ORIGINAL CONTRIBUTION

Long-term Evaluation of Fistulotomy and Immediate Sphincteroplasty as a Treatment for Complex Anal Fistula

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BACKGROUND: Fistulotomy with immediate sphincteroplasty is a technique that can heal fistulas and decrease fecal incontinence more effectively than fistulotomy alone, in selected patients.

OBJECTIVE: We aimed to perform a long-term evaluation of fecal incontinence after fistulotomy and immediate sphincteroplasty in patients with complex anal fistula.

DESIGN: This prospective study included patients undergoing fistulotomy and immediate sphincteroplasty for complex anal fistula from January 2000 to December 2010.

SETTINGS: The study was conducted by 2 colorectal surgeons in the coloproctology unit of the General Hospital of Elche.

PATIENTS: We included patients aged ≥18 years with complex anal fistulas of cryptoglandular origin.

MAIN OUTCOME MEASURES: Main outcomes were recurrence and continence after fistulotomy and immediate sphincteroplasty, according to fistula tract height and preoperative continence status.

RESULTS: A total of 107 patients were included; 68.2% were men, with a mean age of 48 years and mean fistula duration of 12.8 months. The range and median follow-up period were 84 to 204 and 96 months. Thirty-seven fistulas were not primary. The overall healing rate was 84.1%. Primary fistulas healed by the end of follow-up in 58 (82.9%) of 70 patients; recurrent fistulas healed in 32 (86.5%) of 37; high tracts healed in 31 (83.8%) of 37, and nonhigh fistulas healed in 59 (84.3%) of 70. Male sex (OR = 0.66 (95% CI, 0.20–2.13); $p > 0.05$) and recurrent fistulas (OR = 0.43 (95% CI, 0.11–1.68); $p > 0.05$) could have a protective effect against postoperative fecal incontinence; however, more studies with larger sample sizes are necessary to confirm this result, whereas high fistulas showed a 4-fold increased risk of incontinence (range, 1.22–13.06; $p < 0.01$). One in 5 high-tracts patients experienced continence deterioration.

LIMITATIONS: This was a prospective study, and randomized clinical trials with more patients and longer follow-up are needed to compare fistulotomy and immediate sphincteroplasty with other sphincter-preserving techniques.

CONCLUSIONS: Fistulotomy and immediate sphincteroplasty are good options for treating complex anal fistulas, especially for recurrent fistulas, men, and patients with nonhigh tracts, with acceptable recurrence and incontinence rates. See **Video Abstract** at http://links.lww.com/DCR/B498.

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EVALUACIÓN A LARGO PLAZO DE LA FISTULOTOMÍA Y LA ESFINTEROPLASTIA INMEDIATA COMO TRATAMIENTO PARA LA FÍSTULA ANAL COMPLEJA

ANTECEDENTES: La fistulotomía y la esfinteroplastia inmediata es una técnica que puede curar las fístulas

y disminuir la incontinencia fecal de manera más efectiva que la fistulotomía sola, en pacientes seleccionados.

OBJETIVO: Nuestro objetivo fue realizar una evaluación a largo plazo de la incontinencia fecal después de la fistulotomía y la esfinteroplastia inmediata en pacientes con fístula anal compleja.

DISEÑO: Este estudio prospectivo incluyó pacientes sometidos a fistulotomía y esfinteroplastia inmediata por fístula anal compleja, desde enero de 2000 hasta diciembre de 2010.

ENTORNO CLINICO: El estudio fue realizado por dos cirujanos colorrectales de la Unidad de Coloproctología del Hospital General de Elche.

PACIENTES: Se incluyeron pacientes ≥ 18 años con fístulas anales complejas de origen criptoglandular.

PRINCIPALES MEDIDAS DE VALORACION: Los principales resultados fueron la recurrencia y la continencia después de la fistulotomía y la esfinteroplastia inmediata, de acuerdo con la altura del trayecto de la fístula y el estado de continencia preoperatoria.

RESULTADOS: Se incluyeron un total de 107 pacientes; El 68,2% eran varones, con una edad media de 48 años y una duración media de la fístula de 12,8 meses. El rango y la mediana del período de seguimiento fue de 84-204 y 96 meses, respectivamente. Treinta y siete fístulas no fueron primarias. La tasa de curación general fue del 84,1%. Las fístulas primarias cicatrizaron al final del seguimiento en 58/70 (82,9%) pacientes; las fístulas recurrentes cicatrizaron en 32/37 (86,5%); los tractos altos cicatrizaron en 31/37 (83,8%) y las fístulas no altas cicatrizaron en 59/70 (84,3%). El sexo masculino (razón de posibilidades: 0,66 [0,20-2,13], $p > 0,05$) y las fístulas recurrentes (razón de posibilidades: 0,43 [0,11-1,68], $p > 0,05$) podrían tener un efecto protector contra la incontinencia fecal postoperatoria, sin embargo, más estudios con una muestra más grande son necesarios para confirmar este resultado. Fistulas altas mostraron un riesgo cuatro veces mayor de incontinencia ([1.22-13.06], $p < 0.01$). Uno de cada cinco pacientes con tractos altos experimentó un deterioro de la continencia.

LIMITACIONES: Este fue un estudio prospectivo y se necesitan ensayos clínicos aleatorios con más pacientes y un seguimiento más prolongado para comparar la fistulotomía y la esfinteroplastia inmediata con otras técnicas de preservación del esfínter.

CONCLUSIÓN: La fistulotomía y la esfinteroplastia inmediata son buenas opciones para el tratamiento de fístulas anales complejas, especialmente para fístulas recurrentes, varones y pacientes con tractos no altos, con tasas aceptables de recurrencia e incontinencia. Consulte

Video Resumen en http://links.lww.com/DCR/B498.
(Traducción—Dr Adrian Ortega)

KEY WORDS: Complex anal fistula; Continence; Fistulotomy; High fistula; Primary fistula; Sphinteroplasty

Cryptoglandular fistulas are challenging for patients and colorectal surgeons and negatively affect the health and quality of life of patients. Despite several different therapeutic options for high and complex anal fistulas, there is no clear consensus on optimal treatment. Most techniques have a significant risk of complications, including recurrence or impairment of incontinence.[1,2]

With a success rate of >90% but a rate of continence impairment that ranges from 0% to 73%,[3,4] simple fistulotomies have been indicated for simple fistulas in patients who have a low risk of fecal incontinence.[5] For complex anal fistulas, advancement flaps are one of the most widespread techniques for the treatment of complex anal fistulas. However, although success rates range from 59.6% to 70.0%,[6] this technique also shows variable incontinence rates (0%–45%).[2,7]

Several sphincter-preserving techniques, such as ligation of intersphincteric fistula tract,[4,8] FiLaC,[9,10] photodynamic therapy,[11] fibrin glue,[2] fistula plugs,[12] and others, have been proposed to avoid this incontinence and generally report high recurrence rates (30%–60%).[3] However, there is no consensus on a gold-standard treatment for complex anal fistulas.

In the absence of an ideal sphincter-preserving procedure that has a high success rate and low or no risk of continence disturbance, fistulotomy and primary sphincteroplasty (FIPS) is an alternative technique for treating complex perianal fistulas, with the aim of eradicating infection and anatomically reconstructing the muscular defect. FIPS may be a good treatment option for selected patients with complex fistulas. However, most published studies on FIPS lack long-term evaluations, with follow-up periods of ≈6 to 12 months,[13–16] which are inadequate to establish strong conclusions about the rate of recurrence and fecal incontinence developed after FIPS.

There is also heterogeneity in the type of fistula included in these studies, which limits their generalizability. Most patients included had simple fistulas and low tracts, and studies either did not report separately or included only a small number of patients with high fistulas.[13,15,17,18] This leads to increased errors in defining the true rate of recurrence and continence impairment in higher fistula patients, because in the majority of patients, lower tracts may produce no continence disturbance even when sphincteroplasty fails. In addition, there are currently no studies that clearly define the group of patients in which FIPS is the treatment of choice.

The aim of this study was to conduct a long-term evaluation of fecal incontinence and recurrence after FIPS in patients with complex anal fistula, reported according to fistula height and other variables, with the goal of identifying groups of patients for whom FIPS is suitable and defines the true risk of recurrence and continence disturbance after high fistula.

PATIENTS AND METHODS

This was a prospective study including 107 patients with complex anal fistulas who underwent FIPS in the coloproctology unit of the General Hospital of Elche between October 2000 and December 2010. The study was approved by the hospital's clinical research ethics committee, and all of the patients signed informed consent forms.

Physical examination, proctoscopy, anorectal manometry, and ultrasound were performed during the preoperative period. Incontinent patients were specifically asked about fecal leakage from the anus (to avoid confusion regarding fistula discharge and associated pad usage), and findings were confirmed by physical examination.

An endoanal ultrasound was performed preoperatively to define the fistula height and amount of external sphincter involvement, with intraoperative clinical evaluation to confirm the preoperative classification. We analyzed the concordance between clinical evaluation and ultrasound classification and obtained a κ value (Table 1).

We included complex anal fistulas and divided them into 2 groups: high tract (suprasphincteric and high transsphincteric [HT]) cases and nonhigh tract (medium transsphincteric) cases in accordance with the Parks classification.[19] Suprasphincteric tracts broke through the intersphincteric space between the puborectal fibers and the external sphincter and returned to the perianal skin.

TABLE 1. Baseline demographic and clinical features of 107 patients treated by fistulotomy and primary sphincteroplasty

Variables	*Data*
Sex, n (%)	
Men	73 (68.2)
Women	34 (31.8)
Age, y	
Mean (range)	48.4 (18–71)
Duration of symptoms, mo	
Mean (range)	12.8 (2–60)
Fistula type, n (%)	
Primary	70 (65.4)
Recurrent	37 (34.6)
Fistula tract, n (%)	
High	37 (34.6)
Nonhigh	70 (65.4)
Continence status, n (%)	
Wexner <3	67 (62.6)
Wexner ≥3	40 (37.4)

A *transsphincteric fistula* was defined as one that crossed both sphincters. In this study, an *HT* was defined as involving >50% of the external sphincter as identified on ultrasound and confirmed in exploration under anesthesia, and *nonhigh fistulas* as involving <50% of the external anal sphincter. Intersphincteric tracts and subcutaneous fistulas were excluded. Noncryptoglandular fistulas such as those in patients with Crohn's disease or ulcerative colitis were excluded, as were pregnant patients, those with ASA IV, patients aged <18, immunocompromised patients (eg, those with HIV), and patients who refused consent.

The FIPS was performed by 2 colorectal surgeons. Both surgeons used the same technique for the procedure, which was determined by discussion and by viewing each other's operations. Anal incontinence was evaluated using the Wexner scale: 0 corresponded with full continence and 20 to total incontinence. Results from physical examinations and ultrasound were compared with operative findings.

Preoperative and Intraoperative Stages

All of the patients were preoperatively prepared with sodium dihydrogen phosphate enemas. Single-dose preoperative low-molecular-weight heparin for thromboembolic prophylaxis was used. Patients also received preoperative metronidazole and tobramycin for antibiotic prophylaxis.

With the patient in a prone jackknife position, the fistula tract was identified with hydrogen peroxide through the external opening. Then, fistulotomy of the main tract was performed from the external opening to the outer edge of the external anal sphincter. The internal opening was excised, and tract curettage was performed. The quantity of sphincter involved was measured, and reconstruction was evaluated. Sphincter bundles were marked with identifying sutures, and the fistula was laid open.

Reconstruction was carried out in 2 layers: rectal and anal mucosas were sutured with an internal sphincter using polyglactin 3-0 (Vicryl, Ethicon Inc, Bridgewater, NJ) , whereas puborectal muscles and external sphincters were reconstructed with an end-to-end interrupted suture technique using polyglactin 2-0 (Vicryl). The skin was sutured with a polypropylene 0 suture, leaving gaps between knots to allow spontaneous drainage (Fig. 1).[20,21]

Postoperative Stage

All of the patients received postoperative treatment with intravenous metronidazole for 3 days, followed by oral metronidazole for 4 days. Oral liquids were started on the second postoperative day and solids on the third day. The patients were discharged on the fourth postoperative day. The polypropylene suture was removed by nurses in the outpatient clinic at ≈15 days postoperation.

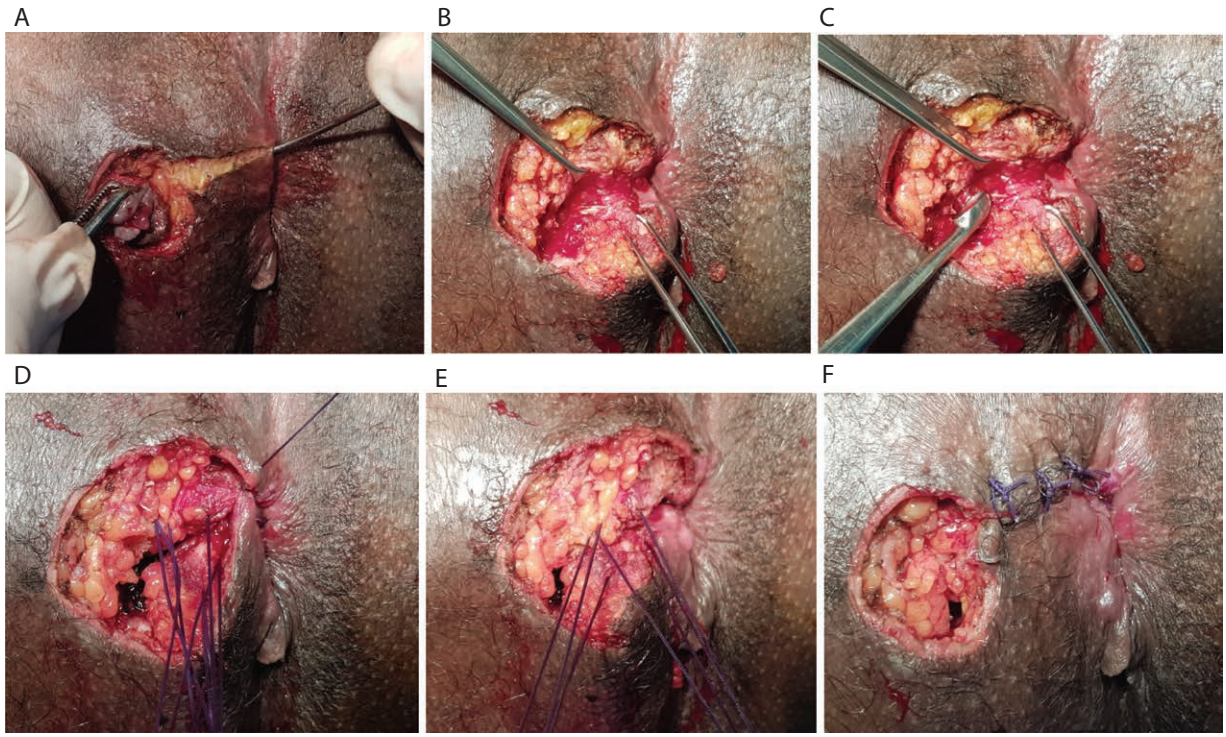

FIGURE 1. Steps of fistulotomy and primary sphincteroplasty in a high tract. A, Identification of fistula tract with a probe. B, Fistulotomy. C, Curettage of the tract. D, Sphincter bundles with identifying sutures. E, Sphincteroplasty. F, Skin partial suture.

Follow-up

During follow-up, continence was measured by colorectal surgeons from our colorectal unit using a continence diary that was delivered previously by coloproctology nurses. Data registration was undertaken by all of the involved colorectal surgeons and nurses. Patients were examined at 1, 3, 6, and 12 months postsurgery. Long-term evaluation appointments were scheduled during 2017, with a median follow-up of 96 months and a minimum follow-up of 84 months. The method of follow-up was the same throughout the study period.

At every visit to the outpatient clinic, a physical examination and proctoscopy were performed. In addition, at every visit we evaluated continence according to the Wexner score and patient continence diaries. Because of the close follow-up with history and physical examination at every medical visit, we were able to confirm that any fecal leakage was attributed to anal incontinence and that any changes in the Wexner score were not because of fistula discharge that was incorrectly assessed as anal leakage preoperatively.

We defined fistula healing as the absence of purulent drainage through the fistula and when external and internal openings had healed or closed without symptoms. Our primary outcome was *recurrence*, which was defined as any purulent leakage from the fistula, openings 90 days after FIPS, or the occurrence of a new tract after primary cure. Our secondary outcome was postoperative continence. We defined *full continence* or *minor alterations of continence* (normal, soiling, or flatus) as a Wexner score <3, and *incontinence* or *major alteration of continence* as a Wexner score of ≥3.

Statistical Analysis

Descriptive analyses were calculated according to continuous (mean and SD) or discrete (percentage) variables. The Fisher exact test was used for categorical variables, Mann–Whitney *U* or Kruskal–Wallis tests for ordinal variables, ANOVA for continuous variables by applying rank conversion on the dependent variable, and the Friedman test of repeated measures for difference between groups.

To identify possible predictors of response and to evaluate risk (ORs and 95% CIs), logistic regression analysis was performed. We only selected variables with significant likelihood ratio and Wald tests for our multivariate logistic regression model.

All tests of significance were 2-tailed. Statistical significance was set at $p < 0.05$. Statistical tests were performed using R software 3.5.1 (R Core Team, 2018, R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

A total of 107 patients were included in this study, including 73 men (68.2%) and 34 women (31.8%). The mean age was 48.4 ± 11.6 years (range, 18–71 y). Seventy patients

(65.4%) had anal abscesses drained previously, of whom 30 had experienced >2 episodes. The range of follow-up was 84 to 204 months, with a median of 96 months. The concordance between clinical evaluation and ultrasound classification was analyzed, and a κ value of 0.9 was obtained. Demographic and surgical data are described in Table 1.

Primary Healing and Recurrence

Overall recurrence after 90 days across the series was observed in 17 patients. The FIPS procedure was repeated in 5 patients: an advancement flap was performed in 2 patients, and photodynamic therapy was used in 5 patients. The other 5 patients declined additional reparative surgery and had loose setons placed (Fig. 2). Overall total healing after FIPS was 84.1%.

Of 70 primary fistulas, 51 healed during the first month after FIPS, and 7 patients healed during the first 3 months (58/70 healed primarily by 3 months. Four patients experienced recurrence 6 months after FIPS, and 3 additional recurrences were observed 1 year later. At the end of follow-up, 5 more fistula recurrences were observed. Total healing in this group at the end of follow-up was therefore 58 (82.9%) of 70. Of 37 patients with recurrent fistulas, 32 healed during the first 3 months after FIPS. We observed 1 recurrence 6 months after surgery and another 12 months later. At the end of the follow-up, 3 patients experienced recurrence for a total of 5 recurrences in this group. Total healing in this group at the end of follow-up was 32 (86.5%) of 37. There was no difference in recurrence according to fistula type (12/70 (17.1%) primary fistula vs 5/37 (13.5%) recurrent fistulas; $p > 0.05$).

Of the 37 high fistulas, 28 healed primarily during the first month after surgery and 3 during the first 3 months. At 6 months after FIPS, 2 patients experienced recurrence and 2 more were observed 1 year later. At the end of the follow-up period, 2 more fistula recurrences were observed. Total healing in the high fistula group at the end of follow-up was 31 (83.8%) of 37.

Of the 70 nonhigh fistulas, 54 healed during the first month after surgery, and 5 healed during the first 3 months. We identified 3 recurrences 6 months after FIPS, and 2 more than 1 year later. At the end of follow-up, 6 additional fistula recurrences were observed. Total healing in the nonhigh fistula group at the end of the follow-up period was 59 (84.3%) of 70. High fistulas recurred slightly more frequently than nonhigh fistulas (6/37 (16.2%) vs 11/70 (15.7%)).

Continence

Continence was analyzed by fistula type, fistula tract height, and preoperative continence, to answer key questions about the influence of FIPS on continence impairment. Specifically, we asked whether recurrent and high fistulas were associated with a greater risk of incontinence and whether FIPS improved continence in patients with a preoperative continence deficit. Mean Wexner scores before and after surgery for primary and recurrent fistulas according to their preoperative continence status are shown in Table 2 and Figure 3.

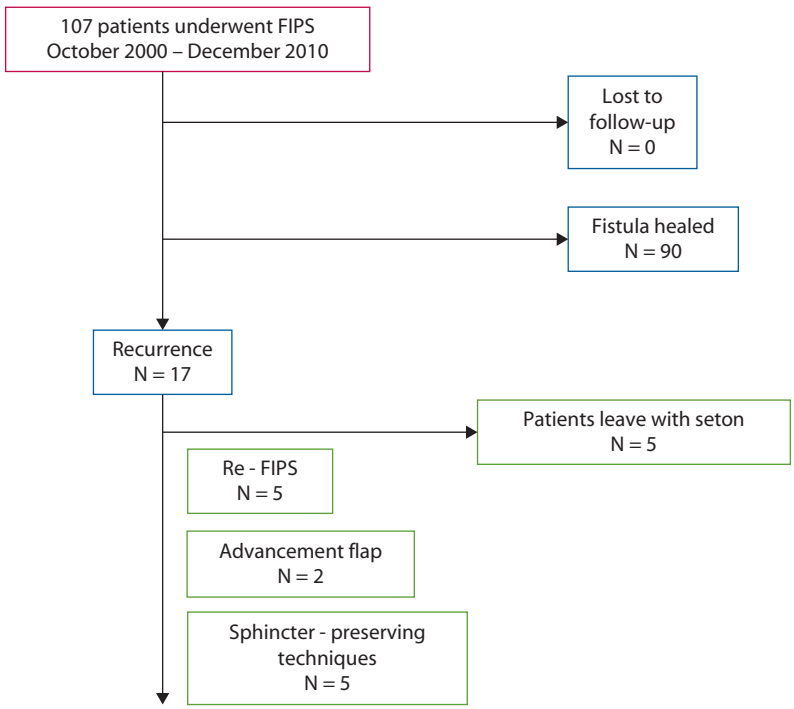

FIGURE 2. Flow chart. FIPS = fistulotomy and primary sphincteroplasty.

Fistula Tract

Of the 107 patients, 12 (11.2%) showed deterioration in continence at the end of follow-up, 39 (36.5%) improved, and 56 (52.3%) had no modification to their Wexner values.

High Fistulas (n = 37)

Eleven patients (29.7%) showed improved Wexner scores after FIPS. Of these, 8 had a Wexner value <3 at the end of follow-up (1 suprasphincteric, 7 HT) and 3 (1 suprasphincteric, 2 HT) remained incontinent (mean Wexner value = 4.3). Seven (18.9%) of 37 patients with high fistulas with mean preoperative Wexner values of 2.03 (range, 1.00–10.00) showed deterioration in their continence. Three were suprasphincteric fistulas with a final mean Wexner of 7 (range, 5–13), and 1 had major incontinence (Wexner >9). Four patients had HT with a mean Wexner score of 6 (range, 3–13), and 1 had major incontinence.

Nonhigh Fistulas (n = 70)

Twenty-eight patients (40%) had improved Wexner scores after FIPS. Of these, 25 had a Wexner score <3 at the end of follow-up, and 3 remained incontinent (mean Wexner value = 7.7). Five (7.1%) of 70 patients had worsened by the end of follow-up, all with Wexner values ≥3 (mean = 6.4; range, 3.0–15.0) and 1 with major incontinence.

Preoperative Full Continence (Wexner <3) (n = 67)

In 57 patients (85.1%) with preoperative full continence, treatment did not have an effect on continence. The other 10 patients (15%) reported a deterioration to postoperative incontinence (Wexner ≥3), with 9 having Wexner values between 3 and 6 and 1 patient having a Wexner value of 15. The mean preoperative Wexner score was 0.1, rising to 0.5 at the first postoperative visit, 0.2 at 6 months, 2.2 at 1 year, and 0.8 at a median of 96 months postoperation ($p < 0.05$). Although the Wexner score increased, the mean score remained <3, which is the threshold for incontinence (Fig. 4).

Preoperative Incontinent Patients (Wexner ≥3) (n = 40)

Forty patients (37.4%) were incontinent before surgery (mean Wexner value = 8). The continence status of 32 patients (80%) improved significantly, but 8 (20%)

TABLE 2. Variation of mean Wexner value and mean SD in primary and recurrent fistulas

Type	*<3 (N = 67)*	*3+ (N = 40)*	*Total (N = 107)*	*p*
Primary				
Wexner preoperative				
Mean (SD)	0.122 (0.484)	7.476 (3.558)	2.329 (3.918)	<0.001
Range	0.000–2.000	3.000–16.000	0.000–16.000	
Wexner 1–3 mo				
Mean (SD)	0.102 (0.586)	2.190 (3.558)	0.729 (2.200)	<0.001
Range	0.000–4.000	0.000–10.000	0.000–10.000	
Wexner 6 mo				
Mean (SD)	0.041 (0.200)	1.143 (1.982)	0.371 (1.194)	<0.001
Range	0.000–1.000	0.000–7.000	0.000–7.000	
Wexner 12 mo				
Mean (SD)	2.400 (4.526)	2.400 (3.836)	2.400 (4.083)	0.772
Range	0.000–14.000	0.000–10.000	0.000–14.000	
Wexner 2016–2017				
Mean (SD)	1.083 (2.624)	1.286 (3.289)	1.145 (2.819)	0.779
Range	0.000–15.000	0.000–13.000	0.000–15.000	
Recurrent				
Wexner preoperative				
Mean (SD)	0.000 (0.000)	8.632 (3.745)	4.432 (5.113)	<0.001
Range	0.000–0.000	3.000–16.000	0.000–16.000	
Wexner 1–3 mo				
Mean (SD)	1.556 (2.382)	3.053 (4.527)	2.324 (3.675)	0.225
Range	0.000–7.000	0.000–18.000	0.000–18.000	
Wexner 6 mo				
Mean (SD)	0.778 (1.309)	1.632 (2.565)	1.216 (2.070)	0.249
Range	0.000–3.000	0.000–10.000	0.000–10.000	
Wexner 12 mo				
Mean (SD)	0.000 (NA)	1.000 (1.247)	0.909 (1.221)	0.386
Range	0.000–0.000	0.000–3.000	0.000–3.000	
Wexner 2016–2017				
Mean (SD)	0.167 (0.514)	2.211 (3.994)	1.216 (3.029)	0.007
Range	0.000–2.000	0.000–13.000	0.000–13.000	

NA = not applicable.

remained incontinent. From the first postoperative follow-up, the mean Wexner score was <3 ($p < 0.01$), although 8 patients had a score of ≥3 (Fig. 4).

Factors Associated With Incontinence (Wexner ≥3)

In a logistic regression analysis (Fig. 5), we have observed that male sex was related to a lower risk of incontinence compared with female sex (OR = 0.66 (95% CI, 0.20–2.13); $p > 0.05$). In addition, recurrent fistulas were related to a lower risk of postoperative incontinence too (OR = 0.43 (95% CI, 0.11–1.68); $p > 0.05$). This magnitude was not statistically significant; however, it is clinically relevant and could be confirmed by studies with larger sample size.

Fistula recurrence during follow-up was associated with a 6-fold increase in the risk of incontinence (OR 5.64 vs no recurrence (95% CI, 1.74–18.24); $p < 0.01$). High fistulas were associated with a 4-fold increase in the risk of incontinence (range, 1.22–13.06; $p < 0.01$).

DISCUSSION

This study is one of the largest series of FIPS to date, with the longest follow-up period (Table 3). Our group previously reported excellent results with FIPS for complex anal fistulas in short- and medium-term follow-up periods.[17,22] We now present our results after a mean of 96 months of follow-up, analyzing recurrence and continence according to fistula type and tract height.

Our overall healing rate was 84.1%, after a median follow-up period of 96 months, with a minimum follow-up of 84 months and several patients with a follow-up >200 months. Our recurrence rate was therefore higher than

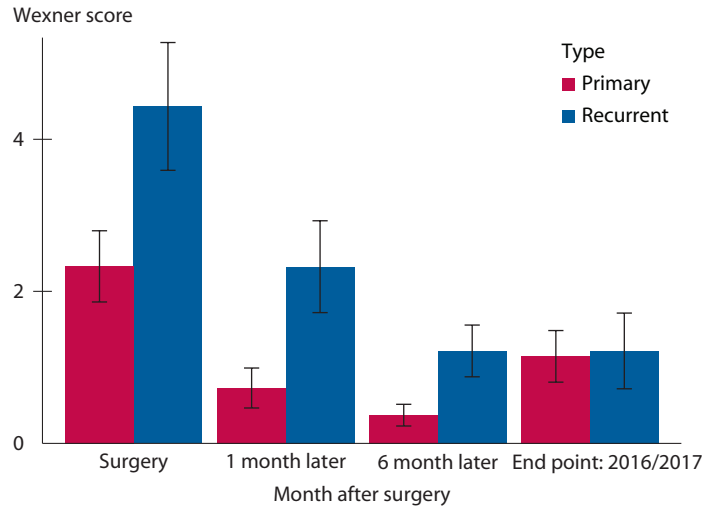

FIGURE 3. Mean and SE of continence by type.

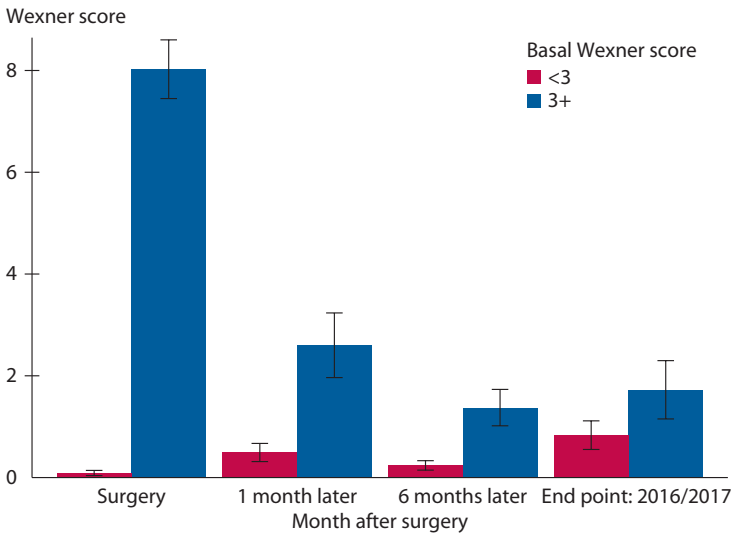

FIGURE 4. Mean and SE of continence by previous Wexner score.

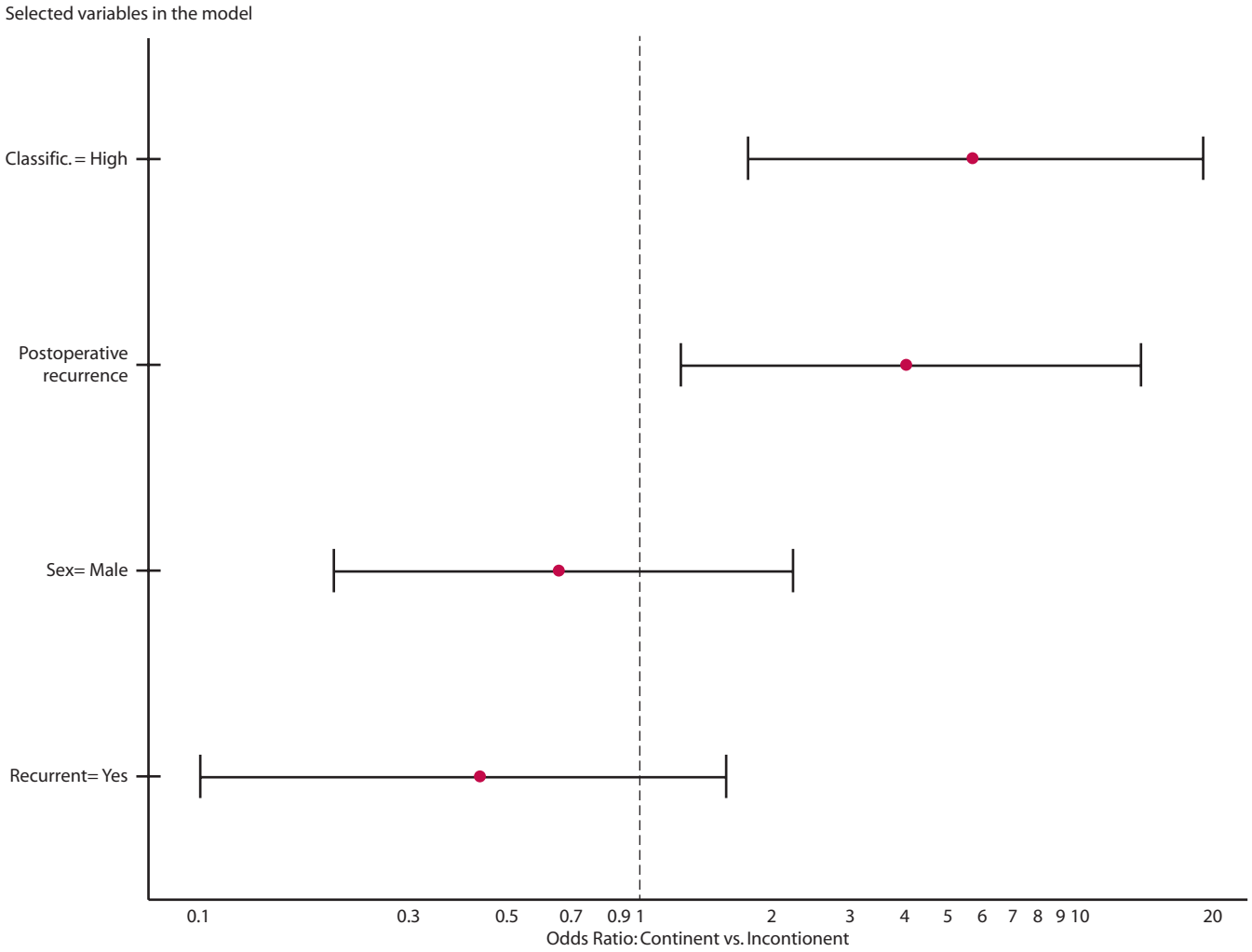

FIGURE 5. Logistic regression analysis.

that of other published studies, ranging from 0% to 14% (Table 3). Our recurrence rate is likely to be more realistic than those obtained from other series with fewer patients, different types of fistulas, and shorter follow-up periods.

This study presents the largest series of complex anal fistulas, including medium and HT fistulas and suprasphincteric fistulas. By separating high and nonhigh fistulas and reporting continence impairment in these 2 groups separately, we were able to assess the impact of the technique on continence without including patients with simple tracts and low fistulas that might falsely improve the appearance of our results. In addition, logistic regression analyses show results equivalent to our personal experience as a referral coloproctology unit in Spain. In our opinion, FIPS must not be indicated in patients with high tracts and women because of them being patients with a high risk of experiencing complications. Female sex does not have significant results in the multivariate analyses. Larger studies with longer follow-up are needed to confirm our results. However, for these cases, we adopt sphincter-preserving techniques. This is the most unique and noteworthy feature of our study. Moreover, this has allowed us to identify the true impact of FIPS in the most crucial group: those with high fistulas that are unsuitable for fistulotomy alone.

Parkash et al[17] presented a larger study with 120 fistula cases, but of these 98 were intersphincteric, 20 were transsphincteric, 1 was suprasphincteric, and only 1.6% had high fistulas. Recurrence rate in this study was 2.5%, for which Lux and Athanasiadis[18] reported 0% recurrence, but only had 5.5% of included cases had high fistulas.

A study by Christiansen and Rønholt[13] had an insufficient number of patients (14 complex fistulas), and some of these had only 12 months of follow-up, with a recurrence rate of 14.3%. Similarly, a study by Lewis and Phillips[14] had a recurrence rate of 9.4% but had only 32 complex fistula cases and an unclear follow-up duration. Roig et al[15] reported a 9.7% recurrence rate but included simple and low-tract fistulas, with most patients followed up for 12 months. Ratto et al[16] reported recurrence rates <10%, with

TABLE 3. FIPS in the literature

Author	*Year*	*N*	*CF (%)*	*RF (%)*	*FU*	*R (%)*	*I (%)*
Parkash et al[17]	1985	120	2 (1.6)	–	6–60	2.5	3.6
Lux et al[18]	1991	46	26 (5.5)	20 (4.5)	15.3	0	21.7
Christiansen et al[13]	1995	14	14 (100)	14 (100)	12–96	14.3	21.4
Lewis and Phillips[14]	1996	32	32 (100)	–	–	9.4	–
Roig et al[15]	1999	31	27 (87)	11 (35.5)	12–59	9.7	16.7
Perez et al[20]	2005	35	35 (100)	16 (45.7)	32	5.7	12.5
Arroyo et al[22]	2012	70	70 (100)	30 (42.9)	81(48–120)	8.6	16.6
Ratto et al[16]	2013	72	72 (100)	12 (16.7)	29 (6–91)	4.3	11.6
Ratto et al[3]	2015	666	501 (75.2)	107 (16.1)	28.9 (12–81)	6.8	12.4
Litta et al[21]	2019	203	103 (51)	17 (8)	56	7	19
Our article	2020	107	107 (100)	37 (34.6)	96 (84–204)	16	16.8

FIPS = fistulotomy and primary sphincteroplasty; CF = complex fistula; RF = recurrent fistula; FU = follow-up (months, mean, and interquartile range); R = recurrence; I = incontinence.

a longer median follow-up, but some patients were only followed up for 6 months, highlighting the importance of publishing a minimum follow-up duration for a given series rather than simply a median.

Recently, Litta et al[21] published a study of 203 patients. Again, this series had only 51% complex tract cases and a mean follow-up period of 56 months. The recurrence rate was 7% but included simple and low fistulas. The incontinence rate was ≈19%.

Ratto et al[3] published a systematic review of 17 studies and 501 patients who underwent FIPS. The mean follow-up period was 28.9 months, and they reported a recurrence rate of 6.8%. Nevertheless, many studies were of low quality, with heterogeneity in fistula types and short follow-up durations.

Our series confirmed the importance of a long minimum and median follow-up duration. In this study, 47% of recurrences (8 of 17) occurred after 12 months, suggesting that a long follow-up period is necessary to assess the true efficacy of these (and probably all) fistula techniques.

Another strength of our study is our analysis of results according to Parks classification, providing real rates of recurrence in complex anal fistulas rather than in a mixed cohort. In our study, patients with high tracts demonstrated higher recurrence rates, and higher tracts had a 5-fold increase in the risk of continence deterioration after surgery. Previous studies have not analyzed continence after FIPS based on fistula height. Additional studies analyzing FIPS outcomes according to tract height with long-term evaluations of complex anal fistula cases are crucial to facilitate data pooling on recurrence and efficacy of FIPS in different cohorts. In addition, these studies would help to establish ideal indications based on patient selection. For example, it is important to determine whether FIPS is most valuable in patients with lower fistulas and patients with preexisting continence impairment rather than in patients with higher fistulas with normal preoperative continence.

Incontinence rates in the literature are variable, as shown in Table 3. In our opinion, for a correct analysis, patients should be divided into a previously continent or minor continence dysfunction (Wexner <3) group and a previously incontinent (Wexner ≥3) group. Changes in patient function after surgery should be presented on a per-patient basis rather than as an average. In this way, the true impact of surgery on continence can be identified.

In our series, continent patients generally did not show a large variation in their Wexner score during follow-up, although ≈1 in 5 continent patients with high tracts developed a significant continence impairment after FIPS. Moreover, 4 of 5 preoperative incontinent patients significantly improved their Wexner values in long-term evaluations. This was observed in both groups at the end of the follow-up, as others have also reported.[16,20,22] As a result, FIPS could be considered a suitable technique for incontinent patients.

The 1 in 5 risk of new significant continence impairment after FIPS in high fistula is a crucial finding from our study. This is consistent with the idea that sphincteroplasty has a functional failure rate that is only visible in fistula cases high enough that a simple fistulotomy would produce significant continence impairment. A lower fistula may also show functional failure in repair, but if adequate functional muscle remains above, no significant clinical deterioration in continence will be seen. When studies contain mostly lower fistulas and report their results in a single group, this detail is lost. In addition, when studies report average rather than per-patient continence rates, this error is confounded, and a technique that we have shown to have a continence impairment rate of 20% in high fistulas might demonstrate a much lower level of continence impairment or none at all.

Logistic regression showed possible risk factors for the development of postoperative fecal incontinence after FIPS. Female sex could be related to the development of postoperative incontinence, and high fistula tracts were identified as a risk factor for postoperative incontinence. In continent, higher-risk patients, sphincter-preserving

techniques should perhaps be considered as the first surgical step before performing other procedures such as FIPS.

In the case of recurrence after FIPS, there is no consensus about future treatment options. In our opinion, the next step after a FIPS failure involves a personal discussion between the patient and doctor, with discussion of the available techniques and options, including the option for no additional surgery. The patient's goals, continence, and tract height/complexity should play key roles in discussion.

In previous studies, only Ratto et al[16] analyzed risk factors for postoperative incontinence, finding recurrent fistula and seton before FIPS as risk factors. Patients with recurrent fistulas had a 5-fold increased risk of postoperative incontinence. However, in this study it was concluded that these data were controversial, because other authors like Christiansen and Rønholt,[13] Parkash et al,[17] and Roig et al,[23] were in the same view as us, taking into account this group of patients as the ideal candidates for performing FIPS. Advancement flaps in complex recurrent fistulas could fail because of local conditions such as intense fibrosis; and new procedures, for instance, sphincter-preserving techniques, have a high rate of recurrence. FIPS could be a useful technique in this group of patients without modifying continence and with an acceptable recurrence rate. Nevertheless, more studies and meta-analysis are necessary to confirm this.

Fistulectomy associated with primary sphincteroplasty is performed with the aim of eradicating the entire fistula and minimizing the rate of postoperative incontinence, in contrast with fistulotomy and sphincteroplasty, in which the tract is laid open but not fully excised before repair of the divided sphincter complex. According to Roig et al,[23] fistulectomy associated with sphincteroplasty is indicated in patients with complex anal fistulas, especially in those with concomitant abscesses. In studies that compare the postoperative outcomes of fistulectomy versus fistulotomy with sphincteroplasty, both procedures show similar postoperative incontinence rates. According to Ratto et al,[3] differences (12.4% and 12.0% incontinence in the fistulotomy and fistulectomy groups) are attributed to the method of sphincteroplasty (overlapping or not) rather than the nature of the fistula division or excision. Also, Roig et al[23] explained that radical treatment in patients with high fistulas or in patients with nonhigh fistulas but classical risk factors like advanced age and previous incontinence could be unsafe. In these cases, genuine sphincter-preserving techniques may be a better option, but randomized controlled trials are needed to confirm this.

The advancement flap is one of the most widespread techniques for the treatment of complex fistulas, but recurrence can occur in up to one third of patients, and continence impairment can also occur.[2] Only 1 randomized study compared FIPS with advancement flap.[24] In this study, our group compared 60 patients, 30 with advancement flaps against 30 with FIPS. Two fistulas from each group recurred (7.4% for flap and 7.1% for FIPS), and recurrences were detected in patients with high tracts. However, the advancement flap may be difficult to perform in patients with anal or rectal fibrosis or in patients with recurrent fistula, and FIPS might have a special benefit in these cases. In terms of postoperative fecal incontinence, up to 33% of patients demonstrated some degree of continence impairment after an advancement flap.[2,24,25] Nevertheless, it is difficult to compare these studies because there is often great variability in fistula type and complexity and in flap thickness or technique. In a randomized trial comparing FIPS with advancement flap,[25] patients who were treated with advancement flap experienced incontinence more frequently than those undergoing FIPS.

In our opinion, randomized clinical trials with more patients and longer follow-up are needed to compare FIPS and advancement flap and to confirm whether FIPS is superior to advancement flap in high-tract fistulas. Randomized trials could also be used to compare FIPS with genuine sphincter-preserving techniques. Evaluating recurrence, continence impairment, patient satisfaction, and patient selection according to the nature of the fistula tract in complex anal fistulas could be very informative.

One of the limitations of this study is the use of prophylactic and postsurgery antibiotics. Complex anal surgery has changed its protocols over time. Until 2010, most colorectal surgeons used antibiotic prophylaxis before and after surgery because the surgical wound was considered contaminated.[23] Because of low complication rates after surgery, some groups have modified their protocols and no longer administer antibiotics before or after surgery, with good results.[21] Whether antibiotic prophylaxis produces a real decrease in the complication rate after surgery, especially the surgical wound infection rate, remains unknown.

The long postoperative inpatient stay seen in this study has also since decreased after the introduction of enhanced recovery after surgery protocols. Patients are discharged earlier in our unit, typically on the first or the second day after surgery.[21]

To our knowledge, this study represents the largest series of FIPS with long follow-up to date. Although it is limited by its single-center nature, it has several strengths: procedures were standardized and performed in a referral hospital with a dedicated colorectal unit. This permitted close follow-up of patients and a realistic depiction of FIPS outcomes. Crucially, analysis was performed according to fistula height and preoperative continence status. This allowed the true impact of FIPS on patient continence to be described, ideal indications for this technique to be elucidated, and risk factors for recurrence and fecal incontinence to be evaluated.

CONCLUSION

Complex anal fistulas remain a significant clinical issue. FIPS is a good option for the treatment of complex anal fistulas with acceptable recurrence and incontinence rates.

Multicentric, adequately powered, randomized studies are desirable to determine the best technique, but FIPS may be the ideal technique for recurrent fistulas in male patients with nonhigh tracts and could be considered for those with preoperative continence impairment regardless of tract height. High and primary fistulas have an increased risk of recurrence and incontinence, and continent patients with these fistulas would be candidates for genuinely sphincter-preserving techniques and would require careful counseling if FIPS is considered.

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