PAPER

Predictors of Outcome for Anal Fistula Surgery

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Objectives: To review our experience with patients treated for anal fistula secondary to cryptoglandular disease and to determine factors that influence postoperative outcome.

Design: Retrospective review.

Setting: A regional tertiary referral center.

Patients: Adult patients with anal fistula secondary to cryptoglandular disease.

Interventions: Fistulotomy, advancement flap, and fistula plugging.

Main Outcome Measures: Rates of operative failure (persistent fistula), incontinence, and septic complications. We evaluated age, sex, previous operation, fistula type, number of fistula tracts, horseshoe fistula, and intervention type to determine their independent influence on outcomes.

Results: One hundred seventy-nine patients (79.3% male) underwent fistula operation from October 1, 2003, through December 31, 2008. Median age was 45 years. Fistulotomy was undertaken in 82.7% of patients, advancement flap in 10.6%, and plugging in 6.7%. The rates of operative failure, postoperative incontinence, and septic complications were 15.6%, 15.6%, and 7.3%, respectively. Plugging carried the highest failure rate (83.3%) compared with fistulotomy (10.1%) (odds ratio [OR], 44.3 [95% confidence interval (CI), 8.9-221.0; $P < .001$]) and was the only independent predictor for failure after adjusting for all variables. Being older than 45 years was associated with a higher postoperative incontinence rate compared with the younger group (adjusted OR, 2.8 [95% CI, 1.0-7.7; $P = .04$]). High transsphincteric and suprasphincteric fistulas were predictors of incontinence compared with subcutaneous fistulas (adjusted OR, 22.9 [95% CI, 2.2-242.0; $P = .009$] and 61.5 [4.5-844.0; $P = .002$], respectively). The only predictor of septic complications was plugging compared with fistulotomy (adjusted OR, 15.1 [95% CI, 2.3-97.7; $P = .004$]).

Conclusions: Fistulotomy is the preferred operation for anal fistula. Plugging is associated with the highest operative failure and septic complication rates. Incontinence was influenced more by fistula type and age rather than procedure.

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ANAL SEPSIS IS ONE OF THE most common benign anorectal disorders treated by surgeons. Of all patients who present with an initial perianal abscess, up to 65% will develop a chronic or recurrent anal fistula.[1] Operative intervention remains the only effective modality to treat this condition. Although the principal goal of treatment

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is to eradicate the fistula, it is important to preserve anal continence, minimize postoperative complications, and decrease risk of recurrence.[2-8] The anatomy of the fistula and degree of anal sphincter muscle involvement can cause a significant challenge to the surgeon. Several surgical options are currently available, including fistulotomy, fistulectomy, endorectal advancement flap, anocutaneous flap, fibrin glue injection, anal fistula plug, seton drainage, and ligation of the intersphincteric fistula tract (known as the LIFT procedure).[9-19] To date, no standardized algorithm exists to guide the care of patients with anal fistula, and the choice of operation is based on patient-related factors, the patient's surgical history, and the surgeon's experience and familiarity with the various operations.

The aims of this study were to review our experience with patients treated for anal fistula secondary to cryptoglandular disease and to determine factors that influence postoperative outcome.

METHODS

The study was approved by the institutional review board of Kaiser Permanente Southern California. A retrospective review was conducted of all patients who underwent surgical inter-

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Table 1. Characteristics of 179 Patients With Anal Fistula

Characteristic	No. (%)[a]
Age, median (range), y	45 (22-73)
Sex, No. (%)	
Male	142 (79.3)
Female	37 (20.7)
Median duration of symptoms, wk	32
Previous operation for anal sepsis	107 (59.8)
Baseline incontinence	13 (7.3)
Stool	9 (5.0)
Gas	4 (2.2)
Fistula type	
Subcutaneous	26 (14.5)
Intersphincteric	21 (11.7)
Low transsphincteric	84 (46.9)
High transsphincteric	37 (20.7)
Suprasphincteric	11 (6.1)
Single vs multiple tracts	169/10 (94.4/5.6)
Horseshoe fistula	18 (10.1)

[a] Percentages have been rounded and may not total 100.

vention for anal fistula from October 1, 2003, through December 31, 2008. All operations were performed by a single colon and rectal surgeon (M.A.A.) at Kaiser Permanente Los Angeles Medical Center, a regional tertiary referral center. Exclusion criteria were age younger than 18 years, noncryptoglandular fistula (ie, fistula due to inflammatory bowel disease, human immunodeficiency virus, malignant neoplasm, radiotherapy, and obstetrical trauma), and rectovaginal or rectourethral fistula. The outpatient and inpatient electronic medical records were reviewed, and the abstracted data included demographics; surgical history; type of fistula; number of fistula tracts; baseline continence; type of procedure performed; postoperative complications, including septic complications and incontinence; and recurrence. Fistulas were classified according to anal sphincter involvement as subcutaneous (no sphincter), intersphincteric (internal sphincter), low transsphincteric (<50% of external sphincter), high transsphincteric (≥50% of external sphincter), or suprasphincteric (above the entire external sphincter). A horseshoe fistula was diagnosed when 2 fistulous tracts were present in both ischioanal fossae with 1 internal opening in the midline. Preoperative endoanal ultrasonography was performed preoperatively in patients with persistent or recurrent anal fistula after prior interventions and in patients with multiple external fistula openings. Because this study was limited to patients with anal fistula secondary to cryptoglandular disease, all internal openings were at the level of the dentate line. The continence level was assessed and documented preoperatively and postoperatively in all patients. If present, incontinence was qualified as gas or stool incontinence. Patients who had both symptoms were listed under the more severe of the 2 symptoms (stool incontinence). Operative interventions were fistulotomy (laying open the fistula with curettage of the tract), transanal endorectal advancement flap, and anal fistula plugging (Surgisis AFP; Cook Surgical, Inc, Bloomington, Indiana). A noncutting seton was initially placed in all patients who underwent a transanal endorectal advancement flap or the placement of the anal fistula plug. On average, the noncutting seton remained in place for 2 months and was removed at the time that the transanal endorectal advancement flap or the anal fistula plug was placed. Outcomes assessed were rates of operative failure, postoperative incontinence, and postoperative septic complications. Operative failure was defined as persistence or recurrence of symptoms within 6 months of intervention. Postoperative septic complications were defined as wound cellulitis or abscess that required antibiotics and/or surgical drainage.

Table 2. Operative Intervention and Overall Outcome

	No. (%) of Patients
Fistula operation	
Fistulotomy	148 (82.7)
Advancement flap	19 (10.6)
Anal plug	12 (6.7)
Failure	28 (15.6)
Postoperative incontinence[a]	28 (15.6)
Stool	19 (10.6)
Gas	9 (5.0)
Postoperative septic complications	13 (7.3)

[a] Excludes patients with baseline incontinence.

For univariate analyses, we applied contingency table analysis to test for an association between the predictor variable and the outcome of postoperative failure, incontinence, or sepsis. Predictor variables analyzed were age (categorized as ≤45 or >45 years), sex, previous operation for anal fistula, fistula type, number of fistula tracts, horseshoe fistula, and intervention type. The likelihood of each of these outcomes was estimated by applying multivariable logistic regression models and adjusting for preoperative variables in a forced model. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated. All *P* values were 2-tailed, and $P<.05$ was the criterion for statistical significance on final multiple regression models. All analyses were performed using commercially available software (SPSS, version 15.1; SPSS, Inc, Chicago, Illinois).

RESULTS

One hundred seventy-nine patients underwent an anal fistula operation during the study period. **Table 1** summarizes their characteristics. The median age was 45 years with a predominance of male patients (79.3%). In all, 59.8% of patients had undergone previous operations to treat anal sepsis (median number of operations, 2). Baseline stool or gas incontinence symptoms were seen in 7.3% of patients. Most of the patients (94.4%) had a single fistula. A low transsphincteric fistula was the most common type (46.9%), and a suprasphincteric fistula was present in 6.1% of patients. A horseshoe configuration was noted in 18 patients (10.1%).

Fistulotomy was performed in 82.7% of patients (**Table 2**). The median follow-up was 53 days (range, 6 days to 40 months). In 28 patients (15.6%), the operative intervention failed. Of these 28 patients, persistence of disease was apparent in 20 within 1 month of the intervention and in 8 within 1 to 6 months. New postoperative incontinence was noted in 15.6% of patients (stool incontinence in 10.6% of patients and gas incontinence in 5.0%).

Table 3 reports the effect of the individual variables on operative failure. Horseshoe fistula was associated with a higher failure rate (44.4%) compared with nonhorseshoe fistula (12.4%) (OR, 5.6 [95% CI, 2.0-16.0; $P=.001$]). Anal fistula plugging carried the highest failure rate (83.3%) compared with fistulotomy (10.1%) (OR, 44.3 [95% CI, 8.9-221.0; $P<.001$]) and was the only independent predictor of failure after adjusting for all other variables (55.4 [8.3-369.0; $P<.001$]).

Table 3. Predictors of Operative Failure in Patients With Anal Fistula

	Operative Failure, %	OR (95% CI)	*P* Value	AOR (95% CI)	*P* Value
Age, y					
≤45	16.2	1 [Reference]		1 [Reference]	
>45	15.0	0.9 (0.4-2.1)	.83	1.1 (0.4-3.1)	.87
Sex					
Male	15.5	1 [Reference]		1 [Reference]	
Female	16.2	1.0 (0.4-2.5)	.91	1.0 (0.2-4.4)	.95
Previous operation					
No	15.3	1 [Reference]		1 [Reference]	
Yes	15.9	1.0 (0.5-2.4)	.91	0.5 (0.2-1.6)	.25
Fistula type					
Suprasphincteric	27.3	1 [Reference]		1 [Reference]	
Subcutaneous[a]	0	. . .		. . .	
Intersphincteric	9.5	0.3 (0.04-2.0)	.21	1.0 (0.1-17.3)	.99
Low transsphincteric	10.7	0.3 (0.1-1.4)	.14	0.8 (0.1-8.5)	.82
High transsphincteric	37.8	1.6 (0.4-7.2)	.52	3.4 (0.3-42.6)	.34
No. of fistula tracts					
Single	15.4	1 [Reference]		1 [Reference]	
Multiple	20.0	1.4 (0.3-6.8)	.70	2.2 (0.3-14.5)	.42
Horseshoe fistula					
No	12.4	1 [Reference]		1 [Reference]	
Yes	44.4	5.6 (2.0-16.0)	.001	2.5 (0.5-12.1)	.25
Procedure					
Fistulotomy	10.1	1 [Reference]		1 [Reference]	
Advancement flap	15.8	1.7 (0.4-6.4)	.46	0.8 (0.2-3.8)	.79
Anal plug	83.3	44.3 (8.9-221.0)	<.001	55.4 (8.3-369.0)	<.001

Abbreviations: AOR, adjusted odds ratio (OR); CI, confidence interval; ellipses, not applicable.
[a] Subcutaneous fistulas were not included in the model because there were no failures in that group.

Table 4 reports the association of the individual variables and postoperative incontinence. Horseshoe fistula carried a higher risk for postoperative fecal incontinence (44.4%) compared with nonhorseshoe fistula (13.5%) (OR, 5.1 [95% CI, 1.8-14.5; *P*=.002]). Being older than 45 years was associated with a higher postoperative incontinence rate (23.2%) compared with the younger group (12.4%) (adjusted OR [AOR], 2.8 [95% CI, 1.0-7.7; *P*=.04]). High transsphincteric and suprasphincteric fistulas were more likely to predict incontinence compared with subcutaneous fistulas (AOR, 22.9 [95% CI, 2.2-242.0; *P*=.009] and 61.5 [4.5-844.0; *P*=.002], respectively).

Table 5 summarizes the effect of the individual variables on postoperative septic complications. Horseshoe fistula was associated with a higher septic complication rate (33.3%) compared with nonhorseshoe fistula (4.3%) (OR, 11.0 [95% CI, 3.2-40.0; *P*<.001]). Anal fistula plugging carried the highest postoperative septic complication rate (33.3%) compared with fistulotomy (4.7%) (OR, 10.1 [95% CI, 2.4-41.7; *P*=.001]) and was the only independent predictor for postoperative septic complications after adjusting for all other variables (AOR, 15.1 [95% CI, 2.3-97.7; *P*=.004]). Finally, only the patients with single fistulas had postoperative sepsis; the 10 patients with multiple fistulas never had postoperative sepsis, and the variable was not included in the adjusted model.

COMMENT

Treating anal fistula remains a challenge because of the anatomical location of the disease and the potential risks of postoperative stool incontinence and septic complications. Although the primary objective of operative intervention is to heal the fistula, equally important is the morbidity of the procedure. Fistulotomy remains one of the most commonly performed operations for anal fistula with a reported success rate ranging from 87% to 94%.[2,4,5,7,9,10,20] Fistulotomy entails the division of a various degree of anal sphincter muscle, putting the patient at risk for postoperative incontinence, adversely affecting the patient's quality of life. Postoperative incontinence has been noted in 6% to 40% of patients who undergo fistulotomy.[2,4-7,20,21] This finding has prompted surgeons to identify the subgroups of patients who are at an increased risk of developing postfistulotomy incontinence and to offer such patients sphincter-preserving operations. Patients who are predisposed to incontinence include patients with baseline incontinence, those with a history of anal operations, women with anterior-based fistulas, and patients with horseshoe fistulas or high tracts involving a significant amount of sphincter muscle.[5,7-9,22,23] Several sphincter-preserving operations are currently available to treat such patients, including the transanal advancement flap, fibrin glue injection, anal fistula plugging, and the LIFT procedure.[11-19,24-30] Although early results with fibrin glue injection appeared promising, several large studies including a prospective clinical trial from St Mark's Hospital in London, England, showed a low success rate of 14%.[13,27-29] The LIFT procedure was recently introduced with encouraging short-term success rates ranging from 57% to 94%, but the long-term results of this technique are still unknown.[17-19]

Table 4. Predictors of Postoperative Incontinence in Patients With Anal Fistula[a]

	Postoperative Incontinence, %	OR (95% CI)	*P* Value	AOR (95% CI)	*P* Value
Age, y					
≤45	12.4	1 [Reference]		1 [Reference]	
>45	23.2	2.1 (0.9-4.9)	.07	2.8 (1.0-7.7)	.04
Sex					
Male	15.8	1 [Reference]		1 [Reference]	
Female	21.2	1.4 (0.6-3.7)	.46	1.6 (0.5-5.3)	.44
Previous operation					
No	13.6	1 [Reference]		1 [Reference]	
Yes	19.0	1.5 (0.6-3.5)	.37	1.0 (0.4-2.7)	.97
Fistula type					
Subcutaneous	4.2	1 [Reference]		1 [Reference]	
Intersphincteric	10.5	2.7 (0.2-32.3)	.43	2.6 (0.2-33.4)	.45
Low transsphincteric	7.6	1.9 (0.2-16.5)	.57	2.4 (0.3-21.7)	.44
High transsphincteric	40.0	15.3 (1.8-127.0)	.01	22.9 (2.2-242.0)	.009
Suprasphincteric	55.6	28.8 (2.6-315.0)	.006	61.5 (4.5-844.0)	.002
No. of fistula tracts					
Single	17.2	1 [Reference]		1 [Reference]	
Multiple	11.1	0.6 (0.1-5.0)	.64	0.5 (0.1-6.0)	.61
Horseshoe fistula					
No	13.5	1 [Reference]		1 [Reference]	
Yes	44.4	5.1 (1.8-14.5)	.002	1.1 (0.3-4.4)	.92
Procedure					
Fistulotomy	15.2	1 [Reference]		1 [Reference]	
Advancement flap	27.8	2.1 (0.7-6.6)	.19	0.5 (0.1-1.9)	.29
Anal plug	20.0	1.4 (0.3-7.0)	.69	0.4 (0.1-2.6)	.32

Abbreviations: AOR, adjusted odds ratio (OR); CI, confidence interval; ellipses, not applicable.
[a] Includes the 166 patients who did not have baseline incontinence.

Table 5. Predictors of Postoperative Sepsis in Patients With Anal Fistula

	Postoperative Sepsis, %	OR (95% CI)	*P* Value	AOR (95% CI)	*P* Value
Age, y					
≤45	5.1	1 [Reference]		1 [Reference]	
>45	10.0	2.1 (0.7-6.7)	.21	2.9 (0.7-12.3)	.16
Sex					
Male	7.7	1 [Reference]		1 [Reference]	
Female	5.4	0.7 (0.1-3.2)	.63	0.4 (0.05-3.7)	.43
Previous operation					
No	4.2	1 [Reference]		1 [Reference]	
Yes	9.3	2.4 (0.6-8.9)	.20	2.3 (0.5-11.2)	.32
Fistula type					
Suprasphincteric	9.1	1 [Reference]		1 [Reference]	
Subcutaneous[a]	0	. . .		. . .	
Intersphincteric	4.8	0.5 (0.03-8.8)	.64	1.4 (0.04-44.6)	.90
Low transsphincteric	3.6	0.4 (0.04-3.9)	.41	0.8 (0.04-14.0)	.85
High transsphincteric	21.6	2.8 (0.3-24.9)	.37	1.9 (0.1-30.6)	.65
No. of fistula tracts					
Single	7.7	1 [Reference]			
Multiple	0	0	>.99		
Horseshoe fistula					
No	4.3	1 [Reference]		1 [Reference]	
Yes	33.3	11.0 (3.2-40.0)	<.001	4.9 (0.8-29.5)	.08
Procedure					
Fistulotomy	4.7	1 [Reference]		1 [Reference]	
Advancement flap	10.5	2.4 (0.5-12.3)	.31	1.0 (0.1-7.7)	.97
Anal plug	33.3	10.1 (2.4-41.7)	.001	15.1 (2.3-97.7)	.004

Abbreviations: AOR, adjusted odds ratio (OR); CI, confidence interval; ellipses, not applicable.
[a] Subcutaneous fistulas were not included in the model because there was no postoperative sepsis in that group.

During our study period, all patients were treated with fistulotomy or 2 other sphincter-preserving techniques, the endorectal advancement flap and anal fistula plugging. We achieved the highest operative success with fistulotomy and the endorectal advancement flap. The anal fistula plug was associated with the lowest success. The

early experience with the anal fistula plug was very promising, but more recent studies have shown success rates from 20% to 34%, which are consistent with our results.[9,14,15,25,26,30] Two retrospective studies and 1 randomized prospective study compared anal fistula plugging with endorectal fistula in patients with transsphincteric fistulas.[25,26,30] In all 3 studies, the endorectal advancement flap had a better outcome with a success rate of 62% to 88% compared with the 20% to 34% seen with the plug. In our study, 16.7% of patients treated with fistula plugging experienced closure of their fistula compared with 84.2% of patients who underwent endorectal advancement flap. Furthermore, fistula plugging was associated with the highest rate of postoperative septic complications.

Postoperative fecal incontinence developed in 28 patients (15.6%) who did not have prior baseline incontinence. Being older than 45 years and having high transsphincteric and suprasphincteric fistulas were independent predictors of postoperative fecal incontinence. These findings can be explained physiologically as loss of muscle tone due to aging or loss of muscle mass due to surgical intervention, both which would affect continence level. Horseshoe fistula was associated with a higher risk of postoperative incontinence in univariate analysis but was not an independent risk factor when adjusting for all other variables. Two studies on horseshoe anal fistula reported postoperative incontinence rates of 21% to 29%.[22,23]

Finally, there are several limitations to our study. It is retrospective in nature, and the patients were not randomized to the various operative interventions. The choice of operation was driven by the surgeon's judgment of what would potentially close the fistula with the least postoperative morbidity, based on the patient's surgical history, fistula anatomy, body habitus, and baseline continence level. Most of the patients underwent fistulotomy, and a sphincter-preserving operation was offered when the patient was perceived to be at higher risk for incontinence. Thus the transanal advancement flap and the anal fistula plug were used in a smaller number of patients. All of these factors can introduce bias. A significant number of the patients (59.8%) had anal fistula surgery before referral to our tertiary care center. Therefore the results of our study need to be interpreted within the contest of these limitations.

CONCLUSIONS

The surgical treatment of anal fistula is a balancing act aimed at eradicating disease, preserving continence, and limiting the morbidity of intervention. In this study, the scales seem to support fistulotomy compared with the other procedures. Anal fistula plugging was associated with the highest operative failure and persistence of disease when compared with fistulotomy and endorectal advancement flap. Furthermore, plugging was associated with the highest postoperative septic complication rate. Patients with high transsphincteric or suprasphincteric fistula and those older than 45 years were at higher risk of developing postoperative incontinence. These findings can potentially guide the future care of patients with anal fistula and help the surgeon with the choice of operation for an individual patient.

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INVITED CRITIQUE

Still Looking for the Ideal Procedure for Complex Anal Fistula Treatment

The basic surgical principle for the treatment of anal fistula of the cryptoglandular variety is simple: the identification of the primary opening, eradication of the infection, and exposure of the fistula tract. In reality, it is far from simple. Complex anal fistulas with significant involvement of the deep external anal sphincter challenged our pioneering surgeons decades ago, and they continue to challenge us now. In general, the more superficial the fistula tract, the easier it is to cure the disease, and anal fistulotomy or fistulectomy will have a very good outcome, with no recurrence and no incontinence. The high transsphincteric and suprasphincteric fistulas are a different story.

Nearly 20 years ago, we had a brief run with the use of fibrin glue.[1] It generated some initial excitement and good research data,[2] but eventually it proved to be ineffective.[3] More recently, along came the anal fistula plug repair, which appeared logical in concept and simple in its application.[4] It was met with enthusiasm, but the initial good data could not be duplicated uniformly throughout this country and globally.

Dr Abbas and his colleagues[5] have put together a critical review of the surgical experience of the Kaiser Permanente Medical Group in Los Angeles, California, and their data clearly show the ineffectiveness of the anal fistula plug repair. It has a high failure rate as well as postoperative problem with sepsis. These findings are in keeping with recent publications in our surgical literature.[6]

Seton drainage to control the sepsis initially is still highly advocated, particularly in our own practice. Setons can be left in place for several weeks if needed. We do not advocate using the seton as a cutting device; therefore, it cannot be viewed as an option for definitive surgical treatment for these complex anal fistulas.

Finally, as the authors have so mentioned, the new approach of ligation of the intersphincteric fistula tract (the LIFT procedure) holds promise.[7,8] In our limited experience during the past 6 months, we have some encouraging results and, even if there is a recurrence of the fistula, the tract is rendered much more superficial and a subsequent fistulotomy procedure can be safely performed without further recurrence and with minimal risk of incontinence. Let us hope that, with more collaborative data, the LIFT procedure may make more sense and may be the definitive approach to the challenge of complex anal fistula treatment.

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