Long-term Outcomes of Stapled Hemorrhoidopexy vs Conventional Hemorrhoidectomy
A Meta-analysis of Randomized Controlled Trials

Pasquale Giordano, MD, FRCSEd, FRCS; Gianpiero Gravante, MD; Roberto Sorge, PhD; Lauren Ovens, MBChB, MRCS; Piero Nastro, MD, MRCS

Objectives: To assess the long-term results of stapled hemorrhoidopexy (SH) compared with conventional hemorrhoidectomy (CH) and to define the role of SH in the treatment of hemorrhoids.

Data Sources: Published randomized controlled trials of CH vs SH with a minimum clinical follow-up of 12 months were searched and selected in the MEDLINE, EMBASE, and Cochrane Library databases using the keywords hemorrhoid, stapl, and anopexy, without language restrictions.

Study Selection: Potentially relevant studies were identified by the title and the abstract, and full articles were obtained and assessed in detail.

Data Extraction: Studies were scored according to the presence of 3 key methodologic features of randomization, blinding, and accountability of all patients, including withdrawals, and the scores ranged from 0 to 5. Studies that received a score from 3 to 5 were considered high-quality studies, whereas those with a score of 2 or less were considered of low quality. A specifically designed data form was used to collect all relevant data, including details of the experimental design, patient demographics, technical aspects, outcome measures, and complications.

Data Synthesis: Fifteen articles met the inclusion criteria for a total of 1201 patients. Outcomes at a minimum of 1 year showed a significantly higher rate of prolapse recurrences in the SH group (14 studies, 1063 patients; odds ratio, 5.5; P < .001) and patients were more likely to undergo further treatment to correct recurrent prolapses compared with the CH group (10 studies, 824 patients; odds ratio, 1.9; P = .02).

Conclusion: Stapled hemorrhoidopexy is a safe technique for the treatment of hemorrhoids but carries a significantly higher incidence of recurrences and additional operations compared with CH. It is the patient's choice whether to accept a higher recurrence rate to take advantage of the short-term benefits of SH.

Arch Surg. 2009;144(3):266-272

IN MODERN TIMES, SURGICAL MANAGEMENT OF HEMORRHNOIDS SHOULD AIM TO PROVIDE A DEFINITE CURE OR LONG-TERM RELIEF OF SYMPTOMS USING TECHNIQUES THAT ARE SAFE, PRESERVE THE ANORECTAL FUNCTION, AND MAKE THE PATIENT'S QUALITY OF LIFE AN IMPORTANT PRIORITY. IN 1998, A TRANASAL CIRCULAR STAPLING INSTRUMENT, INITIALLY USED ON MUOCAL PROLAPSES,1 WAS USED TO TREAT HEMORRHNOIDS VIA A PROCEDURE CALLED STAPLED HEMORRHNOIDOPEXY (SH).2 THE TECHNIQUE INTRODUCED A COMPLETELY NEW CONCEPT FOR TREATING HEMORRHNOIDAL DISEASE. IT CONSISTED OF A CIRCUMFERENTIAL RECTAL MUCOSECTOMY THAT PERFORMED A MUCOSAL LIFTING (ANOPEXY), AIMED NOT AT EXCISION OF THE “DISEASED” HEMORRHNOIDAL CUSHIONS BUT RATHER AT RECONSTITUTION OF THE HEALTHY ANATOMICAL AND PHYSIOLOGICAL ASPECTS OF THE HEMORRHNOIDAL PLEXUS.2 IT IS THOUGHT THAT THE STAPLING DEVICE WORKS BY REPOSITIONING THE RECTAL MUCOSA HIGHER (MUCOSAL LIFTING),1,2 RESTORING THE NORMAL ANATOMY OF THE ANAL CANAL AND ENABLING THE HEMORRHNOIDAL CUSHIONS TO PERFORM THEIR ROLE IN CONTINENCE, AS OPPOSED TO HEMORRHNOIDECTOMY TECHNIQUES THAT ONLY EXCISE ABUNDANT TISSUES. HOWEVER, THE STAPLER OPERATION ALSO INFLUENCES THE BLOOD FLOW, AFFECTING VEINOUS VESSELS AND LEADING TO AN IMPROVEMENT OF THE VEENOUS REFLUX.1,3

Since the introduction of this procedure, several studies1-3,5 have reported on its safety and efficacy. The short-term benefits of SH have clearly been demonstrated in studies on short-term outcomes and recent reviews. Undoubtedly, SH is quicker to perform, and patients experience less postoperative pain, have a shorter hospital stay, and return to their normal activities earlier. Other short-
term outcome measures also seem to favor SH. In a review of almost 2000 patients, although the overall postoperative complication rate was comparable in both procedures, SH had less postoperative bleeding (P = .02). Furthermore, the requirement for nonsurgical and surgical reintervention and the readmission rate were similar after SH and conventional hemorrhoidectomy (CH).

However, most of the initial trials reported on short-term outcomes, and until recently only a few data were available on long-term safety and effectiveness. Recent meta-analyses confirmed the short-term benefits of SH but also demonstrated a higher rate of recurrent prolapses, persistent pain, and fecal urgency at 6 months of follow-up. Finally, concerns have been raised by reports of rare but potentially catastrophic complications after SH.

For all these reasons, the definitive role of SH in the treatment of symptomatic hemorrhoids remains to be established. The aim of this study was to assess the long-term outcomes of SH vs CH through an evidence-based meta-analysis to outline the role of SH.

STUDY SELECTION AND DATA EXTRACTION

We followed the Quality of Reporting of Meta-analyses (QUORUM) guidelines for the development and description of this study. Published randomized controlled trials of CH vs SH with a minimum clinical follow-up of 12 months were searched and selected in the MEDLINE, EMBASE, and Cochrane Library databases using the keywords hemorrhoid*, stapl*, and anopexy, without language restrictions. We defined a randomized trial as one in which patients were assigned prospectively to CH or SH by a random allocation. Conventional hemorrhoidectomy was defined as a sharp or diathermic excision of hemorrhoidal tissue, anoderm, and perianal skin with or without closure of the ensuing defect. Stapled hemorrhoidectomy was defined as the excision of an annulus of rectal mucosa using a dedicated transanal circular stapler.

Potentially relevant studies were identified by the title and abstract, and complete articles were obtained and assessed in detail. The methodologic quality of studies was assessed independently by 2 reviewers (G.G. and P.N.) according to the Jadad score. Briefly, studies were scored according to the presence of 3 key methodologic features: randomization, blinding, and accountability of all patients, including withdrawals; the score ranged from 0 to 5. Studies that received a score from 3 to 5 were considered high-quality studies, whereas those with a score of 2 or less were considered of low quality. A specifically designed data form was used to collect all relevant data, including details of the experimental design, patient demographics, technical aspects, outcome measures, and complications. Data collection was performed independently by 2 researchers (G.G. and P.N.) and then compared.

Primary outcome measures of our review were hemorrhoidal recurrences, in terms of recurrent bleeding or prolapse, and need for further interventions. Secondary outcomes were pain at defecation, anal stenosis, fecal urgency, fecal incontinence, and patient satisfaction. Other complications (fistulas, skin tags, pruritus ani, and fissures) were also analyzed.

STATISTICAL ANALYSIS

Data analysis was performed using commercially available software programs (SPSS for Windows, version 13.0; SPSS Inc, Chicago, Illinois; and Meta-analysis with Interactive Explanations, version 1.6; Kitasato Clinical Research Center, Sagamihara, Kanagawa, Japan). Descriptive statistical analysis for qualitative variables was performed with occurrences and described in detail. The methodologic quality of studies was assessed in-
One study involved both degrees and specified results among patients with fourth-degree hemorrhoids (65 SH vs 72 CH). Three studies analyzed 137 patients included only third-degree hemorrhoids (58 treated with SH vs 51 with CH). Another 2 studies21,24,26,28 reported on long-term incidence of recurrent bleeding and prolapse, 5 studies21,23,24,26,28 reported the incidence of recurrent prolapse, and 2 studies17,25 reported the incidence of recurrence but did not specify the symptoms, and 1 study25 had no recurrences. One study16 did not clearly report the number of recurrences and was not included in the primary outcomes analysis.

Outcomes at 1 year showed a significantly higher rate of prolapse recurrence in the SH group (14 studies, 1063 patients; OR, 5.5; P < .001) (Table 2 and Figure 2). Bleeding was similar in both groups (7 studies, 362 patients; OR, 1.1; P = NS) (Table 2). Ten studies commented on further intervention for hemorrhoidal symptoms: patients treated with SH were 1.9 times more likely to undergo further treatment to correct recurrent prolapses compared with patients with CH (10 studies, 824 patients; OR, 1.9; P < .03) (Table 2 and Figure 3). Of those in which treatment type was specified (9 studies), patients in the CH group received rubber band ligation (n = 4) and an additional CH (n = 1), whereas patients in the SH group received a rubber band ligation (n = 10), local excision of a single nodule (n = 1), additional SH (n = 1), and a conventional mucosectomy (n = 1).16,18,20,21,23,26,28,30 Three studies18-20 that included a total of 109 patients with only third-degree hemorrhoids showed a recurrence rate of 20.7% for SH and 3.9% for CH (OR, 10.4; P = .001). Results were not statistically different among different patients. Finally, 9 studies did not specify the hemorrhoidal degree, and the difference between SH and CH in terms of recurrences was significant (817 patients; OR, 3.1; P < .02) (Table 2).

Nine studies16,18,20,21,23,24,25,28,29 commented on pain at defecation at long-term follow-up. Results were not statistically significant (560 patients; OR, 0.4; P = .35) (Table 3). Another 2 studies21,30 (131 patients) found that 13.8% of patients who underwent SH experienced tenesmus at 1 year, whereas none of the patients in the CH group had this symptom (OR, trend to infinite; P < .001) (Table 3). Five studies22-24,26,30 presented data on anal manometry. All of them detected no difference in the resting and squeeze pressures before and after SH, whereas 2 studies23,26 demonstrated a significant decrease of both after surgery.
However, in such studies, no differences in incontinence rates were reported by the authors. Furthermore, no differences between groups were found for bleeding at defecation, anal stenosis, anal fissures, anal fistulas, and fecal urgency (Table 3). Finally, patient satisfaction at 1 year was assessed in 6 studies. It was similar among groups, except in 1 study in which it was greater after SH.

Table 3. Secondary Outcomes of the Included Studies

<table>
<thead>
<tr>
<th>Long-term Secondary Outcomes</th>
<th>Conventional Hemorrhoidectomy</th>
<th>Stapled Hemorrhoidopexy</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenesmus</td>
<td>0/66 (0)</td>
<td>9/65 (13.8)</td>
<td>. . . b</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Fecal incontinence</td>
<td>9/352 (2.6)</td>
<td>4/352 (1.1)</td>
<td>0.4 (0.1-1.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Anal stenosis</td>
<td>16/520 (3.0)</td>
<td>10/519 (1.9)</td>
<td>0.7 (0.3-1.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Pain at defecation</td>
<td>15/279 (5.4)</td>
<td>6/281 (2.1)</td>
<td>0.4 (0.1-1.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Fecal urgency</td>
<td>32/392 (8.1)</td>
<td>32/394 (8.1)</td>
<td>1.5 (0.8-2.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Skin tags</td>
<td>52/410 (12.7)</td>
<td>14 (8.2)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Pruritus ani</td>
<td>25/213 (11.7)</td>
<td>9/213 (4.2)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Anal fissure</td>
<td>6/213 (2.8)</td>
<td>5/213 (2.3)</td>
<td>1.2 (0.4-4.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Anal fistula</td>
<td>3/171 (1.8)</td>
<td>0/162 (0)</td>
<td>. . . c</td>
<td>NS</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; NS, not significant; OR, odds ratio.

a Only studies that specified results were included in the analysis.
b Trend to infinite.
c Trend to 0.
Long-term outcomes after SH and CH have been recently investigated in 2 recent reviews\(^4,5\) that found higher incidences of recurrence rates after SH. In the Cochrane study, SH was associated with higher rates of hemorrhoidal recurrence after 1 year of follow-up (5 trials, 417 patients; OR, 3.60, CI 1.24-10.49, \(P = .02\)). This result was also reflected in a non–statistically significant trend that patients who had SH were more likely to require additional operations for treatment in the long term (7 articles, 668 patients; OR, 1.63; \(P = 0.0\)). Similar results at 1 year of follow-up were also found in the review by Tjandra and Chan.\(^4\) The overall recurrence of hemorrhoids once again was higher after SH (585 patients; OR, 3.48; \(P = .02\)). In the same review it was stated that, although there was a tendency toward more subsequent surgical interventions for recurrent hemorrhoids after SH, no significant difference was present between the 2 groups (OR, 3.5; \(P = .05\)).

Our meta-analysis was specifically aimed at outlining the long-term results of SH compared with CH. Therefore, we deliberately included only studies with a minimum follow-up of 12 months. In more than 1200 patients, long-term outcomes showed a significant increase in occurrence of prolapses after SH vs CH, evident for all degrees of hemorrhoids. The incidence of recurrences among studies varied from 0% to 53.3%. Although there is no explanation for this result, it is possible that a number of factors may influence the recurrence rate after SH. Technical characteristics, such as the placement of the purse string, the level of the staple line, and the completeness of the mucosectomy ring, may influence the outcome. Unfortunately, no information regarding the placement of the purse string or the level of the staple line was available in any of the studies analyzed. The number of centers involved in the different studies also differed greatly (from 1 to 17) (Table 1), possibly creating differences of the incidence of late symptoms.\(^4\) The overall recurrence of hemorrhoids once again was higher after SH (585 patients; OR, 3.48; \(P = .02\)). In the same review it was stated that, although there was a tendency toward more subsequent surgical interventions for recurrent hemorrhoids after SH, no significant difference was present between the 2 groups (OR, 3.5; \(P = .05\)).

In conclusion, CH and SH are safe procedures with similar long-term morbidities; however, SH carries a significantly higher incidence of recurrence, additional operations, and tenesmus compared with CH. We believe that the results of this review finally provide definite information on the long-term outcome of SH. This information needs to be openly and fairly discussed with patients who require surgical treatment of hemorrhoids. It will ultimately be the patient’s choice whether to accept a higher recurrence rate to take advantage of the short-term benefits of SH.

Previous studies\(^50,51\) described some degree of incontinence after SH, and internal sphincter injuries were demonstrated with the use of endoanal ultrasonography and histologic analysis. In the current review, most cases of incontinence, when present, resolved within the first 6 months after the operation. The small number of cases with persistent symptoms after 1 year was not different between patients with SH and CH (Table 3).\(^16,18,27,30\) Furthermore, when SH involved excision of muscle layers, no correlation was found between recurrences, postoperative pain, and continence.\(^19,21-23,30\) The fact that a variable thickness of muscular layer was sometimes trapped into the stapler did not seem to have a deleterious effect on anal function and was not related to any change in anal pressure or continence,\(^22,25,30\) as demonstrated in other studies.\(^31,49\) Finally, although 7 studies\(^18,19,21-23,29,30\) in this review commented on the histologic features of the excised ring of mucosa, only 2 of these studies\(^18,29\) mentioned whether the excised tissue was in a complete doughnut shape: 1 of 3 recurrences in the SH group corresponded to an incomplete excision.\(^18\)

Recurrence rate, reintervention, and complications are important outcome measures when assessing a procedure; however, quality of life and patient satisfaction are also important and need to be considered. Unfortunately, quality of life was not assessed in any of the studies reviewed. Some of the studies reported on patient satisfaction, and, interestingly, despite higher recurrences and rate of reintervention, patients in the SH group reported similar satisfaction to patients in the CH group. Similar findings were also reported in a recent study that examined long-term patient satisfaction after SH. The authors found that 89% of patients were either very satisfied (64%) or satisfied (25%) despite a high incidence of postoperative symptoms.\(^4\) This result is possibly explained by the fact that the early postoperative benefits of SH could overcome the higher incidence rate of late symptoms.

Accepted for Publication: November 27, 2007.

Correspondence: Pasquale Giordano, MD, FRCS, FRCSEd, Department of Colorectal Surgery, Whipps Cross University Hospital, London E11 1NR, England (pasquale.giordano@whippsx.nhs.uk).

Author Contributions: Dr Giordano had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Giordano, Gravante, and Nastro. Acquisition of data: Ovens and Nastro. Analysis and interpretation of data: Giordano, Gravante, and Sorge. Drafting of the manuscript: Giordano, Gravante, Sorge, Ovens, and Nastro. Critical revision of the manuscript for

REFERENCES


36. Ho KS, Ho YH. Prospective randomised trial comparing stapled hemorrhoidopexy.


