Comparison of Outcome of LigaSure Hemorrhoidectomy with Conventional Milligan-Morgan Hemorrhoidectomy

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ABSTRACT

Introduction : Hemorrhoidal disease is nearly present in 5% of the community and more likely after the age of 40. Pain is one of the most distressing symptom of conventional treatment of hemorrhoids Different treatment methods are used for hemorrhoids, Surgery is indicated for the third and fourth grade hemorrhoidal disease. We compared the outcome of conventional Milligan Morgan hemorrhoidectomy for symptomatic third and fourth grade hemorrhoids. Materials and methods: This is a randomized control study in which 60 patients with symptomatic third and fourth-grade hemorrhoids were included results are compared regarding pain ,bleeding ,operative time ,healing time and postoperative complications. Results: The mean age of the conventional group patients was 36.5 ± 4.9 years with a male: female ratio of 21:9 while the mean age of LigaSure group patients was 37.30 ± 4.03 years with a male: female ratio of 19:11 In conventional hemorrhoidectomy, the mean operative time was 27.25min (SD±6.53). In LigaSure hemorrhoidectomy, the mean operative time was 15.83 (SD \pm 2.32). P value <0.001. intra operative bleeding was less in ligasure group p value < 0.022 The mean Pain score on 1st day postoperative was 5.59 (SD±1.76) in conventional hemorrhoidectomy, While in LigaSure hemorrhoidectomy the Mean Pain score on 1st day postoperative was 2.63 (SD \pm 2.47) P value < 0.001. Wound discharge and infection were statistically much less in the LigaSure group (P value <0.006) The mean wound healing time In conventional hemorrhoidectomy was 4.59 weeks ($SD\pm0.48$) P value < 0.05. In LigaSure hemorrhoidectomy, the mean wound healing time was 2.53 weeks (SD±0.52). Conclusion: LigaSure hemorrhoidectomy is a sutureless, It depends on on a electrosurgical energy source to achieve tissue and vessel sealing. It is feasible and safe with fewer complications mainly less postoperative pain and less intraoperative blood loss when comparing it to conventional technique. Technically simple because there is no suturing and hemostasis is easy to achieve. The drawback is the cost.

INTRODUCTION

Hemorrhoids are defined as submucosal beds which contain three components arterial, venous and smooth muscle fibers. They are located inside the anal canal.Hemorrhoidal disease is nearly present in 5% of the community and more likely after the age of 40.^{1,2} Being normal anatomical structures of the anal canal they do not need treatment unless symptomatic. These symptoms may be in the form of bleeding, thrombosis, or even prolapse³. Different treatment methods are used for hemorrhoids, starting with conservative medical treatment, rubber band ligation, infrared photocoagulation, sclerotherapy⁴, open hemorrhoidectom⁵, closed hemorrhoidectomy⁶, **Doppler**-guided hemorrhoidal artery ligation^{7,8} and stapled hemorrhoidectomy⁹. Conservative medical treatment is usually successful for first and second-grade hemorrhoids; however, third and fourth-grade hemorrhoids need a surgical

procedure to treat. Two popular surgical approaches for hemorrhoidectomy: the open (Milligan-Morgan)⁵ and the closed (Ferguson)⁶. These two methods have nearly the same drawbacks, for example, blood loss and postoperative pain. Hospital stay time and time to restore normal daily activities are comparable ¹⁰.

LigaSure hemorrhoidectomy is another option to open hemorrhoidectomy in the treatment of third and fourth grade hemorrhoidal disease ¹¹. A modified energy source device, the LigaSureTM (Valley Lab, Boulder, CO, USA) has become for the last_years as a 'vessel-sealing framework. This device conducts electro-diathermy energy across its blades much like the bipolar_diathermy device with the advantage of the minimal lateral spread of the electrothermal energy. LigaSure provides complete occlusion and sealing of blood vessels with diameters reaching up to 7 mm.^{12,13}. We used the Ligasure device for hemorrhoidectomy in third and fourth-grade hemorrhoids and we

compared the results with conventional Milligan and Morgan hemorrhoidectomy. The primary outcome was postoperative pain evaluation secondary outcomes include intraoperative bleeding, time for healing and postoperative complications

METHODOLOGY

This is a prospective comparative study in which 60 patients with diagnosed as third and fourth-grade hemorrhoids were included. The patients were divided into two groups using a computer-generated randomization. The first group (conventional group) will be treated by conventional hemorrhoidectomy (Milligan and Morgan) the second group (LigaSure group) Ligasure hemorrhoidectomy will be done to treat their disease.

This study was performed at the colorectal unit of the general surgery department at Cairo University from November 2014 to November 2015.After being approved by the committee of research ethics. All patients signed informed consents and agreed to have the treatment and to participate in the study.

Cirrhotic patients, uncontrolled diabetic patients, or patients with associated perianal disease, inflammatory bowel disease, pregnancy, or bleeding diathesis were excluded from the study. Colonoscopy was done for all patients older than 40 years of age to exclude colorectal cancers. Spinal anesthesia was used for all patients. The patient was positioned in lithotomy position and slightly reverse Trendelenburg angle. The basic procedures in both surgeries were initially examination under anesthesia, bringing of hemorrhoids out by two artery forceps, one of them applied at the mucocutaneous junction while the other at the apex of hemorrhoid followed by a skin incision at the hemorrhoidal base.

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In the conventional group, A skin incision vshaped around the hemorrhoid base by the scalpel followed by scissors dissection in the submucosal plane separating all of the hemorrhoidal tissue from its bed. The dissection is continued up to the pedicle, which is ligated with an absorbable suture then the distal hemorrhoidal tissue is excised. Hemostasis was achieved then the wound was left open.

In the LigaSure group, the same previous skin incision but instead of scissors dissection ligasure was applied separating the hemorrhoidal tissue from the internal sphincter Ligasure till reaching the level of the vascular pedicle. Then the vascular pedicle is sealed using the Ligasure without trans fixation. Hemostasis was achieved then the wound was left open.

Operative time was calculated from the beginning of examination under anesthesia until achieving complete hemostasis and applying the external dressing.

Amount of intraoperative blood loss was estimated by Gauze Visual Analogue (Figure 1).



Fig. 1: Gauze Visual Analogue

Analgesia during first 24 hours in the hospital stays non-steroidal anti-inflammatory drugs at a regular interval (every 8 hours). All patients were prescribed antibiotics in the form of Metronidazole 500mg every eight hours and 500mgeverv Ciprofloxacin twelve hours. Paracetamol 500 mg two tablets every eight hours and Diclofenac 50 mg as per required orally were advised to both groups as postoperative analgesia.

The patients were asked to take Sitz bath on the night of surgery and were given osmotic laxative in the form Lactulose for one week.

The visual analog scale (VAS) for pain was explained to patients. They were trained on how to complete the 0 to 10 VAS interview (Figure 2). They were asked to grade the pain severity on 0-10 on the night of the day of surgery (day 0), the following day (day 1) the patients were asked to record at home at night before sleeping their highest pain level daily for one week.



Fig. 2: visual analog score (VAS)

Wound discharge was measured by amount and frequency during the follow-up period. Wound healing assessment defined as complete epithelialization was accessed every visit Continence was evaluated preoperative and postoperative by Wexner score. Postoperative complications were monitored in both groups like urine retention, postoperative bleeding, and anal stenosis. Follow up was weekly visits for eight weeks then monthly for ten months for late complications as anal stenosis.

Statistical Data were described using range, mean, standard deviation (SD), median, frequencies (number of cases) and percentages when suitable. Mann Whitney U was used to compare quantitative variables between groups test for independent samples. Chi-square test was used for comparing categorical data. But when the expected frequency is less than 5 Exact test was used as an alternative. P values less than 0.05 was considered statistically significant. Statistics were done using Microsoft Excel 2010 (Microsoft Corporation, NY, and USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 17 for Microsoft Windows

RESULTS

Sixty patients with third and fourth-degree hemorrhoids participated in the current study. The mean age of the conventional group patients was 36.5 ± 4.9 years with a male: female ratio of 21:9 while the mean age of LigaSure group patients was 37.30 ± 4.03 years with a male: female ratio of 19:11. No statistically significant differences were found in age, gender, between the two study groups.

Regarding the operative time, a statistically significant difference exists between the two study groups. In conventional hemorrhoidectomy, the mean operative time was 27.25min (SD \pm 6.53). In LigaSure hemorrhoidectomy, the mean operative time was 15.83 (SD \pm 2.32). P value < 0.001.

During conventional hemorrhoidectomy. All patients suffered from blood loss, 4 patients with minimal blood loss representing 13.3% of conventional patients, 18 patients with mild blood loss representing 60.1% of conventional patients and 8 patients with moderate blood loss representing 26.6% of conventional patients. In LigaSure hemorrhoidectomy, 12 patients didn't experience any Blood loss 39.6% of this group. 6 patients with minimal blood loss, 6 mild blood loss and 6 moderate blood loss, each of these groups representing around 19.8% of this group. this difference was statistically of significant value P value < 0.022.

The difference in postoperative pain between the two groups was of high statistical significance P-value < 0.001. LigaSure hemorrhoidectomy patients experienced less postoperative pain in day 0 and day 1 than the conventional hemorrhoidectomy group. There is no difference in both groups in postoperative pain after 1 week. The mean Pain score on 1st day postoperative was 5.59 (SD±1.76) in conventional hemorrhoidectomy, While in LigaSure hemorrhoidectomy the Mean Pain score on 1st day postoperative was 2.63 (SD±2.47).

Wound discharge and infection were statistically much less in the LigaSure group (*P*

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value 0.06). .In LigaSure hemorrhoidectomy patients had less infection and discharge than the conventional group.

The mean wound healing time In conventional hemorrhoidectomy was 4.59 weeks (SD \pm 0.48). In LigaSure hemorrhoidectomy, the mean wound healing time was 2.53 weeks (SD \pm 0.52). this difference was significant between both groups in wound healing duration (P-value < 0.05).None of the patients suffered from anal incontinence or anal stenosis during the follow-up period Hospital stay was the same in both groups ranging from 1 to 2 days without the need for readmission for any case.

DISCUSSION

The main finding of the present study was a less post-operative pain when treating hemorrhoids using ligasure if compared to the conventional Milligan Morgan. Traditional surgical approaches to hemorrhoidectomy have similar complications, especially magnitude of blood loss and degree of postoperative pain ^{14,15}. This pain is mainly due to the excessive trauma of the sensitive anoderm ¹⁶.

The LigaSure system (bipolar electrocoagulation) offers a bloodless dissection of vascular tissues. In addition, it confines thermal spread to within 2 mm of the adjacent tissue, allowing complete coagulation with the negligible thermal spread. This may reduce anal spasm and pain^{17,18}.

In the current study, we standardized numerous variables to avoid inaccuracy and variation in the results of pain assessment, by excluding patients with other anorectal pathology and patients with neurological defects or chronic pain syndromes and those currently taking narcotic analgesics with low pain threshold. Regarding the surgical technique, we used the open method to avoid the controversy about the effect of using the closed technique on postoperative pain perception. We used spinal anesthesia in both groups.

A significant reduction of anal pain after the LigaSure procedure was observed on discharge and also during and after the first bowel movement, which supports the concept of the decrease of lateral thermal spread results in decreased postoperative pain. LigaSure hemorrhoidectomy was found to be associated with a significant reduction in analgesic needs during the first 24 hours, post-operative pain in the postoperative score in the first week and also pain related complications such as urine retention and constipation.

Similarly, in a randomized trial of 34 patients undergoing LigaSure or conventional diathermy, Franklin *et al.*²¹ observed a decrease of postoperative pain in the LigaSure group after the first defecation, as well as on days 1, day 7 and day 14 after surgery. Most other randomized trials LigaSure comparing with other hemorrhoidectomy techniques have also shown less postoperative pain for LigaSure^{19,20,21,17} except Palazzo *et al.*²², who found in their study that no difference exists in the pain score. Conventional hemorrhoidectomy is associated with significant complications like urinary retention and constipation mainly induced by pain^{5,6}

The effectively achieved hemostasis by complete coagulation of the vessels. The flow of energy is automatically stopped by a computer controlled feedback System when complete coagulation is achieved.

Jayne and colleagues¹⁹ showed that the LigaSure system decreases intraoperative blood loss (median 0 ml *versus* 20 ml in the conventional group). A similar finding of reduced postoperative bleeding was observed in other smaller studies^{17, 21}

In the current study Wound healing was significantly faster in the present study with use of the LigaSure compared with conventional group 2.53 weeks versus 4.59 weeks respectively, in agreement with the results of other studies ^{17,20}

In line with previous smaller randomized trials, ^{19,20,21,22} use of the LigaSure system in the present series significantly reduced the time required to perform hemorrhoidectomy. This is a significant advantage of this technique for two reasons as no time was needed to secure hemostasis or to ligate the pedicles, and the hemostasis produced by LigaSure has made the operative technique more simple and done quickly.

The main drawback of the LigaSure technique is its cost but this limitation has been observed with all new techniques. The charge of the handle for each patient is nearly 8000 Egyptian pounds.

Although the LigaSure procedure has an additional cost to the surgical procedure it is still

cost-saving. The method is simple and easy to learn, and the reduced operating time as a daycase procedure with early resuming daily activities and work may result in significantly reduced costs, particularly in comparison with other methods ^{16, 19}

An area of great concern with anorectal surgery is potential anal sphincter injury resulting in fecal incontinence. In the present trial no sphincter damage was detected, nor was there any complaint of flatus incontinence or soiling at follow-up. However, reports of anal injury suggest that LigaSure hemorrhoidectomy is not without complications^{23,24}.

None of the study patients developed anal canal stenosis in. Other studies have a rate of 4%-5% anal stenosis for conventional haemorroidectomy^{25,26} Gravante and Venditti²⁷ described four patients (2.0 percent) who developed postoperative anal stenosis. Further, Wang et al.²⁰ reported one case of anal stenosis in 42 patients treated with LigaSure. Ramcharan and Hunt²⁸, pointed out that after incision of the perianal skin, the skin edges should be separated away from the LigaSure blades to decrease as much as possible the thermal injury

CONCLUSION

LigaSure hemorrhoidectomy is a sutureless, It depends on on a electrosurgical energy source unit to achieve tissue and vessel sealing. It is feasible and safe with fewer complications mainly less postoperative pain and less intraoperative blood loss when comparing it to conventional technique. Technically simple because there is no suturing and hemostasis is easy to achieve. The drawback is the cost

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