



Research Paper

A Comparative Study between Ligasure Hemorrhoidectomy and Conventional Hemorrhoidectomy

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Abstract

Aims And Objectives: The aim of the study was to compare the results of Ligasure hemorrhoidectomy and conventional haemorrhoidectomy in terms of Operating time and Blood loss, Post operative pain, Post operative complications, Hospital stay and Time to return to work.

Methods: The study population consisted of 60 patients who were admitted with Grade III or Grade IV Hemorrhoids. Patients were submitted to one of the surgical procedures mentioned above after randomising. The time for each surgical procedure, the per operative bleeding and Post-operative pain using visual analogue scale, time for defecation after operation and pain and bleeding associated with it were assessed. Early post-operative complications, patients length of hospital stay and time to return to work were compared. A follow up examination was conducted for minimum period of 6 months.

Results: The duration of surgery (25.50 ± 9.50 min versus 41.67 ± 4.97 , P value < 0.001), per-operative bleeding (17.50 ± 6.66 ml versus 27.17 ± 2.52 ml, P value: < 0.001), duration of stay in hospital (6.20 ± 1.37 versus 10.40 ± 1.52 days, P value: < 0.001) was (statistic) significantly less with Ligasure Hemorrhoidectomy when compared to conventional Hemorrhoidectomy. Also Post operative pain and time taken to return to normal activity was almost similar in both methods. One patient in Ligasure Hemorrhoidectomy developed Anal stenosis and needed operative intervention.

Conclusion: Ligasure Hemorrhoidectomy is a sutureless, safe and effective procedure for haemorrhoids when compared with conventional variety and is a simpler technique and has the ability to make Hemorrhoidectomy a day care procedure.

Keywords: Hemorrhoids, Ligasure Hemorrhoidectomy, Conventional Hemorrhoidectomy.

Introduction

Hemorrhoids are one of the most common anorectal disorders. HEMORRHOIDS term is derived from the Greek adjective meaning bleeding (haema=bleed, rhoos=flowing) and emphasises the most important symptom of this disease. The word PILE derived from Latin word "pila" meaning ball can be applied to all patients presenting with this disease as every patient with

this disease present with some sort of swelling. John goligher says "atleast 50% of the people over the age of fifty have some degree of haemorrhoid formation". Hemorrhoids are of 2 types: external and internal, which are classified anatomically based on their location relative to dentate line. Internal Hemorrhoids are further graded into four grades.

Conventional haemorrhoidectomy is the most commonly practiced surgical procedure and is considered the gold standard in the treatment of piles, but conventional excision is a notoriously painful operation. Most patients have pain on defecation and discomfort at rest in the second and third weeks after surgery from wound infection and sphincter spasm. The conventional haemorrhoidectomy includes open method (Milligan – Morgan) and closed method (Fansler, Ferguson).

Ligasure vessel sealing system is a recently introduced method (Valleylab, Boulder, CO, USA) and consists of a bipolar electro-thermal device which offers an optimized combination of pressure and radiofrequency, sealing blood vessels upto 7mm in diameter and limits the thermal spread within 0.5 to 2mm of the adjacent tissue. Only a few studies have been published and they have shown that ligasure haemorrhoidectomy is superior to conventional haemorrhoidectomy with reduced operative time, bleeding, post operative pain and duration of stay in the hospital.

Materials and Methods

The study was conducted at KIMS hospital, Bangalore. This prospective study included a total number of 60 patients with a minimum follow-up of 6 months. Of the total of 60 patients in the study, 30 underwent Ligasure Hemorrhoidectomy and 30 patients conventional haemorrhoidectomy procedures.

Inclusion Criteria: all patients who presented with symptomatic hemorrhoids of Grades III and IV in all age groups and both sexes were included in this study.

Exclusion Criteria: Patients with acute episodes of thrombosed hemorrhoids, co-existing anal diseases, inflammatory bowel diseases, tuberculosis and patients with secondary hemorrhoids due to an intra abdominal pathology to be excluded from the study.

The study was randomised. All the patients received prophylactic antibiotics in the

preoperative period and also an enema, either soap water or proctoclysis.

Operative Technique

All the procedures were performed under spinal anaesthesia and the patient was placed in the lithotomy position for all the procedures.

Conventional Hemorrhoidectomy: Proctoscopy done initially under anaesthesia to assess the degree, position of haemorrhoids and to rule out other pathologies. Digital dilatation of the anus is done. With traction on the haemorrhoids V shaped incision is made in the mucocutaneous skin junction and haemorrhoids is dissected and its pedicle transfixated and ligated using Vicryl 2-0. After securing the ligature and clearing other haemorrhoids in a similar fashion, the pile mass is excised leaving behind a raw surface (Open method). In 5 cases of 30, the raw surface approximated using vicryl 2-0 because of excessive raw surface (Closed method).

Ligasure Hemorrhoidectomy: After initial Proctoscopy and assessment as described earlier, similar V shaped incision at the mucocutaneous skin junction and haemorrhoids is dissected and its pedicle is coagulated, sealed and cut using either Ligasure Precise™ instrument or Ligasure 5mm Blunt tip instrument (20cm). After clearing other haemorrhoids in a similar fashion, the pile mass is excised leaving behind a raw surface.

Assessment

The duration of surgery noted from the time of painting (after placing the patient in lithotomy position) to the placement of anal pack after completion of the procedure,

Per-operative bleeding noted by counting the number of gauze pieces (4*4). Each blood soaked gauze accounted for 5 ml of blood loss.

Post-operative pain was assessed using visual analogue scale (VAS) provided to the patient in which 0 corresponds to no pain and 100 to maximum pain. All patients were administered either inj. Tramadol (Tramadol) 50 mg IV or Inj. Dolo (Paracetamol) 1g IV in immediate post op

period and additional analgesics (Diclofenac- Inj Inac 3cc IM or Nupatch 200mg Transdermal patch) added as per subjective pain assessment.

Post operative parameters like the time for defecation after operation and pain and bleeding associated with defecation were assessed.

Early post operative complications like urinary retention, secondary bleeding, anal incontinence, wound infection were compared.

Patients' length of hospital stay and time to return to work were compared.

Follow Up: Examination was conducted for minimum period of 6 months. Late post op complications like anal stenosis, recurrence and other complaints were compared between the two procedures.

Statistical Analysis

The significance of differences was determined using the t-test and chi-square test. Confidence intervals within 95% were considered significant. The descriptive statistics like mean, SD, 95% confidence interval for mean as well as mean differences are computed. VAS score for pain is analyzed using repeated measures for ANOVA and Greenhouse-Geisser F-value is considered here because the assumption on sphericity has failed.

Results

1) **Age Distribution:** the youngest patient was 18 yrs. and the oldest was 75 yrs. old in the study.

Table: 1

Age in years	Ligasure		Conventional	
	No	%	No	%
<20	1	3.3	0	0.0
21-30	6	20.0	8	26.7
31-40	7	23.3	7	23.3
41-50	7	23.3	6	20.0
51-60	5	16.7	6	20.0
61-70	3	10.0	3	10.0
>70	1	3.3	0	0.0
Total	30	100.0	30	100.0
Mean ± SD	43.73±14.34		42.83±13.32	

2) **Sex Distribution:** The majority of the patients included in the study were males (26 in Ligasure group and 28 in Conventional group).

3) **Grade of Hemorrhoids**

26 in Ligasure group had Grade III and 4 had Grade IV

21 in Conventional group had Grade III and 9 had Grade IV

Table: 2

Grade of Hemorrhoids	Ligasure		Conventional	
	No	%	No	%
III	26	86.7	21	70.0
IV	4	13.3	9	30.0

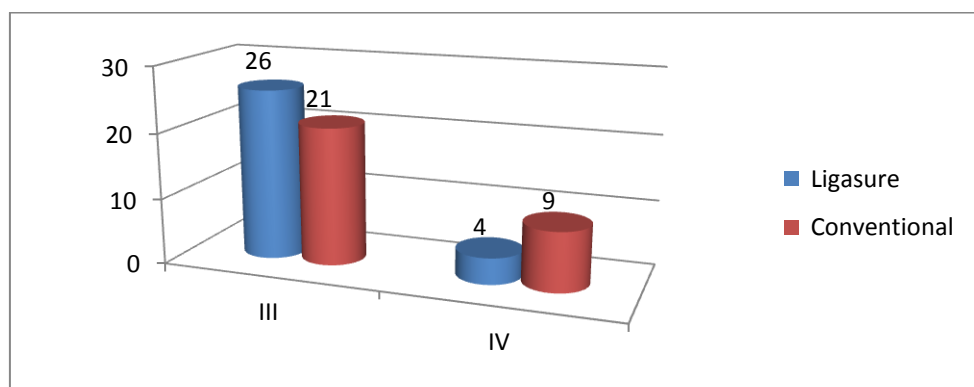


Figure: 1

4). **Chief Complaints**

Mass per rectum was the chief complaint in 48 cases (21 in Ligasure group and 27 in

conventional group); Bleeding per rectum in 44 cases (22+22); Painful defecation in 19 cases; Constipation in 19 cases; Itching in 11 cases.

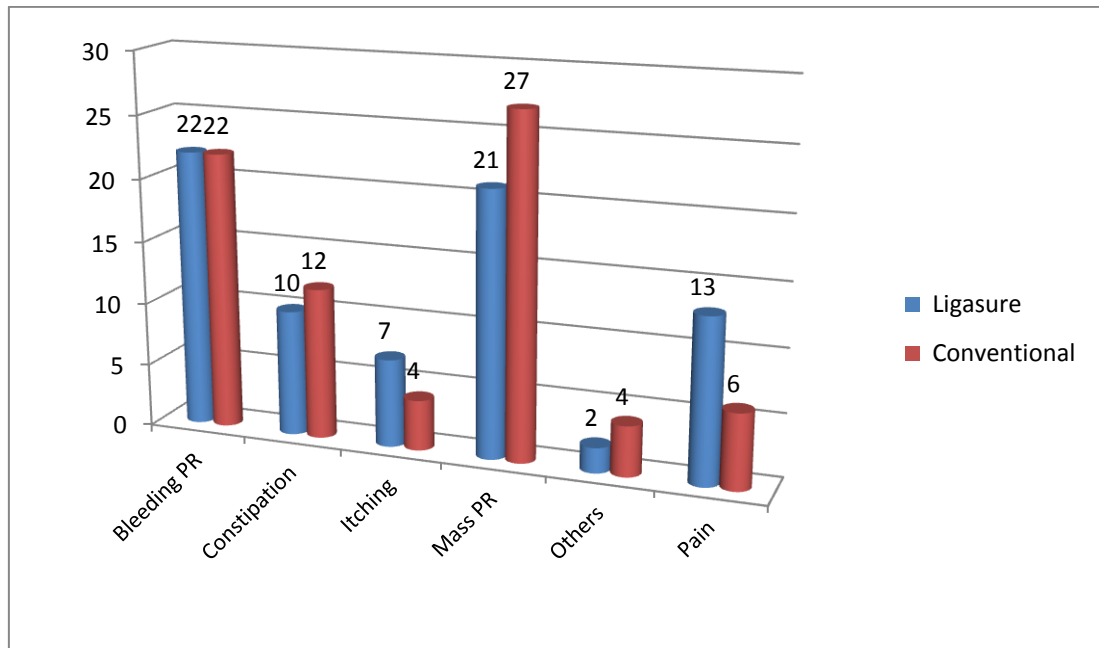


Figure: 2

5) Duration of Surgery (mins)

Table: 3

Duration of Surgery (mins)	Ligasure		Conventional	
	No	%	No	%
11-20	15	50.0	0	0.0
21-30	11	36.7	3	10.0
31-40	3	10.0	13	43.3
41-50	0	0.0	14	46.7
51-60	1	3.3	0	0.0
Total	30	100.0	30	100.0
Mean ± SD	25.50±9.50 (Min)		41.67±4.97 (Min)	

Mean duration of surgery is significantly less in Ligasure with P<0.001**

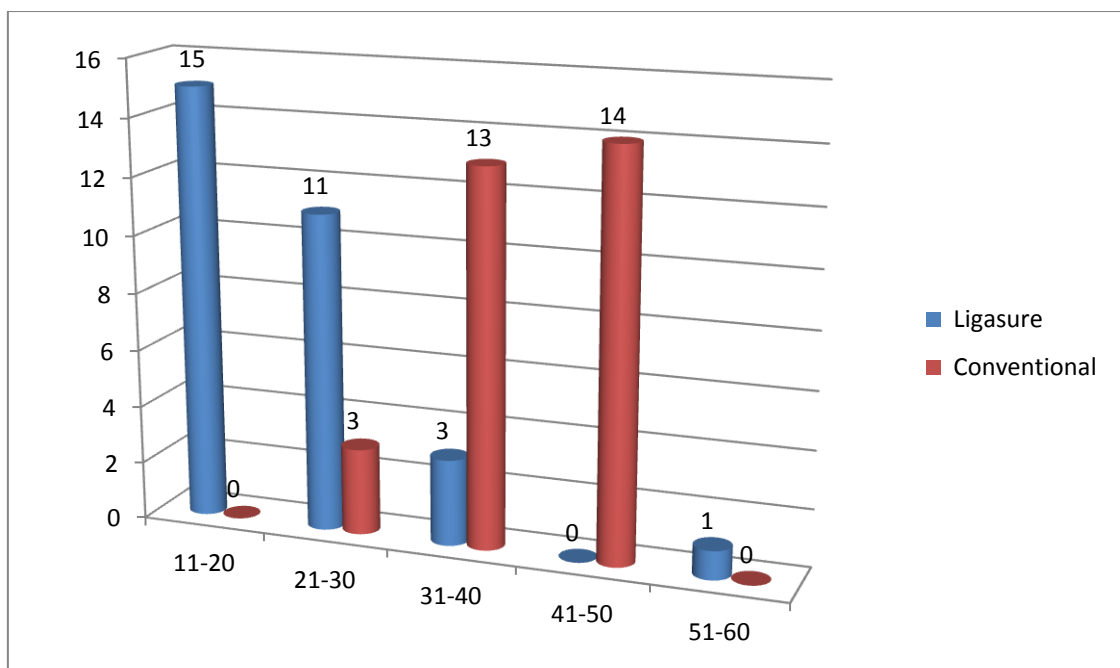


Figure: 3

6). Per operative bleeding (ml)

Table: 4

Per operative bleeding (ml)	Ligasure		Conventional	
	No	%	No	%
5-10	6	20.0	0	0.0
10-20	16	53.3	0	0.0
21-30	6	20.0	30	100.0
Total	30	100.0	30	100.0
Mean+/- SD	17.50±6.66		27.17±2.52	

Per Operative bleeding is significantly less in Ligasure with P<0.001**

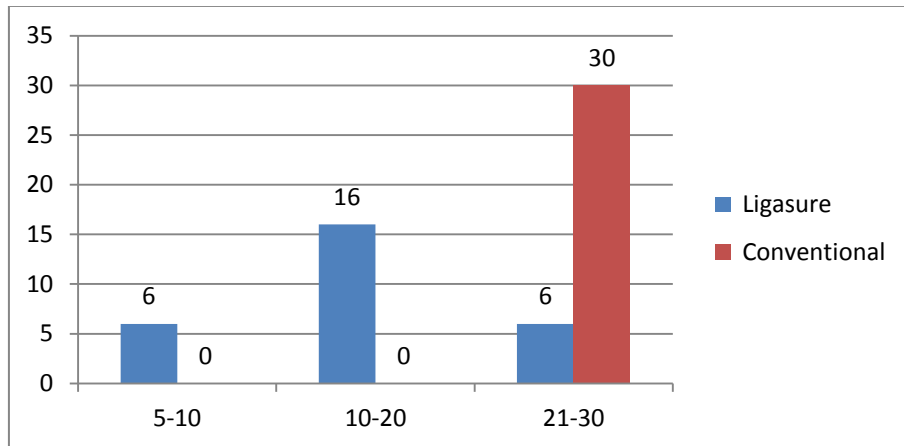


Figure: 1

7). Post operatively stool passage and pain associated with defecation was similar in both groups.

8). Post operative retention of urine was noted more in Conventional group(18 cases or 60%) than in Ligasure group (5cases or 16.66%).

9). Post operative pain assessed by Visual analogue score showed less pain with Ligasure hemorrhoidectomy than with conventional hemorrhoidectomy, with statistical significance on post-operative Day2.

Table: 5

Visual Analogue pain score	Ligasure	Conventional	P value
Day 1	46.00±8.14	47.33±5.83	0.469
Day 2	26.00±9.68	32.33±4.30	0.002**
Day 3	13.33±9.22	16.67±6.61	0.113

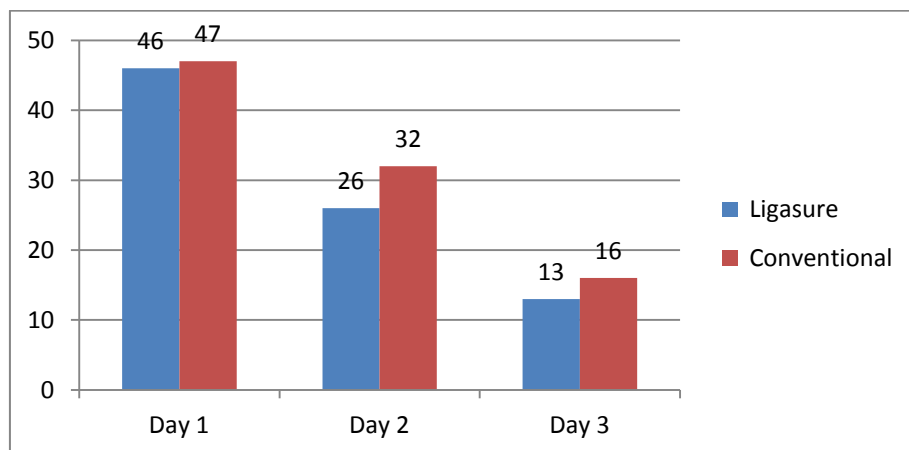


Figure: 5

10). Duration of stay in the hospital was significantly less in Ligasure group (6.20±1.37

days) than in Conventional group (10.40±1.52 days).

Table: 6

Duration of stay in the hospital (days)	Ligasure		Conventional	
	No	%	No	%
1-5	9	30.0	0	0.0
6-10	21	70.0	24	80.0
11-15	0	0.0	6	20.0
Total	30	100.0	30	100.0
Mean ± SD	6.20±1.37		10.40±1.52	

P<0.001**

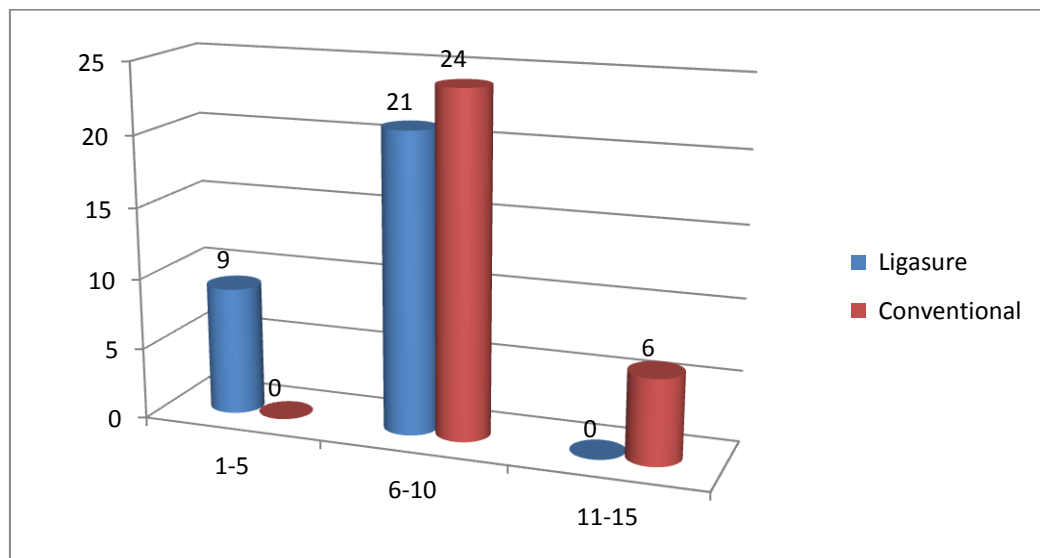


Figure: 6

11). Time to return to normal activity was similar in both groups.

Time (days)	Ligasure		Conventional	
	No	%	No	%
8-10	12	40.0	21	70.0
11-15	17	56.7	9	30.0
>15	1	3.3	0	0.0
Total	30	100.0	30	100.0
Mean ± SD	11.90±2.04		10.20±1.42	

12). One patient in Ligasure group developed Anal stenosis and required re-admission and operative intervention i.e., Lord's dilatation+ Lateral sphincterotomy.

13). Majority of patients had complaints in the follow up in conventional group (24). The most common complaints in the follow up were Pain, Painful defecation, Bleeding per rectum. Whereas 11 patients in Ligasure had the above mentioned complaints. if sphincter spasm was present on Per rectal examination, Patient was advised to continue Sitz bath and return for follow up after 1

week. Also Xylocaine gel (containing Lignocaine 2%) was advised following sitz bath. Also stool softener (Syp. Cremaffin) was advised if complaints of passing hard stools and dietary advice of High fiber diet given. For complaint of Bleeding per rectum, Tab. Thank OD forte (containing Calcium Dobesilate Euphorbia Prostrate Extract) was advised for upto 2 weeks after ruling out slipped ligature or visible cause of bleeding.

14). There was no case of recurrence in either groups.

Discussion

For symptomatic grade 3 and 4 hemorrhoids, some form of hemorrhoidectomy remains the accepted modality of treatment. The traditional (Conventional) methods like the Milligan—Morgan method and the Ferguson's method have been in practice for more than half a century for want of a better alternative. Recent years have seen the introduction of newer techniques with relative merits and demerits. The most significant recent introduction has been the circular stapling device for prolapsed hemorrhoids. This has been criticized for not treating the external component of hemorrhoids and the skin tags. Additionally the stapler cartridges are expensive and beyond the reach of most patients.

From last few years there is availability of the Ligasure™ device. It is an electro-surgical device, which is an improved version of bipolar diathermy. It is so effective in achieving hemostasis that it is described as a 'vessel sealing system'. The energy is delivered only to the tissue grasped within the jaws of the hand piece with minimal spread of electrical or thermal energy to adjacent tissues. Complete coagulation of vessels and also tissues is achieved with minimal charring in contrast to conventional diathermy. A computer controlled feedback loop automatically stops the flow of energy when coagulation of the vessels and mucosa is achieved. The vascularized tissue caught between the jaws is reduced to a wafer thin seal, which can be cut across with scissors.

Conventional hemorrhoidectomy is associated with significant pain-related complications such as urinary retention and constipation. Additionally meticulous hemostasis needs to be ensured to avoid postoperative hemorrhage. Occasionally the operative field can become quite bloody, prolonging the surgery. We found that Ligasure hemorrhoidectomy was a major improvement over the conventional technique in all these parameters. Technically the Ligasure method is much more simpler and can be safely and effectively carried out by relatively inexperienced surgeons.

In comparison with Conventional method Ligasure™ hemorrhoidectomy had a shorter operating time (25.50 ± 9.50 min versus 41.67 ± 4.97 , P value < 0.001 ;) and had less per operative blood loss (17.50 ± 6.66 ml versus 27.17 ± 2.52 ml, p value: < 0.001). This was similar to study done by Palazzo et al¹., Jayne et al²., Franklin et al³., Wang et al⁵., Tan et al¹³., and Bessa et al⁶., However not significant difference was found in studies done by Milito et al¹⁴., Chung et al¹⁶., and Attomare et al¹⁵.,

The VAS pain scores to assess Post operative Pain were lesser in Ligasure than Conventional Hemorrhoidectomy with statistically significance on Post operative Day 2. In other studies similar results are found in Thorbeck et al., Muzi et al., and Bessa et al.,

Postoperative complications such as urinary retention was significantly lower in the Ligasure group, Similar to as found in studies done by Palazzo et al., Milito et al¹⁴., Chung et al., Wang et al., Tan et al., and Bessa et al., Muzi et al.,

The postoperative duration of stay in the hospital was also significantly less with Ligasure as compared to Conventional group (6.20 ± 1.37 versus 10.40 ± 1.52 days). P value < 0.001 .

The time taken to return to normal activity was similar with Ligasure and Conventional Hemorrhoidectomies.

Previous randomized controlled trials have also found similar results.

Also similar results found in study done by Rahul Khanna et al¹⁰.,

The submucosal dissection avoids inadvertent anal sphincter injury. Compared with Conventional hemorrhoidectomy, the Ligasure™ method reduces post-operative pain and the requirement for parenteral analgesia because of minimal collateral thermal spread, limited tissue charring and absence of sutures.

At present conventional hemorrhoidectomy is an in-patient procedure with patients spending 7-10 days in hospital. Ligasure™ hemorrhoidectomy with its numerous proven advantages has the

potential to make hemorrhoidectomy into a day—care procedure.

It scores over stapled hemorrhoidectomy because of cost advantages and the inherent treatment of the external component of hemorrhoids which are left untreated in stapled hemorrhoidectomy.

Conclusion

Ligasure Hemorrhoidectomy is a suture less, closed hemorrhoidectomy technique dependent on a modified electrosurgical unit to achieve tissue and vessel sealing. It is safe and effective, has less blood loss, postoperative pain and complications compared to conventional hemorrhoidectomy. Technically it is much simpler because suturing is not required and hemostasis is easy to achieve. It has the potential of making hemorrhoidectomy in to a day-care procedure.

Acknowledgements

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