

Long-term Outcomes of Stapled Hemorrhoidopexy vs Conventional Hemorrhoidectomy

A Meta-analysis of Randomized Controlled Trials

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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 de-

signed 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.

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IN MODERN TIMES, SURGICAL MANAGEMENT of hemorrhoids 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 transanal circular stapling instrument, initially used on mucosal prolapses,¹ was used to treat hemorrhoids via a procedure called stapled hemorrhoidopexy (SH).² The technique introduced a completely new concept for treating hemorrhoidal disease. It consisted of a circumferential rectal mucosectomy that performed a mucosal lifting (anopexy), aimed not at excision of the "diseased" hemorrhoidal cushions but rather at reconstitution of the healthy anatomical and physiological aspects of the hemorrhoidal 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 hemorrhoidal cushions to perform their role in continence, as opposed to hemorrhoidectomy techniques that only excise abundant tissues. However, the stapler operation also influences the blood flow, affecting venous vessels and leading to an improvement of the venous reflux.¹⁻⁵

Since the introduction of this procedure, several studies³⁻⁵ 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-

Table 1. Characteristics of the Studies Included in the Review

Source	Country	No. of Centers Involved	Conventional Hemorrhoidectomy/ Stapled Hemorrhoidopexy			Degree of Hemorrhoids	Follow-up, mo (Range)	Jadad Score ¹⁵
			Total No. of Patients	No. of Males	Mean Patient Age, y			
Senagore et al, ¹⁶ 2004	United States	17	73/65	58/49	48/51	Third	12	2
Hetzer et al, ¹⁷ 2002	Switzerland	1	20/20	14/15	49/50	Second-third	12	2
Au-Yong et al, ¹⁸ 2004	United Kingdom	1	9/11	6/7	58/53	Third	42	3
Kairaluoma et al, ¹⁹ 2003	Finland	1	30/30	19/13	48/47	Third	12	2
Ortiz et al, ²⁰ 2002	Spain	1	28/27	17/15	47/49	Third-fourth	15 (12-24)	3
Ortiz et al, ²¹ 2005	Spain	1	16/15	11/8	49/47	Fourth	12	3
Boccasanta et al, ²² 2001	Italy	1	40/40	18/15	51/50	Fourth	20	3
Van de Stadt et al, ²³ 2005	Belgium	1	20/20	13/16	49/47	Second-third	46 (12-56)	1
Racalbuto et al, ²⁴ 2004	Italy	1	50/50	25/31	44/48	Third-fourth	49	2
Smyth et al, ²⁵ 2003	United Kingdom	1	16/20	9/6	56/57	Third-fourth	37 (33-39)	2
Shalaby and Desoky, ²⁶ 2001	Egypt	1	100/100	64/60	49/44	Second, third, fourth	12	2
Gravié et al, ²⁷ 2005	France	7	63/63	NA	44/51	NA	26	2
Ganio et al, ²⁸ 2007	Italy	5	37/43	NA	NA	Third-fourth	84 (80-91)	2
Basdanis et al, ²⁹ 2005	Greece	1	45/50	25/29	44/46	Third-fourth	18 (12-24)	3
Ascanelli et al, ³⁰ 2005	Italy	1	50/50	33/46	NA	Second-third	12	3

Abbreviation: NA, not available.

term outcome measures also seem to favor SH. In a review⁴ of almost 2000 patients, although the overall post-operative complication rate was comparable in both procedures, SH had less postoperative bleeding ($P=.001$), fewer wound complications ($P=.005$), and less constipation ($P=.02$). Furthermore, the requirement for non-surgical and surgical reintervention and the readmission rate were similar after SH and conventional hemorrhoidectomy (CH).⁴

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^{4,5} 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.⁶⁻¹⁴

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.

METHODS

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 hemorrhoidopexy* 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 the 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.¹⁵ 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 with relative frequencies. The odds ratios (ORs) for primary and secondary outcomes of patients in the SH and CH groups were evaluated with meta-analysis tests. Results were considered statistically significant if the probability of chance of occurrence was less than .05.

RESULTS

Fifteen randomized controlled trials that met the inclusion criteria were identified (**Table 1** and **Figure 1**).¹⁶⁻³⁰ An additional 25 were excluded.³¹⁻⁵⁵ The selected studies included a total of 1201 patients: 597 in the CH group and

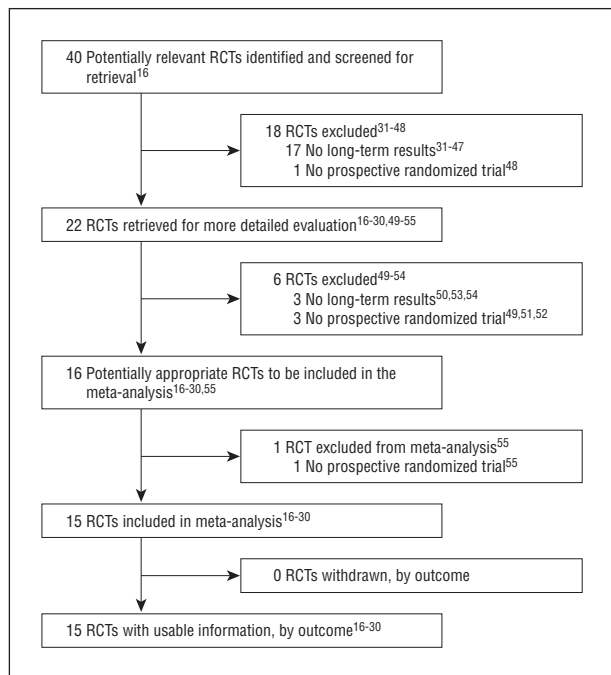


Figure 1. Flowchart of included and excluded studies. RCT indicates randomized controlled trial.

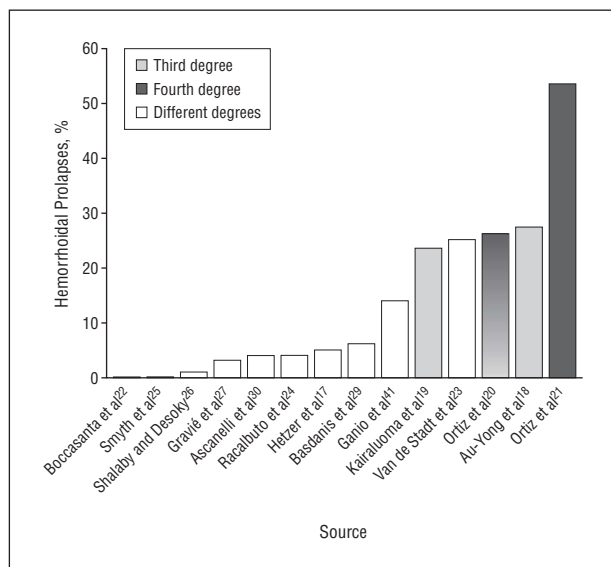


Figure 2. Incidences of recurrences following stapled hemorrhoidopexy in the studies analyzed.

604 in the SH group. Patients in the conventional group were treated with the Ferguson hemorrhoidectomy in 2 studies^{16,17} and with the Milligan-Morgan technique in all the others.¹⁸⁻³⁰ Three studies¹⁸⁻²⁰ with a total of 109 patients included only third-degree hemorrhoids (58 treated with SH vs 51 with CH). Three studies²⁰⁻²² analyzed 137 patients with fourth-degree hemorrhoids (65 SH vs 72 CH). One study²⁰ involved both degrees and specified results according to the disease severity. All the remaining studies involved patients with different degrees of hemorrhoids^{17,23-26,29,30} or the degree was not specified^{27,28} (Table 1). Only 6 studies reported the surgeons as being well-trained in SH (12-52 procedures performed); however, 2

studies were conducted on fourth-degree hemorrhoids, 1 was conducted on third-degree hemorrhoids, and the remaining ones did not have specified outcomes according to hemorrhoidal degree.^{17,20,21,23,25,27} Five studies^{18,22,24,26,28} enrolled patients before the year 2000, 8 studies^{17,19-21,23,27,29,30} enrolled from the year 2000 onward, and 1 study²⁵ did not specify the enrollment period. One hundred seven procedures in the CH group and 106 in the SH group were performed as day cases.^{19,23}

Follow-up ranged from 12 to 84 months. Fourteen studies reported the incidence of recurrences at the long-term follow-up (**Figure 2**). Six studies^{18-20,22,27,30} reported on long-term incidence of recurrent bleeding and prolapse, 5 studies^{21,23,24,26,28} reported the incidence of recurrent prolapse, 2 studies^{17,29} 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 3**). Bleeding was similar in both groups (7 studies, 362 patients; OR, 1.1; $P = \text{NS}$) (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 CH ($n = 13$), rubber band ligation ($n = 10$), local excision of a single nodule ($n = 1$), additional SH ($n = 1$), and a conventional mucosectomy ($n = 1$).^{16,18-21,23,26,28,30} 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; $P < .003$) (Table 2). Three studies²⁰⁻²² that included only fourth-degree hemorrhoids investigated a total of 137 patients and showed an overall recurrence rate of 20.0% for SH and no recurrences for CH (OR trend to infinite; $P < .001$) (Table 2). These studies, however, showed different results. Boccasanta et al²² found no recurrences after SH (40 patients treated), but Ortiz et al had a 53.3% recurrence rate (8/15) in a first study²¹ and a 50.0% recurrence rate (5/10) in a second study,²⁰ including 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 studies^{16-21,24,25,28} 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 studies^{21,30} (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 studies^{22-24,26,30} presented data on anal manometry. All of them detected no difference in the resting and squeeze pressures before and after SH, whereas 2 studies^{23,26} demonstrated a significant decrease of both after

Table 2. Primary Outcomes of the Included Studies^a

Long-term Primary Outcomes	No. (%) of Patients		OR (95% CI)	P Value
	Conventional Hemorrhoidectomy	Stapled Hemorrhoidopexy		
Recurrent prolapse				
Overall ¹⁷⁻³⁰	9/524 (1.7)	47/539 (8.7)	5.5 (2.7-11.3)	<.001
Third degree ¹⁸⁻²⁰	2/51 (3.9)	12/58 (20.7)	10.4 (2.3-47.1)	<.001
Fourth degree ²⁰⁻²²	0/72 (0)	13/65 (20.0)	... ^b	<.001
Degree not specified, or mixed ^{17,23-30}	7/401 (1.7)	22/416 (5.3)	3.1 (1.3-5.2)	<.02
Recurrent bleeding ^{18-22,25,28}	15/176 (8.5)	18/186 (9.7)	1.1 (0.5-2.3)	NS
Additional operations ^{16,18-21,23,24,26,28,30}	17/413 (4.1)	31/411 (7.5)	1.9 (1.0-3.5)	<.03

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

^aOnly studies that specified results were included in the analysis.

^bTrend to infinite.

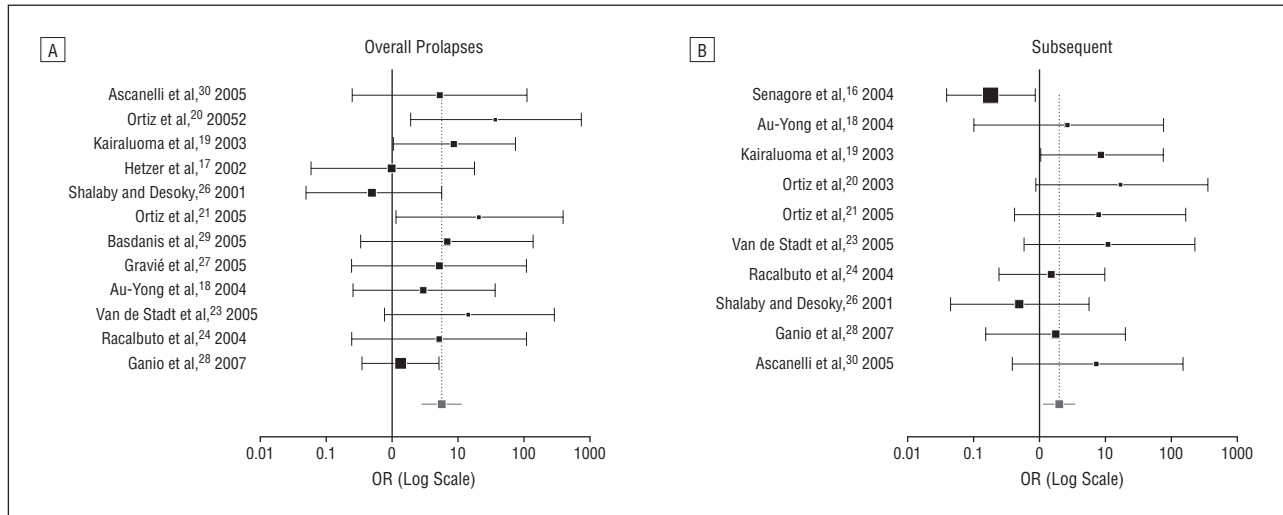


Figure 3. Standard forest plot with odds ratios (ORs) of stapled hemorrhoidopexy vs conventional hemorrhoidectomy. A, Overall prolapses. B, Subsequent operations. When incidences were not present in both the stapled hemorrhoidopexy and conventional hemorrhoidectomy groups, such studies were not included in the figure.

Table 3. Secondary Outcomes of the Included Studies^a

Long-term Secondary Outcomes	No. (%) of Patients		OR (95% CI)	P Value
	Conventional Hemorrhoidectomy	Stapled Hemorrhoidopexy		
Tenesmus ^{21,30}	0/66 (0)	9/65 (13.8)	... ^b	<.001
Fecal incontinence ^{16-18,26-28,30}	9/352 (2.6)	4/352 (1.1)	0.4 (0.1-1.4)	NS
Anal stenosis ^{16-20,22-24,26-28,30}	16/520 (3.0)	10/519 (1.9)	0.7 (0.3-1.6)	NS
Pain at defecation ^{16-21,24,25,28}	15/279 (5.4)	6/281 (2.1)	0.4 (0.1-1.0)	NS
Fecal urgency ^{16,18-21,23-25,27,28,30}	22/392 (5.6)	32/394 (8.1)	1.5 (0.8-2.6)	NS
Skin tags ^{16,19-26,28}	40/410 (9.8)	52/410 (12.7)	1.4 (0.8-2.2)	NS
Pruritus ani ¹⁸⁻²⁵	26/209 (12.4)	25/213 (11.7)	0.9 (0.5-1.6)	NS
Anal fissure ^{24,26,27}	5/213 (2.3)	6/213 (2.8)	1.2 (0.4-4.0)	NS
Anal fistula ^{16,17,20,24}	3/171 (1.8)	0/162 (0)	... ^c	NS

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

^aOnly studies that specified results were included in the analysis.

^bTrend to infinite.

^cTrend to 0.

CH. 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,^{19,23,25,27,28} except in 1 study²⁴ in which it was greater after SH.

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 had SH were more likely to require additional operations for treatment in the long term (7 articles, 668 patients; OR, 1.63; $P=0$).⁵ 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 outcomes.^{16,17,20,21,25} Only 5 studies¹⁸⁻²² with a total of 246 patients provided useful information regarding the degree of hemorrhoids treated and the related outcome. Patients affected by third-degree hemorrhoids were 10.4 times more likely to develop recurrences when operated on via SH (Table 2).¹⁸⁻²⁰ On the contrary, the studies²⁰⁻²² that included fourth-degree hemorrhoids described discrepant results for SH recurrences, ranging from 0% to 53% (Figure 2). Another recently published trial,⁵⁵ not included in the analysis because it was not a prospective randomized trial, also focused on fourth-degree hemorrhoids. The authors found that recurrences were present in 22.0% of patients treated with SH (11/50) vs 3.6% treated with CH (4/11). Other studies^{50,51} that reported on the outcome of SH for patients with fourth-degree hemorrhoids have shown recurrence rates of 19% and 59%.

Studies have shown that, because of the higher incidence of recurrence after SH, those patients are more likely to undergo additional treatment of hemorrhoids.^{4,5} In our study, patients in the SH group were almost 2 times more likely to require further treatment of hemorrhoidal symptoms compared with the CH group.

Previous studies^{56,57} 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,^{21,23,30} 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.

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.

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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*

important intellectual content: Giordano, Gravante, and Sorge. Statistical analysis: Sorge. Study supervision: Giordano, Gravante, Ovens, and Nastro. Financial Disclosure: None reported.

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