

COMPARISON OF HAEMORRHOIDECTOMY OUTCOMES USING LIGASURE SMALL JAW DEVICE VERSUS CONVENTIONAL MILLIGAN-MORGAN TECHNIQUE

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Abstract: Haemorrhoids are a common anorectal condition, affecting about 10% of the population. Hemorrhoidectomy remains the preferred treatment for grade III and IV haemorrhoids, with the Milligan-Morgan technique being the traditional method since 1937. Recently, the LigaSure vessel sealing system has emerged as a novel approach, utilizing bipolar electro-thermal technology for precise tissue sealing. Studies suggest LigaSure offers benefits such as reduced operating time, less intraoperative bleeding, lower postoperative pain, and shorter hospital stays. This study aims to compare postoperative pain, operative time and blood loss during the procedure between the LigaSure techniques and the Milligan-Morgan to optimize patient outcomes. Objective: To compare haemorrhoidectomy with Ligasure Small Jaw device versus conventional Milligan Morgan technique in terms of operation time, intra-operative blood loss and postoperative pain. Methods: 100 patients were included in this study. Patients were randomly assigned to 2 groups: Group A (Haemorrhoidectomy with Ligasure small jaw device) and Group B (Milligan Morgan Haemorrhoidectomy); 50 patients in each group. The data from both groups was recorded on a predesigned questionnaire and the required variables for the study i.e. VAS pain score, operative time and blood loss etc. were noted and the data was analyzed via SPSS version23. **Results:** The majority of patients were aged 50-59 years (45%), with a mean age of 46.01 \pm 7.377 years. Males predominated (67%), and most patients had a healthy BMI (55%), with a mean BMI of 25.03 ± 3.1 . Grade 4 hemorrhoids were more common (65%) than grade 3 (35%). Most patients experienced symptoms for 12-24 months (52%) and had an ASA score of 1 (79%). In Group A, the mean operative time was significantly shorter at 39.66 \pm 6.46 minutes compared to 59.8 \pm 14.04 minutes in Group B (p<0.001). Group A also had a shorter mean hospital stay (2.16 ± 0.911 days vs. 2.18 ± 1.043 days, p<0.001). Blood loss was significantly lower in Group A (51.04 \pm 6.22 ml) compared to Group B (71.76 \pm 9.8 ml, p<0.001). Pain scores on the day of surgery were lower in Group A (5.1 \pm 0.57) than Group B (6.5 \pm 0.50, p<0.001), a trend that continued on the 1st, 14th, and 28th postoperative days (p<0.001). Conclusion: Through our comprehensive analysis, we affirm that the Ligasure technique demonstrates superior outcomes in terms postoperative pain assessed via Visual Analog Scale (VAS), operative blood loss, duration of hospitalization, and operative time when compared to the Milligan-Morgan technique.

Keywords: Haemorrhoids, Haemorrhoidectomy, Milligan Morgan Technique, Ligasure Technique, Post-Operative Pain, Post-Operative Complications

Introduction

Haemorrhoids, deriving its name from the Greek words for bleeding (haema=bleed, rhoos=flowing), and colloquially known as "piles," represent one of the most prevalent anorectal disorders, affecting approximately 10% of individuals (1). Characterized by dilated anal cushions, haemorrhoids manifest with symptoms such as rectal bleeding, prolapse, pain, mucous discharge, and pruritus. Anatomically classified into external and internal types, the latter further stratified into four categories based on their location relative to the dentate line. Haemorrhoids pose significant clinical challenges due to their varying symptomatology and potential complications. Different treatment options are available according to their grades (2). Haemorrhoidectomy, acknowledged as the most effective treatment for grade III and IV hemorrhoids, remains the cornerstone of surgical management as gold standard (3). The conventional open haemorrhoidectomy technique, initially described by Milligan and Morgan in 1937 (4). And later refined by Ferguson in 1959, persists as the gold standard due to its affordability and technical simplicity (5). Despite the advent of alternative procedures, open haemorrhoidectomy continues to be favored for its efficacy in addressing advanced haemorrhoidal disease.

Various surgical techniques, including stapler hemorrhoidectomy (6). Ferguson closed hemorrhoidectomy (7). Harmonic scalpel hemorrhoidectomy (8). ligasure (9). And Doppler-guided haemorrhoidal artery ligation (10). Have been proposed for the treatment of hemorrhoids. Among these, the Ligasure vessel sealing system (Valley lab, Boulder, Covidien) has emerged as a promising advancement. Limited studies have suggested potential advantages of ligasure hemorrhoidectomy over standard techniques, including reduced operating time, decreased bleeding, alleviated post-surgical pain, and shortened hospitalization duration (11, 12, 13, 14).

The Ligasure vessel sealing system by Covidien is an advanced surgical device designed to achieve hemostasis and tissue sealing during surgical procedures. Here's a brief description of how it works: Bipolar Electro thermal

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Technology, Optimized Combination of Pressure and Temperature, Sealing Blood Vessels and Minimizing Thermal Spread. As the device is applied to the tissue, the bipolar energy causes local heating, denaturing collagen and sealing the blood vessels. This effectively stops bleeding and reduces the risk of postoperative complications such as haemorrhage.

Giving the foregoing, our study aims to investigate and compare the efficacy and safety profiles of two primary surgical approaches for haemorrhoidectomy: the conventional Milligan Morgan haemorrhoidectomy and the Ligasure vessel sealing system haemorrhoidectomy. By systematically evaluating postoperative complications, including pain, bleeding, and hospital stay and operating time, this study seeks to contribute to the development of improved surgical strategies for haemorrhoidal disease management, with the overarching goal of enhancing patient outcomes and reducing healthcare resource utilization.

Methodology

This Randomized controlled trial was conducted in the surgical department Unit-III, Nishtar Medical University/ Hospital, Multan, from 1st January 2023 to 31st December 2023 Sample size of 100 patients (50 in each group) was calculated by using Non probability consecutive sampling technique with 95% power of the test, 5% level of significance. Using Nonprobability consecutive sampling technique. Patient were selected by lottery method. Both Genders. Grade III or IV haemorrhoids Age between 18 to 60 years. Grade me and II haemorrhoids Liver cirrhosis Accompanying perianal disease. Inflammatory bowel disease bleeding diathesis Diabetes mellitus Pregnancy

Once the hospital's ethical review committee has approved the study, 100 patients from Nishtar Medical University Hospital, Multan, who have been admitted to Surgical Unit-III and are undergoing hemorrhoidectomy for grade III and IV haemorrhoids and meet the inclusion and exclusion criteria, were included in the study. Patients who participate in the study gave written informed consent.

Patients were be randomly assigned to one of two groups: group A (Haemorrhoidectomy with LigaSure tiny jaw device) and group Β. (Milligan Morgan Haemorrhoidectomy). 50 patients in each group. It is intended to use a standardized spinal anesthesia / saddle block. The patient placed in the lithotomy position, with a minor reverse Trendelenburg position. Both procedures had the same major steps, as following: Examination, delivery of haemorrhoids by artery forceps, one at the mucocutaneous junction of the haemorrhoid, the other at the apex, and a skin incision at the base of haemorrhoids, and separation of hemorrhoid tissue from the internal sphincter fibers by monopolar diathermy.

During a Milligan Morgan's surgical procedure, a Vicryl suture with the number 0 was used to transfix the haemorrhoid pedicle. The jaws of the handset fastened to the pedicle during the LigaSure operation, and the device actuated. Sutures were not used on this group of patients. Anal canal was packed with gauze, and the operative time was recorded by an operating room staff member. Intra operative bleeding was evaluated by weighing the swabs used during the operation, with one gram equaling to one milliliter of blood loss (in other words, one gram equals one milliliter of blood).

All patients were advised to drink two table spoons of Ispagol husk twice a day for two weeks after surgery to aid with defecation. All patients were given the medications Metronidazole 400mg three times a day and Ciproxin 500mg twice a day for 10 days. Injectable analgesia was given on operative day as required. All patients given two paracetamol tablets three times a day and Diclofenac 50 mg orally as required for postoperative analgesia. Patients were discharged on the first postoperative day. All patients advised to take sitz bath twice day to keep their wounds clean. After discharged, patients came in OPD clinic for follow-up consultations at two and four weeks later. Patients were taught how to assess their pain on a visual analogue scale from 0 to 10. On the day of surgery, as well as the first, fourteenth, and twenty-eighth post-operative days, pain was assessed. A score of 0 shows no pain, a score of 1-3 suggests mild pain, a score of 4-7 indicates moderate pain, and a score of 8-10 indicates severe pain.

The data from both groups were recorded on a predesigned questionnaire. All the surgeries were carried out by the same surgical team in group A and in group B. Surgeon having more than 5 years post fellow ship experience in haemorrhoidal surgery. To keep confounders and bias in the study under tight control, the exclusion criteria were strictly followed.

SPSS Version 23 was used to enter and analyze the data. The mean and standard deviation for quantitative data, such as age, VAS pain, blood loss, and operation time, are calculated. Gender and ASA grade, for example, are qualitative factors are quantified as a percentage of the total. Stratification utilized to control impact modifiers like age and gender and grade of haemorrhoids. An independent sample T-test used to evaluate operating time, intraoperative blood loss, and postoperative pain in both groups. The Chi-square test will be used for stratification in both groups. A p value of \leq 0.05 is considered as significant.

Results

Among the recruited patients, different age groups were defined. The majority of patients belonged to the 50-59 years age group (45%), followed by the 40-49 and 30-39 years age groups respectively. Mean age of the patients was determined as 46.01 ± 7.377 years. The patients were predominantly male (67%) followed by females (33%). The BMI of the patients was also recorded, with the majority having a healthy BMI (55%), followed by overweight patients (43%). The mean BMI of the patients was noted as 25.03 ± 3.1 . The grade of hemorrhoids upon admission was assessed, with the majority of patients (65%) having grade 4 hemorrhoids compared to grade 3 (35%). The duration of symptoms experienced by patients was categorized into three groups. The majority of patients had been experiencing symptoms for 12-24 months (52%), followed by less than 12 months (33%) as shown in. The health status of patients, assessed for their ability to undergo surgery, was determined via the American Society of Anesthesiologists

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(ASA) classification. The majority of patients (79%) had an ASA score of 1 (normal health) compared to ASA 2 (Mild systemic disease) as shown in Table 1.

In Group A, the mean operative time was recorded as 39.66 \pm 6.46 minutes, as compared to mean operative time of 59.8 \pm 14.04 minutes observed in Group B, which is significant (p<0.001) . Similarly, the mean hospital stay was 2.16 \pm 0.911 days for Group A and 2.18 ± 1.043 days for Group B patients, with a significant difference noted in P value (p<0.001). Furthermore, mean blood loss in milliliters was significantly lower in Group A (51.04 \pm 6.22 ml) as compared to Group B (71.76 \pm 9.8 ml), with a p-value of less than 0.001 as shown in the Table 2.

Regarding pain scores, the mean Visual Analog Scale (VAS) pain score on the day of surgery was significantly lower in Group A (5.100 \pm 5.7) compared to Group B (6.5 \pm 0.50), with a p-value of less than 0.001. This trend continued on the 1st post-operative day, where Group A had a lower mean VAS pain score (3.46 ± 0.50) compared to Group B (5.4 ± 0.50) (p<0.001). On the 14th and 28th days post-surgery, Group A maintained lower mean VAS pain scores compared to Group B, with p-values less than 0.001 as shown in the Table 2, respectively. Stratification of VAS among the patients at different post op days was not significant statistically except on 28th POD where male patients have more pain scale as shown in the table no.3.

Table -1 Descriptive	Analysis and	Demographic details
n = 100		

Character	Frequency	Percentage			
1.Gender					
Male	67	67			
female	33	33			
2. Age groups years					
30-39	24	24			
40-49	31	31			
50-59	45	45			
3.BMI Groups					
Underweight	2	2			
Healthy	55	55			
Overweight	43	43			
4.Haemorrhoids Grade					
3	35	35			
4	65	65			
5.Duration of Symptoms					
<12 months	33	33			
12-24 months	52	52			
>24 months	15	15			

Case Type	Character	Ν	Mean	Std. Deviation	P-Value (Chi square)
Operative time	Ligasure device	50	39.6600	6.46690	
	Milligan Morgan	50	59.8600	14.04077	< 0.001
Hospital Stay (days)	Ligasure	50	2.1600	0.91160	< 0.001
	MM	50	2.1800	1.04374	
Mean Blood Loss	Ligasure	50	51.0400	6.22687	< 0.001
(ml)	MM	50	71.7600	9.80121	
VAS -DOS	Ligasure	50	5.1000	.79673	< 0.001
	MM	50	6.5400	.50346	
VAS- 1st Day	Ligasure	50	3.4600	.50346	< 0.001
	MM	50	5.4600	.50356	
VAS 14th Day	Ligasure	50	1.6400	.48487	< 0.001
	MM	50	2.6800	.47121	
VAS 28th Day	Ligasure	50	.3800	.49031	< 0.001
	MM	50	.6000	.49487	

Case Type			VAS 28th	Day	Total	p-value
Ligasure Small Jaw Device	Gender	Male	19	14	33	0.369
		Female	12	5	17	
	Total	Total		19	50	
Milligan Morgan's Technique	Gender	Male	17	17	34	0.035
		Female	3	13	16	
	Total		20	30	50	

Discussion

Haemorrhoidectomy remains the standard therapy for symptomatic grade 3 and 4 haemorrhoids when more effective alternatives are unavailable. Traditional approaches, such as the Milligan-Morgan and Ferguson methods, have been the mainstays for over half a century due to the lack of superior options. However, recent years have witnessed the introduction of new techniques, each with its own advantages and drawbacks. Among these innovations, the LigaSure vessel-sealing device stands out as a promising option. It offers precise coagulation and minimal collateral thermal spread, resulting in rapid, bloodless dissection with minimal tissue damage. Multiple

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randomized studies comparing the LigaSure device with traditional Milligan-Morgan and Ferguson's closed hemorrhoidectomy have demonstrated its effectiveness in addressing common postoperative issues associated with

hemorrhoidectomy. The less operative time with the LigaSure device in haemorrhoidectomy can be explained by its advanced technology and efficiency. The LigaSure system is designed to seal blood vessels and tissue bundles quickly and effectively, allowing for rapid dissection with minimal bleeding. These are the key factors contributing to the reduced operation time, intra operative blood loss and postoperative pain which are our primary end points and also mention in different Studies (11, 15, 16, 17, 18, 19). These study have shown that these advantages lead to statistically significant reductions in operation times when using the LigaSure device compared to conventional techniques like the Milligan-Morgan method. Our study results shows significant statistically difference (p<0.001), showing the efficiency of the LigaSure system as compared to open hemorrhoidectomy as shown in table No.2 in all the 3 outcomes.

Similarly, blood loss is significantly lower in the LigaSure technique compared to conventional techniques. The primary reason for this reduced blood loss is the LigaSure system's ability to effectively seal blood vessels with minimal thermal spread, resulting in smaller and more controlled surgical injuries, which in turn reduces bleeding 19. Our study results shows significant statistically difference (p<0.001), showing the efficiency of the LigaSure system as compared to open hemorrhoidectomy as shown in table No. 2. Multiple other studies, (11, 15, 16, 17, 18, 19). Have also reported similar findings. These studies consistently highlight that the LigaSure device reduces blood loss by providing precise and effective vessel sealing, thereby improving overall surgical outcomes and reducing intraoperative complications.

Our study results shows significant statistically difference (p<0.001), in mean hospital stay showing the efficiency of the LigaSure system as compared to open hemorrhoidectomy as shown in table No.2 as shown in others studies (16, 17, 18, 19).

In terms of pain VAS (Visual Analog Scale) scores, multiple studies have reported lower pain scores with the LigaSure technique compared to traditional methods. Our study corroborates these findings, providing a comprehensive view of pain relief over a 28-day period posthemorrhoidectomy. The VAS pain scores in our study are significantly lower for patients undergoing the LigaSure technique, starting from the day of surgery. Pain gradually diminishes after the 14th day, with very few patients reporting minor pain on the 28th day. This reflects a thorough and sustained pain relief achieved with the LigaSure method. The consistent reduction in pain scores highlights the effectiveness of the LigaSure device in minimizing postoperative discomfort and enhancing patient recovery. Our study results shows significant statistically difference (p<0.001), showing the efficiency in term of low pain score of the LigaSure system group as compared to open hemorrhoidectomy group as shown in table No.2. Multiple studies (15, 16, 17, 18, 19, 20) have shown lower VAS pain scores with the LigaSure technique. These studies attribute the reduced pain to the device's ability to minimize tissue trauma and inflammation.

In this study, we conducted stratified analyses of postoperative pain at various intervals (0, 1, 7th, 14th, and 28th POD days) across different age groups, genders, and grades of haemorrhoids to assess their correlation with postoperative complications. Among patients aged 50-59, those undergoing LigaSure hemorrhoidectomy consistently reported lower Visual Analog Scale (VAS) scores, indicating less pain, compared to those undergoing Milligan-Morgan hemorrhoidectomy, which reported higher VAS scores across all observation dates. However, the p-values exceeded 0.05 in all cases, suggesting nonsignificance statistically.

Regarding gender stratification, male patients reported higher VAS scores in both treatments, though the differences were not statistically significant, likely due to the higher number of male patients enrolled, except on28th POD, VAS score was more in male patients as compared to female patients in case of Milligan Morgan technique, which was statistically significant as P value is 0.035 as shown in table NO. 3. Stratification based on the grade of hemorrhoids revealed no significant difference in VAS scores between Grade 3 and Grade 4 patients undergoing LigaSure hemorrhoidectomy. Conversely, patients undergoing Milligan-Morgan hemorrhoidectomy displayed higher VAS scores, particularly among Grade 4 patients.

Conclusion

In conclusion, LigaSure haemorrhoidectomy emerges as a superior technique compared to the conventional Milligan-Morgan method, offering significant reductions in operative time, postoperative pain, and blood loss. These improvements suggest that LigaSure technology can enhance patient care and surgical outcomes in the treatment of advanced haemorrhoidal disease. Adoption of this technique in clinical practice could lead to better patient satisfaction and more efficient use of healthcare resources.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript. Ethics approval and consent to participate Approved by the department Concerned. (IRBEC-NHMMO-1233/23) Consent for publication Approved Funding Not applicable

Conflict of interest

The authors declared absence of conflict of interest.

Author Contribution

UZMA SHAHEEN (MBBS)

Coordination of collaborative efforts. Study Design, Review of Literature. MUHAMMAD SABIR MBBS (MBBS)

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Conception of Study, Development of Research Methodology Design, Study Design,, Review of manuscript, final approval of manuscript. Conception of Study, Final approval of manuscript. SHAHID HUSSAIN (MBBS) Manuscript revisions, critical input. Coordination of collaborative efforts. JAMIL AHMAD TAHIR (MBBS)

Data acquisition, analysis. Manuscript drafting. NAVEED AKHTAR (Professor) Data entry and Data analysis, drafting article. UZMA RASHEED Data acquisition, analysis. Coordination of collaborative efforts.

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