



Ligasure™ Hemorrhoidectomy versus Conventional Hemorrhoidectomy: Comparison in Outcome

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Abstract

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BACKGROUND: Hemorrhoids are a common problem faced in the surgical practice that cause a variety of symptoms ranging from bleeding per rectum to prolapsed, non-reducible and painful anal masses. Therefore, hemorrhoidectomy is one of most frequently performed surgical procedures worldwide.

AIM: In this study, we will compare between the conventional surgical method and between LigaSure™ hemorrhoidectomy.

PATIENTS AND METHODS: All 120 patients underwent hemorrhoidectomy by conventional and LigaSure™ method between September 2015 and September 2018 in Al-Kafeel hospital in Karbala city in Iraq. All cases underwent surgery by the three authors under regional anesthesia or general anesthesia by anesthetic team. A thorough history taking and physical examination were done and an informed consent has been taken from each patient before the surgery. Conventional hemorrhoidectomy was done for 50 patients randomly selected. The operation was done in the open method (Milligan Morgan's). LigaSure™ hemorrhoidectomy was done for 70 patients randomly selected as well. Quantification of intra-operative bleeding was done by counting the number of gauzes. Patients were evaluated 5 days and a month and 3 months after the operation for complications and improvement of symptoms. The data were analyzed using Statistical Package for Social Sciences version 22.0.

RESULTS: There were significant differences regarding the operation time, number of gauzes soaked with blood, hospital stay, pain score, post-operative bleeding, wound infection, residual mass, fecal incontinence and anal stenosis in favor of the LigaSure™ method. There was no significant difference regarding urine retention and post-operative discharge between the two methods.

CONCLUSION: LigaSure™ hemorrhoidectomy can be a good alternative to conventional methods to reduce pain and make a more rapid recovery after hemorrhoidal surgery.

Introduction

Hemorrhoids are cushions of submucosal vascular tissue located in the anal canal starting just distal to the dentate line. Hemorrhoidal disease is a common anorectal disorder which has symptoms of bleeding, prolapse, pain, thrombosis, mucus discharge, and pruritus. Hemorrhoidectomy is one of most frequently performed anorectal operations worldwide.

Formal hemorrhoidectomy can be done surgically by Milligan - Morgan's method (Open method) or Ferguson's method (Closed method) [1]. Both methods were associated with significant pain and bleeding postoperatively and late return to work and daily activities. But still, Milligan Morgan's technique is regarded as the gold standard in the treatment of third and fourth degree hemorrhoids [2].

The open Milligan - Morgan technique was first introduced by Salmon in 1830, then popularized by Milligan Morgan in 1937 [3]. It is an open surgical technique through which the hemorrhoidal mass

is excised and the pedicle is controlled with Vicryl suture and the wound left open to heal by secondary intention [4]. Milligan – Morgan's technique is advocated in the United Kingdom while Ferguson's technique is most commonly used in the U.S [5].

Ferguson's closed method was described by Ferguson in 1931 [3]. It employs excising the hemorrhoidal mass and securing the pedicle with suture material and the wounds closed by continuous suturing. Its advantage is less scarring of the anal area [3]. we

Transanal hemorrhoidal dearterialization was described by Morigana *et al.* in 1995 [3]. It uses a special kit and localizes the branches of the hemorrhoidal arteries by a Doppler device. Relevant branches are ligated with Vicryl suture and a mucopexy is done for the redundant anal mucosa. This procedure is less painful but with a recurrence rate as high as 22%.

Stapling devices were introduced in 1998 by Longo [3]. The principle of using such devices is to remove a doughnut of prolapsed anal mucosa. It is associated with less pain and more rapid recovery.

LigaSure™ (Covidien USA) and Harmonic ultrasonic blades (Ethicon, USA) were invented in the beginning of this century. The use of Ligasure™ to treat hemorrhoids was first proposed by Sayfan in 2001 [3].

Harmonic Scalpels use very high frequency ultrasound waves to generate energy in the tissue impacted between the blades. This will lead to coagulation and eventually cutting of the tissue with absolute hemostasis and minimal collateral damage [6].

The LigaSure™ is a vessel-sealing system that allows complete coagulation of blood vessels with minimal damage to the surroundings. This advantage has been extended to the excision of hemorrhoids as it provides vessel sealing with as little damage as possible in a small area such as the anus.

Aim of the Study

1. Comparison of conventional surgical hemorrhoidectomy and LigaSure™ hemorrhoidectomy in terms of hospital stay, intra-operative blood loss and post-operative complications
2. Evaluation of healing times for both methods.

Patients and Methods

About 120 patients were selected in this study and assigned for the conventional group or the LigaSure™ group randomly (50 patients were submitted for conventional surgery and 70 patients for LigaSure™ surgery). Patients selected were admitted to Al-Kafeel hospital in Karbala city at the period from September 2015 to the end of August 2018. Patients were admitted to the hospital in the same day of the surgery. At time of admission, full data were taken from the patient according to the data sheet (questionnaire) which included: (name, age, gender, symptoms, previous anal surgery, previous and current medication history and past medical history). Each patient has been prepared by giving him rectal enema at the night of operation. All patients were given a single dose of ceftriaxone 1000 mg at induction of anesthesia. Follow-up of the cases was undertaken by visits scheduled 5 days, 1 month and 3 months' post-surgery to seek the outcome of the procedures.

Inclusion criteria

1. Patients with symptomatic hemorrhoids
2. Patients with second degree hemorrhoids who had not responded to conservative treatment
3. Third and fourth degree hemorrhoids (Table 1).

Exclusion criteria

1. Patients with bleeding disorders
2. Presence of other rectal pathology (tumors, rectal prolapse)
3. Patients with recurrent hemorrhoids after previous hemorrhoidectomy.

The procedures used in this study are:

1. Open hemorrhoidectomy or also known as conventional hemorrhoidectomy (CH)
2. LigaSure™ hemorrhoidectomy.

First there are few similar steps between these procedures like:

1. After spinal or general anesthesia, patient prepared in lithotomy position with slight reversed Trendelenburg position
2. Standard application of skin disinfectant and draping
3. PDRE while patient sedated
4. Delivery of hemorrhoid with artery forceps, one being applied at the pedicle of hemorrhoid and, the other at the mucocutaneous junction
5. Incision at the mucocutaneous junction of hemorrhoids and submucosal dissection to lift the hemorrhoid mass off the internal sphincter.

The practiced techniques are:

1. Open hemorrhoidectomy (CH): Pedicles of the hemorrhoids were identified and controlled by hemostats. a V shaped incision was done at the mucocutaneous border of each pedicle. Hemorrhoidal masses were isolated and ligated with 2/0 Vicryl suture. The remaining bed was left open. A Lidocaine 5% impregnated wick was put after securing hemostasis in the anal area. Packing was done
2. LigaSure™ hemorrhoidectomy: This device works by using a very high frequency current which cause hemostasis by denaturing collagen and elastin from the vessels wall and surrounding connective tissues. The jaws of the LigaSure™ device were applied to the hemorrhoidal mass and pedicle. Care is exercised during this step not to include the internal sphincter within the application of the jaws. Energy is applied through activating the electrosurgical unit. After complete isolation of the pedicle, the device cuts the pedicle and the hemorrhoid excised. A Lidocaine 5% impregnated gel foam was put after securing hemostasis in the anal area.

Table 1: Classification of hemorrhoids [1]

I	Bleeding hemorrhoids without prolapse
II	Prolapsing hemorrhoids that reduce spontaneously
III	Prolapsing hemorrhoids that need manual reduction
IV	Irreducible complicated hemorrhoids

All patients were discharged after passing urine, regaining full awareness, completing their medication and were pain free. All patients were given analgesia according to their needs. After discharge, they were instructed on warm sitz bath, high fiber diet, regular walking and maintenance of hygiene. All patients were given bulk forming laxatives and analgesics prescribed only on need. Topical application of proprietary ointments was also prescribed.

Patients were evaluated 5 days and a month after operation. All of them were asked about the following symptoms: pain, bleeding, discharge, change in bowel habit and incontinence. Examination of the anal area was done only by inspection to exclude wound infection. Pain score was assessed using visual analogue scoring system.

The data were analyzed using Statistical Package for Social Sciences version 22.0. The descriptive data were calculated by mean, standard deviation and percentage. The groups were compared by independent sample t-test and Chi-square. The degree of association between variables was calculated by pearson's and spearman's correlation coefficient. The results were considered statistically significant when $p < 0.05$.

Results

Classification of the study groups

About 120 patients complaining from hemorrhoids were enrolled in the present study, all patients then divided into 2 groups according to the type of hemorrhoidectomy:

1. 50 patients were treated by conventional method of hemorrhoidectomy
2. 70 patients were treated by LigaSure™ method of hemorrhoidectomy.

Table 2: Demographic data of the study groups

Parameter	Conventional group n = 50	LigaSure™ group n = 70	p-value
Age (years) (Mean ± SD)	41.68 ± 12.01	39.56 ± 13.15	0.368
Gender			
Female (%)	24 (48)	22 (31)	0.066
Male (%)	26 (52)	48 (69)	
Hemorrhoids no. (Mean ± SD)	3.46 ± 1.4	3.49 ± 1.3	0.918
Hemorrhoids degree (%)			
2 nd	5 (10)	8 (11)	0.763
3 rd	41 (82)	59 (84)	
4 th	4 (8)	3 (5)	

Demographic features of the study groups

There were no significant differences between conventional and ligasure hemorrhoidectomy groups regarding the age ($p = 0.368$), gender ($p = 0.066$), hemorrhoids numbers ($p = 0.918$), and hemorrhoids degree ($p = 0.763$) as demonstrated in (Table 2) and (Figures 1 and 2).

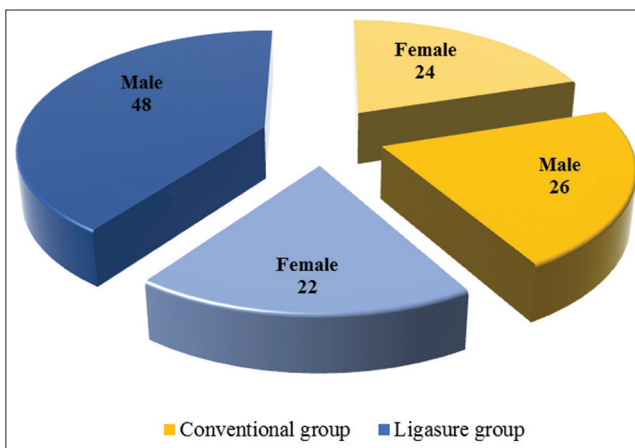


Figure 1: Gender distribution of the study groups

Pre-operative presentations of conventional and LigaSure™ groups

The pre-operative presentations of patients in conventional and LigaSure™ groups including bleeding, pain, mass, limb pain, anemia and constipation were demonstrated in (Table 3) and (Figure 3) as percentage of total patients.

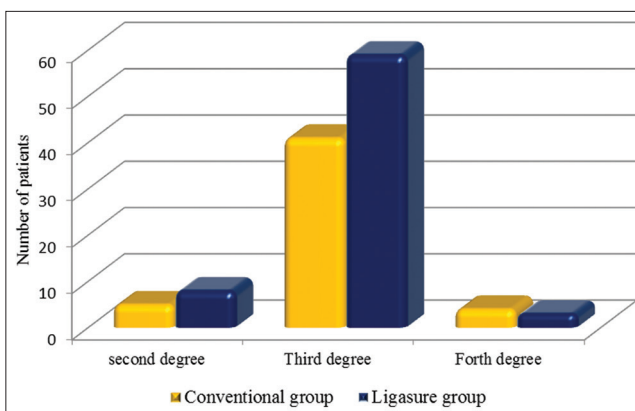


Figure 2: Hemorrhoids degree frequencies of the study groups

Comparison of operative notes and post-operative complications between conventional and LigaSure™ groups

Table 4 and Figure 4 demonstrate the comparison of operative notes and post-operative complications between conventional and LigaSure™ groups, according to the results there were significant differences regarding the operation time, number of gauzes, hospital stay, pain score, post-operative bleeding, constipation, wound infection, residual mass, fecal incontinence, anal stenosis, use of local treatment and the duration of local treatment ($p < 0.05$) in favor of the LigaSure™ technique group.

Table 3: Clinical presentation of the study groups

Parameter	Conventional group (%)	LigaSure™ group (%)
Anal pain	33 (27.5)	43 (35.8)
Bleeding per rectum	23 (19.2)	23 (19.2)
Perianal swelling	47 (39.2)	66 (55)

Table 4: Comparison of operative notes and post-operative complications

Parameter	Conventional group n = 50	LigaSure™ group n = 70	p-value
Type of anesthesia (%)			
General	23 (46)	28 (40)	0.512
Spinal	27 (54)	42 (60)	
No. of gauzes (Mean ± SD)	3.46 ± 1.4	1.04 ± 0.32	<0.001*
Operation time (minutes) (Mean ± SD)	28.1 ± 11.72	18.69 ± 4.76	<0.001*
Hospital stay (hours) (Mean ± SD)	22.44 ± 8.81	18.93 ± 7.05	0.017*
Pain score (Mean ± SD)	5.28 ± 1.92	4.1 ± 1.97	0.001*
Post-operative bleeding (%)	19 (38)	15 (21.4)	0.047*
Post-operative discharge (l)	11 (22)	27 (38.6)	0.054
Urine retention (%)	0	3 (4.3)	0.265
Wound infection (%)	5 (10)	1 (1.4)	0.048*
Residual mass (%)	10 (20)	4 (5.7)	0.036*
Fecal incontinence (%)	5 (10)	1 (1.4)	0.034*
Anal stenosis (%)	8 (16)	3 (4.3)	0.028*
Use of local treatment (%)	44 (88)	51 (72)	0.044*
Wound healing time (days) (Mean ± SD)	29.2 ± 7.3	26.5 ± 5.8	0.049*

SD: Standard deviation; n: Number of patients; *p < 0.05 (significant).

Comparison of operative and post-operative parameters between male and female in the study groups

Comparison of operative and post-operative parameters between male and female were demonstrated in

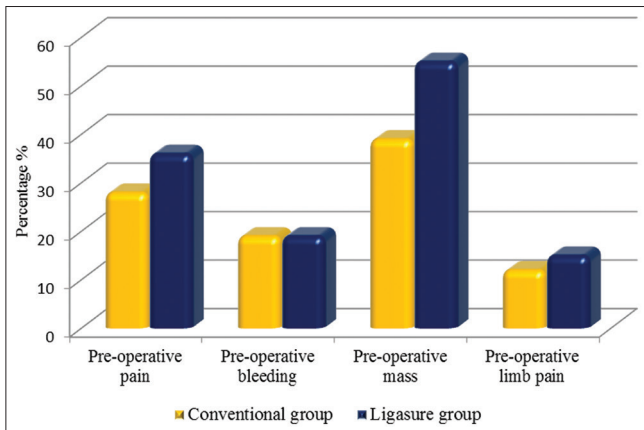


Figure 3: Pre-operative presentations of the study groups

(Table 5 and Figures 5 and 6). According to the results, in the conventional group there was higher levels in female with significant

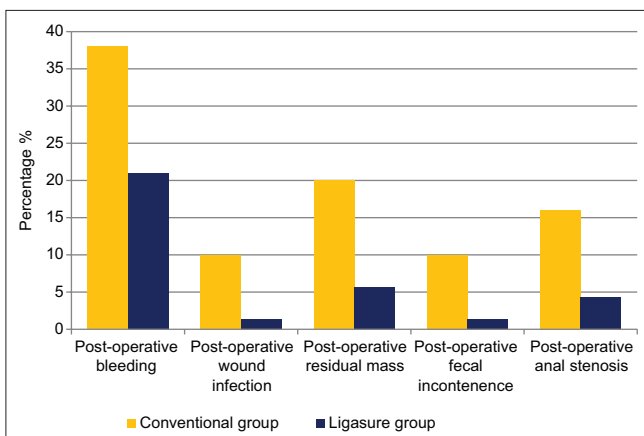


Figure 4: Comparison of post-operative complications of the study groups

Table 5: Comparison of operative and post-operative parameters between male and female in the study groups

Conventional group	Male	Female	p-value
Hemorrhoids number	4.12 ± 1.3	2.75 ± 1.15	<0.001*
Number of gauzes	2.15 ± 0.78	5.04 ± 1.81	<0.001*
Operation time (minutes)	22.69 ± 4.23	33.95 ± 14.29	<0.001*
Pain score	4.5 ± 1.75	6.13 ± 1.75	0.002*
Healing time (days)	26.75 ± 6.34	31.25 ± 0.76	0.041*
LigaSure™ group	Male	Female	p-value
Hemorrhoids number	3.83 ± 1.14	2.73 ± 1.35	0.001*
Number of gauzes	1.04 ± 0.36	1.05 ± 0.21	0.963
Operation time (minutes)	19.5 ± 4.74	16.91 ± 4.39	0.033*
Pain score	4.06 ± 1.91	4.19 ± 2.16	0.806
Healing time (days)	26.62 ± 5.87	26.2 ± 5.81	0.819

*p < 0.05 (significant)

difference in number of gauzes (p < 0.001), operation time (p < 0.001), pain score (p = 0.002), and duration of local treatment (p = 0.041), there was also lower significant number of hemorrhoids (p < 0.001).

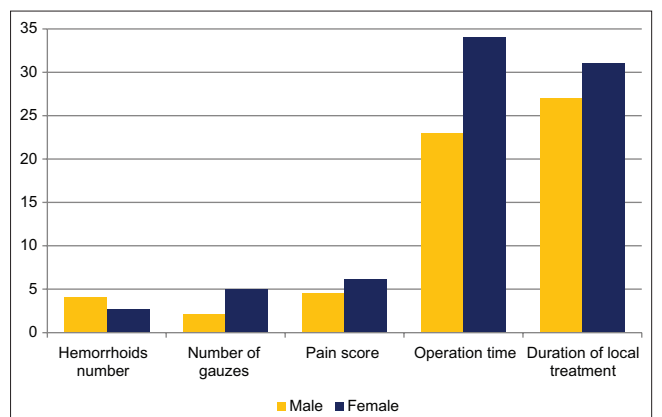


Figure 5: Comparison of operative and positive operative data between male and female in the conventional group

In LigaSure™ group there were significant difference between male and female regarding the number of gauzes (p = 0.001) and operation time (p = 0.033), there was no significant difference regarding the other parameters.

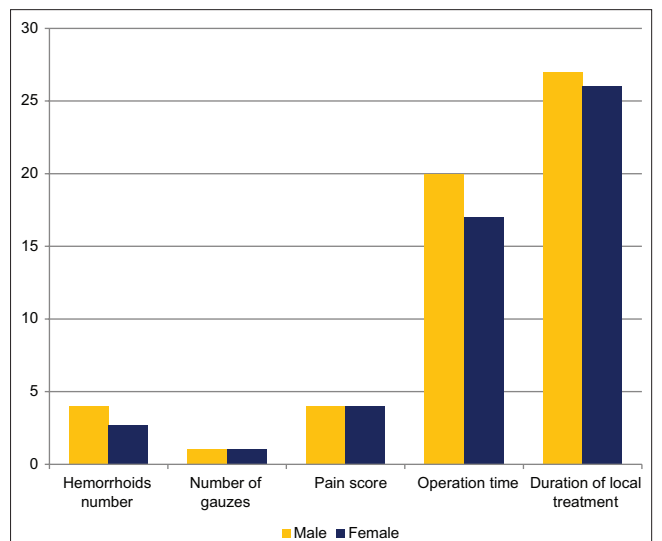


Figure 6: Comparison of operative and positive operative data between male and female in the LigaSure™ group

Table 6: Correlations between patient's age, operation time, pain score and hemorrhoids degree in all patients enrolled in the study

Parameters	Age (years)	Operation time (minutes)	Pain score	Hemorrhoids degree
Age (years)				
Correlation coefficient (r)	1	-0.061	-0.002	0.096
p-value		0.507	0.986	0.295
Operation time (minutes)				
Correlation coefficient (r)	-0.061	1	0.320	0.088
p-value	0.507		<0.001*	0.342
Pain score				
Correlation coefficient (r)	-0.002	0.320	1	-0.025
p-value	0.986	<0.001*		0.787
Hemorrhoids degree				
Correlation coefficient (r)	0.096	0.088	-0.025	1
p-value	0.295	0.342	0.787	

Correlations between patient's age, operation time, pain score and hemorrhoids degree in all patients enrolled in the study groups

Table 6 and Figure 7 demonstrate the correlations between patient's age, hemorrhoids degree, operation time and pain score and the results showed a positive significant correlation between operation time and pain score ($r = 0.320$, $p < 0.001$). There were no other correlations between these parameters.

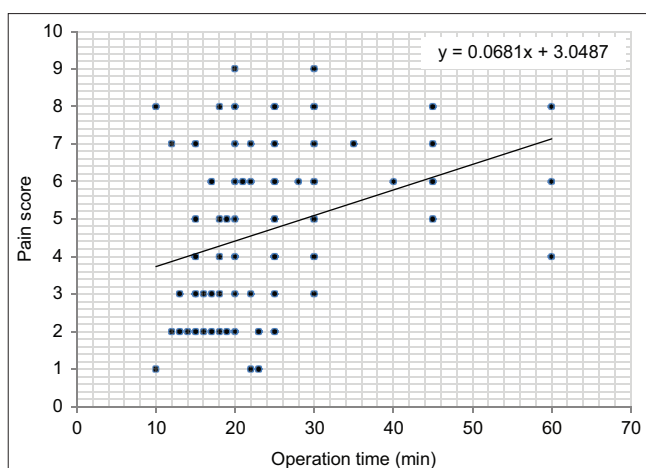


Figure 7: Correlation between operation time and pain score in all patients enrolled in the study

Discussion

The gold standard in the surgical treatment of hemorrhoids is open hemorrhoidectomy with its two types: Milligan Morgan's hemorrhoidectomy (Open) and Ferguson's hemorrhoidectomy (closed). However, both procedures are associated with significant blood loss and post-operative pain and various other complications.

The advent of LigaSure™ technique to this procedure had reduced the frequency of intra- and post-operative complications and led to significantly reduced healing times, shorter hospital stays and more hastily recovery.

Haksal *et al.* (8) reported a mean operative time of 15 min in the LigaSure™ group in comparison

with 20 min in the open group. Intra-operative blood loss had been reduced significantly in a study done by Noori in Iraq [7]. (20–50 ml in the excisional group in comparison with only 0–5 ml in the LigaSure™ group) comparable to our study. He also reported significant reduction of operative time (23.6 min in the conventional group vs. 16.4 min in the LigaSure™ group) [7]. Hospital stay was reduced when using LigaSure™ device during hemorrhoidectomy in a study done by Khanna *et al.* LigaSure™ use during hemorrhoidectomy is associated with lower post-operative pain scores which makes it more superior in terms of patient's tolerance. This effect can be attributed to the sutureless nature of the technique and the minimal collateral damage that it may exert.

A comparison between our study and other studies in terms of early post-operative complications that occurred in both LigaSure™ groups and conventional groups can be summarized in (Table 7).

Table 7: Comparison of rates of early post-operative complications reported in other studies between LigaSure™ hemorrhoidectomy (LH) and CH

Study	Post-operative bleeding (%)	Wound infection (%)	Urinary retention (%)
Our study	LH 21.4 CH 38	LH 1.4 CH 10	LH 4.3 CH 0
Noori	LH 0 CH 4.2	LH 0 CH 6.25	LH 2 CH 6.25
Haksal <i>et al.</i> (8)	LH 4.7 CH 12.9	LH 0 CH 0.5	-
Khanna <i>et al.</i> (1)	LH 3.5 CH 10	LH 14 CH 4	LH 3.5 CH 10

CH: Conventional hemorrhoidectomy.

In our study, it has been observed that 38.6% of the patients subjected to LigaSure™ hemorrhoidectomy were found to have a post-operative serous discharge from their wounds in comparison with 22% in the conventional group. No other study had indicated this finding.

Late post-operative complications were observed in our study to be significantly reduced in the LigaSure™ group, and it is comparable to the findings of other studies as it is shown in (Table 8).

Table 8: Comparison of late post-operative complications rates in other studies comparing LigaSure™ hemorrhoidectomy (LH) with CH

Study	Residual disease (%)	Anal stenosis (%)	Incontinence (%)
Our study	LH 5.7 CH 20	LH 4.3 CH 16	LH 1.4 CH 10
Noori	LH 0 CH 0	LH 6.25 CH 8.3	LH 0 CH 1
Haksal <i>et al.</i> (8)	LH 3.43 CH 5.4	LH 2.7 CH 0.5	LH 5 CH 3.8
Khanna <i>et al.</i> (1)	LH 3.5 CH 5	LH 0 CH 0	LH 0 CH 0

CH: Conventional hemorrhoidectomy.

LigaSure™ hemorrhoidectomy has found to reduce early post-operative pain scores significantly

in our study (4.1 ± 1.97 – LigaSure™ vs. 5.28 ± 1.92 Conventional). Haksal *et al.* compared the need for post-operative analgesia. He found that post-operative analgesics were required in (88.3%) of cases in the conventional group and in (67.3%) of cases in the LigaSure™ group.

Wound healing also was reported to be faster in those patients subjected to hemorrhoidectomy with LigaSure™ device in comparison with those subjected to conventional procedure. Noori reported mean healing time for the LigaSure™ group to be of 11.6 days versus 19.5 days in the conventional group [7]. In our study, Healing was a little bit faster in the LigaSure™ group (mean =26.5 days vs. 29.2 days).

Conclusion

LigaSure™ hemorrhoidectomy can be a good alternative to conventional methods to reduce pain and other post-operative complications after hemorrhoidal surgery. Technically LigaSure™ hemorrhoidectomy is much simpler and of lower operative time because suturing is not required and hemostasis is easy to achieve.

AQ3 References

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