

“A single-arm, open-labeled pilot study to evaluate the efficacy of a polyherbal combination Arshna and Sepnil cream for the management of Arsha (Hemorrhoids)”

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Abstract-

Background- Hemorrhoids are dilated veins within the anal canal in the sub epithelium and are formed by the radicals of the superior, middle and inferior veins. In other words hemorrhoids are swollen veins that occur in the anus and lower rectum. The prevalence of hemorrhoids in India is around 40 million. In Ayurveda Management of Arsha is mentioned in all three main *Samhitas*. **Material and Methods-** In this study 41 patients with 1st, 2nd, 3rd degree hemorrhoids visiting Ayushakti Ayurveda Pvt Ltd Malad, Mumbai-64 were recruited. The assessment was carried out at the end of every 8 weeks during study. During each visit following signs and symptoms were analyzed- Pain in ano rectum VAS grade, inflammation, Itching per Ano, Bleeding per ano, Constipation. **Results-** Highly significant difference (<0.0001) was observed in pain in ano, inflammation, per rectum bleeding, itching in perianal area, constipation. In all the symptoms 100% results was observed at the end of the study. **Conclusion-** This pilot study concludes tablets *Arshna* and Sepnil cream for local application have the potential to cure *Arsha*/hemorrhoids.

Keywords- Arsha, Hemorrhoids, Arshna tablet, Spnil cream.

INTRODUCTION-

Hemorrhoids are dilated veins within the anal canal in the sub-epithelium and are formed by the radicals of the superior, middle, and inferior veins. In other words, hemorrhoids are swollen veins that occur in the anus and lower rectum. The prevalence of hemorrhoids in India is around 40 million according to a recent survey ^[1]. The prevalence of hemorrhoids in the adult population in India is about 11% ^[2]. Hemorrhoids swelling occurs when there is an increase in the pressure in the small vessels causing them to swell and engorge with blood, the major causes of hemorrhoids include chronic constipation, poor dietary habits, sedentary lifestyle, lack of required consumption of water, and straining while defecation ^[3]. The most common symptoms associated with hemorrhoids are itching, tenesmus, perianal pain, bleeding, while defecation, and even mucus in the stool. Bleeding per rectum is the most common and troubling symptom seen in patients^[4]. The management depends on the severity of the signs and symptoms present in the patients. Medical management focuses on the management of symptoms of perianal pain by using local anesthetics, topical analgesics, and corticosteroid creams. Some oral supplements with fibers, some laxatives, and some oral NSAIDs are used to get relief from pain. The surgical management includes cryotherapy, sclerotherapy, and rubber band ligation, open, closed, or stapled hemorrhoidectomy^[5].

Sushrutacharya has mentioned four tools in the management of *Arsha* and they are *Bheshaj* (medicines), *Kshar karma* (application of kshar), *Agnikarma* (cautery), and *Shashtra karma* (surgery)^[6]. On the other hand Charakacharya has given more weight to *Bheshaj chikitsa* (medicines) even he has given separate chapters as *Arsha Nidan* and *Arsha chikitsa*⁷. Still in this time there is tomophobia in people and to avoid post-surgical complications in anorectal diseases society searches for alternate therapies that can treat the disease from root, and here is the scope for integrated medicines to open their hand with great results. Hence

here the study was planned to check usefulness of Arshna and an ointment Sepnil in patients diagnosed with *Arsha* (hemorrhoids).

OBJECTIVES-

1.To assess the efficacy of Tablet Arshna and ointment Sepnil in the management of *Arsha* (hemorrhoids).

MATERIAL AND METHODS-

As this is proof of concept, the sample size of 41 patients in the study was considered sufficient. 41 patients visiting Ayushakti Ayurveda Pvt Ltd, Bhadran Nagar cross lane-2, near Milap cinema, Malad, Mumbai-64 and having complaints of pain in ano, inflammation, per rectum bleeding, itching in the perianal area, constipation selected in the study. Detailed clinical history, and physical and other disease-related findings were recorded in the clinical research proforma.

Ethical clearance-

This study was approved by Ayushakti Independent Ethics Committee, malad, Mumbai-64 (ECR/370/Indt/MH/2023). As it's a pilot study CTRI registration was not done.

Inclusion criteria-

- Patients irrespective of gender and between the ages of 18 years and 60 years having 1st, 2nd, and 3rd degree of hemorrhoids confirmed by proctoscopy.
- Patients who agree with the study procedure and were ready for a written informed consent and satisfying the selection criteria.

Exclusion criteria-

- Patients with Grades-4 or prolapsed hemorrhoids.
- Patients with pregnancy induced hemorrhoids and lactating women.
- Patients suffering from chronic diseases like Carcinoma of Anus & Rectum, Ulcerative colitis, Perianal Abscess, Proctitis, etc. other complications were not included.
- Patients currently using other anti haemorrhoidal medicines.
- Patients have taken any herbal medications in the last 30 days.
- Patients planning to undergo any surgical procedure for hemorrhoids.
- Patients with anemia or any major hepatic, renal or cardiovascular ailments were excluded.

Investigations-

Hematological investigations viz. hemoglobin, total and differential leucocyte count, ESR

Biochemical investigations viz. liver function test and renal function test

Trial herbal remedies-

The study tablet Arshna and Sepnil cream for local application were supplied by Ayushakti Ayurveda Pvt Ltd.

Table.1: Arshna tablet ingredients-

Ingredients	Latin name	Part used	Quantity in Mg
Chitraka	Plumbago zeylanica	Root	33.20
Suran	Amorphophallus paeoniifolius	Root	54.35
Kanchanar	Glycerrhiza Glabra	Root	38.50

Gairik	Red Ochre		12.00
Haridra	Curcuma longa	Rhizome	35.50
Haritaki	Terminalia chebula	Fruit	38.50
Kalmegh	Andrographis paniculata	Whole plant	62.00
Kutaj	Wrightia antidysenterica	Bark	40.50
Nagkeshar	Mesua ferrea	Flowers	68.53
Trikatu	Zinziber officinale,Piper nigrum,Piper longum.	Rhizome,fruit , fruit.	33.20
Saindhav	Rock salt/Bay salt		33.20

Table.2: Sepnil cream ingredients-

Ingredients	Latin name	Part used	Quntity in Mg
Mahatikta ghruta	Bhaishajya ratnavali	Ghrut	20.00
Gughruta	Bhaishajya ratnavali	Gughruta	15.00
Kumari	Aloe vera	Leaf	1.4
Shodhan tail	Bhaishajya ratnavali	Oil	7.00
Guduchi extract	Tinospora cardifolia		6.800
Neem extract	Azadirachta indica	Leaf	3.600
Khadira extract	Acasia Catechu	Bark skin	5.700
Daruharidra extract	Berberis aristata	Rhizome	3.600
Cream base			qa

Dose and Duration-**Tablet-**

Tablet Arshna 2 times a day after food with lukewarm water.

Ointment-

Local application of sepnil cream with finger before and after defecation in sufficient quantity around the anal opening..

Study Duration-

Each participant will be in the study for 2 months. The entire study duration was around 5 months.

Study Procedures-

Potential trial participants were screened at Ayushakti Ayurved Pvt Ltd, Badhran nagar cross lane-2, near Milap cinema, Malad west, Mubmbai-64, following written informed consent, eligible participants were enrolled in the study. During the study period, there were a total of 5 visits including the Screening visit. After reviewing the eligibility of the patient he/she were enrolled in the study

Assessment Criteria-

The assessment was carried out at the end of every 8 weeks during study, and the patient will be in the study for 32 weeks. During each visit following signs and symptoms were analyzed- Pain in ano rectum VAS grade, inflammation, Itching per Ano, Bleeding per ano, Constipation.

Assessment-

Complete remission- 100% improvement in signs and symptoms.

Marked improvement - >75-99% improvement in signs and symptoms.

Moderate improvement- >50-75%improvement in signs and symptoms.

Mild improvement - > 25-50 % improvement in signs and symptoms.

No improvement - < 25%improvement in signs and symptoms.

Statistical analysis-

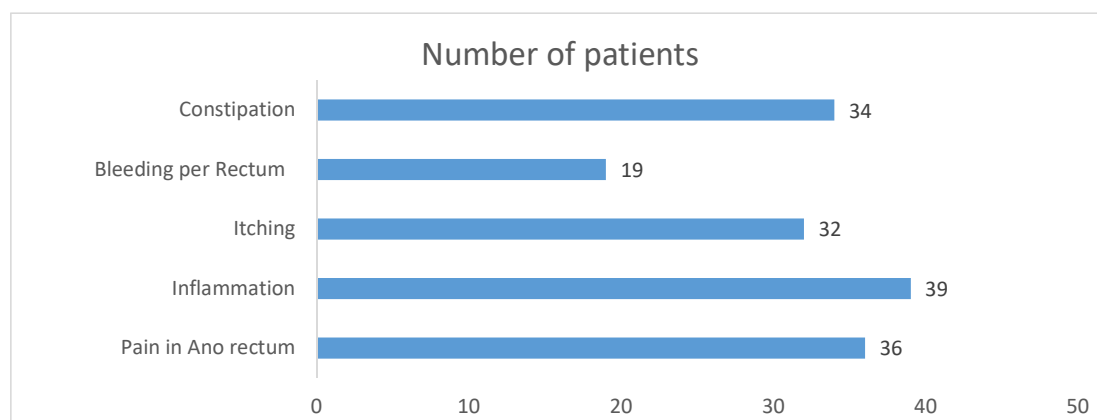
Wilcoxon sign rank test was used to analyze the results and then final conclusion was obtained.

OBSERVATION AND RESULTS-

In this study, out of 51 patients, a maximum 23 patients were males because of male predominance in Ayushakti anorectal department. Total number of patients completing the study as per protocol were 41 patients. The average age of the patients was 48.21 years with standard deviation of 11.32.

Among all the cases 87.8 % patients had a complaint of pain in ano rectum region, 95.1% patients had inflammation around the anal area, about 70% patients' complaint itching around the anal area, 47.3 % had bleeding per rectum,82.9 % patients had a history of constipation. Results are shown in Chart-1

Chart-1 :symptom wise distribution of patients.



It was observed that 36% patients had 1st degree internal piles, patients with 2nd degree hemorrhoids were observed 24%, and about 4% patients had 3rd degree hemorrhoids, 11% patients had external hemorrhoids and 25% had both internal and external hemorrhoids. Results are shown in Chart-2

The pain was reduced by 66% in first 15 days and 99.85 relief was found at the end of the study after 2 months. Inflammation was reduced by 60 % in first and 15 days and 99.85% difference was observed at the end point. Itching was found to be reduced by 99.17 % in the first 15 days itself. Bleeding was reduced in almost all the 19 patients with 100% significant difference. Constipation was reduced by 99.97% at the end of the study in 2 months. (Table-3)In overall assessment it was found that 7 patients were completely cured, and 34 patients got marked improvement. (Table-4)

Chart-2 : Degree and type of hemorrhoids.

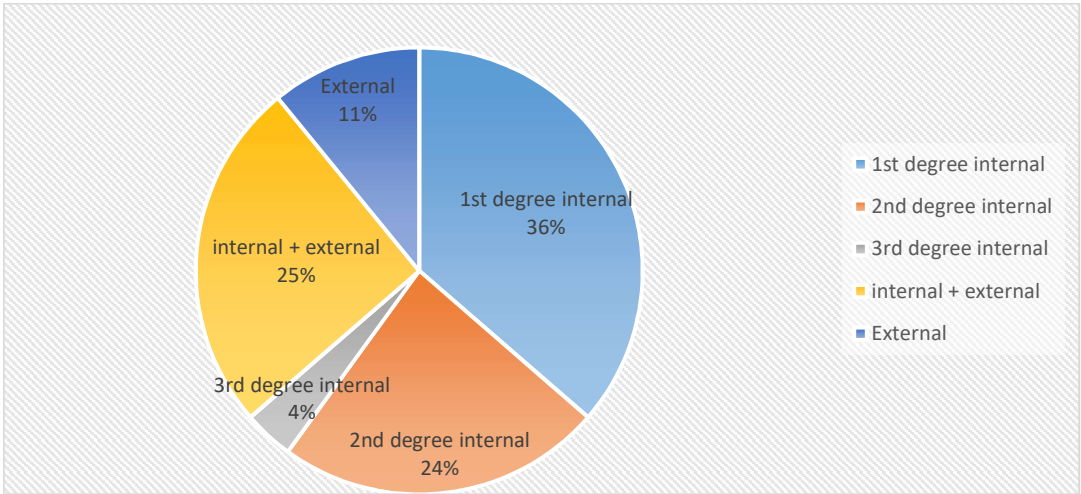


Table-3: Effect of therapy on hemorrhoids symptoms.

	Mean						
Symptoms	BT	AT	% Relief	SD	W	P value	Significance
Pain in Ano rectum	1.24	0.15	99.85	0.45	816	<0.0001	****
Inflammation	1.2	0.15	99.85	0.42	528	<0.0001	****
Itching	1.09	0.024	99.97	0.47	586	<0.0001	****
Bleeding per Rectum	0.76	0.024	99.97	0.29	171	<0.0001	****
Constipation	0.80	0.024	99.97	0.36	561	<0.0001	****

Table-4: Overall assessment of patient.

Improvement	Number of patients
Complete cured	6
Marked improvement	34
Moderate improvement	1
Mild improvement	0
Unchanged	0

DISCUSSION-

According to Sushruta *Nidanas* (causative factors) vitiates of *Doshas* in a single, combination of two or more along with *Rakta* in the individuals with a complaint of *Mandagni*, *Dosha* move downwards reaching *Guda* and affecting the *Gudavalitraya* ultimately causing *Arshas* ^[8]. Charaka opined that *Arshroga* is produced due to the vitiation of *Tridosha* which affects the *Gudavalitraya* ^[9]. As per Vagbhatacharya vitiated *tridosha* causes *Mandagni* (decreased appetite) and vitiation of *Apan vayu* resulting in *Malavshatambh* (constipation) and prolonged contact of *Mala* in *Gudavalitraya* leads to the formation of *Arshas*. The treatment fundamentals in Piles are shrinking piles mass, reducing the inflammation, curing the itching, preventing bleeding from the rectum, and relieving constipation.

Table.5: Tablet Arshna-

Probable mode of action of Arshna table			
Sr. no.	Sanskrit name	Latin name	Properties
1	<i>Nagkeshar</i>	Mesua ferrea	Nagkeshar leaves are tested for antioxidant activity, leaves possess analgesic activity, stem bark have promising anti-inflammatory activity, extract have antispasmodic activity, and it also has wound activity ^[10]
2	<i>Haritaki Ghan</i>	Terminalia Chebula	It is used as a laxative, carminative, and antioxidant action ^[11]
3	<i>Suran</i>	(Amorphophallus campanulatus)	It has properties of <i>Deepana</i> , <i>Pachana</i> , <i>Vatanulomana</i> , and <i>Ushna guna</i> hence it has anti-inflammatory activity, it has <i>Prabhav</i> (special effect) as <i>Arshoghna</i> . <i>Ushna</i> and <i>Tikshna guna</i> help <i>rakta</i> dhatu to flow regularly at veins hence <i>shotha</i> (swelling) reduces and eventually pile mass decreases. ^[12]
4	<i>Kutaj</i>	Holarrhena antidysenterica	<i>Tikta</i> , <i>kashaya rasa</i> and <i>shita virya</i> of <i>Kutaja</i> bark have <i>stambhana</i> property to stop bleeding. ^[13]

5	<i>Haridra</i>	Curcuma longa	<i>It is Tridosha shamaka, Varnya, Lekhana, Vishagna, Krimigna, vranashifhaka, vranropana and Ushna Veerya analgesic and anti microbiotics.</i> ^[14]
6	<i>Kanchanar</i>	Glycerrhiza Glabra	It is <i>Kashaya, laghu</i> and <i>Sheet</i> hence it's a blood purifier, It has anthelmintic activity, anti-inflammatory activity, and wound healing property. ^[15]
7	<i>Kalmegh</i>	<i>Andrographis paniculata</i>	It exhibits anti-inflammatory, antibacterial, antioxidant, ant parasitic, antispasmodic activities. ^[16]
8	<i>Praval</i>	Clerodendrum serratum	It is <i>Madhura</i> and <i>Sheet</i> hence it's a <i>raktaprasadak, pittashamak.</i> ^[17]
9	<i>Gairik</i>		Being astringent, sweet in taste (<i>Rasa</i>), sweet after digestion (<i>Vipaka</i>), and cool in potency (<i>Virya</i>), It is <i>Shonitsthapana</i> (Haemopoitic & Haemostatic). ^[18]

Table-6: Sepnil cream-

Probable mode of action of Sepnil cream			
Sr. no.	Sanskrit name	Latin name	Properties
1	Mahatikta ghruta	Bhaishajya ratnavali	It has anti-inflammatory, and pain relieving action, it works on boils. ^[19]
2	Gughruta	Bhaishajya ratnavali	It is <i>Mrudu</i> (soft), and <i>Snigdha</i> (oily) hence it is smooth, lubricating, and nurturing. ^[20]
3	Kumari	Aloe vera	It shortens the duration of healing, its wound healing, anti-inflammatory,

			immunity, antioxidant, laxative, antibacterial, antifungal effects [21,22]
4	Shodhan tail	Bhaishajya ratnavali	It's an antibacterial, anti-slough properties ultimately healing the wound.[23]
5	Guduchi extract	Tinospora cardifolia	It boosts the healing process of wound by removing skin debris, pus and dirt particles.[24]
6	Neem extract	Azadirachta indica	Local applications have an anthelmintic effect, it has antimicrobial and antioxidant properties. [25]
7	Khadira extract	Acasia Catechu	It has Tikta, kashay rasa, laghu, Ruksha guna hence it functions as anti-itching, Raktaprasadak [26]
8	Daruharidra extract	Berberis aristata	It is of Tikta and Kashaya ras hence it has Arshoghna, Shothaghna, Raktashodhak and Vranaropaka properties. [27]
9	Yashtimadhu extract	<i>Glycyrrhiza glabra</i>	It reduces mucosal congestion hence heal the pile mass.[28]

CONCLUSION-

From this pilot study, we can conclude that tablet Arshna and Sepnil cream are effective in the treatment of primary and secondary, bleeding hemorrhoids. During the treatment, no side effect was found. All the safety parameters were found within normal limits. Even with the help of this combination bleeding per rectum was also stopped. However long-term follow study with larger participants is necessary.

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