

Management of Various Types of Fistula-in-ano by Medicated Seton (Ksharasutra) and Open Fistulotomy- A Comparative Study

DEEPAK PANKAJ¹, NITESH KUMAR², SWETA MUNI³, VIBHUTI BHUSHAN⁴, NITESH⁵, PRADYOT SHAHI⁶, NIRUPAM⁷, PRIYANKA CHAUBEY⁸



ABSTRACT

Introduction: Fistula-in-ano is treated by various modalities in modern era, but still today no single modality has proved to be complete cure for it. Ksharasutra is being practiced in Indian system of medicine since ancient time for management of ano-rectal disorders.

Aim: To evaluate the efficacy of ksharasutra in comparison to standard open fistulotomy in the management of fistula-in-ano and to find better patient compliance.

Material and Methods: This prospective study was planned and conducted among 60 patients who reported with fistula-in-ano to IGIMS, Patna. Patients were divided into two groups with 30 patients in each group on the basis of treatment plan i.e., open fistulotomy in one group and ksharasutra in the second group. The present study measured and compared operating time, healing time and hospital stay as primary variables and postoperative complications as secondary variables. Patient was followed at regular intervals of 1 week, 1 month and 3 months. The postoperative pain was evaluated using Visual Analogue Scale (VAS) ranging from 0 to 10 with mild cases with value of 0-3, moderate from 4-7 and severe from 8-10. Data so obtained was evaluated using the chi-square test with $p < 0.05$ as significant value.

Results: Operating time was significantly lower in ksharasutra group as compared to fistulotomy group, average of 38 minutes in fistulotomy group while average of 16 minutes in ksharasutra group ($p=0.0021$). Average healing time in patients who underwent fistulotomy was 22 days, and in Ksharasutra group it was 43 days ($p=0.014$). Duration of hospital stay was more in fistulotomy group while in ksharasutra group, it was an Out-Patient Department (OPD) procedure with observation time of one to two hours postprocedure ($p=0.001$). Among postoperative complications, pain (measured on VAS) was significantly high (36.7%) in patients with fistulotomy as compared to those with ksharasutra, (13.3%) while infection was slightly higher in fistulotomy group. Recurrence was observed in 16.7% of cases in fistulotomy group while it was 3.3% in ksharasutra group.

Conclusion: Anal fistula causes physical as well as psychological burden to the patient. At present when there are various treatment options for anal fistula, authors have concluded that Ksharasutra with less complications along patient compliance is a cost effective option in this setting as postoperative complications, longer hospital stay adds extra economic burden to patient.

Keywords: Anal fistula, Ano-rectal disorders, Faecal-incontinence

INTRODUCTION

Anal fistula has been a great concern for mankind since ages due to the discomfort it causes, based on the site of the disease. Surgical therapy for anal fistulous disease was revealed by Hippocrates in about 430 BC and the use of seton as ksharasutra method has been mentioned in ancient surgical practice by Sushruta [1].

Anal fistula (plural fistulae), or fistula-in-ano, is an abnormal communication which lies between the perianal skin and the epithelialised surface of the anal canal. It is chronic in nature and its origin is comprised from the anal glands, which lies between the internal and external anal sphincter and drain into the anal canal [2].

People with a history of anal abscesses generally develop anal fistula as a consequence of inappropriate healing of these anal abscesses. A generally accepted consensus is that they develop in the intramuscular space as an intersphincteric abscess [3].

Open surgery in the form of fistulotomy or fistulectomy, in which surgical lay open technique is mostly practiced [4]. Two types of setons are used in management of anal fistula which is cutting seton for incising through the tissue and other is a noncutting seton to facilitate drainage of the tract [5]. The use of setons in contemporary treatment modalities is confined to complex cases and is rarely used to treat fistula which are prone to recurrence [6,7].

Various treatment modalities have been utilised to manage and cure anal fistula which consist of fistulectomy with perianal skin grafting

and fistulectomy with or without primary closure [8,9]. Several minor variations have been added in classical operation of lay open which is mentioned in principles and practice of rectal surgery by Gabriel WB [10]. However, routine surgical management modalities like fistulotomy and fistulectomy still remain the gold standard in most centres. Despite best efforts, the problems of recurrence and anal incontinence are high in the classical lay open method [11]. In India, Ksharasutra therapy was being opted as treatment modality in the management of complicated anal fistula with recurrence rate of around 3.33% [12]. Application of this chemical Seton named Ksharasutra (a cotton thread medicated with coating of Ayurvedic medicines) is indicated in the ancient Indian writings as well as is still considered in various centres in India. Treatment and follow-up of Ksharasutra are relatively simple, demands less hospital stay, have very low rate of complications and most imperatively, the cost-factor of this therapy is minimal [12,13].

Advent of antibiotics and drainage procedures has led to satisfactory management of anorectal sepsis, however, preservation of continence is yet a challenge and focus still remains to attain an optimal management procedure which aims at patient care [2]. Since lot of patients of chronic and recurrent type of fistula-in-ano reported to the present hospital, current comparative study was designed to find an effective treatment option which could be beneficial for further management of cases in this tertiary care

hospital of Bihar. With this background, the aim of study is to evaluate the efficacy of ksharasutra in comparison to standard open fistulotomy in the management of fistula-in-ano and to find better patient compliance.

MATERIALS AND METHODS

The prospective study was planned and conducted among 60 patients who reported with Fistula-in-ano to the Department of General Surgery at Indira Gandhi Institute of Medical Sciences (IGIMS), Patna over a period of 18 months from July 2018 to December 2019. The ethical approval was taken from the Institute's Ethics Committee (986/IEC/2018/IGIMS) and informed consent was obtained from the patients before the commencement of this study.

The study was based on nonprobability purposive sampling technique. It means the researcher decides purposely to select the samples that are judged to be typical of the population or knowledgeable about the issues under study. Sample size was calculated as 60 subjects at 20% allowable error with 95% confidence level.

Inclusion criteria: Comprised of patients with discharge (mucoid, pus) around anal canal, as well as cases of recurrent fistula (occurring within one year after previous surgical procedure).

Exclusion criteria: Consisted of patients with extremes of age (<10 years or >70 years), patients who were immunocompromised (HIV infection or had undergone or on chemotherapy treatment), patients with history of Tuberculosis/Crohn's disease, patients with more than one external opening and cases of high types of anal fistula.

Patients aged 10-60 years selected for the study were divided into two groups with 30 patients in each group on the basis of treatment plan i.e., open fistulotomy in one group and ksharasutra in the second group.

Surgical procedure was carried taking all universal aseptic precautions, patients were put in lithotomy position, the external fistulous opening was identified and the discharge, if any, was sent to the microbiology department for culture and sensitivity. Per-rectal and proctoscopic examinations were done for clinical diagnosis in all the patients. Required blood and radiological investigations (Fistulogram or MRI) were carried before treatment.

For application of Ksharasutra, a metallic malleable probe with an eye was introduced through the external opening and was made to pass the tip of probe through the internal opening with every attempt not to create a false passage. The eye was used to thread with Ksharasutra and probe was gently drawn with the purpose

of threading whole tract with medicated Ksharasutra [Table/Fig-1]. Following this, the two ends of the thread were securely tied using knots outside the anus. Thread was changed after one week interval and was tightened gradually [Table/Fig-2]. A new ksharasutra was applied after assessing wound discharge and pain.



[Table/Fig-2]: Thread was changed after one week interval and was tightened gradually.

For open fistulotomy, a metallic probe was put in whole fistulous tract, and the whole fistulous tract was laid open over the metallic probe. Few patients bleed significantly during the procedure and needed suturing with absorbable suture.

The postoperative pain was evaluated using VAS ranging from 0 to 10 with mild cases with value of 0-3, moderate from 4-7 and severe from 8-10. Patients were followed at regular intervals (1 week, 1 month and 3 months).

STATISTICAL ANALYSIS

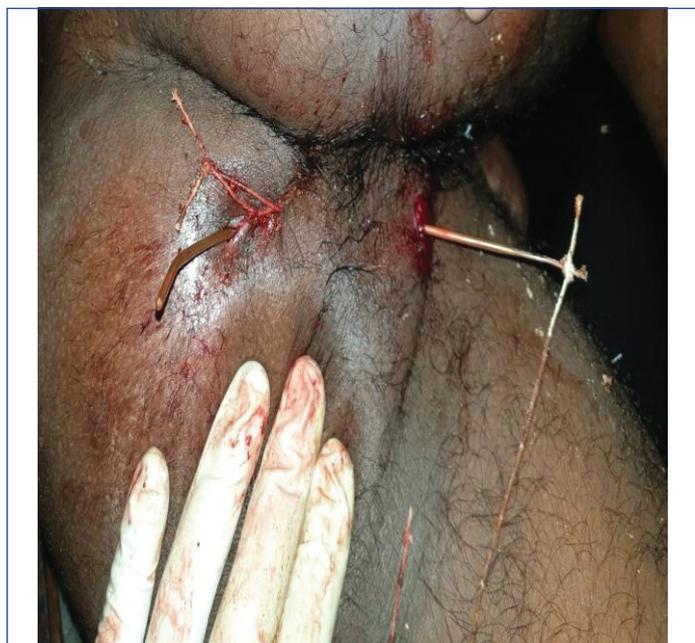
Statistical analysis was done using Statistical Package for the Social Sciences (SPSS) version 20 through chi-square test. $p < 0.05$ was considered as statistically significant.

RESULTS

Maximum patients were in the age group 31 to 50 years. Operating time was significantly lower in ksharasutra group as compared to fistulotomy group, with an average of 38 minutes in fistulotomy group while an average of 16 minutes in ksharasutra group ($p=0.0021$). Duration of hospital stay was more in fistulotomy group (3 ± 1.2 (in days)) while in ksharasutra group it was an OPD procedure with observation time of one to two hours postprocedure (3 ± 0.5 (in hours)) ($p=0.001$) [Table/Fig-3].

Characteristics	Total cases N=60	Ksharasutra N=30	Fistulotomy N=30	p-value	
Age group (years)	11-30	17	8/30 (26.7%)	9/30 (30%)	0.048
	31-50	35	17/30 (56.7%)	18/30 (60%)	
	51-70	8	5/30 (16.6%)	3/30 (10%)	
Operating time (in minutes)	-	16 \pm 3.2	38 \pm 5	0.0021	
Healing time (in days)	-	43 \pm 3.4	22 \pm 2.2	0.014	
Hospital stay	-	3 \pm 0.5 (in hours)	3 \pm 1.2 (in days)	0.001	
Postoperative pain (visual analogue scale at 24 hours postoperative)	-	6.92 \pm 0.23	5.19 \pm 0.41	0.062	

[Table/Fig-3]: Clinical presentation of fistula-in-ano. Value less than 0.05 - statistically significant



[Table/Fig-1]: Showing application of new ksharasutra over previously applied ksharasutra.

Perianal discharge was the most common presenting symptom. External opening was anterior in 38.3% cases and posterior in 61.7% cases. Escherichia coli was the most common pathogen in patients in which pus culture was done for perianal discharge accounting for 11.6% of cases [Table/Fig-4].

Characteristics		N=60
Presenting symptoms	Perianal discharge	38 (63%)
	No pus discharge	22 (36.7%)
	Perianal Itching	22 (37%)
External opening	Anterior	23 (38.3%)
	Posterior	37 (61.7%)
Type of fistula	Intersphincteric	44(73.3%)
	Transsphincteric	16 (26.6%)
Pus culture	Escherichia coli	7 (11.6%)
	Enterococcus spp	6 (10%)
	Bacteroides	4 (6.7%)
	Staphylococcus Aureus	2 (3.3%)
	Streptococcus Pyogenes	1 (1.7%)
	No growth	18 (30%)

[Table/Fig-4]: Clinical and microbiological characteristics.

Among postoperative complications, pain was high (36.7%) in patients with fistulotomy as compared to those with ksharasutra (13.3%). In fistulotomy group, among total 11 cases which reported pain; all 11 reported pain during 1 week follow-up while 7 cases reported pain at 1 month follow-up whereas none of them reported pain at 3 month follow-up. In Ksharasutra Group, among total 4 cases which reported pain; all 4 reported pain during 1 week follow-up while 3 cases reported pain at 1 month follow-up whereas none of them reported pain at 3 month follow-up. Recurrence was observed in 16.7% of cases in fistulotomy group while it was 3.3% in ksharasutra group [Table/Fig-5].

DISCUSSION

Anorectal abscess and fistulas include a major group of illness that affects human beings causing inconvenience due to pain, discharge and incontinence [14].

Anal fistula are categorised into five types depending on their relationship with the internal and external sphincter muscles, i.e.,

Extra-sphincteric fistulae, Transphincteric fistulae, Suprasphincteric fistulae and Intersphincteric fistula as well as Sub mucosal fistulae [15]. Sometimes, it is difficult to diagnose anal fistula, when patient presents with unusual signs and symptoms of disease, sometimes only pain and sometimes an opening which is very small, unable to delineate properly on clinical examination and from which discharge has been absent for some time [12,13].

Careful inspection and local examination, Digital Rectal Examination (DRE), probing and radiological imaging are primary methods of diagnosis. Transrectal ultrasound is gaining popularity these days in diagnosis and proper delineation of the fistulous tract [16].

It is notorious for its chronicity, recurrences and frequent acute exacerbations. Hippocrates in the earliest literature described the use of seton to cure fistula-in-ano [8,9].

Various modalities of treatment are available for fistula-in-ano which are applications of seton, chemical cauterisation by corrosives, fibrin glue or fistula plug application. Also, mucosal advancement flap technique, adipose derived stem cell and LIFT (ligation of the intersphincteric fistula tract without excision) procedure have been used for anal fistula treatment. Video Assisted Anal Fistula Treatment (VAAFT) is being currently practiced at some centres as one of the recent modality of treatment [16].

In the present study, average operating time was also quite less in ksharasutra group as it was an OPD procedure and was done under local anaesthesia. While average operating time was more in fistulotomy group as it was an operation theatre procedure done under spinal anaesthesia. This is also evident when compared with studies over recent and past times [Table/Fig-6] [4,17,18]. Duration of hospital stay was more in fistulotomy group as the wound was open and required dressings over a period of time. From this study, it was observed that fistulotomy patients as compared to ksharasutra, needed more mean operative time, postoperative analgesia and have more number of recurrence. Most patients in ksharasutra group returned to normal daily activities very next day, whereas fistulotomy patients took more time before returning to routine activities. Most importantly there was no incidence of incontinence in ksharasutra group, while fistulotomy group had incidence of minor incontinence in 6.7% cases. Complete healing time was variable in various studies conducted over time while it was more in ksharasutra

Complications	Fistulotomy Group n=30				Ksharasutra Group n=30			
	Total (postoperative till 3 month follow-up)	1 week follow-up (n=30)	1 month follow-up (n=30)	3 month follow-up (n=30)	Total (postoperative till 3 month follow-up)	1 week follow-up (n=30)	1 month follow-up (n=30)	3 month follow-up (n=30)
Pain	11 (36.7%)	11 (36.7%)	7 (23.3%)	0	4 (13.3%)	4 (13.3%)	3 (10%)	0
Infection (abscess formation)	4 (13.3%)	2 (6.7%)	2 (6.7%)	0	1 (3.3%)	1 (3.3%)	0	0
Bleeding	2 (6.7%)	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Incontinence	2 (6.7%)	1 (3.3%)	1 (3.3%)	0	0	0	0	0
Recurrence	5 (16.7%)	0	1 (3.3%)	4 (13.3%)	1 (3.3%)	0	0	1 (3.3%)

[Table/Fig-5]: Incidence of Various postoperative complications in Fistulotomy and Ksharasutra group.

Various studies	Operating time		Healing time	
	Ksharasutra	Fistulotomy	Ksharasutra	Fistulotomy
Present study	16±3.2 min	38±5 min	43±3.4 days	22±2.2 days
Madankar SP et al., (2018) [17]	23.19±6.8 min	46±9.2 min	67.35 ±21.2 days	24.9±10.2 days
Litake MM and Sudheer K, (2017) [18]	16 min	28 min	30 days	47.5 days
Dutta G et al., (2017)[4]	14.8±min	25.8±14 min	53±26.6 days	35.7±9.1 days

[Table/Fig-6]: Average operative time and healing time in ksharasutra and Fistulotomy group done by various researchers.

group in the present study. The reason being ksharasutra was a multistaged procedure and patient had to come weekly for change of ksharasutra. In fistulotomy group regular dressings healed the wound and patient was discharged after satisfactory apposition of the wound.

Most importantly there was no incidence of incontinence in ksharasutra group, while fistulotomy group had incidence of minor incontinence in 6.7% cases. Thus, the Ksharasutra therapy, a unique method of drug delivery, is most appropriate for healing the fistulous tract which offers an effective, ambulatory and safe alternative treatment in patients with fistula-in-ano [19].

Limitation(s)

The limitation of the present study was that all cases were followed up to 1 month; however, the present study recommends commencement of studies with large sample size with long follow-up for longer duration to further achieve promising results.

CONCLUSION(S)

Anal fistula causes physical as well as psychological burden to the patient. At present, when there are various treatment options for anal fistula, authors have concluded that Ksharasutra with less complications along patient compliance is a cost-effective option in there setting.

REFERENCES

- [1] Patel S, Thumar N, Sharma R, Shah H. Ksharasutra ligation with partial fistulectomy-as a treatment for anterior trans-sphincteric fistula-in-ano-a case study. *Asian Journal of Pharmaceutical Research and Development*. 2019;7(1):46-49.
- [2] Rao KN, Lavanya KM, Nayak SR, Ashrith P. Ksharasutra vs. fistulectomy for fistula-in-ano-A Randomised Controlled Trial in East Godavari district, Andhra Pradesh, India. *MRIMS Journal of Health Sciences* 2018;6(2):79-82.
- [3] Kumara AAJP, Jayaratne DL, Antony DJ. Microbiological Assessment of the Chronic Anal Fistula. *Int J Pharma Res Health Sci*. 2017;5(1):1536-38.
- [4] Dutta G, Bain J, Ray AK. Comparing Ksharasutra (Ayurvedic Seton) and open fistulotomy in the management of fistula-in-ano. *Journal of Natural Science, Biology and Medicine*. 2015;6(2):406-10.
- [5] Hamalainen KJ, Sainio AP. Cutting setons for anal fistulas: High risk of minor control defects. *Dis Colon Rectum*. 1997;40:1443-47.
- [6] Hammond TM, Graahn MF, Lunniss PJ. Fibrin glue in the management of the anal fistulae. *Colorectal Dis*. 2004;6:308-19.
- [7] Isbister WH, Sanea NA. The cutting seton- The experience at King Faisal Specialist Hospital Dis Colon Rectum. 2001;44:722-27.
- [8] Hanley PH. Conservative surgical correction of horseshoe abscess and fistula. *Diseases of the Colon & Rectum*. 1965;8(5):364-68.
- [9] Parks AG. Pathogenesis and treatment of fistula-in-ano. *British Medical Journal*. 1961;1(5224):463.
- [10] Gabriel WB. *The principles and practice of rectal surgery*. HK Lewis; 1963.
- [11] Goligher JC. *Surgery of the anus, rectum, and colon*. Thomas; 1961.
- [12] Pankaj S, Manoranjan S. Efficacy of Ksharasutra (medicated Seton), therapy in the management of fistula-in-ano. *World Journal of Colorectal Surgery*. 2010;2(2):01-10.
- [13] Radhakrishna S. Multicentric randomised controlled clinical trial of Ksharasootra (Ayurvedic medicated thread) in the management of fistula-in-ano. *Indian journal of Medical Research. Section B, Biomedical Research Other Than Infectious Diseases*. 1991;94(JUN):177-85.
- [14] Akhtar M. *Fistula-in-ano- An overview*. JIMSA. 2012;25(1):53-55.
- [15] Parks AG, Gardon PH, Hardcastle JD. A classification of fistula-in-ano. *Br J Surg*. 1976;63:1-12.
- [16] Kharadi B, Shah B, Dudhamal TS, Bhadja M. Effect of partial fistulectomy with ksharasootra application in the management of bhagandara (fistula-in-ano)-A case report. *International Journal of Pharmaceutical Sciences and Research*. 2017;8(11):4904-08.
- [17] Madankar SP, Jatkar GL, Bhusari B. Comparison of "medicated seton versus fistulectomy" in the management of fistula-in-ano in tertiary care hospital. *International Surgery Journal*. 2018;5(8):2857-61.
- [18] Litake MM, Sudheer K. A comparative study of treatment of Fistula-in-ano-fistulectomy versus seton. *Indian Journal of Basic and Applied Medical Research*. 2017;6(2):588-95.
- [19] Srivastava PD, Sahu MP. Efficacy of Kshar Sutra (medicated seton) therapy in the management of Fistula-in-Ano. *World Journal of Colorectal Surgery*. 2010;2(1):6.

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of General Surgery, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
2. Assistant Professor, Department of General Surgery, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
3. Assistant Professor, Department of Microbiology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
4. Additional Professor, Department of General Surgery, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
5. Senior Resident, Department of General Surgery, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
6. Senior Resident, Department of General Surgery, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
7. Senior Resident, Department of General Surgery, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
8. Senior Resident, Department of General Surgery, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Sweta Muni,
Shanti Niwas, Amba Vihar Colony, Ambedkar Path, Near Mahima Mandir
Rukanpura, Patna-800014, Bihar, India.
E-mail: drswetamuni@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Apr 27, 2020
- Manual Googling: Jun 10, 2020
- iThenticate Software: Jun 27, 2020 (12%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Apr 25, 2020**

Date of Peer Review: **May 12, 2020**

Date of Acceptance: **Jun 15, 2020**

Date of Publishing: **Jul 01, 2020**