

Randomized Clinical Trial of LigaSure Haemorrhoidectomy versus Open Diathermy Haemorrhoidectomy

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Abstract

Introduction: Haemorrhoidectomy is the most effective and definitive treatment for grade III or IV haemorrhoids. The traditional surgical approaches include the open (Milligan–Morgan) and the closed (Ferguson and Parks) haemorrhoidectomy. Both procedures entail similar complications, in particular protracted postoperative pain that causes longer hospital stays. Recently, a variety of instruments have been used in an attempt to reduce postoperative pain and a quicker return to normal activities. A new option in performing Milligan–Morgan haemorrhoidectomy involves the LigaSure system, a bipolar electrothermal vessel sealing device.

Objective: The randomized clinical trial was carried out to see the benefits of using LigaSure over monopolar diathermy in haemorrhoid surgery in terms of operating time, postoperative pain and complications.

Materials and Methods: This randomized clinical trial was carried out in the Department of Surgery at Combined Military Hospital, Dhaka. The study was conducted for a period about two years. The sample size was one hundred cases of haemorrhoidectomy divided into 50 cases of two groups, which is LigaSure haemorrhoidectomy and open diathermy haemorrhoidectomy. Patients were included in the trial if they had symptomatic prolapsing internal haemorrhoids. All patients were randomized using sealed envelopes. Patients were blinded to the type of surgery performed. Patients kept a record of postoperative pain by means of a visual analogue scale. Symptom control and patient's satisfaction were assessed at 12 weeks' follow-up. LigaSure haemorrhoidectomy was performed by the medium-sized LigaSure™ forceps.

Results: The operating time was less in LigaSure haemorrhoidectomy (mean 7.7 min with range of 4 to 16min) as compared with open diathermy haemorrhoidectomy (mean 18.2 with range 7-24 min) ($p < 0.001$). The median postoperative pain score was 4.3 (range 1-8.5) in the LigaSure group and 7.0 (range 3-9) in the open diathermy haemorrhoidectomy group. The difference was statistically significant ($p < 0.001$). The median number of administrations of analgesia in postoperative period was less in the LigaSure group (10 with range 4-20) as compared with the open diathermy group (19.5 with range 6-24) ($p < 0.001$). There were five cases of complications in LigaSure haemorrhoidectomy group, whereas eleven cases developed complications in open diathermy haemorrhoidectomy group. The complications were postoperative bleeding, urinary retention and anal fissure.

Conclusion: Evidence to date confirms that LigaSure haemorrhoidectomy is an effective technique. LigaSure appeared to be an effective tool for the dissection and haemostasis required for an excisional haemorrhoidectomy procedure.

Key-words: LigaSure vessel system, LigaSure haemorrhoidectomy, Diathermy haemorrhoidectomy.

Introduction

Haemorrhoidectomy is the most effective and definitive treatment for grade III or IV haemorrhoids¹. At present, the traditional surgical approaches include the open (Milligan–Morgan) and the closed (Ferguson and Parks) haemorrhoidectomy¹⁻⁴. However, both procedures entail similar complications, in particular blood loss and protracted postoperative pain that cause longer hospital stays^{1,5}.

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The postoperative pain is linked to excessive tissue trauma involving sensitive perianal skin and anoderm⁵. Much of this discomfort may arise from thermal injury because of electrocoagulation and from the presence of sutures. Use of preoperative lactulose and metronidazole to reduce perioperative pain^{6,7} has recently been included in evidence-based guidelines for the practice of haemorrhoidectomy⁸. Recently, a variety of instruments including circular stapler, ultrasonic scalpel, laser and a bipolar electro-thermal device are used with an attempt to reduce postoperative pain and blood loss, and to permit fast wound healing and a quicker return to normal activities⁹⁻¹⁴. A new option in performing Milligan-Morgan haemorrhoidectomy involves the LigaSure system, a bipolar electrothermal vessel sealing device^{15,16}. LigaSure™ (Valleylab, Boulder, Colorado, USA) is a novel haemostatic device designed primarily for use in abdominal surgery. LigaSure vessel sealing system is a bipolar electrothermal device that seals blood vessels by an optimized combination of pressure and radiofrequency ablation that permanently changes collagen and elastin within the vessel wall² to achieve complete and permanent fusion of the vessel lumen. The LigaSure system allows effective, bloodless haemorrhoid excision with minimal tissue injury, reducing postoperative pain, infection rate, time for wound healing and time to return to normal activities^{13,15,17,18}. Several randomized trials comparing LigaSure and conventional haemorrhoidectomy have shown that the LigaSure procedure is a safe and simple method of improving surgical outcome. However, these series have involved limited numbers of patients with only a short term follow-up^{13,15,17,19-22}. Some Western studies have shown benefits of using LigaSure over diathermy in terms of operative time, postoperative pain and wound healing^{13,15,17}. This study will certainly provide some knowledge and information about the better option for haemorrhoidectomy. The LigaSure is available in Combined Military Hospital, Dhaka. The proper use of this device can provide a better outcome in haemorrhoid surgery in terms of operation time, postoperative pain, wound healing and complication.

Materials and Methods

The study was a randomized clinical trial, carried out to see the benefits of using LigaSure over monopolar diathermy in terms of operating time,

postoperative pain and complications. The study was carried out in the Department of Surgery at Combined Military Hospital, Dhaka Cantonment. The study was conducted for a period about two years from September 2008 to July 2009 and again from August 2011 to October 2012. The sample size was one hundred cases of haemorrhoidectomy divided into Group-I consisting of 50 cases of LigaSure haemorrhoidectomy and Group-II consisting of 50 cases of open diathermy haemorrhoidectomy. Patients were included in the trial if they had symptomatic prolapsing internal haemorrhoids and were medically fit for spinal or general anaesthesia. Exclusion criteria were haematological disorders, regular use of anticoagulants, immunosuppressants or analgesics; American Society of Anesthesiologists grade III or IV, pregnancy, obesity (body mass index greater than 35 kg/m²), those undergoing simultaneous procedures for fissure or fistula, and those previously operated upon for haemorrhoids and these having insulin-dependent diabetes mellitus, epilepsy, known hypersensitivity to local anaesthetics; and drug or alcohol abuse. All patients were randomized to receive either LigaSure haemorrhoidectomy or open haemorrhoidectomy using sealed envelopes. The randomization was nonconsecutive in nature. Randomization was performed in the operating theatre just prior to surgery. Patients were blinded to the type of surgery performed. Written informed consent was obtained from all patients who were admitted for haemorrhoidectomy with symptomatic prolapsing haemorrhoid. In both groups a standard pre-operative protocol was followed, which included 20 ml lactulose twice daily from the day before operation to aid in defecation after the operation and 500 mg metronidazole given intravenously at the start of the operation. After surgery all patients received lactulose 20 ml per day for two weeks, and metronidazole 400 mg three times daily for one week. On the day of operation diclofenac sodium injection was used to control postoperative pain. Oral diclofenac sodium 50 mg two times daily, on demand, never more than three times per day, were prescribed to all patients for postoperative analgesia from the first postoperative day. All patients were asked to clean the wound by sitz bath twice daily. Patients kept a record of postoperative pain by means of a visual analogue scale. Patients were familiarized with an 11-point visual analogue pain score from 0 to 10, before operation.

The patients were asked to record before bed-time their maximum pain score for the day. Pain scores were recorded for seven days from the first postoperative day; from this a weekly mean score was calculated. The patients were also asked to record the total number of analgesic tablet taken for that day. Subjective postoperative assessment of pain was evaluated by considering the dose of analgesics used by each patient daily. All data concerning duration of surgery, postoperative pain, analgesic requirement, and complications were recorded. Patients were assessed at the first follow-up visit at the end of second week when wound was examined. Subsequent follow-up was at third, fourth and sixth weeks. Complete wound healing was defined as absence of swelling of the wound. Symptom control and overall patient's satisfaction were assessed at 12 weeks' follow-up. All patients were encouraged to contact the authors if necessary. In both groups haemorrhoidectomy was undertaken using a Sim's or Pratts rectal speculum with the patient in the lithotomy position. All procedures were performed under general or spinal anaesthesia. Milligan-Morgan techniques for open diathermy haemorrhoidectomy were performed by either a consultant or a higher surgical trainee. All LigaSure procedures were performed by same surgeon. No anal canal pack dressing was employed in either group. After the haemorrhoids had been prolapsed out from the anal canal with an artery forceps, LigaSure haemorrhoidectomy was performed by applying the medium-sized LigaSure™ forceps close to the edge of each haemorrhoid together with any associated skin tag. Completion of coagulation was signalled by the feedback sensors and the tissue was excised along the line of coagulum. Repeated applications of the device were performed and excision was continued into the anal canal, lifting the haemorrhoidal tissue from the internal anal sphincter, to the level of the vascular pedicle, which was finally divided. The area was then inspected with rectal speculum to ensure haemostasis. Surgical suture was used either to ligate pedicle or for haemostasis when required. In the diathermy group, haemorrhoidectomy was performed by submucosal dissection of the haemorrhoidal tissue from the internal sphincter using standard monopolar diathermy. Pedicles were transfixed, taking care to avoid incorporation of the underlying sphincter; haemorrhoids were excised and the wounds left open.

At the end of the study, individual interview schedule and checklist were checked to see completeness and consistency of data. Data analysis was performed using the Statistical Package for the Social Sciences for Windows version 12.0 (SPSS, Chicago, Illinois, USA). After controlling for the homogeneity of the groups, to test for statistical significance, the t-test was used for continuous variables. The Mann-Whitney U test was used to establish the difference between LigaSure and open haemorrhoidectomy with respect to the duration of operation, postoperative pain and analgesic requirement. A value of $p < 0.05$ was considered statistically significant.

Results

Hundred patients were included in this study. There were 32(64%) men and 18(36%) women in the LigaSure haemorrhoidectomy group, and 34(68%) men and 16(32%) women in open diathermy haemorrhoidectomy group. The mean age was 36.9 (range 20-65) years in LigaSure haemorrhoidectomy group and 40.3 (range 21- 65) year in open haemorrhoidectomy group with no statistical difference ($p=0.283$) in patients characteristics (Table-I).

Table-I: Patient characteristics.

	LigaSure (n = 50)	Diathermy (n = 50)	P
Sex			
Male	32(64%)	34(68%)	
Female	18(36%)	16(32%)	
Mean (range) age (years)	36.9(20-65)	40.3 (21-65)	$p=0.283$

*Student's t- test (Independent Sample T test)

The operating time was less in LigaSure haemorrhoidectomy group (mean 7.7min with range 4-16 min) as compared with open diathermy haemorrhoidectomy group (mean 18.2 with range 7-25 min) ($p < 0.001$) (Fig-1).

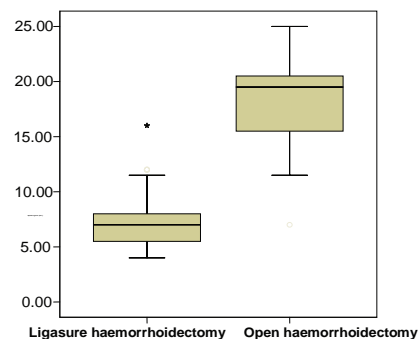


Fig-1: Mean operating time for LigaSure and open diathermy haemorrhoidectomy. Boxes denote the range $P < 0.001$ (Mann-Whitney U test).

The median postoperative pain score was 4.3 (range 1- 8.5) in the LigaSure group and 7.0 (range 3-9) in the open diathermy haemorrhoidectomy group. The difference was statistically significant ($p < 0.001$) (Fig-2).

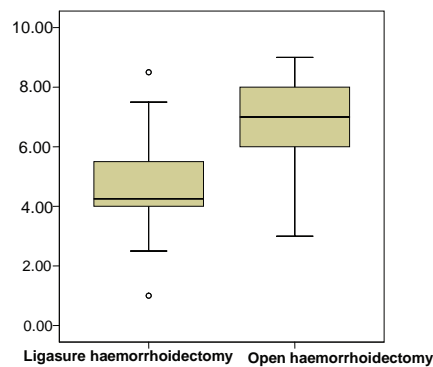


Fig-2: Comparison of median daily pain score following LigaSure and open diathermy haemorrhoidectomy. Boxes denote the range $p < 0.001$ (Mann-Whitney *U* test).

The median number of analgesia administered in postoperative period was less in the LigaSure group 10 with range 4-20) as compared with the open group (19.5 with range 6-24) ($p < 0.001$). The clinical outcomes of two studies are shown in Table-II.

Table-II: The clinical outcomes of two study groups.

Variables	LigaSure (n = 50)	Diathermy (n = 50)	P
Operating time	Mean 7.7 (range 4-16) min	Mean 18.2 (range 7-24) min	<0.001
Postoperative pain score	Median 4.3 (range 1-8.5)	Median 7.0 (range 3-9)	<0.001
Number of analgesia	Median 10 (range 4-20)	Median 19.5 (range 6-24)	<0.001

*Mann-Whitney *U* test

Only two cases of LigaSure group required haemostatic sutures. There were five complications in the LigaSure haemorrhoidectomy group and eleven complications in open diathermy haemorrhoidectomy group (Table-III).

Table-III: Complications in two patients.

Complications	LigaSure (n= 50)	Diathermy (n= 50)
Bleeding	2	4
Urinary retention	1	5
Anal fissure	2	4

The complications were postoperative bleeding, urinary retention and anal fissure. All urinary retentions developed in the evening of the day of operation and responded to temporary bladder catheterization. Patients of both groups complained of protracted pain after defecation resulting from the development of anal fissure. All of them responded to treatment with stool softeners, sitz bath and topical glyceryl trinitrate paste. All patients with secondary bleeding had single episode of haemorrhage in both groups but did not require any blood transfusion or operative manoeuvre. At 12th week follow up, there was no difference in over all outcomes between the two groups of patients.

Discussion

Haemorrhoidectomy is the procedure that cures prolapsing haemorrhoids most effectively¹. The widely performed excision-ligation procedure first described by Milligan and Morgan³ can be bloody and is associated with troublesome postoperative pain. Haemorrhoidectomy using diathermy excision has been shown to be associated with less bleeding, a shorter operating time and a lower postoperative analgesic requirement, but the technique is not intrinsically less painful than conventional haemorrhoidectomy²³.

Different techniques and devices have been developed to overcome postoperative pain, including modifications of the techniques, introduction of new surgical instruments, perioperative use of lactulose, metronidazole, and the addition of lateral internal sphincterotomy or the intraoperative injection of botulinum neurotoxin^{6,7,9-14,23-26}. The LigaSure vessel-sealing system allows complete coagulation of blood vessels along with confinement of the thermal spread to within 2 mm of adjacent tissue and also limited tissue charring. Its application results in a discrete line of coagulation that allows bloodless haemorrhoid excision, making it an ideal instrument for haemorrhoidectomy. This study shows that the new technique offers advantages over conventional open diathermy haemorrhoidectomy as confirmed by other studies^{2,17}. A significant decrease in operative time when compared to open diathermy haemorrhoidectomy was also observed. In this study, mean operating time (min) was 7.7 (range 4-16) in LigaSure group and 18.2 (range 7-25) in

open diathermy group. Tan KY et al²⁷ reported mean operative time (min) as 9.4 and 18.2 in LigaSure group and open diathermy group respectively whereas Palazzo FF et al¹⁷ reported 5.1 (range 2-9) and 9.2 (range 7.6-14.1) min of median duration of operation in LigaSure group and open diathermy group respectively. The absolute bloodlessness is the characteristic of the LigaSure haemorrhoidectomy; it offers better visibility and therefore more accurate dissection. The absence of blood in the operative field is such that no time is required to secure haemostasis¹⁷ and as a consequence the mean operating time in this study was less than half in LigaSure group than open diathermy group.

This study demonstrates that the LigaSure group experienced less postoperative pain than the open diathermy group (P < 0.001). In this series median postoperative pain score was 4.3(range 1-8.5) in LigaSure group and 7(range 3-9) in open diathermy group. Muzi MG et al² reported pain score as 1.5(range 0-3) and 3.3 (range 2-6) in LigaSure group and open diathermy group respectively whereas Milito G et al¹⁵ reported median postoperative pain score 4.7(range 2-8) in LigaSure group and 5.2 (range 2-8) in diathermy group. Anal spasm after haemorrhoidectomy has been implicated in postoperative pain and poor wound healing^{8,28}. It has been postulated that LigaSure haemorrhoidectomy is associated with reduced anal spasm²⁹. This is because the collateral damage with LigaSure is less than that with diathermy. The median postoperative analgesic requirement following the LigaSure haemorrhoidectomy was lower than that of open diathermy haemorrhoidectomy. However, in this study the pain on the day of operation was not measured. The incidence of different complication of this study and comparison with other series are shown in Table-IV.

Table-IV: Comparison of postoperative complications reported by other randomized controlled trials comparing LigaSure (LS) with open diathermy (OD) haemorrhoidectomy.

Reference	Number of patient	Bleeding	Urinary retention	Anal fissure
Present series	LS 50	LS 2	LS 1	LS 2
	OD 50	OD 4	OD 5	OD 4
Chang YC et al ³³	LS 30	LS 3	LS 1	LS 0
	OD 31	OD 3	OD 2	OD 0
Milito G et al ²⁴	LS 29	LS 1	LS 1	LS 0
	OD 27	OD 2	OD 1	OD 0
Jayne DG et al ¹⁹	LS 20	LS 1	LS 1	LS 1
	OD 20	OD 1	OD 0	OD 1

In this study there have been no unexpected complications. In contrast, circular stapling haemorrhoidectomy has been followed by reports of serious complications including pelvic sepsis³⁰ and anastomotic stenosis³¹. Furthermore, failure to deal with external haemorrhoidal components and skin tags can lead to an unsatisfactory cosmetic result in some 20-40 per cent of patients treated with circular stapling³². Although residual skin tags are believed to shrivel over time, this will be verified only with further long- term follow-up. This problem is avoided with the use of LigaSure diathermy, which can deal effectively with both internal and external haemorrhoidal components, giving excellent cosmesis.

Conclusion

Evidence to date confirms that LigaSure haemorrhoidectomy is an effective technique. The new technique is safe, comparatively simple and easy to learn; it is bloodless and rapid to perform. LigaSure haemorrhoidectomy takes significantly less time to complete and is associated with significantly less postoperative pain and reduction in the amount of postoperative analgesia than open diathermy haemorrhoidectomy. LigaSure appears to be an effective tool for the dissection and haemostasis required for an excisional haemorrhoidectomy procedure.

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