Comparative study between stapled and open hemorrhoidectomy results with one-year follow-up

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Background
Hemorrhoids are one of the most prevalent diseases of mankind, affecting 4%–36% of the general population. Most patients are asymptomatic. Anal bleeding during the act of defecation is the most common presenting symptom. Many techniques were described for treatment, including stapled hemorrhoidectomy and conventional (open) ones.
Objective
The objective is to compare the effectiveness, short-term outcomes, and postoperative complications of stapled hemorrhoidopexy against open hemorrhoidectomy in the treatment of symptomatic primary piles.
Methods
A total of 76 patients were operated on at Al-Azhar University Hospital. They were divided into two equal groups: the stapled group (operated using a proximate PPH hemorrhoidal stapler of 33 mm) and the open group. All patients were followed for 1 year. Preoperative complaints, operative time and blood loss, postoperative pain, complications, and resumption of daily activities were recorded for both groups.
Results
Intraoperative blood loss and duration of operation were less in the stapler group. Postoperative bleeding, postoperative pain, and discomfort were less in the stapler group, with a significant difference from the open group. Healing and resumption of daily activities were faster in the stapler group. Regarding early recurrence, it happened in two cases in the stapler group and in the open group as well. There are no differences between both groups regarding urine retention. Anal incontinence did not happen in both groups. Mild anal stenosis occurred in one case in every group and occurred late.
Conclusion
Stapled hemorrhoidectomy is a promising procedure with less pain, a shorter duration of hospital stay, and a faster resumption of daily activity than open hemorrhoidectomy. However, long-term follow-up for many years is still needed to define the recurrence rate in stapled hemorrhoidectomy.

Keywords:
hemorrhoids, stapler

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Introduction

Hemorrhoids are one of the most common diseases of mankind, affecting 4%–36% of the general population. Simply, naturally present anal cushions that generate clinical symptoms (expand, bleed, become thrombosed, or prolapse) are referred to as hemorrhoids [1].

Two types are described: internal hemorrhoids, which have their origin in the sub-epithelial plexus of the anal canal above the dentate line, and external hemorrhoids, which are collections of congested exterior perianal vascular plexus covered by perianal skin [2].

Internal hemorrhoids are further categorized into four main grades based on how much they prolapse: Grade I, where hemorrhoids are non-visible or palpable outside the anal verge; Grade II, which prolapse on straining but reduce spontaneously; Grade III, which need reduction manually; and Grade IV, which include permanently prolapsed hemorrhoids. However, this may not always reflect the severity of the patient's symptoms [3].

Many people have no symptoms. The most typical first symptom is bleeding when defecating. In addition to prolapsed hemorrhoids, other symptoms include mucus seepage, pruritus, lack of anal discriminating power, flatus continence, and extremely infrequent fecal incontinence. Hemorrhoids often do not cause discomfort, but when they become thrombosed, they do [4].

The majority of patients start with conservative treatment, which involves dietary and lifestyle changes to reduce constipation. The symptoms of piles can be managed with a variety of pharmaceutical substances, including lotions, non-surgical office procedures, sitz baths, and more [5].

About 40% of people suffering from hemorrhoids need a surgical procedure. Open hemorrhoidectomy (OH) is a generally accepted operation for hemorrhoids. It has obvious effects but is a painful procedure that leads to extended sick leave for 2 to 6 weeks. The affected person, however, additionally faces the headaches of hemorrhage (immediate, reactionary, or secondary), retention of urine, and overdue headaches like stenosis or incontinence [6].

Excision using the open technique (usual diathermy and scissors) is a well-accepted technique with good perioperative and postoperative outcomes [7–10].

A relatively more expensive and new approach for the treatment of hemorrhoids is to use a circular stapler gun, to interrupt the hemorrhoidal vessels, stretch and elevate the prolapsed mucosa [11].

Due to the absence of a perianal incision and the lack of somatic nerve terminations on the rectal wall above the dentate line, Stapler hemorrhoidopexy (SH) is linked with decreased postoperative discomfort. It is linked to a shortened recovery period, a shorter hospital stay, less discomfort, and an earlier return to regular activities [4].

Methods

This clinical study was conducted on 76 patients diagnosed as having symptomatic primary hemorrhoids (second, third, and fourth degrees). They were admitted and operated on in the general surgery department at Al-Azhar University Hospitals. The patients were categorized into two study groups (each included 38 patients): group 1 was treated by stapled hemorrhoidectomy, and group 2 had conventional hemorrhoidectomy.

Inclusion criteria

All patients had symptomatic primary hemorrhoids (second, 3rd, or 4th degree) without age limits (up to 65 and only one 70-year-old very fit patient).

Exclusion criteria

Contraindications to surgery, such as coagulopathy, cases with recurrent piles or 1st-degree piles, associated anal pathology, such as anal fistula and chronic anal fissure ASA (American Society of Anesthesiologists) III, IV, and V, those unable to follow-up, such as patients who will travel very soon,

Study procedure

A full history was taken, which included personal history, chronic diseases, surgical history, and delicate anal history (anal pain, bleeding, and sensation of mass per anus).

General examination was carried out with special emphasis on local anal examination for piles (external or internal, its degree, local complications) for all participant patients.

Routine laboratory investigations were done, including CBC, coagulation profile, hepatitis markers, liver and kidney function tests for patients above 50 years.

ECG and ECHO were performed for any cardiac patients and ECG for those above 40 years old.

Colonoscopy was done for those patients above 50 years old presenting with anal bleeding especially if atypical symptoms were noted.

An intravenous antibiotic (1 gm Ceftriaxone) was administered before surgery. At least one enema was performed in the morning before surgery, and when feasible, a second one was advised to be performed the night before.

Operative technique

In all cases, spinal anesthesia was used as the standard form of anesthesia. At the beginning of the surgery, all patients received 500 mg of metronidazole intravenously. They were also given the prescription to take 500 mg of metronidazole orally three times per day for seven days. Most patients received two enemas before surgery—one at night and another in the morning—and were advised to take 15-20 ml of lactulose twice daily until their bowels started functioning normally again. We chose the lithotomy position to perform the operations for all patients.

Open hemorrhoidectomy

A Kelly clamp was placed over one hemorrhoidal pedicle. The external skin was incised in a v-shaped manner, followed by dissection of the hemorrhoidal plexus in a good plane without any muscle injury using scissor and diathermy towards the clamped pedicle. A Vicryl 2/0 suture was used to ligate the pedicle that was cut at the end and left open to heal. The procedure was

repeated for the remaining hemorrhoid pedicles. Diclofenac suppository was used, and then Bactigrass with gauze impregnated in local anesthetic cream was put into the anus as packing.

The stapler haemorrhoidectomy procedure

After anal dilatation and insertion of the anal ring and fixing it, we made a purse-string suture 2 cm above the dentate line using prolene 2/0 to include only mucosa and submucosa. Haemorrhoidal circular stapler (HCS) was then inserted and the suture was tightened. Closure of the circular stapler was done and kept closed for 30 s then firing it and gentle withdrawal of the stapler, including the doughnut. Examination of the stapler line for any bleeding and controlling it. Finally, diclofenac suppositories were kept, and gentle anal packing was done. The pack was removed after 12 h.

Postoperative follow-up

Patients were discharged home after the removal of the anal pack and ensuring hemostasis. Daily antibiotics and oral analgesics were instructed; three-time sitz baths with disinfectant and then local healing cream was advised to be used.

Daily lactulose was instructed for 3 weeks in addition to Daflon tablets for 1 week.

Patients were advised to avoid excessive movement for the first few days and not to worry if any minor bleeding happened.

A schedule of follow-up was given to patients as follows: every week for 4 weeks, then every 3 months.

The aim of the later follow-up was to check for recurrence, bleeding, and stenosis and assess their satisfaction with the results. A return to work after the third postoperative week was advised.

Figure 1

PROXIMATE® PPH Hemorrhoidal Circular Stapler Set.

Figure 2

Large 3rd degree piles in patient 65 years old presented by bleeding per rectum with negative colonoscopy.

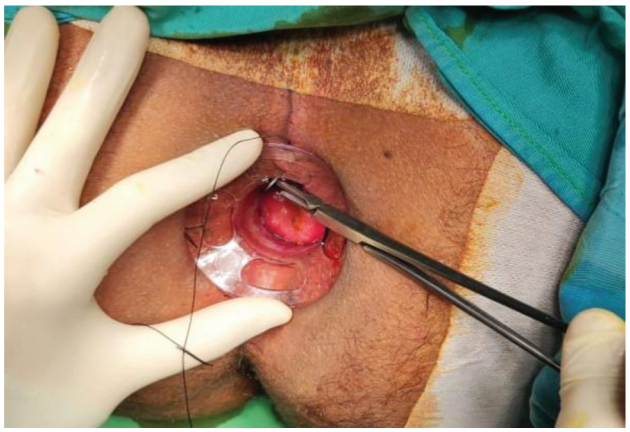
Figure 3

Large internal piles in the patient in Fig. 2.

Figure 4

Anal dilatation then insertion of anal port over dilator.

Figure 5



Fixing anal working port.

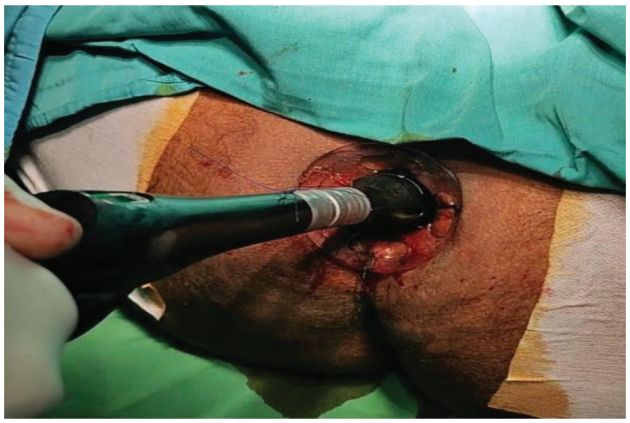
Figure 6

Insertion of purse-string suture speculum.

Figure 7

Preparing stapler gun before insertion into purse-string suture.

Figure 8



Closing the gun and firing after the green sign appears.

Figure 9

Stapling site after firing the gun. The complete disappearance of internal piles was noted.

Figure 10

Final appearance of anal verge at the end of operation.

The time from the start of sterilization to the application of dressing was defined as operative time. Any postoperative complication was reported based on clinical findings, especially pain, bleeding, urine

retention, recurrence, wound infection, and fecal incontinence.

To assess pain, we used a 10-cm linear analog pain scale starting from 0 (where there was no pain at all) to 10 (the worst pain ever experienced).

The low anterior resection syndrome (LARS) score was used to evaluate incontinence

Flatus incontinence was scored as 0–7, liquid stool incontinence was scored as 0-5, re-evacuation was scored as 0–11, and evacuation urgency was scored as 0–16 (0–20 no LARS, 21–29 light LARS, and 30–42 strong LARS).

Estimated dates for returning to work include the day of discharge and the day of resuming work again. We recorded any recurrent piles at any point throughout the research period.

Ethical consideration

Patient information and informed consent: before being enrolled into the study, the patient consented to participate after the nature, scope and possible consequences of the clinical study had been explained in a form understandable to them.

Protocol approval: before the beginning of the study and any accordance with the local regulation followed, the protocol and all the corresponding documents were declared for ethical and research approval by the council of general surgery department, Al-Azhar University.

Concerning safety and efficacy: no evidence of harmful effects of study interventions except postoperative pain that could be managed expectantly.

Statistical analysis

Utilizing SPSS Inc., a statistical program for social sciences, version 23.0 (Chicago, Illinois, USA), researchers examined the data that had been collected. The numerical information was displayed as a mean, standard deviation, and range. Numbers and percentages were also used to illustrate qualitative factors. Using the Kolmogorov-Smirnov and Shapiro-Wilk tests, the data were examined for normality.

The following tests were done:

(1) For non-parametric data, the Mann-Whitney U test and the independent-samples t-test of significance were employed to compare two means.
(2) When comparing groups using qualitative data, χ^2 tests and Fisher's exact tests were used instead of the χ^2 test, but only when the anticipated count in any cell was less than 5.
(3) 95% was set as the confidence interval, while 5% was chosen as the acceptable margin of error. In light of the above, the P value was deemed significant or insignificant as follow:
(4) Probability (P value)

(a) P value <0.05 is significant.
(b) P value <0.001 is highly significant.
(c) P value >0.05 is insignificant.

Table 1 Comparison between stapled group and open group according to clinical characteristic

Clinical characteristic	Total (*n*=76)	Stapled group (*n*=38)	Open group (*n*=38)	Test value	*P* value
Age (years)					
Mean±SD	40.53±11.96	41.71±11.43	39.34±12.50	*t*:0.862	0.392
Range	18–70	18–70	18–70		
		Gender			
Female	26 (34.2%)	10 (26.3%)	16 (42.1%)	x^2:2.105	0.147
Male	50 (65.8%)	28 (73.7%)	22 (57.9%)		
				Hemorrhoids degree	
GRAD 2	20 (26.3%)	17 (44.7%)	3 (7.9%)	x^2:13.300	$<0.001^{**}$
GRADE 3	29 (38.2%)	13 (34.2%)	16 (42.1%)	x^2:0.502	0.479
GRADE 4	26 (34.2%)	8 (21.1%)	18 (47.4%)	x^2:5.846	0.016^{*}
				Preoperative complaints:	
Anal pain	30 (39.5%)	15 (39.5%)	15 (39.5%)	x^2:0.000	1.000
Anal bleeding	40 (52.6%)	21 (55.3%)	19 (50.0%)	x^2:0.211	0.646
Mass per rectum	54 (71.1%)	23 (60.5%)	31 (81.6%)	x^2:4.094	0.043^{*}

Data are expressed as Mean±SD or number (%).
Using: t-Independent Sample; x^2: Chi-square test for Number (%).
P value >0.05 is insignificant.
**P* value <0.05 is significant.
***P* value <0.001 is highly significant.

Results

Out of the total 76 patients, 73.7% were males and 26.3% were females in the SH group; 57.9% were males and 42.1% were females in the open group, as shown in (Table 1). The number of patients with Grade II, III, and IV hemorrhoids in each patient group is shown in (Table 2). The mean age of patients in SH was 41.71 ± 11.43, while in CH groups, the mean age was 39.34 ± 12.50. There was a statistically significant higher grade 4 for hemorrhoids in the open group than the stapled group, as well as a statistically significant higher complain of mass per rectum in the open group than the stapled group with a P value < 0.05, while the rest had an insignificant difference between groups with a P value of $P > 0.05$.

There was a statistically significant higher mean value in the open group than the 0.010 There was a statistically significant higher mean value in the open group than the stapled group according to intraoperative blood loss, with a P value = 0.033

There was a highly statistically significant higher median in the open group than the stapled group according to average pain by VAS, with a P value > 0.001, and a statistically significant higher mean value of times for resumption of daily activities ('days') in the open group compared to the stapled group, with p value ($p > 0.001$). Table 3.

Discussion

Stapled hemorrhoidopexy is an innovative and special method for treating hemorrhoids. Dr. Antonio Longo, an Italian colorectal surgeon, developed the technique. This surgery provides a lot of reasons for concern as, especially in the wrong hands, it might be dangerous

Table 2 Comparison between stapled group and open group according to details of surgical treatment and secondary outcome

Surgical details	Total (n=76)	Stapled group (n=38)	Open group (n=38)	Test value	P value
Intraoperative blood loss (ml)					
Mean±SD	9.55±6.44	5.61±3.01	13.50±6.55	*t*:6.748	<0.001**
Range	1-30	1-15	5-30		
Duration of procedure (minutes)					
Mean±SD	20.54±7.62	18.89±8.24	22.18±6.66	*t*:1.915	0.059
Range	10–40	10–40	10–40		
Duration of hospital stay (days)					
Mean±SD	1.07±0.45	0.93±0.44	1.20±0.43	*t*:2.651	0.010*
Range	0.5-2	0.5-2	0.5-2		
Early postoperative complications					
Postoperative anal bleeding	13 (17.1%)	3 (7.9%)	10 (26.3%)	FE	0.033*
Partial Anal incontinence	2 (2.6%)	0 (0.0%)	2 (5.3%)	FE	0.152
Urine retention	12 (15.8%)	5 (13.2%)	7 (18.4%)	x^2:0.396	0.529
Late postoperative complications:					
Anal stenosis	2 (2.6%)	1 (2.6%)	1 (2.6%)	FE	1.000
Recurrence	4 (5.3%)	2 (5.3%)	2 (5.3%)	FE	1.000

Data are expressed as Mean±SD or number (%).
Using: t-Independent Sample; x^2: Chi-square test for Number (%) & FE: Fisher Exact test.
P value >0.05 is insignificant.
*P value <0.05 is significant.
**P value <0.001 is highly significant.

Table 3 Comparison between stapled group and open group according to average pain by VAS & times for resumption of daily activities (days)

Outcome data	Total (n=76)	Stapled group (n=38)	Open group (n=38)	Test value	P value
Average pain by VAS					
Mean±SD	3.36±2.07	1.82±1.14	4.89±1.59	*U*:9.713	<0.001**
Median (IQR)	3 (2–5)	2 (1–3)	5 (4–6)		
Range	0-8	0-4	2-8		
Times for resumption of daily activities (days)					
Mean±SD	2.82±1.31	2.24±1.08	3.39±1.28	*U*:4.258	<0.001**
Range	1-6	1-5	1-6		

Data are expressed as Mean±SD & Median and Interquartile range (IQR).
Using: U-Mann-Whitney test.
**P value <0.001 is highly significant.

and unworthy. Numerous studies have demonstrated this technique's optimal applications, restrictions, and drawbacks. The majority of research has revealed that SH has fewer potential long-term consequences but also reduces postoperative discomfort and shortens hospital stays. One factor that favors one procedure over another is postoperative discomfort, which must be taken into account [12].

In the present study, stapler hemorrhoidectomy resulted in 3 fewer visual analog scores for postoperative discomfort than open hemorrhoidectomy. It is better than the findings observed in research by Palimento D *et al.*[13], who discovered that the visual analog score in SH is equivalent to 4 (2 to 6), whereas the score in OH is equal to 5 (2 to 6). There was reduced postoperative discomfort and pain in the group that received staples, according to studies by Nisar PJ *et al.*[14], P Thejeswi *et al.*[15], Ttandea JJ and Chan MK [16], and RS Bhandari *et al.*[17].

The technique, being performed above the dentate line, where there are no nerve endings, explains why there is less pain. Stapled hemorrhoidopexy results in noticeably decreased postoperative discomfort, according to Gravies J. F. *et al.*[18].

With a score of 0.27 and a *P* value of 0.010, the postoperative hospital stay was shown to be statistically significant, which is less for the stapled group. The shorter hospital stay in the group operated by staplers was also validated in a study by Daniel R. *et al.*[19].

Mehigon BJ *et al.*[20] did not discover any statistically significant differences in the group that was stapled, in contrast. However, a meta-analysis by Nisar PJ *et al.* [14] and a systemic review by Tjandra JJ *et al.*[16], a study by RS Bhandari *et al.*[21], and research revealed that stapler hemorroidopexy resulted in a postoperative hospital stay that was unquestionably shorter than that of the standard hemorrhoidectomy group. Less postoperative discomfort may have led to an earlier discharge.

During visits, patients will discuss starting their normal daily activities. In comparison to the open hemorrhoidectomy group, patients in the stapled group should have begun their usual daily activities 1.15 days earlier. The *p* value for this variable was less than 0.001. This can be a result of decreased postoperative discomfort, less postoperative bleeding, or early patient release from the hospital. Several studies may be compared to this. An early return to regular daily exercise was determined by Mehigan B. J. *et al.*[22].

The results of systematic reviews by Tjandea J. J. *et al.* [16] and meta-analyses by Nisar P. J. *et al.*[14] clearly show that patients who received stapled hemorrhoidectomy returned to their regular daily activities earlier than those who had traditional hemorrhoidectomy.

Regarding postoperative anal bleeding, we found an incidence of 7.9% in the SH group and 26.3% in the open group. All bleeding was minor, with no need for any intervention, but it was just annoying patients. When we revise the literature and find an incidence of bleeding to be 21.6% in patients in the stapled group and 13.6% in the open group [Palimento D *et al.*] [13] and then find a systemic review by Tjandea JJ and Chan M K [16] that revealed reduced postoperative anal bleeding in the stapled group, it will lead us to believe that the individual abilities of the operating surgeon may be blamed for the large differential for this characteristic.In the present study, postoperative urine retention was 13.2% in the stapled group, whereas it was 18.4% for open hemorrhoidectomy. Spinal anesthesia and improper urine evacuation may be the causes. The reason may be because of incidentally higher prostatic disease in patients; their evaluation was beyond the scope of our study.

Anal incontinence was not identified in either group of patients. Anal incontinence rates were comparable in the stapled group and standard open hemorrhoidectomy in research by Dr. HO Yh *et al.* [23].

Research by KH Khalil *et al.*[24] found findings that were similar to ours in that there was no record of anal incontinence in the group who underwent stapled hemorrhoidectomy.

According to Shalaby and Desky, 2% of patients get anal stenosis after undergoing stapled hemorrhoidectomy. Additionally, one person in each group of individuals in the current research exhibited anal stenosis. The results by Dr. Ho Yh *et al.*[25] are also comparable.

Conclusion

Stapled hemorrhoidectomy is a promising procedure with less pain, a shorter duration of hospital stay, and a faster resumption of daily activity than conventional

hemorrhoidectomy. However, long-term follow-up for many years is still needed to define the recurrence rate in stapled hemorrhoidectomy.

The stapler haemorrhoidectomy procedure

After anal dilatation and insertion of the anal ring and fixing it, we made a purse-string suture 2 cm above the dentateline using prolene 2/0 toincludeonlymucosa and submucosa. Haemorrhoidal circular stapler (HCS) was then inserted and the suture was tightened. Closure of the circular stapler was done and kept closed for 30 s then firing it and gentle withdrawal of the stapler, including the doughnut. Examination of the stapler line for any bleeding and controlling it. Finally, diclofenac suppositories were kept, and gentle anal packing was done. The pack was removed after 12 h (Figs 1–10).

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Conflicts of interest

None declared.

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