



Randomized clinical trial of stapled hemorrhoidectomy vs open with Ligasure for prolapsed piles

G. Basdanis, V. N. Papadopoulos, A. Michalopoulos, S. Apostolidis, N. Harlaftis

1st Propedeutic Surgical Clinic, Aristotle's University of Thessaloniki, A.H.E.P.A. Hospital, T. Ikouomidi 21, 551 31, Kalamaria, Thessaloniki, Greece

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Abstract

Background: The aim of the study was to compare the results in 95 patients randomly allocated to undergo either stapled or open hemorrhoidectomy using Ligasure.

Methods: Ninety-five patients with grade III and IV hemorrhoids were randomly allocated to undergo either stapled (50 patients) or open using Ligasure (45 patients). Stapled hemorrhoidectomy was performed with the use of a circular stapling device. Open hemorrhoidectomy was accomplished according to the Milligan-Morgan technique by using Ligasure. Postoperative pain was assessed by means of a visual analog scale (VAS). Recovery evaluation included return to pain-free defecation and normal activities. A 6-month clinical follow-up and an 18 (12–24) month median telephone follow-up were obtained in all patients.

Results: Operation time for open hemorrhoidectomy using Ligasure was shorter [median 13 (range 9.2–16.1) min vs 15 (range 8–17) minutes, $p < 0.05$]. Median range of VAS score in the stapled group were significantly lower [VAS score after 8 h: 3 (2–6) vs 5 (3–8), $p < 0.01$; VAS score after first defecation: 5 (3–8) vs 7 (3–9), $p < 0.001$]. The stapled hemorrhoidectomy was associated with an increased incidence of intraoperative bleeding in 18 cases (36%) vs four cases (8.8%) of the Ligasure group. There were three cases (6%) from the stapled group with recurrence of the hemorrhoids and none from the open technique.

Conclusions: Hemorrhoidectomy with a circular stapler device is easy to perform, but one more line of clips must be added to the device to avoid intraoperative bleeding from the cut line. Hemorrhoidectomy performed using Ligasure is more painful postoperatively but is a more radical operation.

Key words: hemorrhoids — circular stapler — Ligasure — piles

Introduction

Hemorrhoids are part of normal human anatomy. It has been estimated that 58% of people over 40 years of age have hemorrhoidal disease to some extent [2]. Indications for operative treatment of hemorrhoids are not well defined. Most surgeons agree that these include fourth-degree, prolapsing irreducible hemorrhoids, and most third-degree, prolapsing during straining hemorrhoids [4, 5, 7]. The operative treatment can also be indicated in hemorrhoids of second degree with mucosal prolapse or recurrent bleeding. In addition, patients who present with acutely thrombosed or strangulated prolapsed hemorrhoids may benefit from emergency hemorrhoidectomy. The vast majority of surgeons perform the hemorrhoidectomy with the open (Milligan-Morgan) [10] or closed (Ferguson) technique [3]. An operative method using a circular stapler was developed recently by Peck, O'Connor, and finally by Longo [8]. The method was based on Thompson's theory of the physiologic role of "anal cushions" and the prolapse of rectal mucosa [16]. The rationale of the procedure is to decrease the blood flow to hemorrhoids and to reset them in their normal position without damaging the sensitive anal canal mucosa in the region of the dentate line.

The Ligasure (Valleylab, Boulder, CO, USA) is a new hemostatic device designed primarily for use in abdominal surgery. The device seals blood vessels of up to 7 mm in diameter using a precise amount of bipolar energy and pressure that permanently changes collagen and elastin within the vessel wall. The purpose of this randomized study was to determine the efficacy and the

Table 1. Preoperative symptoms of patients underwent stapled (STP; $n = 50$) hemorrhoidectomy and with Ligasure (LT; $n = 45$)

	Group STP	Group LT
Mucosal rectal prolapse ^a	8	5
Bleeding ^a	40	35
Itching ^a	45	40
Discharge ^a	36	38
Swelling ^a	44	40
Skin tags ^a	10	14
Irreducible piles (fourth degree) ^a	10	12

^a Nonsignificant statistical difference

safety of the stapled hemorrhoidectomy in comparison with the open Milligan-Morgan operation modified by the utilization of Ligasure.

Patients and Methods

Local ethics committee approval was obtained. Appropriate informed written consent was obtained from patients admitted for hemorrhoidectomy for symptomatic prolapsing hemorrhoids. Randomization was performed at the time of anesthesia by randomization using sealed envelopes.

Ninety-five patients were surgically treated for third- and fourth-degree hemorrhoids in the 1st Surgical Department of Aristotle's University of Thessaloniki, from October 2000 to September 2002. In 50 patients (group A) a circular stapler No. 33 (Ethicon) was used (stapled "hemorrhoidectomy"-STP). In another group (B) of 45 patients, hemorrhoidectomy was performed using Ligasure-LT). The patients in both groups suffered from hemorrhoids of third and fourth degree, and their characteristics are shown in Table 1. Group A included 29 (58%) men and 21 (42%) women (median age 46 years, range 25–72) and group B, 25 (55.5%) men and 20 (44.4%) women (median age 44 years, range 22–69). Five patients from group B were lost during the follow-up period. All patients routinely underwent a pre-operative proctoscopy. All the women of both groups had previously uneventful vaginal deliveries, and none of them had any degree of incontinence. In group A, spinal anesthesia was used in 28 patients and general anesthesia in 22 patients. The circular stapler was adjusted in the anal canal in the following manner. A special anal dilator (Ethicon PPHOI, Johnson & Johnson) was used to set an interrupted purse-string suture (Prolene 2-0) 4–5 cm above the dentate line. The suture was tight around the anvil of the circular stapler (Ethicon number 33), so that the final suture line was located 3 cm above the dentate line, an area that is considered painless (Fig. 1). In eight patients (16%) two circular interrupted sutures were used because of a significant prolapse of the anal mucosa. In 18 patients (36%) interrupted stitches were inserted to control bleeding points after removal of the stapler.

The patients in group B were operated with the open Milligan-Morgan technique using diathermy Ligasure (Tyco, USA) (Fig. 2). The Ligasure procedure was performed using an Eisenhammer retractor. The hemorrhoidal tissue was grasped and brought toward the lumen of the anal canal. The medium-sized Ligasure device was applied across the base of the hemorrhoidal complex two to three times, taking care not to grasp the internal anal sphincter (horizontal position of the instrument as shown in Fig. 2). The coagulation foot pedal was pressed until a characteristic two-tone sound from the machine confirmed complete coagulation of the tissue. The feedback-controlled response system delivers the appropriate amount of energy required to seal the tissue, and the flow of current is automatically halted to prevent further coagulation. The coagulated strip was then cut and the hemorrhoid removed. No further hemostasis or dressing was required. Spinal anaesthesia was used in 31 patients and general in 14. Patients of both groups were operated in lithotomy position.

The removed specimens of the anal mucosa of the patients of both groups were sent for pathological examination. The operative

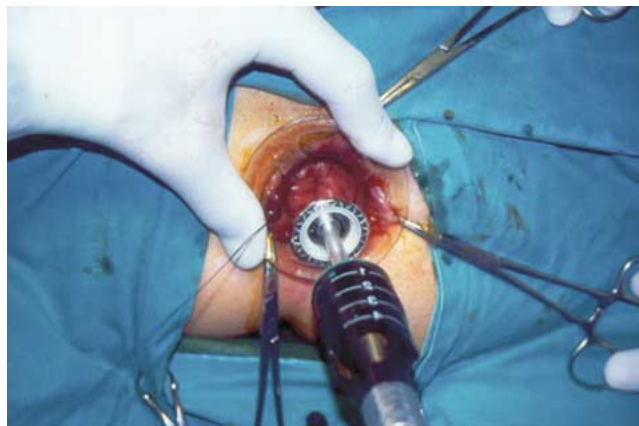


Fig. 1. Application of stapler.

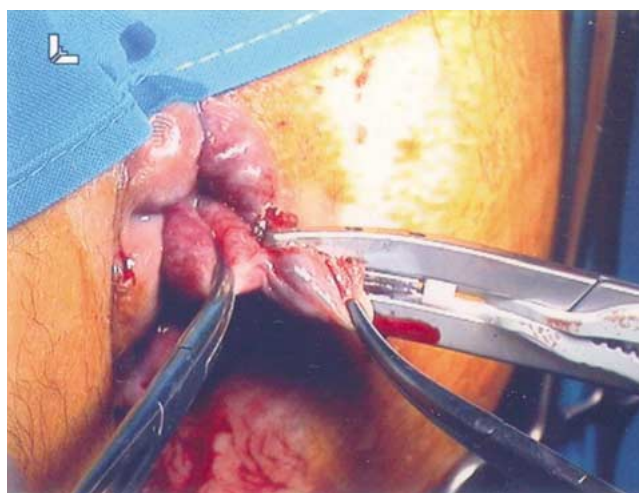


Fig. 2. Application of Ligasure.

time of both methods was recorded. Antibiotics were used in both groups, one dose (cephalosporin 2nd generation + metronidazole) preoperatively and one postoperatively. The postoperative status of the patients was evaluated with respect to intensity of pain, occurrence of hemorrhage, discharge, and local septic complications. The duration of postoperative hospitalization was also recorded. Direct questioning of the patient about the need for analgesics estimated the intensity of the postoperative pain. We used the visual analogic scale (VAS) with pain values that ranged from 0 (no pain) to 10 (unbearable pain). Continence was assessed in all patients and anorectal manometry was carried out pre- and postoperatively. Cost was assessed by hospital stay, time to resume work, and total related medical costs incurred during the study period. The patients were followed in 1 week, 1 month, and 6 months after their discharge from the hospital. A long-term follow-up 12- to 24-month period was obtained in all patients by telephone.

Results

Characteristics of patients are shown in Table 1. The two groups were similar with respect to age, sex, and grade of hemorrhoidal prolapse. The median operative time was 15 (range 8–17) min in group A vs 13 min (range 9.2–16.1) in group B ($p < 0.05$, Mann-Whitney U test).

Table 2. Wound condition and bowel function in patients after stapled ($n = 50$ and Ligature ($n = 45$) hemorrhoidectomy

	Immediately postoperative			One month after surgery		
	STP	LT	<i>p</i> -value ^a	STP	LT	<i>p</i> -value ^b
Major bleeding	3	1	0.50			
Reintervention	1	1	1.0			
Minor wound bleeding	7	20	0.05		1	
Pruritus	6	39	0.001	2	1	
Wound discharged	4	37	0.005	0	2	
Fecal impaction (requiring enema)				0	1	
Wounds fully healed				50	45	
Tenderness to digital rectal examination	12	43	0.6	0	1	

Figures are number of patients. STP: Stapled group; LT: Ligasure technique

^a Fisher's exact probability test

^b Not statistically significant

Table 3. Pain score and analgesic requirements in patients who underwent stapled hemorrhoidectomy ($n = 50$) and Ligature technique ($n = 45$)

	24 h after surgery		One week after surgery	
	STP	LT	STP	LT
Maximal pain (VAS)	3 (1–6)	6 (3–7)	–	–
Pain at stool evacuation	5 (3–8)	7 (3–9)	1 (1–2)	2 (1–3)
Diclofenac i.v.	3.8 (2–12)	3.2 (1–8)	–	–

STP: Stapled group; LT: Ligasure technique; VAS: Visual analogue scale

Figures are mean and (range)

Pain score range was 0 (no pain) to 10 (worst pain experienced)

Intraoperative and postoperative complications are listed in Table 2. Intraoperative bleeding occurred in 18 (36%) patients in the stapled group vs four patients (8.8%) of the Ligasure group ($p < 0.05$, Fisher's exact test). Bleeding was stopped with suture ligation of the bleeding sites in all cases. Postoperative bleeding occurred in three patients (6%) after stapled hemorrhoidectomy and in one patient (2.2%) in the Ligasure group. Reintervention to stop bleeding was necessary in one patient from each group. Urinary retention was present in seven patients (14%) in the stapled group and five patients (11.1%) in the Ligasure group ($p < 0.5$, Fisher's exact test).

Median (range) parenteral diclofenac consumption in the stapled group was less than in the Ligasure group. Pain scores 8 h and 24 h after operation and at first defecation are shown in Table 3. Median (range) VAS scores in the stapled group were significantly lower than in the Ligasure group [VAS score after 8 h: 3 (2–6) vs 5 (3–8), $p < 0.01$; VAS score after 24 h: 3 (1–6) vs 6 (3–7), $p < 0.01$; VAS score after first defecation: 5 (3–8) vs 7 (3–9), $p < 0.001$; Mann-Whitney U test]. In the STP group, all the stapler doughnuts were found to be complete. All the excised piles and doughnuts were sent for histopathology examination, which showed that no anal sphincter muscle fibers were included.

Continence was assessed by direct questioning and anorectal manometry (Table 4). Two patients of the LT group and one of the STP group had minor incontinence

Table 4. Anorectal manometry in-patients who underwent stapled hemorrhoidectomy ($n = 50$) and Ligature technique ($n = 45$)

	Before surgery		4 weeks after surgery	
	STP	LT	STP	LT
Mean anal resting pressure (mmHg)	69.3 (4.3)	71.2 (2.9)	67.8 (3.9)	76.5 (4.1)
Maximum anal squeeze pressure	176 (13)	171.6 (12.3)	179 (8.5)	173.9 (11.7)
Rectal compliance (ml/mm Hg)	3 (0.3)	2.9 (0.4)	3.2 (0.5)	3.1 (0.4)

STP: Stapled group; LT: Ligasure technique

Figures are mean and (standard error of the mean) No significant differences found between LT and STP when postoperative changes were compared, using Fisher's exact probability

Table 5. Economic differences between the two groups (euro)

	Stapler (euro)	Ligasure (euro)
Surgical expenses	1175	780
Hospital stay	139	278
Medication expenses	190	210
Out of work	300	410
Total	1804	1678

to gases of these patients, only in one patient from the LT group did the problem last a month.

Immediate postoperative pain felt by the STP group was different in nature, being more dull, vague, and deeper in the perineum than the sharper, more superficial pain in the LT group. The LT patients had more pain during their bowel movements for 2 weeks after surgery and required analgesics for a longer time. However, pain was absent in both groups after 1 month.

The hospital stay in both groups was similar: LT, mean 2.1 (range 2–3) days; ST, 1.6 (range 1–2) days-not significantly different.

LT patients return to normal activity or work later [mean 9.8 (1.9) vs 6.3 (1.5) days, $p < 0.05$], but the total costs and the economic differences incurred are listed in Table 5.

Recurrence was found in three patients in the stapled group and appeared after 6 months.

Discussion

Hemorrhoidal disease is a very common condition in clinical practice. The presence of hemorrhoids is not itself an indication for treatment. The treatment must be aimed at symptomatic relief and the correction of anatomic deformity [17].

The advantages of LT according to our study were the shorter operative time, the cheaper medical charges, and the better long-term results. The advantages of STP were earlier postoperative bowel movement, less pain at bowel movements, lower analgesic requirements during the first 2 weeks, no external wound healing problems, and earlier resumption of normal activity or work (mean, 6.3 days vs 9.8).

The widely performed excision-ligation procedure that cures prolapsing hemorrhoids was first described by Milligan and Morgan [5, 9], can be bloody, and is associated with troublesome postoperative pain. Many modifications in the surgical technique and perioperative care have been suggested but few have produced sufficient evidence to change clinical practice. The use of Ligasure is preferable for fourth-degree hemorrhoids because of the shortened operative time. Improved hemostasis may also offer better visibility and therefore a more accurate dissection. The reduced operative time associated with electrocautery dissection is related to better hemostatic control and lack of any need to ligate the pedicles. The absence of blood in the operative field is such that no time is required to secure hemostasis, and as a consequence the mean operative time is lessened.

In 1993, Longo used a circular stapler which diminished blood perfusion to the anal cushions, resulted in a decrease in size and the reduction of hemorrhoids in their normal position [8]. The procedure was based on Thompson's theory of the physiologic role of anal cushions and the prolapse of anal mucosa [16]. Straining during constipation results in the rupture of the ligament of Treitz and the descent of hemorrhoids into the anal canal. Prolapse of the cushions results in diminution of the venous drainage and further engorgement of the hemorrhoids. The removal of the mucosal and submucosal layer at a level 2–3 cm above the dentate line with the stapler technique provides two advantages: (a) the reduction of mucosal and hemorrhoidal prolapse, which improves venous drainage, and (b) the interruption of the arterial perfusion of the cushions through the superior haemorrhoidal artery. The method is theoretically painless, since the sensitive anal mucosa below the dentate line is not damaged.

We found that the resolution of main hemorrhoidal symptoms was equivalent in the two groups. Some reports are less favorable for STP, involving complications such as chronic anal pain and fecal urgency [1, 14], retrovaginal fistula [15], and pelvic sepsis [6, 11]. In our study there were no such complications in the STP group. Only transient fecal urgency was noticed in five patients of the STP group, while pruritus and discharge were present for <1 month in the Ligasure technique group. However, the

unusual nature of these isolated cases does not support the routine prophylactic use of antibiotics after all stapled hemorrhoidectomies [13].

Minor incontinence occurred postoperatively in two LT patients and one STP patient. Only one patient in LT group remained incontinent to gas for a month. Changes between preoperative and postoperative anorectal manometry were similar in the two groups. A possible cause for this minor incontinence is impaired anal sensation, which may be transiently present up to 6 weeks after LT hemorrhoidectomy [6]. The postoperative pain and the lack of the cushions may be also possible causes of minor incontinence.

STP was found to be safely applicable to most instances of symptomatic prolapsed hemorrhoids, especially of the third degree. Specialist colorectal consultants could readily adapt to this technique, with no life-threatening complications and morbidity rates not different from LT. For patients with hemorrhoids of fourth degree, previous perianal surgery, and perianal scarring, the LT technique is more appropriate, because it is the one that corrects anatomic deformities such as skin tags. The patients' perceived satisfaction and quality-of-life assessment were not different after the two procedures, probably because there was no morbidity from extensive perianal wounds. LT patients resumed work later [mean 9.8 (1.9) vs 6.3 (1.5) days, $p < 0.05$], and the total costs incurred were less.

Stapled hemorrhoidectomy is also indicated whenever there exists a degree of mucosal rectal prolapse and secondary piles are formed between the major ones. One must think of the LT operation when severe external piles are dominant, when the piles are fibrosed, and big skin tags accompany hemorrhoid prolapse [12]. The LT operation has also the advantage of the pathologically examined specimen of excised hemorrhoids to differentiate other pathologies, since the stapler doughnut has no hemorrhoidal tissue. The efficiency and long-term results of stapled hemorrhoidectomy are just becoming apparent, in the present study the recurrence rate was 6% in the STP group.

Conclusions

The stapled technique is a safe and effective option in treating prolapsed piles. It is a little bit more expensive but less painful, with less time needed off work. It remains to be seen whether stapled hemorrhoidectomy becomes the treatment of choice for third-degree hemorrhoids and in cases where secondary piles exist in between the three major ones. This option could be offered to patients on the understanding that the long-term recurrence rates are less well documented. In the meantime, excision hemorrhoidectomy with Ligasure remains the definitive treatment for prolapsing hemorrhoids. The Ligasure technique offers some technical advantages making the excision process easier, quicker, and bloodless. As a technique Ligasure is a better choice for fourth-degree hemorrhoids with excessive skin tags.

References

1. Cheetham Mj, Mortensen NJM, Kamm MA, Phillips RKS (2000) Persistent pain and faecal urgency after stapled haemorrhoidectomy. *Lancet* 356: 730–733
2. Cohen Z (1985) Alternatives to surgical haemorrhoidectomy. *Can J Surg* 28: 230–231
3. Ferguson JA, Heaton JR (1959) Closed haemorrhoidectomy. *Dis Colon Rectum* 2: 176–179
4. Gordam PH, Nivatrons S (1992) Principles and practice of surgery for colon, rectum and anus. Quality Medical, St Louis
5. Hass PA, Fox TA, Haas GP (1984) The pathogenesis of hemorrhoids. *Dis Colon Rectum* 27: 442–450
6. Ho YH, Seow-Choen F, Goh HS (1995) Haemorrhoidectomy and disordered rectal and anal physiology in patients with prolapsed haemorrhoids. *Br J Surg* 82: 596–598
7. Khubchandani IT (1988) Operative haemorrhoidectomy. *Surg Clin North Am* 68: 144–146
8. Longo A (1998) Treatment of hemorrhoids disease by reduction of mucosa and hemorrhoidal prolapse with a circular suturing device: a new procedure. Sixth World Congress of Endoscopic Surgery
9. MacRae HM, McLeod RS (1995) Comparison of haemorrhoidal treatment modalities. A meta-analysis. *Dis Colon Rectum* 38: 687–694
10. Milligan ETC, Morgan C, Naunton Jonws LE (1937) Surgical anatomy of the anal canal and the operative treatment of haemorrhoids. *Lancet* ii: 1119–1124
11. Molloy RG, Kingsmore D (2000) Life threatening pelvis sepsis after stapled haemorrhoidectomy. *Lancet* 355: 810
12. Palazzo FF, Francis DL, Clifton MA (2002) Randomized clinical trial of Ligasure versus open haemorrhoidectomy. *Br J Surg* 89: 154–157
13. Palimento D, Picchio M, Attanasio U, et al. (2003) Stapled and open hemorrhoidectomy: randomized controlled trial of early results. *World J Surg* 27: 203–207
14. Rowsell M, Bello M, Hemingway DM (2000) Circumferential mucosectomy (stapled haemorrhoidectomy) versus conventional haemorrhoidectomy: randomised controlled trial. *Lancet* 4; 355 (92006): 779–781
15. Seow-Choen F (2001) Stapled haemorrhoidectomy: pain or gain. *Br J Surg* 88: 1–3
16. Thompson WHF (1975) The nature of haemorrhoids. *Br J Surg* 62: 542–552
17. Yik-Hong Ho, Wai-Kit Cheong, Tsang C, et al. (2000) Stapled hemorrhoidectomy-cost and effectiveness. Randomized, controlled trial including incontinence scoring, anorectal manometry, and endoanal ultrasound assessments at up to three months. *Dis Colon Rectum* 43: 1666–1675