

# Effects of Stapled Hemorrhoidopexy on Anorectal Function: A Prospective Randomized Controlled Trial

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## What's Known

- Stapled hemorrhoidopexy is a safe and acceptable alternative to traditional hemorrhoidectomy with shorter hospital stay, better satisfaction, and less postoperative pain.

## What's New

- These data represent a series of patients with 3 months' follow-up after stapled hemorrhoidopexy and suggest that this technique is safe in experienced hands. It may have protective effects on anorectal function in patients with imperfect continent scores.

## Abstract

**Background:** Stapled hemorrhoidopexy is a safe and acceptable alternative to traditional hemorrhoidectomy with shorter hospital stay, better satisfaction, and less postoperative pain. There have, however, been reports on early and late complications. Therefore, the present study was designed to assess the impact of stapled hemorrhoidopexy on anorectal function and continence.

**Methods:** Sixty-one patients with rectal prolapse and/or symptomatic circumferential hemorrhoidal disease, as validated by the Wexner incontinence score, were included. Anal manometric indices were measured. The Wexner scores and anal manometric measures were compared pre- and postoperatively using the Mann–Whitney U test. (A  $P < 0.05$  was considered significant.)

**Results:** Mean age was 46.8 years (range=18–80 y), with a mean follow-up time of 3 months. Fifty-one patients completed their follow-ups. For 45 patients with a Wexner score of 0 and no history of incontinence, the anal maximum squeezing pressure (AMD) was  $125.3 \pm 43.1$  mm Hg, the anal resting pressure (ARD) was  $27.8 \pm 12.8$  mm Hg, and the mean pressure was  $40.0 \pm 16.8$  mm Hg. The changes in the anorectal manometric indices before and 3 months after the operation were not statistically significant ( $P=0.99$ ,  $P=0.55$ , and  $P=0.32$ , respectively). In 6 patients with Wexner scores of 1 or higher, the mean values of the AMD, ARD, and mean pressure not only decreased but also increased postoperatively, but the changes were not statistically significant ( $P=0.32$ ,  $P=0.42$ , and  $P=0.45$ , correspondingly).

**Conclusion:** These data represent a series of patients with 3 months' follow-up after stapled hemorrhoidopexy and suggest that this technique is safe in experienced hands. It may have protective effects on anorectal function in patients with imperfect continent scores.

**Trial Registration Number:** IRCT2015101324504N1

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**Keywords** • Anorectal • Hemorrhoids • Continent score • Rectal Prolapse • Recovery of Function

## Introduction

The procedure for prolapse and hemorrhoids (PPH) is a method based on stapled transanal mucosectomy. This is the most important surgical treatment with respect to a normal anal

anatomy.<sup>1</sup> Widespread usage of this modality began in 1988 after modifications done by Longo.<sup>2</sup>

Stapled hemorrhoidopexy is done with a circular stapler device, which circumferentially removes the mucosa and submucosa above the hemorrhoidal cushions.<sup>1</sup> Many studies have reported low pain, short hospital stay, and early return to work in comparison with conventional hemorrhoidectomy,<sup>3</sup> which accounts for the inclination among patients toward stapled hemorrhoidopexy.<sup>2</sup>

The Longo procedure for treating symptomatic circumferential hemorrhoidal prolapse is based on a new concept vis-à-vis hemorrhoids. In this theory, the hemorrhoidal disease is always associated with an internal prolapse. Through the resection of the prolapse, the internal prolapse is lifted up and the hemorrhoidal piles are reduced to the normal position.<sup>4</sup>

Piles have a main role in continence, and atrophy of anal cushions is observed in patients with idiopathic incontinence.<sup>4,5</sup> Thus, excision of the mucosa above the level of the piles instead of excision of the piles, conducted via the PPH, should reserve the sampling effect and finally continence. There is, however, concern that incontinence may follow stapled hemorrhoidopexy, although it is not usual.<sup>5</sup>

Soon after Cheetham et al. reported fecal urgency after stapled hemorrhoidopexy, concern arose whether this new technique might cause incontinence.<sup>1,6</sup> It may be only gas incontinence, but temporary stool incontinence and soiling has been reported, especially in the fourth-degree piles.<sup>6</sup>

We performed stapled hemorrhoidopexy in 61 patients during the study period. The patients were specifically evaluated for postoperative incontinence, an important early and late complication. Lack of prospective clinical and functional results after stapled hemorrhoidopexy motivated us to design the present study to assess the impact of the Longo technique on anorectal function and stool continence.

## Patients and Methods

The present study was conducted in Shahid Faghihi Hospital, Shiraz, Iran, from April 2015 to March 2016. In this prospective study, 61 patients randomly underwent the PPH for rectal prolapse and/or symptomatic circumferential hemorrhoidal disease.

All patients with symptomatic circumferential hemorrhoidal disease grades 3 or 4 and/or rectal prolapse after conservative treatment failure were included. Written informed consent was obtained from all the participants in the study.

Patients with a history of diabetic mellitus, neurological disease, and other anal pathologies (i.e., fistula, fissure, and anal stenosis) were excluded. Patients with a history of fecal incontinence and/or Wexner scores more than 0 were categorized into a separated group to be compared with them. The operations were performed by different residents and surgeons, but all were done under the supervision of a single experienced colorectal surgeon and with the same devices.

Anal anatomy was assessed by rectal examination. The patients were questioned and examined personally by a single surgeon about their anorectal function before and after the surgery prospectively. All the patients were asked to complete the Wexner scale scoring system of incontinence at baseline. To evaluate the anal function, we measured a validated Wexner incontinence scale score system (total incontinence score 0: best and 20: worst) and anal manometric indices 1 day preoperatively and 3 months postoperatively. The Wexner scale, described by Wexner and Jorge, consists of items regarding the frequency of fecal and gas incontinence.<sup>7</sup> The anal manometric measures and Wexner scores were compared pre- and postoperatively.

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences, Shiraz, Iran, and registered in the Iranian Registry of Clinical Trials (IRCT2015101324504N1).

To undergo anorectal manometry, the patients were positioned in the left lateral decubitus position with knees flexed. Manometry was done by a single technician.

For anal manometry, a sphinctrometer system (MSM Promedico GmbH) was used. After calibration, a probe was introduced into the rectum about 6 cm from the anal verge. The anal resting pressure (ARD), anal maximum squeezing pressure (AMD), and mean pressure were calculated. The resting anal canal pressure mainly reflects the internal anal sphincter function, while the voluntary squeeze pressure predominantly reflects the external anal sphincter function.<sup>8</sup>

Additionally, we used a questionnaire to register such indices as clinical signs and symptoms, staple-line bleeding requiring suture, distance of the staple line from the dentate line, length of the operation (from the beginning of anal dilatation until the removal of traction sutures), and duration of the patients' disease.

### *Surgical Technique*

The operation was performed in the lithotomy position. First, the anal canal was gently dilated

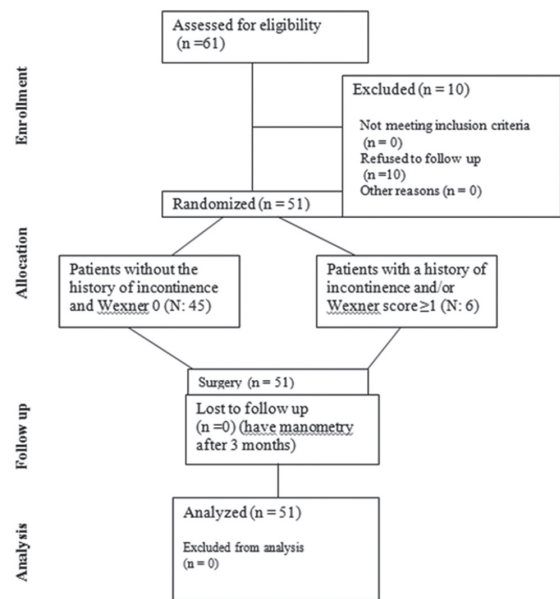
by using an obturator. Traction sutures were applied at 3, 6, 9, and 12 o'clock to fix the circular dilatator (CHEX CPH 34). Efforts were made to prevent the traction sutures from taking the prolapsed tissue so as to enable the complete removal of the prolapsed tissue. With an open-sided anoscope (CHEX CPH 34), a purse suture was inserted into the mucosa and submucosa of the rectum at level 2 of the open-sided anoscope (approximately 3–4 cm above the hemorrhoidal piles). In the females, a vaginal examination was done before firing the stapler to ensure that the posterior vaginal wall was not involved by the sutures. With a circular stapler, a circumferential mucosal resection of about 2 to 3 cm was done. The resulting staple line was seen about 1.5 to 2 cm above the dentate line. Thus, the mucosal prolapse and prolapsed hemorrhoid was lifted up into the proximal anal canal. If the staple line was situated 1 cm or less above the dentate line, it was considered a low-lying staple line. Staple-line bleeding was controlled with absorbable sutures. The excised mucosal doughnut was sent for pathological examination.

#### Statistical Analysis

Differences in gender, age, length of the operation, and duration of the patients' disease were analyzed using the Mann–Whitney U test. In the continuous variables, nonparametric equivalents of the analysis of variance or the Paired Student t-test were used. The correlations between anorectal manometric indices and incontinence and the length of the operation, staple-line bleeding requiring suture, duration of the patients' disease, and site of the staple line were evaluated using the Pearson correlation test. A P value less than 0.05 was considered statistically significant. All the statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) for Windows, version 16.

## Results

From April 2015 through March 2016, a total of 61 patients underwent the PPH for rectal prolapse and/or symptomatic circumferential hemorrhoidal disease. The patients' mean age was 46.8 years (range=18–80 y), with a mean follow-up time of 3 months. The male-to-female ratio was 3.3:1. Ten patients failed to refer for follow-up manometry after 3 months. The remaining 51 patients were categorized into 2 groups: those without a history of incontinence and a Wexner score of 0 (n=45) and those with a history of incontinence and/or a Wexner score equal to or greater than 1 (n=6) (figure 1).



**Figure 1:** CONSORT diagram shows the flow of participants through each stage of a randomized trial.

Regarding the indications for surgery, 17 (33.3%) patients had high-grade hemorrhoids and rectal prolapse, 34 (66.6%) had rectal prolapse and none had hemorrhoids alone. These patients underwent stapled hemorrhoidopexy. The mean length of the operation was 20.6 minutes (12–35 min), and the mean duration of the patients' disease was 3.7 years (0.2–6.2 y). Staple-line bleeding requiring suture was observed in 7 (11.5%) patients, who needed a mean of 3 (1–5) absorbable stitches. In 2 patients, the staple line was situated 1 cm or less above the dentate line. The pre- and postoperative manometric indices and Wexner scores in the 51 patients are depicted in table 1.

Although the mean values of the manometric indices (i.e. AMD, ARD, and mean pressure) and the Wexner scores in all the patients (N=51) were decreased 3 months postoperatively, the changes failed to constitute statistical significance.

For 45 patients with Wexner scores of 0 and no history of incontinence, manometry was performed before the surgery: they had an AMD of  $125.3 \pm 43.1$  mm Hg, ARD of  $27.8 \pm 12.8$  mm Hg, and mean pressure of  $40.0 \pm 16.8$  mm Hg. The changes in the anorectal manometric indices before and 3 months after the operation were not statistically significant ( $P=0.99$ ,  $P=0.55$ , and  $P=0.32$ , correspondingly). In 6 patients with Wexner scores of 1 or higher, the mean values of the AMD, ARD, and mean pressure not only decreased but also increased postoperatively; the changes, however, were not statistically significant ( $P=0.32$ ,  $P=0.42$ , and  $P=0.45$ , respectively).

**Table 1:** Mean values of the pre- and postoperative manometric indices and Wexner scores in the 51 patients

N=51		Minimum	Maximum	Mean±Std Deviation	P value
Age		18	80.0	60.0±46.8	
AMD	preoperatively	26.0	218.0	122.2±44.3	0.71
	postoperatively	26.0	253.0	127.6±53.5	
ARD	preoperatively	0.0	56.0	26.0±13.3	0.75
	postoperatively	0.0	64.0	26.8±13.3	
MEAN	preoperatively	0.00	85.0	39.1±18.1	0.31
	postoperatively	0.0	91.0	37.8±17.9	
Wexner score	preoperatively	0.0	12.0	0.61±1.9	0.74
	postoperatively	0.0	10.0	0.39±1.5	

AMD: Anal maximum squeezing pressure; ARD: Anal resting pressure; MEAN: Mean pressure

There were no correlations between the length of the operation, site of the staple line, duration of the patients' disease, staple-line bleeding requiring suture, and values of the AMD, ARD, and mean pressure preoperatively and postoperatively.

In the Pearson correlation analysis, the first changes in the AMD, ARD, and Wexner scores pre- and postoperatively were measured: the results showed no correlations between the changes in the AMD, ARD, mean pressure, and the Wexner scores and the length of the operation (P=0.27, P=0.19, P=0.75, and P=0.33, respectively). In addition, our results revealed no correlations between the changes in the AMD, ARD, mean pressure, and Wexner scores and the duration of the patients' disease, staple-line bleeding requiring suture, and distance of the staple line from the dentate line.

### Discussion

In the current study, we sought to analyze the correlation between the length of the operation, site of the staple line, staple-line bleeding requiring suture, and effects on anorectal function by anorectal manometry and the Wexner score. We observed an approximate drop of 2, 0.5, and 2 mm Hg in the AMD, ARD, and mean pressure, respectively, following stapled hemorrhoidopexy in all of the 51 patients, although the changes failed to constitute statistical significance. Conversely, in 6 patients with Wexner scores equal to or greater than 1, the mean values of the ARD, AMD, and mean pressure improved postoperatively. These results suggest that stapled hemorrhoidopexy did affect the anorectal pressure, but these changes were not significant. This finding runs contrary to that reported by Hong et al.,<sup>9</sup> who demonstrated statistically significant reductions in mean resting pressure after stapled hemorrhoidopexy.

Given the impact of hemorrhoids on continence, upper lifting of the piles by the PPH technique may preserve continence. However, the PPH may cause gas or fecal incontinence, although it is not a frequent occurrence.<sup>4</sup> It may be only gas incontinence, but temporary fecal incontinence, leakage, and soiling have been reported in some studies.<sup>10</sup> Several randomized trials have demonstrated that the PPH is associated with low postoperative pain, low analgesic consumption, short length of surgery, early return to normal activities, and high patient satisfaction rates compared with traditional hemorrhoidectomy because the surgical staple line is situated above the dentate line, where there is no pain sensory receptor.<sup>11,12</sup>

Fecal incontinence developed only in 1 patient in the current study. We observed an increase in the Wexner score of about 0.2 in 45 patients with Wexner scores of 0 preoperatively. Nevertheless, in 6 patients with Wexner scores of 1 or higher preoperatively, the scores improved from 3.8 to 1.8 after hemorrhoidopexy. As was reported in previous articles, the decrease in the Wexner score and fecal incontinence after stapled hemorrhoidopexy is very low and it is highly unlikely that an altered anorectal pressure can cause fecal incontinence. In the current study, the improvement in the Wexner score and anorectal function in the 6 patients with Wexner scores of 1 or higher may have been the result of the deletion of the prolapsed tissue after hemorrhoidopexy. Further investigations with larger groups are, however, needed in this regard.

Low-lying staple lines and fragmentations of the internal anal sphincter induced fecal soiling in studies by Pigot et al.<sup>13</sup> and Ho et al.<sup>11</sup> Even if the internal and external sphincters are not incorporated into the mucosal doughnuts, they may be damaged when they are stretched by the circular anoscope or the stapler head

during the operation. In the study by Ho et al.,<sup>11</sup> it was shown that the anoscope damaged the sphincter when using a stapled ileal-pouch anal anastomosis model.

Hong et al.<sup>9</sup> demonstrated that the ARD and AMD were decreased after stapled hemorrhoidopexy but the changes were not statistically significant. Their findings shows what ours in so far as according to the Pearson correlation analysis, there were no relationships between the length of the operation and changes in the ARD, AMD, mean pressure, and Wexner scores. Further, our study showed no correlations between the duration of the patients' disease and the changes in the AMD, ARD, and Wexner scores after hemorrhoidopexy.

The location of the staple line is very important because a staple line which is too high may be responsible for early recurrence and a staple line which is too low may be associated with severe pain and discomfort. Moreover, low-lying staple lines may incorporate the internal and/or external anal sphincter and cause damage.<sup>12,14</sup> It has been suggested the staple lines about 2 cm above the dentate line are appropriate.<sup>12,14</sup> In our hospital, we made an attempt to apply a purse suture in an area between 3 and 4 cm above the hemorrhoidal piles and a staple line about 2 cm above the dentate line.

In the current study, we did not find any correlation between the manometric indices and the site of the staple line. Our results have some biases because only in 3 of our patients was the staple line situated in a low position. More investigations with more cases will be required to verify the effects of low-lying stapled hemorrhoidopexy on anorectal function and manometric indices.

Even though the surgeon must always check the staple line for any bleeding at the end of the operation, postoperative bleeding is not a rare occurrence (approximately 5%).<sup>5</sup> Staple-line bleeding requiring suture was observed in 7 (11.5%) of our patients, and 2 of these cases were returned to the operating room. It seems that bleeding after stapled hemorrhoidopexy requiring suture had no influence on the Wexner score, AMD, ARD, and mean pressure ( $P=0.7$ ,  $P=0.2$ ,  $P=0.5$ , and  $P=0.9$ , respectively).

The main limitation of the present study is that the surgical operations were conducted by different surgeons and residents. However, all of the surgeons and residents used the same device and all of the operations were supervised by a single experienced colorectal surgeon. A small sample size and a short follow-up duration can also be deemed noteworthy drawbacks of our study.

To the best of our knowledge, this study is one of the first studies of its kind to prospectively investigate the correlation between changes in pre- and postoperative anorectal manometric indices following stapled hemorrhoidopexy. Our results are interesting in that they showed improvement in terms of incontinence, manometric indices, and Wexner scores in our patients with rectal prolapse after the PPH. Accordingly, we suggest that surgeons try to apply the Longo procedure in a safe manner and minimize any injury during the operation.

## Conclusion

Mucosal resection, described by Longo, is an ideal method; it is, nonetheless, difficult to claim that all of its complications are preventable. Although the incidence of fecal incontinence is rare and the decrease in the Wexner score is not significant, stapled hemorrhoidopexy may influence anorectal function and pressure. On the other hand, it may have protective effects on anorectal function in patients with imperfect continence scores.

The present data revealed that the mean length of the operation, bleeding from the suture line, mean duration of the patients' disease, and position of the staple line had no significant negative impact on anorectal function and the Wexner score. Thus, effectiveness of the PPH, lack of pain, and low risk of infection in this noninvasive method in incontinent patients could be the most important points in this study.

**Conflict of Interest:** None declared.

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