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Original Research Article

A comparative study of Ligation of Intesphincteric Fistula Tract versus conventional fistulectomy in management of low fistula in ano: a randomized control trial

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ABSTRACT

Background: Fistula in ano (FIA) is a chronic complex condition of ano-rectal sepsis characterized by cylical-pain and intermittent chronic purulent discharge. The management of fistula is challenging. In spite of all the advances in the management of FIA, no single method is univresally applicable to all types of FIA due to incontinence and recurrences associated with the individual procedures.
Methods: Aims of this study were to compare the outcomes between ligation of intersphincteric fistula tract (LIFT) and conventional fistulectomy (CF) with 60 patients randomized into 2 groups, 30 in each group.
Results: Mean age in LIFT was 44.17 years and in CF was 41.1 years. Successful primary healing was observed in 86.7% of LIFT and 100% of CF. Mean pain scores were lower in LIFT compared to CF when checked on Postoperative days 1, 3 and 7 significantly. Anal incontinence was seen in 10% of CF and none in LIFT and recurrence was seen at same site in LIFT in 6.66% of LIFT and none in CF both being not statistically significant.
Conclusions: LIFT is a promising and sphincter saving technique which is simple and easy to learn with faster healing rates and better patient contentment but with risk of failure and recurrence. Modifications of LIFT have to be probed for minimizing the failures.

Keywords: Conventional fistulectomy, Fistula in ano, LIFT, Ligation of intersphincteric fistula tract

INTRODUCTION

Fistula in ano (FIA) is a chronic condition of ano-rectal sepsis characterized by cylical pain and chronic purulent discharge. It usually starts with abscess re-accumulation and then continues as repeated episodes of intermittent spontaneous decompression.[1,2] This condition does not heal spontaneously because of the persistent closed sepsis within the fistula tract constantly entering through its internal opening.[3] Considering the complexity of underlying disease and the recurrence of the condition, the management of fistula is challenging and not satisfactory in many cases as it is rightly said that most of the reputations of great surgeons are lost in the management of fistula in ano than in any surgery.[4]

The main aims of management of FIA are- to cure the fistula, to prevent or minimize the recurrence and to retain the continence.[5-7]

In spite of all the advances and the developments in the management of FIA, no single method is applicable to all the FIA due to the complexity and the chronicity of the condition and also the healing rate, incontinence and recurrences associated with the individual procedures.[8]

This study was done to compare the effectiveness of ligation of intersphincteric fistula tract (LIFT) compared to conventional fistulectomy (CF).

METHODS

Aims of the study

The aims of this study were to compare the outcomes between ligation of intersphincteric fistula tract (LIFT) and conventional fistulectomy (CF).

Methods

A prospective study was conducted between January 2019 and June 2020 at S. Nijalingappa Medical College and Hanagal Shri Kumareshwara Hospital and Research Centre, Bagalkot, Karnataka.

Total 60 cases were randomized by a computer generated software into 2 groups of 30 patients each. Group A 30 patients undergoing LIFT and Group B 30 patients undergoing CF.

Inclusion criteria

Age more than 18 years of both genders; patient willing to give informed consent; patients with low fistula in ano

Exclusion criteria

Patients with comorbid conditions like immuno-compromised patients, patients on cancer chemotherapy, immunotherapy and on long term steroids; fistula in ano associated with inflammatory bowel disease, TB and malignancy; patients with high fistula in ano.

After obtaining approval and clearance from the SNMC Institutional Ethics Committee on Human Subjects Research, the patients fulfilling the inclusion criteria were enrolled for the study after obtaining informed consent. Detailed History is obtained and thorough clinical examination is done. Radiological investigations like x-ray fistulogram and MR fistulogram was done in selected patients. In all cases, bowel preparation in the form of enema is given on the prior night and early morning of the day of surgery.

In the group A (cases), FIA was treated with LIFT. In the group B (controls), FIA was treated with CF.

A specific structural pro-forma was used to collect the information for individual cases. Patients were asked to answer the questionnaire and patients were also observed for immediate post-operative complications like pain and healing time and followed up for late complications like anal incontinence and recurrence. All the patients were followed for a period for 12 weeks.

Statistical analysis

Categorical data was represented in the form of frequency and percentage. Association between variables were assessed with Chi Square test, Fisher's Exact test was applied where the cell value was small for the 2 × 2 tables. Quantitative data was represented as mean and SD. Comparison of variables been done with Unpaired t test. Intra group comparison done with paired t test. P value of <0.05 was considered statistically significant.

Data was analyzed with IBM SPSS version 22 for windows.

Procedure

Ligation of intersphincteric fistula tract

Under spinal anesthesia patient was put in lithotomy position. Internal opening was identified by injecting dye through the external opening. Incision was made at the intersphincteric groove and dissected along the intersphincteric plane using artery forceps until the intersphincteric fistulous tract was identified. The intersphincteric tract was identified and hooked out. The tract was suture ligated using absorbable suture material and the fistula tract divided. From the external opening curette was passed up to the ligature and curettage was done. Intersphincteric wound was closed (Figure 1).

Figure 1: Fistula tract in intersphincteric space in LIFT.

RESULTS

The mean age in LIFT was 44.17 years and in CF was 41.1 years. As only intersphincteric and low trans-sphincteric fistulae were included in the study there were 22 intersphincteric out of which 9 underwent LIFT and 13 underwent CF and 38 were low trans-sphincteric fistulae, of which 21 underwent LIFT and 17 underwent CF.

Pain scores were taken on evening of the day of the surgery i.e. post-operative day (POD) 0 and on post-operative days 1, 3 and 7 using Wong Baker pain VAS. The mean pain score on POD 0 was 7.23±1.25 for LIFT and 7.07±1.31 for CF with a p=0.616 which was not statistically significant. Mean pain scores on POD 1 were 5.73±1.2 and 6.37±1.2, on POD 3 were 3.0±1.0 and 4.43±0.86 and on POD 7 were 1.90±0.76, and 2.87±0.97

for LIFT and for CF respectively. Pain scores on POD 1 had p=0.04 which was statistically significantly and on POD 3 and POD 7 the p value was p=0.001 and p=0.001 respectively which was highly significant statistically concluding that LIFT had better pain scores on POD 1, 3 and 7 owing to patient tolerance and satisfaction (Table 1).

Table 1: Post-operative pain scores-Wong Baker's VAS.

Pain post-operative day (POD)	LIFT (mean scores)	CF (mean scores)	Unpaired t test	
			T value	P value
POD 0	7.23±1.25	7.07±1.31	0.504	0.616
POD 1	5.73±1.2	6.37±1.2	2.1	0.04
POD 3	3.2±1.0	4.43±0.86	5.14	0.001
POD 7	1.90±0.76	2.87±0.97	4.29	0.001

Anal incontinence when checked after 1 week using Wexner incontinence scale showed that no incontinence was observed in LIFT and incontinence was seen in 3 (10%) patients in CF. Of the 3, 2 had incontinence usually to gas with Wexner score of 3 and 1 had incontinence always to gas and rarely to liquids with Wexner score of 5. After first post-operative week (POW) the statistical analysis for incontinence gave p=0.119 which was not statistically significant. The patients were encouraged to do Kegel's exercises and increase the sphincter tone by voluntarily contracting and relaxing sphincter repeatedly and were followed after 4 weeks postoperatively and all had developed perfect continence by the end of 4 weeks (Table 2).

Table 2: Anal incontinence.

Anal incontinence		LIFT		CF		Total	Fisher's exact test
		N	%	N	%		
At post op 1 week	Perfect continence	30	100	27	90	57	p<0.119
	Incontinence	0	0	3	10	3	
At post op 4 week	Perfect continence	30	100	30	100	60	
	Incontinence	0	0	0	0	0	

Table 3: Recurrence.

Recurrence	LIFT		CF		Total	Fisher's exact test
	N	%	N	%		
Absent	28	93.3	30	100	58	p<0.246
Present	2	6.7	0	0	2	

Recurrence was seen in 2 (6.66%) patients of LIFT, 1 at POW 10 and another at POW 12 with external opening at same. These patients underwent further CF and were relieved of the symptoms. The statistical analysis gave p=0.246 which was not significant (Table 3).

Successful primary healing was seen in 26 patients (86.7%) of LIFT and all 30 patients (100%) of CF (Table 4). Out of the 4 unhealed LIFT, 2 presented as intersphincteric tracts with external opening at the intersphincteric incision site, 1 presented as a blind sinus with external opening at the original site and 1 presented as the same original tract probably due to slippage of the ligature and presence of the original internal and external opening. No failures were seen in CF as the whole tract was removed. All the 4 failures of LIFT underwent additional procedure and the whole of the tract was removed in the 2 intersphincteric and the original tract remnant by CF whereas the blind sinus remnant underwent laying open of the tract up to external sphincter and curettage of the tract. The mean healing time in LIFT was 2.9 weeks and the mean healing time in CF was 6.3 weeks which had a p<0.001 and was statistically significant concluding LIFT had faster healing rates than CF.

Table 4: Primary healing.

Primary healing	LIFT		CF		Total
	N	%	N	%	
Absent	4	13.3	0	0	4
Present	26	86.7	30	100	56
Total	30	100	30	100	60

Chi square test =4.29 , p<0.03

DISCUSSION

FIA is a chronic callous condition showing no signs towards self-healing on itself. 90% of all FIA occur as anorectal abscess as a result of progression of cryptoglandular infection of the anal glands which are distributed around the circumference of dentate line with a posterior predominance.[2,9-13] The anal crypt gland penetrates the anal sphincter to varying degrees and if it gets obstructed, infection will ensue and the suppuration will trickle down the path of least resistance which determines the location of abscess and the type of fistula.[5]

Due to the complexity of the disease the management of FIA is not only challenging but also not satisfactory in many cases. Though there have been a number of old and new techniques, none can be universally accepted for all the types of fistulae. The sphincter sacrificing procedures like fistulotomy or fistulectomy have a very good result but have a high risk of incontinence considering the extent to which the sphincters are sacrificed in surgery.[14] The sphincter saving procedures have a varying healing rates with risks of recurrence but have no postoperative incontinence due to which now the sphincter saving procedures are being probed into new techniques and are more famous than the sphincter sacrificing techniques.[15,16]

One such technique was given by Matos et al in 1993 wherein he approached the tract through the intersphincteric plane, ligated the tract near the internal opening and excised the whole primary tract distal to the ligation and repaired the hole in the external sphincter.[17] This laid the foundation of the intersphincteric approaches. Rojanasakul et al of Thailand in 2007 developed a new modification to this approach in which the tract was not excised but divided between the ligature.[18,19] The tract was curetted from the external opening and left open for residual drainage and he named it as ligation of intersphincteric fistula tract (LIFT).

In 2018 Arunraj et al did a study and observed that mean pain scores were significantly low in LIFT at 3rd POW compared to fistulectomy (0.43 compared to 1.33).[20] Dong et al in 2020 did a study comparing LIFT and fistulectomy in which he observed pain scores were lower in LIFT with significant p=0.013, p<0.001 and p=0.037 on POD 1, 3 and 5 respectively.[21] In our study also the pain scores on the day of surgery (POD 0) were quite similar in both groups with p=0.616 which was not significant probably due to the time of survey being the same day as the surgery and few hours being passed since the spinal anesthesia was worn off. Whereas the pain scores on POD 1, 3 and 7 were significantly lower with a p=0.04, p=0.001 and p=0.001 respectively in LIFT due to the smaller wound created and non-involvement of the anal mucosa in the operative field so the patient had no pain while passing stools on the further days whereas in CF due to the exposed wound to the feces and during straining resulted in higher pain scores. Thus pain was relatively significantly lesser in patients undergoing LIFT than CF.

Median healing time in studies by Shanwani et al in 2010 and Vinay et al in 2017 was 7 weeks and 3 weeks in LIFT respectively.[1,22] Parthasarathi et al in his study had a median healing time of 4 weeks in LIFT.[3] In our study, the primary healing was significantly faster in LIFT with mean being 2.9 weeks and in CF 6.3 weeks owing to the lesser surface area of the wound created in LIFT.

In study by Arunraj et al in 2018, FI scores were significantly higher in fistulectomy than LIFT (4.9 versus 0.73).[20] Vinay et al observed that Fistulotomy had FI of 4%.[22] In our study, FI was seen in 3 people in CF and with Kegel's exercises and strengthening the pelvic and sphincter muscles all 3 were relieved of the incontinence within 8th POW. In studies done from 2009 many studies have shown that there was no FI in LIFT.[1,3,9,15,18-20,22-36] In our study too none of the patients of LIFT developed FI. Though few patients of CF developed FI the results comparing LIFT and CF were not significant in our study.

Bleier et al observed no recurrence in healed patients of LIFT.[24] Göttgens et al in 2019 in his study observed recurrence of 64.2% after 1 year of surgery.[29] Mushaya et al observed a recurrence of 2% in LIFT after 4 months of surgery at the same site of original tract.[33] In our study, late recurrence was seen in 2 completely healed patients at the same sites as original site in LIFT at follow up of 10 and 12 weeks who underwent additional procedure as CF. None in CF had recurrence as the whole tract removed completely. The results from our study were also not significant when recurrence was compared between LIFT and CF. These recurrences and failures were mainly due to either fecal material entering the internal opening thereby causing recurrent infection or persistent chronic sepsis in intersphincteric space which is normally compressed between internal and external sphincter.

Rojanasakul et al in his pilot study observed success rate of 94.4%.[18] Parthasarathi et al in 2016 in and Malakorn et al in 2017 observed a success rate of 94.1% and 87.65% of patients respectively whereas Bleier et al in 2010 observed a primary successful healing of 57%.[3,23,24] In our study primary healing was successful achieved in 26 (86.66%) patients of LIFT and all 30 (100%) patients of CF. Liu et al in 2013 studied the long term results of LIFT in whom primary healing was observed in 61% patients.[25] He also concluded that for every 1 cm increase in fistula length the odds ratio of healing reduces by 0.55 and that fistulae with length <3 cm had higher primary healing rates (85%) compared to >3 cm (48%). Abacarian et al in 2012 also observed a healing rate of 74% in his study with median follow up of 18 weeks.[37]

In a study by Galan et al in 2017 with a total of 55 patients, failure was seen in 16 patients with complete fistula original tract seen in 7, 6 down staged to intersphincteric tract and 3 external residual tracts.[26] In our study failure was seen in 4 with 2 having down staged the fistula to intersphincteric tract with external opening at intersphincteric incision site and 1 down staging to external blind sinus in 1 with external opening at the original external opening. The 4th being persistence of the complete original tract probably due to slippage of the ligature and recanalization of the tract. All 4 underwent additional procedure and were cured of it.

Thus in our study LIFT had high healing rate of 86.6%. Though there have been observed similar rates ranging from 57 to 94% in other studies, this LIFT has been undergoing several modifications like using Permacol mesh, LIFT-Plus, LIFT-Plug and BioLIFT[31,40] with healing rates higher than those with only LIFT along with lesser complications and better patient satisfaction.[15,31,38-40]

CONCLUSION

FIA is a chronic complex condition with high risk of recurrence and high chances of FI following surgeries for the same as this condition involves the anal sphincter muscles. Almost all of them are due to the crypto-glandular infection rupturing into skin and surrounding tissues or due to improper drainage into perineal skin

around it. Though there have been a number of developments in the management strategies no single technique solves the problem universally for all types of fistulae. The choice for the correct decisive line of management depends solely on the surgeons' experience, knowledge and knack of surgical skills in managing this condition as the impairment of continence has a drastic effect over the quality of life of the patient.

LIFT has given promising results in view of maintaining continence and has better patient satisfaction with faster healing rates compared to other techniques. Though it has risks the benefits outweigh them. LIFT is in fact a simple easy to learn technique with good results. The modifications in LIFT having better results make it a point to probe more in such procedures and improve this technique so that the failures and recurrences are taken care of adequately for better patient contentment.

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