



A CILINICAL STUDY TO EVALUATE THE EFFECT OF SHATAVARI MULA KALKA WITH KSHEERA IN ARSHAS W.S.R TO INTERNAL HAEMORRHOIDS

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Abstract

Arshas has become a common disease entity now-a-days, may be due to mechanical lifestyle and unwholesome dietary habits. In contemporary science this condition is compared to Haemorrhoids. Among the different modalities of treatments described in the classics . *Acharya Sushruta* has recommended *Shatavari mula kalka* with *ksheera* to be one of the oral medications indicated in *Arshas*.

Objective: To evaluate the effect of *Shatavarimula kalka* with *Ksheera* in *Arshas* w.s.r internal hemorrhoids

Material and method: An open labelled single drug clinical study with 30 patients from OPD and IPD of SDM Ayurveda Hospital diagnosed to be suffering from *Arshas* were selected and subjected to clinical trials . *Shatavarimula kalka* 12gm, *pragbhakta* along with *ksheera* OD was orally administered for 30 days. During the treatment patients were assessed for the improvement in the clinical signs and symptoms on 1st, 10th ,20th & 30th days based on subjective and objective criteria. Follow up period was of one month.

Conclusion: *Shatavari mula Kalka* with *Ksheera* is highly effective drug to stop bleeding in internal haemorrhoids, reduction in degree of prolapse and number of mass, relieves constipation helping in regular bowel habit.

KEYWORDS: *Arshas*, Haemorrhoids, *Shatavari mula kalka*.

INTRODUCTION

Ayurveda is the most rational and scientific among the ancient systems of Medicine. This science of life aims at alleviation of diseases as well as maintenance and promotion of good health. The entire science of *Ayurveda* is based upon *Trisutra* ie *hetu*, *linga* and *oushadha*. Among these three, *oushadha* plays an important role in *chikitsa* as this is the tool for the physician in treating the diseases.

Arshas is a common condition among the anorectal diseases in day to day practice in terms of incidence. As the name suggests, it is a disease which haunts a person like an enemy and is considered as one among the *Mahagadas* according to *Ayurveda*. Our *Acharyas* have described four fold treatment modalities for *Arshas* i.e *Bheshaja chikitsa*, *Agni karma*, *Kshara karma* and *Shastra karma*. Among these, administration of *bheshaja* i.e internal medication is the most acceptable means of management to the patient as it has least interference with the daily activity of the patient. The descriptions of these measures in a definite order is suggestive of preference. *Sushruta* has given importance to internal medication accepting their limitations in the management of any surgical disease. Even though primarily a surgeon, *Sushruta*, on many occasions advised surgery as a last option. Prevalent modern surgical and parasurgical measures have their own

limitations and complications and need special training, skills and equipment for their performance. Hence treatment modality which is easy to administer with lesser complications and better rate of success should be the criteria in choosing the management of *Arshas*.

Among the different *yogas* explained in the medicinal treatment, *Shatavarimula kalka* explained by *Acharya sushruta* is described to be effective for the disease *Arshas*.

OBJECTIVES OF THE STUDY

To evaluate the effect of *Shatavarimula kalka* with *Ksheera* in *Arshas* w.s.r to internal haemorrhoids

MATERIALS AND METHODS

- **Source of data–**
30 patients diagnosed with *Arsha* (Internal hemorrhoids) were selected from the IPD and OPD of SDM Ayurveda hospital, Udupi.
- **Source of drug-** *Shatavarimula* powder was procured from SDM pharmacy, Udupi
- **Methods Of Collection Of Data -**
30 patients diagnosed with *Arsha* ((Internal hemorrhoids) were selected from OPD and IPD of SDM Ayurveda Hospital , Udupi for the study with consent. Patients of age between 18-60 years of either gender were selected. They were treated with internal administration of *Shatavarimula kalka* with *Ksheera*.
- **Study design-**
An open labelled Clinical study with pre-test and post-test design.

METHODOLOGY:

Oral administration 12gms of *Shatavarimula Kalka* in *Pragbhakta* (Just before breakfast) was advised along with *Ksheera*.

- **Duration of treatment:** 30 days
- **Observation period:** The patients were observed on day1, 10th, 20th, 30th day of the study.

Follow up Period of 1 month without medications to observe for relapse / recurrence of symptoms.

DIAGNOSTIC CRITERIA:

- Per rectal, Proctoscopic examination diagnosing internal haemorrhoids.
- Bleeding per anum
- Pruritis Ani.
- Mucoid Discharge per anum

INCLUSION CRITERIA:

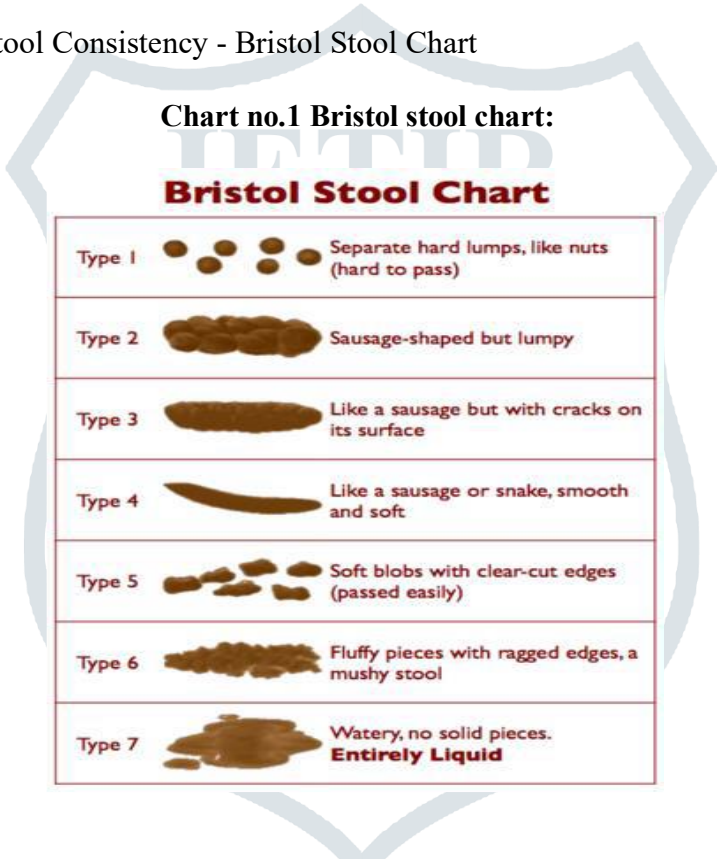
- Patients with clinical signs and symptoms of *Arsha* (Internal Haemorrhoids) as explained in Ayurvedic Contemporary Classics.
- Patients in the age group between 18-60 years, of either gender.

EXCLUSION CRITERIA

- Patients suffering from systemic diseases like uncontrolled diabetes mellitus, tuberculosis, HIV, hepatitis, bleeding disorders.
- Patients having associated ano-rectal diseases having similar features like Polyps, Carcinoma rectum, sentinel tag, external haemorrhoid.
- Patients having internal haemorrhoid complications like strangulated, Thrombosed, infected internal haemorrhoids.
- Patients having hemoglobin less than 7gm/dl.
- Patients below age 18 years and above 60 years.

ASSESSMENT CRITERIA:

Subjective Parameters: Stool Consistency - Bristol Stool Chart



Parameter	Grade	Occurence
Mucoid discharge	1	Absent
	2	Present
Itching P/A	1	Absent
	2	Present

TABLE NO.1 PNR –BLEED CLASSIFICATION

SL.NO	CHARACTERISTIC	GRADE	DESCRIPTION
1	Degree of haemorrhoidal prolapse	1	No haemorrhoidal prolapse
		2	Prolapse on straining reduces spontaneously
		3	Prolapse on straining that needs manual reduction
		4	Prolapsed and irreducible haemorrhoids without ischaemic changes
		5	Prolapsed and irreducible haemorrhoids with ischemic / gangrenous changes
2	No. of haemorrhoidal columns involved	1	None
		2	One
		3	Two
		4	Three
		5	Circumferential (presence of secondary haemorrhoids along with involvement of all primary haemorrhoids)
3	Relation to dentate line	1	Nil (normal anal cushions)
		2	External haemorrhoids
		3	Internal haemorrhoids
		4	Interno-external haemorrhoids
		5	Thrombosed external haemorrhoids
4	Bleeding	1	Nil
		2	Mild, occasional episodes during defecation

		3	Moderate, frequent episodes during defecation
		4	Severe, persistent bleeding even without defecation, with fall of Hb < 10 gm /dL
		5	Very severe, bleeding in the form of jets and splashes with severe fall of Hb <7 gm/dL, requiring blood transfusions.

Haemorrhoid Severity Score : Total score obtained by sum of all 4 characteristics of haemorrhoids in PNR-Bleed classification

STATISTICAL ANALYSIS:

Wilcoxon signed rank test for analysis of before and after treatment of the study group.

INVESTIGATIONS:

- Hemogram
- HbA1c
- BT, CT ;(PTT – if required.)
- ELISA, HBSAg

OBSERVATIONS

Incidence observations: According to proforma prepared for the present study the observations were made regarding the incidence of the *Arshas* with regard to age, Sex, religion, dietary habits, chronicity, nature of work, *prakruti* and *Agni* of the patient.

Table no.02 Distribution of patient according to mucoid discharge

INTERVAL	ABSENT (IN FREQUENCY)	PRESENT (IN FREQUENCY)
DAY 01	28	02
DAY 10	28	02
DAY 20	30	0
DAY 30	30	0

Table no.03 Distribution of patient according to itching

INTERVAL	ABSENT (IN FREQUENCY)	PRESENT (IN FREQUENCY)
DAY 01	29	01
DAY 10	29	01
DAY 20	30	0
DAY 30	30	0

Table no.04 Distribution according to degree of haemorrhoids.

Degree of haemorrhoids on day 01	Frequency	Percent
no haemorrhoids prolapse	9	30.0
prolapse on straining reduce spontaneously	20	66.7
prolapse on straining that needs manual reduction	1	3.3
Total	30	100.0

Degree of haemorrhoids on day 10 th	Frequency	Percent
no haemorrhoids prolapse	9	30.0
prolapse on straining reduce spontaneously	20	66.7
prolapse on straining that needs manual reduction	1	3.3
Total	30	100.0

Degree of haemorrhoids on day 20 th and Day 30 th	Frequency	Percent
Valid.00	30	100.0

Table no.05 distribution according to stool consistency

Stool on 1st day	Frequency	Percent
sausage shape but lumpy	5	16.7
like a sausage but cracks on its surface	10	33.3
like a sausage or snake with smooth and soft	12	40.0
soft blobs with clear cut edges	2	6.7
Flappy pieces with ragged edges a mushy stool	1	3.3
Total	30	100.0

Stool on 10 th day, 20 th day and 30 th day	Frequency	Percent
no constipation (NORMALLY PASSED STOOL)	30	100.0

Table no.06 distribution according to bleeding

Bleeding on day 1st	Frequency	Percent
Mild, occasional episodes during defecation	17	56.7
Moderate frequent episodes during defecation	13	43.3
Total	30	100.0

Bleeding on day 10th	Frequency	Percent
mild	19	63.3
mild, occasional episodes during defecation	11	36.7
Total	30	100.0

Bleeding on day 20th and 30 th	Frequency	Percent
Mild	30	100.0

Table no.07 distribution according to haemorrhoidal columns

no. of haemorrhoidal column on day 1	Frequency	Percent
One	10	33.3
Two	20	66.7
Total	30	100.0

No. of haemorrhoidal column on day 10	Frequency	Percent
One	10	33.3
Two	20	66.7
Total	30	100.0

No. of haemorrhoids column on day 20 and day 30	Frequency	Percent
None	30	100.0

Table no.08 distribution according to dentate line

DAY	Relation to dentate line	Frequency	Percentage
01	Internal haemorrhoids	30	100
10	Internal haemorrhoids	30	100
20 th and 30 th	Normal anal cushion	30	100

Table no.09 distribution according to haemorrhoidal severity score BT

haemorrhoidal severity score before treatment	Frequency	Percent
8	2	6.7
9	10	33.3
10	8	26.7
11	8	26.7
12	2	6.7
Total	30	100.0

Table no.10 distribution according to haemorrhoidal severity score AT

Haemorrhoidal severity after treatment	Frequency	Percent
4	30	100.0

Table no.11 Bleeding before treatment

Bleeding before treatment	Frequency	Percent
mild, occasional episodes during defecation	17	56.7
moderate frequent episodes during defecation	13	43.3
Total	30	100.0

Table no. 12 Bleeding after treatment

Bleeding after treatment	Frequency	Percent
Nil	30	100.0

Table no.13 degree of haemorrhoids before treatment

Degree of haemorrhoids before treatment	Frequency	Percent
no haemorrhoids prolapse	9	30.0
prolapse on straining reduce spontaneously	20	66.7
prolapse on straining that needs manual reduction	1	3.3
Total	30	100.0

Table no.14 Degree of haemorrhoids after treatment

Degree of haemorrhoids after treatment	Frequency	Percent
no haemorrhoids prolapse	30	100.0

Table no. 15 of haemorrhoid columns before treatment

no. of haemorrhoids column before treatment	Frequency	Percent
One	10	33.3
Two	20	66.7
Total	30	100.0

Table no.16 of haemorrhoids columns after treatment

No. of haemorrhoids column after treatment	Frequency	Percent
None	30	100.0

Table no.17 Relation to dentate line before treatment

Relation to dentate line before treatment	Frequency	Percent
internal haemorrhoids	30	100.0

Table no.18 Relation to dentate line after treatment

Relation to dentate line after treatment	Frequency	Percent
normal anal cushion	30	100.0

Table no.19 stool consistency before treatment

Stool consistency before treatment	Frequency	Percent
sausage shape but lumpy	5	16.7
like a sausage but cracks on its surface	10	33.3
like a sausage or snake with smooth and soft	12	40.0
soft blobs with clear cut edges	2	6.7
flappy pieces with ragged edges a mushy stool	1	3.3
Total	30	100.0

Table no.20 stool consistency after treatment

Stool consistency after treatment	Frequency	Percent
no constipation (normally passed stool)	30	100.0

RESULT

The results were analysed and computed based on assessment criteria of the study using Wilcoxon sign rank test. From the analysis of the study, *Shatavarimula Kalka* with *Ksheera* showed clinical and statistical significance in improving bowel habit with soft stool, stoppage of bleeding in internal haemorrhoids, reduced the degree and number of haemorrhoids, mild reduction in itching per anal but no reduction in mucoid discharge

Table no . 21 Effect on mucoid discharge

Mucous Discharge	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
1 st -10 th day	N	MR	SR	N	MR	SR				
	0	0.00	0.00	0	0.00	0.00	2	0.00	1.00	NS
Day 20th	2	1.50	3.00	0	0.00	0.00	0	-1.41	0.157	NS
Day 30th	2	1.50	3.00	0	0.00	0.00	0	-1.41	0.15	NS

Table no.22 effect on degree of haemorrhoids

Degree of Haemorrhoid	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
Day 10th	N	MR	SR	N	MR	SR				
	0	0.00	0.00	0	0.00	0.00	30	0.00	1.00	NS
Day 20th	30	15.50	465.0	0	0.00	0.00	0	-4.97	0.00	HS
Day 30th	30	15.50	465.0	0	0.00	0.00	0	-4.97	0.00	HS

Table no.23 Effect on bleeding

Bleeding	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
Day 1- 10 th	N	MR	SR	N	MR	SR				
	29	15.00	435.0	0	0.00	0.00	1	-5.16	0.00	HS
Day 20th	30	15.50	465.0	0	0.00	0.00	0	-4.93	0.00	HS
Day 30th	30	15.50	465.0	0	0.00	0.00	0	-4.93	0.00	HS

Table no.24 Effect on itching

Itching	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
Day 1-10th	N	MR	SR	N	MR	SR	0	-2.44	0.014	HS
	1	1.00	1.00	0	0.00	0.00				
Day 20th	1	1.00	1.00	0	0.00	0.00	0	-2.44	0.014	HS
Day 30th	1	1.00	1.00	0	0.00	0.00	0	-2.44	0.014	HS

Table no.25 Effect on stool consistency

Stool Consistency	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
Day 10	N	MR	SR	N	MR	SR	0	-4.84	0.00	HS
	30	15.50	465.0	0	0.00	0.00				
Day 20	30	15.50	465.00	0	0.00	0.00	0	-4.84	0.00	HS
Day 30	30	15.50	465.00	0	0.00	0.00	0	-4.84	0.00	HS

Table no.26 Effect on haemorrhoidal columns

No. of Haemorrhoidal column	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
Day 1 -10th	N	MR	SR	N	MR	SR	30	0.00	1.00	NS
	0	0.00	0.00	0	0.00	0.00				
Day 20 th	30	15.50	465.50	0	0.00	0.00	0	-4.98	0.00	HS
Day 30 th	30	15.50	465.0	0	0.00	0.00	0	-4.98	0.00	HS

Table no.27 effect on Relation above the dentate line

Relation above Dentate line	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
Day 1- 10th	N	MR	SR	N	MR	SR				
	0	0.00	0.00	0	0.00	0.00	30	0.00	1.00	NS
Day 20th	30	15.50	465.50	0	0.00	0.00	0	-5.47	0.00	HS
Day 30th	30	15.50	465.50	0	0.00	0.00	0	-5.47	0.00	HS

Table no.28 effect on haemorrhoidal severity score BT

Haemorrhoids severity score	Negative Ranks			Positive Ranks			Tie	Z value	P value	Interpretation
BT mean	N	MR	SR	N	MR	SR				
	30	15.50	465	0	0.00	0.0	0	-4.82	0.00	HS
AT mean	30	15.50	465.0	0	0.00	0.00	0	-4.82	0.00	HS

DISCUSSION

Arshas is one of the *Ashtamahagadas* as it is difficult to cure. This fact is evident from the enumeration of vast number of etiological factors, systematic description of its pathogenesis and different treatment modalities described to manage this condition. Analysing the descriptions said in earlier pages, it can be understood that *Arshas* includes not only haemorrhoids, but anorectal growths like anal epithelium, polyps, hypertrophied papillae, sentinel tags, carcinoma of rectum etc. can also be considered under this heading.

Intervention: *Mandagni* is considered as the prime causative factor for the disease *Arshas*. This disease entity can be described as the local manifestation of systemic derangement of *doshas* and *agni*.

Among the different treatment modalities described for *Arshas*, internal administration of drugs stands first. Even *Susruta* has advocated *bheshaja chikitsa* as the first line of treatment even though he considers *Arshas* as primarily a surgical disease. Internal use of medicines are aimed to relieve the active symptoms of *Arshas* as well as to prevent future recurrence. *Acharya Charaka* describes the general properties of medicines for internal use in *Arshas* as *deepana*, *pachana*, *anulomana*, *raktasangrahi*, *shamshamana* etc.

The present study has shown that *Shatavarimula kalka* significantly helped in relieving the symptoms of constipation, bleeding, pain, itching, mucoid discharge and also in the regression of pile mass. The drug has properties of *Rasa- Madhura Tikta*, *Guna- Guru*, *Snigdha*, *Vipaka- Madhura*, *Virya- Sheeta*. *Vātapitta shamaka* due to *Madhura vipaka* and *Madhura rasa*. *Pitta shamaka* due to *Sheeta Virya*, *Madhura vipaka* and *Madhura Tikta rasa*. It is *Rasayana*, *Medhya*, *Pustivardhaka*. *Netrya*, *Atisarajit*, *Sukravardhaka*, *Stanyavardhaka*, *Balya*, *Shothahara* *Vrishya* and *Gulmanāsaka*.

Roots contain shatavarin I to V sistosterol, Saponins A4, A5, A6, A7 and A8, Sarsapogenin Glycosides of quercetin, rutin, D-glucose, D-mannose and Diasaccharide.

Fruits yield Sistosterol, Stigmasterol, Sarsapogenin, Sitosterol-B-D-glucoside, Stigmasterol-B-D glucoside.

Observations of the clinical study on the vital data:-

Age and sex: – Among 30 patients taken, distribution was, age 20-29 years: 7 patients, age 30-39 years : 9 patients, age 40-49 years : 5 patients, age 50-59 years: 5 patients, age 60-70 years : 4 patients. Age group between 30 -40 years are prone to have internal haemorrhoids.

The study reveals that males have been found to suffer more than females. Out of 30 patients, 12 patients were females and patients 18 were males. However, this figure may not represent the true incidence of *Arshas* in general.

Dietary habits :- Not only that the patient were vegetarian or had mixed type of diet, but from the view point of spicy/ non spicy foods, regular/ irregular food intake, the study showed that who take more of spices, non - vegetarian foods, are irregular in their food habits are likely to suffer from *Arshas*.

BT /AT observations:-

The readings of the observations made in 30 patients, included in the present study, BT and AT with *shatavarimula kalka* with *ksheera* were divided into subjective and objective criteria for easy assessment.

The subjective criteria were constipation, bleeding, itching, pain, during and after defaecation and objective criteria were size of the pile mass and degree. All patients were assessed according to the grading given BT and AT and were analysed for statistical significance.

• Stool consistency:

It was found in the study that almost all patients before test had constipation. Due to the properties of *shatavarimula* like *madhura rasa*, *madhura vipaka* and *vatapittahara* properties indicated in *arshas* brought about soft stools in patients after treatment.

• Mucoïd discharge:

Patients before the treatment had mucoïd discharge. The properties of *pittahara* or *sheeta virya* have a role in reducing the mucous discharge.

• Itching-

Clinically there was no such significant reduction in the itching of anal region in most of the patients, might be due to *madhura rasa*, *madhura vipaka* of the drug.

• Degree of haemorrhoids prolapse –

The internal pile mass on proctoscopy has been found to be reduced which can be attributed due to properties of *vatapittahara* and *sheeta virya* of drug.

• No. of haemorrhoids column –

On proctoscopy examination the no. of haemorrhoidal column involved was found to be reduced after the study due to *vatapittahara kaarmukata* of the drug.

• Relation to the dentate line

According to inclusion criteria only internal haemorrhoids was selected for the study and there was no association of external component found after the study.

• Bleeding--

Clinically all the 30 patients have complete reduction in the bleeding P/R due to properties of drug like *Madura rasa*, *madhura vipaka*, *sheeta virya* and *raktapittasamak*.

CONCLUSION

- The present study was aimed to evaluate of effect of *Shatavarimula kalka* with *ksheera* in *arshas* w.s.r internal haemorrhoids.
- According to the incidence of the study, amongst 30 patients diagnosed with *arshas* (internal haemorrhoids), majority of them were males, aged between 30-40 years belonging to middle socio economic status, consuming non veg and spicy food, and indulging in strenuous works.
- In this study it was found that majority of patients presented with irregular bowel with hard stool, haemorrhoids at primary sites of 3/7/11'o clock position with a normotonic sphincter tone, having 1-2 internal pile masses either of 1st / 2nd degree. Majority of patients had presentation of *pitta-kaphaja* and *shonitaja* variety of *Arshas*.
- The *Shatavarimula Kalka* along with *ksheera* used for the study, clinically helped in reducing the symptoms of constipation, in stoppage of bleeding in internal haemorrhoids, reduction in the degree of prolapse and also number of hemorrhoidal columns, an average reduction in Hemorrhoidal severity score was found reduced from 12 to about 7.
- *Shatavarimula kalka* along with *ksheera* statistically showed highly significant results in reduction of bleeding in internal haemorrhoids, reduction in the degree of prolapse and also number of hemorrhoidal columns. It was found statistically significant in reduction of itching.
- In the follow up period it was noticed that in about 3 patients there was recurrence of symptoms due to repeated indulgence in causative factors.
- To conclude the study *Shatavarimula kalka* along with *ksheera* shows efficacy in bleeding varieties of *Arshas* (*raktaja*, *pittaja* varieties) in the stoppage of bleeding, reduction of the degree and number of the mass of internal haemorrhoids both clinically and statistically .
- Further studies are necessary to be carried out by administering *Shatavarimula kalka* for longer duration to find its long standing efficacy.
- *Shatavarimula kalka* internal administration with different *anupana* can be taken up for the future studies.

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