Efficacy of ligation of intersphincteric fistula tract for the treatment of anal fistula

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Background

Treatment of a perianal fistula is difficult due to the risk of fecal incontinence and recurrence. The ligation of intersphincteric tract (LIFT) procedure is a sphinctersaving procedure associated with quite impressive preliminary results, with more than 90% of patients achieving complete healing within a mean duration of 4 weeks and without any disturbance of the continence state. The aim of this review was to prospectively compare the LIFT procedure with fistulotomy as a treatment for trans-sphincteric anal fistulas with respect to healing time, overall healing rate, recurrence, continence, morbidity, and postoperative pain.

Patients and methods

This study was performed on 30 patients with trans-sphincteric anal fistulas who underwent LIFT and fistulotomy from January 2021 to August 2021 at our Surgery Department of Zagazig University Hospitals in Egypt. All patients were followed up for 6 months through regular visits in the outpatient clinic. The primary end point of the study was healing, whereas the secondary outcome measures were recurrence rate, morbidity, postoperative pain, and incontinence rate.

Results

Healing rate in the LIFT group was 92 versus 70% in the fistulotomy group (P=0.08). There was a highly significant difference in favor of LIFT group regarding fecal incontinence (P=0.0004). Recurrence occurred in two patients in the LIFT group versus four patients in the fistulotomy group. Postoperative pain scores, patient satisfaction, and time taken to return to normal activities were significantly better in the LIFT arm. There was a highly significant difference in favor of LIFT group in the following complications: hemorrhage (P=0.0008), urinary retention (P=0.0001), delayed wound healing (P=0.0004), and persistent pain (P=0.0002). Only a small number of postoperative complications were reported in the fistulotomy group, including a thrombosed external hemorrhoid (n=1), anal fissure (n=2), anal stenosis (n=3), and bleeding (n=2). The bleeding did not require reoperation or hospital readmission.

Conclusion

The LIFT procedure has the advantages of preservation of the anal sphincters, minimal tissue injury, short healing time with no additional costs, and relatively easy procedure.

Keywords:

anal fistula, fistula-in-ano, fistulotomy, intersphincteric plane, ligation of the intersphincteric fistula tract, trans-sphincteric fistula

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Background

Anal fistula, fistula-in-ano, or perianal fistula is a hollow tract lined with granulation tissue, connecting a primary opening inside the anal canal or rectum to a secondary opening in the perianal skin [1]. These defects are distributed in the following proportion, using the classification described by Parks *et al.* (1976): inter-sphincteric (60–75%), trans-sphincteric (15– 20%), supra-sphincteric (5%), and extra-sphincteric (1–3%) fistulas [2].

The term 'simple fistula' describes low transsphincteric and inter-sphincteric fistulas that cross 30% of the external sphincter [3]. The term 'complex fistula' describes fistulas with any of the following characteristics: the tract crosses more than 30–50% of the external sphincter, the fistula is anterior in a female, multiple tracts are present, the fistula is recurrent, or the patient has preexisting incontinence, local irradiation, or Crohn disease [4].

Fistulotomy, simple lay-open of the fistula, is the most effective cure for anal fistulas with success rates above 90% [5], but it carries a variable incontinence risk of

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~10–45% [6], dependent on the amount and quality of muscle left intact. Several sphincter-sparing procedures have been described for the treatment of complex anal fistula, including seton drainage, ligation of the intersphincteric fistula tract (LIFT), laser ablation of the fistula tract, fistula plug, video-assisted anal fistula treatment, and injection of autologous platelet growth factors and stem cells [7].

The concept of the intersphincteric approach is not new. In 1993, the St Mark's group published a series of 13 patients treated with the intersphincteric procedure, with drainage of the space and closure of the fistulous orifices, both in the internal and external sphincters, with final closure of the wound. The technique was completely successful in seven (53.8%) patients. In addition, five patients had inflammatory bowel disease [8]. The main idea of LIFT is that ligation and excision of the inter-sphincteric tract could block the entrance for fecal particles into the tract, thereby eliminating the inter-sphincteric sepsis [9].

The most common complications after LIFT, dehiscence and infection, were related to the perineal wound, which may suggest that leaving the wound open may avoid developing such complications. Recurrence of fistula-in-ano is mainly due to either fecal material entering the internal opening, thereby causing recurrent infection, or intermittent closed septic foci or persistent chronic sepsis in the intersphincteric fistula tract, which is normally compressed between the internal and external anal sphincters.

All of the included studies were uniform in their definition of success, which was based on a clinically observed closure of the external opening and/or absence of drainage. However, it has been shown that skin healing at the external opening does not necessarily mean actual fistula healing [10]. The aim of this review was to prospectively compare the LIFT procedure with fistulotomy as a treatment for trans-sphincteric anal fistulas with respect to healing time, overall healing rate, recurrence, continence, morbidity, and postoperative pain.

Patients and methods

This prospective, observational, randomized study was conducted at the Surgery Department of Zagazig University Hospitals in Egypt during the period from January 2021 to August 2021. The study included 30 patients with trans-sphincteric anal fistulas. The patients were divided into two equal groups (15 patients in each group): LIFT repair (L group) or fistulotomy repair (F group). Randomization was achieved using computer- generated allotments that were disclosed to the surgeon through a sealed envelope.

Ethical issues

The study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The study was done according to the Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. Data were collected prospectively on 30 consecutive patients undergoing LIFT procedure and fistulotomy under institutional review board (IRB) approval.

For inclusion, the patients were informed by the research team on the surgical technique used and on the possible complications of the surgery and had to agree to participate in the study by completing voluntarily informed consent forms.

Outcomes

The primary end point of the study was healing, defined as absence of drainage from the external opening±closure of the internal opening; external opening closure was the most commonly followed end point. The secondary outcome measures were recurrence rate, morbidity, postoperative pain, and incontinence rate.

Inclusion criteria

The study included men and women with transsphincteric perianal fistulas of cryptoglandular source with no previous surgical intervention, between 20 and 60 years of age.

Exclusion criteria

Patients with an intersphincteric fistula, an abscess, rectovaginal fistulas, fistula due to a pilonidal sinus, hidradenitis suppurativa, tuberculosis, HIV infection, inflammatory bowel disease, actinomycosis, and anal carcinoma were excluded.

Preoperative

All patients were subjected to preoperative evaluation including history taking, clinical examination, and basic laboratory investigations. Elderly patients were subjected to further investigations as part of the preanesthetic workup and looked for any complications.

Data were collected regarding demographics, symptoms, medical history, previous perianal surgical procedures, obstetric history, and findings of the proctological examination at first presentation. Physical examination was performed with the patient in the left lateral decubitus position. Patients were referred preoperatively, in our study, for pelvic MRI scan to determine the nature of the fistula tract and to exclude secondary extensions. Most patients received two fleet enemas for preparation the night before. A single dose of antibiotics (usually cefoxitin 1 g for all patients not allergic to B-lactam antibiotics) was administered parenterally within 1h before the procedure. Preoperatively, fecal incontinence was assessed by the patient's ability to hold solid stool, liquid stool, flatus, and soiling. This was determined by the patients' history performed by a surgeon and was classified using the Parks FI classification [11].

Ligation of intersphincteric tract procedure

Patients were operated under general, caudal, or spinal anesthesia. The patients were placed in the prone jack-knife position for the anterior fistula procedure and the lithotomy position for the posterior fistula procedure. An anal examination was performed using an Eisenhammer-Pratt anal retractor. This technique involves disconnection of the internal opening from the fistula tract at the level of the inter-sphincteric plane and removal of the residual infected glands, without dividing any part of the anal sphincter complex.

The main steps were as follows: following the identification of the internal opening by injecting hydrogen peroxide from the external opening (Fig. 1) or gently probing the fistula tract by a Lockhart-Mummery probe (Fig. 2), a 3–4-cm curvilinear incision along the anal margin was performed at the site of the fistula (Fig. 3). The incision was sufficiently far from the anal verge to allow proper closure at the end of the procedure. The fibers of the internal and external sphincter were separated, and the inter-sphincteric groove was entered. Dissection of the inter-sphincteric plane with diathermy (Fig. 4), dissection of the fistulous tract (Fig. 5), and placement of doubly ligated 2 3/0 absorbable sutures were done, followed by removal of

Figure 1



Identification of the internal fistula opening by injecting hydrogen peroxide through the external opening.

the probe and placement of a proximal double knot (Fig. 6). The medial ligature is very close to the internal opening, nearly obliterating it. The tract is then divided distal to the point of ligation (Fig. 7), with removal of the remnant of the fistula tract and any infected gland. Curettage of the distal end (Fig. 8) and closure of the orifice in the external sphincter with absorbable suture in the inter-sphincteric plane were done. The infected granulation tissue was gently scraped away and washed





Probing the fistula tract.

Figure 3



Incision of the intersphincteric plane.

Figure 4



Dissection of the intersphincteric space.

Figure 5



Dissection the fistula tract.

with metronidazole saline. Cauterization of the internal fistula opening was done (Fig. 9). Finally, the internal and external sphincters were then re-approximated, and the skin was closed loosely all with absorbable sutures (Fig. 10).

Fistulotomy procedure

After identification and probing of the fistula tract as shown before, laying open of the tract with curettage was done.

Postoperative

All patients were discharged within the first 24h. Antibiotic treatment was continued for 2 days, with the same initial dosage. If necessary, the dressing was changed daily to keep the incision clean. All patients were required to have a fluid diet within 3 days and oral stool softener for 1 week postoperatively. After hospital discharge, using a shower was allowed, but swimming, sexual activity, and

Figure 6



Ligation of the fistula tract.

Figure 7



Transection of the tract after ligation.

lifting weights were not recommended within the first 2 weeks. Patients were discharged with prescriptions for narcotic analgesics, stool softeners, and laxatives. Patients are instructed to perform a sitz bath two to three times a day until the wound has healed.

Follow-up

The patients were followed up and monitored for complications, recurrence, or incontinence in the clinic at 1, 2, and 6 weeks after surgery with a final followup at 6 months, if completely healed, and as needed if issues such as swelling, pain, and drainage were encountered. Clinical examination was done to assess fistula healing or failure. Fistula healing was defined as complete healing of the surgical inter-sphincteric wound and closure of the external opening without anal pain. Failure was defined as the presence of persistent discharge through the external opening or the intersphincteric wound. Recurrence or persistence of fistula Figure 8



Curettage of the external opening.

Figure 9



Electro-cauterization of the internal fistula opening.

was defined as clinical suspicion owing to continued drainage of pus and later confirmed by examination under anesthesia.

Statistical analysis

All patient data were recorded on a dedicated database with statistical analysis performed using the SPSS v.11.5 software (SPSS Inc., Chicago, Illinois, USA). Parametric data were presented as means±SD. Nonparametric data were presented as medians. Categorical variables were analyzed using the χ^2 test and Fisher's exact test, and the quantitative variables were analyzed using the nonparametric Mann–Whitney test. *P* values less than 0.05 were considered significant.

Results

We included 30 patients from the Surgical Department of Zagazig University from January 2021 to August 2021.

Figure 10



Closure of the intersphincteric plane.

Patients' characteristics	L group (<i>N</i> =15) [<i>n</i> (%)]	F group (<i>N</i> =15) [<i>n</i> (%)]	Р
Male	5 (33)	7 (47)	0.45
Female	10 (67)	8 (53)	
Age (years) (mean±SD)	42.39 ± 13.69	43.28 ± 12.85	0.754
BMI (kg/m²) (mean±SD)	31.12±3.85	28.94 ± 2.86	0.081
Symptom duration, (month) [median (range)]	6 (2–10)	5 (3–9)	0.212
Smoking	3 (20)	3 (20)	_
Diabetes	5 (33)	4 (27)	0.43
High education	9 (60)	6 (40)	0.27
No previous fistula surgery	15 (100)	15 (100)	-

Table 1 shows patients' characteristics in 30 anal fistula cases. The patients' mean±SD age was 42.39±13.69 years in the LIFT group versus 43.28±12.85 years in the fistulotomy group. There were 18 females and 12 males among the patients. The mean±SD BMI was 31.12±3.85 in the LIFT group versus 28.94±2.86 in the fistulotomy group. There were nine diabetic patients using oral medication. Six patients smoked. No previous fistula surgery was found in both groups. Anal fistula characteristics are shown in Table 2. Perioperative parameters in the anal fistula are shown in Table 3, where the mean±SD operative time spent in the operation room from anal examination was performed using an Eisenhammer-Pratt anal retractor till the dressings were done was 30.8±10.8min in the LIFT group versus 25.1 ± 7.3 min in the fistulotomy group (P=0.068). The first operations took longer owing to the learning curve. Mean±SD blood loss was 17.3±4.63 in the LIFT group versus 31.8 ± 10.2 in the fistulotomy group (P=0.008). All patients were followed up for 6 months through regular visits in the outpatient clinic. Postoperative pain

Table 2	Anal	fistula	characteristics
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Characteristics	L group (N=15) [n (%)]	F group (<i>N</i> =15) [<i>n</i> (%)]	Р
Trans-sphincteric (low)	3 (20)	8 (53)	0.15
Trans-sphincteric (mid)	8 (53)	4 (27)	
Trans-sphincteric	4 (27)	3 (20)	
(high)			
Simple	5 (33)	15 (100)	0.004*
Complex	10 (67)	0	
Anterior internal fistula opening (IFO)	8 (53)	6 (40)	0.46
Posterior	7 (47)	9 (60)	
Fistula tract length ≤3 cm	7 (47)	11 (73)	0.13
Fistula tract length >3 cm	8 (53)	4 (27)	

**P* of significance difference.

Table 3 Perioperative parameters in the anal fistula

Parameters	L group (<i>N</i> =15) [<i>n</i> (%)]	F group (<i>N</i> =15) [<i>n</i> (%)]	P value
Operative time (min) (mean±SD)	30.8±10.8 min	25.1 ± 7.3 min	0.068
General anesthesia	5 (33.3)	5 (33.3)	0.62
Spinal	8 (53.3)	6 (40)	
Caudal	2 (13.4)	4 (26.7)	
Blood loss (ml) Mean±SD	17.3±4.63	31.8±10.2	0.008*
Follow-up period, (month)	6 months	6 months	-
*Significant.			

scores, patient satisfaction, and time taken to return to normal activities were significantly better in the LIFT arm. Table 4 shows outcomes of LIFT and fistulotomy procedures. There was a highly significant difference in favor of the LIFT group in the following complications: hemorrhage (P=0.0008), urinary retention (P=0.0001), delayed wound healing (P=0.0004), persistent pain (P=0.0002), and fecal incontinence (P=0.0004). All of the included studies defined successful fistula healing using clinical criteria, specifically epithelialization at the external opening and/or the absence of drainage. Healing rate in the LIFT group was 92 versus 70% in the fistulotomy group (P=0.08). Healing time was 14-40 days in the LIFT group versus 25–70 days in the fistulotomy group (P=0.025). Fecal incontinence to flatus was transient with spontaneous regression, which occurred equally in both groups (one patient for each group). Three patients of fistulotomy group had major fecal incontinence.

The first patient who did not achieve a primary healing in the LIFT group showed recurrence in the incision for ligation of the fistulous tract, that is, his defects turned into inter-sphincteric fistulas and could be subsequently treated by fistulotomy with complete resolution and with no fecal incontinence. Furthermore, in the second patient who had recurrence, rectal advancement flap was done, supporting the notion that a failed LIFT

Table 4 Outcomes of ligation of intersphincteric tract and fistulotomy procedures

Complications	L group (<i>N</i> =15) [<i>n</i> (%)]	F group (<i>N</i> =15) [<i>n</i> (%)]	P value
Hemorrhage	0	2 (13.3)	0.0008**
Urinary retention	3 (20.0)	8 (53.3)	0.0001**
Wound infection	1 (6.7)	6 (40)	0.00**
Delayed wound healing	1 (6.7)	4 (26.6)	0.0004**
Anal stenosis	0	3 (20)	0.01*
Thrombosed piles	0	1 (7)	0.09
Anal fissure	0	2 (13.3)	0.035*
Fecal incontinence	1 minor (flatus) (6.7)	3 major (20) and 1 minor (6.7)	0.0004**
Recurrence rate	2 (13.3)	4 (26.6)	0.037*
Persistent pain	2 (13.3)	6 (40)	0.0002**
Healing time (days) median	27 (14–40 days)	41 (25–70 days)	0.025*
Healing rate	92%	70%	0.08
Length of hospital stay	1.5±0.45 days	1.8±0.68 days	0.075

P values less than 0.05 considered significant.

**Highly significant.

*Significant.

Table 5 Reoperations performed after persistent fistula or recurrent fistula after the ligation of intersphincteric tract procedure

Procedure	Patient no.
Fistulotomy	1
Drainage/debridement of abscess	0
Re-LIFT	0
Advancement flap	1

LIFT, ligation of intersphincteric tract.

does not prohibit the use of other modalities in treatment of a recurrent fistula-in-ano (Table 5). The four cases of recurrence in the fistulotomy group were managed by rectal advancement flap. Only a small number of postoperative complications were reported in the fistulotomy group, including a thrombosed external hemorrhoid (n=1), anal fissure (n=2), anal stenosis (n=3), and bleeding (n=2). The bleeding did not require re-operation or hospital readmission.

Discussion

A number of variations from the surgical LIFT technique originally described by Rojanasakul [12] have been reported. Certain authors described simple ligation rather than ligation and excision of the intersphincteric tract [13], and others used technical adjuncts. These included suture ligation of the internal opening [14] and placement of either a porcine or cadaver-derived bioprosthetic graft into the intersphincteric space [15].

Preliminary results of LIFT were quite impressive with more than 90% of patients achieving complete healing

References	Technique	Patients no; follow-up	Recurrence	Minor incontinence	Major incontinence
Pearl <i>et al.</i> [19]	Staged fistulotomy	116; follow-up 2–61 months	3%		5% major
Van Tets and Kuijpers [20]	Staged fistulotomy	34; follow-up 60 months	8%	17% minor; 38% mild	3.5% major
Garcıa-Aguilar <i>et al.</i> [21]	Staged fistulotomy	59; follow-up 27–33 months	3%	11.5% flatus transient	0
Atkin <i>et al.</i> [18]	Fistulotomy	180; 5 months	3–4%	30%	6–10%

Table 6 Published articles on fistulotomy

Table 7 Impairment of fecal continence after fistulotomy for low anal fistula

Refreences	Year	N	Minor incontinence (%)	Major incontinence (%)
Mylonakis <i>et al.</i> [23]	2001	65	9	0
Van der Hagen <i>et al.</i> [24]	2006	62	5	0
Van Koperen <i>et al.</i> [25]	2008	63	41	5
Bokhari and Lindsey [22]	2010	53	11	5
Atkin <i>et al.</i> [18]	2011	51	23	2

within a mean duration of 4 weeks and without any disturbance of the continence state [9]. Nevertheless, as more evidence started to accumulate and after longer follow-ups, the success rate of the procedure decreased to 76% [16].

Currently, there is a growing interest in ligation of LIFT because the procedure is minimally invasive, easy to learn and perform, and can be used on recurrent cases. The early results of the LIFT procedure were quite impressive, with minimal morbidity and little or no effect on the continence status [17]. Fistulotomy has low rates of efficacy, a prolonged postoperative wound healing, and protracted pain. Recently, Phillips's group reported overall symptoms of sphincter disturbance of 37% after fistulotomy in a large series of patients with a long-term follow-up [18] (Table 6).

Female patients with an anterior fistula in particular are at risk for impaired continence after fistulotomy [22]. The incidence of impaired continence after fistulotomy for low anal fistula has been addressed in mostly retrospective studies [18]. In a recent study, Bokhari and Lindsey [22] observed major and minor incontinence after fistulotomy for low fistulae in 5 and 11% of their patients. Garcia-Aguilar *et al.* [3] reported major and minor incontinence after fistulotomy for low trans-sphincteric fistulae in 44% of their patients. They also found that female sex and an internal opening located in the midline anteriorly were predictive factors of impaired continence after fistulotomy (Table 7).

Of the 15 LIFT procedures performed in our series, the primary closure rate was 92% (P=0.08). This is supported by similar rates reported by the original group of 94%, and two other studies by Shanwani *et al.* [11] at 82% and Bleier *et al.* [26] at 57%.

Success of LIFT is defined as complete healing of the surgical inter-sphincteric wound as well as the external opening without recurrence [16]. In the study by Shanwani *et al.* [11], none of their 45 patients had a seton at the time of the LIFT procedure, providing convincing evidence that if the surgeon determines that the fistula-in-ano is stable and without signs of active infection, the LIFT procedure can be performed as an initial, primary procedure without the need of a seton placement and repeat risks of anesthesia.

The initial study of this procedure in 18 patients with 3 months of follow-up by Rojanasakul *et al.* [9] reported healing of the fistula in 94% of patients. Two further LIFT studies have been published following the article by Rojanasakul *et al.* [9]. Both showed encouraging early outcomes, prompting our unit's interest. Bleier *et al.* [26] reported a 57% success rate after treating 39 patients. Their median follow-up was 20 weeks, whereas the median time to failure was 10 weeks.

Shanwani *et al.* [11] operated on 45 patients and 82.2% had successful fistula healing. The median followup was 9 months, and their cohort of patients had a median healing time of 7 weeks. No major morbidity or incontinence was reported in either group. Other reviews reported healing rates in 759 patients that ranged from 51 to 94% [27]. Another review showed success rates from 40 to 95% in 352 of 495 patients [28]. Other reports from Malaysia and Singapore also revealed high healing rates, exceeding those obtained with the current sphincter-saving techniques [17]. However, recent reports from the USA and Australia indicated that LIFT fails in one of every three patients [29] (Table 8).

The effect on continence is often limited or zero. This fact is recognized in most reviews about the LIFT

References	Year	No. of patients	Follow-up (weeks)	Healing rate	Complications	Type of study
Rojanasakul et al. [9]	2007	18	Up to 26 weeks	94%	NR	Prospective observational
Shanwani <i>et al.</i> [11]	2010	45	Median 9 (2–16) months	82%	NR	Prospective observational
Ellis et al. [15]	2010	31	Median 15 (12–30) months	94%	NR	Retrospective
Bleier et al. [26]	2010	39	10	57%	1 Anal fissure; 1 persistent pain	Retrospective
Ooi <i>et al.</i> [29]	2012	25	Median 22 (3–43) weeks	96%	NR	Prospective observational
Tan <i>et al.</i> [17]	2011	93	Median 23 (1–85) weeks	92%	NR	Retrospective review
Steiner and Omachi [30]	2011	18	Median 6 (4–10) months	83%	1 hemorrhoidal thrombosis	Retrospective
Aboulian <i>et al.</i> [14]	2011	25	Median 24 (8–52) weeks	68%	2 Vaginal fungal infection	Retrospective review
Mushaya <i>et al.</i> [31]	2012	25	LIFT: median 16 (8–31) months	68%	1 secondary bleeding; 2 superficial perineal wound dehiscence	Prospective randomized
Abcarian <i>et al.</i> [32]	2012	50	Median 18 (2–64) weeks	74%	NR	Retrospective
Lo et al. [33]	2012	25	2	98%	NR	Retrospective
van Onkelen et al. [13]	2012	42	Median 15 (7–21) months	51%	NR	Prospective
Chen et al. [34]	2012	10	6	100%	1 perianal hematoma	Retrospective
Lehmann and Graf [35]	2013	17	4	47%	1 wound infection	Prospective
Liu <i>et al.</i> [36]	2013	38	26	61%	NR	Retrospective

LIFT, ligation of intersphincteric tract.

technique and represents a strong point of the technique in cases of recurrence, something that does not occur with other more widespread techniques [37]. Tsunoda *et al.* [38] prospectively evaluated anal continence in 20 patients, using anal manometry and function scores. They found that there were no changes in pressures, rest, or contraction after LIFT-type surgery. There was a high significant difference in favor of LIFT group for fecal incontinence in our study (P=0.0004). There was a significant difference in favor of the LIFT group for the recurrence rate in our study (P=0.037). Table 6 shows published articles on fistulotomy. Table 7 shows impairment of fecal continence after fistulotomy for low anal fistula. Table 8 shows published articles on LIFT.

The most significant limitations of this study are the small sample size and short-term follow-up. In addition, for some patients who could only be followed up by telephone, it was sometimes difficult to accurately assess the recurrence of anal fistula without a clinical examination or MRI. Additionally, factors like smoking, diabetes, Crohn's disease, and tuberculosis, which can affect LIFT efficacy, were not tracked in the current study. A larger prospective, randomized, multicenter study will be needed in the future.

Conclusion

The LIFT operation is a very good choice in complex fistulae. According to the literature, the LIFT procedure has the advantages of preservation of the anal sphincters, minimal tissue injury, short healing time with no additional costs, and relatively easy procedure. In case of failure, the procedure can be readily repeated. Additionally, more studies should be conducted to compare results regarding different approaches of this procedure with longer follow-up and randomization of patients.

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Conflicts of interest

There are no conflicts of interest.

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