

Stapled rectal mucosectomy alone and in combination with other surgical anorectal procedures: multivariate analysis of factors affecting clinical outcome

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Abstract

Background: We undertook this study to compare the clinical outcome of stapled rectal mucosectomy (SRM) alone and in combination with sphincterotomy and cutaneous flap anoplasty and to determine the influence of factors related to complications and patient satisfaction.

Methods: Patients with second- to fourth-degree hemorrhoids who underwent SRM alone or in combination with other anorectal procedures were included. Postoperative complications, symptom resolution and patient satisfaction were analyzed.

Results: Two hundred forty one patients with a minimum follow-up of 1 year were divided into three groups: SRM alone ($n = 187$), SRM combined with sphincterotomy ($n = 31$) and SRM combined with cutaneous flap anoplasty ($n = 23$). Patients with SRM with sphincterotomy showed a higher complication rate than the other groups (32 vs. 12.8% and 13%, respectively, $p = 0.02$). SRM combined with sphincterotomy was associated with a higher rate of complications (OR = 3.5; 95% CI = 1.4-8.7). SRM alone with low mucosal resection was associated with a lower complications rate (OR = 0.4, 95% CI = 0.2-0.8). Resolution of preoperative symptoms was >80% among the three groups. There was no association between complications and type of procedure with satisfaction level. Resolution of symptoms <80% was associated with low/intermediate level of satisfaction ($p < 0.001$).

Conclusions: Resolution of preoperative symptoms is similar among the three groups. SRM combined with sphincterotomy has a higher risk of complications. The satisfaction level is associated with resolution of preoperative symptoms.

Key words: stapled rectal mucosectomy, sphincterotomy, cutaneous flap anoplasty.

Introduction

Hemorrhoidal disease (HD) is a global health problem. The prevalence of this disease is estimated at between 4 and 34%. In the UK it is estimated that from 50 years of age ~50% of the population has a hemorrhoid crisis.^{1,2} Hemorrhoidectomy, open or closed, has proven to be the most effective therapy to treat grades

III and IV HD. However, it is associated with a high complication rate, a significant level of postoperative pain and prolonged recovery. Stapled rectal mucosectomy (SRM) or hemorrhoidopexy or anopexy with stapler³ consists of replacing the prolapsed hemorrhoidal complex to their anatomical site through circumferential resection of the redundant mucosa located above those complexes. Results of various recent clinical trials demonstrate that the procedure is accompanied by minimal pain and disability, with good short- and long-term results.^{4,13} However, reports of apparently isolated cases of serious complications is still worrisome, such as pelvic sepsis and chronic pain. Lack of information on these tendencies or associations that help to understand and, at a given time, prevent such complications is noted.¹⁴⁻¹⁹

HD occurs with some frequency associated with other anorectal diseases that may also require specific surgical treatment and that are traditionally performed at the same time as conventional hemorrhoidectomy because it generally does not increase morbidity.²⁰⁻²² Some authors have reported SRM together with other anorectal surgical procedures, probably based on the history of the results of conventional hemorrhoidectomy with other procedures, even if such inferences may not be correct.²³⁻²⁵ In fact, it is unknown whether there are differences in the clinical

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outcome of SRM alone or combined with other anorectal procedures, mainly from the perspective of complications, some of which may be serious.

The aim of this study was to compare the results of SRM alone and SRM combined with other anorectal surgical procedures, to examine the influence of various factors on complications, symptom resolution and patient satisfaction.

Materials and Methods

From September 2000 to January 2004, 250 patients were operated consecutively at the Colorectal Clinic of Hospital Medica Sur, Mexico City. Those patients requiring surgery, with HD grades II-IV¹ uncomplicated by thrombosis and associated or not with another anorectal disease (anal fissure or large skin tags), were included. All patients signed informed consent to submit to a single SRM or in combination with other anorectal procedures. Excluded from the analysis were six patients who did not complete at least a year of follow-up and three patients who had a fistulotomy performed in combination with the SRM. All patients were operated on by the same group of surgeons.

Surgical Technique

Preoperative preparation consisted of receiving an enema prior to surgery and the administration of cefuroxime (1.5 g IV) or 500 mg metronidazole. Spinal block was used in all patients with the exception of two patients because the regional procedure was contraindicated. All patients were operated in proctological position with surgical technique as described by Longo, which we have previously described, with a 33-mm circular stapler (Proximate HCS Ethicon Endo-Surgery, Cincinnati, OH).^{3,9,13}

Also, Notaras-type subcutaneous sphincterotomy or closed type with or without removal of the sentinel flap was also done on those patients with chronic anal fissure. The procedure was performed prior to SRM, using a scalpel blade #11 in those patients with large tags undergoing resection and plasty after SRM.

Postoperative Period

Resected "doughnuts" were sent to pathology to determine the type of epithelium and presence of smooth muscle fibers. Postoperative complications and their resolution were evaluated. Postoperative symptoms and satisfaction were assessed by direct application of a questionnaire by independent physicians blinded to the surgical team. Satisfaction was assessed by means of the visual analogue scale (VAS) with a satisfaction score with a range of 0-10 (0 = dissatisfied and 10 = maximum satisfaction). Degree of satisfaction was considered very good with scores of 9 and 10, intermediate with a score of 8, and poor with scores of 7 or less. A complication was considered to be those symptoms that

appeared up to 1 month after surgery, and recurrence when the patient required some type of additional treatment (local or surgical) for control of persistent symptoms. Resection of lower mucosa was taken into consideration when it was near the dentate line with involvement of the columnar and transitional epithelium.

Statistical Analysis

Demographic characteristics of patients, surgical procedure and complications are described by percent, means and minimum/maximum range. Differences between qualitative variables were assessed by χ^2 or Fisher exact test. Differences between quantitative variables were analyzed using Mann-Whitney U test. Using logistic regression, we assessed factors associated with complications and factors associated with satisfaction. Included in the multivariate analysis were those factors that on univariate analysis had a *p* value <0.10. Results are presented as odds ratios and 95% confidence interval (CI). Statistical significance was considered when the *p* value was <0.05. Statistical analysis was conducted using SPSS v.13.0 for Windows.

Results

Procedures and Complications

Of the 24 patients included in the study, only 187 patients were subjected to SRM alone (77.6%), SRM plus sphincterotomy, 31 patients (12.9%) and SRM plus cutaneous flap anoplasty, 23 patients (9.5%). There were no significant differences among the three groups with regard to gender (*p* = 0.16) and age group (*p* = 0.09). Some type of complication was present in 12.8% (*n* = 24) of patients who had SRM alone, in 32.3% (*n* = 10) of patients who had SRM plus sphincterotomy and in 13% (*n* = 3) of those who had SRM and flap anoplasty (*p* = 0.02). For patients who were subjected to SRM alone, the most frequent complications were thrombosis (25%), urgent defecation (20.8%) and stenosis (16.6%). In patients who were subjected to SRM + sphincterotomy, the most frequent complications were urgent defecation (40.0%) and perianal abscess (30.0%), whereas those who were subjected to SRM plus cutaneous anoplasty, there were only three complications: local sepsis, stenosis and defecation urgency (Table 1).

Factors significantly associated with complications were the surgical procedure and type of epithelium of the resected doughnut. In regard to patients with complications, the greatest percentage was columnar and transitional epithelium (54.1 vs. 36.3%). In six of those patients, strips of squamous epithelium were also found (Table 2). According to multivariate analysis, surgical procedure and epithelium of the resected doughnut were maintained as independent factors associated with complications (Table 3).

Table 1. Postoperative complications according to procedure

	Surgical procedure						Total (n = 241)	
	Rectal mucosectomy (n = 187)		Mucosectomy and internal sphincterotomy (n = 31)		Mucosectomy and cutaneous flap anoplasty (n = 23)			
	n	%	n	%	n	%	n	%
Complications presented	24	12.8	10	32.3	3	13.0	37	15.4
Hematoma								
Submucosal	2	1.1	0	0.0	0	0.0	2	0.8
Subcutaneous	0	0.0	1	3.2	0	0.0	1	0.4
Perianal abscess	1	0.5	3	9.7	1	4.3	5	2.1
Thrombosis	6	3.2	1	3.2	0	0.0	7	2.9
Hemorrhage								
Early (first 24 h)	1	0.5	0	0.0	0	0.0	1	0.4
Late	1	0.5	0	0.0	0	0.0	1	0.4
Early hemorrhage and stenosis	1	0.5	0	0.0	0	0.0	1	0.4
Stenosis	4	2.1	0	0.0	1	4.3	5	2.1
Urgency	5	2.7	4	12.9	1	4.3	10	4.1
Anal incontinence	1	0.5	1	3.2	0	0.0	2	0.8
Moist anus	2	1.1	1	3.2	0	0.0	3	1.2
Dyspareunia	1	0.5	0	0.0	0	0.0	1	0.4

Postoperative Symptoms

Of all patients, 81.7% were totally asymptomatic and, in 83.8% of patients, 80% or more of their preoperative symptoms were resolved. There were no differences observed among the three groups ($p = 0.54$). Table 4 demonstrates in detail the evolution of preoperative symptoms. Without taking anal incontinence into consideration, symptoms that most frequently persisted in the SRM alone group were urgency (16.7%), perception of skin tags (13.3%) and hemorrhage (9.3%), whereas those persistent symptoms in the SRM plus sphincterotomy group were anal pruritus (28.6%) and hemorrhage (10%). In the group of SRM plus flap anoplasty persistent symptoms were hemorrhage (9.1%) and anal pain or burning (6.7%).

There was recurrence of HD in 2.1% of all patients: 4/189 who were subjected to SRM alone and 1/21 who were subjected to SRM plus flap anoplasty. There was no recurrence in patients with regard to anal fissure.

Postoperative Satisfaction

On the basis of the level of satisfaction reported by patients and according to their expectations, two groups were established: 199 subjects (82.6%) with a high level of satisfaction and 42 remaining subjects (17.4%) with intermediate or poor level of

satisfaction (13.3 and 4.1%) respectively. There was no difference in the percentage of patients with a high level of satisfaction according to surgical procedure: 82.9% for SRM alone, 82.6% for SRM plus anoplasty and 80.6% for SRM + sphincterotomy.

Factors significantly associated with satisfaction level were the appearance of some type of postoperative complication and percentage of symptoms resolved (Table 5); 11.6% of the patients ($n = 23$) with a good degree of satisfaction presented some type of complication compared to 33.3% of patients ($n = 14$) and intermediate or poor level of satisfaction. Similarly, 8% of the patients ($n = 16$) with a high level of satisfaction had a percentage of symptoms resolved of >80% in comparison with 54.8% of subjects ($n = 23$) with an intermediate or poor level of satisfaction. However, according to multivariate analysis, only the percentage of symptoms resolved (>80%) was kept as an independent factor associated with an intermediate/low level of satisfaction ($p < 0.001$, OR = 11.6 [95% CI = 4.9-27.3]). The follow-up period was 17.8 months (range: 12-42 months).

Discussion

SRM alone or combined with subcutaneous sphincterotomy or cutaneous flap anoplasty has a percentage of 81.7% of asymptomatic subjects and a percentage of resolution in >80%

Table 2. Factors associated with the presence of postoperative complications

Variable	Complications (n = 37)		No complications (n = 204)		p
	n	%	n	%	
Female	17	45.9	79	38.7	0.41
Age (years)*	41.1 (27-60)		43.9 (24-72)		0.07
<50 years	32	86.5	149	73.0	0.08
Comorbidities present	5	13.5	22	10.8	0.58
Grade of disease					
2	5	13.5	29	14.2	0.64
3	28	75.7	141	69.1	
4	4	10.8	34	16.7	
Other anorectal disease	12	32.4	41	20.1	0.10
Surgical procedure					
Only SRM	24	64.9	163	79.9	0.02
SRM + sphincterotomy	10	27.0	21	10.3	
SRM + cutaneous flap anoplasty	3	8.1	20	9.8	
Use of hemostatic suture	28	75.7	140	68.6	0.39
Preoperative antibiotics					
Metronidazol	22	59.5	101	49.5	0.26
Cefuroxime	15	40.5	103	50.5	
Dehydrated epithelium (donor)					
Columnar	17	45.9	130	63.7	0.04
Columnar and transitional	20	54.1	74	36.3	
Flaky	4	10.8	2	1.0	
Smooth muscle fibrous area	15	40.5	3	50.5	0.27

*Average (range).

SRM, stapled rectal mucosectomy.

of symptoms of 83.8% at 17.8 months (range: 12-42 months) of follow up. Independent of the surgical procedure, the risk of having any complication among those whose resected doughnut exclusively reported columnar epithelium is less than if it included only transitional epithelium. In fact, other studies have reported the association of some complications with a low staple level or very close to the dentate line.^{15,25}

Whereas the inclusion of smooth muscle in the doughnut, which seems inevitable, does not appear associated with complications or with impaired quality of life,^{14, 15,26} it is difficult for a surgeon who knows and has mastered the technique of SRM to place a staple near the dentate line. The great percentage of complications and the most serious from a clinical standpoint are presented with the combined procedure of SRM + sphincterotomy. In reports on complications of closed and open sphincterotomy, alone and with other anorectal procedures, the most common complication was gas incontinence in 7% to 23%.^{27,24} Other less-frequent complications are bleeding, anal itching, mucous discharge and abscess (the latter only with closed or submucosal technique).²⁴

The majority of the complications (incontinence, moist anus, and abscess) that occurred in our patients following SRM + sphincterotomy are expected according to the literature, except for urgency to defecate. The latter is not reported as a common

Table 3. Multivariate analysis of factors associated with postoperative complications

Factor	OR*	95 % CI	p
Surgical procedure			
SRM only	1.0		
SRM + internal sphincterotomy	3.51	1.41-8.78	0.007
SRM + cutaneous flap anoplasty	1.1	0.29-3.97	0.91
Resected epithelium			
Columnar and transitional	1.0		
Columnar	0.41	0.20-0.86	0.019

*Adjusted by age group.

SRM, stapled rectal mucosectomy.

Table 4. Postoperative symptoms according to procedure

Variable	Surgical procedure							
	Rectal mucosectomy (n = 187)		Mucosectomy and internal sphincterotomy (n = 31)		Mucosectomy + cutaneous flap anoplasty (n = 23)		Total (n = 241)	
	n	%	n	%	n	%	n	%
Some symptoms*	34	18.2	7	22.6	3	13.0	44	18.3
Asymptomatic	153	81.8	24	77.4	20	87.0	197	81.7
Resolution ≥80% of symptoms*	156	83.4	25	80.6	21	91.3	202	83.8
Prolapse								
Disappeared	185	98.9	31	100.0	22	95.7	238	98.8
Persistent	2	1.1	0	0.0	1	4.3	3	1.2
Hemorrhage								
Disappeared	165	91.7	27	90.0	20	90.9	212	90.6
Persistent	17	9.3	3	10.0	2	9.1	22	9.4
Perception of cutaneous flaps								
Disappeared	91	86.7	13	100.0	22	95.7	126	89.4
Persistent	14	13.3	0	0.0	1	4.3	15	10.6
Anal pruritis								
Disappeared	50	86.2	3	42.9	8	100.0	61	83.6
Persistent	5	8.6	2	28.6	0	0.0	7	9.6
Appeared	3	5.2	2	28.6	0	0.0	5	6.8
Pain/anal burning								
Disappeared	98	97.0	30	96.8	14	93.3	142	96.6
Persisted	2	2.0	1	3.2	1	6.7	4	2.7
Appeared	1	1.0	0	0.0	0	0.0	1	0.7
Urgency to defecate								
Disappeared	5	41.6	1	20.0	0	0.0	6	33.3
Persisted	2	16.8	0	0.0	0	0.0	2	11.1
Appeared	5	41.6	4	80.0	1	100.0	10	55.6

* $p > 0.05$ (χ^2 with 2 degrees of freedom).

complication after sphincterotomy, but it has been reported after SRM alone in 5% to 18% of patients.^{6,14,16}

It is likely that the greater frequency of urgency in patients who underwent SRM + sphincterotomy compared with those who underwent SRM alone or with flap anoplasty (12.9% vs. 2.7% and 4.3%) is explained by the simultaneous execution of both procedures.

Unlike complications such as minor anal incontinence, defecation urgency and pain, as in the only report of 26 cases with SRM + sphincterotomy by Kanellos et al.,²⁴ we also observed perianal abscess in 9.7% of our patients.

The frequency of complications reported after closed or subcutaneous sphincterotomy may be up to 5.3%, a figure slightly lower than that found in our study. Moreover, sepsis or perianal

abscess is a complication reported infrequently following SRM alone (<1%).^{13,19} This leads us to consider this complication as inherent to subcutaneous sphincterotomy, in an attempt to explain the increase in the morbidity of SRM combined with sphincterotomy. All complications reported in this analysis can be described as minor in the sense that admission was not required for resolution. It is worth mentioning that in 250 patients we only had a serious complication in a patient who underwent SRM and fistulotomy and presented a perirectal cellulitis that resolved with fasting and IV antibiotics.

The fact that, according to multivariate analysis, complications are not an independent factor associated with the level of satisfaction reported by patients according to their own expectations suggests that the perception of most of these complications by the patient is

Table 5. Factors associated with postoperative grade of satisfaction

Variable	Very good (n = 199)		Intermediate and poor (n = 42)		p
	n	%	n	%	
Female gender	78	39	18	43	0.66
Age (years)*	42.8 (24-72)		46.4 (27-67)		0.02
<50 years	154	77	27	64	0.07
Grade of disease					
2	29	15	5	12	
3	143	72	26	62	0.12
4	27	14	11	26	
Other anorectal diseases	43	22	10	24	0.75
Surgical procedure					
SRM only	155	78	32	76	
SRM + internal sphincterotomy	25	13	6	14	0.95
SRM + flap anoplasty	019	10	4	10	
Postoperative complications	23	11.6	14	33.3	< 0.001
≥80% of symptoms resolved	183	92	19	45	< 0.001
Follow-up ≤2 years	156	78.4	35	83.3	0.47

*Average (range).

minor and therefore have little impact on satisfaction, which in fact seems to be determined by the control of preoperative symptoms.

The residual symptom which appeared uniformly in all three groups was mild and episodic bleeding in most cases and probably secondary to detachment of some staple or arising from subepithelial capillaries from the relocated hemorrhoidal complexes. The vast majority of subjects with persistent skin tags are from the group of patients who underwent SRM alone, but resection of the tags after SRM as well as a traditional hemorrhoidectomy does not guarantee complete disappearance in all subjects. However, in selected cases it may be considered as a possibility because it does not appear to increase morbidity. In addition, SRM + sphincterotomy achieved adequate control of symptoms arising in the anal fissure and control of symptoms caused by HD similar to SRM alone, except for anal itching, which was more associated with factors of continence and, to some degree, affected by sphincterotomy.

We must consider that the type of surgery performed depends on the anorectal ailments of the patient (isolated hemorrhoids, hemorrhoids and skin tags, or hemorrhoids and anal fissure). From the above, it is likely that the final result is closely related to this situation. According to our results, it is possible that patients with hemorrhoids and anal fissure are more likely to experience postoperative complications, regardless of surgical technique.

In conclusion, SRM alone or combined with sphincterotomy or cutaneous flap anoplasty is a procedure that achieves symptom

resolution along with a high level of satisfaction in >80% of patients. Patients undergoing SRM and sphincterotomy simultaneously have more complications than those patients undergoing SRM alone or in combination with anoplasty. Postoperative satisfaction rate was exclusively related to resolution of preoperative symptoms.

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