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Research Article

Comparison of Pedicle Coagulation Haemorrhoidectomy with Ligasure vs Conventional Milligan Morgan Haemorrhoidectomy in Reducing Post-Operative Pain among Patients of 3rd and 4th Degree Haemorrhoids: a Randomised Controlled Trial

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Abstract:

Background:

Hemorrhoids refer to the abnormal enlargement of the anal cushions. They are a common anorectal problem with a prevalence of 5% in the general population aged greater than 40 years. The objective of this study was to compare Milligan Morgan open hemorrhoidectomy with pedicle ligation with LigaSure in terms of postoperative pain on day 1 and day 7.

Materials and methods:

It was a randomised controlled trial conducted in Department of surgery, Rawalpindi, Pakistan. A total of 100 patients were selected and were allotted into the two groups by lottery method. Patients aging from 15 to 60 years who presented with the symptomatic third, and fourth-degree hemorrhoids were included after taking informed consent. Patients who had a previous or concomitant anorectal disease, patients who had undergone previous surgery for hemorrhoids and those who were anesthetically unfit for surgery (American Society of Anesthesiologists (ASA) class 3 or above) were excluded from the study. Data was entered and analyzed using SPSS v. 23.0. Chi-square tests were applied. P-value <0.05 was taken statistically significant.

Results:

Out of 100 patients, 68 (68%) were males while 32 (32%) were females. Mean age was 40.56±9.24 years. Postoperative pain at day 1 was 9.24±0.51 in Milligan Morgan group while that in LigaSure group was 8.44±0.64 (p<0.0001). Postoperative pain at day 7 was 5.00±0.85 in Milligan Morgan group while it was 3.04±1.08 in LigaSure group (p<0.0001).

Conclusion:

Postoperative pain is much lower in the LigaSure group as compared to Milligan Morgan open hemorrhoidectomy.

keywords: hemorrhoids; hemorrhoidectomy; pain

Introduction

Haemorrhoids are normally found in the human body [1-3]. Internal hemorrhoidal plexus gives rise to internal haemorrhoids whereas external hemorrhoidal plexus gives rise to external haemorrhoids. Anatomically, the internal hemorrhoidal plexus is separated from the external one by the dentate line [1,2,4]. Normally, the internal hemorrhoidal plexus consists of three soft vascular cushions known as anal cushions or "haemorrhoids" [5,6]. Thus, the term "internal haemorrhoids" is not a disease according to the anatomical definition but clinically, this term means the abnormal enlargement of these anal cushions [2,5,6]. Haemorrhoids are a common anorectal problem with a prevalence of 5% in the general population aged greater than 40 years [7]. Haemorrhoids are the fourth leading outpatient gastrointestinal diagnosis, accounting for approximately 3.3 million ambulatory care visits in the United States [8].

Symptoms of haemorrhoids include bright red painless per rectal bleed, mucus discharge, and prolapsed anal mucosa. If left untreated, they may lead to complications like strangulation, thrombosis, ulceration, gangrene, fibrosis or portal pyaemia [9]. A haemorrhoidectomy is the standard

treatment for patients with grade III or IV internal haemorrhoids [10]. Milligan Morgan open haemorrhoidectomy remains a very popular treatment modality for third and fourth-degree haemorrhoids due to its cost-effectiveness and good long-term results. The complications include blood loss leading to prolonged operative time, postoperative pain leading to a prolonged hospital stay, a greater requirement for analgesics and delayed return to work or daily activities [9]. With recent advances, haemorrhoidectomies are now being performed with new devices, such as bipolar electro-thermal devices, ultrasonic scalpels, and circular staplers.

The LigaSure is a novel device consisting of a bipolar electro-thermal device with an optimized combination of pressure and radiofrequency, with ability to seal blood vessels up to 7mm in diameter and associated with a collateral thermal injury confined to 2mm over the surgical field. This confined spread decrease reflex anal spasm and a bloodless haemorrhoidectomy is possible with reduced postoperative pain and rapid healing. Thus, this operation can be advocated as the ideal technique because of the potentially decreased collateral tissue trauma [11]. Among the postoperative complications, many patients experience postoperative pain after undergoing a haemorrhoidectomy and many patients complain of discomfort for a long time [12]. The efficacy of haemorrhoidectomy by LigaSure is better than the traditional Milligan Morgan haemorrhoidectomy but we need more clinical trials with large sample size and long-term follow-ups to show that LigaSure is better than Milligan Morgan haemorrhoidectomy [11].

The aim of this study is to evaluate the LigaSure pedicle coagulation in comparison with conventional Milligan Morgan haemorrhoidectomy pedicle ligation and if proved effective it will result in less postoperative pain, more patient satisfaction and less requirement of analgesia

Materials and Methods:

This study was a randomised controlled trial conducted at Department of Surgery from 10th October 2021 to 10th April 2022. A total of 100 patients were divided into two groups of 50 each and were randomly allotted into one of the two groups by lottery method. Group A comprised of patients undergoing Milligan Morgan open haemorrhoidectomy and group B comprised of patients who underwent pedicle coagulation by LigaSure. Both male and female patients aged 15 to 60 years, who presented with symptomatic third, and fourth-degree haemorrhoids were included after taking informed consent. Patients who had a previous or concomitant anorectal disease, patients who had undergone previous surgery for haemorrhoids, and those who were anaesthetically unfit for surgery (ASA class 3 or above) were excluded from the study.

After administering standardized spinal or general anesthesia the procedure was carried out with the patient in the lithotomy position. After examination under anesthesia, haemorrhoids were delivered with the help of artery forceps. One of the artery forceps was applied at the mucocutaneous junction of haemorrhoid and the other at the apex of hemorrhoidal tissue. A skin incision was given at the base of haemorrhoids and dissection was done to separate the hemorrhoidal tissue from the internal anal sphincters. After this, in the Milligan Morgan's open technique, the haemorrhoid pedicle was transfixed with zero number Vicryl suture while in the other group the haemorrhoid pedicle was coagulated with the help of LigaSure.

Post Operatively patient was given ketorolac injection 30 mg 8 hourly and pain was recorded on visual analog pain score ranging from 0 to 10 after 24hrs. Follow-up was done on the seventh postoperative day in the surgical outpatient department. Mean post-operative pain was calculated. This randomised controlled trial was done in accordance with CONSORT guidelines [13].

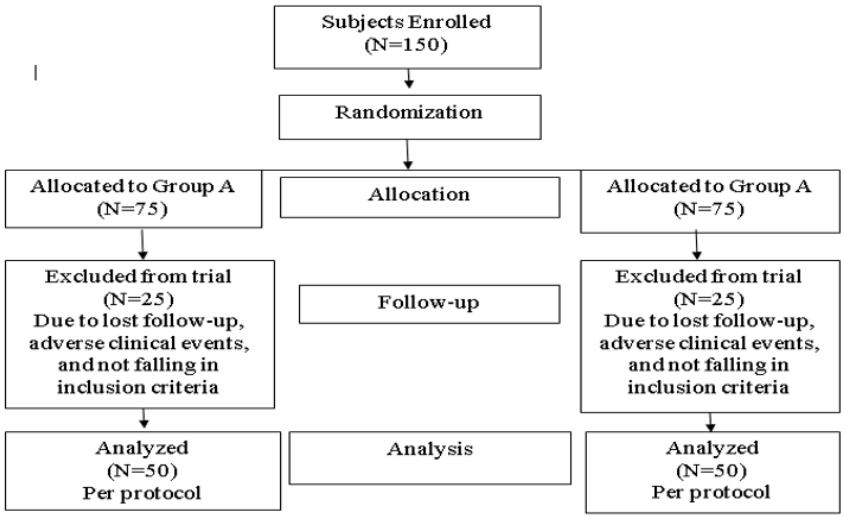

Figure 1: Showing the CONSORT flow chart of study selection

Data analysis:

The collected data was entered in Statistical Package for Social Sciences (version 20.0). Qualitative variables like gender, ASA grade, and grade of haemorrhoids were measured as frequencies and percentages. The quantitative variables like age and postoperative pain were measured as

mean ± SD. Independent samples t-test was used to compare postoperative pain in both groups. Effect modifiers like age, gender ASA class, and grade of haemorrhoids were controlled by stratification. Post-stratification chi-square test was applied. P-value ≤ 0.05 was significant.

Results:

A total of 100 patients were included in the study out of which 68 (68%) were males whereas 32 (32%) were females. Both genders were equally distributed within the study groups. There were 34 males and 16 females in each of the two groups. Mean age of the study participants was 40.56±9.24 years. Mean age of the patients in group A (Milligan Morgan open haemorrhoidectomy) was 43.84±9.98 years and that in group B (pedicle coagulation by LigaSure) was 37.28±7.15 years. Out of 100 patients, 82 (82%) belonged to ASA class I while the rest 18 (18%) were

of ASA class II. Thirty-six out of 82 (43.9%) in ASA class I and 14/18 (77.78%) in class II were in study group A. Forty-six out of 82 (56.1%) in class I and 4/18 (22.22%) in class II were in study group B.

Eighty-four out of 100 (84%) patients had grade 3 haemorrhoids while 16/100 (16%) had grade 4 haemorrhoids. Out of 84 patients with grade 3 haemorrhoids, 38 (45.24%) were in study group A while 46 (54.76%) were in study group B. Similarly, out of 16 patients with grade 4 haemorrhoids 12 (75%) were in group A while 4 (25%) were in group B.

Post-operative pain at day 1 was 9.24±0.51 in Milligan Morgan group while that in the LigaSure group was 8.44±0.64. This difference of mean postoperative pain at day 1 was statistically significant between the two groups ($p<0.0001$). Post-operative pain at day 7 was 5.00±0.85 in Milligan Morgan group while it was 3.04±1.08 in LigaSure group. Mean post-operative pain at day 7 was also statistically significant between the two groups ($p<0.0001$). Comparison of mean postoperative pain in both study groups is shown in Figure-2.

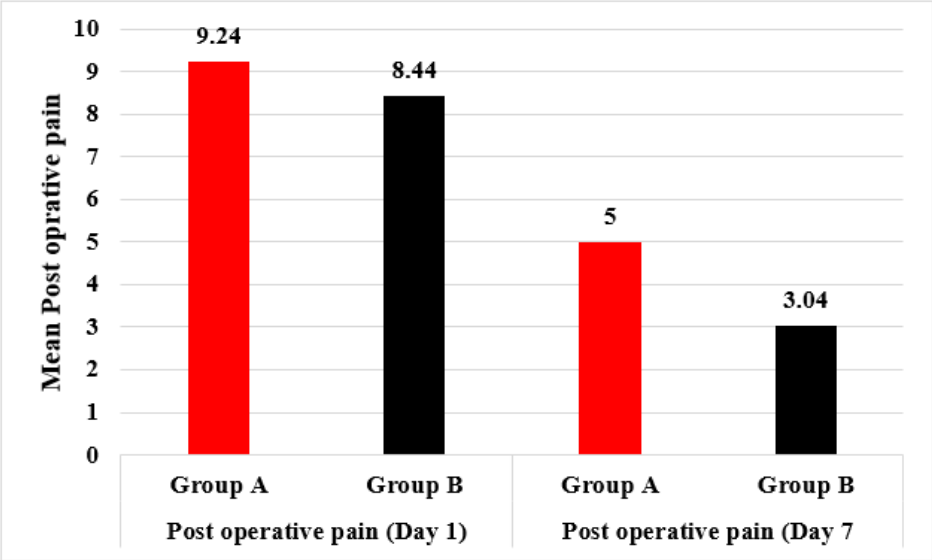

Figure 2: Comparison of mean postoperative pain at day 1 and day 7 in the patients undergoing Milligan Morgan Open Haemorrhoidectomy (Group A) and pedicle coagulation by LigaSure (Group B).

The results of stratification for postoperative pain at day 1 and day 7 with regards to age, gender, ASA class, and haemorrhoids grades are shown in Table-1.

Dependent variables (Outcome variables)	Independent variables (Explanatory variables)	Groups	Milligan Morgan Open Hemorrhoidectomy	Pedicle Coagulation by LigaSure	P value
Postoperative pain at Day 1	Age	15 – 25 years	8.00+0.00	8.12±0.53	0.014
		26 - 60 years	8.88+0.00	8.08±0.88	
Postoperative pain at Day 7		15 – 25 years	2.00+0.00	6.26±0.19	0.002
		26 - 60 years	4.10+1.34	7.21±0.31	
Postoperative pain at Day 1	Gender	Male	8.85±0.94	8.12±0.44	0.791
		Female	8.81±0.09	8.01±0.18	
Postoperative pain at Day 7		Male	4.06+1.42	4.35±0.86	0.685
		Female	3.94±1.31	3.91±0.81	
Postoperative pain at Day 1	ASA Grade	Grade I	8.78±0.68	8.12±0.61	0.072
		Grade II	9.11±0.75	9.06±0.08	
Postoperative pain at Day 7		Grade I	3.85±1.43	5.26±0.03	0.01
		Grade II	4.78±0.80	6.12±0.44	
Postoperative pain at Day 1	Hemorrhoids Grade	Grade 3	8.76±0.68	7.12±0.21	0.011
		Grade 4	9.25±0.68	6.02±0.15	
Postoperative pain at Day 7		Grade 3	3.93±1.32	4.16±0.03	0.131
		Grade 4	4.50±1.63	4.51±1.64	

Table 1: Stratification for postoperative pain at day 1 and day 7 with regards to age, gender, ASA class, and Haemorrhoids grades.

Discussion

Haemorrhoidectomy is an effective treatment for 3rd and 4th-degree haemorrhoids [14]. However, many patients avoid haemorrhoidectomy as

it is associated with painful postoperative recovery [11]. Many other procedures are also used including laser therapy, stapled haemorrhoidectomy, open or closed sharp excision, and ultrasonic scalpel dissection [15-18]. LigaSure is a newer technique which helps to reduce complications as compared to other traditional haemorrhoidectomy procedures [19,20]. In our study haemorrhoids was more common in males (68%) as compared to females (32%). This is similar to results shown by Ravindranath et al., where 66.67% were males while 33.33% were females [21]. In a study by Ali et al., 55% of males had haemorrhoids as compared to 45% females [22].

In our study, the mean age of the patients with haemorrhoids was 40.56 years. This is in consistency with the study by Ravindranath et al., where the mean age was below 40 years of age [21]. Ali et al. showed that the most common age group who presented with haemorrhoids was 20-39 years [22]. In contrast to this, Khan et al. showed that patients aged above 40 years were more at risk as compared to those below 40 years [23].

In our study mean score of post-operative pain at day 1 was 9.24 in open haemorrhoidectomy group as compared to the mean pain score of 8.44 in pedicle ligation with the LigaSure group. Bakhtiar et al. also reported higher pain score in Milligan Morgan group (5.41) as compared to the LigaSure group (3.65) [11]. At day 7, the mean pain score was five in Milligan Morgan group as compared to the mean score of 3.04 in LigaSure group in our study. Similarly, in the study by Bakhtiar et al. mean pain score at 7th postoperative day was higher in Milligan Morgan group (2.44) as compared to LigaSure group (1.34) [11]. This shows that LigaSure is a relatively pain-free technique as compared to Milligan Morgan open haemorrhoidectomy.

The results of stratification showed that post-operative pain at day 1 was higher in the age group 26-60 years (8.88) as compared to age group 15-25 years (8.00) in the Milligan Morgan group. Similarly, post-operative pain at day 7 was also higher in the age group 26-60 years as compared to 15-25 years in both the study groups Postoperative pain at day 1 was higher in grade 4 haemorrhoids (9.25) as compared to grade 3 haemorrhoids (8.76) in the Milligan Morgan group. Whereas post-operative pain at day 7 was more in grade 3 (7.12) as compared to grade 4 haemorrhoids (6.02) in the LigaSure group.

Conclusion:

The study concluded that pedicle coagulation with LigaSure was better as compared to conventional Milligan-Morgan haemorrhoidectomy in terms of mean postoperative pain at 1st day and 7th day which helps in more patient satisfaction and lesser requirement of analgesia.

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Conflict of Interest

None to declare.

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