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RESEARCH ARTICLE

COMPARATIVE STUDY BETWEEN USING ELECTRO THERMAL BIPOLAR VESSEL SEALING DEVICE AND CONVENTIONAL METHOD IN HAEMORRHOIDECTOMY

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ABSTRACT

Objective: This study aims to evaluate the outcome of ligasure hemorrhoidectomy versus conventional (Milligan Morgan) hemorrhoidectomy regarding blood loss, length of the procedure, postoperative pain and wound healing. **Method:** This prospective study was included 40 patients with grade III, or IV hemorrhoid. Patients divided into 2 groups Conventional (Milligan- Morgan) hemorrhoidectomy for 20 patients and Ligasure hemorrhoidectomy for 20 patients. **Result:** This study defined that the application of Ligasure hemorrhoidectomy was associated with shorter operative time, almost bloodless operative field, smooth postoperative period with lower pain score, analgesic requirement and lower incidence of postoperative complications. In addition, it found that patient satisfaction significantly more superior after Ligasure hemorrhoidectomy. **Conclusion:** Ligasure hemorrhoidectomy is safe, effective, associated with lower pain and fewer postoperative complications than conventional hemorrhoidectomy.

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INTRODUCTION

The main pathophysiological theories about hemorrhoids that it is abnormal venous dilatation of the internal haemorrhoidal plexus, abnormal arteriovenous anastomosis dilatation, and prolapse of the surrounding connective tissue and the cushions (Kaidar- Person, 2017). Hemorrhoids classified according to their site; the histoanatomical landmark was dentate line (pectinate line). The one that originate proximal to the dentate line, arising from the superior hemorrhoidal plexus, and covered with mucosa are internal hemorrhoids. The other one that originate distal to the dentate line, arising from the inferior hemorrhoidal plexus are external hemorrhoids, which richly innervated with somatic pain fibers (delta type, unmyelinated) (Corman, 2004). The main symptoms of hemorrhoids are different according to its site; internal hemorrhoids patients complain of pain, bleeding, anemia and Problems of discrimination (Kaidar- Person et al., 2007). External hemorrhoids may be asymptomatic, or some discomfort, the cause of acute pain in hemorrhoid is thrombosis in veins. They both do not bleed (Mounsey, 2011). Lifestyle modifications main effective part of the treatment of haemorrhoidal disease. This is useful in most patients with Grade I and II haemorrhoids. A small group of patients with more severe grades of haemorrhoids, which are unfit for surgery because of age or bad general condition, only conservative management

suitable for them to minimize symptoms (MacKay, 2001). These approaches include increase the intake of dietary fiber and fluids in the diet, improving anal hygiene and avoiding constipation or diarrhea. These methods provide to minimize prolonged straining during bowel movement, which is help to the development of haemorrhoids (Alonso-Coello et al., 2006). Medical treatment including phlebotonics as micronized purified flavonoid fraction (MPFF) in a botanical extract from citrus. Flavonoids increase venous tone, lymphatic drainage, and capillary resistance and normalize capillary permeability⁽¹⁾. Analgesics and anti-inflammatory drugs have effective role during the episodes of external and internal thrombosis (Abramowitz et al., 2001). Milligan – Morgan (open) haemorrhoidectomy was first described of open haemorrhoidectomy from 2 centuries ago; the technique made in the United Kingdom by Milligan and Morgan, in 1937 and still widely used in Europe. In the Milligan- Morgan haemorrhoidectomy, the internal and external components of catch hemorrhoid excised and the skin left open in a 3-leaf clover pattern that heals secondarily for 4-8 weeks (Dajani et al., 1997). Early postoperative complications include pain, acute retention of urine, faecal impaction, infection and reactionary hemorrhage. Late postoperative complications include secondary hemorrhage, anal stricture, anal fissure, fistula, skin tags and incontinence. Postoperative pain remain the major drawback of excisional hemorrhoidectomy and

studies show that most patients do not return to work for 2-4 weeks following surgery (Madoff, 2004). Liga Sure technology has many advantages as it provides a combination of pressure and energy to create vessel fusion permanently fuses vessels up to and including 7mm in diameter and tissue bundles without dissection or isolation. its average seal cycle is 2 to 4 seconds, when used with the force-triad energy platform, Seals with stand three times normal systolic blood pressure and has a feedback-controlled response system automatically discontinues energy delivery when the seal cycle is complete, eliminating the guesswork (Medtronic, 2016). This study aimed to evaluate the outcome of ligasure hemorrhoidectomy versus conventional surgery (Milligan Morgan) hemorrhoidectomy regarding intraoperative blood loss, length of the procedure, postoperative pain and wound healing.

PATIENTS AND METHODS

This prospective study included 40 patients from both sexes with symptomatic grade III, and IV hemorrhoid undergone operation for their hemorrhoids at the department of general surgery, in Aswan university hospital, at a period from October 2017 until April 2018. Patients with Grade I and II hemorrhoids, patients on anticoagulants with the hematological disorder, patients with the concomitant anal disease, or a previous history of ano-rectal surgery, and recurrent cases are excluded from our study with no limitations in age. Patients divided into 2 groups; Conventional (Milligan- Morgan) hemorrhoidectomy included 20 patients and Ligasure hemorrhoidectomy for the other 20 patients. Each patient subjected to Pre-operative assessment included full history taking with stressing on history of chronic constipation, history of fecal incontinence, obstetric history in females. Clinical examination included general and local examination (Digital rectal examination), for detection of hemorrhoids, its grading, complications, and presence of other associated ano-rectal disease. Routine investigation included complete blood picture, liver function tests, kidney function tests, blood glucose level, INR, prothrombin time and concentration and anti HCV, HBsAg. Preoperative preparation with evacuation enema the night before surgery. With the 20 patients under anesthesia and in lithotomy position, the electro-thermal vessel sealing hemorrhoidectomy performed. It is an energy-based method of ligating vessels up to 7 mm in diameter. The system works by applying a precise amount of pressure and energy to the tissue, transforming the collagen and elastin within the vessel walls, to create a permanent seal. An anal retractor placed in the anal canal to reveal the extent of hemorrhoids. We start with the most dominant one. The internal hemorrhoid clamped with a pickup forceps or Alis clamp, so the lines of what would typically be an incision (essentially at the junction of the hemorrhoid and the flat perianal skin) visualized. The Ligasure handset applied to the internal hemorrhoid at this junction and the generator activated. The electrothermal bipolar vessel-sealing device analyze the tissue type and deliver the appropriate amount of the energy adequately desiccate the tissue. When the seal is complete, an end tone sounded and the generator deactivate. The seal appears almost translucent; indicating complete hemostasis. Another application of Ligasure device can be made on the same hemorrhoid due to its large diameter. Using scissors, the seal cut down the middle. Each hemorrhoid dealt with in the same manner until all hemorrhoids excised and complete hemostasis achieved.

The wound cleansed, povidone iodine (Betadine) ointment and a small dressing is applied Fig. (1). Others, 20 patients treated with Conventional (Milligan- Morgan) hemorrhoidectomy Fig. (2). Intraoperatively blood monitored by "Blood Loss Estimation Using Gauze Visual Analogue"⁽²²⁾ Fig. (3) in both groups. Patients discharged between 4 to 12 hours after surgery, and followed for period of 2 to 6 months for detect healing progress and complications. The patients were followed for the level of postoperative pain monitored by using the visual analogue scale⁽²²⁾, analgesic requirement, bleeding, urine retention, complete healing time, discharge, anal stenosis, incontinence, recurrence and duration of operation. The data collected and analyzed with specific statistical tests and presented with respective tables and graphics.

RESULTS

The prospective randomized study was carried on 40 patients (14 male and 26 female) complaining from third (22) and fourth degree (18) hemorrhoids, their age between 25-34 years. Patients divided into two groups, group I included 20 patients subjected to conventional (Milligan- Morgan) hemorrhoidectomy included 8 male (40%) and 12 female (60%). Their mean age was 29.0 ± 3.5 years. As regard, clinical grading there was 12 patients (60%) showed G III hemorrhoids and 8 patients (40%) showed G IV hemorrhoids. Group II included 20 patients subjected to Ligasure hemorrhoidectomy 6 male (30%) and 14 female (70%). Their mean age was 30.1 ± 4.7 years. As regard clinical grading there was 12 patients (60%) showed G III hemorrhoids and 8 patients (40%) showed G IV hemorrhoids. The Ligasure group achieved highly significant shorter operative time; the mean (\pm SD) in minutes was 6.05 ± 1.5 ranges from (4:8) min compared to 21.90 ± 2.34 ranges from (17:26) min. for the Conventional group with P value > 0.001 Intra operative blood loss estimated by the number and the degree of soaking of the gauze, the Ligasure group showed highly significantly lower intraoperative blood loss the mean (\pm SD) in ml was 1.26 ± 0.35 range from (.8-1.8) ml compared to 21.29 ± 4.68 range from (6.5-28.3) ml for the Conventional group with P value < 0.001 Fig. (4). Patients in Ligasure group achieved a significantly lower postoperative pain score in the 7th day after surgery compared to the conventional group. The pain score in Ligasure group during the 7th day was mean (\pm SD) 1.35 ± 1.31 range from (0-4) versus 2.25 ± 1.12 range from (1-4) in conventional group with P value = 0.026. There was 4 cases (10%) of postoperative bleeding in conventional group occurred at the 7th postoperative day, the bleeding was minimal and controlled by hemostatics and antibiotics, but it did not occurred in Ligasure group, P value = 0.487 (table 1). The Ligasure group show significant difference between Ligasure and conventional group regarding the analgesic requirement as Ligasure group required less analgesics than conventional group P value = 0.018. Ligasure group showed 10 cases (50%) of postoperative discharge, on the other hand conventional group showed 18 cases (90%) with P value = 0.006. Ligasure group showed no cases (*) of stenosis while in conventional group there was 2 cases (10%) of stenosis with P value = 0.487. Ligasure group showed no cases (0%) of incontinence while in conventional group there was 2 case (10%) of incontinence, with P value = 0.487. Ligasure group showed 2 case (10%) of P.O. wound swelling on the other hand, conventional group showed 10 cases (50%) with P value = 0.006.

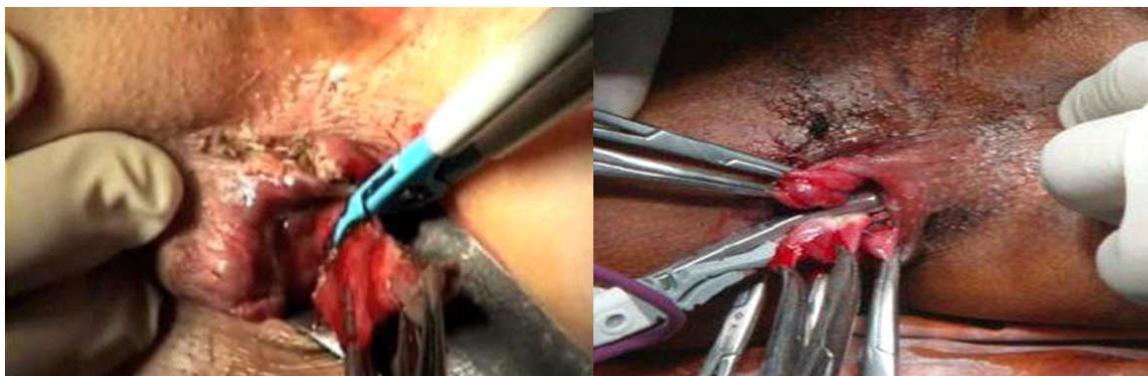


Fig. 1 Ligasure hemorrhoidectomy



Fig. 2. Conventional hemorrhoidectomy (Milligan- Morgan)













		Percentage of Saturation			
		25%	50%	50%	100%
Gauze Size	10×10 cm	 3 mL	 6 mL	 6 mL	 12 mL
	30×30 cm	 25 mL	 50 mL	 75 mL	 100 mL
	45×45 cm	 40 mL	 80 mL	 120 mL	 160 mL

Fig. 3. Visual Guide for Determining Blood Loss for Three Different Sizes of Gauze

		Surgery						Statistical test of sig.	
		Conventional (Milligan- Morgan) hemorrhoidectomy (N=20)			Liagsure hemorrhoidectomy (N=20)				
Post-operative day		Mean / N	SD /%	Range	Mean / N	SD /%	Range	P-Value	Sig.
7	Pain	2.25	1.12	(1 - 4)	1.35	1.31	(0 - 4)	0.026 ^(M)	S
	Bleeding	2	10.0%		0	0.0%		0.487 ^(F)	NS

Table 2. Comparison of the studied groups regarding wound healing and the postoperative complication:

		Surgery						Fisher's Exact test of sig.	
		Conventional (Milligan- Morgan) hemorrhoidectomy (N=20)			Liagsure hemorrhoidectomy (N=20)				
		Mean / N	SD /%	Range	Mean / N	SD /%	Range	P-Value	Sig.
Time healing/week		6.45	1.15	(5 - 8)	3.90	1.37	(2 - 6)	<0.001 ^(T)	HS
Post-operative	Swelling 2nd day	10	50.0%		2	10.0%		0.006 ^(C)	S
	Urine retention	6	30.0%		2	10.0%		0.235	NS
	Stenosis	2	10.0%		0	0.0%		0.487	NS
	Incontinence	2	10.0%		0	0.0%		0.487	NS
	Discharge	18	90.0%		10	50.0%		0.006 ^(C)	S

Ligasure surgery showing statistical significant less risk of wound healing than conventional surgery. Wound healing was faster in Ligasure group with the mean (\pm SD) in week was 3.90 ± 1.37 range from (2-6) weeks versus 6.45 ± 1.15 range from (5-8) weeks with the P value < 0.0001 . There were no cases of recurrence in both groups along period of the study (table 2).

DISCUSSION

Hemorrhoids are part of normal human anatomy. It is one of the common diseases of general population. Hemorrhoidectomy remains the most effective and definitive treatment of choice for prolapsed hemorrhoids. However, postoperative pain is the aftermath most dreaded by patients undergoing the procedure. Therefore, various new treatment modalities have developed with the aim of overcoming postoperative pain. None is clearly superior to the other, and the primary concern remains reduction of postoperative pain and operative time (Sendlbeck *et al.*, 2015). The Ligasure vessel sealing system seems to be ideal for hemorrhoidectomy since it offers a combination of excellent localized coagulation and minimal collateral thermal spread of only 2mm, thus allowing fast bloodless dissection with minimal collateral damage. The present study confirmed this and showed, as other studies have, that the superiority of Ligasure hemorrhoidectomy over Milligan – Morgan's hemorrhoidectomy consists in significantly reducing operative time, postoperative pain, and the amount of parenteral analgesics required (Muzi, 2017). This study was conducted to compare the results of Ligasure hemorrhoidectomy versus conventional (Milligan – Morgan) hemorrhoidectomy. In our study, there was no significant difference between the two groups regarding the preoperative data. Therefore, correlation between both groups could reflect the actual difference between both groups. As regard operative time, this study found a highly significant shorter operative time in the Ligasure group mean (\pm SD) in minutes were 6.05 ± 1.5 ranges from (4-8) min. compared to the conventional group mean (\pm SD) in minutes were 21.9 ± 2.34 range from (17-26) min. with P value < 0.0001 as reported by *Johannsson et al.*, *Jayne et al.* and *Wang et al.* (2002); *Jóhannsson*, 2002; *Wang et al.*, 2006.

Strikingly this study found very highly significant difference between intraoperative blood loss in the two groups, the Ligasure group showed intraoperative blood loss mean (\pm SD) in ml 1.26 ± 0.35 ranges from (.8-1.8) ml compared to 21.29 ± 4.68 ranges from (6.5-28.3) ml for the conventional group with P value < 0.0001 . This was in accordance with *Jayne et al.* (2002) and *Wang et al.* (2006) but in contrast with *Johannsson et al.* who reported that, there is no measurable blood loss in Ligasure hemorrhoidectomy. The significantly lower intraoperative time and blood loss in Ligasure hemorrhoidectomy explained by the effective hemostatic control achieved by the use of Ligasure device (*Palazzo et al.*, 2002). Significantly in Ligasure group, patients achieved lower pain score postoperative week ($p=0.026$) compared to conventional group. As noted by *Johannsson and Wang et al.* (2002); *Wang*, 2006, but *Palazzo et al.* (2002) reported that their study failed to demonstrate any reduction in postoperative pain between the Ligasure and conventional groups, by our study we approved that. The significant lower postoperative pain score encountered with Ligasure hemorrhoidectomy compared to conventional hemorrhoidectomy could be attributed to the fact

that the Ligasure system seals tissue bundles without dissection which causes minimal lateral thermal injury, reduce sticking and tissue charring (*Wang*, 2006). Complementary to the post-operative pain status, the analgesic requirement in the Ligasure group was lower than the conventional group as reported by *Palazzo et al.* and *Wang et al.* (2002); *Wang et al.*, 2006 this concern with our study but In contrast with *Jayne et al.* (2002) who declared that there was no difference in analgesic requirement between the two groups. This difference is logical due to the difference in the severity of pain score between both groups. Postoperative wound discharge was found to be significantly lower in Ligasure group (10 cases = 50%) compared to conventional group (18 cases = 90%), this was in agreement with the result of *Jayne et al.* and *Peters et al.* (10, 21). The lower degree of discharge in Ligasure group attributed to limited tissue injury that reduce wound sepsis and facilitate healing (*Peters et al.*, 2005). In our study, there were no cases of anal stenosis in Ligasure group which was similar to the results reported by *Palazzo et al.*, *Chung and Wu* and *Peters et al.* (2003); *Palazzo*, 2002; *Peters*, 2005, but in contrast to the results of *Wang et al.* (2006) who found that the incidence of stenosis after Ligasure hemorrhoidectomy was 2% and 2.4% respectively. While there was 2 case (10%) in conventional group occurred 6 weeks postoperative and managed by regular manual dilatation at the outpatient clinic, this was in line with the results of *Correa – Rovelo et al.*, *Gencosmanoglu et al.* and *Wang et al.* (2002; *Gencosmanoglu*, 2002; *Wang*, 2006).

Anal spasm after hemorrhoidectomy has been implicated in postoperative pain and poor wound healing. It has been postulated that Ligasure hemorrhoidectomy (LH) is associated with reduced anal spasm because the collateral damage with Ligasure is less than that with diathermy in conventional hemorrhoidectomy (*Tan et al.*, 2008). Significantly, postoperative follow up revealed wound swelling at the seventh postoperative day in a single case (10%) in the Ligasure group compared to 10 cases (50%) in the conventional group, contradicting *Chung and Wu.* (5) who found that there was no significant difference between both groups. Similarly, the Ligasure group achieved significantly faster wound healing, mean \pm SD in weeks 3.9 ± 1.3 , compared to 6.45 ± 1.15 week in conventional groups after Ligasure hemorrhoidectomy observed by *Peters et al.* (2005) and after conventional hemorrhoidectomy, but *Chung and Wu* and *Wang et al.* (2003); *Wang*, 2006 reported that there is insignificant difference between both groups. In our study, there was no significant difference between both groups as regard recurrence as there were no cases of recurrence in both groups, the same results reported by *Chung and Wu*; also *Peters et al.* and *Wang et al.* (2003); *Peters et al.*, 2005; *Wang et al.*, 2006) reported that there were no cases of recurrence after conventional hemorrhoidectomy. The present study showed that after Ligasure hemorrhoidectomy, return to work and normal activities was significantly faster than after conventional hemorrhoidectomy owing to reduced postoperative pain and faster wound healing. This, but although Ligasure was reduced operative time, it may compensate for the higher cost of the Ligasure electrodes (*Altomare et al.*, 2008).

Conclusion

Ligasure hemorrhoidectomy is safe, effective, associated with lower pain and fewer postoperative complications than conventional hemorrhoidectomy. Moreover it preserves the

internal anal sphincter thickness and anal canal pressures, this feature make it the preferred modality in patients with prolapsing piles in whom sphincter function has been compromised by previous anal surgery or obstetric trauma.

Recommendation: We recommend that more researches should be done by other centers to confirm the efficiency of ligasure hemorrhoidectomy over conventional hemorrhoidectomy.

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