

A Comparative Clinical Study of *Gudavarti* and *Kasisadi Taila* in the Management of *Arsha* (1st and 2nd Degree Internal Hemorrhoids): A Randomized Comparative Clinical Trial

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ABSTRACT

Background: Hemorrhoids is a very common disease among ano-rectal condition which is estimated about 50–85% of people worldwide experience hemorrhoids, with approximately 75% of the population in India being affected. **Aims:** To compare the clinical efficacy of *Gudavarti* insertion and *Kasisadi Taila* instillation in the management of *Arsha* (1st & 2nd degree internal haemorrhoids). **Materials and methods:** 30 patients of *Arsha* were registered and allocated into two groups by computer generated randomization method. In group A, 15 patients were treated with *Gudavarti* insertion once in a day. In group B, 15 patients were treated with *Kasisadi Taila* 10ml instillation once daily. Sitz bath with *Panchavalka Kvatha* (10 gm) twice a day and *Triphala Guggulu* one gram three times a day after food was given orally in both the groups for two weeks. **Results:** The result was assessed on the basis of sign and symptoms i.e bleeding per rectum, pain in ano, prolapsed pile mass, discharge per rectum and constipation. Statistical calculation was done using Wilcoxon signed-rank test within the group and Mann Whitney Rank Sum Test between the groups. Significant results were observed in bleeding per rectum and constipation in Group A. Highly Significant results were observed in bleeding per rectum and constipation in Group B. **Conclusion:** The study concluded that *Kasisadi Taila* 10ml instillation is a better option in the management of *Arsha* (1st and 2nd degree internal haemorrhoids) as compare to *Gudavarti* insertion.

Keywords: *Arsha*; *Gudavarti*; Hemorrhoids; *Kasisadi Taila*

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INTRODUCTION

Hemorrhoids are a very common disease among anorectal conditions. It is estimated that 50–85% of people worldwide experience hemorrhoids, with approximately 75% of the population in India being affected.^[1] It causes discomfort, pain, and bleeding, disrupting daily routine life, and some patients may land up in anemia. It is progressively increasing day by day due to sedentary lifestyle, irregular and unhealthy diet, prolonged sitting or standing, and certain psychological disturbances in the present era. If not treated at an early stage, it can progress to a more serious stage, requiring surgery. Moreover, most of people are interested to avoid the surgical procedures due to fear of complications and bleeding. Hence, it would be ideal if it could be treated at an early stage (1st and 2nd degree) with simpler, more accessible treatment options. Furthermore, a greater number of patients can be managed conservatively if diagnosed earlier.

According to *Ayurveda*, four kinds of treatment as per severity of *Arsha* (hemorrhoids) are mentioned in *Sushruta Samhita*, that is, (i) *Bheshaja Chikitsa* (palliative treatment), (ii) *Kshara Karma* (potential cauterization agent therapy), (iii) *Agni Karma* (direct cauterization agent therapy) and (iv) *Shastra Karma* (operation by sharp instruments).^[2] Among the treatment modalities, two of them are available in the form of external application for 1st and 2nd degree hemorrhoids, which are taken for the present study, known as *Gudavarti* and *Kasisadi Taila*. In classics, *Gudavarti* and *Kasisadi Taila* are indicated for the treatment of *Arsha* as a local application.^[3,4] It is mentioned that it destroys the *Arsha* like *Kshara* without hampering the normal structure of *Guda*.^[5] Hence, here *Gudavarti* and *Kasisadi Taila* were selected for the management of 1st and 2nd degree hemorrhoids as conservative measures.

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MATERIALS AND METHODS

The participants were recruited from the outpatient and inpatient sections of the Department of Shalya Tantra, I.P.G.T. and R.A. Hospital, Jamnagar, to participate in this randomized, comparative clinical interventional study. The study was approved by the Institutional Ethics Committee (IEC) (vide letter no. PGT/7-A/Ethics/2018–2019/2638, dated December 18, 2018) and was prospectively registered in the Clinical Trial Registry of India (CTRI/2019/01/017268, dated January 25, 2019) prospectively. Participants were informed about the objectives of the study and the treatment procedures, ensuring their understanding, and written informed consent was obtained before their inclusion in the study.

Inclusion Criteria

A total of 30 patients aged between 18 and 65 years diagnosed with *Arsha* (1st and 2nd degree internal hemorrhoids) presenting with symptoms such as *Raktasrava* (bleeding per rectum), *Guda Shoola* (mild pain or discomfort in the anal region), *Bramsha* (prolapse of hemorrhoids), *Piccha Srava* (mucous discharge per rectum), and *Vibandha* (constipation) were included in the study. Participants were selected irrespective of sex, religion, or occupation.

Exclusion Criteria

Patients suffering from 3rd and 4th degree hemorrhoids, partial or complete rectal prolapse, acute or chronic anal fissure, fistula-in-ano, uncontrolled hypertension, diabetes mellitus, cardiac disorders, malignancy of ano-rectum, pregnant women, and Hepatitis B, tuberculosis, human immunodeficiency virus, and Venereal Disease Research Laboratory positive cases were excluded from the study.

Grouping and Posology

Patients were randomly divided into two groups (15 patients in each group) with *Gudavarti* (Group A) and *Kasisadi taila* (Group B) [Figure 1]. Randomization was carried out by a computerized randomization method (<http://www.randomization.com>). It was

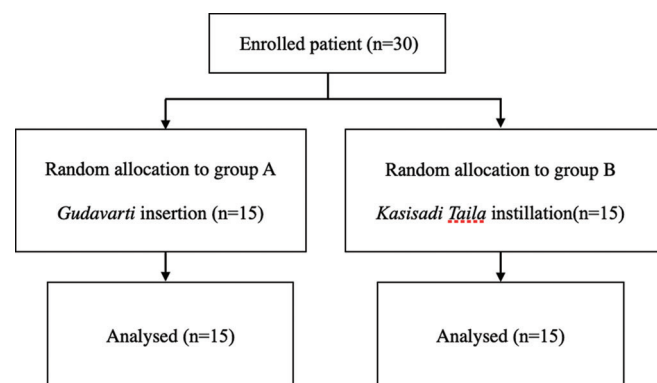


Figure 1: Participant flow in the chart



Figure 2: Gudavarti

an open-labeled study with no blinding. The sample size was calculated for comparison of two independent groups using $n = 2(Z\alpha/2 + Z\beta)^2\sigma^2/d^2$.

n = Sample size required in each group, $Z\alpha/2$ = Standard normal deviate at 5% level of significance (1.96), $Z\beta$ = Standard normal deviate corresponding to 80% power (0.84), σ = Pooled standard deviation of bleeding per rectum improvement was approximately 0.74, d = Expected mean difference between groups was approximately 0.19.^[6] The calculated minimum sample size was approximately 15 participants per group.

Group A: Gudavarti insertion

Gudavarti was prepared by mixing *Jeemutaka* (*Luffa echinata* Roxb.) powder and *Dhanyamla* (sour rice gruel) [Figure 2].^[3] Every morning after defecation, the patient was advised to lie down in the left lateral position and gently insert *Gudavarti* in the anal canal, ensuring sufficient lubrication with *Jatyadi Ghrita*. The patient was asked to lie down for a minimum period of 15 min in the same position. The procedure was repeated daily for 14 days.

Group B: Kasisadi Taila instillation

The patient was taken in the lithotomy position, and 10 mL *Kasisadi Taila* was instilled in the anal canal with the help of 20 mL syringe and No. 7 red rubber catheter. The procedure was repeated daily for 14 days.^[4]

General Management in Both Groups

Sitz bath with *Panchavalka Kwatha* (ten gram) twice a day and *Triphala Guggulu*, two tablets of 500 mg thrice a day (total three gram per day) with lukewarm water after meal were given in both group.

Follow-up

Follow-up was done in 7 days interval for 2 weeks after completion of the treatment.

Assessment Criteria

Efficacy was assessed for reduction in intensity of bleeding per rectum, painful defecation, prolapsed hemorrhoids, discharge per rectum, and constipation based on gradations.

Statistical Analysis

The results were evaluated using the Wilcoxon test within the

Table 1: Clinical characteristics

Clinical characteristics	Observation in percentage
Constipation	70.0
Bleeding per rectum	63.33
Syringing nature of bleeding	57.89
Prolapsed pile mass (spontaneous reducible)	60.0
Position of hemorrhoids	
3 o'clock	29.31
7 o'clock	43.10
11 o'clock	27.58
Degree of pile mass	
1 st degree	65.62
2 nd degree	34.37

Table 2: Effect of Gudavarti on clinical symptoms of Arsha (Group A) (Wilcoxon test)

Symptom	Day 7 Improvement (%)	Day 14 Improvement (%)	P value	Significance
Bleeding per rectum	0	66.66	0.031	Significant
Pain in ano	50	50	0.125	Not significant
Prolapse of hemorrhoids	0	0	0	Not significant
Discharge per rectum	0	100	0.346	Not significant
Constipation	37.5	75	0.0156	Significant

Table 3: Effect of Kasisadi Taila on clinical symptoms of Arsha (Group B) (Wilcoxon test)

Symptom	Day 7 Improvement (%)	Day 14 Improvement (%)	P value	Significance
Bleeding per rectum	0	86.36	0.0001	Highly significant
Pain in ano	25	62.5	0.0547	Not significant
Prolapse of hemorrhoids	28.57	28.57	0.081	Not significant
Discharge per rectum	-	-	-	Not applicable
Constipation	61.53	100	<0.001	Highly significant

Table 4: Intergroup comparison of therapeutic effect between Group A and Group B (n=15 each) (Mann-Whitney Rank Sum Test)

Symptom	Group A Improvement (%)	Group B Improvement (%)	P value	Significance
Bleeding per rectum	66.66	86.36	<0.001	Highly significant
Pain in ano	50	62.5	>0.05	Not significant
Prolapse of hemorrhoids	0	28.57	>0.05	Not significant
Discharge per rectum	100	-	-	Not comparable
Constipation	75	100	0.027	Significant

group. Mann-Whitney Rank Sum Test was used for comparing results between the two groups. Statistical analysis was done by IBM Statistical Package for the Social Sciences software version 27 (IBM Corp., Armonk, N.Y., USA).

RESULTS

A total of 30 participants were enrolled for participation in the study. All 30 participants completed the study, and their data were used for analysis.

Clinical Characteristics

Details of the clinical characteristics are given in Table 1.

Effect of Therapy on Clinical Symptoms

The effect of Gudavarti (Group A) and Kasisadi Taila (Group B) on the clinical symptoms of Arsha was assessed over a treatment period of 14 days.

In Group A, significant improvement was observed in bleeding per rectum (66.66%, $P = 0.031$) and constipation (75%, $P = 0.0156$) by the 14th day of treatment. Relief in pain in ano (50%) and discharge per rectum (100%) was observed; however, the changes were statistically insignificant. No improvement was noted in prolapse of hemorrhoids during the study period [Table 2].

In Group B, bleeding per rectum showed 86.36% improvement with highly significant results ($P = 0.0001$). Constipation also showed highly significant improvement with complete relief (100%) by the 14th day ($P < 0.001$). Improvement was observed in pain in ano (62.5%) and prolapse of hemorrhoids (28.57%); however, these changes were statistically insignificant. No patients in Group B presented with discharge per rectum [Table 3].

On inter-group comparison, a highly significant difference was observed in bleeding per rectum ($P < 0.001$) and a significant

difference in constipation ($P = 0.027$), indicating better therapeutic response in Group B compared to Group A. No statistically significant difference was observed between the groups in pain in ano and prolapse of hemorrhoids [Table 4].

All patients completed the follow-up period without any problems.

DISCUSSION

Maximum 96.66% were male patients in the study, which goes in accordance to other studies.^[7] The maximum number of patients were servicemen, as they are more prone due to sitting job and have an irregular and improper diet, which leads to constipation and thereby hemorrhoids. *Lavana Rasa* and *Madhura Rasa* dominant diet were maximum reported. These *Rasa* increase *Kapha*, which causes *Agnimandhya* leading to constipation. Constipation was noted by maximum patients, which gives rise to pressure on the valve of blood vessels of the rectum during defecation, which leads to engorgement of veins in hemorrhoid.^[11]

Jeemutaka has anti-inflammatory (*Sophahara* properties) and anti-thrombogenic properties, which helped in reduced bleeding per rectum.^[8] *Dhanyamla* has *Ushna*, *Tikshna*, *Laghu* properties, so it reduces local inflammation and pain in the ano. *Lekhana Karma* of *Dhanyamla* helps to reduce the size of the mass, which prevents further mechanical damage.^[8] *Varti* helps to expel *Sanchita Dosha* (*Mala*, *Mutra*, *Puya*, *Rakta*, etc.) from the inserted area, thereby reducing the straining during defecation and also controls the local infections.

Reduction in size of hemorrhoids by local application of *Kasisadi Taila* renders corrosive action on the wall of affected veins by acidic nature. Pain and bleeding may be reduced due to decreased pressure of stool on veins and sphincters by soothing effect of *Kasisadi Taila*. *Ushna*, *Tikshna* and *Snigdha Guna* of *Kasisadi Taila* may correct the *Vatadusti* and regulate the function of *Apana Vata*, which breaks the *Samprapti* (Pathogenesis) and cure the disease.^[9]

Guggulu is *Sukshma*, *Lekhaneeya* and *Sara*, which helped in *Shodhana* and *Ropana*. Pharmacologically, *Guggulu* has properties of anti-inflammatory and immunomodulatory action.^[10] Thus, it acts as an anti-inflammatory and analgesic drug, which helped in relieving congestion of piles and decreased pain in ano.

Warm water sitz bath with *Panchvalkala Kwatha* was advised in both the groups. *Panchvalkala Kwatha* has proven anti-inflammatory properties. It relieves venous congestion and spasm of internal sphincter muscles. It plays an important role in maintaining local hygiene, *Shodhana* and *Ropana* of wound.^[11]

Limitation

This study was done with a small sample size and in a limited geographic area. It may cause the limited findings. Hence, future studies should be done with a larger sample and in a larger area.

CONCLUSION

Kasisadi Taila instillation gave better results than *Gudavarti* insertion in bleeding per rectum, pain in ano, prolapse of pile mass, and constipation in patients. Thus, this study can be concluded that *Kasisadi Taila* instillation is a better option in the management of *Arsha* (1st and 2nd degree internal hemorrhoids) as compared to *Gudavarti* insertion.

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