

# Pre-operative assessment of internal mucosal rectal prolapse in internal hemorrhoids: technical details and results from a single institution

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**Summary.** *Background:* The aim of the study was to assess safety and efficacy of pre-operative assessment for internal mucosal rectal prolapse (IMRP) in internal hemorrhoids, in order to achieve a tailored transanal stapled surgery. *Methods:* All consecutive patients (January 2011 to December 2014; age 18-80 years), affected by prolapses with II-IV degrees hemorrhoids that underwent Longo procedure with EEA<sup>®</sup> Auto Suture stapler (Covidien) were included in the present study. *Results:* A total of 100 consecutive patients (38 females) were enrolled in the study. Preoperative Visual Analogue Scale pain assessment was 7.33±2.68. The mean duration of the procedure was 34.1±17.8 min, and the median hospital stay was 2 days (range 2-6). No major complication occurred, including relapses of mucosal prolapse. Preoperative prolapse measurement with EEA<sup>®</sup> EEA<sup>®</sup> Auto Suture stapler (2.3±0.5 cm) was well correlated direct assessment (2.4±0.6, p<0.001), but a proportional bias was identified, with significant preoperative underestimation of IMRP, particularly for lesions larger than 3 cm (around 10% of actual extent). *Conclusions:* EEA<sup>®</sup> Auto Suture stapler seems to be safe and effective for a tailored approach to anorectal prolapse due to hemorrhoids. However, it reasonable that its actual impact may have been overestimated, benefiting of the repetitive, direct assessment of the operatory field guaranteed by preoperative IMRP measurement. ([www.actabiomedica.it](http://www.actabiomedica.it))

**Key words:** hemorrhoids, hemorrhoidal prolapse, longo procedure, short-term follow-up

## Introduction

Hemorrhoids are a common and underreported condition defined by the symptomatic enlargement and the distal displacement of the normal anal cushion (1): exact data on the hemorrhoid epidemiology are scant, but studies from high income countries suggest a prevalence ranging between 4.4% (United States) and 13-36% (United Kingdom), usually peaking between age 45 to 65 years (1, 2).

The traditional surgical approach is represented by the conventional excisional hemorrhoidectomy (CEH), performed either as an open procedure, as described by Milligan and Morgan in 1937 (M&M), or

as a closed one following Ferguson and Parks (3). Both procedures are associated with similar complications: tissue trauma of the perianal skin and anoderm may elicit severe pain, bleeding and post-operative mucosal discharge, collectively requiring prolonged local care (2-4).

In order to avoid such complications, Antonio Longo in 1998 proposed stapled hemorrhoidopexy (SH) as a more efficient alternative to CEH (5, 6). In SH, hemorrhoidal tissue is not removed. Prolapsed internal hemorrhoids and anoderm are actually re-located and anchored by stapling and excising excess distal rectal mucosa. SH has therefore the potential to generate less post-operative pain than CEH. On the

one hand, the excised wound doesn't involve somatic innervation area. On the other hand, surgical procedure usually impairs the blood flow through superior hemorrhoidal vessels, ultimately enhancing symptom resolution (6, 7). As a consequence, SH would be associated with significant short- and long-term benefits, in particular a faster return to normal activities, which may offset its higher equipment costs (8-10).

Available evidence suggests that SH may be a safe, quick and less painful treatment also for symptomatic second and third degree hemorrhoids (2, 6, 8-12), whereas some uncertainties still remain for large external or thrombosed internal haemorrhoids (IHs) (8, 9, 11, 13, 14). Therefore, the preventive assessment of the patient, including an accurate measurement of the mucosa to be excised is critical for an appropriate selection of surgical procedure, as big full-thickness internal or external prolapses or even rectoceles should receive abdominal or perineal procedures, whereas for IHs without internal mucosal rectal prolapse (IMRP), a transanal hemorrhoidal artery ligation under Doppler control with mucopexy has been acknowledged as a more appropriate approach (4, 11, 15).

In such a setting, preliminary IMRP measurement has become the cornerstone for a more appropriate surgical treatment, and here we present the experience of our institution with a specifically designed instrumentation (EEA<sup>®</sup> Auto Suture stapler; Covidien) aimed to improve the reliability of the preliminary assessment.

## Method

### *Aims*

Primary endpoint of our study was comparing preliminary and intra-operative prolapse assessment. Secondary endpoints included post-operative pain, and incontinence symptoms.

### *Patients*

All consecutive patients with age between 18 and 80 years, male or female, having a rectal prolapse from II to IV grade, that presented to the Surgical Depart-

ment of Codogno Hospital (ASST of Lodi- Italy) between January 2011 to December 2014 were considered eligible for inclusion in the study. Written informed consent was obtained from all patients. Data including the patients' demographic characteristics, pre- and postoperative pain, and complications were recorded in a specifically designed database, whose content was ultimately retrieved and analyzed. Hospital discharge was approved when the patient was fully ambulant and analgesics were no longer required.

### *Exclusion criteria*

Patients with significant comorbidities and patients having a poor understanding of the Italian language.

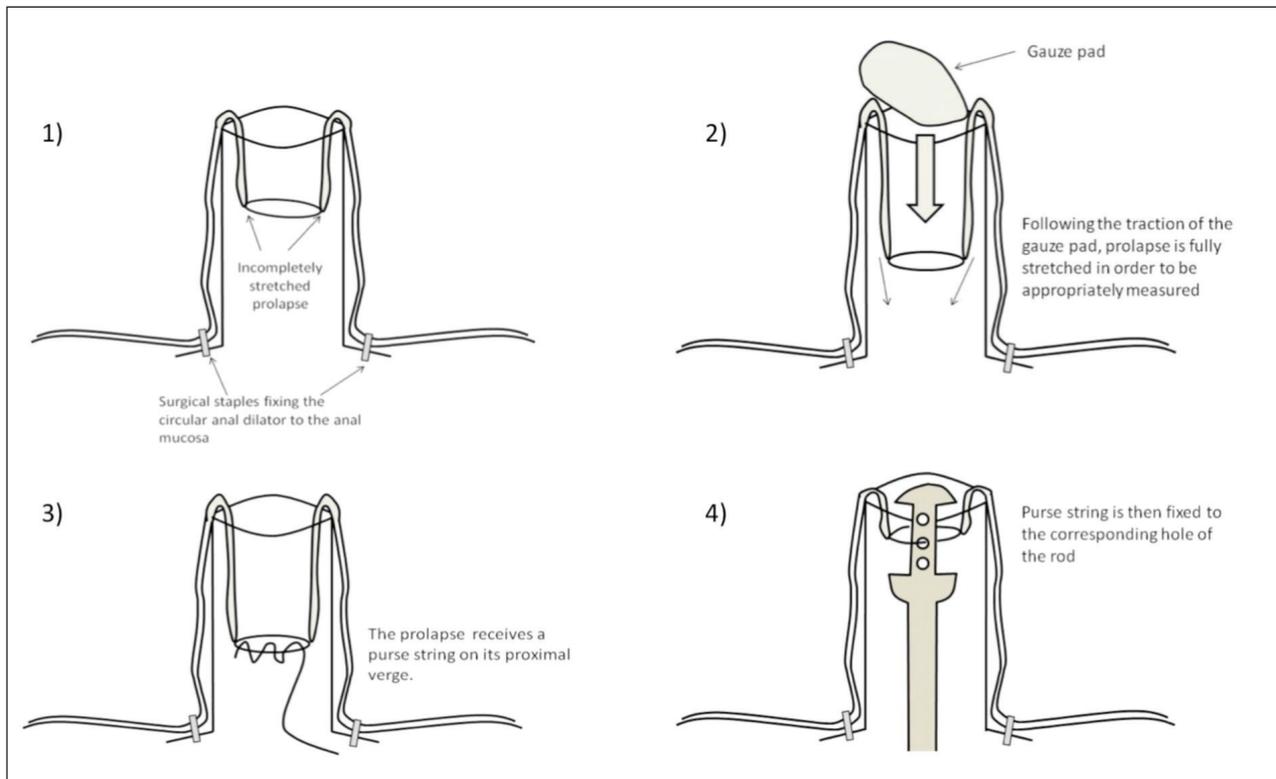
### *Surgical techniques (Figure 1)*

We performed rectoscopy on each patient before surgery to establish stage of the disease and to eliminate any other pathology responsible for hemorrhoid-like syndrome. The IMRP was measured in order to tailor the exact quantity of mucosa to be excised. All measurement were performed by using the device EEA<sup>®</sup> Auto Suture (Covidien) that has an anvil detachable from the stapler with three holes on the rod. As indicated below, the surgical technique is simple, the only critical point is to fix the purse string at the corresponding hole on the rod of the anvil in relation to the length of the prolapse. i.e. for prolapses 1 to 2 cm long, at the first hole; for prolapses 2 to 3 cm long at the second hole; for prolapses longer than 3 cm to the third hole.

All patients received the same regimen of analgesia; analgesics were not routinely given unless the patient reported moderate or severe pain. An oral paracetamol table (1 g per dose) was initially given. The frequency of analgesic use during the first 24 h and days during which the patient required analgesics were recorded.

### *Pain*

Before surgical procedures, the patients were instructed to record pain using a visual analogue scale (VAS), and such data were recorded at hospital admission (T0), at 24<sup>th</sup> hour post-surgery and 6 months after



**Figure 1.** Surgical technique. Following the fixation of the circular anal dilator to the anal mucosa (1), a gauze pad is inserted into the rectum and then dragged downwards in order to stretch the prolapsed mucosa (2), allowing its appropriated measurement. The prolapse (3) then receives a purse string on its proximal verge, that is eventually fixed to the corresponding hole of the rod (4)

surgery (= end of follow up). The scale ranged from 0 to 10, with 0 corresponding to “no pain” and 10 to “the worst pain conceivable”. Similarly, patients were requested to report the presence of itching, bleeding on defecation, soiling, and the need to reduce a mucosal prolapse manually after defecation. The aforementioned questions were graded according to the frequency of the symptoms similarly to pain data, and recorded at admission and at the end of the follow up.

#### Statistical analyses

Student’s t test for two paired data was used for the comparison of continuous variables. Statistical relationship between preliminary and surgical prolapse measurements was assessed through correlation analysis and calculation of the Spearman’s rho coefficient.

As correlation describes linear relationship between two sets of data but not the differences (i.e. their agreement) (16-18), the Bland-Altman method

(BAM) was then applied in order to assess the comparability between methods. As Bland-Altman plot may produce a proportional bias (i.e. the methods do not agree equally through the range of measurement) a linear regression line was fitted (19-20): as stated by Ludbrook, the proportional bias was retained as absent whether the regression line fitted to the Bland-Altman plot was not significantly different from zero.

Sensitivity, Specificity and correspondent Positive and Negative Predictive Values (PNV and NPV, respectively) were calculated through a 2x2 table by assuming a cut-off value of 3 cm.

#### Ethics

Informed consent was obtained from all individual participants included in the study after detailed explanation of possible complications. The use of the device EEA® Auto Suture (Covidien) in common and well known.

## Results

### *Patients characteristics*

Eventually, 100 consecutive patients were included in the study, and their characteristics are summarized in Table 1. Mean age of the sample was  $54.5 \pm 16.0$  years, and 62% of the patients were males. Regarding the grade of prolapses, 73% had a grade 2 and 27% a grade 3. No one among participants had a previous anal surgery. Mean operation time was  $34.1 \pm 17.8$  min, with a median hospital stay of 2 days (range: 2 to 4).

### *Symptoms*

Focusing on pre-operative symptoms, the most frequently reported was dyschezia (17%), followed by constipation (16%), and diarrhea (5%), for a preoperative mean symptom score of  $7.33 \pm 2.68$ . All complaints significantly decreased at the end of the follow up, with

no reported prolapse recurrence and a cumulative score assessment of  $4.48 \pm 1.94$  ( $p < 0.001$ ).

### *Staple Line*

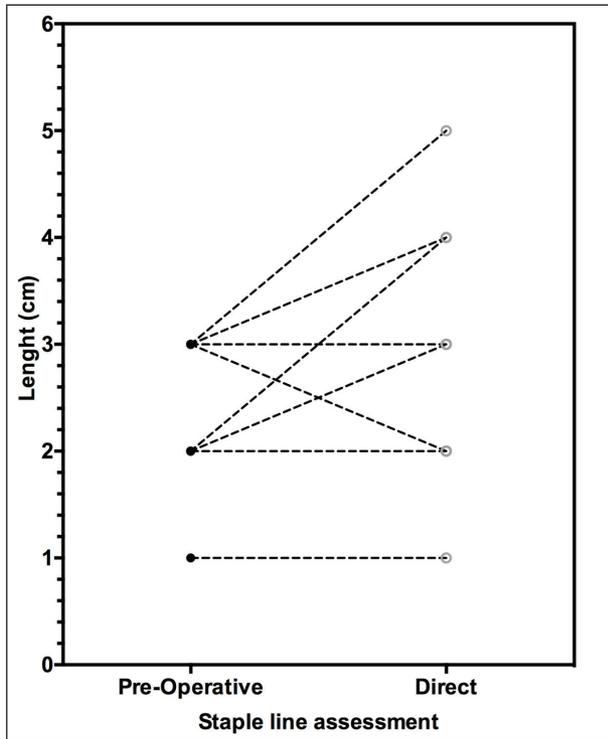
Preoperative height assessment of the staple line was  $2.3 \pm 0.5$  cm, compared to an intra-operative assessment of  $2.4 \pm 0.5$  cm, with a mean difference of  $0.27 \pm 0.6$  cm, and the difference was statistically significant (Student's t test  $p$  value  $< 0.001$ ) (Figure 2).

Focusing on the correlation of pre-operative and intra-operative values, they were significantly correlated (Pearson's  $r = 0.458$ ;  $p < 0.001$ ; Figure 3).

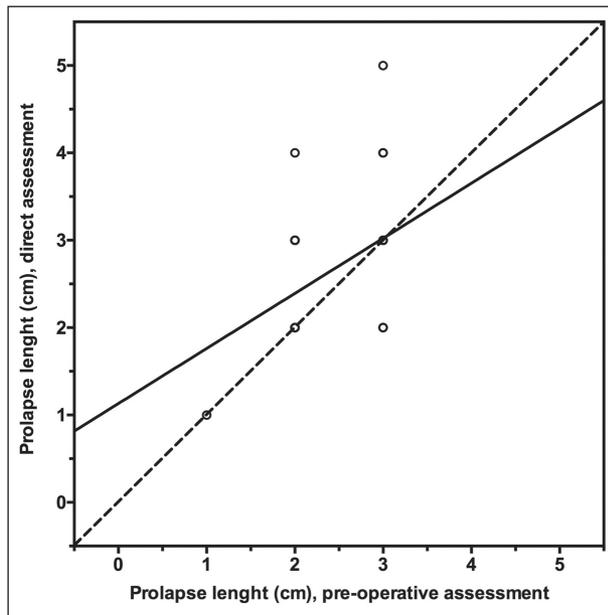
Agreement of the measurements is eventually represented in Figure 4: a bias of  $0.27 \pm 0.6$  cm was calculated, that is pre-operative assessment systematically underestimated height of the staple line of  $9.9\% \pm 22.5$ . As regression analysis identified a slope with a significant  $p$  value ( $< 0.001$ ), proportional bias was not ruled out.

**Table 1.** Clinical details of 100 consecutive patients included in the study sample

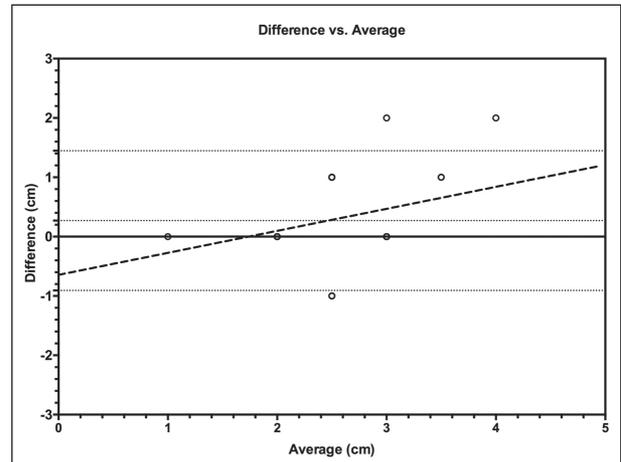
	Characteristics
Age (years; mean $\pm$ S.D.)	54.4 $\pm$ 16.0
Male/Female (No.)	62/38
Grade 2, 3 (No.)	73, 27
Operation time (min; mean $\pm$ S.D.)	34.1 $\pm$ 17.8
Hospital stay (days; median, range)	2, 2 to 4
Height of staple line (cm; mean $\pm$ S.D.)	
Preoperative assessment	2.3 $\pm$ 0.5
Direct assessment	2.4 $\pm$ 0.6
Visual Analogue Scale pain assessment (0-10; mean $\pm$ S.D.)	
Pre-operative	7.33 $\pm$ 2.68
Post-operative	4.48 $\pm$ 1.94
Complained pre-operative symptoms (No.)	
Constipation	16
Dyschezia	17
Diarrhea	5
Previous anal surgery	0
Postoperative complications (No.)	
Bleeding	2
Relapses	0
Surgical site hematoma	1
Thrombosis	0
Urinary retention	12



**Figure 2.** Comparison of pre-operative and operative assessment of staple line (cm). Overall, preoperative assessment significantly underestimate direct, intra-operative assessment of the height of the staple line (Student's t test p value<0.001)



**Figure 3.** Correlation between pre-operative and direct assessment of the staple line (cm). Measurements well positively correlated (Pearson's r=0.458; p<0.001)



**Figure 4.** Bland-Altman plot of Difference vs. Average. Dotted line represent linear regression analysis of plotted data. As regression was not significantly different from zero, proportional bias was not ruled out, i.e. differences of measurements significantly increased across the measured heights. More specifically, we observed increased differences for values of 3 cm or more, as suggested by the low specificity observed

Eventually, sensitivity and specificity were calculated assuming the 3 cm cut-off value, and preoperative assessment through EEA® Auto Suture had a sensitivity of 0.870 (95%CI 0.737-0.951), whereas specificity was 0.519 (95%CI 0.378-0.657), with correspondent positive and negative predictive value of 0.824 (95%CI 0.655-0.932) and 0.606 (95%CI 0.478-0.724), respectively (Table 2).

**Conclusions**

In 1998, Longo proposed SH for treating hemorrhoidal prolapse in order to minimize postoperative discomfort, ultimately improving both short-term prognosis (5). Nowadays, SH is acknowledged as a safe and effective treatment for symptomatic second and third degree hemorrhoids (2, 6, 8-12), while its effectiveness for larger and complicated IHs, as well as on the long-term follow-up still remains largely disputed (8, 9, 11, 13, 14). More specifically, in their metanalysis Yang et al (21) reported a significantly lower incidence of residual skin tags and prolapse in hemorrhoidectomy than in SH patients (OR 0.17, 95%CI 0.06-0.45), with a significantly lower incidence of post-operative recurrence (OR 0.21, 95%CI 0.07-0.59). As recur-

**Table 2.** Sensitivity, specificity, positive and negative predictive values (PNV and NPV, respectively) for preoperative measurement of stapled line as <3 cm

	Preoperative assessment		Sensitivity (95%CI)	Specificity (95%CI)	PPV (95%CI)	NPV (95%CI)
	≥ 3 cm (N = 54)	<3 cm (N = 46)				
Direct assessment						
≥ 3 cm	6 (13.0%)	28 (51.9%)	0.519 (0.378-0.657)	0.870 (0.737-0.951)	0.824 (0.655-0.932)	0.606 (0.478-0.724)
< 3 cm	40 (87.0%)	26 (48.1%)				

rence of mucosal prolapse is likely to be due to failures in removing an adequate volume of prolapsing tissue (21-22), preliminary IMRP measurement through specifically designed instrumentation has the potential to significantly improve surgical outcomes, particularly post-operative pain and recurrence rates (22).

In effect, we identified a mean VAS value of  $4.84 \pm 1.84$ , that is in line with available reports, usually ranging from 3 to 5.3 (21), but the large majority of complaints was associated with symptoms such as urinary retention (12%), that is only partially related with the surgical procedure *per se*. Moreover, no cases of prolapse recurrence were reported at the end of follow up, that is significantly lower than the recurrence rate reported in literature about stapled surgery (i.e. 7.5%) (21-22), and even lower than that reported by Naldini et al in their study on the treatment of hemorrhoids with a similarly designed device (i.e. 1.9%) (22).

In times characterized by increasing attention to the costs-effectiveness of surgical procedures, the opportunity to complicate surgical procedure with a preventive assessment may be questioned. In fact, in our sample we identified a cumulative operating time of  $34.1 \pm 17.8$  minutes, that is significantly longer than that reported by available reports for conventional SH (i.e. ranging from 15 to 27 minutes) (1, 2, 7, 9, 10, 21), but somehow similar to the time range reported by Naldini et al (i.e. 15 to 60 minutes) with a modified stapler device (22).

However, the potential impact of preliminary IMRP measurement on clinical practice should cautiously be assessed. First and foremost, it should be stressed that hemorrhoidectomy is steadily among the

most frequently performed surgical procedures, and because of its limited sample size our study simply lacked the statistical power to provide reliable answers to the question whether this procedure may actually reduce complication and relapse rates (1-10).

Second, we identified a significant proportional bias, that specifically affected larger prolapses: even though preoperative assessment of prolapse was well correlated with intra-operative measurements, its sensitivity (i.e. 51.9%) was unsatisfying, and particularly for lesions larger than 3 cm. In fact, preliminary IMRP measurement of larger prolapses underestimated their extent in nearly half of cases. Therefore, it is reasonable to question whether preliminary measurement had a positive impact on post-operative issues, or other factors were actually involved. As previously stressed by previous reports (14, 23-25), accurate, direct vision of the operative field reduces the risk for severe complications. In other words, it is reasonable to assume that the outcomes recorded in our sample, and particularly the very low recurrence rate, have been extensively influenced by the repetitive assessment of the operative field.

Third, despite we performed a direct clinical examination of patients, including VAS collection, symptoms were neither investigated through a validated questionnaire on the quality of life, nor appropriately blinded towards investigators (25). Therefore, we cannot rule out that our results have been affected by a significant social desirability bias, i.e. participants reporting the "socially appropriated" rather than their authentic complaints in order to satisfy the interviewing clinician (26-28).

In conclusion, the use of EEA® Auto Suture in mucoemorrhoidal prolapse up to 3 cm allows an appropriate measurement of the prolapsed mucosa to be excised. Patient satisfaction both in short- and long-term was good. However, we have observed that the measurement of the excised tissue may be significantly underestimated for lesions larger than 3 cm, but this inaccuracies may have been compensated by the repetitive, direct assessment of the operatory fields. In summary, our results suggest that the use preliminary IMRP measurement through EEA® Auto Suture may be considered as a possible technical option for a tailored surgery. On the contrary, larger studies are required to accurately assess the actual impact of IMRP on surgical prognosis.

**Conflict of interest:** Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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