



Original Article

Long-term outcomes of (Gore) fistula plug versus ligation of intersphincteric fistula tract for anal fistula

Abdullah Alhaddad^{a,b,*}, Ali Mouzannar^b, Aqeel Ashraf^b, Bader Marafi^b,
Ibtisam Albader^{b,c}, Ali Alsaid^b, Jasim Alabbad^{b,c}, Mousa Khoursheed^{b,c}

^a Dar Alshifa Hospital, Hawally, Kuwait

^b Mubarak Alkabeer Hospital, Jabriya, Kuwait

^c Kuwait University, Faculty of Medicine, Safat, Kuwait

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ABSTRACT

Background: The surgical treatment of anal fistula is complex due to the possibility of fecal incontinence. Fistulotomy and cutting Setons have the same incidence of fecal incontinence depending on the complexity of the fistula. Sphincter-preserving procedures such as anal fistula plug and ligation of intersphincteric fistula tract procedure may result in more recurrence requiring repeated operations. The aim of this study was to evaluate and compare the outcomes of treating fistula in Ano utilizing two methods: Fistula plug (Gore Bio-A) and ligation of intersphincteric tract (LIFT).

Methods: Fifty four patients (33 males; 21 female, median ages 42 [range 32–47] years) with high anal inter-transphenteric fistula were treated with LIFT and fistula plug procedures from September 2011 until August 2016 by a single surgeon and were retrospectively evaluated. All were followed for a median of 23.9 (range 4–54) months with clinical examination. Twenty one patients underwent fistula plug and 33 patients underwent LIFT procedure (4 patients of the LIFT group underwent LIFT and rectal mucosa advancement flap). The healing rate and complications were evaluated clinically and through telephone calls.

Results: The mean operative time for the Plug was 25 ± 17 min and for the LIFT was 40 ± 20 min ($p = 0.017$) and the mean hospital stay was 2.4 ± 1.1 and 1.9 ± 0.3 ($p = 0.01$) respectively. The early complications of the plug and LIFT procedures included; anal pain (33.3%, 66.6%, $p = 0.13$), perianal discharge (77.8%, 91%, $p = 0.62$), anal pruritus (38.9%, 50.0%, $p = 0.71$) and bleeding per rectum (16.7%, 33.3%, $p = 0.39$) respectively. The overall mean follow-up was 20.9 ± 16.8 months, $p = 0.68$. There was no statistically significant difference between the two groups (21.9 ± 7.5 months, 19.9 ± 16.1 months, $p = 0.682$). The healing rate was 76.2% (16/21 patients) in the fistula plug group and 81.1% (27/33 patients) in the LIFT group ($p = 0.73$). Patients who had LIFT procedure and a mucosal advancement flap had 100% healing rate (4 out of 4 patients). No incontinence of stool or feces and no fistula plug expulsion were seen in our patients. The healing time ranged from 1 to 6 months after surgery. There was no post-operative perianal abscess, cellulitis or pain.

* Corresponding author.

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Conclusions: LIFT and anal plug are safe procedures for patients with primary and recurrent anal fistula. Both techniques showed excellent results in terms of healing and complication rate. None of our patients had incontinence after 5 years follow-up. The best success rate in our patients was seen after LIFT procedure with mucosal advancement flap. Larger and controlled randomized trials are needed for better assessment of treatment options.

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Desfechos de longo prazo do tampão de fístula (Gore) versus ligadura do trato da fístula interesfincteriana (LIFT) para fístula anal

R E S U M O

Palavras-chave:

Fístula anal

Ligadura do trato de fístula

interesfincteriana

Tampão de fístula

Introdução: O tratamento cirúrgico da fístula anal é complexo devido à possibilidade de incontinência fecal. A fistulotomia e o seton de corte têm a mesma incidência da incontinência fecal, dependendo da complexidade da fístula. Procedimentos de preservação do esfíncter, como o tampão da fístula anal e o procedimento LIFT (ligadura do trato da fístula interesfincteriana), podem resultar em mais recorrência, exigindo cirurgias repetidas. O objetivo deste estudo foi avaliar e comparar os desfechos do tratamento da fístula anal utilizando dois métodos: Tampão de fístula (Gore Bio-A) e Ligadura do Trato Interesfincteriano (LIFT).

Métodos: Cinquenta e quatro pacientes (33 homens; 21 mulheres, com mediana de idade de 42 [variação 32-47] anos) foram tratados com LIFT e procedimentos com tampão de fístula de setembro de 2011 até agosto de 2016 por um único cirurgião e foram avaliados retrospectivamente. Todos foram acompanhados por uma mediana de 23,9 (variação de 4 a 54) meses com exame clínico. Vinte e um pacientes foram submetidos a tampão de fístula e 33 pacientes foram submetidos ao procedimento LIFT (4 pacientes do grupo LIFT foram submetidos a LIFT e retalho de avanço da mucosa retal). A taxa de cicatrização e as complicações foram avaliadas clinicamente e por meio de ligações telefônicas.

Resultados: O tempo cirúrgico médio para o Tampão foi de 25 ± 17 minutos e para o LIFT foi de 40 ± 20 minutos ($p = 0,017$) e o tempo médio de internação foi de $2,4 \pm 1,1$ e $1,9 \pm 0,3$ ($p = 0,01$), respectivamente. As primeiras complicações dos procedimentos de tampão e LIFT incluíram: dor anal (33,3%, 66,6%, $p = 0,13$), secreção perianal (77,8%, 91%, $p = 0,62$), prurido anal (38,9%, 50,0%, $p = 0,71$) e sangramento pelo reto (16,7%, 33,3 %, $p = 0,39$) respectivamente. A média geral de acompanhamento foi de $20,9 \pm 16,8$ meses, $p = 0,68$. Não houve diferença estatisticamente significativa entre os dois grupos ($21,9 \pm 7,5$ meses, $19,9 \pm 16,1$ meses, $p = 0,682$). A taxa de cicatrização foi de 76,2% (16/21 pacientes) no grupo com tampão de fístula e 81,1% (27/33 pacientes) no grupo LIFT ($p = 0,73$). Pacientes submetidos ao procedimento LIFT e um retalho de avanço da mucosa tiveram 100% de taxa de cura (4 de 4 pacientes). Nenhuma incontinência fecal e nenhuma expulsão do tampão da fístula foram observadas em nossos pacientes. O tempo de cicatrização variou de 1 a 6 meses após a cirurgia. Não houve abscesso perianal, celulite ou dor no pós-operatório.

Conclusões: LIFT e tampão anal são procedimentos seguros para pacientes com fístula anal primária e recorrente. Ambas as técnicas apresentaram excelentes resultados em termos de cicatrização e taxa de complicações. Nenhum de nossos pacientes teve incontinência após 5 anos de acompanhamento. A melhor taxa de sucesso em nossos pacientes foi observada após o procedimento LIFT com retalho de avanço da mucosa. Ensaios clínicos randomizados de maior porte e controlados são necessários para melhor avaliação das opções de tratamento.

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Introduction

Anal fistula is an abnormal connection between the anal canal and the perianal skin, leading to persistent purulent drainage or intermittent perianal swelling and tenderness followed by spontaneous discharge. It is estimated to affect 12.3 per 100,000 men and 8.6 per 100,000 women.^{1,2}

Anal fistulas are classified in relation to the sphincter complex into inter-sphincteric, trans-sphincteric, supra-sphincteric, and extra-sphincteric according to Park's classification.³ MRI is the main investigation modality used to assess the fistula and the surrounding soft tissue structures.⁴ The goal of treatment is to repair the fistula while preserving the anal sphincter and preventing of gas or fecal incontinence.

Fistulotomy remains the main type of treatment and provides a high success rate.⁵ However, because of concerns about incontinence especially in trans-sphincteric fistula, other modalities such as loose Seton, anal fistula plug (AFP), ligation of intersphincteric fistula tract (LIFT)⁶ and bio-LIFT,⁷ anorectal advancement flap⁸ and video assisted anal fistula treatment (VAAFT)^{9,10} were introduced with varying degrees of success.

The evolution of fistula in Ano treatment over the past 20 years to prevent incontinence for either gas or feces was dramatic. Different modalities have been introduced including; Seton placement (cutting and loose), mucosal advancement flap, fibrin glue, fistula plug, Acellular matrix, LIFT, BioLIFT, LIFT plug and VAAFT.

The high success rate in the treatment of trans-sphincteric fistula after LIFT and plug procedures will help alleviate concerns about incontinence which most patients fear. Multiple studies have shown very low complications and incontinence in both procedures.^{11,12}

Since the first reports in 2007, LIFT has gained increasing popularity, mainly due to its relative simplicity, the initial high success rate, and low morbidity and because it is relatively simple procedure.⁶ There are two available types of fistula plugs. BioDesign Anal Fistula Plug (Cook Medical, Inc., Bloomington, Indiana, USA) and synthetic plug (GORE BIO-A Fistula Plug) which undergoes hydrolytic and enzymatic degradation, and histological studies have reported that the polymer scaffold is replaced by a layer of new tissue within 7 months without generating a chronic inflammatory response.^{13–15} The BioDesign Plug is a bioprosthetic plug with reported success rates of 43–83%.⁶ However, the incidence of early extrusion of the implant was seen in 4–41%.^{14,15,6} GORE BIO A Fistula plug showed healing rate of 57.5%, depending on the surgeon and previous intervention.¹⁶

The aim of our study is to compare the outcomes of Gore Bio-A fistula plug versus the LIFT procedure for treating anal fistula.

Materials and methods

The institutional ethical board approved this study. A retrospective review of all adult patients over the age of 17 who underwent fistula repair with Gore Bio-A plug or LIFT from September 2011 until August 2016 at two major hospitals in

the state of Kuwait. Fifty-four patients were identified and included for the analysis. A single board certified colorectal surgeon preformed all the procedures.

The data were obtained from the hospital records and follow-up phone call. Healing of fistula was assessed by clinical examination. Success was defined as the healing of fistula without symptoms of gas or solid incontinence.

Surgical technique

Fistula anatomy was defined according to Parks' classification using physical examination and MRI.^{16,17} None of the patients had a preoperative diverting stoma. Sodium phosphate enema was administered in the morning of surgery. Due to institutional regulations, all the procedures were performed as in-patient basis. All patients were given postoperative antibiotics, analgesia, and laxatives.

Patients were positioned according to the location of the fistula, lithotomy for posteriorly located fistula and prone jack-knife for anteriorly located fistula. The decision between the LIFT procedure and Fistula plug was made according to the surgeon discretion, depending on the size of the fistula, the relation of the internal and the external opening to the anal os and the presence of the cavitations or not.

For the GORE (BIO-A Fistula Plug) group, the number of tubes used depended on the width of fistula. The decision whether to add a mucosal advancement flap in addition to the plug was based on the tissue loss status and internal opening size. The fistula tract was cleaned before the placement of the plug with either by curettage or gauze.

For the LIFT procedure group, secure closure of the internal opening and removal of infected cryptoglandular tissue through the intersphincteric space was performed. The location of the internal opening was identified by injection of hydrogen peroxide or by gentle insertion of fistula probe through the external opening. The intersphincteric plane at the site of the fistulous tract was entered via the curvilinear incision. The tract was hooked using a small right-angled clamp and ligated close to the internal sphincter with polyglactin (Vicryl) 2/0 suture. Both ends were assessed for complete closure either by hydrogen peroxide or by probe.

The remnant of the intersphincteric tract and the infected gland were removed and the fistulous tract was thoroughly curetted. The external opening was left open for drainage.

All patients were followed at 2 weeks, 1, 6 and 12 months after surgery and subsequently, once per year.

Statistical methods

Continuous variables were summarized with mean and standard deviation, or median and interquartile range as appropriate and compared with Mann–Whitney *U* test. Categorical variables were described as frequencies (percent) and compared with Fisher's exact test. A level of 0.05 was defined as statistically significant. The analysis was performed using the statistical software package IBM SPSS version 24.

Table 1 – Patients' demographics.

	Plug (n = 21)	LIFT (n = 33)	p-Value
Mean age in years (SD)	40.6 (11.9)	38.9 (13.3)	0.45
Sex			1.00
Male	13 (61.9%)	20 (60.6%)	
Female	8 (38.1%)	13 (39.4%)	
Mean duration of symptoms in days (SD)	18.7 (12.9)	23.9 (25.8)	1.00
Crohn disease	1 (4.8%)	1 (3.0%)	1.00
Diabetes mellitus	2 (9.5%)	1 (3.0%)	0.53
History of abscess drainage	12 (60.0%)	8 (36.4%)	0.22
Preoperative Seton placement	7 (33.3%)	1 (3.0%)	0.004
Type of fistula			0.36
Intersphincteric	6 (28.6%)	16 (48.5%)	
Transphincteric	13 (52.4%)	13 (52.4%)	
Extrasphincteric	1 (4.8%)	1 (4.8%)	
Multiple	1 (4.8%)	1 (4.8%)	
Mean follow up in months (SD)	21.9 (17.5)	19.9 (16.1)	0.68

SD, standard deviation.

Results

Fifty-four patients underwent fistula repair during the study period and were included in the analysis. There were no differences in patient's demographics with regards to age, sex, comorbidities, and follow-up period as illustrated in [Table 1](#). The mean operative time for the Plug was 25 ± 17 min and for the LIFT was 40 ± 20 min ($p = 0.017$) and the mean hospital stay was $2.4 (\pm 1.1)$ days, and $1.9 (\pm 0.3)$ days for plug and LIFT respectively ($p = 0.02$).

History of previous perianal abscess was seen in 12 (60%) patients in the plug group and 8 (36.4%) patients in the LIFT group, ($p = 0.22$). History of recurrent fistula was seen in 10

(47.6%) patients in the plug group and 11 (36.4%) patients in the LIFT group ($p = 0.56$).

The early complications of the plug and LIFT procedures included; anal pain (33.3%, 66.6%, $p = 0.135$), perianal discharge (77.8%, 91%, $p = 0.622$), anal pruritus (38.9%, 50.0%, $p = 0.711$) and bleeding per rectum (16.7%, 33.3%, $p = 0.392$) respectively ([Table 2](#)).

The mean follow-up was $21.9 (\pm 17.5)$ months for the plug group and $19.9 (\pm 16.1)$ days for the LIFT group, $p = 0.68$. The healing rate was 76.2% (16/21) in the fistula plug group and 81.1% (27/33) in the LIFT group, $p = 0.73$. Patients who had LIFT procedure and a mucosal advancement flap had 100% healing rate (4 out of 4 patients). No incontinence to gas or of stool was reported in this cohort. The healing time ranged from 1 to 6

Table 2 – Complications and fistula distribution.

	Type of surgery		Total	p-Value
	Plug	LIFT		
Perianal discharge	14 (77.8%)	11 (91.7%)	25 (83.3%)	0.62
Anal Pruritus	7 (38.9%)	6 (50%)	13 (43%)	0.71
Anal pain	6 (33.3%)	8 (66.7%)	14 (46.7)	0.13
Bleeding per rectum	3 (16.7%)	4 (33.3%)	7 (23.3%)	0.39
Type of fistula				0.356
Intersphincteric				
Count	6	16	22	
% within type of surgery	28.6%	48.5%	40.7%	
Transphincteric				
Count	31	15	28	
% within type of surgery	52.4%	42.4%	46.3%	
Extrasphincteric				
Count	1	0	1	
% within Type of Surgery	4.8%	0.0%	1.9%	
Multiple				
Count	1	2	3	
% within type of surgery	4.8%	6.1%	5.6%	
Total				
Count	21	33	54	
% within type of surgery	100.0%	100.0%	100.0%	

months after surgery. There were no post-operative perianal abscesses, cellulitis or pain.

Discussion

We here present one of the longest follow-up series to date comparing Gore Bio-A fistula plug and LIFT procedures. Both procedures have excellent results with minimal morbidity similar to what have been previously published.

A systematic review of 26 articles that included 187 patients who underwent Gore bio-A fistula treatment has shown that the healing rate was from 15% to 72% and 11 of 187 patients had minor deterioration after a median follow of 19 months.¹⁸ A multicenter prospective study involving 60 patients who had Gore Bio-A fistula plug revealed 52% success rate of and 10% dislodgment rate.¹⁹ Furthermore, anal fistula plug treatment in Crohn's patient has been shown to be promising and 60% success rates was achieved.²⁰ The success rate however, was shown to be 48–73% depending on the type of fistula and the presence of comorbidities.¹⁶ In our study, the success rate after fistula plug was 76.2%. We had one Crohn's patient in each arm who had successful treatment and without recurrence after 36 months of follow up.

A prospective randomized trial involving 70 patients comparing LIFT procedure with mucosal advancement flap for patients with high trans-sphincteric fistula has shown that healing rates after one year follow-up was 65% and 58% respectively. The healing time was longer in the mucosal advancement flap and patients had more pain. Both had similar long-term healing rate, recurrence, continence, and quality of life.²¹

One of the greatest advantages of the LIFT procedure, it converts in some cases a difficult complex fistula to a more manageable one with minimal risk of sphincter injury. In the LIFT group our success rate was 81.8% which is comparable to the studies published in the literature.^{18,19,22} We have seen that the combination of LIFT procedure and advancement flap had the highest rate of success and none of our patients recurred.

Multiple studies and reviews have been published for each modality alone. However, none of the previous studies compared the outcomes of Gore bio-A fistula plug and LIFT procedures. The highest success rates in different studies after fistula plug and LIFT procedures were 76.2% and 81.8% respectively.^{23,24} In our study, two patients in the fistula plug group failed due to iatrogenic injury (one plug was pulled out by another doctor and one patient had iatrogenic injury). We found that diabetes did not influence the outcomes and all have healed completely. However, we were not able to assess the impact of presence of Crohn's disease and diabetes on the success rate due to other confounding factors like the type of fistula, since we have included all types of fistula in our evaluation (intersphincteric, transphincteric, extrasphincteric and multiple fistulae) which were they all high fistulas.

All of our patients underwent preoperative MRI and it was correlated with the operative findings. The intraoperative findings were in accordance with the MRI findings in all of our patients. Most of the previously published studies have shown a higher rate of intersphincteric fistulae^{16,25} however in our

study we have seen more transphincteric fistulas compared to intersphincteric. Previous studies have shown high success rate and very low incidence of incontinence following both procedures in patients with trans-sphincteric fistula.^{9,11,12}

It was shown that plug failure was associated with the presence of abscess.^{1,19} In our study we had 12 (60%) patients in the fistula plug group compared to 8 (36.4%) in the LIFT group who had perianal abscess prior to their present surgical treatment. 102 patients in the plug group, out of 21 number (46.5%) and 11 out of 33 (32%) had recurrence fistula prior to surgery.

LIFT failures can be due to many causes and identifying the type of failure can help direct subsequent therapy. Some authors recommended the routine adoption of endorectal ultrasound to evaluate all primary fistula and failures.²² We used MRI as the main diagnostic tool to assess our patients.

The management of different types of failures varies. Type I failures (unhealed incision fistula site cavity or granulation tissue without evidence of fistula) can be managed with curettage of the tract, silver nitrate applications and short-term antibiotics, and local incision and drainage for underlying sepsis. Type II failures (Intersphincteric fistula) can be managed with simple or staged intersphincteric fistulotomy. Type III failures (persistent transsphincteric fistula and branching complex fistula) can be managed with a cutting Seton followed by plans for a repeat definitive fistula procedure such as LIFT, fistula plug, or mucosal advancement flap. All our failure in the LIFT group was converted to type II failures (intersphincteric fistula) and was treated by simple fistulotomy. All Gore Bio-A group failure were treated by loose seton.

All patients were seen in the OPD clinic at 2 weeks, 6 weeks, 3 months, and 6 months. All failed patient were seen until the fistula healed. Patients were assessed then by telephone annually. None of our patients were assessed objectively as long they were asymptomatic.

Systematic review and meta-analysis of more than 1100 patients have shown a 74% success rate without incontinence and intraoperative complications. The post-operative complication rate was seen in 5.5% of patients.⁷ However, other reports have shown lower than 50% success rates.⁷ These conflicting results were due to non-standardized enrollment criteria among the various sites, varying lengths of follow-up, and non-standardized surgical techniques. Since 2008, many authors have used a combined approach such as the LIFT followed by coring out of the external fistula tract (LIFT plus coring out),^{10,26} placing a bio-mesh in the intersphincteric plane to reinforce the closure of the fistula tract (bio-LIFT)^{11,27} and placing a fistula plug in the external fistula tract (LIFT plus fistula plug).^{28–30}

The limitation of our study is that it is a retrospective, small sample size and all procedures were performed by a single surgeon. It lacks adequate power to detect any potential effect on healing by the presence of previous fistula procedures such as Setons insertion, and patient preoperative characteristics. There was also an element of selection bias by the surgeon. LIFT procedure was performed if the fistula tract was difficult to delineate because of body habitus or presence of large rectal cavity or horseshoe tracts. In addition to the previous limitations, continence was subjectively evaluated and a formal continence scale would yield more accurate results.³¹ Larger, long-term prospective randomized controlled studies

are needed to validate the true comparison between the Gore bio-A fistula plug treatment and LIFT procedure and to identify disease characteristics that can assist in better patient selection to achieve better outcome.

Conclusions

LIFT and anal plug are safe procedures for patients with primary and recurrent anal fistula. Both techniques showed excellent results in terms of healing and complication rate. LIFT procedure had better outcome in this study and the treatment of failures was easier and more successful than the plug group. None of our patients had incontinence after 5 years follow-up. The best success rate in our patients was seen after combining LIFT procedure with mucosal advancement flap. Larger and controlled randomized trials are needed for better assessment of treatment options

Conflicts of interest

The authors declare no conflicts of interest.

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