

AN OPEN LABEL DOUBLE ARM CLINICAL STUDY TO COMPARE THE EFFECT OF GOMUTRA SIDDHA APAMARGA PRATISARANIYA KSHARAKARMA AND UDAKA SIDDHA APAMARGA PRATISRANIYA KSHARAKARMA IN ABHYANTARA ARSHAS

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ABSTRACT

Arshas is mentioned in ashta mahagada by Acharya sushruta. Arshas can be considered as haemorrhoids in modern medicine which needs surgical intervention. These Surgical procedures have their own complications. Acharya sushruta mentioned that Ksharakarma is indicated in management of arshas. In ksharapaka vidhi adhyay two solvent media i.e., udaka and gomutra are mentioned for preparation of kshara. Presence of urea, creatinine, aurum hydroxide, carbolic acid, phenols, calcium, and manganese has strongly explained the antimicrobial and germicidal properties of cow urine. So this study has been conducted to evaluate the efficacy of gomutra siddha Apamarga pratisaraniya kshara karma in management of abhyantara arsha. Udaka siddha Apamarga pratisaraniya kshara karma taken as standard group to compare its effect since it's an established study. 40 patients fulfilling the inclusion criteria of abhyantara arsha w.s.r internal haemorrhoids were randomly selected from OPD and IPD of Shalya tantra, Government Ayurveda Medical College, Bengaluru and divided into two groups i.e. Group A and Group B comprising of 20 patients in each group. In Group A: Gomutra siddha Apamarga pratisaraniya kshara karma, In Group B: Udaka siddha Apamarga pratisaraniya kshara karma was done. The parameters were observed based on the assessment criteria and recorded. The p-value of 0.64 is greater than the common significance level of 0.05, indicating that there is no statistically significant difference between Group A and Group B in terms of their overall effect. Gomutra Siddha Apamarga Pratisaraniya Ksharakarma is as effective as Udaka Siddha Apamarga Pratisaraniya Ksharakarma in the management of Abhyantara Arshas.

KEYWORDS: Abhyantara arshas, Internal haemorrhoids, Gomutra Siddha Apamarga Pratisaraniya Ksharakarma, Udaka Siddha Apamarga Pratisaraniya Ksharakarma.

INTRODUCTION

In the modern era sedentary lifestyle, combined with the consumption of low-fiber and spicy foods, less water intake, strenuous work, and mental stress, significantly disrupts the digestive system, leading to numerous health issues. Among these, anorectal disorders are particularly common with haemorrhoids being a prevalent condition that can severely impact a person's daily activities. Indigestion and constipation are two major problems faced by many people today. These are primary contributors to the development of haemorrhoids.

Arshas are mentioned in *ashta mahagada*^[1] by Acharya sushruta because of its *Dirghakalanubandhi* and *Dushchiktitsya* in nature. Arshas are located in three *gudavalis* situated in the space of four and half *angulas*.^[2] Arshas can be considered as haemorrhoids in

modern medicine. Haemorrhoids are dilated veins within the anal canal in subepithelial region formed by radicle of superior, middle and inferior rectal veins.^[3] Which has clinical features like bleeding per anum, prolapse of mass per anum, pain and mucus discharge from anus.^[4]

Globally the prevalence of haemorrhoids has been estimated as 50- 85% of the total population. The prevalence of haemorrhoids in India has been estimated at 75%. Males and Females both affected with equal frequency. Haemorrhoids affect people most often between 45 and 65 years of age and common in people who have sedentary life style.^[5]

Treatment modalities in modern include, the conservative management by usage of laxative and high residual diet. But there are limitations and no radical cure

by medical management as the pile mass which is formed needs surgical intervention. Surgical methods include Sclerotherapy, Rubber Band ligation, Infrared photocoagulation, Maximal anal dilatation (Lord's procedure), Haemorrhoidectomy, Cryosurgery, Ligature and Excision method, DGHAL (Doppler Guided Haemorrhoidal Artery Ligation), Stapled haemorrhoidectomy, Laser Haemorrhoidoplasty.^[6] These procedures have their own complications. The most common acute complications include bleeding, infection and urinary retention. Pelvic sepsis is relatively rare. The most feared long-term complications include Fecal incontinence, Anal stenosis and Chronic pelvic pain.^[7]

Shalya tantra is considered as most superior among eight branches of ayurveda, because of its *ashukriya*, *sarvatantra samanyata* and use of *yantra*, *shastra*, *kshara* and *agni*. *Acharya* sushruta states four treatment modalities for *arsha* i.e., 1. *Bhaishajya chikitsa* 2. *Kshara karma*, 3. *Agnikarma* 4. *Shastra karma*. *Ksharakarma* is indicated in *mrudu* (soft), *prasruta* (extensive), *avagadha* (deep), and *uchhritani* (raised) *arsha*. *Kshara* does the functions of *chhedana*, *bhedana*, *lekhana karma*.^[8]

In *ksharapaka vidhi adhyay acharya* mentioned two solvent media i.e., *udaka* and *gomutra* for preparation of *kshara*.^[9] *Acharya sushruta* also mentioned properties of *gomutra* like *katu*, *ushna*, *tikshna* and *kshara*.^[10] So, by using *gomutra* as solvent media it can enhance efficacy of *kshara*. Presence of urea, creatinine, aurum hydroxide, carbolic acid, phenols, calcium, and manganese has strongly explained the antimicrobial and germicidal properties of cow urine. *Kshara* sample prepared with *gomutra* can be considered to be more stable when loss on drying is taken into consideration.^[11] It also possesses few components of *gomutra* which may have therapeutic activity of their own. It is also considered to be better as far as the total yield of *kshara* is taken into consideration.

There is a need of clinical study to evaluate efficacy of *gomutra siddha Apamarga pratisaraniya kshara karma* in comparison with *udaka siddha Apamarga pratisaraniya kshara karma* in management of *abhyantara arsha*.

AIM AND OBJECTIVES

1. To evaluate the efficacy of *Pratisaraniya kshara karma* with *Gomutra siddha Apamarga Kshara* in management of *Abhyantara arsha*.
2. To evaluate the efficacy of *Pratisaraniya Ksharakarma* with *udaka siddha Apamarga Kshara* in management of *Abhyantara arsha*.
3. To compare the results of both groups to ascertain the efficacy of *Pratisaraniya Kshara karma* with *gomutra siddha Apamarga Kshara* in *Abhyantara arsha* in comparison with *udaka siddha apamarga kshara*.

Hypothesis

Null hypothesis

1. There is no significant effect of *Gomutra Siddha Apamarga Pratisaraniya Kshara karma* in management of *Abhyantara arsha*.
2. There is no significant difference between the effect of *Gomutra Siddha Apamarga Pratisaraniya Kshara karma* and *Udaka Siddha Apamarga Pratisaraniya ksharakarma* in management of *Abhyantara arsha*.

Alternate hypothesis

1. There is significant effect of *Gomutra Siddha Apamarga Pratisaraniya Kshara karma* in management of *Abhyantara arsha*.
2. There is significant difference between the effect of *Gomutra Siddha Apamarga Pratisaraniya Kshara karma* and *Udaka Siddha Apamarga Pratisaraniya ksharakarma* in management of *Abhyantara arsha*.

METHODOLOGY

Source of data

A. Literary source

Available Ayurveda Classical Texts, Modern Books, Journals and Websites.

B. Sample source

40 Patients with clinical features of internal haemorrhoids (*Abhyantara arshas*) fulfilling the inclusion criteria, were selected for study from out-patient department and in-patient department of Government Ayurveda Medical College and SJGAU Hospital, Bengaluru will be selected for the study.

C. Drug sources

The identified raw drugs required for the clinical study were purchased from approved vendors and the formulation was prepared in the Department of *Rasa shastra* and *Bhaishajya kalpana* of Government Ayurveda Medical College, Bengaluru.

Methods of collection of data

A. Study design

An open label double arm randomized comparative clinical study was conducted.

B. Sampling technique

The subjects who fulfil the inclusion criteria and complying with the informed consent (IC) were selected using method of Computerized Randomization Table.

A) Inclusion criteria

Patient above 18 and below 70 years of age. Patients with clinical features of 1st and 2nd degree haemorrhoids like mass per anum, Bleeding per anum, Pruritis ani and mucoid discharge per anum.

B) Exclusion criteria

Associated with any other anorectal diseases like Condyloma acuminata, Condyloma lata, Ulcerative colitis, Crohn's disease, Fistula in ano. Pregnancy and

Lactating women, Fecal incontinence, Known case of HBV, HCV & HIV I and II, Uncontrolled Diabetes mellitus type 1 and 2 and HTN, Contraindicated for *kshara karma* as per *Ayurveda*, Thrombose Haemorrhoids.

Investigation

CBC, ESR, CT, BT, RBS, HIV I and II and HBSAG.

❖ Intervention

A total of 40 Subjects of internal haemorrhoids, those fulfilling the above criteria shall be included for the study and will be randomly allotted into 2 groups namely Group-A & Group-B with 20 patients each.

Group A	Group B
<i>Gomutra Siddha Apamarga teekshna Pratisaraniya kshara karma in Abhyantara arsha.</i>	<i>Udaka Siddha Apamarga teekshna Pratisaraniya kshara karma in Abhyantara arsha.</i>

Preparation of *Gomutra Siddha Teekshna Pratisaraniya Apamarga Kshara and Udaka Siddha Teekshna Pratisaraniya Apamarga Kshara* was prepared as mentioned in *Sushruta Samhita*.

❖ Procedure of ksharakarma

Patient was admitted in IPD of Government Ayurveda Medical College and SJGAU Hospital, Bengaluru.

Pre-operative procedure

Informed written consent was taken. Part preparation done. Vitals checked. Weight of patient was measured. Inj. T.T 0.5 ml IM was given. Inj. xylocaine test dose 0.1cc was given subcutaneously. Sodium phosphate 100 ml enema was given. Clearance of bowel confirmed then patient was shifted to operation theatre.

Operative procedure

Patient made to laid down in lithotomy position. The surgical area was painted with a 10% povidone iodine solution followed by surgical spirit and then draped with hole towel Local anaesthesia was infiltrated with inj. Lignocaine 2% after calculating maximum dose according to weight. (3.5 – 5 mg/kg). Surgical procedure was started after confirming effect of anaesthesia. Manual anal dilatation was done up to 4-5 fingers. Lubricated proctoscope was introduced. Haemorrhoidal mass and their position were noted. Slit proctoscope was introduced respective to position of haemorrhoidal mass and skin around haemorrhoidal mass was retracted with Alli's tissue holding forceps to get a better view of haemorrhoid. The anal mucosa around the haemorrhoidal mass was covered with wet gauze piece to prevent spilling of kshara on it. Haemorrhoidal mass was gently scraped with the serrations over BP handle. Then *nakhaotshedha* matra (upto 3mm) of *Gomutra siddha teekshna apamarga kshara* in group A and *Udaka siddha teekshna apamarga kshara* in group B was applied over

haemorrhoidal mass and opening of proctoscope was closed for *shata matra kala* (90 seconds) with the palm. Kshara was washed with vinegar followed by normal saline. Haemorrhoidal mass was observed for the change in colour from reddish-pink to bluish- black (*pakwa jambu phala varna*). Same procedure was followed if more than one haemorrhoidal mass present. Slit proctoscope and wet gauze piece were removed from anal canal. An anal pack smeared with povidone-iodine, 2% lignocaine gel, and *Yashtimadhu Ghrita* was applied. Sterile dressing was done. Vitals recorded and patient was shifted to ward.

Post operative procedure

Anal pack was removed after 6 hours. Analgesics were administered according to the need. From Post operative day 1 patient was advised to take *panchavalkala kwatha sitz bath* for 15 minutes twice daily. 20 ml of *Yashtimadhu ghriti* was administered from anal route for 7 days.

Oral medications

- 1) *Triphala churna* in dose of 1 tsp was given at night with luke warm water as laxative.
- 2) *Triphala guggulu 1-1-1 A/F*
- 3) *Gandhaka rasayana 1-1-1 A/F*

Post operative observation regarding the changes in the features and regression of haemorrhoidal mass were observed on 1st, 7th, 14th and 21 day and the same were recorded in the proforma of case sheet prepared for the study.

Followup

In cases where total recovery was obtained, 30 days of follow up was fixed to observe the possibility of recurrence and the same was recorded in the proforma of case sheet.

Assesment criteria

Bleeding per anum

Grade	Bleeding per anum
0	No bleeding
1	Bleeding only during defecation
2	Bleeding during and after defecation
3	Bleeding irrespective of defecation

Pruritis ani

Grade	Pruritis ani
0	Pruritis ani absent
1	Pruritis ani present

Mucoid discharge per anum

Grade	Discharge per anum
0	Discharge absent
1	Discharge present

Pile mass

Grade	Pile mass
0	Pile mass absent
1	Pile mass present

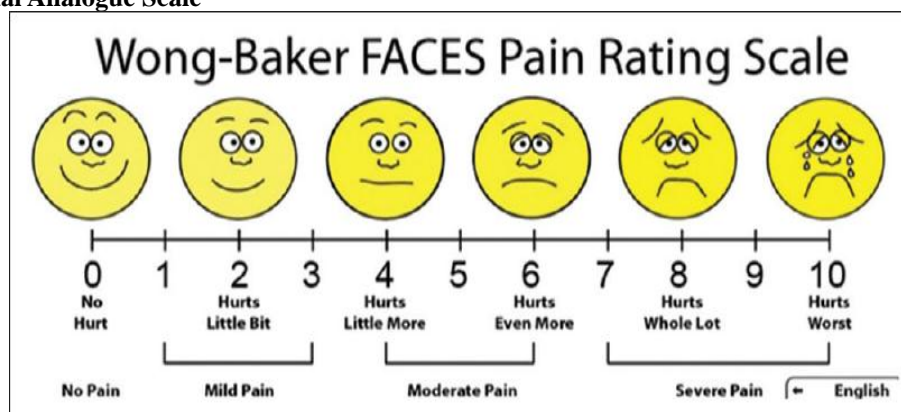
Post operative pain

Grade (0) -VAS Score 0: No pain.

Grade (1) - VAS Score 1-3: Mild pain.

Grade (2) - VAS Score 4-6: Moderate Pain.

Grade (3)- VAS Score 7-10: Severe pain.

As per the Visual Analogue Scale**Post operative burning sensation**

Grade	Burning sensation
0	Burning sensation absent
1	Burning Sensation present

Post operative oedema

Ggrade	Oedema
0	Absent
1	Present

Overall response

Class	Grading
<24%	Poor Response
25-49%	Moderate Response
50-74%	Good Response
75-100%	Excellent Response

Ethical clearance

Ethical clearance obtained from the Institutional ethics committee of Government ayurveda medical college, Bengaluru.

OBSERVATION AND RESULTS**1. Bleeding per anum****Table No. 1: Effect of treatment on bleeding per anum within Group A.**

Ranks ^a	
	Mean Rank
BT	4.60
D1	3.10
D7	2.60
D14	2.35
D21	2.35

Test Statistics ^{a,b}	
N	20
Chi-Square	54.476
df	4
P value	0.000
a. Groups = Group A	
b. Friedman Test	

Statistical analysis reveals significant improvements in bleeding per anum. The p-value < 0.05 supports rejecting the null hypothesis.

Table No. 2: Effect of treatment on bleeding per anum within Group B.

Ranks ^a	
	Mean Rank
BT	4.50
D1	3.00
D7	2.50
D14	2.50
D21	2.50
Test Statistics ^{a,b}	
N	20
Chi-Square	53.333
df	4
P value	0.000
a. Groups = Group B	
b. Friedman Test	

Statistical analysis shows significant improvements in bleeding per anum. The p-value < 0.05 supports rejecting the null hypothesis.

Table No 3: Effect of treatment on Bleeding per anum between Group A and Group B.

Test Statistics ^a					
	BT	D1	D7	D14	D21
Mann-Whitney U	173.000	180.000	180.000	200.000	200.000
Wilcoxon W	383.000	390.000	390.000	410.000	410.000
Z	-1.002	-.721	-1.433	0.000	0.000
P value (2-tailed)	0.316	0.471	0.152	1.000	1.000
a. Grouping Variable: Groups					
b. Not corrected for ties.					

The Mann-Whitney U Test ($p > 0.05$) revealed no significant differences between Group A and Group B at any time point (BT, D1, D7, D14, D21). The p-values > 0.05 indicate insufficient evidence to reject the null hypothesis.

2. Pruritis ani**Table No. 4: Effect of treatment on Pruritis ani within Group A.**

Ranks ^a	
	Mean Rank
BT	3.30
D1	2.93
D7	2.93

D14	2.93
D21	2.93
Test Statistics^{a,b}	
N	20
Chi-Square	12.000
df	4
P value	0.017
a. Groups = Group A	
b. Friedman Test	

Statistical analysis shows significant improvements in pruritis ani. The p-value < 0.05 supports rejecting the null hypothesis.

Table No. 5: Effect of treatment on Pruritis ani within Group B.

Ranks^a	
	Mean Rank
BT	3.28
D1	3.03
D7	2.90
D14	2.90
D21	2.90
Test Statistics^{a,b}	
N	20
Chi-Square	9.714
df	4
P value	0.046
a. Groups = Group B	
b. Friedman Test	

Statistical analysis indicates significant improvements in pruritis ani. The p-value < 0.05 supports rejecting the null hypothesis.

Table No. 6: Effect of treatment on Pruritis ani between the Group A and Group B.

Test Statistics^a					
	BT	D1	D7	D14	D21
Mann-Whitney U	200.000	190.000	200.000	200.000	200.000
Wilcoxon W	410.000	400.000	410.000	410.000	410.000
Z	0.000	-1.000	0.000	0.000	0.000
P value (2-tailed)	1.000	0.317	1.000	1.000	1.000
a. Grouping Variable: Groups					
b. Not corrected for ties.					

The Mann-Whitney U Test ($p > 0.05$) found no significant differences between Group A and Group B at any time point (BT, D1, D7, D14, D21). The p-values > 0.05 indicate no sufficient evidence to reject the null hypothesis.

3. Mucoïd discharge per anum

Table No. 7: Effect of treatment on Mucoïd Discharge within Group A.

Ranks^a	
	Mean Rank
BT	3.20
D1	2.95
D7	2.95
D14	2.95
D21	2.95
Test Statistics^{a,b}	
N	20
Chi-Square	8.000
df	4
P value	0.092
a. Groups = Group A	
b. Friedman Test	

Statistical analysis indicates no significant effect of the intervention on mucoid discharge per anum in Group A. The p-value > 0.05 suggests insufficient evidence to reject the null hypothesis.

Table No. 8: Effect of treatment on Mucoid Discharge within Group B.

Ranks ^a	
	Mean Rank
BT	3.38
D1	3.25
D7	2.88
D14	2.75
D21	2.75
Test Statistics ^{a,b}	
N	20
Chi-Square	15.714
df	4
P value	.003
a. Groups = Group B	
b. Friedman Test	

Statistical analysis shows significant improvements in mucoid discharge per anum. The p-value < 0.05 supports rejecting the null hypothesis.

Table No 9: Effect of treatment on Mucoid discharge between the Group A and Group B.

Test Statistics ^a					
	BT	D1	D7	D14	D21
Mann-Whitney U	170.000	160.000	190.000	200.000	200.000
Wilcoxon W	380.000	370.000	400.000	410.000	410.000
Z	-1.233	-2.082	-1.000	0.000	0.000
P value (2-tailed)	.218	.037	.317	1.000	1.000
a. Grouping Variable: Groups					
b. Not corrected for ties.					

The Mann-Whitney U Test ($p > 0.05$) found no significant differences between Group A and Group B at BT, D7, D14, and D21. The p-values > 0.05 suggest no sufficient evidence to reject the null hypothesis for BT, D7, D14, and D21.

4. Pile mass

Table No. 10: Effect of treatment on Pile mass within Group A.

Ranks ^a	
	Mean Rank
BT	3.35
D1	3.23
D7	3.23
D14	3.10
D21	2.10
Test Statistics ^{a,b}	
N	20
Chi-Square	31.810
df	4
P value	0.000
a. Groups = Group A	
b. Friedman Test	

Statistical analysis shows significant improvements in pile mass. The p-value < 0.05 supports rejecting the null hypothesis.

Table No. 11: Effect of treatment on Pile mass within Group B.

Ranks ^a	
	Mean Rank
BT	3.33
D1	3.33
D7	3.20

D14	2.95
D21	2.20
Test Statistics^{a,b}	
N	20
Chi-Square	27.238
df	4
P value	0.000
a. Groups = Group B	
b. Friedman Test	

Statistical analysis shows significant improvements in pile mass. The p-value < 0.05 supports rejecting the null hypothesis.

Table No. 12: Effect of treatment on Pile mass between the Group A and Group B.

Test Statistics^a					
	BT	D1	D7	D14	D21
Mann-Whitney U	200.000	190.000	200.000	190.000	190.000
Wilcoxon W	410.000	400.000	410.000	400.000	400.000
Z	0.000	-1.000	0.000	-.472	-.313
P value (2-tailed)	1.000	.317	1.000	.637	.755
a. Grouping Variable: Groups					
b. Not corrected for ties.					

The Mann-Whitney U Test ($p > 0.05$) found no significant differences between Group A and Group B at any time point regarding pile mass. The p-values > 0.05 indicate no sufficient evidence to reject the null hypothesis.

5. Post operative pain

Table No. 13: Effect of treatment on Post Operative pain within Group A.

Ranks^a	
	Mean Rank
D0	2.90
D1	4.50
D7	3.70
D14	2.10
D21	1.80
Test Statistics^{a,b}	
N	20
Chi-Square	51.447
df	4
P value	0.000
a. Groups = Group A	
b. Friedman Test	

Statistical analysis shows significant improvements in post-operative pain. The p-value < 0.05 supports rejecting the null hypothesis.

Table 14: Effect of treatment on Post Operative pain within Group B.

Ranks^a	
	Mean Rank
D0	3.68
D1	4.05
D7	3.28
D14	2.40
D21	1.60
a. Groups = Group B	
Test Statistics^{a,b}	
N	20
Chi-Square	47.033
df	4
P value	0.000
a. Groups = Group B	
b. Friedman Test	

Statistical analysis shows significant improvements in post-operative pain. The p-value < 0.05 supports rejecting the null hypothesis.

Table No. 15: Effect of treatment on Post Operative pain Between Group A and Group B.

Test Statistics ^a					
	D0	D1	D7	D14	D21
Mann-Whitney U	95.500	178.500	189.000	120.000	170.000
Wilcoxon W	305.500	388.500	399.000	330.000	380.000
Z	-3.036	-.724	-.408	-2.619	-1.778
P value (2-tailed)	.002	.469	.683	.009	.075
a. Grouping Variable: Groups					
b. Not corrected for ties.					

The Mann-Whitney U Test (p = 0.002) showed a significant difference in post-operative pain on Day 0, with Group B reporting higher pain levels. The p-value < 0.05 supports rejecting the null hypothesis.

6. Post operative burning sensation

Table No. 16: Effect of treatment on Post operative Burning sensation within Group A.

Ranks ^a	
	Mean Rank
D0	3.60
D1	3.73
D7	3.23
D14	2.60
D21	1.85
Test Statistics ^{a,b}	
N	20
Chi-Square	39.692
df	4
P value	0.000
a. Groups = Group A	
b. Friedman Test	

Statistical analysis shows significant improvements in post-operative burning sensation. The p-value < 0.05 supports rejecting the null hypothesis.

Table No. 17: Effect of treatment on Post operative Burning sensation within Group B.

Ranks ^a	
	Mean Rank
D0	3.88
D1	3.88
D7	2.88
D14	2.25
D21	2.13
Test Statistics ^{a,b}	
N	20
Chi-Square	44.878
df	4
P value	0.000
a. Groups = Group B	
b. Friedman Test	

Statistical analysis shows significant improvements in post-operative burning sensation. The p-value < 0.05 supports rejecting the null hypothesis.

Table No. 18: Effect of treatment on Post operative Burning sensation Between Group A and Group B.

Test Statistics ^a					
	D0	D1	D7	D14	D21
Mann-Whitney U	170.000	160.000	120.000	120.000	170.000
Wilcoxon W	380.000	370.000	330.000	330.000	380.000
Z	-1.122	-1.561	-2.498	-2.884	-1.778

P value (2-tailed)	.262	.118	.012	.004	.075
a. Grouping Variable: Groups					
b. Not corrected for ties.					

The Mann-Whitney U Test found no significant differences between Group A and Group B on Day 0 ($p = 0.262$), Day 1 ($p = 0.118$), and Day 21 ($p = 0.075$). The p -value > 0.05 indicates no sufficient evidence to reject the null hypothesis.

7. Post operative oedema

Table No. 19: Effect of treatment on Post operative oedema within Group A.

Ranks ^a	
	Mean Rank
D0	2.93
D1	3.05
D7	3.05
D14	3.05
D21	2.93
Test Statistics ^{a,b}	
N	20
Chi-Square	4.000
df	4
P value	0.406
a. Groups = Group A	
b. Friedman Test	

Statistical analysis shows no significant effect of the intervention on post-operative oedema in Group A. The p -value > 0.05 indicates no sufficient evidence to reject the null hypothesis.

Table No. 20: Effect of treatment on Post operative oedema within Group B.

Ranks ^a	
	Mean Rank
D0	2.38
D1	3.60
D7	3.43
D14	2.98
D21	2.63
Test Statistics ^{a,b}	
N	20
Chi-Square	25.805
df	4
P value	0.000
a. Groups = Group B	
b. Friedman Test	

Statistical analysis shows significant improvements in post-operative oedema. The p -value < 0.05 supports rejecting the null hypothesis.

Table No. 21: Effect of treatment on Post operative oedema Between Group A and Group B.

	Test Statistics ^a				
	D0	D1	D7	D14	D21
Mann-Whitney U	200.000	110.000	129.500	160.000	180.000
Wilcoxon W	410.000	320.000	339.500	370.000	390.000
Z	0.000	-3.147	-2.627	-1.749	-1.433
P value (2-tailed)	1.000	0.002	0.009	.080	0.152
a. Grouping Variable: Groups					

The Mann-Whitney U test showed no significant differences between Group A and Group B at D0 ($p = 1.000$), D14 ($p = 0.080$), and D21 ($p = 0.152$). The p -values > 0.05 for D0, D14, and D21 indicate no significant differences between the groups at those time points.

Table No. 22: Overall response.

Overall effect	Group A	%	Group B	%
Excellent	6	30	8	40
Good	11	55	9	45
Moderate	2	10	3	15
Poor	1	5	0	0
Total	20	100	20	100

Chi-square value (χ^2):	p-value	Degrees of Freedom (dof):
1.69	0.64	4

The p-value of 0.64 is greater than the common significance level of 0.05, indicating that there is no statistically significant difference between Group A and Group B in terms of their overall effect.

DISCUSSION

Discussion on drug

The pH value of an alkali typically ranges from 7 to 14. In this study, the pH of *Apamarga Teekshna Pratisaraneeya Kshara* prepared with *Udaka* was measured at 13.65, indicating a highly alkaline nature. The pH of *Apamarga Teekshna Pratisaraneeya Kshara* prepared with *Gomutra* was found to be 12.87, as measured by a pH meter. The yield of *Apamarga Teekshna Pratisaraneeya Kshara* prepared with *Udaka* was 170 grams, whereas the yield of *Apamarga Teekshna Pratisaraneeya Kshara* prepared with *Gomutra* was 220 grams. Which can be because of *sakshara* property of *gomutra* mentioned by *Acharya sushruta*.

Mode of action of kshara

Pratisaraneeya Kshara acts on haemorrhoids in two ways

- It cauterizes the pile mass directly because of its *Ksharana Guna* (Corrosive nature)
- 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 slough out as blackish brown discharge for 7 to 14 days. The haem present in the slough gives the discharge its colour. The tissue becomes fibrosed and scar formation seen.

After the application of *pratisaraniya kshara karma* color changes of haemorrhoidal mass from reddish-pink to bluish- black (*Pakwa jambu phala varna*) was observed in 90 sec (*Shatamatrakala*). Initially it induces aseptic inflammation at the site of the haemorrhoid. This inflammatory response is crucial as it initiates tissue necrosis without infection. Over the course of 7-14 days, there is progressive sloughing of necrosed tissue, where the damaged and coagulated mass begins to break down and separate from the surrounding healthy tissue. Following the sloughing phase, the site undergoes fibrosis and scar formation. The necrosed tissue is replaced by fibrous tissue, leading to the formation of a scar, which effectively obliterates the haemorrhoidal mass.

During this healing process, the mucus membrane sloughs off and adheres to the muscular coat, which further reduces the size of the haemorrhoidal mass. Ultimately, this leads to the complete cure of *Arshas* (haemorrhoid).

DISCUSSION ON RESULTS

Both Group A and Group B showed effective outcomes, with no significant differences in bleeding resolution ($p > 0.05$) and complete recovery by Day 21. Group A provided faster relief from pruritis ani and mucoid discharge, attributed to *gomutra's* *kapha-vata* alleviating and antimicrobial properties. Both groups achieved significant reductions in pile mass by Day 21. Post-operative pain was higher in Group B on Days 0 ($p = 0.002$) and 14 ($p = 0.009$), but both groups reported minimal pain by Day 21. Group B recovered faster from burning sensation by Days 7 and 14, while Group A lagged slightly, with 15% reporting mild symptoms by Day 21. Group B exhibited greater oedema initially, with slower recovery, while Group A achieved complete resolution by Day 21. Overall, outcomes were similar ($p = 0.64$), though Group B had slightly better results, with no poor outcomes, whereas Group A had a higher proportion of good outcomes but a few poor results.

CONCLUSION

- The parameters of assessment i.e., Bleeding per anum (Group A: 100% and Group B: 100 %), Pruritis ani (Group A: 100% and Group B: 100 %), Mucoid discharge per anum (Group A: 100% and Group B: 100 %), Pile mass (Group A: 50% and Group B: 45%), Post operative pain (Group A: 100% and Group B: 85 %), Post operative burning sensation (Group A: 85 % and Group B: 100 %) and Post operative oedema sensation (Group A: 100 % and Group B: 90 %).
- Group B demonstrated slightly better overall outcomes, with a higher percentage of patients achieving excellent results (40% in Group B compared to 30% in Group A) and no poor outcomes (0% in Group B vs. 5% in Group A). In contrast, Group A had a larger proportion of patients with good outcomes (55% in Group A compared to 45% in Group B), but also recorded a small percentage of poor outcomes.

- Comparative analysis of overall effect of the treatments in both the groups show that both the groups were effective, hence *Gomutra Siddha Apamarga Pratisaraniya Ksharakarma* is as effective as *Udaka Siddha Apamarga Pratisaraniya Ksharakarma* in the management of *Abhyantara Arshas*.
- Based on observation and result, following Null hypothesis can be accepted

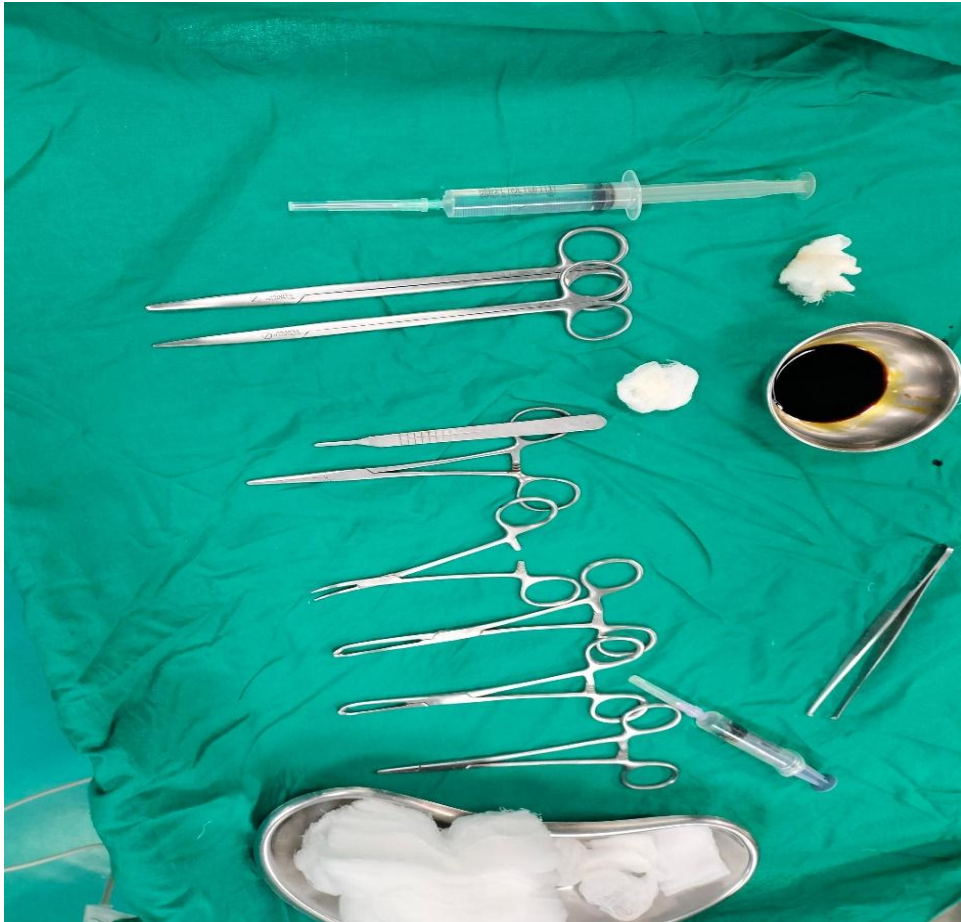
There is no significant difference between the effect of *Gomutra Siddha Apamarga Pratisaraniya Kshara karma*

and *Udaka Siddha Apamarga Pratisaraniya ksharakarma* in management of *Abhyantara arsha*.

Scope of further research

- Similar study can be conducted on large population.
- Study can be conducted by taking equal volume of gomutra and udaka as solvent for preparation kshara in one group.
- Comparative study can be done between *Gomutra Siddha Apamarga Pratisaraniya Kshara karma* and sclerotherapy in abhyantara arshas.

Materials required for ksharakarma



Before and After treatment in Group A Case No. 6



Before treatment



Pratisaraniya kshara karma



After treatment

**Before and After Treatment in Group B
Case No. 2**



Before treatment



Pratisaraniya kshara karma



After treatment

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