

Harmonic Scalpel[®] Hemorrhoidectomy

Five Hundred Consecutive Cases

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PURPOSE: The aim of this study was to evaluate the incidence of postoperative complications after Harmonic Scalpel[®] hemorrhoidectomy and to identify any predisposing factors leading to postoperative complications. **METHODS:** Five hundred consecutive cases of Harmonic Scalpel[®] hemorrhoidectomy were studied in a prospective manner. Postoperative complications were recorded, and any predisposing factors were evaluated. **RESULTS:** Three hundred fifty-five patients (71 percent) underwent Harmonic Scalpel[®] hemorrhoidectomy alone. One hundred twenty patients (24 percent) underwent additional fissurectomy/sphincterotomy for fissure-in-ano, and 25 patients (5 percent) underwent additional fistulotomy. A total of 24 (4.8 percent) patients experienced some form of postoperative complication. Three patients (0.6 percent) experienced a secondary postoperative hemorrhage requiring reexploration under anesthesia. Two of the three patients were taking postoperative oral Toradol[®], and both had undergone an "open" hemorrhoidectomy technique. The third patient required suture ligation of multiple bleeding sites on two separate occasions at 7 and 14 days postoperatively. The patient was subsequently diagnosed as having Ehlers-Danlos syndrome. One patient experienced postoperative incontinence to flatus and stool. The patient had large, Grade IV postpartum hemorrhoids and had undergone a three-quadrant closed hemorrhoidectomy. The sphincter mechanism was intact on postoperative ultrasound, and an underlying pudendal neuropathy likely contributed to the sphincter dysfunction. Postoperative urinary retention was noted in 10 (2 percent) patients, postoperative fissure in 5 (1 percent), and abscess/fistula in 4 (0.8 percent). One patient (0.2 percent) required readmission for colonic pseudo-obstruction. **CONCLUSION:** Harmonic Scalpel[®] hemorrhoidectomy is a safe surgical modality, and postoperative complication rates compare favorably with previously published studies. The combination of an "open" hemorrhoidectomy technique and prolonged oral Toradol[®] administration may result in a higher incidence of postoperative hemorrhage. [Key words: Hemorrhoidectomy; Harmonic Scalpel[®]; Postoperative complications]

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Harmonic Scalpel[®] (Ethicon EndoSurgery, Cincinnati, OH) hemorrhoidectomy is a relatively new surgical modality in the treatment of symptomatic

Grade II or III internal hemorrhoids in association with external components. Its role in the surgical treatment of advanced hemorrhoidal disease is currently under evaluation; however, a recently published study by our group demonstrated diminished postoperative pain after Harmonic Scalpel[®] hemorrhoidectomy, compared with electrocautery controls.¹

The Harmonic Scalpel[®] results in a minimal lateral thermal injury² (0 to 1.5 mm deep), and this is believed to be the reason for the diminished postoperative discomfort. Hemostasis is established by coaptation of blood vessels and disruption of tertiary protein bonds, which results in a protein coagulum in the vessel lumen. One concern surrounding the procedure was the hemostatic stability of a relatively shallow area of vessel coagulation. The incidence of postoperative complications after Harmonic Scalpel[®] hemorrhoidectomy was therefore studied in a prospective manner in a large series of patients. The incidence of primary and secondary postoperative hemorrhage was determined, and any potential predisposing factors were evaluated.

PATIENTS AND METHODS

Patients undergoing Harmonic Scalpel[®] hemorrhoidectomy during a two-year period (October 1998 to October 2000) were evaluated in a prospective manner. Indications for hemorrhoidectomy were symptomatic Grade II or III internal hemorrhoids in conjunction with large external components, or prolapsed, thrombosed Grade IV hemorrhoids. Informed consent for Harmonic Scalpel[®] hemorrhoidectomy was obtained from all patients. Patient demographics, stage of hemorrhoidal disease, associated pathology (fissure and fistula), and admission data were recorded (Table 1). Operative details (open *vs.* closed technique) and any additional surgical procedure (fissurectomy, sphincterotomy, fistulotomy) were noted. Postoperative pain was managed using a combination of oral analgesics (10 mg of hydrocodone every four to six hours as needed), fiber supplements, copious

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Table 1.
Study Variables Recorded for Harmonic Scalpel®
Hemorrhoidectomy Patients

Age (yr)
Gender (M/F)
Admission status (outpatient/overnight/inpatient)
Hemorrhoidal grade (III/IV)
Quadrants (2, 3, or 4)
Incision status (open/closed)
Postoperative complications
Hemorrhage (primary/secondary)
Anorectal incontinence
Fistula/abscess
Fissure/stricture
Urinary retention
Fecal impaction
Readmission <30 days
Reoperation <90 days

oral fluids, mineral oil nightly, and warm soaks or Sitz baths as needed.

All patients were reviewed at two and four weeks postoperatively. The need for further follow-up was determined on an individual basis, depending on the presence of postoperative complications or the need for subsequent surgery. Postoperative complications were recorded for each patient in addition to readmissions to the hospital within 30 days. Any additional surgical procedure required within 90 days was recorded. Urinary retention was defined as the need for an indwelling Foley catheter for a minimum of 24 hours postoperatively. The definition of postoperative hemorrhage was confined to those patients requiring formal surgical exploration under anesthesia.

RESULTS

Five hundred patients underwent surgical hemorrhoidectomy during the two-year study. Three hundred fifty-five (71 percent) patients underwent Harmonic Scalpel® hemorrhoidectomy alone. One hundred twenty patients (24 percent) underwent a combined hemorrhoidectomy, fissurectomy, and sphincterotomy. Twenty-five patients (5 percent) underwent hemorrhoidectomy and fistulotomy. Four hundred forty-five patients (89 percent) had surgery on an outpatient basis, and 48 (9.6 percent) were admitted overnight. Seven patients were operated on as inpatients, either because of severe comorbid disease (paraplegia, two patients), combined surgery (hysterectomy, two patients), or emergency admission for gastrointestinal bleeding (three patients).

Postoperative complications were identified in 24

(4.8 percent) patients (Table 2). Ten patients (2 percent) experienced postoperative urinary retention, requiring an indwelling urinary catheter for a minimum of 24 hours. Five patients (1 percent) developed intractable posthemorrhoidectomy fissure-in-ano requiring surgical correction. Four patients (0.8 percent) developed postoperative abscess/fistula, of which two had undergone combined fistulotomy during their original surgery: these fistulas were probably persistent tracts, rather than surgical in nature. A third patient was eventually diagnosed with anorectal Crohn's disease, and the fourth developed anal stenosis from subcutaneous fistula formation in the (closed) surgical incisions.

No patient experienced early (primary) postoperative hemorrhage; however, three patients (0.6 percent) experienced secondary hemorrhage at 7 to 14 days postoperatively. Two patients (both males) were taking oral Toradol® (Roche, Nutley, NJ) during the postoperative period for five to seven days, and additionally, both had undergone an "open" hemorrhoidectomy technique. Both patients underwent re-examination under anesthesia for secondary postoperative hemorrhage, and the bleeding sites were suture ligated, with permanent resolution of the hemorrhage. It is believed that the combination of an "open" surgical incision in association with Toradol®-induced thrombocytopenia was responsible for both instances. The third patient with postoperative hemorrhage (a 65-year-old female) experienced copious rectal bleeding on day 7 and was returned immediately to the operating room. Multiple bleeding sites were suture ligated; however, she developed a further episode of significant rectal bleeding seven days later, requiring reexploration and suture ligation. The patient was eventually diagnosed with Ehlers-Danlos syndrome. There was no recurrent hemorrhage after the second reexploration.

Table 2.
Postoperative Complications After Harmonic Scalpel®
Hemorrhoidectomy

Complication	Number	%
Hemorrhage	3	0.6
Incontinence	1	0.2
Urinary retention	10	2
Abscess/fistula	4	0.8
Fissure	5	1
Pseudo-obstruction	1	0.2
Fecal disimpaction	0	0
Total	24	4.8

One patient developed anorectal incontinence. The patient (a 26-year-old female) underwent three-quadrant hemorrhoidectomy for large, Grade IV hemorrhoids six weeks after a full-term vaginal delivery. The patient experienced incontinence to stool and flatus soon after surgery, and this persisted for several months, despite fiber supplements. Anorectal ultrasound at six weeks confirmed the integrity of the internal and external sphincters, and by 18 months the patient reported near-complete resolution of her symptoms.

One patient required readmission on the second day postoperatively for colonic pseudo-obstruction. The patient was treated conservatively with intravenous fluids, nasogastric suction, and prokinetic agents. The patient underwent colonoscopic decompression and was discharged on the fifth hospital day.

Of the 24 (4.8 percent) patients experiencing postoperative complications, 13 (2.6 percent) required readmission to the hospital on an urgent or elective basis. Three patients required examination under anesthesia for postoperative hemorrhage, five patients required elective fissurectomy/sphincterotomy for fissure, and four patients required elective procedures for postoperative fistula-in-ano. One patient was readmitted with colonic pseudo-obstruction, for a total of 13 patients.

DISCUSSION

Several authors have previously examined postoperative complication rates after multiple variants of surgical hemorrhoidectomy³⁻¹²; however, no surgical technique or surgical instrument has been consistently demonstrated as being superior over another.

The reported incidence of some postoperative complications varies widely from study to study, primarily as a result of varying definitions of problems such as postoperative hemorrhage, fecal incontinence, and urinary retention (Tables 3 and 4). Nonetheless, post-hemorrhoidectomy complication rates have remained largely unchanged over the last ten years. One consistent trend during the last decade has been a dramatic decrease in the number of hospital days required for the procedure, which is now performed routinely on an outpatient basis.^{3, 9} This is reflected in the current study, in which 89 percent of patients underwent surgery as outpatients, and only 48 (9.6 percent) were admitted overnight.

Postoperative pain is the most distressing concern for the patient after hemorrhoidectomy, and many studies have evaluated various analgesic regimens, operative techniques, and surgical instruments to address this important issue. A previously published study by our group demonstrated diminished postoperative pain after Harmonic Scalpel[®] hemorrhoidectomy *vs.* hemorrhoidectomy using electrocautery.¹ The study prospectively randomized 50 patients into either Harmonic Scalpel[®] or electrocautery groups. Postoperative pain was recorded in all patients, using a linear analog pain scale, and results were compared at 1, 2, 7, 14, and 28 days postoperatively. Significantly less pain was reported in the Harmonic Scalpel group at 1, 2, 7, 14, and 28 days postoperatively. Additionally, the Harmonic Scalpel[®] group also required significantly fewer narcotic analgesics during the postoperative period. A reduced lateral thermal injury from the Harmonic Scalpel[®] may be the reason

Table 3.
Posthemorrhoidectomy Complications: Urinary Retention, Impaction, Abscess, and Fissure

Author	Group	Urinary Retention	Fecal Impaction	Abscess/Fistula	Fissure/Strict
Lacerda-Filho ⁹	Inpatient	36	0	2	6
	Outpatient	2	2	2.1	6.1
Buls ¹¹	—	10	4	0	—
Bleday ¹²	—	17.1	2.4	0.5	—
Neto ⁶	Open	4	—	0	—
	Semiopen	11.3	—	0.6	—
Wang ⁵	Scalpel	—	2.2	—	—
	Laser	—	2.2	—	—
Ho ⁸	Open	—	9	—	—
	Semiopen	—	0	—	—
Seow-Choen ⁷	Radical	—	—	—	21
	Four quadrant	—	—	—	14

Figures are percentages.

Table 4.
Posthemorrhoidectomy Complications: Postoperative Secondary Hemorrhage and Incontinence

Author	Year	Group	Patients	Hemorrhage (%)	Incontinence (%)
Wang ⁵	1991	Scalpel	44	2.2	—
		Laser	44	2.2	—
Neto ⁶	1992	Open	150	0	—
		Semiopen	150	0.6	—
Seow-Choen ⁷	1994	Radical	14	0	0
		Four-quadrant	14	0	16
Ho ⁸	1997	Open	34	5	—
		Semiopen	33	9	—
Lacerda-Filho ⁹	1997	Inpatient	50	2	4
		Outpatient	47	4	2.1
Hosch ¹⁰	1998	Milligan-Morgan	17	0	6
		Parks	17	0	0

for the diminished pain, compared with electrocautery controls.

The two complications causing the most concern after surgical hemorrhoidectomy are postoperative hemorrhage, which can occasionally be life threatening, and anorectal incontinence, which may be permanent, in the setting of sphincter damage. The incidence of postoperative hemorrhage in the current study (3 patients or 0.6 percent) compares very favorably with previous large studies (Table 4), which report rates from 0.4 percent to 4 percent.^{5-10, 13, 14} Neto *et al.*⁶ in 1997 compared an open hemorrhoidectomy technique with a closed procedure. Postoperative hemorrhage was reported as 5 percent in the open procedures but was surprisingly higher (9 percent) after the closed procedure. These figures are much higher than comparable studies; however, the study included patients not requiring formal surgical reexploration in their definition of postoperative hemorrhage. In the current study, two of the three patients who experienced postoperative hemorrhage were taking oral Toradol[®] in the postoperative period in excess of the currently recommended time limit of five days.¹⁵ The resulting thrombocytopenia together with an "open" surgical technique may have been responsible for the hemorrhage. A total of 18 patients underwent an "open" hemorrhoidectomy in the current study, and the remaining 482 underwent a "closed" procedure, as a direct result of this early experience. A closed procedure remains our current preference, in addition to avoiding postoperative Toradol[®] whenever possible, and restricting its use to a maximum of 48 hours, when absolutely necessary. The third patient who experienced postoperative hemorrhage was subsequently diagnosed as having Ehlers-Danlos syndrome. This well-described connec-

tive tissue anomaly characteristically results in postoperative hemorrhage from "open" surgical defects.¹⁶ Although the surgical defects were closed in this particular instance, this did not prevent two postoperative bleeds, each of which required reexploration. The patient was diagnosed with Ehlers-Danlos syndrome after the second reexploration, and a strong family trait was uncovered subsequent to this. The patient and her family had been hitherto unaware of the familial syndrome.

The incidence of anorectal incontinence is rarely mentioned in most large hemorrhoidectomy studies, either because of its extreme rarity or because of difficulties in assessing its severity. What may be regarded as minor soiling in one study may be considered low-grade incontinence in another. In 1997, Lacerda-Filho and Cunha-Melo⁹ reported an incontinence rate of 4 percent in inpatient hemorrhoidectomies, compared with 2.1 percent of outpatient procedures (Table 4). Seow-Choen and Low⁷ in 1994 reported an incontinence rate of 16 percent after a four-quadrant hemorrhoidectomy for circumferential hemorrhoids, compared with 0 percent after "radical" hemorrhoidectomy. This high rate is almost certainly the result of a liberal definition of incontinence; however, these studies serve to emphasize that posthemorrhoidectomy incontinence remains a real possibility. The patient experiencing anorectal incontinence in the current study underwent three-quadrant closed hemorrhoidectomy for large, gangrenous, Grade IV hemorrhoids. The patient underwent surgery six weeks after a normal full-term vaginal delivery. Incontinence to stool and flatus was noted soon after the procedure, and the problem persisted despite fiber supplements and Kegel exercises. A subsequent anorectal ultrasound confirmed the integrity

of the internal and external anal sphincters. An associated postpartum pudendal neuropathy almost certainly contributed to the sphincter dysfunction, and longer-term follow-up is awaited. The case serves to underline the very real nature of postoperative incontinence, which in the hands of an experience surgeon, is most commonly seen in large, high-grade hemorrhoidal disease and often associated with preexisting neuropathy.

The incidence of urinary retention in the current study (2 percent) compares very favorably with the previously reported rates of 2 percent to 36 percent.^{6, 9, 11, 12} Intraoperative intravenous fluid restriction is almost certainly the single most important factor contributing to a low rate of postoperative urinary retention. No patients required manual fecal disimpaction in the current study, which was necessary in 2 percent to 9 percent of patients in previous large studies.^{5, 8, 9, 11, 12}

The current rates of postoperative abscess/fistula (0.8 percent) again compare very favorably with previous reported rates of 0.5 percent to 2.1 percent.^{6, 9, 11, 12} Two of the four patients experiencing postoperative abscess/fistula had undergone a fistulotomy in conjunction with their original hemorrhoidectomy. This almost certainly represents a persistent fistula tract as opposed to an iatrogenic fistula. A third patient was eventually diagnosed with anorectal Crohn's disease, and the fourth patient developed anal stenosis from subcutaneous fistulas in all three surgical closure sites. Three-quadrant subcutaneous fistulotomy was performed, and the stenosis was resolved without impaired continence.

The current configuration of the Harmonic Scalpel[®] blade does not lend itself easily to performing a technically satisfactory fistulotomy, and this technical issue may have contributed to the relatively high rate of persistent fistula. The same issue arises during sphincterotomy for fissure: the current blade configuration does not lend itself easily to isolating and dividing the internal sphincter, although no instance of postoperative abscess was identified in any of the 120 patients undergoing combined sphincterotomy.

The five patients (1 percent) experiencing persistent posthemorrhoidectomy fissure also compares favorably with the previous report by Lacerda-Filho and Cunha-Melo⁹ in 1997, who reported a 6 percent incidence of fissure after inpatient hemorrhoidectomy and 4 percent after outpatient hemorrhoidectomy. This somewhat high incidence in the latter study also

includes patients not requiring surgical correction of the fissure.

An important caveat to this study, and our previous report, concerns the increased expense involved in using the Harmonic Scalpel[®]. This amounts to approximately \$350 each for the disposable Coagulating Shears[®] and an additional \$15,000 capital expenditure for each generator. This important point deserves repeating, because this cost is currently not reimbursed separately under the ambulatory payment class for hemorrhoidectomy. This therefore adds substantially to the cost of the procedure and may have significant implications for a hospital or ambulatory care center performing a large number of hemorrhoidectomies.

Nonetheless, Harmonic Scalpel[®] hemorrhoidectomy is a safe and effective surgical modality. Although the incidence of postoperative hemorrhage compares very favorably with previous large studies, the surgical defects should be closed to minimize the risk, and postoperative Toradol[®] administration should be limited to 24-hour to 48-hour usage. The one instance of anorectal incontinence reported here is likely attributable to advanced hemorrhoidal disease and/or postpartum pudendal neuropathy, rather than an issue of surgical technique or instrument.

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