



Original Article

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

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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 Ligasure and Ferguson hemorrhoidectomy.

Methods: The study sample in this randomized controlled clinical trial study included 54 patients who were randomly divided into two groups of Ligasure and Ferguson surgery. Prior to the surgery, patients were educated about the Visual Analogue Scale (VAS). Patients underwent general anesthesia and the same surgeon performed the surgery in both groups. Immediately after the surgery (once the patient regained consciousness and understood the 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 $\alpha=0.05$.

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

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

Keywords: Ferguson procedure, 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 perceived tissue 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 has always been very important, since pain is the most common problem of patients with hemorrhoids after the surgery, 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. These include bipolar 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 of the 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 Ligasure compared to a conventional hemorrhoidectomy.

Materials and Methods

In total, 54 patients with grade 3 and 4 hemorrhoids and ASA classes 1 and 2 were included in this clinical trial study through convenience sampling. Inclusion criteria included no history of liver, kidney, bronchial asthma, gestational hypertension, preeclampsia, and coagulation disorders. However, the exclusion criteria included patients' leaving the study, concomitancy of hemorrhoids with other perianal problems, or any other unpredictable event for patients. Written informed consent was obtained from all patients or their relatives, and the stages of 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.

The intervention in this study included two methods of Ferguson and Ligasure surgery, which is a new surgical method in the treatment of hemorrhoids. The study was double-blind; therefore, the patient and outcome assessor (surgery resident) did not 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 urinary retention, postoperative bleeding, the 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, immediately and 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 was assumed that each bloody gauze absorbed about 20 cc of the lost blood. Due to the limited amount of bleeding in most patients, long gauzes were divided 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) between 1-4: 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 \pm 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 protocol was approved 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).

All the obtained information was kept confidential and only anonymous information was used in the reported results. Participation in the study was based on willingness, and patients could withdraw 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 Ligasure surgery. The mean \pm SD age of these two groups was estimated at 45.0 \pm 13.6 and 42.5 \pm 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 Ligasure group was significantly longer than that 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

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

*Chi-square test

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According to the results of the study presented in (Table 2), the mean duration of surgery in Ligasure and 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 Ligasure group ($P=0.016$). 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) median (q1-q3) | Duration of hospitalization (days) median (q1-q3) | Bleeding (CC) 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 surgery were not 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 ($P_{lig} < 0.001$, $P_{fer} < 0.001$; (Table 3).

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

| | Ligasure median (q1-q3) | Ferguson median (q1-q3) | P-Value* |
|---------------------------|--|--|-----------------|
| Immediately after surgery | 8 (7-9) ^{a b c} | 7 (7-8) ^{e b c} | $P=0.239$ |
| 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

** 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, $P=0.031$

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 Ligasure group was significantly shorter than that 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,

and the type of Ligasure in different studies, and the demographic characteristics of the patients. The mean length of hospital stays after Ferguson surgery was significantly shorter than that in the Ligasure group ($P < 0.05$). In a study conducted by Zare (14), Mitiligo et al. (2002) (17), Ghorbanpour et al. (2014) (18), and Fareed et al. (15) there was no significant difference in terms of duration of hospitalization in the two groups ($P > 0.05$) which was not consistent with the results of the present study. 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 type of Ligasure, 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 present study. However, one week after the surgery bleeding was significantly less in the Ligasure group, 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 Ligasure is a tool that removes tissue and establishes homeostasis at the same time. Complications after Ligasure surgery were significantly higher compared to Ferguson surgery. The results of the studies conducted by Zare (14) and Ghorbanpour et al. (18) revealed that postoperative complications in the two studied methods (Ligasure method and another traditional method in Zare 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 Ligasure surgery, while in the open hemorrhoidectomy group,

no complications were observed, which was in line with the findings in this study.

In the current study, burn wounds, anal stenosis, and fissures were observed in patients undergoing Ligasure surgery. 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 of the two groups of Ligasure and traditional surgery was not significantly different 6 h after the surgery ($P > 0.05$) which was in line with the obtained results in the present study.

The mean pain 12 and 24 h after the surgery was not significantly different in the Ligasure group 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 Ligasure surgery 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 Ghorbanpour 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 was not in line with this study. 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 for some of these parameters. According to the comparison of the results of this study, it can be stated that in patients with hemorrhoids that underwent surgery by Ligasure, the amount of pain was less compared to other conventional methods employed for the treatment of

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 poor cooperation 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 patient should be selected by the surgeon.

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Conflict of interest

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

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