

A RANDOMISED OPEN LABELLED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SPHATIKA JALA BASTI AND KASISADI TAILA BASTI IN THE MANAGEMENT OF ARSHAS W.S.R TO INTERNAL HEMORRHOIDS

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ABSTRACT

The disease Arshas is included under Ashtamahagadas, as it is Dirghakalanubandhi and Duschikitsa. It can be correlated to Haemorrhoids, which are among the most common anorectal disorders affecting mankind since antiquity. Presenting with clinical features like Bleeding per rectum, Constipation, Pruritis-ani, Pain during defecation and Mass per anum. In contemporary science Numerous interventions exist for their management, ranging from topical medical therapies to outpatient treatment and surgical interventions that aim to fix and excise. Kasisadi taila basti is already a well established formulation mentioned in classical texts for Arshas. On the other hand, Sphatika jala basti is a simple, cost effective and less explored intervention, comparing these two helps to scientifically validate the role of Sphatika jala basti and possibly offer an alternative or supportive therapy. **Materials and Methods:** A total number of 40 patients diagnosed with Arshas of either sex was selected from OPD and IPD of Taranath Government. Ayurvedic medical college and hospital, Ballari and was randomly allotted into 2 groups namely Group-A (Sphatika jala basti) and Group-B (Kasisadi taila basti) with 20 patients each. **Results:** In the present study, the effect of treatment in both the groups showed statistically significant in all parameters and The overall changes is higher in Group A (81.38%) as compared to Group B(74.26%). **Conclusion:** Sphatika jalabasti is more effective than Kasisadi taila basti in the management of Arshas with special reference to internal haemorrhoids.

KEYWORDS: Arshas, Astamahagada, Sphatika jala, Kasisadi taila, basti, Haemorrhoid.

INTRODUCTION

Arsha is a disease in which the mamsankuras occurs at the opening of gudamarga, obstructs the pathway and troubles the person like enemy.^[1] Acharyas included Arshas as one among Ashtamahagada as it is Dirghakalanubandhi and Duschikitsa. The Person who observes no control in food and drinks, intake of viruddhahara there is diminution of agni leading to constipation. Vegadharana, utkatasana, streeprasanga, prustayaana are the viharaja nidanas which causes dosha vitiation along with Rakta which leads to development of

mamsankura in gudavali known as Arsha.^[2] It is included in Astamahagadha,^[3] which shows its nature of difficulty to cure. During the Nepolian era, Nepolian Bonaparte is believed to have suffered from painful, thrombosed haemorrhoids, which some historians suggest may have affected his performance and contributed to French defeat at the Battle of Waterloo.^[4]

It can be correlated to Haemorrhoids. In contemporary science Haemorrhoids are dilated veins within the anal canal in the sub-epithelial region formed by the radicles

of the superior, middle and inferior rectal veins.^[5] Incidence of Hemorrhoids is about 10-12% of all ano rectal cases. Prevalence rate is 4.4% in about 10million cause of lower gastrointestinal bleeding its frequency in India is 30-40%.^[7] Males and Females are both affected with about equal frequency.

The symptoms of internal haemorrhoids are rectal bleeding, mass per anum, discomfort, sometimes pain, mucus discharge and perianal itching.^[8] These symptoms generally affect the quality of life significantly starts from minor discomfort to severe complication like bleeding, strangulation (acute attack of pile), ulceration, suppuration and Anaemia^[9] etc, Although it is not a life threatening condition, it impacts lifestyle and social burden.

Treatment of haemorrhoids starts with bowel regulation which has prophylactic effect. But once the haemorrhoid established there is no evidence that the process is readily irreversible. The treatment of haemorrhoids depends on its degree and associated external haemorrhoids. Management of haemorrhoids in Modern surgery includes open and closed Haemorrhoidectomy, circular stapled haemorrhoidectomy.^[10] Today Haemorrhoidectomy is considered as ideal treatment in haemorrhoids particularly with associated sentinel tags and external haemorrhoids. parasurgical treatment includes Barron's band ligation, Sclerotherapy, infrared coagulation, laser therapy, cryosurgery etc. Advancement in number of procedures shows lack of universal acceptance and complications. Complications of these modalities include - pain, mucosal sloughing, ulcerations, recurrence, anal stricture, haemorrhage, foul smelly discharge etc.

In Ayurveda, management of Arsha includes Bhesaja, Kshara, Agni and Shastra karma.^[11] Among the above said procedures Aushadhi chikitsa is cost effective and acceptable by the patients who fears of surgery. As mentioned in Rasatarangini Sphatika (Potash alum) possess kashaya, katu, tikta rasa, Ushna veerya, does sankocha of gudankura and raktastambhaka.^[12] It also performs actions like antiseptic, hemostatic, analgesic, astringent, anti-inflammatory and antibiotic effects when administered both internally and externally.^[13] Hence the study on Sphatikajala basti is taken in comparison with standard Kasisadi taila^[14] basti in the management of Arsha.

AIMS AND OBJECTIVES

1. To evaluate the efficacy of Sphatika jala basti in the management of Arshas w.s.r to internal haemorrhoids.

people.^[6] Development of haemorrhoids before before age of 20 is unusual. Haemorrhoids are the most common

2. To evaluate the efficacy of Kasisadi taila basti in the management of Arshas w.s.r to internal haemorrhoids.
3. To compare the efficacy of Sphatika jala basti and Kasisadi taila basti in the management of Arshas w.s.r to internal haemorrhoids.

MATERIALS AND METHODS

A. Study design

A Randomized open labelled comparative clinical study containing 40 patients diagnosed with Arshas w.s.r to Internal Haemorrhoids, were included for the study and was randomly allotted into 2 groups namely Group-A (Sphatika jala basti) and Group-B (Kasisadi taila basti) with 20 patients each.

B. Source of patients

A total number of 40 patients diagnosed as Arshas of either sex was selected from OPD and IPD of Taranath Government. Ayurvedic medical college and hospital, Ballari.

DIAGNOSTIC CRITERIA

1. INCLUSION CRITERIA

- All the Patients will be diagnosed and assessed thoroughly on the basis of Ayurvedic and modern signs and symptoms of internal haemorrhoids. Such as Bleeding PR, Constipation, Pruritis-Ani, Pain and Mass per anum.
- 1st, 2nd and 3rd degree haemorrhoid.
- Age group of 20 -70 irrespective of sex, religion, occupation
- Single Pile mass

2. EXCLUSION CRITERIA

- Patients suffering from other systemic illnesses like Uncontrolled DM, HTN, STD, HIV etc.
- Associated with Ca-rectum, Fissure-in-ano, Anal polyp
- Symptoms suggesting Ulcerative colitis, Crohn's disease, Chronic liver disorder.
- Chronic Alcoholic patients.
- Thrombosed pile mass and External haemorrhoids.
- Pregnancy
- Hb% less than 10gm%

INVESTIGATIONS

- CBC, ESR, RBS, CT, BT, HBsAg, HIV 1&2.

MATERIALS REQUIRED FOR STUDY

Surgical gloves	Q.S
Sterile swabs	Q.S
Sterile gauze pieces	Q.S
Povidine Iodine	Q.S
Drape	• 1 in number
Disposable syringe of 50ml	• 1 in number
Disposable rubber catheter no. 7	• 1 in number
Shuddha sphaatika	• 500mg
Kasisadi taila	• 30ml
Distilled water	• 30ml
Steel bowl	• 1 in number
Ot table	• 1 in number

PROCEDURE**GROUP A - SPHATIKA JALA BASTI****PURVAKARMA**

Nature of the study was explained to the patient and consent was taken.

Materials Required: Sphaatika jala, rubber catheter no.7, 50cc syringe, gauze piece, bowl

The patient was instructed to come after a light diet in the morning.

The patient was advised to come after elimination of stool and urine.

PRADHANA KARMA

The patient was advised to lie down in left lateral position.

Anus and surrounding area was cleaned with antiseptic lotion and Draping was done.

30ml of Sphaatika jala(room temperature) was taken in a syringe and a rubber catheter fitted to the syringe.

After expelling the air from the syringe, the rubber catheter was lubricated and inserted into the anus of the patient.

Then the patient was asked to take a deep breath and drug was administered slowly.

Subjective parameter**1. Bleeding per rectum**

Sl. no.	Grade	Descriptions
1.	0	Nil
2.	1	Mild - Occasional episodes (during defecation)
3.	2	Moderate - frequent episodes (during defecation)
4.	3	Severe - Persistent bleeding (even without defecation)

PASCHAT KARMA

After administration of basti, patient was advised to lie down in an supine position for 10 mins

Basti Pratyagamana kala was noticed in each patient.

Pathya to be followed was advised to the patient.

GROUP B-KASISADI TAILA BASTI.

The Procedure of Kasisadi taila basti is same as that of Sphaatika jala basti, instead of Sphaatika jala, Luke warm Kasisadi taila is used.

After completion of 7 days of basti course, follow up assessment was carried out after 15days to evaluate therapeutic outcomes and monitor for any recurrence.

ASSESSMENT CRITERIA**1) SUBJECTIVE PARAMETER**

1. Bleeding per rectum
2. Constipation
3. Pruritis ani
4. Pain during defecation

2) OBJECTIVE PARAMETERS

1. Mass per anum

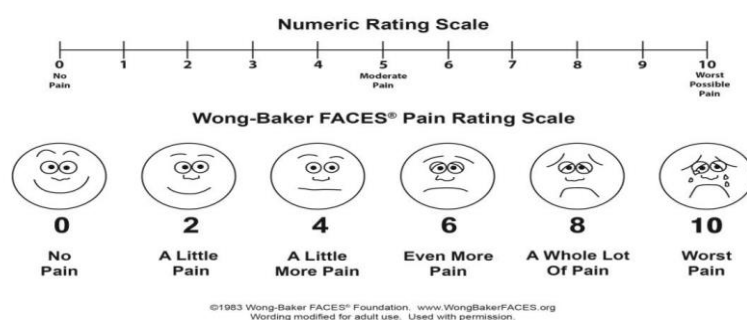
2. Constipation

Sl. no	Grade	Description
1	0	Absent
2	1	Manageable by changes in diet
3	2	Requires laxatives
3	3	Resistance to diet and laxatives, on enema

3. Pruritis ani

Sl. No	Grade	Description
1	0	No itching
2	1	Mild (Occasionally)
3	2	Moderate (Persist all the day)
4	3	Severe (Itch with scratch marks)
5	4	Continuous severe (Itch disturbs routine and night)

4. Pain - VAS SCALE



SL. No	Grade	Description
1	0	No Pain
2	1	Mild Pain(1-3)
3	2	Moderate pain(4-6)
4	3	Severe Pain(7-9)
5	4	Worst pain(10)

2. Objective parameters

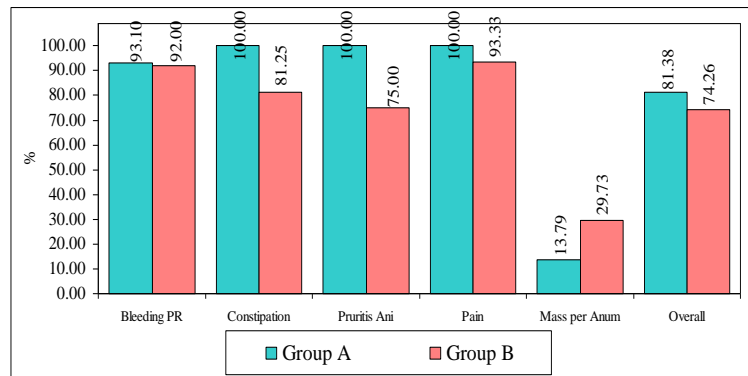
1. Mass per anum

Sl. no.	Grade	Description
1.	0	No Hemorrhoids
2.	1	No Hemorrhoidal prolapse - 1 st degree
3	2	Prolapse upon straining that reduces spontaneously - 2 nd degree
4	3	Prolapse upon straining that needs manual reduction - 3 rd degree

RESULTS

Showing the overall comparative results of Group A and Group B

Parameters	Changes	Group A	Group B
Bleeding PR	Before to after	93.10	92.00
Constipation	Before to after	100.00	81.25
Pruritis Ani	Before to after	100.00	75.00
Pain	Before to after	100.00	93.33
Mass per Anum	Before to after	13.79	29.73
Overall	Before to after	81.38	74.26



OBSERVATIONS

Sphatika jala basti in Group A



Before and After Treatment



Before and After Treatment

Kasisadi Taila basti in Group B



Before and After Treatment.



Before and After Treatment.

DISCUSSION

Probable mode of action of Sphatika jala basti

MECHANISM	MOLECULAR/PHYSIOLOGICAL BASIS	CLINICAL CORRELATION IN ARSHAS
Protein Coagulation and astringency	In aqueous solution, potash alum dissociates into Al^{3+} ions, which bind to negatively charged proteins on the rectal mucosa and vascular endothelium. This leads to protein precipitation, formation of a superficial coagulum, and tightening of tissues.	Shrinkage of haemorrhoidal cushions, reduction in mass per anum, mechanical sealing of small bleeding vessels. (Sankocha of gudankura)
Vasoconstriction and Haemostasis	Protein Coagulation and acidic pH (3-4) Cause capillary contraction and reduced vascular permeability.	Rapid control of bleeding per anum (Rakta srava nirodha)
Desiccant/Anti exudative effect	Alum's strong affinity for water draws fluid out of oedematous tissue.	Decrease in pruritis ani, reduction of mucosal seepage, relief of perianal irritation.
Anti inflammatory and Barrier Formation	Astringent protein film reduces local inflammatory mediators and protects nerve endings.	Decrease in Pain, Burning and Swelling.
Antimicrobial action	Al^{3+} ions and acidic environment are bacteriostatic against E.coli, Staphylococcus, and anaerobic flora.	Prevention of secondary infection and promotion of mucosal healing.
Basti effect (vata anulomana)	Rectal administration hydrates the rectum, softens stool, and stimulates peristalsis without excessive straining.	Relief of constipation, breaking the cycle of venous congestion and further pile formation.

Probable Mode of action of Kasisadi taila basti

Kasisadi taila basti helped in reducing the size of pile pedicle due to its mild corrosive (lekhana) effect. The acidic pH (around 3.7) of the formulation may contribute to controlled coagulation and sloughing of hypertrophied mucosal tissue and vascular walls, leading to shrinkage of the pile mass.

Pilot study and Dosage Standardization

Before initiating the main clinical trial, a pilot study was conducted to assess the tolerance and efficacy of sphatika jala basti in two dosage forms. For one group 500mg Sphatika in 30ml jala, and other group 1gm Sphatika in 30ml jala is given. Patients who received 1gm dosage, reported strong urge for defecation immediately after administration and in contrast the 500mg dosage was well tolerated by patients, allowing retention for adequate duration. Hence for the main study, 500mg in 30ml of shuddha jala was selected as the standardized therapeutic dose for Sphatika jala basti.

Discussion on Quantity and Duration

The basti volume was kept at 30ml, considering the localized action required in Guda pradesha and ensure patient comfort and easy retention. Though 1 pala is the Standard for Matra basti, the reduced volume was appropriate for Arsha management where sthanika karma is desired rather than systemic effect.

The procedure was carried out once daily for 7 consecutive days, following the Matra basti principle of being safe for daily use without Ahara-vihara restrictions. The 7day schedule was sufficient to achieve notable improvement in pain, bleeding, and swelling without causing irritation or dryness of rectal mucosa.

Patient Tolerance and Therapeutic Superiority of Sphatika jala basti.

In this study, Sphatika jala basti showed better results and higher patient comfort compared to Kasisadi taila basti. Patients with erosions or inflamed haemorrhoids often experienced burning or pain with Kasisadi taila due to its Ushna and Teekshna Dravyas. In contrast

eventhough Sphatika possesses Ushna veerya, its predominant Kashaya rasa and Ropana properties counteract the irritant effect and contribute to a soothing and healing effect, and it is better tolerated in patients with sensitive or eroded rectal mucosa, leading to superior symptomatic relief.

CONCLUSION

- The present study was conducted on 40 patients who were diagnosed with Arshas were randomly divided into 2 groups. Patients of Group A were treated with Sphatika jala basti and Group B patients were treated with Kasisadi taila basti.
- The overall changes is higher in Group A(81.38%) as compared to Group B (74.26%).
- Sphatika jala basti is minimally invasive, simpler, cost-effective, and patient-friendly preparation can provide results comparable to the classical standard and broaden the therapeutic options in the management of Arshas.
- Patients of both the groups were cooperative, withstood the procedure well.
- No untoward effects were observed in any of the cases in both the method of management.
- By this study it can be concluded that Sphatika jala basti is more effective than Kasisadi taila basti in the management of Arsha.

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