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A Comparative Study of *Snuhi Pratisaraneeya Kshara* and *Apamarga Pratisaraneeya Kshara* for the management of *Abhyantara Arsha* (Internal Piles).

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ABSTRACT

Introduction: Abnormal fleshy growths or sprouts in anorectal region like haemorrhoids, polyp, warts, sentinel tags and neoplasia either benign or malignant or other fleshy growth of different regions are included under nomenclature of *Arsha*. The incidence rate of this disease is high among people with old age. At least fifty percent of the people over the age fifty years have some degree of symptoms related to piles. Various research works have been carried on the efficacy of *Apamarga*, *Chitraka*, *Aragbadha*, *Saptachhada*, *Arka*, *Palasha*, *Kadali*, *Patala* and *Nimba Kshara* in the management of *Arsha Roga*. These *Kshara* preparations though, are efficient but can still cause post-operative discomfort and pain. Hence, comparison of *Snuhi Pratisaraneeya Kshara* with *Apamarga Pratisaraneeya Kshara* has been selected.

Methods: Total 30 subjects were randomly selected for the study, with ages ranging from 20 yrs to 60 yrs, irrespective of sex, religion etc. and allocated into 15 patients in two groups. Time frame was one month including follow-up. Follow-up was done on the second, third and fourth week.

Results: In Group A (control group), 15 Patients with *Abhyantara Arsha* (first degree, second degree and third degree haemorrhoids) *Apamarga Pratisaraneeya Kshara* was applied and in Group B, *Snuhi Pratisaraneeya Kshara* was applied. In checking the bleeding, *Apamarga Kshara* showed better results than *Snuhi Pratisaraneeya Kshara*. There is the reduction of pile mass, *Apamarga Kshara* has more reduction in mass size than *Snuhi Pratisaraneeya Kshara*. But in case of postoperative pain in the first week, *Snuhi Pratisaraneeya Kshara* caused less pain than *Apamarga Kshara*.

Conclusions: *Apamarga Pratisaraneeya Kshara* application is better to manage *Abhyantara Arsha* in compared to the *Snuhi Pratisaraneeya Kshara*. The result obtained is an outcome of small sample size, therefore, for a more reliable and comprehensive evaluation it should be conducted in a larger sample size.

Keywords: *Apamarga Pratisaraneeya Kshara*; *Arsha*; Piles; *Snuhi Pratisaraneeya Kshara*.

INTRODUCTION

Guda Vikara (ano-rectal disorders) are progressively increasing in the society because of the sedentary lifestyle, irregular and inappropriate dietary habits, prolonged sitting or standing etc. These disorders are outright embarrassing to the patient. *Sushruta*, the author of *Sushruta Samhita*, the available text in Ayurveda surgical practice, has included *Arsha* in *Ashta-Mahagada*.¹ The drastic change in lifestyle has caused rapid increase in the prevalence of this disease. *Charaka* explains that *Arsha* is an abnormal fleshy

overgrowth in *Guda*,² whereas the word "*Arsha*" has also been used for muscular outgrowth in other parts of the body like *Nasa*, *Karna* etc.

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In *Astanga Hrudayam*, it has been mentioned that when muscle like fleshy projections kills a person like an enemy and obstruct the anal region, it is called as *Arsha*.³ *Charaka* mentioned *Meda*, *Mamsa* and *Twak* as the *Adhithana* of all type of *Arsha*.⁴ *Arsha* is divided as *Sahaja* and *Jatasya-uttarakalaja Arsha*.⁵ *Sahaja Arsha* occurs due to *Gudabali-Bija Upaghata* whereas *Jatasya-uttarakalaja Arsha* occurs after birth due to unhealthy dietary habits and lifestyle. While describing the *Chikitsa* of *Arsha*, *Acharya Charaka* has listed its two types as *Ardra* and *Shushka*. *Ardra* also known as *Sravi* are bleeding piles caused due to vitiation of *Rakta* and *Pitta* mainly.⁶ *Acharya Charaka* and *Sushruta* have given clear descriptions about the *Sahaja Arsha*.⁷ *Acharya Vagbhata* has given only a few symptoms regarding *Sahaja Arsha* as *Parusha*, *Dudarshan*, *Ruksha*, *Pandu*, and *Antarmukhi*.⁸

Abnormal fleshy growths or sprouts in anorectal region like haemorrhoids, polyp, warts, sentinel tags and neoplasia either benign or malignant or other fleshy growth of different regions are included under nomenclature of *Arsha*. It signifies that all the haemorrhoids are *Arsha*, while all *Arsha* are not haemorrhoids.

The incidence rate of this disease is high among people with old age. At least fifty percent of the people over the age fifty years have some degree of symptoms related to piles.⁹

In *Sushruta Samhita*, the treatment modality for *Arsha* has been divided into four categories.¹⁰ *Bheshaja Chikitsa* (~medical treatment) for *Achirakala*, *Arsha* with *Alpa Dosha*, *Alpa Lakshana* and *Alpa Upadrava*. *Kshara Karma* (~caustic therapy), for *Mridu*, *Prasrita*, *Avagada* and *Uchchhrita Arsha*. *Agnikarma* (~Thermal cautery therapy) *Karkasha*, *Sthira*, *Prithuk* and *Kathina Arsha*. *Shastra Karma* (~surgery) for *Tanumoola*, *Uchchhrita* and *Kledayukta Arsha*.

Various research works have been carried on the efficacy of *Apamarga*, *Chitraka*, *Aragbadha*, *Saptachhada*, *Arka*, *Palasha*, *Kadali*, *Patala* and *Nimba Kshara* in the management of *Arsha Roga* across various centers in India. These *Kshara* preparations though, are efficient but can still cause post-operative discomfort and pain. Hence, to overcome this problem, *Snuhi Pratisaraneeya Kshara* has been selected which is known for its medicinal value such as *Arshogna*, *Lekhana*, antibacterial, antifungal, antiviral, wound healing property etc. Due to the limitations in conventional medical and surgical management, there is a need for new treatment modalities. *Pratisaraneeya Teekshna Kshara Karma* for the management of *Abhyantara Arsha* yields negligible rate

of recurrence, is cost effective, causes less pain and bleeding, have less infection and anal incontinence and requires minimum hospital stay during treatment. Till now, clinical research has not been carried out compared with the role of *Snuhi* as *Pratisaraneeya Kshara* in the management of *Abhyantara Arsha*.

METHOD

Total 30 subjects were randomly selected for the study, with ages ranging from 20yrs to 60 yrs, irrespective of sex, religion etc. from OPD / IPD of P.G. Department of *Shalya Tantra*, National Institute of Ayurveda, Jaipur. The study was explained clearly to the subjects and their signed, written informed consent was taken before starting of the trial. This study was approved by the Institutional Ethics committee (IEC), National Institute of Ayurveda, Jaipur via letter no. IEC/ACA/2017/65; dated 26/04/2017, before starting the clinical trial in patients of *Abhyantara Arsha*. This study was conducted after getting it registered in Clinical Trials Registry- India with registration number, CTRI/2018/10/015968.

Preparation of *Kshara*:

Apamarga ash (300gm), *Shukti* (Oyster shell 30gm), *Chitrakamula Kalka* (3gm), Water 6 parts (by volume) of *Apamarga* ash was used for the preparation of *Apamarga Pratisaraneeya Kshara*. *Snuhi* ash (300gm), *Shukti* (Oyster shell 30gm), *Chitrakamula Kalka* (3gm) was used for the preparation of *Snuhi Pratisaraneeya Kshara*.

The *Panchanga* of *Apamarga/Snuhi* plant was collected, dried up and burnt. The ash thus collected was mixed with six times of water and filtered 21 times. Filtrate was cleaned and cleared and when filtrate obtained *Gomutra Varna* it was kept on mild fire and reduced to 2/3rd. Then, red hot *Shukti* (~weight 1/10th part of ash) was added into the filtrate solution and was continuously stirred well until it was reduced to 1/3rd. This was further heated up by adding *Chitraka Kalka* (~weight 1/10th part of *Shukti*). Thick solution was obtained as an *Apamarga/Snuhi Pratisaraneeya Teekshna Kshara*. It was collected and stored in an airtight container.

Intervention:

Total 30 patients were randomly selected and divided into two groups, 15 in each group. Time frame was 1 month including follow-up. Follow up was done on the second, third and fourth week (Table No. 1).

Table No. 1 - Intervention	
Arms	Assigned Intervention
Group A - 15 Patients with I, II & III <i>Abhyantara Arsha</i> . <i>Apamarga Pratisaraneeya Kshara</i> Control group	<i>Apamarga Pratisaraneeya Kshara</i> application- The procedure was done under L.A. <i>Kshara</i> and was applied over individual internal pile masses for 2 minutes. The colour of pile mass turned into <i>Pakwa Jambuphala Varna</i> and then it was washed with <i>Nimbu Swarasa</i> .
Group B - 15 Patients with I, II & III <i>Abhyantara Arsha</i> . <i>Snuhi Pratisaraneeya Kshara</i> Trial group	<i>Snuhi Pratisaraneeya Kshara</i> application- The procedure was done under L.A. The <i>Kshara</i> was applied over an individual internal pile mass for 2 minutes. The color of pile mass turned slightly blackish (<i>Pakwa Jambuphala Varna</i> was not achieved). And then it was washed with <i>Nimbu Swarasa</i>

Treatment procedure:

Pratisaraneeya Kshara Karma procedure

Poorva Karma:

Patients selected for the procedure were advised to remain nil orally for at least 4 hours prior to the procedure. Consent was taken before procedure. Part preparation was done in the perianal region. Proctoclysis enema was given. Pre medications were administered according to need. Plain 2% Lignocaine sensitivity test was done.

Pradhan Karma:

Patient was placed in a lithotomy position on the operation table. The perianal region was cleaned with antiseptic solution and draping was done. Local anaesthesia (2% lignocaine with adrenaline) was infiltrated in an operative site. Lubricated normal proctoscope was introduced in anal canal, position of pile mass was noted and proctoscope was removed. Slit proctoscope was introduced and skin around pile mass was pulled laterally with Allis tissue holding forceps to get a better view of pile masses. The healthy anal mucosa was covered with wet cotton balls to prevent spilling of *Kshara* on it. *Apamarga /Snuhi Pratisaraneeya Kshara* was applied over pile mass and the opening of the proctoscope was closed for *Shatamatrakala* (~ 2 minutes) with the palm. The pile mass was cleaned with *Nimbu Swarasa*. It was observed that the pinkish pile mass has turned to blackish (*Pakva Jambu Phala Varna*). If such color was not obtained, *Kshara* was applied once again till the pile mass turned to blackish colour. Once again it was washed with *Nimbu Swarasa*. This procedure was repeated on all the pile masses. Thereafter the anal canal was packed with gauze piece soaked in *Yastimadhu Taila* (*A.H.Chi.* 22/41-44) to prevent burning sensation and local oedema. Dry dressing was done and the patient was shifted to ward.

Paschat Karma (Post-operative treatment)

Patients were kept nil by mouth for 6 hours after the procedure. Intravenous fluids were administered at that time. Packing was removed after 6 hours and 20 ml of *Yasthimadhu Taila* was administered per rectal. From next day onwards, patients were advised to take sitz bath with *Sphatika Bhasma* for 10-15 min twice a day after defecation and *Yasthimadhu Taila* was used rectally after sitz bath for 7 days and *Triphala Guggulu* (2 tablets twice daily), *Haritaki Choorna* (5 grams at bedtime) for 7 days with Lukewarm water was advised. All Patients were advised to follow *Pathya Ahara* and *Vihara*.

Assessment Criteria:

Assessment was done on the basis of subjective and objective criteria (Table No.-2, Table No.-3).

Table No – 2: Subjective parameters	
Pain (VAS Scale)	
Grade	Explanation
0	No Pain
1	Mild Pain (1-3)
2	Moderate Pain (4-7)
3	Severe Pain (8-10)
Raktasrava (BPR)	
0	No Bleeding
1	0-5 drops
2	5-10 drops
3	Bleeding in the form of splash in the pan
4	Bleeding in the form of stream
BPR Grading	
0	No Bleeding
1	0-5 drops
2	5-10 drops
3	Bleeding in the form of splash in the pan
4	Bleeding in the form of stream

Table No.- 3: Objective parameters	
Size of Pile Mass	
Grade	Size of pile mass
0	Not measurable
1	$\leq 1.5 \text{ cm}^3$
2	1.6-2.5 cm^3
3	2.6- 3.5 cm^3
4	3.6-4.5 cm^3
5	$\geq 4.5 \text{ cm}^3$
Colour of piles mass Grading	
0	Reddish black colour (<i>Pakva Jambu Phala Varna</i>)
1	Slightly blackish colour
2	Pinkish colour
3	Plum colour
Anal sphincter tonicity grading	
0	Normal
1	Raised
2	Relaxed

Size of pile mass was measured by using vernier caliper. Height and width of pile mass was measured with this instrument and length measured with thread. Size was obtained by multiplying length, breadth and height ($l \times b \times w$). Colour of pile mass was assessed with the help of proctoscopy examination before and after the procedure. Tone of anal canal was assessed by Digital Rectal Examination (DRE) before and after defecation.

Statistical Analysis:

Values of individual variable obtained in 4 periods BT (Before Treatment- 0 day), 1st week of treatment, 2nd week of treatment, 3rd week of treatment and 4th week of treatment (AT) of 15 subjects in each group were averaged (mean). This Mean data was subjected to "Wilcoxon rank sum test" (two tailed) to assess the significant difference between BT & 1. week, BT & 2. week, BT & 3. week, BT & 4 week of treatment (AT) periods. After collecting the mean data of individual variables and individual subjects of each group in the BT and AT (IV week) period, their Mean Difference (M.D=B.T-A.T) was taken. With this Mean difference (M.D), percentage of change in each variable and each subject after treatment was calculated by using a formula – $(M.D/B.T) \times 100$. Percentage of change in individual variable after treatment of Group-A, and Group-B was compared within.

RESULTS

Results are shown in table from Table No. 4– 6.

Intergroup Comparison of Group A & Group B by Mann-Whitney U test

Table No. -4: Comparison of AT-BT							
Variable	Groups	Mean Rank	Sum of the rank	Z value	U value	p value	Result
Bleeding per Anus	A	17.37	260.50	-1.270	84.500	0.204	NS
	B	13.63	204.50				
Pain	A	17.10	256.50	-1.114	88.500	0.265	NS
	B	13.90	208.50				
Size of Pile Mass	A	20.37	305.50	-3.201	39.500	0.001	ES
	B	10.63	159.50				
Colour of Pile Mass	A	18.67	280.00	-2.249	65.000	0.025	VS
	B	12.33	185.00				
Anal sphincter tonicity	A	14.10	211.50	-1.085	91.500	0.278	NS
		16.90	253.50				
Index: NS- Non significant, ES- Excellent significant, VS- Very significant							

This shows that there is extremely significant variation in both the groups after treatment for the criteria size of pile masses. The group A (mean rank 20.37) has shown extremely significant decrease in the size of pile mass than group B (mean rank 10.63). The group A showed very significant results ($p=0.025$) in color of pile mass. Bleeding per anus, pain and tonicity differences showed not-significant results. group B showed greater difference in pain and tonicity than group A. But the difference is not statically significant (Table No. 4).

Table No.- 5: Percentage difference in individual variable of Group A and Group B			
Sr. no.	Parameter	Group A %	Group B%
1	Bleeding	91.19	83.50
2	Size of pile mass	89	55.06
3	Pain	85.11	78.49

Apamarga Pratisaraneeya Kshara showed 91.19% relief in bleeding criteria while *Snuhi Pratisaraneeya Kshara* showed 83.50% relief in the same. Size of pile mass criteria showed 89% relief by *Apamarga Pratisaraneeya Kshara* and 55.06 % relief by *Snuhi Pratisaraneeya Kshara*.

Percentage relief for pain in group A found to be 85.11% while in group B, it was 78.49 %.(Table No. 5)

Table No.-6: TOTAL EFFECT OF THERAPY IN 30 PATIENTS						
Treatment response	Group A		Group B		Total	
	N o.	%	N o.	%	N o.	%
Cured (80%-100% relief)	13	86.67	2	13.33	15	50.00
Marked improvement (65%-79% relief)	2	13.33	9	60.00	11	36.67
Moderate improvement (40% - 64% relief)	0	0	4	26.67	4	13.33
Mild improvement (25% to 39%)	0	0	0	0	0	0
Unchanged(<25% relief or no change)	0	0	0	0	0	0

The Table No. 6 shows the total effect of therapy in 30 patients with group wise relief of signs and symptoms. In group A, 13 (86.67%) patients got cured, 2 (13.33%) patients got marked improvement. In group B, 2 (13.33%) patients got cured, 9 (60%) patients got marked improvement and 4 (26.67%) patients got moderate improvement. Out of 30 patients 15 (50.00%) got cured, 11 (36.67%) got marked improvement, 4 (13.33%) got moderate improvement.

DISCUSSION

As mentioned in classical texts, muscle-like fleshy projections and obstruction in the anus are main features whereas bleeding and prolapse of mass per *anum* are two main presenting features of the disease under consideration of modern sciences.¹¹ These variables are compared in this study to evaluate the efficacy outcome in the management.

In the study, 26 (86.67%) patients had prolapse of mass and 4 patients (13.33%) had no prolapse of mass. This data reveals that, in early stages of haemorrhoids (first degree), patients are not generally willing to consult any specialist whereas in second and third degree piles, most of the patients are forced to consult the expert for unusual prolapsed pile masses at this stage.

In this study, 22 (83.33%) patients had pile masses at 3, 7 & 11 O'clock position, 3 patients (10%) had pile masses at 3 & 11, 2 patients (6.67%) had pile masses at 7 & 11 O'clock position, 2 patients (6.67%) had pile mass at 11 O'clock position and 1 patient (3.33%) had pile mass at 3 O'clock position. This arrangement is attributed to the termination of the superior rectal artery which divides into right and left two main branches. The left branch

continues as a single vessel and terminates at 3 o'clock, whereas the right branch divides into two branches- one terminates at 11 o'clock [anterior branch] and the other terminates at 7 o'clock (posterior branch). Hence, the chances of development of primary pile masses at 3, 7 & 11 o'clock positions are more.

Taking into consideration the individual assessment parameters, in checking the bleeding, *Apamarga Kshara* (91.19 %) was better than *Snuhi Pratisaraneeya Kshara* (83.50 %). Similarly for the assessment parameter size of pile mass, *Apamarga Kshara* (89.00%) was better than *Snuhi Pratisaraneeya Kshara* (55.06%). But in case of postoperative pain, *Snuhi Pratisaraneeya Kshara* caused less pain than *Apamarga Kshara*. In the first post-operative week after *Kshara Karma*, patients complained of burning type of pain whereas post *Snuhi Pratisaraneeya Kshara*, pain and discomfort was less as compared to *Apamarga Kshara*.

In both group A and group B, patients complained of burning pain in 1st post procedural week for which *Yasthimadhu Taila Matra Basti* was administered as planned in research protocol.

Focusing on recurrence, two patients in *Snuhi Pratisaraneeya Kshara* group reported with complaint of pain and bleeding after two weeks of procedure for which re-application of *kshara* was done.

Out of 15 patients in group A, none of the patients developed recurrence but in trial group B, one patient developed recurrence.

In Group A, by observing the percentage of difference in each individual after 4 week of treatment, among 15 subjects, 13 subjects got cured (80%-100%) and 02 subject got marked improvement (65%-79%) by *Apamarga Pratisaraneeya Kshara*. In Group B, by observing the percentage of difference in each individual after 4 week of treatment, among 15 subjects, 2 subjects got cured (80%-100%), 09 subjects get marked improvement (65%-79%) and 4 subjects got moderate improvement (40%-64%) by *Snuhi Pratisaraneeya Kshara*. Numbers of completely cured patients from disease under consideration were more in trial group A than group B. For the purpose of concluding the study, it can be stated that *Apamarga Pratisaraneeya Kshara* is better intervention than *Snuhi Pratisaraneeya Kshara Karma* for entity under question in terms of relieving the signs and symptoms as well as in terms of patient satisfaction score at the end of trial.

Apamarga and *Snuhi Pratisaraneeya Kshara* acts on haemorrhoids in two ways – It cauterizes the pile mass directly because of its *Ksharana Guna* (corrosive nature) and it coagulates protein in haemorrhoidal plexus. The coagulation of protein leads to disintegration of haemoglobin into haem and globin.

Synergy of these actions results in decreasing the size of the pile mass. Further, necrosis of the tissue in the haemorrhoidal vein will occur. This necrosed tissue sloughs out as a blackish brown discharge for 3 to 7 days. The haem present in the slough gives the discharge its color. The tissue becomes fibrosed and scar formation is seen. The haemorrhoidal vein obliterates permanently and there is no recurrence of haemorrhoids.¹²

DISCUSSION

From the present study, it can be concluded that *Apamarga Pratisaraneeya Kshara Karma* is a better option than the *Snuhi Pratisaraneeya Kshara* for the management of *Abhyantara Arsha*. The result obtained on this trial was obtained in a small sample size. Therefore, for a more reliable and comprehensive evaluation, the study should be conducted in a larger sample size.

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