



## Comparative study between intersphincteric ligation of perianal fistula versus conventional fistulotomy with or without seton in the treatment of perianal fistula: A prospective randomized controlled trial

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### ABSTRACT

**Background:** Fistula-in-ano is one of the most common benign anal conditions in daily surgical practice. The goals in the treatment of an anal fistula are to eradicate sepsis and to eliminate the primary fistula opening, any associated tracts, and any secondary openings without a change in continence. Conventional fistulotomy (lay open of the fistula tract) is a commonly used procedure and is still relied on by the majority of surgeons as the gold standard for the treatment of perianal fistula. Ligation of the Intersphincteric Fistula Tract (LIFT) is a new sphincter-preserving technique for the treatment of anal fistula.

**Objective:** To compare the efficacy of open fistulotomy and ligation of intersphincteric fistula tract (LIFT) procedure based on its post-operative outcomes.

**Patients and methods:** The Present study is A prospective randomized controlled trial which included 30 patients presented with low transsphincteric perianal fistula 27 (90%) males and 3 (10%) females divided into two groups each group consisted of 15 patients. Group, I subjected to inter sphincteric ligation of perianal fistula (LIFT) procedure. Group II patients subjected to conventional fistulotomy. The study lasts 2 years from May 2017 to May 2019 with Follow up for 6 months duration. Operative time in our study was significantly higher in group (I) Managed by LIFT with a mean of 32.53 min than group (II) managed by fistulotomy with a mean of 20.87mins. Wound healing was faster in a group (I) managed by LIFT than group (II) managed by fistulotomy, as the mean time for complete wound healing was (4.53) weeks after LIFT and (5.67) weeks after fistulotomy.

**Results:** There was no case of incontinence after performing the LIFT technique in all our patients in group I. there were 2 cases of incontinence to gases only after fistulotomy in group II. The healing rate after LIFT was 80% (12/15 patients). The healing rate after fistulotomy was 93.3% (14/15 patients).

**Conclusion:** LIFT procedure is an effective and preferred sphincter-saving technique for fistula-in-ano with shorter healing time and lower incidence of postoperative anal incontinence, as compared to open fistulotomy.

### 1. Introduction

The anal canal is the last 4 cm of the alimentary tract. It begins above as a continuation of the rectum. Its actual level is marked by a strong fibromuscular ring that can be felt rectally in normal subjects then the canal terminates at the anal margin [1]. Perianal fistula is a track, lined by granulation tissue that connects deeply in the anal canal or rectum and superficially on the skin around the anus [2]. The categorization of

anal fistula depends on its location relative to the anal sphincter muscles. According to Parks classification, the anal fistulae are classified into inter-sphincteric, trans-sphincteric, supra-sphincteric, or extra-sphincteric [3]. The management of perianal fistula remains surgical although the evolving of newer methods of minimally invasive treatment. Conventional fistulotomy (lay open of the fistula tract) is a commonly used procedure and is still relied on by the majority of surgeons as the gold standard for the treatment of perianal fistula [4].

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LIGATION of the Intersphincteric Fistula Tract (LIFT) is a new sphincter-preserving technique for the treatment of anal fistula. This technique aims to identify the fistula tract within the intersphincteric plane. Once isolated the tract is ligated and divided to prevent the entry of fecal material into the fistula tract [5]. The aim of this work was to compare the efficacy of open fistulotomy and ligation of intersphincteric fistula tract (LIFT) procedure based on its post-operative outcomes.

### 1.1. Patients and Methods

Study design, the present study is a prospective randomized study included 30 patients with low transsphincteric perianal fistula, during the period from May 2017 to May 2019. The patients randomly were divided into two groups each group consisted of fifteen (15) patients. Follow up designed for 6 months duration. Group I patients subjected to inter sphincteric ligation of perianal fistula (LIFT) procedure. Group II patients subjected to conventional fistulotomy. The participants shared in this clinical study gave informed consent after being fully informed about the technique and its circumstances. This clinical study was approved from local ethical committee.

Inclusion Criteria: Age  $\geq 18$  years old. Diagnosis of low transsphincteric fistula by Magnetic Resonance Imaging (MRI).

Exclusion Criteria: High transsphincteric fistula. Inter sphincteric fistula. Branching fistula. Multiple fistulas. Supra sphincteric fistula. Previous anal surgery. Inflammatory Bowel Disease as Crohn's, tuberculosis. History of fecal incontinence.

Preoperative workup: All patients included in the study were subjected to History taking. General examination. Anorectal examination. Magnetic Resonance Imaging (MRI) in the anorectal region. Assessment of the continence by Wexner score (Table 1).

The day before surgery, all patients were instructed to have a soft diet and mineral laxative. The night before surgery, all patients had rectal enema with ordinary tap water.

Operative details: All procedures were performed under spinal anesthesia in the lithotomy position. All patients had a single dose of 1 g of a third-generation cephalosporin intravenously at the induction of anesthesia.

Group (I) Inter sphincteric Ligation of perianal Fistula (LIFT) procedure.

Operation: With the patient in the lithotomy position, inspection and identification of the site of external opening were done and proctoscopy was applied for detection of the internal opening and the fistula tract. Injection of hydrogen peroxide in the external opening to identify the presence and site of an internal opening was done. A probe is passed in the external opening to define the direction of the fistula tract. A 1.5–2.0-cm curvilinear incision is made at the intersphincteric groove overlying the fistula tract. (Fig. 1). Dissection of the intersphincteric tract, the dissection is kept close to the external sphincter to avoid cutting through the internal sphincter. Identifying the intersphincteric tract, the intersphincteric tract is carefully dissected out and hooked. (Fig. 2). Secure ligation of the intersphincteric tract close to the internal



Fig. 1. Incision at the intersphincteric groove overlying the fistula tract.

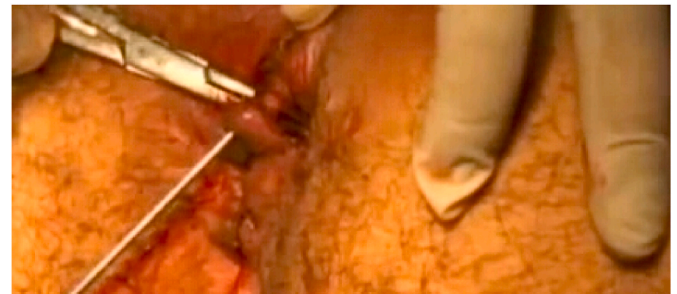


Fig. 2. Identifying the intersphincteric fistula tract.

opening by absorbable sutures (vicryl 3/0). The fistulous tract was doubly ligated as close as possible to the lateral margin of IAS and the medial margin of the EAS & then the tract was divided. After ligation and division of the intersphincteric tract, saline injection or probing through the external opening is again performed to confirm that the correct fistula tract has been divided. Infected granulation tissues in the rest of the fistulous tracts and cavity are thoroughly removed with a curette. The external opening was left open to drain after curettage. The inter sphincteric wound was loosely closed with interrupted, absorbable sutures (vicryl 3/0).

Group II Fistulotomy, by use of diathermy, the perianal skin, and anal epithelium were divided. The internal sphincter, if it was encountered, was identified and partially divided. The fistula tract can be safely opened, any bleeding from the edges should be secured by cautery & a gauze dressing was applied.

Post-operative workup and follow up. Post-operative early complications: urine retention, bleeding, abscess formation, wound infection, and early incontinence. Patients received intravenous third-generation cephalosporin for 3 days postoperatively. And oral antibiotics for one week. Intake of liquid food was resumed in the evening after the operation they were advised to have a soft diet for 2 days and bulk laxatives for at least 2 weeks.

Dressing of the wound was done on the second day postoperatively for all patients. As regarding Pain all patients were instructed how to complete the 0 to 10 visual analogue scale (VAS) interview before surgery. The intensity of postoperative pain was measured every 8 h during the first 24 h through a 0 to 10 visual analogue scale (VAS:0.no pain and 10 maximum pain experienced) and during weekly follow up visits. It was subsequently measured at regular intervals.

All patients were trained on how to clean themselves and how to do the wound dressing. All Patients were followed up every week for two weeks then every two weeks until complete healing. This was followed by two monthly visits, then every two months to complete 6 months follow-up for the detection of any late complications.

The fistula was considered to be healed when the external wound

Table 1

Wexner incontinence score.

Type of incontinence	Frequency				
	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

Never\_ = no episodes in the past four weeks; Rarely = 1 episode in the past four weeks; Sometimes = more than 1 episode in the past four weeks but less than once per week; Weekly = 1 or more episodes a week but less than once per day; Daily = 1 or more episodes a day.

healed completely with no discharge. Persistent or recurrent external opening discharge after 2 months of the procedure was considered as recurrence.

All patients had full clinical assessment and Wexner questionnaire after complete healing or after 6 months (if the healing wasn't completed or in presence of recurrence).

The patients were observed for the recurrence of the fistula during the follow-up period. No patients were lost during the follow-up period.

### 1.2. Statistical analysis of the data

Data management and statistical analysis were done using SPSS vs.25. (IBM, Armonk, New York, United States). Numerical data were summarized as means and standard deviations. Categorical data were summarized as numbers and percentages. Comparisons between both groups were done using the Mann Whitney *U* test for numerical data, Categorical data was compared between the Chi-square test or Fisher's exact test when appropriate. All *P* values were two-sided. *P* values less than 0.05 were considered significant.

## 2. Results

The study was submitted on 30 patients with trans-sphincteric perianal fistula. Of these 30 patients, 27 (90%) were males and 3 (10%) were females. The mean age was (34.4) in group (I) and (35.07) in the group (II). Discharge was the main complaint and presented in all patients of the study. Pain was present in 15 patients of the study. As it was present in 8 (53.3%) patients in group I and 7 (46.7%) patients in group II. Swelling was present in 10 patients of the study, it was present in 4 (26.7%) patients in group I and 6 (40%) patients in group II. Pruritis ani was present in only 5 patients of the study.

The type of fistula was low trans-sphincteric perianal fistula in all patients.

The time of operation was shorter in the group (II) ranging from 15 to 25 min with a mean of 20.87 min, in comparison to group (I) which ranged from 25 to 40 min with a mean of 32.53 min. And there was statistical significance ( $P < 0.001^*$ ) (Table 2).

The postoperative hospital stay was the same in all patients as it was 1 day, with no statistical significance.

Mean Visual Analogue Scale (VAS) was significantly higher in group II (5.7) compared to group I (3.3). Subsidence of pain (VAS Mean  $< 1$ ) was noted at about two weeks post-operative. *P*-value was  $< 0.001^*$  (Table 2).

Wound healing was faster in group (I) than group (II), as the time needed for complete wound healing in group (I) ranged from 3 to 7 weeks with a mean (4.53) weeks which is less than group (II) which

**Table 2**

Comparison between the two studied groups according to time of operation (minutes) and time of complete wound healing (weeks), Visual Analogue Scale (VAS).

Variables	Group I N = 15	Group II N = 15	T	P
Time of operation (minutes)	25–40	15–25	8.42	$< 0.001^*$
Min-max	32.53 ± 4.34	20.87		
Mean ± SD		± 3.15		
Time of complete wound healing (weeks)	3–7	4–8	2.2	0.038*
Range	4.53 ± 1.46	5.67 ± 1.39		
Mean ± SD				
Post-operative pain (VAS)	1.0–5.0	2.0–8.0		0.001*
Min-max	3.3 ± 1.4	5.7 ± 2.2		
Mean ± SD				

SD = standard deviation.

\* = significant.

Mann Whitney *U* test was used.

ranged from 4 to 8 weeks with mean (5.67) weeks. And there was a statistically significant difference (Table 2).

According postoperative complications in our study were as followed:

Wound infection, post-operative wound infection occurred in 2 (13.3%) Patients in group (I) and 2 (13.3%) patients in group (II), with no statistical significance.

Incontinence: There were no cases of incontinence after performing the LIFT technique in all our patients in group I. there were 2 (13.3%) cases of incontinence to gases only after fistulotomy in group II with a score of 4/20 by (WIS).

Recurrence: recurrence occurred in 4 patients from both groups as recurrence occurred in 3 (20%) patients in group I and 1 (6.7%) patient in group II. all 4 cases had a recurrence in the form of intersphincteric fistula.

Urine retention occurred in 2 (13.3%) Patients in group (I) and 2 (13.3%) patients in group (II), with no statistical significance.

## 3. Discussion

The goal of surgical management for a perianal fistula is to effectively eradicate current and recurrent septic foci, associated epithelialized tracts and preserve continence. No single technique achieves these aims for all types of anal fistulas [5].

This study was performed on 30 patients with low trans-sphincteric perianal fistula 27 (90%) males and 3 (10%) females. The same as the study done by Sahai [6] that was carried on 50 patients, 45 (90%) were males and 5 (10%) were females, and nearly close to the study done by Vinay and Balasubrahmanya [7] that was carried on 50 patients, 38 (76%) were males and 12 (24%) were females. with the predominance of perianal fistula among males.

The ages of the patients involved in this study ranged from 24 to 50 years old, the mean age in group (I) Managed by LIFT was (34.4) years and in group (II) Managed by fistulotomy was (35.05) years with no statistically significant difference between the two groups. This is closely similar to the studies done by Elkaffas [8], Sahai [6], and Vinay and Balasubrahmanya [7] mentioned that the mean age of patients in their studies from (30–41) years. This may signify the high incidence of perianal fistula in younger patients. In our study, there was a history of abscess drainage in all patients, and there is no statistically significant difference between the two groups, which is similar to the study done by Elkaffas [8]. There was a history of abscess drainage in 30 patients (100%) of the study. On the other hand, in the study done by Sahai [6] on 50 patients, there was a history of abscess drainage in 32 patients (64%) of the study.

Discharge was the main presenting complaint and was present in all patients (100%), which is similar to the study done by Elkaffas [8]. In which discharge was present in all patients of the study. Pain was also an important complaint by patients of our study and was present in 15 patients (50%) of the study, which is similar to the studies done by Elsebai et al. [9]; Zuhair. [10]; Bagh Baghdadi and Metwalli [11], in which pain was present in 20 patients (66.7%), 45 patients (60%), and 15 patients (60%) respectively.

As regards operative time in our study it was significantly higher in group (I) Managed by LIFT than group (II) Managed by fistulotomy with the mean operative time 32.53 min for LIFT group and 20.8 min for fistulotomy group, which is similar to the results illustrated in the studies done by Vinay and Balasubrahmanya [7]. and Elkaffas [8] mentioned that the LIFT procedure means operative time was (28 and 34 min) and fistulotomy mean operative time was (19.6 and 17 min) respectively.

Post-operative pain perception and need for analgesics were more in group (II) Managed by fistulotomy, than group (I) managed by LIFT. We assessed how many days the patient needed analgesic according to the Visual Analogue Scale (VAS) and numerical rating scale (NRS), it was found that Mean Visual Analogue Scale (VAS) was significantly higher in

group II (5.7) compared to group I (3.3) which means that pain is far less severe in the LIFT group than that of the fistulotomy group. In the same way, the studies done by Sahai [6] and Elkaffas [8] mentioned that the mean Visual Analogue Scale (VAS) was (6) for the LIFT group and (8) for the fistulotomy group.

The mean time of hospital stay was (1 day) with no significant difference between both groups. On the other hand, the study done by Elkaffas [8] had a mean hospital stay of 2 days for both LIFT and fistulotomy groups. As regards postoperative wound infection in our study it occurred in 2 patients (13.3%) in group (I) Managed by LIFT and in 2 patients (13.3%) For fistulotomy group with no significant difference between both groups. which is similar to results illustrated by Elkaffas [8], in which wound infection occurred in 4 (26%) patients treated by LIFT and 3 (20%) patients treated by fistulotomy with no significant difference between both groups. On the other hand, the study done by Vinay and Balasubrahmanya [7] mentioned that Wound infection was significantly higher in the LIFT group than the fistulotomy group as wound infection occurred in (8% 2/25) patients of the LIFT group and (4% 1/25) patients of fistulotomy group. Wound infection was treated early by antibiotics and regular dressing and had a good response. In our study, 4 patients in both groups suffered from post-operative urine retention that occurred in 2 patients (13.3%) in group (I) and 2 patients (13.3%) in group (II) with no statistical significance. This condition was occurred temporarily on the operation day and improved soon after analgesics and urinary catheterization. This result is similar to the result of the study done by Elkaffas [8] which mentioned that urinary retention occurred in (2/15) patients.

In our study, no case in both groups suffered from other minor complications as bleeding or abscess formation. On the other hand, in the study done by Elkaffas [8] there were 2 cases (13.3%) of post-operative bleeding after the LIFT procedure and 1 case (6.7%) of abscess formation after fistulotomy. According to the time needed for complete wound healing, it was significantly higher in group II managed by fistulotomy (4–8 weeks with mean 5.6) compared to group I managed by LIFT (3–7 weeks with mean 4.5). This is similar to the results reported by Vinay and Balasubrahmanya [7]. and Elkaffas [8] which mentioned that the mean healing time was (5weeks) for the LIFT group and (8 weeks) for the fistulotomy group. On the other hand, in the study done by Sakda and Araya [12] the mean healing time was (2 weeks) for the LIFT group which is a short healing time than our study. In our study, temporary change in the continence status occurred in 2 patients (6.7%) scoring 4/20 by (WIS) in group (II) Managed by fistulotomy this result is similar to studies done by Sakda and Araya. [12] and Vinay and Balasubrahmanya [7]. in which temporary partial incontinence to gas occurred in 6 patients (16.2%) and 1 patients (4%) respectively for the fistulotomy group. On the other hand, Laiwattanapaisal [13] and Sahai [6] reported no case of incontinence after fistulotomy.

There was no case of incontinence after performing the LIFT technique in all our patients. This was also reported by Vinay and Balasubrahmanya [7]; Sahai [6] and Elkaffas [8] all reported no case of incontinence in their studies which indicates the safety of the procedure on the sphincters. No patient suffered from a permanent change in the continence status from both groups in our study. All patients in our study were assessed according to the Wexner incontinence score (WIS) before the operation and in the postoperative period, the 2 patients with a change in the continence status scored 4/20 by Wexner score and were assured, this condition was temporary as the incontinence to gases disappeared after 6–8 weeks and the patients regain complete continence after that, during the follow-up period.

The 3 cases of recurrence after LIFT in the form of transforming to a more simple intersphincteric fistula that managed by fistulotomy. The one case of recurrence after fistulotomy in the form of intersphincteric fistula was managed by fistulotomy. There was no significant difference between both groups regarding the outcome with a healing rate of 12/15 (80%) for the LIFT procedure which correlates well with the healing rates of Sakda and Araya [12] 38/48 (79%), Elkaffas [8] 13/15 (87%)

and Vinay and Balasubrahmanya [7]. 22/25 (88%), On the other hand, the healing rate of the study done by Sahai [6] on LIFT was 15/22 (68%) which is a lower healing rate than our study.

Regarding the fistulotomy healing rate in this study was 14/15 (93.3%) which correlates well with what was illustrated by Elkaffas [8] 14/15 (93%) and Vinay and Balasubrahmanya [7]. 25/25 (100%) respectively.

We followed up on the patients for 6 months after the operation, which may not be enough to predict the long term results and other complications that might arise. But according to the study done by Tan et al. [14], the follow-up period was 15 months. The longest follow-up period was achieved by Lin et al. [15] was 26 months. The limitations in our study include a Small sample size, short time of follow up. Further studies evaluating these procedures, overcoming the above limitations is highly desired.

#### 4. Conclusion

LIFT procedure is an effective and preferred sphincter-saving technique for fistula-in-ano with shorter healing time and lower incidence of postoperative anal incontinence, as compared to open fistulotomy. This work recommends LIFT procedure in low transsphincteric perianal fistulas to be more popular, to be implemented as a corner stone procedure along various and classic operations for such cases as it's easy, feasible, sphincter saving technique.

#### Ethical approval

Ethical approval was given from IRB menoufia faculty of medicine May 2016 SURG.

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#### CRediT authorship contribution statement

**Olfat I. Al Sebai:** Conceptualization, Methodology, Supervision. **Mohammed S. Ammar:** Data curation, Methodology, Supervision. **Samy H. Mohamed:** Writing - review & editing. **Mohammed A. El Balsky:** Visualization, Investigation, Validation, Supervision.

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