



Randomised controlled trial between stapled circumferential mucosectomy and conventional circular hemorrhoidectomy in advanced hemorrhoids with external mucosal prolapse

Paolo Boccasanta, M.D.^{a,*}, Pier Giuseppe Capretti, M.D.^a, Marco Venturi, M.D.^a,
Ugo Cioffi, M.D.^b, Matilde De Simone, M.D.^b, Giovanni Salamina, M.D.^a,
Ettore Contessini-Avesani, M.D.^b, Alberto Peracchia, M.D.^a

^aDepartment of General and Oncological Surgery, Milano, Italy

^bDepartment of General and Thoracic Surgery, IRCCS Ospedale Maggiore Policlinico, Milano, Italy

Manuscript received July 26, 2000; revised manuscript February 14, 2001

Abstract

Background: This randomized prospective study compared the outcome of circular hemorrhoidectomy according to the Hospital Leopold Bellan (HLB) technique (Paris) with Longo stapled circumferential mucosectomy (LSCM) in two homogeneous groups of patients affected by circular fourth-degree hemorrhoids with external mucosal prolapse.

Methods: From December 1996 to December 1999, 80 consecutive patients with fourth-degree hemorrhoids and external mucosal prolapse were randomly assigned to two groups. Forty patients (group A: 18 men, 22 women, mean age 50.5 years, range 21 to 82) underwent HLB hemorrhoidectomy, and 40 patients (group B: 15 men, 25 women, mean age 51.0 years, range 29 to 92) underwent LSCM. Before surgery, all patients were selected with a standard questionnaire for symptom evaluation, full proctological examination, flexible rectosigmoidoscopy, dynamic defecography, and anorectal manometry. No significant differences among the two groups were found. All patients were controlled with follow-up questionnaire and with clinical examination at 1, 2, 4, 12, and 54 weeks after the operation. A postoperative manometry was performed 3 months after surgery.

Results: The length of the operation was significantly lower in group B (25 ± 3.1 SD versus 50 ± 5.3 minutes, $P < 0.001$). Mean hospital stay was 3 ± 0.4 days in group A and 2 ± 0.5 days in group B ($P < 0.01$). Mean duration of inability to work was 8 ± 0.9 days in group B and 15 ± 1.4 days in group A ($P < 0.001$). Postoperative pain was significantly lower in group B ($P < 0.001$). Mean length of follow-up was 20 ± 8.0 months in group A and 20 ± 7.8 months in group B. Late complications were similar in the two groups, with 0%, at present, recurrence rate.

Conclusions: Our results confirm that both operations are safe, easy to perform, and effective in the treatment of advanced hemorrhoids with external mucosal prolapse. However, the LSCM seems to be preferable owing to the fewer postoperative complications, easier postoperative management, and shorter time to return to work. A longer follow-up is required to confirm the true efficacy of this surgical method. © 2001 Excerpta Medica, Inc. All rights reserved.

Keywords: Rectal mucosal prolapse; Advanced hemorrhoidal disease; Prospective study; Circular hemorrhoidectomy; Stapled hemorrhoidectomy

The treatment of external mucosal prolapse and hemorrhoids with a circular stapler, recently suggested by Longo [1], shows some theoretical advantages when compared with the conventional techniques. This technique is faster and easier to perform, causes less postoperative bleeding and pain, and is associated with a shorter hospital stay and

earlier return to work [2]. Long-term results of this technique are not well known. Recently, some prospective studies have compared the Longo with the Milligan-Morgan techniques in patients with third-degree hemorrhoids without external mucosal prolapse [3,4]. In the present study we have prospectively compared two homogeneous groups of patients affected by fourth-degree hemorrhoids with external mucosal prolapse treated by Hospital Leopold Bellan (HLB) and Longo stapled circumferential mucosectomy (LSCM) techniques. For these patients, the HLB technique

* Corresponding author's address: Via Laura Ciceri Visconti 14, 20137 Milano, Italy. Tel.: +39-02-55018063; fax: +39-02-55035568.
E-mail address: pboccasanta@tiscalinet.it

[5], which is a modified Milligan-Morgan, seems the best option, allowing the surgeon to correct both hemorrhoids and mucosal prolapse.

Patients and procedures

From December 1996 to December 1999, 80 consecutive patients with fourth-degree hemorrhoids and external mucosal prolapse were randomly assigned into two groups, using the double blind method with closed envelope. Forty patients (group A: 18 men, 22 women, mean age 50.5 years, range 21 to 82) underwent the HLB technique, and 40 patients (group B: 15 men, 25 women, mean age 51.0 years, range 29 to 92) underwent LSCM after giving informed consent.

Before surgery, all patients were studied with a standard questionnaire for the evaluation of symptoms, a full proctological examination to exclude the presence of polyps, tumors or rectum solitary ulcer, a dynamic defecography, and anorectal manometry to exclude rectal intussusception, rectocele, or reduced sphincter contraction. Fourth-degree hemorrhoids were defined those that are constantly external and circular. The standard questionnaire consisted of a visual analogue scale (VAS) with a score from 0 (no complaint) to 10 (maximum distress) for the evaluation of preoperative and postoperative pain. The same standard questionnaire, filled in by the patient, and clinical examination were repeated at 1, 2, 12, 24, and 54 weeks after the operation.

Dynamic defecography was performed introducing 250 mL of contrast (Mixobar esophagus; Astra, Goteborg, Sweden) in the rectum. According to Mahieu et al [6], radiographs were made in the lateral projection at rest, during and after straining, until the complete evacuation of the contrast. Rectocele with depth >2.5 cm, with a diameter of the rectal ampulla <6.5 cm in the lateral view, was considered pathological. Anorectal manometry was carried out preoperatively and 12 weeks after the operation with the patient lying in the left lateral position with flexed hips at 90 degrees. A silicone elastomer tube (3 mm in diameter, with 3 transducers) was inserted into the anus. The transducers were positioned at 1, 1.5, and 2 cm from the anal verge and connected to a recorder (Beckman R601, Shiller Park, Illinois). Insufflation was obtained with an inflatable balloon (Durex LCR Ltd, London, England). The following parameters were recorded: mean resting and squeezing pressures, maximum tolerable volume, and rectoanal inhibitory reflex.

Operative procedure

Patients were admitted the day before the operation. An enema and short-term antibiotic prophylaxis with cefotaxime 1 g intravenously were carried out. General anesthe-

sia was performed in 24 (60%) patients of group A and in 28 (70%) of patients in group B; spinal anesthesia was used for 16 (40%) patients of group A and 12 (30%) of group B [7]. All patients were placed in the lithotomic position.

HLB technique

For the HLB operation we used the previously described technique [8]. Briefly, the HLB circular hemorrhoidectomy differs from the Milligan-Morgan operation in the following ways: (1) exposure of 4 radial points of the circular mucohemorrhoidal prolapse with 3 to 4 clamps for each pile (the last placed in healthy rectal mucosa); (2) dissection of the anal skin until the submucosa containing the mucohemorrhoidal tissue, up to the last clamp with preservation of the internal anal sphincter; (3) resection of the prolapsed tissue, after transfiction above the proximal clamp with Vicryl 0 (Ethicon, Inc., Somerville, New Jersey); (4) creation of 4 thin (5 to 7 mm) mucocutaneous bridges and their lateral dissection with complete elimination of the residual piles; and (5) restoration of the 4 bridges that must be separated from the internal sphincter, adjusted, shortened, and eventually reimplanted.

LSCM technique

We used a purpose-designed circular stapler with a disposable circular anal dilator and a purse-string suture anoscope (P.P.H. Ethicon-Endosurgery, Inc, Pomezia, Italy). After dilation of the anal verge, one purse-string with Prolene 2-0 (Ethicon, Inc.) was prepared 4 to 5 cm above the dentate line. The size 33 circular stapler was then opened, and its head was placed above the suture (Fig. 1). The stapler device was then closed, fired, and withdrawn. The hemostasis was accurately controlled, occasionally using supplementary hemostatic sutures of the anastomotic ring with 1 to 2 stitches of Vicryl 3-0 (Ethicon, Inc.). All surgical specimens obtained from both procedures were histologically examined.

Postoperative care

A diet without fibers was started on the first postoperative day, including vaseline oil or oral laxatives (lactulose 5 mL two times a day) for 3 weeks. Dexametopfen (Desketo, Malesci, Italy) 25 mg three times a day orally was used to control the pain for the first week and 25 mg twice a day for another week. Later on, we used analgesic drugs only when needed. Patients were monitored weekly until healing. In order to prevent anal stenosis, all patients submitted to HBL operation carried out at-home anal calibration after the first postoperative week using anal dilators of progressive diameter (Dilatan anal cryothermic dilator; Sapimed, Alessandria, Italy). All patients were controlled with follow-up questionnaire, filled in by the patients, and with clinical examination at 1, 2, 4, 12, and 54 weeks after the operation. Patients were

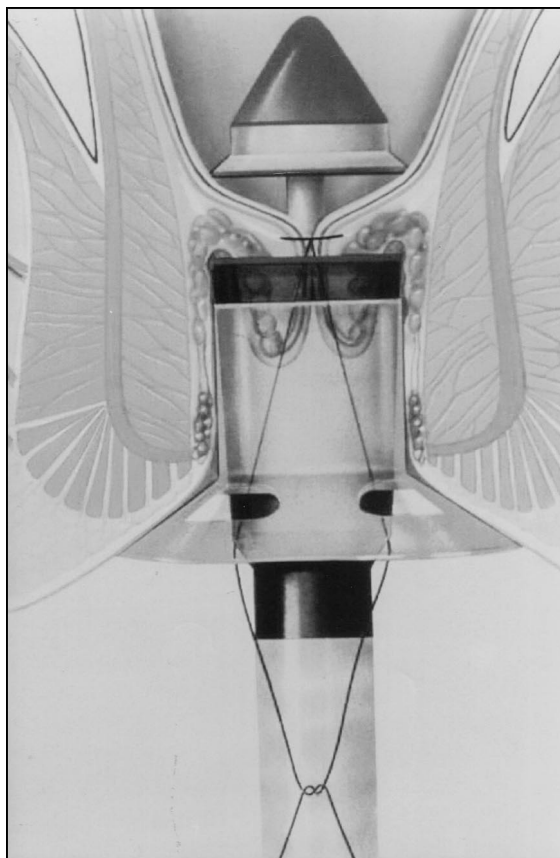


Fig. 1. Longo stapled circumferential mucosectomy. After preparation of the purse-string the circular stapler (P.P.H.), size 33, is opened and its head is placed above the suture line. The stapler device is then closed.

asked how long after the operation they returned to their normal activities.

Statistics

The chi-square and Student's *t* tests, as appropriate, were used to compare preoperative and postoperative data. Differences were considered significant when *P* was <0.05.

Table 1
Preoperative clinical data in group A (40 patients) and in group B (40 patients)

Preoperative clinical data	Group A		Group B		<i>P</i> value*
	Number of patients	%	Number of patients	%	
Symptoms and signs					
Bleeding	31	77.5	33	82.5	NS
Rectal dyschezia	24	60.0	22	55.0	NS
Incomplete evacuation	20	50.0	21	52.5	NS
Constant pain	12	30.0	11	27.5	NS
Soiling	23	57.5	26	65.0	NS
Pruritus	8	20.0	9	22.5	NS

* Chi = square test used.

NS = not significant.

Results

Preoperative clinical data

The characteristics of 80 randomized patients were similar in the two groups. As shown in Table 1, no significant differences concerning symptoms were found in the two groups. The most frequent symptoms were bleeding, soiling, and rectal dyschezia.

Proctosigmoidoscopy

None of patients had associated anorectal diseases such as inflammatory bowel disease, rectum solitary ulcer, polyps or cancer.

Defecography

All patients had circular internal mucosal prolapse without muscular rectoanal intussusception, or complete rectal prolapse. Eleven patients (27.5%) of group A and 10 patients (25%) of group B had an asymptomatic rectocele.

Anorectal manometry

All patients were studied preoperatively and were controlled 3 months after the operation. No significant differences were found preoperatively between the two groups, and all parameters considered were not modified by surgery (Table 2).

Surgery

Mean operative time was 50 ± 5.3 minutes in group A and 25 ± 3.1 in group B ($P < 0.001$ by Student's *t* test). Five patients (12.5%) of group B required supplementary hemostatic sutures. Mean hospital stay was 3 ± 0.4 days in group A and 2 ± 0.5 days in group B ($P < 0.01$). Cumulative economic cost (surgical materials and hospital stay) was similar ($\$1,546 \pm 241$ in group A versus $\$1,380 \pm 201$ in group B; *P* not significant). Mean duration of inability to

Table 2
Anorectal manometry data

Manometry	Group A		Group B		P value*
	Mean value	SEM	Mean value	SEM	
Preoperative data					
Resting pressure (mm Hg)	47.2	6.3	51.4	7.2	NS
Squeeze pressure (mm Hg)	97.4	3.7	99.3	5.2	NS
Maximum tolerable volume (mL)	180.4	3.3	177.7	4.1	NS
Rectoanal inhibitory reflex (mL)	16.2	0.7	15.7	1.0	NS
Postoperative data					
Resting pressure (mm Hg)	45.2	5.8	49.9	6.4	NS
Squeeze pressure (mm Hg)	94.7	3.6	96.7	4.8	NS
Maximum tolerable volume (mL)	175.6	3.1	173.5	4.0	NS
Rectoanal inhibitory reflex (mL)	15.4	0.6	14.8	0.9	NS

* Student's *t* test used.

SEM = Standard error of the mean; NS = not significant.

work was 15 ± 1.4 days in group A and 8 ± 0.9 in group B ($P < 0.001$).

Postoperative complications

Mean length of follow-up was 20 ± 8.0 months in group A and 20 ± 7.8 in group B. Early complications (within 10 days after the operation) are shown in Table 3. The intensity of the postoperative pain was significantly lower in group B (17.5% versus 42.5% with VAS >5 , $P < 0.001$). The pain score of each group is shown in Fig. 2. Postoperative hemorrhage was not significantly higher in group A. In 2 patients of group A (5%) who had arteriolar bleeding from the internal sphincter on the first and fifth postoperative day, a transfixed suture under local anesthesia was required: the first patient was also given blood transfusion.

As expected, perineal ecchymosis and thrombosis of the residual piles were significantly higher for the more invasive HLB procedure ($P = 0.034$).

As shown in Table 3, the late complications (<1 year after the operation) did not significantly differ in the two

groups. A strict follow-up with postoperative anal dilation significantly reduced the high risk of stenosis due to the large removal of anal tissue with HLB technique. Patients of both groups with anal stricture had progressive dilation under local anesthesia to avoid surgical anoplasty.

Histology

No patients of group A had dysplasia of the removed piles. In 75% of patients of group B the histological examination of the removed mucosal rings showed mucosa and submucosa.

Comments

The incidence of rectal mucosal prolapse is high in patients with impaired defecation (51% in our series) [9], and it is frequently associated with prolapsed hemorrhoids. Patients are always symptomatic, with frequent rectal bleed-

Table 3
Complications

Complication type	Group A		Group B		P value*
	Number of cases	%	Number of cases	%	
Early					
Hemorrhage	3	7.5	2	5.0	NS
Thrombosis and perineal ecchymosis	6	15.0	2	5.0	0.034
Pain >5 (VAS)	17	42.5	7	17.5	<0.001
Acute urinary retention (spinal anesthesia)	2	5.0	2	5.0	NS
Late					
Stenosis	3	7.5	2	5.0	NS
Residual skin tags	2	5.0	1	2.5	NS
Hemorrhage	2	5.0	0	0.0	NS
Soiling	1	2.5	1	2.5	NS
Recurrence	0	0.0	0	0.0	NS

* Chi-square test used.

VAS = visual analogue scale; NS = not significant.

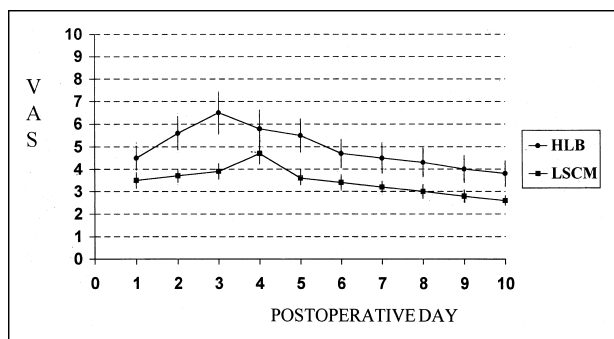


Fig. 2. Mean (SD) visual analog scale (VAS) after circular hemorrhoidectomy according to the Hospital Leopold Bellan (HLB) technique and the Longo stapled circumferential mucosectomy (LSCM) technique.

ing, soiling, and dyschezia; therefore, surgical treatment is often necessary.

We demonstrated that in these patients the circular hemorrhoidectomy with the HLB technique [10] is a good choice because of its radicality and good results. Nevertheless, the pain, requiring high dose of analgesic drugs, is common, early and late bleeding reaches 12.5% incidence, and there is high risk of anal stenosis. A strict follow-up is therefore required, and in all cases it is mandatory to use anal dilators until the complete healing of the wound. The LSCM, instead, was demonstrated to be easier and faster to perform, with moderate postoperative pain, excellent medium-term results, and a low incidence of bleeding, incontinence, and anal stricture [4,11]. Differently from other authors [3,4], in our series we compared two similar surgical techniques, allowing correction at the same time not only the hemorrhoidal disease but also the external mucosal prolapse. Our results demonstrated that LSCM has some advantages in the early postoperative period: operative time is shorter, postoperative pain and local trauma are reduced, postoperative home care is easier, and the time of inability to work is reduced. Nevertheless, as shown by other authors [12], the incidence of early hemorrhages is not significantly lower than after conventional operation, and pain is reduced but not abolished using the stapler. Some authors [4] used morphine or dihydrocodeine for postoperative analgesia, and this was probably the reason they reported no pain after LSCM. Furthermore, most of the published studies on LSCM have too short a follow-up. We therefore prefer to strictly check the stapled patients during the first 48 hours after the operation. The medium-term results and complications are similar in both techniques. Regarding the anal stenosis, we believe that the higher incidence reported in our series was due to the more advanced disease in our patients. Anorectal manometry demonstrated that, even if small lesions of the internal sphincter may happen, no alterations of the manometric values occurred. Total costs of the two techniques were similar because the higher cost of LSCM was balanced by the shorter hospital stay. Finally, until now we have had no recurrences among the patients of either group.

Conclusion

LSCM might be the ideal replacement for conventional surgery for the treatment of advanced hemorrhoids with external mucosal prolapse because it gives the same results as the HLB technique without, in our opinion, the necessity of postoperative anal dilations. We recommend a strict follow-up after LSCM, particularly in the early postoperative period when, as verified in our series, the risk of bleeding is not so low as suggested by some authors [4,11]. Up to now the medium-term results do not differ from those obtained with the conventional procedures, as the HLB operation. Certainly a longer follow-up (5 to 10 years) is required for an exact evaluation of this technique. Furthermore, as reported in the literature [3,4], we believe that the day-surgery procedure is indicated only in selected cases. In these cases, LSCM seems to be the technique of choice because of the lower risk of early postoperative complications.

Acknowledgments

This work was supported by a grant from “Fondazione Camillo Corti per la Ricerca sulle Malattie del Colon,” Milano, Italy.

References

- [1] Longo A. Treatment of hemorrhoids diseases by reduction of mucosa and hemorrhoidal prolapse with a circular suturing device: a new procedure. Proceedings of 6th World Congress of Endoscopic Surgery, Rome, 3–6 June 1998. Bologna: Monduzzi Ed, 1998, p 777–84.
- [2] Pescatori M, Favetta U, Dedola S, Orsini S. Transanal stapled excision of rectal mucosal prolapse. *Coloproctology* 1997;1:96–8.
- [3] Rowsell M, Bello M, Hemingway DM. Circumferential mucosectomy (stapled haemorrhoidectomy) versus conventional haemorrhoidectomy: randomized controlled trial. *Lancet* 2000;355:768–9.
- [4] Mehigan BJ, Monson JRT, Hartley JE. Stapling procedure for haemorrhoids versus Milligan-Morgan haemorrhoidectomy: randomised controlled trial. *Lancet* 2000;355:782–5.
- [5] Arnous J, Parnaud E, Denis J. Une hemorrhoidectomie de sécurité. A propos de 5000 observations. *Press Med* 1971;3:87.
- [6] Mahieu P, Pringot J, Bodart P. Defecography: II. Contribution to the diagnosis of defecation disorders. *Gastrointest Radiol* 1984;9:253–61.
- [7] Marti MC. Choix d'un type d'anesthésie en proctologie et intérêt des blocs postérieurs. *Ann Gastreenterol Hepatol* 1981;17:95–7.
- [8] Boccasanta P, Venturi M, Orio A, et al. Circular hemorrhoidectomy in advanced hemorrhoidal disease. *Hepatogastroenterology* 1998;45: 969–72.
- [9] Boccasanta P, Segalin A, Montorsi M, Peracchia A. Posterior rectal inclination in the radiological diagnosis of the alterations of the pelvic floor anatomy. *Coloproctology* 1995;17:200–5.
- [10] Denis J, Dubois N, Ganansia R, et al. Hemorrhoidectomy: Hospital Leopold Bellan procedure. *Int Surg* 1989;74:152–3.
- [11] Altomare DF, Rinaldi M, Chiuraruolo C, Palasciano N. Treatment of external anorectal mucosal prolapse with circular stapler. *Dis Colon Rectum* 1999;42:1102–5.
- [12] Marti MC. Mechanical hemorrhoidectomy using circular staplers: warning to colleagues. *Swiss Surg* 1999;5(3):151–2.