

Comparison of Laparoscopic Cholecystectomy Performed using Harmonic Scalpel as the Sole Instrument or by using Standard Clip and Electrocautery Technique

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ABSTRACT

Introduction: Laparoscopic cholecystectomy using clips and cautery, has been the gold standard treatment for symptomatic cholelithiasis since long. But the technique still has areas requiring refinement, including complications of clips being dislodged and electrical arcing injuries, due to the use of monopolar electrocautery. This study was undertaken to demonstrate the efficacy and safety of the Harmonic scalpel as the sole instrument to achieve complete hemobiliary stasis.

Material and methods: A comparative study was conducted at GMC Rajindra Hospital Patiala including sixty patients divided into two equal groups of 30 each, which underwent laparoscopic cholecystectomy using standard clip and cautery technique or the Harmonic scalpel (HS) technique. Harmonic scalpel was used to ligate and cut both the cystic duct and artery. Comparison was made with regard to the operative time, lens cleaning, intraoperative and postoperative complications.

Results: The use of Harmonic scalpel results in shorter operative time and reduces the number of times lens requires cleaning, but there is no significant difference in intraoperative and postoperative complications in both group of patients.

Conclusion: Harmonic scalpel is safe and effective in providing complete hemobiliary stasis, it significantly reduces the operative duration and the number of times lens is cleaned, hence making the surgeon more comfortable.

Keywords: Laparoscopic cholecystectomy, Harmonic scalpel, Monopolar electrocautery.

INTRODUCTION

Laparoscopic cholecystectomy is the revolutionary new method for the treatment of gallstone disease and has now become the gold standard for the surgical treatment of symptomatic cholelithiasis.^{1,2} The traditional laparoscopic cholecystectomy is commonly performed by means of dissector, the electrosurgical hook, spatula, and/or scissors, and this method has been used in most centers. Simple metal clips are frequently used to achieve cystic duct and artery closure.³ Although the surgical clip was known to be a safe closure method, bile leakage due to clip displacement from the cystic duct stump is a potential complication of laparoscopic cholecystectomy.⁴ There are many other complications that have been found to be associated with the use of the clips like accidental clipping of common bile duct leading to obstruction, strictures, slippage of clips etc.⁵⁻⁸ Therefore, various new methods are now used to control the cystic artery like absorbable or non-absorbable sutures, Monopolar or Bipolar electro coagulation and Harmonic scalpel have also been used for this purpose but due to its high cost Harmonic scalpel has been used less frequently.⁹ Designed as a safe alternative to electro cautery for the haemostatic dissection

of tissue, the ultrasonically activated Harmonic scalpel was introduced into clinical use nearly a decade ago. Several studies have described the use of ultrasound dissection technology in the LC, which concluded that ultrasonic dissection was safe and easy to use.¹⁰ Its technology relies on the application of ultrasound within the harmonic frequency range to tissues and allows two effects: ultrasonic coagulation and cavitation effects provided by a rapidly vibrating blade contacting various tissues.¹¹ The heat generated as a result of stress and friction is below 80 degree Celsius, as a result tissue charring and desiccation from loss of moisture is minimized. The cavitation or cutting effect is produced by a relatively sharp blade vibrating 55,500 times per second over a distance of 60–100 µm. It cuts the tissue by stretching it beyond its elastic limit and by breaking molecular bonds. Large series studies have demonstrated the effectiveness and safety of the use of the HS for dissection of the gallbladder.¹² The Harmonic scalpel is also an effective tool for closure of biliary ducts and vessels whose diameter is 4mm to 5mm (as certified by the FDA in 2006). This study was undertaken to demonstrate the efficacy and safety of the Harmonic scalpel as the sole instrument to achieve complete hemobiliary stasis in the performance of Laparoscopic cholecystectomy. Moreover, the use of a single instrument during the whole procedure averts or decreases the risk of distant organ injuries.¹³

Material and Methods

A prospective randomized clinical trial was conducted in the department of surgery, Government Medical College (Rajindra Hospital) Patiala from November 2012 to November 2014 on 60 patients admitted with the diagnosis of symptomatic cholelithiasis that gave an informed consent and underwent elective laparoscopic cholecystectomy. Patients were randomly divided into 2 groups: the study group and control group with 30 patients each. In the study group, patients with symptomatic cholelithiasis underwent laparoscopic cholecystectomy using the harmonic scalpel (HS) to ligate and cut cystic artery and cystic duct as well as dissection of the liver bed, whereas in the control group patients were operated by conventional method using electrocautery and clips. Both the groups were

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comparable for age, sex, indication for cholecystectomy. Ethical clearance was taken from the institutional Ethics committee. Uncomplicated symptomatic cholelithiasis, medically fit and stable patients, adult patients (>18 years) were included in the study and patients with Multiple co-morbid diseases, coagulation disorders, Suspected/proven malignancy, Contraindication to laparoscopic cholecystectomy e.g. upper major abdominal surgery, common bile duct stone, pregnant patient, emphysema of the gallbladder, unfavorable anatomy (as shown by USG) e.g. sessile gallbladder, very short cystic duct, wide cystic duct more than 6mm.abnormal liver functions were excluded from the study.

Procedure

Pre-operative assessment: Detailed clinical history and physical examination was done. Preoperative data was collected which included patient's demographics and co-morbid conditions (genitourinary, cardiac, pulmonary, gastrointestinal, renal, or rheumatologic) and a detailed history of symptom onset.

Pre-operative investigations include

All routine blood investigations including Ultrasonography, liver function test, prothrombin index and serum amylase.

Operative technique

The surgical procedure was carried out with patients under general anesthesia. They were in supine position with their legs extended, in an anti-Trendelenburg position and inclined laterally to the left at an angle of 30 degrees to facilitate exposure of the hepatic region. A nasogastric tube was placed into the stomach at the beginning of the procedure. Prophylactic intravenous antibiotics were administered before surgery. A 10-mm trocar was introduced into the peritoneal cavity and was placed in the periumbilical site with an open technique, and pneumoperitoneum to a pressure of 12mm Hg is created. Standard four trocar technique was used. A laparoscope was introduced through the umbilical trocar site, fundus of gall bladder was held by a ratchet grasper and retracted by the assistant in a cranial direction exposing the Calot's triangle and hilum of liver. An atraumatic non hooking (dolphin nosed) grasper was introduced through the left hand working port to hold the infundibulum and retract it down and to right. Study group (Harmonic): the harmonic scissors were inserted through epigastric port and used as a dissector for dissection of the cystic artery and duct when both artery and duct were well visualized and isolated, their section was performed with a single application of ultrasonically activated scissors on minimum power level 3. The blades were closed carefully and slowly and lateral traction on the structure was avoided. In case of large cystic ducts (with an external diameter exceeding 5mm), an additional ligature with clips was performed. To assess its diameter, the duct was positioned between the blades of the ultrasonically activated scalpel: if the cystic duct cannot be

entirely included between them, an extra ligature is necessary. The additional clips were placed on the cystic duct and that was then sectioned distally using the Harmonic scalpel. The gallbladder dissection from the liver bed is carried out using the ultrasonically activated scalpel at maximum power level 5 from the infundibulum to the fundus, taking advantage of the positive effects of ultrasound, cavitation, and coagulation. In control group (monopolar coagulation plus clips), different instruments were used and introduced through trocar: first, a dissector and a monopolar hook, which were used to isolate and visualize the artery and the duct, and, second, clips (disposable) and scissors (disposable), which were used to close and to cut them. The dissection from the liver bed was carried out using a monopolar hook. In both the groups subhepatic drain was placed to check for any postoperative bile leak, haemorrhage which was removed on the first postoperative day.

RESULTS

The age range for study group was 9-65 years. There were 8 patient's in the age group of (21-30) 26.7%, 6 in the age group of (31-40) 20%, 8 in the age group of (41-50) 26.7%, 5 in the age group of (51-60) 16.7%, 2 in the age group of (>60 years) 6.6%. There was one patient in the age group of (<20 years) 3.3%. The mean operative time conversion to open cholecystectomy rate, hospital stay, intraoperative and postoperative complications were compared. Laparoscopic cholecystectomy was successfully completed in 57 patients (95%). Conversion was necessary in one patient in Study Group (3.33%), whereas two cases in Control Group required conversion to open (6.66%) due to dense peritoneal adhesions. The mean duration of hospital stay (table 1) required in control group was 2.21±0.876days (range 1-4days) and in Study group was 2.24±1.154days (mean 1-7 days). On statistical analysis (p=0.921). No statistically significant difference was found. The mean operative time in study group was 37.28±7.860 minutes (range 20-56 min) and in control group was 49.50±8.053minutes (range 32-70) p-value (p<0.001). The mean number of times lens cleaning was required in control group (28 cases)* was (2.21 ±0.498), in comparison to study group (29 cases)* (1.48 ±0.57) with a p-value (p<0.001), on statistical analysis (p<0.001), significant difference was found in operative time and no of times lens was cleaned in both the groups (table 2). A drainage tube was positioned in subhepatic space in all the cases and was kept till the first postoperative day or 24hrs. None of the cases had any postoperative bile leak or haemorrhage.

In our study, the mean duration of hospital stay required in control group was 2.21±0.876days days (range 1-4days) and in study group was 2.24±1.154days days (mean 1-7 days) (table 3). On statistical analysis (p=0.921) no significant difference was found in both these groups.

In our study, mean postoperative pain score on VAS scale for

	Control Group*(N=28)	Study Group *(N=29)	Total (N=60)	p	Sig.
Mean duration (min)	49.50	37.28	43.28	<0.001	S
Min. duration (min)	32	20	20		
Max. duration (min)	70	56	70		
Std. deviation	8.053	7.860	10.008		
(p<0.001), significant dif					
Table-1: Total Duration of Surgery (In Minutes)					

the study group was (mean 2.18 ± 0.54) and that for the control group (mean 2.172 ± 0.548) (table 4). On statistical analysis ($p=0.966$) no significant difference was found in post-operative pain scores between the two groups.

In our study, there were 2 cases in control group and 1 case in study group which required conversion to open cholecystectomy (table 5). It was due to dense adhesions that critical angle of safety could not be made so they were converted to open. Statistically the difference in rate of conversion between both the groups was not significant. Therefore, operative time, lens cleaning, hospital stay, intraoperative and postoperative complications were not calculated for these cases.

Intraoperative complications in the form of bleeding and CBD Injury were not present in both the groups but gall bladder perforation with subsequent stone spillage was found in one case 3.3% from the control group (table 6).

DISCUSSION

The Harmonic scalpel is a system for endoscopic cutting, utilizing vibration as its energy source. The power box is attached to a forceps or blade which vibrates at a frequency of 55,500cycles/

second this causes a knife like action of the blade through the tissue, with enough heating to create coagulation of small vessels.¹⁴ In 1999 the 1st case of Laparoscopic cholecystectomy using Harmonic scalpel for dissection and closure of both cystic duct and artery was reported.¹⁵ Histological examination of the tissues divided with the ultrasonic techniques retained more or near normal tissue architecture at the site of anastomosis two weeks after the surgery. Also the wound healing was rapid and complete.¹⁶ Tebala et al demonstrated that because the harmonic scalpel can replace 4 Instruments [scissors, clipper, dissector, and electrocautery hook] owing to the multiple functions of the harmonic scalpel. It thus eliminates the need for instrument change, making operative time short, whereas in the classical technique using electrocautery frequent change (extraction and reinsertion) of instruments can increase the risk of tissue injury such as bowel or liver.¹⁷ One case in the control group required conversion to open as compared to two in study group. Therefore Operative time, lens cleaning, duration of hospital stay, intraoperative and postoperative complications were not calculated for them. It was statistically not significant as it could be attributed to the small sample size. According to Janssen et al¹⁸ (2003) harmonic scalpel (HS) provides lower rate of conversion to open cholecystectomy (OC). In our study the duration of operating time was found to be significantly shorter in the study group. Mean operative time in study group was 38.37 ± 9.764 min (range 20-70 min) as control group was 51.20 ± 10.851 minutes (range 32-90) ($p < 0.001$). On statistical analysis significant difference was found in operative time of both the groups. The number of times Lens cleaning was required was also significantly lower in HS group. The mean for control group was 2.21 ± 0.498 (range 1-3) and the mean for study group was 1.48 ± 0.57 (range 1-3), ($p < 0.001$) which is statistically significant implying less frequent change of instruments so the critical view of operating site is not lost. This is in accordance with the studies conducted by Mahabaleshwar et al¹⁹ 2012 and Gelmini et al²⁰ There was no incidence of any significant intra-operative or post-operative haemorrhage (bleeding) in any of the groups. One case in control group had gall bladder perforation with subsequent bile leakage and stone spillage which was not reported in any of the study cases. Intraoperative gall bladder perforation occurs in 13%-50% of patients who undergo laparoscopic cholecystectomy, and in 10%-40% of these patients, bile leakage and stone spillage are present.²¹ Laceration due to grasper traction and electrocautery dissection is the most common mechanism of gallbladder rupture during laparoscopic cholecystectomy.²² Reduction of gallbladder perforation during laparoscopic cholecystectomy using the ultrasonic dissector has also been reported in other studies also.²³⁻²⁵ There was no post-operative complication in the form of hemorrhage, bile leak, umbilical port site suppuration and subhepatic abscess in both the groups.

In our study, mean postoperative pain score on (VAS) scale for

Groups	Mean	p	Sig.
Control group*(n=28)	2.21	<0.001	S
Study group *(n=29)	1.48		
*(Two cases from the control group required conversion to open and one from study group which were not included as candidates for which lens cleaning was done.)			
Table-2: Mean number of times lens cleaned in both groups			

Duration (in days)	Control Group *(n=28)	Study Group *(n=29)	p	Sig.
Mean (days)	2.21	2.24	0.	NS
Minimum (days)	1	1		
Maximum (days)	4	7		
Std. deviation	0.876	1.154		
Table-3: Duration of Hospital Stay				

Score	Control group *(n=28)	Study group *(n=29)
Minimum pain score	1	2
Maximum pain score	4	4
Mean pain score	2.172	2.18
Std. deviation	0.548	0.54
Table-4: Post-Operative Pain Score on VAS scale		

Groups	Cases converted to open	%age
Control Group (n=30)	2	6.66
Study Group (n=30)	1	3.33
Table-5: Conversion to Open Cholecystectomy		

Intraoperative complication	Control Group (n=28)	%age	Study Group (n=29)	%age
Bleeding	NIL	0	NIL	0
Gall bladder perforation	1	3.3%	NIL	0
Stone spillage	1	3.3%	NIL	0
CBD Injury	NIL	0	Nil	0
Table-6: Intraoperative Complications				

the study group was (mean 2.26 ± 0.739) and that for the control group (mean 2.4 ± 1.0034). On statistical analysis ($p=0.5407$) no significant difference was found in post-operative pain scores between the two groups. The mean duration of hospital stay in control group was 2.33 ± 1.133 days (range 1-6 days) and in study group were 2.40 ± 1.241 days (mean 1-7 days). On statistical analysis no significant difference was found in both these groups. This was comparable with a study conducted by Yilmaz et al²⁶

In conclusion Harmonic scalpel provides complete hemobiliary stasis and results in significant reduction of operative time when used as a sole instrument in laparoscopic cholecystectomy.

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