

“Ligation of Intersphincteric Fistula Tract (Lift)” The Solution in Perianal Fistulae? – A Prospective Observational Study in 30 Simply Randomised Cases.

Santanu Sinha¹, Bibekananda Bera², Abhimanyu Basu³, Radha Raman Mondal⁴

¹Associate Professor, Department of General Surgery, IPGMER and SSKM Hospital, Kolkata – 700020, India

²Specialist Medical Officer, General Surgery, Dinhat SD Hospital, Dist. Coochbehar, WB, India

³Professor, Department of General Surgery, IPGMER and SSKM Hospital, Kolkata – 700020.

⁴M.S. Resident, Department of General Surgery, IPGMER and SSKM Hospital, Kolkata – 700020.

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ABSTRACT

Background: Ligation of Intersphincteric Fistulous Tract (LIFT) is a novel and promising technique in the management of Fistula in ano. We tried to assess the outcome of LIFT procedure in our institute in terms of healing rate, incontinence and recurrences. **Methods:** A prospective observational study was performed in the Department of General Surgery, IPGMER and SSKM Hospital, Kolkata, India between January 2016 and August 2017. Thirty patients were selected with simple randomization after applying all inclusion and exclusion criteria and all underwent LIFT procedure. **Results:** Among the 30 patients included in our study, the healing rate varied from 76.7% in 2-week follow-up to 93.3% on 6 months follow-up. One patient had Grade B incontinence from which he recovered within 1 month. One diabetic patient had recurrence of the disease. **Conclusion:** LIFT is a promising procedure for both simple or complex fistulas with single or multiple tracts with minimum incidence of incontinence or recurrence. However, larger randomised controlled trials with large study population is required.

Keywords: Intersphincteric Fistula Tract, Perianal Fistulae .

INTRODUCTION

Fistula-in-ano is the chronic phase of anorectal infection and is characterized by chronic purulent drainage and /or pain associated with acute relapse of the abscess followed by intermittent spontaneous decompression. Abscesses and anal fistulas represent about 70% of perianal suppuration, with an estimated incidence of 1/10,000 inhabitants per year and representing 5% of queries in coloproctology.^[1] The treatment of anal fistula aims at treating the fistula, prevent recurrence and preserve anal continence. Among the current treatment options are: Fistulotomy, Fistulectomy, Application of fibrin glue,^[2] Endorectal advancement flap mainly in high fistula, VAAFT (video-assisted technique) and Ligation of the Intersphincteric Fistula Tract (LIFT). The results of each of them has been variable and each have certain specific indications and no one procedure is superior to the other as far as cure rates are concerned. There is no consensus regarding

optimum surgical treatment.^[3]

Recently, techniques with minimal morbidity and maximum preservation of the anal sphincter such as the LIFT procedure is gaining popularity in the treatment of anal fistula. In 2007 Arun Rojanasakul et al. Department of Colorectal Surgery, Chulalongkorn University, Bangkok, Thailand, developed the technique Ligation of the Intersphincteric Fistula Tract (LIFT). The central idea of this procedure is that the ligation and excision of intersphincteric tract can occlude the entry of faecal particles in the fistula and, at the same time, eliminate the intersphincteric septic focus. This results in the cure of anal fistula. This procedure aims to maintain the anal sphincter intact, preserving continence postoperatively. LIFT technique is the novel modified approach through the intersphincteric plane for the treatment of fistula-in-ano. LIFT procedure is based on the secure closure of the internal opening and removal of infected cryptoglandular tissue through the intersphincteric approach. This procedure is simple, safe, and minimally invasive. It is also effective, with a high and rapid healing rate without any resultant incontinence. This technique results in faster healing of Fistula-in-ano and does not divide the anal sphincters and postoperative anal function remain intact.^[1]

Name & Address of Corresponding Author

Dr. Radha Raman Mondal
M.S. Resident,
Department of General Surgery
IPGMER and SSKM Hospital,
Kolkata – 700020.

Researchers agree that the LIFT technique may cause some injury to internal sphincter, but theoretically LIFT causes less trauma of the internal sphincter than the other fistula operations. Our study was to assess the efficacy of LIFT technique as a procedure for cure for fistula-in-ano in terms of healing rate, development of incontinence and recurrences.

MATERIALS AND METHODS

Selection

We conducted a prospective observational study in the Department of General Surgery, IPGIMER and SSKM Hospital, Kolkata, among patients with fistula-in-ano admitted for elective surgery under our unit from Jan 2016 to Aug 2017. Patients aged between 18 – 70 years with Intersphincteric, trans-sphincteric, supra-sphincteric fistula (Simple and complex) and recurrent fistulas were included in the study. Any patient with Fistula-in-ano because of proved or suspected granulomatous diseases (tuberculosis, Crohn's disease), active anorectal abscess, anorectal malignancy, immunocompromised patients and patients with pre-existing anal incontinence were excluded from our study. By simple random sampling we selected 30 patients for the study.

Patients were assessed with relevant history, clinical examination, pathological and radiological (MR Fistulogram or Endoanal Ultrasound with or without Hydrogen peroxide) investigations. After screening and taking written informed consent, patients underwent LIFT procedure under regional/ general anaesthesia. All patients were given fluoroquinolone + metronidazole for five days starting from the time of operation.

Surgical Technique [Figure 1-4]

The location of the internal opening was identified by injection of methylene blue through the external opening or gently probing the fistula tract. An incision of about 2 centimetres was made parallel to the anal verge over the intersphincteric groove on the same side as the internal opening. Dissection deep down into intersphincteric space was carried out with scissors and electric cautery to identify the fistula tract. The tract was then ligated close to the internal sphincter with polyglactin no. 3/0. After that, the tract was divided distal to the point of ligation. The intersphincteric part of the fistula tract, possibly the infected gland, was removed and sent for histopathological study. Water was injected through the external opening once more to confirm that the tract was correctly divided. The remnant of the fistulous tract was then thoroughly curetted. The external opening was either closed primarily if no significant purulent discharge or left open to drain if there was purulent discharge noted during operation.

Re-approximation of the inter-sphincteric incision was done loosely with interrupted stitches.

Outcome Measurements:

All patients were followed up clinically in the OPD at 2 weeks, 1 month, 2 months, 3 months and at 6 months or reappearance of symptoms (at least 3 months) postoperatively. Outcomes of the LIFT procedure was measured in terms of fistula healing rate, development of incontinence and recurrence. Report of post-operative histopathological report were assessed.

Healing was defined as healing of the external opening and intersphincteric incision. Wound was assessed in each visit as follows:

Grade 1: Complete epithelisation of wound.

Grade 2: Healing wound with granulation.

Grade 3: Granulation with purulent discharge.

Grade 4: Non healing, not healed at 12 wks.

Failure was defined as nonhealing of the surgical wound or fistula at the end of 3 months. Faecal incontinence was considered in patients who were continent before the operation but had postoperatively obvious damage to sphincter function.

Assessment of clinical continence was done according to Browning and Parks criteria⁴ as follows:

Category A: Continent of solid & liquid stools & flatus (i.e. normal continence)

Category B: Continent of solid & usually liquid stools but not flatus (no faecal leakage)

Category C: Acceptable continence for solid stool but no control over liquid stool or flatus.

Category D: Continued faecal leakage.

Recurrence was defined as the reappearance of the fistula after initial healing.

All data was collected in a predesigned proforma and analysed using descriptive and inferential statistics with Microsoft Excel, SPSS 24.0 and Graph Pad Prism version.^{15]} Z-test (Standard Normal Deviate) was used to test the significant difference of proportions. P-value ≤ 0.05 was considered for statistically significant.

RESULTS

Among the total 30 study population, the mean age (mean \pm SD) of patients was 42.2000 ± 9.4956 years with range 27.00-69.00 years and the median age was 42.00 years. Two (6.7%) patients were female and 28 (93.3%) patients were male (Z-Score = 6.7132, p-value = <0.0001 , significant).

Twenty-Seven (90.0%) patients presented with primary disease and 3 (10.0%) patients had recurrent disease (Z-Score = 6.1968, p-value = <0.0001 , significant). Five (16.7%) patients presented with itching. Fifty percent (15 of 30) of patients had pain in perianal region and 24 (80%) patients had swelling.

Seventy percent (21 of 30) patients was non-smoker. When considered co-morbidities, 1 (3.3%) patients had DM, 1 (3.3.0%) patients had HTN, and 28(93.3%) had no DM or HTN.

In our study, two (6.7%) patients had multiple external opening, 28 (93.3.0%) patients had single external opening. The anatomical location of external and internal openings are presented in [Table 1 & 2] respectively.

Table 1: Anatomical Location of External Opening

| External Opening | Frequency (N=30) | Percentage (%) |
|------------------|------------------|----------------|
| 2 O'Clock | 2 | 6.7% |
| 3 O'Clock | 3 | 10% |
| 4 O'Clock | 2 | 6.7% |
| 5 O'Clock | 5 | 16.7% |
| 6 O'Clock | 5 | 16.7% |
| 7 O'Clock | 6 | 20% |
| 9 O'Clock | 2 | 6.7% |
| 10 O'Clock | 1 | 3.3% |
| 11 O'Clock | 4 | 13.3% |

The Z-Score is 0.3336. The p-value is 0.7414. The result is not significant at p <0.05.

Table 2: Distribution of INTERNAL OPENING as per Anatomical Location

| Internal Opening | Frequency (N=30) | Percentage (%) |
|------------------|------------------|----------------|
| 2 O'Clock | 2 | 6.7% |
| 3 O'Clock | 2 | 6.7% |
| 4 O'Clock | 1 | 3.3% |
| 5 O'Clock | 4 | 13.3% |
| 6 O'Clock | 8 | 26.7% |
| 7 O'Clock | 4 | 13.3% |
| 9 O'Clock | 3 | 10.0% |
| 11 O'Clock | 4 | 13.3% |
| 12 O'Clock | 2 | 6.7% |

The Z-Score is 1.291. The p-value is 0.19706. The result is not significant at p <0.05.

Two (6.7%) of our patients had multiple tract and 28 (93.3%) patients had single tract. (The Z-Score is

6.7132. The p-value is <0.0001. The result is significant). Six (20.0%) patients had no induration. Ninety percent (27 of 30) patients had active discharge.

The distribution of patients with different continence categories has been depicted in [Table 3].

Table 3: Distribution of CONTINENCE CATEGORY

| Continence Category | Frequency | Percent |
|---------------------|-----------|---------|
| Category-A | 29 | 96.7% |
| Category-B | 1 | 3.3% |
| Category-C | 0 | 0.0% |
| Category-D | 0 | 0.0% |
| Total | 30 | 100.0% |

According to Park's classification as on MR Fistulogram, 25 (83.3%) patients had intersphincteric, 2 (6.7%) patients had suprasphincteric, 3 (10.0%) patients had trans-sphincteric type of fistula. As on MR Fistulogram, 2 (6.7%) patients had complex and 28 (93.3%) patients had simple fistula. Four (13.3%) patients had associated anal fissure.

When post-operative histopathological reports were analysed, two (6.7%) patients had CHRONIC INFLAMMATORY GRANULATION TISSUE, 3 (10.0%) patients had FIBROCOLLAGENOUS TISSUE AND INFLAMMATORY CELL, 22 (73.3) had GRANULATION TISSUE and 3 (10.0%) had INFLAMMATORY GRANULATION TISSUE.

All 30 patients were followed up for three months (completed 4 follow up visits). Six patients missed the 5th follow up visit. The grade of wound healing was analysed at 2 weeks, 1 month, 2 months, 3 months and 6 months. Results are presented in [Table 4].

Table 4: Distribution of HEALING GRADE at follow-up period.

| Follow-up | Healing Grade | Frequency | Percentage | Z Score | P Value |
|----------------|---------------|-----------|------------|---------|---------|
| FU1 (2 Weeks) | Grade- I | 1 | 3.3% | 5.4252 | <0.001 |
| | Grade- II | 25 | 83.3% | | |
| | Grade- III | 4 | 13.3% | | |
| | Grade- IV | 0 | 0.0% | | |
| FU2 (1 Month) | Grade- I | 23 | 76.7% | 4.9305 | <0.001 |
| | Grade- II | 4 | 13.3% | | |
| | Grade- III | 3 | 10.0% | | |
| | Grade- IV | 0 | 0.0% | | |
| FU3 (2 Months) | Grade- I | 25 | 83.3% | 5.614 | <0.001 |
| | Grade- II | 5 | 16.7% | | |
| | Grade- III | 0 | 0.0% | | |
| | Grade- IV | 0 | 0.0% | | |
| FU4 (3 Months) | Grade- I | 28 | 93.3% | 6.7132 | <0.001 |
| | Grade- II | 0 | 0.0% | | |
| | Grade- III | 0 | 0.0% | | |
| | Grade- IV | 2 | 8.3% | | |
| FU5 (6 Months) | Grade- I | 22 | 91.7% | 5.2705 | <0.001 |
| | Grade- II | 0 | 0.0% | | |
| | Grade- III | 0 | 0.0% | | |
| | Grade- IV | 2 | 8.3% | | |

In the first follow up visit 29 (96.7%) patients were fully continent (Continence grade A) and 1 (3.3%) patient had grade B continence. All patient was found continent (grade A) from second follow up visit onwards. No patients were found to have Grade C or grade D incontinence at any point of time.

DISCUSSION

Anal fistula management has long been a challenge for surgeons. Presently, no technique exists that is ideal for treating all types of anal fistula, whether simple or complex. A higher incidence of poor sphincter function and recurrence after surgery has encouraged the development of a new sphincter-sparing procedure, ligation of the intersphincteric fistula tract (LIFT), first described by Van der Hagen et al. in 2006.

Fistulotomy has been performed since ancient times. The outcome is generally acceptable. However, fistulotomy causes various degrees of anal sphincter injury. The incontinence status was underestimated and under-reported. The seton technique was to minimize incontinence, but only with moderate success. Recently, many techniques have been developed, such as endorectal advancement flap, anoderm island flap, excision and closure of internal opening, fibrin glue, and fistula plug. These techniques have less risk of anal incontinence, despite some recurrences. These procedures are technically demanding, operator dependent, interfering with re-operation when needed, unable to perform in the previously scarred anus and the cost of required materials.^[5]

In the study by Arun Rojanasakul et al. LIFT procedure showed no post-operative complication. Primary healing occurred in 17 patients (94.4%) with an average healing time of 4 weeks. No clinical incontinence was reported by the patients. Arun Rojanasakul proposed that the advantages of the LIFT technique are 1) anal sphincter saving, 2) minimal tissue injury resulting in a shorter healing time, 3) small scar, 4) the procedure can be done in previously-operated patients, and lastly 5) the procedure will not compromise any need for re-operation in case of recurrence. The major concern is long-term recurrence. The procedure has been economic since healing time is short and no specialized or expensive materials were required⁶.

Wendy et al study showed that the overall primary healing rate was 61% (23 of 38), and it was 62% (16 of 26) in patients followed for over 12 months. Eighty percent (12/15) of the failures are early failures (persistent symptoms or failure at ≤ 6 months), and 20% are late failures (> 6 months) with 1 failure occurring 12 months post-procedure. Increase in length of fistula tract was associated with decreased healing (OR 0.55, 95% CI 0.34–0.88, $p = 0.01$). There were no intraoperative complications and no reported incontinence.^[7]

In our study, 2 female patients and 28 male patients had fistula in ano and underwent for LIFT having no difference in success rate. The healing rate is in the range from 76.7 % to 93.3%, out of 30 patients, after six months follow-up. These data corroborate with findings by Rojanasakul et al. and Wendy et al.

As per incontinence concerned only one patient showed Grade B continence in first follow-up at 2 weeks in our study. After regular pelvic floor exercise, he became fully continent after 1 month. Most previous reports of the LIFT technique also showed minimal or no impact on continence, and minimal morbidity, even though the healing rates varied.^[7,8]

In our study, 93.3% presented with simple fistulous tract, defined as “low transphincteric and intersphincteric fistulas that cross 30% of the external sphincter” as documented by Magnetic Resonance Fistulogram and two patients had complex fistulous tract defined as “high transphincteric fistulas with or without a high blind tract, suprasphincteric and extra-sphincteric fistulas, horseshoe fistulas and those associated with inflammatory bowel disease, radiation, malignancy, pre-existing incontinence or chronic diarrhoea”. All patients who followed the inclusion criteria of our study underwent for LIFT pointing the success rate of ranging from 76.7 % to 93.3%. In our study, 24 patients had induration surrounding the external opening of fistulous tract and they underwent for LIFT, showing a satisfactory healing outcome though initially it was thought that patients with induration might not have good result. Three patients had recurrent fistula-in-ano and they all underwent for LIFT showing a good success rate. Complex fistulas are amenable for LIFT with same results as shown in various studies.^[5]

As of comorbidities concerned, one patient in our study with diabetes mellitus underwent LIFT procedure and unfortunately developed recurrence of the fistula-in-ano.

It should be noted that in this study there were no cases of persistent anal abscess, which may be a common cause of treatment failure, so it should not be assumed that incomplete removal of the fistula tract is the only possible cause of treatment failure. Recurrence of anal fistula is mainly due to infection and technical errors. Infection was one of the reasons for non-healing of internal opening wounds, because it caused the breakdown of the closure wound on the internal sphincter. In our study, there was no incidence of anal abscess.

Our study was limited to small sample size, unequal distribution of fistula type and short follow-up period. However, as for results concerned, the LIFT procedure shows to be relatively easy to perform, has a high healing rate and appears to be safe with low morbidity and no impact on continence.

CONCLUSION

LIFT is a promising procedure for both simple or complex fistulas with single or multiple tracts with minimum incidence of incontinence or recurrence. However, larger randomised controlled trials with large study population is required.

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