European **Rev**iew for **Med**ical and **Pharmacol**ogical **Sci**ences 2004; 8: 79-85

A randomised trial comparing submucosal haemorrhoidectomy with radiofrequency bistoury vs. diathermic haemorrhoidectomy

V. FILINGERI, G. GRAVANTE, E. BALDESSARI, P. CRABOLEDDA[*], *F. BELLATI*[**], *C.U. CASCIANI*

Department of Surgery, University of Rome Tor Vergata – Rome (Italy)
[*]*U.O.C. Department of Pathology, S. Eugenio Hospital – Rome (Italy)*
[**]*Department of Gynecology, Campus Biomedico University – Rome (Italy)*

Abstract. – ***Background:*** **Haemorrhoid disease has become more and more frequent during the past years among western populations. Great attention has been paid in development of surgical procedures, in order to reduce post-operative pain (the main adverse effect of surgical treatment for haemorrhoids) and shorten execution time and hospital stay. This randomised clinical study compares the results obtained using submucosal haemorrhoidectomy with radiofrequency vs. diathermic haemorrhoidectomy.**

Methods: **Thirty-one patients were randomised to undergo submucosal haemorrhoidectomy with radiofrequency bistoury (16 patients, Group A) or diathermic haemorrhoidectomy (15 patients, Group B). The operating time, amount of pain and postoperative analgesic requirement, intra and post-operative complications and patient satisfaction were documented.**

Results: **The mean values for operative time have been 35.8 min for group A and 23.2 min for group B. According to pain score, patients' mean values for first day postoperative pain were 3.8 (A) and 5.8 (B). Pain at first evacuation 4.7 (A) and 6.5 (B). Pain at 7th postoperative day was 2.3 (A) and 3.7 (B). Patient's postoperative satisfaction rate was 6.0 (A) vs. 5.2 (B) at 3rd day and 6.7 (A) and 5.7 (B) at 6 months.**

Conclusions: **In spite of relatively difficult execution and longer operating times, submucosal haemorrhoidectomy with radiofrequency bistoury appears to be the most precise and accurate treatment for IV degree haemorrhoids. Performing submucosal haemorrhoidectomy with radiofrequency bistoury allows us to reduce postoperative pain, bleeding and shorten hospital stay.**

Key Words:

Haemorrhoidectomy, Radiofrequency surgery, Proctology.

Introduction

Postoperative pain has always been considered the main adverse effect of surgical treatment of haemorrhoids. Thus, the surgical techniques for haemorrhoids treatment are numerous and still an argument of discussion. New techniques have been introduced as well as modifications to the standard techniques of open and closed haemorrhoidectomies, in order to avoid postoperative troubles (bleeding, recurrences, stenosis). In this study, we use the technique of a modified submucosal haemorrhoidectomy using radiofrequency bistoury already published[1] and present the results of a randomised trial comparing it with diathermic haemorrhoidectomy[2].

Patients and Methods

We followed CONSORT criteria for the development and description of this randomised clinical trial[3].

Eligibility criteria were patients with IV degree haemorrhoids that came to our attention. Exclusion criteria were the presence of previous proctologic surgery or associated proctologic diseases on the base of a preoperative physical examination and a sigmoidoscopy. Moreover, we excluded pregnant patients and those with American Society of Anaesthesiologists Score III or IV[4]. 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 submucosal haemorrhoidectomy using radiofrequency bistoury.

Under general anaesthesia and standardized lithotomic position, a Parks' self-retraining retractor is positioned and adrenaline in a saline solution 1:200,000 concentrated has been infiltrated to reduce bleeding and facilitate the search for the planes of cleavage between mucosa, vascular peduncle and underlying muscular plane.

The nodule is then grasped with an Ellis clamp and initial incision with radiofrequency bistoury is an inverted "T" incision along the muco-cutaneous junction[1].

Underlying planes are separated in layers up to the margin of the internal sphincter. Dissection of the mucosal edges must be performed with extreme caution. The haemorrhoidal tissue is freed from the sphincter. The freed vascular pedicle is then tied at its base with a transfixed stitch of an absorbable suture (Vicryl 2/0) and removed.

Mucosal reconstruction is then performed with few introverted stitches of absorbable suture (Vicryl 3/0). The mucosal edges are then anchored to the muscular plane and a part of the cutaneous margin is not sutured at the external portion of the wound.

Group B. All patients were submitted to diathermic haemorrhoidectomy[2].

Haemorrhoidal prolapses were retracted by an Ellis clamp. A small V-shaped incision was then made in the skin around the base of the prolapse using the diathermy scalpel. The prolapsed haemorrhoidal nodule and the vascular pedicle were dissected by taking small bites of tissue using fine forceps and touching this with the diathermy scalpel. This was continued until the pedicle was divided; no ligature was used. Accurate hemostasis completed the operation.

No patient of both groups underwent internal sphincterotomy.

Postoperatory treatment consisted of Metronidazole (400 mg three times, only the first postoperative day), Ketorolac p.r.n. as analgesic and Diazepam p.r.n. by mouth to sedate particularly anxious patients. All patients begin to assume Vaseline oil by mouth the day after the operation. After 48 hours, a bland laxative (Lactulose per os) was administered to stimulate evacuation in those patients that still didn't evacuate.

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 at 3, 7, 15, 45 days and 6 months by outpatient visits. Pain scores and analgesics requirements, faecal incontinence, stenosis, and overall patient satisfactions were recorded. During visits on day 15^{th}, 45^{th} and at 6 months, patients underwent accurate inspection of the wound and anoscopy by a monouse pediatric device.

We analysed, as primary endpoints, the pain, intra- and postoperative bleeding and operating time. Secondary endpoints were the patient's postoperative satisfaction rate and any complications as fecal incontinence, stenosis and recurrences. We recorded the pain using a score based on patients' statements with 0 as minimum value (no pain) and 10 as maximal value (maximal pain experienced in the past by patients). Additionally, a similar score was used for patients' satisfaction at three days and six months (0 referring to minimal patient's satisfaction and 10 as maximal satisfaction for the results obtained).

Randomisation was carried out using closed envelopes allocation before surgery at the time of admittance in hospital. Both patients and the researchers were blinded to treatment strategy before and after surgery.

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 or Fisher's exact test.

Results

Between January and December 2002, we recruited forty patients for this study. Based on the exclusion criteria, we selected 36 pa-

Table I. Referred symptoms at presentation.

Symptoms at presentation	*N. of patients (n = 31)*	*Percentage*
Prolapse	31	100%
Haemorrhage	24	77.5%
Pain	22	70.9%
Perianal irritation	9	29.0%
Anal pruritus	8	25.8%
Secretions	7	22.6%

tients. Eighteen patients underwent radiofrequency surgery (Group A), 18 the diathermic haemorrhoidectomy (Group B). On successive follow-up examinations, we lost two patients in group A and 3 patients in group B, resulting in 31 patients.

There were 8 males and 8 females in Group A and 8 males and 7 females in group B. Mean age at the time of operation was 42 years for Group A and 39 years for Group B. Symptoms reported are illustrated in Table I and persisted from more than one year.

The mean values for operative time have been 35,8 min. for group A (range 30-45 min) and 23,2 min. for group B (range 19-26 min) (Figure 1).

According to pain score, patients' mean values for first day postoperative pain were 3,8 for group A (range 2-8) and 5,7 for group B (range 4-8) (Figure 2). Pain at first evacuation 4,7 for group A (range 3-8) and 6,5 for group B (range 5-8). Pain at 7th postoperative day was 2.3 for group A (range 1-5) and 3,7 for group B (range 1-6) (Figure 3). Six patients in group A and 12 patients in group B required analgesics. Doses required were in most cases one or two i.m. daily injections of Ketorolac during the first two postoperative

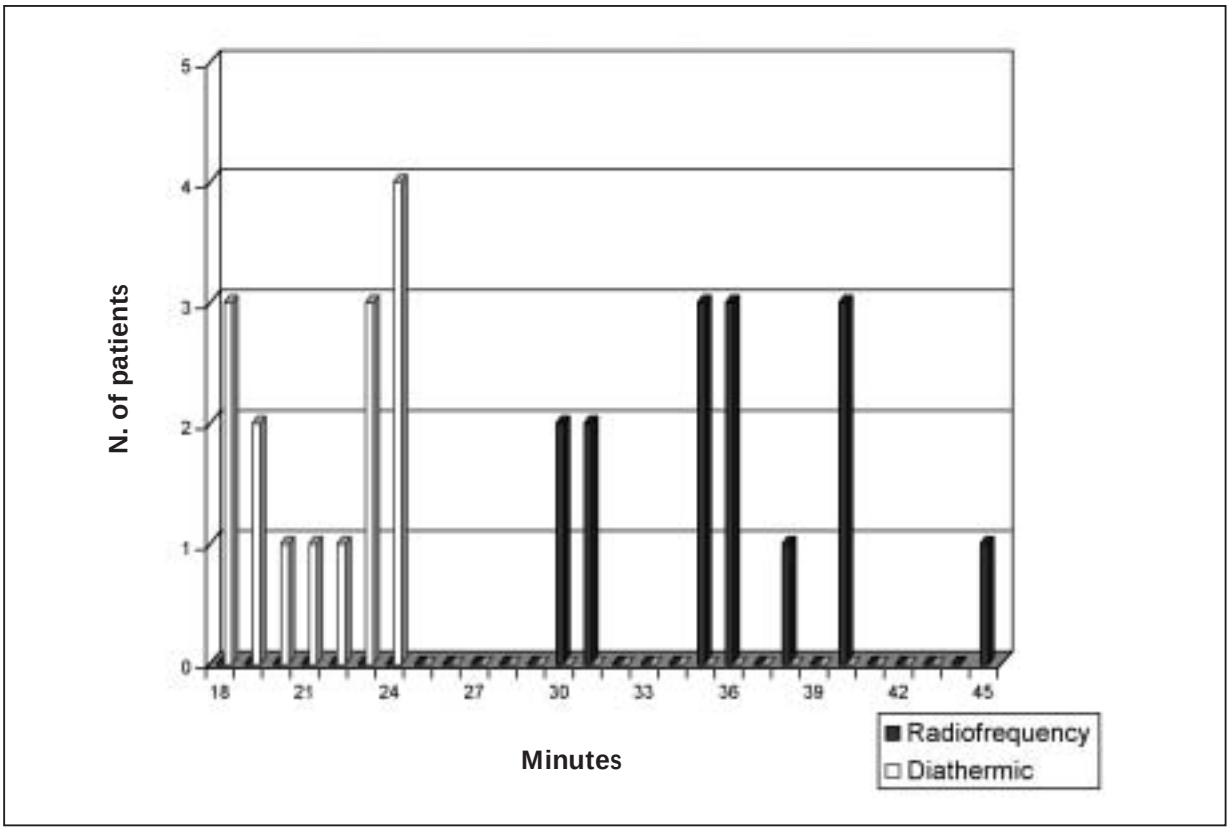

Figure 1. Operating time.

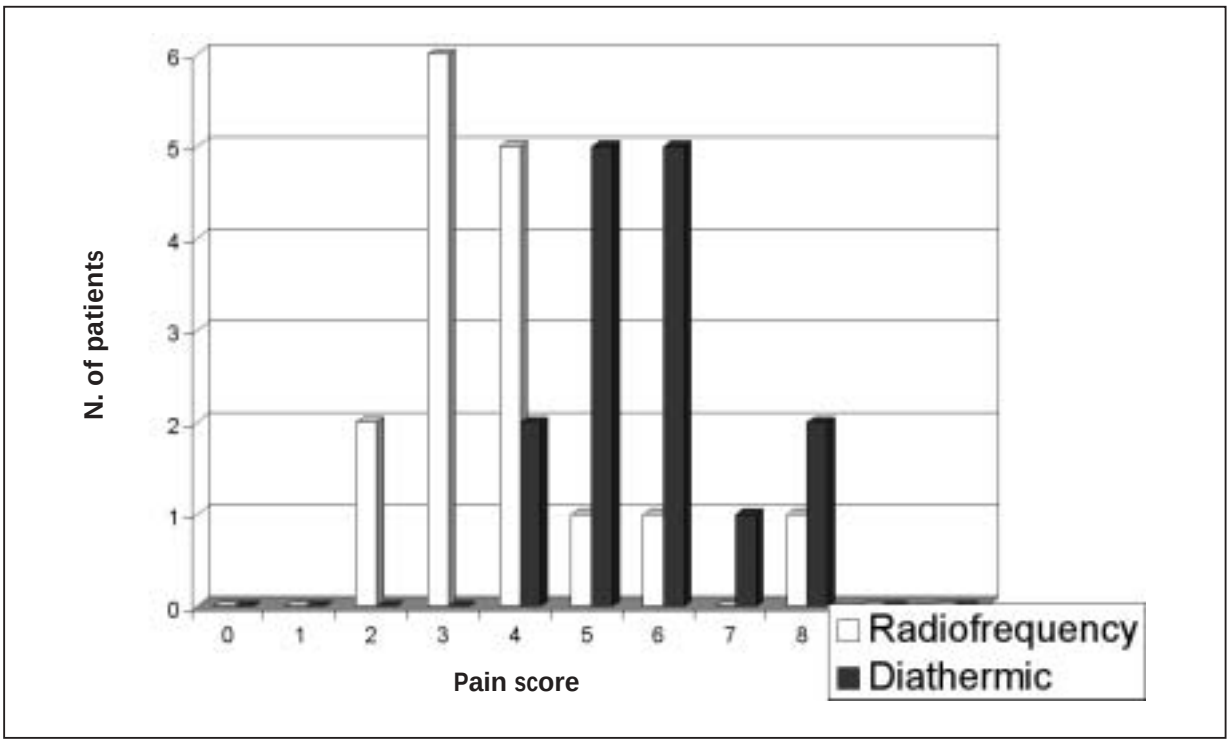

Figure 2. Pain at first postoperative day (score 0-10).

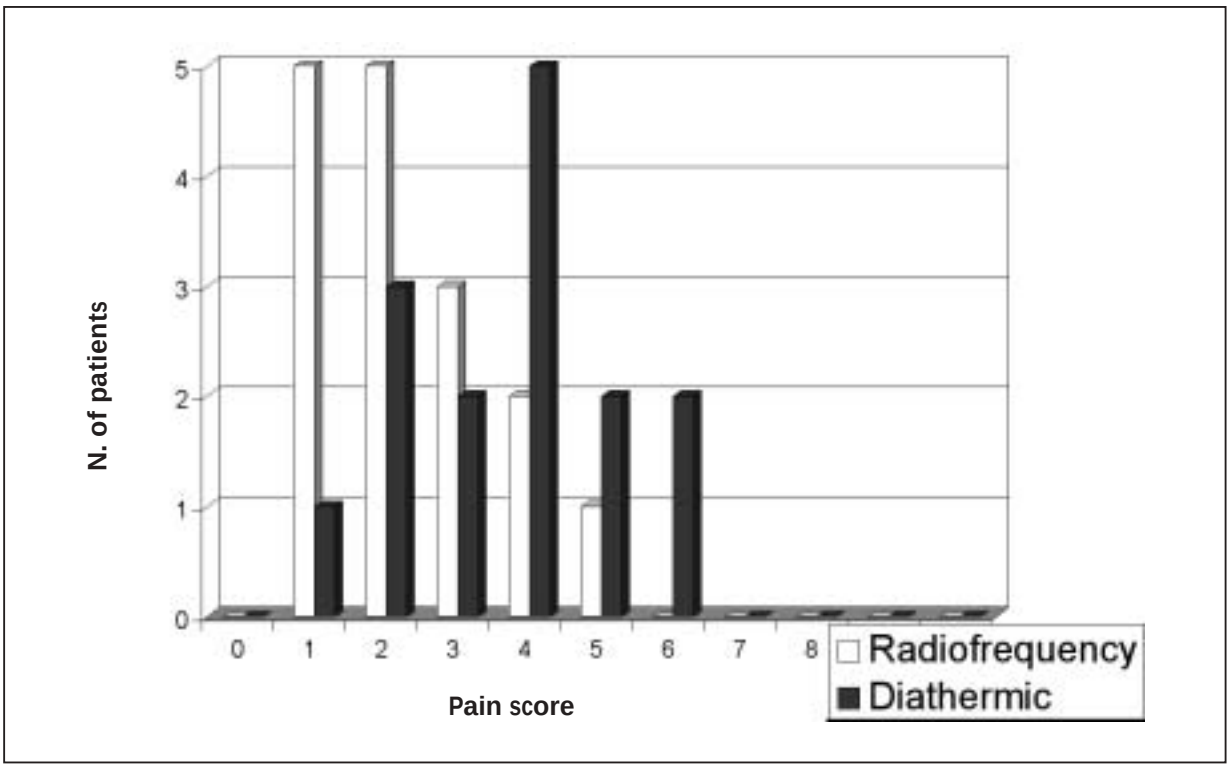

Figure 3. Pain at seventh postoperative day (score 0-10).

days. Only in 1 case for Group A and 2 cases for Group B it was necessary to administer benzodiazepine in order to sedate particularly anxious patients.

Intraoperative bleeding has always been negligible. Postoperative bleeding was mild and not properly called "haemorrhage".

Patient's postoperative satisfaction rate was 6.0 group A (range 4-9) vs. 5.2 for group B (range 3-8) at 3rd day and 6.7 for group A (range 3-9) and 5.7 for group B (range 2-7) at 6 months.

The Mann-Whitney test analysis shows that all the results are highly significative recording a difference between the two groups except for 7th postoperative day pain score which seems not to be related to the choice of the surgical techniques used. Conversely, Fisher's exact test analysis (5% confidence interval, χ^2 0.05, 1 = 3.841) shows a non significative difference for all the variables except for first postoperative day pain ($p < 0.05$).

Faecal incontinence was never observed. On the first postoperative day, 6 patients (4 males) in Group A and 6 patients (3 males) in group B had urinary retention that required catheterisation.

Long-term results (follow-up at forty-five days and six months) did not evidence complications, recurrences as well as stenosis for both groups.

Discussion

Submucosal haemorrhoidectomy with radiofrequency is the evolution of the original Parks' haemorrhoidectomy that, despite the known advantages described in literature, has some intrinsic disadvantages consisting in a difficult execution and in the long training by the young surgeon. We modified the original technique and introduced into practice the use of radiofrequency bistoury[1].

Parks' technique has its fundamental principle in the removal of the vascular pedicle corresponding to every haemorrhoidal nodule and in the preservation of the overlying mucosa, which is accurately reconstructed[5]. The opposed "V" incision on the mucosa of the anal canal described by Parks has been modified by us in an inverted "T" incision that is more comfortable in the successive phases of reconstruction, considering the extreme fragility of the mucosa that renders it more easily prone to tearing upon suturing. Reconstruction of the mucosal plane is very important since it facilitates immediate or late haemostasis, protects innervation of the internal sphincter's muscle fibers, and allows for rapid scaring process and rapid recovery of anal canal sensibility. The anatomical shape of the edges, at the same time, does not avoid spontaneous external drainage of the virtual residual cavity lying between the dissected mucosa and muscular plane. In this way, wound scaring is quicker and without complications. Moreover, the particular reconstruction of the mucosa in the anal canal, with the edges delicately approximated and primarily closure of the wound, is a contributing factor to early evacuation, it allows for reduction in hospitalisation and, last but not least, reduces the risk of stenosis.

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 heat 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 with 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 section 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 results analysing some of the removed haemorrhoidal specimens; we found that heat damage generated by radiofrequency is less than a half of diathermic haemorrhoidectomy, respectively 0.75 mm and 1.58 mm on average. (Figures 4 and 5). Even Parks' technique, using the cold bistoury, apparently works in an atraumatic

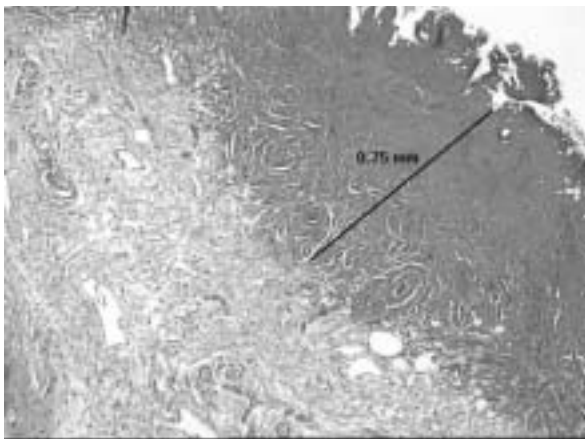

Figure 4. Histological damage caused by radiofrequency bistoury.

way, but the prominent bleeding from the haemorrhoids forces the surgeon to coagulate with traditional electrical bistoury much more frequently than radiofrequency. This generates more heat damages to the mucosa and consequently more oedema and postoperative pain. For these reasons, radiosurgery facilitates, accelerates and improves surgical procedure.

The diathermic haemorrhoidectomy is easy to perform, is not more time consuming and blood loss appears to be less with respect to the traditional Milligan Morgan dissection operation and traditional Parks' operation[2,7]. However, we found that long-term results appeared soon to be less satisfactory than submucosal haemorrhoidectomy with radiofrequency bistoury even if not reaching a statistical significance. This technique present an increased radicality compared to traditional techniques other than diathermic haemorrhoidectomy[2] as Milligan-Morgan[7], CO_2 Laser haemorrhoidectomy[8], stapling procedure[9] and haemorrhoidectomy using the Ligasure[10-11], because the former allow to remove the haemorrhoidal nodule with the entire vascular column up to its limits with the integral mucosa. The high sectioning of the vascular pedicle reduces the risk of recurrence. For these reasons, submucosal haemorrhoidectomy with radiofrequency scalpel is, in our opinion, the elective method for treatment of IV grade haemorrhoids.

According to what is described in literature[12-13], we frequently observed episodes of urinary retention, especially in male patients. For this reason, sometimes catheterisation was deemed necessary during post-operative course. A widely spread opinion is that urinary retention is consequent to excessive liquid retention during anaesthesia, to the type of anaesthesia administered and to intense stimulation of anal receptors during intervention which gives a reflex ureteral spasm[14].

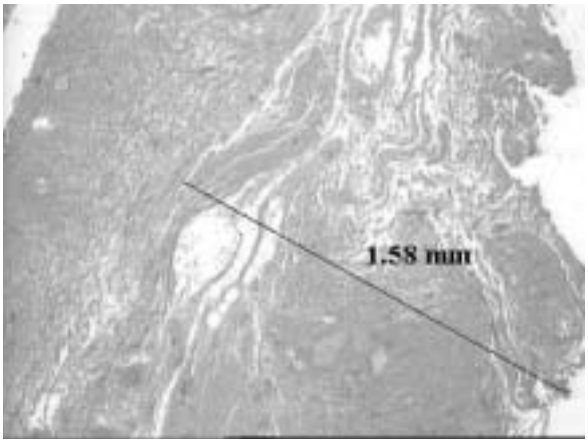

Figure 5. Histological damage caused by diathermy.

The cases of transient incontinence to gas we observed represent a negligible incidence if compared to what is described in literature. Anal incontinence post-haemorrhoidectomy reported by Bennet is 26%[15]. However, its relationships with damages of the internal sphincter have not been demonstrated. Thompson[16] has in fact hypothesised that anal haemorrhoidal cushions contribute to the control of continence. We agree with this hypothesis and believe that the use of Parks' anal retractor and the sphincter stretch during surgery may even contribute to the pathogenesis of this complication.

Radiofrequency submucosal haemorrhoidectomy presents some technical difficulties stemming from the necessity to operate into the anal canal lumen. This technique requires accuracy and availability of time to the surgeon and anaesthetist that usually proctology, being a septic surgery, has not. In fact, proctology often occupies the last schedules of the operative session and "must not" require long periods. In our opinion, the excellent results obtained with this accurate method amply justify the difficulties and duration of the operative times.

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