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ORIGINAL ARTICLE

Laparoscopic Splenectomy: Comparative Study between Using of LigaSure and Harmonic scalpel

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ABSTRACT

Background: Advanced laparoscopic solid organ surgery is now possible with the use of LigaSure and the Harmonic scalpel, which drastically cut down on operating time and blood loss. This work aimed to compare the effectiveness of LigaSure or Ultracision in Laparoscopic Splenectomy (LS) regarding dissection, operative time, and blood loss.

Methods: in this randomized prospective clinical trial 36 patient candidates for LS were randomized into two groups (18 patients in each group): in Group A LS was performed and in Group B Harmonic was performed. Intra-operative measures/difficulties (Operative time, occurrence of bleeding/ blood loss, presence of accessory spleen, need for intraoperative blood transfusion) were assessed in addition to postoperative hospital stay.

Results: In the LigaSure group, no intraoperative encountered difficulties (0%), while in the Harmonic group, 5 cases (27.78%) experienced such issues, representing a significant increase ($p = 0.0152$). The LigaSure group had statistically shorter operation time compared to the harmonic group (124.94 ± 16.24 vs. 149.28 ± 12.87, $p < 0.0001$). Intraoperative blood loss was also statistically lower in the LigaSure group (81.67 ± 19.22 vs. 124.17 ± 14.55, $p < 0.001$), the LigaSure patients required significantly fewer blood transfusions intraoperatively (0% vs. 22.22%, $p = 0.1039$). Post-operative CBC analysis showed a significant decrease in Hb levels in the Harmonic group (9.78 ± 0.34 g/dl) compared to the LigaSure group (10.09 ± 0.34 g/dl) ($p = 0.0121$).

Conclusion: When it comes to benign hematological problems, LS should always be the primary option for spleen removal. LigaSure and Ultracision both could offer important advantages in laparoscopy. Using LigaSure in LS reduced the operative time, blood loss, and the need for intraoperative blood transfusion.

Keywords: Laparoscopic Splenectomy, LigaSure, Harmonic scalpel.

INTRODUCTION

A growing number of patients are opting for laparoscopic splenectomy (LS), which was pioneered by Delaitre and Maignien in 1991 [1,2]. When it comes to benign conditions, LS is the "gold standard" method for removing the spleen. Compared to the open approach, LS has many benefits, including less postoperative pain, quicker recovery, better cosmesis, and less morbidity [3].

Advanced laparoscopic solid organ surgery has been made possible with the help of more effective energy-based hemostatic devices like the Harmonic Scalpel (Ultracision; Ethicon Endo-Surgery, Cincinnati, OH, USA) and Tyco Valleylab's LigaSure. These devices have considerably decreased operating time and blood loss [4].

Both of these innovative energy-based tools have seen growing applications in laparoscopic surgery,

but they operate on distinct principles. By denaturing collagen and elastin within the vessel wall and surrounding connective tissue, LigaSure uses a bipolar electro-thermal high current and low voltage energy to close vessels up to 7 mm in diameter. A device that uses ultrasonic energy to seal vessels up to 5 mm in diameter with a coagulum and denature proteins in tissues and vessels is called an Ultracision. This device relies on high-frequency vibrations [5,6]. LigaSure and Ultracision have been compared in a few research regarding laparoscopic adrenalectomy and colectomy [7,8].

So, the current study aimed to compare between the effectiveness of LigaSure and Ultracision in Laparoscopic Splenectomy (LS) regarding dissection, operative time, and blood loss.

METHODS

this randomized prospective clinical trial was performed in General Surgery Department, Zagazig University Hospitals on 36 patients candidate for LS from December 2022 to December 2023.

The approval for the study was obtained from the General Surgery Department of Zagazig University Hospitals after obtaining approval from the Institutional Review Board (#10539) and the research was conducted in accordance with the Helsinki Declaration.

Inclusion criteria: We included all patients candidates for the General surgery department, at Zagazig University Hospitals who had a recommendation for a splenectomy from either the internal medicine or pediatric (hematology) departments, aged ≥12, with no upper abdominal surgery, and their preoperative low platelet counts to be ≥30,000/ml, a platelet count below 30,000/ml before surgery.

Exclusion criteria: We excluded all cases aged less than 12, patients with enormous splenomegaly (spleen palpable below and to the right of the umbilicus) or maximum diameter of 23 cm or more, or weight more than 2000 g), those who had preoperative low platelet counts <30,000/ml, and excluded cases who were unfit for anesthesia according to ASA criteria or those who either did not want to be part of the study or who had splenectomy along with other procedures such as gastrectomy, cholecystectomy, or distal pancreatectomy.

Methods: Complete history taking including Age, sex, occupation, past history of previous operations, or hematological disorders.

Clinical evaluation: Assessment of vital signs (blood pressure, heart rate, respiratory rate, body temperature) to assess fitness for surgery and anesthesia.

Radiological imaging included abdominal Ultrasonography to assess the spleen and its size, as well as possible gallstones. Laboratory: Blood tests were done on admission and included full complete blood count, Coagulation profile, and kidney as well as liver functions.

Pre-operative preparation

Low molecular weight heparin (enoxaparin) was administered 12 hours prior to the operation as a deep vein thrombosis prophylaxis measure. Elastic stockings were used for the lower limbs as a further precaution.

Either LigaSure or Ultracision were used randomly according to filing number as patients were divided into two groups: Group A: 18 patients underwent LS with the use of LigaSure, and Group B: 18 patients underwent LS with the use of Ultracision.

Operation:

General anesthesia and mechanical ventilation were administered to the patients. During the induction of anesthesia, the patient was given a 1-gram dose of the prophylactic antibiotic Ceftriaxone. They were then placed in a right-lateral semi-supine (60°) posture, and a 10-millimeter umbilical port was introduced using an open approach utilizing a blunt Hassan trocar at the midline. Direct vision was used to install the remaining ports. Two further ports measuring 10 and 5 millimeters were located on the left flank, and a fifth, measuring 5 millimeters, was located in the epigastrium, below the xiphoid process. In every instance, a 30° scope was employed, and the spleen was mobilized using either LigaSure (a cautery equipment manufactured by Valleylab) or an Ethicon Harmonic ultrasonic energy source, depending on the patient's group. The hilar vessels and short gastric vessels were secured using Hem-o-lok clips after opening the gastrolienal ligament and dividing the gastric vasculature. There was no use of staplers or bulk ligation. Ligaments that attach to the lower extremities were separated. The spleen was placed in endogenous bags made of urobags (Romo-10, India) with the mouth sutured with retractable silk suture. It was then morcellated intra-corporeally with the help of sponge-holding forceps and a Yankauer suction tip through a 10〉mm port. The spleen was then removed piecemeal through the midclavicular port, with the urobag intact to protect the wound. The splenic beds were equipped with 18-Fr drains from Romovac-Romson in India in every instance. When dealing with large spleens, splenectomy with

hemorrhage, or both, the spleen is delivered through a transverse left lumbar or Pfannenstiel incision since it cannot be introduced into a bag.

Parameters for evaluation of Post-operative outcome:

The patient's vital signs, including temperature, pulse, and blood pressure, were monitored after surgery in a dedicated postoperative ward. The platelet and hemoglobin counts were assessed first thing in the morning. Assuming the amount of drainage is less than 50 cc, the drains were removed 48 hours prior to discharge following the pelvic ultrasonography. Daily blood tests for hemoglobin and platelet counts, as well as chest X-rays and abdominal ultrasounds, were performed to detect any abnormalities. Patients who met the discharge requirements (U/S free, drains removed, normal CBC regarding Hb, PLTs count) were given antibiotics for 7 days after surgery and 500 mg of oral paracetamol for pain.

Follow up:

Patients were followed up as outpatients for 1 week for 2 weeks postoperatively in the General Surgery Outpatients to make sure of good healing of the wounds and removal of the stitches and pelviabdominal ultrasound follow-up to exclude portal vein thrombosis. Patients were also seen at the outpatient clinic if they developed symptoms between their follow-up visits.

Parameters of evaluation: included Intra-operative measures/difficulties (Operative time, occurrence of bleeding/ blood loss, presence of accessory spleen, need for intraoperative blood transfusion), Time to start oral intake, postoperative hospital stay, and conversion to open, mortality and morbidity.

STATISTICAL ANALYSIS

The information was analyzed using Stata (version 23.0), statistical software designed for the social sciences (SPSS Inc., Chicago, Illinois, USA). The continuous variables were compared using the t-test or Mann-Whitney test, which is appropriate for normally distributed data. For categorical variables with frequencies below 5, the chi-square test or Fischer's exact test was selected.

RESULTS

Table 1 presented the demographic data and past medical history for both study groups, LigaSure (N = 18) and Harmonic (N = 18). There was no discernible variation in the groups' age distributions (27.28 ± 5.72 vs. 24.61 ± 5.11, p = 0.161). Sex distribution, body mass index (BMI), and past medical history exhibited no statistical differences between the two groups.

Table 2 outlines spleen evaluation and causes of splenectomy in both study groups. The size of the spleen showed no statistical difference between LigaSure and Harmonic groups (15.61 ± 1.35 vs. 15.08 ± 1.27, p = 0.2488). The distribution of causes for splenectomy, including ITP, thalassemia, hypersplenism, spherocytosis, and thrombocytopenia, demonstrated no significant variations between the groups. In both groups, the prevalence of extensive adhesions was 5.56%, and there was no statistical difference observed (p = 0.99). Regarding the presence of a large-sized spleen, it was reported in 11.11% of the LigaSure group and 16.67% of the Harmonic group, with no significant variation between the groups (p = 0.6414). Similarly, the occurrence of varicose veins was consistent in both groups, with a prevalence of 5.56% in each, showing no statistical difference (p = 0.99).

In the LigaSure group, none of the cases (0%) encountered intraoperative difficulties, while in the Harmonic group, 5 cases (27.78%) experienced such issues, representing a statistical increase (p = 0.0152) (Table 3).

Table 4 shows operative data, the LigaSure group had statistically shorter operation time compared to the harmonic group (124.94 ± 16.24 vs. 149.28 ± 12.87, p < 0.001). Blood loss during the operation was also statistically lower in the LigaSure group (81.67 ± 19.22 vs. 124.17 ± 14.55, p < 0.0001). Operative difficulties were encountered only among the Harmonic Group such as enlarged sized spleen in hypersplenism patients, extensive adhesions, and varicose veins at the splenic hilum. In cases complicated with o0perative difficulties, all 5 cases were initially managed with bleeding control and blood transfusion, only one case was managed however the other cases needed to be managed with open surgery. In cases with hypersplenism needing extraction through pfannensteil incision blood transfusion was necessary in one case.

Table 5 displayed postoperative follow-up evaluations, Between the LigaSure and Harmonic groups, there was no discernible variation in the duration of oral intake, length of hospital stay following surgery, or rate of postoperative mortality. Also, the need for intraoperative blood transfusion was significantly lower in the LigaSure group (0% vs. 22.22%, p = 0.1039) with no cases needing transfusion in the LigaSure Group.

Post-operative CBC analysis revealed a significant decrease in Hb levels in the Harmonic group (9.78 ± 0.34 g/dl) compared to the LigaSure group (10.09 ± 0.34 g/dl) (p = 0.0121). Assessing the change in CBC

parameters, it was found that there was a significant decrease in Hb levels in the Harmonic group (7.1 ± 1.36%) compared to the LigaSure group (11.29 ± 1.38%) ($p < 0.001$). (Table 6).

In cases complicated with operative difficulties, all 5 cases were initially managed with bleeding control and blood transfusion, only one case was managed however the other cases needed to be managed with open surgery. Blood transfusion was necessary in one case (Table 7).

Table (1): Demographic data and past history among cases in both study groups.

	LigaSure Group (N = 18)	Harmonic Group (N = 18)	P. Value
Age (Years)	27.28 ± 5.72	24.61 ± 5.11	0.161
Sex			
Female	12 (66.67%)	11 (61.11%)	0.7376
Male	6 (33.33%)	7 (38.89%)	0.7376
Body Mass Index (Kg/m^2)	21.61 ± 3.04	20.83 ± 3.11	0.4662
Past history			
ITP	6 (33.33%)	4 (22.22%)	0.4711
Thalassemia	3 (16.67%)	3 (16.67%)	0.99
Hypersplenism	4 (22.22%)	5 (27.78%)	0.7101
Spherocytosis	2 (11.11%)	4 (22.22%)	0.3855
Thrombocytopenia	3 (16.67%)	2 (11.11%)	0.6414

Table (2): Spleen evaluation and Cause of Splenectomy among cases in both study groups

	LigaSure Group (N = 18)	Harmonic Group (N = 18)	P. Value
Size of Spleen (Cm.)	15.61 ± 1.35	15.08 ± 1.27	0.2488
Cause of Splenectomy			
ITP	6 (33.33%)	4 (22.22%)	0.4711
Thalassemia	3 (16.67%)	3 (16.67%)	0.99
Hypersplenism	4 (22.22%)	5 (27.78%)	0.7101
Spherocytosis	2 (11.11%)	4 (22.22%)	0.3855
Thrombocytopenia	3 (16.67%)	2 (11.11%)	0.6414
Extensive Adhesion	1 (5.56%)	1 (5.56%)	0.99
Large Size Spleen	2 (11.11%)	3 (16.67%)	0.6414
Varicose Vein at splenic hilium	1 (5.56%)	1 (5.56%)	0.99

ITP: immune thrombocytopenic purpura

Table (3): Occurrence of intraoperative difficulties in both study groups

	LigaSure Group (N = 18)	Harmonic Group (N = 18)	P. Value
Yes	0 (0%)	5 (27.78%)	0.0152*
No	18 (100%)	13 (72.22%)	

Table (4): Operation data among cases in both study groups

	LigaSure Group (N = 18)	Harmonic Group (N = 18)	P. Value
Operation Time (min.)	124.94 ± 16.24	149.28 ± 12.87	<0.0001*
Blood loss (cc)	81.67 ± 19.22	124.17 ± 14.55	<0.0001*
Conversion to open	0 (0%)	4 (22.22%)	0.0344*

Table (5): Postoperative follow-up evaluations among cases in both study groups

	LigaSure Group (N = 18)	Harmonic Group (N = 18)	P. Value
Post-operative hospital stay (days)	2.5 ± 0.5	2.61 ± 0.49	0.5162
Need for blood transfusion intraoperative	0 (0%)	5 (27.78%)	0.1039
Postoperative morbidity	0 (0%)	0 (0%)	
Post operative spleno-portal thrombosis	0 (0%)	0 (0%)	
Postoperative mortality	0 (0%)	0 (0%)	
Management		Value [N (%)]	
Conversion to open Surgery		4 (22.22%)	
Blood Transfusion		5 (27.78%)	
Bleeding control		5 (27.78%)	

Table (6): CBC data comparison between cases in both study groups

	LigaSure Group (N = 18)	Harmonic Group (N = 18)	P. Value
CBC preoperative			
Hb (g/dl)	10.86 ± 0.33	11.02 ± 0.31	0.1417
Platelets (*10^3/mL)	96.39 ± 50.85	101 ± 48.58	0.7885
CBC post-operative			
Hb (g/dl)	10.09 ± 0.34	9.78 ± 0.34	0.0121*
Platelets (*10^3/mL)	167.78 ± 39.8	173.33 ± 30	0.6487
CBC Change (%)			
Hb	7.1 ± 1.36	11.29 ± 1.38	<0.0001*
Platelets	122.04 ± 110.62	124.1 ± 126.37	0.9599

CBC: Complete blood count, HB: Hemoglobin

Table (7): Dealing with operative difficulties among the harmonic group

Management	Value [N (%)]
Conversion to open Surgery	4 (22.22%)
Blood Transfusion	5 (27.78%)
Bleeding control	5 (27.78%)

DISCUSSION

Technological progress has led to the rise in popularity of new energy-based devices like Ultracision and LigaSure. The enhanced laparoscopic solid organ surgery is made possible with their help, allowing for safe and successful vessel sealing and tissue dissection. Despite their differences, they serve the same objective in most cases. During the dissection part of the surgery, ultracision, an ultrasonically actuated scalpel, is useful. With superior hemostatic power, the electrothermal bipolar vessel-sealing technology LigaSure [9].

The effectiveness of LigaSure and Ultracison was demonstrated by Diamantis et al. [10] to be higher than that of conventional bipolar and monopolar electrocautery. Ultracision and LigaSure have been the subjects of multiple safety and effectiveness studies, all of which have confirmed the former's superior ability to accomplish hemostasis and tissue dissection while the latter has demonstrated less risk [11].

In the present study, there was no discernible variation in the distribution of demographic data among the studied groups. Age was distributed as (27.28 ± 5.72 vs. 24.61 ± 5.11, p = 0.161). Sex distribution (female/male) was (12/6 vs 11/7). There were also no statistically significant differences between the groups with respect to smoking, BMI, or previous medical history.

In the present study, we operated on splenomegaly caused by hematological diseases such as ITP which represented 33.3% (6 cases) in the LigaSure group vs 22.2% (4 cases) in the Harmonic group. Other disorders such as thrombocytopenia (16.6% vs 11.11%), spherocytosis (11.11% vs 22.2%), hypersplenism (22.2% vs 27.7%), and Thalassemia (16.6%) in both groups demonstrating no significant variations between the groups.

In the present study, the size of the spleen showed no significant difference between LigaSure and Harmonic groups (15.61 ± 1.35 vs. 15.08 ± 1.27, p = 0.2488).

Additionally, our results were in agreement with those of Gelmini et al. [13], who found that splenic weight averaged 485 g (range, 265-1,800) and an average splenic diameter of 15.2 cm (range, 9-25).

While in Kurt et al. [12], spleen size was smaller and ranged (from 9–18) with a mean of 12.1 cm in the LigaSure group vs 13.5 cm (9–26) in the LigaSure + Ultracision group. Spleen weight was 235.5 gm (138–654) in the LigaSure group vs 249 gm (142–743) in the LigaSure + Ultracision group.

In the present study, regarding the intraoperative actual risks, in the LigaSure group, none of the cases (0%) encountered intraoperative difficulties, while in the Harmonic group, 5 cases (27.78%) experienced such issues, representing a significant increase (p = 0.0152). So LigaSure was much better at dealing with these intraoperative risks than Harmonic.

We found that the LigaSure group had significantly shorter operative time compared to the harmonic group (124.94 ± 16.24 vs. 149.28 ± 12.87, p < 0.0001)**.** In Romano et al. [14] study, the average operating time was 120 min in the LigaSure group vs 145 min in the harmonic group. Unlike Kurt et al. [12], where the combined use of LigaSure and Ultracision resulted in a considerably reduced mean operative time (112.3 vs. 147.5 min; P = 0.002) compared to the LigaSure-only group. This is because dissection and hemostasis were accomplished in that trial by utilizing the combined advantages of both devices. While in Barbaros et al. [15], the mean duration of LS using LigaSure was 71.3 ± 19.8 minutes.

Blood loss during the operation was also statistically lower in the LigaSure group (81.67 ± 19.22 vs. 124.17 ± 14.55, p < 0.0001). As a result, there were 5 cases (27.7%) in the Harmonic group that needed intraoperative blood transfusion. While no case in the LigaSure group needed a blood transfusion. No accessory spleens were present in either group.

In Barbaros et al. [15] no patients required a blood transfusion, and the average blood loss was 60 to 80 mL, which is consistent with previous studies. In the study by Romano et al. [14], all patients in the LigaSure group had individual estimated blood losses of no more than 80 mL (range 50-100 m), while in the Harmonic group, it was 265 mL (range 175-450 m).

So, we agreed with the previous studies that indicated that blood loss during the operation was lower in the LigaSure group as compared to the harmonic group revealing that LigaSure could be superior in decreasing blood loss during laparoscopic splenectomy.

The primary reasons for converting LS to open surgery were intraoperative bleeding from hilar arteries and capsular damage; reports of this conversion rate range from 1.7% to 17.2%. Bleeding makes it harder to see during LS and makes dissection less safe [17].

In the present study, 4 cases (22.22%) were converted to open surgery in the Harmonic group while none of the cases in the LigaSure group encountered the need for open surgery. In cases complicated with operative difficulties in the Harmonic group, all 5 cases were initially managed with bleeding control and blood transfusion, only one case could be managed however the other cases needed to be managed with open surgery.

In a study made by Gelmini et al. [13] Fifty-eight patients were able to successfully finish LS utilizing LigaSure. The conversion was required in five instances (7.9% of the total) because of splenic hilar dissection being difficult in one case, severe splenomegaly in another, hilar hemorrhage in three cases (two of which were caused by the inappropriate application of LigaSure), and other complications.

While in Kurt et al. [12]**,** In both groups, the conversion rate was 8% (two patients). An open splenectomy was performed on one patient in the LigaSure group who had Hodgkin's lymphoma. The dissection was made more difficult and blood was lost due to hilar lymphadenopathy. Due to uncontrolled hilus bleeding, one patient in the LigaSure + Ultracision group had to undergo an open operation.

In the present study, regarding postoperative follow-up evaluations, there was no morbidity or mortality

In a study by Kurt et al. [12] Both groups had similar average lengths of hospital stays following surgery (2.3 vs. 2.9 days; P = 0.093).

While Gelmini et al. [13] found that patients spent an average of 4.2 days in the hospital following surgery

(range, 3-7). No one died after the operation. One case of splenic-portal vein thrombosis was found 10 days after LS, leading to a hospital readmission and heparin infusion. Two cases of hemoperitoneum were treated laparoscopically, one case of which was caused by bleeding of the pancreatic tail. One case of superficial surgical wound infection was also treated medically, and one case of pleural effusion was also treated medically, bringing the morbidity rate to 7.9 percent (one case).

In the present study, pre-operative CBC analysis showed no significant difference in hemoglobin (Hb) levels between the LigaSure group (10.86 ± 0.33 g/dl) and the Harmonic group (11.02 ± 0.31 g/dl) ($p = 0.1417$). Similarly, platelet count (Plts) did not significantly differ between the groups ($p = 0.7885$). Post-operative CBC analysis revealed a significant decrease in Hb levels in the Harmonic group (9.78 ± 0.34 g/dl) compared td to the LigaSure group (10.09 ± 0.34 g/dl) ($p = 0.0121$*). This could be due to the significant blood loss intra-operatively in the Harmonic group in comparison to the LigaSure group.

Kurt et al. [12] discovered that 16 out of 37 patients (or 84.2% of the total) with ITP—defined as a thrombocyte count greater than 150,000/mm—had an immediate positive response to LS.

CONCLUSION

When it comes to benign hematological problems, LS should be the primary option for spleen excision. We found a fundamental component necessary to accomplish advanced laparoscopic surgery, like LS. Two new energy-based devices, Ultracision and LigaSure, have revolutionized laparoscopy and offer significant benefits. Laparoscopy benefits greatly from the use of LigaSure and Ultracision. There was less blood loss, less operating time, and no need for intraoperative blood transfusions when LigaSure was used in LS. To validate this finding, additional prospective randomized trials are necessary.

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