PROSPECTIVE, RANDOMIZED CONTROLLED TRIAL OF LIGASURE™ VERSUS CONVENTIONAL HEMORRHOIDECTOMY FOR GRADE III AND IV HEMORRHOIDS

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ABSTRACT

Background: Performing hemorrhoidectomy with LigaSure™ vessel sealing system is a rapid and simple new technique. The aim of this study was to evaluate LigaSure™ hemorrhoidectomy (LH) to open hemorrhoidectomy (OH) performed by the conventional diathermy. **Patients and methods:** One hundred and sixteen patients with grades III and IV hemorrhoids were prospectively randomized to either LigaSure™ or open conventional diathermy hemorrhoidectomy. Primary end point was a postoperative pain. Secondary endpoints were operative time, blood loss, complications, need for analgesics and time to achieve complete wound healing. **Results:** The LigaSure™ group achieved a significant reduction in operative time, blood loss, first postoperative day pain score, seventh-day pain score, and overall pain score. Patients in the LigaSure™ group required less pethidine analgesia on the first postoperative day. Time to achieve complete wound healing were shorter in the LigaSure™ group. There was difference in postoperative complications. **Conclusion:** LigaSure™ hemorrhoidectomy provides a valid alternative to conventional hemorrhoidectomy. Based on our results, further studies addressing long-term functional results are needed to prove that LigaSure™ hemorrhoidectomy is the ideal method of hemorrhoidectomy for the patients.

KEYWORDS Hemorrhoids, LigaSure™, Hemorrhoidectomy, Milligan-Morgan

Introduction

Hemorrhoidectomy is the standard operation for grades III and IV hemorrhoids; it is superior to any proposed conservative procedure, including sclerotherapy, rubber band ligation, photocoagulation, and cryotherapy. [1] Unfortunately, it is often associated with post-operative complications, including severe pain especially during the first post-operative week, bleeding, incontinence and anal stenosis, which can result in delayed convalescence [2], this stimulated the researchers to develop new techniques with a less severe course and faster recovery. [3]

Recent advances in instrumental technology including the bipolar electrothermal device, ultrasonic scalpel, and circular stapler are gaining popularity as effective alternatives in hemorrhoidectomy [4]. Of these instruments, the LigaSure™ vessel sealing system (Valley Lab, Boulder, CO) has been recently introduced [6] as a tool conceived to upgrade the conventional treatment of haemorrhoids:it consists of a bipolar electrothermal device sealing blood vessels up to 7mm in diameter and generating energy, with a thermal injury confined to 2mm over to surgical site. This limited spread reduces anal spasm and allows to perform a bloodless haemorrhoidectomy with reduced post-

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operative pain and fast healing [5,6]. Thus this operation can be recommended as the ideal technique because of its limited tissue injury, facilitated wound healing, and decreased post-operative pain. Many trials were performed to compare LigaSure™ hemorrhoidectomy with conventional hemorrhoidectomy, and it is suggested that LigaSure™ hemorrhoidectomy is a safe and efficient method to improve surgical outcomes. The primary goal of some trials was to evaluate the benefits of the system over traditional approaches [7,8] although an overall favorable trend exists toward LigaSure™, conclusions are not univocal and definitive; this creates some uncertainty, also considering the increasing cost for this disposable device: thus it is essential to keep on experimenting to determine whenever an actual advantage exists [9,10]. This prospective study was designed to verify if the use of the LigaSure™ system can be proposed as a less painful and bloodless alternative to conventional hemorrhoidectomy.

PATIENTS AND METHODS

This prospective study included 116 consecutive patients with symptomatic grade III, or IV hemorrhoid operated on at the Department of Surgery, Khamis Mushayte General Hospital between December 2011 and January 2015. This study has been approved by the research ethics committee of the hospital and is not supported by any commercial company. Written informed consent was obtained from all patients and/or guardians after full explanation of the procedure. The exclusion criteria included patients with Grade I and II hemorrhoids, on anticoagulants, with the hematological disorder, with the concomitant anal disease, or a previous history of anorectal surgery, age older than 75 years and patient lost at the follow-up.

All patients were evaluated preoperatively with a complete proctological examination and anoscopy: a colonoscopy was performed in those aging over 50 years to rule out colonic cancer. All patients undergoing elective haemorrhoidectomy were recruited to this study. Patients were randomized using coin test into two groups before the time of anesthesia: Group I for whom LigaSure™ (Covidien Healthcare, Boulder) hemorrhoidectomy was done and Group II for whom conventional diathermy open hemorrhoidectomy (Milligan-Morgan) was done. Patients were blinded to the result of randomization. All operations were performed under general anesthesia in the lithotomy position by the author. All patients were required to record pain after the discharge day until the 14th postoperative day on a self-administered visual analog scale from 1to 10 scale (VAS).

Patients were assessed weekly for the first month then one month, six months, and twelve months after the operation. The patient demographics, duration of symptoms, operative time, intraoperative blood loss, and hospital stay, post-operative complications and time off work or regular activity in all patients was recorded.

Operative Technique

As a preoperative protocol, both groups of patients were cleaned by a saline enema on the evening before the operation. Preoperative antibiotic prophylaxis was given in the form of 1 gm third generation cephalosporin and 500mg of Metronidazole intravenously with the induction of anesthesia and continued for the following hospital stay period every 12 hours. Patients received analgesic administration of intramuscular Pethidine 50 mg on demand not exceeding three times in the first postoperative day and regular NSAIDs 75mg Diclofenac sodium IM twice daily till discharge, and the total count of analgesic ampoules was calculated for the patient. After hospital discharge, analgesia was achieved by 50 mg Diclofenac sodium tablet on demand (never exceeding three times a day).

The operation was performed under general anesthesia in lithotomy position in both groups. Anal dilatation for two finger breadth to apply proctoscope was done in both groups. In the LigaSure™ group, the procedure was performed by applying LigaSure™ forceps to the vascular pedicle: scissors were then used to cut along the line of coagulum, lifting the pile from the internal sphincter. LigaSure™ sealed the vascular pedicle without transfixion. The wound was left open. The procedure was repeated for each pile group. In diathermy group, a conventional open hemorrhoidectomy was performed according to Milligan-Morgan technique [11].The piles were lifted from the internal sphincter by diathermy, and Vicryle 0 sutures transfixed the vascular pedicle and then excised by scissor. The wounds were left open. A piece of gauze with xylocaine gel was left in the anal canal at the end of the procedure.

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences Version 20 software (SPSS Inc., Chicago, IL). Results were expressed as a mean ± standard deviation. The two-sided Pearson $\chi 2$ test and the student t-test were used to comparing the variables between the two groups. AP values less than 0.05 was considered statistically significant.

RESULTS

One hundred and sixteen patients with third and fourth-degree hemorrhoids were randomly divided into two groups: Group I of 62 patients treated with LigaSure™ haemorrhoidectomy, and group II of 54 patients underwent conventional diathermy (Milligan-Morgan) operation. All patients had a minimum follow-up of nine months (range 9–40).The two groups were comparable for age (mean age: 31.18 years for diathermy, 32.35 years for LigaSure™ patients; overall range (18–72), gender (male/female ratio not statistically significant), the characteristics of patients are summarized in (Table 1).

The mean operative time for the LigaSure™ group was 11.22 minutes compared to 28.42 for conventional diathermy, with a statistically significant difference (< . 0 0 0 1) .Blood loss was significantly less in group I than group II. (Table 2)

There was no difference in hospital stay since patients were discharged 24 ± 8 hours after the operation in both groups, and delayed discharges were noted in three cases of the conventional group (second and third postoperative day) due to minor bleeding (2 cases) and acute urinary retention in one case. The overall incidence of complications was more in group II patients (Table 2)

Pain: patients in the LigaSure™ group had a significantly lower pain score on the first day, continued daily until the seventh day, and second postoperative week compared with the conventional group. In the current group, all patients required NSAIDs injections and Pethidine three doses on the first postoperative day, while in the LigaSure™ group patients required NSAIDs in the same form and at the same dose as mentioned above and only twelve (19.35%) patients required three doses of petidine. The LigaSure™ group needed less amount of analgesics compared with the conventional group. (Table 3)

Discharge: Group I had five patients (8.06%) with postoperative discharge, in contrast to group II, which had 13 patients (24.07%) (P =0.03).The discharge in both groups was bloody at

Table 1 Patients characteristics in the two groups (* = significant).

parameter	LigaSure™ group I (n=62)	Conventional Group II (n=54)	P value
Age mean (years)	32.35±12.5	31.18±11.88	0.6
Range	18-67	18-67	
Male/female,(ratio)	44/18(2.4)	32/20(1.6)	0.72
Duration,of symptoms	19.39±12.8 months	17.68±12.7	0.47
Range(months)	4-42	4-42	

Table 2 Comparison of operative outcomes and postoperative complications in the two groups (* = significant)

parameter	LigaSure™ group I (n=62)	Conventional Group II (n=54)	P value
Average operating time	11.22 ± 2.9 min	28.79 ± 0.01 min	0.0001*
range	8-18	20-45	
Average blood loss	6.53 ± 2.9 ml	28.42 ± 7.32 ml	0.0001*
Range	5-10	20-45	
Wound healing	15.24± 3.3 days	31.16± 6.7days	0.001*
range	10-21	20-42	
Return to work or normal	6.93 ± 1.7	15.46± 3.2	0.001*
activity (days) range	5-11	10-20	
Post-operative complications			
Hemorrhage	0 (0%)	2(3.7%)	0.42
Urinary retention	0 (0%)	1(1.85%)	0.94
Post-operative Discharge	5(8.06%)	13(24.07%)	0.034*
Recurrence of hemorrhoids	0 (0%)	1(1.85%)	0.94
Prolonged Hospital stay	0 (0%)	3(5.55%)	0.19
Overall complications	5(8.06%)	20(37.03%)	0.0004*

first and then mucoid, except for two patients in group II in whom the discharge turned purulent indicating infection, which was controlled with antibiotics and strict follow-up.

Stenosis: was not reported in both groups along the follow-up period.

Wound healing was faster in the LigaSure™ group: mean was 15.24 ± 3.3 days (ranging from 10 to 21 days), versus 31.16 ± 6.7 days (ranging from 10-42 days) in the conventional group (P =0.001) The overall incidence of complications was different between the two groups: 20 patients (37.3%) after conventional diathermy versus 5 patients (8.33%) in LigaSure™ group (= .0.004)

Discussion

Hemorrhoidectomy remains the most effective treatment for prolapsed hemorrhoids. However, postoperative pain is the most dreaded aftermath for patients undergoing the procedure. [7] Therefore, various new modalities have been developed to overcome this, none is clearly superior to the other, and the primary concern remains reduction of postoperative pain and operative time [12]. The LigaSure™ vessel sealing system seems to be ideal for hemorrhoidectomy as it produces localized coagulation and minimal collateral thermal spread of maximum only 2 mm, thus allowing fast bloodless dissection with minimal collateral damage. The present study assured this and showed, the superiority of LigaSure™ hemorrhoidectomy over Milligan-Morgan's hemorrhoidectomy especially in reduced operative time, reduced postoperative pain, and a reduced amount of parenteral analgesics required. [13-23]. In our study, there was no significant difference between the two groups on preoperative data. (Table 1) This study found a highly significant shorter operative time in the LigaSure™ group compared with the conventional group. [13-15]

Shorter operative time in LigaSure™ hemorrhoidectomy could be related to the better hemostatic control and bloodless field. We found a significant difference between intraoperative blood loss in the two groups. The LigaSure™ group showed mean intraoperative blood loss of 6.53 ± 2.9 compared with

Table 3 Pain score and analgesic consumption in the studied groups (* = significant)

parameter	LigaSure™ group I (n=62)	Conventional Group II (n=54)	P value
Postoperative pain score Day1 (range)	4.58±1.2 (3-7)	6.42±1.51 (4-9)	0.0001*
Postoperative pain score Day2	4.66±1.15 (3-7)	5.61±1.42 (4-8)	0.0001*
Postoperative pain score Day3	4.51±1 (3-6)	5.42±0.98 (4-7)	0.0001*
Postoperative pain score Day4	4.54±1.01 (3-6)	5.24±1 (3-7)	0.0001*
Postoperative pain score Day5	4.51±1.002 (3-6)	5.29±1.02 (3-7)	0.0001*
Postoperative pain score Day6	4.33±1.02 (3-6)	5.22±1.02 (3-7)	0.0001*
Postoperative pain score Day7	3.69±1.05 (1-6)	4.24±1.08 (3-6)	0.0001*
Postoperative pain score Day14	1.23±0.83 (1-3)	2.6±0.91 (2-4)	0.0001*
Postoperative Analgesic Consumption day 1(range)	2.19±0.64 Ampules (1-3)	3.24±0.84 Ampules (2-5)	0.047*
Postoperative mean total Analgesic Consumption day 14 (range)	19.56±4.06 tablets (14-28)	32.09±5.78 tablets (18-42)	0.007*

28.79 ± 0.01 ml in the current group, in contrast with the study by Johnson, who found no measurable blood loss in LigaSure™ hemorrhoidectomy. The significantly lower intraoperative blood loss in LigaSure™ hemorrhoidectomy may be explained by the effective hemostasis achieved by the use of LigaSure™ device.

We found in agreement with other studies that, in LigaSure™ group, patients achieved lower pain score on the first day and continued until the second postoperative week compared with the conventional group [5, 13-15]. Meanwhile, Chung and Wu [14] found a significant reduction in postoperative pain in the LigaSure™ group on the first and second day and no significant difference on the seventh and 14^th day postoperatively. While others [15,16] studies failed to demonstrate any reduction in postoperative pain between the LigaSure™ and conventional groups. The significant lower postoperative pain score encountered with LigaSure™ hemorrhoidectomy compared with conventional hemorrhoidectomy can be explained by minimal lateral thermal injury and reduced sticking and tissue charring [15].The absence of sutures transfixing vascular pedicles could be another additional advantage in reducing pain by decreasing the development of local ischemia and necrosis that might cause acute postoperative pain and secondary bleeding [10].

We found that analgesic requirement in the LigaSure™ group was lower than that of the regular group, in contrast, Jayne et al. and Palazzo et al. [16] reported similar pain score but the lower need for analgesics in LigaSure™. While others found that there was no difference in analgesic requirement between the two groups. This difference is logical because of the difference in the severity of pain score between the two groups [15].

Postoperative wound discharge was found to be significantly lower in the LigaSure™ group (five cases =8.06%) compared with the conventional group (13 cases = 24.07%) [17].The lower degree of discharge in the LigaSure™ group may be due to limited tissue injury, which reduced wound sepsis and facilitated healing [17].In our study, there were no cases of anal stenosis in both groups, as reported by Wang and colleagues. The incidence of stenosis after LigaSure™ hemorrhoidectomy was 2 and 2.4%, respectively [18.19]. Anal spasm after hemorrhoidectomy has been implicated in postoperative pain and poor wound healing. LigaSure™ hemorrhoidectomy is associated with reduced anal spasm because the collateral damage with LigaSure™ is less compared with diathermy in conventional hemorrhoidectomy [19]. We did not have cases of postoperative fecal incontinence as reported by other studies. The reported incidence

of fecal incontinence after LigaSure™ hemorrhoidectomy was 15% [15] and 4.5% [19]. This could be attributed to excessive sphincter stretching done by mistake before using LigaSure™ as done during conventional hemorrhoidectomy. This component of sphincter stretching usually is minimized by using our LigaSure™ technique [15]. Moreover, in conventional hemorrhoidectomy, the incorporation of underlying sphincter muscle in the hemorrhoidal excision by mistake from the surgeon and the postoperative inflammatory healing process play a role in postoperative incontinence. LigaSure™ group achieved faster wound healing (15.24 ± 3.3 days), compared with the conventional group (31.16 ± 6.7 days), this was observed by others, but Wang and colleagues [5] reported that there was the insignificant difference between the two groups. Reduced anal spasm and the smaller size of surgical wounds associated with LigaSure™ hemorrhoidectomy may have contributed to the significantly earlier wound healing observed after LigaSure™ hemorrhoidectomy compared with conventional hemorrhoidectomy. In our study we did not found a significant difference between the two groups regarding recurrence as there were no cases of recurrence in either group, this coincides with others [5,14,19]. In our study, return to work and normal activities was significantly earlier after LigaSure™ hemorrhoidectomy than after conventional hemorrhoidectomy owing to decreased postoperative pain and faster wound healing. All the preceding advantages of LigaSure™ hemorrhoidectomy may compensate for the higher cost of the LigaSure™ electrodes [15].The minimal complications reported here, suggest that LigaSure™ hemorrhoidectomy is a safe procedure. There were statistically significant differences in the incidence of complications between LigaSure™ hemorrhoidectomy and conventional hemorrhoidectomy especially for delayed wound healing, which was significantly higher after conventional hemorrhoidectomy. Similar findings but not statistically significant were reported by Peters and others [17,20].

Conclusions

This prospective controlled randomized trial confirms the advantages of LigaSure™ haemorrhoidectomy over conventional diathermy. Limitations of the present study were the small sample size the limited follow-up and the cost effective measurement: thus, the benefits and cost of LigaSure™ as a low-pain and long-term effective technique need to be further evaluated in larger series

Authors' Statements

Competing Interests

The authors declare no conflict of interest.

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