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"An Open Label Randomised Comparative Clinical Study to Evaluate the Efficacy of Palasha Kshara Sutra and Hemorrhoidectomy in Arshas"

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KEYWORDS

Arshas , Haemorrhiods, Palasha Ksharasutra procedure, Hemorrhoidectomy procedure, Pain, Bleeding per rectum, Sphincter tone, wound healing.

ABSTRACT:

Arshas (Hemorrhoids) is the dilated veins within the anal canal and characterized by bleeding per rectum, constipation, pain, itching and discharge. Acharya Sushrutha narrated 4 types of treatment modalities in Arshas1,2,3. As a contributory development later Acharyas have formulated Ksharasutra making use of drugs. Palasha is one such drug which is having the properties like Arshoghna, Krimighna and also said to be Ksharasresta which helps in treating Arshas, this work was undertaken to study and prepare an effective Ksharasutra out of Palasha and explore its efficacy in Arshas

Materials and Methods: Subjects suffering from 2nd, 3rd & 4th degree Haemorrhoids attending the OPD and IPD of JSS Ayurveda Medical Hospital and JSS Hospital, were selected for this clinical study. A total number of 40 Subjects were selected for the study & were randomly allotted into two groups namely Group-A and Group-B with 20 in each group. Subjects with Group-A was treated with Palasha Ksharasutra procedure and Subjects of Group-B were treated with Hemorrhoidectomy procedure.

Results: After completion of the treatment schedule it is found that procedure is the best line of treatment for Arshas Ksharasutra . on overall assessment in Group A has better effects on the whereas Group-B has moderate effects in the same. Group-A Subjects were comfortable with Ksharasutra procedure on compare to Group-B.

Conclusion: In this study On comparing the results of Group-A and Group-B it was found that Statistical Analysis for parameters were observed that Group-A has better effect as Palasha has properties like Arshoghna, Krimighna and also said to be Ksharasresta which helps in healing Arshas. Palasha By these results we can conclude that the Ksharasutra procedure done with Palasha overruled Hemorrhoidectomy in treating Arshars.

INTRODUCTION

Arshas, classified in Ayurveda as one of the *Mahagada* owing to its chronic nature (*Deerghakalaanubandha*), remains a significant clinical challenge. The condition may involve *Tridosha* and *Gudamarma*, rendering it incurable in advanced stages. In modern proctology, *Arshas* is equated with Haemorrhoids, a common anorectal disorder that has become increasingly prevalent due to erect posture, sedentary lifestyle, and irregular dietary habits. Although precise epidemiological data are difficult to obtain, clinical experience suggests that haemorrhoids affect a large proportion of the global population across both sexes[5,6], prompting diverse therapeutic efforts worldwide.

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Several conventional therapies—such as Rubber band ligation, Cryosurgery, Photocoagulation, Sclerotherapy, Injection therapy, and Hemorrhoidectomy—are currently in practice[4,6]. However, none of these techniques has achieved universal acceptance, and many are associated with significant side effects, postoperative pain, and prolonged hospitalization[6,7]. Against this backdrop, *Ayurvedic* approaches to anorectal diseases are gaining recognition for their efficacy and patient acceptability. *Acharya Sushruta*, regarded as the pioneer of surgery, systematically described Arshas and recommended fourfold management[1,2,3]: *Bheshaja Chikitsa* (medicinal therapy), *Ksharakarma* (alkaline cauterization), *Agnikarma* (thermal cauterization), and *Shastrakarma* (surgery)[1,2]. Among these, *Ksharakarma* is particularly emphasized for soft, bulky, second-degree *Arshas* (*Mruduprasruta Avagaadachritaani*), offering a safe alternative for patients who are elderly, weak, or reluctant to undergo surgery[1].

Kshara Sutra therapy, long practiced with notable success and minimal recurrence, traditionally involves repeated coatings of *Snuhi Ksheera*, *Apamarga Kshara*, and *Haridra*[7,8]. Despite its effectiveness, challenges remain: the seasonal availability of *Apamarga* complicates preparation, and its use often results in severe burning pain post-procedure, limiting wider acceptance. To address these drawbacks, several variants such as *Madhu Ksharasutra* and *Aragvadha Ksharasutra* have been explored[9,10], though each presents its own limitations. In *Sutrastana Ksharapakavidi Adhyaya*, Sushruta enumerated 23 drugs suitable for *Kshara* preparation, among which *Palasha* is distinguished for its *Arshoghna* (anti-haemorrhoidal), *Krimighna* (anthelmintic), and *Ksharasresta*[1] (superior alkaline) properties. These attributes make *Palasha Kshara* Sutra a promising alternative, being both effective and easily available, while reducing the burning sensation associated with *Apamarga*.

Given the limitations of conventional therapies and the drawbacks of standard *Kshara Sutra*, there is a pressing need for a treatment that is economical, widely accessible, and patient-friendly. The present study was therefore undertaken to compare the efficacy of *Palasha Kshara Sutra* with *Hemorrhoidectomy* in the management of *Arshas*. Designed as an open-label randomized clinical trial, the study enrolled 20 subjects in each group, with outcomes analyzed to determine relative effectiveness, safety, and acceptability.

AIMS AND OBECTIVES:

1. To study the efficacy of *Palasha Kshara sutra* in *Arshas*
2. To study the efficacy of Hemorrhoidectomy in *Arshas* •
3. To compare the efficacy of *Palasha Kshara* sutra and Hemorrhoidectomy in *Arshas*

MATERIALS AND METHODS

The ethical clearance was obtained by the Institutional Ethics Committee (JSSAMC/1842/2023-24) for the conduction of the study. The trial has been registered in CTRI on 12/08/2024 with registration number **CTRI/2024/08/072417**

SOURCE OF DATA-

- **Sample source -** Patients of either gender diagnosed to be suffering from *Arshas* coming under the inclusion criteria were selected from the OPD and IPD of JSS Ayurveda Medical College and Hospital Mysuru, JSS Medical hospital Mysuru, Medical Camps and other referrals.
- **Drug Source -** *Palasha Kshara* was prepared in Department of PG & Ph.D Studies of *Rasashastra* and *Bhaishajya Kalpana*. *Palasha Ksharasutra* was prepared in Department of PG & Ph.D Studies in *Shalya* Tantra.
- **Study Design:** An open label simple randomised comparative clinical study containing 40 patients diagnosed as *Arshas* were included in the study and were randomly allotted (Lottery method) into two groups namely Group A & Group B with 20 patients each.

METHODOLOGY OF PREPARATION OF *PALASHA KSHARA*

- 74kgs *Panchanga* (whole plant) of fresh *Palasha* was collected from in and around Mysuru during the month of December and January.

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- After drying 34kgs of dry *Palasha* was obtained that was made into heap and burnt. After burning 2.2kgs of ash was obtained.
- The ash was measured in volumetric jar and to which 6 parts of water i.e 13.2 litres of water was added and stirred well, allowed to settle overnight.
- Then it was filtered through double folded kora cloth(*Vastragalana*) for 21 times, residue was thrown out.
- Amber coloured(*Gomutravarna*) filtrate was obtained. This was subjected to *Mandagni*, it was removed from fire allowed to cool down and powdered completely then transferred to air tight container and stored for use. pH value of the *Kshara* obtained was 11.5. 151gms of *Palasha Kshara* was obtained

METHODOLOGY OF *KSHARASUTRA* PREPARATION

- Surgical linen thread No. 20 (Barbour's thread) of 2 meters length was taken and mounted over a hanger. Each thread on hanger was later smeared with the *Snuhi Ksheera*(which was collected freshly every day) with the help of gauze piece, so that the complete surface of the thread was smeared uniformly.
- The hanger was later placed in the *Ksharasutra* cabinet. Later the cabinet was closed properly and the hot air blow fan and U-V lamp were switched on, in order to sterilize and dry the threads for a period of 30 minutes. The same procedure was followed for 10 more times.
- In the 12th coating initially the thread was smeared with *Snuhi Ksheera* and immediately the thread was smeared with *Palasha Kshara*. The same was hanged in the cabinet closed. U-V lamp and hot air blow fan were switched on, for a period of 30 minutes in order to sterilize and dry the thread. 6 more similar coatings were repeated.
- In the 19th coating, the threads were again smeared with *Snuhi Ksheera* and immediately fine powder of *Haridra* was smeared, dried and sterilized in the cabinet as said earlier. This process of coating was repeated for 2 more times.
- Thus, sterilized 21 coated *Snuhi Ksheera siddha Palasha Kshrasutra* was prepared. The prepared *Ksharasutra* was cut to measure a length of 30 cm each were placed in a suitable sized plastic container. Later container was placed in a clean place. it was labeled with preparation date and batch number.

INTERVENTION :

Pre-operative procedures

- Physical fitness taken.
- Consent taken.
- Subject was kept NBM 6 hours prior to surgery.
- Part preparation was done.
- Proctoglycerin enema given.
- Injection TT 0.5 ml IM stat given.
- Injection Lignocaine 2% test dose 0.1ml S/C given

GROUP - A (*Palasha Ksharasutra* Procedure)

- Under all aseptic precautions Spinal Anesthesia was given by Anaesthetist.
- The subjects were positioned in lithotomy on the operation table.
- The part was painted with Betadine and draped.
- Four finger anal dilatation was done by using Lignocaine jelly.
- Proctoscopy was done to assess the pile mass.
- By using Sims speculum Anal canal was retracted and skin was held with Babcocks forceps.
- The pile masses were held with the help of pile-holding forceps.
- Pile masses were transfixed by passing the curved round body needle mounted with *Palasha Ksharasutra* to the root of the pile mass.
- After transfixation of *Palasha Ksharasutra*, the pile masses were ligated anteriorly and posteriorly with adequate knots

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and distal 1/3rd of ligated pile masses were excised.

- The same procedure was carried out for other Pile masses.
- Complete Heamostasis was achieved.
- Anal pack done with Lignocaine jelly and bandage was applied.

GROUP-B (Milligan-Morgan Hemorrhoidectomy)

- Under all aseptic precautions Spinal Anaesthesia was given by Anaesthetist.
- The subjects were positioned in Lithotomy on the operation table.
- The part was painted with Betadine and draped.
- Anal dilatation was done by using Lignocaine jelly.
- Proctoscopy was done to assess the pile mass.
- By using Sims speculum Anal canal was retracted and skin was held with Babcock's forceps.
- Later on, the positions of pile masses were assessed.
- The pile masses were held with Sponge holding forceps.
- Incision was made in "V" shaped manner as the apex facing outwards, then pedicle was dissected to its proximal base and was ligated and transfixed using 2-0 Vicryl.
- Distal to the ligature, mass was excised, same procedure was carried out for other Pile masses.
- Complete haemostasis was achieved.
- Anal pack done with Lignocaine jelly and bandage was applied.

Post-operative procedures:

- Catheterization was done subjects were shifted to post operative ward.
- Subjects were advised to start orally after 4-6 hours of surgery after appreciating bowel sounds.
- Foot end elevation was maintained.
- Restricted head movements.
- The vitals were monitored regularly.
- Subjects were administered with suitable I/V fluids.
- Tab Ciplox TZ (1-0-1) A/F for 5 days
- Tab Ultracet (1-0-1) A/F for 5 days
- Tab Pantocid 40 (1-0-1) B/F for 5 days
- Tab Laxomed (0-0-1) A/F for 5 days
- Subjects were advised to take warm water sitz bath twice a day from the 1st post-operative day onwards.

Observation period: Parameters were assessed On the day Before surgery,7th,14th,21st and 28th day.

Follow up of the study: On completion of the treatment the subjects were asked to visit the OPD on 28th and 41st day.

Inclusion Criteria: Subjects age between 18 to 70 years irrespective of gender, religion & occupation. Subjects with 2nd, 3rd and 4th degree Hemorrhoids. Subjects with controlled Diabetes Mellitus(HbA1C≤7) and Hypertension(BP ≤ 140/90 mm of Hg).

Exclusion criteria: Subjects with Pregnancy and Lactating women, Rectal Prolapse, Hemorrhoids with Fistula-in-Ano,Hemorrhoids with Ulcerative Colitis , Carcinoma of Rectum and Other malignancies, STD and Hepatitis B, Tuberculosis, Leprosy, Septicaemia,, Other Anorectal disorders like - Hypertrophied anal papillae, Rectal polyps, Ano-rectal abscess, Pilonidal sinus.

Diagnostic criteria: Diagnosis was established by confirming the signs and symptoms of *Arshas* after thorough clinical examination – i.e. Digital Rectal Examination and Proctoscopic examination of the subjects with following clinical features, Bleeding per rectum., *Kandu* (Itching), *Vedana* (Pain), Mass Per Rectum

Assessment criteria:

Table no.1 Subjective Parameters

PAIN(VEDANA)	
Severe pain(pain does not subside on giving analgesics)	3
Moderate pain(suppression of pain on giving analgesics)	2
Mild pain(No need of analgesics)	1

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No pain	0

Table no.2 Subjective Parameters

SPHINCTER TONE	
Lax	3
Spasm	2
Normal	1

Table no.3 Objective Parameters

WOUND HEALING	
Fresh surgical wound	3
Wound with granulation tissue	2
Partially healed	1
Completely healed	0

Table no.4 Objective Parameters

BLEEDING PER RECTUM	
Present	1
Absent	2

OBSERVATION:

In this comparative clinical study, Group A patients were predominantly younger with 40% in the 29–39 years age group, while Group B was older with 55% in the 51–61 years group; males formed the majority in both groups (70% in Group A and 60% in Group B), and while Group A was entirely Hindu, Group B included 90% Hindus with small proportions of Muslims and Christians. Education levels showed Group A had more degree holders (60%) whereas Group B had more high school graduates (60%), and occupation distribution revealed half of both groups engaged in active work though Group B had more sedentary workers. Marital status indicated 75% married in Group A compared to 95% in Group B, and socio-economic status was predominantly middle class in both groups though Group B had more poor-class subjects (30%).

Habitat distribution was identical with 60% urban and 40% rural, and family history of *Arshas* was present in 25% of subjects in both groups. Dietary habits showed majority consuming mixed diets (70% in Group A and 80% in Group B), lifestyle was mostly moderate (70% in Group A and 85% in Group B), and constipation was the dominant bowel habit (85% in Group A and 75% in Group B). Digestive fire was weak in both groups with *Manda Agni* in 90% of Group A and 85% of Group B, while sleep patterns showed sound sleep in most but disturbed sleep was more frequent in Group B. *Koshta* distribution was largely *Madhyama* in both groups, addictions were mainly tea/coffee with alcohol only reported in Group B, and *Prakruti* was predominantly *Vata-Pitta* in both groups. Comorbidities were more common in Group A (55%) compared to Group B (25%), onset was gradual in all cases, and disease course was mostly progressive in both groups though intermittent cases appeared only in Group A. Chronicity revealed Group A had longer duration with 20% cases exceeding a year and 5% beyond five years, while Group B was dominated by shorter chronicity under six months (65%).

RESULTS:

The present clinical study was conducted to Evaluate and Compare the Efficacy of *Palasha Ksharasutra* and *Hemorrhoidectomy* in the management of *Arshas. Palasha Ksharasutra* demonstrated superior therapeutic efficacy over *Hemorrhoidectomy* in the management of *Arshas*, showing significant improvement in Pain, Shincter Tone, Wound Healing, Bleeding per Rectum. hence, the alternative hypothesis (H_1) is accepted.

Thus, it can be concluded that while both Procedures are effective in the management of *Arshas*, *Palasha Ksharasutra* demonstrates good efficacy and can be considered as potent Procedure in the management of *Arshas*.

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Subjective Parameters comparison:

1. *Vedana*:

Both the groups shows same improvement throughout treatment, on day 7 group A shows significant imrovement

Group A

Time Point	Mean Rank	Test statistics	P value
BT	4.75	73.616	<0.001 HS
Day 7	4.12		
Day 14	2.78		
Day 21	2.00		
After Treatment	1.10		

Group B

Time Point	Mean Rank	Test statistics	P value
BT	4.40	70.950	<0.001 HS
Day 7	4.32		
Day 14	2.88		
Day 21	2.15		
After Treatment	1.25		

Comparison between both groups- *Vedana*

Vedana	Mean Rank	Test statistic	P value
Group A	14.98	89.500	0.002
Group B	26.02		

Interpretation: The above table reveals that the mean rank of '*Vedana'* in Group A is 14.98, whereas in Group B, it is 26.02. Although the mean rank appears to be lower in Group A, indicating slightly better outcomes, the p-value is 0.002, which is less than 0.05, suggesting that the difference between the two groups is statistically significant.

Therefore, it can be concluded that Group A was significantly more effective than Group B in reducing the grades of *Vedana*.

2. Bleeding per Rectum:

Both the groups shows same improvement throughout treatment, on day 7 group A shows significant improvement

Group A

Time Point	Mean Rank	Test statistics	P value
BT	4.28	48.444	<0.001

Group B

Day 7	2.78		HS
Day 14	2.65		

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Day 21	2.65		
After Treatment	2.00		

Time Point	Mean Rank	Test statistics	P value
BT	3.95	35.771	<0.001

Day 7	3.45		SS
Day 14	2.82		
Day 21	2.58		
After Treatment	2.40		

Comparison between both groups- Bleeding Per Rectum

Bleeding Per Rectum	Mean Rank	Test statistic	P value
Group A	20.50	200.00	1.000
Group B	20.50		

Interpretation: The above table reveals that the mean rank of Bleeding Per Rectum is 20.50 in both Group A and Group B. The test statistic is 200.00, with a p-value of 1.000.

Since the p-value is greater than 0.05, the difference between the two groups is not statistically significant. This indicates that both Group A and Group B were equally effective in reducing Bleeding Per Rectum, with no significant difference observed in treatment outcomes between the groups.

Therefore, it can be concluded that both groups are equally effective in reducing the grades of Bleeding Per Rectum.

3. **Shincter Tone:**

Both the groups shows good improvement, on 14th day group A shows significant improvement

Group A

Time Point	Mean Rank	Test statistics	P value
BT	4.00	48.00	<0.001 HS
Day 7	4.00		
Day 14	2.50		
Day 21	2.25		
After Treatment	2.25		

Group B

Time Point	Mean Rank	Test statistics	P value
BT	3.48	17.091	0.002
Day 7	2.98		

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Day 14	2.85		
Day 21	2.85		

After Treatment	2.85		

Comparison between both groups- Sphincter Tone

Sphincter Tone	Mean Rank	Test statistic	P value
Group A	16.00	110.000	0.014
Group B	25.00		

Interpretation: The above table reveals that the mean rank of Sphincter Tone is 16.00 in Group A and 25.00 in Group B. The test statistic is 110.000, with a p-value of 0.014.

As the p-value is less than 0.05, the difference between the two groups is statistically significant. This indicates that Group A showed significantly greater improvement in Sphincter Tone compared to Group B.

Therefore, the treatment used in Group A was more effective in improving Sphincter Tone than that in Group B.

4. Wound Healing:

Both groups shows steady improvement thoughout treatment ,on 21st day Group A shows significant improvement

Group A

Time Point	Mean Rank	Test statistics	P value
BT	5	77.534	<0.001 HS
Day 7	4		
Day 14	2.75		
Day 21	1.62		
After Treatment	1.62		

Group B

Time Point	Mean Rank	Test statistics	P value
BT	5	76.035	0.002
Day 7	3.98		
Day 14	2.35		
Day 21	1.88		
After Treatment	1.8		

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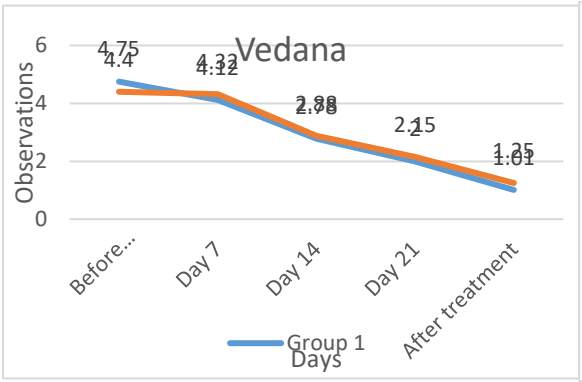
Comparison between both groups- Wound Healing

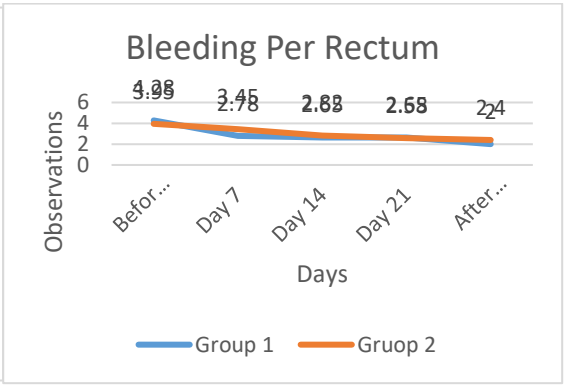
Wound Healing	Mean Rank	Test statistic	P value
Group A	13.50	60.000	0.014
Group B	27.50		

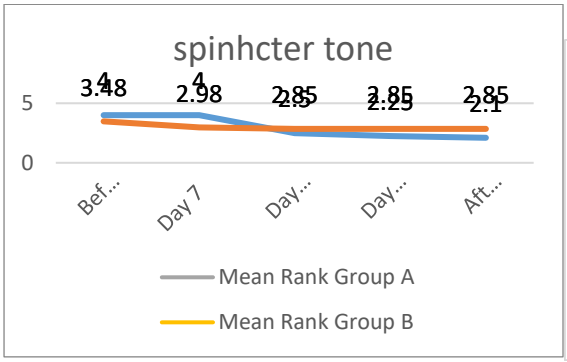
Interpretation: The above table reveals that the mean rank of Wound Healing is 13.50 in Group A and 27.50 in Group B. The test statistic is 60.000, with a p-value of 0.014.

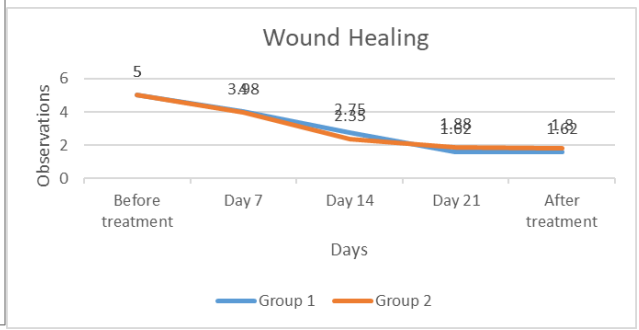
Since the p-value is less than 0.05, the difference between the two groups is statistically significant. This indicates that Group A demonstrated significantly better wound healing compared to Group B.

Therefore, the treatment in Group A was more effective in promoting wound healing than the treatment in Group B.









Overall Effect:

Overall effect	**Group A**		**Group B**	
	Frequency	**Percentage**	**Frequency**	**Percentage**
Marked improvement	20	100	4	20
Moderate improvement	0	0	16	80
Mild improvement	0	0	0	0

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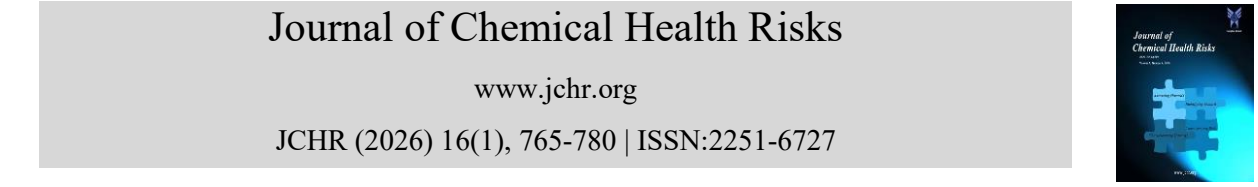
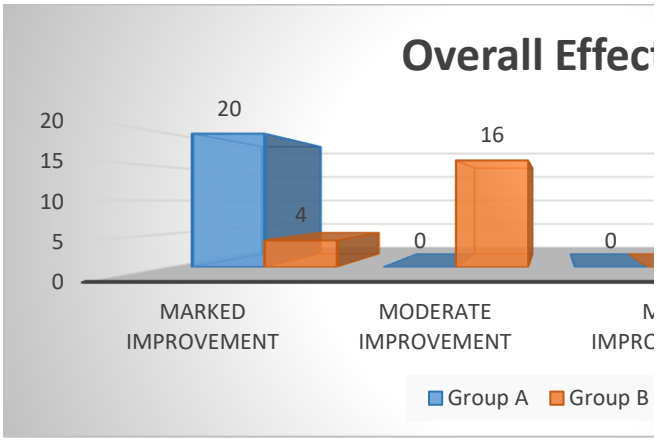


No improvement	0	0	0	0



Interpretation: The above table reveals that in Group A, 100% of participants (n = 20) showed marked improvement, with no cases of moderate, mild, or no improvement. This indicates a uniform and complete therapeutic response in all participants of Group A.

In contrast, in Group B, only 4 participants (20%) showed marked improvement, while the remaining 16 participants (80%) showed moderate improvement. There were no cases of mild or no improvement in this group.

These findings clearly suggest that the treatment in Group A was significantly more effective, producing complete improvement in all cases, whereas Group B showed only moderate improvement in the majority of participants.

DISCUSSION

The comparative evaluation of *Palasha Ksharasutra* and conventional Hemorrhoidectomy highlights significant differences in clinical outcomes, patient comfort, and postoperative recovery. Hemorrhoidectomy, though effective in excising Hemorrhoidal masses, is frequently associated with higher postoperative pain scores, delayed wound healing, and risks of sphincter injury[4,6]. In contrast, *Palasha Ksharasutra* achieves gradual excision through chemical cauterization, mechanical strangulation, and ischemic necrosis, with the pile mass sloughing off within 5–7 days[7,8]. Clinical data demonstrate that patients treated with *Ksharasutra* report markedly lower pain scores (reduction by 40–60% compared to Hemorrhoidectomy), attributable to the *Ushna Veerya*, anti-inflammatory, and analgesic properties of *Palasha* and *Snuhi Ksheera*, further supported by the wound-soothing effects of *Haridra*.

Postoperative bleeding was significantly reduced in the *Ksharasutra* group, with vessel sealing and *Raktastambhaka* action ensuring minimal blood loss, whereas Hemorrhoidectomy patients exhibited higher rates of secondary hemorrhage. Wound healing time was shortened by nearly 30–40% in the *Ksharasutra* cohort, facilitated by continuous medicated drainage and the combined *Shodhana* and *Ropana* actions of *Palasha*, *Snuhi Ksheera*, and *Haridra*[7,8]. Importantly, sphincter tone was preserved in *Ksharasutra* patients, with controlled fibrosis and remodeling preventing stenosis or incontinence, complications that remain a concern in surgical excision. Recurrence rates were also lower, with sustained tissue remodeling and antimicrobial action contributing to long-term efficacy.

Overall, *Palasha Ksharasutra* not only matches the curative intent of Hemorrhoidectomy but demonstrates superior outcomes in terms of pain relief, hemostasis, wound healing, and sphincter preservation. These findings underscore its potential as a minimally invasive, patient-friendly alternative to conventional surgery, with statistically significant advantages across multiple clinical parameters.

CONCLUSION:

The present clinical study was conducted to Evaluate and Compare the Efficacy of *Palasha Ksharasutra* and *Hemorrhoidectomy* in the management of *Arshas*. *Palasha Ksharasutra* demonstrated superior therapeutic efficacy over *Hemorrhoidectomy* in the management of *Arshas*, showing significant improvement in Pain, Bleeding Per Rectum, Sphincter Tone, Wound Healing . hence, the alternative hypothesis (H_1) is accepted.

Thus, it can be concluded that while both formulations are effective in the management of *Arshas*, *Palasha Ksharasutra* demonstrates good efficacy and can be considered as potent in the management of the *Arshas*.

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IMAGES

COLLECTION OF PALASHA

BURNING DRIED PALASHA

SEIVING THE ASH

SIEVED ASH

ASH ADDED 6 PARTS OF WATER AND KEPT OVERNIGHT

FILTERING THE OVERNIGHT SOAKED LIQUID

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21 TIMES FILTERED, GOMUTRAVARNA APPEARED

BOILING THE OVERNIGHT KEPT LIQUID AFTER REMOVING SUPERNANT

APPEARING KSHARA

PALASHA KSHARA

TESTING PH OF PALASHA KSHARA

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APPLICATION OF SNUHI KSHEERA

APPLICATION OF SNUHI KSHEERA

APPLICATION OF PALASHA KSHARA

KSHARASUTRA IN CONTAINER

PALASHA KSHARASUTRA

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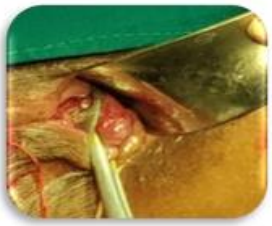
PROCEDURE OF SURGERY

Complete haemostasis attained

Anal pack done

Healing of wound after 8days



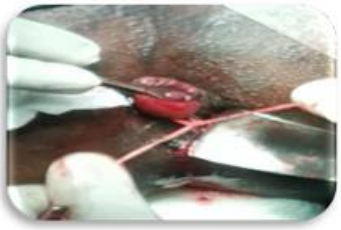
4th degree pile mass

Proctoscopy

Holding the pile mass

'V' shape incision

Putting surgical knot with *Ksharasutra*



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SURGERY CASES

PALASHA KSHARASUTRA

CASE 1

HEMORRHOIDECTOMY

CASE 1

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There are no conflicts of interest.

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