



A COMPARATIVE CLINICAL STUDY OF THE EFFECT OF KALYANA PRATISARANEEYA KSHARA AND APAMARGA PRATISARANEEYA KSHARA IN ARSHA WITH SPECIAL REFERENCE TO INTERNAL HAEMMORRHOIDS

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ABSTRACT

Background and Objectives: Among the diseases of ano-rectal region, haemorrhoids are common. It is called as Arshas in ayurvedic classics. The references are available on etiological factors, pathogenesis and different treatment modalities of Arshas. The clinical efficacy of the application of kalyana pratisaraneeya kshara and apamarga pratisaraneeya kshara in arsha. **Methodology:** The study was conducted in BLDEA's AVS Ayurveda Mahavidyalaya Vijayapur. 40 cases of Arshas were selected from OPD and IPD BLDEA's AVS Ayurveda Mahavidyalaya Vijayapur. 40 diagnosed patients of Arshas were randomly selected and divided into two groups consisting of 20 patients each and subjected to clinical trial. Patients in Group-A were treated by Kalyana pratisaraneeya kshara and Group-B by Apamarga pratisaraneeya kshara. **Result:** It was found that clinical features like Bleeding was reduced 81% in Group A and 95% in Group B. Pain was reduced 73% in Group A and 94% in Group B. Itching sensation was reduced 73% in Group A and 94% in Group B and Size of Pile mass were reduced 55% in Group A and 98% in Group B. **Conclusion:** On comparing the results of Group A and Group B the test shows that treatments are statistically significant in both the groups. But Group B has shown highly significant results than Group A.

Key Words: Arshas, Kalyana Kshara, Apamarga Kshara,

INTRODUCTION

Ayurveda has immense potential to solve many challenging and unsolved problems of the medical world. Among them Arsha is one such grave disease. Acharya Sushruta, the father of ancient surgery elaborately described about the Arsha in the treatise. He considered Arsha as one among the Asta Mahagadas and indefinitely curable.

The Etymology of the term Arsha is "Arivat", i.e. as an enemy it torments a person^{1,2}. Arsha is clinically an engorged condition of haemorrhoidal venous plexus along with abnormally enlarged displaced anal cushion, characterised by inflamed or prolapsed pile mass, bleeding per rectum and some discharge from anus. It is usually resulted by straining during defecation, chronic constipation, diarrhoea, pregnancy etc. In modern science many procedures are described for management of internal haemorrhoids³ among which haemorrhoidectomy is commonly preferred by surgeon, but after some time of excision there is great possibility of reoccurrence. But in Ayurveda Sushruta has told the fourfold management of Arsha⁴. They are Bhesaja Karma, Kshara Karma, Agni Karma and Shastra Karma. Among these the Bhesaja Karma and Kshara Karma show wonderful result.

As per the available treatment modalities of Arsha, the Kshara Karma modality is the best one, so Ksharakarma is taken into the consideration.

In present modern science many treatment are available, but the recurrence rate is high. So to avoid this the study was planned. The treatment being non-invasive, implement, doesn't need any hospitalization. To provide simple affordable and effective management of *Arsha* this is beneficial to patient. So to fulfil the lacuna, the present study is undertaken. *Kalyana Kshara* is an *Ayurvedic* formulation which is mentioned in the *Astanga hridayam*^(5,6) in the context of *Arsha Chikitsa Adhaya* with the properties of *udavartaha*, *vibandahara*, *Arshohara* etc for internal administration. As *Kshara* has got properties like *Chedana*, *Bhedana*, *Lekhana*, *Ropana* etc. this study was done to evaluate the efficacy of *Kalyana Pratisaraneeya Kshara*⁷ in the management of Internal Haemorrhoids.

METHODOLOGY

SOURCE OF DATA :

Literary Source :

All available classical, modern literatures and contemporary texts including the websites about the disease and procedures were reviewed and documented for the intended Study.

Sample Source :

Patients were selected from OPD and IPD of B.L.D.E.A'S A.V.S Ayurveda Mahavidyalaya Vijaypur. Special Medical Camps and other referrals.

Drug Source :

Raw drugs were properly identified, selected and purchased from the local market and authenticated by the Department of PG studies in Dravyaguna.

Kalyana Pratisaraneeya Kshara prepared according to classical method in pharmacy attached to the Department of PG studies in Rasashastra and Bhaishajya Kalpana.

Method of Preparation of *Kalyana Kshara*

Sunthi, Maricham, Pippali, Hareethaki, Vibheetakee, Amalaki, Saindhavam, Sauvarchala lavana, Vida lavanam, Bhallataka, Chitraka and Danti. Take sorted and cleaned Raw material, Disintegrate and pulverize the raw material. Mix the powdered raw material in to 8 parts of Eranda taila and 16 parts of Gomutra, and dry sunlight

/Less than 40 degree temperature, dryer (Evaporate the gomoothra) . Dried Raw material Fry into iron pan till it become black and pulverize it, then this ash dissolved in 6 parts of water the mixture is stirred well and kept undisturbed overnight. Next morning the supernatant liquid collected and filtered for 21 times with white thick cloth. The filter boiled in open large vessel with constant slow stirring, when liquid turns brown, slimy, clear, pungent smelling, it is removed from the fire and allowed to settle. The clear supernatant liquid is called as *Ksharodaka*. From here on the obtained *Ksharodaka* is subjected for further boiling to get it in paste or dry powder form. To make it *Teekshna Pratisaraneeya Kshara* *Sudhavargiya Dravyas* are added to the boiling *Kshara Jala* and boiling was continued. When the content attained semi solid consistency it was removed from the fire and stored in the container. This is *Teekshna Pratisaraneeya Kshara*. It is dull white in colour and pH is 9.3

Method of Preparation of *Apamarga Kshara*

12kgs of *Apamarga* (*Panchanga*) was collected and dried, and formed into a heap. The whole twig was burnt into ashes and then was allowed to cool by itself. The whole ash was collected (1kg) and mixed with six liters of water and stirred well, allowed to settle overnight. Then it was filtered through cotton cloth for 21 times, the residue was thrown out. Amber colored filtrate was obtained.

This filtrate was subjected to *Mandagni* in an iron vessel and subjected to heat till all the water content gets evaporated. The obtained *Kshara* should be stored in a tight glass container.

To make it *Tikshna*, meanwhile 10 gms of *Chitraka Moola Sukshma Choorna* was added to it and was allowed to boil for few more minutes till it attained to a semisolid consistency. Then it was removed from fire and the finally obtained quantity was 500gm of *Kshara*.

A part of the prepared *Kshara* was sent for physicochemical analysis. Later it was transferred into a separate glass container with lid and was stored for use.

Method of collection of data: -

Study Design – Present study is the randomized comparative clinical study.

Sample Size : A total number of patients taken for the study is 40. The patients were divided into 2 groups Group A & Group B consisting of 20 patients each.

Group A : Patients were treated with *Kalyana Pratisaraneeya Kshara*

Group B : Patients were treated with *Apamarga Pratisaraneeya Kshara*

Diagnostic Criteria: -

Diagnosis were been made on the basis of *Lakshana* of *Arsha*.

Inclusive Criteria :

Patients with diagnosed *Arsha* symptoms.

Patients of 16 to 60 years of age group with irrespective of sex.

Patients unwilling for surgery.

Patient with Internal haemorrhoids.

Exclusive Criteria :

Patient having systematic pathology, malignancies, HIV, HbsAg, DM, HT, ulcerative colitis and cirrhosis of Liver
 External Thrombosed pile mass
 3rd and 4th degree pile mass where surgery is needed.

PROCEDURE:

Group A : Kalyana Pratisaraneeya Kshara

Procedure : Ksharakarma

Purvakarma: The patient were been clearly explained about the procedure and treatment shall started only after he/she convienced about the treatment and with written consent. Perianal hair were been shaved and the part were been painted with antiseptic solution 1 day earlier. Soap water enema were been given on the night prior to and 2 h prior to the procedure. Inj. tetanus toxoid (0.5 ml), I/M were been given and xylocain sensitivity test werebeen performed in each patient. On the night prior to the operation, the patient were been given a light diet and, afterwards, kept nil orally. First the required instruments like slit proctoscope, Apamarga pratisaraneeya kshara, lemon juice, ghruta ,yastimadhu taila, allis forceps, artery forceps, spatula are kept ready with proper sterilization.

Pradhana karma: Anal dilatation were been done suitably using xylocaine jelly (2%) to carry out the procedure. Then lubricated slit proctoscope using xylocaine jelly is introduced into the anus and haemorrhoidal mass is visualized and positions of the mass is confirmed. Sterile gauze is inserted into anus and heamorrhoidal mass made to protrude by pulling the inserted sterile gauze. The mucus membrane around the mass is suitably covered by sterile guaze so that Apamarga Kshara does not come in contact with anal mucosa. Apamarga Kshara were been applied to the pile mass and waited for 100 matra kalas by closing the proctoscope aperture with hand. After the pile mass attains pakwa jambu phala varna or krishna varna, the kshara is neutralized by amla dravya (nimbu swarasa) .Then a paste of ghritha and yeshtimadhu is applied. Proctoscope and gauze are removed. Anal packing is done with Betadine and xylocaine jelly soaked gauze.

Paschat karma: Patient is advised to take rest for about 30 minutes at post operative room. Patient were been advised to remove the anal packing when he gets the urge of defaecation and after defaecation and cleaning, warm water sitz bath were been advised. This procedure is repeated for each pile mass separately at the same sitting.

Paschat Karma :

Light diet is allowed by the evening.

Follow Diet (Rich fibrous diet)

Laxatives like Haritaki Choorna is given.

Duration : Kalyana Pratisaraneeya Kshara was applied on each pile mass at one sitting.

Follow Up : It was done once weekly for 28 days to see for recurrence of the symptoms and any adverse effect.

Group B : Apamarga Pratisaraneeya Kshara

Procedure : Ksharakarma

Procedure :

Purvakarma: The patient were been clearly explained about the procedure and treatment shall started only after he/she convienced about the treatment and with written consent. Perianal hair were been shaved and the part were been painted with antiseptic solution 1 day earlier. Soap water enema were been given on the night prior to and 2 h prior to the procedure. Inj. tetanus toxoid (0.5 ml), I/M were been given and xylocain sensitivity test were been performed in each patient. On the night prior to the operation, the patient were been given light diet and, afterwards, kept nil orally. First the required instruments like slit proctoscope, Apamarga pratisaraneeya kshara, lemon juice, ghruta ,yastimadhu taila, allis forceps, artery forceps, spatula are kept ready with proper sterilization.

Pradhana karma: Anal dilatation were been done suitably using xylocaine jelly (2%) to carry out the procedure. Then lubricated slit proctoscope using xylocaine jelly is introduced into the anus and haemorrhoidal mass is visualized and positions of the mass is confirmed. Sterile gauze is inserted into anus and heamorrhoidal mass made to protrude by pulling the inserted sterile gauze. The mucus membrane around the mass is suitably covered by sterile guaze so that Apamarga Kshara does not come in contact with anal mucosa. Apamarga Kshara were been applied to the pile mass and waited for 100 matra kalas by closing the proctoscope aperture with hand. After the pile mass attains pakwa jambu phala varna or krishna varna, the kshara is neutralized by amla dravya (nimbu swarasa) .Then a paste of ghritha and yeshtimadhu is applied. Proctoscope and gauze are removed. Anal packing is done with Betadine and xylocaine jelly soaked gauze.

Paschat karma: Patient is advised to take rest for about 30 minutes at post-operative room. Patient were been advised to remove the anal packing when he gets the urge of defecation and after defaecation and cleaning, warm water sitz bath were been advised.

Laxatives like Haritaki Choorna is given 2gm BD

This procedure is repeated for each pile mass separately at the same sitting

Follow up : It was done once weekly for 28 days to see for recurrence of the symptoms and any adverse effect

Duration : Apamarga Pratisaraneeya Kshara is applied on pile mass at one sitting.

Assessment Criteria: Effect of treatment were assessed on the basis of gradation of both subjective and objective parameters before and after treatment.

Subjective Parameters:-

The improvement provided by therapy has been assessed on the basis of classical signs and symptoms, all the signs and symptoms were assigned with a score depending upon their severity to assess the effect of the drug objectively

CRITERIA FOR ASSESMENT:

Assessment was done based on the following parameters.

For Subjective Criteria:

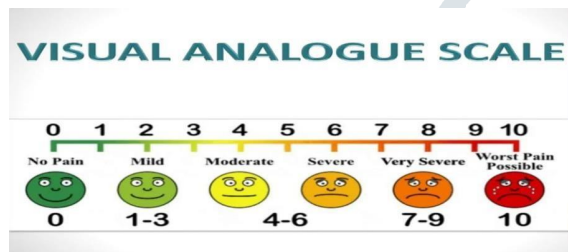
Pain
Raktasrava
Kandu

For Objective Criteria:

Size of pile mass

GRADING FOR THE ASSESSMENT CRITERIA

Subjective Parameters: PAIN: (VAS) Grading



Sign	Score
No Pain	0
Mild	1
Moderate	2
Severe	3

BLEEDING:

Sign	Score
No bleeding	0
Mild bleeding during only defecation	1
Bleeding during and after defecation	2
Severe bleeding during defecation	3

ITCHING:

Sign	Score
Absent	0
Itching at time of defecation only	1
Intermittent itching	2

Continuous itching causing local excoriation	3
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Objective Parameter:**SIZE OF PILE MASS**

Sign	Score
No pile mass	0
Upto ½ Inch	1
½ Inch to 1 Inch	2
More than 1 inch	3

SOURCE OF DATA :**Literary Source :**

All available classical, modern literatures and contemporary texts including the websites about the disease and procedures were reviewed and documented for the intended Study.

Sample Source :

Patients were selected from OPD and IPD of B.L.D.E.A's A.V.S Ayurveda Mahavidyalaya Vijaypur. Special Medical Camps and other referrals.

Drug Source :

Raw drugs were properly identified, selected and purchased from the local market with the help of dept. of PG studies in Dravyaguna. Kalyana Pratisaraneeya Kshara was prepared according to classical method in pharmacy attached to the Department of PG studies in Rasasastra and Bhaishajya Kalpana, B.L.D.E.A's A.V.S. Ayurveda Mahavidyalaya Vijaypur.

METHOD OF PREPARATION OF KALYANA KSHARA

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METHOD OF PREPARATION OF APAMARGA KSHARA

12kgs of Apamarga (Panchanga) was collected and dried, and formed into a heap. The whole twig was burnt into ashes and then was allowed to cool by it self. The whole ash was collected (1kg) and mixed with six liters of water and stirred well, allowed to settle overnight. Then it was filtered through cotton cloth for 21 times, the residue was thrown out. Amber colored filtrate was obtained.

This filtrate was subjected to Mandagni in an iron vessel and subjected to heat till all the water content gets evaporated. The obtained Kshara should be stored in a tight glass container.

To make it Tikshna, mean while 10 gms of Chitraka Moola Sukshma Choorna was added to it and was allowed to boil for few more minutes till it attained to a semisolid consistency. Then it was removed from fire and the finally obtained quantity was 500gm of Kshara.

A part of the prepared Kshara was sent for physicochemical analysis. Later it was transferred into a separate glass container with lid and was stored for use.

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Study Design – Randomised comparative clinical study.

Sample Size : A total number of patients taken for the study is 40. The patients were been divided into 2 groups

Group A & Group B consisting of 20 patients each.

Group A : Patients were been treated with Kalyana Pratisaraneeya Kshara

Group B : Patients were been treated with Apamarga Pratisaraneeya Kshara

Diagnostic Criteria: -

Diagnosis were been made on the basis of Lakshana of Arsha.

Inclusion Criteria :

Patients with diagnosed Arsha symptoms.
 Patients of 16 to 60 years of age group with irrespective of sex.
 Patients unwilling for surgery.
 Patient with Internal haemorrhoids.

Exclusion Criteria :

Patient having systematic pathology, malignancies, HIV, HbsAg, DM, HT, ulcerativecolitis and cirrhosis of Liver
 External Thrombosed pile mass
 3rd and 4th degree pile mass where surgery is needed.

PROCEDURE:

Group A : Kalyana Pratisaraneeya Kshara

Sample Size : 20 patients

Procedure : Kalyana Pratisaraneeya Kshara

Purvakarma: The patient were been clearly explained about the procedure and treatment shall started only after he/she convinced about the treatment and with written consent. Perianal hair were been shaved and the part were been painted with antiseptic solution 1 day earlier. Soap water enema were been given on the night prior to and 2 h prior to the procedure. Inj. tetanus toxoid (0.5 ml), IM were been given and xylocaine sensitivity test werebeen performed in each patient. On the night prior to the operation, the patient were been given a light diet and, afterwards, kept nil orally. First the required instruments like slit proctoscope, Apamarga pratisaraneeya kshara, lemon juice, ghruta ,yastimadhu taila, allis forceps, artery forceps, spatula are kept ready with proper sterilization.

Pradhana karma: Anal dilatation were been done suitably using xylocaine jelly (2%) to carry out the procedure. Then lubricated slit proctoscope using xylocaine jelly is introduced into the anus and haemorrhoidal mass is visualized and positions of the mass is confirmed. Sterile gauze is inserted into anus and heamorrhoidal mass made to protrude by pulling the inserted sterile gauze. The mucus membrane around the mass is suitably covered by sterile guaze so that Apamarga Kshara does not come in contact with anal mucosa. Apamarga Kshara were been applied to the pile mass and waited for 100 matra kalas by closing the proctoscope aperture with hand. After the pile mass attains pakwa jambu phala varna or krishna varna, the kshara is neutralized by amla dravya (nimbu swarasa) .Then a paste of ghritha and yeshtimadhu is applied. Proctoscope and gauze are removed. Anal packing is done with Betadine and xylocaine jelly soaked gauze.

Paschat karma: Patient is advised to take rest for about 30 minutes at post operative room. Patient were been advised to remove the anal packing when he gets the urge of defaecation and after defaecation and cleaning, warm water sitz bath were been advised. This procedure is repeated for each pile mass separately at the same sitting.

Duration : Kalyana Pratisaraneeya Kshara is applied on each pile mass at one sitting.

Follow Up : It is done weekly for 28 days to see for recurrence of the symptoms and anyadverse effect.

Group B : Apamarga Pratisaraneeya KsharaSample Size : 20 patients

Procedure : Apamarga Pratisaraneeya Kshara

Procedure :

Purvakarma: The patient were been clearly explained about the procedure and treatment shall started only after he/she convinced about the treatment and with written consent. Perianal hair were been shaved and the part were been painted with antiseptic solution 1 day earlier. Soap water enema were been given on the night prior to and 2 h prior to the procedure. Inj. tetanus toxoid (0.5 ml), I/M were been given and xylocain sensitivity test were been performed in each patient. On the night prior to the operation, the patient were been given a light diet and, afterwards, kept nil orally. First the required instruments like slit proctoscope, Apamarga pratisaraneeya kshara, lemon juice, ghruta ,yastimadhu taila, allis forceps, artery forceps, spatula are kept ready with proper sterilization.

Pradhana karma: Anal dilatation were been done suitably using xylocaine jelly (2%) to carry out the procedure. Then lubricated slit proctoscope using xylocaine jelly is introduced into the anus and haemorrhoidal mass is visualized and positions of the mass is confirmed. Sterile gauze is inserted into anus and heamorrhoidal mass made to protrude by pulling the inserted sterile gauze. The mucus membrane around the mass is suitably covered by sterile guaze so that Apamarga Kshara does not come in contact with anal mucosa. Apamarga Kshara were been applied to the pile mass and waited for 100 matra kalas by closing the proctoscope aperture with hand. After the pile mass attains pakwa jambu phala varna or krishna varna, the kshara is neutralized by amla dravya (nimbu swarasa) .Then a paste of ghritha and yashtimadhu is applied. Proctoscope and gauze are removed. Anal packing is done with Betadine and xylocaine jelly soaked gauze.

Paschat karma: Patient was advised to take rest for about 30 minutes at post operative room. Patients were advised to remove the anal

packing when they get the urge of defecation and after defecation and cleaning, warm water sitz bath was been advised.

Laxatives like Haritaki Choorna is given 2gm BD

This procedure is repeated for each pile mass separately at the same sitting

Follow up : It is done weekly for two months to see for recurrence of the symptoms and anyadverse effect.

Duration : Apamarga Pratisaraneeya Kshara is applied on pile mass at one sitting.

Assessment Criteria: Effect of treatment were assessed on the basis of gradation of both subjective and objective parameters before and after treatment.

Subjective Parameters:-

The improvement provided by therapy has been assessed on the basis of classical signs and symptoms, all the signs and symptoms were been assigned with a score depending upon their severity to assess the effect of the drug objectively

CRITERIA FOR ASSESMENT:

Assessment has been done based on the following parameter.

For Subjective Criteria:

1. Raktasrava
2. Pain
3. Kandu

For Objective Criteria:

1. Size of pile mass

Sign	Score
No pile mass	0
Upto ½ Inch	1
More than ½ -1 Inch	2
More than 1 inch	3

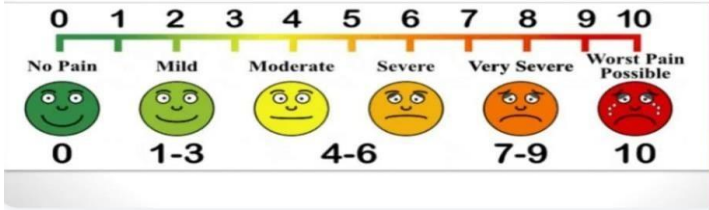
GRADING FOR THE ASSESSMENT CRITERIA

BLEEDING:

Sign	Score
No bleeding	0
Mild bleeding during only defecation	1
Bleeding during and after defecation	2
Severe bleeding during defecation	3

Subjective Parameters: PAIN: (VAS) Grading

VISUAL ANALOGUE SCALE



Sign	Score
No Pain	0
Mild	1
Moderate	2
Severe	3

ITCHING:

Sign	Score
Absent	0
Itching at time of defecation only	1
Intermittent itching	2
Continuous itching causing local excoriation	3

RESULTS

EFFECTS OF TREATMENT WITHIN THE GROUPS

TABLE : 1

Comparison of effect of treatment on Gudagata Raktasrava between groups.

Groups	Gudagata Raktasrava		Mean Difference	In %	Wilcoxon signed ranks test	P value
	Mean	±SD				
KALYANA PRATISARANEEYA KSHARA						
Day 0	2.60	0.503	2.1	81%	4.030	0.0001*
Day 7	0.50	0.688				
APAMARGA PRATISARANEEYA KSHARA						
Day 0	2.20	0.696	2.1	95%	3.976	0.0001*
Day 7	0.10	0.308				

*:Statistically significant

Effect on Gudagata Raktasrava in Group A

An assessment of Gudagata Raktasrava in patients of Arsha before and after the treatment in Group-A statistical analysis showed that the mean score at day 0 which was 2.60 before the treatment. It was reduced to 0.50 after the treatment on day 7 with 81% improvement. Analysis of this data shows statistically highly significant improvement with p value 0.0001. and Wilcoxon test value is 4.030.

Effect on Gudagata Raktasrava in Group B

An assessment of Gudagata Raktasrava in patients of Arsha before and after the treatment in Group-B statistical analysis showed that the mean score at day 0 which was 2.20 before the treatment. It was reduced to 0.10 after the treatment on day 7 with 95% improvement. Analysis of this data shows statistically highly significant improvement with p value 0.0001 and Wilcoxon test value is 3.976. The details are shown with statistical data in Table 1 and graphically represented in Graph : 1



GRAPH : 1

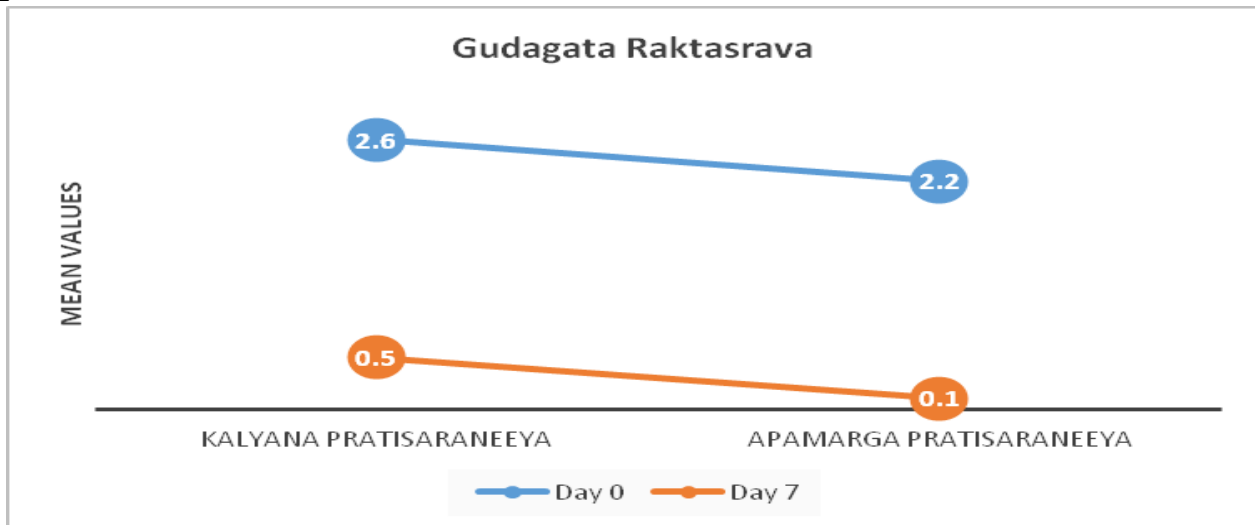


TABLE 2

Comparison of effect of treatment on Pain during defecation between groups.

Groups	Pain during defecation		Mean difference	In %	Wilcoxon signed ranks test	P value
	Mean	±SD				
KALYANA PRATISARANEeya KSHARA						
Day 0	2.55	0.510	1.85	73%	3.873	0.0001*
Day 7	0.70	0.733				
APAMARGA PRATISARANEeya KSHARA						
Day 0	2.65	0.587	2.5	94%	4.035	0.0001*
Day 7	0.15	0.366				
*:Statistically significant						

Effect on Pain during defecation in Group A

An assessment of Pain during defecation in patients of *Arsha* before and after the treatment in Group-A was assessed and analyzed statistically. The mean score at day 0 which was 2.55 before treatment. It reduced to 0.70 after the treatment on day 7 with 73% improvement. Analysis of this statistically data shows highly significant improvement with p value 0.0001 and Wilcoxon test 3.873

Effect on Pain during defecation in Group B

An assessment of Pain during defecation in patients of *Arsha* before and after the treatment in Group-B was assessed and analyzed statistically. The mean score on day 0 which was 2.65 before treatment. It reduced to 0.15 after the treatment with 94% improvement. Analysis of this data shows statistically highly significant improvement with p value 0.0001 and Wilcoxon test 4.035. Further the particulars are tabled in Table 2 and graphically represented in Graph: 2

Graph: 2

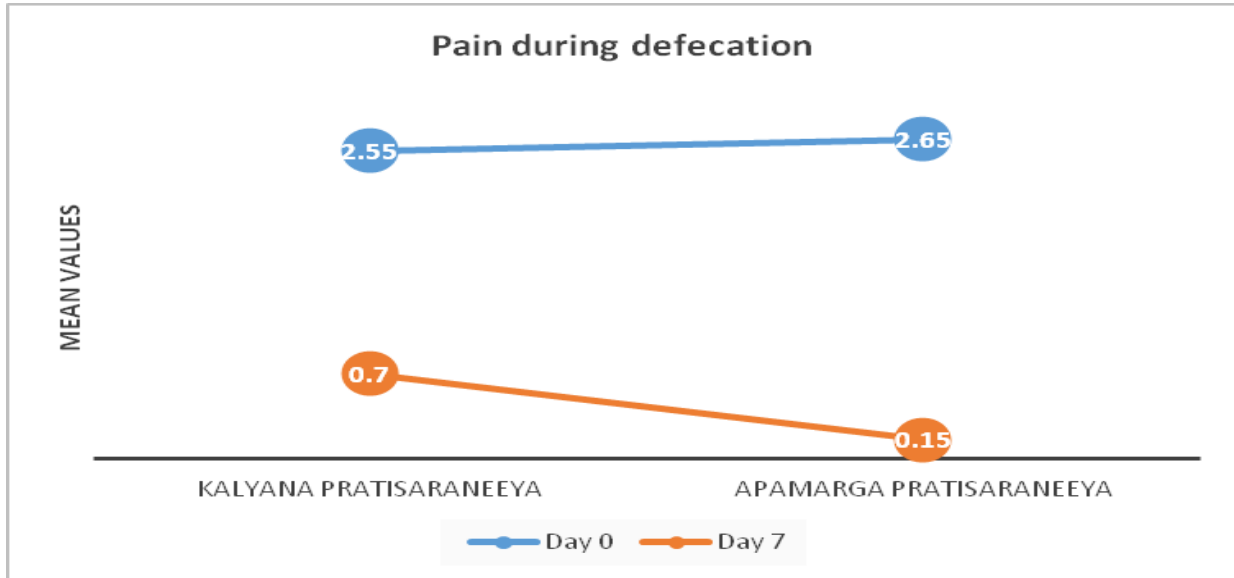


Table: 3

Comparison of effect of treatment on Itching (Kandu) between groups

Groups	Itching		Mean difference	In %	Wilcoxon signed ranks test	P value
	Mean	±SD				
KALYANA PRATISARANEYYA KSHARA						
Day 0	2.60	0.503	1.9	73%	3.994	0.0001*
Day 7	0.70	0.657				
APAMARGA PRATISARANEYYA KSHARA						
Day 0	2.40	0.681	2.25	94%	4.018	0.0001*
Day 7	0.15	0.366				
*:Statistically significant						

Effect on Itching in Group A

An assessment of itching in patients of *Arsha* before and after the treatment in Group-A was assessed and analyzed statistically. The mean score on day 0 which was 2.60 before treatment. It reduced to 0.70 after the treatment on day 7 with 73% improvement. Analysis of this data shows statistically highly significant improvement with p value 0.0001 and Wilcoxon test 3.994.

Effect on Itching in Group B

An assessment of itching in patients of *Arsha* before and after the treatment in Group-B was assessed and analyzed statistically. The mean score which was 2.40 before treatment. It reduced to 0.15 after the treatment on day 7 with 94% improvement. Analysis of this data shows statistically highly significant improvement with p value 0.0001 and Wilcoxon test 4.018.

Further the particulars are tabled below in Table No.3 and graphically represented in Graph 3

GRAPH : 3

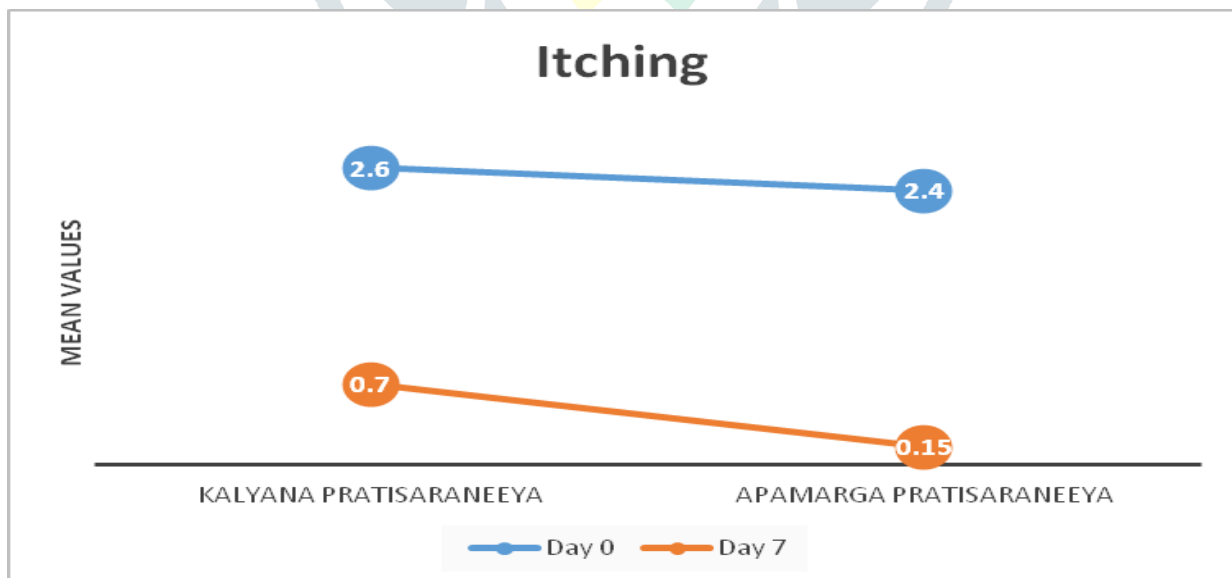


TABLE: 4

Comparison of effect of treatment on Size of Pile Mass between groups

Groups	Size of Pile Mass		Mean difference	In %	Wilcoxon signed ranks test	P value
	Mean	±SD				
KALYANA PRATISARANEEYA KSHARA						
Day 0	1.90	0.641	1.05	55%	4.379	0.005*
Day 7	0.85	0.587				
APAMARGA PRATISARANEEYA KSHARA						
Day 0	2.30	0.657	2.25	98%	3.993	0.0001*
Day 7	0.05	0.224				
*:Statistically insignificant						

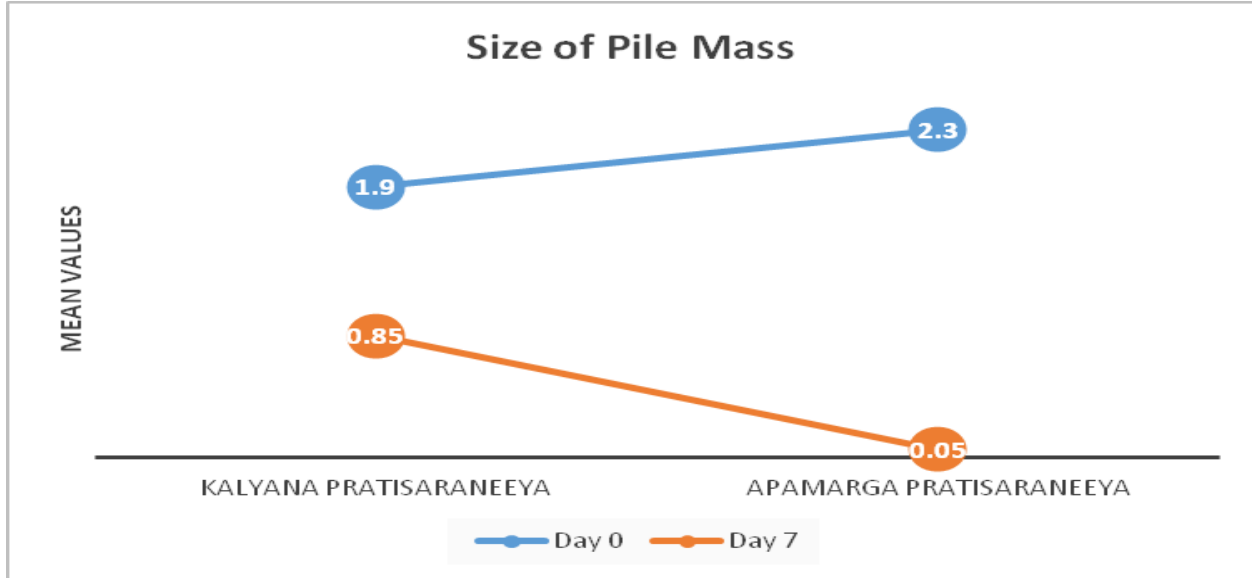
Effect on Size of Pile Mass in Group AAn assessment of Size of Pile Mass in patients of *Arsha* before and after the treatment in

Group-A was assessed and analyzed statistically. The mean score on day 0 which was 1.90 before treatment. It reduced to 0.85 after the treatment on day 7 with 55% improvement. Analysis of this data shows statistically highly significant improvement with p value 0.0001 and Wilcoxon test 4.379.

Effect on Size of Pile Mass in Group B

An assessment of Size of Pile Mass in patients of *Arsha* before and after the treatment in Group-B was assessed and analyzed statistically. The mean score which was 2.30 before treatment. It reduced to 0.05 after the treatment on day 7 with 98% improvement. Analysis of this data shows statistically highly significant improvement with p value 0.0001 and Wilcoxon test 3.993. Further the particulars are tabled below in Table No.4 and graphically represented in Graph 4

GRAPH : 4



EFFECTS OF TREATMENT BETWEEN THE GROUPS

TABLE : 5

Comparison of Gudagata Raktasrava between Kalyana Pratisaraneeya Kshara and Apamarga Pratisaraneeya Kshara

Comparison of Gudagata Raktasrava between groups						
Gudagata Raktasrava	Mean	±SD	Mean difference	In %	Mann Whitney Utest	P value
Day 0						
Kalyana RPratisaraneeya	2.60	0.503	0.4	15%	138.000	0.061
Apamarga Pratisaraneeya Kshara	2.20	0.696				
Day 7						
Kalyana RPratisaraneeya	0.50	0.688	0.4	80%	138.000	0.026*
Apamarga Pratisaraneeya Kshara	0.10	0.308				
*: Statistically Insignificant						

An assessment of Gudagata Raktasrava in patients of Group-A and Group-B before, during and after the treatment was done and statistical analysis showed that the difference between the Groups is statistically insignificant with p value 0.061 and Mann Whitney U test value of 138.000.

The details are shown with statistical data in Table No.5 and graphically represented in Graph : 5.

GRAPH : 5

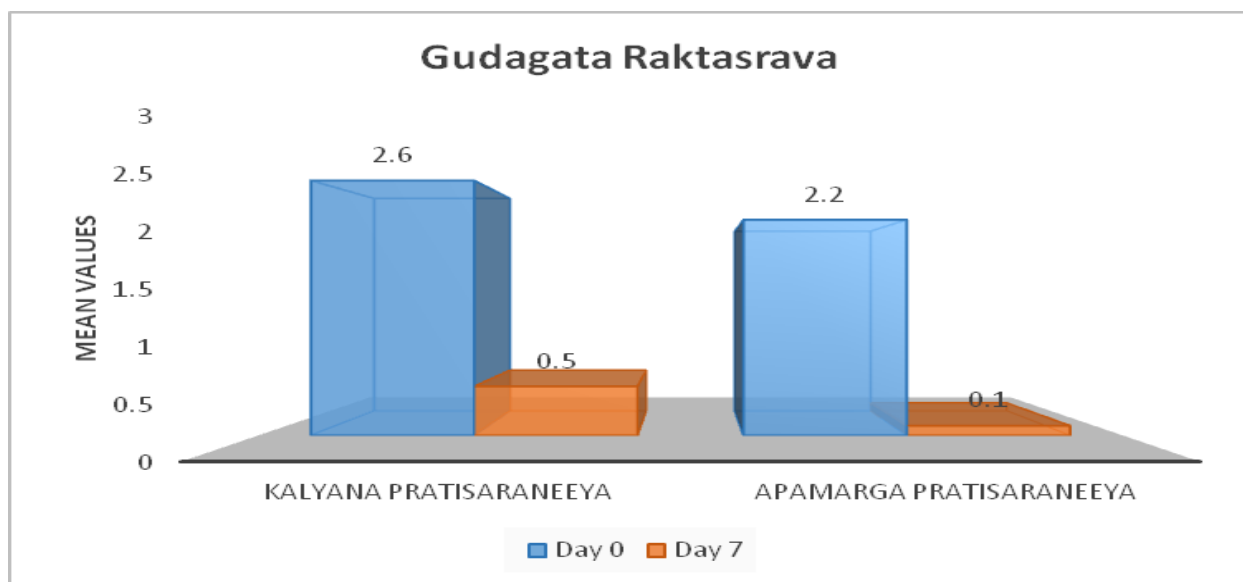


TABLE 6

Comparison of Pain During Defecation between Kalyana Pratisaraneeya Kshara and Apamarga Pratisaraneeya Kshara

Comparison of Pain during defecation between groups						
Pain during defecation	Mean	±SD	Mean difference	In %	Mann Whitney U test	P value
Day 0						
Kalyana Pratisaraneeya Kshara	2.55	0.510	0.1	4%	174.500	0.414
Apamarga Pratisaraneeya Kshara	2.65	0.587				
Day 7						
Kalyana Pratisaraneeya Kshara	0.70	0.733	0.55	79%	115.500	0.006*
Apamarga Pratisaraneeya Kshara	0.15	0.366				
*: Statistically Insignificant						

An assessment of Pain during defecation in patients of Group-A and Group-B before, during and after the treatment was done and statistical analysis showed that the difference between the Groups is statistically insignificant with p value 0.006 and Mann Whitney U test value of 115.500.

The details are shown with statistical data in Table No.6 and graphically represented in Graph : 6.

GRAPH :6

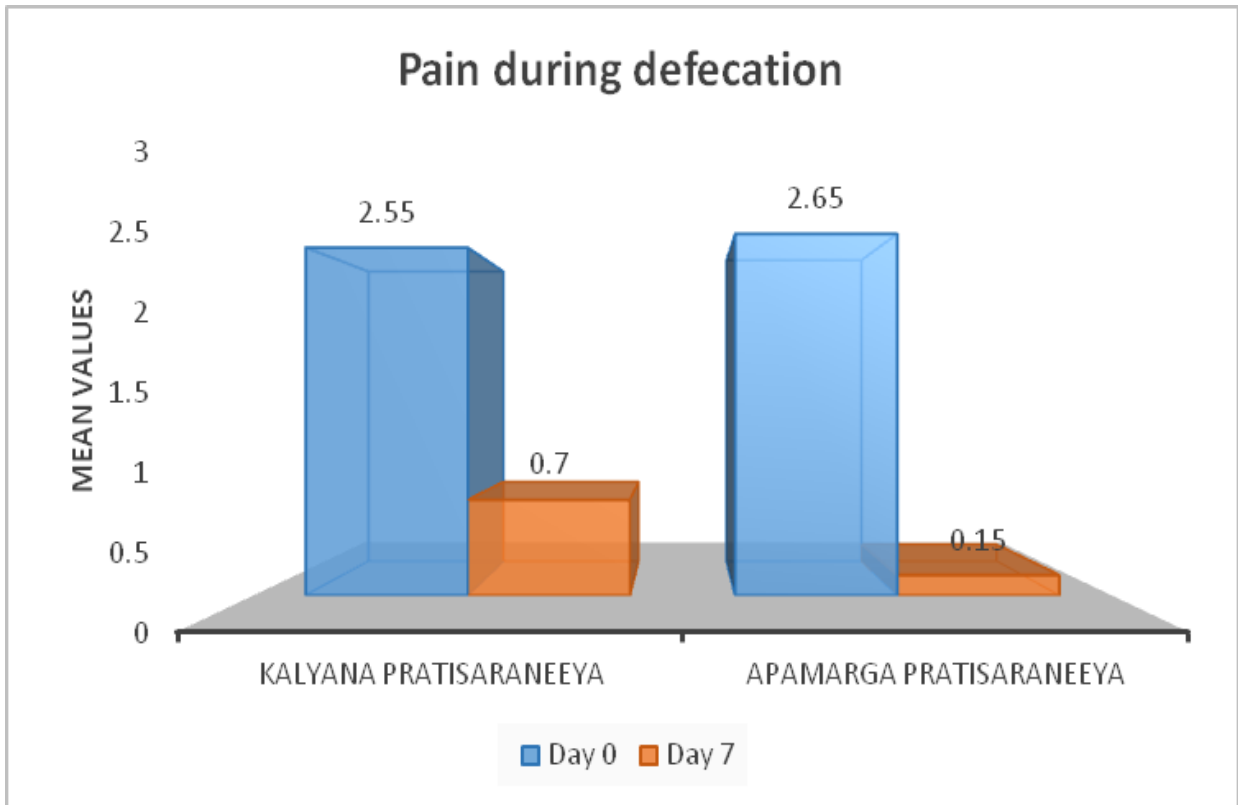


TABLE 7

Comparison of Itching between Kalyana Pratisaraneeya Kshara and ApamargaPratisaraneeya Kshara

Comparison of Itching between groups						
Itching	Mean	±SD	Mean difference	In %	Mann Whitney U test	P value
Day 0						
Kalyana Pratisaraneeya Kshara Kshara	2.60	0.503	0.2	8%	172.000	0.388
Apamarga Pratisaraneeya Kshara Kshara	2.40	0.681				
Day 7						
Kalyana Pratisaraneeya Kshara Kshara	0.70	0.657	0.55	79%	107.000	0.003*
Apamarga Pratisaraneeya Kshara Kshara	0.15	0.366				
*: Statistically Insignificant						

An assessment of Itching during defecation in patients of Group-A and Group-B before, during and after the treatment was done and statistical analysis showed that the difference between the Groups is statistically insignificant with p value 0.003 and Mann Whitney U test value of 107.000.

The details are shown with statistical data in Table No.7 and graphically represented in Graph :7.

GRAPH :7

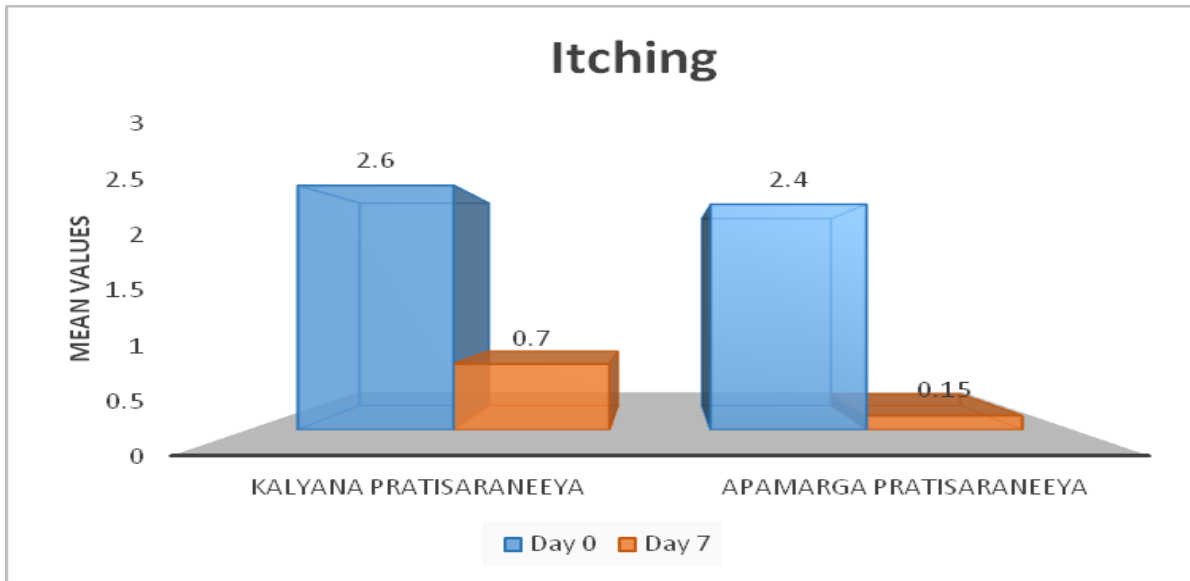


TABLE 8

Comparison of Size Of Pile Mass Between Kalyana Pratisaraneeya Kshara And Apamarga Pratisaraneeya Kshara

Comparison of Size of Pile Mass between groups						
Size of Pile Mass	Mean	±SD	Mean difference	In %	Mann Whitney U test	P value
Day 0						
Kalyana Pratisaraneeya Kshara	1.90	0.641	0.4	17%	137.000	0.058
Apamarga Pratisaraneeya Kshara	2.30	0.657				
Day 7						
Kalyana Pratisaraneeya Kshara	0.85	0.587	0.8	94%	59.000	0.001*
Apamarga Pratisaraneeya Kshara	0.05	0.224				
*.:Statistically Insignificant						

An assessment of Itching during defecation in patients of Group-A and Group-B before, during and after the treatment was done and statistical analysis showed that the difference between the Groups is statistically insignificant with p value 0.001 and Mann Whitney U test value of 59.000.

The details are shown with statistical data in Table No.8 and graphically represented in Graph : 8.

GRAPH : 8

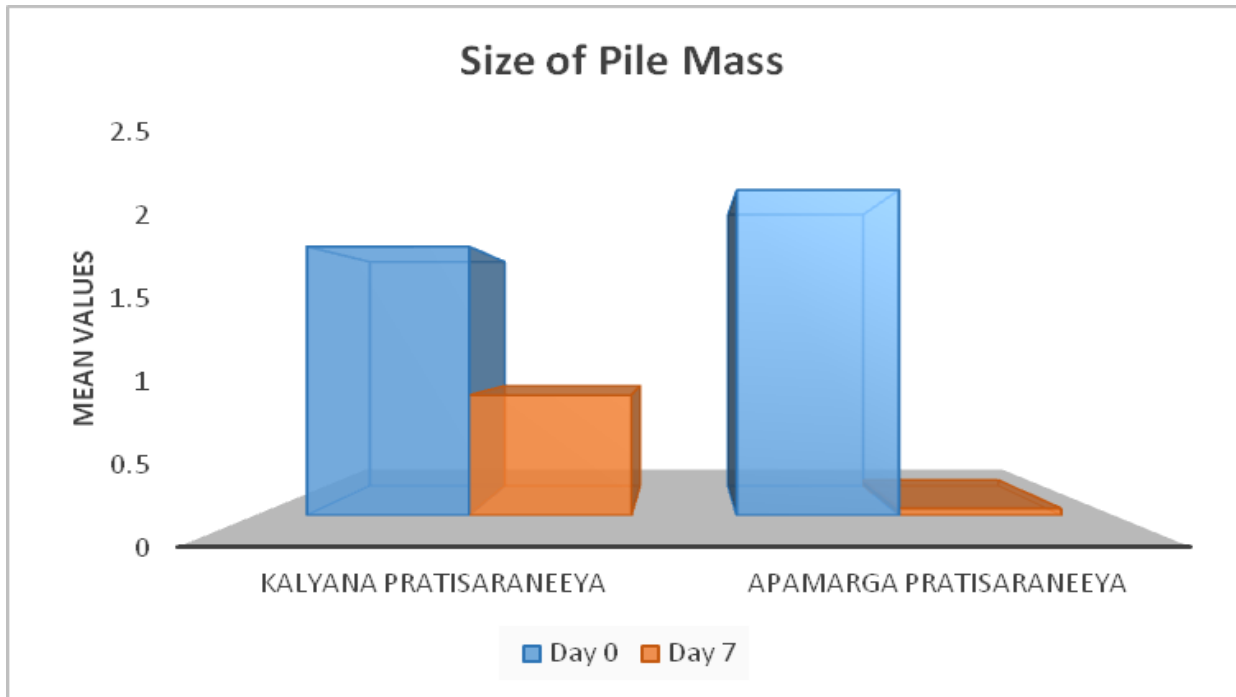
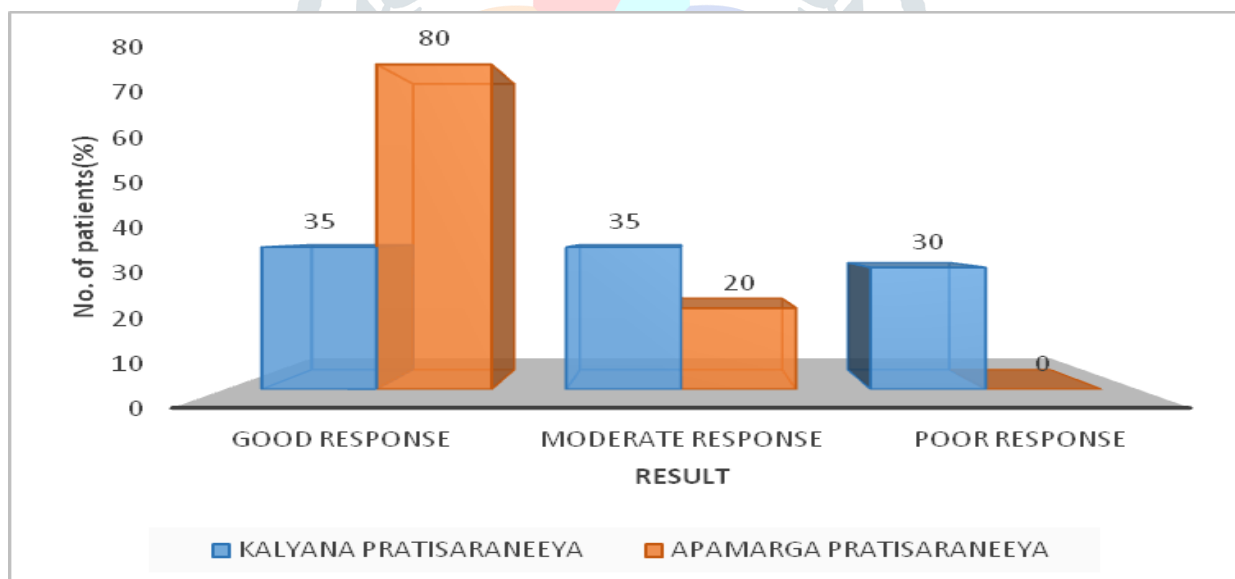


TABLE:9 RESULT

RESULT	KALYANA PRATISARANEeya KSHARA		APAMARGA PRATISARANEeya KSHARA		Chi square test	P value
	No. of Patients	Percentage	No. of Patients	Percentage		
Good Response	7	35.0	16	80.0	10.340	0.0057*
Moderate Response	7	35.0	4	20.0		
Poor Response	6	30.0	0	0		
Total	20	100.0	20	100.0		

GRAPH : 9

**Overall Results in both Groups:**

After considering all the changes in parameters of both the groups and statistical analysis, the overall result in Group A (Kalyana Pratisaraneeya Kshara) was 70.5% and in Group B (Apamarga Pratisaraneeya Kshara) was 95.25%.

DISCUSSION**Anatomy and physiology aspect****Role of guda marma**

Guda is one among the major marmas and all the diseases manifesting in marma regions is either incurable or difficult to cure. This is true even in the gudaja arshas also.

Anatomy-physiological aspects of anorectal region are important in understanding pathogenesis of the disease.

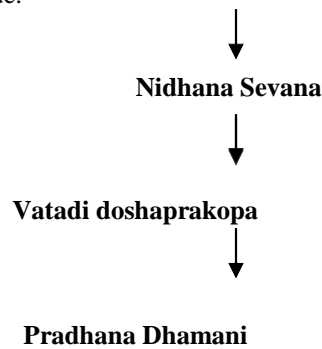
In humans, the erect posture results in heavy pressure on the valveless rectal venous plexuses which makes the humans prone to this disease.

The function of ano-rectal region is defecation. This function is disturbed in haemorrhoids and in turn disturbance in defecation itself may prove a causative factor for haemorrhoids.

Role of agni and agnimandyata in the pathogenesis of arshas :

Vagbhata mentioned that arshas, grahani and atisaara are the causative factor for each other in producing disease when the agni is weak and not when the agni is strong has proven true.

Samprapti of arshas - Acharya susruta:



Vitiates Apana Vatta

Leads to Vibandha

Affects Gudavali

Arsha

About the treatment:

In Ayurvedic literature in arsha cikitsa, bhesaja cikitsa, sastra cikitsa and anusastra cikitsa using kshara, agni and jaluka are indicated. From practical utility point of view,

- Therapeutic classification of charaka i.e. Sushka (Without bleeding) and Ardra (bleeding) arshas - helps to analyse the dosha dominance and plan the treatment .
- Avastha based cikitsa of susruta like Bhesaja, kshara, agni and sastrakarma is significant in the selection of suitable modality of treatment corresponding to their clinical presentation of arshas.

Bhesaja chikitsa:

Bhesaja is the first line of treatment at early stage in general in any disease, so also in arshas. It is indicated in arshas where the mamsa ankura is adharsya, of recent onset having alpadosha, alpa linga, alpa upadrava.

Samprapati ghatakas of arshas are:

Dosha	– vaata (apana), pitta, kapha Dooshya	– Tvak, mamsa, medas, rakta
Srothas	– Raktavaha , mamsavaha , purishavaha.	
Srotodusti	– Sangha, sira granthi Udbhavasthana – Amapakvasayotbhava Vyaktasthana	– Gudavalithraya Rogamarga
	– Abhyantara marga Agni	– Mandagni.

Samprapti vighatana with measures having following characteristics:

Acharya vagbhata mentioned that, the arsha rogi should adopt to diet, drinks and drugs that can relieve vibandha, produce anuloma and strengthen the agni and to avoid those with opposite effects i.e., nidana parivarjana.

The drugs such as Abhaya, citraka, nagara, cavya, vacha, ativisha, dhanvayaasaka, daru haridra, ativisa etc are considered as Arshoghna due to these properties.

Based on duration and prognosis:

When Arshas becomes chronic and difficulty arises in curing them by bhesajacikitsa, then comes the preference of other modality of treatments like sastra and anusastra karmas based on the clinical presentation of arshas.

Kshara karma

Mrdu, prasrta, avagaada, ucchritaani avastha of arshas is burnt by kshara having katu-lavana rasa, with tiksna ushna-agneya guna, and dahana, pachana, chedana, bhedana lekha, Vilayana, medohara karma.

Agni karma

Agnikarma being more teeksna than kshara can produce dahana action(dagdha)quickly in mamsa ankura with Karkasa,Sthira,Prithu,Katina avastha and destroy it.

Sastra karma

In mamsa ankura which has tanu moolani,uchritaani,kledavanti,it is easy to dochedana karma followed by agni karma as told in classics.

Importance of Apamarga

Rasa : Katu, Tikta

Guna : Laghu, Ruksha, Tikshna

Virya : Ushna

Vipaka : Katu

Doshagnata : Kapha vaatahara..

Karma : Depana,paacana,lekhana,medohara.

Apamarga in bhesaja cikitsa - with tandulodaka/ghee having agni depana, and arshogna karma.

Apamarga in kshara cikitsa because of its kshara guna attained by the method of ksharapreparation as told in classics.

Importance of Kalyana Kshara:

India is a vast country, with varied flora and there is a need for selection of alternate plants which can play the same role as Apaamaarga in the preparation of Kshara. So, exploration of the new plants for the preparation of kshara as a better substitute to Apaamaarga is the need of the hour. Astanga Hridayam, in Arsha Chikitsa, has used Kalyanaka Kshara especially in the form of internal administration and having the properties like Udavarta, Vibhanda, Arsha, Gulma, Panduroga. Udara, Krimiroga, Mutraghata, Askhari, Shotha, Hrudroga, Grahani, Prameha. Pliharoga. Shula, Anaha, Swasa, Kasa. Moreover in the ethnic practice in Arsha as a folklore treatment in Kerala. That is why it was selected as an alternate plant for the preparation of Kshara Sootra used in the treatment of Arsha in this study.

Method and duration adopted for applying kshara, in case of multiple pilemass:

Compared to Apamarga Kshara, Kalyana Kshara have less advantage in treating all the hemorrhoidal mass in one sitting, reducing the total duration of treatment in case of pile masses located in multiple positions, compared to classical method. i.e., where kshara is applied on only one pilemass in one sitting, which requires comparatively longer time duration of treatment.

On the basis of successful clinical trials of Kalyana Pratisaraneeya kshara and Apamarga Pratisaraneeya kshara the present study was undertaken at B.L.D.E.A'S A.V.S Ayurveda Mahavidyalaya Vijaypur to compare the efficacy of Kalyana Pratisaraneeya kshara and Apamarga Pratisaraneeya kshara in the management of Arshas.

Care during kshara karma procedure:

1) Care should be taken to apply kshara on the target area; without spilling out to the healthy tissues, using cotton swabs and thus preventing the injury to the adjacent healthy tissues from necrosis and stricture formation. While making an attempt to remove the cotton swabs also, precaution should be taken to prevent injury of the tissues which leads to bleeding.

2) In case of multiple pile masses:

After the kshara application is completed on one pile mass and before applying kshara for the pilemass in other position, the slit proctoscope was removed out and reinserted to prevent injury of the tissues and its complication bleeding. Same method was adopted in pile masses located in all positions.

Kshara and kshara karma:

In Ayurveda, Arshas is a tridoshaja vyadhi, though sushka Arshas finds a separate mention; it presents features of vaataja and kaphaja features. The treatment modalities of haemorrhoids either medical, surgical or para surgical, come under four treatment principles of Arshas told by Susrutha. Even though Kshara Karma is a simple procedure, this is not being practiced by many, may be because of difficulty in preparing Pratisaraneeya Kshara with correct potency. The criteria of assessing the correct potency of Pratisaraneeya Kshara are getting Jambuphala Varna within Shatamatra Kala (approximately 35 sec to one minute). This has been achieved here by rigidly following the technique of Kshara preparation told by Susrutha.

Preparation of kshara:

For the present study, drugs selected for Kshara preparation are Apamarga, trikatu, tripatu

,triphala ,dhanti, bhallataka, Chitraka, gomutra, and eranda taila. Apamarga and kalyana both are easily available herbs. Further, the Apamarga usage in Arshas is recommended by most of Ayurveda Acharyas. Whereas, kalyana kshara is indicated in the choice of drugs to prepare kshara by vagbhata in sahasrayoga and not much indicated in Arshas.

The pH value of Apamarga Kshara prepared for the study was 11.75 and Kalyana Pratisaraneeya Kshara was 8.5, by adding Sudavargeya Dravya the PH value of Teekshna Kalyana Pratisaraniya Kshara is 9.3.

Probable mode of action of Apamarga kshara and Kalyana kshara.

- It cauterizes pile mass directly by its Ksharana Guna (corrosive nature).
- It coagulates 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 haemin 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).

Advantages

- Post operative pain is mild in intensity. No scope for recurrence.
- No stricture formation .
- No bleeding - as the coagulation of Haemorrhoidal veins occur, and Minimum Hospitalization.
- Application of kshara is found to be a safe, efficacious and cost effective method for management of internal haemorrhoids.

CONCLUSION

- The disease described as arshas in ayurvedic literature can be regarded as haemorrhoids in modern medical science. The description of anatomy and physiology of anorectal region is also found in Ayurvedic literature though scattered.
- Observation of present study reveals that the incidence of arshas is more among the age group of above 20 to 60 years age group, middle income group, all religion, mixed dietary habits, vaatakapha prakrti, mandagni, irregular bowel habits and in the individuals indulging in sedentary work.
- Maximum number of patients had haemorrhoids at all three primary positions. The Apamarga Pratisaraneeya Kshara prepared for the present study with pH of 11.75 is very effective than Kalyana Pratisaraneeya Kshara with pH of 9.4 in the treatment of haemorrhoids.
- The Hemorrhoidal mass treated with Apamarga Pratisaraneeya kshara and Kalyana Pratisaraneeya kshara requires maximum number of five days of debridement.
- The wound heals within three weeks in all the patients.
- Apamarga Pratisaraneeya Kshara has more advantages than Kalyana Pratisaraneeya Kshara treating first degree and second degree haemorrhoids with less pain, minimum bleeding, no stricture formation and no recurrence.

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