

**ARTICLE ON “A STUDY TO EVALUATE THE EFFICACY OF KARANJA
KSHARASUTRA, CHINCHA KSHARASUTRA AND APAMARGAKSHARASUTRA IN
THE MANAGEMENT OF BHAGANDARA W.S.R TO FISTULA-IN-ANO”****Anjaneya^{1*}, Shivalingappa J. Arakeri², Mohasin Kadegaon³ and Ashwini Hallad⁴**¹PG Scholar, Department of Shalya Tantra, Taranath Government Ayurvedic Medical College, Ballari (Karnataka, India).²Professor & HOD, Department of Shalya Tantra, Taranath Government Ayurvedic Medical College, Ballari (Karnataka, India).^{3,4}Assistant Professor Department of Shalya Tantra, Taranath Government Ayurvedic Medical College, Ballari (Karnataka, India).***Corresponding Author: Dr. Anjaneya**

PG Scholar, Department of Shalya Tantra, Taranath Government Ayurvedic Medical College, Ballari (Karnataka, India).

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ABSTRACT

Fistula in ano is an infective disease of anal canal usually caused by crypto glandular infection of anal crypts, there is an abnormal communication between two epithelial surfaces and the track is lined by unhealthy granulation tissue. It can be correlated with Bhagandara described in Ayurveda texts. Which is considered as Kricchrasadhy Vyadhi (difficult to treat). The disease Bhagandara is explained in the Ayurvedic classics. It is one of the most common diseases pertaining to Ano-rectal region. Incidence of Fistula in India is 17-20% in a defined population of some states. It is the recurrence nature of Fistula which makes difficult for treatment. *Ksharasutra* is a proven para-surgical procedure for the management of Fistula-in-ano. 45 patients of *Bhagandara* of either sex will be selected from OPD and IPD, Department of Shalya Tantra, Taranath Govt. Ayurvedic Medical College and Hospital, Bellary, divided into Group A, Group B and Group C. Patients under Group A were treated with *Karanja Ksharasutra*, Group B with *Chincha Ksharasutra* and Group C with *Apamarga Ksharasutra* and got significant results.

KEYWORDS: *Bhagandara, Ksharasutra, Fistula-in-ano.***1. INTRODUCTION**

The disease Bhagandara is explained in the Ayurvedic classics. Acharya Sushruta has included Bhagandara as one among the Ashtamahagadas.^[1] It is one of the most common diseases pertaining to ano-rectal region. The earliest reference of Bhagandara is seen in Agnipurana.^[2] Detailed description about the Nidana, Samprapti, Laxana and Chikitsa is available in Sushruta Samhitha^[3] (1500 B.C) and Ashtanga Hridaya among Brihatrayees while, Charaka^[4] (1000 B.C.) has mentioned in Shothachikitsa adhyaya and advocated Ksharasutra and other remedies in the management of Bhagandara.

The literal meaning of Bhagandara is daarana which is splitting up/bursting up of pakwapidaka in the bhaga, guda and bastipradesha results in the formation of a communicating track, thus causing discomfort to the patient.^[5]

Prevalence rate of fistula-in-ano is 8.6 cases per 100,000 populations. The mean age of patients is 38.3 years. The

prevalence in men is 12.3 cases & in women is 5.6 cases per 1,00,000 population. Male:female ratio is 1.8:1.^[6]

Operative procedures adopted are Fistulectomy, Fistulotomy and use of a seton newer methods like fibrin plug, Endo anal flap etc. Because of the lack of satisfactory results newer techniques have constantly been adopted for its management. Ayurvedic line of treatment for Bhagandara includes medical, para-surgical and surgical management. Parasurgical management includes Kshara karma, Agni karma and Varti. The Ksharasutra treatment was in fact first mentioned in the Nadivrana Adhikara^[2] and the same treatment was said to be followed in Bhagandara. The preparation of this was mentioned much later by Chakrapanidatta.^[7] The standard Ksharasutra as we see today was the result of the extensive research of Dr. P. J. Deshpande and his team, who finally standardized its preparation,^[8] preservation and application.

Mode of action^[9] of *Ksharasutra* can be understood as- Various drugs (*ksheera, kshara, Haridra*) present in

ksharasutra along with mechanical pressure of tying cause gradual, continuous drainage and cutting as well as healing of fistulous tract." The ICMR has validated this and the Ksharasutra therapy is also under active consideration of the WHO for its globalization. This type of therapy is considered as a minimal invasive parasurgical measure at global level.^[10] There is a reference of ksharasutra for the management of of fistula-in-ano in Modern Surgical books^[11] shows its wide acceptance and importance.

Sushruta has enlisted 24 drugs for source of *kshara*.^[12] *Apamargaksharasutra* is standardized and effectively used, it is a seasonal plant. Pain and burning sensation during treatment are very often complained by the patient. *Karanjahave Kapha Vatahara, Shothahara, Bhedana, and Krimihara* properties.^[13] *Chincha*^[14,15] is *KaphaVatahara, Deepana* and one among *Ashtaksharas*. *Karanja* and *Chincha* both the drugs are available throughout the year. Hence *Karanja* and *Chincha* are selected for this study in comparison to *Apamarga Ksharasutra*.

Apamargaksharasutra	Karanja ksharasutra	Chinchaksharasutra
<i>Snuhiksheera</i>	<i>Snuhiksheera</i>	<i>Snuhiksheera</i>
<i>Apamargakshara</i>	<i>Karanja kshara</i>	<i>Chinchakshara</i>
<i>Haridra churna</i>	<i>Haridrachurna</i>	<i>Haridrachurna</i>

Materials

- Surgical Linen thread No.20
- *Ksharsutra* cabinet

Drugs were identified, collected as per classical techniques authenticated and certified by Department of *DravyaGuna*, TGAMC&H Ballari. Preparation of *Kshara* and *ksharasutra* were carried out in the post graduate Department of Shalya Tantra of TGAMC& H Ballari

Sampling technique

Total 45 Patients presenting with the clinical features of Fistula-in-ano were selected randomly, i.e, Group A, Group B and Group C.

Method of preparation

- **Preparation of apamargakshara**
 - Collected *Apamarga (Panchanga)* were cut into small Pieces and Dried under shade.
 - Once they are completely dried the pieces were burnt Uniformly and Completely until it becomes ash.
 - This ash were stored in a clean container after cooling, 6 parts of water was added to ash, stirred well and kept undisturbed overnight.
 - Next day it was filtered through double layered muslin cloth for 21 times and lastly through whatmans filter paper and collected clear filtrate was boiled over mild heat till it attains powdery form.
 - The final product, a clear white powder collected and stored in an airtight container.

OBJECTIVES

- To know the Efficacy of *Karanjaksharasutra* in the management *Bhagandara* (Fistula-in-ano).
- To know the Efficacy of *Chinchaksharasutra* in the management of *Bhagandara* (Fistula-in-ano).
- To know the Efficacy of *Apamargaksharasutra* in the management of *Bhagandara* (Fistula-in-ano).
- To compare the efficacy of *Karanjaksharasutra* and *Chinchaksharasutra* with standard *Apamargaksharasutra* in the management of *Bhagandara* (Fistula-in-ano).

2. MATERIALS AND METHODS

Source of data

45 patients of *Bhagandara* of either sex were selected from OPD and IPD, Department of Shalya Tantra, Taranath Govt. Ayurvedic Medical College and Hospital, Bellary.

Drug source

Drugs used for preparation of *KaranjaKsharasutra*, *Chinchaksharasutra* and *Apamargaksharasutra* are

- **Preparation of apamargaksharasutra**

- Surgical linen thread No. 20 were tied throughout the length on *ksharasutra* hanger.
- Freshly collected *Snuhiksheera* were smeared on thread equally throughout its length and it was dried in Thermostatic cabinet. The same procedure was repeated for 10 more days.
- On 12th day thread was smeared with *Snuhiksheera* and then hanger was passed through a heap of *Apamargakshara*, and then dried in cabinet. Then same procedure was repeated for 6 more days
- On 19th day the thread was smeared with *Snuhiksheera* and was passed through heap of fine *Haridrachurna* and dried in cabinet. The same procedure was repeated for 2 more days.
- Lastly the prepared *ksharasutras* are kept in cabinet for till it becomes dry Under UV light radiation for sterilization. And then it was packed in a sterile, airtight tubes with proper labeling.

<i>Snuhiksheera</i>	11 coatings
<i>Apamargakshara</i>	7 coatings
<i>Haridra churna</i>	3 coatings

- Preparation of *Karanja* and *chinchakshara* is same as that of *Apamargakshara*, instead of *Apamarga*, *Karanja* and *Chincha* was used.

- **Preparation of Chinch and Karanja ksharasutra**

- Preparation of *Chincha* and *karanjaksharasutra* is same as that of *Apamargaksharasutra*, instead of

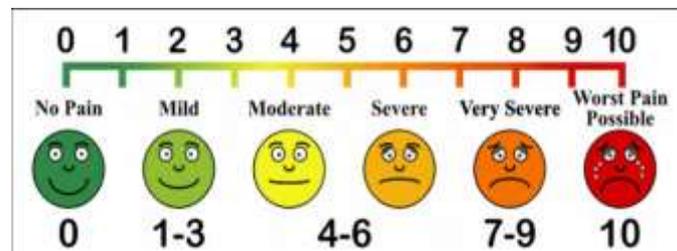
Apamargakshara, Chinchakshara Karanja kshara was used.

3. METHODOLOGY

- After explaining the *ksharasutra* procedure to patient, written consent was taken.
- Patient was made lie in lithotomy position. Probing was done to the fistulous track under all aseptic precautions and primary threading was done using surgical lenin thread No.20.
- On 7th day primary thread was replaced using *ksharasutra* (In Group A- *Karanjaksharasutra*, Group B-*Chinchaksharasutra* and Group C-*Apamargksharasutra*) by adopting Rail-Road Method. Later on every subsequent 7th day new *ksharasutra* was changed until the Fistulous track is completely cut and healed.

• Subjective parameters

➤ Pain



Grade	Pain
0	No pain
1	Mild pain (1-3)
2	Moderate pain(4-6)
3	Severe pain(7-10)

➤ Discharge

- Do – No discharge
- D1 – Mild discharge (Wets 2×2 cm gauze piece per day)
- D2 – Moderate discharge (Wets 2×2 cm 2 gauze pieces per day)
- D3 – Severe discharge (Wets 2× 2 cm >2 gauze pieces per day)

➤ Pruritus-ani

- Po – Pruritus-Ani absent
- P1 – Pruritus-Ani present.

• Objective criteria

- Length of the track is measured at every sitting in cm.

Length of the tract (In cms)	
0	L ₀
0.1-2	L ₁
2.1-4	L ₂
4.1-6	L ₃
6.1- 8	L ₄
8.1-10	L ₅

- Patient is advised to attend his normal day today activities during the course of treatment.
- Observations are made before the treatment and on every 7th day of fresh application of *ksharasutra*.

4. CLINICAL STUDY

Study design: Open randomized clinical Comparative study.

Diagnostic criteria

- Clinical features of Fistula-In-Ano (Sero- purulent discharge, pain, Pruritus-ani).
- Fistula-In-Ano is confirmed by probing.

I. Criteria for assessment

Assessment was done before and after treatment as per parameters with pre and post test design.

- Unit Cutting Time (UCT) – It represents the number of days required to cut one cm of the track. This is calculated by dividing the total number of days taken by a Fistula to heal by the initial length of the track denoted as days/ cm.

$$U.C.T = \frac{\text{TOTAL NO. OF DAYS}}{\text{INITIAL LENGTH OF TRACK (THREAD)}}$$

II. Inclusive criteria

- Patients with single low anal Fistulous track.
- Patients with clinical features of Pain, Sero-purulent discharge from perianal skin.
- Age group of 16 to 70 years irrespective of Sex, religion, occupation and duration of the symptoms.

III. Exclusion criteria

- Fistula-In-Ano secondary to Tuberculosis, Crohn's disease, Ulcerative colitis, HIV, Regional ileitis and Pelvic malignancy and associated with any other systemic disorders.

- Associated with other Ano-rectal disorders (Ca rectum and Anal canal, Hemorrhoids, Acute Fissure-In-Ano).
- High anal Fistula, Multiple Fistula-in-ano.
- Pregnancy.

Note: The pathological conditions which are mentioned in the exclusion criteria was ruled out after considering the features and required investigation

Investigations

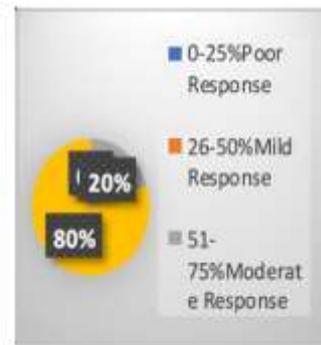
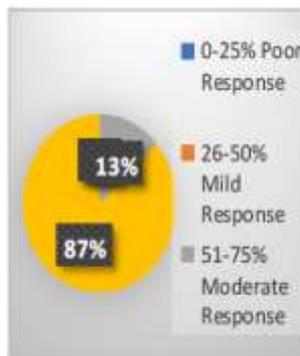
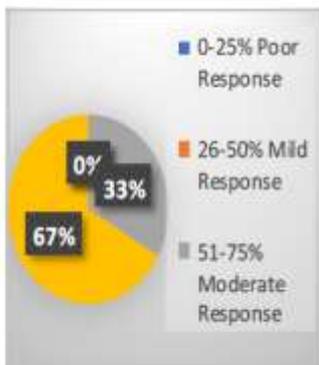
- Complete blood count
- Haemoglobin%
- Erythrocyte sedimentation rate
- Clotting time and Bleeding time
- Random blood sugar
- HIV 1 and 2
- HbsAg
- Transrectal ultrasonography.

Intervention

Assessment of total effect of therapy

Table No. 61: Overall effect of treatment on Group-A, Group-B and Group-C.

Effect of Treatment				
class	Grading	No of patients in Group-A	No of patients in Group-B	No of patients in Group-C
0-25%	Poor Response	0	0	0
26-50%	Mild Response	0	0	0
51-75%	Moderate Response	5	2	3
76-100%	Marked Response	10	13	12



Graph No. 28: Overall effect on Group A, Overall effect on Group B Overall effect on Group C.

Result of Treatment in Group A



Fig. 9: Before treatment.



Fig. 10: During treatment.

- Total 45 patients of Fistula-in-anowas selected and randomly assigned into Groups- Group A, Group B and Group C, each comprising of 15 Subjects.
- The nature of study was explained to the patient and written consent was taken
- Subjects will have all the rights to withdraw from the study at the course of time.
- All the data related to subjects was kept confidential.

IV. Duration of the study

- Till the *ksharasutra* gets cut through the track completely.

V. Assessment

Assessment was made before the treatment and on every 7th subsequent day. A total duration of 30 days from the day of total cutting and healing fistulous track would fixed to observe the possibility of recurrence and the same should recorded in the proforma of case sheet. Length of the tract.



Fig. 11: After Treatment.



Fig. 12: After Treatment.

Result of Treatment in Group B



Fig. 13: Before Treatment.



Fig. 14: During Treatment.



Fig. 15: During Treatment.



Fig. 16: After Treatment.

Result of treatment in Group C



Fig. 17: Before Treatment.



Fig. 18: During Treatment.



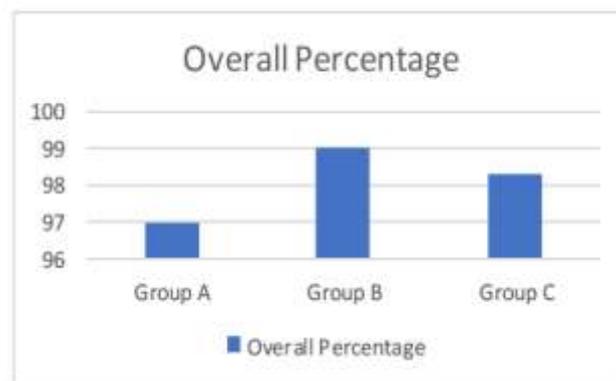
Fig. 19: During Treatment.



Fig. 20: After Treatment.

Table No. 8: No Overall effect of treatment on Group-A, Group-B and Group-C.

Group	Group A	Group B	Group C
Percentage	97%	99%	98.3%



Graph No. 1: No Overall effect of treatment.

5. DISCUSSION

Probable mode of action of *Ksharasutra* on *Bhagandara*

- **Theory of chemical cauterization:** The Alkaline nature of *kshara* causes saponification of fat and formation of alkaline protinates which subsequently results in liquification necrosis when applied over the tissue.
- **Theory of antibacterial effect:** Microbicidal action of the drugs present in *Ksharasutra* destroys the infected anal glands, and promotes the cutting and healing.
- **Mere mechanical Cut and Open theory:** Moderately tight ligation of *Ksharasutra* in the tract allows close contact of the medicaments with the diseased tract. The traction and tension of the thread mechanically cuts the tract and the medicinal coating over the thread heals the track.
- ❖ **Navel technique of local drug delivery:** Thread acts like a vehicle for the medicines to reach the targeted area (infected cryptal glands) and the multiple coatings over the thread renders a sort of sustained release effect of the medicines in the disease tract.

6. CONCLUSION

- ❖ Mean UCT in Group A is 13.5 days/cm, Group B 11.71 days/cm and Group C is 12.07 days/cm

- ❖ Overall results of treatment in Group A are 97%, Group B it is 99% and in Group C 98.3%.
- ❖ Based on the observations and results following hypothesis are accepted.
- ❖ Chinchaksharasutra is more efficacious than Karanjaksharasutra and ApamargaKsharasutra in the management of Bhagandara with special reference to Fistula-in-ano.

LIST OF REFERENCES

1. Sushruta. Sushruta samhita. (Nimbandhasangraha commentary of Dalhanacharya and Nyaya panjika commentary of Gayadasa), Edited by Jadavjirikamji. Chaukambasanskritasamsthana, Varanasi. Sutrasthana, Chapter, 2013; 33: 4-144.
2. Maharshi Vedavyasa, Agni purana, Edited by Acharya Baladeva Upadhyaya; Cowkamba Sanskrit series office, Varanasi, Chapter, 1996; 283,23,286: 60-61, 298, 14-15, 563, 417.
3. Sushruta. Sushruta samhita. (Nimbandhasangraha commentary of Dalhanacharya and Nyaya panjika commentary of Gayadasa), Edited by Jadavjirikamji. Chaukambasanskritasamsthana, Varanasi. Nidanasthana, chapter, 2013; 4: 3-280.
4. Charaka. Charaka samhita. (Ayurveda Dipika commentary of Chakrapani data), Edited by Jadavji Trikamji. Chaukamba Sanskrit samsthana, Varanasi Chikitsasthana, Chapter, 2013; 12.

- Verse, 97-490.
- Verse, 96-490.
- 5. Somen Das. A concise textbook of Surgery. Edited by Dr. S. Das, 9: 1071.
- 6. <https://emedicine.medscape.com>article>
- 7. Chakrapanidatta. Chakradatta. Edited by Brahmashankar Mishra. Chaukambasanskritseries office. Varanasi, 2012.
- Chapter, 05: 147-61.
- Chapter, 45: 10-11, 360.
- 8. SK Sharma, KR Sharma, Kulwantsingh. Ksharasutra therapy in Fistula-in-ano and other Ano rectal disorders. Rashtriya Ayurveda Vidyapeeth. New delhi, 48-59.
- 9. <https://www.easyayurveda.com2017/03/19/mode-of-action-of-kshara-sutra/amp> .
- 10. Pib.Nic.in/newsite/erelease.apex?reid 09/03/2014.
- 11. Bailey and Loves?. Short practice of surgery. Edited by, Norman S Williams, P Ronan O'connel, Andrew W Mc Caskie. CRC Press, Chapter, 2018; 74: 1367.
- 12. Sushruta. Sushruta samhita. (Nimbandhasangraha commentary of Dalhanacharya and Nyaya panjika commentary of Gayadasa), Edited by Jadavjitrikamji. Chaukambasanskritsamsthana, Varanasi. Sutrasthana, Chapter, 2013; 11.
- Verse no, 11, 46.
- Verse no, 03, 45.
- Verse no, 04, 45.
- Verse no, 6, 46.
- Verse no, 11, 12, 13: 46-47.
- Verse no, 5, 45.
- Verse no, 5, 16, 45-48.
- Verse no, 17, 48.
- Verse no, 10. 46 (Dalhana commentary)
- Verse no, 07, 8-46.
- Verse no, 9, 28. 46, 50.
- Verse no, 18, 19-49.
- Verse no, 26, 50.
- Verse no, 39, 50.
- 13. Acharya Priyavat Sharma-Kaiyadeva Nighantu, Edited by Guru Prasad Sharma.(Hindi commentatary). Reprint edition; Chaukamba Sanskrit samsthana, Varanasi, 2013.
- 14. BhavaprakasaNigantu (Indian Materia Medica) of Sri Bhavamishra forwarded by Prof.K.CChunekar (English commentatary by Prof. D.S Lucas. Reprint edition; Chaukamba Sanskrit Samsthana, Varanasi, 2017.
- 15. Rasa Tarangini. By Pranacharya Shri Sadananda Sharmana Virachita, Editor Kashinath Shastrina, Motilal Banarasi Das, Varanasi.