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Randomized clinical and manometric study of advancement flap versus fistulotomy with sphincter reconstruction in the management of complex fistula-in-ano

Francisco Perez, M.D.[a,b,*], Antonio Arroyo, Ph.D.[a], Pilar Serrano, Ph.D.[a], Ana Sánchez, M.D.[a], Fernando Candela, Ph.D.[a], Maria Teresa Perez, Ph.D.[a], Rafael Calpena, Ph.D.[a]

[a]*Coloproctology Unit, Department of Surgery, University Hospital of Elche, C/Huertos y Molinos s/n, 03202 Elche, Alicante, Spain*
[b]*C/General Bonanza 4, 4° B, 03007 Alicante, Spain*

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Abstract

Background: The goal of this study was to compare the outcomes of advancement flap (AF) versus fistulotomy with sphincter reconstruction (FSR) for primary complex fistula-in-ano in terms of recurrence and anal function.
Methods: A randomized clinical trial was conducted to compare AF with FSR. Preoperative and postoperative evaluation included physical examination, anal ultrasonography, and anal manometry, with a minimum follow-up period of 24 months. Anal continence was evaluated using the Wexner Continence Grading Scale (scale, 0–20).
Results: Sixty patients were randomized to AF (group 1, N = 30) or FSR (group 2, N = 30). Three patients from group 1 and 2 patients from group 2 were excluded from the study because of active sepsis at surgery. Fistulas were classified as high transsphincteric in 44 patients (80%) and suprasphincteric in 11 patients (20%). Demographic and clinical features showed no differences between the 2 groups. The mean Wexner Continence Grading Scale did not vary significantly after surgery in either group, and there was no difference between the groups. On anal manometry there was a significant decrease in the maximum resting pressure after surgery in both groups, and in the maximum squeeze pressure in the AF group, but neither the maximum resting pressure nor the maximum squeeze pressure differed significantly between groups, either before or after surgery. Two fistulas from each group recurred after surgery (7.4% and 7.1%, respectively). The mean follow-up period was 36 months (range, 24–52 mo).
Conclusions: FSR compares with AF in terms of postoperative continence and recurrence. Anal continence and manometric values are not jeopardized in either technique.

Keywords: Complex anal fistula; Fistula-in-ano; Advancement flap; Anal sphincter reconstruction; High-transsphincteric fistula; Suprasphincteric fistula

Complex fistula-in-ano is a frequent source of concern for both patients and surgeons because of its high rate of recurrence and postoperative anal incontinence. Total sphincter-preserving surgery may result in a high rate of recurrence whereas the more radical approaches may lead to embarrassing disturbances of continence.

Advancement flap (AF) has a fair reputation because of the good results reported in the literature. However, in the more complicated fistulas an extensive intrarectal mobilization may be necessary to ensure a tension-free closure of the internal opening, and may be associated with higher recurrence and postoperative incontinence.

Fistulotomy with sphincter reconstruction (FSR) might play a role in the surgery of complex fistula-in-ano, particularly in patients with unfavorable local conditions, such as anal or rectal fibrosis, yet it has been studied little and implemented rarely. After having obtained good initial results with FSR in the management of recurrent complex fistulas [1], we decided to conduct a randomized study aimed at comparing the outcomes of AF versus FSR in the management of primary complex fistula-in-ano. The primary end points of the study were fistula recurrence, anal continence (Wexner Continence Grading Scale [WCGS]), and anorectal manometry.

* Corresponding author. Tel.: +34-670333057; fax: +34-966679377.
E-mail address: faperez@vodafone.es

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Patients and Methods

Sixty patients were allocated to either AF (group 1, N = 30) or FSR (group 2, N = 30) by individual computer-generated randomization in the Coloproctology Unit of the Department of Surgery at the University Hospital of Elche in Spain from January 2001 to October 2003. The study was approved by the hospital ethics committee and detailed written informed consent was obtained before randomization.

We included primary fistulas with high transsphincteric and suprasphincteric tracks according to the classification of Parks et al [2] for fistula-in-ano. Patients suffering from acute anal sepsis were excluded from the study, as were patients with fistulas considered noncryptoglandular in origin and those suffering from inflammatory bowel disease. Recurrent complex fistulas also were excluded because we considered that it was not advisable for their treatment to be decided at random. Patients with prior anal or rectal surgery and fecal incontinence ranging more than 2 points (on the WCGS) also were excluded from the study.

Preoperative assessment included physical examination, anorectal manometry, and anal endosonography. The data were collected in a standardized fistula protocol, designed specifically for the study. Anal continence was evaluated using the WCGS (Table 1), the score being calculated after the patients' completion of a daily defecatory questionnaire. A score of 0 meant full continence, whereas a score of 20 meant total incontinence.

Physical examination and anal endosonography were intended to achieve delineation of the anatomy of the fistula with regard to primary track, internal opening, horseshoe extension, secondary cavities or extensions, and associated sphincteric lesions. These assessments were contrasted afterward with surgical findings.

Anorectal manometry was performed using a low-compliance water perfusion system with a filled 6-lumen catheter having radially arranged ports in cross-section. Pressures were recorded by means of a pressure transducer situated within each infusion line and connected to a chart recorder. Both maximum resting pressure (MRP) and maximum squeeze pressure (MSP) were registered. The pressure ranges of 30 healthy patients (control group) obtained in our laboratory of anorectal physiology were taken as the reference (MRP, 76 ± 22 mm Hg; MSP, 178 ± 58 mm Hg).

Table 1
WCGS

	Never	Occasionally (<1 mo)	Sometimes (>1 mo, <1 wk)	Usually (>1 wk, <7 wk)	Always (≥1 d)
Flatus	0	1	2	3	4
Liquid stools	0	1	2	3	4
Solid stools	0	1	2	3	4
Wears pad	0	1	2	3	4
Alteration in lifestyle	0	1	2	3	4

Score ranges from 0 (normal continence) to 20 (maximum incontinence with maximum disturbance of lifestyle).

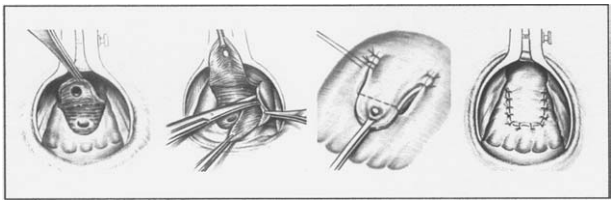

Fig. 1. Advancement rectal flap for complex fistula-in-ano.

Full mechanical bowel preparation with phosphosoda was prescribed routinely before surgery. Antithrombotic prophylaxis (enoxaparin 20 mg subcutaneous) and antibiotic prophylaxis (metronidazole 1.5 g intravenous and tobramycin 250 mg intravenous) also were administered. Once in the operating room, the patients received a povidone iodine enema and gentle brushing of the perianal skin.

Advancement flap

The patient was placed in either the prone jack-knife position for anterior flaps, or the lithotomy position for posterior flaps (Fig. 1). Proper exposure of the anal canal was achieved using Park's speculum and the plastic anal retractor included in the PPH-33-01 kit (Ethicon Endosurgery, Cincinnati, OH). The fistula track was verified with hydrogen peroxide injected through the external opening. The submucosa of the rectal wall and the intersphincteric space were infiltrated with 1:200,000 epinephrine. A 180° rectal flap containing the internal ostium was elevated upward at least 5 to 6 cm. The flap included mucosa, submucosa, and the full thickness of the internal anal sphincter in the lower half, and part of the circular muscle fibers of the rectum in the upper half. The distal portion of the flap with the internal opening was excised. Curettage of the accessory cavities was performed. The flap was advanced downward and sutured with interrupted polyglactin 2-0. Finally, a core-out of the main track was performed from the external opening up to the outer edge of the external anal sphincter and was left open to heal by secondary intention.

Fistulotomy and sphincter reconstruction

The patient was placed in the prone jack-knife position (Fig. 2). The fistula track was verified with hydrogen per-

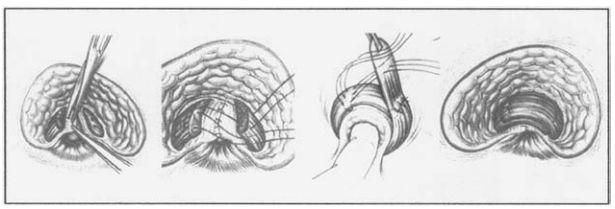

Fig. 2. Fistulotomy with sphincter reconstruction for complex fistula-in-ano.