



COMPARISON BETWEEN CONVENTIONAL AND SPHINCTER-SAVING PROCEDURE (INCLUDING LASERS) IN TREATMENT OF FISTULA-IN-ANO – A PROSPECTIVE, DOUBLE ARM, SINGLE CENTRE, INDIAN STUDY

General Surgery

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ABSTRACT

Background: Sphincter-saving procedures for anal fistula have been seldom assessed compared to conventional procedures. This study addressed this research need gap with respect to outcomes, incontinence, and recurrence rate. **Methodology:** The prospective, comparative, single-center study included patients with history of fistula-in-ano between the age group of 18–60 years of coming to surgical OPD or ward. All patients were subjected to the usual standardized pre-operative and post-operative protocol. The assessment of Cleveland Clinic Florida Fecal incontinence score (CCF-FI) and pain visual analogue score (VAS) was done to evaluate patient outcomes post-surgery. **Results:** 100 fistula-in-ano cases were enrolled and randomized in conventional-surgery group and the sphincter-saving-surgery groups (50 patients each). Baseline patient characteristics were comparable ($p>0.05$). Most patients in both, the conventional fistulectomy group (64%) and sphincter saving group (62%) were having trans-sphincteric type of anal fistula. At all time-points, the mean CCF-FI scores for gas, use of pad for stools, lifestyle alteration, as well as the total CCF-FI scores were comparable between study groups ($p>0.05$). Mean pain VAS score was significantly lower in the sphincter saving group at 2-weeks and 4-weeks post-surgery ($p<0.05$) versus conventional fistulectomy group. 1 patient in conventional fistulectomy group and 3 patients in sphincter-saving group experienced recurrence. **Conclusion:** Based on fecal incontinence status, no difference in outcomes was noted between the conventional and sphincter-saving surgery groups. However, the postoperative pain was noted to be significantly lower in the sphincter saving surgery group. Recurrence rates were low and comparable between both surgery groups.

KEYWORDS

Cleveland Clinic Florida Fecal incontinence score, Visual analogue score, Anal fistula, conventional fistulectomy, sphincter-saving group.

INTRODUCTION

Anal fistula is characterized by a connection between two spaces that is epithelial lined, with one of the two spaces being either the rectum or anus. A per-rectal inflammatory reaction may consequently cause abscess development in the acute phase, and fistula formation may be noted eventually in the chronic phase.¹ According to the scientific literature, the incidence of anal fistula following peri-anal abscess is about 34.5%.² In almost all cases, fistula-in-ano occurs secondary to ano-rectal abscess. Other reasons for fistulae include Crohn's disease, trauma, anal fissures, carcinoma, radiation therapy, Human Immunodeficiency Virus (HIV) as well as chlamydial infections.³ Cases diagnosed with anal fistula are usually adults between 30 and 40 years of age, and the occurrence rate of this disorder in males is greater than females.⁴ Additionally, to severely disturbing the quality of life of cases, anal fistula has also a negative influence on the psychology of patients who frequently suffer from anxiety or depression features. The basis of proper treatment of fistula-in-ano is dependent on exact diagnosis, subsequent to which a surgical intervention of fistula is conducted, conserving the anal continence.⁵

The chief principles of anal fistula treatment are closing of internal opening of fistula tract, drainage of necrotic tissue or infection, and abolition of fistulous tract with conservation of sphincter function.⁶ Studies have shown that high fistulae have low incidence rates. Low fistulae are the most noted anal fistulae and can be managed easily by conventional laying-open technique. High fistula-in-ano are problematic to manage as the conventional laying-open will cause division of majority anal sphincter muscles causing incontinence. To attain the objective in high anal fistulae, different surgical methods have been defined in scientific literature over a period of time. These include Park's fistulotomy, two stage fistulotomy, insertion of a seton, fistulectomy with primary repair of the sphincter, primary fistulectomy with occlusion of the internal ostium, endorectal advancement flaps, repair of fistula using fibrin adhesive glue, anocutaneous advancement flap, and re-routing the fistula.⁷

The average rate of continence disturbance after treatment with a cutting seton is around 12% which rose when the internal opening of fistula tract was placed more proximally.⁸ Consequent to lay open techniques, the frequency of flatus incontinence or liquid stool leakage was noted in around 20–25% patients.⁹ This effect on continence has led to a universally accepted notion that these techniques may be less favourable for complex anal fistulas and the appetite for the usage of minimally invasive techniques is rising. Numerous sphincter-preserving techniques were presented in clinical practice in the last decade or so, with diverse success rates. Few of the new techniques include video-assisted anal fistula treatment (VAAFT), fistula-tract laser closure (FILAC), ligation of inter-sphincteric fistula tract (LIFT), rectal advancement flap (RAF), and combinations of techniques.¹⁰

Literature search revealed that though there are some studies which have evaluated the sphincter-saving procedures, including laser closure, they are mostly non-comparative studies and done as only single-arm retrospective studies. A study by Giamundo et al. in 2014 investigated the safety as well as effectiveness of the new laser closure technique in the treatment of anal fistula. This single arm study concluded that the laser FiLaC™ procedure for fistula-in-ano is a safe, relatively easy, minimally invasive, sphincter-saving procedure with a great chance of success.¹¹ Another retrospective single-arm study published in 2021 by Wolicki et al. concluded that FiLaC® procedure is related with good healing rates in long-term follow-up and must be considered as a treatment possibility for both trans-sphincteric and inter-sphincteric anal fistulae, particularly because of the low complication rate as well as low risk of sphincter injury.¹² Additionally, Indian studies to compare conventional and sphincter sparing surgeries are lacking. Hence, this study was conducted to evaluate the sphincter sparing surgeries, including laser procedures, in fistula-in-ano cases and compare these novel techniques to conventional ones. This will help in creating crucial evidence with regards to the novel surgical techniques in Indian population and help the Indian surgeons in understanding their utility and advantage over conventional procedures.

Methodology

Patient disposition

The present study had a prospective, comparative and interventional design. The study population included male and female patients with history of fistula in ano between the age group of 18 – 60 years of coming to surgical OPD or surgical ward of Apollo hospitals, Navi Mumbai. A total of 100 patients of fistula in ano were enrolled in the study, who were distributed in the conventional-surgery group and the sphincter-saving-surgery study groups (50 patients in each of the study group). These patients were randomized a computer-generated random number table. The same method of randomization was used in a similar study by Vinay et al. and Goudar et al.^{11,12} The table was generated from the following online link : <https://www.graphpad.com/quickcalcs/randomN1/>. Data was collected between July 2020 to June 2022. Patients diagnosed with complex fistula-in-ano, secondary fistula-in-ano because of inflammatory bowel diseases, radiation therapy, extrapulmonary tuberculosis, or anorectal malignancy were excluded. Written informed consent was taken from all enrolled cases in study.

Assessment of patients

A full medical history was noted, and proctoscopy was undertaken to assess the sphincter strength and to exclude associated conditions. The key points noted were the site of the internal opening; the site of the external opening(s); the course of the primary track; the presence of

secondary extensions; and the presence of other conditions complicating the fistula.

Palpable induration between external opening and anal margin suggested a relatively superficial track, whereas supralelevator induration suggested a primary track above the levators or high in the roof of the ischiorectal fossa, or a high secondary extension. Intersphincteric fistulae usually have an external opening close to the anal verge.

Goodsall's rule was used to indicate the likely position of the internal opening according to the position of the external opening(s), is helpful but not infallible. The site of the internal opening was felt in cases as a point of induration or seen as an enlarged papilla.

Full examination under anaesthesia was repeated before surgical intervention. Methylene Blue, instilled via the external opening, was used to demonstrate the site of the internal opening; gentle use of probes and a finger in the anorectum usually delineates primary and secondary tracks and their relations to the sphincters.

Any concerns about fistula topography during clinical examination or examination under anaesthesia was taken into consideration for decision on further investigations before surgical intervention.

All the patients were subjected to routine blood investigations, chest X-ray and ECG prior to surgery. MRI Perineum was performed to delineate fistulae.

Surgical And Post-operative Protocols

The various surgical techniques which were conducted on the patients randomly were fistulotomy, LIFT, VAAFT, fistula laser closure, and Submucosal ligation of fistula tract (SLOFT). All the surgeries were conducted by a single senior surgeon with a vast experience, and he was blinded to the study participants' assessment.

All patients were prescribed an anti-inflammatory analgesic, a pain medication, and a fiber supplement for 1 week postoperatively. Antibiotics were prescribed as per requirement. Diet was not restricted. Patients were instructed to undertake a sitz bath 2 to 3 times a day until the wounds healed. Patients were reviewed in clinics at weeks 2, 4, 16 weeks and annually thereafter.

Surgical outcome assessment

Preoperative and postoperative incontinence scores were assessed using the Cleveland Clinic Florida Faecal Incontinence score (CCF-FI) (Table 1). The post-operative pain was measured with help of VAS score immediately post-operatively, at week 2, week 4 and week 16, and compared with the pre-operative mean VAS score in the study groups. A VAS Scale with a 10 cm vertical score ranged from “no pain” to “worst possible pain” was used to assess the pain at the necessary time-points (Figure 1). Complications were also noted in both the study groups, along with recurrence rates for fistula-in-ano.

Table 1: Cleveland Clinic Florida Faecal Incontinence Score¹³

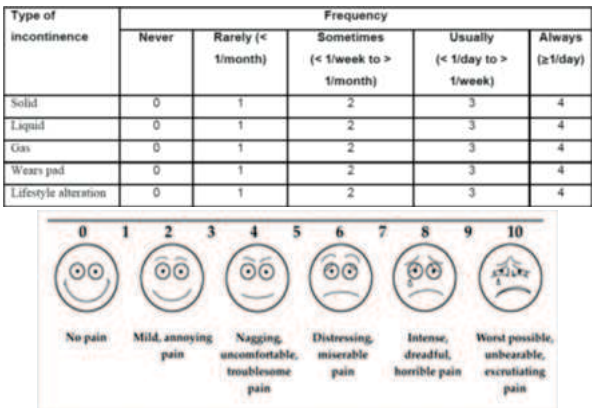


Figure 1: Visual Analogue Scale (VAS) for assessment of Pain

Statistical Analysis

Data entry was done in a Microsoft Excel sheet by a blinded surgery resident doctor. Data analysis was done with the help of statistical software Graphpad InStat.v3.0 Quantitative data (age, duration of

surgery, VAS scores etc.) was presented with the help of Mean and Standard deviation. Comparison of CCF-FI, VAS scores at various time-points between groups was done using unpaired t test. Intragroup analysis for change in pain VAS score and CCF-FI was assessed was done using ANOVA for repeated measures. Comparison of complications and other discrete variables between the study groups was done using Chi-square test. P value of less than 0.05 was considered to be statistically significant.

RESULTS

Demographic and baseline details

A total of 100 patients of fistula-in-ano were enrolled in the study, 50 were managed by conventional fistulectomy while 50 patients were managed by sphincter-saving surgery. The mean age as well as the gender distribution were comparable between the study groups (p>0.05). The age distribution showed that majority of the patients in both the study groups were belonging to the 31-40 years' age group (38% in Conventional surgery group and 36% in sphincter sparing group), followed by 32% of cases each in the age group of 41-50 years' age group. Majority of patients in both, the conventional fistulectomy group (72%) and sphincter saving group (76%) were having no comorbidity. Table 2 gives details of demographic and baseline characteristics in study groups.

Table 2: Demographic and baseline details of enrolled cases (n=100)			
	Conventional fistulectomy (n=50)	Sphincter saving surgery (n=50)	P Value
Mean age (years)	40.42 ± 10.41	39.52 ± 8.79	0.59 [†]
Median age with range (years)	40 (23-63)	39 (24-58)	-
Gender distribution			
Number of males (%)	40 (80%)	37 (74%)	0.63 [§]
Number of females (%)	10 (20%)	13 (26%)	
Age distribution			
18-30 years	7 (14%)	11 (22%)	0.43 [§]
31-40 years	19 (38%)	18 (36%)	0.84 [§]
41-50 years	16 (32%)	16 (32%)	1 [§]
>50 years	8 (16%)	5 (10%)	0.55 [§]
Comorbidities			
DM	4 (8%)	2 (4%)	0.67 [§]
HTN	5 (10%)	6 (12%)	0.75 [§]
Both DM and HTN	5 (10%)	4 (8%)	0.73 [§]
Unknown / No comorbidity	36 (72%)	38 (76%)	0.82 [§]
Type of anal fistula			
Inter-sphincteric	16 (32%)	19 (38%)	0.67 [§]
Trans-sphincteric	32 (64%)	31 (62%)	0.84 [§]
Supra-sphincteric	4 (8%)	0	0.13 [§]

P>0.05 considered NOT significant by [†]Unpaired t test or [§]Chi-square test.

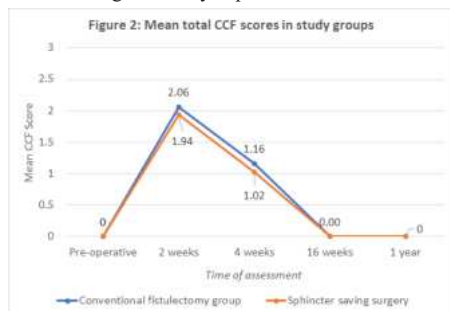
CCF scores for fecal incontinence

The mean CCF-FI solid score was significantly lower in the sphincter saving group (p<0.05) at 4-weeks after surgery, while the mean CCF-FI liquid score was significantly lower in the sphincter saving group (p<0.05) at 2-weeks post-surgery. The mean CCF-FI (gas) scores, mean CCF-FI (use of pads for stool) scores and mean CCF-FI (lifestyle alteration) scores were comparable between study groups (p>0.05). The mean total CCF-FI scores were comparable between study groups (p>0.05). Table 3 below gives the mean values for CCF-FI scores in study groups, while figure 2 shows the mean total CCF scores trend in study groups.

Table 3: CCF-FI scores noted in study groups				
Type of CCF score	Time of assessment	Conventional fistulectomy group (n=50)	Sphincter sparing group (n=50)	P value
CCF-FI (Solid)	Pre-operative	0	0	-
	2 weeks post-op	0.32 ± 0.21	0.3 ± 0.23	0.68
	4 weeks post-op	0.38 ± 0.37	0.14 ± 0.18	0.01*
	16 weeks post-op	0	0	-
	1 year-post-op	0	0	-
CCF-FI (Gas)	Pre-operative	0	0	-
	2 weeks post-op	0.46 ± 0.61	0.44 ± 0.48	0.59
	4 weeks post-op	0.12 ± 0.29	0.16 ± 0.31	0.48
	16 weeks post-op	0	0	-
	1 year-post-op	0	0	-

CCF-FI (Use of pads for stool)	Pre-operative	0	0	-
	2 weeks post-op	0.52 ± 0.84	0.62 ± 0.7	0.23
	4 weeks post-op	0.3 ± 0.45	0.26 ± 0.56	0.57
	16 weeks post-op	0	0	-
	1 year-post-op	0	0	-
CCF-FI (lifestyle alteration)	Pre-operative	0	0	-
	2 weeks post-op	0.22 ± 0.41	0.24 ± 0.42	0.73
	4 weeks post-op	0.18 ± 0.29	0.2 ± 0.3	0.61
	16 weeks post-op	0	0	-
	1 year-post-op	0	0	-
Total CCF-FI scores	Pre-operative	0	0	-
	2 weeks post-op	2.06 ± 1.39	1.94 ± 1.45	0.12
	4 weeks post-op	1.16 ± 0.94	1.02 ± 1.01	0.18
	16 weeks post-op	0	0	-
	1 year-post-op	0	0	-

P<0.05 considered significant by unpaired t test

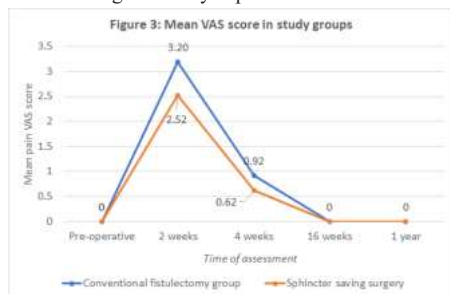


Pain VAS Scores

The mean pain VAS score was significantly lower in the sphincter saving group at 2-weeks and 4-weeks post-op ($p<0.05$) as compared to conventional fistulectomy group (Table 4, figure 3).

Time of assessment	Conventional fistulectomy group (n=50)	Sphincter sparing group (n=50)	P value
Pre-operative	0	0	-
2 weeks post-op	3.2 ± 1.03	2.52 ± 0.8	0.01*
4 weeks post-op	0.92 ± 0.76	0.62 ± 0.51	0.03*
16 weeks post-op	0	0	-
1 year-post-op	0	0	-

P<0.05 considered significant by unpaired t test



Recurrence Rate

1 patient in conventional fistulectomy group and 3 patients in sphincter saving group experienced recurrence. However, no statistical difference was noted between the study groups ($p>0.05$).

DISCUSSION

Present study was conducted to evaluate the sphincter sparing surgeries, including laser procedures, in fistula-in-ano cases and compare these novel techniques to conventional ones in Indian context. Both, high and low anal fistula, were enrolled in the study to get a holistic view on the management outcomes in all fistula cases. The CCF-FI is one of the most used scoring systems globally to help patients assess severity with their doctors. By using the scoring system, we tried to get a universal view of all aspects of fecal incontinence, and the overall impact on the incontinence was assessed by evaluating the total CCF-FI score.¹⁴

Most of the patients belonged to 31-40 years' age group, followed by

41-50 years; majority being males. This finding was in sync with literature, which noted that cases diagnosed with anal fistula are usually adults between 30 and 40 years of age, and the occurrence rate of this disorder in males is greater than females.⁴

The mean total CCF-FI scores were all noted to be comparable between the conventional fistulectomy group and the sphincter sparing surgery group ($p>0.05$). This indicates that there was no difference in the continence status of both the study groups at any time-points. However, the mean pain VAS score was significantly lower in the sphincter saving group at 2-weeks and 4-weeks post-op ($p<0.05$) as compared to conventional fistulectomy group. This indicates that the post-operative pain was significantly lower in the sphincter-saving surgery group post-operatively till the 4-weeks period, however after that both the study groups had similar pain outcomes. No complications were noted in present study in either of the study groups. In the study by Alapach et al., lower incontinence rates in sphincter-sparing surgery group versus conventional group (2.1% versus 16.2%) but the overall significance was not established in the findings.¹⁵ In the single arm non-comparative study by Kang et al., successful fistula closure was attained with sphincter saving procedure in 3/4th cases, and none developed fecal incontinence features.¹⁶ Ramachandra et al. concluded that postoperative pain more in seton placement group versus sphincter-sparing LIFT procedure, a finding similar to our study.¹⁷ No post-operative complication in LIFT surgery group was noted in the study, again finding similar to our study. In the study by Goudar et al., sphincter-sparing surgery group had lower pain scores on POD 1, 3 and 7 owing to patient tolerance and satisfaction, a finding replicated in our study.¹² Wexner incontinence scale showed no incontinence in LIFT and incontinence seen in 3 (10%) patients in conventional surgery group in the study. In the study by Sebai et al., mean VAS was significantly higher in conventional surgery group (5.7) compared to the sphincter-sparing surgery group (3.3), identical to our study findings.¹⁸

The recurrence rate in our study was comparable between conventional fistulectomy group and the sphincter-saving surgery group. Most of the other studies also did not show any significant difference statistically between the study groups when it comes to recurrence findings (Table 5).

Study	Recurrence in conventional group	Sphincter saving surgery group
Present study	2%	6%
Vinay et al. (2017) ¹¹	0%	12%
Kang et al. (2018) ¹⁶	-	18%
Ramachandra et al. (2018) ¹⁷	25%	15%
Goudar et al. (2021) ¹²	0%	6.7%
Sebai et al. (2021) ¹⁸	6.7%	20%

The study did have a few limitations. The sample size was limited as study was conducted at only one study centre. In addition, follow-up was possible till 1 year due to duration constraints. Future Indian studies with larger sample size, multiple centre study design and longer follow-up can help validate our study findings in a better way.

CONCLUSION

Based on fecal incontinence status, no difference in outcomes was noted between the conventional fistulectomy group and sphincter saving surgery group. However, the postoperative pain was noted to be significantly lower in the sphincter saving surgery group versus the conventional fistulectomy group. Recurrence rates were low and comparable in both the types of surgery.

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