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## A COMPARATIVE CLINICAL STUDY OF EFFICACY OF *PIPPALYADILEPA* AND *TEEKSHNA APAMARGA KSHARA PRATISARANA* IN THE MANAGEMENT OF *ARSHA VIS-A'-VIS HAEMORRHOIDS*

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### ABSTRACT

*Arsha* is one of the lifestyle disorders, common among anorectal diseases. As the treatment is concerned, modern management of *Arsha* is mainly surgical approach but the result was found to be less satisfactory. In *Ayurveda*, management involves *Bheshaja Chikitsa*, *Kshara Karma*, *Agnikarma* and *Shastrakarma*. Among these *Bheshaja* and *Kshara karma* have shown significant results. Hence the present study includes a comparative study of efficacy of *Pippalyadi Lepa* and *Teekshna Apamarga Kshara Pratisarana* in *Arsha*.

**Objectives:** To compare the efficacy of *Pippalyadi lepa* and *Teekshna Apamarga Kshara Pratisarana* in the management of *Arsha*.

**Methods:** Randomized open labelled comparative clinical study. 40 diagnosed patients of *Arshas* were randomly selected from OPD, Muniyal Institute of Ayurveda medical Sciences, Manipal. Further divided into two groups consisting of 20 patients each and subjected to clinical trial

**Group - A (Study Group):** Treated with *Pippalyadi lepa*.

**Group - B (Standard Group):** Treated with *Teekshna Apamarga kshara Pratisarana*. In both the groups' *avipattikara churna/triphala hurna (for K/C/O DM)* was given as a concomitant oral medication. Duration of the study - 36 days, including follow-ups. The data collected was graded based on the assessment criteria and were analyzed statistically.

**Results-** The outcome of treatment after 36 days was statistically significant based on the assessment criteria.

**Discussion & Conclusion-** *Teekshna apamarga kshara pratisarana* (Group B) showed good result in constipation, reduction of degree and size of pile mass compared to *Pippalyadi lepa* Group (Group A). *Pippalyadi Lepa* Group (Group A) showed good result in bleeding P/R as compared to Group A

**Key words:** *Arsha; Pippalyadi Lepa; Teekshna Apamarga Kshara Pratisarana*.

## INTRODUCTION

*Arsha* (piles) is a common anorectal disorder with highest prevalence rate among anorectal cases. By looking into the history we can understand that even famous rulers like “Napolean” suffered from this disease.<sup>1</sup> Incidence of *Arsha* increases with advancing age but unfortunately recent statistics reveal that irrespective of age, sex, socio-economic status people suffer from piles. Nowadays nearly half of the population generally experience one haemorrhoidal episode at some point in their lives.

The term haemorrhoids is popularly used to denote pathological varicosity of the haemorrhoidal veins due to increased pressure usually related to straining during defecation, chronic constipation, diarrhea, pregnancy etc. In the literature of *Ayurveda*, it has been considered as one of the “*Ashtamahagada*” because of *dirghanubandha*, *duschikitsya* and location in *marma sthana*.<sup>2, 3</sup> Since time immemorial efforts have been made to combat the condition through different treatment modalities but not all of them have been uniformly successful. Prevalent modern surgical and para-surgical measures like sclera-therapy, cryosurgery, rubber band ligation and infrared coagulation have their own limitations & complications and needs special training skills and equipments for their performance along with high cost and requirement of sophisticated instruments and hospitalization.<sup>4, 5</sup>

In *Ayurveda* fourfold management of *Arsha* has been indicated viz. *Bheshaja*, *Kshara*, *Agni&Shastra karma* according to the presentation and chronicity of the disease.<sup>6</sup> Among these *Bheshaja* and *Kshara karma* have shown encouraging results in the management of *Arsha*. Thus we come across references about treatment aspect in terms of *lepa* and *Kshara Pratisarana* in text of *Sushruta Samhita*.<sup>7, 8</sup>

Among them *Pippalyadi Lepa* and *Teekshna Apamarga Kshara* explained in *Sushruta Samhita* has been selected for the study.<sup>9, 10</sup> Usage of *Teekshna Apamarga Kshara* holds prime importance and has been proved effective. Hence here an attempt has been made to compare the efficacy of *Pippalyadi Lepa* and *Teekshna Apamarga Kshara Pratisarana* in the management of *Arsha*.

## METHODOLOGY

### Selection of Patients

40 patients fulfilling the clinical criteria for diagnosis of *Arsha* were randomly selected

irrespective of their age, sex, religion, occupation etc. from OPD and IPD of Muniyal Ayurveda Hospital, Manipal, Karnataka.

**INCLUSION CRITERIA:**

- Internal haemorrhoids.
- Haemorrhoids of 1<sup>st</sup> and 2<sup>nd</sup> degree.
- Patients of both genders between the age group of 18-60 years.

**EXCLUSION CRITERIA:**

- 3<sup>rd</sup> and 4<sup>th</sup> degree internal haemorrhoids.
- External haemorrhoids.
- Interno-external haemorrhoids.
- Haemorrhoids associated with other ano-rectal conditions like fissure, fistula in ano, sinus, malignancy, ulcerative colitis, polyps, ulceration, vascular anomalies, abscess, enlarged prostate, stricture urethra etc. requiring immediate medical intervention.
- Haemorrhoids associated with other chronic or acute systemic diseases requiring immediate medical intervention.
- Haemorrhoids that are thrombosed, strangulated, inflamed.
- Haemorrhoids during pregnancy.

**Grouping with Dose and Duration in Therapy**

40 clinically diagnosed patients of arsha were equally divided into two groups A & B, 20 patients in each group.

- **Group - A:** Treated by *Pippalyadi lepa applied* locally on the pile mass under direct supervision of a surgeon, once in a day for a period of 1 week. (Procedure is carried out in Minor Operation Theatre) *Lepa* was applied after passing the stools and kept for 3 hrs. And then patient was advised to take warm water sitz bath for 20 minutes in order to wash the *lepa*.
- **Group - B** Treated by *Teekshna Apamarga kshara* applied locally over the pile mass under LA. (Procedure carried out in Operation Theatre).

## **Preparation of Medicine:**

### ***Pippalyadi Lepa***

It has been explained by *SushrutaSamhita* in *arshodhikara* while explaining different types of *lepa* in *arsha chikitsa*.<sup>11</sup>

The same reference can be noted in *Bhaisajya Ratnavali* as *arsha sthanika yoga*.<sup>12</sup>

Equal quantity of *Pippali*, *Saindhava Lavana*, *Kustha* and Fruit of *Sirisha* are powdered and mixed together along with the latex of *Arka*. (Photo 1)



PHOTO 1: Pippalyadi Lepa In varti form

### ***Teekshna Apamarga Kshara***

The ingredients used in the preparation of *teekshna kshara* are *apamarga*, *gomutra*, *suktika*, and *citraka*. In *Sushruta Samhita*, 11<sup>th</sup> Chapter of *Sutrasthana* deals with *kshara*, its *guna*, method of preparation etc. After reviewing all texts, *Sushruta's* technique is found to be ideal in *apamarga kshara* preparation. Hence the same procedure was followed. The *kshara* prepared for the present study was having Hof 13.27. (Photo 2)



PHOTO 2: Pratisaraneeya Kshara

**Intervention:**

**PROCEDURE OF APPLICATION OF PIPPALYADI LEPA**

*Pippalyadi lepa* applied locally on the pile mass under direct supervision of a surgeon, once in a day for a period of 1 week. (Procedure is carried out in Minor Operation Theatre) *Lepa* was applied after passing the stools and kept for 3 hrs. And then patient was advised to take warm water sitz bath for 20 minutes in order to wash the *lepa*.



Fig.A.1 Before Treatment

Fig A.2 After treatment

Photo 3: Pippalyadi Lepa

**PROCEDURE OF KSHARA KARMA:**

Like any other operative procedure, *Kshara Karma* was done in three stages

- *Purva Karma* (pre-operative)
- *Pradhana karma* (Operative) and
- *Paschat Karma* (post-operative).

**Pre-Operative Procedure:** Patient selected for the procedure was asked to remain nil orally for at least 4 hours prior to the procedure. Informed consent was taken. Part preparation was done. Proctolysis enema was given. Vitals were checked. Pre-medications were given: IV DNS 1<sup>o</sup>, Inj. TT 1amp IM, Inj. Diclofenac 1amp IM.

**Operative procedure:** Patient was made to lie down in lithotomy position. Painting of Anus and Perianal region was done with Betadine and spirit. Draping was done. Local

Anaesthesia with 2% xylocaine with adrenaline was administered. Once the part was anaesthetized, manual anal dilatation was done. Lubricated normal proctoscope was introduced, position of pile mass was noted and proctoscope was removed. Then slit proctoscope was introduced and skin around pile mass was pulled laterally with the Alli's forceps to get a better view of haemorrhoids. The healthy anal mucosa was covered with wet cotton balls to prevent spilling of *kshara* on it. Later the pile mass was gently scraped with the rough surface of spatula and *kshara* was applied on the pile mass, and the opening was closed with the hand for *shata-matra kala* (ie 35 sec), till the colour of the pile mass turn to black (*Pakva jambuphala Varna*). If not, *kshara pratisarana* was done again, till the pile mass turned to blackish colour. Thereafter the pile mass was cleaned with lemon juice and then sterile water wash was given. This procedure was repeated on all the pile masses. Once the *kshara* karma is completed, the proctoscope is removed. The anal canal was packed with gauze piece soaked in *Jatyadi Taila* to prevent local oedema & pain. Dry dressing was done and the patient was shifted to the ward.

**Post-operative procedure:** Vitals were checked. After half an hour patient was advised to take soft diet. After 6-8 hrs sitz Bath with Luke warm water was given (10min)

#### **Common treatment for both the groups/Adjuvant Therapy**

In both the groups, Advised - *Avipattikara choorna* -5gms at Bed time with luke warm water. **If k/c/o Diabetes Mellitus–*Triphala choorna***–5gms at Bed time with luke warm water.

**Sitz bath** -15 minutes twice daily

Patients were asked to follow *pathya*, not to consume spicy food, more of fiber rich diet like raw vegetables and adequate amount of water.

***Teekshna Apamarga Kshara pratisarana***



Fig.B.1 Before Treatment

Fig B.2 After treatment

**ASSESSMENT CRITERIA**

**SUBJECTIVE PARAMETERS**

1. Constipation/Vibandha
2. Bleeding/Raktasrava

**OBJECTIVE PARAMETERS**

1. Degree of Haemorrhoids
2. Size of Pile Mass

**DURATION OF THE STUDY:**

Patient will be examined on 7<sup>th</sup>, 14<sup>th</sup>& 21<sup>st</sup> day after treatment and follow-up is done on 36<sup>th</sup>day accordingly the parameters will be recorded.

**STATISTICAL METHOD:**

The data collected is analyzed statistically for significance between the group and within group using Wilcoxon rank sum test and Mann-Whitney U test respectively.

**RESULTS:**

Comparison within the Group:

Group A	BT Mean	MEAN SCORE		Diff	%	Wilcoxon rank test			
						SD	SEM	P	Significant
Constipation	0.90	AT	0.55	0.35	38.8	0.60	0.13	0.0313	S
		AT1	0.45	0.45	50	0.60	0.13	0.0039	VS
		AT2	0.25	0.65	72.2	0.44	0.09	0.0002	ES
		AF	0.40	0.50	55	0.59	0.13	0.0020	VS
Bleeding	1.25	AT	0.40	0.85	68	0.50	0.11	0.0001	ES
		AT1	0.30	0.95	76	0.47	0.10	0.0001	ES
		AT2	0.10	1.15	92	0.30	0.06	<0.0001	ES
		AF	0.00	1.25	100	0.00	0.00	-	-
Degree of Haemorrhoids	1.70	AT	1.55	0.15	8.8	0.60	0.13	0.2500	NS
		AT1	1.15	0.55	32.3	0.74	0.16	0.0010	ES
		AT2	0.95	0.75	44.1	0.75	0.16	0.0001	ES
		AF	0.75	0.95	55.8	0.78	0.17	<0.0001	ES
size of Pile Mass	1.35	AT	1.15	0.20	14.8	0.58	0.13	0.1250	NS
		AT1	0.80	0.55	40.7	0.41	0.09	0.0010	ES
		AT2	0.70	0.65	48.1	0.47	0.10	0.0005	ES
		AF	0.55	0.80	59.2	0.51	0.11	<0.0001	ES

Group B	BT Mean	MEAN SCORE		Diff	%	Wilcoxon rank test			
						SD	SEM	P	Significant
Constipation	0.55	AT	0.45	0.10	18.1	0.60	0.13	0.5625	NS
		AT1	0.15	0.40	72.7	0.36	0.08	0.0078	VS
		AT2	0.20	0.35	63.6	0.41	0.09	0.0156	S
		AF	0.15	0.40	72.7	0.36	0.08	0.0078	VS
Bleeding	1.75	AT	0.85	0.90	51.4	0.48	0.10	0.0001	ES
		AT1	0.50	1.25	71.4	0.60	0.13	<0.0001	ES
		AT2	0.20	1.55	88.5	0.52	0.11	<0.0001	ES
		AF	0.00	1.25	100	0.00	0.00	-	-
Degree of Haemorrhoids	1.85	AT	1.20	0.65	35.1	0.76	0.17	0.0010	ES
		AT1	0.55	1.30	70.2	0.51	0.11	<0.0001	ES
		AT2	0.30	1.55	83.7	0.47	0.10	<0.0001	ES
		AF	0.15	1.70	91.8	0.36	0.08	<0.0001	ES
size of Pile Mass	1.70	AT	1.0	0.70	41.1	0.72	0.16	0.0002	ES
		AT1	0.65	1.05	61.7	0.58	0.13	<0.0001	ES
		AT2	0.30	1.40	82.3	0.57	0.12	<0.0001	ES
		AF	0.15	1.55	91.1	0.36	0.08	<0.0001	ES

Comparison between the Groups:

AT											
	Group	N	Mean	SD	Mean diff	Mann-Whitney test					
						U	U'	Sum of rank	P	Significant	
Constipation	A	20	0.55	0.60	0.10	181	219	429	0.6108	NS	
	B	20	0.45	0.60				391			
	AF										
	A	20	0.40	0.13	0.25	158.50	241.50	451.50	0.2542	NS	
B	20	0.15	0.08	368.50							

AT											
	Group	N	Mean	SD	Mean diff	Mann-Whitney test					
						U	U'	Sum of rank	P	Significant	
Bleeding	A	20	0.55	0.40	0.50	0.45	116	284	326494	0.0219	
	B	20	0.45	0.85	0.48			391			
	AF										
	A	20	0.00	0.00	0.10	-	-	-	-	-	
B	20	0.10	0.06	-							

AT											
	Group	N	Mean	SD	Mean diff	Mann-Whitney test					
						U	U'	Sum of rank	P	Significant	
Degree of Haemorrhoids	A	20	1.55	0.60	0.35	150	250	460	0.1742	NS	
	B	20	1.20	0.76				360			
	AF										
	A	20	0.75	0.78	0.60	114	286	496	0.0189	S	
B	20	0.15	0.36	324							

AT											
	Group	N	Mean	SD	Mean diff	Mann-Whitney test					
						U	U'	Sum of rank	P	Significant	
Size of Pile Mass	A	20	1.55	0.60	0.35	150	250	460	0.1742	NS	
	B	20	1.20	0.76				360			
	AF										
	A	20	0.75	0.78	0.60	114	286	496	0.0189	S	
B	20	0.15	0.36	324							

\*BT-Before treatment,\*AT-After treatment(7 days), AT1-After treatment(14 days), AT2-After treatment(21 days), \*AF-After follow up\* DIFF-Difference ,\*SD-Standard deviation,\*SEM-Standard error of mean ,\*ES-Extremely significant,\*VS-Very significant,\*S-Significant,\*NS-Not significant.

## **DISCUSSION:**

### **Effect of therapy on constipation:**

Constipation occurs due to *Vikruti* of *Vayu* (*pratiloma gati* of *apan vayu*) and *pureeshavaha srotas dushti*. This is caused by improper food habits (*vishamashana*), suppression of the urge of defecation, food indigestion, *madagni*, lack of water intake in the diet. Reduction of constipation was observed in both the groups of patients of *Arsha*. There was no statistical significance in the amount of reduction in constipation between the groups. The group B showed better results with a reduction percent of 72.7% compared to 55 % of group A. *Avipattikara/triphala Churna* was given to both groups which are aid as stool softeners. *PippalyadiLepa* and *kshara pratisarana* help to reduce the local obstruction, thus reduces the spasm of anal sphincter muscles which helps in reducing the constipation. Being of *Ushna guna* the sphincters relax allowing the free passage of stools.

### **Effect on Bleeding P/R:**

For internal hemorrhoids, bleeding is the most commonly reported symptom. The occurrence of bleeding is usually associated with defecation and almost always painless. Reduction of bleeding P/R was observed in both groups of patients of *Arsha*. There was statistically extremely significant reduction in the amount of bleeding between the groups. The group A showed better results with a reduction percent of 100% compared to 94.2% of group B. Ingredients of *Pippalyadi Lepa* have *Shodhana* and *Ropana* properties which help in reducing bleeding. *Sirisha phala* is *kashaya rasatmaka* hence is *sandhaniya* . *Arka Kshira* acts like *Kshara* which contracts blood vessels.

### **Effect on Degree of Pile mass:**

Degree of Haemorrhoids is dependent on the extent of the prolapse as well as reducibility of the mass. Straining during defecation is a cause of the prolapsed mass. In the present study, the patients who had 1st and 2nd degree pile mass were selected thus it is obvious that the mass does not prolapse out of the rectum. It was found that

degree of pile mass was reduced in both groups of patients of *Arsha*. There was statistical significance in the amount of Degree of Pile mass reduction between the groups. The group B fared better with a reduction percent of 91.89% compared to 55.89% of group A. *Kshara* having the properties mainly *chhedana*, *bhedana* and *lekhana* and by virtue of these properties, *kshara* produced shrinking effect on pile masses thus reducing the degree of it.

**Effect on Size of Pile mass:**

In *vyadhi Arsha*, the *prakupita doshas do sthana samshraya* in *tvaka mamasa* and *meda* of *guda* causing its *sthanik dushti*. This *dosha sanghat* causes *mamsankura utpatti* i.e mass in the anal canal. Presence of mass causes obstruction and patient has to strain to defecate which will further add on to the initial pathology leading to increase in its size. Reduction of size of pile mass was observed in both groups of patients of *Arsha*. There was statistical significance in the amount of Size of Pile mass reduction between the groups. The group B fared better with a reduction percent of 91.18% compared to 59.25% of group A. *Kshara* having the properties mainly *chhedana*, *bhedana* and *lekhana* and by virtue of these properties, *kshara* produced shrinking effect on pile masses thus reducing its size.

**Probable Mode of Action:**

The ingredients of *pippalyadi lepa* contain drugs are *ushna tikshna lekhaneya shulahara* and *shothara* properties. When applied locally cause *shodhana* and *ropana*. This drug break the *sthanik dosha sanghat* in *arsha*, Causes relaxation of sphincter muscles leading to easy passage of stools. *Sirisha phala* is *kashaya rasatmaka* and *Arka kshira* having *kshariya dharma* ceases bleeding. *Teekshna Apamarga kshara Pratisaranacoagulates* protein in haemorrhoidal plexus leads to disintegration of haemoglobin into haem and globin. Cauterization and coagulation decreases the size of pile mass. Results in necrosis of tissues of burnt haemorrhoidal vein: Necrosed tissue sloughs out (3 to 7 days) as blackish brown discharge due to presence of haem in the slough. The tissue become Fibrosed and scar formation takes place. Obliteration of Haemorrhoidal vein occurs permanently resulting in non- recurrence of haemorrhoids.

Complete wound healing occurs (15 days).

## CONCLUSION

The description of anatomy and physiology of anorectal region is found in Ayurvedic literature though scattered. Basically, the field of disease *arsha* is too wide, it conceals spectrum of pathology. Haemorrhoids are dealt rationally under the same nomenclature. This signifies that all the haemorrhoids are *arsha*, while all *arsha* are not haemorrhoids.

*Teekshna apamrga kshara pratisarana* showed good result in constipation, reduction of degree and size of pile mass compared to *Pippalyadi lepa* Group where as *Pippalyadi Lepa* Group showed good result in bleeding P/R as compared to Standard Group.

The Hemorrhoidal mass treated with *pippalyadi lepa* took longer time to show its effectiveness whereas the *kshara pratisarana* requires maximum number of 7 days for debridement. *Teekshna apamarga kshara pratisarana* was found more effective than *pippalyadi lepa* statistically. (Fig. A & B)

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