



**A COMPARATIVE CLINICAL STUDY ON NIMBA PRATISARANEYYA KSHARA AND APAMARGA PRATISARANEYYA KSHARA IN THE MANAGEMENT OF ARDRA ARSHA (INTERNAL HAEMORRHOIDS)**

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**ABSTRACT**

Haemorrhoids are varicosities of the tributaries of the Haemorrhoidal vein. At least 5% of the general population suffers from *Arsha* (Haemorrhoids). *Arsha* is a disease which is very unkind towards mankind. *Acharya Sushruta* explained four modalities of treatment for *Arsha* i.e. *Bheshaja*, *Kshara*, *Agni* and *Shastra Karma*. *Kshara* is one of the important methods which can be practiced safely. *Nimba Pratisaraneeya Kshara* has been emphasized throughout the classical literature for *Arsha*, described as an *Upakrama*, substitute for surgical procedure. *Nimba Pratisaraneeya Kshara* which is a known modality having antibacterial, antiviral and antifungal properties and have specially been mentioned by *Acharya Sushruta*. *Kshara Karma* does the function of *Chhedana*, *Bhedana* and *Lekhana* without using *Shashtra*. 15-15 (both group) Patients suffering from *Ardra Arsha* (First, Second and Third degree Internal Haemorrhoids) was selected from the O.P.D & I.P.D. of P.G. Department of *Shalya Tantra*, N.I.A., Jaipur and was treated with *Nimba Pratisaraneeya Teakshna Kshara* application. No any major or minor complication was reported by the patient in a follow up period of one month. The patients were assessed on the parameters as per grading and it was seen that the patients was completely cured from the disease in terms of signs and symptoms with no post-operative discomfort. Hence *Nimba Pratisaraneeya Teakshna Kshara* can be successfully used in the management of *Ardra Arsha* with no post-operative complications.

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**INTRODUCTION**

*Arsha* is included under *Asta-Mahagada* by *Acharya Sushruta*<sup>1</sup>. While explaining the *Arsha Chikitsa*, *Sushruta* mentioned *Kshara Karma* as one among the treatment modalities in *Arsha Roga*<sup>2</sup>.

*Acharya Sushruta* explained *Kshara* in the *Sushruta Samhita* in detail in *Sutra Sthana* Chapter 11. In this chapter he said that *Kshara* is *Pradhantama* among *Shastra* and *Anushastra*<sup>3</sup>. He explains in detail about types, indications, contraindications, properties, advantages and disadvantages. Both *Paneeeya* and *Pratisaraneeya Kshara* are indicated in *Arshah* which are *Mrudu*, *Prasrutha*, *Avaghada* and *Uchchruta*<sup>4</sup> should be treated by *Kshara Karma*. While explaining preparation of *Pratisaraneeya Kshara*, he gave a list of drugs which can be used for preparation of *Kshara*. The research studies have already been carried on the efficacy of *Apamarga*, *Chitraka*, *Aragvadha*, *Saptachhada*, *Arka*, *Palasha* and *Patla Kshara* in the management of *Arsha Roga* across various centers in India.

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These *Kshara* preparations though having efficacy but still cause discomfort and pain especially in *Apamarga Teekshana Kshara*. Hence to overcome this problem I studied the efficacy of *Nimba Pratisaraneeya Kshara*<sup>5</sup> which is a known modality having antibacterial, antiviral and antifungal properties and have specially been mentioned by *Acharya Sushruta*. Furthermore no studies have been carried out on this drug in the management of *Arsha*, therefore there is a need to evaluate its efficacy. Hence I studied the efficacy of *Nimba Kshara* in the management of *Ardra Arsha*. The advantage of *Kshara Karma* is that it has less rate of recurrence, cost effective, less painful having less chances of bleeding, anal incontinence and requires minimal hospitalization during treatment. This study is to assess the efficacy of *Nimba Pratisaraneeya Kshara*.

**Clinical study**

**Aims**

The main aim of the study is to evaluate and compare the efficacy of *Nimba Pratisaraneeya Kshara* and *Apamarga Pratisaraneeya Kshara* in the management of *Ardra Arsha*.

**Objectives**

1. To evaluate the effect of *Nimba Pratisaraneeya Kshara* in the Management of *Ardra Arsha*.

- To compare the effect of *Nimba Pratisaraneeya Kshara* and *Apamarga Pratisaraneeya Kshara* in the Management of *Ardra Arsha*.

## MATERIALS AND METHODS

**Selection of sample size:-** After thorough clinical and proctoscopic examination 30 patients who has suffering from first, second and third degree internal Haemorrhoids has been selected and divided in two groups, 15 subjects in each group have been randomly selected for the study, with ages ranging from 20yrs to 60 yrs, irrespective of sex, religion etc.

### Source of Subjects

OPD / IPD of P.G. Department of *Shalya Tantra*, National Institute of Ayurveda, Jaipur.

### Informed Consent

The study was explained clearly to the subjects and their signed, written informed consent will be taken before starting of the trial.

### Selection Criteria

#### Inclusion Criteria

- Patients between the ages of 20yrs to 60 yrs of either sex.
- First, second and third degree Internal Haemorrhoids.
- Arsha* having *Pittaja* and *Raktaja* origin.
- Arsha* which are *Mrudu* (soft), *Prasrutha* (elaborated), *Avaghada* (deep) and *Uchruta* (projected).

#### Exclusion Criteria

- Patients with other systemic illness like uncontrolled Diabetes mellitus, Hypertension, malignancy, HBsAg and Retrovirus positive patients.
- Fourth degree internal piles, external piles and other associated Ano-rectal diseases.
- Infective and Neoplastic conditions of rectum, Rectal prolapsed.
- Pelvic pathology and Pregnancy.

#### Assessment Criteria: A. Subjective Parameters:

- Ruja (Post operative pain)** - VAS scale was used to assess the pain.
- Raktasrava (Bleeding)** - The bleeding per rectum was graded on the basis of different criteria according to patient's own words.
- Nissaran/ Bransha (Prolapse of Pile mass)**- The Prolapse of Pile masses was graded on the basis of different criteria according to patient's own words.

#### Objective Parameter

- Size of pile mass**- 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× b× w)
- Colour of pile mass**- This objective criterion was assessed with the help of proctoscopy examination before and after the procedure.
- Condition of anal sphincter**- Tone of anal canal was assessed by DRE before and after defecation.

## Secondary Outcome Measures

- Recovery time
- Time to return to work
- Parental/patient satisfaction-

Not satisfied - 0  
Somewhat satisfied- 1  
Extremely satisfied- 2

### Pratisaraneeya Kshara Karma Procedure

The *Nimba /Apamarga Pratisaraneeya Teekshna Kshara* was prepared with proper measures in P.G. Department of *Shalya Tantra*, National Institute of Ayurveda, Jaipur and the patient selected from NIA OPD. After all premedication, informed consent and lignocaine sensitivity the patient was taken in the lithotomy position and the perianal area painted with the antiseptic solution (10% Povidone iodine). The sterile drape sheets were placed over operative area. The operative site was anesthetized with the infiltration of inj. 2% Lignocaine with adrenaline. After achieving appropriate anesthesia, slit proctoscope smeared with *Ghritha* is to be introduced in to the anal canal and assessed the masses. The pile mass should be scraped or rubbed and cleaned with cotton swab with warm water. Then application of the paste of *Nimba /Apamarga Pratisaraneeya Teekshna Kshara* with *Darvimukha Shalaka* was done at Internal Haemorrhoid of 3 o'clock position. After application of *Kshara* waited to 2 min the mouth of the *Arsho Yantra* is kept closed by the hand for a period of hundred *Matra Kala* or till the pile mass turns to the colour of *Pakwa Jambuphala Varna*<sup>6</sup>. Then neutralized *Kshara* with *Nimbu Swarasa* and washed with Normal Saline. Care was taken to avoid blowout of *Kshara* over the normal mucosa which may cause burning of unwanted tissue. Same procedure was done at 7 and 11 o'clock positions. The anal canal was packed with gauze pieces soaked in iodine-povidone solution. A tight T-bandage was applied to complete the procedure.

**Post-Operative Treatment-** For 21 days 1. Tablet *Triphala Guggulu* 500 mg twice daily after meal with luke warm water. 2. Laxative- *Triphala Choorna* 5 gm. at bed time with Luke warm water. 3. Warm Sitz bath by *Tankan Bhasma* 3 gm. Twice daily after defecation. 4. *Yasthimadhu Taila Matra Vasti* 30 ml. once daily for seven days.

**Data Collection:** Values of individual Variable were recorded in 4 periods BT (Before Treatment- 0 day), 1<sup>st</sup> week of Treatment, 2<sup>nd</sup> week of Treatment, 3<sup>rd</sup> week of treatment and 4<sup>th</sup> week of treatment (AT) of 15 subjects in each group.

Collected data of individual variables of Group A and Group B was recorded in Table as follows:-

<b>Result Gradations:</b>	Complete Relief	(100%)
	Marked Relief	(>75%)
	Moderate Relief	(50-75%)
	Mild Relief	(25-50%)
	Marginal or No relief	(<25%)

### Observation and Results

#### Effect of therapies

In this series of 30 patients of *Ardra Arsha* patients of Group-A were treated with *Apamarga Pratisaraneeya Kshara* as a standard control and patients of Group-B were treated with *Nimba Pratisaraneeya Kshara*. The group wise results in detail are being described under the separate headings.

**Individual Analysis**

**Individual Variable wise Analysis In Group-A**

**Results of Subjective and Objective Parameter in Group- A by Wilcoxon Matched Test**

S.N.	Subjective parameter	Period	Mean		Diff.	% Relief	SD	SE	P value	Result
			BT	AT						
1.	Bleeding	1 wk	2.467	1.200	1.267	51.35	0.593	0.153	0.0001	ES
		2 wk	2.467	0.600	1.867	75.67	0.639	0.165	<0.0001	ES
		3 wk	2.467	0.267	2.200	89.17	0.676	0.174	<0.0001	ES
		4 wk	2.467	0.133	2.334	94.60	0.617	0.159	<0.0001	ES
2.	Pain	1 wk	0.266	1.866	1.600	-	0.736	0.190	<0.0001	ES
		2 wk	0.266	0.800	0.533	-	0.833	0.215	0.0266	S
		3 wk	0.266	0.266	0.000	-	0.755	0.195	>0.999	NS
		4wk	0.266	0.200	0.066	24.81	0.703	0.181	0.3669	NS
3.	Size of pile mass	1wk	3.200	2.133	1.067	33.34	0.258	0.067	<0.0001	ES
		2 wk	3.200	1.533	1.667	52.33	0.617	0.159	<0.0001	ES
		3wk	3.200	1.067	2.133	66.65	0.743	0.191	<0.0001	ES
		4 wk	3.200	0.333	2.867	89.59	0.743	0.191	<0.0001	ES

(wk – week, BT – Before Treatment, AT - After Treatment, S.D.-Standard Deviation, S.E. - Standard Error, ES – extremely Significant, VS – Very Significant, S – Significant NS- Not significant)

**Individual Variable Wise Analysis in Group-B**

**Results of Subjective and Objective Parameter in Group- B by Wilcoxon Matched Test**

S.N.	Subjective parameter	Period	Mean		Diff.	% Relief	SD	SE	P value	Result
			BT	AT						
1.	Bleeding	1wk	2.800	1.267	1.533	54.75	0.516	0.133	<0.0001	ES
		2 wk	2.800	0.733	2.067	73.82	0.593	0.222	<0.0001	ES
		3wk	2.800	0.266	2.533	90.46	0.639	0.165	<0.0001	ES
		4 wk	2.800	0.066	2.734	97.64	0.798	0.206	<0.0001	ES
2.	Pain	1 wk	0.466	0.600	0.133	28.54	0.833	0.215	0.5781	NS
		2 wk	0.466	0.200	0.266	57.08	0.883	0.228	0.3125	NS
		3 wk	0.466	0.133	0.333	71.45	0.816	0.210	0.1875	NS
		4wk	0.466	0.066	0.400	85.83	0.828	0.213	<0.0538	S
3.	Size of pile mass	1wk	3.333	2.000	1.333	39.99	0.488	0.126	<0.0001	ES
		2 wk	3.333	1.667	1.667	50.06	0.617	0.159	<0.0001	ES
		3wk	3.333	0.800	2.533	75.99	0.743	0.191	<0.0001	ES
		4 wk	3.333	0.133	3.200	96.09	0.861	0.222	<0.0001	ES

After treatment Group-A showed 24.81% relief in pain with p value of (0.366) while Group-B showed 85.83% relief in pain with p value (<0.05).

**Percentage of Difference after Treatment**

**Individual Variable Wise**

**Means and Percentage Difference of Individual Variable In All subjects of Group- A**

**Percentage Difference of Individual Variable in Group-A**

Sr.No.	Parameter	BT	AT	Mean diff.	% Diff.
		Mean	Mean		
1.	Bleeding	2.467	0.133	2.333	94.56
2.	Size of pile mass	3.200	0.333	2.867	89.59
3.	Pain	0.266	0.200	0.066	24.812

**Variable in All Subjects of Group- B**

**Percentage Difference of Individual Variable in Group-B**

Sr.No.	Parameter	BT	AT	Mean diff.	% Diff.
		Mean	Mean		
1.	Bleeding	2.800	0.066	2.733	97.60
2.	Size of pile mass	3.333	0.133	3.200	96.00
3.	Pain	0.466	0.066	0.400	85.83

**Internal Comparison**

Percentage Difference in Individual Variable After Treatment of Group – A and Group – B

Percentage difference in individual variable of Group –A and Group – B

Sr. no.	Parameter	Group A %	Group B %
1	Bleeding	94.56	97.60
2	Size of pile mass	89.69	96.00
3	Pain	24.812	85.83

**Intergroup Comparison of Group-A and Group-B by Mann-Whitney test**

After comparing after treatment data of both groups by above mentioned test, showed

Sr. No.	Parameter	P value	Significance
1.	Bleeding	>0.050	NS
2.	Size of pile mass	>0.050	NS
3.	Pain	<0.0001	ES

This result shows there is no significant variation in data of both groups after treatment for the criteria, bleeding and size of pile mass but pain in first follow up week showed extremely significant result. As pain was initially raised in post *Kshara Karma* period then it was reduced in follow up weeks by sitz bath and *Madhuyashti Tail Matravasti*. So to compare the post operative pain, data of 1<sup>st</sup> follow up week was considered and inter group comparison for pain was done by applying Mann-Whitney test and it showed extremely significant result with p value (<0.0001)

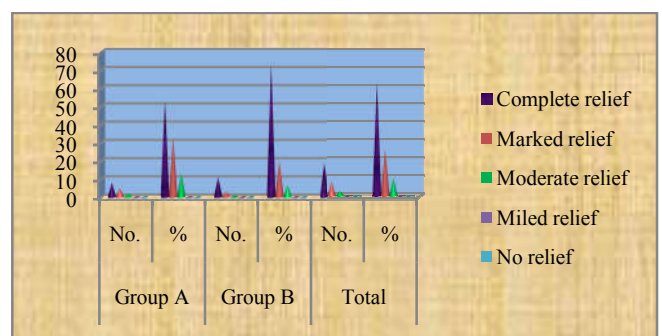
**Intergroup comparison of Group A and Group B**

Variable	Groups	Mean	SD±	SE±	P	S
Bleeding per Anus	A	2.333	0.617	0.1594	>0.050	NS
	B	2.733	0.798	0.2063		
Size of pile mass	A	2.867	0.743	0.1919	>0.050	NS
	B	3.200	0.861	0.2225		
Pain	A	0.066	0.703	0.1817	<0.0001	ES
	B	0.400	0.828	0.1902		

On inter group comparing effect of therapy in both groups it showed not significant results in bleeding and size of pile mass criteria while it showed extremely significant(<0.0001) results in pain criteria.

**Total Effect of Therapy in 30 Patients**

Treatment response	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Complete relief	08	53.33	11	73.33	19	63.33
Marked relief	05	33.33	03	20.00	08	26.66
Moderate relief	02	13.33	01	06.67	03	10.00
Mild relief	0	0	0	0	0	0
No relief	0	0	0	0	0	0



Graph Showing total effect of therapy

## DISCUSSION ON EFFECTS OF THE THERAPY

### Bleeding per anus

- *Apamarga Pratisaraneeya Kshara* (group-A) provided extremely significant ( $p < 0.0001$ ) results in bleeding per anus with percentage of relief by 51.35% after one week of the treatment.
- On 2<sup>nd</sup> week follow up it showed extremely significant ( $p < 0.0001$ ) results with percentage of relief by 75.67%.
- On 3<sup>rd</sup> week it showed extremely significant ( $p < 0.0001$ ) results with percentage of relief by 89.17% on last follow up 4<sup>th</sup> week it showed extremely significant relief of 94.60% with p value ( $< 0.0001$ )
- 02 patient showed complete stoppage of bleeding in first week, 05 Patients in group-A showed complete stoppage of bleeding in 2<sup>nd</sup> week of treatment, 04 patients showed complete stoppage of bleeding in 3<sup>rd</sup> week of treatment while 02 patients showed reduction in bleeding in 4<sup>th</sup> week.
- Over all 13 patients showed complete stoppage of bleeding after treatment in Group-A.
- *Nimba Pratisaraneeya Kshara* (group-B) also provided extremely significant ( $p < 0.0001$ ) results in bleeding per anus with percentage of relief by 54.75% after one week of the treatment.
- On 2<sup>nd</sup> week follow up it showed extremely significant ( $p < 0.0001$ ) results with percentage of relief by 73.82%.
- On 3<sup>rd</sup> week it showed extremely significant ( $p < 0.0001$ ) results with percentage of relief by 94.46% and on last follow up 4<sup>th</sup> week it showed extremely significant relief of 97.64%
- 14 patients in group-B showed complete stoppage of bleeding 4<sup>th</sup> week after treatment, while 01 patients showed reduction in bleeding in 4<sup>th</sup> week.

When the after treatment data of bleeding for both groups was compared it showed p value ( $> 0.05$ ) with no significance. That means both *Apamarga* and *Nimba Pratisaraneeya Kshara* are effective in checking bleeding per anus but *Nimba Kshara* is quite more potent as percentage relief for bleeding by *Nimba Kshara* is (97.64%) which is more than that of *Apamarga Kshara* (94.60%).

Over all, the symptoms of bleeding per rectum were completely reduced during the period of 7 to 15 days after the treatment.

No severe adverse effects were reported by any patient. But some adverse effects were observed which were burning sensation and prolapse of pile mass in first postoperative day. Some cases of 3<sup>rd</sup> degree haemorrhoids showed Sphincter spasm which was completely relieved within 7-14 days by administering *Madhuyasti Taila* and sitz bath. No single patient complained about anal stricture as high chances of occurrence was there by this therapy. But to get rid of this complication few precautions were taken like performing lord's anal dilatation and proper application of *Kshara* only on the affected site (*Arsha*).

Bleeding per anus might be stopped due to the properties of *Kshara* such as *Stambhana*, *Pachana* and *Dahana* mentioned in the texts to achieve haemostasis.

### Size of pile mass

- *Apamarga Pratisaraneeya Kshara* provided extremely significant ( $p < 0.0001$ ) results in size of pile mass with percentage of relief by 33.34% after 1 week of treatment.
- In 2<sup>nd</sup> week it showed extremely significant ( $p < 0.0001$ ) results with percentage relief by 52.33%.
- In 3<sup>rd</sup> week it showed extremely significant ( $p < 0.0001$ ) results with percentage relief by 66.65% and on last follow up week it showed extreme relief of 89.59% .
- 10 patients showed complete reduction and 05 patients shows marked reduction in size of pile mass in group-A.
- *Nimba Pratisaraneeya Kshara* provided extremely significant ( $p < 0.0001$ ) results in size of pile mass with percentage of relief by 39.99% after 1 week of treatment.
- In 2<sup>nd</sup> week it showed extremely significant ( $p < 0.0001$ ) results with percentage relief by 50.06%.
- In 3<sup>rd</sup> week it showed extremely significant ( $p < 0.0001$ ) results with percentage relief by 75.99% and on last follow up 4<sup>th</sup> week it showed extremely significant relief of 96.09%.
- 14 patients showed complete reduction and 01 patients shows marked reduction in size of pile mass in group-B.
- After comparing the after treatment data for size of pile mass in both groups it showed p value of ( $> 0.05$ ) with no significance that means data showed no significant variation. This showed both *Apamarga* and *Nimba Kshara* are effective in reducing size of pile mass where *Apamarga Kshara* showed 89.59% relief and *Nimba Kshara* showed 96.09% relief.

Size of pile mass might be reduced due to *Pachana*, *Vilayana*, *Shodhana*, *Shoshana* and *Lekhana* properties of *Kshara*. *Kshara* also works as *Chedana*, *Bhedana* and *Lekhana*. All the patients those who got treated with *Pratisaraneeya Kshara*, had blackish brown discharge per anus as it shows the therapeutic effect of *Kshara*.

### Pain

- Observation the data for pain showed that *Apamarga Kshara* showed **extremely** significant pain with p value of ( $< 0.0001$ ) in first week while *Nimba Kshara* showed **not** significant pain with p value of (0.57) in first week.
- On comparing pain in both groups on first follow up week it showed group-A extremely significant results with p value ( $< 0.0001$ ).this means group A showed more variation in data.
- In last week percentage relief in group-A was 24.81% and in group-B was 85.83%.this proves that *Nimba Pratisaraneeya Kshara* is causing less post *Kshara Karma* pain as compared to *Apamarga Pratisaraneeya Kshara*.

Pain gradually reduced in next follow up weeks in both groups.

*Nimba* is having properties like *Sheeta Veerya*, *Tiktta* and *Kashaya Ras*. These properties may be the reason for minimal post *Kshara Karma* burning sensation and pain as compared to *Apamarga Kshara*.

### Colour of pile mass

Data for colour of pile mass showed extremely significant result in both groups that means both *Kshara* gave *Pakva*

*Jamboophala Varna* as Group-A showed variation in data by 92.85% and Group-B by 95.25%, still colour of pile mass found to be reduced in both the groups. This minimal difference in data in both groups may vary due to difference in their pH value (*Apamarga Pratisaraneeya Kshara*-13.8 and *Nimba Pratisaraneeya Kshara*-12.8)

**Sphincter tone**

Both groups showed no significant change in sphincter tone before and after treatment. In first follow up week both groups showed very significant result. This shows that both *Apamarga* and *Nimba Kshara* do not affect sphincter tone in the form of stricture.

**Total effect of therapy in both groups**

- In Group-A by observing the percentage of difference in each individual after four week of treatment, among 15 subjects, 08 subjects got complete relief (100%), 05 subject got Marked relief (>75%) and 02 subject got Moderate relief (50-75%) by *Apamarga Pratisaraneeya Kshara*.
- In Group-B by observing the percentage of difference in each individual after four week of treatment, among 15 subjects, 11 subjects got complete relief (100%), 03 subject got Marked relief (>75%) and 01 subject got Moderate relief (50-75%) by *Nimba Pratisaraneeya Kshara*.

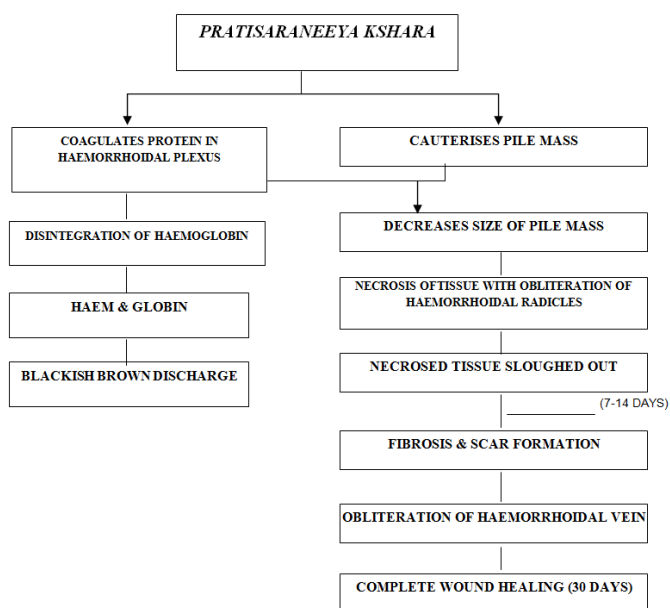
**Secondary outcome of both therapies**

Average recovery time was 14 days, average time to return to work was 4 days and average patient satisfaction score was 2 (extremely satisfied).

**Probable Mode of Action of Pratisaraneeya Kshara**

*Pratisaraneeya kshara* acts on Haemorrhoids in two ways –

1. It cauterizes the pile mass directly because of its *Ksharana Guna* (corrosive nature).
2. It coagulates protein in Haemorrhoidal plexus.



**CONCLUSION**

The conclusions drawn from the present study conducted on 30 patients of internal Haemorrhoids are as follows:-

- The *Nidana* that are mentioned for *Arsha*, remain same till today with little bit of modification like bike riding and distant travelling in place of *Prishstayana* etc.
- *Ardra Arsha* presents predominant features of *Raktaja* and *Pittaja Arsha*.
- The signs and symptoms of *Ardra Arsha* are similar to second degree Haemorrhoids.
- *Sushruta* had explained clear cut anatomy of anal canal.
- Maximum number of patients had Haemorrhoids at all three positions of primary Haemorrhoids.
- The wound heals within 30 days in the treated group.
- The *Kshara Karma* is a cost effective Para surgical procedure which requires minimum hospital stay with low recovery time, low recurrence and extremely patient’s satisfaction.
- Hence by observing the results obtained it can be concluded that *Nimba Pratisaraneeya Kshara* can be used effectively in internal Haemorrhoids in degree 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> with very minimal postoperative pain than *Apamarga Pratisaraneeya Kshara*, while in 3<sup>rd</sup> degree internal Haemorrhoids, *Nimba Kshara* reduces size of pile mass so that patient do not complains of prolapse of pile mass, burning and very less postoperative pain remains up to 1-2 weeks and in *Apamarga Kshara* pain reported up to 4 weeks.
- Study concludes that *Nimba* can be used for preparation of *Pratisaraneeya Kshara* instead of *Apamarga* as both are effective in controlling bleeding and in reducing size of pile mass.
- *Nimba Pratisaraneeya Kshara* causes very less post operative pain as compared to *Apamarga Pratisaraneeya Kshara*.

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