### **Original Research Article**

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# A prospective interventional study of postoperative pain, healing rates and incontinence rates following ligation of intersphincter fistula tract procedure

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#### **ABSTRACT**

**Background:** Fistula in ano is one of the oldest ailments known to us, troublesome both to the patient and also challenging to the treating surgeon. The treatment of fistula in ano has evolved so much, to reduce complications and to improve patient's compliance. This study was conducted to compare the age old method of open fistulectomy to that of recently developed technique of ligation of intersphincter fistula tract (LIFT), in patients suffering from low fistula in ano.

**Methods:** A totally of 80 patients, suffering from low anal fistula was divided randomly into two groups. Group A: undergoing LIFT procedure and Group B: undergoing open fistulectomy procedure. The two groups were compared in the postoperative period for wound healing, postoperative pain (by visual analog scale) and fecal incontinence (by Wexner incontinence score).

**Results:** Group A patients who underwent LIFT at the end of 3<sup>rd</sup> postoperative week had a pain score of 0.43 when compared to group B patients (1.33) who underwent fistulectomy. Group A patients had 100% continence preservation, whereas a 17.5% of moderate incontinence was documented in Group B patients. About 97.5% of patients under Group A had complete wound healing by the 3<sup>rd</sup> postoperative week, as compared to group B patients, where 100% complete wound healing was noted at 6 weeks, postoperatively.

**Conclusions:** It was found that LIFT was a promising procedure in reducing the postoperative pain significantly, with better wound healing rates. It was effective in maintaining good sphincter function, thereby providing better faecal continence following surgery, in low anal fistula.

**Keywords:** Low anal fistula, Ligation of intersphincter fistula tract, Open fistulectomy

#### INTRODUCTION

Fistula in ano is one of the oldest ailments known to us, described since the last 200 years, as early as 430 BC by Hippocrates, with the application of seton as his recommended treatment. It has been estimated that an annual prevalence of 8.6 to 10/100,000 of the population suffers from nonspecific anal fistulae, with a male to female ratio of 1.8:1.1

Fistula in ano is an abnormal communication between the epithelialized surface of anorectal lumen (internal opening) to the skin of the perineum (external opening). Various hypotheses have been proposed for to understand the etiopathogenesis and chronicity of this disease. Of this cyptoglandular hypothesis, proposed by Eisenhammer, states that infected anal glands leads to the formation of perianal abcess, which in turn on draining, leads to the formation of fistula in ano.<sup>2</sup> It has been

documented that fistula in ano develops in nearly 8-40% of cases of perianal abscess.<sup>3</sup> Lunniss et al proposed that nonspecific epithelialization of the fistula tract rather than presence of chronically infected gland was the cause for chronicity of the condition.<sup>4</sup>

The disease is known to be troublesome both to the patients as well as to the treating Surgeons, as it associated with high rates of recurrence and complications associated with the treatment, especially fecal incontinence. The treatment for fistula in ano had evolved so much since the times of Hippocrates and it implies that most of the treatment strategies were unsatisfactory or associated with complications that had lead to the development of newer techniques like, mucosal advancement flap, Gore Bio-A fistula plug and the ligation of intersphincteric fistulous tract procedures. Ligation of intersphincteric fistula tract (LIFT) is one such technique developed by a Surgeon from Thailand named Rojanasakul to avoid the fecal incontinence.

This prospective interventional study was conducted in our tertiary care hospital setup and was intended to compare the mean healing rate, postoperative pain and incontinence rate between ligation of intersphincteric fistula tract (LIFT) and open fistulectomy procedures in low anal fistulas.

#### **METHODS**

After getting Institutional Ethical Committee approval, the study was conducted over a period of 18 months. A sample size of 80 was calculated using our hospital statistics and other references, with the help of statistician. Patients suffering from low anal fistula, between 18-55 yrs of age and who are able to understand the merits and demerits of both procedures alone were included in the study. Those patients presenting with complex high anal fistulas, associated inflammatory bowel disease, malignancy, critically ill and with known history of immuno-suppressed states were excluded from the study. Using randomized sampling technique, 80 patients were divided into two groups, 40 patients in each group. Group A underwent LIFT and group B, underwent open fistulectomy. Procedures were explained to the patients and only those patients who gave informed consent alone were included in the study population. A proctosccopy, thorough clinical examination, sigmoidoscopy/ colonoscopy and radiological evaluation by MR fistulography were done in every patient preoperatively for confirmation and standardization. The patients then underwent surgery according to the group allotted to them.

#### Open fistulectomy in control group B

In this procedure the external opening was probed and the entire fistulous tract was excised completely up to its internal opening. No consideration is given to the divided sphincter muscle. The whole of the tissue was laid open or closed partially (large wounds were closed upto 3cms from anal verge) for healing.

#### LIFT procedure in test group A

In this method dilute methylene blue dye was injected into the external opening to delineate the tract and internal opening. The intersphincteric groove was palpated directly overlying the internal opening and an incision was made along the groove between external sphincter and internal sphincter. The dissection was carried out in the intersphincteric plane and the fistula tract communication was identified and isolated.

Once isolated, the intersphincteric tract was hooked using a small, right-angled clamp and the tract was ligated close to the internal sphincter and then divided distal to the point of ligation. Hydrogen peroxide was injected through the external opening to confirm the division of the correct tract. The external opening and the remnant fistulous tract were curetted to the level of the proximity of the external sphincter complex. Finally, the intersphincteric incision was loosely re -approximated with an absorbable suture. The curetted wound was left open and dressing done.

#### Postoperative follow up

At the time of discharge patients were prescribed appropriate analgesics and advised Seitz bath and high fibre diet. Each patient was followed up for a period of 3 months. The follow-up visits were scheduled on 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 6<sup>th</sup>, 8<sup>th</sup>, 10<sup>th</sup> and 12<sup>th</sup> post-operative weeks. At each visit wound healing, pain score and incontinence rate were documented.

Postoperative pain was assessed using visual analog scale, which is a subjective method of evaluation of pain in the postoperative patients. Patients were given the visual analog scale and asked to mark the amount of pain experienced by them on the scale and graded as follows;

0-No pain, 1-3 Mild pain, 4-7 Moderate pain, 8-10 severe pain.

Incontinence rate was assessed using Wexner incontinence score, which is a subjective method of evaluation of fecal incontinence.

#### Interpretation

- 0 Perfect continence
- 1-7 Good continence
- 8-14 Moderate incontinence
- 15-20 severe incontinence.

Table 1: Wexner incontinence score.

Two of incontinuous	Frequency					
Type of incontinence	Never	Rarely	Sometimes	usually	Always	
Solid	0	1	2	3	4	
Liquid	0	1	2	3	4	
Gas	0	1	2	3	4	
Wears pad	0	1	2	3	4	
Lifestyle alteration	0	1	2	3	4	

The results were documented systematically and statistically analysed using SPSS excel software.

## RESULTS

This study was conducted in a tertiary care hospital, among 80 consented patients diagnosed with low anal fistula. The study population was divided into two groups, Group A: 40 patients who have undergone LIFT and Group B: 40 patients who have undergone open fistulectomy procedure.

The mean age of the patients in group A was 37.98 years and those in group B was 37.5 years. Majority of the patients were in the 26-40 years age group. In group A,

28 patients were males and 12 were females. In group B, 27 patients were males and 13 were females (Table 2).

Table 2: Age distribution of the study population.

Age (in years)	Group A	Group B	
<25	5	5	
26-40	19	21	
41-55	15	10	
>55	1	4	
Total	40	40	
Mean	37.975	37.5	
SD	11.016	10.495	
P value	0.866 (non-significant)		

Table 3: Mean postoperative pain score assessment among two study groups.

Postoperative period	Mean pain score			
r ostoperative period	Group A	Group B	P value	
Immediate postoperative period	6.03	6.85	< 0.001	
1 <sup>st</sup> postop week	4.18	4.96	< 0.001	
2 <sup>nd</sup> postop week	2.58	3.83	< 0.001	
3 <sup>rd</sup> postop week	0.43	1.33	< 0.001	

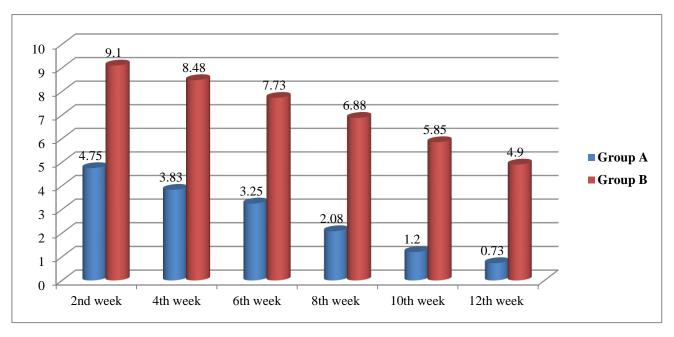


Figure 1: Mean fecal incontinence score, among the study groups.

The mean postoperative pain score at the 3<sup>rd</sup> postoperative week was 0.43 among group A patients who underwent LIFT procedure when compared to 1.33 among group B patients who underwent open fistulectomy. This was found to be statistically significant. The pain scores in immediate postoperative period, 1<sup>st</sup> postoperative week and 2<sup>nd</sup> postoperative week too were significantly low in group A as compared to group B patients.

Patients who underwent LIFT procedure had better pain scores than patients who had underwent open fistulectomy procedure, with significant p value (Table 3).

In the above chart it is notable that mean incontinence scores at follow up on 2<sup>nd</sup> 4<sup>th</sup>, 6<sup>th</sup> 8<sup>th</sup> and 10<sup>th</sup> week

postoperative was significantly low in group A as compared to group B. The average mean fecal incontinence score of 40 patients in group A at the end of 12<sup>th</sup> postoperative week was 0.73, when compared to 4.9 in group A patients, with statistical significance (p <0.001) (Figure 1).

About 97.5% of patients in group A showed complete wound healing even at 3<sup>rd</sup> postoperative week ,when compared to Group B patients where only 25% showed complete wound healing which is statistically significant (p<0.05). 100% of wound healing was observed within 5<sup>th</sup> postoperative week in group A patients. On the other hand 100% wound healing was observed only during 6<sup>th</sup> postoperative week in Group B patients (Table 4).

Table 4: Compar	ison of wound healing among	study groups.
Group A (40)	Group B (40)	P value

Postoperative	Group A (40)		Group B (40	))	P value
period	Healed	Unhealed	Healed	Unhealed	
1st week	8	32	-	40	0.02 (significant)
2 <sup>nd</sup> week	22	18	8	32	0.047 (significant)
3 <sup>rd</sup> week	39	1	10	30	0.002 (significant)
4 <sup>th</sup> week	39	1	14	26	0.011 (significant)
5 <sup>th</sup> week	40	-	35	40	0.862 (not significant)
6 <sup>th</sup> week	40	-	40	-	

#### **DISCUSSION**

Fistula in ano is one of the most common diseases with significant morbidity and complications, especially recurrence and fecal incontinence. Many surgical modalities have been developed to prevent complications and promote wound healing. LIFT is one such surgical procedure devised primarily to maintain sphincter function. This study was conducted to evaluate the incontinence rate, postoperative pain and mean healing rate between LIFT and open fistulectomy in low anal fistulas.

The mean age of the patients in group A was 37.98 years and those in group B was 37.5 years with majority of the patients in the 26-40 years age group. There was no statistical difference in age between the two groups (P =0.866).

The mean postoperative pain score during the immediate postoperative period was 6.03 among group A patients and 6.85 among Group B patients. Whereas at the 3<sup>rd</sup> postoperative week, pain score was 0.43 among Group A patients who underwent LIFT procedure when compared to 1.33 among group B patients. Present study reveals, LIFT procedure produces lesser postoperative pain and thereby lesser morbidity when compared to open

fistulectomy and hence patients with LIFT procedure can resume their daily activities early.

At the end of 12<sup>th</sup> postoperative week almost all the patients who had LIFT procedure fell either into the category of perfect continence (72.5%) or 'good continence' category (27.5%). Open fistulectomy produces incontinence rate of 17.5% (8-14 category), with 2.5% of patients in the category of perfect continence and 55% under good continence score at the end of 12th postoperative week. Thus LIFT procedure produces 100% continence preservation whereas open fistulectomy produces 17.5% of moderate incontinence. In other words, the mean incontinence score was better among group A (patients who underwent LIFT) than group B (patients who underwent open fistulectomy).

In LIFT group wound healing was faster with 97.5% wounds healed in the 3<sup>rd</sup> post-operative week itself and remaining in the 5<sup>th</sup> postoperative week. Whereas in open fistulectomy group only 25% wounds healed in 3<sup>rd</sup> postoperative week and it required 6 weeks for the remaining patients to heal their wounds. This proves that LIFT procedure provides better healing rates than conventional open fistulectomy procedure. In a prospective study by Shanwani et al, with 45 patients (71.1% male) of mean age 41.5 years, the cure rate was 82.2%. Average follow-up period was 9 months. Mean

healing time was 7 weeks. None of the patients had fecal incontinence and recurrence rate was 17.7%.<sup>8</sup> Present study showed a lesser mean complete wound healing time of 5 weeks following LIFT surgery and better healing rates (97.5% at three weeks) when compared to Shanwani et al.<sup>8</sup>

Various studies conducted worldwide documented their results, emphasizing the benefits of LIFT procedure in patients with low anal fistula. Ooi et al, reported a healing rate of about 68% during the follow-up period of 22 weeks. 25 patients (17 males) with a mean age of 40 years were included in the study. About 40% of patients had a previous history of surgery. The average preoperative Wexner score was 2 and postoperative score was 4. The Wexner score among the patients who achieved healing was 0. The mean healing time was 6 wks. Patient satisfaction rate of 72% and recurrence rate of 28% was reported.<sup>9</sup>

A retrospective and prospective trial was conducted by Bleier et al. 39 patients were included in the study. Of them 51.3% were male. The mean age of the study population was 49 years. 2.74% of the patients had at least one previous history of failed surgical treatment. Average follow-up period was 20 wks. The success rate reported was 57%. The incontinence rate was 0%. 10

In multicentre prospective randomized study (NCT01478139) conducted by Han et al comparing LIFT and LIFT-plug there were no reported incontinence and recurrence within the follow-up period of 6 months. They reported higher healing rate, less healing time, and a lower early postoperative pain score. <sup>11</sup>

Aboulian et al, did the LIFT procedure with large number of patients and with longer follow-up period. 38 patients were followed up during the study after surgery and the mean follow up period was 26 months. Out of them, 68% had a follow-up period in excess of 12 months. 61% healing rate was reported following the first LIFT procedure. The median healing time was reported to be 8 wks. No incontinence was reported.<sup>12</sup>

The results of the by Abcarian et al, conducted study on 40 patients in mean age of 43 years and mean follow-up period of 18 wks. He reported mean healing rate of 74% and there were no functional change in continence.<sup>13</sup>

Present study results correlates with various other study results, where the mean healing time was reported around 4 weeks to 6 weeks and revealed that LIFT procedure can effectively prevent the occurrence of fecal incontinence which is comparable to our study.

#### **CONCLUSION**

Present study concludes that LIFT procedure produces less post-operative pain, faster wound healing and better fecal continence preservation compared to open fistulectomy in the management low anal fistula. The procedure is simple, safe and effective in management of low anal fistulas in Indian subpopulation. This study however did not include more complex and recurrent fistulas hence this remains the limitations of this study.

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Institutional Ethics Committee

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