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Clipless Cholecystectomy in Adult and Pediatric Populations: Harmonic versus LigaSure Sealing

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ABSTRACT

Background: Laparoscopic cholecystectomy is the commonest surgical intervention in adults and pediatrics. The controversy still exists about the ideal sealing system.

Aim of the work: The study aimed to evaluate the Harmonic scalpel and the LigaSure in laparoscopic clipless cholecystectomy in adults and pediatrics.

Patients and methods: 60 adults and 30 pediatric patients were selected from our institution and scheduled for total clipless laparoscopic cholecystectomy, either by Harmonic or LigaSure sealing system. Preoperatively, all patients were evaluated by history taking, clinical examination, Lab investigation, and ultrasound examination. Demographic, operative, and postoperative data were documented.

Results: Both groups of sealing systems were comparable regarding demographics, operative time, blood loss, postoperative pain, and complications. In adult patients, 6.7% had complications [bile leak and common bile duct injury] in the harmonic group. In contrast, in the LigaSure group, 10.0% had complications [pneumonia in 3.3% and common bile duct injury with bile leak in 6.7%]. On the other hand, no bile leak or common bile duct injury was reported in the pediatric age group. The majority of pediatrics had chronic hemolytic anemia. Conversion to open in pediatrics was reported in 2 patients in harmonic and none in the LigaSure group. Surgical site infection was reported in 1 patient in LigaSure, while pneumonia was reported in 2 patients in the harmonic group.

Conclusion: LigaSure and Harmonic sealing systems are effective and safe in total clipless cholecystectomy in adult and pediatric populations.

Keywords: Cholecystectomy, clipless, LigaSure, Harmonic; Adults; Pediatrics.

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* Main subject and any subcategories have been classified according to the research topic.

INTRODUCTION

Gall stone disease is usually treated by laparoscopic cholecystectomy [LC]. Before dividing the cystic duct and artery, there were traditionally closed [secured] by titanium clips. It could be associated with clip dislodgement and an increased risk of bile leak. Slipped clips could also act as a nidus for stone formation^[1-3]. Electrocautery was used as an alternative to titanium clips. It is associated with excess smoke production [which may compromise dissection precision] and subsequent tissue destruction. In addition, there is an increased risk for iatrogenic injury of adjacent tissue and vessels such as the common bile duct^[4] and the small intestine^[5] by side effects of thermal energy^[6-8]. The LigaSure system was developed to prevent the dislodgement of titanium clips. It is a disposable instrument that seals vessels by applying controlled energy to produce a collagen seal during physical pressure. This denatured collagen is attached to the native vessel and thus resists slippage. This seal assessment revealed that it is free of tissue reactivity^[9].

In addition, the harmonic scalpel was identified to have the power to seal vessels of up to 5 mm thickness without increased risk of a leak. This technology transmits minimal energy to the adjacent tissues and thereby decreases collateral thermal damage^[10-11]. The Harmonic system is composed of ultrasound surgical appliances, able to cut and coagulate simultaneously. The Harmonic Scalpel performs ultrasonic wave function by applying electromagnetic energy in the hand-piece. The electrical field produces a wave that travels from the hand-piece to the blade with mechanical vibrations [about 55500 vibrations/second], leading to bleeding vessels' coaptation when pressure is applied^[12].

The harmonic scalpel versus the LigaSure system's safety and efficacy not yet adequately addressed in clipless cholecystectomy in adult and pediatric populations.

AIM OF THE WORK

The current study aimed to evaluate the use of the Harmonic scalpel and the LigaSure in laparoscopic clipless cholecystectomy in adult and pediatric populations.

PATIENTS AND METHODS

Sixty adult and thirty pediatric patients undergoing elective laparoscopic cholecystectomy were included in the present work. They were selected from the General and pediatric surgery departments from October 2015 to August 2018. They were randomized into two equal groups [30 patients for each group of adult populations and 15 for each pediatric patient group]. The first subgroup included those allocated for harmonic scalpel [HS group], and the second included those allocated for the LigaSure system [LS group]. Randomization was done by the closed envelope method, where random series of numbers [1 for HS group and 2 for LS group] were generated. Each number was enclosed in an envelope that opened directly before surgery by a nurse not included in the study. The study protocol was approved by the local research and ethics committee of Al-Azhar Faculty of Medicine [New Damietta] [IRB 00012367/20-01-013]. Informed consent was signed by each participant or his/her guardian before inclusion in the study. **The inclusion criteria** were: 1] symptomatic cholelithiasis after the failure of conservative treatment, 2] an American Society of Anesthesiology [ASA] stage I or II, 3] patients with a history of gallstone comorbidities [e.g., acute cholecystitis, cholangitis, pancreatitis, or choledocholithiasis]. **Exclusion criteria** were: 1] patients with previous surgery of upper abdomen suspected GB carcinoma, 2] known cirrhosis of the liver, 3] ASA score of 3 or higher, 4] BMI > 40kg/m², 4] concomitant existence serious cardiopulmonary, hepatorenal, or endocrine diseases, 5] pregnant or lactating females. The preoperative clinical evaluation included a history taking, clinical examination, routine hematology laboratory investigations, viral markers, electrocardiography, chest X-ray, and upper abdominal ultrasound. Also, magnetic resonance cholangio-pancreato-graphy [MRCP] if needed.

Operative procedure: All patients were operated on under general anesthesia and received intravenous antibiotic [ceftriaxone sodium] prophylaxis. Laparoscopic cholecystectomy was performed as described by **Tebala**^[13] using harmonic scalpel but through the standard 4-port technique [three 5 mm and one port of 11 mm] positioned on the upper abdomen, while the patient

lying in the supine position with legs apart and the surgeon stands between them]. In summary, pneumoperitoneum was performed with carbon dioxide insufflation and maintained at [an average of 10 ± 2 mmHg in pediatrics and 14 ± 2 mmHg in adults]. The harmonic scalpel was used for dissection during the whole procedure once the energy device was needed. The GB was separated from the liver bed by the harmonic shear and harmonic hook [the power level set at "5" [more cutting-less coagulation]]. Closure and sealing of the cystic duct and cystic artery were performed with the harmonic device [the instrument was set at the power level "2" [less cutting, more coagulation]].

In the LigaSure group, division of the cystic duct and artery were done by LigaSure™. The jaws were positioned at a safe distance from the common bile duct to prevent its injury. The cystic duct was coagulated, and the LigaSure™ reapplied distally, and tissues were divided. The cystic artery was also isolated and separated using the LigaSure™ system. Postoperatively, patients were asked to restart ambulatory activities and oral intake of a semiliquid diet on day 1. All patients underwent a follow-up abdominal ultrasound on the discharge day. Then they asked to come for a follow up one week and one month after discharge and evaluated by clinical examination and abdominal ultrasound. For each patient, age, sex, weight [kg], height [m], operative technique, operative time [min] [starting from skin incision for port placement to the final port closure], postoperative pain [evaluated by the visual analog scale at 12 and 24 hours postoperatively], analgesic requirements, complications, conversion to open cholecystectomy, postoperative hospital stay [days], and mortality were collected and documented. Patient satisfaction with the surgical scar was also assessed.

A statistical analysis of data was done using the SPSS 20.0 software [IBM®SPSS®, Armonk, New York, United States] for Windows. All qualitative data between both groups were compared using the chi-square test. Data related to continuous numerical variables were compared using the Independent Samples Student t-test.

RESULTS

In the present work, adult patient demographics were presented in detail in table [1]. The patient age

ranged from 18 to 53 years, and there was no significant difference between HS and LS groups [44.56 ± 5.82 vs. 46.30 ± 3.67 years respectively]; 66.7% of HS groups were females, compared to 63.3% of LS group [$p > 0.05$]. Besides, there was no significant difference between HS and LS groups regarding BMI [25.67 ± 0.89 vs. 25.64 ± 0.73 , respectively]. ASA class was grade I in 56.7% and 46.7%, while Class II was reported in 43.3% and 53.3% of HS and LS groups, respectively. Finally, diabetes and hypertension were reported in 23.3% and 16.7% in the HS group and 16.7% and 26.7% in the LS group, with no significant difference.

Regarding the outcome in adult populations, both HS and LS groups were comparable regarding operative time, blood loss intraoperatively, postoperative pain and analgesia, and post-operative complications. In the HS group, the encountered complications were surgical site infection, PO pneumonia [both occurred in the same patient who converted to open laparotomy], and CBD injury and bile leak [the same patient]. Thus, collectively, 2 patients [6.7%] had complications in the HS group. On the other hand, PO pneumonia was reported in 1 patient [3.3%] and CBD injury with bile leak in two patients [6.7%] in the LS group. Thus, complications were reported collectively in 3 patients [10.0%] of this group [Table 2]. In the pediatric age group, results were similar to those in the adult groups, where demographic data revealed that patient age ranged from 4 to 14 years, and there was no significant difference between HS and LS groups [12.06 ± 2.65 vs. 12.46 ± 1.88 respectively]. In addition, males represented 26.7% of the HS group and 40% of the LS group. Furthermore, there was no significant difference between both groups regarding patient weight, height, BMI, or ASA classification. No patient had diabetes or hypertension. However, most pediatric age groups had chronic hemolytic anemia, where 53.3% and 40.0% of the HS group had thalassemia and sickle cell disease, respectively. In comparison, 60.0% and 33.3% of the LigaSure group had thalassemia and sickle cell disease, with no significant difference between groups [Table 3]. The outcome in the pediatric population was presented in table [4]. It revealed that both groups were comparable as regards the outcome. No significant difference was found regarding operative time,

intraoperative blood loss. Conversion to open was reported in two patients in the HS group, while no one in the LS group was converted to open. However, surgical site infection was reported in 1

patient in the LS group, while PO pneumonia was reported in two HS groups. No bile leak or CBD injury was reported in any patient of both groups.

Table [1]: Comparison between HS and LS groups of adults as regards to patient demographics, ASA class, and comorbid disease

Variables		HS group	LS group	P-value
Age [years]		44.56±5.82; 18- 52	46.30±3.67; 35-53	0.17
Sex	Male	10[33.3%]	11[36.7%]	0.78
	Female	20[66.7%]	19[63.3%]	
Weight [kg]		69.77±4.67; 63-80	70.00±5.35; 63-82	0.85
Height [cm]		164.77±4.32; 158-172	165.10±4.95; 1.58-1.75	0.78
BMI [kg/m ²]		25.67±0.89; 24.01- 27.64	25.64±0.73; 24.39 – 26.96	0.87
ASA Class	I	17[56.7%]	14[46.7%]	0.30
	II	13[43.3%]	16[53.3%]	
Diabetes		7[23.3%]	5[16.7%]	0.51
Hypertension		5[16.7%]	8[26.7%]	0.34

HS: Harmonic scalpel; LS: Ligasure; ASA: American Society of Anesthesiologists

Table [2]: Comparison between HS and LS groups of adults as regard to the outcome

Variables		HS group	LS group	P-value
Operative time [minute]		44.90±5.66	47.26±7.25	0.16
Intraoperative blood loss [ml]		16.43±2.50	15.86±2.33	0.36
Conversion to open		1[3.3%]	0[0.0%]	0.31
PO VAS [12 h]		4.46±0.73	4.53±0.62	0.70
PO VAS [24h]		2.33±0.71	2.46±0.50	0.40
Analgesics in first day [tab]		2.86±0.73	2.73±0.44	0.39
Surgical site infection		1[3.3%]	0[0.0%]	0.31
PO pneumonia		1[3.3%]	1[3.3%]	1.0
CBD injury		1[3.3%]	2[6.7%]	0.55
Bile leak		1[3.3%]	2[6.7%]	0.55
Hospital stay [hours]		34.80±10.61	34.00±8.38	0.74

HS: Harmonic scalpel; LS: Ligasure; PO VAS : Postoperative visual analogue scale; CBD: common bile duct.

Table [3]: Comparison between HS and LS groups of pediatrics as regard to patient demographics, ASA class, and comorbid disease

Variables		HS group	LS group	P-value
Age [years]		12.06±2.65; 4-14	12.46±1.88; 10-14	0.63
Sex	Male	4[26.7%]	6[40.0%]	0.34
	Female	11[73.3%]	9[40.0%]	
Weight [kg]		48.26±7.43	45.53±8.53	0.35
Height [cm]		146.53±4.92	149.67±5.28	0.10
BMI [kg/m ²]		22.05±2.48	20.31±3.54	0.13
ASA Class	I	8[53.3%]	9[40.0%]	0.71
	II	7[46.7%]	6[40.0%]	
Diabetes		0[0.0%]	0[0.0%]	-
Hypertension		0[0.0%]	0[0.0%]	-
Thalassemia		8[53.3%]	9[60.0%]	0.70
Sickle cell disease		6[40.0%]	5[33.3%]	0.70

HS: Harmonic scalpel; LS: Ligasure; ASA: American Society of Anesthesiologists

Table [4]: Comparison between HS and LS groups of pediatrics as regard to the outcome

Variables	HS group	LS group	P-value
Operative time [minutes]	43.13±4.53	44.13±4.22	0.53
Intraoperative blood loss [ml]	17.93±10.72	15.53±4.56	0.43
Conversion to open	2[13.3%]	0[0.0%]	0.14
PO VAS [12 h]	4.73±0.79	4.46±0.74	0.35
PO VAS [24h]	2.53±0.63	2.60±0.50	0.73
Analgesics in first day [tab]	2.60±0.50	2.66±0.48	0.71
Surgical site infection	0[0.0%]	1[6.7%]	0.31
PO pneumonia	2[13.3%]	0[0.0%]	0.14
CBD injury	0[0.0%]	0[0.0%]	-
Bile leak	0[0.0%]	0[0.0%]	-
Hospital stay [hours]	43.20±10.92	42.40±10.98	0.84

HS: Harmonic scalpel; LS: Ligasure; PO VAS : Postoperative visual analogue scale; CBD: common bile duct.

DISCUSSION

The present work results revealed that both harmonic scalpel and LigaSure were effective and safe for dissection and closure of cystic duct and artery in clipless cholecystectomy. Both groups were also comparable regarding patient demographics and associated comorbid diseases, both in adult and pediatric populations. These results are comparable to those reported by **Abdallah et al.**^[14], who reported no significant difference between studied groups regarding age, sex distribution, and comorbidities.

In the present work, most pediatric patients had chronic hemolytic disease. These results are comparable to those reported by **Bai et al.**^[15] who said that cholelithiasis' incidence is much higher in children with risk factors such as hemolytic disorders. Besides, different studies from Africa and Mediterranean countries have shown a very higher prevalence of thalassemia and sickle cell disease^[16-17], explaining the higher number of pediatric populations included in the current work. Besides, gall stone pancreatitis is responsible for this increased number of 5 pediatric patients [16.7%].

The shift from clips to clipless cholecystectomy is attributed to the fact that clips could be associated with many complications like ulceration of the duodenum with subsequent severe bleeding, migration of clips to CBD, embolism, bile leak due to clip slippage, and clip-induced biliary stone^[18]. The harmonic scalpel was reported to be a safe and effective alternative. Different studies demonstrated

that HS is a safe substitute for standard clipping of the cystic duct in LC. It was also reported to be associated with shorter operative time, less incidence of gallbladder perforation, and less postoperative pain^[19]. It must be emphasized that these studies compared HS to traditional clipping. However, no significant difference was found when compared to the LigaSure system. **Kassem and Hassouna**^[20] confirmed the safety of harmonic scalpel in laparoscopic cholecystectomy in cirrhotic patients. They reported the conversion to open procedure only in two patients [3.2%], which is an acceptable rate when compared to previous studies [6% in **Nguyen et al.**^[21] and 10 in **Shaikh and Muneer**^[22].

Westervelt^[23] reported no bile leaks in 100 patients, where HS completely did the cystic duct's closure and division. Similar findings were reported by **Tebala**^[13]. However, **Hüscher et al.**^[24] reported bile leaks in 7 of 331 patients [2.1%], in whom HS was used for division and closure of cystic duct and artery. On the other side, the LS system has been effective for sealing blood vessels compared with mono- or bi-polar coagulation or ultrasonic techniques^[25]. Besides, **Turial et al.**^[26] reported no bile leak after LS to seal the cystic duct in 22 pediatric patients receiving LC [as in the present work]. The authors concluded that LS is a safe and effective sealer.

Al-Talhi et al.^[17] confirmed laparoscopic cholecystectomy safety in children with sickle cell disease regardless of the hemostasis maneuver. Also, in adults, **Schulze et al.**^[27] reported that LS provided adequate sealing of cystic duct with

absent bile leak in 102 patients.

On the other hand, in an interesting *ex vivo* study, **Abdallah et al.**^[14] concluded that the harmonic scalpel is the best sealer for cystic duct and artery in LC. They rated HS first, followed by clips, and at the end of the least, the LigaSure. They depend on the pressure inside the common bile and cystic duct, especially if transcystic CBD exploration was performed in a clinical situation [which may increase the cystic bile duct pressure], and good sealing of the cystic duct was preferred without CBD decompression. This could be reflected in the present work, where the leak occurred in two patients in LigaSure compared to 1 patient in the HS group, although the difference was statistically non-significant. In another study, **Kim et al.**^[28] studied the safety profile of different sealing systems by measuring the temperature generated by each system. They concluded that the HS system leads to high peak temperature after deactivation when applied against the liver. The other instruments increased peak temperatures to a lower level than HS. They added that the HS system's high temperature could harm adjacent structures. Thus, they recommend judicious use of such devices during laparoscopic surgery. These two studies reflected the importance of the device's physical properties in controlling safety profile and effectiveness.

The LigaSure™ system was initially introduced to seal vessels up to 7 mm and was just as effective as other sealing devices such as HS, clips, and traditional hemostasis^[29]. Its usage was expanded to permit parenchymal dissection/ transection, with minimal blood loss^[30].

Downes et al.^[32] proposed using LS for cystic duct diameter up to 5 mm to confirm complete sealing along its whole length of transection. This is particularly important in the acute condition where the cystic duct wall might be edematous and inflamed. They added that it is recommended to keep a safe distance from other intra-abdominal organs when using thermal energy devices to prevent thermal collateral injury.

Finally, **Diamantis et al.**^[25] compared the

Harmonic Scalpel and the LigaSure hemostatic profiles and concluded that both reached full hemostasis with no complications.

Although not addressed in the current work, the Harmonic scalpel disadvantage is its high cost and need for training. This is in line with **Sasi**^[6] who reported that, harmonic scalpel disadvantages are its handling difficulty and cost. Training programs could overcome handling, but many institutions can not overcome the cost.

The current work's strength point is the comparison between two maneuvers in two age groups, pediatrics and adults, which reflected the effectiveness and safety of Harmonic and Ligasure for nearly any age.

One limiting step of the current work is the absent cost analysis between both devices. This is attributed to the availability of both devices in our institution. However, the learning curve represented another issue that was not addressed in the current study.

Conclusion: Both LigaSure and Harmonic Scalpels were effective and safe in clipless laparoscopic cholecystectomy. Thus, using one of them should depend on surgeon preferences and availability.

Financial and Non-Financial Relationships and Activities of Interest

None

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