

EVALUATION OF THE EFFICACY OF *NIMBA KSHARASUTRA* IN THE MANAGEMENT OF *ARSHAS*

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ABSTRACT

Background: Haemorrhoid is a quite common health problem pertaining to the ano-rectal region characterized by engorgement of haemorrhoidal venous plexus. In Ayurvedic classics, the disease can be correlated to *Arshas* and is included under *Ashtamahagadas* owing to the difficulty in its management. Even though the disease is not life threatening, suffering from haemorrhoids is embarrassing. In contemporary medicine, the common treatment procedures adopted are Haemorrhoidectomy, Haemorrhoidopexy, Banding & Cauterization. The four therapeutic measures explained by Acharya Sushruta for the management of *Arshas* are *Bheshaja chikitsa*, *Shastrakarma*, *Ksharakarma* and *Agnikarma*. Acharya Chakrapani has mentioned

Ksharasutra as treatment modality in the context of management of *Arshas*, which possess cutting and healing properties. *Ksharasutra* treatment has become standardized & popular nowadays and exploration of new drugs for *Kshara* preparation, as a better substitute for *Apamarga* is the need of the hour. **Objective:** To evaluate the efficacy of *Nimba Ksharasutra* in comparison with standard *Apamarga Ksharasutra* the management of *Arshas*. **Methodology:** 40 patients diagnosed with *Arshas* were selected and were randomly allocated into two groups i.e. Group A (Standard group-*Apamarga Ksharasutra* ligation) and Group B (Trial group-*Nimba Ksharasutra* ligation). The effect of treatment was assessed on the basis parameters of like bleeding per rectum, pain, sloughing and falling of pile mass and spasticity of anal sphincter. **Results:** The symptoms of bleeding per rectum, pain, spasticity of anal sphincter and pile mass were completely relieved in all the 40 patients of both the groups within 21 days after the procedure. Those patients who underwent *Apamarga Ksharasutra* ligation showed slight faster sloughing and falling of the pile mass than those who underwent

Nimba Ksharasutra ligation. But both the *Ksharasutras* were having almost similar effect.

Conclusion: This study proved the efficacy of *Ksharasutra* in the management of *Arshas* and found that *Nimba Ksharasutra* as an effective and potent alternative for *Apamarga Ksharasutra*.

KEYWORDS: Haemorrhoids, *Arshas*, *Apamarga Ksharasutra*, *Nimba Ksharasutra*.

INTRODUCTION

Arshas is a disease in which the “*Mamsankuras*’ or *fleshy masses* which occur at the opening of *Gudamarga* obstruct the pathway and tortures the patient like an enemy. The disease is progressively increasing nowadays, due to multifold factors like improper and irregular dietary habits, disturbed daily routines, faulty habits of defecation, prolonged standing or sitting, sedentary occupation and mental stress etc. Haemorrhoids are present universally in healthy individuals as cushions surrounding the anastomoses between rectal arteries. But, the term haemorrhoid is commonly used to describe the pathologic condition of haemorrhoidal engorgement, instead of normal anatomic structure.

Haemorrhoids constitute about 50% of colorectal investigations^[1] and if untreated can potentially pose serious medical problems. It is estimated that 50-85% of people around the world have haemorrhoids. In India 75% of the population is affected.^[2] Its incidence can be seen at any age and in both genders equally. Haemorrhoids are very rare in nations where people squat to defecate. Its incidence can be seen in any age. Both genders report peak incidence from age 45 to 65 years.

In contemporary medicine the common treatment procedures adopted are haemorrhoidectomy, haemorrhoidopexy banding and cauterization. Topical ointments, corticosteroid creams, lignocaine creams etc are practiced as conservative management. Along with these, treatments like sclerotherapy, infrared photocoagulation cryosurgery, direct current electrotherapy etc. are also in practice.

According to Acharya Susrutha, management of *Arshas* includes *Bheshaja*, *Kshara karma*, *Agni karma*, and *Sastra karma*.^[3] Acharya Chakrapani has mentioned *Ksharasutra* as a treatment modality in the context of management of *Arshas*^[4], which possess cutting and healing properties. The procedure of *Ksharasutra* ligation can be considered as a “*Sastra karma*” as excision of pile mass is achieved. At the same time as the thread is processed with successive

coatings of *kshara*, it incorporates the actions of *Kshara* like *Chedana*, *Bhedana*, *Lekhana* also. *Ksharasutra* procedure thus enables simultaneous cutting and healing. Ayurveda Acharyas have mentioned different types of drugs for the preparation of *Kshara* and *Ksharasutra*. Acharya Sushruta has explained 23 drugs for the preparation of *Kshara* in *Ksharapakavidhi Adhyaya*; like *Aparmarga*, *Kadali*, *Arka*, *Kutaja*, *Palasha* etc. In *Rajanighatu*, *Nimba* comes under the group of *Ksharadashaka*^[5], having properties; *Kashaya Tikta Rasa*, *Laghu Rooksha Guna*, *Katu Vipaka*, and *Sheeta Veerya*.^[6] *Dhanwantari Nighatu* emphasizes *Shothahara* and *Vedanashamaka* properties of *Nimba*.^[7] In *Kshara* form it attains *Chedana*, *Bhedana* and *Lekhana* properties. *Nimba* is easily available, cost effective and easy to prepare *Kshara*. So in this study an effort is made to evaluate the efficacy of *Nimba Ksharasutra* in the management of *Arshas*.

MATERIALS AND METHODS

Sample Source: 40 Patients of *Arshas* attending the OPD and IPD of Alva's Ayurveda College and Alva's Health Centre, Moodubidire were selected and were divided randomly into two equal groups A and B. 20 patients were treated with *Nimba Ksharasutra* and 20 with *Apamarga Ksharasutra*.

Study Design: Controlled Clinical Study.

Diagnostic Criteria

Patients showing classical symptoms of *Arshas* like

1. *Mamsankura*–Mass per anus
2. *Rudhira srava*- Bleeding per anus
3. *Guda marga nirodham*-Obstruction in the anal canal
4. Mucous discharge per anus

Inclusion Criteria

- The patients having classical symptoms of *Arshas* were selected.
- Patients were selected between the age group of 16-60 years of either gender, irrespective of religion, occupation, and socio-economic status.
- Controlled systemic illness like Hypertension, Diabetes Mellitus

Exclusion Criteria

- Patients suffering secondary to inflammatory diseases like Ulcerative colitis and Crohn's disease.

- Haemorrhoids associated with Fissure in Ano, Fistula in Ano, Anal stricture, Perianal abscess, Malignancy and Polyps.
- Patients suffering from HIV, Tuberculosis and Ca of rectum.
- Pregnant women.

Interventions

In Group A and B

- Study period: Total study period including observation period and follow up- 60 days.
- Treatment procedure was done on 1st day.
- Observation period was the next 28 days and the patients were advised to come on 3rd, 5th, 7th, 14th, 21st and 28th days.
- Follow up was done on 45th day and 60th day

Procedure for group A and Group B

Purva Karma

- Obtained informed consent from the patient.
- Established investigation report with the patient.
- Perianal part was shaved and prepared.

Pradhana Karma

- The patient made to lie down in lithotomy position on the operation table.
- Painting and draping of the part done.
- Local Anaesthesia given with Inj.Lignocaine 2%
- Dilatation of anal canal done after lubricating the finger with 2% lignocaine gel.
- Catch hold: Skin was retracted with Allie's tissue holding forceps and exposed the pile mass. Then the pile mass was held with the help of Pile- holding forceps.
- Transfixation and Ligation: Each pile mass was transfixed by passing the curved round bodied needle mounted with *Kshara Sutra* (For Group A - *Apamarga Kshara Sutra* and Group B- *Nimba Kshara Sutra*) at its base. After transfixation of *Kshara Sutra*, the pile mass was ligated anteriorly and posteriorly with adequate knots. After ligation the pile mass was placed in position.
- Proper haemostasis achieved.
- Pressure packing was done using *Yashtimadhu taila*.
- Then the patient was shifted to the recovery room.

Paschat Karma

- Packing removed after 3 to 4 hours.
- 8 hours after the procedure:
 - Hot water sitz bath was given for 10-15 minutes twice daily.
 - 10 ml of Yashtimadhu taila applied per rectally twice daily.
 - Tab Triphala Guggulu - one tablet (250mg) thrice a day after food.
 - Tab Gandhaka Rasayana one tablet (125mg) thrice a day after food.
 - Triphala Choorna 2 teaspoon with warm water at bed time.
 - Antibiotics and Analgesics were given as per requirement.

Assessment Criteria

Effect of treatment was assessed on the basis of gradation of both subjective and objective parameters before and after treatment.

Subjective parameters

- Rakta srava (Bleeding per rectum)
- Ruja (Post-operative pain)

Objective parameter

- Spasticity of anal sphincter
- Sloughing and falling of pile mass.

RESULTS

The study was carried out in 40 patients of *Arshas* in 2 equal groups. Assessment of the condition was done based on detailed proforma adopting standard scoring method of subjective and objective parameters. Pre and post comparison was done by Wilcoxon sign rank test, Friedman test, McNemars test & Cochran Q test. Comparison between the groups A & B was done by Mann-Whitney U test. IBM SPSS Version 20 was used for the statistical analysis.

Effect on Pain: Group A Apamarga kshara showed statistically highly significant difference on 7th day, 14th day & 28th day.($p < 0.001$) from 0th day, ie before treatment. Group B showed statistically significant difference in terms of pain on 14th day & 28th day ($p < 0.05$) from 0th day. On 3rd day, both the groups were found to be statistically highly significant, but

clinically insignificant, because of the aggravated pain due to surgery. On comparison between the groups, group A showed better effect than group B.

Effect on Bleeding: Both groups A & B have shown statistically highly significant changes in bleeding on 3rd, 7th, 14th & 28th day, from compared to before treatment. Since the base of haemorrhoidal masses were ligated, bleeding was nil after the treatment, from 3rd day of observation in both group A & group B.

Effect on Spasticity of anal sphincter: Group A showed statistically significant difference on 3rd day, 14th day & 28th day. Group B showed statistically significant difference on 3rd day, 7th day, 14th day & 28th day. On comparison of day 3 & day 7, day 3 & day 14, day 3 & day 28, group B showed significant difference. ($p < 0.05$) On comparison of day 14 & day 28, group A showed highly significant difference ($p < 0.001$). In group A and group B tonicity of anal sphincter increased slightly post operatively due to the loss of skin, but later attained normal tone.

Effect on Sloughing and Falling of pile mass: Both group A & B showed statistically highly significant effect on sloughing and falling of pile mass ($p < 0.001$) In group A, by 7th day the pile masses have fallen off in 85%. By 14th day it became 100%. In group B, by 7th day the pile masses have fallen off in 20%. By 14th day it became 100%. In group A, complete sloughing and falling of pile masses occurred within 5-8 days. In group B, complete sloughing and falling of pile masses occurred within 6-12 days. This can be due to the decreased pH value of *Nimba kshara*, compared to the standard.

DISCUSSION

In group A & group B, all the signs and symptoms like pain, bleeding, tonicity of anal sphincter & sloughing and falling of pile mass got statistically significant changes from the 1st assessment day. There was 100% relief in all the signs and symptoms in both the groups on 28th post-operative day. On comparison, Group A showed better results in terms of pain & sloughing and falling of pile mass, and there was statistically significant difference from group B. In group A and group B tonicity of anal sphincter increased slightly post operatively due to the loss of skin, but later attained normal tone. There was no post-operative infection, recurrence of any symptoms and other complications noted until 60th post-operative day. Both the *Ksharasutras* showed significant effect over 3rd and 4th degree haemorrhoids. Faster sloughing and falling of pile mass was observed in group A (*Apamarga Ksharasootra*)-

within 5-8 days. *Nimba Ksharasutra* took 6-12 days for complete sloughing and falling of pile mass. This may be due to the increased pH of *Apamarga Kshara*. Wound healing after fall of mass was good in both standard and trial groups (maximum 2-3 weeks). In both the groups, after the falling of mass wound healing occurred in all patients within 3 weeks. But this is not sufficient to draw a conclusion because, the sample size is small. Overall study suggests that both the groups are having equal efficacy and potency in the management of *Arshas*.

Probable mode of action of *Ksharasutra*

Due to the *Ksharana guna of Kshara*, it cauterizes the pile mass directly (Corrosive action). *Kshara* and *Snuhi Ksheera* present in *Ksharasutra* produces debridement of tissue by way of proteolytic enzymes present in it. Thus the resulting coagulation of protein in the haemorrhoidal plexus leads to disintegration of haemoglobin into heam and globin. Mechanical strangulation by *Sutra* to haemorrhoidal vein leads to necrosis. Synergy of these actions results in decrease in the size of pile mass. Further necrosis of tissue in the haemorrhoidal vein will occur. This necrosed tissue slough out as blackish mass along with *Sutra* in 5-10 days. After that the tissue becomes fibrosed with scar formation. *Ksharasootra* does not allow any bacterial multiplication in its presence, due to its anti bacterial action. The haemorrhoidal vein obliterates permanently and there is no recurrence of haemorrhoids.

Probable mode of action of *Nimba Ksharasutra*

Nimba is having qualities of *Tikta Kashaya Rasa*, *Laghu Rooksha Guna*, *Sheeta Virya* and *Katu Vipaka*. Moreover it is having *Shothahara* and *Vedanashamaka* properties. In *Kshara* form even it attains the quality of *Chedana*, *Bhedana* and *Lekhana*. *Nimba* possess almost the same qualities of *Apamarga*, except in terms of *Virya*. Still it possess the property of alleviating *Pitta & Kapha*. In *Kshara* form it possess extra *Lekhana Guna*, which helps in eradicating *Dushita Mamsa* and enhances healing. Hence *Nimba Ksharasutra* can be used as an alternative for *Apamarga Ksharasutra* in the management of *Arshas*.

Table 1: Comparitive effect of treatment between groups A & B on 3rd day.

Ranks								
	GROUP	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Wilcoxon W	Z value	P VALUE
PAIN	GROUP A	20	26.35	527.00	83.000	293.000	-3.399	<0.05
	GROUPB	20	14.65	293.00				
	Total	40						
BLEEDING	GROUP A	20	22.30	446.00	164.000	374.000	.269	>0.05
	GROUPB	20	18.70	374.00				
	Total	40						
TONICITY	GROUP A	20	18.05	361.00	151.000	361.000	-1.497	>0.05
	GROUPB	20	22.95	459.00				
	Total	40						
PILEMASS	GROUP A	20	20.50	410.00	200.000	410.000	.000	>0.05
	GROUPB	20	20.50	410.00				
	Total	40						

Table 2: Comparitive effect of treatment between groups A & B on 7th day.

	GROUP	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Wilcoxon W	Z value	P VALUE
PAIN (D7)	GROUP A	20	27.75	555.00	55.000	265.000	-4.123	<0.001
	GROUPB	20	13.25	265.00				
	Total	40						
BLEEDING (D7)	GROUP A	20	11.50	230.00	20.000	230.000	-5.163	<0.001
	GROUPB	20	29.50	590.00				
	Total	40						
TONICITY (D7)	GROUP A	20	14.70	294.00	84.000	294.000	-3.334	<0.05
	GROUPB	20	26.30	526.00				
	Total	40						
PILEMASS (D7)	GROUP A	20	27.00	540.00	70.000	280.000	-4.064	<0.001
	GROUPB	20	14.00	280.00				
	Total	40						

Table 3: Comparitive effect of treatment between groups A & B on 14th day.

Ranks								
	GROUP	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Wilcoxon W	Z	P VALUE
PAIN (D14)	GROUP A	20	27.73	554.50	55.500	265.500	-4.071	<0.001
	GROUPB	20	13.28	265.50				
	Total	40						
BLEEDING (D14)	GROUP A	20	10.50	210.00	.000	210.000	-6.009	<0.001
	GROUPB	20	30.50	610.00				
	Total	40						
TONICITY (D14)	GROUP A	20	11.50	230.00	20.000	230.000	-5.196	<0.001
	GROUPB	20	29.50	590.00				

	Total	40						
PILEMASS (D14)	GROUP A	20	20.50	410.00	200.000	410.000	.000	>0.05
	GROUP B	20	20.50	410.00				
	Total	40						

Table 4: Comparative effect of treatment between groups A & B on 28th day.

	GROUP	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Wilcoxon W	Z VALUE	P VALUE
PAIN	A	20	26.35	527	83	293	3.399	<0.05
	B	20	14.65	293				
	Total	40						
BLEEDING	A	20	11.50	230	20	230	-5.163	<0.001
	B	20	29.50	590				
	Total	40						
SPASTICITY	A	20	20.50	410	200	410	0	>0.05
	B	20	20.50	410				
	Total	40						
PILEMASS	A	20	20.50	410	200	410	.000	>0.05
	B	20	20.50	410				
	Total	40						

Table 5: Percentage relief in group A and B.

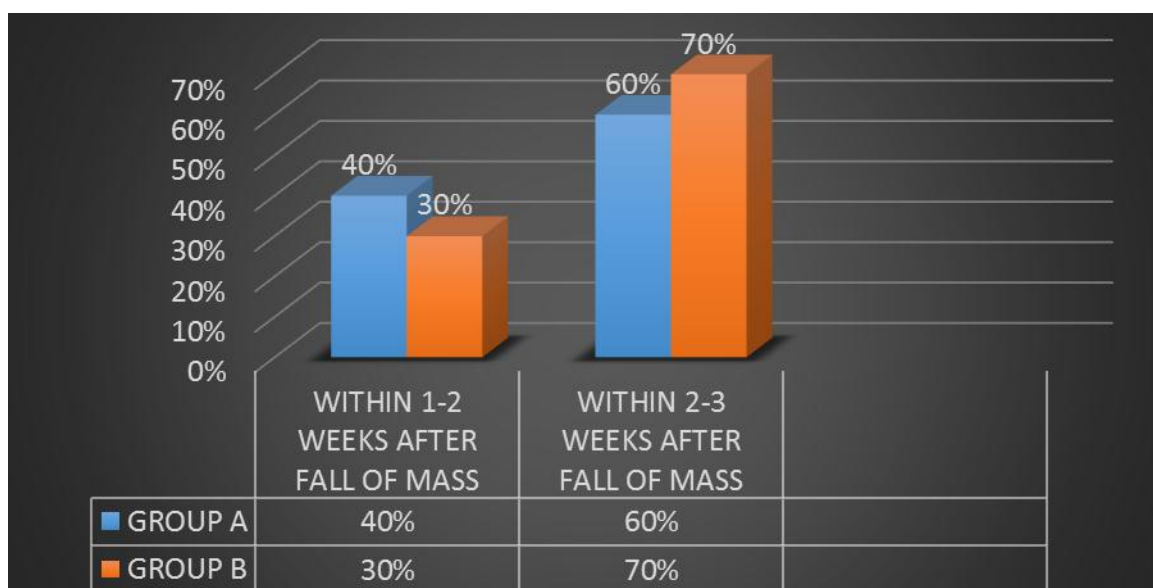
PERCENTAGE RELIEF					
CRITERIA	GROUP	3 RD DAY	7 TH DAY	14 TH DAY	28 TH DAY
PAIN	A	----	48.27%	100%	100%
	B	----	58.33%	83.3%	100%
BLEEDING	A	100%	100%	100%	100%
	B	41.07%	100%	100%	100%
TONICITY	A	16.6%	20%	33.33%	100%
	B	30.55%	66.66%	100%	100%
PILE MASS	A	0%	85%	100%	100%
	B	0%	20%	100%	100%



Graph 1: Falling of Pile Mass in Group A.



Graph 2: Falling of Pile Mass in Group B.



Graph 3: Healing of resulting wound after falling of mass.

CONCLUSION

Kshara is alkaline in nature and its value (pH) ranges from 7-14. pH of *Apamarga kshara* used in this present study was 13.93 and that of *Nimba Kshara* was 10.77. The synergic action of mechanical striangulation by *sutra*, corrosive effect of *Kshara* and proteolytic action of *Snuhiksheera* results in cauterization and necrosis of haemorrhoidal tissue. This necrosed tissue sloughs out as a blackish mass along with *sutra* in 5-10 days. After that the tissue becomes fibrosed with scar formation. The haemorrhoidal vein obliterates permanently and there is no recurrence of haemorrhoids. The *Ksharasootra* does not allow any bacterial multiplication in its presence, due to its anti bacterial action. This clinical study suggests that both the groups are having equal efficacy and potency in the management of *Arshas*. So *Nimba ksharasootra* can be used as an alternative for *Apamarga Ksharasootra*.

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