Sphincter-sparing surgery for complex anal fistulas: radiofrequency-thermo-coagulation of the tract is of no help

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SPHINCTER-SPARING SURGERY FOR COMPLEX ANAL FISTULAS: RADIOFREQUENCY-THERMO-COAGULATION OF THE TRACT IS OF NO HELP

Subtitle or alternative title: Radiofrequency does not work for anal fistula

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ABSTRACT

Aim: To compare the rate of failure of radiofrequency-thermo-coagulation for anal fistula to that of rectal advancement flap in a case-matched study.

Method: Patients who underwent radiofrequency treatment were compared with Crohn's disease, age and sex-matched patients who underwent a rectal-flap procedure. Fistula features, general characteristics, and main clinical events were recorded in a prospective database. Failure was defined by at least one of following: abscess, purulent discharge, visible external opening, or further drainage procedure.

Results: A total of 62 patients (median age: 45 [36.8-57.5] years, gender F/M: 22/40, Crohn's disease: 22) were analyzed. The failure rate of radiofrequency was higher than that of rectal flap (74.2% *vs* 32.2%; p=0.004). The cumulative probabilities of failure rate of the radiofrequency were 53.8% [38.8-68.3], 71.8% [55.3-84.0] and 87.4% [70.6-95.3] at 3, 6 and 12 months respectively. Three patients in the radiofrequency group required drainage for an abscess and one had severe thermal ulceration. The Cox proportional hazards regression model (surgical procedure, obesity, Crohn's disease) showed rectal flap (3.48 [1.60-8.07]; p=0.001) and Crohn's disease (2.60 [1.16-6.41]; p=0.02) to be the main independent predictors of healing.

Conclusion: Radiofrequency is a less satisfactory sphincter-sparing surgery for the management of anal fistula than rectal flap.

What does this paper add to the existing literature?

In patients with high and/or complex anorectal fistulas, surgeons frequently avoid dividing the sphincter during a fistulotomy. Among sphincter-sparing procedures, thermocoagulation of the fistula tract seems to have less efficacy than rectal advancement flap.

INTRODUCTION

The therapeutic management of anal fistulas is complex for several reasons, depending, in particular, on the anatomical presentation of the fistula and the presence of Crohn's disease (CD). This is especially true for high and/or complex cases because consecutive surgeries may alter both the sphincter and continence. Strategies with a sufficient risk-benefit ratio for the treatment of anal fistulas are widely debated. The expected benefit is the durable healing of suppuration with a low risk of recurrence. Ideally, the technique is also simple, inexpensive, and reproducible, while avoiding the risk of fecal continence disorders related to sphincter lesions or significant deformation of the anal canal (1,2). New strategies enter evaluation as soon as there is evidence that they avoid the necessity of a sphincter division (sphincter-sparing surgery). Rectal advancement flap methods are the most classic strategies. Other approaches attempt to achieve coagulation or closure of the fistulous tract through heat destruction, occlusion, or ligation. However, these new methods are mainly case series without any comparative evaluation (4).

Our aim was to compare a new mini-invasive thermo-coagulation procedure of the fistula tract (radiofrequency) with rectal advancement flap surgery in a case-control evaluation. Factors associated with treatment failure were analyzed.

METHODS

Study Population

All prospective medical data were recorded between January 2006 and January 2018 in our proctology unit database. The following data were recorded: gender, age, obesity, smoking habits, CD, past medical and surgical history, including sphincter-sparing surgery (fibrin glue, collagen plug, ligation of the intersphincteric fistula tract), and fistula drainage. The characteristics of the fistula were assessed on the day of the surgical procedure: simple/complex fistula, infra or supralevator fistula, horseshoe fistula, or anovaginal fistula. Data of patients with carcinoma fistulas and those with anovaginal or rectovaginal fistulas were not used. Patients who underwent radiofrequency were case-matched with those who underwent rectal flap according to age, gender, and the occurrence of CD.

Study design

This was a case-control retrospective investigation after extraction of selected items of a prospective maintained database.

Rectal-flap surgical technique

Patients were admitted on the day of the intervention and received preoperative prophylaxis (1000 mg metronidazole). With the patient in the Lloyd Davis position, the external opening was enlarged and the fistulous tract excised as far as possible without reaching the external sphincter. The internal opening of the fistula was exposed and the tissue and overlying anodermis excised. Two to three stitches, facing and occluding the internal opening, provided plication of the muscle. Then, the submucosal area was dissected to create a flap with a large buttonhole shape, without acute edges. The plicated muscle was covered with the thus produced mucosal flap. All stitching was performed with resorbable sutures. Sealing of the

closure was verified at the end of the procedure. A local anesthetic block with 150 mg ropivacaine hydrochloride completed the procedure. Occlusion of the tract was verified at the end of the procedure by gentle saline injection through the external orifice. The patients were discharged on the day of the procedure. The rectal-flap advancements were performed by the principal surgeon. There was no prior bowel preparation, but analgesics and stool softeners were used during the postoperative period (three weeks).

Radiofrequency surgical technique

All patients were admitted on the day of the intervention and received preoperative prophylaxis (1000 mg metronidazole). With the patient in the Lloyd Davis position, the surgeon performed a clinical examination that confirmed that drainage was effective and selected the method that would most easily close the internal orifice. If the opening was small, the technique involved a simple mucosa resorbable suture (figure of eight). In patients with a large internal opening, rectal flap advancement was preferred over radiofrequency. Tissues around the fistula were protected from thermal destruction by injection with fresh saline solution around the fistula. The radiofrequency energy was applied along the fistula tract while removing an endovascular flexible probe (radial emitting) from the internal to external orifice. The strategy is derived from endovascular procedures for varices (4). Energy was delivered every 5 mm with an endovenous radiofrequency source (EVRF®, F care systems, Belgium). Each impact was up to 0.8 seconds and equivalent to 25 watts. The total dose delivered along the length of the fistula tract was calculated. Occlusion of the tract was verified at the end of the procedure using a smooth probe applied through the external orifice. A local anesthetic block with 150 mg ropivacaine hydrochloride completed the procedure. The patients were discharged on the day of the procedure.

Definitions and follow-up

Obesity was defined by a Body Mass Index (BMI) ≥ 30 kg/m^2.

Complex fistulas were defined as deep trans-sphincteric fistulas, supralevator fistulas, fistulas with an abscess or extension with of the primary tract, low anovaginal fistulas, or horseshoe fistulas.

Failure of the procedure was defined as the occurrence of at least one of the following: abscess, purulent discharge, visible external opening, or a further drainage procedure. Failure could be observed in the early follow-up but a minimum follow-up of 12 weeks was request to distinguish failure and late healing. A medical assessment with clinical examination was conducted at each visit.

Follow-up was defined as the duration between the day of the surgery procedure (rectal flap or radiofrequency) and the first assessment of failure or the last visit for patients for whom the procedure was successful.

Statistical analysis

Quantitative variables are presented as medians and percentiles (interquartile range: 25% and 75%). Categorical variables are presented as numbers and percentages of the cohort. The data of the radiofrequency group were compared to those of the rectal-flap group. The main outcome was the failure of the surgical procedure, confirmed by the persistence of the fistula tract. The cumulative probabilities of surgical failure were estimated from the day of the evaluated procedure (at referral) to the occurrence of failure using the Kaplan–Meier method with 95% confidence intervals [CIs]. Factors associated with failure of the cohort were identified by univariate analysis using the log-rank test. The results are shown as hazard

ratios (HRs) with 95% confidence intervals [CIs]. Independent predictors of each outcome were identified by multivariate analysis. All significant variables with p < 0.1 in the log-rank test were retained and integrated into a Cox proportional hazards regression model for surgical failure. The results are shown as hazard ratios (HRs) with 95% confidence intervals [CIs]. Statistical analyses were performed using JMP Pro 13.2 software.

Ethical considerations

The purpose of the database was to facilitate enrollment in prospective trials and retrospective assessments of therapeutic strategies in several colorectal pathogenesis fields. This database was approved by the "Commission Nationale Informatique et Liberté" (CNIL n°1412467). Radiofrequency request for authorization of use was obtained from the « Agence Nationale de Sécurité du Médicament et des Dispositifs Médicaux» (ANSM n° DMDPT-BLOC/MM/2016-A01107-44).

RESULTS

Study population

Among 633 patients with anal fistulas identified from the prospective database, 87 underwent at least one rectal anal advancement flap procedure and 31 underwent a radiofrequency-thermo-coagulation procedure. Among the 87 patients who underwent the rectal-flap procedure, 31 were case-matched according to the presence of CD, gender, and age. The characteristics of the population are summarized in **Table 1**. The fistula tracts were complex in all except three cases. Three patients had a simple direct transsphincteric tracts that could be treated by fistulotomy. All these three had an anteriorly placed fistula which increased the risk of faecal incontinence. Two patients were already incontinent before procedure.

Anterior tracts were reported in 10 cases: five in each group. All patients had prior drainage with inserted setons. The median duration of the fistula before referral was approximately two years and one third of the population experienced a previous sphincter sparing procedure before referral. CD was reported for 22 patients (35.5%), but all were in remission at the time of surgery: they all received anti-TNF alpha.

Procedure

The median duration of the procedure was 30 min: it was significantly longer for rectal flap than for radiofrequency (**Table 1**). Closure of the internal part of the tract was effective in all rectal flap and 28/31 radiofrequency procedures. The length of the tract was precisely measured during the radiofrequency but not rectal-flap procedure. There were no intraoperative complications. Significant secondary effects were reported in three patients (two abscesses and hemorrhoidal prolapse) after rectal flap and five patients (three abscesses, one hematoma, and one thermic ulceration with rectovaginal fistula) after radiofrequency.

Follow-up evaluation

The median follow-up after referral was five [3-27] months. The median follow-up was significantly longer for the rectal-flap group (23 [5-45] months) than the radiofrequency group (4 [2-5]) months) due to the recent development of the radiofrequency procedure (**Table 1**). After a median follow-up of 5 months, the global failure rate was 10/31 (32.2%) in the rectal-flap group and 23/32 (74.2%) in the radiofrequency group (p = 0.04). The cumulative probability of surgical failure is shown in **Figure 1**. The cumulative probabilities of failure rate of rectal-flap advancement were 18% [9.0 -32.8], 22.9% [12.3-38.6], 28.8% [16.2-45.8], and 35.7% [20.5-54.5] at 3, 6, 12, and 24 months, respectively. The cumulative

probabilities of failure rate of the radiofrequency were 53.8% [38.8-68.3], 71.8% [55.3-84.0] and 87.4% [70.6-95.3] at 3, 6 and 12 months respectively. The differences were highly significant (p = 0.0004). Failure occurred very early in the radiofrequency group as 15/31 (48%) had a recurrence within the first month of follow-up and 20/31 (65%) within the two months of follow-up. Univariate analysis using the log-rank test to identify factors associated with failure of the global cohort showed three main factors to be associated with a higher failure rate: the radiofrequency procedure (3.59 [1.73-8.02]; p = 0.0004), obesity (3.18 [1.17-7.40]; p = 0.026), and the absence of CD (2.68 [1.25-6.40]; p = 0.01). The fistulas of obese subjects did not heal, regardless of the type of surgical procedure. The fistula tracts of patients with CD healed in 14 of 22 (63.6%) cases. None of the following factors were associated with less favorable healing rates: age, gender, tobacco consumption, past surgical history, and type and complexity of the fistula. The Cox proportional hazards regression model (three independent variables included in the model:surgical procedure, obesity, CD) showed rectal flap (3.48 [1.60-8.07]; p = 0.001) and CD (2.60 [1.16-6.41]; p = 0.02) to be the main independent predictors of healing.

DISCUSSION

We quantified the failure rate and assessed predictive factors using sphincter-sparing surgeries for anal fistulas. Sphincter-sparing surgical options are usually offered in patients with high fistula tracts because fistulotomy expose to faecal incontinence. In this tertiary centre, different strategies have been developed over time with the main goals to be mini invasive and to avoid sphincter division. Rectal flap remains a common strategy over time when other recent techniques failed to provide satisfactory results in our hands. Because the retrospective nature of the study and the historical perspective of mini invasive techniques, the treatment selection was mainly based on the opportunity to offer a new strategy or not.

This is the first evaluation to compare thermo-coagulation-radiofrequency with a classic strategy (rectal-flap advancement).

The main strengths of this study were the sample size, systematic clinical evaluation by experts in the field of proctology, and technical homogeneity of the surgery. The data were recorded in a prospective database using recommended classifications. In CD patients, disease characteristics and both therapeutic and surgical strategies were recorded. Finally, the study was a case-matched comparative evaluation with rectal-flap advancement in a single tertiary referral centre.

This study also had several limitations. The study design was a retrospective analysis of a prospective database. In addition, this study was performed in a tertiary referral centre, which may have resulted in a selection bias in the recruitment of patients. Magnetic resonance imaging (MRI) was not performed for all consecutive patients, and thus this data could not be assessed. Indeed, assessment under general anaesthesia may be as useful as MRI, but neither ultrasound scan nor MRI are yet recommended before rectal flap advancement surgery. The median follow-up was short because the tested procedure is new, but it did not have an impact because the recurrence occurred shortly after the surgery. We could also advocate that the short follow-up did not allow to assess late healing after 6 months. Finally, faecal incontinence was not assessed.

Radiofrequency appears to be a promising mini-invasive surgery, with a high-level of satisfaction at the end of the procedure. The fistula tract is coagulated and occluded by the probe, as shown by the absence of catheterization in nine of ten patients. This technique is easy to learn, simple to perform, and rapidly performed. It offers a comparable approach using other strategies of tract coagulation, such as laser. However, disappointment within the first month of follow-up was associated with a very high recurrence rate in our study. These results are markedly poorer than those obtained with laser thermocoagulation. Coagulation

methods offer symptomatic benefit in two thirds of cases (5). Post-operative complications are ultimately quite rare, but there may be lasting pain, bleeding complications, and oedematous reactions. There are scientific limitations to the previously performed studies, as they were uncontrolled, with a short follow-up and insufficient evaluation of failure. The definition of primary failure or success has often been imprecise, and relapse occurred early. Moreover, the long healing time is still a potential problem after such an occlusion strategy. Long-term evaluation is more appropriate for assessing these new methods (6). Long-term evaluations have shown that primary success varied between 55 and 65%, that several techniques were combined during the same procedure (closure of the internal orifice, lowering flap, rerouting), and that they were repeated to obtain a more favourable healing rate (7). Another study also mentioned the need for prior drainage to obtain a better result for thermocoagulation methods (8). In our hands, radiofrequency had a healing rate lower than those reported for loose setons. A retrospective Egyptian study examined factors associated with recurrence after the placement of a drain (removed secondarily three months after without further surgical procedures) for the treatment of high and/or complex anal fistulas (9). This study is informative because it provides an appreciation of the level of therapeutic response that would be spontaneously observed without surgery to achieve fistula tract closure. Surprisingly, recurrence was very low after simple removal of the drain: recurrent suppuration was observed in 10% of cases after a median follow-up of 16 months. In this retrospective cohort series, the therapeutic success rate was superior to that of the best methods of occlusion or coagulation of the tract. This puts into question the true mini-invasive effect of thermocoagulation. We observed at least one thermic ulceration after treatment of the fistula tract. It is conceivable that these new techniques are not as "mini-invasive" as reported, leading to unclosed fibrotic tracts.

The failure rate for rectal flap advancement reported in our cohort is comparable to that of some studies in the literature (10). In a recent meta-analysis, the pooled failure rate for rectal flap advancement was 21%, with better results for full-thickness (7.4%) than partial-thickness flaps (19%) (11). In our study, the surgeons performed a partial thickness flap and the failure rate was higher (34.1%) than that reported by the meta-analysis. However, the anal fistulas in our study were mainly complex and/or horseshoe fistulas. These factors have been reported to be predictive of failure (9).

Anal fistulas related to CD are classically the most challenging to treat because the tracts are complex and perianal lesions affect both the local and luminal prognosis. Paradoxically, our study suggests a better healing profile for patients with CD than those without. Indeed, a previous study testing the long-term benefit of laser thermocoagulation also showed that it tended to be greater for patients with CD (7). Randomized control trials have been carried out on the combined use of biologics and surgical closure, but success rates have been difficult to assess because it has been difficult to determine the contribution of each procedure (12,13). Surgical closure of the tract was shown to improve healing rates better than treatment with biologics or thiopurines in a recent study (14). However, half of the patients with perianal fistulising CD relapsed within five years after discontinuation of anti-TNFα (15). Thus, it is conceivable that anti-TNFα could also offer a benefit to patients with complex fistulas of cryptoglandular origin; the impact on the inflammatory process of the tract may enhance the benefit of -sphincter-sparing surgery.

CONCLUSION

Coagulation of the tract has the conceptual goal of fistula healing without dividing the anal sphincter. However, this mini-invasive technique requires a careful prospective evaluation, whereas optimistic assessments have been based on retrospective studies in which several combined and/or repeated techniques were used. Promising methods should associate the good healing rate reported in retrospective trials with a low frequency of side effects. Radiofrequency does not fulfil these criteria and the technique needs improvement (lower intensity, larger diffusion). The place of biologics in such treatment strategies is still under evaluation. Randomized-controlled trials will be necessary to identify the most effective sphincter-sparing techniques.

REFERENCES

1: Vogel JD, Johnson EK, Morris AM, Paquette IM, Saclarides TJ, Feingold DL, Steele SR. Clinical Practice Guideline for the Management of Anorectal Abscess, Fistula-in-Ano, and Rectovaginal Fistula. Dis Colon Rectum. 2016;59:1117-1133.

2: Fichera A, Zoccali M; Crohn's & Colitis Foundation of America, Inc. Guidelines for the surgical treatment of Crohn's perianal fistulas. Inflamm Bowel Dis. 2015;21:753-8.

3: Altomare DF. Anal fistula closure with FiLaC: new hope or the same old story? Tech Coloproctol. 2015;19:441-2.

4: Spiliopoulos S, Theodosiadou V, Sotiriadi A, Karnabatidis D. Endovenous ablation of incompetent truncal veins and their perforators with a new radiofrequency system. Mid-term outcomes. Vascular. 2015;23:592-8

5: Narang SK, Keogh K, Alam NN, Pathak S, Daniels IR, Smart NJ. A systematic review of new treatments for cryptoglandular fistula in ano. Surgeon. 2017;15:30-39.

6: Adegbola SO, Sahnan K, Pellino G, Tozer PJ, Hart A, Phillips RKS, Warusavitarne J, Faiz OD. Short-term efficacy and safety of three novel sphincter-sparing techniques for anal fistulae: a systematic review. Tech Coloproctol. 2017;21:775-782.

7: Wilhelm A, Fiebig A, Krawczak M. Five years of experience with the FiLaC™ laser for fistula-in-ano management: long-term follow-up from a single institution. Tech Coloproctol. 2017;21:269-276

8: Giamundo P, Esercizio L, Geraci M, Tibaldi L, Valente M. Fistula-tract Laser Closure (FiLaC™): long-term results and new operative strategies. Tech Coloproctol. 2015;19:449-53

9: Emile SH, Elfeki H, Thabet W, Sakr A, Magdy A, El-Hamed TMA, Omar W, Khafagy W. Predictive factors for recurrence of high transsphincteric anal fistula after placement of seton. J Surg Res. 2017;213:261-268

10: Sonoda T, Hull T, Piedmonte MR, Fazio VW. Outcomes of primary repair of anorectal and rectovaginal fistulas using the endorectal advancement flap. Dis Colon Rectum. 2002;45:1622–8.

11: Balciscueta Z, Uribe N, Balciscueta I, Andreu-Ballester JC, García-Granero E. Rectal advancement flap for the treatment of complex cryptoglandular anal fistulas: a systematic review and meta-analysis. Int J Colorectal Dis. 2017;32:599–609.

12: Panés J, García-Olmo D, Van Assche G, Colombel JF, Reinisch W, Baumgart DC, Dignass A, Nachury M, Ferrante M, Kazemi-Shirazi L, Grimaud JC, de la Portilla F, Goldin E, Richard MP, Leselbaum A, Danese S; ADMIRE CD Study Group Collaborators. Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn's disease: a phase 3 randomised, double-blind controlled trial. Lancet. 2016;388(10051):1281-90.

13: Senéjoux A, Siproudhis L, Abramowitz L, Munoz-Bongrand N, Desseaux K, Bouguen G, Bourreille A, Dewit O, Stefanescu C, Vernier G, Louis E, Grimaud JC, Godart B, Savoye G, Hebuterne X, Bauer P, Nachury M, Laharie D, Chevret S, Bouhnik Y; Groupe d'Etude Thérapeutique des Affections Inflammatoires du tube Digestif [GETAID]. Fistula Plug in Fistulising Ano-Perineal Crohn's Disease: a Randomised Controlled Trial. J Crohns Colitis. 2016;10:141-8

14: Brochard C, Landemaine A, L'Heritier AM, Dewitte MP, Tchoundjeu B, Rohou T, Garros A, Bouguen G, Siproudhis L. Anal Fistulas in Severe Perineal Crohn's Disease: Mri Assessment in the Determination of Long-Term Healing Rates. Inflamm Bowel Dis. 2018;24:1612-1618.

15: Legué C, Brochard C, Bessi G, Wallenhorst T, Dewitte M, Siproudhis L, Bouguen G. Outcomes of Perianal Fistulising Crohn's Disease Following Anti-TNFα Treatment Discontinuation. Inflamm Bowel Dis. 201;24:1107-1113.

Table 1: Population characteristics at referral (N=62) and according to the surgical procedure of anal fistula

Variables	Population	Rectal flap	Radiofrequency	
	N=62	N=31	N=31	
	n (%) or median [IQR 25-75]	n (%) or median [IQR 25-75]	n (%) or median [IQR 25-75]	p-value
Sex ratio (F/M)	22/40 (35.5/64.5)	11/20 (35.5/64.5)	11/20 (35.5/64.5)	1.0
Age at surgery (years)	45 [36.8-57.5]	44 [35.1-57.5]	45 [37.3-57.7]	0.95
Obesity (yes)	6 (9.7)	1 (3.1)	5 (16.1)	0.09
Crohn disease (yes)	22 (35.5)	11 (35.5)	11 (35.5)	1.0
Smoking	18 (29.0)	10 (32.3)	8 (25.8)	0.52
Fistula follow-up before the procedure (months)	22 [11-50]	25 [10-39]	21 [12-64]	0.9033
Number of fistula drainages before the procedure	3 [1-4]	3 [1-4]	3 [1-4]	0.25
Sphincter sparing surgery before rectal flap/radiofrequency	21 (33.9)	12 (38.7)	9 (29.0)	0.42
Characteristics of the fistula at surgery time				
Simple/Complex	3/59 (4.8/95.2)	0/31 (0/100)	3/31 (9.7/90.3)	0.07
Anovulvar fistula (yes)	10 (16.9)	5 (16.1)	5 (16.1)	1.0
Length of the fistula (millimeters)	-	-	30 [20-38]	-
Closure of the internal orifice (yes)	-	-	28 (90.3)	-
Delivered energy (joules)	-	-	1225 [981-1781]	-
Rapport number of joules/length of the fistula	-	-	53 [41-61]	-
Duration of the surgery (minutes)	30 [29-36]	35 [30-45]	30 [25-30]	0.0031
Healing rate & follow-up (months)				
Failure of the rectal flap/radiofrequency	33 (53.3)	10 (32.2)	23 (74.2)	0.004
Duration of the follow-up (months)	5 [3-27]	23 [5-45]	4 [2-5]	0.0023

Figure 1: The cumulate probabilities of failure rate of the rectal flap advancement were 18% [09-32.8], 22.9% [12.3-38.6], 28.8% [16.2-45.8] and 35.7% [20.5-54.5] at 3, 6, 12 and 24 months respectively. The cumulative probabilities of failure rate of the radiofrequency were 53.8% [38.8-68.3], 71.8% [55.3-84.0] and 87.4% [70.6-95.3] at 3, 6 and 12 months respectively.