

PROTOCOL FOR A COMPARATIVE CLINICAL STUDY OF PRATISARNIYA KINSHUK KSHARA AND SCLEROTHERAPY IN THE MANAGEMENT OF ABHYANTAR ARSHA (INTERNAL HAEMORRHOIDS)

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ABSTRACT

Background: Arsha (haemorrhoids) is one of the most frequently encountered anorectal disorders. In Ayurveda, it is categorized among the Ashta Mahagada (eight grave diseases) because of its chronicity, recurrence, and impact on quality of life. Various treatment modalities have been described, including Aushadha, Kshara, Agni, and Shashtra Karma. Among these, Pratisarniya Kshara is considered an effective parasurgical therapy. Sclerotherapy using polidocanol is a widely accepted modern minimally invasive treatment for internal haemorrhoids. Comparative evidence between these two interventions remains limited. **Objective:** To evaluate and compare the clinical efficacy of Pratisarniya Kinshuk Kshara and injection polidocanol sclerotherapy in the management of first- and second-degree internal haemorrhoids. **Methods:** This prospective randomized comparative clinical study will include 40 patients diagnosed with Grade I and Grade II internal haemorrhoids. Participants will be randomly allocated into two groups. Group A will receive Pratisarniya Kinshuk Kshara application, while Group B will undergo injection polidocanol sclerotherapy. Patients will be assessed for bleeding per rectum, pain, constipation, prolapse, and proctoscopic findings over a follow-up period of 21 days. **Expected Outcome:** The study is expected to provide scientific evidence regarding the efficacy and safety of Kinshuk Kshara compared with sclerotherapy and may establish an economical, minimally invasive Ayurvedic alternative for haemorrhoid management.

KEYWORDS: Arsha, Internal haemorrhoids, Kinshuk Kshara, Palasha, Sclerotherapy, Polidocanol, Kshara Karma.

INTRODUCTION

Arsha is described extensively in Ayurvedic literature and is included among the Ashta Mahagada by Acharya Sushruta due to its difficult prognosis and tendency for recurrence.^[1] The disease is characterized by abnormal growths in the anorectal region resulting from derangement of Dosha, Dushya, and impairment of digestive fire (Agni).^[2]

Sedentary lifestyle, irregular dietary habits, chronic constipation, and faulty bowel practices contribute significantly to the development of haemorrhoids. In modern medicine, haemorrhoids are vascular cushions within the anal canal that become symptomatic due to enlargement, prolapse, inflammation, or bleeding.^[3]

The global prevalence of haemorrhoids has been reported to be approximately 4–5%, making it one of the most common anorectal conditions worldwide.^[4] Common symptoms include rectal bleeding, prolapse, pain, itching, and discomfort.

Ayurveda advocates four principal treatment modalities for Arsha: Bhesaja (medical management), Kshara Karma, Agni Karma, and Shashtra Karma.^[5] Among these, Pratisarniya Kshara has gained importance because of its minimally invasive nature, cost-effectiveness, and ability to induce controlled chemical cauterization.

Kinshuk (*Butea monosperma*) possesses Katu, Tikta, and Kashaya properties and has been traditionally indicated in Arsha and other anorectal disorders.^[6] Modern pharmacological studies have demonstrated anti-inflammatory, antimicrobial, and wound-healing properties of the plant.^[7]

Polidocanol sclerotherapy is a standard outpatient procedure that induces endothelial damage, fibrosis, and obliteration of haemorrhoidal vessels, thereby reducing symptoms.^[8] A direct comparison between Kinshuk Kshara and sclerotherapy may help identify a safer and more effective treatment strategy.

Rationale of the Study

Although numerous treatment modalities are available for haemorrhoids, recurrence, postoperative pain, bleeding, and procedural costs remain concerns. Kinshuk Kshara offers a parasurgical Ayurvedic intervention that may overcome several limitations associated with conventional procedures.

Scientific evaluation through a comparative clinical study is necessary to generate evidence regarding its efficacy and safety compared with modern sclerotherapy.

AIM

To compare the clinical efficacy of Pratisarniya Kinshuk Kshara and injection polidocanol sclerotherapy in the management of Abhyantar Arsha (internal haemorrhoids).

OBJECTIVES

Primary Objective

- To evaluate the therapeutic effect of Kinshuk Kshara in Grade I and Grade II internal haemorrhoids.

Secondary Objectives

- To compare Kinshuk Kshara with injection polidocanol regarding reduction in bleeding, pain, prolapse, and constipation.

- To assess safety and tolerability of both interventions.
- To evaluate overall patient improvement through clinical and proctoscopic assessment.

MATERIALS AND METHODS

Study Design

Prospective, randomized, comparative clinical study.

Study Setting

Department of Shalya Tantra, Jammu Institute of Ayurveda and Research, Jammu.

Sample Size

A total of 40 patients will be enrolled.

Group Allocation

Group	Intervention	Number of Patients
Group A	Pratisarniya Kinshuk Kshara	20
Group B	Injection Polidocanol Sclerotherapy	20

Randomization

Participants will be randomized using computer-generated randomization software.

Duration of Study

3–4 months.

Inclusion Criteria

1. Patients aged 18–60 years.
2. Diagnosed cases of Grade I and Grade II internal haemorrhoids.
3. Patients willing to participate and provide written informed consent.

Exclusion Criteria

1. Grade III and Grade IV haemorrhoids.
2. Pregnancy.
3. Rectal prolapse.
4. Carcinoma rectum.
5. Tuberculosis.
6. HIV infection.
7. Ulcerative colitis or Crohn's disease.
8. Cirrhosis of liver.
9. External thrombosed haemorrhoids.
10. Associated anorectal disorders such as fistula-in-ano.

Intervention**Group A: Pratisarniya Kinshuk Kshara**

Kinshuk Kshara will be prepared according to classical Ayurvedic procedures described in Sushruta Samhita.^[9]

The Kshara will be applied directly over the haemorrhoidal mass using a slit proctoscope until the pile mass attains the characteristic Pakva Jambu Phala Varna (blackish-purple discoloration). The area will subsequently be neutralized using an acidic medium as per standard Kshara Karma protocol.

Group B: Injection Polidocanol

Injection polidocanol will be administered through a proctoscope into the submucosal plane above the haemorrhoidal pedicle. The sclerosant induces endothelial destruction, thrombosis, and subsequent fibrosis of haemorrhoidal vessels.^[8]

Outcome Measures**Subjective Parameters****Pain**

- 0 – No pain
- 1 – Mild pain
- 2 – Moderate pain
- 3 – Severe pain

Constipation

- 0 – Normal evacuation
- 1 – Mild difficulty
- 2 – Moderate difficulty
- 3 – Severe difficulty

Bleeding Per Rectum

- 0 – Absent
- 1 – Droplets
- 2 – Syringing
- 3 – Stream bleeding

Prolapse

- 0 – Absent
- 1 – During defecation only
- 2 – Spontaneously reducible
- 3 – Digitally reducible
- 4 – Irreducible

Objective Parameters

- Proctoscopic assessment of pile mass.
- Site and number of haemorrhoids.
- Surface characteristics.

- Degree of prolapse.
- Reduction in pile size.

Statistical Analysis

Data will be analyzed using appropriate statistical methods. Quantitative variables will be expressed as mean $\pm$ standard deviation. Paired and unpaired statistical tests will be employed according to data distribution. A p-value <0.05 will be considered statistically significant.

Expected Results

Kinshuk Kshara is expected to demonstrate significant improvement in bleeding, prolapse, and pile mass regression. Owing to its cauterizing, haemostatic, and tissue-sclerosing properties, it may offer results comparable or superior to sclerotherapy while remaining economical and minimally invasive.

Ethical Considerations

The study will be conducted following institutional ethical guidelines. Written informed consent will be obtained from all participants before enrolment. Confidentiality and patient safety will be maintained throughout the study.

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