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ORIGINAL RESEARCH

A comparative study of clip-less laparoscopic cholecystectomy using harmonic scalpel vs conventional laparoscopic cholecystectomy in a tertiary care teaching hospital.

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Abstract

Background: This study evaluates the effectiveness and safety of the Harmonic scalpel for dissection of the gallbladder and its efficacy in the closure of the cystic artery and duct. This study, albeit at a preliminary stage, aims to demonstrate that the ultrasonically activated scalpel is safe instrument that, similarly to the standard titanium clips, is effective for correct and complete division & closure of the cystic duct & artery in laparoscopic cholecystectomy. Use of a single instrument during the whole procedure averts or decreases the risk of organ injuries related to thermal damage & alleviate the need for changing instruments frequently.

Materials & methods: All cases of having gall bladder stones detected preoperatively by ultrasound & symptomatic gall stone disease were divided equally into 2 groups and planned for harmonic scalpel assisted clipless laparoscopic cholecystectomy & conventional laparoscopic cholecystectomy, were included in this study. Patients with Mirizzi syndrome, Age < 18 and >70 years, Impaired liver function tests, Concomitant common bile duct calculi, Chronic liver disease/cirrhosis, Suspected GB carcinoma, Pregnant women and patients in whom subtotal cholecystectomy was done were excluded from this study. A prospective study was carried out for 76 patients for 1.5 year from December 2022 to June 2024 by single surgeon and his team. Half of the patients were subjected to harmonic scalpel assisted laparoscopic cholecystectomy without application of the titanium clips, using 3 port technique after documentation of GB calculi using ultrasonography for diagnosis other half were subjected to conventional method of laparoscopic cholecystectomy. All patients were followed up for 1 month for SSI. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software.

Results: We performed total 76 laparoscopic cholecystectomies from December 2022 to June 2024. Out of them, 78.94% were female and 21.05% were males in both the groups. In the Conventional Cautery group, the majority of subjects (36.84%) are in the 36-45 years category, while the next highest distribution is in the 46-55 years group (18.42%). Similarly, in the Harmonic Scalpel group, the majority of subjects (31.57%) are also in the 36-45 years category, followed by a significant portion (26.31%) in the 26-35 years category. The mean age in the Conventional Cautery group is 46.57 ± 14.00 years, while the Harmonic Scalpel group has a lower mean age of 40.73 ± 13.36 years. We found that the Intraoperative time for clipless Laparoscopic Cholecystectomy using the Harmonic scalpel is far lower than the conventional method of using cautery, Easy dissection of calot's triangle. Harmonic scalpel can seal & cut the cystic duct and artery without using thermal energy with no lateral spread & therefore saving the time to apply titanium clips & preventing inadvertent damage. Easy dissection of gall bladder from the fossa and dissection of adhesions over it. There is no smoke while using harmonic scalpel therefore no difficulty in vision. There was no GB perforation & CBD injury. None of the patients converted to open & none of them had bile leak or postop SSI.

Conclusion: Harmonic scalpel assisted laparoscopic cholecystectomy is better in all aspects & can be routinely used without any intra & post operative complications using standard operative guidelines. Laparoscopic cholecystectomy without application of titanium clips did not produce any harm to patient with the mean operative time was significantly shorter, with shorter hospital stay. It was observed that it is easy to dissect gall bladder from fossa, dissection of adhesions from gall

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bladder with the help of Harmonic scalpel. There was reduced intraoperative time & Anaesthesia time therefore mild postoperative pain and analgesia requirement in patients.

Key words: Cholelithiasis, harmonic scalpel assisted clip-less laparoscopic cholecystectomy & Conventional laparoscopic Cholecystectomy

Introduction

Gallstones can lead to many complications such as, temporary obstruction of the cystic duct can lead to biliary pain, known as biliary colic, while persistent obstruction cause acute cholecystitis. If a gallstone blocks the commonbile duct, it can lead to jaundice, a condition known as choledocholithiasis. Additionally, gallstones can cause pancreatitis by blocking the pancreatic ducts, and in severe cases perforating the gallbladder wall, creating a fistula with the bowel and therefor causing bowel obstruction or ileus. These complications highlight the importance of timely medical attention to prevent these serious consequences. This study demonstrates the effectiveness and safety of the Harmonic scalpel for dissection of the gallbladder & its efficacy in the closure of the cystic artery and duct. This study, albeit at a preliminary stage, aims to demonstrate that the ultrasonically activated scalpel is safe instrument that, similarly to the standard clips, is effective for correct and complete closure & division of the cystic duct & artery in laparoscopic cholecystectomy. Use of a single instrument during the whole procedure averts or decreases the risk of organ injuries related to thermal damage and alleviate the need for changing instruments frequently. The study determines the more convenient method for the dissection of Calot's Triangle, sealing the cystic artery, cystic duct and the dissection of the GB from the GB fossa during LaparoscopicCholecystectomy based on perioperative outcomes. Laparoscopic cholecystectomy is the "gold standard" in the treatment of cholelithiasis. Still some pitfalls are associated with the use of the monopolar hook, such as the risk of thermal injuries and biliary complications. The ultrasonically activatedscalpel, ie, Harmonic scalpel in laparoscopic cholecystectomies has been increasingly used for dissection of the gallbladder and for division of vessels and the cystic duct. Harmonic scalpel where ultrasonic energy is converted to mechanical energy at the active blade. The main mechanism is the active blade which delivers high-grade frictional force while the inactive upper arm holds tissue in apposition. The objectives of this study are to observe the effectiveness to occlude the cystic duct & artery by Harmonic scalpel, Dissection Of adhesions from gall bladder, Dissection of gall bladder from the fossa, The operating time in minutes, Intraoperative Blood loss, GB perforation, CBD injury & Bile leak, Conversion to open cholecystectomy, Post op vitals & headache, Postoperative pain, Analgesic requirement, Hospital stay and Surgical site infection (SSI) up to day 30 postoperatively

Materials & methods

All cases of having gallstones detected preoperatively by ultrasound & symptomatic gall stone disease were randomly divided into two groups using closed envelopes, group A (conventional) and group B (Harmonic). For group A patients, the conventional four-port cholecystectomy was performed. The cystic arteryand duct were clipped using titanium clips and divided. The GB was dissected from the GB fossa with monopolar diathermy/spatula and hook. For group B patients, 3 port laparoscopic cholecystectomy was done with the harmonic scalpel as the single instrument, which was used inthe 10 mm epigastric working port for GB dissection. The cystic duct & cystic artery was divided and sealed with the harmonic scalpel only. Patients with Mirizzi syndrome, Age < 18 and >70 years, Impaired liver function tests, Concomitant common bile duct calculi, Chronic liver disease/cirrhosis, Suspected GB carcinoma, Pregnant women and patients in whom subtotal cholecystectomy was done were excluded from this study. A prospective study was carried out for 76 patients for 1.5 year from December 2022 to June 2024 by single surgeon and his team. Documentation of GB calculi using ultrasonography for diagnosis with all routine blood investigations including LFT to be within normal limits. Ethicon Harmonic scalpel GEN 11 and Hand piece No.054 was used. All patients received prophylactic antibiotics Preoperatively.

All patients were subjected to the intraoperative assessment of Time (was measured from the insertion of last port to delivery of the gallbladder),incidence of gall bladder perforation, CBD injury or bile leak, sealing and closure of cystic duct and artery, blood loss (was measured by keeping a gauge piece at the site of GB dissection of size 10x10cm which was weighed before and after the surgery), conversion to open procedure, post operative pulse, SPO2, Headache, post operative pain and analgesia requirements at mild, moderate and severe analgesia requirement was seen, hospital stay and SSI observed up till 30 days. The patients started oral feeding 8h postoperatively. All patients received prophylactic antibiotics. At the time of discharge, during the first postoperative visit and at the 30th postoperative day, patients will be examined for wound infection to rule out any surgical site infections. Postoperative pain will be assessed using the visual analogue scale (VAS) score at 12 and 24 hours after surgery. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software

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Results

We performed total 76 laparoscopic cholecystectomies from December 2022 to June 2024. Out of them, 78.94% were female and 21.05% were males in both the groups. In the Conventional Cautery group, the majority of subjects (36.84%) are in the 36-45 years category, while the next highest distribution is in the 46-55 years group (18.42%). Similarly, in the Harmonic Scalpel group, the majority of subjects (31.57%) are also in the 36-45 years category, followed by a significant portion (26.31%) in the 26-35 years category. The mean age in the Conventional Cautery group is 46.57 ± 14.00 years, while the Harmonic Scalpel group has a lower mean age of 40.73 ± 13.36 years. The p-value of 0.066. The Conventional Cautery group has a mean surgery duration of 76.47 minutes with an SD of 10.69, while the Harmonic Scalpel group has asignificantly shorter mean duration of 34.39 minutes with an SD of 5.76. The p-value is <0.0001, indicating a statistically significant difference in surgery duration between the groups. The Conventional Cautery group had a mean blood loss of 8.15 ml (SD = 7.86), while the Harmonic Scalpel group had significantly less blood loss with a mean of 3.5 ml (SD = 0.79). The p-value of 0.000. In the Conventional Cautery group, 6 subjects experienced gallbladder (GB)perforation, while no subjects in the Harmonic Scalpel group had such injuries. None of patients had CBD injury nor did they convert to open in both the groups. The Conventional Cautery group had a mean pulse rate of 87.29bpm, while the Harmonic Scalpel group had a significantly lower mean pulse rate of 79.05 bpm. The SpO2 levels were also significantly different, with the Conventional Cautery group showing a mean SpO2 of 96% and the Harmonic Scalpel group showing a higher mean of 99%. Thep-value for both parameters is <0.0001, indicating significant differences in vitals between the groups. 12 subjects of Conventional Cautery group and 2 subjects of Harmonic scalpel group reported postopheadache which was statistically significant (P=0.003). In the Conventional Cautery group, 42.10% had mild analgesia requirement, 47.36% had moderate analgesia requirement, and 10.52% had severe analgesia requirement. In contrast, the Harmonic Scalpel group had 57.59% had mild analgesia requirement, 42.10% had moderate analgesia requirement, and no participants had severe analgesia requirement, indicating a better postoperative pain profile in the Harmonic Scalpel group. The Conventional Cautery group had a mean VAS score of 6.10 at 12 hours and 2.68 at 24hours, whereas the Harmonic Scalpel group had lower pain scores with a mean of 3.47 at 12 hours and 0.86 at 24 hours. The p-value is <0.0001 for both time points, indicating a statisticallysignificant difference in pain levels between the groups. The Conventional Cautery group had a mean hospital stay of 4.13 days (SD = 1.49), whilethe Harmonic Scalpel group had a shorter mean stay of 2.44 days (SD = 1.13). The p-value is <0.000. None of the patient experienced post SSI after 30 days in the either group.

Table 1: Age group wise distribution of study subjects

Age Group	Conventional Cautery group		Harmonic scalpel group	
	No. of patients	Percentage	No. of patients	Percentage
<25 years	3	7.89	4	10.52
26-35 years	4	10.52	10	26.31
36-45 years	14	36.84	12	31.57
46-55 years	7	18.42	7	18.42
56-65 years	6	15.78	4	10.52
>65 years	4	10.52	1	2.63
Total	38	100.00	38	100.00
Mean + SD Age	46.57+ 14.00		40.73+ 13.36	
P value	0.066			

Table 2: Gender wise distribution of study subjects

Gender	Conventional Cautery group		Harmonic scalpel group	
	No. of patients	Percentage	No. of patients	Percentage
Male	8	21.05	8	21.05
Female	30	78.94	30	78.94
Total	38	100.00	38	100.00

Table 3: Mean duration of surgery wise distribution of study subjects

Gender	Mean time (minutes)	SD	t value	P value
Conventional Cautery group	76.47	10.69	-22.33	**<0.0001**
Harmonic scalpel group	34.39	5.76		

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Table 4: Mean Blood loss wise distribution of study subjects

Group	Blood loss (ml)		t value	P value
	Mean	SD		
Conventional Cautery group	8.15ml	7.86	-3.90	0.000
Harmonic scalpel group	3.5ml	0.79		

Table 5: GB Perforation wise distribution of study subjects

Parameters	Conventional Cautery group		Harmonic scalpel group		P -value
	Yes	No	Yes	No	
GB Perforation	6	32	0	38	0.01

Table 6: Vitals among study subjects

Parameters	Conventional Cautery group		Harmonic scalpel group		t value	P value
	MEAN	SD	MEAN	SD		
Pulse rate	87.29bpm	1.75	79.05bpm	9.86	**-5.01**	**<0.0001**
SPO2 (at room air)	96%	0.04	99%	00.00	448.52	**<0.0001**

Table 7: Postop Headache wise distribution of study subjects

Parameters	Conventional Cautery group		Harmonic scalpel group		P-value
	Yes	No	Yes	No	**0.003**
Postop Headache	12	26	2	36	

Table 8: Postop Analgesia requirement wise distribution of study subjects

Postop Analgesia	Conventional Cautery group		Harmonic scalpel group	
	No. of patients	Percentage	No. of patients	Percentage
Mild	16	42.10	22	57.59
Moderate	18	47.36	16	42.10
Severe	4	10.52	0	0.00

Table 9: Mean VAS score at different time intervals wise distribution of study subjects

Group	VAS at 12 hours		VAS at 24 hours	
	Mean	SD	Mean	SD
Conventional Cautery group	6.10	1.75	2.68	1.35
Harmonic scalpel group	3.47	1.38	0.86	0.81
t value	-7.27		-7.12	
P value	<0.0001		<0.0001	

Table 10: Mean hospital stay wise distribution of study subjects

Group	Hospital stay (days)		t value	P value
	Mean	SD		
Conventional Cautery group	4.13	1.49	-5.57	<0.0001
Harmonic scalpel group	2.44	1.13		

Discussion

Laparoscopic cholecystectomy is the "gold standard" in the treatment of cholelithiasis. Harmonic scalpel where ultrasonic energy is converted to mechanical energy at the active blade.The main mechanism is the active blade which delivers high-grade frictional force while the inactive upper arm holds tissue in apposition. Its main advantages include precise dissection, reliable hemostasis, less lateral thermal spread and charring mainly works by applying pressure and then sealing with a denatured protein coagulum while applying ultrasonic vibration to denature tissue. The transducer in the hand-piece consisted of piezoelectric crystal sandwiched under pressure among metal cylinders. The ultrasonic generator converts ultrasonic energy into mechanical energy. The sealing of the vessels is achieved due to denatured protein coagulum which occurs due to tamponade and coaptation of hydrogen bonds perform vessel coagulation. The temperature obtained and the lateral energy spread are lower than those detected when the monopolar hook is used, thus reducing the risk of tissue damage. It ensures less tissue damage and it is claimed to be stronger, more reliable sealing device and is successful in being able to seal vessels with 5- 7 mm diameter. The device divides tissue by usinghigh-frequency (55,000 Hz) ultrasonic energy transmitted between the instrument blades. Theactive blade of the instrument vibrates longitudinally against an inactive blade over an excursion of 50-100 µm. The harmonic scalpel is indeed recognized as a safe and effective tool for

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vessel sealing, even in challenging environments. Its safety in high-pressure systems such as the superior and inferior mesenteric arteries and veins has been well-documented, showcasing its ability to provide effective haemostasis. Given that the biliary tract operates under much lower pressure, and considering the typically small diameter of the cystic duct and artery (generally under 5 mm), the harmonic scalpel is an appropriate choice for procedures like cholecystectomy. Its benefits include reduced smoke production, which improves visibility during surgery, as well as minimized blood loss, contributing to overall surgical safety. Additionally, the reduced thermal spread of the harmonic scalpel may lower the risk of bile duct or gallbladder perforation, furtherenhancing its suitability for use in gallbladder surgery. This is particularly valuable in cases without extensive inflammatory changes, as seen in patients with recurrent episodes of cholecystitis or cholangitis. The significant reduction in operating time can be attributed to the harmonic scalpel's multifunctionality. By combining the roles of the dissector, clip applier, scissors, and electrosurgical hook or spatula, the harmonic scalpel minimizes the need for instrument changes during surgery, streamlining the process and saving valuable time.The harmonic scalpel operates at relatively low temperatures (50-100°C), which is significantly lower than the temperatures used in electrosurgery or lasers (150-400°C). This lower temperature is sufficient to cut and coagulate tissue through a process called **coaptive coagulation**. This controlled coagulation minimizes collateral tissue damage and is effective at sealing both small capillaries and larger vessels. In contrast, **electrosurgery** and **laser techniques** rely on much higher temperatures, leading to **obliterative coagulation**, which burns tissues and forms **eschar** (dead tissue) to cover and seal bleeding vessels. However, this eschar is more prone to disruption, which can lead to rebleeding if the surgical blade inadvertently dislodges it.

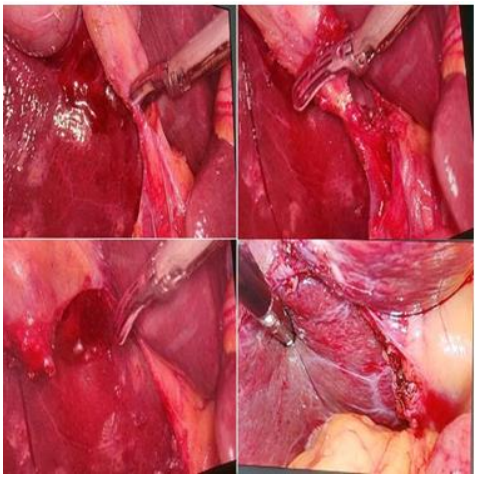

Figure 1: Intra-operative picture of clipless Cystic artery & duct ligation.

Figure 2: Harmonic scalpel

Conclusion

Harmonic scalpel assisted laparoscopic cholecystectomy is better in all aspects & can be routinely used with minimal intra operative bleeding, dissection of Calot’striangle and Gallbladder from the fossa.

Laparoscopic cholecystectomy without application of titanium clips didn't cause any intraoperative or postoperative complications to patient with the mean operative time was significantly shorter, with shorter hospital stay.

It was observed that it is easy to dissect adhesions over the gallbladder and gall bladder itself from the fossa with the help of Harmonic scalpel with minimal lateral thermal organ injury.

There was reduced intraoperative period & anaesthesia time. therefore, early postoperative recovery, lesser postoperative pain thereby decreasing analgesia requirement, post-op headache and other postoperative anaesthesia complications.

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