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Stapled Hemorrhoidopexy versus Harmonic Scalpel Hemorrhoidectomy: A Randomized Trial

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Abstract
Background: Approximately 5% of the population experiences hemorrhoids. Grade III and IV hemorrhoids that cause symptoms, as well as those for whom medicinal therapy has not been successful or when other complications such anal fissures or ulcers are present, need surgical intervention. Hemorrhoids may be treated using a variety of procedures, including Milligane Morgan's open hemorrhoidectomy and Ferguson's closed hemorrhoidectomy. There are a number of new tools and techniques that may make the surgery easier and reduce postoperative pain for patients. Comparing stapled hemorrhoidopexy with harmonic scalpel hemorrhoidectomy was the primary goal of this research. **Methods** At Banha, researchers undertook a randomised controlled experiment on one hundred patients suffering from hemorrhoidal illness of Grade III or IV. A harmonic scalpel hemorrhoidectomy was performed on Group 2, whereas stapled hemorrhoidopexy was performed on Group 1 patients. The participants were randomly allocated to either group. Laboratory testing, clinical and rectal exams, and medical histories were all part of the data collecting process. At one week, three months, and six months after surgery, the two groups were compared with respect to postoperative discomfort, complications, recovery time, and recurrence rates. **Results** When comparing Group 1 to Group 2, there was a substantial decrease in postoperative discomfort, hospital stay, and recovery time[$P < 0.001$]. There was no statistically significant difference between the groups with regard to postoperative bleeding, infection, or recurrence. There were no instances of anal stenosis found. **Conclusion:** In comparison to harmonic scalpel hemorrhoidectomy, stapled hemorrhoidopexy had a lower risk of complications and a shorter recovery time for patients.

Keywords: hemorrhoids, harmonic scalpel hemorrhoidectomy, stapled hemorrhoidopexy etc.

Introduction:

A prevalent anorectal ailment, hemorrhoidal disease affects around 5% of the population and is more common in those over the age of 40. When hemorrhoids of Grade III and IV cause symptoms, surgical intervention is necessary. When non-surgical methods of therapy are exhausted or when other health issues, including anal fissures or ulcers, are present, surgical intervention may be necessary[1].

Hemorrhoidal disease may be surgically treated using a variety of treatments. Traditional methods include the use of either a scalpel or electrocautery to execute procedures such as Milligane Morgan's open hemorrhoidectomy or Ferguson's closed hemorrhoidectomy. Furthermore, several tools and techniques have been developed to ease the process and lessen the likelihood of postoperative pain for patients[2].

For the first time in 1992, the harmonic scalpel used ultrasonic radiation to coagulate and cut soft tissue with minimum thermal injury to the surrounding tissue. Gynecological surgeries like myomectomy, general surgery procedures like cholecystectomy and hemorrhoidectomy, and thoracic surgery procedures like cutting the internal mammary artery have all made substantial use of harmonic scalpels[3]

A lot of places now utilize harmonic scalpel hemorrhoidectomy[HSH] as a regular procedure. Because the surrounding tissue is not heated during HSH, there is little to no postoperative discomfort. Protein coagulum is formed and bleeding arteries are sealed during surgery using a harmonic scalpel. This technique reduces the amount of blood loss and operating time required to remove big hemorrhoids[4].

A relatively recent surgery, stapled hemorrhoidopexy[SH] was first reported in 1998 by Longo. Furthermore, SH seeks to eliminate submucosal vessels while simultaneously repositioning prolapsed rectal mucosa to its normal level and restoring the anorectal mucosa's topographic relationship to the underlying muscle[5].

By resecting a ring of rectal mucosal and submucosal tissue about 3–4 cm above the dentate line, this technique may restore the prolapsed hemorrhoidal plexus to its natural anatomical position while also interrupting the distal branches of the superior rectal artery that supply the hemorrhoids. In theory, SH offers less postoperative pain and shorter hospitalization compared to traditional procedures[6] because it includes the rectum, where pain feeling is absent, instead than the anoderm.

In terms of operation time, postoperative discomfort, bleeding, infection, recovery time, and long-term consequences such anal stenosis and recurrence, this research compares stapled hemorrhoidopexy with harmonic scalpel hemorrhoidectomy.

Patients and Methods:

Patients:

The general surgery department at Banha University conducted this randomized controlled trial research from November 2022 to November 2023. The study included one hundred individuals suffering from hemorrhoidal illness of Grade III or IV. Two groups were formed from the patients by random assignment. The patients who had stapled hemorrhoidopexy were categorized into Group 1, while those who underwent harmonic scalpel hemorrhoidectomy were categorized into Group 2.

Patients had to be at least 18 years old, have hemorrhoids of the third or fourth degree, and have an anesthesiology score of I or II according to the American Society of Anesthesiologists in order to be included.

Patients who had undergone anorectal surgery in the past, were diagnosed with acute thrombosed hemorrhoid, or had hemorrhoid in addition to anal fissure, fistula, or abscess were not included in the research. Additionally, patients were not included if they were known to have an immunodeficiency, coagulation disease, or if they declined to take part in the trial.

Methods:

After obtaining informed permission from each patient, data was collected from all patients who fulfilled the prior criteria.

For every patient in the study, we took their medical history, performed a thorough physical exam, and did standard laboratory tests, including a full blood count, random blood sugar, kidney and liver function tests, serum CRP level, ESR, PT/PTT/INR, Na, and K.

The patient was placed in the lithotomy position while they were under spinal or general anesthesia, and the same surgical team conducted each treatment. In the first group, SH was done using a 33-mm circular stapler, while in the second group, each hemorrhoidal complex was grasped using either mosquito forceps or non-toothed forceps.

The two sets of participants underwent Participants in both groups were recorded as experiencing postoperative problems such as wound infection, postoperative discomfort, bleeding, anal stenosis, and recurrence. For one week after surgery, patients were given oral antibiotics. Patients were instructed to consume a soft diet for two days and bulk laxatives for a minimum of two weeks after the surgery, and they were allowed to begin drinking liquids in the evening following the procedure. All patients had their wounds dressed on the second postoperative day. One week, three months, and six months after surgery, patients were re-evaluated. The amount of time it took for each group to recover was recorded.

Statistical analysis

Statistical software developed by IBM, Illinois, Chicago, USA, known as SPSS, version 26, was used to organize, code, tabulate, and analyze the gathered data. The data were parametric, and to ensure normality, we employed a one-sample Kolmogorov—Smirnov test. When dealing with numerical numbers, the standard deviations, ranges, and means were determined. Using a student t-test for parametric data, we looked for differences between the two means.

The number and percentage were computed for categorical variables, and a chi-square test was used to test for differences across subcategories. The correlation between variables was calculated using Pearson's correlation coefficient[r]. In order to estimate the risk, the predictor variables were identified using Univariate and multivariate logistic regression analysis using the backward wald technique. A significance threshold of $p<0.05$ was used.

Results:

Among the 123 patients who were considered for inclusion in the trial, 17 were deemed ineligible, and 6 declined to take part. Half of the remaining patients were split evenly between the two groups. Statistical analysis was performed on all assigned subjects.

The two groups did not vary substantially with respect to age or sex. Furthermore, there was no statistically significant difference between the two groups with regard to comorbidities[diabetes, hypertension, diabetes, and hypertension]. Also, there was no statistically significant difference in the severity of hemorrhoids between the two groups. Table 1

Table 1: Demographic data, Comorbidities and Grades of haemorrhoids of studied groups

		Group 1 [n=50]	Group 2 (n=50]	P value
Age[years]	**Mean ± SD**	41.8 ± 12.14	40.18 ± 10.9	0.484
	Range	20 - 60	23 - 56	

Sex	**Male**	40[80%]	33[66%]	0.115
	Female	10[20%]	17[34%]	
Diabetes		10[20%]	13[26%]	0.437
Hypertension		9[18%]	13[26%]	
Diabetes and hypertension		6[12%]	7[14%]	
No		25[50%]	17[34%]	
Grades of hemorrhoids	**III**	32[64%]	39[78%]	0.123
	IV	18[36%]	11[22%]	

*: significant as P value ≤0.05.

The difference in operating time and blood loss between the two groups was not statistically significant. Group 1 had a much shorter hospital stay compared to group 2[P value <0.001]. In group 1, the recovery period was much shorter compared to group 2[P value <0.001]. As shown in Table 2. Group 1 had substantially reduced postoperative VAS score measures at 1 week, 3 months, and 6 months compared to Group 2[P value <0.05]. In Table 3.

Table 2: Operative time, blood loss and hospital stay and Recovery time of the studied groups

		Group 1 [n=50]	**Group 2 (n=50)**	**P value**
Operative time[min]	**Mean ± SD**	29.84 ± 5.08	31.52 ± 5.06	0.101
	Range	20 - 38	22 - 40	
Blood loss[cc]	**Mean ± SD**	13.42 ± 10.18	15.12 ± 14.81	0.505
	Range	5 - 40	8 - 50	
Hospital stays[days]	**Mean ± SD**	25.9 ± 5.64	35.36 ± 8.98	**<0.001***
	Range	14 - 35	25 - 55	
Recovery time[days]	**Mean ± SD**	15.52 ± 3.75	19.74 ± 3.37	**<0.001***
	Range	10 - 22	15 - 25	

Table 3: Postoperative VAS score measurements of the studied groups

	Group 1 [n=50]	**Group 2 (n=50]**	**P value**
After 1week	4(3-5]	5(3-7]	**0.016***
After 3 months	2(1-3]	2(1.25-4]	**0.043***
After 6 months	1(0-1]	1(0-2]	**0.020***

There was no statistically significant difference between the two groups in terms of postoperative infection or bleeding at 3 or 6 months. Neither group showed a statistically significant difference in recurrence at 6 months. Anal stenosis did not arise[Table.4].

Table 4: Postoperative bleeding and infection and Complications of the studied groups

		Group 1 [n=50]	**Group 2 (n=50)**	**P value**
Postoperative bleeding	**After 1 week**	0(0%]	0(0%]	--
	After 3month	2[4%]	3[6%]	0.646
	After 6month	0(0%]	1(50%]	0.500
Postoperative infection	**After 1 week**	0(0%]	0(0%]	--
	After 3month	0(0%]	2[4%]	0.153
	After 6month	0(0%]	1[2%]	0.558
Recurrence	**After 1 week**	0[0%]	0[0%]	--
	After 3month	0[0%]	0[0%]	--
	After 6month	2[4%]	2[4%]	0.93
Anal stenosis	**After 1 week**	0[0%]	0[0%]	--
	After 3month	0[0%]	0[0%]	--
	After 6month	0[0%]	0[0%]	--

Discussion:

One hundred patients with Grade III or IV hemorrhoidal disease were enrolled in this randomized controlled trial to compare stapled hemorrhoidopexy with harmonic scalpel hemorrhoidectomy in terms of operation time, postoperative pain, postoperative infection,

recovery time, and long-term complications like anal stenosis plus recurrence.

The average age of patients in both group 1 and group 2 varied from 40.18 ± 10.9 to 41.8 ± 12.14 years, according to our research. This lines up with the results of a research conducted by Lin et al., which compared the safety and effectiveness of circumferential stapled hemorrhoidopexy with partial stapled hemorrhoidopexy over the long term. The average age of hemorrhoid patients was found to be between forty and forty-two years old[1]. The results of individuals who had SH during multiple thread ligations[MTL] to treat grade III hemorrhoids were also investigated in a research by Zhou et al. Consistent with our findings, the patients' ages varied between 42 and 44 years[7].

We found that men constituted the majority of hemorrhoid cases. Oberi et al., in contrast, set out to determine how common hemorrhoids are and what variables put adults in Jazan, Saudi Arabia, at risk for developing them. Adults in the Jazan area who have been diagnosed with hemorrhoids were the subjects of this cross-sectional research. The majority of the participants were females, comprising 60% of the sample[8].

Curiously, Al-Masoudi et al. examined the frequency of hemorrhoids and the variables that put adults in Makkah, Saudi Arabia, at risk for developing them. A total of 338 cases, or 84.5% of the total, were found to be female. Differences in study population or methodology could explain why our results vary from theirs[9].

Hemorrhoids were shown to be more common in ladies than in men, according to the research. The fact that more males are actively seeking medical evaluation and treatment measures for this disease might be the reason for this disparity. Hemorrhoidal illness was also more common among married women who had been pregnant before compared to those who had never been pregnant. Increased intra-abdominal pressure, pelvic venous congestion, and labor-related injury are likely to blame for this[10].

Our research showed that only 23% of hemorrhoid patients were diabetic. This is in line with the findings of a research conducted by Tseng that examined the risk of hemorrhoid in individuals with type 2 diabetes mellitus who used metformin ever vs. never. They discovered that those with type 2 diabetes mellitus had a reduced incidence of hemorrhoid when they were treated with metformin chronically.[11].

The majority of patients[88.75%] had grade III hemorrhoids, according to our research. Athar et al. routinely assessed stapled hemorrhoidopexy's clinical efficacy at Aga Khan University Hospital. In a study conducted between July 2002 and July 2007, 140 patients undergoing stapled hemorrhoidopexy for symptomatic second-, third-, or fourth-degree hemorrhoids as well as circumferential mucosal prolapse were included. The researchers found that third-degree hemorrhoids were present in 84.3% of the individuals[12].

Results showed that compared to group 2, patients in group 1 spent far less time in the hospital. This reminds me of a study that Nisar et al. performed to compare stapled hemorrhoidopexy to traditional hemorrhoidectomy and find out whether one is better for hemorrhoids. According to their findings, stapled hemorrhoidopexy resulted in a shorter duration of hospital stay compared to hemorrhoidectomy[weighted mean difference, -1.02 days; 95 percent confidence range, -1.47 to -0.57; P = 0.0001][13].

Also, Kumar et al. evaluated postoperative discomfort, operation length, postoperative complications, return to regular employment, and recurrence for grade III and IV hemorrhoids using the stapler vs open hemorrhoidectomy. Results showed that the stapler hemorrhoidectomy group required significantly less time in the hospital than the open surgery group, based on a comparison of 60 patients with hemorrhoids of grades III and IV[14].

Group 1 had a much shorter recovery period compared to group 2, according to our research. Wang et al. compared the short-term results after stapled hemorrhoidopexy[SH] using the PPH and the DST stapler for patients with grade III and IV hemorrhoids, and their findings are consistent with this research. In comparison to traditional hemorrhoidectomy, stapled hemorrhoidopexy provides a number of benefits, including a shorter recovery time and reduced postoperative discomfort[15].

In addition, Towliat Kashani et al. compared the outcomes of stapled hemorrhoidopexy with Milligan-Morgan Hemorrhoidectomy in regards to recovery time, symptom relief, and complication incidence. The time frame of this research was from 2008–2010. Both treatments were linked with a recovery rate of more than 95%[16], and they were effective in treating hemorrhoids of grades III and IV.

After one week, three months, and six months after surgery, our research found that Group 1 patients' VAS scores were much lower than Group 2 patients' scores. Kim et al. conducted a research comparing the Milligan-Morgan operation to stapled hemorrhoidopexy in a

group of patients with circumferential third-degree hemorrhoids, and their findings are consistent with ours. There was a substantial decrease in postoperative discomfort for patients who had stapled hemorrhoidopexy, according to their reports[17]. The mean VAS ratings at week 1, week 2, and week 4 were 3.1, 0.5, and 0.6, respectively, with a p-value of less than 0.001.

Apart from that, Chung et al. compared stapled hemorrhoidopexy to excisional hemorrhoidectomy using the Harmonic Scalpel and assessed the two procedures. During the course of the study, researchers randomly assigned patients with Grade III hemorrhoids who were working to one of two groups:[1] a hemorrhoidectomy using a Harmonic Scalpel, and[2] a hemorrhoidectomy using staples. After surgery, patients in the SH group reported much less pain on the VAS[18].

In addition, compared to the open hemorrhoidectomy group, the group that received staple hemorrhoidectomy experienced decreased post-operative discomfort[measured by visual analogue scale at 24 hours post-operative], according to Kumar et al. At one week's follow-up, 13.3% of patients in the stapler group reported discomfort, and at three months' follow-up, no pain complaints were reported[14].

It is important to note that the research had several limitations. For example, the results may not be applicable to a wider population since the study only included 100 individuals. The study's limitations include its single-center design, which makes it difficult to draw larger conclusions. Recurrence and anal stenosis are long-term consequences that may have gone unmeasured because to the short 6-month follow-up period.

Conclusion:

Our research found that compared to harmonic scalpel hemorrhoidectomy, stapled hemorrhoidopexy had many benefits, including shorter hospital stays, quicker recoveries, and lower pain ratings one week, three months, and six months after surgery. Patients aiming for a speedier recovery with less postoperative pain may find stapled hemorrhoidopexy to be the better alternative, according to these studies.

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Contribution of the author

All writers made equal contributions to the research.

Possible biases

Absence of any potential bias

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