

Original Research Paper

General Surgery

COMPARATIVE STUDY BETWEEN LIFT PROCEDURE VERSUS SETON PLACEMENT IN THE MANAGEMENT OF FISTULA IN ANO

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ABSTRACT INTRODUCTION: A fistula-in-ano, is a chronic abnormal communication, usually lined by granulation tissue, which runs outwards from the anorectal lumen. The standards of anal fistula surgery are to obliterate the fistula, prevent recurrence and maintain sphincter work. Ligation of Intersphincteric Fistula Tract (LIFT) is the most promising surgical technique based on secure closure of the internal opening and removal of the infected crypto glandular tissue through intersphincteric approach. AIMS: To compare the effectiveness of LIFT over SETON procedure based on Postoperative pain on day 1 and2, Short term recurrence, Healing, Procedural visits PATIENTS AND METHODS: A prospective, single centered, interventional study in 60 patients with fistula-in-ano admitted to general surgical wards in Narayana Medical College and Hospital, Nellore. From November 2018 to November 2020. Patients were divided into two groups, group A including patients undergoing LIFT procedure and group B, including patients undergoing SETON placement of Fistula-in- ano. RESULTS: Maximum patients were in 41-60 years in the LIFT Group 18(60%), 51-60 years in the SETON group 12(40%). Maximum patients were male 21 in each group (70%), and female were 9 in each group (30%). In the present study, Visual Analog Scale (0,1,2,3) in LIFT group on POD 1, were 2, 20, 6, 2 and in SETON group on POD 1 were 0, 9, 16, 5 respectively. Similarly, visual analogue scale (0,1,2,3) in LIFT group on POD 2, were 19.8.3.0 and in SETON group on POD 2 were 5, 20, 5, Orespectively. Patients who underwent LIFT procedure had a satisfactory postoperative period and the wound healed in all the cases. CONCLUSION: we conclude that LIFT gives good outcomes in terms of Postoperative pain on day 1 and 2, wound healing rate, single time procedure and recurrence during our short follow-up period of 6 months.

KEYWORDS: Fistula In Ano, Seton, LIFT, Recurrence

INTRODUCTION

A fistula-in-ano,¹ or anal fistula, is a chronic abnormal communication, usually lined by granulation tissue, which runs outwards from the anorectal lumen, i.e., the internal opening to an external opening over the skin of the perineum or buttock (or rarely, in women, to the vagina). It is sometimes present in specific conditions, like tuberculosis, actinomycosis, Crohn's disease, lymphogranuloma venereum, rectal duplication, foreign body, and malignancy (Colorectal carcinoma). But a majority of them are nonspecific, or cryptoglandular. Intersphincteric anal gland infection is a common aetiology.

The standards of anal fistula surgery are to obliterate the fistula, prevent recurrence and maintain sphincter work 2,3 . Many alternative therapeutic procedures have been followed to maintain the sphincter components such as setons, infill substances such as fibrin glue or collagen plug and the rectal mucosal advancement flap 4,5 .

For several decades, seton has been practised to manage anal fistula; though, in the literature, setons were principally used just for the high or complex anal fistula to avoid faecal incontinence and recurrence⁶. Currently, several materials have been used as setons, like silk, braided silk, rubber band, silastic tube, linen, proline, braided polyester, vascular loop, nylon, cable tie, and others⁷. The reported incontinence and recurrence rate varies from 0-62% and 0-16%, respectively, with different materials used as seton. There is a continuous demand to decrease the complications associated with the use of seton. The most common weak points of this technique are the high incontinence rates, prolonged discharge and numerous visits to check and adjust the seton. The tight (cutting) seton is any string-like material which when passed and tied within the fistula track develops gradual transection of the external sphincter muscle due to pressure necrosis with a minor splitting of the cut ends. In this way, it preserves sphincter continuity during the cutting process10.

Ligation of Intersphincteric Fistula Tract (LIFT) is the most promising surgical technique based on secure closure of the internal opening and removal of the infected crypto glandular tissue through intersphincteric approach. This procedure is simple, safe, and minimally invasive. It is also useful with a high and rapid healing rate without any resultant incontinence. It is now widely adopted because of satisfactory early results.

Hence this study is designed to confirm the admirable effects of LIFT procedure over Seton.

AIMS AND OBJECTIVES OF THE STUDY

To compare the effectiveness of LIFT over SETON procedure based on

- Postoperative pain on day 1 and 2
- · Short term recurrence
- · Healing
- · Procedural visits

PATIENTS AND METHODS

A prospective, single centered, interventional study was done in patients with fistula-in-ano admitted to general surgical wards of Narayana Medical College and Hospital, Nellore.

Source of patients: Those patients with fistula in intervals admitted to Narayana Medical College and Hospital's general surgical wards are taken up for study.

Study period: November 2018 to November 2020.

Study sample: 60 cases with fistula-in-ano.

Inclusion Criteria:

- a. All the patients above 20 years of age
- b. All the patients presenting with primary fistula-in-ano.
- c. All patients with transphincteric Fistula only.
- d. Patients with a single fistula opening.

Exclusion criteria:

- a. Children below 20 years of age, pregnant patients
- b. Patients did not fit for surgery and anaesthesia.
- c. Patients who have not given consent for surgery.
- Recurrent fistulae, with diseases like tuberculosis, Crohn's and anorectal malignancies present with multiple perianal fistulous openings, with immune-suppressed conditions.

e. Patients with high fistula-in-ano

The plan of study submitted to the hospital ethics committee and their approval obtained.

Method of data collection:

Patients satisfying inclusion and exclusion criteria selected for the study after obtaining informed and written consent. Demographic data like age, sex, name, occupation noted, clinical symptoms of presentation with duration, associated complaints, past medical and surgical history, personal and family history will be noted.

Examination findings on DRE, proctoscopy, and investigations like total counts, Xray fistulography findings will be noted. Patients were divided into two groups, group A including patients undergoing LIFT procedure and group B, including patients undergoing SETON placement of Fistula-in- ano. Patients allocated into groups by random allocation technique.

All patients were taken up for concerned procedures under spinal anaesthesia after obtaining fitness — single-dose of preoperative antibiotics given to all patients.

The outcomes of surgery assessed postoperatively. Visual analogue scale (VAS) is used to assess subjective pain on the first and second postoperative days and documented. The Visual Analogue Scale ranged from 0 to 5, where five stands for worst pain ever faced, and 0 stands for no pain. After discharge, all patients were followed once a month for six months and assessed for recurrence. All patients were assessed for any persistent fistula postoperatively.

STATISTICS

Data collected were entered in Microsoft Excel and analyzed using SPSS -22.0. Mean and percentages, Standard Deviation was used for descriptive analysis. Significance of difference is measured using p-value, tvalue.

OBSERVATIONS AND RESULTS TABLE NO 1: AGE DISTRIBUTION IN THE STUDY

Age in	L	IFT	SETON		
years	No of	Percentage	No of	Percentage	
	patients		patients		
13-20	0	0	0	0	
21-30	0	0	0	0	
31-40	5	16.7	4	13.3	
41-50	9	30	8	26.7	
51-60	9	30	12	40	
>60	7	23.3	6	20	
Total	30	100	30	100	

TABLE NO 2: SEX DISTRIBUTION IN THE STUDY

Sex	LIFT	SETON	Total
Male	21 (70%)	21 (70%)	42
Female	9 (30%)	9 (30%)	18
Total	30	30	60

TABLE NO 3: SCORE ON VAS SCALE IN THE STUDY

VAS	LIFT		SETON	
	POD 1	POD 2	POD 1	POD 2
Score 0	2	19	0	5
Score 1	20	8	9	20
Score 2	6	3	16	5
Score 3	2	0	5	0

TABLE NO 4: COMPARISON OF POSTOPERATIVE CRITERIA IN THE STUDY

Criteria		LIFT	SETON
Patient Satisfaction	Comfort	30	0
	Discomfort	0	30

Healing	Healing Healed		24 (80%)
Persistent		0	6 (20%)
Recurrence at 1	0	0	
Recurrence at 3	1 (3.3%)	3 (10%)	
Recurrence at 6	1 (3.3%)	3 (10%)	
Incontinen	0	0	

TABLE NO 5: DESCRIPTIVE STATISTICS FOR LIFT PROCEDURE

Variables		N	Minimum	Maximum	Mean	Std.
						Deviation
A	ge	30	35	74.00	52.0000	10.64797
VAS	POD 1	30	.00	3.00	1.2667	.69149
	POD 2	30	.00	2.00	.4667	.68145
Pat	tient	30	1.00	1.00	1.0000	.00000
Disco	omfort					
Hospi	tal stay	30	3.00	5.00	3.3000	.65126

In the present study, the mean age in the LIFT procedure was 52, with an SD of 10.647.

Mean VAS on POD 1 was 1.266, on POD 2 was 0.466 with an SD of 0.69 and 0.68 respectively. Mean hospital stay was 3.3, with an SD of 0.65.

TABLE NO 6: DESCRIPTIVE STATISTICS FOR SETON PROCEDURE

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Variables		N	Minimum	Maximum	Mean	Std.
						Deviation
Αç	ge	30	35.00	77.00	52.8000	10.35374
VAS	POD 1	1.00	3.00	1.8667	.68145	.69149
	POD 2	.00	2.00	1.0000	.58722	.68145
Pat	ient	30	2.00	5.00	3.0000	.58722
Disco	mfort					
Hospit	al stay	30	2.00	7.00	3.7333	1.04826

In the present study, the mean age in SETON procedure was 52.8, with an SD of 10.353.

Mean VAS on POD 1 was 1.866 and, on POD 2 was 1.000, with an SD of 0.69 and 0.68 respectively. Mean hospital stay was 3.73, with an SD of 1.048.

TABLE NO 7: INFERENTIAL STATISTICS

	Group	N	Mean	Std.	t-value	p-value	
				Deviation			
Age	LIFT	30	52.0000	10.64797	-0.295	>0.05	
	SETON	30	52.8000	10.35374			
POD 1	LIFT	30	1.2667	.69149	-3.385	0.001 S	
	SETON	30	1.8667	.68145			
POD 2	LIFT	30	.4667	.68145	-3.247	0.002 S	
	SETON	30	1.0000	.58722			
Discomfort	LIFT	30	1.0000	.00000	-18.655	0.000 S	
visits	SETON	30	3.0000	.58722			
Hospital	LIFT	30	3.3000	.65126	-1.923	0.059	
stay	SETON	30	3.7333	1.04826			

In this study, the mean age in LIFT procedure was 52 and in SETON procedure was 52.8 with a p-value of >0.05 (Not Significant). Mean VAS scale on POD 1 in LIFT versus SETON was 1.266 and 1.866 with a p-value of 0.001 (significant). Mean VAS scale on POD 2 in LIFT versus SETON was 0.466 and 1.00 with a p-value of 0.002 (significant). Mean discomfort visits in LIFT was 1.00 and in SETON was 3.00 with a p-value of 0.00 (significant). Mean hospital stay in LIFT was 3.30 and in SETON was 3.73 with a p-value of 0.059 (Not significant).

TABLE NO 8: CROSSTAB FOR SEX

Sex	LIFT	SETON	Total				
Male	21 (70%)	21 (70%)	42				
Female	9 (30%)	9 (30%)	18				
Total	30	30	60				
	p = 0.05 not significant						

In the present study, maximum patients were male 21 in each group (70%), and female were 9 in each group (30%) with a p-value of 0.05 (Not significant).

TABLE NO 9: CROSSTAB FOR POSTOPERATIVE EVENTS

Crite	eriα	LIFT	SETON	P-value
Patient	Comfort	30	0	<0.0001S
Satisfaction	Discomfort	0	30	
Healing Healed		30	24 (80%)	0.010 S
	Persistent	0	6 (20%)	
Recurrence	at 1 month	0	0	
Recurrence at 3 months		1 (3.3%)	3 (10%)	>0.05NS
Recurrence	at 6 months	1 (3.3%)	3 (10%)	>0.05NS
Inconti	nence	0	0	

In this study, there was a significant statistical difference in both the groups inferring LIFT procedure was a better option in terms of patient satisfaction and healing. There were recurrences in the follow-up period in both the groups, but it was statistically not significant.

DISCUSSION

Age incidence:

In this present study, maximum patients were in 41-60 years in the LIFT group 18 (60%), with mean age group 50.5 years. In a study by Michel Romaniszyn et al., 11 , the mean age of the study group was 45.9 years. In the study by Dushyant Kumar Rohit et al., 12 the ages of the patients ranged from21-56. In the present study, maximum patients were in 51-60 years in the SETON group 12 (40%), with a mean age of 55.5 years. In a study done by M Noor et al., 13 operated on 57 patients of fistula-in-ano with seton, the patients mean age was 38.2 ± 6.8 years.

Sex incidence:

In this study, maximum patients were male 21 in each group (70%), and female were 9 in each group (30%) In a study by Michel Romaniszyn et al. 11 study group consisted of 13 males and one female. The study by Dushyant Kumar Rohit et al. 12 consisted of 14 males (87.5%) and 02 females (12.5%). In a study done by M Noor et al., 13 on 57 patients of fistula-in-ano with seton during 46 (80.7%) were males, and 11(19.3%) were female.

Postoperative pain:

In this study mean VAS with LIFT procedure on POD 1 was 1.266, and on POD 2 was 0.466, with an SD of 0.69 and 0.68 respectively, and with SETON procedure on POD 1 was 1.866 and on POD 2 was 1.000 with an SD of 0.69 and 0.68 respectively. Postoperative pain was assessed using a visual analogue scale, represented by a straight-line measuring 10cms, the extremes of which correspond to no pain at one end and worst at the other end. In the study by Yansong Xu and Welzhohong Tang¹⁴, two patients had persistent pain. Patients were assessed on 1st and 5th post operative day in the morning, and as per results, it was observed that post-op pain gradually decreased.

Duration of hospital stay:

In this study, mean hospital stay after LIFT procedure was 3.3 with an SD of 0.65. In the study by Yansong Xu And Welzhohong Tang, 14 the postoperative hospital stays ranged from 1-4 days with a mean of 2 days. In this study, Mean hospital stay after SETON procedure was 3.73 with an SD of 1.048. In a study done by Ashish Kharadi et al 15 . in the analysis of the management of fistula-in-ano Seton placement was associated with the maximum duration of postoperative hospital stay (average 14.2 days)

Recurrence:

Initially, LIFT had a success rate of 40% and with subsequent surgical treatment 75%. Recurrence after LIFT is related to the height of the internal fistula opening and is associated with

diminished quality of life. ¹⁶ In the present study, following the LIFT procedure, there was no recurrence at one month follow up, but one patient showed recurrence at 3^{rd} month and 6^{th} month follow-up respectively. In studies of Yassin et al. and Liu et al., mean follow up was at 19 and 28 months, and the recurrence rate was 36% and 32%, respectively. In the study by Caroline Sauter Dalbem et al., ¹⁷ the mean follow up was for 14, and the recurrence rate was 23%. In the present study, following SETON procedure, there was no recurrence at one month follow up, but three patients showed recurrence at 3^{rd} month and 6^{th} -month follow-up respectively. In a study done by M Nooretal., ¹³ operated on 57 patients of fistula-in-ano with seton, recurrence was found in 4 (7%) patients.

Incontinence:

In the present study, both groups (LIFT and SETON) showed no incontinence. In a study done by Dalbem CS, et al. Assessment of LIFT (ligation of the intersphincteric fistula tract) technique in patients with perianal transsphincteric fistulas, out of 22 patients treated with LIFT, one female patient developed mild faecal incontinence. In a study done by Mahammad Ali Sutar, 18 Role of Seton in the management of Fistula-in ano, Two out of 66 patients (3.0%) were observed as having incontinence, and one patient having transient stool incontinence and one had gas incontinence.

CONCLUSION

Based on the results of our study in 60 patients comparing the efficacy of LIFT Verses SETON procedure for fistula in ano, the LIFT procedure can be considered as an effective sphinctersparing technique in the management of transsphincteric fistula with an acceptable long-term outcome with minimal discomfort to the patient and effective wound healing than seton placement which needs multiple visits and discomfort due to the presence of suture material.

Hence, we conclude that LIFT gives good outcomes in terms of Postoperative pain on day 1 and 2, wound healing rate, single time procedure and recurrence during our short follow-up period of 6 months.

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