

# Comparison of Efficacy Between Conventional Excisional Technique and Ligasure® for Haemorrhoids- An Observational Study

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## ABSTRACT

**Introduction:** Ligasure® is a new modern device used in a variety of surgery, with demonstrable advantages over conventional hand-tying technique.

**Aim:** To compare the use of the Ligasure® device and conventional excisional technique in the treatment of prolapsing haemorrhoids (grade III and IV) and compare the postoperative complications of each in a prospective randomised controlled study.

**Materials and Methods:** A prospective study was conducted on 66 patients from November 2012 to September 2014, admitted to hospitals attached to Kasturba Medical College, Mangalore. The patients were divided using convenient sampling into two groups of 33 patients each having Grade III and IV haemorrhoids and were operated using conventional excisional technique and Ligasure®. Postoperative pain, bleeding, urinary retention, faecal incontinence, number of days to return to work and

complications was assessed and analysed using SPSS v18 and independent sample t-test.

**Results:** Ligasure® was statistically superior for postoperative pain 12 hours after surgery (6.34 vs 6.97), at 1<sup>st</sup> bowel movement (5.43 vs 6.03) and 1 week (3.57 vs 4.54). One patient had faecal incontinence which resolved within one day of surgery. One patient had anal stenosis 2 weeks postsurgery which resolved by conservative means. The number of days for the patient to be pain-free was better for Ligasure® (7.9 vs 11.1 days). Patient in Ligasure® group also had lower use of analgesic days (6.34 vs 10.51 days), had fewer patients postoperative bleeding (12 vs 23 patients) and the patient returned faster to work (9.97 vs 12.94).

**Conclusion:** Ligasure® haemorrhoidectomy, demonstrated reduced postoperative pain, use of analgesic, postoperative bleed and the patient returned faster to work.

**Keywords:** Bipolar, Diathermy, Haemorrhoidectomy, Milligan morgan

## INTRODUCTION

Haemorrhoids is a common condition affecting humans with the condition being mentioned in ancient text. It may be considered as downward displacement of the vascular, submucosal cushions of the anal cushion [1].

Although the word haemorrhoids and piles are used interchangeably etymologically the words have different meanings. The term haemorrhoid is derived from the Greek adjective haemorrhoids meaning bleeding (haima=bleed, rhoos=flowing), and emphasises the most important symptoms of this disease but it cannot be applied to all the patients presenting with this disease as a number of them do not present with bleeding [2]. The word Pile is derived from the Latin word pila meaning ball can be applied to all the patients with this disease as every patient with this disease will develop swelling of some kind. Contrary to popular belief, a haemorrhoid is considered as a part of normal anal anatomy [3], although in medical literature haemorrhoids are used almost exclusively to refer to pathological haemorrhoids.

Haemorrhoids occur at three locations: left lateral, right anterior, right posterior positions. They receive vascular supply by the superior, middle and inferior haemorrhoidal arteries; while venous drainage is through the inferior and middle haemorrhoidal veins. Haemorrhoids are classified into four grades: grade I haemorrhoids bulge into the anal canal and do not prolapse; grade II haemorrhoids prolapse during defecation and reduce spontaneously; grade III haemorrhoids prolapse and require manual reduction; grade IV haemorrhoids prolapse and are irreducible [4]. Pain or discomfort is associated with haemorrhoidal size, thrombosis, and location [5]. Although generally considered congenital, secondary triggers include constipation or diarrhoea, use of contraceptive pills, pregnancy and delivery as well as Premenstrual Syndrome (PMS) [6]. Histologically haemorrhoidal

tissue consists of dilated submucosal thickened blood vessel often with thrombi [7].

There are many treatments for haemorrhoids. These include prescription of medications, change in dietary and stool habits by stool softeners; laxatives and different surgical interventions as rubber band ligation, Doppler-guided ligation, injection sclerotherapy, cryotherapy, infrared photocoagulation (IRC), laser excision, ultrasonic dissection devices, modified bipolar diathermy coagulation (Ligasure®), stapling procedure for Prolapsing Haemorrhoids (PPH) or haemorrhoidopexy [8].

As a result, treatment plans are individualised for each patient to maximise results and to minimise complications. While excisional haemorrhoidectomy is standard for patients that fail medical treatment (persistence of bleeding or prolapsing haemorrhoid) [9], recently, many new surgical treatment modalities have been developed like Ligasure® device (modified bipolar diathermy coagulation) which are safe and effective alternative to traditional techniques, which aim to reduce postoperative pain, bleeding after haemorrhoidectomy and operative time [10].

In conventional open haemorrhoidectomy, three major haemorrhoid blood vessels are excised. To avoid stenosis, three pear-shaped incisions are left open, separated by bridges of skin and mucosa. Ligasure® achieves haemostasis by vessel compression and obliteration through the emission of bipolar energy. In a similar study by Gentile M et al., Ligasure® was considered the treatment of choice for IV degree haemorrhoids although considered more expensive than the conventional technique [11].

Its use in India is limited to a few centre and literature search are also limited in the Indian context. Kaushik R et al., concluded that Ligasure® haemorrhoidectomy is safe and effective, has lesser blood loss, shorter operative time, shorter hospital stay,

lesser postoperative pain, a lesser requirement for analgesia, early return to daily activities and had the absence of major complications [12]. Also, technically it was found to be a much simpler procedure. Khanna R et al., concluded that in the absence of any suturing in Ligasure® haemorrhoidectomy and relative fewer complications, the technique has the potential to be a day-care procedure [13]. In a study by Ahmed M et al., postoperative complications like pain and urine retention were significantly less in the Ligasure® group with lesser hospital stays, faster healing time and early return to routine life [14].

This study, by comparing the conventional method with a newer technique using Ligasure®, tried to establish the usefulness and cost of Ligasure® and compare it with conventional haemorrhoidectomy.

## MATERIALS AND METHODS

This prospective cohort study was conducted on sixty-six (66) patients with a prolapsing haemorrhoid (Grade III and IV) admitted to hospital attached to Kasturba Medical College, Mangalore. The study was started in November 2012 and ended in September 2014 ensuring a minimum follow-up of 6 months. The patients were divided using convenient sampling into two groups of 33 patients each using the formula  $N=(1.96)^2 \sigma^2/E^2$ , wherein  $\sigma=4.14$  and  $E=1$ .

Ethical approval from the ethical committee was taken in June 2012, Letter No. KMCMG/Med.Edu/2012/18. Detailed written informed consent was obtained from all patients.

**Inclusion criteria:** Patients with a prolapsing haemorrhoid (Grade III and IV), age between 20 to 65 years, for both genders.

**Exclusion criteria:** A history of inflammatory bowel diseases, associated anal fissure or fistula, previous haemorrhoid surgery, faecal incontinence, recent use of anticoagulation and coagulation disorders, pregnancy.

All patients underwent routine preoperative investigations. A sigmoidoscopy or colonoscopy was performed depending on the need of the patient and the criterion of the operating surgeon.

Preoperative antibiotic and soap water enema were given to all patients before the surgery. The surgery was conducted either under general or spinal anaesthesia in the operation theatre. After each procedure, an anal pack was inserted which was removed in the evening of the surgery. All the surgeries were conducted by a single unit which consisted of two faculty surgeons.

Postoperative pain was assessed using the Visual Analogue Scale (VAS) (0-no pain and 10-maximum pain). The patients were administered Injection Diclofenac sodium 75 mg i.m. in the immediate postoperative period as well as twice-daily the next day onward. It was gradually changed to oral Diclofenac sodium 50 mg orally twice daily until the patient became pain-free. (VAS of 1 or less). The patients were discharged from the hospital after it was assessed that pain could be managed by oral analgesics.

Urine retention was assumed if a patient failed to pass urine spontaneously 12 hours post-surgery or if the patient complained of intolerable lower abdominal pain with suprapubic bulge and dullness on percussion. Conservative methods like verbal encouragement, suprapubic warm compression and instructing the patient to listen to the sound of running water were sought before declaring the patient was in retention.

Postoperative bleed was considered to be present if there was active bleeding on the removal of the anal pack or the patient complained of blood passed per anus either by itself or tinged with stool. The number of days of such episode was noted.

Other parameters of faecal incontinence, return to work and other complications were actively sought after. The patient was reviewed every 12 hours during his/her stay in hospital and was asked to

come for follow-up one week after the day of his surgery. The researcher's contact number was given to the patient at the time of discharge for telephonic follow-up. The patient contact number was also recorded for 6 months follow-up wherein queries regarding pain, bleeding or any other complications as well as the requirement of analgesic if any were made. All patients responded with no pain or use of analgesic or any other complications.

## STATISTICAL ANALYSIS

Software SPSS v18 and independent sample t-test were used for statistical analysis. p-value less than 0.05 was considered as statistically significant.

## RESULTS

Out of the 66 patients, 33 underwent open haemorrhoidectomy and 33 underwent Ligasure® haemorrhoidectomy.

### Demography

In the study, the youngest patient was 28-year-old and the oldest was 65-year-old at the time of inclusion in the study. In the conventional group, there were 25 males and 8 females with a mean age of 47 and 40 years, respectively. In the Ligasure® group there were 25 males and 8 females with a mean age of 49 and 43 years, respectively [Table/Fig-1].

Surgery type	No. of patients		Mean age		Std. dev. (age)	
	Male	Female	Male	Female	Male	Female
Conventional	25	8	46.66667	40.22222	11.06211	9.806775
Ligasure®	25	8	49.26923	43.375	12.38037	12.16488

[Table/Fig-1]: Demography comparison.

### Pain

Ligasure® group demonstrated a superior pain control in all time frames except 6 months follow-up. Mean days for complete relief from pain for conventional surgery and Ligasure® surgery is 11.11 days vs 7.9 days, respectively, and this difference is statistically significant at 95% level of confidence. ( $p=0.01$ ). In the 6 months follow-up the patient in both groups had no pain symptoms and hence there is no difference in the mean pain score value [Table/Fig-2].

	Mean		t	df	Sig. (2 tailed)
	Conventional	Ligasure®			
After 12 h	6.97	6.34	2.65	62.88	0.01
After 1 <sup>st</sup> bowel	6.03	5.43	2.12	66.49	0.04
After 1 week	4.54	3.57	3.67	50.04	0.01
6 months	0	0	*	-	-

[Table/Fig-2]: Statistical analysis of pain in various time frames.

\*t cannot be computed because the standard deviations of both groups were 0  
p-value less than 0.05- statistically significant

Mean hospital stay for conventional and Ligasure® group was 2.41 and 2.23 days, respectively, which was statistically insignificant at 95% confidence level ( $p=0.296$ ).

### Use of Analgesics

Mean number of days for which analgesia was used for conventional surgery and Ligasure® surgery was 10.51 days vs 6.34 days, respectively ( $p=0.01$ ).

### Urinary Retention and Postoperative Bleeding

With the mean number of days with urinary retention (1.36 days vs 1.67 days), there was no statistical significance between conventional and Ligasure® technique, whereas for postoperative bleed with a mean of (2.59 days vs 1.46 days) there was a statistical difference [Table/Fig-3]. There were less patients with postoperative bleed in the Ligasure group (12 vs 23).

	Mean		t	df	Sig. (2-tailed)
	Conventional	Ligasure®			
Urinary retention	1.36	1.67	0.96	14.27	0.47
Postoperative bleed	2.59	1.46	2.91	33.00	0.01

**[Table/Fig-3]:** Urinary retention and postoperative bleed.  
p-value less than 0.05- statistically significant

### Return To Work

With a mean number of days being higher for the conventional method (12.94 vs 9.97) it was statistically significant at 95% confidence (p=0.01) [Table/Fig-4].

Mean		t	df	Sig. (2 tailed)
Conventional	Ligasure®			
12.94	9.97	3.10	39	0.01

**[Table/Fig-4]:** Return to work.  
p-value less than 0.05- statistically significant.

### Other Complications

One patient who was operated upon by conventional method had anal stenosis, when the patient presented for follow-up 2 weeks post-surgery. Bulk-forming agent Normacol and an anal dilator of 4 cm diameter were prescribed. The patient became free of symptom at 1 month follow-up. One patient had faecal incontinence which resolved within one day of surgery.

### DISCUSSION

Conventional haemorrhoidectomy has been done for more than half a century for the want of a better alternative. Recent years have seen the introduction of electrosurgical devices such as Ligasure® which allowed the surgeon to conduct the surgery easily and with less complication. The choice of diathermy is the difference between the two techniques. Ligasure® is an effective instrument when a large tissue demolition is required. This study was designed to compare haemorrhoidectomy using both conventional and Ligasure® technique to evaluate the advantage and disadvantage of each. The study consisted of 66 patients, wherein 33 were assigned to each group.

In both conventional and Ligasure® group males were more commonly affected (75.75%). This was comparable to the study conducted by Chung CC et al., and Bessa SS [15,16].

The VAS pain score was less for Ligasure® technique at 12 hours post-surgery (6.34 vs 6.97), after the first bowel moment (5.43 vs 6.03) and 1 week (3.57 vs 4.54). Such superiority in pain assessment was also found in a study conducted by Franklin EJ et al., and Tan KY et al., [17,18].

Use of analgesics was less for Ligasure® group, as seen in study conducted by Nienhuijs SW and de Hingh IH [19]. Statistically, significant postoperative bleed in terms of fewer patient with postoperative bleed as well as few days of postoperative bleed was noted in Ligasure® group. This concurred with studies done by Bessa SS [16].

The patient returned to work faster if operated by Ligasure® technique. (9.97 vs 12.94, p<0.05), comparable to study done by Wang D et al., and Milto G et al., [20,21]. Ligasure® without the use of suture was reported to be a much easier technique by the operating surgeon and with less collateral damage to tissue could result in less postoperative pain.

The cost of the surgery operated upon by Ligasure® device was INR 23500 whereas those operated by the conventional device was INR 13300.

### Limitation(s)

The shortcoming of the study includes limited female participant. More long term risk of recurrence of the haemorrhoidal disease needs to be evaluated in future studies.

### CONCLUSION(S)

Ligasure® is a modified electric surgical device which achieves tissue and vessel coagulation with minimal collateral damage. It is safe with less postoperative pain as compared with the conventional method of haemorrhoidectomy. It is also superior in postoperative pain management with less postoperative bleed and the patient can return to work faster. Technically, it is an easier procedure to perform as suture is not required to achieve haemostasis. Although the cost of surgery is higher than the conventional technique, the cost-benefit ratio may justify its use as the technique of choice for haemorrhoidectomy.

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