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ORIGINAL RESEARCH

Comparative analysis of fistulectomy and seton placement in the management of fistula-in-ano: A prospective study

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ABSTRACT

Fistula-in-ano is a common anorectal condition requiring surgical intervention to eradicate the fistula while preserving anal sphincter function. This study compares the clinical outcomes of Fistulectomy and Seton placement for the management of fistula-in-ano. A prospective study was conducted at R.D. Gardi Medical College, Ujjain, involving 56 patients diagnosed with fistula-in-ano. Patients were categorized into two groups: Fistulectomy and Seton placement. Outcomes assessed included operative time, hospital stay, healing time, pain, infection, recurrence, and incontinence at one week, one month, and three months postoperatively. The mean age of participants was 38.96 years, with a male predominance (80.4%). Low fistulas were more prevalent (60.7%), and common symptoms included discharge (89.3%) and swelling (80.4%). Operative time was significantly shorter in the Seton group, while Fistulectomy resulted in shorter hospital stays. Infection rates at one week were higher in the Fistulectomy group (24.8% vs. 10.3%). Recurrence and incontinence rates were significantly lower in the Seton group at three months (recurrence: 17.2% vs. 33.3%; incontinence: 3.4% vs. 29.6%).

INTRODUCTION

Fistula-in-ano is a common anorectal condition characterized by a chronic granulating tract that connects the anal canal or rectum to the perianal skin or perineum, often causing significant discomfort and morbidity. Parks et al. classified fistula-in-ano into four types: intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric, based on the location of the fistula tract relative to the anal sphincter muscle [1]. Treatment options for fistula-in-ano include surgeries like fistulectomy or fistulotomy, and Seton treatment (both chemical and cutting). Seton treatment was first described by Hippocrates, and the use of "chemical" Seton (Ksharasutra) for treating fistula-in-ano is mentioned in ancient Indian texts [2,3]. A Seton is a string-like material placed through the fistula tract to induce an inflammatory reaction, promoting fibrosis that stabilizes, cuts, and prevents sphincter retraction [4]. Complex fistulas, which cross more than 30–50% of the external sphincter, involve multiple tracts, or recur, pose a significant risk to continence [5,6].

The conventional treatment for most fistula-in-ano cases is the lay-open method, which is effective but has drawbacks [7]. Setons have been used for managing anal fistulas for centuries, though they are often discussed in the context of high or complex anal fistulas to avoid fecal incontinence and recurrence [8]. The "lay open" technique has associated drawbacks, including prolonged hospitalization, a high rate of recurrence, and the risk of anal incontinence. Recovery after the procedure can be uncomfortable, often leading to a few days of work loss. On the other hand, Seton application is a relatively straightforward procedure, requiring a shorter hospital stay, less pain, and fewer complications. Additionally, Seton therapy is cost-effective compared to other treatment methods such as fibrin glue, Ligation of Intersphincteric Fistula Tract (LIFT), and collagen plugs, although LIFT has shown promising results [9,10]. This study aimed to compare the management, follow-up, and outcomes of patients treated with fistulectomy versus Seton application for fistula-in-ano at the Department of Surgery, C R Gardi Hospital, Ujjain.

Aim

The study aims to compare the use of Seton and fistulectomy for the management of fistula-in-ano.

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Objectives

1. To evaluate the curative efficiency of Seton versus fistulectomy.
2. To study the outcomes of Seton and fistulectomy with respect to recurrence and incontinence.

MATERIALS AND METHODS

Study Design

This observational comparative study was conducted on 56 adult patients diagnosed with low trans-sphincteric fistula-in-ano undergoing surgical procedures. The study took place between January 2023 and June 2024 in the Department of Surgery at C R Gardi Hospital and R D Medical College Hospital.

Study Population

The study included all patients diagnosed with low trans-sphincteric fistula-in-ano who were admitted for surgery at the participating hospitals during the study period.

Sample Size Calculation

The sample size was calculated to detect a difference in the Visual Analog Scale (VAS) score between the two surgical methods, with a 95% confidence level and a power of 80%. The calculation was based on the following parameters:

- Standard deviation (σ): 4.0
- Expected difference (Δ): 3.0 (3-point difference in VAS score)
- Significance level (α): 0.05
- Power ($1-\beta$): 0.80

The minimum required sample size was determined to be 27 patients per group.

Study Groups

The 56 cases were divided into two groups based on patients' preference:

- **Group A (Seton):** 28 patients
- **Group B (Conventional Fistulectomy):** 28 patients

Inclusion Criteria

- Patients aged between 20 and 65 years with fistula-in-ano
- Patients willing to undergo either Seton or fistulectomy procedures

Exclusion Criteria

- Pediatric or geriatric patients
- Patients unwilling to undergo Seton or fistulectomy
- Patients with preoperative incontinence
- Patients with comorbidities or chronic illnesses affecting the healing process, such as immune system disorders or chronic inflammatory bowel diseases

Methodology

1. **Enrollment**: A total of 56 patients scheduled for surgery for fistula-in-ano were enrolled in the study.
2. **Randomization**: Patients were randomly divided into two groups (min. 27 each) using computer-generated random numbers:
- Group A: Patients were posted for Seton.
- Group B: Patients were posted for conventional fistulectomy.
3. **Outcome Variables**: The following outcomes were assessed:
- Operative time
- Post-operative hospital stay
- Healing time
- Post-operative anal incontinence
- Recurrence (up to 3 months)
- Complications associated with each technique

Statistical Analysis

- **Quantitative Data**: Data were represented as mean ± standard deviation (SD). The t-test was used for analyzing quantitative data.
- **Categorical Data**: Data were expressed in percentages and analyzed using the chi-square test.
- **Significance Level**: A p-value of less than 0.05 was considered statistically significant.

OBSERVATIONS AND RESULTS

The study collected data from 56 cases, with a mean age of 38.96 years and a median age of 40 years, indicating a relatively diverse age range between 20 and 74 years. Age distribution revealed that 32.1% of the cases were aged 30 years or younger, 23.2% were between 31-40 years, 30.4% were between 41-50 years, and 14.3% were over 50 years old.

Table: 1 Cross-Tabulations Between demographic Variables and Study Groups

Variable	Category	Fistulectomy (n, %)	Seton (n, %)	p-value
Age Group	≤ 30 years	11 (40.7%)	7 (24.1%)	>0.05
	31-40 years	6 (22.2%)	7 (24.1%)	
	41-50 years	8 (29.6%)	9 (31.0%)	
	> 50 years	2 (7.4%)	6 (20.7%)	
Gender	Male	22 (81.5%)	23 (79.3%)	>0.05
	Female	5 (18.5%)	6 (20.7%)	
Type of Fistula	High	11 (40.7%)	11 (37.9%)	>0.05
	Low	16 (59.3%)	18 (62.1%)	

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Complaints	Pain (Yes)	19 (70.4%)	23 (79.3%)	>0.05
	Pain (No)	8 (29.6%)	6 (20.7%)	
	Swelling (Yes)	22 (81.5%)	23 (79.3%)	>0.05
	Swelling (No)	5 (18.5%)	6 (20.7%)	
	Discharge (Yes)	23 (85.2%)	27 (93.1%)	>0.05
	Discharge (No)	4 (14.8%)	2 (6.9%)	
External Opening	1 o'clock	9 (33.3%)	4 (13.8%)	>0.05
	12 o'clock	7 (25.9%)	9 (31.0%)	
	2 o'clock	3 (11.1%)	6 (20.7%)	
	3 o'clock	4 (14.8%)	3 (10.3%)	
	5 o'clock	4 (14.8%)	7 (24.1%)	
Duration of Disease	≤ 6 months	7 (25.9%)	11 (37.9%)	>0.05
	7-12 months	19 (70.4%)	17 (58.6%)	
	> 12 months	1 (3.7%)	1 (3.4%)	

The gender distribution was predominantly male, with 80.4% male cases and 19.6% female cases. Most of the cases (60.7%) had low fistulas, while 39.3% had high fistulas. Common complaints included pain (75.0%), swelling (80.4%), and discharge (89.3%), with 42.9% of the operations completed in 60 minutes or less. Disease duration was mostly between 7 and 12 months (64.3%). Postoperative complications at one week showed that 25.0% of the cases experienced pain, while 10.7% had infections and 8.9% experienced incontinence. At the one-month follow-up, 21.4% had recurrence, 21.4% had infections, and 8.9% had incontinence. By the three-month follow-up, recurrence, infection, and incontinence rates were 25.0%, 16.1%, and 16.1%, respectively.

Table: 2 Cross-Tabulations Between clinical Variables and Study Groups

Variable	Category	Fistulectomy (n, %)	Seton (n, %)	p-value
Operating Time	≤ 60 min	8 (29.6%)	16 (55.2%)	<0.05
	61-90 min	8 (29.6%)	11 (37.9%)	
	> 90 min	11 (40.7%)	2 (6.9%)	
Hospital Stay	≤ 1 week	12 (44.4%)	25 (86.2%)	<0.05
	> 1 week	15 (55.6%)	4 (13.8%)	
Healing Days	< 1 month	6 (22.2%)	9 (31.0%)	>0.05
	1-3 months	11 (40.7%)	12 (41.4%)	
	> 3 months	10 (37.0%)	8 (27.6%)	
Complications at 1 Week	Pain (Yes)	6 (22.2%)	8 (27.6%)	<0.05
	Infection (Yes)	4 (14.8%)	2 (6.9%)	<0.05
	Incontinence (Yes)	4 (14.8%)	1 (3.4%)	<0.05
Complications at 1 Month	Pain (Yes)	2 (7.4%)	14 (48.3%)	0.001
	Recurrence (Yes)	9 (33.3%)	3 (10.3%)	0.036
Complications at 3 Months	Incontinence (Yes)	8 (29.6%)	1 (3.4%)	0.008

A statistical analysis of treatment outcomes revealed that neither age, gender, type of fistula, complaints, external opening location, disease duration, nor healing days significantly affected the choice of treatment between Fistulectomy and Seton ($p > 0.05$). However, there were significant differences between the two groups in operating time, hospital stay, and postoperative complications, with Fistulectomy cases having longer operating times and hospital stays compared to Seton cases. The Fistulectomy group also reported higher rates of pain, infection, and incontinence within the first week post-operation, though no cases of recurrence were observed in either group at one week.

DISCUSSION

Fistula-in-ano is an abnormal tract between the anal canal and the perianal area, commonly treated surgically to eradicate the tract and preserve anal sphincter function. Surgical options include fistulotomy/fistulectomy, seton placement, advanced flaps, fistula plugs, fibrin glue, and newer techniques like LIFT, VAAFT, and FILAC. This study compares outcomes between Fistulectomy and Seton placement for treating fistula-in-ano at R.D. Gardi Medical College, Ujjain.

In the present study, most cases were aged 30-50 years, with a mean age of 38.96 years, consistent with findings by Pankaj D et al (11) and Kapoor S et al (12). Male predominance was observed (80.4%), aligning with Akhtar M et al (13). Regarding fistula types, low fistulas (60.7%) were more common, similar to findings by Kapoor S et al (12). Symptoms such as discharge (89.3%) and swelling (80.4%) were prevalent, corroborating results by Pankaj D et al and Kapoor S et al.

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Disease duration was mostly between 7-12 months (64.3%). Operating times varied significantly between groups, with shorter times for Seton placement (42.9% <60 minutes). Hospital stays were shorter for Fistulectomy, while healing times were comparable, consistent with findings by Manjusha L et al (14).

Postoperative outcomes revealed significant differences. One-week follow-ups showed higher infection rates in the Fistulectomy group (24.8%) compared to Seton (10.3%). Pain was more prevalent in the Seton group at one month (48.3%) but lower at three months. Recurrence rates were higher for Fistulectomy at both one month (33.3% vs. 10.3%) and three months (33.3% vs. 17.2%). Incontinence was significantly lower in the Seton group at three months (3.4% vs. 29.6%), supporting findings by Akhtar M et al (13) and Pankaj D et al (11).

CONCLUSION

Seton placement demonstrated advantages in recurrence and incontinence rates, while Fistulectomy offered shorter hospital stays. The choice of treatment should consider fistula type, patient symptoms, and desired outcomes.

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