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COMPARISON OF EFFICACY BETWEEN CONVENTIONAL EXCISION TECHNIQUE AND LIGASURE® FOR HAEMORRHOIDS A PROSPECTIVE OBSERVATIONAL COHORT STUDY IN A TERTIARY CARE HOSPITAL IN MANDYA

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Abstract- Background: Haemorrhoids are a common anorectal condition characterized by the abnormal dilation of veins in the anal and rectal regions. While conventional Milligan-Morgan haemorrhoidectomy remains a definitive treatment, it is often associated with significant postoperative pain and longer recovery. The LigaSure® vessel sealing system offers a novel approach, promising reduced blood loss, postoperative pain, and faster recovery.

Objective: To compare the efficacy, postoperative complications, and recovery outcomes of haemorrhoidectomy performed using LigaSure® versus the conventional Milligan-Morgan technique in patients with Grade III and IV prolapsing haemorrhoids.

Methods: A hospital-based prospective observational cohort study was conducted from December 2023 to December 2024 on 60 patients aged 20–65 years with Grade III and IV haemorrhoids. Patients were randomly allocated to LigaSure® haemorrhoidectomy (Group A, n=30) or conventional Milligan-Morgan haemorrhoidectomy (Group B, n=30). Key parameters assessed included operating time, intraoperative blood loss, postoperative pain (12 hours, first bowel movement, and one week), duration of analgesic use, postoperative complications, and time to return to work.

Results: The mean age of patients was 51 years, with most common group of age involved was between 40 – 60 years. LigaSure® haemorrhoidectomy resulted in significantly less blood loss (51.92 ± 15.68 mL vs. 70.34 ± 25.59 mL), lower pain scores at 12 hours (6.30 vs. 6.98), first bowel movement (5.40 vs. 6.03), and one-week post-surgery (3.57 vs. 4.57), as well as faster pain

resolution (7.9 vs. 11.1 days) and fewer analgesic use days (6.40 vs. 10.14). Postoperative bleeding was lower in the LigaSure® group (10 vs. 23 patients), and return to work was quicker (9.86 vs. 12.74 days). Operating time was similar between groups (38.5 ± 11.9 minutes vs. 36.6 ± 9.8 minutes).

Conclusion: LigaSure® haemorrhoidectomy demonstrates superior outcomes compared to the conventional technique, with reduced intraoperative blood loss, postoperative pain, analgesic use, and complications, as well as faster recovery and return to work. Despite its higher cost, LigaSure® is a promising alternative for managing Grade III and IV haemorrhoids.

Key words- LigaSure® haemorrhoidectomy; Milligan-Morgan haemorrhoidectomy; Urinary retention;

INTRODUCTION

Haemorrhoids are a common anorectal condition characterized by the abnormal enlargement and dilation of veins in the anal and rectal regions.[1] 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.[2]

Various treatment options have been explored, including cryotherapy, laser therapy, and infrared coagulation. Among the available treatment options, excisional haemorrhoidectomy, a surgical procedure that involves the removal of the affected haemorrhoidal tissue, has long been considered a reliable and effective approach, particularly in the management of more advanced stages of the condition. Excisional haemorrhoidectomy, though considered the most definitive and reliable treatment for both internal and external hemorrhoidal disease, is often associated with significant postoperative pain.[3]

A number of surgeons believe that by avoiding vascular pedicle ligation the chances of secondary bleeding can be decreased. The reason behind this is belief that it may lead to ischaemia and necrosis at the region where these sutures are applied it may also integrate the sphincter muscle

and consequently causes acute postoperative pain, wound infection and bleeding. Additionally, if the sutures are applied deeply, they can also cause firm circular scarring at the anus later on. Therefore, many authors have said that we do not transfix vascular pedicles of haemorrhoids, but we seal them by LigaSure.[5]

The LigaSure vessel sealing system is a groundbreaking surgical technology that has revolutionized the way surgeons' approach various procedures. This advanced bipolar electrosurgical device utilizes a unique tissue-fusion algorithm to effectively seal blood vessels, lymphatics, and tissue structures, reducing intraoperative blood loss and surgical time.[6] In recent years, the LigaSure® vessel sealing system has emerged as an alternative to conventional excisional techniques, promising reduced postoperative pain and faster recovery times.

MATERIALS AND METHODS

This hospital-based prospective observational cohort study was conducted from December 2023 to December 2024 on 60 patients aged 20–65 years with Grade III and IV haemorrhoids.. The sample size was calculated using the equation $N = 2(Z1\text{-}\alpha/2 + Z1\text{-}p)2\ \sigma2/d2$, where $Z1\text{-}\alpha/2 = 1.96$ standard Normal Variate, $Z1\text{-}p = 0.84$ Power of the test, $\bar{X}1 = 52.5$ – mean operating time with conventional technique.[4] $\bar{X}2 = 36.6$ – mean operating time with LigaSure.[4] $d = \bar{X}1 - \bar{X}2 = 15.9$, $\sigma1 = 11.9$ – standard deviation with conventional technique.[4] $\sigma2 = 9.8$ – standard deviation with LigaSure technique. 4, the sample size comes up to 30 in each group. Ethical approval from the ethical committee was taken. Inclusion criteria: Patients with a prolapsing haemorrhoid (Grade III and IV), aged between 20 to 65 years & giving informed consent to participate. Exclusion criteria: history of inflammatory bowel diseases, associated anal fissure or fistula, previous haemorrhoid surgery, faecal incontinence, recent use of anticoagulation and coagulation disorders and pregnancy. Following Patients were randomly allocated to group A (Haemorrhoidectomy by Ligasure) and group B (Milligan Morgan Haemorrhoiectomy) by using the random allocation software version 1.0.0. A standardized spinal or general anesthesia was used. The procedure was carried out with the patient in lithotomy position and a minor reverse Trendelenberg angle. Group A underwent LigaSure® haemorrhoidectomy while Group B underwent a conventional Milligan-Morgan haemorrhoidectomy. The operative time was recorded by an operating theatre nurse. Blood

loss was recorded as the number of soaked gauzes. Soakage of one 4×4 gauze piece was considered as 30 ml blood loss.

A standard medication package was given to all patients postoperatively. All patients were advised injectable antibiotics Ceftriaxone 1g twice daily and Metronidazole 100 ml thrice daily with injectable paracetamol 100 ml thrice daily during intial 24 hours post op period. Key parameters assessed included operating time, intraoperative blood loss, postoperative pain (12 hours, first bowel movement, and one week), duration of analgesic use, postoperative complications, and time to return to work was assessed using a structured questionnaire. Patients were taught with an 11-point visual analogue pain score from zero to ten. The patients were asked to record at home before bed-time their maximum pain score for the day.

Statistical analysis was performed with SPSS software version 17. Independent sample T- test was applied to compare the operative time, blood loss and post operative pain in both groups. Post stratification Independent Sample T- test was applied; value ≤ 0.05 will be taken as significant.

RESULT

Out of total 60 patients 34 were male and 26 were females. The most common group of age involved was between 40 – 60 years with mean age of 51 years. Third degree Hemorrhoids were present in 43 (71.6%) of patients while remaining 17 (28.3%) had fourth degree Hemorrhoids. Group A included 30 cases who underwent LigaSure hemorrhoidectomy with mean operating time was 38.5 with standard deviation of 11.9 while Group B included 30 cases and underwent conventional hemorrhoidectomy with mean operating time 36.6±9.8 in the other group. The mean blood loss in group A was 51.92 with standard deviation of 15.68 while it was 70.34±25.59 in group B indicating that LigaSure® may be more effective in minimizing blood loss during the procedure. Overall pain score was less in those patients who underwent Heamorrhoidectomy by Ligasure method. Ligasure® was statistically superior for postoperative pain 12 hours after surgery (6.30 vs 6.98), at 1st bowel movement (5.40 vs 6.03) and pain after 1 week (3.57 vs 4.57). 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 associated with fewer days of analgesic use (6.40 vs 10.14 days), had fewer postoperative bleeding (10 vs 23 patients) and the patients returned to work faster (9.86 vs 12.74).

CONCLUSIONS

Ligasure® haemorrhoidectomy, despite its higher cost, shows several advantages, less intra operative bleed, less postoperative pain, reduced need for analgesics, lower incidence of postoperative bleeding, and quicker return to work for patients.

Table 1: Comparison of operative outcomesin patients undergoing Ligasure and Milligan Morgan's hemorrhoidectomy

	LigaSure® Group A (n=30)	**Milligan Morgan Group B (n=30)**
Male	18	16
Female	12	14
IIIrd Degree	22	17
IVth Degree	8	13
Mean Operative time (minutes)	38.5±11.9	36.6±9.8
Blood loss (in ml)	51.92±15.68	70.34±25.59
12 Hours post operation	6.30	6.98
After first bowel movement	5.40	6.03
1 week post operation	3.57	4.57
Days taken to be pain-free	7.9	11.1
Days of analgesic use	6.40	10.11
Postoperative bleeding	10	23
Return to work faster	9.86	12.74

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PROFORMA

Title:

Comparison of Efficacy between Conventional excision technique and Ligasure® for haemorrhoids an Observational study in a Tertiary Care Hospital in Mandya

Part 1: Socio-demographic Profile

1. Name:
2. Age: _____ years
3. Sex: Male/Female
4. Residence: Rural / Urban
5. IP No:

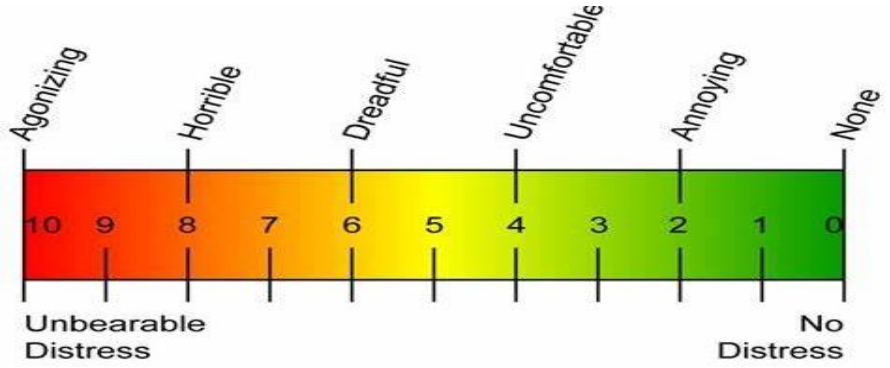
Part 2: Related to the disease

1. Chief Complaint Duration:
   - Mass per rectum
   - Bleeding
   - Pain
   - Constipation
   - Itching
   - Others
2. Past History
   - History of similar complaint
   - History of any major co morbid condition
   - History of any surgery in the past.

3. Personal History
    - Appetite
    - Sleep
    - Bowel and Bladder habit
    - Addictions
4. Per abdominal and Per Rectal Examination
5. Diagnosis
6. Pre-Op investigations
7. Operative details:
    - Operating surgeon
    - Anaesthesia
    - Type of Haemorrhoidectomy
    - Operation time
    - Blood loss

Part 3: Post-Op Complication

1. Pain
    - Use Visual Pain Analogue Scale



12 hours after operation	After first bowel movement	1 week after operation	Days after operation patient was pain free

2. Use of analgesics

- Yes
- Name of drug
- How many days

3. Urinary retention

- Yes
- No
- How many days

4. post op bleeding

- Yes
- No
- How many days

5. Fecal Incontinence

- Yes
- No
- How many days

6. Other Complication

- Yes
- No
- How many days

7. Return to work

- Yes
- No
- How many days