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Research Article

FISTULA-IN-ANO: *KSHARSUTRA* A MINIMAL INVASIVE TREATMENT MODALITY

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ABSTRACT

Fistula-in-ano is troublesome problem encountered in general practice. It consists of 1.6% of all surgical admissions and leads to physical, psychological and social problems. The management consists of multiple modalities with varied results. Present study evaluates medicated seton (*Ksharsutra*) as a minimal invasive modality of treatment. **Methodology:** The study was randomized control trial carried out at tertiary care hospital with an aim to assess the efficacy of *Ksharsutra* Vs fistulectomy. The subjects were clinically diagnosed and MRI confirmed cases of low fistula-in-ano. They were block randomized into two interventional groups. Study group were subjected to introduction of *Ksharsutra* under local anesthesia while control group under saddle block had a formal fistulectomy done. The outcome measures were wound healing time, hospital stay and recurrence. **Results:** A total of 63 patients were evaluated of which 33 were allocated to *Ksharsutra* group and 30 patients underwent fistulectomy. The male: female ratio was 8:1 and mean age of the patients was 38.4 years SD ± 11.03. Perianal sinus with or without pain and discharge was presenting complaints in all patients. 1/3rd patient gave history of past incision and drainage while 2/3rd patients had spontaneous rupture. Majority (76%) fistulae were intersphincteric and rest were transsphincteric. The mean healing duration was 5.5 weeks in fistulectomy and 6 weeks in *Ksharsutra* (p>0.1 [NS]). Recurrence rate and incontinence rates were also significantly not different. **Conclusion:** The equivalence of results of *Ksharsutra* with traditional fistulectomy made it an alternative minimal invasive modality of treatment which can be offered on outpatient basis.

KEYWORDS: Fistula-in-ano, Fistulectomy, Seton, *Ksharsutra*, Medicated seton.

INTRODUCTION

Fistulae-in-ano forms a common treatable benign lesion of the rectum and anal canal. Most of the fistulae develop after rupture or inadequate drainage of pyogenic anorectal abscess which develop secondary to infection of the cryptic gland.[1] The vast majority are contributed by acute infection whereas minority by chronic & low-grade infections pointing to varying etiologies. Patients below the age group of 40 years and non-diabetics appeared to have a higher risk for fistula formation resulting in loss of valuable productive man hours[2]. In India anal fistula constitutes 1.6% of all surgical admissions with chances of recurrence 0.7 to 26.5% & incidence of anal incontinence 5 to 40%.[3]

Surgery for fistula-in-ano may account for 5% of the operative workload of a colorectal service[4]. The surgery itself thus constitutes only a small fraction of the work undertaken, but poorly performed surgery may result in considerable patient morbidity, including multiple re-operations and minor-to-major degrees of anal incontinence.

Setons have been used to manage fistula-in-ano for hundreds of years were commonly described only for the high or complex anal fistula in order to avoid faecal incontinence and recurrence[5]. The usage of this method was deemed cumbersome and too slow.

The aim of this study was to evaluate the role of Ayurvedic setons in treatment of low fistula-in-ano and compare it with established surgical treatment of fistulectomy.

PATIENTS AND METHODS

The study was conducted at Department of Surgery in a Tertiary care Hospital after approval from hospital ethics committee. A sample of 63 patients with fistula-in-ano were enrolled in this hospital based randomized control trial. All patients presenting with fistula for more than 3 weeks, not responding in spite of adequate antibiotic therapy & local treatment, Internal opening clinically palpable and or visualized on proctoscopy and single or multiple external openings were included in the present study. All clinical and or histologically diagnosed cases of Crohn's disease, Tuberculous fistula, immunocompromised patient and fistula with abscess were excluded. All patients were subjected to MRI scan of perineum region to know the type of fistula and edge biopsy of external opening were taken to rule out secondary fistula-in-ano. Using a predesigned proforma demographic factors like age**,** gender and causes of anal fistula which included previous abscess bursting, incision & drainage, recurrence after surgical procedure and clinical factors which included site of external opening, site of internal opening, number of openings, position of both openings, discharge from the opening, nature of discharge from both openings, recurrent fistulae, history of any previous anorectal surgery were studied. In view of operative procedure, patients were grouped under two

Categories, Fistulectomy and Medicated Seton (*Ksharsutra*) by block randomization of 10 by envelope method. Study group were subjected to introduction of *Ksharsutra* under local anesthesia while control group under saddle block had a formal fistulectomy done. The outcome measures were wound healing time and hospital stay calculated from day of procedure and recurrence of fistula and anal incontinence.

RESULTS

A total of 67 subjects were enrolled in the present study of them 63 subjects fulfilled the inclusion criteria. The rest 4 cases were high anal fistulas & they were excluded from the study.

The mean age of the patient in the present study was 38.40 yrs SD ± 11.03.Out of 63 patients 56 (88.89%) were males & 7 (11.11%) were females suggesting age of occurrence of fistula in females was younger than males. All the patients presented with both pus discharge & pain. The mean duration of pus discharge was 12.62 months SD ±10.05 & range of 1 – 48 months. A mean duration of pain was 13.16 months SD ± 9.72 & range of 1 – 39 months. Out of 63 patients, 22 patients (34.92%) underwent incision & drainage and 41 patients (65.08%) reported bursting of perianal abscess suggesting more patients develop fistula after spontaneous rupture of perianal abscess. Out of 63 patients, 59 patients (93.65%) presented with single external opening, 3 patients (4.76%) with 2 external openings and only one patient (1.59%) with 3 external openings. Out of 68 external openings, 26 (38.24%) openings were found in 3 – 5 O'clock position followed by 18 (28.57%) openings in 9 – 11 O'clock position followed by 14 (22.22%) openings in 6 – 8 O'clock position followed by 10 (15.87%) openings in 12 – 2 O'clock position suggesting majority of external opening was in posterior plane. Out of 63 internal openings majority of the internal openings 63.49% was situated in posterior midline and rest situated in anterior midline. On MRI scan, out of 67 patients 51 (76.12%) were found to have Intersphincteric course, 12 (17.91%) patients were having Transsphincteric course and 4 (5.97%) patients were having Suprasphincteric course.

Out of 63 patients in the present study 31 patients (49.21%) underwent Fistulectomy & 32 patients (50.79%) underwent Medicated Seton (*Ksharsutra*) procedure. The basic demographic & clinical features of two groups when compared showed that they were similar suggesting adequate randomization of the two groups was statistically comparable on baseline characteristics. [Table 1]

Table 1: Showing comparison of Basic parameters of Fistulectomy & Medicated Seton (Ksharsutra) group

	Fistulectomy	Medicated Seton (*Ksharsutra*)	p value
Mean Age (years)	39.12	37.53	0.5310
Gender			
Male	27	29	0.9645
Female	4	3	
Pus Discharge Duration (months)	11.80	13.40	0.5318
Pain Duration	11.58	14.69	0.2074
MRI **Type of Fistula**			
Intersphincteric	26	26	0.7950
Transphincteric	5	7	

The mean healing duration in the present study was 40.98 days with SD ± 11.90 & range of 22 – 73 days. The result signifies equivalence between two modalities that is Fistulectomy & Medicated Seton (*Ksharsutra*) when healing was compared. Out of 31 patients of Fistulectomy in the present study 1 patient (3.23%) developed abscess which required I& D & none of the patient presented with recurrence & none of them presented with incontinence. Out of 32 patients of Medicated Seton (*Ksharsutra*) 2 patients (6.25%) developed abscess which required Incision & drainage and 2 (6.25%) patients were presented with recurrence & none of them presented with incontinence.

Of all the histological findings of the 63 patients which was obtained from the tract or opening it was found to be chronic inflammation or dense mixed inflammation.

DISCUSSION

Fistula-in-ano is a common perineal condition causing appreciable morbidity & inconvenience to patient. It is believed to originate from an infection of an anal gland. Majority of these fistulas are simple & low and identified by digital examination. They pose surgical challenge as surgical technique to perineum to damage anal sphincters leading to incontinence or incomplete removal leading to recurrence. Multiplicity of treatment modalities & lack of interest by a surgical faculty managing fistula leads to patients shifted from one clinic to another finally getting operated by an inexperienced surgeon or quack. The present study has aimed to assess the cause, presentation & management in Indian scenario.

A total of 67 patients were recruited in present study of them 4 excluded as they were suprasphincteric

fistula diagnosed by perineal MRI. The male female ratio was 8:1 with 38.4 years as the mean age of presentation.

All 63 patients presented with pain and perineal discharge. These findings were different from other published studies

Proper incision and drainage of the perineal abscess is associated with lesser incidence of fistula-in-ano. These facts could be collaborated in the present study where 1/3rd of the patients give history of incision and drainage in the past, while spontaneous rupture of the abscess has led to increased occurrence of fistula-in-ano i.e., more than 2/3rd of the patients, emphasizing the need for incision and drainage of the perineal abscess to reduce the occurrence of fistula in future. These results are consistent with literature except Ahmed Uraiqat et al (2010)[6] who has quoted a very high incidence of fistula development after incision and drainage.

Majority of 76% cases were belonging to intersphincteric group. This occurrence is distinctly higher than those quoted in literature ranging from 30 to 55%, the reason for which cannot be explained. The occurrence of suprasphincteric fistula quite matched with those reported in literature.

The optimal management of fistula is aimed at eradicating the fistula, preserving the anal sphincter, preventing the recurrence and allowing early return to normal activity. These were the real challenge in the present study. Hence patient once classified to be operable either in intersphincteric or transsphincteric group underwent either a Fistulectomy or Medicated Seton (*Ksharsutra*) therapy. The rationale for selecting Fistulectomy as one of the modes of management was due to very few studies done to evaluate the modalities.

This modality of treatment has 2 advantages

1. Most of the present series of fistula were low variety and the tract could be subjected to Histopathological examination after properly dissecting it out.
2. Other advantage was finding associated tract while dissecting the main tract due to fibrous extensions.

Table 2: Showing healing duration of Fistulotomy, Fistulectomy and Medicated Seton

Study	Fistulectomy (weeks)	Fistulotomy (weeks)	Medicated Seton (*Ksharsutra*) (weeks)
Ahmad Uraiqat (2010)[6]	-	6	-
K.S. HO. Et al (2001)[7]	-	4	8
O. Kronborg (1985)[8]	5.51	6.28	-
Present study	5.5	-	6

The results of Fistulectomy are quite consistent with series of Kronborg (1985)[8] with healing duration of approximately 5 weeks. It is a fact that Fistulotomy is a more practised modality and Fistulectomy is avoided by most surgeons for the fear of dissection and more of perianal damage. But this procedure in the present study has given results similar to Fistulectomy with an added advantage of removal of diseased tract in toto.

Medicated Seton (*Ksharsutra*) has been used in Ayurveda since the time of Sushruta and being practised till today without any good clinical evidence. To make this ancient modality a more evidenced based treatment *Ksharsutra* was used and evaluated in the present study. The results of healing by *Ksharsutra* in the present study were quite consistent with very limited evidence in literature.[6,7,8]

CONCLUSION

To summarise fistula-in-ano continues to remain challenging condition to manage despite surgical advances. The treatment objective remains the same, i.e., eradication of septic focus, alleviation of symptoms, effective fistula healing, prevention of recurrence, preservation of anal sphincter and rapid patient recovery. The present study was able to fulfil its aim to find out the etiological aspect as most of the fistulas were cryptoglandular in origin. The clinical manifestations were evaluated and were similar to those reported in literature. Perianal MRI was an important tool in classifying the fistula-in-ano and of great help in treatment planning. The role of conventional fistula surgery and ancient *Ksharsutra* were also evaluated and found to be promising. In this world of developing scientific advances, ancient modalities like *Ksharsutra* can be an important modality to be practised in surgical out-patients.

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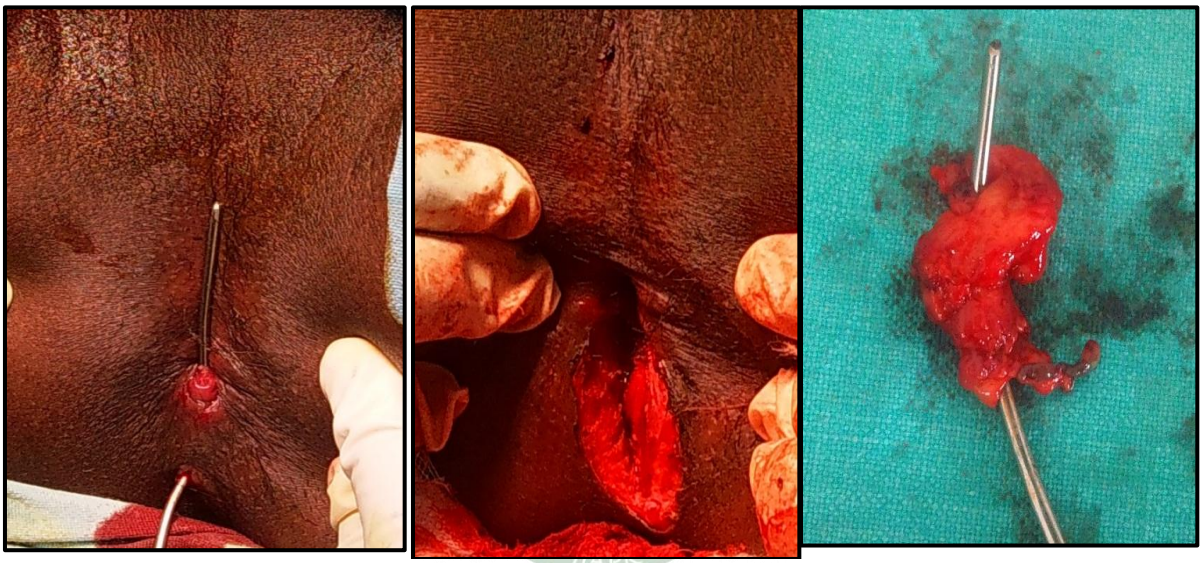

Figure 1: Showing operative steps of Fistulectomy

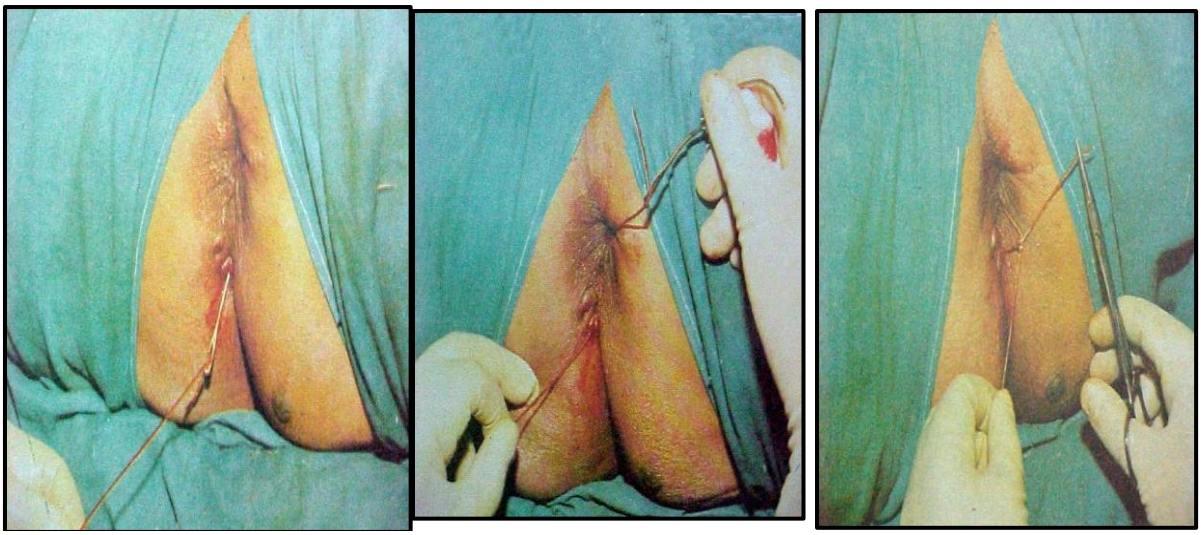

Figure 2: Showing operative steps of Medicated Seton (*Ksharsutra*) insertion