

ROLE OF ASPHOTA (HEMIDESMUS INDICUS R.BR.) KSHARASUTRA IN THE MANAGEMENT OF LOW-ANAL FISTULA

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ABSTRACT

In this modern era, due to a sedentary lifestyle and improper dietary habit digestive disorder shows greater incidence. Among them, fistula-in-ano is troubleshooting one, which is a communicating tract between two epithelial surfaces lined by granulation tissues. Due to the higher recurrence rate and postoperative complication fistula-in-ano is a headache in the present era. In Ayurvedic classics, Ksharasutra prayoga is mentioned for the treatment of Nadi Vrana, which can be adopted in the management of anal fistula. The objective of the present study was to be evaluated the efficacy of Asphota Kshara sutra in the management of low anal fistula. The clinical trial was conducted in OPD and IPD of Shalyatantra department at Pankajakasthuri Ayurveda Medical College. The intervention was ligation of the fistulous tract with Asphota Ksharasutra. 25 subjects were selected satisfying inclusion and exclusion criteria. The clinical assessment was done before treatment, after treatment and follow up on the 30th day after cutting through of the tract. The assessment was done based on parameters prepared for anal fistula by Paul O Madson and Peter. Pain, burning sensation, inflammation, itching, discharge and unit cutting time was statistically analysed in different periods. Outcome variables were analysed statistically by using the Friedman test and Wilcoxon signed-rank test, and a conclusion was drawn. Pain, burning sensation, inflammation, discharge, itching was effectively managed using Asphota Ksharasutra. The unit cutting time of Asphota ksharasutra was found to be more

than standard Ksharasutra. The result showed that Asphota Ksharasutra is effective in the management of low anal fistula.

Keywords: Fistula-in-ano; Asphota ksharasutra.

INTRODUCTION

Ayurveda is one of the holistic healing systems, which apart from providing various therapeutic measures for various diseases, emphasizes maintenance and which help in the promotion of health and prevention of diseases through diet and lifestyle regimens. Out of eight branches of Ayurveda Shalyatantra is the pioneer of surgery and Acharya Susrutha is the real torch bearer of surgical practitioners and the people considers him as the 'father of surgery'. He had laid down the unique principles regarding surgical treatment like ksharasutra, agnikarma, rakthamoksha, and shastrakarma. Among them, the ksharakarma is the most important para surgical procedure and ksharasutra is the chief piece of work of ksharakarma.

The anal canal is the site of many diseases. Most conditions arising in this area are incapacitating and interfere with the quality of life. Among them, bhagandara is a troubleshooting one. The tearing of бага, guda and vasthi with acute pain is known as bhagandara. This disease starts as a pidaka or boil which suppurates and burst open to form bhagandara^{1,2,3}. The surgical management of bhagandara (fistula-in-ano) carries several complications and a higher recurrence rate. To overcome this problem ksharasutra therapy has been described^{4,5,6}. It is found to be very successful with a very less recurrence rate of 3.8%. This procedure is economical, safe and cost-effective with fewer adverse effects and a higher success rate.

In the present study, the treatment procedure adapted is ksharasutra prayoga. The drug used for the preparation of ksharasutra is Asphota (*Hemidesmus indicus* R. Br) which is mentioned in ksharapaka vidhi adhya of Susrutha Samhita. Acharya Dalhana explained Asphota as Sariba in his commentary. This drug has Madhura, Tikta Rasa, Sheetha virya and Madhura Vipaka.

The objective of the study is to evaluate the efficacy of Asphota Ksharasutra in the management of low anal fistula.

The aim of the study is a better understanding of fistula-in-ano, to evaluate the efficacy of Asphota ksharasutra in the management of low anal fistula.

Materials and Method

Trial Design

The study design is an interventional pre-test and post-test study without a control group. The period of intervention depends on the length of the fistulous tract, till complete cutting of the tract is attained. The present study was done fully adhering to GCP-ICH guidelines with IEC approval. The IEC clearance was obtained vid reference no: PKAMC/IEC/37/19

Study Setting

OPD and IPD, of Department of Shalyatantra Pankajakathuri Ayurveda Medical College and PG centre, Kattakada, Trivandrum.

Study Population

Subjects of age group between 18 to 70 years with low anal fistula irrespective of gender. The sample size for the study was 25 considering 10% dropout.

Sampling Technique

The subjects were selected by consecutive sampling methods from the OPD and IPD of the Department of Shalyatantra, Pankajakathuri Ayurveda Medical College and PG Centre, Kattakada, Trivandrum till sample size was obtained.

Diagnostic Criteria

Diagnosed by classical signs and symptoms of Bhagandara (fistula-in-ano)³

The fistulous tract was confirmed after probing.

Inclusion Criteria

1. Subjects of age group between 18 to 70 years
2. Subjects were selected irrespective of gender, religion, caste and economic status.
3. Subjects diagnosed with low anal fistula.

Exclusion Criteria

1. Subjects with high anal fistula
2. Pregnant women
3. Subjects with uncontrolled Diabetes Mellitus
4. Diagnosed cases of HIV, HBsAg positive patients and cardiovascular patients.
5. Fistula in ano secondary to
 - Ulcerative colitis
 - Crohn's disease
 - Tuberculosis
 - Colloidal Carcinoma of the rectum

Assessing criteria

1. Pain
2. Burning sensation
3. Inflammation
4. Discharge
5. Itching
6. Unit cutting time

Signs and symptoms found were graded based on the scoring system prepared for that by Paul O Madson and Peter.

1. PAIN

Grade 0	No pain
Grade1	Negligible or tolerable pain. No need for any medicine
Grade2	Localized tolerable pain completely relieved by hot sitz bath.
Grade 3	Intolerable pain, not relieved by sitz bath, relieved by oral analgesics. No sleep disturbance.
Grade 4	Continuous and intolerable pain with sleep disturbance. The patient seeks medical help as early as possible.

2. BURNING SENSATION

Grade 0	No burning sensation.
Grade 1	The negligible feeling of burning sensation for a few minutes in a day
Grade 2	Tolerable burning sensation completely relieved by hot sitz bath or local oleation
Grade3	Tolerable but constant burning sensation relieved by hot sitz bath or local oleation
Grade4	The unbearable burning sensation makes the patients seek medical help as soon as possible

3. INFLAMMATION

Grade0	No sign of inflammation around the external opening
Grade1	Very little inflammation around the external opening
Grade2	Inflammation in 1 cm diameter of the external opening
Grade3	Inflammation in 2cm diameter of the external opening

4. DISCHARGE

Grade 0	No sign of any discharge
Grade 1	The occasional appearance of discharge and patients use a single cotton pad in 24 hrs
Grade 2	The frequent appearance of discharge and patient used 3-4 cotton pads in 24 hrs
Grade 3	Increased frequency of discharge and patient use 5-6 cotton pads in 24 hrs
Grade 4	Continuous discharge.

5. ITCHING

Grade 0	No complaint of itching
Grade 1	Negligible itching for a few minutes a day
Grade 2	The occasional sensation of itching
Grade 3	The frequent sensation of itching with 4-6 hours interval
Grade 4	The continuous sensation of itching with 15-30 minutes intervals.

Unit cutting time

Total number of days for cut-through

The initial length of *ksharasutra* (in cm)

Withdrawal Criteria

1. The unwillingness of the subject to continue
2. Adverse drug reaction

Investigation

- Haematological examination: Hb %, TC, DC, ESR, RBS
- Coagulation profile: BT, CT
- X-ray Fistulogram was done in necessary subjects.

Data Collection

Assessment parameters were collected by personal interview, clinical examination and case record form. The assessment was done before treatment, after treatment (after cutting through of tract) and in follow up period (30th day after completing cut through of tract).

Duration of Study

Total duration 18 months

Period of intervention- depending on the length of the fistulous tract.

Procedure

All the subjects in the trial group were treated using the *Asphota kshara sutra*.

Preparation of trial drug-*Asphota Kshara sutra*

Preparation of *Asphota Mridhu Kshara*

Raw drugs were collected from an authorized dealer and *Ksharasutra* was prepared in the Department of Salyatantra, Pankajakasthuri Ayurveda Medical College and Post Graduate Centre, Trivandrum.

The whole plant of *asphota* was taken, it was dried well and burned on a clean surface, all the ash was collected

and kept in a vessel to cool. The next day the whole ash was dissolved in six times of water. Then it was kept undisturbed for 12 hours duration. The next day the mixture was filtered 21 times and the filtrate was heated on the gas furnace in a stainless-steel pot until all water was evaporated and till white amorphous powder was obtained. The amorphous powder obtained was made fine powdered with pestle and mortar and sieved through double layer muslin cloth and kept in an airtight glass container.

Preparation of *Asphota Kshara Sutra*

The *Asphota kshara sutra* was prepared by a repeated coating of *snuhi ksheera*, *asphota kshara* and *haridra choorna* over surgical barbus linen tread no 20. This thread is tied tightly throughout lengthwise in hangers. Each thread on the hanger was smeared with *snuhi* latex with help of a gauze piece soaked in *snuhi* latex. This wet hanger is transferred into *kshara sutra* cabinet. The same process was repeated the next day. Eleven such coatings with *snuhi ksheera* alone were accomplished. The twelfth coating was done by first smearing the thread with *snuhi ksheera* and in wet condition, a thread was smeared with *asphota kshara*. It is again transferred into the cabinet for drying. This process was repeated till seven coatings of *snuhi ksheera* and *asphota kshara* is achieved. The final three coatings were completed with *snuhi ksheera* and fine powder of *haridra* in the same manner. Thus, twenty-one coatings over the thread were completed.

The order of coating is divided as follows

Table 1: *Asphota ksharasutra* preparation

Ingredients	No of coating
<i>Snuhi ksheera</i>	11
<i>Snuhi ksheera</i> + <i>asphota Mridhu Kshara</i>	7
<i>Snuhi ksheera</i> + <i>haridra</i>	3
Total coating	21

Preservation of *Kshara Sutra*: After the 21 coatings and exposure to UV rays, each thread was sealed into a glass tube. The tube was open only at the time of use.

Pre-Operative Procedure: After obtaining informed consent, vitals were measured and recorded. The patient was kept nil per oral for at least 4 to 6 hours. Soap water or phosphate enema was given 2hours before the

procedure. The later perianal and perineal region was prepared.

Materials used: - Mosquito forceps-2, suture cutting scissors, malleable copper probe, sponge holding forceps, instrument tray, cotton swab, sterile cotton pad, *Asphota kshara* sutra, micropore.

Operative Procedure

The patient was kept in lithotomy position and part was prepared by using betadine solution 10% followed by surgical spirit. Local anaesthesia was given using injection lignocaine hydrochloride 2% in the presence of a trained surgeon. The patient was advised to relax his thigh and anal sphincter. After reassuring the patient, digital and proctoscopy examinations were conducted. Then a malleable copper probe was inserted through the external opening of the fistula. The tip of the probe was forwarded along the path of least resistance and was guided by the gloved finger in the lumen of the anal canal to support the advancement of

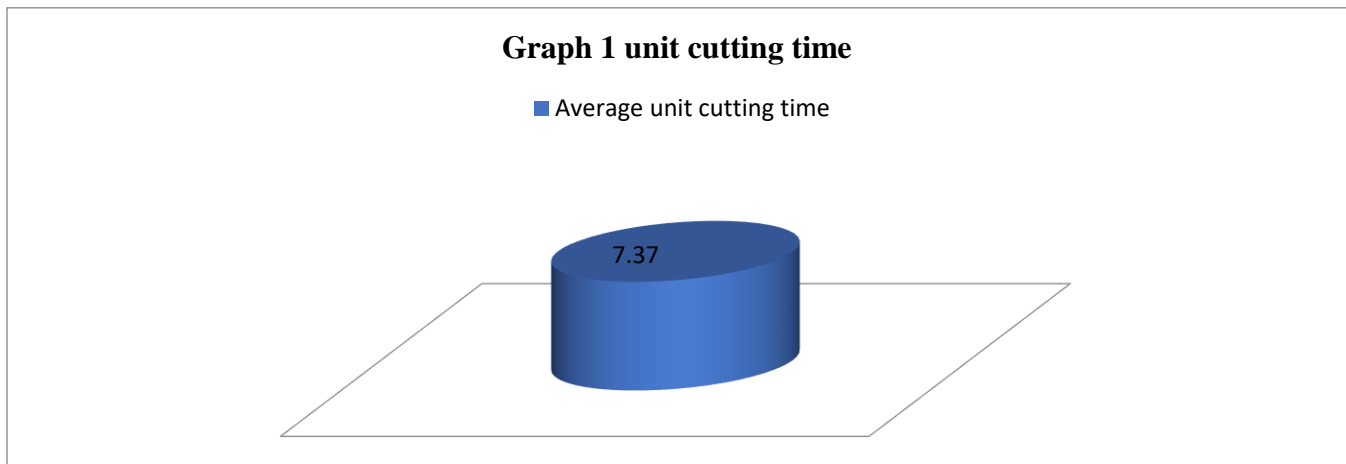
the probe towards the internal opening. The tip of the probe was finally directed to come out through the anal orifice. A then suitable length of *Asphota kshara* was taken and threaded into the eye of the probe. Thereafter the probe was pulled out through the anal orifice to leave the thread behind in the fistulous tract. The two ends of the *Ksharasutra* were tied together with a moderate tightness outside the anal canal.

Post-Operative Procedure: Blood clots in and around the anal canal and perineal region were cleaned. Then a surgical pad was placed in the area. Haemostasis was attained. Vitals were checked and recorded. The anal dressing was done.

Follow Up: The patient was reviewed every week for wound care and thread change.

1. Unit Cutting Time

Unit cutting time of patients lies in the range 4.4 – 11.3. The calculated average unit cutting time is 7.37.



RESULTS – Statistical Analysis and Interpretations

1. Effect Of Intervention on Pain

Table 2: Result of Friedman Test for Pain

Period	Mean rank	SE
BT	3	0.206
AT	1.5	0
Follow up	1.5	0

Table 3: Effect of intervention on pain

Chi-square	46.00
P-value	<0.001

The chi-Square value for the Friedman test for comparing the effect of the intervention on pain at different periods [46.00] was found to be significant and P-value was <0.001. Hence rejected the null hypothesis, and accept that there exists a significant difference between at least one pair of the period in

terms of pain. As there exists a significant difference between different periods, pairwise comparison was done by using the Wilcoxon Signed-Rank test for finding out which of the periods are different and which are not different.

Table 4: Result of Wilcoxon Signed Rank Tests for Pain

Pairs	Calculated value (Z)	P-value	Significance difference
BT and AT	-4.238	<0.001	Present
BT and Follow up	-4.238	<0.001	Present
AT and Follow up	0	1.00	Absent

The result shows that there exists a significant difference between the before treatment group and after treatment group at the 1% level. Also, there exists a significant difference between the before treatment

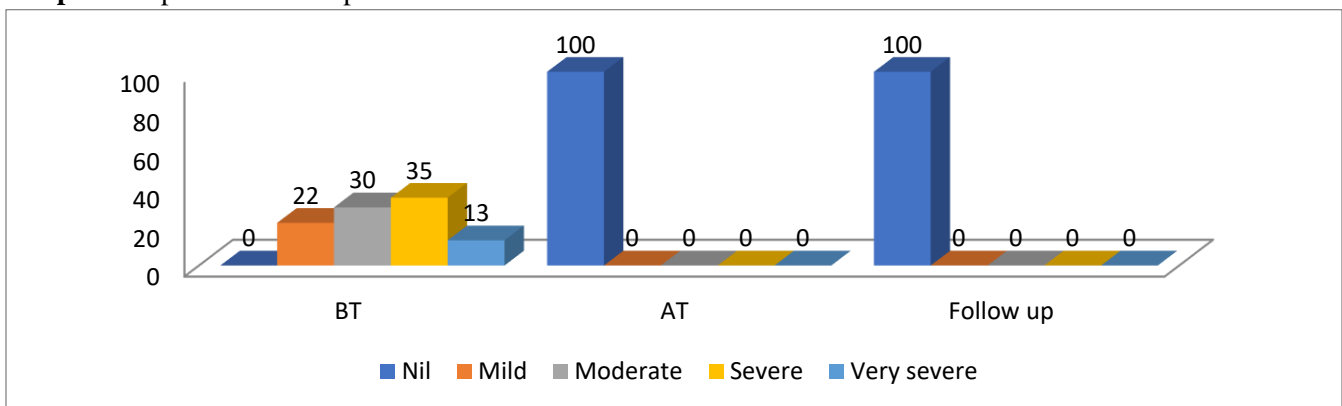
group and follow up group at the 1% level. There is no significant difference between after treatment group and follow up the group. It means that intervention helps to reduce pain.

Table 5: Assessment of pain based on Paul O Madson & Peter scoring system

Period	Response									
	Nil		Mild		Moderate		Severe		Very severe	
	N	%	N	%	N	%	N	%	N	%
BT	0	0	5	22	7	30	8	35	3	13
AT	23	100	0	0	0	0	0	0	0	0
Follow up	23	100	0	0	0	0	0	0	0	0

All the mild, moderate, severe and very severe cases of pain before treatment had been cured after treatment. There were no nil pain cases before treatment. But after treatment nil cases had increased to 100%.

Graph 3: Representation of pain



2. Effect Of Intervention on Burning Sensation

Table 6: Result of Friedman Test for Burning Sensation

Period	Mean rank	SE
BT	2.74	0.224
AT	1.63	0
Follow up	1.63	0

Table 7: Effect of intervention on the burning sensation

Chi-square	34.00
P-value	<0.001

Chi-Square value for the Friedman test for comparing the effect of the intervention on burning sensation at different periods [34.00] was found to be significant and P-value was <0.001. Hence rejected the null hypothesis, and accept that there exists a significant difference between at least one pair of the period in

terms of burning sensation. As there exists a significant difference between different periods, pairwise comparison was done by using the Wilcoxon Signed-Rank test for finding out which of the periods are different and which are not different.

Table 8: Result of Wilcoxon Signed Rank Tests for burning sensation

Pairs	Calculated value (Z)	P-value	Significance difference
BT and AT	-3.674	<0.001	Present
BT and Follow up	-3.674	<0.001	Present
AT and Follow up	0	1.00	Absent

The result shows that there exists a significant difference between before treatment group and after treatment group at 1% level. Also, there exists a significant difference between the before treatment

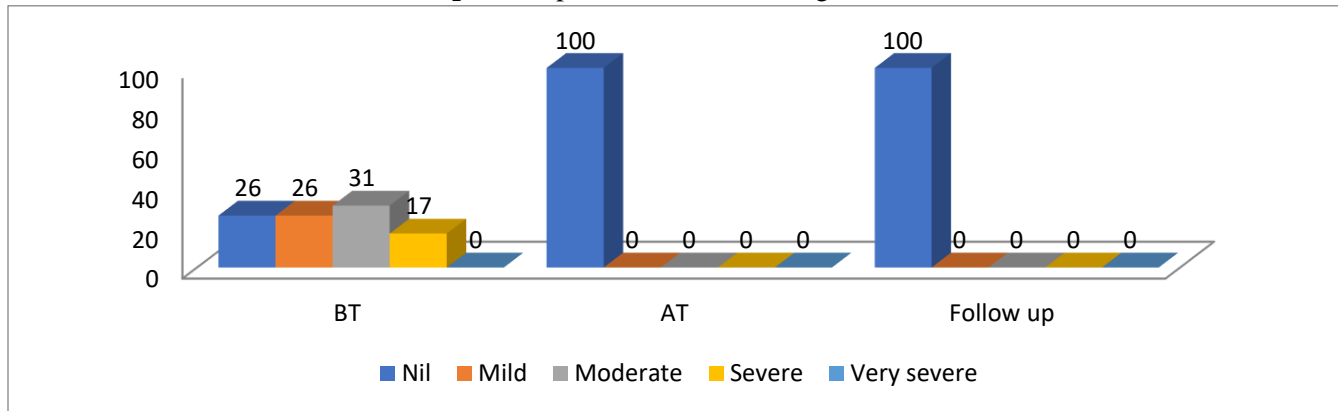
group and follow up group at the 1% level. There is no significant difference between after treatment group and follow up the group. It means that intervention helps to reduce the burning sensation.

Table 9: Assessment of burning sensation based on Paul O Madson & Peter scoring system

Period	Response									
	Nil		Mild		Moderate		Severe		Very severe	
	N	%	N	%	N	%	N	%	N	%
BT	6	26	6	26	7	31	4	17	0	0
AT	23	100	0	0	0	0	0	0	0	0
Follow up	23	100	0	0	0	0	0	0	0	0

Before treatment, there were 17% severe cases, 31% moderate cases and 26% mild cases of burning sensation. But after treatment, all those cases had cured and nil cases of burning sensation had increased from 26% to 100% during the study period.

Graph 5: Representation of burning sensation



3. Effect of intervention on inflammation

Table 10: Result of Friedman Test for inflammation

Period	Mean rank	SE
BT	3	0.17
AT	1.5	0
Follow up	1.5	0

Table 11: Effect of intervention on inflammation

Chi-square	46.00
P-value	<0.001

Chi-Square value for the Friedman test for comparing the effect of the intervention on inflammation at different periods [46.00] was found to be significant and P-value was <0.001. Hence rejected the null hypothesis, and accept that there exists a significant difference between at least one pair of the period in

terms of inflammation. As there exists a significant difference between different periods, pairwise comparison was done by using the Wilcoxon Signed-Rank test for finding out which of the periods are different and which are not different.

Table 12: Result of Wilcoxon Signed Rank Tests for inflammation

Pairs	Calculated value (Z)	P-value	Significance difference
BT and AT	-4.256	<0.001	Present
BT and Follow up	-4.256	<0.001	Present
AT and Follow up	0	1.00	Absent

The result shows that there exists a significant difference between before treatment group and after treatment group at 1% level. Also, there exists a significant difference between the before treatment

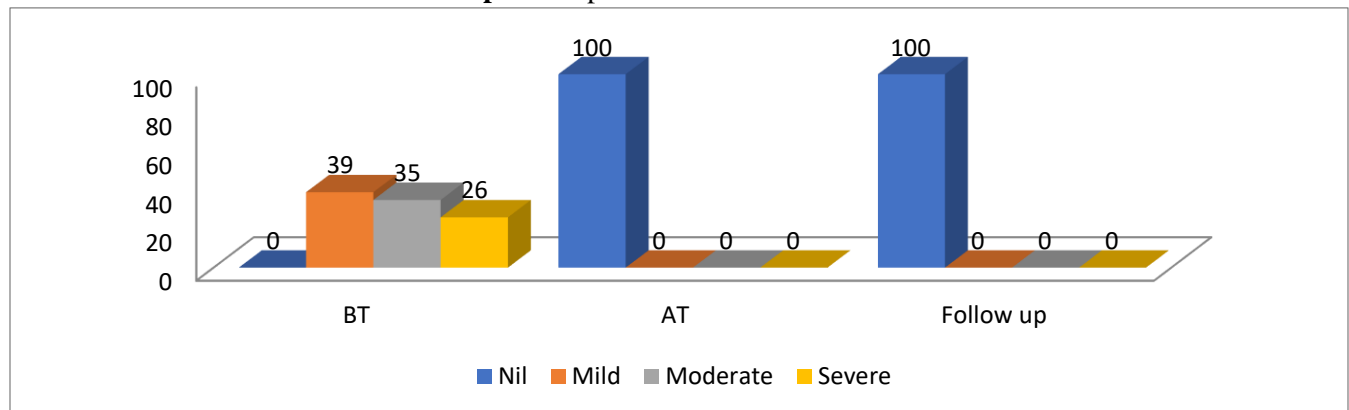
group and follow up group at the 1% level. There is no significant difference between after treatment group and follow up the group. It means that intervention helps to reduce inflammation.

Table 13: Assessment of inflammation based on Paul O Madson & Peter scoring system

Period	Response							
	Nil		Mild		Moderate		Severe	
	N	%	N	%	N	%	N	%
BT	0	0	9	39	8	35	6	26
AT	23	100	0	0	0	0	0	0
Follow up	23	100	0	0	0	0	0	0

All the mild, moderate and severe cases of inflammation before treatment had cured after treatment. Nil cases had increased from 0% to 100% during the study period.

Graph 7: Representation of inflammation



4. Effect of intervention on discharge

Table 14: Result of Friedman Test of discharge

Period	Mean rank	SE
BT	2.83	0.197
AT	1.59	0
Follow up	1.59	0

Table 15: Effect of intervention on discharge

Chi-square	38.00
P-value	<0.001

Chi-Square value for the Friedman test for comparing the effect of the intervention on discharge at different periods [38.00] was found to be significant and P-value was <0.001. Hence rejected the null hypothesis, and accept that there exists a significant difference between at least one pair of the period in terms of

discharge. As there exists a significant difference between different periods, pairwise comparison was done by using the Wilcoxon Signed-Rank test for finding out which of the periods are different and which are not different.

Table 16: Result of Wilcoxon Signed Rank Tests on discharge

Pairs	Calculated value (Z)	P-value	Significance difference
BT and AT	-3.921	<0.001	Present
BT and Follow up	-3.921	<0.001	Present
AT and Follow up	0	1.00	Absent

The result shows that there exists a significant difference between before treatment group and after treatment group at 1% level. Also, there exists a significant difference between the before treatment

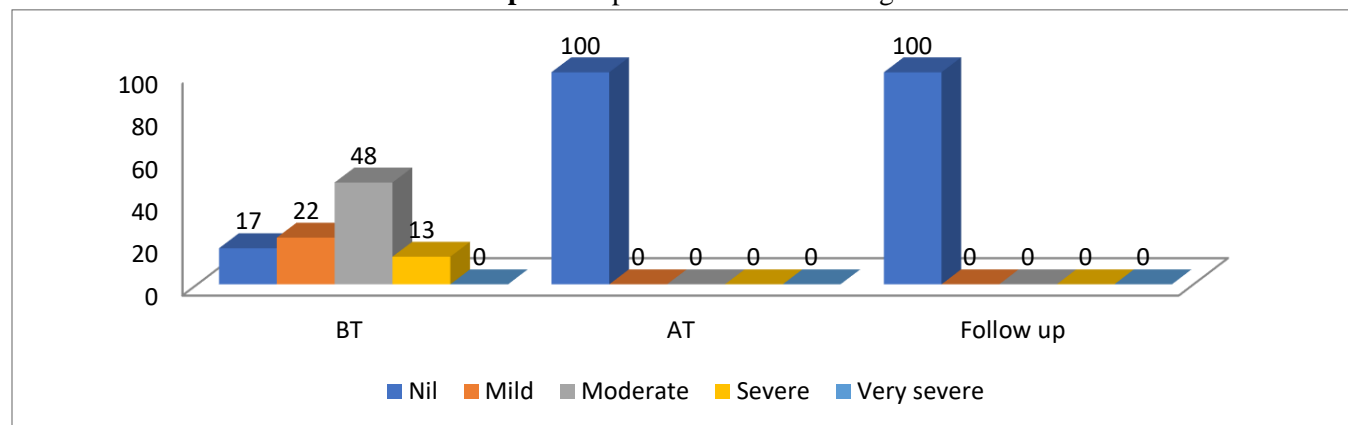
group and follow up group at the 1% level. There is no significant difference between after treatment group and follow up the group. It means that intervention helps to reduce discharge.

Table 17: Assessment of discharge based on Paul O Madson & Peter scoring system

Period	Response									
	Nil		Mild		Moderate		Severe		Very severe	
	N	%	N	%	N	%	N	%	N	%
BT	4	17	5	22	11	48	3	13	0	0
AT	23	100	0	0	0	0	0	0	0	0
Follow up	23	100	0	0	0	0	0	0	0	0

All the mild, moderate and severe cases of discharge before treatment had been cured after treatment. Nil cases had increased from 17% to 100% during the study period.

Graph 9: Representation of discharge



5. Distribution according to itching

Table 18: Result of Friedman Test for itching

Period	Mean rank	SE
BT	2.57	0.166
AT	1.72	0
Follow up	1.72	0

Table 19: Effect of intervention on itching

Chi-square	26.00
P-value	<0.001

Chi-Square value for the Friedman test for comparing the effect of the intervention on itching at different periods [26.00] was found to be significant and P-value was <0.001. Hence rejected the null hypothesis, and accept that there exists a significant difference between at least one pair of the period in terms of

itching. As there exists a significant difference between different periods, pairwise comparison was done by using the Wilcoxon Signed-Rank test for finding out which of the periods are different and which are not different.

Table 20: Result of Wilcoxon Signed Rank Tests for itching

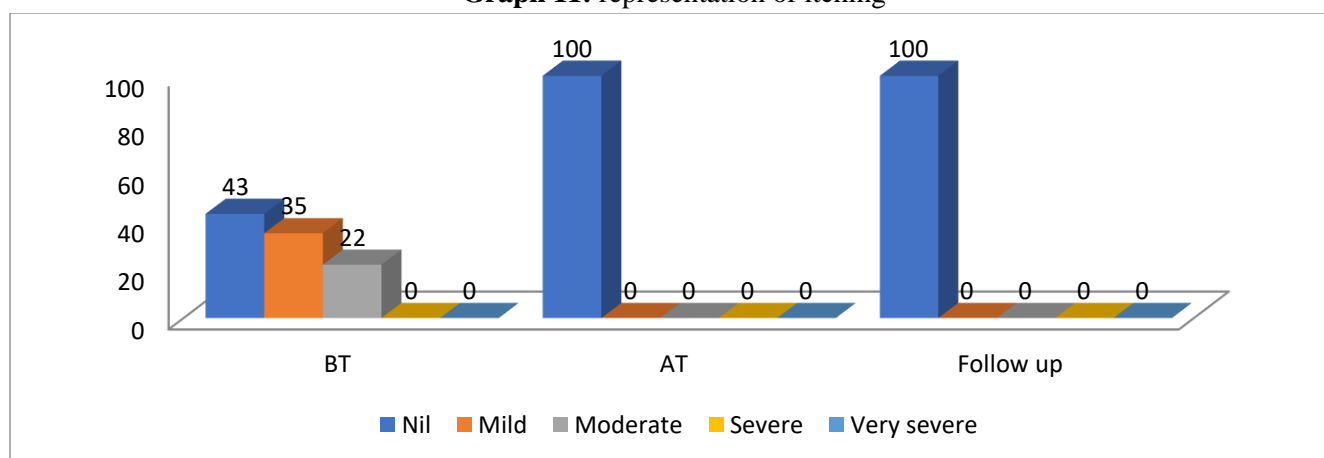
Pairs	Calculated value (Z)	P-value	Significance difference
BT and AT	-3.286	< 0.001	Present
BT and Follow up	-3.286	< 0.001	Present
AT and Follow up	0	1.00	Absent

Table 21: Assessment of itching based on Paul O Madson & Peter scoring system

Period	Response									
	Nil		Mild		Moderate		Severe		Very severe	
	N	%	N	%	N	%	N	%	N	%
BT	10	43	8	35	5	22	0	0	0	0
AT	23	100	0	0	0	0	0	0	0	0
Follow up	23	100	0	0	0	0	0	0	0	0

There were no severe and very severe cases of itching before treatment. All the mild and moderate cases of itching before treatment had cured after treatment. Nil cases of itching had increased from 43% to 100% during the study period.

Graph 11: representation of itching



PROBABLE MODE OF ACTION OF ASPHOTA KSHARASUTRA

Asphota drug is having *tikta*, *madhura rasa* and also belongs to *Madhura vipaka*, *sheethavirya* and *tridosha shamaka*. It is *vatahara* because of its *Madhura vipaka*, *pitta samaka* because of its *sheetha virya* and *Madhura vipaka*, *tikta* and *madhura rasa*. *Kaphasamaka* due to *tikta rasa*. It is also having the property of *kusthaghna*, *kandughna*, *raktasodhana* and *raktapittahara*. The fistula is a tract lined by unhealthy granulation tissue. So, we need a treatment modality that can ensure cutting and healing of the track simultaneously. *Tridosahara*, *raktapittahara*, *vranaropana* action of asphota along with mechanical cutting action of the

thread along with the properties of *haridra* and *snuhi* works in the disease.

The caustic property of *kshara* helps in the destruction of the unhealthy tissue and provide a healthy granulation tissue and promotes healing. *ksharasutra* helps in cutting and draining the track with simultaneously helping to attain the healing of the track. *Raktapittahara* and *tridosha hara* and *vrana ropana* property fasten the wound healing. *Asphota* when made into *kshara* form which is having more potency, and when applied as *ksharasutra* has an added effect in managing fistula-in-ano. The post-operative care with sitz bath and daily dressing, *pathya karma* followed after

and during treatment might have helped in preventing the recurrence.

The caustic property of the *asphota kshara* will cause the disintegration of unhealthy granulation by the protein denaturation process. The curcumin content in the *haridra* act as a catalyst to activate the denaturation process. Along with antimicrobial action *haridra* and alkaloids present in the *snuhi* helps in the cutting, draining and healing of the fistulous tract.

DISCUSSION

Pain

The pain was the common complaint in all the subjects before treatment. During the treatment period pain gradually decreased, after treatment and in follow up time pain was completely absent in all subjects. The data was statistically analysed using the Friedman test. The P-value was found to be <0.001 which rejects the null hypothesis. And pairwise comparison was done using Wilcoxon signed-rank test and observed a significant difference between before treatment and after treatment, before treatment and follow up. There was no significant difference between after treatment and follow up. It means that the intervention helped to reduce pain, and there is no recurrence of pain in follow up period. This result may be due to *vatahara* property of the drug, *vata* is the main *dosha* that causes pain. *Vatahara* action of the drug is because the *Madhura vipaka* and *asphota Kshara* will have similar properties and help in reducing pain. When *Asphota* is converted to *kshara* from *tridoshaghana* and *ropana* property of *kshara* will combine with the *vranaropana* and *vranasodhana* property of *haridra* and *snuhi* respectively and help in reducing pain.

Burning Sensation

The burning sensation was a common symptom present in all subjects at different levels. During treatment burning sensation gradually decreased and became absent after treatment and follow up. The data were analysed using the Friedman test. The P-value was found to be <0.001 which rejects the null hypothesis. Pairwise comparison was done using Wilcoxon signed-rank test. The result shows that there exists a significant difference between before treatment, after

treatment and before treatment and follow up. And there is no significant between after treatment and follow up. It means that the study intervention helps reduce burning sensation and there is no recurrence of burning sensation in follow up period. This result may be due to *pitta samaka* action of the drug due to *sheetha virya* of the drug, so while converting it into *kshara Soumya guna* of *kshara* and along with the *sheetha virya* of *Asphota* and *pitta samaka* action of *haridra* might have helped to reduce the burning sensation.

Inflammation

Inflammation was present in all the subjects at different grades. During treatment inflammation gradually decreased and became absent after treatment and follow up. The data were analysed using the Friedman test. The P-value was found to be <0.001 which rejects the null hypothesis. Pairwise comparison was done using Wilcoxon signed-rank test. The result shows that there exists a significant difference between before treatment, after treatment and before treatment and follow up. And there is no significant between after treatment and follow up. It means that the study intervention helps reduce inflammation and there is no recurrence of inflammation in follow up period. This result may be due to *pittashamaka* action of the *Asphota* which is due to *madhura rasa*, *madhuravipaka* and *sheetha virya*. These properties might be maintained while converting it into *kshara*. Along with *shodhahara* property of *haridra* helped in the reduction of inflammation in *ksharasutra* form.

Discharge

Before treatment discharge was present in all subjects in variable grades. During treatment discharge gradually decreased and became absent after treatment and follow up. The data were analysed using the Friedman test. The P-value was found to be <0.001 which rejects the null hypothesis. Pairwise comparison was done using Wilcoxon signed-rank test. The result shows that there exists a significant difference between before treatment, after treatment and before treatment and follow up. And there is no significant between after treatment and follow up. It means that intervention helped reduce discharge and there was no recurrence of

discharge in follow up period. This result is probably due to *kaphahara* property of the drug due to *tikta rasa* while converting it to *kshara* the *stambaka* property of *kshara* along with *kaphahara* property of *Asphota* and *haridra* might be the probable mode of action to reduce the discharge.

Itching

Before treatment itching was absent in 43% of subjects and was present in the rest of the subjects at variable grades. During treatment itching gradually decreased and became absent after treatment and follow up. The data were analysed using the Friedman test. The P-value was found to be <0.001 which rejects the null hypothesis. Pairwise comparison was done using Wilcoxon signed-rank test. The result shows that there exists a significant difference between before treatment, after treatment and before treatment and follow up. And there is no significant between after treatment and follow up. It means that the intervention helps reduce itching and there is no recurrence of itching in follow up period. This result may be due to *kaphahara* property of *Asphota* due to its *tikta rasa* and also due to *kusthaghna* and *kandughna* property along with *rakta-shodhana*, *vishahara* action of *haridra* *vishaghna* property of *snuhi* might have helped in reducing itching.

Unit cutting time

Average unit cutting was evaluated, and the analysis shows that the average unit cutting time was 7.37 days/cm. The unit cutting time of standard *kshara sutra* is 7 days/cm¹⁰⁴.so, while analysing the unit cutting time it is assumed here that *asphota ksharasutra* is not superior to the standard *ksharasutra*.

CONCLUSION

In this study, the trial *ksharasutra* proved its efficacy in the cut-through of the low anal fistulous tract with a unit cutting time (UCT) of 7.37 days/cm. it is also found to have a significant effect in reducing the clinical symptoms of fistula -in-ano like, pain, inflammation, burning sensation and itching as assessed in the study. It was found to be free from any sort of side effects or adverse reactions during the clinical trial. Thus, the present clinical study proves that *Asphota*

ksharasutra can be used as a safe effective alternative *Ksharasutra* in treating low anal fistula.

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