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Ligasure™ Haemorrhoidectomy Versus Closed Haemorrhoidectomy in Treatment of Third and Fourth-Degree Haemorrhoids: A Prospective Comparative Study

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ABSTRACT

Background: Excision haemorrhoidectomy is notoriously associated with significant postoperative pain but remains the gold standard treatment for Grade III and IV haemorrhoids because it is efficacious and affordable. The objective of this study was to compare Ligasure™ Haemorrhoidectomy (LH) and Closed Haemorrhoidectomy (CH).

Methods: This prospective comparative study was conducted at Omdurman Teaching Hospital over two years from May 2015 to May 2017. The outcome parameters were operative time, postoperative pain, postoperative complications, time to complete healing, and time to return to work.

Results: A total of 100 patients were included in the study, 50 patients in each group. The baseline characteristics were comparable between the two groups. The mean age was 40.5 ± 14.2 years, and the M:F ratio was 1.7:1. The operative time for the LH was shorter than that for the CH (8.1 ± 3.1 vs. 25.5 ± 10.1 minutes, p value=0.001). The length of hospital stay was significantly shorter in the LH group (P value=0.001). The risk for rectal bleeding and urine retention in the first postoperative 48 hours was greater in the CH group than in the LH group (34% vs. 2%, P value=0.001 and 22% vs. 6%, P value=0.01, respectively). However, there was no difference in the number of patients who required rescue analgesia during the first 48 hours (74% in the CH group vs. 2% in the LH group; P value=0.01). Patients who underwent LH resumed their work earlier than those who underwent CH (P value 0.001). The surgical wound was completely epithelized in the LH earlier than in the CH (P value 0.001).

Conclusion: Compared with closed haemorrhoidectomy, Ligasure™ haemorrhoidectomy was associated with a significantly shorter operation time, fewer postoperative complications, a shorter hospital stay, earlier return to work, and shorter postoperative healing time.

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Ligasure™ haemorrhoidectomy; Closed haemorrhoidectomy; Complications; Complete epithelization

Introduction

Treatment for haemorrhoids involves a wide range of options, ranging from diet and lifestyle modifications to different types of surgical procedures, depending on the severity and severity of symptoms [1,2]. In clinical practice, surgical intervention is indicated for third-degree and fourth-degree patients, and pain is a recognized postoperative complication after haemorrhoidectomy [3]. Other postoperative complications include acute urinary retention, postoperative rectal bleeding, bacteraemia and septic complications, wound breakdown, unhealed wounds, loss of anal sensation, mucosal prolapse, anal stricture, and even faecal incontinence [4]. Several studies have been published to investigate the optimal option for the treatment of haemorrhoids in recent years, and

new devices and procedures have been proposed to overcome haemorrhoidectomy drawbacks, such as diathermy pedicle coagulation, the Harmonic Scalpel, the Ligasure™ system, stapling haemorrhoidopexy and Doppler-guided haemorrhoidal vessel ligation [5-9]. Several studies and randomized controlled trials have suggested that both the Harmonic Scalpel and the Ligasure™ systems potentially reduce tissue trauma and damage and are associated with less postoperative pain than traditional diathermy haemorrhoidectomy [10-14].

Closed haemorrhoidectomy was described by Ferguson and Heaton [15], and it was suggested that this procedure provides less postoperative pain and better wound healing [16,17].

This study aimed to compare closed-technique

haemorrhoidectomy and Ligasure™ for the treatment of third- and fourth-degree haemorrhoids.

Materials and Methods

This study was carried out at the Department of Surgery at Omdurman Teaching Hospital, Khartoum, Sudan, from May 2015 to May 2017. All patients with Grade III or IV haemorrhoids who presented during the study period were eligible for inclusion in this study. The exclusion criteria were patients younger than the age of 18 years, complicated haemorrhoids (thrombosed or strangulated haemorrhoids), coexisting peri-anal disease, previous history of preanal surgery, immunocompromised patients, bleeding tendency, and pregnancy. All patients were subjected to preoperative evaluation, including medical history, clinical examination, and basic laboratory investigations. Patients were divided into two groups by a team of two surgeons to undergo one of two operations; Ligasure™ Haemorrhoidectomy (LH) or Closed Haemorrhoidectomy (CH). In this study, patients were assigned to surgery not by randomization but by systemic allocation. The operations of both groups were performed under spinal anaesthesia. Anaesthesia was examined with a proctoscope before haemorrhoidectomy commenced in all patients. In addition, all patients were advised to use a sitz bath and were prescribed regular laxatives.

Ligasure™ Haemorrhoidectomy (LH) the jaws of the handset were applied to the pedicle, and the instrument was activated by the foot paddle. A computer-controlled feedback loop automatically stopped the flow of energy when coagulation of the vessels and mucosa was achieved. A scissor was used to excise the haemorrhoid mass by cutting across the coagulated tissue seal, no sutures were applied, as the Ligasure™ device achieved mucosal fusion, and anal canal packing was not routinely performed except when there was doubt about complete homeostasis.

Closed Haemorrhoidectomy (CH) The procedure was carried out as described by Ferguson and Heaton [15]. Piles were lifted from the internal sphincter by diathermy, and the vascular pedicle was fixed with 2/0

chromic catgut sutures and the mucosal edges of the defect as opposed to 2/0 chromic catgut. Anal canal packing was not routinely performed except when there was doubt regarding complete homeostasis.

The primary outcomes were postoperative complications, rectal bleeding, anal pain, urine retention, and wound complications. The secondary outcome parameters were operative time, time to complete epithelization, and time to return to work. Patients were called up for follow-up at 2, 6, and 8 weeks after the operation to observe complications and study outcomes. The Numerical Rating Scale (NRS) was used to assess postoperative pain at 6 hours after the operation (range from 0 to 10; 0 indicates no pain, and 10 indicates the worst possible pain).

This study was approved by the Sudan Medical Specialization Board's ethical committee and the hospital's local ethical committee. Written informed consent was obtained from all the participating patients after each procedure was explained and the purpose of the study was explained. The data were collected using a well-constructed redesigned questionnaire and predicted data. The statistical analysis was conducted with the help of Microsoft Excel and SPSS software version 23 for Windows. Variables were presented as the mean and standard deviation for quantitative data and percentages for qualitative data or as appropriate. AP value ≤ 0.05 was considered to indicate statistical significance.

Results

A total of 100 patients who satisfied the inclusion criteria were divided equally between the CH group and the LH group. The mean age was 40.5 ± 14.2 years, and most patients (83%) were aged between 21 and 60 years. The male-to-female ratio was 1.7:1. All patients had either Grade III or IV haemorrhoids (74% vs. 26%). Most patients (72%) had three haemorrhoids. There were no significant differences between the CH group and LH group regarding age, number of haemorrhoids, or degree of hemorrhoids (Table 1). The NRM pain score measured at 6 hours post-surgery was greater in the CH group than in the LH group (6.5 ± 1.5 vs. 3.0 ± 1.0 , respectively).

Table 1. Baseline characteristics of the included population.

Parameter		Closed haemorrhoidectomy. N (%), (total n=50)	Ligasure™ haemorrhoidectomy N (%), (total n=50)	P value
Age group	0 - 20	05 (10.0%)	03 (06.0%)	0.191
	21- 40	28 (56.0%)	21 (42.0%)	
	41- 60	15 (30.0%)	19 (38.0%)	
	61-80	02 (04.0%)	07 (14.0%)	

Gender	Male	22 (44.0%)	41 (82.0%)	0.001
	Female	28 (56.0%)	09 (18.0%)	
Number of haemorrhoids	one	01 (02.0%)	05 (10.0%)	0.173
	Two	09 (18.0%)	12 (24.0%)	
	Three	40 (80.0%)	32 (64.0%)	
	Four	00 (00.0%)	01 (02.0%)	
Haemorrhoids degree	Third	35 (70.0%)	39 (78.0%)	
	Fourth	15 (30.0%)	11 (22.0%)	

Operative time and hospital stay

The operative time for LH was shorter than CH, and the mean operative durations were 8.1 ± 3.1 minutes and 25.5 ± 10.1 minutes, respectively ($P=0.001$). Regarding hospital stay, 78% of patients were discharged on the same day as the operation, 18% were discharged on the second postoperative day, and only 4% were discharged on the third postoperative day. The LH group had a shorter hospital stay duration (P value=0.001).

Complications

At 48 hours, 18 patients developed rectal bleeding during the first 48 hours after surgery. The risk for postoperative rectal bleeding was greater in the CH group than in the LH group (34% vs. 2%, respectively) (P value=0.01). Moreover, the CH group had a greater risk of urine retention (22%) than did the LH group (6%) (P value=0.01). There was no significant difference in the incidence of postoperative pain between patients who required IV analgesia for pain control (P value=0.58). None of our patients developed any surgical wound infection or dehiscence.

At 2+6 weeks, there was a significant difference in the number of patients who suffered from anal pain that required oral analgesia between the CH group and the LH group (74% in the CH group vs. 02% in the

CH group; P value=0.01). There were no differences regarding rectal bleeding, wound dehiscence/infection, or rectal discharge, with P values of 0.37, 0.27, and 0.40, respectively.

At 4+6 weeks, 26 patients (52%) in the CH group reported anal pain that required oral analgesia, while none of the patients in the LH group complained of anal pain (P value=0.01). No other complications were noted. Notably, no postoperative complications were reported at six weeks in either group. The complications are shown in Table 2.

The patient returned to work and completed epithelization

Patients who underwent LH resumed their work earlier than those in the CH group (P value=0.001), and all patients in the LH group returned to work by the third week. The amount of time required to return to work is shown in Table 3. Complete epithelization of the surgical wound was observed beginning in the third week after surgery, and 59% of the patients showed complete epithelization by the fourth week. The difference in the time required for complete epithelization was significant in favor of that in the LH group (P value=0.001). A comparison of the time required for complete epithelization is shown in Table 4.

Table 2. Comparison of complication rates between CH and LH at 48 hours, 2 weeks, and 4 weeks after the operation.

Time	Outcome	Closed haemorrhoidectomy N (%), (total n=50)	Ligasure™ haemorrhoidectomy N (%), (total n=50)	P value
6 hours postoperative	NRS pain score	6.5 ± 1.5	3.0 ± 1.0	NA
48 hours postoperative	Rectal bleeding	17 (34.0.0%)	01 (02.0%)	0.01
	pain that requires IV analgesia	40 (80.0%)	40 (80.0%)	0.58
	Urine retention	11 (22.0%)	03 (06.0%)	0.01
	Wound dehiscence/infection	00 (00%)	00 (00%)	NA

Two weeks postoperative	Rectal bleeding	01 (02.0%)	00 (00.0)%	0.37
	pain that requires PO analgesia	37 (74.0%)	01 (02.0)%	0.01
	Wound dehiscence/infection	01 (02.0%)	00 (0.0%)	0.27
	Rectal discharge	04 (08.0%)	02 (02.0%)	0.4
Four weeks postoperative	Rectal bleeding	00 (00%)	00 (00%)	NA
	pain that requires PO analgesia	26 (52.0%)	00 (00.0%)	0.01
	Wound dehiscence/infection	00 (00%)	00 (00%)	NA
	Rectal discharge	00 (00%)	00 (00%)	NA

Table 3. Comparison of the time to return to work between the closed haemorrhoidectomy group and the Ligasure™ Haemorrhoidectomy group.

Time to return to work (week)	Closed haemorrhoidectomy N (%), (total n=50)	Ligasure™ haemorrhoidectomy N (%), (total n=50)	P value
one week	00 (00.0%)	06 (12.0%)	0.001
Two week	17 (34.0%)	28 (56.0%)	
Three weeks	16 (32.0%)	16 (32.0%)	
Four weeks	17 (34.0%)	00 (00.0%)	

Table 4. Comparison of the time required to complete surgical wound epithelization between the CH group and LH group.

Time to complete epithelization	Closed haemorrhoidectomy N (%), (total n=50)	Ligasure™ haemorrhoidectomy N (%), (total n=50)	P value
One week	00 (00.0%)	00 (00.0%)	0.001
Two weeks	00 (00.0%)	00 (00.0%)	
Three weeks	03 (06.0%)	35 (70.0%)	
Four weeks	44 (88.0%)	15 (30.0%)	
Five weeks	02 (04.0%)	00 (00.0%)	
Six weeks	01 (02.0%)	00 (00.0%)	

Discussion

Haemorrhoidectomy is considered one of the most common surgical procedures performed at Sudanese hospitals. Surgical treatment of haemorrhoids was reserved for Grade 3 or 4 haemorrhoids, while Grade 1 or 2 haemorrhoids were treated conservatively. There is continuous development in the surgical management of haemorrhoidectomy to improve patient outcomes and overcome drawbacks and complications, mainly pain, bleeding, and recurrence.

Rectal bleeding may occur in 1%-2% of patients after haemorrhoidectomy, mainly due to eschar separation, and may stop spontaneously during the first week [18]. Many surgeons insert anal tampons to prevent bleeding; however, this may increase pain intensity. In this study, the LH group had a lower risk of rectal bleeding than the CH group, which is consistent with previous reports in the literature [19-23]. It was suggested that there is minimal tissue damage associated with Ligasure™ because Ligasure™ combines pressure and electrical energy to coagulate blood vessels, which allows faster and less bloody dissection [24,25]. Only one patient continued to bleed after the first 48 hours post-surgery, which is like the percentage of 0.9-10 reported in previous studies for delayed rectal bleeding after haemorrhoidectomy [26,27].

The intensity of post-haemorrhoidectomy pain is multifactorial and affected by a combination of the patient's pain tolerance threshold, operative technique, quality of anaesthesia, delivery of postoperative analgesia, and use of pre-and postoperative laxatives to aid bowel movement [28,29]. The pain score was greater in the CH group; however, there was no significant difference in the number of patients who required IV analgesia during the first 48 hours. The difference was significantly greater at 2 and 4 weeks in the CH group. This result is in line with previous reports [30,31]. Again, the reason could be that there is less sphincter spasm, less tissue damage, and less thermal spread with Ligasure™ [24,25]. Other outcomes in favour of LH superiority were operative time, risk of urine retention, and return to work, and all these outcomes were reported in the literature [21, 28,29,32]. Considering that postoperative urinary retention can complicate up to 70% of anorectal surgery cases [33], with haemorrhoidectomy patients being at highest risk [34], our finding of a low rate of urinary retention in the LH group is very promising. This complication often results in an overnight hospital stay and can result in further appointments, management, and health costs.

Seventy percent of patients in the LH group achieved complete epithelization by the third week, which is

slightly greater than the 60% rate of epithelization reported previously [35]. The overall rate of epithelization was greater in the LH group than in the CH group in this study, possibly due to the smaller wounds and minimal tissue damage caused by LH. However, this approach has unavoidable side effects, and the authors proposed that topical glyceryl triturate ointment reduces anal sphincter spasm and provides a good blood supply to the mucosa after haemorrhoidectomy, which may facilitate epithelization and wound healing [36,37].

Moreover, several authors have suggested that the risk for sphincter muscles is lower in LH than in conventional haemorrhoidectomy [32,38]. However, we could not estimate the percentage of smooth muscle in the specimen due to limited resources.

Conclusion

Patients who underwent Ligasure™ haemorrhoidectomy had significantly fewer postoperative complications, shorter operative times, shorter hospital stays, shorter return to work, and shorter postoperative healing times than those who underwent closed haemorrhoidectomy.

What is already known on this topic?

- Ligasure™ haemorrhoidectomy has better postoperative pain control than a closed haemorrhoidectomy.
- Ligasure™ haemorrhoidectomy provides a shorter hospital stay.

What does this study add?

- The first study to compare Ligasure™ and closed haemorrhoidectomy in the Sudanese population.
- Strength the superiority of Ligasure™ over closed haemorrhoidectomy for 3rd and 4th - degree haemorrhoids in terms of postoperative complications, pain control, hospital stay, and return to work.
- Ligasure™ haemorrhoidectomy results in faster epithelization than closed haemorrhoidectomy.

Competing interests

None.

Authors' contributions

EE, AYM, and AAH conceived the idea for the study. EE, AYM, YAA, and AAA contributed equally to the data collection and data analysis. EE, AYM, YAA, and AAH contributed to the writing and review of the manuscript. All the authors approved the manuscript.

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