

COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF SHALLAKI NIRYAS KSHARASUTRA IN THE MANAGEMENT OF ARSHA: A STUDY PROTOCOL

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ABSTRACT

Background - Haemorrhoids or Piles are a common anorectal disease that arises from the congestion of the internal and external venous plexuses around the anal canal. Hemorrhoids are of two types, external and internal. The external hemorrhoids occur outside the anal verge and are often painful when accompanied by swelling and irritation. The internal hemorrhoids occur inside the rectum and are usually not painful but may bleed when irritated. *Acharya Sushruta* has described a fourfold method for treating *Arsha*, which are *Bheshaja*, *Kshara*, *Agni*, and *Shastra*. *Ksharasutra* therapy is a minimal invasive *Ayurvedic* para surgical procedure and time-tested *Ayurvedic* technique in managing anorectal disorders. It is a safe, sure, and cost-effective treatment method for fistula-in-ano, hemorrhoids, and other sinus

diseases. **Aims and Objectives:** 1 - Assessment of the efficacy of *Shallaki niryas Ksharasutra* and *Snuhi ksheer Ksharasutra* in the Management of *Arsha*. 2 - To evaluate the effective measures for the management of *Arsha*. 3 - To compare the duration period for cutting and healing of *Shallaki niryas Ksharasutra* and *Snuhi ksheer Ksharasutra* in the Management of *Arsha*. **Methodology** - Eighty patients of *Arsha* are divided into two groups, group A and group B, each having 40 patients irrespective of age and gender. *Shallaki niryas Ksharasutra* ligation as Group A and *Snuhi ksheer Ksharasutra* ligation as a Group B. **Conclusion** - conclusions will be pointed out after data analysis.

KEYWORDS: *Arsha*, Hemorrhoids, *Ksharasutra*, *Shallaki*.

INTRODUCTION

According to 2019 ICD-10-CM Diagnosis Code, K64.9, Haemorrhoids are dilated veins in the lower part of the rectum or anal canal. Hemorrhoids can be internal or external or protruding from inside to outside of the anal canal and have bleeding, itching, and pain. *Guda* (anus) is undoubtedly a *Marma* (vital points), and it is well known for its chronicity and difficult management. Vitiating *Dosha* (ailments) localizes in *Gudavali* (folds), *Pradhana dhamani* (vein), and *Mansadhara Kala* (layers) and vitiates *Twak* (skin), *Mansa* (muscle), *Meda* (fats), and *Rakta* (blood), resulting in the *Annavaha Srotodushti* (obstruction of the digestive system). *Snuhi ksheer Ksharsutra* is considered the standard *Ksharsutra*; although this *Ksharsutra* has been a landmark success, it has certain drawbacks like pain, burning sensation, and itching associated with therapy. Hemorrhoids are dilated veins within the anal canal in the subepithelial region formed by radicals of the superior, middle and inferior rectal veins. Internal hemorrhoid is within the anal canal and internal to the anal orifice. It is covered with a mucous membrane, and it is bright red or purple in color. It usually commences at the anorectal ring and ends at the dentate line. The external hemorrhoid is situated outside the anal orifice and is covered by skin. The two varieties may coexist, and the condition is called interno-external hemorrhoids. The internal variety may be first degree where the piles remain within the anus, and that may bleed but do not prolapse in second-degree piles that prolapse on straining during the defecation but return or recede spontaneously in the third-degree piles that prolapse during stool passing but can be replaced by manual help or digital pressure or protruded. Fourth-degree piles that prolapse and cannot push back in the anal canal.^[1] *Sushruta Samhita* (800 – 1000 B.C.) *Charak Samhita* (1000 B.C.) and *Acharya Vagbhata* (7th A.D.) all of them have dedicated separate chapter to describe aetiology pathogenesis symptomatology and the management of *Arshas*. One of the contributions during this period is application of *Ksharsutra* described by Chakrapani (11 th A.D.) in his *Chakradutta* in the context of *Arshobhagandar chikitsa*.^[2] *Ayurveda* classified different types of *Arsha*, including *Vataj*, *Pittaj*, *Kaphaj*, *Sannipataj*, *Raktaj* and *Sahaj*.^[3] *Ayurveda* described some factors for *Arsha* like cold water, continuous seating, and riding suppression of normal urge of urination and defecation.^[4] *Arsha* can be managed by various para surgical measures such as *Agnikarma*, *Ksharkarma*, *Ksharsutra*. *Acharya Sushruta* has advised applying *Ksharasutra* in weak, feeble, fearful, and difficult to treat patients.^[5] Generally, *Snuhi ksheer Ksharsutra* is used for ligation purposes, but it also suffers from some adverse effects such as pain, irritation, and burning sensation. Therefore, it was required to evaluate the efficacy of some other *Ksharsutra* in the management of *Arsha*.

Considering this fact present study was carried out to measure the efficacy of *Shallaki niryas Ksharsutra* in the management of *Arsha*. *Shallaki Ksharsutra* is made with water-soluble *Shallaki niryas* liquid instead of *Snuhi kheer*. *Shallaki niryas*, *Apamarga*, and *Haridra* were used to prepare *Shallaki niryas Ksharsutra*. [Table - 1]

Table 1: Method of Preparation *Shallaki niryas Ksharsutra*.

S. No.	Ingredients combination for <i>Shallaki niryas Ksharsutra</i>	No. of coatings	Total coatings
1	<i>Shallaki niryas</i>	11	21
2	<i>Shallaki niryas + Apamarga Kshara</i>	7	
3	<i>Shallaki niryas+ Haridra Churna</i>	3	

1. Purpose of study

Snuhi apamarga Ksharsutra is considered the standard *Ksharsutra*; although it has been a landmark success, it has certain drawbacks like pain, burning sensation, and itching associated during therapy. In order to overcome these disadvantages of *Snuhi apamarga ksharsutra*, an effort will be made to prepare *Shallaki niryas ksharsutra* and to study its efficacy in the management of *Arsha*. *Shallaki niryas* are described as *Vranaropaka* and *Arshoghna* in *Dhanvantari nighantu*.^[6]

2. AIMS AND OBJECTIVES

- 1 - Assessment of the efficacy of *Shallaki niryas Ksharsutra* and *Snuhi ksheer Ksharsutra* in the Management of *Arsha*.
- 2 - To evaluate the effective measures for the management of *Arsha*.
- 3 - To compare the duration period for cutting and healing of *Shallaki niryas Ksharsutra* and *Snuhi ksheer Ksharsutra* in the Management of *Arsha*.

3. Research Question

Whether ligation of *Shallaki niryas Ksharsutra* is more effective than ligation of *Snuhi ksheer Ksharsutra*?

4. Hypothesis

Ligation of *Shallaki niryas Ksharsutra* is effective in the management of *Arsha*.

5. Null Hypothesis

Ligation of *Shallaki niryas Ksharsutra* is less effective than *Snuhi ksheer Ksharsutra* in the management of *Arsha*.

6. Study Type Randomized comparative clinical trial.

MATERIALS AND METHODS

1. Methodology

The study was initiated after seeking approval from institutional ethical committee Study at a glance.

- **Place of study:** Mandsaur institute of ayurvedic education and research, Mandsaur, Madhya Pradesh
- **Duration of study:** - 30 days.
- **Sample size:** - 80 patients
- **Grouping:** - Total 80 patients will be included in this study which is divided into 2 equal groups.

Group A- having 40 patients and ligation will be done with *Shallaki niryas Ksharsutra*.

Group B– having 40 patients, ligation will be done with *Snuhi ksheer Ksharsutra*.

After taking a detailed history, a completely general, systemic, and local anorectal examination will be carried out in all the patients.

2. Diagnostic criteria^[7]

- Bleeding during defecation
- Mucous discharge
- Pruritus ani
- Prolapsed of hemorrhoids
- Proctoscopic examination

Patients of 3rd degree internal hemorrhoids were selected from OPD & IPD irrespective of gender & age subjective. Patients fulfilling the above criteria were selected and enrolled in the study upon their consent and based on inclusion and exclusion criteria.

3. Inclusion criteria

- Patients with age ranging 20 to 60 years, irrespective of sex.
- Proctoscopic diagnosed cases of 3rd degree hemorrhoids (with or without bleeding/painful or painless)
- Hemoglobin more than 10 gm. / 100 ml.

4. Exclusion criteria

Pre diagnosed cases of

- Thrombosed, strangulated, and infected hemorrhoids
- Fissure in ano and prolapse of rectum, anal polyp
- Haemorrhoid with ulcerative colitis, Koch's, DM, crohn's disease, carcinoma of rectum, pregnancy, cirrhosis of liver.
- Blood dyscrasias,
- Myocardial infarction, stroke, severe arrhythmia in last 6 months.

5. Laboratory investigations

Complete blood count, Hb%, CT, BT, HIV, HBsAg, blood urea, S.creatinine, Blood sugar (Random), Antigen for covid 19.

6. Assessment criteria

The patients of *Arsha roga* (Haemorrhoids) were assessed on the basis of subjective and objective parameters such as Pain, Discharge, and Bleeding. The total information of subjective or objective assessment pre-operatively or post-operatively has been done in a systemic and scientific manner on regular weekly information. The treatment effect has been assessed on the basis of the relief of signs and symptoms of the major symptoms of the disease.

➤ Subjective parameter

The patients were assessed on the basis of following

Parameters before and after treatment are as follows:

- Pain on VAS (Visual Analogue Scale): Pain was recorded on the Visual Analog Scale on days 1, 3, 7, 15, and 30 after the operation.
- Grading of Discharge: The grading of discharge amount was based on this table.
- Post-Operative Bleeding Per Rectum: Recorded on days 1, 3, 7, 15, 30 post-operatively

➤ Objective parameter

• Complete Healing Time

Complete healing time is the total time taken for the entire treatment. This is recorded in the patients who are on the follow-up regimen. The patients with hemorrhoids were asked to attend the OPD on days 1,3,7,15,30 after *Kshara Sutra* ligation, then every fortnightly for 3 months, then monthly till six months.

- **Pain Relief Day (P.R.D.)**

This is the day when the patient is totally relieved or free from post-operative pain. Due to the irritation effect of *Kshara* on the local tissue, there will be burning and scalding type of pain often encountered. However, the pain is relieved after dissolving the *Kshara*, generally after the 3rd or 4th day in different conditions. The pH value of the *Kshara sutra* and type of tissue probably affect their action. Therefore in this study, it is recorded as the pain relief day i.e. (P.R.D.)

- Time is taken for sloughing out of hemorrhoid masses (in days)
- Photography: Grading was based on this table.

Visual Analogue Scale

0 - 0 mark: No Absence of pain/ no pain.

1 - 1-3 mark: Mild pain that can be easily ignored.

2 - 4-6 mark: Moderate pain that cannot be ignored and needs treatment.

3 - 7-10 mark: Severe pain which needs constant attention.

Grading of Discharge

0 - No discharge/dry dressing

1 - Mild Patient requires changing up to 1 pad of 4x4 cm gauze.

2 - Moderate Patient requires changing up to two pads of 4x4 cm gauze.

3 - Severe Patient requires changing more than two pads of 4x4 cm gauze.

Grading of post-operative bleeding per rectum

0- No bleeding.

1- -Mild Patient requires to change up to 1 pad of 4x4 cm gauze.

2- - Moderate Patient requires change up to two pads of 4x4 cm gauze.

3- - Severe Patient requires a change of more than two pads of 4x4 cm gauze.

Photography

1: local gangrene of pile mass tissue.

2. Ischemic necrosis and debridement of unhealthy tissue

3. Sloughing of pile mass

4. Wound was healed.

Method of Preparation of *Shallaki niryas Ksharsutra*

For this purpose, a surgical linen thread No.20 will be spread lengthwise in the *Kshara Sutra* hangers. Each thread on the hanger will be smeared with *Shallaki niryas* solution soaked in gauze piece. Then these wet threaded hangers will be placed in the *Kshara Sutra* cabinet for drying. The same process will be repeated daily till eleven such coatings with *Shallaki niryas* alone will be accomplished. The twelfth coating will be done by first smearing the thread with *Shallaki niryas* solution, and in the wet condition, the thread will be passed through the *Apamarga Kshara*. Then it will be placed into the cabinet for drying. This process will be repeated daily till seven coatings of *Shallaki niryas* and *Apamarga Kshara* are achieved. The final three coatings will be given with *Shallaki niryas* and *Haridra choornain* the same way. Thus the twenty-one coatings over the thread will do to prepare *Shallaki Ksharasutra* for use in this study.

Method of *Ksharasutra* Application**Pre-operative preparation of the patient**

After enquiring the history performing the examinations and investigations, the patient will be explained the procedure, and informed written consent was taken.

- Part preparation will be done.
- Enema with Glycerine 30ml + 60ml lukewarm water will be administered to encourage the complete evacuation of the bowel.
- Injection Tetanus toxoid 0.5 ml IM will be given.
- Injection Xylocaine 2 % - 0.5 cc SC for sensitivity test will be done
- If Spinal anesthesia is going to be applied, the patient will be kept nil by mouth from the night before operation, and if the Local anesthesia is going to be applied, the patient will be allowed for breakfast.

Operative Procedure

The patient will be kept in a lithotomic position on the operation table. The part will be cleaned with aseptic solutions, and then after local anesthesia, will be given with 2% xylocaine injection under the advice of anesthetics, and draping will be done. Later on, the position of various pile masses will be assessed. The pile will be mass hold with the help of pile holding forceps. Then the slight pull will be exerted over the pile mass so that its base is clearly demarcated along with the blood vessels.

Transfixation Pile mass

Transfixation Pile mass has been transfixed, bypassing the curved round body needle with *Ksharasutra* at its base. The transfixation was made horizontally or vertically according to the suitable position of hemorrhoid mass, preferably horizontal, then a stab cut is made on the budge of transfixed hemorrhoid mass to prevent strangulation. Then warm water irrigation will be done following T bandaging.

Post-*Ksharasutra* Regime

The patient will be advised to have a sitz bath (Luke warm water) twice a day. Ambulation of the patients will be made as a routine to encourage all the patients to remain as active as possible and to lead a normal life. The patients will be advised to take an easily digestible diet along with adjuvant therapies if required.

7. Criteria for Discontinuing or Modifying Allocated Interventions

The subject will be pulled back from the study if any troublesome charge, highlights of medication affectability or some other difficulty or issue emerges; the subject will be offered free treatment till the issue dies down.

8. Methods

Literature review search, plan of work, blueprint in the form of flow chart, raw materials collection, preparation of medicine, data collection, treatment, and its effect will be observed and statistically analyzed.

Data Collections Methods: Randomized sampling

Data Management: The data coding will be done by the principal investigator

Statistical Analysis: Data will be analyzed on the basis of appropriate statistics by Mann-Whitney test for comparison and Wilcoxon's signed-rank test by using Graph Pad software.

Consent or Assent: The patient will be given detailed information regarding intervention in his own language. Then written consent will be taken from patients before starting the study. During the study, the confidentiality of each patient will be maintained.

Dissemination Policy: The data will be disseminated in the form of paper publication and a Monograph: authorship eligibility guidelines and any intended use of professional writers. Informed consent material- patient will be given all consent material in the form of hard copy and other related documents.

Strengths: *Shallaki niryas* are described as *Vranaropaka* and *Arshoghna* in *Dhanvantari nighantu*. If the proposed study results in positive outcomes, then it will be established as a new approach as ligation of *Ksharsutra* in the management of *Arsha*.

Limitation: Specific geographical area, convincing the patients for research.

Primary Outcomes

In this research work, we will scrutinize the impact of *Shallaki niryas Ksharsutra* ligation and *Snuhi ksheer Ksharsutra* ligation in the management of *Arsha*. Information will be communicated as an ordinary mistake of mean at 5% level of distinction. It is hypothesized that *Shallaki niryas Ksharsutra* ligation will be less painful and less post-operative bleeding as compared to *Snuhi ksheer Ksharsutra* in whole trial period.

Secondary Outcomes

We will distinguish the effect of *Shallaki niryas Ksharsutra* on all standard assessment parameters in the management of *Arsha*.

DISCUSSION

Shallaki (*Boswellia serrata*) is a multipurpose plant. Many textbooks in *Ayurveda* describe its morphology, habitat, *ras panchak*, and its therapeutic uses, as mentioned above. *Boswellia* has *Madhur*, *Tikta*, and *Katu rasa*, due to which it pacifies *Pitta dosha*. Due to *Guru*, *Snigdha guna*, and *Ushna virya*, it pacifies *Vata dosha* (which pacifies the pain). Phytochemicals present in different parts of the plant have many pharmacological activities effective against various diseases. The use of *Shallaki* has been reported in some chronic inflammatory diseases like rheumatoid arthritis, bronchial asthma, osteoarthritis, ulcerative colitis, and Crohn's disease, which also show its anti-inflammatory and analgesic properties.^[8] Boswellic Acids decrease the pro-inflammatory 5-lipoxygenase products, including leukotriene B4 (LTB-4) levels. As a result, the inflammation response is dampened, thus allowing for quicker healing. Boswellic acid also helps in getting rid of foul odor and eliminating any pest in the surroundings, which makes wound healing faster^[9] *Snuhi* possesses *Katu-Tikta Rasa* (taste), *Guru-Tikshna Guna* (properties), *UshnaVirya* (potency), and *Katu Vipaka*. According to *Ayurvedic Pharmacopeia of India* *Snuhi* is *Tikshna Virechana* and have *Bhedana* and *Aama-kapha-vatahara* Karma. Cycloartenol and euphol is the major active constituent of *Snuhi*. On reviewing Classical literature, it is found that *Snuhi* is useful in the treatment of *Shoola*, *Aam*, *Asthilika*, *Adhaman*, *Gulma*, *Udararoga*, *Vataparkopa*, *Dushivisha*, *Plihavridhhi*, *Kustha*, *Unmada*, *Ashmari* *Dushitavrana*, *Arsha*, *Bhagandara*, and *Pandu*.

From *Ayurvedic* literature and modern literature review, it is found that the Pharmacological activities, which are proved after following pharmacological studies, are already explained in our *Ayurvedic* classics like *Vranahara* karma resembles Wound healing property, *Shoolahara* resembles Analgesics property, and so on.^[10]

CONCLUSION

The conclusion will be drawn from the calculated and analyzed data.

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