Stapled Hemorrhoidopexy: The Argument for Usage

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ABSTRACT

Stapled hemorrhoidopexy is a new procedure for the treatment of symptomatic internal hemorrhoids. Experience and prospective trials are helping to define this procedure's role. Published data confirm that stapled hemorrhoidopexy offers similar control of symptoms with the benefits of reduced postoperative pain when compared with excisional techniques. Reduction in pain is the most significant benefit of this operation. Clearly, the cost of the stapling device exceeds the cost of the sutures required to perform an excisional hemorrhoidectomy. Patients should undergo medical therapy and rubber band ligation first; however, patients being considered for excisional hemorrhoidectomy should be offered stapled hemorrhoidectomy as a less painful alternative.

KEYWORDS: Hemorrhoidectomy, stapled hemorrhoidopexy, hemorrhoids

Objectives: Upon completion of this article, the reader will be able to discuss the advantages and limitations of a stapled hemorrhoidopexy.

Stapled hemorrhoidopexy has gained wide attention in recent years, stimulating a large number of academic presentations, editorials, retrospective reviews, and prospective clinical trials.[1–16] This new operation has the potential to transform the treatment of internal hemorrhoids as it represents a fundamental change in the surgical management of hemorrhoids. A substantial body of evidence now exists to support the fact that stapled hemorrhoidopexy causes less postoperative pain than excisional hemorrhoidectomy while achieving equivalent postoperative results. This review examines the mechanism of action, operative technique, clinical data, and complications of stapled hemorrhoidopexy that have been published to date.

Stapled hemorrhoidopexy is clearly an operative technique and therefore should be considered an alternative to excisional hemorrhoidectomy. Any discussion of stapled hemorrhoidectomy must be centered around the other operative therapies available for hemorrhoids. The Ferguson closed hemorrhoidectomy and the Milligan-Morgan open hemorrhoidectomy have been demonstrated to be equally effective while causing similar postoperative pain.[17] The substantial postoperative pain caused by these operations is related to the wounds on the anoderm, postoperative inflammation, edema, sphincter spasm, secondary bacterial infection, passage of hard stools, psychological background, and pain tolerance. A variety of techniques used in the perioperative time have been closely examined in clinical trials; however, none have become convincingly effective at significantly reducing postoperative pain after excisional hemorrhoidectomy.[17–31]

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In 1998, Italian surgeon Antonio Longo described the "procedure for prolapse and hemorrhoids" (PPH),[32] which we prefer to call stapled hemorrhoidopexy. This procedure combines the favorable aspects of both fixative and excisional techniques. It corrects the anatomic and physiologic abnormalities of symptomatic, prolapsing hemorrhoids without leaving painful external wounds. The stapled hemorrhoidopexy makes use of the theory of fixation by returning the vascular cushions to their anatomic location high in the anal canal. As successful outcomes inherently depend on the surgical technique and perioperative management for any procedure, the details of stapled hemorrhoidopexy will be discussed. Significant variation from these recommendations may, in some cases, account for less than satisfactory results.

Operative Technique

Stapled hemorrhoidopexy makes use of a specifically designed circular stapling device that differs from traditional circular staplers used for the purpose of creating full-thickness anastomoses. The Proximate® HCS Hemorrhoidal Circular Stapler (Ethicon Endo-Surgery, Cincinnati, OH) is the only device recommended for this operation. Although conventional circular staplers have been used to treat hemorrhoids,[33–35] we do not recommend this practice because of the risk of creating a full-thickness anastomosis. The housing around the head of the hemorrhoidopexy stapler can accommodate the redundant mucosa while excising and stapling only the mucosa-submucosa of the rectum. The operation can be safely performed in the prone, lithotomy, or left lateral position, depending on the surgeon's preference. In our practice, prone jackknife is used because we believe it allows the most thorough assessment of the anal canal. Furthermore, placement of the purse-string suture can be awkward if the patient is in the lithotomy position, particularly while operating on the anterior aspect of the anal canal. However, any position would be acceptable as long as the surgeon is comfortable placing the circumferential purse-string suture.

The circular anoscope included in the Ethicon kit has an external diameter of 37 mm; therefore, the anus should be progressively dilated up to four fingers to accommodate this large anoscope. After dilation, the circular anoscope and obturator are inserted into the rectum. The obturator is removed and the purse-string suture anoscope inserted through the circular anoscope to facilitate the placement of a circumferential purse-string suture (2-0 polypropylene) into the mucosa and submucosa, about 2 cm proximal to the apex of the hemorrhoids. In female patients, the surgeon inserts a finger into the vagina while placing the sutures in the anterior rectal wall to ensure that the suture was not placed into the posterior vaginal wall. Once completed, the purse-string suture is gently tightened to draw the redundant mucosa into the lumen of the rectum. Next, the fully opened stapler is inserted across the anus and through the purse-string suture. The purse-string suture is then tightened and tied around the shaft of the stapler. The suture threader is used to pull the free ends of the suture through lateral channels on the stapler housing. Next, three maneuvers are simultaneously performed: gentle traction on the suture, tightening of the stapler head, and advancing the stapler into the rectum. When the head is fully tightened, the 4-cm mark on the housing of the stapler should be at the anal verge. In female patients, the vagina is examined again to confirm that the posterior vaginal wall was not drawn into the head of the stapler. Patients with a deep pouch of Douglas, such as multiparous females with rectoceles, may be at higher risk of entrapment of the peritoneum or vagina with the anterior aspect of the rectal wall at this stage of the operation. The stapler is then fired and held closed for 1 minute to assist in hemostasis. The head of the stapler is opened two full turns, and the stapler and circular anoscope are removed together as a single unit. The specimen is retrieved from the stapler and inspected by the surgeon to verify that a complete circumferential ring of tissue was excised. A digital examination confirms that the staple line is circumferential. The purse-string anoscope or a large Hill-Ferguson retractor is then inserted into the anus to inspect for bleeding at the staple line. If bleeding is present, 3-0 absorbable sutures are used to oversew the staple line. Concomitant procedures should be performed only as necessary on an individual basis.

The stapled hemorrhoidopexy is not a true hemorrhoidectomy. The stapling device excises a circumferential strip of the redundant mucosa-submucosa at the proximal aspect of the internal hemorrhoids. The excised tissue contains only a small portion of the internal hemorrhoidal tissue. The stapled anastomosis returns the internal hemorrhoids to their anatomic position within the anal canal, thereby serving as a neosuspensory ligament that is ultimately replaced by native fibrotic tissue. Thus, the stapled hemorrhoidopexy is primarily a suspensory, or fixative, technique. By restoring the internal hemorrhoids to this position and avoiding prolapse, venous drainage is improved and the remaining hemorrhoidal tissue will decrease in size back to the normally present vascular cushions. In addition, the circumferential division of the submucosal plane interrupts the terminal branches of the superior hemorrhoidal arteries (i.e., the arterial inflow to the hemorrhoids), further contributing to the reduction in size of the hemorrhoids. The reduction of arterial inflow to the hemorrhoids is probably a secondary contribution.[36] It is more probable that the repositioning of the mucosa and the subsequent improvement in venous drainage are the keys to treatment. Because there are no wounds in the

anoderm and the staple line is well above, or proximal, to the dentate line, postoperative pain is significantly reduced compared with excisional techniques. Thus, stapled hemorrhoidopexy provides the fixation of nonoperative techniques while offering patients single-session treatment and avoiding a painful cutaneous wound.

The purse-string suture essentially drives the remainder of the operation. The stapling itself is done blindly because the surgeon cannot see inside the anal canal as the stapler draws tissue into the head. Only correct placement of the suture can guarantee that the proper depth of tissue is drawn into the head, thereby preventing a full-thickness anastomosis, and also the proper position above the dentate line. Attempts to minimize postoperative pain by placing the purse-string suture too proximal to the dentate line result in inadequate retraction of the redundant mucosa in the cephalad direction and yield a poor outcome. In addition, placing the staple line very high may place it at an intraperitoneal location, increasing the chances for intra-abdominal complications. Placing the suture and resultant staple line too low, that is, near the dentate line, gives a much improved cosmetic result with excellent retraction of the hemorrhoids into the anal canal; however, this puts the patient at significant risk for severe postoperative pain. Therefore, our recommendation is that the suture line is placed 2 cm above (proximal) to the apex of the hemorrhoids. This yields a staple line approximately 2 to 4 cm proximal to the dentate line, once the mucosectomy and stapled anastomosis are performed. The amount of hemorrhoidal tissue included in the stapler head is inconsequential and should be ignored during the operative procedure.

Anesthesia

Stapled hemorrhoidopexy can be safely performed with general,[2–5,8,13,16] regional,[4,7–10,15,16] or local anesthesia.[37] At our institution, we primarily use regional anesthesia as it allows a thorough examination of the anorectum and accommodates additional procedures that are deemed necessary at the time of the hemorrhoidopexy. The choice of anesthetic technique should be the decision of the patient, surgeon, and anesthesiologist, as all three are safe and feasible.

Bowel Preparation

A formal mechanical bowel preparation is not necessary as the stapled anastomosis does not violate the full thickness of the rectal wall. Although perforation and full-thickness anastomosis are risks of this operation, they occur so infrequently that preoperative antibiotics or mechanical bowel preparation is not justified. A Fleet enema on the morning of the operation is adequate bowel preparation.

Selection of Patients

Stapled hemorrhoidopexy is an alternative to excisional hemorrhoidectomy; therefore, selection of patients should include only patients being considered for excisional hemorrhoidectomy. This includes primarily patients with grade III hemorrhoids (prolapsing internal hemorrhoids requiring manual reduction). In addition, patients with large grade II hemorrhoids that would be unlikely to respond to one or two sessions of rubber band ligation (RBL) are suitable operative candidates. The manufacturer of the stapling device does not recommend it; however, evidence exists suggesting that stapled hemorrhoidopexy is safe and effective in patients with grade IV (irreducible prolapse) and even thrombosed internal hemorrhoids.[4,5]

Randomized Trials

Although a large number of editorials, case reports, and individual and institutional experiences and reviews[38–59] have been published, this discussion focuses on the prospective randomized trials[1–16] currently published in the literature. The majority of the randomized trials compared stapled hemorrhoidopexy with either Milligan-Morgan[1–6,9–15] or Ferguson[7,8,16] hemorrhoidectomies, but one trial compared stapled hemorrhoidopexy and RBL.[60] This trial is discussed individually as it represents a unique comparison.

Several authors[33–35] describe the use of conventional circular staplers for the purpose of stapled hemorrhoidopexy. We do not recommend, and therefore do not discuss, the use of these staplers because of the risk of creating a full-thickness anastomosis, which is the intended purpose of those instruments.

Because of the wide variety of studies and outcomes measured, we discuss the data by outcome measure rather than assessing each study individually. This discussion highlights the overall conclusions that can be drawn from the existing literature.

Operating Time

Mean operative time was compared in 14 studies (Table 1). Stapled hemorrhoidopexy was significantly shorter in 11 of these trials and similar in the remaining 3 trials. Of note, none of the trials demonstrated excisional techniques to be faster than stapled hemorrhoidopexy. Most trials demonstrated that PPH requires about 15 to 25 minutes, which is consistent with our own experience.

Intraoperative Blood Loss

Only two trials reported intraoperative blood loss, both of which significantly favored stapled hemorrhoidopexy (Wilson et al[11] 7 versus 39 g, $p < .001$; Senagore et al[16] 26.4 versus 46.9 mL, $p = .016$).

Table 1 Operative Time for Stapled Hemorrhoidopexy (Procedure for Prolapse and Hemorrhoids) and Excisional Hemorrhoidectomy

Author	PPH (min)	Excisional (min)	*p* Value
Ho[1]	17.6	11.4	<.001
Mehigan[2]	18	22	.007
Rowsell[3]	14.1	14.8	NS
Boccasanta[4]	25	50	<.001
Brown[5]	15	15	<.05
Shalaby[6]	9	19.7	<.001
Correa[7]	11	46.4	<.001
Hetzer[8]	30	43	<.001
Ortiz[9]	19	33.5	.001
Pavlidis[10]	23	35	<.05
Wilson[11]	12	18	<.001
Kairaluoma[13]	21	22	NS
Palimento[15]	25	30	.041
Senagore[16]	31	35	NS

Note that all trials showed the procedure for prolapse and hemorrhoids to be similar to or faster than excisional hemorrhoidectomy.

Table 2 Time to Return to Regular Activity and Work

Author	PPH (days)	Excisional (days)	*p* value
Ho[1]	17.1	22.9	<.05
Mehigan[2]	17	34	.0002
Rowsell[3]	8.1	16.9	<.005
Boccasanta[4]	8.0	15	<.001
Brown[5]	14	28	<.05
Shalaby[6]	8.2	53.9	<.001
Hetzer[8]	6.7	20.7	.001
Ortiz[9]	23	27	NS
Wilson[11]	6.1	15.2	<.001
Cheetham[12]	10	14	.15
Kairaluoma[13]	8	14	.5
Palimento[15]	28	34	.522

Length of Stay

In the United States, hemorrhoid operations are typically performed as outpatient procedures unless complications, medical comorbidities, or social factors necessitate hospital admission. Stapled hemorrhoidopexy can be performed on an outpatient basis or with a short hospital stay.[2–6,10,13,16,50,52,59] Most of these data have been generated outside the United States. The length of stay data reported in these studies may be important in the countries of origin, but payment structure in these countries is often tied to inpatient stays and therefore may not reflect American practices. For this reason, length of postoperative hospital stay is not discussed in detail.

Return to Work and Normal Activities

Return to normal activity is difficult to assess because these measurements carry inherent biases created by the survey instrument as well as patients' expectations, employment, insurance compensation, personal motivation, and so forth (Table 2). However, this remains a critical feature of stapled hemorrhoidopexy as it is intimately related to postoperative pain and will be an important factor stimulating patients' demand for this operation. All trials found stapled hemorrhoidopexy similar to or significantly better than excisional hemorrhoidectomy in terms of time back to normal activities or work.

Pain

The majority of published trials focus on postoperative pain as a primary study outcome because reduction in pain was the impetus for the original development of stapled hemorrhoidopexy. A reduction in postoperative pain, relative to excisional techniques, is likely to become the primary benefit of this procedure and drive patients' demand. Postoperative pain is the principal reason that patients avoid hemorrhoid operations. In our initial cohort of stapled hemorrhoidopexy patients, the mean time of hemorrhoid symptoms reported was in excess of 9 years,[37] confirming that patients delay treatment. When stapled hemorrhoidectomy became an available treatment option, this cohort of patients was eager to undergo treatment. As this was the initial group of patients in the United States, there were not yet any data in this country to suggest that PPH would cause less pain than Ferguson hemorrhoidectomy; however, even the potential of less postoperative pain was enough to motivate this group of patients. In essence, if postoperative pain were less severe and safety and efficacy similar to those of excisional hemorrhoidectomy, stapled hemorrhoidopexy would have a definite role in the management of hemorrhoids because pain is the primary drawback of excisional hemorrhoidectomy. For this reason, a detailed discussion of published data on pain is warranted.

Early Postoperative Pain (Days 0–14)

Most studies examined early postoperative pain (postoperative days 0–14). In general, severity of pain was assessed using a visual analog scale (0–10). Two studies recorded postoperative pain while patients remained in the hospital and documented significantly less pain for the stapled hemorrhoidopexy patients (Ho et al,[1] Shalaby and Desoky[6]). Pavlidis,[10] Palimento,[15] Senagore,[16] and Correa[7] and their colleagues also documented reduced pain in the first several postoperative days. Hetzer,[8] Shalaby,[6] Ortiz,[9] Boccasanta,[4] Cheetham,[12] Rowsell,[3]

and Mehigan[2] and their coworkers reported reduced pain in the first 10 postoperative days. Brown et al[5] and Kairaluoma et al[13] reported less pain at 2 weeks postoperatively and Ho et al[1] reported the same at 3 months postoperatively.

Late Follow-Up ($\geq$6 Months)

Late postoperative pain ($\geq$6 months) can be difficult to assess because the etiology of pain at this time can be unclear. Most operative wounds should be healed within 6 months; therefore, persistent surgical pain is possible but unlikely for an uncomplicated operation. A staple line too close to the dentate line could cause persistent pain, but this would probably be diagnosed much sooner than 6 months postoperatively. The pain may be due to unrelated perianal pathology, such as fissures or fistulae. Finally, the pain may be due to recurrent hemorrhoid pain. Traditional teaching dictates that internal hemorrhoids do not cause pain as their origin is proximal to the dentate line, therefore relatively devoid of somatic pain fibers. It may be artifact of the assessment tool, but we have previously demonstrated that patients report significant preoperative anal pain due to internal hemorrhoids.[37] Subjects may have used "pain" as a surrogate for other complaints such as itching, wetness, or incontinence. Most instruments do not investigate these symptoms carefully enough to determine the difference. However, it may, in fact, be that internal hemorrhoids do cause pain that has been previously unrecognized in both the preoperative and late postoperative time periods. Three studies documented similar incidences of late postoperative pain.[9,7,15] Several authors demonstrated a significant reduction in pain at the time of bowel movement.[5,6,15,16]

Hemorrhoid Prolapse

Control of hemorrhoid prolapse was a primary endpoint of most studies as it represents control of one of the most significant symptoms of hemorrhoids. As discussed earlier, stapled hemorrhoidopexy is a technique of fixation rather than excision. As such, a significant quantity of internal hemorrhoid tissue remains in situ, which has led some to be suspicious of recurrent prolapse. A review of the published data suggests that hemorrhoidopexy controls prolapse at least as well as excisional hemorrhoidectomy.[3,6,7,9,12,13,16]

Perianal Skin Tags

The issue of perianal skin tags frequently arises during discussion of stapled hemorrhoidopexy. Critics argue that fixation of the internal hemorrhoids and redundant mucosa does not address the external skin tags. In fact, the external disease, including external hemorrhoids, is addressed by the stapled hemorrhoidopexy procedure. It is unclear whether this is due to the interruption of the arterial supply to the tags, the cessation of mucosal prolapse, or resolution of internal hemorrhoid symptoms simply diverting attention away from the anus. In any case, few patients require delayed skin tag excision after stapled hemorrhoidectomy.

Several authors do report the incidence of postoperative skin tags, but this information can be somewhat misleading. Unfortunately, most authors do not report the incidence of preoperative skin tags, so it is unclear whether the postoperative tags are new or persistent. Furthermore, the incidence of postoperative tags may not be as relevant as the incidence of symptomatic tags, that is, requiring excision. The reported data suggest that stapled hemorrhoidopexy and excisional hemorrhoidectomy result in similar incidences of tags postoperatively,[2,4,6,7,9,13,16] and this number decreases with time. The contribution of tag excision to postoperative pain is small, but it does cause a certain degree of pain. Very few, if any, patients require delayed tag excision after stapled hemorrhoidopexy; therefore, our recommendation is that perianal skin tags be excised at the time of stapled hemorrhoidopexy only if the specific tags are known to be symptomatic (e.g., bleeding, excoriated) or at the specific request of the patient for reasons of hygiene or cosmesis.

Intraoperative Bleeding

Intraoperative bleeding at the staple or suture line should be considered not a complication but an expected part of the operation. Meticulous inspection of the entire circumference of the staple line is essential to treat intraoperative bleeding adequately. Senagore et al[16] documented that 84% of patients with stapled hemorrhoidopexy required hemostatic sutures at the staple line. The risk of postoperative hemorrhage far outweighs the cost of a few sutures and a few additional minutes of operating. We recommend closing the stapler head for an additional 30 to 60 seconds and liberal use of hemostatic sutures at the staple line to prevent the complication of early postoperative hemorrhage. The manufacturer of the stapling instrument is currently evaluating a redesigned product that includes staples with a shorter leg height (PPH 03, Ethicon). This may provide improved hemostasis at the staple line.

Early Postoperative Bleeding (<30 Days)

Postoperative bleeding is a well-known complication of excisional techniques, with incidences usually reported in the range 2 to 4%.[60,61] As stapled hemorrhoidopexy leaves behind most of the internal hemorrhoid tissue and does not immediately correct external hemorrhoids, it is expected for patients to experience a limited degree

of persistent bleeding in the early postoperative period. It is only when the suspended internal hemorrhoids decrease in size that they stop bleeding. Most publications report the rate of clinically significant postoperative bleeding, that is, the number of patients requiring hospital admission, transfusion, or other intervention.

Early postoperative bleeding is caused either by the operation itself, such as staple or suture line bleeding, or by persistent bleeding from residual hemorrhoid tissue. This is particularly true in patients with stapled hemorrhoidopexy because most of the internal hemorrhoid tissue remains in the anal canal. Several studies have documented similar or decreased rates of early postoperative bleeding after stapled hemorrhoidopexy.[1,4,5,7,9–12,16]

Delayed Postoperative Bleeding (>30 Days)

Delayed postoperative bleeding is more likely to be caused by persistent hemorrhoidal bleeding that did not resolve with treatment or recurrent hemorrhoidal bleeding because most operative wounds would presumably have healed by this time. Several studies documented that stapled hemorrhoidopexy caused similar or reduced rates of postoperative bleeding.[1,5–7,9,11,12,15]

Urinary Retention

The incidence of posthemorrhoidectomy urinary retention is reported to be about 20%.[60,61] Urinary retention is a well-known complication of all anorectal operations, which suggests that stapled hemorrhoidopexy should be no different. In fact, 11 studies documented a similar incidence of postoperative urinary retention.[1,2,4,6,7–9,11,13,15,16] Postoperative urinary retention is probably related to a variety of factors including type of anesthesia, perioperative intravenous fluid load, and postoperative pain. Whatever the exact cause, the incidence is similar to that with excisional hemorrhoidectomy in the large majority of published trials.

Anal Stenosis and Stricture

Experience with full-thickness anastomoses raises the concern that a stapled anastomosis 2 to 4 cm proximal to the dentate line may potentially result in a postoperative stricture. The Ethicon stapling device creates a circumferential staple line that is 33 mm in diameter, which should be adequate for most patients. Rates of anal stenosis were similar between groups in most studies.[1,4–7,13,16]

Several authors agree that the stenosis in the stapled patients is easier to treat because the stenosis is high in the rectum, making it amenable to manual dilation in the office or at home.[1,4,5] Ho et al[1] concluded that single office dilation was painless for stapled hemorrhoidopexy patients, but excisional hemorrhoidectomy patients required serial dilations at home over several weeks. In conclusion, stapled hemorrhoidopexy carries a finite risk of anal stenosis, but it is comparable to that for excisional hemorrhoidectomy and the stenosis is possibly easier to treat.

Internal Sphincter Injury

One of the most significant complications of any new anorectal operation would be sphincter damage. Rendering a patient incontinent while treating hemorrhoids is clearly not a successful outcome; therefore, this significant event necessitates detailed analysis. Insertion of the large stapler and even larger circular anoscope could potentially cause stretch injury to the sphincters. Also, the circumferential excision of tissue just centimeters above the dentate line raises concern about internal sphincter damage. Theoretically, the excised tissue contains only mucosa and submucosa, but inappropriate depth of the purse-string suture or excess traction of the purse-string could possibly draw full-thickness rectum into the jaws of the stapler with resultant excision of internal sphincter fibers. A variety of techniques have been used to investigate the question of sphincter injury including clinical continence assessments, ultrasonography, histology, and anorectal manometry.

Incontinence and Fecal Urgency

It is not unexpected for patients to experience a short duration of mild incontinence after any type of anorectal operation; therefore, we will examine the data regarding persistent incontinence or fecal urgency. Multiple trials reported similar or better rates of fecal incontinence or urgency after stapled hemorrhoidopexy.[1,4,7,9–11,13,16]

Anal Manometry

Anal sphincter injuries have been reported after application of other types of transanal stapling devices.[62–64] It may be possible that postoperative incontinence is due to the introduction and manipulation of the stapler and the dilating anoscope, which has a 37-mm outer diameter. To evaluate postoperative function further, several investigators performed anal manometry. Boccasanta et al[4] reported no significant differences between groups for both resting pressures and squeeze pressures. Shalaby and Desoky,[6] however, reported that the excisional group had reduced pressures compared with the stapled group in the postoperative evaluation. Also, squeeze pressure was similar in the preoperative and postoperative periods but significantly lowered between operative groups. Wilson et al[11] found that there was not a significant difference between groups preoperatively or at 6 weeks postoperatively. Ho et al[1]

performed manometry and reported no significant differences preoperatively between operative groups. The changes from preoperative status to 6 weeks and 3 months postoperatively were not different between groups. At 6 weeks the resting and squeeze pressures were decreased in excisional patients only.

Ultrasonography

Brown et al[5] assessed the integrity of the internal anal sphincter postoperatively using endoanal ultrasonography. Fourteen percent of patients in both the stapled and excisional groups were found to have ultrasonic evidence of internal anal sphincter damage, although all of these patients reported normal continence. A single partial defect at the distal anal canal was noted at the site of a hemorrhoid excision, although the preoperative status of this patient's sphincter is unknown and a preexisting lesion cannot be ruled out. In addition, Ho et al[1] found ultrasonic evidence of sphincter damage at a similar frequency in the stapled and excisional groups.

Histology

The key aspect of the stapled hemorrhoidopexy is the creation of a mucosa-submucosa resection and anastomosis. The muscular wall and certainly extraluminal structures are to be excluded from the anastomosis. This is accomplished primarily by careful placement of the purse-string suture into the submucosal plane. If the suture is placed full thickness or excess traction is placed on the suture at the time of closing the stapler, full-thickness rectum or extrarectal tissues will be incorporated into the anastomosis. Damage to the internal sphincter could occur if it were incorporated into the anastomosis. This could potentially alter postoperative continence. Therefore, in an effort to determine the incidence of full-thickness anastomoses, sphincter damage, and any correlation with postoperative incontinence, several authors have examined the histology of the resected ring of tissue. None of the studies that examined the histology of the specimens could definitively conclude that the presence or absence of sphincter fibers in the resected hemorrhoidopexy specimens correlated with clinical outcome.[3,6–13]

Complications

A large variety of complications have been reported as part of the randomized trials as well as individual case reports. The vast majority of these are similar to complications of excisional hemorrhoidectomy or other anal operations. Several severe complications merit discussion.

Rectovaginal fistula has been reported as a complication of stapled hemorrhoidopexy.[7,47,56] This complication is not unique to stapled hemorrhoidopexy and can occur after a full-thickness colorectal or coloanal anastomosis. Careful attention to the rectovaginal septum during placement of the purse-string suture prevents this highly morbid complication. The rectovaginal septum can be as thin as millimeters; therefore, precise position of the purse-string suture is essential. As previously mentioned, the location of the purse-string suture drives the remainder of the procedure. If the suture is placed full thickness at the anterior aspect of the rectum and into the posterior vaginal wall, the vagina is incorporated into the anastomosis. A finger should be inserted into the vagina while placing the purse-string suture. Also, the suture should be tightened and placed under tension while examining the vagina for dimpling, suggesting incorporation into the suture line. Finally, when the stapler is closed, but prior to deployment of the staples, the vagina should be examined again for dimpling at the posterior aspect. These simple maneuvers can prevent this difficult complication. Postoperatively, dyspareunia must raise suspicion of a rectovaginal fistula and the surgeon should perform a thorough pelvic examination including vaginal speculum and anoscopy. It should be noted that patients reported with this postoperative complication did not necessarily experience dyspareunia.[7]

Much has been published regarding the infectious complications of stapled hemorrhoidopexy; however, bacteremia is certainly not unique to this operation and occurs with excisional techniques and RBL. In fact, septic complications are sufficiently rare that perioperative antibiotics and full bowel preparation are unnecessary. A review of the clinical reports and experimental data supports this conclusion.

The incidence of bacteremia after either sclerotherapy[65] or excisional hemorrhoidectomy[66] has been reported as 8%. Septic complications are also well known to occur after RBL.[67–70] Stapled hemorrhoidopexy may potentially cause bacteremia at several instances—tearing of the mucosa with anal dilatation, insertion of the purse-string suture, or the introduction of the staples themselves. Some have suggested the need for preoperative antibiotics before stapled hemorrhoidopexy.[2,43,56,71] To assess the utility of such a recommendation, Maw et al[14] conducted a prospective randomized trial examining the rates of culture-proven bacteremia and the associated clinical outcomes after stapled hemorrhoidopexy and diathermy hemorrhoidectomy. Aerobic and anaerobic blood cultures were obtained after the induction of general anesthesia, immediately before instrumentation of the anal canal, and 3 minutes after firing the stapler or performing the diathermy excision. Eleven percent of the stapled patients and 5% of the diathermy patients had positive blood cultures considered to be caused by the operation ($p = .19$). There were no septic complications and no consequences related to bacteremia. In summary, each operation caused similar rates of

bacteremia, which did not have any clinical significance. The incidence of bacteremia is comparable to that of other hemorrhoid treatments and no correlation can be made with clinical outcome; therefore, the routine use of antibiotics is not justified on the basis of bacteremia. Only patients at risk for severe complications of bacteremia should receive antibiotics.

Rectal perforation with subsequent peritonitis has been reported following stapled hemorrhoidopexy.[53] This complication was probably due to a low peritoneal reflection that was drawn into a full-thickness anastomosis. A single case of pneumoretroperitoneum with pneumomediastinum has also been reported.[54] One case of life-threatening pelvic sepsis has been reported.[71] A single case of rectal obstruction due to obliteration of the lumen by the staples has also been reported.[48] These complications are significant but exceedingly rare and related to technical considerations during the operation.

Comparison with Rubber Band Ligation

Stapled hemorrhoidopexy is essentially a technique of fixation. In that sense it is similar to office techniques, such as RBL. RBL is known to be a highly effective and safe procedure, which represents the best first-line intervention for most symptomatic hemorrhoids.[72] Only a small minority of patients ultimately require operative intervention; therefore, some have suggested that direct comparison of RBL with stapled hemorrhoidopexy is more appropriate. Peng et al[73] conducted a trial in Singapore at an institution with considerable experience in stapled hemorrhoidopexy.[1,5,74] The aim was to determine whether stapled hemorrhoidopexy could be used as an alternative to RBL. Fifty-five patients with grade III or IV hemorrhoids were randomly assigned to either stapled hemorrhoidopexy or RBL. The conclusion of the authors was that if patients are willing to suffer moderate postoperative pain and undergo anesthesia, stapled hemorrhoidopexy offers a significantly better opportunity for avoiding a further procedure.

In our opinion, this study confirms that stapled hemorrhoidopexy should not be offered as an alternative to RBL. Certainly there was more early postoperative pain in the stapled group, but this would be expected with a more significant operative procedure, although this difference disappeared as all patients were pain free at the intermediate-term follow-up. Although hemorrhoidopexy patients may experience more complications, including the risk of potential septic complications, RBL is well documented to have caused sepsis and even death.[75] Regarding control of symptoms, 20% of RBL patients required subsequent excisional hemorrhoidectomy but none of the hemorrhoidopexy patients required additional operative therapy. The authors stated that control of symptoms was similar for the two groups at 6 months, excluding the patients converted from RBL to excisional hemorrhoidectomy. This is an unfair comparison. These patients represent the treatment failures and must be included in the overall assessment of the group. Our conclusion would be that stapled hemorrhoidectomy was similar to RBL when RBL was successful, but 20% of patients failed RBL initially. It is these 20% that should have been compared with stapled hemorrhoidopexy. This is the true comparison group, not the group that can successfully be treated with simple outpatient nonoperative treatment. Diet modification, improved hygiene, and topical agents should remain the initial treatment modalities, followed by RBL only if the initial maneuvers fail. However, patients who fail RBL, are unwilling to undergo multiple treatments, have contraindications, or have significantly large and circumferential prolapsing hemorrhoids that the surgeon assesses to not be amenable to RBL should be offered operative treatment. The decision should be made first to operate and then decide between the various excisional techniques or the stapled hemorrhoidopexy. The vast majority of patients do not require[60] operations, and the introduction of stapled hemorrhoidopexy should not change this at all.

CONCLUSIONS

Stapled hemorrhoidopexy treats prolapsing internal hemorrhoids by restoring symptomatic vascular cushions to their anatomic position, interrupting arterial inflow, and improving venous drainage, thus eliminating the cause of symptoms without necessarily excising the redundant tissue itself and, most important, sparing the patient incisions in the highly sensitive anoderm. The published data confirm that stapled hemorrhoidopexy offers similar control of symptoms with the benefits of reduced postoperative pain when compared with excisional techniques. Reduction in pain is the most significant benefit of this operation (Table 3).

Clearly, the cost of the stapling device exceeds the cost of the sutures required to perform an excisional hemorrhoidectomy. International data suggest that stapled hemorrhoidopexy reduces the length of hospital stay; however, in the United States hemorrhoid operations are performed as outpatient procedures. Therefore a reduced length of stay cannot account for cost savings. An application for a unique reimbursement code is currently pending. If approved, this would facilitate adequate reimbursement for the operation. The real cost savings will be realized only after the patients are discharged from the hospital and are able to return to work or resume their normal activities. Unfortunately, these benefits are not considered by third-party payers, but ultimately this will be one of the forces driving patients' demand for stapled hemorrhoidopexy.

There is little doubt that excisional hemorrhoidectomy is a safe, effective, and durable operation.

Table 3 Prospective Randomized Trials Comparing Stapled Hemorrhoidopexy and Excisional Hemorrhoidectomy

Reference	Author	Year	Location	Number of PPH Patients	Number of Excisional Patients	Follow-up	Conclusions Regarding Stapled Hemorrhoidopexy
1	Ho	2000	Singapore	57	62 MM	3 months	Similar LOS, less pain at bowel movement, less analgesics, earlier return to work, similar complications, similar manometry and US data
2	Mehigan	2000	UK	20	20 MM	4 months	Less pain, same LOS, similar complications, earlier return to activity.
3	Rowsell	2000	UK	11	11 MM	6 weeks	Shorter LOS, less pain, earlier return to activity
4	Boccasanta	2001	Italy	40	40 MM	20 months	Less OR time, less pain, similar complications, earlier return to work, same recurrence
5	Brown	2001	Singapore	15	15 MM	6 weeks	For thrombosed internal hemorrhoids: less pain, more complications, earlier return to work
6	Shalaby	2001	Egypt	100	100 MM	1 year	Less OR time and LOS, less pain, earlier return to work, less anal discharge, less complications
7	Correa-Rovelo	2002	Mexico	42	42 Ferg	6 months	Less OR time, Less pain, less complications, shorter time to BM, earlier return to activity
8	Hetzer	2002	Switzerland	20	20 Ferg	1 year	Less OR time, less pain, similar complications, earlier return to work, same recurrence
9	Ortiz	2002	Spain	27	28 MM	1 year	Less OR time, less pain, similar return to work, similar complications, more recurrent prolapse
10	Pavlidis	2002	Greece	40	40 MM	1 year	Less OR time, shorter LOS, less pain, less analgesics, greater satisfaction, similar symptom control
11	Wilson	2002	UK	32	30 MM	8 weeks	Less OR time, shorter LOS, shorter postop time with anal pad, more postop bleeding, reduced anal discharge, shorter time to work
12	Cheetham	2003	UK	15	16 MM	18 months	Less pain, earlier time to work, 2 PPH patients with persistent pain/fecal urgency, same satisfaction, similar symptom control
13	Kairaluoma	2003	Finland	30	30 MM	1 year	Less pain, earlier return to work, similar complications, more treatment failures
14	Maw	2003	Singapore	101	98 MM	Perioperative	No difference in rate of bacteremia
15	Palimento	2003	Italy	37	37 MM	6 months	Less OR time, less pain, less pain with BM, similar return to activity, similar symptom control
16	Senagore	2003	United States	77	79 Ferg	1 year	Less pain, less pain at BM, less analgesics, fewer retreatments, similar symptom control

BM, bowel movement; Ferg, Ferguson hemorrhoidectomy; LOS, length of stay; MM, Milligan-Morgan hemorrhoidectomy; OR, operating room; PPH, procedure for prolapse and hemorrhoids; US, ultrasound.

However, the notorious postoperative pain simply deters patients from undergoing proper treatment of a significant disease. Stapled hemorrhoidopexy has now been shown to offer similar control of symptoms at 1 year with less postoperative pain and similar safety. The indications for operative therapy should not change with the advent of this procedure. Patients should undergo medical therapy and RBL first, but patients being considered for excisional hemorrhoidectomy should be offered stapled hemorrhoidectomy as a less painful alternative.

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