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Original Article

Comparison of complications and safety of hemorrhoidectomy with ligasureand hemorrhoidectomy with ferguson: a randomized controlled clinical trial study

Yaser Dadpour Roudi¹, Hamid Salehiniya², Zabihullah Mohaqiq³, Mohsen Najmodini¹

- ¹Department of Surgery, School of Medicine, Birjand University of Medical Sciences, Birjand, Iran
- ² Social Determinants of Health Research Center, Birjand University of Medical Sciences, Birjand, Iran
- ³ Student Research Committee, Birjand University of Medical Sciences, Birjand, Iran

Corresponding Author:

Tel: +98 5632226776

Email: <u>Dr.mohsen_najmaddini@yahoo.com</u>

Abstract

Introduction: Hemorrhoid is one of the most common anorectal diseases which affects 5% of the general population. Complications and pain are inevitable after all surgeries with different intensities and degrees. Management and control of these complications is one of the most important aspects of postoperative care. There are surgical techniques and interventions for the treatment and control of pain after hemorrhoid. According to the contradictory results of the studies on surgical methods, the present study aimed to compare the effectiveness, complications, and safety of hemorrhoidectomy with Ligasureand Ferguson hemorrhoidectomy.

Methods: The study sample in this randomized controlled clinical trial studyincluded54 patientswhowere randomly divided into two groupsofLigasureandFerguson surgery. Prior to the surgery, patients were educated abouttheVisual Analogue Scale(VAS). Patients underwent general anesthesia and the same surgeon performed the surgery in both groups. Immediately after the surgery (oncethe patient regainedconsciousness and understoodthe environment), 6, 12, and 24 hours after the surgery, patients' pain and complications were assessed. The collected data were analyzed using SPSS software (version 18)through independent t-test, Mann-Whitney, Friedman, Chi-square and Fisher's exact test at a significance level of α =0.05.

Results: The mean bleeding during the surgery was significantly lower in the Ligasuregroupthan the Ferguson group. The mean pain at 0, 6, 12, and 24 hafterthe surgery was not significantly different between the two groups. Postoperative complications were significantly higher in the Ligasuregroup than the Ferguson group.

Conclusion: Ligasurehemorrhoidectomy is not superior to the Ferguson method in terms of analgesia up to 24 h after the surgery; however, this method of surgeryis preferable to the Ferguson method in terms of bleeding during the surgery.

Keywords: Fergusonprocedure, Hemorrhoidectomy, Ligasure Procedure

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Introduction

Hemorrhoid is one of the most common diseases of the gastrointestinal tract, which causes pain and bleeding due to local damage to the veins in the anal area during defecation (1-2). It is one of the most common anorectal diseases, affecting 5% of the general population and about 50% of people over the age of 50 who complain of symptoms associated with the disease (3). The ideal and standard treatment for hemorrhoids is surgery. Conventional open or closed hemorrhoidectomy is one of the most common methods of hemorrhoid surgery; however, this method has a long and painful treatment period and is involved with complications, such as bleeding, stenosis, and recurrence (4). Anal surgery is usually performed on an outpatient basis and the main reason for this is the lack of control over postoperative pain and related problems (5-7). Similar to other methods of treatment, this surgery has a number of complications, such as pain, bleeding, urinary retention, infection, compression and density of stool, and damage to the internal sphincter (8). In the meantime, it seems that several factors are involved in the occurrence of such complications as patient tolerance, surgical techniques, type of anesthesia, as well as analgesia used after hemorrhoidectomy(9-10).

One of the most important complications of surgery is pain which is described as an unpleasant emotional experience associated with actual or perceivedtissue damage(11), which is one of the most annoying problems after all types of surgery and can have adverse physiological effects.

Reduction of pain after hemorrhoidectomy hasalways been veryimportant, sincepainisthe most common problem of patients with hemorrhoidsafter thesurgery, especially in the first and second days post-surgery. Therefore, effective and appropriate treatment of the disease prevents adverse and psychological consequences.

New tools and techniques were developed to reduce complications. Theseincludebipolar electrothermal (scalpel), scalpel ultrasound, and circular stapler which are effective in the treatment of hemorrhoids(12-13). Prevention and treatment of complications, especially pain, after surgery is one

of the main issues in the surgical wards and plays an important role in the acceleration and improvement ofthe general condition of patients admitted to the surgical ward.

According to the contradictory results of studies conducted on these two surgical methods, this study was performed to evaluate the effectiveness, complications, and safety of hemorrhoidectomy with Ligasurecompared to a conventional hemorrhoidectomy.

Materials and Methods

In total, 54 patients with grade 3 and 4 hemorrhoids and ASA classes 1 and 2 wereincluded in this clinical trial study throughconveniencesampling. Inclusion criteria includedno history of liver, kidney, bronchial asthma, gestational hypertension, preeclampsia, and coagulation disorders. However, the exclusion criteria includedpatients'leaving the study, concomitancy of hemorrhoids with other perianal problems, or any other unpredictable event for patients. Writteninformed consent was obtained from all patients or their relatives, and thestagesof the study, as well as objectives, were explained to the patients or their companions. The reluctance of patients to participate in the study had no effect on their treatment process. Placement of patients in each group was randomly simplified and blocked. Patients were divided into two groups: Ferguson (A) surgery or Ligasure(B) surgery. Initially, various quadrilateral blocks were created (AABB, BBAA, ABAB, BABA, ABBA, and BABA). Afterward, one of these blocks was randomly selected and the patients were divided into one of two groups of surgeries by A or B method. Moreover, randomization was performed for other patients.

Theintervention in this study included two methods of Ferguson and Ligasuresurgery, which is a new surgical method in the treatment of hemorrhoids. The study was double-blind; therefore, the patient and outcome assessor (surgery resident) didnot know about the surgery procedure. The surgeries were performed in a lithotomy position by a surgeon. 2 cc of buprenorphine was injected into the L4 and L5 vertebrae with a 25 gauge needle for spinal

anesthesia. Postoperative complications including retention, postoperative bleeding, the urinary amount of pain, duration of hospitalization, incontinence, nausea, and vomiting were assessed and recorded by a nurse who was ignorant of the type of surgery,immediatelyand one day after the operation. The mean bleeding during the operation was estimated based on the amount of suctioned blood stored at the suction tank, as well as the surgical field and the number of used gauzes. It wasassumedthateach bloody gauze absorbedabout 20 cc of thelostblood. Due to the limited amount of bleeding in most patients, long gauzesweredivided into 4 equal parts and the amount of bleeding was measured based on the impregnation of these pieces of gauze (5 cc). Furthermore, the blood of the operation field, the surgical seam, and the bleeding of the drain were estimated by the surgeon as well and added to the above values. The mean pain score after transferring patients to the recovery section and the recovery of each patient was examined in terms of visual assessment criteria at 0 hours (when the patient regains consciousness and can perceive the environment), 6, 12, and 24 hours after the surgery using Visual Analogue Scale (VAS) form. Subsequently, the results of each patient evaluation were recorded in a checklist for each patient. A 10-point graduated ruler is used in this method that scores the pain as 1)0:no pain,2)between1-4: mild pain, 3)between 5-8: moderate pain, 4)between 9-10: Severe pain. The pain intensity of patients in both groups was recorded accordingly.

Data were analyzed in SPSS software (version 18). Descriptive results were reported as mean±SD

(dispersion index) and relative frequency. The Shapiro-Wilk test was used to examine the normal distribution of data (only the age of the distribution was normal) along with an independent t-test or Mann-Whitney test. Friedman's test was utilized to compare pain at different times. Moreover, Chi-square test or Fisher's exact test was adopted to analyze the qualitative variables. A p-value less than 5% was considered statistically significant.

The study protocolwasapproved by the Ethics Committee of Birjand University of Medical Sciences, Birjand, Iran(Ir.bums.REC.1398.336). The study was also registered on the Iranian clinical trial site (IRCT20190618043934N3).

Alltheobtained information was kept confidential and only an onymous information was used in the reported results. Participation in the study was based on willingness, and patients could with draw from the study at any stage if they did not wish to continue.

Results

In this study, 54 patients with hemorrhoids were divided into two groups of Ferguson and Ligasuresurgery. The mean±SD age of these two groups was estimated at 45.0±13.6 and 42.5±14.9 years, respectively. There was no significant difference between these two groups in terms of the mean age (P=0.521) and gender frequency distribution (P=0.785).

According to the results of the present study, the postoperative period in the Ligasuregroup was significantly longerthanthat in the Ferguson group (P<0.05; Table 1).

Table 1. Comparison of the frequency distribution of postoperative complications in patients participating in the study

	Postoperativecomplications		
Group	N (%)		
	Yes	No	
Ligasure	6 (22.2)	21 (77.8)	
Ferguson	0 (0)	27 (100)	
P-Value*		P=0.023	

^{*}Chi-square test

According to the results of the study presented in (Table 2), the mean duration of surgery in Ligasureand Ferguson methods were not significantly different (P=0.056). The mean length of hospital stay in patients of the Ferguson group

was significantly shorter than those of patients in the Ligasuregroup (P=0.016). In addition, the mean bleeding rate in the ligation surgery group was significantly lower than that in the Ferguson group (P=0.001; Table 2).

Table 2. Comparison of mean duration of surgery, length of hospital stay, and bleeding in the studied patients

	Duration of surgery (minutes)	Duration of hospitaliza- tion (days)	Bleeding (CC)
	median (q1-q3)	median (q1-q3)	median (q1-q3)
Ligasure	25 (20 -30)	1 (1-2)	0 (0-10)
Ferguson	25 (35 – 25)	1 (1-1)	10 (10-20)
P-Value*	P=0.056	P=0.016	P=0.001

^{*}Mann-Whitney Test

According to the results of the study, the mean pain immediately (P=0.239), 6 (P=0.692), 12 (P=0.164), and 24 (P=0.107) h after the surgerywerenot significantly different in the two

groups. Regarding the results of the Friedman test, the mean pain was significantly reduced in the two groups during the evaluation period(Plig<0.001, P Fer<0.001; (Table 3).

Table 3. Comparison of mean pain scores at 0, 6, 12, and 24 hours after hemorrhoidectomy in patients

	Ligasure	Ferguson	
	median (q1-q3)	median (q1-q3)	P-Value*
Immediately after surgery	8 (7-9) abc	7 (7-8) e bc	P=0.239
6 hours after surgery	6 (5-7) ^d	6 (5-7) ^f	P=0.692
12 hours after surgery	4 (3-5)	5 (4-6) ^g	P=0.164
24 hours after surgery	3 (2-4)	4 (3-5)	P=0.107
P-Value **	P<0.001	P<0.001	

^{*}Mann-Whitney test

Discussion

In the present study, the mean duration of surgery in the two groups was not significantly different (P>0.05). In the studies conducted by Zare (2014) (14), Rahmani et al. (4), Fareed et al.(15) (2009), and Khanna et al.(16) (2010), it has been reported that the

duration of surgery in patients in the Ligasuregroup was significantly shorterthanthat in the traditional surgery group (P<0.05), which was inconsistent with the results of the present study. However, this discrepancy can be attributed to differences in the surgeon's skill, differences in the used facilities,

^{**} Freidman Test

a:Significant difference in data between 0 and 6 hours, P<0.001

b: Significant difference in data between 0 and 12 hours, P<0.001

c: Significant difference in data between 0 and 24 hours, P<0.001

d: Significant difference in data between 6 and 24 hours, P<0.001

e: Significant difference in data between 0 and 6 hours, P=0.005

f: Significant difference in data between 6 and 24 hours, P<0.001

g: Significant difference in data between 12 and 24 hours, P=0.031

and thetypeofLigasurein different studies, and the demographic characteristics of the patients. The mean length of hospital staysafterFerguson surgery was significantly shorter than that in the Ligasuregroup (P<0.05). In a study conducted by Zare(14), Mitiligo et al. (2002) (17), Ghorbanpour et al. (2014) (18), and Fareed et al.(15)there wasno significant difference in terms of duration of hospitalization in the two groups (P>0.05) which was not consistent with the results of the presentstudy. This discrepancy can be due to the differences in the demographic characteristics of the studies, as well as differences in the skill level of the surgeons, and such factors as drug addiction, differences in the typeofLigasure, and the degree of hemorrhoids.

Based on the results of the study conducted by Ghorbanpour et al. (18)the mean intraoperative bleeding in the two groups was not significantly different (P>0.05), which was inconsistent with the presentstudy. However, one week after the surgery bleedingwas significantly less in the Ligasuregroup, compared to that in the Ferguson group (P<0.05) which was in line with the results of the present study. The average amount of bleeding in the Ligasure method is expected to be less than that in other conventional methods due to the fact that Ligasureisa tool that removes tissue and establishes homeostasis at the same time. Complications after Ligasuresurgery were significantly higher compared to Ferguson surgery. The results of the studies conducted by Zare(14) and Ghorbanapour et al. (18)revealedthat postoperative complications in the two studied methods (Ligasuremethod andanother traditional method inZare study and Ferguson method in the study by Ghorbanpour) were not significantly different (P>0.05) which was inconsistent with the results obtained in the present study.

This discrepancy can be explained by differences in the demographic characteristics of patients and differences in the experience of the two surgeons. In a study conducted by Tan et al. (2008) (19), it has been reported that postoperative complications were observed in patients undergoing Ligasuresurgery, while in the open hemorrhoidectomy group,

no complications were observed, which was in linewiththe findings in this study.

In the currentstudy, burn wounds, anal stenosis, and fissures were observed in patients undergoing Ligasuresurgery. In the same line, Ghorbanpour et al. reported that anal stenosis was observed in patients undergoing Ligation surgery.

The mean amount of pain at 0 and 6 h after the surgery was not significantly different in the two groups (P>0.05). Zare(14), reported that the mean pain in patients ofthe two groups of Ligasureand traditional surgery was not significantly different 6 h after the surgery(P>0.05) which wasinline with the obtained results in the presentstudy.

The mean pain 12 and 24 h after the surgery was not significantly different in the Ligasuregroup compared to that in the Ferguson group (P>0.05). In the study conducted by Zare(14), Tan et al. (19), and Rahmani et al.(4) (2012) the mean amount of pain up to 24 h after the surgery was not significantly different in the study groups(P>0.05). However, after this time, the amount of pain in the Ligasuresurgery was significantly lower than that in the traditional group (P<0.05), which was in line with the results of the present study.

In a study conducted by Mitiligo et al. (17), Fareed et al. (15), Khanna et al. (16), and Ghorbanapour et al. (18), it was reported that the average pain in patients undergoing ligation surgery was significantly lower, compared to that in the traditional group (P<0.05) which wasnot in linewiththisstudy. This discrepancy can be due to differences in the experience of the two surgeons, demographic characteristics of patients, as well as factors such as drug addiction, type of Ligasure, equipment, and facilities, the amount of tissue trauma, and the degree of hemorrhoids that can affect the amount of pain after the surgery. Some factors may not have been considered and evaluated in this study and those of others, since there is virtually no evaluation forsome of these parameters. According to the comparison of the results of This study, it can be stated that in patients with hemorrhoidsthat underwent surgery by Ligasure, the amount of pain wasless compared to other conventional methods employed for the treatment of

conventional

this disease. However, no difference can be observed in this regard between this surgery method and other conventional methods in the first hour after the surgery.

Regarding the limitation of the present study, one can refer to the poorcooperation of patients after discharge from the hospital.

Conclusion

Based on the obtained results in this study it can be concluded that although the Ligasure method is not superior to the Ferguson method in terms of analgesia up to 24 h after the surgery, this method of surgery is preferable to the Ferguson method in terms of bleeding and long-term analgesia. Therefore, it is suggested that considering the surgeon's skill and the demographic characteristics of patients, the type of surgery for each patientshould be selected by the surgeon.

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Conflict of interest

The authors declare that they have no conflict ofinterest regarding the publication of the present study.

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