

LigaSure, Hemorrhoidectomy versus Excisional Diathermy Hemorrhoidectomy for All Symptomatic Hemorrhoids. Clinical trial and Literatures review

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ABSTRACT

Hemorrhoidectomy by LigaSure electrosurgical unit seems to be very effective treatment and results in better surgical outcomes when compared with the conventional excisional hemorrhoidectomy. The aim of this study was to compare the feasibility and the surgical outcomes of LigaSure hemorrhoidectomy with that of conventional diathermy excisional hemorrhoidectomy. **Patients and method:** 96 patients with symptomatic mainly grade III and IV piles were randomized for either conventional excisional hemorrhoidectomy (48 patients) or to LigaSure hemorrhoidectomy (48 patients) for the period from the April 2014 to July 2016. The surgical outcomes of both procedures including the operative time, intra-operative blood loss, postoperative pain, analgesic requirements, early and late postoperative complications, wound healing, recovery time and return to work, recurrence and patient satisfaction were recorded, compared and evaluated. **Results:** Patients characteristics were comparable in both groups. The mean operative time and amount of intra-operative blood loss were significantly lower in LigaSure hemorrhoidectomy group. Postoperative pain and need for parenteral analgesia were comparable in the first 24-48 hours postoperatively, but they were significantly lower in LigaSure group after the second postoperative day. Faster wound healing and early return to work were obviously noted among patient subjected to LigaSure hemorrhoidectomy. Early postoperative complications were lower in LigaSure group while late complications were comparable in both groups. Lastly, LigaSure group showed high satisfaction rate compared to conventional hexcisional hemorrhoidectomy group. **Conclusion:** LigaSure hemorrhoidectomy is superior and more advantageous in term of operative time, blood loss, post-operative complications, faster wound healing and return to work. It is simple, feasible and easy to learn.

Key words: haemorrhoids, conventional hemorrhoidectomy, diathermy, . LigaSure

INTRODUCTION

Hemorrhoids or piles are quite common in general surgical practice. More than half of populations will suffer from hemorrhoids during their life time. They presented initially as asymptomatic lesion, but with time they give rise distressing symptoms like anal discomfort, itching, prolapsed and ultimately bleeding. Occasionally, hemorrhoids presented as complications like inflammations, strangulation and thrombosis. [1] All symptomatic piles definitely need surgical excision especially when conservative measures or non surgical interventions failed to resolve the symptoms. Excision of piles whether surgically, or by diathermy or even by stapler hemorrhoidopexy is usually indicated for symptomatic grade 3 and 4 piles or when conservative measures failed for earlier grades of hemorrhoids or presence of concomitant chronic anal fissure or fistula[2] Excision of hemorrhoids is usually associated or results in sever and sometime intolerable postoperative pain which take about 2 to 8 weeks postoperatively. Such pain remains the main concern which make some patients reluctant to perform haemorrhoidectomy. [2,3]

Recently, new modality of haemorrhoidectomy was introduced by usage of bipolar electrosurgical ligaSure vessels sealing device for the treatment of symptomatic piles. LigaSure haemorrhoidectomy was tried and rapidly gained popularity as a valid and efficient alternative to conventional excisional haemorrhoidectomy. LigaSure

electrosurgical unit is multi-functional device due to its ability of grasping, sealing, blunt dissection and ultimately dividing tissues.[4] It is actually a modification of bipolar diathermy which acts by a combination of pressure and radiofrequency, sealing blood vessels up to 7mm in diameter and providing energy tailored to the tissue impedance with a thermal injury confined to 2 mm over the operative field.[5] The confined thermal spread permit the surgeon to perform a relatively bloodless hemorrhoidectomy and reduce the anal spasm which responsible for most pain after hemorrhoidectomy, in addition to the potential reduction in thermal tissue trauma and charring of highly sensitive anoderm. Besides, LigaSure electrosurgical unit stops energy delivery as soon as the tissue sealing is complete.[6]

The main aim of this prospective randomized controlled study was to compare the effectiveness and surgical outcomes of LigaSure haemorrhoidectomy with that of conventional excisional diathermy in term of operative time , blood loss, postoperative pain, early and late post op. complications, time to return to work and daily activity, recurrence and finally patient satisfaction about LigaSure haemorrhoidectomy.

PATIENTS AND METHODS

This is a prospective controlled randomized study conducted for the period from April 2014 to July 2016 including 96 patients (70 males and 26 females) with age ranges from 19 to 82 years, means 56.8) presented with grade III and IV symptomatic piles were randomized into either open diathermy excisional haemorrhoidectomy (group A: 48 patients) or to LigaSure haemorrhoidectomy (group B: 48 patients).

Patients with concomitant ano-rectal pathology such as anal fissure or fistula, piles secondary to other pathology and those presented with strangulated , thrombosed and inflamed piles were excluded from this study.

Patients in both groups of haemorrhoidectomy were submitted to the same preoperative evaluation which include routine blood investigations such as CBC, blood sugar , blood urea and s.creatinine as well as coagulation and viral profiles.

Although the majority of our patients has primary piles, sigmoidoscopy was offered for all patients elder than 60 years looking for and ruling out any rectal or colonic pathology.

Anal sphincter complex continence was assessed for all patients in this study depending on the Wexner continence score.

Detailed and complete explanation of both procedures was offered to all patients preoperatively including the possible complications , recurrence rate, and time average to return to normal daily activity, then, informed consent was obtained from each particular patient. The choice of procedure whether excisional diathermy or LigaSure one was done randomly by asking the patient to choose a sealed envelope including the type of the procedure.

All procedures were performed as an outpatients ambulatory basis. Bowel preparations was not required. Pre-medication in form of 5 mg/ 2ml midazolam plus 75 mg diclofenac or tramadol intramuscular injection. All patients in this study were operated on by same surgeon either under local perianal block (majority, 85 patients) (or under spinal or general anesthesia (only 11 patients

Operative time of both types of hemorrhoidectomy, postoperative pain immediately after surgery (within 4 to 6 hours), day 1, day 3, 1 week, and 3 weeks after surgery was recorded and assessed depending on Visual Analogue Scale (VAS) of 0 – 10 score both during rest and post defecation.

Amount of intra-operative blood loss, early postoperative complications (such as bleeding, urine retention, wound breakdown and infection , soiling and incontinence) and late complications (such as anal stenosis and recurrence) were also traced and recorded during the follow-up period of 6 – 9 months

Measurement of convalescent period and time taken by patients to return to the work in both types of hemorrhoidectomy as well as patient satisfaction were studied and compared

-Procedures:

Patients after giving pre-medications, were placed in lithotomy position with few elderly and frail patients were placed in prone jackknife position.

Patients in **group A (48patients)**, conventional open hemorrhoidectomy was adapted, which performed by initial digital rectal examination and dilatation of anal sphincter with localization and grasping of piles masses, followed by V-shaped incision at the muco-cutaneous junction by a scalpel followed by separation and dissection of hemorrhoidal mass off the underlying anal sphincter using the monopolar diathermy up to the level of dentate line with transfixion of each pedicles with 2.0 catgut chromic sutures. Skin and mucosal bridge between dissected piles is always preserved to prevent post-op anal stenosis. The wound left open to heal by secondary intention

Patients in the **group B (48patients)**, the procedure started as in the group A with digital examination and dilatation of anal sphincters, followed by grasping of the hemorrhoidal mass with 2 Kelly clamps at the muco-cutaneous junction and the internal mucosal component . The procedure start then with dissection and excision of piles masses by coagulation and sealing the vascular pedicle using either the LigaSure vessels sealing open small jaw or precise hand-piece forceps of Valleylab Covidien type, which provide integrated coagulation mechanism of both the soft tissues and blood vessels. The hemorrhoidal masses then excised and cut along the line of coagulation by using a fine well-tipped scissor with no transfixion needed and without any blood loss. The wounds produced after this procedure is quite small and left open .

At the end of procedures in both groups, homeostasis is checked and ensured followed by dressing of operative sites externally by sterile dressing soaked with xylocaine jelly with no dressing inside the anal canal. All patients were monitored and checked 1 hour, 2 hours, and discharged 4 to 6 hours postoperatively. Before sent to home, instructions of warm sitz path were given to all patients in the same evening, twice daily after that and after each bowel motion. Patient were put on pain killers and antibiotic (optional) and stool softener before discharge.

Operative time of both procedures, amount of intra-operative blood loss, postoperative pain and analgesic requirement, early and late postoperative complications, patient return to work and patient satisfaction about each procedure were recorded and analyzed.

RESULTS

This is a prospective study in which 96 patients presented with grade III and IV symptomatic hemorrhoids were randomly subjected to either conventional diathermy open excision by mono-polar diathermy (48 patients) or to hemorrhoidectomy by LigaSure vessels sealing electrosurgical unit (48 patients).

Patients ages range from 19 – 82 years, mean 56.8 years. Patients in both groups were identical for age (mean age for conventional diathermy group 55.9 year, and 57.2 years for LigaSure group).The majority of our patients were males(70 males and 26 females). Anal continence was assessed preoperatively using Wexner continent score. Almost all patients were continent (Wexner score 0-2). The duration of symptoms, severity (degree) and the number of piles need to be excised were comparable between the two groups and there was no statistical differences. Patients (characteristics and the main symptoms are summarized in table (1

Table (1): Patients characteristics and their clinical presentations

Patients characteristics & symptoms	Group A (48patients)	Group B (48patients)
Age	55.9	57.2
Duration of symptoms (months)	8.6	9.6

Prolapsed hard lump	36	40
Bleeding		32
	3	
Pruritis & itching		15
	17	
Pain	8	11
Mucus discharge	7	8
Wexner continence score	0-2	0-2

The mean operative time for conventional excisional hemorrhoidectomy group was 23.6 minutes compared to 16.4 minutes for LigaSure hemorrhoidectomy group. The difference was statistically significant ($P < 0.001$).

The amount of intra-operative blood loss as measured by weighing the gauze before and after being soaked with blood was significantly higher in the conventional diathermy hemorrhoidectomy group compared to relatively bloodless LigaSure hemorrhoidectomy group. (20- 50ml vs. 0-5ml). Since both procedures are ambulatory day-case surgery, all patients in both groups were discharged to home 4-6 hours after the operation and thus there was no significant difference in respect to hospital stay.

Management of pain in both procedures was started before surgery by giving patients premedication consisting of intramuscular NSAID in form of diclofenac 75 mg and short acting midazolam 5mg in 2ml. Since surgery on a very sensitive anoderm is associated with postoperative pain, all patients in this study were put on pain killers postoperatively. The need for analgesia and evaluation of postoperative pain using VAS score were recorded and studied. There was no significant difference in VAS score and the need for parental analgesia in the first 48 hours after surgery, (VAS for excisional hemorrhoidectomy was 4.6 vs. 4.1 for LigaSure hemorrhoidectomy). The VAS scores and analgesic requirements after 48 hours till the 3 weeks postoperatively were significantly less in the LigaSure group compared to conventional group. (VAS scores for LigaSure group in the 3rd, 7th, 14th, 21st and 28th were 3.1, 2.6, 2.1 and 1.6, 0.8 respectively compared to conventional group scores 4.8, 4.2, 3.9, 2.8, 1.9 for the same periods. The differences were significant ($P < 0.01$). Table (2)

Table (2): Postoperative pain scores (VAS) among patients in both groups

Post-operative pain scores(VAS)	Conventional group	LigaSure group
0-2 nd day		
	4.6	4.1
3 rd day		
	4.8	3.1
7 th day		
	4.2	2.6
14 th day		
	3.9	2.1
21 st day		
	2.8	1.6
28 th day		
	1.9	0.8

Regarding the incidence of early postoperative complications, bleeding occurred in 2 patients (4.2%), urine retention in 3 patients (6.25%), infection and wound breakdown in 3 patients, (6.25%), temporary incontinence to flatus in one patient (2%) in conventional hemorrhoidectomy group, while in the LigaSure hemorrhoidectomy group, bleeding, wound infection and incontinence were not observed in any patient, while urine retention in one patient (2%). It is worthwhile to mention that 11 patients

(22.9%) in the conventional group suffered from seepage and perianal soiling, a finding which not observed in any patients subjected to LigaSure hemorrhoidectomy. There was statistically significant faster wound healing in the LigaSure hemorrhoidectomy (8.6 days versus 19.5 days for conventional hemorrhoidectomy). Consequently the time required to the the daily work and normal daily activity was

quite shorter in the LigaSure group. (7-10 days vs. 14-21days)

During the fellow up 6 to 9 months period of this study, late complications were traced and recorded. Anal stenosis developed in 5 patients (10.4%) in conventional group and 3 patients(6.25%) in LigaSure group. Recurrence of piles was not observed in any patient in both groups during the same fellow up period of this study. Patients satisfaction about the two types of hemorrhoidectomy was another important concern in this study. The majority of the patients underwent LigaSure hemorrhoidectomy were satisfied about their operations with overall satisfaction rate recorded was 87.5%,42/48 patients(excellent in 26 patients, good in 15 patients, accepted in 5 patient and bad in one patient) compared to 77% 37/48 patients for conventional diathermy hemorrhoidectomy (excellent in 16 patients, good in 20 patients, accepted in 9 patients and bad in 3 patients

Table (3): Surgical outcomes among patients in both groups:

Surgical outcomes	Conventional Haemorrhoidectomy	LigaSure haemorrhoidectomy
Operative time	23.6 min.	16.4 min.
Operative blood loss	ml 20-50	0-5ml
Hospital stay	4-6 hours	4-6 hours
Postop. Pain scores	3.7	2.4
Bleeding Postop.	2	0
Urine retention	3	0
Wound healing	8.6	19.5
Incontinence	1 (temporary)	0
Return to work	7-10 days	14-21 days
Anal stenosis	4 (8.3%)	3 (6.25%)
Recurrence	0	0
Patient satisfaction	77%	87.5%
Overall complications	16.6	6.25

DISSCUSSION

Hemorrhoidectomy is one of commonly performed surgical procedure since piles are quite common among population. Excision is usually needed especially for grade III and IV piles and for symptomatic piles that failed to heal by conservative treatment. Conventional excisional hemorrhoidectomy is still the gold standard and most effective procedure. Although this operation is considered as a minor procedure that can be done even in an ambulatory setting under general, spinal or even local

anesthesia, it is usually associated with significant postoperative pain due to excision of very sensitive anoderm. In addition to that, several complications like bleeding, urine retention, delayed wound healing, anal stenosis and recurrence could occur [1,3,7]. Therefore, the search for less painful, feasible and effective alternative is still going on and still the main concern of many surgeons. Even when hemorrhoidectomy

performed by diathermy using a mono-polar cautery, still the pain is a well-known postoperative complication due to thermal spread and damage to nearby richly innervated tissue. Thus limitation and minimizing the extent of thermal injury is expected to result in significant reduction of postoperative pain.[4,8]

Recently, the introduction of LigaSure vessels sealing electro-surgical unit for the treatment of piles had gained wide acceptance and popularity. LigaSure vessels unit is an improved version of bipolar diathermy with further advantage of achieving homeostasis by its vessels sealing system. It can seal blood vessels up to 7 mm in diameter. The delivered energy is confined only to the tissue grasped between the jaw of hand piece forceps with no or very minute spread of thermal energy to sensitive adjacent tissues.[8]

Therefore, hemorrhoidectomy conducted by LigaSure vessels sealing device is an upgrade modification of conventional excisional hemorrhoidectomy. LigaSure hemorrhoidectomy is considered now superior to conventional diathermy hemorrhoidectomy as it designed specifically to be used in a confined surgical field that necessitate delicate and precise visibility and dissection. [9]

In this study, we present our experience of using LigaSure electro-surgical unit for treatment of our patients who presented with symptomatic piles and compared the results and surgical outcomes with that recorded after conventional excisional diathermy hemorrhoidectomy. We found that, LigaSure hemorrhoidectomy when compared with conventional hemorrhoidectomy, is simple, safe, and very effective treatment modality. It characterized by bloodless sub-mucosal dissection, less operative time, less postoperative pain and less overall postoperative complications, besides, excellent surgical outcomes.

We found that the operative time and the amount of intra-operative blood loss were significantly less in the LigaSure group. Our findings were consistent with the that of Bakhtiar N et al [10] in their similar study which found that the mean operating time, the mean blood loss and overall pain score were less in those patient underwent hemorrhoidectomy by LigaSure technique. Pattana et al [11] found that LigaSure hemorrhoidectomy is superior to closed hemorrhoidectomy in term of decreasing the time of operation but the postoperative complications were comparable.

Gentile et al [12] in their randomized clinical trial which compared between LigaSure and conventional hemorrhoidectomy for IV degree hemorrhoids showed that the LigaSure system is simple and more effective with short operating time, less postoperative pain score due to limited tissue damage and free from pain earlier than those with conventional hemorrhoidectomy. Altomare et al [13] recorded in their similar study of 273 patients that LigaSure hemorrhoidectomy resulted in significant decrease in operating time but no difference in the incidence of postoperative bleeding.

Although the VAS scores were comparable in both groups of hemorrhoidectomy in early postoperative period in our study, analgesic requirement and postoperative pain control were significantly less after 48 hours in LigaSure group. These findings can be explained by the fact that all patients in both groups were covered adequately by good and potent analgesia in addition to the use of long acting bupivacaine as a local anesthetic agent in the majority of the patients. Pain score by VAS from the 3rd to 14th day postoperatively were significantly less in LigaSure group. Pain after the third week decreased in both groups similarly. Our results were consistent with the results obtained from Palazzo et al [14] and Jayne et al [15]. Neinhuijs et al [16] in their similar study which compared the patients tolerance and postoperative pain after LigaSure and conventional hemorrhoidectomy showed that LigaSure technique is superior in term of postoperative pain, patients tolerance and without any adverse effect on the surgical outcomes and postoperative complications. Milito et al [17] recorded in their study which compared between hemorrhoidectomy with LigaSure vs

conventional excisional techniques showed that patients treated with LigaSure had a significantly shorter operative time, postoperative pain, wound healing time and time off from the work than patients submitted to excisional hemorrhoidectomy.

The usage of LigaSure vessels sealing technique was found by many researchers to result in reduction of postoperative pain and analgesia. This could be related to its very minimal thermal injury to the tissues, the sutureless nature of this technique, proper tissue apposition resulting in rapid wound healing and irreversible nerve ending thermal injury are the main factors that decrease the postoperative pain after LigaSure hemorrhoidectomy. Bessa [18] showed that LigaSure electrosurgical unit provides a superior alternative to conventional diathermy for hemorrhoid surgical excision by decreasing the operative time, postoperative pain, and need for parenteral analgesia in the early postoperative period as well as faster wound healing.

Early and late postoperative complications such as bleeding, urine retention, wound breakdown, delayed wound healing and anal stenosis, we found that these complications were significantly less in LigaSure hemorrhoidectomy group. Same findings were also observed in similar studies of Gentile et al [12] and Altomare et al [13] and Frankline et al [19]. Mastakove et al [20] showed in their comparative study between LigaSure and excisional hemorrhoidectomy that LigaSure technique is very effective and resulted in better surgical outcomes apart from the incidence of postoperative complications that were comparable and not significant. Although anal stenosis developed in 3 patients (6.25%) in the LigaSure group and 4 (8.3%) patients in the conventional excisional group, all patients were treated successfully by conservative measures with anal dilatation and applications of Calcium channel blocker ointment in form of 2% Diltiazem with no need for further surgery. Gentile et al [12] recorded anal stenosis in one patient only out of 25 patients treated by LigaSure technique. Wang et al [21] also reported anal stenosis in one patient in their series of 42 patients, while 4 patients developed anal stenosis in Filingeri et al [22] study.

Wound healing in present study was significantly faster in LigaSure group patients than those in conventional group (11.6 days vs. 19.5 day). This means that return to the work and daily activity was faster in LigaSure group. Sayfan et al [4], Gentile et al [12], as well as Thorbeck and Montes et al [23] reported faster wound healing and short convalescent period after LigaSure hemorrhoidectomy while Chung et al [9] and Wang et al [21] showed no difference in healing time (6weeks) and time off work between LigaSure and conventional excisional techniques.

The follow up period of this study was 6 to 9 months. The complications which looked for during the follow up period were Incontinence, recurrence, and persistent pain or bleeding. Anal incontinence and recurrence of piles were not observed in any patient in both groups in our study. Same findings were observed in similar studies of Mostakove et al. [21] and Thorbeck et al [23]. Longer follow up period were recorded in similar studies. Palazzo et al [14], of 15 months and Jayne et al [15] of 36 months tracing the long-term complications. They found that although LigaSure hemorrhoidectomy resulted in earlier wound healing, it didn't affect the late complications such as incontinence and recurrence. Peters et al [24] found in their randomized clinical trial that LigaSure is effective as conventional hemorrhoidectomy for long-term symptoms control. They suggested that LigaSure technique is the preferred operation for patients with compromised internal sphincter such as multiparous women and elderly patients since less radical excision with LigaSure procedure is achieved. Muzi et al [25] demonstrated that LigaSure hemorrhoidectomy is simple, reducible, with reduced postoperative pain, fast wound healing, low complication rate and fast return to work. Xu et al [26] showed in their meta-analysis of randomized control trial that compared the LigaSure versus Ferguson hemorrhoidectomy that LigaSure hemorrhoidectomy is superior to Ferguson hemorrhoidectomy in the short term outcomes.

Patients satisfaction among patients was significantly higher in LigaSure group than in conventional hemorrhoidectomy since it results in less postoperative pain, faster wound healing and early return to work and daily activity, and postoperative complications are similar or even less than that of conventional hemorrhoidectomy including the recurrence rate and incontinence. Lawes et al [27] showed that patients

satisfaction and continence score one year postoperatively are comparable for LigaSure and open conventional hemorrhoidectomy

CONCLUSION

Compared with conventional excisional hemorrhoidectomy, LigaSure hemorrhoidectomy was superior and more advantageous in terms of short operative time, minimum or even no blood loss, less postoperative pain, low complications rate, faster wound healing and early return to work. It is simple, safe, easy to learn procedure. The surgical outcomes of LigaSure hemorrhoidectomy showed high patients satisfaction and low recurrence. LigaSure hemorrhoidectomy could be the gold standard procedure for all symptomatic piles to which other procedures are compared.

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