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RESEARCH ARTICLE

External Sphincter-Sparing Anal Fistulotomy Plus Seton Drainage for Complex Fistula-In-Ano

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ABSTRACT

Aim: Several sphincter-saving surgical techniques have been developed, but overall healing rates have been mediocre. An external sphincter-sparing anal fistulotomy plus seton drainage (ESSAF-S) prioritizes the management of the intersphincteric space and involves dividing the internal sphincter and debriding the intersphincteric space to remove the focus of fistula formation.

Method: This was a retrospective review of all patients who underwent ESSAF-S between January 2020 and December 2021 in a single institution. The primary outcome was the primary healing rate. Secondary outcomes included overall healing rate, postoperative complications, and incontinence rate based on the postoperative Wexner incontinence score (WIS).

Results: A total of 21 patients (11 men, 10 women, mean age 43.1±12.3 years) underwent ESSAF-S during the study period. The mean follow-up time was 11.9±4.4 months. The primary healing rate was 76.2%. Five patients required a second procedure (3 fistulotomy, 2 fistula-tract laser closure), and 1 patient had a persistent fistula afterward. The overall healing rate was 95.2%. Two (9.5%) patients developed gas incontinence after the procedure. The median WIS was 0 (range: 0-13). There was no significant difference between the preoperative and postoperative WIS (p>0.05).

Conclusion: An external sphincter-sparing anal fistulotomy plus seton drainage is an effective procedure for complex anal fistula with a high overall healing rate and low complication rate.

Keywords: Complex anal fistula, FiLAC, fistula-in-ano, seton, LIFT, VAAFT

Introduction

Perianal abscesses emerging from infected intersphincteric proctodeal glands are the main instigator of perianal fistulae, with other causes, such as inflammatory bowel disease, malignancies, and perianal trauma, making up <10% of perianal fistula origin.[1-4] Classifying fistulae into simple and complex fistulae using the Standard Practice Task Force classification streamlines the management pathway, although other classifications, such as Park's, St. James University Hospital, and Garg's, also have their advantages.[5,6]

Simple fistulae are effectively managed by a fistulotomy, with an average healing rate of 93.7% and low morbidity.[7] However, there is no gold standard treatment for complex fistula-in-ano. Attempts to balance sphincter preservation against a high cure rate produced various surgical techniques with variable success rates. Currently practiced techniques range from those that minimally disrupt the sphincter complex, such as fistula-tract laser closure (FiLAC), video-assisted anal fistula treatment (VAAFT), definitive drainage seton, anal fistula plug, fibrin glue, and over-the-scope-clip closure of internal fistula opening, to techniques that disrupt the sphincter complex and

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surrounding tissue to different degrees (albeit in a controlled manner), such as the ligation of intersphincteric tract (LIFT), endorectal advancement flap (ERAF), and fistulotomy or fistulectomy with primary sphincteroplasty (FIPS). However, no technique has emerged as the best, with most having recurrence rates of >10%.[8,9]

The importance of addressing the intersphincteric space in the management of complex anal fistula has been gaining attention.[3,9] The nodus of the complex anal fistula is within this space, and one approach is that the intersphincteric space should be treated like an abscess within a closed space.[3,9-12] Hence, applying the principles of abscess management (i.e., incision and drainage) should be part of a fistula treatment. This involves laying open the intersphincteric space, debridement of the affected area, and letting healing occur by secondary intention.[10,11] The concept was eloquently described by Garg as the ISTAC (*intersphincteric tract is like an abscess in closed space*), DRAPED (*draining all pus and ensuring continuous drainage*), and HOPTIC (*healing occurs progressively till it is interrupted irreversibly by a collection*) principles.[9] Several papers have been published showing techniques respecting this concept but with different procedural names, such as transanal opening of intersphincteric space (TROPIS), modified Park's procedure, tunnel-like fistulectomy plus draining seton combined with incision of internal opening of anal fistula (TFSIA), and external sphincter-sparing anal fistulotomy (ESSAF).[10,12-14] An external sphincter-sparing anal fistulotomy plus seton drainage (ESSAF-S) is a technique that combines ESSAF with a loose draining seton to assure adequate drainage after the debridement of the intersphincteric space, hence promoting better wound recovery and reducing recurrence rate.[11] This report presents our results using this technique.

Materials and Methods

Patients and study design

This was a retrospective analysis of prospectively collected data. Data that were recorded included patients' demographics, past medical history, previous surgical treatment for fistula-in-ano, symptoms and clinical findings on physical examination during the first clinic review, duration of hospital stay, duration of surgical procedure, interval between definitive procedure and last clinic follow-up, and outcomes. The study was approved by the University of Health Sciences Turkey, İzmir Tepecik Training and Research Hospital Non-Interventional Research Ethics Committee (approval number: 2022/12-28, date: 11.01.2023).

The ESSAF-S procedure was offered to all adult patients with high (involving more than one-third of the external sphincter), recurrent, and complex fistula-in-ano conditions during the study period. Transsphincteric fistula, suprasphincteric fistula, and extrasphincteric fistula were defined as complex fistula-in-ano. An active ongoing perianal abscess was not considered an exclusion criterion. Patients who did not want to undergo the ESSAF-S procedure were treated with other suitable methods, which included FiLAC, loose seton, and tunnel fistulectomy.

The exclusion criteria were as follows:

1. Simple fistula-low or superficial fistula (involving less than one-third of the external sphincter) and intersphincteric fistula,
2. Tuberculous fistula,
3. Neoplastic fistula,
4. Inflammatory bowel disease (Crohn's disease and ulcerative colitis)-associated fistula-in-ano,
5. Anovaginal fistula.

Treatment protocol

All patients underwent a clinical examination, rigid rectoscopy, and/or flexible sigmoidoscopy as part of their preoperative assessment. Pelvic magnetic resonance imaging was performed on patients with recurrent fistula. The procedure was performed under either spinal or general

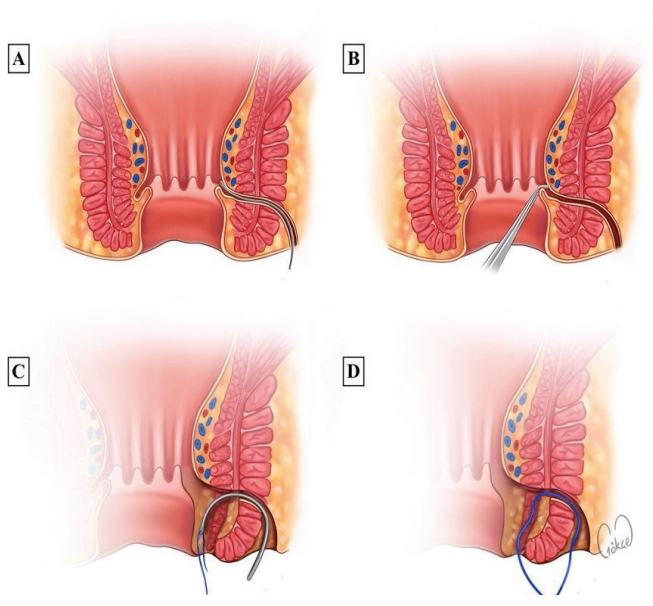

Figure 1. (A-D) show the illustrated sequence of the external sphincter-sparing anal fistulotomy plus seton drainage procedure. (A) The fistula tract is identified, and a metal probe is used to cannulate the tract. (B) The tip of a right-angled forceps is introduced into the internal opening of the fistula. The anal canal mucosa is cut caudally towards the external anal fistula opening. A fistulotomy is performed starting from the external opening until the external sphincter muscle. (A) Fistulotomy is also performed to the proximal portion of the anal fistula, cutting the internal sphincter, until the intersphincteric space. The intersphincteric space and the remnant fistula tract within the external sphincter are debrided thoroughly. (C,D) A seton is looped around the external sphincter and loosely secured. The wound is left to heal by secondary intention

anesthesia. Antibiotics were only given in cases with active abscesses. The patients were placed in a lithotomy position with sterile preparation. A video demonstrating the technique is linked with this article. The surgical steps are as follows (Figures 1, 2):

1. The fistula tract is identified, and a metal probe is used to cannulate the tract.

2. The tip of a right-angled forceps (i.e., Mixter forceps) is introduced into the internal opening of the fistula. The anal canal mucosa is cut caudally towards the external anal fistula opening.

3. A fistulotomy is performed starting from the external opening. The fistula tract is laid open to the level of the external sphincter muscle. The skin overlying the tract is cut towards the previously made cut edge of the anal mucosa. The sphincter muscle is easily visualized after the incisions are made.

4. A fistulotomy is performed to the proximal portion of the anal fistula until the intersphincteric space, using a right-angled forceps tip as a guide. The internal sphincter muscle containing the fistula is also divided at this stage.

5. The intersphincteric space and the remnant fistula tract within the external sphincter are debrided thoroughly. This is to remove any residual epithelial or granulation tissue and reduce the possibility of fistula recurrence.

6. A seton is looped around the external sphincter and loosely secured. The wound is left to heal by secondary intention.

All the procedures were performed by experienced colorectal surgeons (M.C.T. and A.E.C.).

Postoperative management

The procedures were performed as day cases when possible. The patients were discharged with non-opioid analgesia. Patients with active abscesses were discharged with a complete course of oral antibiotics. All patients had an outpatient follow-up examination at postop day seven, 1 month after the procedure, and followed by 3-monthly outpatient clinic reviews. The loose seton was left *in situ* for at least 3 months.

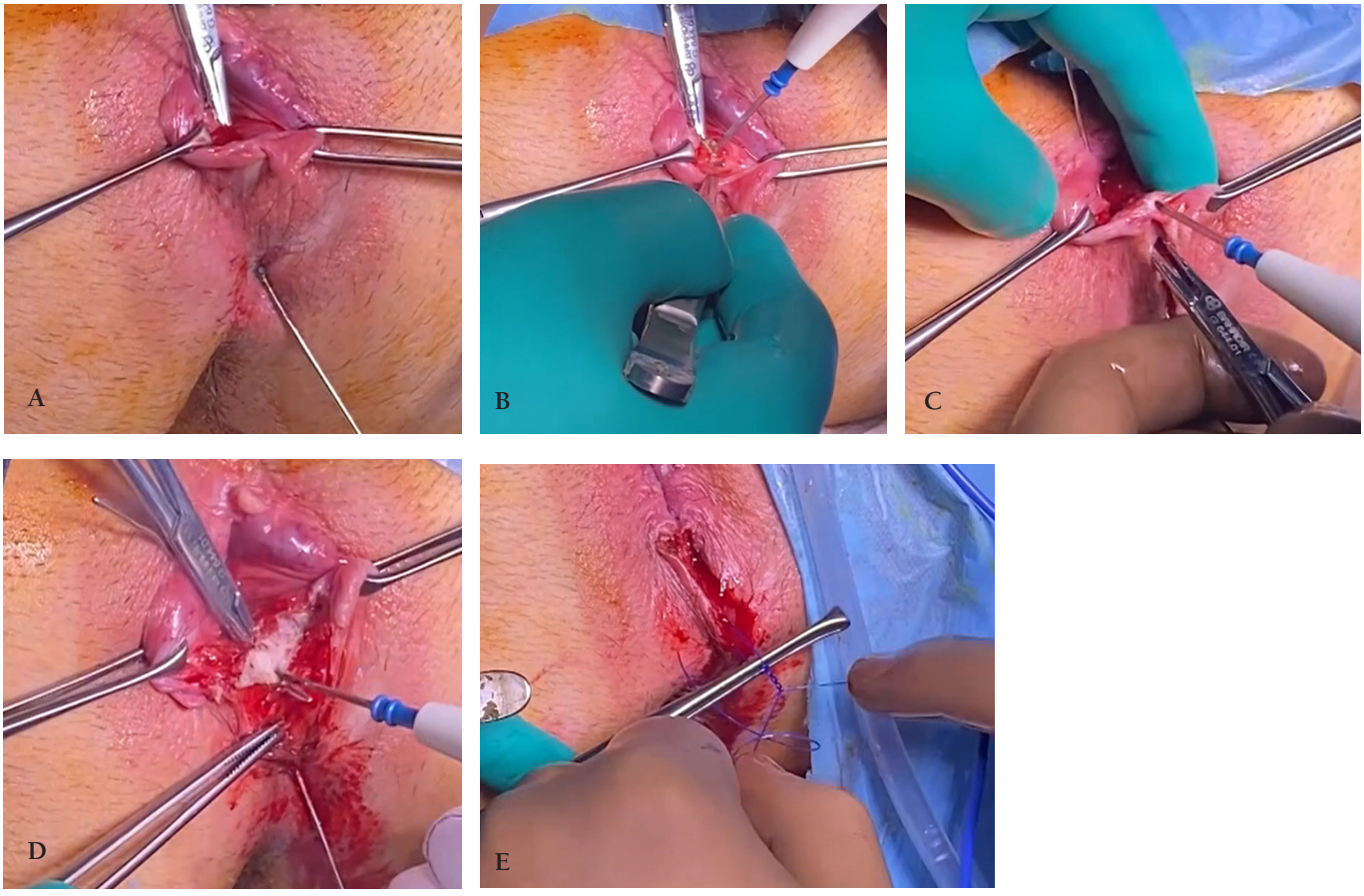

Figure 2. (A-E) show the sequence of the external sphincter-sparing anal fistulotomy procedure. (A) The fistula tract is identified, and a metal probe is used to cannulate the tract. (B) The tip of a right-angled forceps is introduced into the internal opening of the fistula. The anal canal mucosa is cut caudally towards the external anal fistula opening. (C) A fistulotomy is performed starting from the external opening until the external sphincter muscle. (D) A fistulotomy is also performed to the proximal portion of the anal fistula, cutting the internal sphincter, until the intersphincteric space. The intersphincteric space and the remnant fistula tract within the external sphincter are debrided thoroughly. (E) A seton is looped around the external sphincter and loosely secured. The wound is left to heal by secondary intention

Outcomes measures

The primary outcome measure was the primary fistula healing rate. Secondary outcome measures included the overall healing rate, complications, and incontinence rate. Patients were classified according to the Parks classification at the time of surgery.[6] Healing was assessed using a perianal fistula severity scoring system, as follows: 0- no active disease or complete healing, 1- slight drainage with minimal symptoms, 2- persistent symptomatic drainage, and 3- severe perianal disease, potentially requiring diversion.[15] A score of 0 or 1 would result in the removal of the indwelling seton. Patients with higher scores at the end of 3 months would be assessed again for persistent or non-healing fistula. Patients were asked whether they experienced any major incontinence symptoms (solid or liquid stool or gas incontinence) and were asked to complete the Wexner incontinence score (WIS) questionnaire before the ESSAF-S procedure and during their last follow-up. Patients with a WIS ≥1 were considered incontinent. A WIS ≤4 was defined as mild incontinence and a WIS ≥5 was defined as severe incontinence.[16] A validated Turkish version of the questionnaire was used.[17]

Statistical Analysis

Statistical analysis of data was performed using SPSS version 26 (IBM Corp; Armonk, NY, US). Continuous data were described using mean ± standard deviation or median and range (minimum-maximum). Numbers and percentages were used to present categorical data. The paired sample sign test was applied to analyze the preoperative and postoperative WIS. The significant cut-off point was set at $p<0.05$.

Results

Between January 2020 and December 2021, 21 consecutive patients agreed for ESSAF-S to be performed. There were 11 (52.4%) men and 10 (47.6%) women. The mean age was 43.1±12.3 years (range: 16-69 years). Nine (43%) patients had a body mass index >30 kg/m^2. Three (14.3%) patients were active smokers and 13 (61.9%) patients were ex-smokers. Nineteen (90.5%) patients had a transsphincteric fistula and 2 (9.5%) had a suprasphincteric fistula. Almost two-thirds of the patients had undergone previous anal fistula surgery (Table 1). Table 2 summarizes the outcomes of the study. The average operative time was 25.2±5.7 minutes (range: 15-41 minutes). All patients were managed as day cases. Two patients had active abscesses and were discharged with a course of oral antibiotics. One patient was readmitted on the same day due to pain and was discharged after 2 days of parenteral analgesia. The mean follow-up period was 11.9±4.4 months (range: 7-23 months). Five (23.8%) patients had persistent fistula. Three patients only required a simple fistulotomy, whereas two patients were treated using FiLAC. One recurrence was recorded after the FiLAC treatment and a draining seton was placed afterwards. The medians for preoperative and postoperative WIS were both 0 (range: 0-13) and were not significantly different ($p>0.05$, paired sample sign test). Two (9.5%) patients noted a new onset of difficulty to control flatus postoperatively. Their WIS were 3 and 8. The number of patients who had impaired continence preoperatively and postoperatively was four (gas only - two, gas and liquid - two), and six (gas - four, gas and liquid - two), respectively. No patients complained of solid stool incontinence (Table 3).

Discussion

Highlighting the importance of managing the intersphincteric space in treating fistula-in-ano implied that the treatment strategy had to change. The primary aim is no longer to close the fistula tract but. to treat the space as if it were an abscess. The intersphincteric space must be laid open, similar to the de-roofing of an abscess, thoroughly debrided, and left to continuously drain and heal by secondary intention.[3,12-14] Continuous drainage is important to prevent any collection

Table 1. Patient demographics

Parameters	
Mean age (years)	43.1±12.3
Gender	
- Male	11 (52.4%)
- Female	10 (47.6%)
Mean BMI (kg/m^2)	27.9±5.2
Cigarette smoker	
- Active	3 (14.3%)
- Ex-smoker	13 (61.9%)
Diabetes mellitus	0 (0%)
Mean preoperative Hb level	13.5±1.1
Mean preoperative WCC level	8.0±3.1
Mean preoperative platelet level	281.5±52.0
Fistula type	
- Transsphincteric	19 (90.5%)
- Extrasphincteric	2 (9.5%)
Previous anal fistula surgery	13 (61.9%)
- FiLAC	10
- LIFT	1
- Loose seton	2

Data presented as mean ± standard deviation, or number (%)

BMI: Body mass index, Hb: Hemoglobin, WCC: White cell count, FiLAC: Fistula-tract laser closure, LIFT: Ligation of intersphincteric tract

from forming, which could halt the healing process.[9] The effect of this process translated to the high healing rate seen in fistulotomy and FIPS (Table 4).[7,9,18] Procedures that do not fulfill the principle in its entirety, such as LIFT, FiLAC, VAAFT, and ERAF (Table 4), have not managed to reach healing rates as high as the procedures listed in Table 5. The ESSAF-S technique respects these principles by laying open the intersphincteric space and the placement of a loose seton. The seton allows continuous drainage and promotes healing by causing an inflammatory response and fibrosis.[11,19]

Table 5 summarizes the outcomes of published studies of fistula surgery techniques similar to ESSAF-S. All of the techniques involved laying open the intersphincteric space by dividing the internal sphincter. This study's primary healing rate of 76.2% was similar to the two largest studies.[12,20] The modified Park's procedure reported the highest primary cure rate of 93.75%.[13] The authors endorse closing the external sphincter defect after debriding the intersphincteric space and the remnant tract within the external sphincter. The TFSIA technique by Yan and Ma[14] also had a commendable primary cure rate. The technique involved complete excision of the fistula tract from the external opening to the intersphincteric space. These variations are unique compared with other techniques. However, whether the proprietary methods made a difference is uncertain, as they were small studies with a short follow-up duration.

When combined with a secondary treatment for patients with persistent fistula, our overall success rate was comparable

Table 2. Outcome of ESSAF-S procedure

Parameter			
Mean operative time (min)	25.2±5.7		
Total hospital stay (days)	1		
Follow-up duration (months)	11.9±4.4		
Primary healing rate	16 (76.2%)		
Persistence	5 (23.8%)		
Re-operation			
- Fistulotomy	3		
- FiLAC	2		
- Seton*	1		
Overall healing rate	20 (95.2%)		
New onset postprocedure incontinence	2 (9.5%)		
Median Wexner score (min.-max.)	**Preop**	**Postop**	
	0 (0-13)	0 (0-13)	p=0.5
- Perfect continence (score = 0)	17 (81%)	15 (71.4%)	
- Mild incontinence (score ≤4)	2 (9.5%)	3 (14.3%)	
- Major incontinence (score ≥5)	2 (9.5%)	3 (14.3%)	

* Loose draining seton for one patient with persistent fistula after a second operation (FiLAC). Data presented as mean ± standard deviation, median (range minimum-maximum), or number (%). FiLAC: Fistula-tract laser closure

Table 3. Preprocedural and postprocedural Wexner incontinence scoring by all patients. New onset of incontinence involved difficulty in controlling flatus only

	None		**Rarely**		**Sometimes**		**Usually**		**Always**	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
Solid stool	21	21	0	0	0	0	0	0	0	0
Liquid	19	19	2	2	0	0	0	0	0	0
Gas	17	15	2	2	1	2	0	1	1	1
Pad usage	18	17	0	0	0	1	2	2	1	1
Lifestyle alteration	19	17	0	1	1	1	0	1	1	1

Table 4. List of anal fistula surgical techniques with healing rate and/or recurrence rate, and incontinence rate based on recent systematic review or meta-analysis

Procedure	Follow-up (months)	Healing rate	Recurrence rate	Complication/incontinence rate
LIFT (25)	Mean 10.3 (8.4-12.2)	76.4% (95% CI: 68.9-82.5%)		Pooled mean 0%
VAAFT (26)	Median 16.5 (8-48)	83% (95% CI: 81-85%)	16% (95% CI: 14-18%)	WIS 1.09 (95% CI: 0.9-1.27)
Loose Seton (27)	Median 16 (6-42)		10.3% (95% CI: 7.2-14.7%)	9.5% (6.5-13.8%)/3.2% (95% CI: 1.6-6.1%)
FiLAC (28)	Median 23.7 (2.33-60)	69.7% (95% CI: 54.4-85%)		1% (95% CI: 0-2%)
ERAF (29)	-		21% (95% CI: 15.3-26.8%) - Mucosal flap: 30.1% (95% CI: 25.5-34.7%) - Partial thickness flap: 19% (95% CI: 15.5-22.6%) - Full thickness flap: 7.4% (95% CI: 4-10%)	13.3% (95% CI: 8-18.6%) Incontinence rate by flap thickness: - Mucosal flap: 9.3% (95% CI: 5.4-13.1%) - Partial thickness flap: 10.2% (95% CI: 0.5-14.6%) - Full thickness flap: 20.4% (95% CI: 14.2-26.6%)
FIPS (18)	Weighted average 28.9 (12-81)	93.2% (range: 85.7-100%) 69.9% (range: 28.6-100%) (healing rate without dehiscence)	6.8% (range: 0-15%)	Sphincter dehiscence 2.2% (range: 0-8.3%) Incontinence 12.4% (2.7% major incontinence)

CI: Confidence interval, WIS: Wexner incontinence score, LIFT: Ligation of intersphincteric fistula tract, VAAFT: Video-assisted anal fistula treatment, FiLAC: Fistula-tract laser closure, ERAF: Endorectal advancement flap, FIPS: Fistulotomy or fistulectomy with primary sphincteroplasty

with the other studies (Table 4). Garg's TROPIS study had the lowest overall success rate, at 87.6%.[20] However, it is the largest prospective study on the technique which gave the result heavier significance. The study limited re-do surgery to the same surgical method (i.e., TROPIS), whereas other studies treat persistent or recurrent fistulas using variable techniques such as fistulotomy, ERAF, FiLAC, and a loose seton.[11-14,21] Excluding Garg's series, more than half of the patients who needed a second procedure were successfully managed with a simple fistulotomy. The combination treatment strategy produced an overall healing rate of 93-100%, but these studies also involved small sample numbers, and further investigation is needed.

The immunity of the internal sphincter from surgical division was challenged by Eisenhammer[22] in the early 1950s with the development of the lateral internal sphincterotomy (LIS) procedure.[16] The internal sphincter is in a closely confined space, splinted by a longitudinal muscle sheath and the external sphincter, which prevents any significant retraction of the internal sphincter when divided.[22] This translated to transient mild to moderate incontinence in approximately one-third of patients receiving an LIS, and <5% clinically significant incontinence after 5 years post-surgery.[16,23] The majority of this was difficulty in controlling flatus, and incontinence to solid feces was rare. Several risk factors for incontinence have been identified, such as two or more vaginal deliveries, instrumentation during vaginal deliveries, multiple previous perianal abscess drainage or anal fistula surgery, reduced external anal sphincter thickness on endoanal ultrasound, and reduced pre-operative voluntary contraction pressure on anal manometry.[16,23,24] It is worthwhile considering these factors before recommending internal sphincter division to patients.

Our incontinence rate of 9.5% is comparable with the other similar techniques, albeit slightly higher (Table 5). However, 61.9% of our patient cohort had previously undergone a different type of anal fistula surgery. We also report our incontinence rate based on the WIS, which is more sensitive than patient-reported incontinence; significant differences between the two methods of enquiring about incontinence have been observed.[23] Garg's TROPIS series had similar proportions of patients who had previous anal fistula surgery, but the reported incontinence rate was only 7.8%.[20]

Table 5. Comparison of outcomes with other techniques similar to ESSAF-S

Procedure name	Authors	Number of patients	Follow-up (months)	Primary healing rate	Persistence/ recurrence rate after primary surgery	Overall success rate	Incontinence rate
ESSAF-S	[a]Current study	21	Mean 11.9±4.4	76.2%	23.8%	95.2%	- 9.5% gas incontinence - No significant difference between preoperative and postoperative WIS - WIS median 0 (0-13)
	[a]Kennedy and Zegarra[11]	32	Mean 36 (13-65)	78%	22%	93%	- 33% gas incontinence - 3.1% occasional liquid seepage
TROPIS	[b]Garg et al.[20]	306	Median 36 (7-67)	78.4%	21.6%	87.6%	- 7.8% (majority gas incontinence) - No significant difference between preoperative and postoperative incontinence rate and Vaizey's incontinence score - Postoperative Vaizey's incontinence score 0.014±0.39
	[b]Li et al.[21]	41	Median 22.2 (6-35)	85.3%	14.7%	100%	- No significant difference between preoperative and postoperative incontinence rate and Wexner incontinence score - Postoperative mean WIS 0.22±0.47
Modified Park's	[b]El-Said et al.[13]	32	Median 12 (6-24)	93.75%	6.25%	100%	- No significant difference between preoperative and postoperative incontinence rate and Wexner incontinence score - WIS Median 0 (0-17)
TFSIA	[b]Yan and Ma[14]	40	6	87.5%	12.5%	-	- Not mentioned - Postoperative mean WIS 0.68±0.47
ESSAF	[a]Parnasa et al.[12]	59	Mean 12±14.7	71%	29%	93%	- 1.7% fecal incontinence

[a]Retrospective, [b]Prospective, ESSAF-S: External sphincter-sparing fistulotomy plus seton drainage, TROPIS: Transanal opening of intersphincteric space, TFSIA: Tunnel-like fistulectomy plus draining seton combined with incision of internal opening of anal fistula, ESSAF: External sphincter-sparing anal fistulotomy, WIS: Wexner incontinence score

The study did have a longer follow-up period (average 36 months) compared with our study. As the function of the internal sphincter after division has a high potential of recovering with time, this may account for the lower rate.[22,23]

Study Limitations

The main limitations of this study were its retrospective nature and small sample size. The study also lacked more objective continence assessments, such as an anorectal manometry study and sphincter assessment using endoanal ultrasound. There was no quality-of-life assessment to convey patients' perspectives on the treatment regime. This was also a single-center study with a short-term follow-up.

Conclusion

An external sphincter-sparing anal fistulotomy plus seton drainage is an effective technique for complex fistula-in-

ano with a success rate and complication rate comparable with other previously described similar techniques. The rate of clinically significant incontinence is also relatively low. However, larger prospective studies with objective continence assessment, longer follow-ups, and randomized trials comparing the method to other surgical techniques are required to investigate the safety and efficacy of this treatment.

Ethics

Ethics Committee Approval: The study was approved by the University of Health Sciences Turkey, İzmir Tepecik Training and Research Hospital Non-Interventional Research Ethics Committee (approval number: 2022/12-28, date: 11.01.2023).

Informed Consent: Retrospective study.

Authorship Contributions

Surgical and Medical Practices: H.A.T., M.A.S.A., S.D.A., A.E.C., M.C.T., Concept: H.A.T., M.A.S.A., S.D.A., A.E.C., M.C.T., Design: H.A.T., A.E.C., M.C.T., Data Collection or Processing: H.A.T., M.A.S.A., S.D.A., Analysis or Interpretation: H.A.T., A.E.C., M.C.T., M.F., Literature Search: H.A.T., M.A.S.A., Writing: H.A.T.

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