

A Comparative Study between Stapled and Harmonic Hemorrhoidectomy for Treatment of Third-and Fourth-Degree Piles

Eslam Fayz Tolba Nada*, Hany Mohamed, Hatem Mohammad, Elsayed I. Elhendawey

Department of General Surgery, Faculty of Medicine, Zagazig University, Egypt

*Corresponding author: Eslam F. Nada, Mobile: (+20) 01090879745, Email: islamfaiznada33@gmail.com

ABSTRACT

Background: The best surgical method for hemorrhoidectomy is still unknown; hence innovative procedures like harmonic scalpel hemorrhoidectomy and stapled hemorrhoidectomy need to be researched.

Objective: The aim of this work was the selection of best method of treatment of third and fourth degree primary haemorrhoids.

Patients and methods: The present clinical trial included 36 patients with the diagnosis of symptomatic 3rd and 4th degree primary hemorrhoids, admitted to the Department of General Surgery, Zagazig University Hospitals for surgical management. The patients were divided equally into *Group 1* who underwent Stapled hemorrhoidectomy, and *Group 2* who underwent harmonic scalpel hemorrhoidectomy. All patients in both groups were followed up weekly for the first 4 postoperative weeks. Postoperative pain, fecal incontinence, time of complete healing, and early recurrence were evaluated.

Results: Postoperative pain was less in the Stapler group with significantly difference from the harmonic group. Fecal incontinence was higher in harmonic group but with no statistically significant difference from Stapler group. Healing and return work were significantly higher among Stapler group with no significant difference from harmonic group. Regarding early recurrence, Stapler group had two cases, while harmonic group had only one case with no statistically significant difference between both groups.

Conclusion: Stapled hemorrhoidectomy had better results than harmonic scalpel hemorrhoidectomy because it was associated with less postoperative pain, less fecal incontinence and less incidence of wound complications.

Keywords: Scalpel Hemorrhoidectomy, Stapled hemorrhoidectomy, Fecal Incontinence, Wound Healing.

INTRODUCTION

The symptomatic expansion and/or distal displacement of anal cushions, which are prominences of the anal mucosa created by loose connective tissue, smooth muscle, artery, and venous vessels, is a fairly common anorectal illness known as haemorrhoids (1).

Hemorrhoids typically manifest with painless rectal bleeding with faeces, either with or without prolapsing anal tissue. Internal haemorrhoids, which originate above the dentate line and are covered by anal mucosa, external haemorrhoids, which originate below the dentate line and are covered with anoderm, and mixed type haemorrhoids are the three main categories (2).

Hemorrhoids can be divided into three categories: primary haemorrhoids, secondary haemorrhoids, and circumferential haemorrhoids, which are caused by a variety of disorders, the most significant of which is anorectal cancer (3).

On the basis of how they appear and how much they prolapse, internal haemorrhoids are graded further: Hemorrhoids are classified into four grades: Grade I, which are non-prolapsing haemorrhoids, Grade II, which prolapsing haemorrhoids on straining but reduce spontaneously, Grade III, which require manual reduction, and Grade IV, which includes intensely thrombosed, imprisoned haemorrhoids (4).

Therefore, this study aimed to determine which better procedure in treatment of third and fourth degree primary piles, comparing the efficiency, short-term results, and complications of stapled hemorrhoidectomy and harmonic scalpel hemorrhoidectomy.

PATIENTS AND METHODS

The present clinical trial included 36 patients with the diagnosis of symptomatic 3rd and 4th degree primary hemorrhoids, admitted to the Department of General Surgery, Zagazig University Hospitals for surgical management.

The patients were divided into two groups, each included 18 patients: *Group 1* underwent Stapled Hemorrhoidectomy, and *Group 2* underwent harmonic scalpel hemorrhoidectomy. Randomization to each group was done by computer software.

Inclusion Criteria: All patients with symptomatic 3rd and 4th degree primary haemorrhoids with age of >18 years and <55 years old.

Exclusion Criteria: Patients with age <18 years and >55 years old. Contraindication to surgery such as bleeding tendency. Recurrent cases of piles. Cases of 1st and 2nd degree piles. Coincident anal pathology e.g. Perianal fistula. ASA (American Society of Anesthesiologists) III, IV and V.

All patients had full history taken including name, age, sex with emphasis on associated medical disorders and previous surgical interventions. Careful general examination carried out, together with local examination of the piles for its degree and associated pathology like rectal prolapse. Routine laboratory investigations included CBC, liver function tests (LFTs), kidney function tests (KFTs), random blood glucose level, coagulation profile, and hepatitis

markers. ECG and ECHO were done for cardiac patients or for patients above 40 years old. A dose of preoperative antibiotic intravenous was given (1gm Ceftriaxone IV).

All patients were instructed to make two enemas one the night before the operation and the other in the morning of the operation day.

Surgical Techniques:

Patients underwent spinal anaesthesia on the operating table in lithotomy position with hips fully flexed in order to expose the whole perineum in both groups.

Group 1: Stapled Hemorrhoidopexy.

Insertion of the circular anal dilator (CAD) with obturator was made by applying traction with the silk sutures. After that, the obturator was removed and the CAD is fully placed into the anal canal. The stay sutures were threaded through the CAD's flange apertures to keep it in place during the surgery. The purse string endoscope was inserted and round body needle with a 2/0 polypropylene suture used. The purse string begins

at 12 o'clock in the anterior midline ensuring that a continuous purse string was used eliminating gaps that might result in stapled mucosa bridges later.

The whole length of a suitable circular stapling device was opened then the lubricated stapler head was inserted and the purse string was cinched closed around the central rod to ensure the whole circle of the rectal mucosa was snug around the central rod. The two suture tails were used for gently traction on the purse string. The PPH stapler's head was entirely closed at the same time by moving the closure mechanism in an anticlockwise manner with the orange position marker in the green firing zone on the handle of the 33 mm PPH instrument confirming closure

In females, the posterior vaginal wall was examined to ensure that it was not pinched in the instrument's head then release the safety mechanism and close the handles completely in one stroke. The stapler was removed after it has been fired by opening the head and twisting the closing mechanism one half turn clockwise. The stapled line was checked for good hemostasis and a piece of gauze was placed.

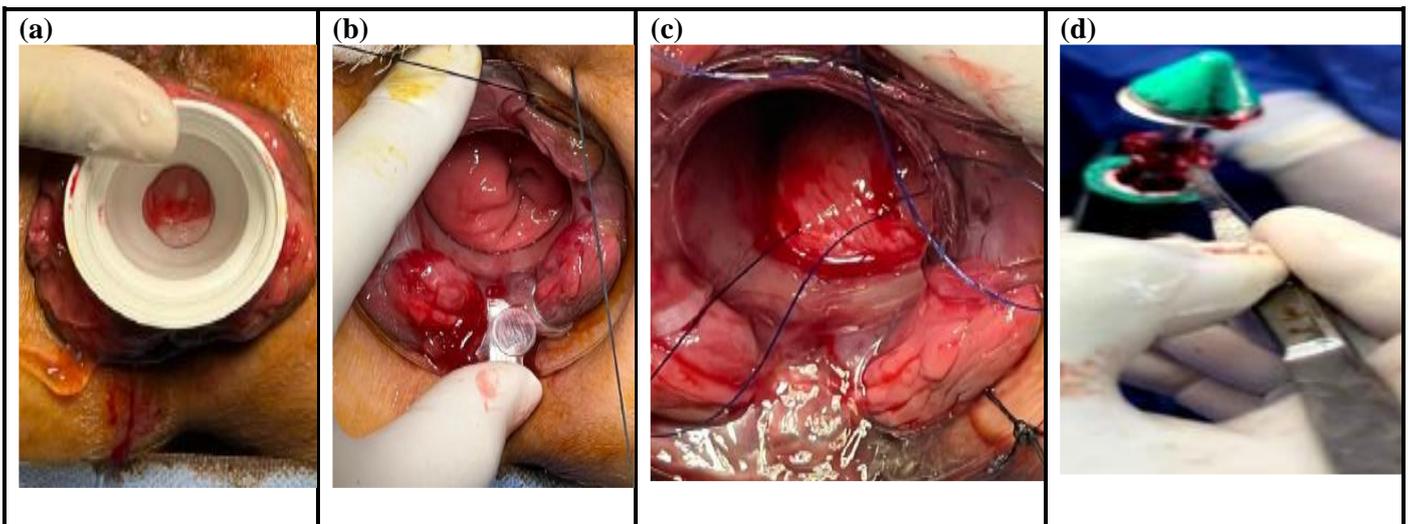


Figure (1): Surgical technique of stapled hemorrhoidopexy: (a) Insertion of the circular anal dilator; (b) Anoscope is kept in place with stay sutures; (c) Purse string sutures are taken in mucosa and submucosa; (d) Check of the stapled part and stapled line for hemostasis.

Group 2: Harmonic scalpel hemorrhoidectomy.

Allis clamp and artery forceps were used to grab and elevate the internal and exterior components of each hemorrhoidal complex. The hemorrhoid bundle was delicately separated from the internal anal sphincter using the Harmonic Scalpel® shears. Coagulation with the same device was used to control the pedicle. Local anaesthetic was administered around the operating site again at the end of the surgery for long-term pain management. The area was inspected with the Eisenhammer retractor to ensure perfect hemostasis. All

incisions were left open, and the anal verge was covered with a dry dressing.

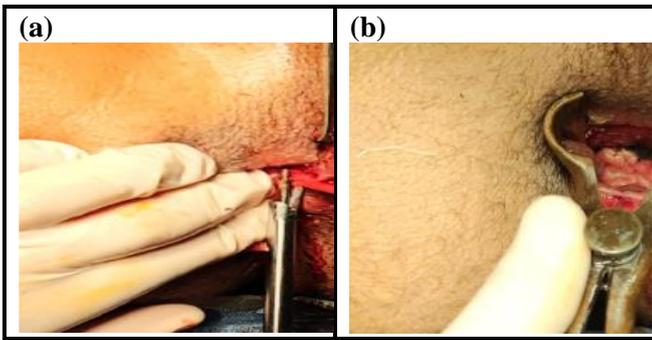


Figure (2): Surgical technique of harmonic scalpel hemorrhoidectomy: (a) Separation of hemorrhoid bundle using harmonic and (b) Check for other hemorrhoid and for good hemostasis.

Post-operative and follow up for both methods:

Patients stayed at hospital for one day with a dose of antibiotic and analgesics. On discharge, patients were instructed to pay meticulous attention to hygiene rules and walking was unrestricted. Instructions for home dressing were given for each patient (wound washing with warm water after defecation and before sleeping, from 5 to 6 times a day). Ceftriaxone IM/24h was prescribed as a post-operative prophylaxis and NSAIDs 3 times daily as pain killer and Garamycin oint locally 3 times daily.

Patients were followed up weekly for the first 4 postoperative weeks and after that, they were told to pay us a visit monthly for 3 months (to check for recurrences and assess their satisfaction with the results). Patients were allowed to return to work by the third post-operative week.

Operative time was defined as the time from the start of sterilization to the put of dressing. Postoperative complications were reported based on clinical findings with emphasis on pain, bleeding, wound infection and fecal incontinence.

The pain assessment was to be made using a 10cm linear analogue pain scale from 0 (no pain at all) to 10 (the worst pain ever experienced).

Incontinence was evaluated according to LARS score (Low Anterior Resection Syndrome Score): Flatus incontinence 0-7, Liquid stool incontinence 0-5, Re-evacuation 0-11, Evacuation urgency 0-16. (0-20 no LARS, 21-29 light LARS, 30-42 intense LARS). Return to work was estimated from the day of discharge to the day of joining work. Recurrent disease was reported if observed at any time throughout the study period.

Ethical Consideration:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Written informed consent of all the participants was obtained. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 22 for Windows® (IBM SPSS Inc, Chicago, IL, USA). Data were tested for normal distribution using the Shapiro Walk test. Qualitative data were represented as frequencies and relative percentages. Chi square test (χ^2) to calculate difference between two or more groups of qualitative variables. Quantitative data were expressed as mean \pm SD (Standard deviation). Independent samples t-test was used to compare between two independent groups of normally distributed variables (parametric data). Differences between quantitative independent multiple groups were examined by ANOVA or Kruskal Wallis test. P value ≤ 0.05 was considered significant.

RESULTS

The current study showed no statistically significant difference between Group I and Group 2 as regard age and sex. The majority of both groups were females (Table 1).

Table (1): Demographic data among the studied groups.

Variable	Stapled Hemorrhoidoexy Group (N=18)		Harmonic scalpel hemorrhoidectomy Group (N=18)		t-test	P-value
Age (years): Mean \pm SD Range	35.4 \pm 5.4 18-54		33.5 \pm 4.6 16-54		-1.2	0.239 (NS)
Variable	N	%	N	%	χ^2	P-value
Sex:						
Male	8	44.4	7	38.9	0.11	0.749
Female	10	55.6	11	61.1		(NS)

Data is shown as number (percentage) or mean \pm standard deviation. NS: Non-Significant, Chi-square (χ^2) and t- tests were used.

There was statistically significant difference between Stapled Hemorrhoidopexy Group and Harmonic scalpel hemorrhoidectomy Group as regard postoperative pain score; being higher in Harmonic scalpel hemorrhoidectomy Group ($p < 0.05$) (Figure 1).

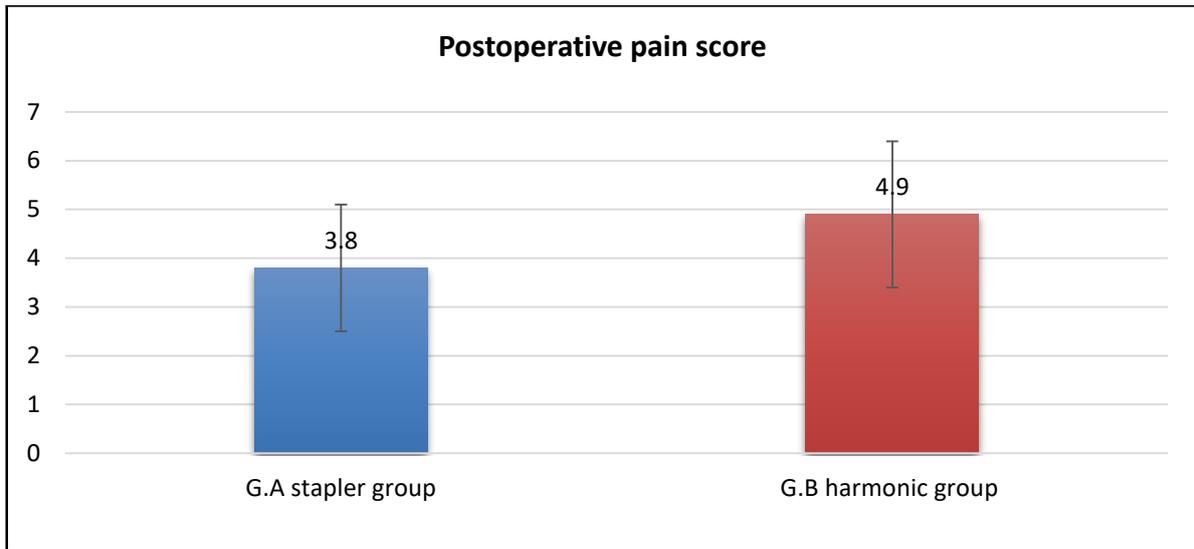


Figure (1): Postoperative pain score among the studied groups.

There was no statistically significant difference between G.A stapler group and G.B harmonic group as regard hospital stay duration ($p > 0.05$) (Table 2).

Table (2): Hospital stay duration among the studied groups.

Variable	Stapled Hemorrhoidopexy Group (N=18)	Harmonic scalpel hemorrhoidectomy Group (N=18)	t-test	P-value
Hospital stays duration (days):				
Mean ± SD	2.3 ± 0.67	2.4 ± 0.69	-0.488	0.629
Range	2- 4	2- 4		(NS)

NS: Non-Significant

There was no statistically significant difference between Stapled Hemorrhoidopexy Group and Harmonic scalpel hemorrhoidectomy Group, as regard postoperative wound infection ($p > 0.05$) (Figure 2).

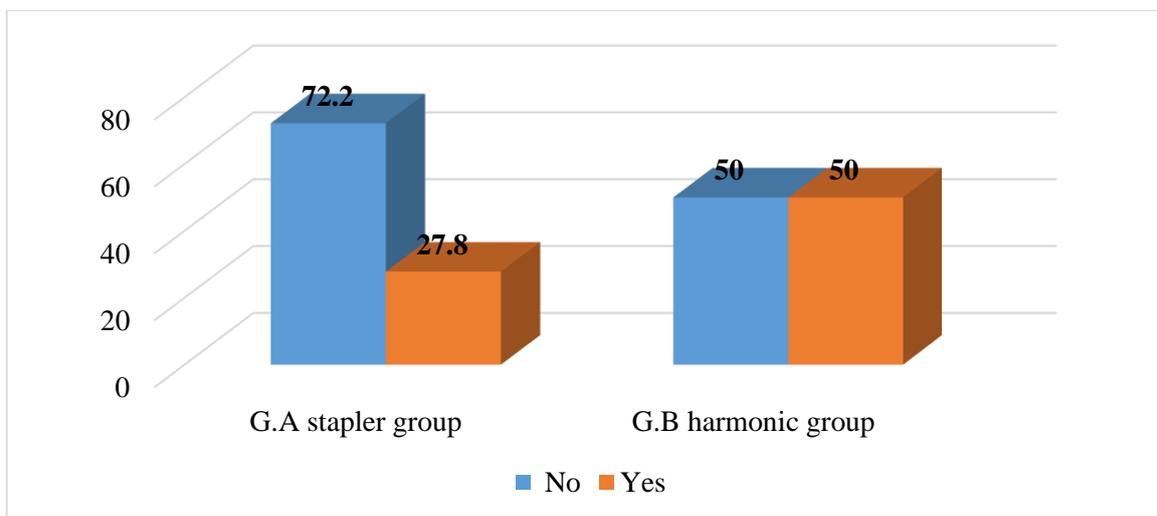


Figure (2): Postoperative wound infection among the studied groups.

There was no statistically significant difference between G.A stapler group and G.B harmonic group as regard postoperative fecal incontinence score (LARS) ($p>0.05$) (Table 3).

Table (3): Postoperative fecal incontinence scores (LARS) among the studied groups:

Variable	Stapled Hemorrhoidopexy Group (N=18)	Harmonic scalpel hemorrhoidectomy Group (N=18)	t-test	P-value
LARS:				
Mean ± SD	7.4± 5.9	8.2 ± 5.5	-0.377	0.706
Median	5	6.5	(MW)	(NS)
Range	0-22	0-22		

MW: Mann Whitney test

There was highly statistically significant difference between Stapled Hemorrhoidopexy Group and Harmonic scalpel hemorrhoidectomy Group, as regard time of complete healing with shorter time of healing in G.A stapler group (Figure 3).

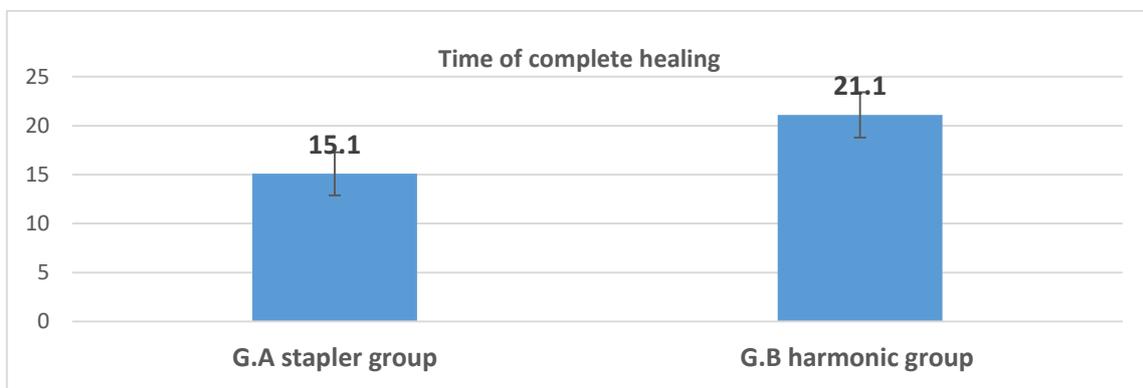


Figure (3): Time of complete healing among the studied groups.

There was no statistically significant difference between Stapled Hemorrhoidopexy Group and Harmonic scalpel hemorrhoidectomy Group, as regard Quality of life ($p>0.05$). Also, there was no statistically significant difference between Stapled Hemorrhoidopexy Group and G.B Harmonic scalpel hemorrhoidectomy Group, as regard early recurrence ($p>0.05$) (Table 4).

Table (4): Quality of life and early recurrence among the studied groups:

Variable	Stapled Hemorrhoidopexy Group (N=18)		Harmonic scalpel hemorrhoidectomy Group (N=18)		P-value
	N	%	N	%	
Quality of life:					
Worse	1	5.6	2	11.1	1
Better	17	94.4	16	88.9	
Early recurrence:					
No	16	88.9	17	94.4	1
Yes	2	11.1	1	5.6	

Stapled Hemorrhoidopexy Group was with less complication from Harmonic scalpel hemorrhoidectomy Group but with no significant difference statistically ($p>0.05$) (Table 5).

Table (5): Complications among the studied groups:

Variable	Stapled Hemorrhoidopexy Group (N=18)		Harmonic scalpel hemorrhoidectomy Group (N=18)		P-value
	N	%	N	%	
Severe pain:					
No	17	94.4	16	88.9	1
Yes	1	5.6	2	11.1	
Infections:					
No	13	72.2	9	50	0.305
Yes	5	27.8	9	50	
Bleeding:					
No	15	83.3	13	72.2	0.691
Yes	3	16.7	5	27.8	
Fecal incontinence:					
No	18	100	16	88.9	0.486
Yes	0	0	2	11.1	
Early recurrence:					
No	16	88.9	17	94.4	1
Yes	2	11.1	1	5.6	

DISCUSSION

The excision of abnormally enlarged hemorrhoidal tissue and the realignment of the remaining hemorrhoidal tissue are both accomplished using the advantageous procedure known as stapled hemorrhoidectomy. The use of stapled hemorrhoidectomy, according to many lines of evidence, is associated with better outcomes, less problems, and shorter hospital stays than other procedures ⁽⁵⁾.

A more recent method of excision has been claimed to produce better intraoperative and postoperative results: "harmonic scalpel excision". It facilitates the creation of coagulum vessels under hypothermic conditions, breaks the hydrogen bond, and lessens harm to the surrounding tissue. Depending on the surgeon's preference, the resulting mucosal defect is either left open or closed ⁽⁶⁾.

However, several studies have considered each of harmonic scalpel and Circular stapler, only one study directly compared harmonic scalpel and Circular stapler ⁽⁷⁾. So, the main aim of this study was to find the best method of treatment of 3rd and 4th degree piles harmonic scalpel or Circular stapler.

This randomized controlled clinical trial was conducted in General Surgery Department, Zagazig University Hospitals. This study was conducted on 36 patients with symptomatic 3rd and 4th degree piles. All patients were divided into 2 equal groups, circular stapler group and harmonic scalpel group each group contain 18 patients.

The present study enrolled two well matched groups as regard age and sex. It showed that the majority of both groups were females.

In agreement with the present study **Bilgin et al.** ⁽⁷⁾ aimed to compare the short and long-term results of harmonic scalpel hemorrhoidectomy and stapler hemorrhoidopexy methods in the surgical treatment of Grade III and Grade IV hemorrhoidal disease. The study enrolled 60 patients treated with either harmonic scalpel hemorrhoidectomy or stapler hemorrhoidopexy procedures, both treatment groups were similar in baseline characteristics.

The present study showed that there was statistically significant difference between stapler hemorrhoidopexy group and harmonic scalpel hemorrhoidectomy group as regard postoperative pain score; being higher in harmonic scalpel hemorrhoidectomy group.

This was supported by **Bilgin et al.** ⁽⁷⁾ who reported that overall pain scores were not significantly different between the groups, although severe pain was significantly more common in the harmonic group compared to stapler group.

Sadeghi et al. ⁽⁵⁾ reported that there was a significant decline in the pain stapler group. Also, **Khan et al.** ⁽²⁾ support our results that postoperative pain was significantly lesser in stapler group. The same result was reported by **Jalil et al.** ⁽⁸⁾.

However, **Al-Thoubaity et al.** ⁽⁹⁾ reported that pain was significantly lesser on the postoperative days 3, 7, and 14, but it was non-significantly lesser on the first postoperative day.

The present study showed that there was no statistically significant difference between stapler hemorrhoidopexy group and harmonic scalpel hemorrhoidectomy group, as regard hospital stay duration.

In agreement with our results **Bilgin et al.** ⁽⁷⁾ reported that Hospital stay was 2.4 days in the harmonic group and 2.6 days in the stapler group with no statistically significant difference. However, **Megahed** ⁽¹⁰⁾ reported that there was significant decrease in mean hospital stay in days (1.0 ± 0.2) in harmonic scalpel group.

The current study showed that there was no statistically significant difference between stapler hemorrhoidopexy group and harmonic scalpel hemorrhoidectomy group, as regard postoperative wound infection.

This come in agreement with **Bilgin et al.** ⁽⁷⁾ who revealed that there was no significant difference between the two groups in terms of wound problems including irritation, itching, and moisture. However, **Alhomoud et al.** ⁽¹¹⁾ reported that there was no wound infections were found in harmonic group without statistically significant difference.

The current study showed that there was no statistically significant difference between stapler hemorrhoidopexy group and harmonic scalpel hemorrhoidectomy group, as regard postoperative fecal incontinence score.

However, **Bilgin et al.** ⁽⁷⁾ reported that no solid incontinence was encountered in both groups, also gas incontinence was not encountered in the harmonic group; in the stapler group, only one patient whose primary complaint prior to the surgery was gas incontinence, continued to have the same complaint (2%) with no significant difference between both groups.

The study by **Al-Thoubaity et al.** ⁽⁹⁾ and **Megahed** ⁽¹⁰⁾ reported no any incidence of incontinence in harmonic and conventional groups. Also, **Sadeghi et al.** ⁽⁵⁾ and **Jalil et al.** ⁽⁸⁾ reported no any incidence of incontinence in stapler and conventional group.

The present study showed that there was highly statistically significant difference between stapler hemorrhoidopexy group and harmonic scalpel hemorrhoidectomy group, as regard time of complete healing with shorter time of healing in harmonic scalpel hemorrhoidectomy group. This agrees with **Malyadri and Allu** ⁽¹²⁾ that reported faster time of wound healing in stapler group.

Furthermore, **Talha et al.** ⁽¹³⁾ reported that harmonic hemorrhoidectomy procedure has lesser operative time, lesser postoperative pain, and lesser analgesic consumption during the first day postoperatively in addition to faster wound healing.

Al-Thoubaity ⁽⁹⁾ also reported that harmonic hemorrhoidectomy procedure also resulted in higher rate of wound healing.

The present study showed that there was no statistically significant difference between stapler hemorrhoidopexy group and harmonic scalpel hemorrhoidectomy group, as regard quality of life. We

also, found that there was no statistically significant difference between stapler hemorrhoidopexy group and harmonic scalpel hemorrhoidectomy group, as regard early recurrence.

However, **Bilgin et al.** ⁽⁷⁾ reported that the long-term outcome was no significantly differed in both groups; the harmonic method was associated with fewer recurrences than the stapler method.

Furthermore, **Al-Thoubaity** ⁽⁹⁾ reported that harmonic hemorrhoidectomy procedure also resulted in higher patient satisfaction and wound healing. Recurrence was occurred in one patient in each group. Also, **Alhomoud et al.** ⁽¹¹⁾ reported that harmonic scalpel hemorrhoidectomy appears to be a better procedure for symptomatic grades III and IV hemorrhoids with patient acceptance.

In addition, **Sadeghi et al.** ⁽⁵⁾ reported that evaluation of recurrence rate 6 and 12 months after interventions showed that patients who underwent stapled hemorrhoidectomy had a significant higher recurrence rate within 12 months. Also, **Khan et al.** ⁽²⁾ reported that recurrence rate was high in patients with stapled hemorrhoidopexy group. As well, **Shafiquzzaman et al.** ⁽¹⁴⁾ reported that stapled hemorrhoidopexy is a comparatively safer treatment method with many short-term as well as long-term benefits like shorter hospital stays, lower pain, and better patient satisfaction.

In conclusion, the two techniques, stapler hemorrhoidopexy and harmonic scalpel hemorrhoidectomy, are effective in treatment of third and fourth degree primary hemorrhoids. However, stapled hemorrhoidopexy has better results and satisfaction than harmonic scalpel hemorrhoidectomy because of its associated with less postoperative pain, less fecal incontinence, earlier return to work, faster healing time with less incidence of wound complications and significantly higher patient satisfaction.

Conflict of interest: The authors declare no conflict of interest.

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Author contribution: Authors contributed equally in the study.

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