

Early and Late Surgical Outcomes after LigaSure and Conventional Diathermy Hemorrhoidectomy: A Comparative Randomized Study

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Background: Hemorrhoidectomy is a known painful operation associated with a delayed convalescence.

Aim: To report the early and late surgical outcomes after LigaSure and conventional diathermy hemorrhoidectomy.

Patients and methods: Seventy-Seven patients with grade III and IV hemorrhoids were randomized into two groups; Group (I) treated with LigaSure hemorrhoidectomy and group (II) treated with conventional diathermy hemorrhoidectomy. The operative time, hospital stay, postoperative pain, analgesia, time of wound healing, return to work, postoperative complications and patients' satisfactions were recorded in each group.

Results: The patients treated with LigaSure hemorrhoidectomy had significantly less mean operative time (12.19 versus 35.3 min), postoperative pain score (5.12 versus 6.11), analgesia (11.97 versus 13.8 tablets) and time to return work (10.35 versus 14.94 days) than the patients who underwent conventional diathermy hemorrhoidectomy.

Early postoperative complications were significantly less in the LigaSure group ($P = 0.001$), while late postoperative complications showed non-significant difference between both groups ($P > 0.05$). Patients' satisfactions were in favor of LigaSure group with significant statistical difference ($P = 0.026$).

Conclusion: LigaSure is a superior alternative to conventional diathermy in doing hemorrhoidectomy due to less post-operative pain and analgesia, fast wound healing, early return to work and lower postoperative complications. Moreover, it is a simple and short time technique easy to learn.

Keywords: Hemorrhoidectomy, LigaSure, conventional diathermy, randomization.

Introduction

Hemorrhoids are still considered common disease affecting about 5% of the general population. Excisional hemorrhoidectomy remains the treatment of choice for patients with grade III and IV disease.¹ It is effective in control of hemorrhoidal symptoms but is associated with delayed patient recovery due to postoperative pain, bleeding and prolonged time of wound healing.² Various techniques have been developed to overcome these problems including modifications of the original operation, perioperative use of diosmin (daflon) & metronidazole (flagyl), addition of lateral internal sphincterotomy or application of glyceryl trinitrate cream postoperative, but none of them is satisfactory.^{3,4} Different devices like LigaSure, harmonic scalpel, and circular stapler have been introduced in an attempt to reduce the postoperative pain, blood loss, permits fast wound healing and quicker return of patients to normal activities.^{5,6} LigaSure™ vessel sealing system is a bipolar electro thermal device that uses the high frequency current, combination of pressure and radiofrequency and active feedback control over

the power output to seal the blood vessels up to 7 mm in diameter with minimal thermal spread to the adjacent tissue (within 2 mm). It ensures complete coagulation of the vascular hemorrhoidal tissue and bloodless piles excision.^{7,8} This study was conducted to report the early and late surgical outcomes after LigaSure and conventional diathermy hemorrhoidectomy to determine the related advantages, disadvantages, postoperative complications and patients' satisfaction after each procedure.

Patients and methods

Seventy-seven patients with hemorrhoids met the inclusion criteria and were included in this study and recruited for analysis. Inclusion criteria included the patients with grade III or IV hemorrhoidal disease, fit for anesthesia and not having bleeding tendency or receiving anticoagulant therapy. Exclusion criteria were the patients with previous history of anorectal surgery or with associated anorectal lesions like anal fissure, perianal fistula or abscess, patients with thrombosed piles and the patients who had any sort incontinence.

The patients admitted at the general surgery department in Tanta University Hospital during the period from January 2013 to December 2016 were randomized blindly into two groups using closed envelopes allocation.

Group (I) was treated with LigaSure hemorrhoidectomy and Group (II) was treated with conventional diathermy hemorrhoidectomy. An informed consent was taken from each patient after explained and counseled for the type of surgical procedure and anesthesia. The preoperative and postoperative medications were standardized in all patients to avoid variations in the results. Before the operation, the patients received oral daflon and flagyl 500 mg t.d.s for 3 days, Lactulose 20 ml twice the day before operation and a cleansing enema and the patient fasted at the midnight of operation.

Procedures

Both operations were performed under general or spinal anesthesia with the patient in lithotomy position using the Eisenhammer retractor.

LigaSure hemorrhoidectomy

Adequate traction on the pile bundle or submucosal infiltration of saline was done to elevate it off the underlying anal sphincter, allowing safe application of the LigaSure forceps. The LigaSure forceps was applied across the hemorrhoidal tissue till coagulation. Completion of coagulation was known by a characteristic feedback signal. Cut along the middle of the line of the coagulum with a scissor was made. Multiple applications using the long and short jaw LigaSure forceps were done until complete excision of the pile cushion was achieved. The first application included the external component of the hemorrhoid with the skin tag, the other applications included the part overlying the internal sphincter and the last one included the pile pedicle 0.5 cm above the dentate line (**Figures. 1a,1b,1c**).



Fig 1a: LigaSure Apparatus

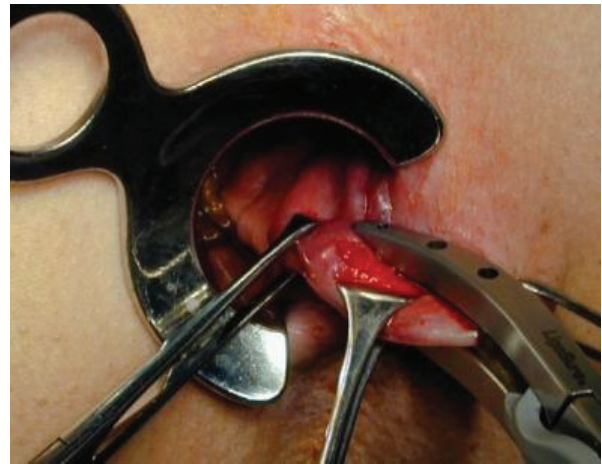


Fig 1b: Application of LigaSure forceps beneath the hemorrhoidal cushion



Fig 1c: Partial detachment of hemorrhoid after cutting through the sealed area.

Conventional diathermy hemorrhoidectomy

V-shaped incision in the perianal skin including the external component of pile cushion was made followed by submucosal dissection of the hemorrhoidal tissue from the internal sphincter till the pedicle using the conventional monopolar diathermy. Transfixion ligation of the pile pedicle was made 0.5 cm above the dentate line taking care to avoid incorporation of the underlying sphincter. The hemorrhoidal tissue was excised and the wound left open (**Figures. 2a,2b,2c**).



Fig 2a: V-Shaped incision in the perianal skin around the pile bundle after grasping it.



Fig 2b: Dissection of the hemorrhoidal cushion from the internal sphincter then transfixion ligation of its pedicle.

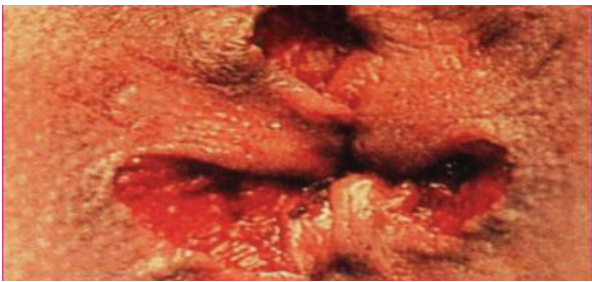


Fig 2c: Completion of conventional diathermy hemorrhoidectomy.

The excised specimens from both procedures were sent for histopathological examination to see the degree of tissue destruction, presence of internal sphincter fibers and extent of thermal injury. The operative time and intraoperative blood loss were recorded in every patient. After operation, every patient was asked to score his pain from 1 to 10 using the visual analogue scale (VAS) to assess his postoperative pain. The postoperative analgesia were standardized in the form of 75 mg diclofenac sodium IM as required and 50 mg diclofenac sodium tablets t.d.s. The pain scores and number of ampoules and tablets required by the patients during the postoperative course were recorded. The length of hospital stay, time of first bowel motion and occurrence of early postoperative complications were recorded in each patient. After discharge, the patients were reviewed weekly in the outpatient clinic for the first four weeks, then every 6 months for three years. The time of wound healing, patients' return to work and late postoperative complications were assessed.

At the end of the study, the patients were given questionnaire to assess their satisfaction with the outcome of the surgical procedure (fully satisfied, satisfied, disappointed or unsatisfied).

Statistical analysis

All data were analyzed using the Statistical Package for the Social Sciences Version 19 software (SPSS Inc., Chicago, IL). Continuous variables were analyzed using the student t-test, the results were expressed as mean±standard deviation. Chi-square two-sided Pearson χ^2 test or Fisher Exact test was used to compare the categorical variables between the two groups. P value less than 0.05 was considered statistically significant.

Results

This study was carried out on 77 patients with grade III (71.4%) and grade IV (28.6%) hemorrhoids, they were 53 males (68.8%) and 24 females (31.2%) and their age incidence ranged between 20 and 65 years (mean, 36.8). The patients were admitted and blindly randomized into 2 groups. Group I (LigaSure group) included 42 patients, 32 (76.2%) males and 10 (23.8%) females, their ages ranged between 20 and 65 years (mean, 36.76) and group II. (Conventional group) included 35 patients, 21 (60%) males and 14 (40%) females, their ages were between 23 and 62 years (mean, 37.74). Regarding the grades of hemorrhoids; 32 patients (76.2%) of group (I) had grade III hemorrhoids and 10 (23.8%) had grade IV, while in group (II), 23 patients (65.7%) had grade III hemorrhoids and 12 (34.3%) had grade IV. The hemorrhoidal bundles in both groups were of the commonest type (3 bundles) present in 24 patients (57.1%) of group (I) and in 19 patients (54.3%) of group (II). There were no significant statistical differences between both groups regarding the age, sex, grade of hemorrhoids and the number of affected hemorrhoidal bundles.

The main presenting symptoms in patients of group (I) were bleeding & protruded piles in 36 patients (85.7%), bleeding & pain in 2 patient (4.8%) and bleeding only in 4 patients (9.5%), while in group (II), bleeding & protruded piles were present in 21 patients (60%), bleeding & pain in 2 patients (5.7%) and bleeding only in 12 cases (34.3%) with no statistical difference between both groups ($p>0.05$). The mean operative time was significantly less in LigaSure group than that in the conventional group (12.19 versus 35.3 minutes). The mean intraoperative blood loss was also less in group I (4.59 ml) than in group II (9.28 ml). The mean postoperative pain VAS scores in the first and second postoperative days in LigaSure group were significantly less ($P<0.05$) than in the conventional group (5.12 versus 6.11 & 4 versus 4.86), while in the third

postoperative day, it was not significant between both groups (2.19 versus 2.71). The mean number of intramuscular analgesia needed by the patients in the first postoperative week was 4.86 ampoules in group I versus 5.49 in group II (significant) and the mean number of oral analgesia during all postoperative course was 11.97 tablets in group I versus 13.8 in group II (significant). The length of hospital stay was not significant between both groups (mean; 2.35 versus 2.63 days). The mean time needed by the patients to return to their work

was significantly in the LigaSure group less than that in the conventional group (10.35 versus 14.94 days) (**Table 1**).

Table 1: Shows the mean age, operative time, intraoperative blood loss, hospital stay, postoperative pain scores, analgesia and time to return work after LigaSure and conventional diathermy hemorrhoidectomy

Variable	LigaSure (n= 42)		Conventional (n= 35)		T- test	
	Mean ± SD	Range	Range	Mean ± SD	T	P- value
Age (years)	20-65	36.76 ± 9.9	23-62	37.74 ± 11.28	-0.356	0.723
Operative time (minutes)	7-20	12.19 ± 2.89	17-54	35.3 ± 9.53	-14.9	< 0.001*
Intraoperative blood loss (ml)	2-7	4.59 ± 1.62	4-19	9.28 ± 3.71	-7.387	< 0.001*
Hospital stay (days)	1-3	2.35 ± 0.62	2-4	2.63 ± 0.64	-1.88	0.064
1st day postoperative pain (VAS score)	4-8	5.12 ± 1.15	5-9	6.11 ± 1.2	-3.69	< 0.001*
2nd day postoperative pain (VAS score)	2-8	4 ± 1.9	3-7	4.86 ± 1.21	-2.292	0.025*
3rd day postoperative pain (VAS score)	1-5	2.19 ± 1.09	1-5	2.71 ± 1.58	-1.715	0.091
P.O Parenteral analgesia (ampoules)	3-7	4.86 ± 1.16	5-9	5.49 ± 0.95	-2.56	0.012*
P.O oral analgesia (tablets)	8-17	11.97 ± 2.37	9-20	13.8 ± 2.93	-3.019	0.003*
Return to work (days)	7-15	10.35 ± 2.28	10-28	14.94 ± 5.38	-5.014	< 0.001*

*Mean P Significant

The time of first bowel motion was earlier in the patients of group I (28 patients (66.7%) in day 1, 10 (23.8%) in day 2 and 4 (9.5%) in day 3) than in patients of group II (20 patients (57.1%) in day 1, 14 (40%) in day 2 and 1 (2.9%) in day 3) but with no significant difference. In the early postoperative period, there was significant difference between both groups regarding the early postoperative complications (P < 0.05). Spotting of blood occurred in 2 patient (4.76%) of LigaSure group, while in the conventional group, 3 patients (8.57%) developed reactive bleeding stopped with the conservative treatment in two patients

and required hospital admission and hemostatic stitches in the third patient. Persistent anal pain was observed in one patient (2.38%) of group (I) and in 3 patients (8.57%) of group (II). Postoperative urine retention didn't occur in patients of group (I), however, occurred in 4 patients (11.43%) of group (II), two of them required catheterization. Transient partial incontinence (to flatus and fluids) was observed in 3 patients (8.57%) of the conventional group, while in LigaSure group, none of the patients developed incontinence. (**Table 2**).

Table 2: Shows the early postoperative complications after LigaSure and conventional diathermy hemorrhoidectomy

Early Postoperative complications	Ligature n=42		Conventional n=35	
	N	%	N	%
Bleeding	2	4.76	3	8.57
Persistent anal pain	1	2.38	3	8.57
Urinary retention	0	0	4	11.43
Partial Incontinence	0	0	3	8.57
Chi-Square	X2		10.438	
	P-value		0.001*	

*Mean P Significant

In the late follow up period, there was no significant difference between both groups regarding the late postoperative complications. Anal stenosis occurred in one patient (2.38%) of group (I) and in one (2.86%) of group (II), both patients responded successfully to repeated anal dilatations. A skin tag was observed in one patient

(2.86%) of group (II) due to development of anal fissure. The partial incontinence observed early in our study in 3 patients of the conventional group improved and no patient of both groups complained of incontinence at the end of the follow up period (**Table 3**).

Table 3: Shows the late postoperative complications after LigaSure and conventional diathermy hemorrhoidectomy

Late Postoperative complications	Ligature n=42		Conventional n=35	
	N	%	N	%
Stenosis	1	2.386	1	2.86
Skin Tags	0	0	1	2.86
Incontinence	0	0	0	0
Recurrence	0	0	0	0
Fisher's Exact Test	Two-tailed	P= 0.5880		
	One-tailed	P= 0.4311		

*Mean P Significant

Histopathological examination of excised specimens showed only remnants of superficial fibers of internal sphincter in 15 cases (35.7%) of group I and 12 cases (34.3%) of group II with no sphincter damage in both groups. Complete wound healing was observed in 85.7% of patients of group (I) at 4 weeks, reached to 100% at 5 weeks with no anal fissure or skin tags (good cosmetic results of the anal verge), while in group II, 62.9% of patients showed healed operation site at 5 weeks and reached to 100% at 7 weeks.

Regarding the patients' satisfactions, 26.2% of patients of LigaSure group were fully satisfied with the outcome of the surgical procedure, 61.9% satisfied and 11.9% disappointed or unsatisfied, while in the conventional group, 14.3% of patients were fully satisfied, 45.7% satisfied and 40% disappointed or unsatisfied from delayed wound healing, persistent anal pain, postoperative complications and prolonged time to return to their normal activities indicating significant difference ($P=0.026$) in favor of the LigaSure group (**Table 4**).

Table 4: Shows the patients' satisfaction after LigaSure and conventional diathermy Hemorrhoidectomy

Patient's satisfaction	Ligature n=42		Conventional n=35	
	N	%	N	%
Fully satisfied	11	26.2	5	14.3
Satisfied	26	61.9	16	45.7
Disappointed	2	4.8	5	14.3
Unsatisfied	3	7.1	9	25.7
Total	42	100	35	100
Chi-Square	X2	9.245		
	P-value	0.026*		

*Mean P Significant

Discussion

Although excisional hemorrhoidectomy remains the mainstay operation for advanced and complicated hemorrhoids, several minimally invasive operations, including LigaSure, harmonic scalpel, stapled hemorrhoidectomy and doppler-guided hemorrhoidal artery ligation, have been introduced into surgical practices in order to avoid the post-hemorrhoidectomy pain.⁹

Postoperative pain after conventional hemorrhoidectomy continues to be a major problem. It is supposed to be due to excessive tissue trauma involving the sensitive perianal skin and anoderm, thermal injury of electrocoagulation and from presence of transfixing sutures. It is also believed to be due to painful spasm of the internal anal sphincter after operation which causes increase in the resting anal pressure and propagation of anal pain.¹⁰ Another reason is that the manipulation of mucosa distal to the dentate line activates the stretch and somatic pain receptors. A controversial belief is, pain may be due to epithelial exposure from delayed wound healing.¹¹ Research over the last two decades, was mainly directed towards modification of the surgical techniques and use of variety of surgical devices in hope to decrease the post-operative pain and delayed patients' convalescence after conventional hemorrhoidectomy.^{2,12}

Our study showed several advantages of LigaSure over conventional diathermy. It achieved bloodless dissection of the vascular hemorrhoidal tissues with minimal thermal spread leading to less tissue injury, less anal sphincter spasm and consequently less postoperative pain. It also accelerates wound healing and patients' return to work. Moreover, the technique is simple, easy to learn and rapid to apply reducing the operation time. In agreement with our study, several randomized trials comparing LigaSure with other techniques of hemorrhoidectomy showed improved surgical outcomes after LigaSure due to limited thermal extension.^{7,13,14} Wang stated that, the significant lower postoperative pain score after LigaSure hemorrhoidectomy could be attributed to the fact that LigaSure seals the hemorrhoidal tissue without dissection and the minimal thermal injury reduces the tissue sticking and charring.¹⁵ On the other side, many experimental studies showed poorer hemostasis and perforation of the neighboring tissues from the side thermal injury after conventional monopolar electrocoagulation.^{16,17} Although harmonic scalpel hemorrhoidectomy, stapled hemorrhoidopexy and trans-hemorrhoidal de-arterialization have the advantages of pain-free, short hospital stay and faster return to social activities as LigaSure hemorrhoidectomy but, the first has a higher cost and requires a longer

operation time,^{18,19} the second is associated with serious complications, including pelvic sepsis, stenosis of anastomosis, recto-vaginal fistula, high recurrence rate and failure to deal with external component of hemorrhoid and skin tags resulting in unsatisfactory cosmetic results,²⁰⁻²² and the third technique is associated with higher recurrence rates than open, closed and vessel seal hemorrhoidectomies.²³ Kraemer and co-workers observed a slightly favorable trend for LigaSure in terms of postoperative complications, ease of handling, and outcome for patients with fourth-degree pile than stapled hemorrhoidopexy.²⁰

The significant lower intraoperative blood loss could be explained by the effective hemostatic control of LigaSure device and the reduced operation time could be related to a bloodless operative field that does not require time to secure hemostasis and to the lack of any need to ligate the pile pedicles.^{7,24} Transfixion ligation of the vascular pile pedicle in conventional hemorrhoidectomy to avoid postoperative bleeding, on the contrary, may lead to development of pedicle ischemia, necrosis and secondary infection & bleeding. It also incorporates the sphincter muscle causing acute postoperative pain. Furthermore, the bulk of incorporated sphincter might play a role in impairment of fecal continence, moreover, chronic mucosal ulceration, scarring and stricture or stenosis in the late follow up period.⁸

Intraoperative sphincter stretching, incorporation of the underlying muscle sphincter in the transfixing sutures, removal of the sensory bearing anal canal mucosa and the prolonged postoperative inflammatory healing process during conventional hemorrhoidectomy may play a role in postoperative continence impairment, which are not present with the LigaSure system.^{24,25} Although the blades of LigaSure forceps are applied blindly on the hemorrhoidal tissue, an adequate traction on the pile bundle or sub mucosal infiltration of saline make the hemorrhoidal plexuses to be readily elevated off the underlying anal sphincter, allowing safe application of LigaSure forceps without incorporation of the internal sphincter. Absence of cases of incontinence in the current study in the early and late follow up periods after LigaSure hemorrhoidectomy suggests that it is a safe procedure not affecting the sphincter function and absence of internal anal sphincter remnants on histological examination, proves that this is always superficial in nature.¹³ LigaSure system preserves the thickness of internal anal sphincter and consequently the anal canal pressures; this feature makes it the preferred modality in patients with prolapsing piles in whom sphincter function has been compromised by previous anal surgery or obstetric trauma.²⁵ LigaSure can cause anal

stenosis from thermal or electrical injury of skin bridges like the case recorded early in our study. To avoid that, the perianal skin should be retracted away from the bipolar blades of LigaSure forceps, thereby avoiding contact and stenosis.⁸

The small sized wound and reduced anal spasm and pressure associated with LigaSure increase the anodermal blood flow and contribute to a significantly faster wound healing. Good wound healing is essential to prevent perianal irritation, discharge, pain, and secondary infection & bleeding.¹¹ Higher levels of patient satisfaction after LigaSure hemorrhoidectomy could be related to less postoperative pain, fast wound healing, early return to work and normal activities and lower postoperative complications, compared with the conventional diathermy hemorrhoidectomy.^{24,26} Along the follow up period of our study, no case of pile recurrence occurred in both groups, however, in Muzi study, one case of recurrence was detected in each group (0.8%) during the mid-term follow-up period.²⁷ LigaSure may add cost to the surgical procedure but, the short operative time, hospital stay, days-off work and lower postoperative complications still make it a cost-effective procedure.^{13,28}

Conclusion

We can conclude that, LigaSure is a superior alternative to conventional diathermy in doing hemorrhoidectomy due to less postoperative pain and analgesia, fast wound healing, early return to work and normal activities and lower postoperative complications.

Moreover, it is a simple and short time technique easy to learn. The feared late postoperative complications of fecal continence and anal stenosis can be avoided, if LigaSure blades are applied correctly on the pile cushions.

Conflict of interest

The author has nothing to declare.

Source of Support

Nil

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