

Radiofrequency fistulectomy vs. diathermic fistulotomy for submucosal fistulas: a randomized trial

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Abstract. – **Background:** Anal fistula represents one of the most frequent anorectal disease. Fistulotomy is considered the gold standard treatment but related problems are numerous (postoperative pain, bleeding, delayed or impaired wound healing). Fistulectomy lowers the recurrences but is less feasible with longer operating time and healing process. We applied the radiofrequencies to fistulectomy and compared the early and late results with those obtained from traditional fistulotomy.

Methods: Twenty patients were randomized to undergo radiofrequency fistulectomy (10 patients, Group A) or conventional fistulotomy (10 patients, Group B). We analysed the first postoperative day pain, intra- and postoperative bleeding, operating time, complications (impaired or delayed wound healing, fecal incontinence) and any recurrences.

Results: The mean values for operative time have been 18.3 min for group A (range 15-26 min) and 17.9 min for group B (range 13-21 min). According to VAS scale, first postoperative day pain mean values were 2.8 for group A (range 2-4) and 4.1 for group B (range 3-5). Intra- and post-operative bleeding has always been negligible and faecal incontinence was never observed. Healing time mean values have been 3.5 weeks for group A (range 3-5) and 5.9 weeks for group B (range 4-8 weeks). Long-term results did not evidence complications or recurrences for both groups.

Conclusions: The application of radiofrequencies to fistulectomy renders more feasible and eases the operation. Postoperative pain is smaller than traditional fistulotomy because of the lower temperatures used and for the shorter time spent in coagulating. This gives a faster wound healing.

In conclusion we think that radiofrequency fistulectomy is technically more advantageous than traditional fistulotomy and furnishes better results.

Key Words:

Fistulectomy, Radiofrequency surgery, Proctology.

Introduction

Anal fistula represents one of the most frequent anorectal disease combined with hemorrhoids and anal fissure. A correct diagnosis and treatment influence positively and reduce the risk of recurrences as well as complications¹.

The classic technique of fistulotomy is believed to be a correct therapy from most of the surgeons and, actually, the gold standard of treatment. Problems related to fistulotomy are numerous and, among them, we recall postoperative pain, bleeding, delayed or impaired wound healing². Fistulectomy lowers the incidence of recurrences³ but it's less feasible than fistulotomy, requires a longer operating time and a longer healing process because the residual wound is wider than with fistulotomy¹. For this reason this technique is less used.

We applied the radiofrequencies to the fistulectomy and we compared the early and late results with those obtained from traditional fistulotomy.

Patients and Methods

We followed CONSORT criteria for the development and description of this randomised clinical trial⁴.

Eligibility criteria were patients with submucosal fistula with posterior internal and external orifices (according to Goodsall's rule) that came to our attention^{1,5}. Exclusion criteria were the presence of associated inflammatory colorectal diseases on the base of a preoperative physical examination and a colonoscopy in suspected cases. Moreover,

we excluded previous proctologic surgery, fistulas with multiple orifices, non submucosal fistulas, anterior fistulas according to Goodsall's rule⁵, pregnant patients and those with American Society of Anaesthesiologists Score III or IV⁶. Oral anticoagulants, when present, were discontinued 7 days before surgery.

Preoperative preparation consisted of one enema applied the previous day and 4 hours before the operation. Metronidazole 400 mg and Ceftriaxone 2 gr. I.V. have been administered at the induction of anaesthesia as prophylaxis.

Patients have been operated always by the same surgeon.

Techniques Employed

Group A. Patients underwent the fistulectomy using radiofrequency bistoury.

Under general anaesthesia and standardized lithotomic position, a Parks' self-retracting retractor is positioned. We injected methylene blue with hydrogen peroxide through the external orifice of the fistula with a 20 G cannula.

We introduced a sinus probe to sample the fistula and visualize the internal opening. After that a superficial incision with the radiofrequency bistoury was made along its guide, we used two Ellis clamp to open the margins of the wound and we shaved off almost 2 mm of circumferential tissue around the probe from the external to the internal orifice. We coagulated residual vessels. Medication consisted of antiseptic solution washing and absorbent dressings.

Group B: All patients were submitted to classic fistulotomy⁷.

Under general anaesthesia and standardized lithotomic position, a Parks' self-retracting retractor is positioned. We injected methylene blue with hydrogen peroxide through the external orifice of the fistula.

We used a sinus probe to sample the fistula and visualize the internal opening. We made a superficial incision with a cold knife along the guide of the probe and we continued on the section line with a diathermic bistoury until we reached the probe. We removed the probe and we used a Volkmann's curette to remove residual granulation tissue. Hemostasis and medications were the same of the group A.

Postoperative treatment in both groups consisted of Metronidazole (400 mg three times, only the first postoperative day), Ketorolac p.r.n. as analgesic. All patients begin to assume Vaseline oil by mouth the day after the operation for 10-15 days to soften the stools. Patients were discharged home in the first postoperative day. Discharge medications consisted of Ketorolac p.r.n., an appropriate high-fiber diet, Vaseline Oil as stool-softeners and regular hygiene with chloride solutions. Follow-up was performed weekly until complete wound closure by outpatient visits.

We analysed, as primary endpoints, the pain at the first postoperative day, the intra- and postoperative bleeding and the operating time. Secondary endpoints were any complications as impaired or delayed wound healing, fecal incontinence and any recurrences. We recorded the pain using VAS scale⁸ with 0 as minimum value (no pain) and 10 as maximal value (maximal pain experienced in the past by patients).

Randomisation was carried out using closed envelopes allocation before surgery at the time of admittance in hospital.

All data analysis was performed using Statistical Package for the Social Sciences Windows version 10.0. Continuous variables were compared using the Mann-Whitney U test and categorical variables using the χ^2 test.

Results

Between July 2001 and December 2003, we recruited 36 patients for this study. Based on the exclusion criteria, we selected 22 patients. Eleven patients underwent radiofrequency fistulectomy (Group A), 11 the diathermic fistulotomy (Group B). On successive follow-up examinations, we lost one patient in group A and 1 patient in group B, resulting in 20 patients.

There were 6 males and 4 females in Group A and 7 males and 3 females in group B. Mean age at the time of operation was 39 years for Group A and 37 years for Group B. Symptoms reported are illustrated in Table I and persisted from more than one year.

Table I. Referred symptoms at presentation.

Symptoms at presentation	N. Patients (n = 20)	Percentage
Secretions	20	100%
Pain	10	50%
Perianal irritation	9	45%
Anal pruritus	8	40%
Fever	5	25%

The mean values for operative time have been 18.3 min for group A (range 15-26 min) and 17.9 min for group B (range 13-21 min) (Figure 1).

According to VAS scale, patients' mean values for first day postoperative pain were 2.8 for group A (range 2-4) and 4.1 for group B (range 3-5) (Figure 2). Two patients in group A and 4 patients in group B required analgesics. Doses required were in most cases one or two i.m. daily injections of Ketorolac during the first postoperative day. Intra- and post-operative bleeding has always been negligible, more prominent in the fistulotomy group only during the removal of the granulation tissue with the Volkmann curette.

Faecal incontinence was never observed. Incontinence to flatus has been observed in three patients in group A and four patients in group B and spontaneously disappeared within 5-7 days. Healing time mean values have been 3.5 weeks for group A (range 3-5)

and 5.9 weeks for group B (range 4-8 weeks) (Figure 3).

Long-term results (follow-up at six months) did not evidence complications or recurrences for both groups. Only one patient of group A presented nine months later for a new fistula. In this case, we consider that this should not be a recurrence because he was operated for a posterior fistula and presented with an anterior one.

The statistical analysis shows that there is a significant difference between the groups for the three parameters analysed (first day postoperative pain, healing time and operative time) (Table II).

Discussion

Fistula in ano represents one of the most common proctologic diseases after hemor-

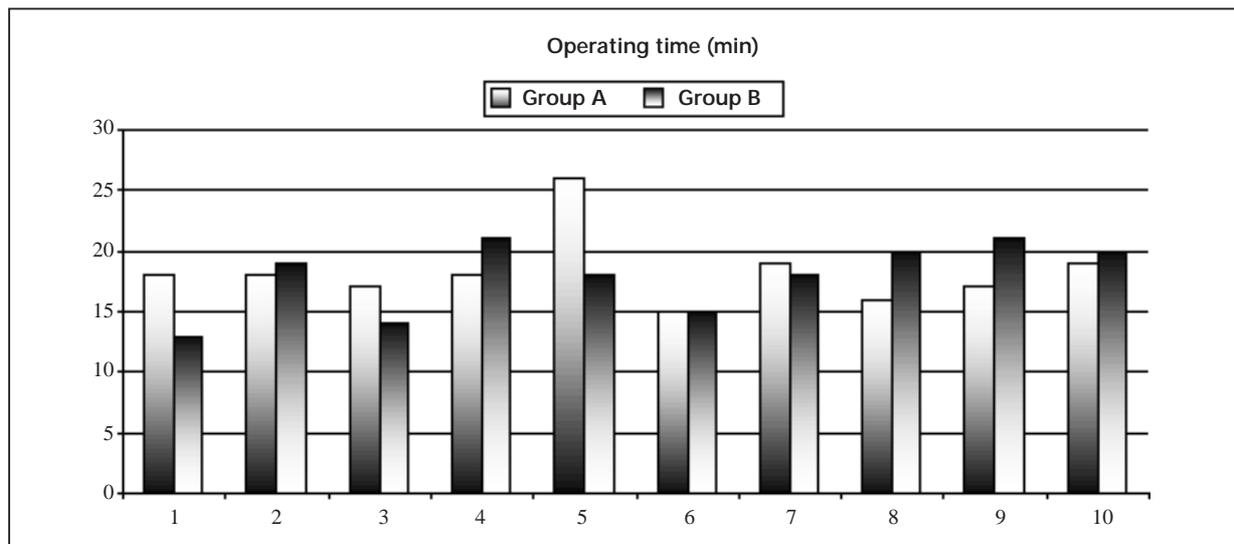


Figure 1. Operating time.

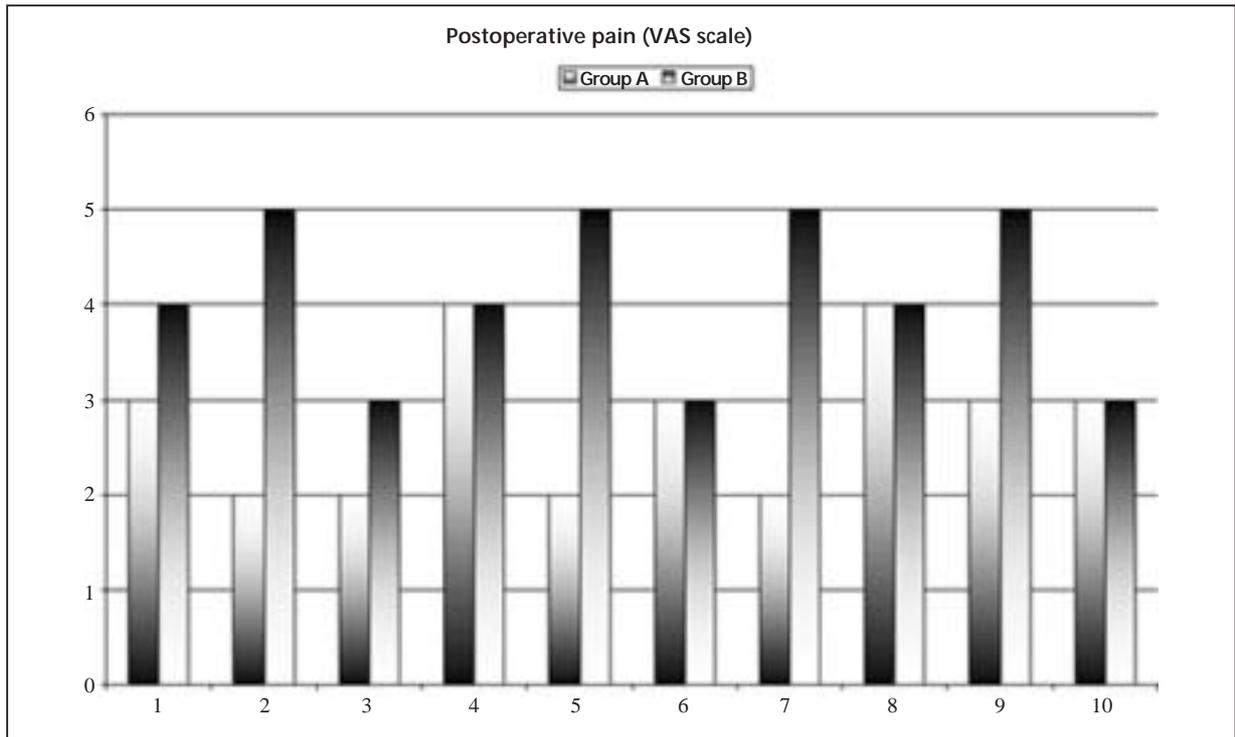


Figure 2. Postoperative pain (VAS Scale).

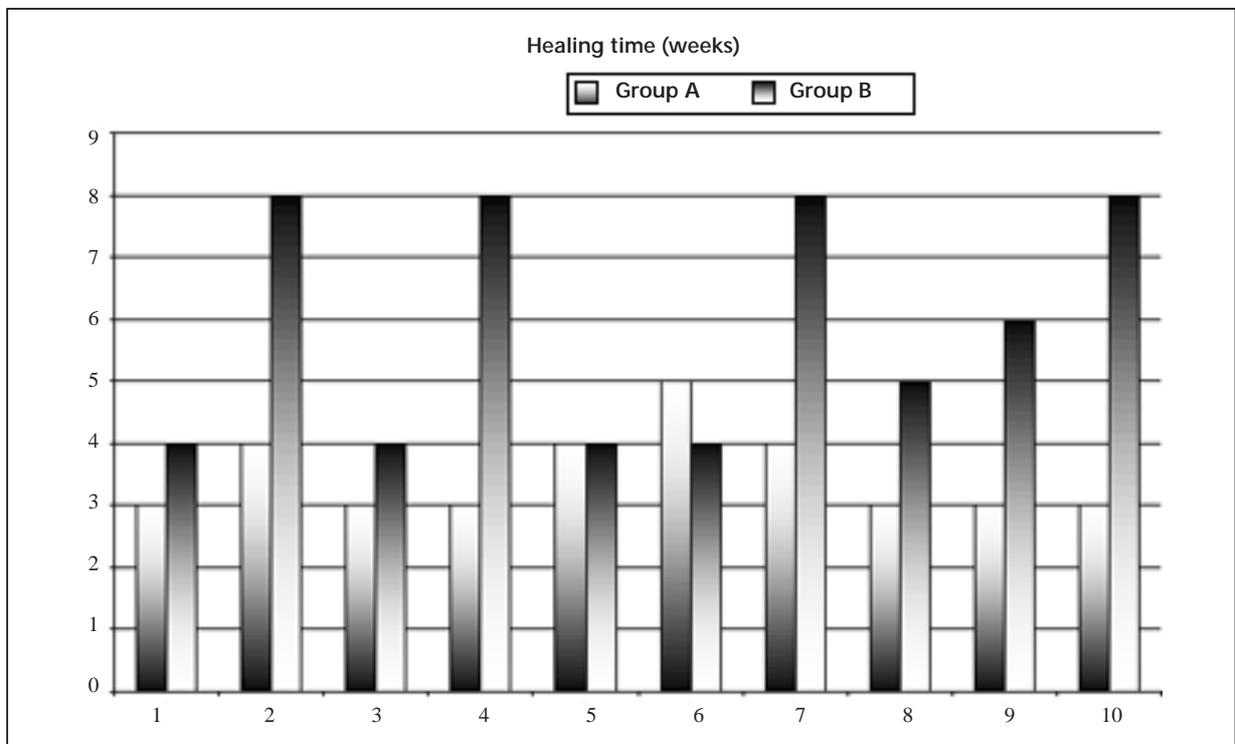


Figure 3. Healing time (weeks).

Table II. Statistical analysis.

Variable analysed	χ^2 value for statistical significance	χ^2 value obtained	Statistical significance
Operative time	10.533	13.369	YES ($p = 0.05$)
First day postoperative pain	7.815	8.343	YES ($p = 0.05$)
Healing time	9.488	11.143	YES ($p = 0.025$)

rhoids and anal fissures. The most common treatment is represented by traditional fistulotomy because this is simple and gives good results. Fistulectomy is a valid alternative but, even if it's more radical compared to traditional fistulotomy, is less used because of some disadvantages: longer operating time, wider surgical wound, prolonged time of healing and more than tripled incidence of incontinence to flatus¹. We performed traditional fistulectomy using the radiofrequency bistoury to investigate how this new device affects the disadvantages.

The radiofrequency bistoury allows to cut and coagulate tissues in an atraumatic manner, contrarily to the electric bistoury, because it works via radio waves. The wiring encountered through the passage of these waves generates heat⁹ with a final temperature that does not exceed 80° C, conversely to the higher temperatures of electric bistoury. This lower temperature disintegrates cells and fuses tissues, changing them into a dense connective and allowing the surgeon to incise like a sharp blade without any bleeding. In this way, radiofrequency bistoury eliminates diffuse bleeding because all vessels up to 1.5-2 mm of diameter are coagulated on the sectioning line. Thus, haemostasis is controlled without difficulty with a correct, easy and bloodless exposure of the operative field.

Furthermore, the cutting-coagulating ability avoids the postoperative sequelae of pain and oedema both for the lower temperatures used, that do not burn tissues, and for the shorter time spent in coagulating, being already performed during the cut. This was confirmed by our previous published results on hemorrhoids treatment analysing some of the removed specimens; we found that heat damage generated by radiofrequency is less

than a half of diathermy¹⁰. For these reasons, radiosurgery facilitates, accelerates and improves surgical procedure.

According to our results, the application of radiofrequencies to fistulectomy has many advantages. Technically, it renders more feasible and eases the operation for the ability of cutting-coagulating at the same time. The electrode is small and fine in shape and this allows a more precise dissection of the granulation tissue from the healthy one at the same time of the incision along the probe. Our results show that the operating time of radiofrequency fistulectomy is a bit longer than traditional fistulotomy and we think that the difference relates with the time spent in the more precise dissection; on the contrary, it's faster than traditional fistulectomy for the ability of cutting-coagulating at the same time that the latter has not.

According to our results, postoperative pain is smaller than traditional fistulotomy because of the lower temperatures used, that do not burn tissues, and for the shorter time spent in coagulating, being already performed during the cut and without using the diathermic bistoury. The surgical wound bed is smaller than traditional fistulectomy and, for this reason, we have a faster wound healing. We found that the healing process is shorter even when compared to that of traditional fistulotomy, which, as a widespread opinion, is the shortest.

The cases of transient incontinence to gas we observed represent a negligible incidence if compared to what is described in literature. ASCRS¹ states that fistulectomy has a triple incidence of transient flatus incontinence compared to fistulotomy. We believe that the use of Parks' anal retractor and the sphincter stretching during surgery may contribute to the pathogenesis of this complication and not

the fistulectomy itself. In fact, we observed that the incidence of this complication is almost the same in the two groups because Parks' anal retractor was used in both of them. Moreover, in our study we operated only submucosal fistulas that, by definition, does not involve the sphincter.

We deliberately did not evaluate in this study the postoperative return to normal activity because we think that the time off work depends on the activity of the patient.

In conclusion, the radiofrequency fistulectomy for submucosal anal fistula is technically more advantageous than traditional fistulotomy and furnishes better results.

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