LIGASURE COMPARED WITH BIPOLAR ELECTRO-CAUTERY HEMORRHOIDECTOMY: A PROSPECTIVE RANDOMIZED STUDY

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ABSTRACT

Introduction: Surgical excision using Ligasure is a modern technique used for ablation of symptomatic third degree and all fourth-degree hemorrhoids. Compared with electrocautery, Ligasure causes minimal lateral thermal injury during tissue dissection. The resulting mucosal defect is then left open. The aim of this work was to evaluate the value of using Ligasure in reducing incidence of postoperative complications following hemorrhoidectomy.

Patients & Methods: This is a prospective randomized study done in general surgery department Zagazig University hospital during the period from July 2009 to December 2010. Patients underwent surgical excision of complex grade III or grade IV hemorrhoids. They were divided into two groups: Ligasure hemorrhoidectomy group (A) where ligasure was used only and bipolar electrocautery hemorrhoidectomy group (B). Pain levels scoring and postoperative complications were analyzed.

Results: Postoperative pain in Group (A) was significantly less with less analgesic requirement. Postoperative urine retention was significantly less in Group (A). There was no significant difference between both groups regarding other postoperative complications.

Conclusion: This study demonstrates significantly reduced postoperative pain after Ligasure hemorrhoidectomy compared with bipolar electrocautery. So Ligasure is better than bipolar electrocautery hemorrhoidectomy.

INTRODUCTION

Hemorrhoids arise from congestion of internal and /or external vascular plexuses around the anal canal. They are classified into four degrees. In many cases hemorrhoidal disease can be treated by dietary modifications, topical medications and soaking in warm water, which temporarily reduce symptoms of pain and swelling. Additionally, painless non-surgical methods of treatment are available to most patients as a viable alternative to a permanent hemorrhoid cure. In a certain percentage of cases, however, surgical procedures are necessary to provide satisfactory long-term relief.[1]

Surgical hemorrhoidectomy is a notoriously painful procedure. Considerable research over the last two decades has concentrated on reducing postoperative pain. Investigators have concentrated in three areas; analgesic delivery during the postoperative period, modification of the surgical technique and the use of variety of surgical instruments in the hope of decreasing postoperative pain.[2]

Alternatives to traditional oral narcotic analgesics for postoperative pain have included subcutaneous morphine infusion,[3] transdermal fentanyl patch[4] and parenteral toradol administration.[5] Modifications of the surgical technique have included open, semiopen[2] and closed incisions,[1] routine performance of lateral internal sphincterotomy[6] and the use of stapling devices.[7] None of these techniques have been demonstrated to be conclusively superior to the other techniques.[8-11]

Laser hemorrhoidectomy gained wide-spread publicity but has not been consistently demonstrated to be superior to conventional hemorrhoid-ectomy in reducing postoperative complications. In addition, the need for using a combination of Nd-YAG and CO2 lasers to utilize the benefits of both to complete the procedure, makes it a cumbersome and expensive one.[12]

Ligasure Electrothermal Bipolar Vessel Sealer System (EBVS) was developed for ligating vessels up to 6 to 7 mm in diameter and tissue bundles. It provides sealing by applying high current and low voltage, which differ from the energy used for standard monopolar and bipolar cautery (high voltage, low current).[13]

The EBVS system, which consists of a bipolar surgical generator and handset operated by a foot pedal, provides precise energy control with physical compression, including a brief cool down. This mechanism denatures

proteins within the vessel wall and produces a translucent seal that can transected by scissors. Thermal alterations are limited to less than 1.5 mm beyond the tissue within the jaws.[14] In this study we present our experience in using Ligasure in hemorrhoidectomy and evaluating the postoperative complications in comparison to the use of bipolar electrocautery .

PATIENTS AND METHODS

From July 2009 to December 2010, 60 patients (38 males and 22 females) in surgical department Zagazig University hospital requiring surgical hemorrhoidectomy were randomly assigned by using the sealed envelope technique to the Ligasure hemorrhoid-ectomy group (A) or the bipolar electrocautery hemorrhoidectomy group (B). All patients were initially evaluated in outpatient clinic by full history taking, digital rectal examination and sigmoidoscopy. Indications for hemorrhoidectomy (Inclusion criteria) were either; (1) Symptomatic Grade III internal hemorrhoids in association with large external components or (2) Prolapsed, thrombosed Grade IV hemorrhoids. Meanwhile exclusion criteria included; (1) Patients with other anorectal pathology as fissure or fistula-in-ano, (2) Patients with neurological deficit as paraplegia or previous cerebro-vascular accidents, (3) Patients with chronic pain syndromes, and (4) Patients chronically taking narcotic analgesics. The study had been previously approved by the Research Ethics Committee of the university. Informed consents were obtained from all patients.

SURGICAL TECHNIQUE

All operations were performed under a standardized spinal anesthesia technique with the patient in the lithotomy position. Three-quadrant hemorrhoidectomy[15] was performed in all patients.

For Ligasure hemorrhoidectomy[16], each hemorrhoidal cushion was managed as follows. Three applications of the ligasure device were required to excise each hemorrhoidal cushion. The first application included the perianal skin, including the external component of the hemorrhoidal cushion, the second included the part overlying the internal sphincter, and the third included the pedicle 0.5 cm above the dentate line. After each application, completion of coagulation was signaled by the characteristic two-tone sound from the machine and a pair of scissors was used to cut along the middle of the line of the coagulum until complete excision of the hemorrhoidal cushion was achieved.

For bipolar electrocautery hemorr-hoidectomy[17], each hemorrhoidal cushion was managed as follows. A V-shaped incision was made in the perianal skin distal to the hemorrhoidal cushion to include the external component with the diathermy in the cutting mode. Dissection of the hemorrhoidal tissue from the internal sphincter was performed with the diathermy in the coagulation mode. The pedicle was coagulated by bipolar electrocautery 0.5 cm above the dentate line, hemorrhoidal tissue was excised and the wound was left open. No anal packing was used.

Postoperative pain was evaluated by means of a visual analogue scale[18] that was explained to the patients. Pain was evaluated by a score of 0 (no pain) to 10 (worst pain possible). Patients were asked to rate their pain both preoperatively and on postoperative days 1, 3, 4, 7, 14 and 28. Follow up was done in the outpatient clinic and by the telephone after overnight keeping in the hospital. Postoperative analgesia was administered as a narcotic analgesic (Pethidine) up to the end of the third postoperative day and thereafter using NSAIDs (Diclofenac Sodium, DS). Required analgesic doses were recorded and analyzed as a marker for pain severity. All patients complete the study to the end.

Mean pain scores for each day of follow up in both groups were compared using Wilcoxon's rank-sum test. Also, the amount needed of narcotic analgesics and NSAIDs were calculated for each group and compared using two-sample t-test.

RESULTS

Demographics of the study population are summarized in Table 1. The two groups were comparable regarding the age and sex distribution. There was no significant difference between both groups in history of previous surgery, grade of hemorrhoids at time of surgery and degree of preoperative pain. Also, no significant difference as regarding the degree of education of the patients between both groups as shown in Table 2.

Postoperative pain was found to be significantly less in Group (A) in all days of postoperative follow up, as depicted in

(Fig.1).The mean dose of narcotic analgesia was used in the first three days postoperatively was significantly reduced in Ligasure group when compared to the electrocautery group, (P-value <0.01) (Fig.2). There was also significant difference between both groups in required Diclofenac sodium with less doses needed in Group (A) (Fig. 3). This was found up to day 14 after which the difference was statistically non-significant between both groups.

Other postoperative complications were also reported as plotted in Table 3 Incidence of postoperative bleeding was nearly comparable in both groups. Only one patient in Group (B) had reactionary hemorrhage and was managed by anal packing under anesthesia. Post hemorrhoidectomy urine retention was markedly less in group (A) (only 3 out of 30 patients) while in Group (B) it occurred in 12 patients that was found statistically significant(P-value <0.05). Again, no difference was found between both groups regarding wound infection, major short-term incontinence and swelling of the skin bridges.

No significant correlation was found between grade of hemorrhoids, technique used and the incidence of postoperative complications. About 74% of patients of Group (A) reported full-time return to work within the first two weeks postoperatively. The remaining patients joined their jobs by the end of the 4th week. While for Group (B), this happened only for about 47% of patients. Other patients of Group (B) required more time to return to work extended up to 45 days. This difference was also found statistically significant (P-value <0.05) as shown in Table 4.

Table 1: Demographic data of the patients and other study variables.

Variable	Age/yrs (Mean ± SD.)	Sex M F	Previous Surgery Yes No	Grade III IV	Preoperative pain
Group A (30cases)	46 ± 3.2	20 10	6 24	24 6	3.2 ± 0.7
Group B (30cases)	44 ± 2.1	18 12	5 25	26 4	2.8 ± 0.4
P-value	NS	NS	NS NS	NS NS	NS

Ns = Non-significant, SD = Standard Deviation. Tow-sample t-test was used to test ages between groups; Chi-squared test was used for sex; Fisher's exact test was used for grade and previous surgery and Wilcoxon's rank-sum test was used for preoperative pain.

Table 2: The degree of education of the patients.

Variable	Illiterate	Primary school	Prep. School	Secondary school	University	Total
Group(A)	3 (10%)	2 (6.7%)	4(13.3%)	12 (40%)	9 (30%)	30(100%)
Group (B)	4(13.3%)	3 (10%)	3 (10%)	12 (40%)	8 (26.7%)	30(100%)
P-value	Ns	Ns	Ns	Ns	Ns	Ns

Table 3: Incidence of postoperative complications other than pain.

Variable	Bleeding	Urine Retention	Wound Infection	Skin Swelling	Short- term Incontinence
Group A	0 (0%)	3 (10%)	2 (6.7%)	6 (20%)	2 (6.7%)
Group B	1(3.3%)	12 (40%)	2 (6.7%)	8 (26.7%)	3 (10%)

Table 4: Time needed to return to work in both groups.

Variable	1st Week	2nd Week	4th Week	6th Week	Total
Group A	10(33.3%)	12 (40%)	8 (26.7%)	0 (0%)	30(100%)
Group B	6 (20%)	8 (26.7%)	9 (30%)	7 (23.3%)	30(100%)

P-value <0.05 was recorded using Wilcoxon's rank-sum test.

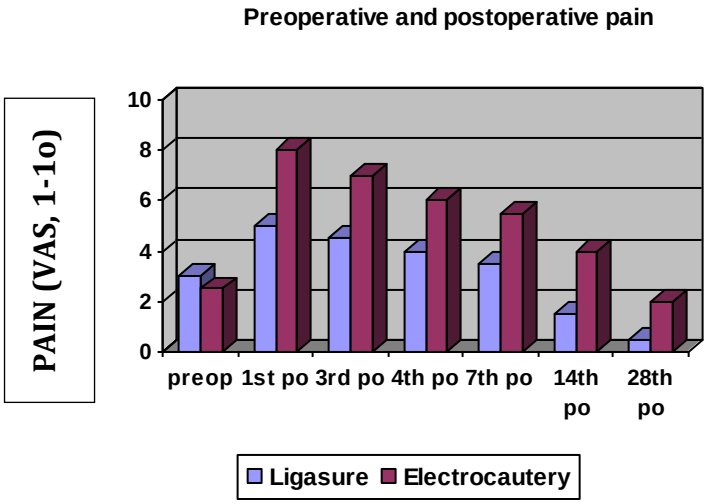

Fig.1. Pain scores (visual Analog scale, VAS), before (Preop) and after (Po) Ligasure and bipolar electrocautery hemorrhoidectomy. Preoperative pain was more or less similar between both groups. Meanwhile, Ligasure patients experienced significantly less pain than Electrocautery group on all postoperative days (p-value <0.01, using Wilcoxon's rank-sum test).

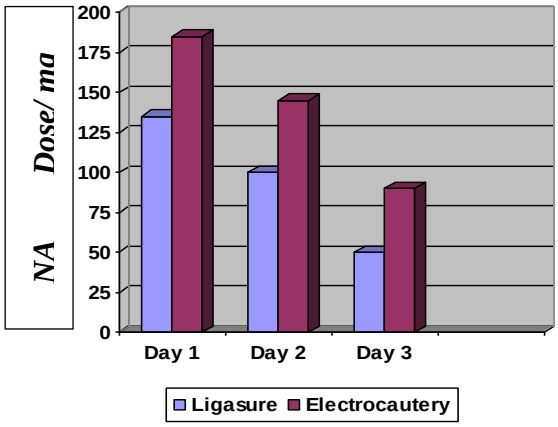

Fig. 2. Mean dose of narcotic analgesics (NA) used in the first three days of postoperative period in both groups. Significantly reduced dose was found in Group A (P-value < 0.01, using Wilcoxon's rank-sum test)

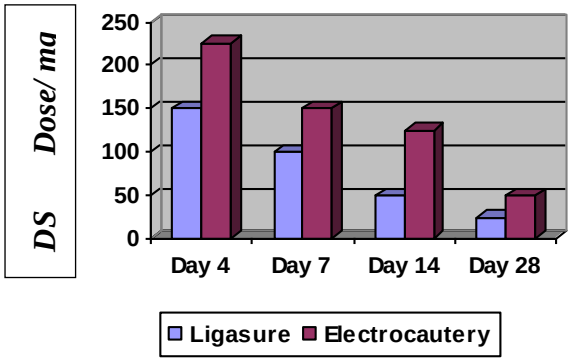

Fig. 3. Mean dose of diclofenac sodium (DS) used from the 4th postoperative day in both groups. Significantly reduced dose was found in Group A (P value < 0.01, using Wilcoxon's rank-sum test). While at day 28 the difference was non significant.

DISCUSSION

Surgical hemorrhoidectomy is generally reserved for symptomatic grade III internal hemorrhoids with prominent external ones or for grade IV disease.[15] Pain following haemorrh-oidectomy is a well known complic-ation. One possible explanatory factor is tissue damage by thermal spread of diathermy. Avoiding or minimizing extended thermal injury might result into decreased postoperative pain. It has been postulated that such minimal thermal injury can be achieved with the use of Ligasure. In contrast to electrocautery, this device uses a very high frequency current providing haemostasis by denaturating collagen and elastin from the vessel wall and surrounding connective tissue. Furthermore ,it has the potential to reduce thermal damage through use of active feedback control over the power output and the head of the device is heat-sink engineered to ensure a cool (below 45 degrees Celsius) surface. Negligible evidence of thermal damage has been shown in histological studies and in situ thermal imaging.[19]

The Ligasure possesses the advantage of causing very little lateral thermal injury in the tissues. A decreased lateral thermal injury (<1.5 mm) at the surgical site is translated into decreased postoperative pain.[14]

However the depth of thermal injury in porcine small bowel mesentery was found to be up to 15 mm with mono-polar electrocautery, up to 9mm with bipolar electrocautery, up to 4 mm when using CO2 laser and up to 4.2 mm using Nd:YAG laser.[20]

In the current study, we avoided many potential confounders by standardizing many variables. Starting with choice of the patients, we excluded patients with other ano-rectal pathology and patients with neurological defects or chronic pain syndromes and those currently taking narcotic analgesics. This gave us the advantage of avoiding variation in the results of pain assessment. Also, we fixed our patient selection to those having symptomatic Grade III internal hemorrhoids with prominent external ones and Grade IV disease. Regarding the surgical technique we adopted the open method to avoid the debate around the effect of using the closed technique on postoperative pain perception and also we used standard technique of spinal anesthesia.

Some authors have compared the Milligan-Morgan technique using Ligasure with Ferguson's[21,22], Parks' hemorrhoidectomy[23], or stapled hemorrhoiddopexy[24,25] because these techniques have a better reputation regarding postoperative anal pain. Wang et al.[21], in their series of 84 patients with third-degree and fourth-degree hemorrhoids, demonstrated that ligasure hemorrhoidectomy results in a significantly reduced intraoperative blood loss, shorter operative time, less postoperative pain, and earlier resumption of working activity compared with Ferguson's hemorrhoidectomy. Similar results were obtained in comparison with Parks' hemorrhoidectomy,[23] A randomized comparison with stapled hemorrhoidectomy was performed in two studies: whereas in the first study[24] stapled hemorrhoidectomy was significantly less painful but had a higher risk of postoperative bleeding, in the other[25] there were no differences at all in terms of all the major outcomes analyzed, such as postoperative pain, patients' satisfaction, and self-assessment of activity. However, the stapler operation is more expensive.

This study clearly demonstrates the superior pain control profile of Ligasure in hemorrhoidectomy and also the less need for analgesics, both narcotic and NSAIDs. In the American Gastroenterological Association Technical Review on the Diagnosis and Treatment of Hemorrhoids four trials randomizing between open and closed technique were reviewed.[26] In three no difference in pain was found, one reported less pain following the open technique. In another randomized controlled trial (RCT) on this subject less pain was reported after the closed technique.[27] In our opinion, this was a potential flaw in their studies, although it did not affect their final conclusion ,so we standardized the technique to the open one to avoid such flaw.

The decrease in thermal spread is not unique to the Ligasure device. It can also be provided by sealing with ultrasonic coagulating shears. In two studies there was no difference in thermal spread between these two devices.[28,29] An ultrasonic device (Harmonic Scalpel) has been used in haemorrhoidectomy and was compared to the Ligasure in one randomized controlled trial, in which the use of an ultrasonic device was associated with more postoperative pain. The results for patients' tolerance favored the Ligasure technique. [30]

The study done by Armstrong et al. 2001[31] they used the narcotic analgesics (NA) for the whole period of postoperative follow up. We believed that long term use of such (NA) may lead to habituation or even drug addiction. So, we replaced the NA from the third day on by using Diclofenac sodium (DS) for the rest of the period of postoperative follow up. In

addition to the finding mentioned before regarding the significantly reduced dose of both NA and DS in the Group (A) (Ligasure group) in comparison to Group (B) (bipolar electro-cautery group), it was quite adequate to use narcotic analgesic (Pethidine) for the first three postoperative days only, then to continue after that by DS either by intramuscular injection or through the oral route for adequate pain control.

Altomare et al., 2008[32] reported 5 versus 2 bleedigs and 2 versus 1 redo-surgery within30 days for the Ligasure and conventional group respectively In this study this was not the case, as there was no bleeding versus 1 for Ligasure and conventional group respectively, so there was significantly reduced postoperative pain, better hemostasis and less analgesic consumption. These results were positively correlated with the time needed to return to work which was found to be much faster in Ligasure group (Table 4) This may be explained by the growing learning curve of using the Ligasure in such type of surgery and better healing rates following its use.

Meanwhile, this study yielded comparable results to those of Bessa 2008[33]and Franklin et al.,2003[34] who mentioned that Ligasure hemorrhoid-ectomy statistically significantly reduced postoperative pain, induced better hemostasis and less analgesic consumption.

With respect to the postoperative analgesic dose, it is clearly evident in this study that within the first three postoperative days, the mean dose of narcotic analgesia used was significantly reduced in Ligasure group (Fig. 2). After that, from day 4 to day 14, the dose of (DS) used for analgesia, was much less in Ligasure group also (Fig. 3). This is considered different from those mentioned by Nienhuijs and de Hingh 2010.[35] They mentioned that there was no significant difference noted in the overall amount of analgesics used in the two groups after the first day postoperative.

Although a correct analysis of the cost of any surgical practice is difficult to do, it should be considered that the use of Ligasure Precise™ device increases the cost of the operation by only 500 pounds (about 85$), which could be balanced by an earlier return to work. Furthermore, reduction of postoperative anal pain, even if limited to 1 or 2 VAS points, is welcomed by the patients.

Although the use of the Ligasure carries some disadvantages as prolonged learning curve and increased cost over the electrocautery hemorrhoidectomy, it carries several advantages, reduced postoperative pain, reduced doses of NA and DS postoperatively, excellent hemostasis and reduced amount of vapor released during the procedure are considered as great advantages. Also, secondary to the reduced postoperative pain there was significantly reduced incidence of postoperative urine retention and finally reduced time-off work. So, and for all these merits Ligasure provide superior alternative to bipolar electrocautery in hemorrhoidectomy in patients with symptomatic grade III internal hemorrhoids in association with large external components and those with prolapsed, thrombosed grade IV hemorrhoids.

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مقارنة استخدام جهاز الليجاشور و الكى الكهربائى ثنائى القطبية فى استئصال البواسير

ان استخدام جهاز الليجاشور فى استئصال البواسير هو من الطرق الحديثة مقارنة باستخدام جهاز الكى الكهربائى ثنائى القطبية حيث انه يقلل من الأضرار الحرارية للأنسجة المجاورة أثناء العملية . والهدف من هذا البحث هو تقييم استخدام جهاز الليجاشور فى تقليل حدة الألم والمضاعفات بعد استئصال البواسير. وقد أجريت هذه الدراسة على ستين مريضا يعانون من الدرجة الثالثة والرابعة للبواسير بقسم الجراحة العامة بمستشفيات جامعة الزقازيق فى الفترة من يوليو2009 الى ديسمبر 2010 وتم تقسيم المرضى الى مجموعتين كل مجموعة ثلاثون مريض. المجموعة الأولى (أ) نستخدم جهاز الليجاشور والمجموعة الثانية (ب) نستحدم جهاز الكى الكهربائى ثنائى القطبية. وأوضحت النتائج أن شدة الألم بعد العملية أقل بكثير فى المجموعة الأولى عن المجموعة الثانية وأن جرعة المسكنات المستخدمة أقل فى المجموعة الأولى عن الثانية كما أن معدل الأحتباس البولى بعد العملية أقل فى المجموعة الأولى عن الثانية ولا يوجد اختلاف واضح بين المجموعتين فى باقى المضاعفات.

ونستخلص من هذا أن استحدام جهاز الليجاشور فى استئصال البواسير يقلل من حدة الألم بعد العملية وكذلك جرعة المسكنات المستخدمة مقارنة بجهاز الكى الكهربائى ثنائى القطبية ولذلك ننصح باستخدامة.