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A randomized open labelled controlled clinical study to evaluate the role of *Krutamalakadya Sutra* in the management of *Bhagandara* with special reference to *Fistula-In-Ano*

Naveen Kumar J¹, Muralidhara N², KM Sweta³

¹Post Graduate Scholar, Department of Shalya Tantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.

²Professor, Department of Shalya Tantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.

³Professor & HOD, Department of Shalya Tantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.

ABSTRACT

Acharya Sushruta has included *Bhagandara* as one among the *Ashtamahagadas*. *Fistula in ano* is an ano-rectal condition with a worldwide prevalence of 8.6 cases per 100,000 population. *Ksharasutra* ligation is one of the popular modalities in treatment of *Bhagandara*. In present era, there are different types of *Ksharasutra* available. Most widely used *Ksharasutra* is *Apamarga Ksharasutra* which is having *Chedana*, *Bhedana*, *Lekhana* properties and anti-inflammatory effect on the fistula tract. But some of the problems are faced during preparation and also in the course of *Ksharasutra* therapy viz, collection and preservation of *Snuhi* (*Euphorbia nerifolia*) latex is very difficult and time taking process. The main complaints reported by the patients are pain and discomfort during the course of treatment with *Ksharasutra* for *Bhagandara*, which requires management with oral analgesics. Considering the above problems, a non irritant preparation such as *Krutamalakadya Varti* mentioned in *Sushruta Samhita* in the chapter of *Bhagandara Chikitsa Adhyaya* is modified in the form of *Krutamalakadya Sutra* which contains following ingredients such as *Aragvadha*, *Haridra*, *Ahimsra*, *Madhu* and *Ghrita* is taken for the study. *Krutamalakadya Sutra* is also having a good binding property, as well as *Chedana*, *Bhedana*, *Lekhana*, *Vedanasthapana*, *Vrana Shodhana* and *Vrana Ropana* properties. A total of 30 subjects were taken, Trial group treated with *Krutamalakadya Sutra* and control group treated with *Apamarga Ksharasutra*. The study shows that preparation of *Krutamalakadya Sutra* is much easier than *Apamarga Ksharasutra* and had high efficacy in subjective parameters like burning sensation compared to *Apamarga Ksharasutra*.

Key words: *Krutamalakadya Sutra*; *Apamarga Ksharasutra*; *Bhagandara*; *Fistula in ano*.

INTRODUCTION

Acharya Sushruta counted *Bhagandara* among the *Ashtamahagadas*,^[1] which are difficult to cure. *Acharya Sushruta* has described different therapeutic measures for the management of *Bhagandara* as in

terms of various oral medications, local applications, surgical procedures and para - surgical intervention. Presently *Ksharasutra* therapy is found most approaching and attractive treatment modality among para-surgical procedures for fistula in ano. It is a standard treatment modality found in surgical practice for the management of fistula in ano. Most widely used is *Apamarga Ksharasutra* which is having *Chedana*, *Bhedana*, *Lekhana* properties and anti-inflammatory effect on fistula tract.^[2] But some of the problems are faced during preparation and also in the course of *Ksharasutra* therapy viz, collection and preservation of *Snuhi* (*Euphorbia nerifolia*) latex is very difficult and time taking process. *Kshara* does not permit to prepare in humid climate. The main complaints reported by the patients are pain and discomfort during the course of treatment with *Ksharasutra* for *Bhagandara*, which requires management with oral analgesics.

Address for correspondence:

Dr. Naveen Kumar J

Post Graduate Scholar, Department of Shalya Tantra, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru, Karnataka, India.

E-mail: drnaveennlc@yahoo.in

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Considering the above problems, a non irritant preparation such as *Krutamakadya Varti* mentioned in *Sushruta Samhita* in the chapter of *Bhagandara Chikitsa Adhyaya* is modified in the form of *Krutamakadya Sutra* which contains following ingredients such as *Aragvadha*, *Haridra*, *Ahimsra*, *Madhu* and *Ghrita* is taken for the study.^[3]

Krutamakadya Sutra is also having a good binding property, as well as *Chedana*, *Bhedana*, *Lekhana*, *Vedanasthapana*, *Vrana Shodhana* and *Vrana Ropana* properties.^[4]

AIM

To evaluate the role of *Krutamakadya Sutra* in the management of *Bhagandara* w.s.r. to *Fistula in ano*.

OBJECTIVES OF THE STUDY

1. To evaluate the role of *Krutamakadya Sutra* in the management of *fistula-in-ano*.
2. To re-evaluate the role of *Apamarga Ksharasutra* in the management of *fistula-in-ano*.
3. To compare the role of *Krutamakadya Sutra* with *Apamarga Ksharasutra* in the management of *fistula-in-ano*.

MATERIALS AND METHODS

The study design was open label, randomized controlled clinical study, in this study 30 patients who fulfilled the inclusion criteria were selected from OPD, IPD department of *Shalya Tantra*. They were divided into two groups Group A (N=15) and Group B (N=15). Group A being the control group and Group B being the trial group. IEC approval was taken before starting the Trial, informed written consent of all patients was taken before the operative procedure. Duration of treatment was 4 weeks.

Preparation of *Krutamakadya Sutra*

Materials Required

1. *Aragvadha (Phala Majja)* (fig. 1)
2. *Ahimsra* (Root) (fig. 2)
3. *Haridra* (Rhizome) (fig. 3)

4. *Madhu* (fig. 4)
5. Thread (*Barbour's linen no .20*) (fig. 5)
6. *Ghrita* (fig. 6)
7. *Ksharasutra* cabinet

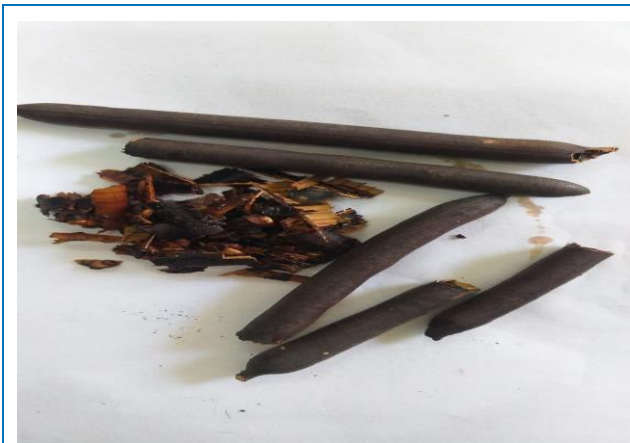


Figure 1: *Aragvadha (Phala Majja)*



Figure 2: *Ahimsra (Root)*



Figure 3: *Haridra Choorna*



Figure 4: Madhu



Figure 5: Barbour's linen no. 20



Figure 6: Ghrita



Figure 7: Paste of drugs



Figure 8: Thread coating with medicated paste



Figure 9: Krutamalakadya Sutra

Preparation

1. *Krutamalakadya Sutra* were prepared by using Barbour's thread number 20.
2. Linen thread were tied throughout the length of the hanger, which were then mounted over hanger stand. Each thread on the hanger were uniformly smeared with mixture of *Aragvadha Phala Majja*, *Ahimsra* root powder, *Haridra* powder, *Madhu* and *Ghrita* which was taken in equal quantity. The hanger were replaced into to the cabinet. The cabinet was closed properly and the hot air was blown in order to dry the threads. Same process were repeated till it attain standard diameter of 1.9mm of *Apamarga Ksharasutra*.
3. *Krutamalakadya Sutra* was sterilized by ultraviolet radiation by placing them in *Ksharasutra* cabinet for 20-30 minute at 40 OC.
4. Sterilized *Krutamalakadya Sutra* measuring approximately 10 inches was cut away at two ends and packed in sterilized glass tubes by aseptic precaution. (fig no-9)

5. It took 5 days to achieve a thickness of 1.9 millimeters and complete the preparation

Poovakarma

1. Well informed written consent was taken prior to the procedure.
2. Xylocaine Sensitivity test (SC) and Tetanus Toxoid (IM) given prior to procedure.
3. Perianal Part Preparation was done.
4. Laxatives (*Triphala Churna*) were given prior to procedure

Pradhana Karma

Group A:

Application of *Apamarga Ksharasutra* Patient was taken into lithotomy position and cleaning and draping was done. The appropriate anesthesia was used. The patient was assured and gloved finger was gently introduced into the rectum. Then a suitable probe was passed through the external opening of fistula. The tip of the probe was forwarded along the path of least resistance being guided by the finger in rectum to reach into the lumen of anal canal through the internal opening and its tip was finally directed to come out of anal orifice. Primary thread was taken and threaded into the eye of probe, thereafter the probe was pulled out through the anal orifice to leave the thread behind in the fistulous track. The two ends of the thread were then tied together with a moderate tightness outside the anal canal.

Group B:

Application of *Krutamakadya Sutra* Patient was taken into lithotomy position and cleaning and draping done. The appropriate anesthesia was used. The patient was assured and gloved finger was gently introduced into the rectum. Then a suitable probe was passed through the external opening of fistula. The tip of the probe was forwarded along the path of least resistance being guided by the finger in rectum to reach into the lumen of anal canal through the internal opening and its tip was finally directed to come out of anal orifice. Primary thread was taken and threaded into the eye of probe, thereafter the probe was pulled out through the anal

orifice to leave the thread behind in the fistulous track. The two ends of the thread were then tied together with a moderate tightness outside the anal canal.

Paschat Karma

After Application of *Ksharasutra*

1. Tab. *Triphala Guggulu* 2 bid before food for 4 weeks
2. Tab. *Gandhaka Rasayana* 2 bid after food for 4 weeks
3. Patient were asked to do sitz bath with *Panchavalkala Kashaya* twice daily from post op day 1.
4. Regular dressing was done.

Thread change

In both the groups *Ksharasutra* was changed once in a week. i.e., on 7th day, 14th day, 21st day and 28th day.

Diagnostic Criteria

Subjects with classical features of *Bhagandara* (Fistula-in-ano) were selected for study such as *Pidaka* associated with *Ruk*, *Kandu*, *Daha*, *Srava* and *Shophra* around perianal region.

Inclusion Criteria

1. Subjects within the age of 21-60 years.
2. Subjects irrespective of gender, religion, occupation, economic status and education status.
3. Subjects with well controlled Diabetes Mellitus and hypertension.

Exclusion Criteria

1. Fistula-in-ano caused secondary to or associated with diseases like- Tuberculosis, Crohn's disease, Ulcerative colitis, Osteomyelitis, Venereal diseases, HIV, Appendicitis, Regional Ileitis and Intestinal & Pelvic Malignancies.
2. Fistula-in-ano associated with other anorectal disorders such as Carcinoma rectum and anal canal, 3rd degree Hemorrhoids or bleeding hemorrhoids, acute fissure in ano, thrombosed sentinel pile.

Assessment Criteria**(A) Subjective Parameter**

1. Assessment of pain
2. Assessment of burning sensation

(B) Objective Parameter

1. UCT - Unit Cutting Time calculation.
2. Assessment of discharge
3. Length of the tract
4. Local Tenderness

Grading of the Parameters

1. Visual Analogue Scale (VAS) for Pain Assessment.^[5]
2. Burning Sensation.^[6]
 - Grade 0 - No burning sensation
 - Grade 1 - Mild burning sensation
 - Grade 2 - Moderate burning sensation
 - Grade 3 - Severe burning sensation.
3. UCT- Unit Cutting Time.^[7]

UCT =

$$\frac{\text{Initial length of the tract} - \text{length of the tract remaining}}{\text{Number of weeks treated}}$$

4. Discharge.^[8]
 - Grade 0: No discharge
 - Grade 1: Mild discharge
 - Grade 2: Moderate discharge
 - Grade 3: Profuse discharge
5. Length of the tract ^[9]
 - Grade 0: No tract
 - Grade 1: Up to 1 cm
 - Grade 2: 1.1cm - 2cm
 - Grade 3: 2.1cm - 3cm
 - Grade 4: 3.1cm - 4cm
 - Grade 5: 4.1cm - 5cm
 - Grade 6: More than 5cm

6. Local Tenderness^[9]

- Grade 0 - No Tenderness
- Grade 1 - Tenderness to palpation, without grimace or flinch
- Grade 2 - Tenderness with grimace and/ or flinch to palpation
- Grade 3 - Tenderness with withdrawal “jump sign”
- Grade 4 - Withdrawal “jump sign” to non-noxious stimuli (i.e., superficial palpation, pin prick, gentle percussion).

OBSERVATIONS**Observation during preparation and intervention****Group A - Apamarga Ksharsutra**

1. Collection and preservation of *Snuhi Ksheera* and *Apamarga* is a laborious and hazardous process.
2. *Apamarga Panchanga* burnt quickly and easily as it was completely dried. Comparatively, seeds took more time to burn.
3. The resulting ash from burning the *Panchanga* was whitish in color and possessed a characteristic taste
4. After proper filtration, boiling, and drying, a whitish *Kshara* substance was obtained.
5. *Sutra* was evenly coated with a mixture of *Snuhi Ksheera*, *Apamarga Kshara*, and *Haridra*.
6. The preparation of *Ksharasutra* is a meticulous process. It took 21 days to complete 21 coatings.
7. During the procedure of thread change subjects experienced more pain and discomfort.

Group B - Krutamalakadya Sutra

1. The accessibility of *Aragvada* fruit simplifies the sourcing process for its usage in the preparation of *Sutra*.
2. *Phala Majja* readily dissolves in water.
3. During the dissolution process, a pleasant and sweet aroma is released, enhancing the sensory experience.

- The severe allergic conjunctival reactions were noted during the process of boiling the mixture to evaporate water, thus effective safety measures were taken.
- A paste was prepared by combining *Aragvada Phala Majja*, *Ahimsra* root powder, *Haridra*, *Madhu* and *Ghrita*. The binding nature of the ingredients allows for the even spreading of the paste on the thread.
- The *Sutra*, when treated with the aforementioned drug, undergoes rapid drying, resulting in a quick attainment of approximately 1.9mm thickness within a short period of 5 days.
- During the procedure of thread change subjects experienced less pain and discomfort.

Table 1: Assessment of pain by Friedman’s test and Mann whitney rank sum test

Group	Pain assessment at different points of time (Data: Median, 25th & 75th Percentile)				
	0 Day	7 th day	14 th day	21 th day	28 th day
Group -A Control	3.00(3.0 0-3.00)	3.00(3.0 0-3.00)	2.00(2.0 0-2.00)@	2.00(1.0 0-2.00)@	1.00 (1.00-1.00) @
Group -B Trial	3.00(3.0 0-3.00)	2.00(2.0 0-3.00)*	2.00(1.0 0-2.00)@	1.00(1.0 0-2.00)@*	1.00 (1.00-1.00) @

@P<0.05 in comparison to D0 value (Friedman’s test)
 *P=0.012 In Comparison to Group A values (Mann whitney rank sum test)
 **P=0.033 In Comparison to Group A values (Mann whitney rank sum test)

Table 2: Assessment of Burning sensation by Friedman’s test and Mann whitney rank sum test

Group	Burning sensation assessment at different points of time (Data: Median, 25th & 75th Percentile)				
	0 Day	7 th day	14 th day	21 th day	28 th day
Group -A	3.00(3.0 0-3.00)	3.00(2.0 0-3.00)	2.00(2.0 0-2.00)@	2.00(1.0 0-2.00)@	1.00

Control					(1.00-2.00) @
Group -B Trial	3.00(3.0 0-3.00)	2.00(2.0 0-3.00)**	2.00(1.0 0-2.00)@	1.00(1.0 0-1.00)@*	1.00 (0.00-1.00) @

@P<0.05 in comparison to D0 values (Friedman’s test)
 *P=0.001 In Comparison to Group A values (Mann whitney rank sum test)
 **P=0.03 In Comparison to Group A values (Mann whitney rank sum test)

Table 3: Assessment of Discharge by Friedman’s test and Mann whitney rank sum test

Day of assessment	0 Day	7 th day	14 th day	21 th day	28 th day
Group-A Control	3.00(3.0 0-3.00)	3.00(3.0 0-3.00)	2.00(2.0 0-2.00)@	2.00(1.0 0-1.00)@	1.00 (1.00-1.00) @
Group-B Trial	3.00(3.0 0-3.00)	2.00(2.0 0-2.00)*	1.00(1.0 0-2.00)@**	1.00(1.0 0-1.00)@*	1.00 (0.00-1.00) @

@P<0.05 in comparison to D0 value(Fried man’s test)
 *P=0.001 in comparison to Group A value (Mann whitney rank sum test)
 **P=0.024 in comparison to Group A value (Mann whitney rank sum test)

Table 4: Assessment of length of the tract by Friedman’s test and Mann whitney rank sum test

Group	Length of the tract assessment at different points of time (Data: Median, 25th & 75th Percentile)				
	0 Day	7 th day	14 th day	21 th day	28 th day
Group -A Control	4.00(3.0 0-4.00)	4.00(3.0 0-4.00)	3.00(2.0 0-4.00)	2.00(2.0 0-3.00)@	1.00 (1.00-1.00) @
Group -B Trial	5.00(4.0 0-6.00)	4.00(3.0 0-5.00)	3.00(3.0 0-4.00)	2.00(2.0 0-3.00)@	1.00 (1.00-2.00) @

@P<0.05 in comparison to D0 value((Friedman’s test)

Table 5: Assessment of local tenderness by Friedman’s test and Mann whitney rank sum test

Group	Local tenderness assessment at different points of time (Data: Median, 25 th & 75 th Percentile)				
	0 Day	7 th day	14 th day	21 th day	28 th day
Group-A Control	4.00(4.00-4.00)	4.00(3.00-4.00)	3.00(2.00-3.00)@	2.00(2.00-2.00)@	2.00(1.00-2.00)@
Group-B Trial	4.00(4.00-4.00)	3.00(3.00-3.00)	2.00(2.00-3.00)@*	2.00(1.00-2.00)@*	1.00(1.00-1.00)@***

@P<0.05 in comparison to D0 valve((Friedman’s test)

*p=0.028 in comparison to Group A valve (Mann whitney rank sum test)

**p=0.019 in comparison to Group A valve (Mann whitney rank sum test)

***p=0.002 in comparison to Group A valve (Mann whitney rank sum test)

RESULTS

The comprehensive analysis of all the results reveals that both the intervention produced significant results but Group-B delivered better out come over Group-A (Table 6)

Table 6: Summary of statistical results

Parameter	Within the Group		Between the Groups
	Group-A	Group-B	
Pain	Significant	Significant	Group B had significant reduction over Group A
Burning sensation	Significant	Significant	Group B had significant reduction over Group A
Discharge	Significant	Significant	Group B had significant reduction over Group A
UCT	No-Significant	No-Significant	No significant difference between the groups

Length of the tract	No-Significant	No-Significant	No significant difference between the groups
Local tenderness	Significant	Significant	Group B had significant reduction over Group A

Trial group



Day 0



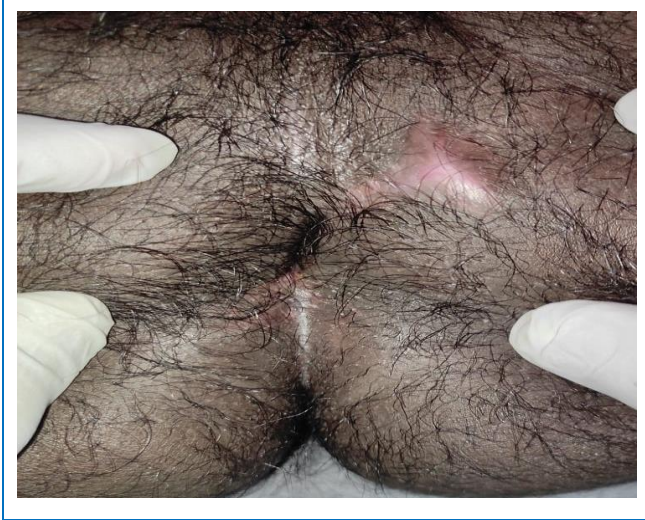
Day 7



Day 14



Day 21



Day 28

Control group



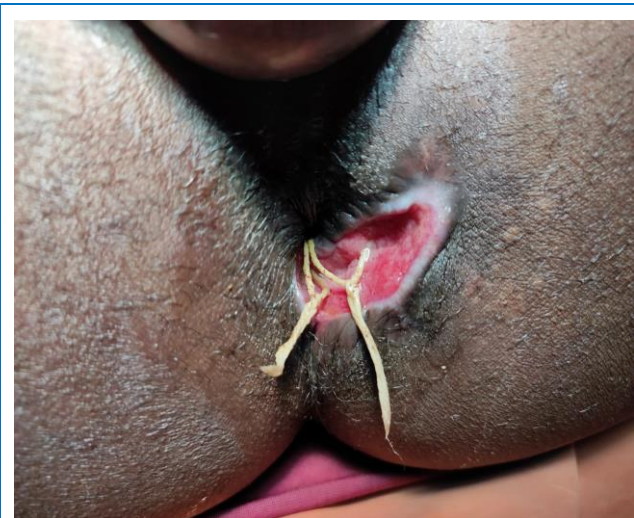
Day 0



Day 7



Day 14



Day 21



Day 28

Analytical results of Krutamalakadya Sutra

Physio-chemical analysis was done at Ramaiha Advanced Laboratory, Bengaluru and Microbiological studies were done at Krishna Diagnostic Laboratory, Sagara. Which showed following results:

SN	Parameter	Results	Test Method
1.	Ph (10% solution)	10.1	Physio-chemical method
2.	Thickness (mm)	1.9	
3.	Length (cm)	10	
4.	Tensile strength (kg)	5.8	

Microbiology

Test	Report
Culture and sensitivity	Sample has showed no microbial growth after 48 hours of incubation

Limitations

1. The entire procedure of preparation of *Krutamalakadi Sutra* caused severe irritation to the conjunctiva.
2. Regulation of the temperature required for *Paaka* depending on the source of drug is still to be standardised as boiling even for a longer duration leads to *Khara Paaka* in some sources of same drug.
3. The study duration was of short period, sample size was limited to 30 subjects in this study.

DISCUSSION

In the present clinical study 15 cases were treated with *Apamarga Ksharasutra* and 15 cases were treated with *Krutamalakadya Sutra*. The observations were made on different parameters like pain, Burning sensation, Unit Cutting Time, Length of tract, Discharge and Local tenderness

Pain

In Group-A Significant decrease in pain was observed on D14, D21 and D28. whereas, in Group-B Significant decrease in pain was observed on D7, D14, D21 and D28. Thus statistically, the scores for pain obtained in Group-B ($P=0.001$) is much better than Group-A ($P=0.005$)

The effect size difference of pain between Group A and Group B was small band on the 28th day. This suggests that Group B experienced a better clinical benefit from pain than Group A. When mean score percentage was calculated, it found that Group-A had 66.66% and Group-B had 64.43% reduction of pain. However, Group-B showed Significant decrease in pain during course of treatment.

The reduced pain experienced during the treatment is attributed to the *Vedanasthapana* and *Vranasodhana*

properties of *Aragvadha*,^[17] *Ahimsra*^[18] and *Haridra*.^[19] These drugs contain beneficial compounds such as Anthraquinones, alkaloids, flavonoids, saponins, tannins, polyphenols, and curcumin. The combined effects of these medicinal properties alleviate pain and promote the healing process. which is achieved through the drug action in *Krutamakadya Sutra*.

Burning sensation

In Group-A Significant decrease in burning sensation was observed on D14, D21 and D28. whereas, in Group-B Significant decrease in burning sensation was observed on D7, D14, D21 and D28. Thus statistically, the scores for burning sensation obtained in Group-B (P=0.001) is much better than Group-A (P=0.05).

The difference in burning sensation relief between and within the two group was also evident in effect size analysis, which showed that Group-B experienced a marked reduction in burning sensation during the course of treatment. The mean score percentage analysis revealed that Group-B experienced 66.66% greater burning sensation relief than Group-A 54.55%.

As *Ahimsra* which possesses the *Tiktha Rasa*, along with *Kruthamala*, *Madhu*,^[20] and *Ghritha*,^[21] which have *Sheeta Veerya*, which contribute to the alleviation of burning sensation during the treatment. Due to presence flavonoids and polyphenols in *Madhu* and *Kruthamalaka*, which exhibit anti-inflammatory properties and helps in reducing the burning sensation. Moisturization and cooling effect of *Madhu*, and *Ghritha*, attributes to relieve burning sensation.

Discharge

In Group-A Significant decrease in discharge was observed on D14, D21 and D28. Whereas, in Group-B Significant decrease in discharge was observed on D7, D14, D21 and D28. Thus statistically, the scores for discharge obtained in Group-B (P=0.024) is much better than Group-A (P=0.05).

The effect size analysis revealed a significant decrease in discharge between and within two groups, it suggests that Group-B experienced a better clinical benefit from decrease in discharge over the course of treatment. According to mean score percentage

analysis Group-B had 75.55% decrease in discharge more effective than Group-A 66.66%.

Krutamakadya Sutra possesses *Vrana Shodhana*, and *Vrana Ropana* properties. This can show beyond doubt by anti-inflammatory and antimicrobial properties of drug i.e., *Kruthamala*, *Ahimsra* and *Haridra* which helps to decrease the microbial load, there by promoting and sloughing and fasting the healing process.

Unit Cutting Time

In this study, the average Unit Cutting Time (UCT) was utilized as a standardized measure to evaluate the efficacy of *Krutamakadya Sutra* and *Apamarga Ksharasutra* in cutting and healing of fistulous tracks.

The average UCT recorded for *Krutamakadya Sutra* was 0.8cm/7 days, while for *Apamarga Ksharasutra* it was 0.7cm/7 days.

Statistical analysis revealed that there was no significant difference observed in UCT between the groups. Furthermore, within each group, no significant differences in UCT were found.

These findings indicate that both *Krutamakadya Sutra* and *Apamarga Ksharasutra* exhibited equal efficacy in terms of the rate of healing of the fistulous tracks, as evidenced by the similar UCT values obtained.

Therefore, based on the UCT assessment, it can be concluded that there was no significant difference in the healing effectiveness between the two treatment groups, suggesting that both *Krutamakadya Sutra* and *Apamarga Ksharasutra* are viable therapeutic options for the management of fistulous tracks . But there is mild clinical difference seen.

Length of the tract

In Group-A Significant decrease in length of the tract was observed on D14, D21 and D28. Whereas in Group-B Significant decrease in length of the tract was observed on D7, D14, D21 and D28.

These findings highlight the effectiveness of both treatment modalities in reducing the length of fistulous tracts. However, Group-B demonstrated a more pronounced and consistent response, with significant decreases observed at all time points.

The effect size difference of length of the tract between Group A and Group B was not much significant.

When mean score percentage was calculated. It is found that Group-A had 72.40% and Group-B had 70.00% decrease in length.

Kshara Sutra works by pressure necrosis, chemical cauterization by *Kshara* and sloughing of the fistula track tissue along with adequate drainage. It leads to an easy debridement of unhealthy tissue and pus and thus providing a cleaner base for the wound healing of the fistulous track.

Local tenderness

In Group-A Significant decrease in local tenderness was observed on D14, and D21. Whereas in Group-B Significant decrease in pain was observed on D7, D14, D21 and D28. Thus, statistically the scores for local tenderness obtained in Group-B is much better than Group-A.

The effect size difference of local tenderness between groups and within groups is large band. This suggests that Group-B experienced a better clinical benefit from local tenderness than Group-A. When mean score percentage is calculated. It is found Group-B had 74.14% reduction of local tenderness than Group-A 59.31%.

The properties of *Aragvadha*, *Ahimsra*, and *Haridra* are attributed to their *Vedanasthapana* and *Vranasodhana* effects. These drugs possess antioxidant, antimicrobial, and anti-inflammatory properties due to the presence of alkaloids, Anthraquinones, flavonoids, saponins, tannins, polyphenols, and curcumin. These beneficial effects help to reduce inflammation and local tenderness during treatment. Overall, the drugs' action in *Krutamalakadya Sutra* contributes to the reduction of local tenderness.

CONCLUSION

Krutamalakadya Sutra demonstrated significant efficacy in relieving symptoms associated with fistula-in-ano, including pain, burning sensation, discharge, and local tenderness. Moreover, it achieved these

outcomes in a shorter duration of time. Evaluation of subjective and objective parameters indicated that *Krutamalakadya Sutra* exhibited superior clinical relief compared to *Apamarga Ksharasutra* in most aspects. *Krutamalakadya Sutra* was cost-effective treatment options, as they could be easily prepared and applied as compared to *Apamarga Ksharasutra*. The statistical analysis supported to rejected null hypothesis and accepted alternative hypothesis, indicating that *Krutamalakadya Sutra* is having more efficacy than *Apamarga Ksharasutra* in the management of *Bhagandara* with special reference to *Fistula-in-ano*.

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