

Stapled vs Excision Hemorrhoidectomy

Long-term Results of a Prospective Randomized Trial

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Hypothesis: Stapled hemorrhoidectomy offers several advantages over excision hemorrhoidectomy, including reduced postoperative pain, a reduced hospital stay, and an earlier recovery time. Furthermore, stapled hemorrhoidectomy is associated with lower hemorrhoidal recurrence on long-term follow-up.

Design: A randomized prospective trial. Patients were blinded to the operation technique used. Follow-up occurred at 1 and 3 weeks and 12 months postoperatively.

Setting: A university hospital providing primary, secondary, and tertiary care.

Patients: Forty patients with second- and third-degree hemorrhoid disease were randomized to undergo either stapled or excision hemorrhoidectomy. Two patients were excluded. All patients were subject to a follow-up examination.

Interventions: Stapled hemorrhoidectomy (Longo technique) vs excision hemorrhoidectomy (Ferguson technique).

Main Outcome Measures: Operating time, postoperative pain (measured by the visual analog scale), hos-

pital stay, histologic features, morbidity, defecation habit, continence, recovery time (return to work), and hemorrhoid recurrence at 1 year.

Results: Stapled vs excision hemorrhoidectomy was associated with a significantly reduced operating time (30 vs 43.25 minutes; $P < .001$), reduced postoperative pain scores (visual analog score) on the first 4 postoperative days (day 1: 2.7 vs 6.3; day 2: 1.7 vs 6.3; day 3: 0.8 vs 5.4; and day 4: 0.5 vs 4.8, where 0 indicates no pain, and 10, maximum pain; $P \leq .001$), and an earlier return to work (6.7 vs 20.7 days; $P = .001$). There were no differences for stapled vs excision hemorrhoidectomy in length of hospital stay (2.4 vs 2.1 days), complications (3 [15%] of 20 patients vs 5 [25%] of 20 patients), and recurrence rate (1 [5%] of 20 patients vs 1 [5%] of 20 patients).

Conclusions: Stapled hemorrhoidectomy is associated with reduced postoperative pain, earlier recovery time and return to work, and a similar recurrence rate compared with the excision technique. Provided further clinical trials confirm these findings, stapled hemorrhoidectomy may become a future gold standard.

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EXCISION hemorrhoidectomy is associated with significant postoperative pain because of trauma of the sensitive anal mucosa (anoderm). Furthermore, the patients have to maintain a precise wound dressing to prevent local infection, because local wound exposure may lead to fecal contamination and prolonged wound healing.¹ In a small series including 23 patients,² it was shown that the stapled hemorrhoidectomy initially described by Longo³ leads to less postoperative pain, a shorter postoperative hospital stay, and a shorter recovery time in patients with third-degree hemorrhoids

compared with conventional hemorrhoidectomy. Faster wound healing and less postoperative pain have also been observed.⁴ Larger studies^{5,6} comparing the 2 techniques confirmed less postoperative pain and an earlier return to work in the stapler group but showed no difference in total hospital stay and overall complications. However, severe complications following stapled hemorrhoidectomy have been reported in 0.12% of the cases; these complications include sphincter lesions, persistent postoperative pain, rectal perforations, and even lethal sepsis.⁷⁻¹⁰

These controversial results suggest the need for further prospective evalua-

PATIENTS AND METHODS

Between January 1, 1999, and July 31, 2000, 42 patients with symptomatic second- or third-degree hemorrhoid disease, according to the grading of Milles,¹² were included in this prospective randomized study. Two patients refused to participate. The study was approved by the local ethics committee. Following written informed consent, the patients were allocated by drawing lots—generated randomization to undergo either stapled hemorrhoidectomy (the Longo technique³) (n=20) or excision hemorrhoidectomy (the Ferguson technique¹³) (n=20). During the hospital stay, the patients were not informed of the technique performed, but this information was given during a 3-week follow-up examination on request. Because the patients were blinded to the technique used, the same care and dressing of the anal region was performed in both groups in the postoperative period.

The operation was performed under either general anesthesia (in 22 [55%] of the 40 patients) or spinal anesthesia (in 18 [45%] of the 40 patients), depending on the patient's preference and the anesthesiologist's advice, and by the same surgeon (F.H.H.), who was experienced in colorectal and proctologic surgery, with a previous learning curve in stapled hemorrhoidectomy (>30 procedures). Patients were placed in a position for lithotomy. A cleaning enema was given preoperatively. Before extubation, the patients received basic analgesia intravenously (2 g of acetaminophen); patients who were operated on using spinal anesthesia received 0.5% bupivacaine hydrochloride locally. No antibiotics were given in this trial. The hemorrhoidectomy in the conventional group was performed according to the Ferguson technique.¹³ The base of the hemorrhoid was excised and the wound was sutured with a 3.0 polyglactin 910 thread (Vicryl rapid; Ethicon, Inc, Norderstedt, Germany). In 13 patients, this was a 3-pile excision; in 7, it was a 2-pile excision.

In the stapler group, a circular anal dilator (CAD 33; Ethicon Endo-Surgery, Inc, Norderstedt) was introduced to reduce the prolapse of the anoderm and parts of the anal mucous membrane. After removal of the obturator, the prolapsed mucous membrane falls into the lumen of the circular anal dilator. Thus, a purse-string suture, nonabsorbable surgical, of 2-0 polypropylene (Prolene; Ethicon,

Inc) was placed circumferentially 3 to 5 cm above the dentate line through the window of the purse-string suture anoscope (PSA 33; Ethicon Endo-Surgery, Inc). Subsequently, a hemorrhoidal circular stapler (HCS 33; Ethicon Endo-Surgery, Inc) was positioned and fired.³ Finally, in both groups, a hemostatic endoanal dressing (Spongostan anal; Ferrosan, Soeborg, Denmark) was applied. The operating time was defined as the time from the beginning of the operation until the application of the endoanal dressing.

All patients received a normal diet postoperatively and were given lactulose for preventing hard stool. Patients in both groups were requested to perform the same cleaning of the anal region 2 to 3 times per day using a shower. The same type of external anal dressing was applied, and the patients agreed not to inspect the anal region themselves to maintain blinding during the postoperative period.

A pain score data sheet (visual analog scale) was filled out by the patients postoperatively (0 indicates no pain; and 10, maximum pain). Pain scores were evaluated 12 hours later and on the next 3 consecutive postoperative days by a surgeon not involved in the operation. Pain therapy consisted of a basic analgesia (acetaminophen) and addition of subcutaneous injections of meperidine hydrochloride, 25 mg every 3 to 6 hours, on request. At discharge from the hospital, the patients received lactulose, 20 mL daily, and basic analgesia (acetaminophen).

All specimens were analyzed histologically after hematoxylin-eosin staining to detect skeletal or smooth muscle fibers. A continence score was evaluated using the Williams score¹⁴ preoperatively and after 12 weeks.

A follow-up examination was performed 3 and 12 weeks postoperatively by an independent surgeon (not a member of the operating team). Endosonographic control or sphincter manometry were only performed if clinical evidence of sphincter lesions was present. Postoperative complications (with special regard to rectal stenosis), defecation habit, frequency, and return to work postoperatively were evaluated. In addition, a 1-year follow-up examination was performed with special regard to hemorrhoid recurrence. At this examination, defecation habits were evaluated and a proctologic examination was performed.

Statistical analysis was performed by the Mann-Whitney test and the Wilcoxon rank sum test for unpaired data. $P < .05$ was regarded as significant. A power calculation was not performed before the study.

tion and a randomized comparison of stapled vs conventional hemorrhoidectomy. To our knowledge, there are few data comparing the long-term results of stapled vs excision hemorrhoidectomy.¹¹ This prospective randomized study analyzes the outcome of stapled vs excision hemorrhoidectomy in patients with second- or third-degree hemorrhoid disease blinded to the operation technique used, with special regard to the long-term results and recurrence rate.

RESULTS

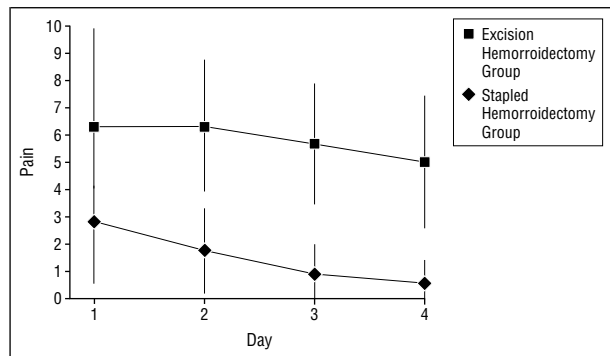
Forty patients were operated on for second-degree (n=12) or third-degree (n=28) hemorrhoids, according to the Milles classification.¹² Ten patients with second-degree hemorrhoids were treated previously by rubber band ligation, and 2 refused the rubber band.

These 12 patients were operated on and included in the study.

Patient characteristics were comparable for age, sex, and grade of hemorrhoid disease. The characteristics of the patients in the 2 groups are as follows:

Characteristic	Stapled Group	Excision Group
Total No.	20	20
Degree of hemorrhoids		
Second	6	6
Third	14	14
Recurrent hemorrhoid	2	3
Age, mean (range), y	50.4 (32-72)	44.8 (28-74)
Male-female ratio	15:5	14:6

The overall operating time was 30 minutes (range, 15-45 minutes) in the stapler group and 43 minutes (range, 25-60 minutes) in the excision group ($P < .001$).



Postoperative pain evaluated by the visual analog scale. Data are given as mean±SD.

Surgery was performed under general anesthesia in 12 of the 20 patients in the stapler group and in 10 of the 20 patients in the excision group, while spinal anesthesia was applied in 8 and 10 patients, respectively.

Using the visual analog scale, mean pain scores were 2.7 (range, 0-8), 1.7 (range, 0-6), 0.8 (range, 0-3), and 0.5 (range, 0-2) on days 1, 2, 3, and 4, respectively, in the stapler group; in the excision group, the respective values were 6.3 (range, 0-10), 6.3 (range, 1-10), 5.4 (range, 1-9), and 4.8 (range, 1-10). The average amount of pain in the stapler group was significantly lower than in the excision group ($P \leq .001$) (**Figure**).

The mean length of the hospital stay after hemorrhoidectomy was 2.4 days (range, 1-4 days) in the stapler group and 2.1 days (range, 1-4 days) in the excision group; this difference was not statistically significant ($P = .17$). Patients returned to work at an average of 6.7 days (range, 2-14 days) in the stapler group and 20.7 days (range, 7-45 days) in the excision group ($P = .001$).

Histologic examinations of resected specimens revealed small parts of skeletal muscle fibers in 3 patients (15%), all in the excision group ($P = .43$). Smooth muscle fibers were found in 4 patients (20%) in the stapler group and in 5 patients (25%) in the excision group ($P = .80$).

Of the 40 study patients, perioperative complications observed included bleeding in 2 patients and perianal thrombosis in 1 patient in the stapler group, and urinary retention in 1 patient and suture dehiscence in 4 patients in the excision group, all occurring within the first postoperative week.

The 2 bleeding complications occurred within 2 hours following surgery and required a subsequent operation. In one patient, a bleeding arterial vessel had to be sutured; in the other patient, the bleeding stopped after internal compression with a balloon catheter for 30 minutes. The total postoperative complication rate was 15% (3 of 20 patients) in the stapler group and 25% (5 of 20 patients) in the excision group ($P = .60$). There were no deaths in either group; and at 1 year, recurrent hemorrhoidal disease occurred in 1 (5%) of the patients in both groups.

A follow-up examination after 3 and 12 weeks (follow-up, 100%) revealed impaired wound healing because of suture dehiscence in 4 of the 40 patients, all in the excision group. No impaired wound healing was observed in the stapler group. No cases of incontinence were observed during the follow-up period. The Williams score, evaluating for incontinence, was 1.0 preoperatively and

postoperatively in the stapler group and 1.1 preoperatively and postoperatively in the excision group.

After 1 year, a total of 2 patients presented with second-degree recurrent hemorrhoidal disease; one was operated on by the excision technique and one was operated on by stapled hemorrhoidectomy. Both recurrent hemorrhoids were treated successfully with a rubber band ligation.

After 1 year, there were neither signs of rectal stenosis nor perirectal fistulas in either group, and none of the patients had residual perianal pain. Because neither signs of sphincter damage nor incontinence were observed in both groups, we did not perform postoperative endosonography or a manometric examination.

COMMENT

The use of a stapler in the treatment of hemorrhoids remains controversial. The results of a prospective randomized study comparing the gold standard—excision hemorrhoidectomy—with the new stapler technique, with patients blinded to the type of procedure, are important. We observed a significant reduction of postoperative pain in the patients who underwent stapled hemorrhoidectomy. Four patients in the stapler group were pain free on the first operative day. Our results confirm those of 5 previous randomized trials^{2,4,6,11} on stapled vs conventional hemorrhoidectomy.

The total operating time was significantly shorter with the stapler technique in this trial (30 vs 43 minutes; $P < .001$). However, this time is 5 to 10 minutes longer than observed by others.^{2,4,5} We routinely performed a dilatation of the anal sphincter before stapler introduction, which may explain this slightly prolonged operating time.

Except for one postoperative bleeding episode, which required a blood transfusion and revision, no other severe complications were observed in the stapled hemorrhoidectomy group, especially no local or systemic infections.¹⁵ The bleeding observed resulted most likely from an undetected vessel within the stapler line. This complication may be prevented if adequate hemostasis around the stapler line is obtained routinely and each bleeding vessel is sutured.

A concern about stapled hemorrhoidectomy is the potential risk of strictures after rectal wall resection.¹⁶ Even though a total of 20 histologic examinations of stapled hemorrhoids revealed partial rectum wall margins with smooth muscle, there was no clinical sign of rectal strictures or stenosis after 12 months. It was not possible to differentiate if the smooth muscle fibers originated from the rectal wall or from the internal sphincter. However, we observed no incontinence in any patient at any time. The histologic analysis revealed skeletal fibers in 3 patients in the excision group but only in a small quantity. This finding excludes the possibility that the excision hemorrhoidectomy may have been performed too deeply. Moreover, there was no incontinence in any patient at any time.

As expected in the excision group, there were always parts of mucosa from the anal canal. If the resection is high enough above the dentate line in the stapler group, absence of mucosa of the anal canal in the histologic finding may exclude potential sphincter damage. Squamous cell epithelia were never demonstrated, but in 2 patients, small

parts of epithelium of the anal canal were observed. One of these patients complained about more postoperative pain (visual analog scale score: day 1, 7; day 2, 6; and day 3, 3) than the mean of patients in the stapler group. This finding is most likely a result of a resection margin close to the sensitive epithelium of the anal canal area, and may explain the bad results on pain observed in a famous study on stapled hemorrhoidectomy performed in an established colorectal center by Cheetham et al.⁷ The researchers decided to interrupt their study because patients in the stapler group had significantly more postoperative pain. This publication remained controversial, and was challenged in several letters to the editor.¹⁷⁻²⁰

In our series including a 1-year follow-up, none of the patients had persistent residual pain. This suggests that great attention has to be given to the level of the stapler line 3 to 5 cm above the dentate line, as initially recommended by Longo²¹ and confirmed by others.^{2,19} Thereafter, the complete resection line is located above the anodermal line, out of the sensitive nerves, thus explaining the absence of pain.

The pathophysiologic background of the treatment of hemorrhoidal disease by stapler is different than the pathophysiologic basis for excision hemorrhoidectomy, and is being controversially discussed. The complete circular mucosa cranial to the hemorrhoidal plexus is resected, allowing reduction of mucosa prolapse by mucosa lifting and by fixing the prolapsed mucosa at the rectum wall. The reduction of arterial blood flow to the hemorrhoidal plexus is probably not the main point of the treatment. A Doppler investigation with preoperative and postoperative measurement of the arterial inflow to the hemorrhoidal cushion did not show any significant differences.²² The repositioning of the prolapsed mucosa and thereby the improvement of the venous reflux may be the key of the treatment, but further investigations are necessary to clarify this point.

The indication for stapled hemorrhoidectomy in our study included third-degree hemorrhoids and second-degree hemorrhoids after an unsuccessful nonoperative treatment (eg, a rubber band ligature). Fourth-degree hemorrhoids are usually not regarded as a contraindication for stapled hemorrhoidectomy,³ but were not included in the present study.

The incidence of hemorrhoid recurrence did not differ in the 2 groups within the 1-year follow-up, but a longer follow-up should be observed.

We did not evaluate the postoperative analgesic medication taken, which may limit the interpretation of this observation; however, even though both patient groups had free access to minor analgesics, the stapler group had significantly less pain than the excision group (average visual analog scale score, 1.4 vs 5.7; $P < .001$). In a randomized trial, Mehigan et al⁵ reported a 50% reduction in postoperative pain medication consumption in patients who underwent stapled hemorrhoidectomy compared with patients who underwent excision (Milligan-Morgan) hemorrhoidectomy. The rather small number of patients who were included in the study limits the interpretation of the results. However, the results of our prospective, randomized, patient-blinded study are in accordance with the results of the 4 other studies^{2,4-6} comparing stapled hemorrhoidectomy with excision hemorrhoidectomy.

We conclude that with an adequate handle of the stapler procedure, including sufficient sphincter dilatation before stapler placement, a resection line at least 3 cm above the dentate line, and a cautious hemostasis during surgery, stapled hemorrhoidectomy is a safe and reliable procedure in the treatment of second- and third-degree hemorrhoids. It offers a similar clinical outcome as excision hemorrhoidectomy while offering a significantly shorter operating time, significantly reduced postoperative pain, an earlier return to work, and low recurrence at 1 year. Provided further clinical trials confirm the findings of our study, stapled hemorrhoidectomy may become a new standard in the treatment of hemorrhoid disease.

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