



A CLINICAL STUDY TO EVALUATE THE EFFICACY OF AN INDIGENOUS COMPOUND LEPA IN ABHYANTARA ARSHAS.

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ABSTRACT

The term Arsha is generally defined as the disease, which tortures the person like an enemy. Arsha is considered as one of the Asthamahagada by Acharya Sushruta. Aetiological factors are vitiation of Doshas in Gudavalis, injury due to throne, stone, nail, vehicle, regular contact of cold water etc. Arsha is commonly known as Haemorrhoids (Piles). Haemorrhoids are the varicosity of haemorrhoidal veins. Depending on the site these are 3 types viz, Internal, External and Interno-external Haemorrhoids.

The presently available treatment measures are Bleshaja, Shashtra, Kshara and Agnikarma. Local application is described by Sushruta, Charaka, Yogaratnakara and others. Hence the present clinical study was aimed to evaluate the efficacy of an Indigenous Compound Lepa in Abhyantara Arsha mentioned in Arshoadhikara of Yogaratnakara.

A total number of 40 patients were randomly selected for the study. The Indigenous compound lepa (i.e, Haridra + Koshataki + Saindhava Lavana + Snuhi ksheera + Gomutra) was applied locally on Abhyantara arsha ankura for 2 minutes by sterile scoop under local anesthesia for 1 sitting. Being local application, the quantity of the drug depended upon the size of Arsha ankura. Assessment was made on 1st, 7th and 15th day and results were statistically analyzed.

Keywords: AYURVEDA; ABHYANTARA ARSHA; HAEMORRHOIDS; INDIGENOUS COMPOUND LEPA.

INTRODUCTION

Ayurveda is the science of life. Since time immemorial, Ayurveda has been showing the ideal way of living, which promises a disease free, happy and long-life. The entire science of Ayurveda is based upon Trisutra i.e. Hetu, Linga and Oushadha. Among these three, Aushadha plays an important role in chikitsa. The Shalyatantra, a prime branch is rich in much aspect of modern surgical concepts. Acharya Sushruta, the Father of Surgery elaborately described about the Arsharoga in his treatise under the heading of Astamahagadas¹ as it is Deerghakalanubandhi, Dushchikitsya in nature, & Tridoshaja Vyadhi and involves the marma.

Arsha is defined as the fleshy projection which creates obstruction in anal passage, kills the life like enemy². This dreadful disease can affect anyone, anytime, anywhere. Arsha occurs in Guda region, manifestation of the disease occurs due to many factors ex., sedentary lifestyle, improper diet intake, prolonged standing or sitting, faulty habits of defecation etc, which results in derangement of Jatharagni leading to vitiation of Tridosha, mainly Vata dosha. These vitiated Doshas get localized in Gudavali and Pradhana Dhamani which further vitiates Rakta, Mansa, Meda and Twak, dhatus due to Purishavaha srotodushti which in turn leads to constipation, itching, burning sensation and pain in the region of Guda and finally bleeds leading to development of Arsha³.

Arsha may be compared with Haemorrhoids, derived from the Greek word Haima (Bleed) + Rhoos (flowering), means bleeding, which is the dilatation of the haemorrhoidal plexus of veins; situated in the lower portion of the rectum and in the sub epithelial region of anal canal⁴. Approximately, 50% of the populations over the age of 50 years are suffering from Haemorrhoids⁵. It is found more in persons who are prone to the usage of incompatible foods and low roughage diet, suppression of natural urges, sedentary life-style, alcoholism, worry, tension. Other contributing factors include pregnancy, ageing, chronic constipation or diarrhoea and some other ano-rectal diseases.

The modern modalities of treatment for Haemorrhoids are sclerotherapy, rubber band ligation, cryosurgery, infrared photo coagulation, staple techniques, haemorrhoidectomy have their own limitations.

"Acharya Sushruta" - a pioneer in the field of surgery has developed four treatments for Haemorrhoids, apparently categorized based on specific symptoms. (a) Bhashaj Chikitsa (b) Kshara Karma (c) Agni karma (d) Shashtra karma⁶. He has emphasized (first and foremost) more on medicinal and para-surgical procedures then has laid importance to surgery.

Acharyas like Sushruta, Charaka, Chakradutta, Vangasena, Yogaratnakara explained curative measures for management of Arsha, including oral medications and local applications which are simple, effective and least invasive. Lepas can also be used in the persons who have fear to undergo surgery. Among them an Indigenous Compound lepa prepared with equal quantity of Haridra churna, Koshataki churna, Saindava lavana added with Snuhi ksheera and Gomutra mentioned in the Arshoadhikara Adhyaya of Yogaratnakara⁷ is undertaken for the present study.

OBJECTIVES OF THE STUDY

To evaluate the efficacy of an Indigenous compound Lepa in the management of Abhyantara Arsha.

MATERIALS AND METHODS

Source of data

For the present clinical study 40 Patients were selected from the OPD of Shalya tantra Department of Sri Siddharoodha Charitable Hospital, attached to N.K.Jabshetty Ayurvedic Medical College & P.G Research Centre, Bidar.

Method of collection of Data

In this clinical study, 40 patients suffering from Abhyantara Arsha were selected by Simple Randomized Sampling procedure on the basis of inclusion and exclusion criteria.

SELECTION CRITERIA

INCLUSION CRITERIA

1. Patients with 1st and 2nd degree Internal Haemorrhoids.
2. Irrespective of sex.
3. 20 - 60 years of age group.

EXCLUSION CRITERIA

1. Patients suffering from external Haemorrhoids.
2. Patients suffering from 1st and 2nd degree Internal Haemorrhoids, associated with other proctological diseases (fistula in ano, fissure in ano, rectal prolapse, rectal polyps and malignant growth) will be excluded.
3. The patients suffering from other severe systemic and metabolic disorders.

Examination of Patients

- Interrogation
- Systematic examination
- Local examination
- Local examination has given up most importance and it was carried out as follows
 - Inspection
 - Palpation
- Instrumentation

INVESTIGATIONS:

1. CBC
2. RBS
3. Clotting time / Bleeding time
4. HIV and HBSAG
5. Routine Urine Examination

Investigation Routine investigation were done for every patients such as blood, urine, stools and radiological.

TREATMENT MODULE

METHOD OF APPLICATION OF INDIGINEOUS LEPA

PURVA KARMA:

- One day prior, mrudu-virechan was given to the patient for the clear emptying of the bowel.
- Patients were counseled and explained about the procedure.
- Written consent of the patient was taken.
- Patient is made lie on the table in lithotomy position. Then part painting and draping was done.

PRADHANA KARMA:

- Pile mass was exposed with the help of slit proctoscope under local anaesthesia.
- Healthy anal mucosa was covered with wet cotton to prevent spilling of Lepa on healthy mucosa.
- Indigeneous lepa was applied by sterile scoope on internal pile mass. The quantity of drug depends upon the size of arsha ankura.
- After the application of lepa, pile mass was washed with distilled water after 2 minutes.

PASHCHATA KARMA:

- After completion of procedure patient was advised to keep the area clean, avoid exertion and unwholesome diet.
- Sitz bath was Advised.
- Instructions
- The patients were advised to maintain the hygiene and nidana parivarjan. Deepana, Pachana, Shakas, Yava, Yusha, Mamsa rasa, khada, ksheera, takra & vatanulomana, agni bala vrudhikara ahara oushadhas were advised to all the patients.

• Duration of Treatment: -

- The duration of treatment for was 1 sitting.
- Assessment was made on 1st day 7th day and 15th day and the progress was noted.

PARAMETERS FOR ASSESSMENT

Bleeding per rectum (nature, character & amount)

- G₀ - No bleeding
- G₁ - Found on toilet paper
- G₂ - Dripping
- G₃ - Sluice

Pain (was assessed by Visual analog scale)

- G₀ - Absence of pain/no pain. (0 on scale)
- G₁ - Mild - Pain that can easily be ignored. (1 to 3 on scale)
- G₂ - Moderate - pain that cannot be ignored, interferes with function, and needs treatment from time to time. (4 to 6 on scale)
- G₃ - Severe - That is present most of the time demanding constant attention. (7 to 10 on scale)

Number of pile mass

- G₀ - No pile
- G₁ - One pile mass
- G₂ - Two pile mass
- G₃ - Three pile mass

Size of pile mass (circumferential length)

- G₀ - Complete regression of pile mass
- G₁ - 1cm - 2cm (approx. size of tip of little finger)
- G₂ - 2.1cm - 3cm (approx. size of tip of index finger)
- G₃ - 3.1cm - 4cm (approx. size of tip of thumb)

STATISTICAL ANALYSIS –In the present study, the statistical assessment of the result was done by using Paired T-test.

OBSERVATIONS AND RESULTS

The clinical observations from different aspects approaching to the treatment have been represented showing the incidence, statistical analysis according to various factors like age, sex, religion, marital status, diet, bleeding per rectum, intensity of pain, constipation etc.

Gender - In this study higher incidence 31(77.5%) was observed in males than females 9(22.5%). Though both sexes experience approximately the same incidence of haemorrhoids but females due to their timid and shy nature don't present her with anorectal complaints until and unless it is severe.

Age - It has been observed from the study that out of 40 patients, maximum no. of patients i.e. 16 (40%) were in between the age group 30-39 years, followed by 10 patients (25%) in the age group of 40-49 years, 8

patients (20%) in age group of 20-29 years, 6 patients (15%) in the age group of 50-59 years. The present clinical study shows that the out of total 40, 40% i.e. 16 patients were in between 30- 49 years. Because of busy lifestyle, active work of this age group, considerable time of bike ride, stress and strain etc.

Religion - It was evidenced from the study that maximum no. of patients i.e. 26(65%) were Hindus, whereas 10(25%) were Muslims and 4(10%) was Christian.

Occupation - It was evidenced from the study that, out of 40 patients maximum no. of patients i.e. 14(35%) were labour, whereas 13(32.5%) patients were service holder, 6(15%) patients were students, 4(10%) were housewives, 3 patients (7.5%) business personals. This data suggests that most of the people in service group had prolonged sitting position.

Marital status - Maximum number of patients 31(77.5%) were married and rest of the patients i.e. 9(22.5 %) were unmarried.

Socio-economic status - Analysis of socio-economic status of 40 patients revealed that majority of patients belonged to middle class i.e. 20(50%), 17(42.5%) were poor and 3 (7.5%) were rich. Prolonged sitting posture at work, mental strain, and the living standard of middle class, may be the reason.

Diet - Maximum patients i.e. 27 (67.5%) were Non-vegetarian and 13 (32.5%) were vegetarians. prone because non-vegetarian food have zero fiber and is a very rich source of animal protein so takes more time to digest. The delayed digestion results in the chronic constipation with occurrence of haemorrhoids.

Bleeding P/R - As observed that chief complaint of Bleeding P/R was present in all patients i.e. 40 (100%) and pain was present in 22(45%) patients.

Number of pile mass - It was observed that 24 patients (60%) shows 1 pile mass, whereas 12 patients (30%) shows 2 pile mass and 4 patients (10%) shows 3 pile mass.

Constipation - It was observed that 29(72.5%) patients had constipation and rest 11(27.5%) patients had no complaint of constipation.

Statistical Analysis of BPR (Paired sample statistics)

Symptom		Mean	S.E	t-Value	P Value	Effectiveness
Bleeding per rectum	BT	1.5	0.101	--	--	--
	AT 1	0.85	0.136	8.510	<0.001	43.33%
	AT 2	0.7	0.139	9.789	<0.001	53.33%
	AT 3	0.45	0.113	17.074	<0.001	70%

The above table shows that, the mean \pm S.E. before treatment was 1.5 ± 0.101 and was reduced to 0.85 ± 0.136 after 1 day, 0.7 ± 0.139 after 7 days, 0.45 ± 0.113 after 15 days. The test shows that Indigenous compound lepa is highly significant in reducing bleeding P/R with 70% effectiveness and the P-value <0.001 in 1st, 7th and 15th day of assessment.

Statistical Analysis of Pain on VAS

Symptom		Mean	S.E	t-Value	P Value	Effectiveness
Pain	BT	0.65	0.104	--	--	--
	AT 1	0.425	0.093	2.966	0.003	34%
	AT 2	0.325	0.083	4.333	<0.001	50%
	AT 3	0.175	0.061	5.94	<0.001	73.07%

The above table shows that, the mean \pm S.E. before treatment was 0.65 ± 0.104 and was reduced to 0.425 ± 0.093 after 1 day, 0.325 ± 0.083 after 7 days, 0.175 ± 0.06 after 15 days. The test shows that Indigenous compound lepa is highly significant in reducing pain with 73.07% effectiveness and the P-value 0.003, <0.001, and <0.001 in 1st, 7th, and 15th day of assessment respectively.

Statistical Analysis of Number of Pile mass

Symptom		Mean	S.E	t-Value	P Value	Effectiveness
Number of Pile mass	BT	1.5	0.107	--	--	--
	AT 1	1.225	0.145	3.439	<0.001	18.33%
	AT 2	1.0	0.152	5.701	<0.001	33.33%
	AT 3	0.775	0.158	7.660	<0.001	48.33%

The above table shows that, the mean \pm S.E. before treatment was 1.5 ± 0.107 and was reduced to 1.225 ± 0.145 after 1 day, 1 ± 0.152 after 7 days, 0.775 ± 0.158 after 15 days. The test shows that Indigenous compound lepa is highly significant in reducing number of pile mass with 48.33% effectiveness and the P-value <0.001 in 1st, 7th and 15th day of assessment.

Statistical Analysis of Size of pile mass

Symptom		Mean	S.E	t-Value	P Value	Effectiveness
Size of pile mass	BT	1.075	0.042	--	--	--
	AT 1	0.875	0.815	3.122	0.002	18.6%
	AT 2	0.775	0.091	4.008	<0.001	27.9%
	AT 3	0.575	0.01	6.245	<0.001	46.5%

The above table shows that, the mean \pm S.E. before treatment was 1.075 ± 0.042 and was reduced to 0.875 ± 0.815 after 1 day, 0.775 ± 0.091 after 7 days, 0.575 ± 0.10 after 15 days. The test shows that Indigenous compound lepa is highly significant in restoring the size of pile with 46.5% effectiveness and the P-value 0.003, <0.001, and <0.001 in 1st, 7th, and 15th day of assessment respectively.

DISCUSSION

In the present study, the effect of the therapy was assessed on each sign and symptom of Arsha, being scored before and after treatment and were assessed statistically.

EFFECT ON BLEEDING PER RECTUM:

- Bleeding per rectum showed 70% effectiveness with significant p-value < 0.001.
- The raktashodaka and kapha pitta shamaka property of Koshataki reduces bleeding and the Tanin present in Koshataki has vasoconstriction action.
- Snuhi Ksheera due to its tikshna guna acts as irritant and corrosive substance which causes chemical cauterization and further stops bleeding. Hemostatic activity of Proteases enzyme of Snuhi ksheera aids in formation of blood clot which is essential to stop bleeding.
- While curcumin of Haridra has anti-inflammatory and healing property so combined effect of both stabilizes vascular endothelium which results in reduction of bleeding.

EFFECT ON PAIN:

- The parameter Pain showed 73.07% effectiveness with significant p-value <0.001.
- Due to sulahara, shotha hara property of Snuhi, Haridra and Gomutra it is effective in reducing pain.
- Tanins and Flavanoids of Koshataki has anti-inflammatory and analgesic property and Curcumin of Haridra also have anti-inflammatory property that helps in healing and reducing pain.

EFFECT ON NUMBER OF PILE MASS:

- Number of pile masses showed 48.33% effectiveness with significant p-value <0.001.
- Due to presence of “polycyclin diterpene” in the latex of Snuhi makes it irritant and corrosive, causes chemical cauterization which dissolves tissue of pile mass and simultaneously healing is done by Curcumin of Haridra due to its shotha hara, vrana ropaka and lekhaneya karma thus reducing the number of pile mass.

EFFECT ON SIZE OF PILE MASS:

- Size of pile masses showed 46.5% effectiveness with significant p-value <0.001
- The ksharana guna of Snuhi ksheera and Gomutra causes necrosis of tissue in hemorrhoidal vein which results into fibrosis of tissue and scar formation thus reducing pile mass.
- Ushna tikshna guna of Haridra helps in dilation of channels of raktavaha strotas and reduces shota and decreases the size of pile mass.

Hence it can be concluded that the administration of the “Indigenous lepa” as local application was most effective to relieve the symptoms, without any complications. The recurrences of protruding masses were not seen during follow up.

It shows this medicine is not for complete eradication of the disease. It is only a partial treatment, which helps the patient to get relief from symptoms and more over the present study helps to avoid the surgical intervention and its complications and helps those patients who were unwilling for surgery. In this way the present study shows significant effects in relieving symptoms and brings the patients to the stage of palliative treatment to avoid the surgery.

CONCLUSION

“Indigenous Compound Lepa” has shown complete regression of 1st degree piles in patients. However, majority of cases shows partial regression of 2nd degree piles and reduction of signs & symptoms. All most all age groups responded to “Indigenous compound lepa”. “Indigenous Compound Lepa” is curative, safe and effective in relieving symptoms in early stage of disease and also useful in patients who are unwilling for surgery. “Indigenous Compound Lepa” helps in relieving agony and discomfort to the patients without hospitalization. Hence the “Indigenous Compound Lepa” is an ambulatory type of treatment which gives quick action and also can be used as a better alternative to surgery.

REFERENCES

1. Shastri Ambikadutta Kaviraja, Sushruta Samhita, Sutra Sthana 33/4, Vol 1, Varanasi, Chaukhambha Sanskrit Sansthan, Reprint 2016:163pp.
2. Upadhaya Yadunandana. Madhava Nidana of Madhavakara-part -1 5th Edition reprint. Varanasi, Chaukhamba Sanskrita Samsthan, 2004:194pp.
3. Shastri Ambikadutta Kaviraja, Sushruta Samhita, Nidana Sthana 2/4, Vol 1, Varanasi, Chaukhambha Sanskrit Sansthan, Reprint 2016:306pp.
4. Das. Somen, A concise Text book of surgery. chapter 54. 3rd edition. Culcutta; S. Das publication; 2002:105pp.
5. Lohsiriwat V (2012) Hemorrhoids: from basic pathophysiology to clinical management. World J Gastroenterol 18(17):2009–2017 [PMC free article] [PubMed].

6. Shastri Ambikadutta Kaviraja, Sushruta Samhita, Chikitsa Sthana 6/3, Vol 1, Varanasi, Chaukhambha Sanskrit Sansthan, Reprint 2016:46pp.
7. Pandey Rameshwar – Yogaratnakara, Priyasiddhida Hindi Commentary, Arshoadhikara 5/126, Varanasi, Chaukhambha Vishvabharati, 1st ed 2019:274pp.

