

Short-Term Outcomes of Eldemerdash Modification of LIFT (Ligation of Inter-sphincteric Fistula Track) Technique for High Trans-Sphincteric Fistula, A prospective Pilot Study of A promising Novel Technique

Original Article

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ABSTRACT

Background: Although ligation of intersphincteric fistula tract (LIFT) technique has been widely accepted as a sphincter-sparing technique, fistula recurrence is still high up to 43–60%. We developed a novel technique, Eldemerdash modification LIFT (LIFT-EM), which is based on adding internal fistulotomy, aiming to eradicate the causative cryptoglandular infection and trying to minimize recurrence rates.

Patients and Methods: This is a prospective pilot study on 18 patients with high trans-sphincteric fistula diagnosed with preoperative MRI fistulogram. All patients underwent LIFT-EM. Follow-up intervals were 1 day, 1 week, 3, and 6 months. Cleveland Clinic Florida Fecal Incontinence questionnaire was requested from all participants both pre and postoperatively. Postoperative outcomes were assessed in terms of recurrence, change incontinence status perioperative complications.

Results: The mean age of study cases was 36.4±6.0 years, ranging between 27 to 45 years. The mean BMI was 35.3±9.5 with males representing all cases. Recurrence/persistence was recorded in only one (5.6%) patient. Pre and postoperative Cleveland Clinic Florida Fecal Incontinence scores were similar. Study variables did not significantly impact recurrence/persistence. There was a higher mean VAS score at 24h and 1 week in posterior fistula cases, P 0.001. There was a higher mean duration of hospital stay among ASA grade 2 cases (P 0.001). Inversely, patients with previous anorectal abscess had significantly shorter hospital stay (P 0.018).

Conclusion: In properly selected cases, LIFT-EM could be a safe and effective sphincter-sparing technique in treating high trans-sphincteric fistula with low recurrence rates. Randomized clinical trials with larger sample and longer follow-up periods comparing LIFT modifications are encouraged to consolidate our findings.

Key Words: Eldemerdash modification, high trans-sphincteric fistula, ligation of intersphincteric fistula track, recurrence.

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INTRODUCTION

The essential aims of anal fistula treatment are to eliminate the fistula and the underlying anorectal sepsis, avoid its recurrence/persistence, and simultaneously maintain intact sphincter functions. In (2007), Rojanasakul^[1] described intersphincteric ligation of the fistulous tract (LIFT) by utilizing the intersphincteric approach previously described by the St. Mark's group in (1993)^[2]. The LIFT technique entails dissection and ligation of the fistula tract in the intersphincteric plane (ISP), which mandates presence of healthy tissues and the absence of sepsis^[3].

The LIFT procedure has been acquiring popularity in the last years by achieving an acceptable percentage of cure, greater than 70% with follow-up duration exceeding 1 year, with little impact on anal continence^[4-6]. Tsunoda et al. found that there were no changes in resting or contracting pressures by anal manometry and function scores after LIFT surgery^[7]. Several LIFT modifications have been created attempting to enhance its cure rates^[6]. The minimal distortion that occurs in the anal anatomy and the absence of continence alterations allow for new procedures to be developed.

Dissection of the fistulous tract in the LIFT procedure has resulted in new patterns of recurrence and persistence. In failures, there is often downstaging of the fistulas to a more medial position involving the intersphincteric wound. That is why the majority cases of recurrence/persistence have been treated with fistulotomy plus curettage of residual sinus^[5,6].

To minimize the failure rate of LIFT, we have developed a novel technique which is named after our university hospital [Eldemerdash modification LIFT, (LIFT-EM)]. Besides the conventional step of intersphincteric ligation of the fistula track (FT), this technique involves laying open of the proximal fistula portion traversing the internal sphincter (internal fistulotomy), fistulectomy (coring out) of the outer fistula part, and curette of residual track inside the external anal sphincter (EAS). This work is a pilot study aiming to evaluate the safety and effectiveness of our proposed technique (LIFT-EM) regarding success rates and impact on continence status.

PATIENTS AND METHODS:

The following are characteristics of the study depicted in the PICOS format:

Participants: All cases who were diagnosed with primary high trans-sphincteric fistula-in-ano and have undergone LIFT technique with the proposed EM between October 2022 and May 2024 at two hospitals:

- a. Ain Shams University Hospitals, Cairo, Egypt.
- b. Mouwasat Hospital, Dammam Branch, Eastern Province, Kingdom of Saudi Arabia.

Follow-up data have been extracted from patients' files at 1 day, 1 week, 3, and 6 months intervals. Each participant is requested to respond to the Cleveland Clinic Florida Fecal Incontinence (CCF-FI) questionnaire both pre and postoperatively.

Exclusion criteria

- a. Less than 16 years old, more than 70 years old.
- b. Recurrent fistula-in-ano.
- c. Previous anal surgery.
- d. Presence of specific anorectal disease such as Crohn's.
- e. Patients with ASA grades more than III.

Intervention (Exposure) includes patients with primary high trans-sphincteric fistula-in-ano and have undergone LIFT technique with the proposed LIFT-EM. LIFT-EM entails lay open of the proximal fistula portion traversing the internal sphincter (internal fistulotomy), fistulectomy

(coring out) of the outer fistula part, and curette of the residual track inside EAS, besides the conventional steps of intersphincteric ligation of the FT. Control: No control group is included.

Outcomes

- i. Primary outcome: recurrence rate of the proposed LIFT-EM.
- ii. Secondary outcomes: faecal incontinence rates, pain scores, length of hospital stay and postoperative complications.
- a. Study design: A prospective cohort study with data extraction from patients' files.

Research Question: Is the LIFT technique with the proposed EM safe and effective in treatment of high trans-sphincteric fistula-in-ano?

Hypothesis

LIFT technique with the proposed EM is safe and effective in the treatment of primary high trans-sphincteric fistula-in-ano.

Definition of fistula persistence and recurrence

Persistence of fistula is defined as nonhealing of the FT with sustained discharge beyond 12 weeks postoperatively, while fistula recurrence means reopening of the FT and relapse of discharge from the same fistula location after complete healing of the fistula tract. Parks' classification was utilized to define high trans-sphincteric fistula-in-ano.

Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score

The scale was scored according to the frequency and type of incontinence (solid stool, fluid, gas, pad use, and its effect on daily life). Mild, moderate, and severe incontinence were scored as less than or equal to 8, 9–14, and 15–20, respectively.

Surgical details

- i. **Preoperative preparation:** Thorough history taking, physical examinations, including digital rectal examination were routinely done. All patients underwent an MRI fistulogram (MRI with IV contrast) before the surgery (Figure 1).
- ii. Operative steps and techniques (Figures 2–4):
 - a. General anesthesia
 - b. Lithotomy position with padding of both legs, to avoid common peroneal nerve palsy.
 - c. Patient insulation by diathermy pad.
 - d. Skin preparation and draping by Chlorhexidine.

- e. Routine EUA using anoscope for initial assessment.
- f. Probing and proper identification of internal opening (IO), FT, and external opening (EO). Sometimes hydrogen peroxide is used to locate IO.
- g. Skeletonization and excision of the outer part FT till EAS, where contractions are noticed.
- h. Curette of granulation tissue in the FT traversing EAS.
- i. Complete preservation of EAS.
- j. Probing the track using a malleable probe again.
- k. 2cm curvilinear incision parallel to the anal orifice.
- l. Creation of ISP with complete preservation of EAS while the probe in place, utilizing right angle clamp and monopolar diathermy.
- m. Identification and LIFT, using 2–3 sutures of PDS or Vicryl 2/0 (Ethicon, Inc., Somerville, NJ, USA), followed by its division.
- n. Lay open the proximal part of the FT, traversing the internal anal sphincter (IAS).
- o. Ensuring no more side tracks.
- p. Hemostasis.
- q. SC Infiltration of LA: 20ml bupivacaine 0.25% diluted in 20ml saline, after anesthetist notification.
- r. Packing with paraffin-soaked gauze.

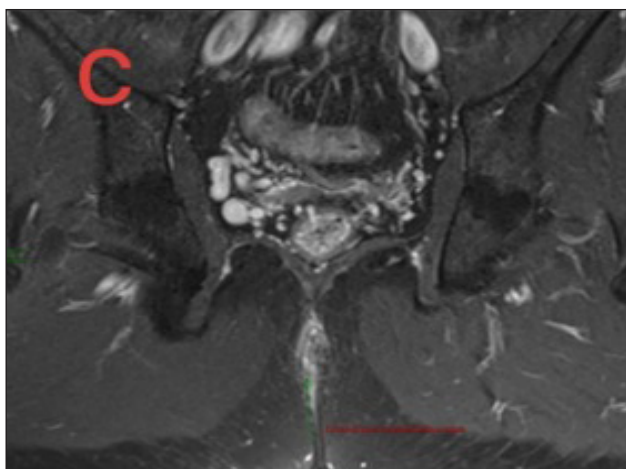


Figure 1: Shows coronal postcontrast fistula track.

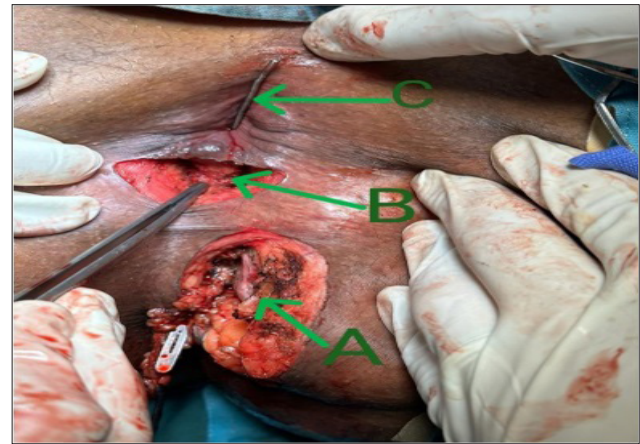


Figure 2: Shows the steps of the modified LIFT technique; (Arrow A): Fistulectomy of the outer part till external anal sphincter; (Arrow B): Dissected FT in the intersphincteric plane; (Arrow C): A metallic probe inside the whole FT.

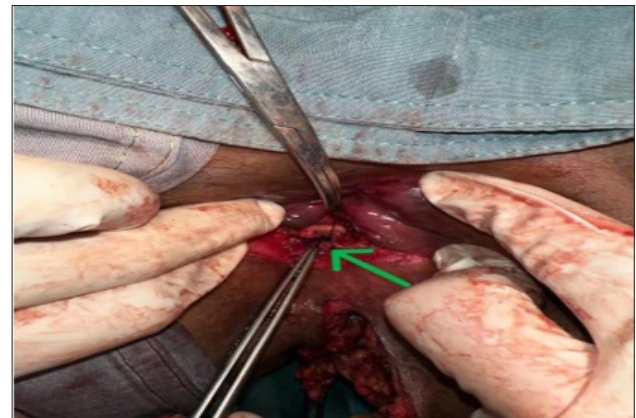


Figure 3: The green arrow refers to the ligated FT with PDS suture in the intersphincteric plane.

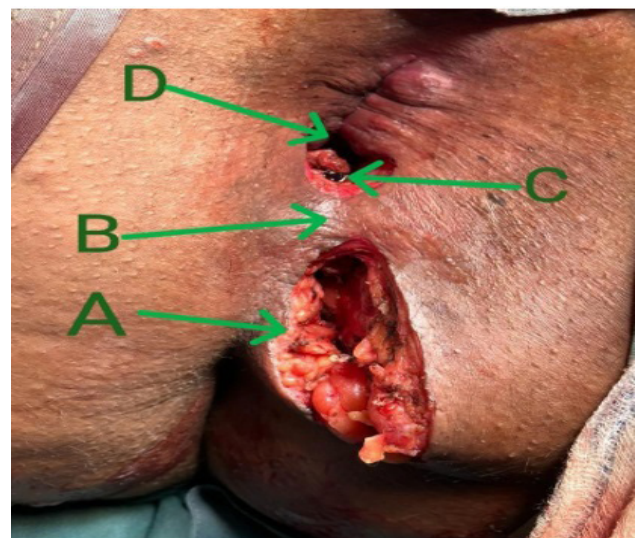


Figure 4: Shows the final view of modified LIFT technique; (Arrow A): Fistulectomy of the outer part till external anal sphincter with a laid open wound; (Arrow B): Preserved external anal sphincter under the skin; (Arrow C): Ligated FT with PDS suture in the intersphincteric plane; (Arrow D): Divided FT traversing internal anal sphincter with elimination of IO.

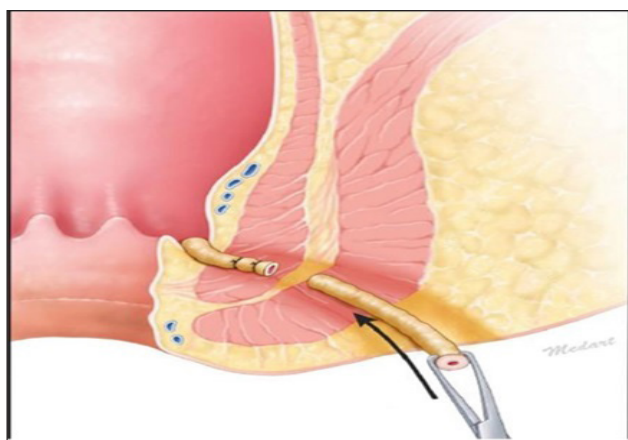


Figure 5: Shows the dissection direction and high ligation by the lateral approach.



Figure 6: Shows the statue of Eldemerdash Pasha, the founder of Eldemerdash Hospital, inside the hospital campus.

Postoperative management: All patients were allowed to start oral feeding after recovery from anesthesia as they were tolerating, offered adequate analgesia on demand, planned for VTE prophylaxis according to the local guidelines, and encouraged to mobilize early. Patients were encouraged to start warm sits bath once they pass their first motion, ingest high fiber diet and to use topical local anesthetics.

Statistical analysis

After collecting the data, it was cleaned and coded using IBM SPSS software. Data analysis was performed using the Statistical Package for Social Sciences, version 25.0 (IBM Corp. Released (2017). Armonk, New York, USA). Shapiro–Wilk’s test was used to evaluate normal distribution of numerical data which were presented as mean and Standard deviation values. Categorical results are presented as numbers of cases and percentages. Student *t* test was used to compare numerical variables between two study groups. Categorical variables were compared using the Fisher exact test. The McNemar test was used to compare a categorical variable measured twice for the same study group. Pearson correlation coefficient were used to assess the correlation between numerical variables. A significance level of *P* less than 0.05 was used in all tests.

RESULTS:

The mean age of study cases was 36.4 ± 6.0 years, ranging between 27 and 45 years. The mean BMI was 35.3 ± 9.5 with males representing all cases (100%). About 83% of cases were ASA Grade 1, with three (16.7%) cases having diabetes mellitus and one (5.6%) case having psoriasis. The mean FT length was 6.6 ± 2.3 cm, ranging between 5 and 15cm. Trans-sphincteric fistula represented the type of fistula among all cases (100%). 50% of cases had an anterior fistula. Preoperative CCF-FI score was 0 in 16(88.6%) cases, and one in only two (11.1%) cases (11.1%). About 83% of cases did not have a previous anorectal abscess, while none had a preoperative seton (Table 1).

The mean operative time was 59.1 ± 11.1 min, ranging between 40 and 75min. PDS was the used ligation material among 66.7% of cases. All cases had no intraoperative complications (100%). The estimated blood loss was less than 20ml, and the type of wound closure was lay open among all cases. The mean hospital stay among study cases was 38.5 ± 9.1 h, ranging between 27 and 48h. The mean time to complete wound healing was 11.3 ± 1.1 weeks. The mean VAS score at 24h and 1 week was 3.3 ± 0.9 and 2.2 ± 0.9 , respectively. All cases had no postoperative complications (100%). Recurrence/persistence was present in only one (5.6%) case, with recurrence occurring after 180 days. The postoperative CCF-FI score was 1 in 11.1% of cases (Table 2).

Table 1: Description of patient demographics and fistula characteristics:

	Mean \pm SD	Minimum	Maximum
Age (years)	36.44 \pm 6.01	27.00	45.00
BMI (kg/m ²)	35.33 \pm 9.54	25.00	50.00
Sex			
Male	18 \pm 100.0		
ASA grade			
1	15 \pm 83.3		
2	3 \pm 16.7		
Co-morbidities			
None	14 \pm 77.8		
DM	3 \pm 16.7		
Psoriasis	1 \pm 5.6		
Fistula track length (cm)	6.64 \pm 2.34	5.00	15.00
Fistula Type			
Trans-sphincteric	18 \pm 100.0		
Fistula location			
Anterior	9 \pm 50.0		
Post	9 \pm 50.0		
Preoperative CCF-FI score			
0	16 \pm 88.9		
1	2 \pm 11.1		

	Mean±SD	Minimum	Maximum
Previous anorectal abscess			
No	3±16.7		
Yes	15±83.3		
Preoperative seton			
No	18±100.0		
Yes	0±0.0		

There was a significant positive correlation between BMI and hospital stay (P 0.023), otherwise, no other significant correlation was found between each of the

personal or clinical characteristics and postoperative secondary outcomes (Table 3). There was a higher mean VAS score at 24h in posterior fistula cases, P 0.001. There was a higher mean VAS score at 1 week in posterior fistula cases, P 0.001.

There was a higher mean duration of hospital stay among ASA grade 2 cases (P 0.001). Inversely, patients with previous anorectal abscess had significantly shorter hospital stay (P 0.018) (Table 4). There was no significant difference between pre and postoperative CCF-FI score among cases.

Table 2: Description of intra and postoperative variables.

	Mean±SD	Minimum	Maximum
Operative Time (min)	59.17±11.15	40.00	75.00
Estimated Bl loss (ml)			
< 20ml	18±100.0		
Wound closure			
lay open	18±100.0		
Ligation material			
PDS	12±66.7		
Vicryl	6±33.3		
Intraoperative complications			
No	18±100.0		
Yes	0±0.0		
Hospital stay(h)	38.50±9.12	27.00	48.00
Time to complete wound healing (weeks)	11.35±1.17	10.00	13.00
VAS score (24h)	3.33±0.97	2.00	5.00
VAS score (1 week)	2.33±0.97	1.00	4.00
Post-op complications			
No	18±100.0		
Yes	0±0.0		
Recurrence			
No	17±94.4		
Yes	1±5.6		
Time to recurrence (days)			
No recurrence	17±94.4		
180 days	1±5.6		
Postoperative CCF-FI score			
0	16±88.9		
1	2±11.1		

Table 3: Correlation between age, BMI, fistula track length, and postoperative secondary outcomes:

	Hospital Stay(h)	VAS score (24h)	VAS score (1 week)
Age (years)			
R^*	0.278	0.064	0.064
P	0.264	0.801	0.801
Significance	NS	NS	NS
BMI (kg/m²)			
R^*	0.532*	-0.051	-0.051
P	0.023	0.841	0.841

	Hospital Stay(h)	VAS score (24h)	VAS score (1 week)
Significance	S	NS	NS
Fistula track length (cm)			
<i>R</i> [*]	-0.153	0.082	0.082
<i>P</i>	0.543	0.747	0.747
Significance	NS	NS	NS

*: Pearson correlation coefficient.

Table 4: Correlation between ASA grade, fistula location, previous anorectal abscess, ligation material, and hospital stay:

	Hospital Stay (h)		Significance
	Mean±SD	<i>P</i>	
ASA grade			
1	36.60±8.82	0.001*	HS
2	48.00±0.00		
Fistula location			
Anterior	37.00±8.53	0.502*	NS
Post	40.00±9.95		
Previous anorectal abscess			
No	46.00±3.46	0.018*	S
Yes	37.00±9.21		
Ligation material			
PDS	38.75±9.15	0.88*	NS
Vicryl	38.00±9.92		

*: Student *t* test.

DISCUSSION

Study variables

Study variables did not demonstrate a statistical impact on the occurrence of recurrence/persistence. In parallel, there was no significant difference between pre and postoperative CCF-FI score among cases, reflecting that the addition of internal fistulotomy did not negatively impact continence status. Our results showed that higher VAS scores, at 24h and 1 week, were closely associated with posterior fistulas. Longer hospital stay was significantly linked to BMI and ASA 2, while it was shorter in patients with a history of previous anorectal sepsis.

Criticism of original ligation of intersphincteric fistula tract

Many authors have criticized the original LIFT due to persistence of IO and preservation of primary cryptoglandular infection, which can lead to recurrence up to 43–60%^[8]. Ker-Kan *et al.*,^[9] described that most of the failures occur in the intersphincteric wound, raising the need for a second surgery which includes the division of the lower part of the IAS^[10], ending up with the same rationale as per our study.

Types of failure after ligation of intersphincteric fistula tract

Several authors described three common patterns of failures after the LIFT technique. In Type 1, there is a blind discharging track from the intersphincteric wound without evidence of primary IO or EO. In Type 2, there is medialization of the EO towards the anal canal. IO leads to the intersphincteric wound forming neo-EO with the disappearance of the primary EO. A safe subsequent fistulotomy seems a logical solution. In our proposed technique, we suggest adding this step routinely during LIFT without waiting for type 2 recurrences. Finally, in Type 3, the original FT persists wholly without involvement of the intersphincteric wound. Nine factors for failure of the LIFT procedure can be categorized into several groups: procedural or technical, the condition of local tissues, and the adequacy of drainage of the fistula tract^[5,6].

Rationale and merits of ligation of intersphincteric fistula tract-Eldemerdash modification

Based upon the disadvantages of the original LIFT discussed above, we developed our novel technique (LIFT-EM), attempting to achieve the following merits:

Lay open of the fistula part traversing IAS with complete eradication of IO and cryptoglandular infection -the main drive of fistula- sacrificing a part of IAS without affecting the integrity of sphincter functions. This preemptive step guards against the occurrence of type 2 failure and subsequently bypasses a potential future surgery of simple fistulotomy.

- i. Coring out of external part of EAS, to shorten the length of the tract to minimize infection reactivation. In a study by Liu and colleagues, the length of the fistula was found to be inversely proportional to the cure rate of LIFT. The longer the fistula, the more the unhealthy tissue residues, with increasing chances of infection, resulting in difficult treatment and higher recurrence risk. They selected 3cm to be a cutoff level and assumed that a fistula tract shorter than 3cm has a significantly higher healing rate^[11].
- ii. Curette of the remaining tract inside EAS with its complete preservation, accelerating its fibrosis and obliteration. There are various ways to manage the external portion of the tract outside the intersphincteric ligation: curettage, core-out, or seton. The scarce literature dealing with this aspect does not demonstrate a clear superiority of any of those different options^[12,13].

Those main steps are collectively integrated to ensure eradication of the infected lesion, ensure sufficient cryptoglandular drainage, and promote the closure of the fistula, while minimizing damage to the anal sphincter.

Preconditions of successful ligation of intersphincteric fistula tract-Eldemerdash modification

The success of LIFT-EM is closely linked to proper patient selection to ascertain the presence of favorable factors, which are: a) a Mature well-formed FT with absence of side branching. b) Absence of active infection^[14]. c) Acceptable sphincter tone by clinical assessment. If fecal continence disorder is suspected, preoperative anal manometry is warranted. d) IO should be at the dentate line, not higher in the rectum. Otherwise, a significant alteration in fecal continence is predicted to occur. e) Strict local hygiene should be taught to all patients during counseling.

Potential demerits of ligation of intersphincteric fistula tract-Eldemerdash modification

Some authors may oppose our technique, claiming that ligation over the FT becomes exposed to the fecal material during defecation, and therefore the

straining effect may cause ligature slippage or knot sloughing. But we advocate it as ISP becomes well-drained with the eradication of the underlying IO and cryptoglandular infection. Avoiding constipation and strict local hygiene are essential maneuvers that ensure completion of healing and avoid failures.

The only case of persistent fistula was treated by cutting seton technique. This is because after opening the ISP, internal fistulotomy, and eradication of IO, redo LIFT-EM seems infeasible. This could be one of the potential demerits of our proposed modification. The reason for persistence in that case is attributed to inadequate local hygiene and excessive fecal soiling, which has presumably led to disrupted ligature of the external tract and its re-canalization.

Ligation of intersphincteric fistula tract modifications in the literature

Ligation of intersphincteric fistula tract plus internal sphincterotomy

A very interesting study conducted by Bastawrous et al. investigated adding internal sphincterotomy at the level of the IO, to LIFT for trans-sphincteric anal fistula. They retrospectively reviewed 66 patients with a median follow-up of 20.98 weeks. Overall cure rate was 71.42%, with a recurrence rate of 5.35% and fistula persistence in 16.07%. They concluded that Modified LIFT is a safe and feasible procedure, eradicates the intersphincteric space, and has comparable healing rates with the original LIFT^[15]. In fact, their modification is similar to ours but with the following differences: 1) Our study design is prospective. 2) Their case series included patients with a seton, while we excluded all patients with previous fistula surgeries i.e, we included only primary fistulas. 3) They started internal sphincterotomy before ligation, whereas we ligated the tract, divided it then laid open IS. We believe that our order of steps is more convenient because it allows better identification and subsequently more precise ligation of the tract. 4) They only curetted the outer fistula portion, while we did fistulectomy of that part, plus curette of the portion traversing EAS to shorten the track length and ensure adequate fistula cleansing and drainage.

Ligation of intersphincteric fistula tract plus external fistula coring out

Shanwani *et al.*,^[16] investigated a similar step to ours, by combining the LIFT technique with coring out of the external fistula tract, achieving a primary cure rate of 82.2%, with a median healing time of 7 weeks. We agree with Shanwani et al. that coring out the external tract may guard against perianal sinus formation and accelerate wound healing postoperatively.

Ligation of intersphincteric fistula tract via Lat. Approach

Kang *et al.*,^[17] developed a lateral approach to access the ISP rather than creating a new incision. Their prospective study involved 28 patients (only nine with complex fistula) with median follow-up of 16 months. Successful fistula closure was achieved in 21(75%) patients. We oppose this technique because of the following reasons: 1. It preserves IO which can easily predispose to cryptoglandular infection reactivation. 2. It may be technically difficult in long FTs and obese patients (Figure 5).

BioLIFT

Ellis conducted the first research of BioLIFT (placement of biosynthetic mesh in the intersphincteric plane after dividing fistula tract) on 31 patients achieving an initial success rate of 94%^[18]. Lau *et al.* investigated utilizing Surgisis (Cook Biotech, Bloomington, IN, USA). In their series, seven out of 11 BioLIFTs had primary failures. That is why they recommended to spare BioLIFT as a salvage procedure for recurrent cases^[19]. Zwiap *et al.*, compared 79 cases of LIFT with 44 cases of BioLIFT, concluding a significantly better healing rate for BioLIFT group but at the expense of higher cost^[20]. We encourage initiating Randomized clinical trials (RCTs) to compare this technique with other sphincter-sparing procedure.

LIFT-plug

LIFT-plug method is a relatively new modification of the original LIFT by adding a bioprosthetic anal fistula plug. In (2016), a multi-center prospective randomized trial demonstrated that the LIFT-plug is superior to the original LIFT in terms of enhanced healing rate (from 83.9 to 94%) and shortened the time required for healing^[21]. Via a long-term retrospective cohort study, Zhao *et al.*,^[22] similarly demonstrated that LIFT-plug technique was associated with a high cure rate together with preservation of anal continence during treating trans-sphincteric perianal fistulas.

A glimpse about Eldemerdash Hospital

We named this proposed technique after Eldemerdash hospital which is the main and the oldest hospital belonging to Ain Shams University, Cairo, Egypt. In (1928), Eldemerdash hospital was founded as a charity by Eldemerdash Pasha (Figure 6) for the sake of treating destitute people free of charge. After the establishment of Ain Shams University in (1950), Eldemerdash Hospital has become the first Ain Shams University hospital where medical education and clinical training commenced. Over the past century, Eldemerdash hospital has treated millions of needy patients and graduated thousands of talented doctors, pioneer scholars, and eminent leaders in all specialties^[23]. We all owe Eldemerdash Hospital for providing us with tremendous medical education and

clinical training, rendering us very proud of being affiliated to it.

Strengths and limitations of the study

This research is a pilot study investigating the safety and effectiveness of a novel technique in treatment of high trans-sphincteric fistula-in-ano. It proposes fistula eradication with potential merits of low recurrence rates and intact fecal continence. Preoperative anorectal MRIs were routinely performed to all patients to study the anatomy, amount of sphincter involvement, and structure of fistulas. This study included only primary cases to eliminate the confounding effect of previous fistula procedures. Subsequently, the sample size is small with no comparison group and lack of randomization. Another limitation is that anorectal manometry was not performed after surgery to objectively assess fecal continence. Hence, we encourage other authors to initiate RCT studies comparing our proposed LIFT modification with both conventional LIFT and other LIFT modifications utilizing anorectal manometry studies with longer follow-up periods.

CONCLUSION

LIFT-EM entails the conventional step of intersphincteric fistula ligation with addition of internal fistulotomy, external fistulectomy, and curette of residual track. In properly selected cases, LIFT-EM could be a safe and effective sphincter-preserving technique in treating high trans-sphincteric fistula achieving potential merits of complete elimination of cryptoglandular infection with low recurrence rates, without disturbing sphincter functions. RCTs with larger sample and longer follow-up periods comparing various LIFT modifications are warranted to consolidate our data.

ETHICAL CONSIDERATIONS

An IRB approval was obtained from the Department of Surgery, Faculty of Medicine, Ain Shams University, Egypt. Informed consent was obtained from all participants in the study, after complete clarification of the procedure with emphasis on their right to withdraw at any time throughout the study. The procedures performed in studies complied with the 1964 Helsinki declaration and its later amendments.

AUTHORS' CONTRIBUTIONS

M.G.Q., idea conception, PI, teamwork recruitment, operating surgeries, data collection, data interpretation, literature review, manuscript writing, and reviewing. A.E., statistical analysis, data interpretation, literature review, manuscript writing, reviewing and submission. M.A.A.H., data collection,

data interpretation, literature review, manuscript writing, and reviewing. A.S.M.O., data interpretation, literature review, manuscript writing, and reviewing.

CONFLICT OF INTEREST

There are no conflicts of interest.

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