

with the Wilcoxon signed-rank test and paired t-test (significance at $p < 0.05$). **Results:** All four parameters improved significantly from baseline to the end of treatment ($p < 0.001$ for each). Bleeding fell by 87.5%, itching by 96.3% and prolapse by 93.3%, while the colour score followed the expected biphasic pattern of chemical cauterisation followed by healing. Twenty-six of the thirty patients (86.7%) achieved complete resolution, and an equal proportion reported satisfaction with the outcome. No major systemic adverse effects occurred; one patient (3.3%) withdrew because of persistent local pain. **Conclusion:** Kadali Pratisarneeeya Kshara produced a statistically significant and clinically meaningful improvement in second-degree internal haemorrhoids with a favourable safety profile, supporting its classical standing as a simple, cost-effective, outpatient-based alternative to surgery. As a single-arm exploratory study, these findings are hypothesis-generating and warrant confirmation in a randomised controlled trial with a longer follow-up.

KEYWORDS: Arsha; Haemorrhoids; Kshara Karma; Kadali; Musa paradisiaca; Pratisarneeeya Kshara; Ayurveda; Shalya Tantra.

1. INTRODUCTION

Haemorrhoids, known in Ayurveda as Arsha, are cushions of vascular and connective tissue in the anal canal that become engorged, prolapse and bleed when the venous plexus they contain is chronically overloaded. Acharya Sushruta placed Arsha among the Ashtamahagada — the eight great and difficult-to-treat diseases — a classification that still feels apt in everyday surgical practice, where the condition is common, frequently under-reported out of embarrassment, and capable of eroding quality of life through recurrent bleeding, itching, discomfort and mass prolapse.

Modern surgery classifies internal haemorrhoids into four degrees according to the extent of prolapse, ranging from painless bleeding without prolapse (first degree) to permanently prolapsed, irreducible masses (fourth degree). Second-degree disease — a pile mass that prolapses on defecation or straining but reduces spontaneously or manually — occupies a useful middle ground clinically: symptomatic enough to need active treatment, yet usually still amenable to outpatient, non-excisional methods before surgery becomes the only option.

Conventional haemorrhoidectomy remains effective for advanced disease, but it asks a good deal of the patient: anaesthesia, a hospital stay, a genuinely painful recovery, and a real (if variable) rate of complications such as bleeding, stricture or incontinence. Many patients —

particularly those who are elderly, medically unfit, or simply reluctant to undergo an operation for what still feels like a private and minor complaint — would rather avoid this route if a gentler option exists.

This is precisely the gap that Kshara Karma was designed to fill. Sushruta described four lines of treatment for Arsha — Bheshaja (medicines), Shastra Karma (surgical excision), Kshara Karma (application of a caustic alkali) and Agnikarma (thermal cauterisation) — and rated Kshara Karma as the Pradhantama Chikitsa, the most preferred among the para-surgical (Anushastra) procedures. His reasoning still holds up: a controlled alkaline application destroys diseased tissue layer by layer while sparing the surrounding healthy mucosa, avoids the bleeding risk and anaesthetic burden of open surgery, and sidesteps the deeper thermal injury that Agnikarma can sometimes cause.

Kadali (*Musa paradisiaca*, the common banana) is one of the classical Kshara-yielding plants named by Sushruta for exactly this purpose. It is locally abundant, inexpensive and simple to process into Kshara. What makes it pharmacologically interesting is that, unlike most Kshara-yielding drugs, which are uniformly Ushna (hot) and Tikshna (sharp) in classical terms, Kadali itself carries Madhura (sweet) Rasa, Sheeta (cooling) Veerya and Guru-Snigdha (heavy, unctuous) Guna. The working hypothesis behind choosing it for this study was that these soothing qualities might temper the harshness of an otherwise aggressive alkaline Kshara — reducing post-application discomfort — while the high pH achieved during preparation would still deliver adequate causticity for effective Kshara Karma.

This study was therefore designed as an exploratory, hypothesis-generating clinical trial to evaluate, through objective grading and formal statistical testing, whether topical Kadali Kshara produces a demonstrable improvement in bleeding, itching, pile-mass colour and prolapse in this specific patient group, and whether it can be administered safely in routine outpatient practice.

2. MATERIALS AND METHODS

2.1 Study design and setting

This was a single-arm, open-label, prospective, interventional, exploratory clinical study, registered with the Clinical Trials Registry of India (CTRI/2025/04/085045). Patients were recruited from the outpatient and inpatient departments of the University College of Ayurveda Hospital (Sanjeevani Chikitsalaya), Dr. Sarvepalli Radhakrishnan Rajasthan

Ayurved University, Jodhpur. The treatment period ran for 21 days per patient, with a further 60-day follow-up window to capture recurrence or delayed complications.

2.2 Participants

Thirty patients meeting the eligibility criteria were enrolled after written informed consent, irrespective of sex, occupation or religion. Eligible patients were aged 16–70 years and presented with second-degree internal haemorrhoids — bleeding per rectum, prolapse of the pile mass, pain and/or discharge, with the pile mass classically described as Mrudu (soft), Prasruta (spread), Avagadha (deep-seated) and Uchrita (projected).

Patients were excluded if they had uncontrolled diabetes mellitus, hypertension, an infective or neoplastic anorectal condition, HIV or hepatitis B infection, rectal prolapse or other pelvic pathology, intestinal tuberculosis, third- or fourth-degree piles or other associated anorectal disease, a strangulated or thrombosed pile mass, or were pregnant, or fell outside the 16–70-year age band. Patients could be withdrawn at any stage for hypersensitivity to the intervention, a serious adverse event requiring urgent care, or on their own request; the pre-specified investigations obtained at entry (complete blood count, bleeding time, clotting time, random blood sugar, HIV, HBsAg and VDRL) also served as a basic safety screen.

2.3 Preparation of Kadali Kshara

Kadali Kshara was prepared according to the method described by Sushruta. A mature banana plant was cut into pieces, dried and burned along with limestone; the resulting ash was filtered through clean linen cloth twenty-one times in a fixed proportion of ash to water, and the filtrate was boiled down in an iron vessel with continual stirring until it became clear, red, sharp and slightly viscous — the Ksharodaka. A portion of this was combined with additional alkaline and Kshara-enhancing substances (Katsharkara, Bhasma Sharkara, purified Jalashukti and Shankhanabhi) and reduced further to a semi-solid consistency to yield Madhyama (medium-strength) Kshara. To obtain the Tikshna (potent) form used clinically, a set of classical Kshara-enhancing drugs — including Danti, Dravanti, Chitraka, Langali and others named in the text — was powdered and incorporated into the Madhyama Kshara solution. The pH of the finished Tikshna Kshara was measured before each clinical use and was consistently found to exceed 12, confirming adequate causticity; the prepared Kshara was stored in an airtight glass container.

2.4 Clinical Procedure

Each Kshara application followed the same three-stage format described in the Sushruta Samhita.

Pre-procedure preparation (Poorva Karma)

Routine part preparation and bowel clearance were carried out, along with a tetanus toxoid injection and a lignocaine sensitivity test.

Procedure (Pradhana Karma)

With the patient in the lithotomy position and under local anaesthesia (2% lignocaine), the anal canal was gently dilated to admit four fingers and a slit proctoscope was introduced. The pile mass was drawn into view with Allis tissue-holding forceps, and the surrounding healthy mucosa was shielded with wet cotton to prevent the Kshara from spreading beyond the target tissue. The Kshara was then applied directly to the pile mass and left in contact for a timed interval (Shatamatra Kala), after which it was washed off with distilled water and lime juice. The surgeon checked whether the pile mass had turned the expected blackish, ripe-jamun colour (Pakvajambuphala Varna); if not, a further application was given until this end-point was reached. Because Sushruta specifically cautions against treating more than one pile mass at a single sitting, the procedure was repeated on the remaining pile masses (classically at the 3, 7 and 11 o'clock positions) at seven-day intervals rather than all at once.



Figure 1.



Figure 2.

Figure 1. During procedure - Proctoscopic appearance of the pile mass during the ksharkarma procedure.

Figure 2. After procedure - Proctoscopic appearance of the pile mass immediately after Kadali Tikshna Pratisarneeya Kshara application, showing the characteristic blackish, ripe-jamun (Pakvajambuphala Varna) discolouration that confirms adequate depth of chemical cauterisation.



Figure 1.



Figure 2.

Figure 1. During procedure - pile mass during the ksharkarma procedure

Figure 2. After procedure

These images were uploaded after obtaining the patients informed consent.

Post-procedure care (Pashchat Karma)

A gauze pack soaked in Madhuyashti Ghrita was placed in the anal canal to reduce burning and local oedema, and removed once the patient felt the urge to defecate; 5 ml of Jatyadi Taila was then instilled per rectum. From the following day, patients took a sitz bath in Sphatika Bhasma solution for 10–15 minutes, twice daily after defecation. All patients also received the dietary and lifestyle advice (Pathya-Apathya) laid down for Arsha in the Sushruta Samhita as a standard adjunct to the procedure.

2.5 Outcome measures

Grade	0	1	2	3
Bleeding	No bleeding	0–5 drops	5–10 drops	Stream/pouring
Itching	No itching	Once/twice a day	Frequent, discomfort	Severe, all day
Colour of pile mass	Reddish-black (healed)	Slightly blackish	Pinkish (congested)	Plum colour
Prolapse	No prolapse	On straining only	Reducible prolapse	Irreducible prolapse

Two subjective parameters — bleeding per rectum and itching — and two objective parameters — colour of the pile mass on proctoscopy and degree of prolapse — were scored on a 0–3 grading scale at baseline (Day 0), Day 7, Day 14, Day 21 and at a final follow-up assessment. The grading criteria are summarised in Table 1.

Table 1. Grading criteria for the four assessment parameters (0 = best, 3 = worst; note that for the colour parameter Grade 0 denotes the intended immediate post-cauterisation appearance rather than the ultimate healing end-point — see Discussion).

2.6 Statistical analysis

Baseline-to-follow-up change in each parameter was analysed with the paired t-test and cross-checked with the non-parametric Wilcoxon signed-rank test appropriate for paired ordinal grade data; interval-wise (week-by-week) comparisons used the Wilcoxon signed-rank test. A p-value below 0.05 was taken as statistically significant and below 0.001 as highly significant. Percentage relief was calculated as the proportional fall in mean score from baseline to the final assessment.

3. RESULTS

3.1 Demographic and baseline profile

The thirty enrolled patients had a mean age of 39.17 ± 9.93 years (range 22–58 years); the largest single group, 11 patients (36.67%), fell in the 36–45-year band, followed by 9 (30%) in the 26–35-year band. Twenty-four patients (80%) were male and six (20%) female. Service-class occupations (40%) and manual labour (16.67%) together accounted for over half the cohort, and the majority belonged to the middle (53.33%) or lower (36.67%) socioeconomic strata; 60% described a sedentary lifestyle. Constitutionally, Vata-Kapha Prakriti predominated (36.67%), followed by Vata-Pitta and Kapha-Pitta (23.33% each) — a distribution that fits the classical view of Arsha as a Tridoshaja disease with a Vata-Kapha bias towards mass formation and prolapse.

Notably, 80% of patients gave a history of constipation and 66.67% reported habitual straining at stool, findings that tie in directly with the mechanical theory of haemorrhoid formation through chronically raised intra-abdominal pressure. At entry, all 30 patients (100%) had Grade 2 (reducible) prolapse and all four cardinal features of the disease, confirming a homogeneous baseline severity across the cohort; 70% had a plum-coloured (Grade 3) pile mass on proctoscopy and the remainder a pinkish (Grade 2) mass. Twenty-five

patients (83.33%) had all three classical pile masses at the 3, 7 and 11 o'clock positions requiring sequential treatment, four (13.33%) had two, and one (3.33%) had a single pile mass.

3.2 Bleeding (Raktasrava)

The mean bleeding score fell steadily from 2.67 ± 0.48 at baseline to 1.17 ± 0.87 by Day 7, 0.38 ± 0.82 by Day 14, and 0.33 ± 0.61 at the final assessment — an overall relief of 87.5% (paired t-test, $t = 15.93$, $df = 29$, $p < 0.0001$; Wilcoxon $p < 0.001$). The steepest fall occurred between Day 7 and Day 14 (Wilcoxon $p < 0.001$); the change from Day 14 onward was not statistically significant, indicating that the haemostatic effect was essentially established within the first two weeks and simply maintained thereafter. Ninety percent of patients (27/30) became completely bleeding-free at some point during follow-up, with a median time-to-relief of 14 days.

3.3 Itching (Kandu)

Itching resolved faster than any other parameter. The mean score dropped from 0.90 ± 0.71 at baseline to 0.17 ± 0.38 by Day 7 and 0.03 ± 0.18 at the final assessment, a relief of 96.3% ($t = 6.50$, $df = 29$, $p < 0.0001$). Twenty-five patients (83.33%) were completely free of itching within the first week, with a median time-to-relief of just 7 days; only one patient (3.33%) never achieved complete relief.

3.4 Colour of the pile mass

This parameter behaved differently from the other three, because it tracks a healing sequence rather than a symptom that simply gets better. The mean score fell sharply from 2.70 ± 0.47 at baseline to 0.73 ± 0.45 by Day 7 as the pile mass turned the expected blackish, cauterised colour, then rose again through 0.97 ± 0.33 at Day 14 to 1.50 ± 0.78 at the final assessment as the eschar separated and the area re-epithelialised with a healthier pink hue. All the interval-to-interval changes were statistically significant (p ranging from 0.001 to < 0.001), reflecting an actively evolving healing process rather than a static score. Taking the full baseline-to-endpoint change at face value, colour improved by 34.1% overall ($t = 9.33$, $df = 24$, $p < 0.0001$), though — as discussed below — this figure should be read alongside the biphasic pattern rather than in isolation.

3.5 Prolapse of the pile mass

Prolapse showed the largest relative improvement of all four parameters. Every patient entered the study with uniform Grade 2 (reducible) prolapse (mean 2.00 ± 0.00); by the final assessment the mean score had fallen to 0.13 ± 0.35 , a 93.3% relief ($t = 29.57$, $df = 29$, $p < 0.0001$). Twenty-six of thirty patients (86.7%) had no prolapse at all by the end of treatment, and no patient developed irreducible (Grade 3) prolapse at any point in the study.

3.6 Composite symptom score

Combining all four parameters into a single composite severity score (range 0–12), the mean fell from 8.27 ± 0.94 at baseline to 2.00 ± 1.23 at the final assessment — an overall relief of 75.8% ($t = 20.68$, $df = 29$, $p < 0.0001$), confirming that the improvement was consistent across the disease as a whole and not confined to any single measure.

3.7 Overall therapeutic response and patient satisfaction

Twenty-six of the thirty patients (86.67%) achieved complete resolution of their disease within the 21-day study period. Three patients (10%) had an unsatisfactory response and required further treatment — one of whom ultimately underwent conventional haemorrhoidectomy — and one patient (3.33%) was withdrawn on Day 7 because of persistent pain. Patient-reported satisfaction closely mirrored the clinical outcome: 26 patients (86.67%) were satisfied with their treatment and 4 (13.33%) were not.

3.8 Safety

No major systemic adverse effects — fever, sepsis, significant haemorrhage requiring transfusion or anal stenosis — occurred in any of the thirty patients. Mild, self-limiting local burning and oedema in the immediate post-application period were managed routinely with Madhuyashti Ghrita packing and Jatyadi Taila and required no additional intervention. Only one patient (3.33%) developed persistent local pain severe enough to warrant discontinuation and referral for alternative management.

3.9 Summary of key outcomes

Parameter	Baseline (Mean $\pm$ SD)	End of treatment (Mean $\pm$ SD)	% Relief	p-value
Bleeding	2.67 ± 0.48	0.33 ± 0.61	87.5%	< 0.0001
Itching	0.90 ± 0.71	0.03 ± 0.18	96.3%	< 0.0001
Colour of pile mass*	2.70 ± 0.47	1.50 ± 0.78	34.1%*	< 0.0001
Prolapse	2.00 ± 0.00	0.13 ± 0.35	93.3%	< 0.0001
Composite score (0–12)	8.27 ± 0.94	2.00 ± 1.23	75.8%	< 0.0001

Table 2. Change in assessment parameters from baseline to end of treatment. *The colour parameter follows a biphasic cauterisation-then-healing pattern rather than a linear improvement (see §3.4); its percentage figure should be interpreted accordingly.

4. DISCUSSION

This exploratory study set out to test, with objective grading and formal statistics rather than impression alone, whether Kadali Pratisarneeeya Kshara lives up to its classical reputation in second-degree internal haemorrhoids. On every parameter measured, it did: bleeding, itching and prolapse each improved by more than 85%, and the pile mass followed the textbook cauterisation-to-healing colour sequence that surgeons trained in Kshara Karma look for as confirmation that the procedure has worked as intended.

The demographic picture that emerged is a familiar one in anorectal practice. The disease clustered in the middle-aged, economically active years, with a strong male predominance and a background of sedentary work, constipation and habitual straining — a combination that, from a purely mechanical standpoint, raises intra-abdominal and intra-rectal venous pressure until the haemorrhoidal cushions give way, and, from an Ayurvedic standpoint, maps closely onto Vata obstruction and Kapha-driven mass formation in the Guda Marga. The very high prevalence of constipation (80%) in this cohort is worth dwelling on: it is a modifiable factor, and the fact that every patient in this study also received the classical Pathya-Apathya dietary advice alongside the Kshara application means that bowel regularisation should be regarded as a necessary companion to the procedure, not an optional extra.

Mechanistically, the results make sense in terms of what a strongly alkaline ($\text{pH} > 12$) Kshara does on contact with mucosal tissue. It denatures surface proteins and produces immediate superficial chemical cauterisation, sealing the small feeding vessels responsible for bleeding — which fits the early, sharp fall in the bleeding score by Day 7 and its near-complete resolution by the end of treatment. The same cauterisation, by abolishing superficial nerve endings and reducing local congestion, plausibly explains why itching cleared even faster than bleeding: pruritus in haemorrhoidal disease is driven largely by superficial irritation and moisture, both of which are removed almost immediately once the tissue is cauterised and desiccated. The colour parameter is best read not as a symptom score but as a window onto the healing process itself — the initial blackish, ripe-jamun appearance (Pakvajambuphala Varna) is the intended end-point of an adequate application, and its later return towards a

healthy pink as the eschar separates and the area re-epithelialises is evidence that healing proceeded normally, not that the disease was worsening. Prolapse showed the most dramatic relief of all, consistent with the combined scraping (Lekhana) and desiccating (Shoshana) action of the Kshara progressively debulking the vascular cushion, followed by fibrotic contraction during healing that anchors the residual tissue more firmly — a chemical route to much the same mechanical fixation that sclerotherapy or rubber-band ligation achieve by other means.

The four patients whose outcome fell short of complete resolution are worth looking at individually rather than folding into a single failure rate. One patient's bleeding initially improved and then worsened, suggesting a particularly friable or vascular pile mass that the depth of chemical penetration achieved was not enough to control durably. A second had only partial regression and opted to pursue further treatment outside the study, again pointing to a larger or more deeply projected pile mass than the Kshara could fully resolve within 21 days. A third eventually required conventional haemorrhoidectomy — a useful reminder that, however effective Kshara Karma is for most patients with first- and second-degree disease, it has a ceiling, and some pile masses, particularly larger or more fibrosed ones, will still need surgery. The fourth was the single patient withdrawn for persistent local pain, a recognised though uncommon complication of Kshara Karma that underlines the importance of careful technique, correctly timed application (Shatamatra Kala), and attentive post-procedure pain management.

Reassuringly, no patient in this series developed a major systemic complication — no fever, sepsis, significant bleeding requiring transfusion, or anal stenosis — over either the 21-day treatment period or the subsequent follow-up. This supports the classical claim that Kadali Kshara, prepared and applied correctly, is a safe outpatient procedure, and is broadly consistent with why Sushruta rated Kshara Karma above Agnikarma (which carries a higher risk of deeper thermal injury) and, for this stage of disease, favoured it over Shashtra Karma, which brings the added burdens of anaesthesia, hospitalisation and a longer, more painful recovery.

Taken together, the statistical picture across all four parameters — p-values comfortably below 0.001 in every case — supports rejecting the null hypothesis that Kadali Pratisarneeeya Kshara has no effect on second-degree internal haemorrhoids, in favour of the alternative that it does produce a real, measurable therapeutic effect.

4.1 Limitations

These findings need to be read with the design of the study clearly in mind. This was a single-arm, open-label trial with no placebo or active comparator arm, so while the improvement against each patient's own baseline was statistically robust, the study cannot on its own show that Kadali Kshara is better than, equivalent to, or worse than any other treatment for the same condition. Every patient also received the same dietary and lifestyle advice alongside the Kshara application, which makes it impossible to fully separate the effect of the Kshara itself from the contribution of improved bowel habit. The sample size ($n = 30$) is modest, which limits how precisely the effect sizes can be estimated and how confidently predictors of non-response can be identified. The 21-day treatment period and short follow-up window, while sufficient to demonstrate short-term efficacy and immediate safety, cannot speak to longer-term recurrence, which matters a great deal for any haemorrhoid treatment. Finally, this was a single-centre study in one hospital population, so the demographic and clinical picture described here may not generalise directly to other settings.

5. CONCLUSION

In this exploratory single-arm study of 30 patients with second-degree internal haemorrhoids, topical Kadali (*Musa paradisiaca*) Pratisarneeeya Kshara produced a statistically highly significant and clinically meaningful improvement across all measured parameters — bleeding fell by 87.5%, itching by 96.3%, and prolapse by 93.3%, while the colour of the pile mass followed the expected cauterisation-and-healing sequence. Twenty-six of thirty patients (86.7%) achieved complete resolution, matched almost exactly by the proportion reporting satisfaction with their treatment, and no major systemic adverse effects occurred over the study period.

These results support the classical regard for Kshara Karma, and for Kadali specifically, as a simple, inexpensive, outpatient-based para-surgical option well suited to patients who are unwilling or medically unfit for conventional haemorrhoidectomy. That said, given the single-arm, uncontrolled design, the modest sample size and the relatively short follow-up, these findings should be treated as preliminary and hypothesis-generating rather than conclusive. A randomised controlled trial with an appropriate comparator arm, a larger sample and a follow-up of at least six to twelve months would be the natural next step before

Kadali Pratisarneeeya Kshara can be recommended as a standard first-line treatment for second-degree internal haemorrhoids.

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