

A Prospective Randomised Comparative Study Between Clip Less Versus Conventional Laparoscopic Cholecystectomy

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Abstract

To evaluate safety and efficacy of ultrasonic scalpel in closure/division of the cystic duct and artery, and gallbladder dissection in laparoscopic cholecystectomy as a single working instrument compared conventional technique using clips and electro-cautery. **Method:** This study included 60 patients with symptomatic gallstone disease were randomly assigned for laparoscopic cholecystectomy by either ultrasonic shear (Study Group = 30 patients), and clip / cautery (Control Group=30 patients). **Results:** The mean operative time was significantly shorter in study group as compare to control group (p value =0.002), and postoperative pain scores (VAS) were significantly shorter (p value = 0.001) in first 24 hours but no significant difference was found in the incidence of intra-operative & post-operative complications. **Conclusion:** Ultrasonic shear is as safe and effective as clip/cautery technique in achieving hemobiliary stasis, with shorter operative time with decreased pain, especially if used as a sole working instrument.

Keywords: Clipless laparoscopic cholecystectomy (CLLC); Conventional laparoscopic cholecystectomy (CLC); Ultrasonic scalpel.

Introduction

Laparoscopic Cholecystectomy is now the standard of care for the patients with symptomatic gallstone disease.[1] Use of electro-cautery for dissection can lead to accidental burn and electrosurgical injuries,

majority of them go unrecognized and lead to severe morbidity and mortality. Calot's triangle and gallbladder dissection can be performed with ultrasonic dissector & cystic duct and artery can be sealed and divided without the usage of clips.[2] Ultrasonic dissector has minimal lateral thermal tissue damage, minimal smoke emission and minimal charring. Moreover there is no use of electricity and lesser complications than electrocautery.[3] Any improvement in this field will benefit many patients by reducing morbidity, mortality, conversion rate, operating time, hospital stay, postoperative pain and return to normal activities.[4] Aim of this study was to evaluate safety and efficacy of ultrasonic scalpel in clip less laparoscopic cholecystectomy (CLLC) as a sole working instrument in closure and division of the cystic duct, artery, and gallbladder dissection as compared to conventional laparoscopic cholecystectomy (CLC) using clip and electro-cautery. The study compared mean operative time, intra-operative complications, postoperative pain score and postoperative complications. Data were analysed using student 't' test and χ^2 test.

Material and methods

The study was conducted in Department of Surgery, Vardhman Mahavir Medical College and Safdarjang Hospital, New Delhi from March 2011-Feb. 2012.

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Inclusion criteria

All medically fit patient with no contraindication for laparoscopy between 18 to 70 years of age, if they did not fall in exclusion criteria and Cystic duct diameter <5 mm (measured preoperatively by ultrasound and intra-operatively by comparing with tip of Maryland's dissector).

EXCLUSION CRITERIA: Age <18 years and > 70 years, Cystic duct diameter > 5 mm, Cystic duct and CBD stones, Acute cholecystitis, Pregnancy, Gallbladder malignancy, Abnormal ultrasound (Dilated CBD, Dense adhesions), h/o upper abdominal surgery.

Method

Total 60 patients were included and randomized into two groups using sealed envelope method. Study group (30 cases) underwent CLLC using ultrasonic scalpel for sealing cystic duct and artery and dissection of gallbladder from liver bed. Control group (30 cases) underwent CLC by using titanium clips and dissection of gallbladder from liver bed using electro-cautery. Informed consent was taken after explaining about disease, procedure and possible complications. Standard four ports LC was done in all cases. Ultrasonic scalpel at power level of 2 was used for sealing cystic artery and cystic duct in study population. Cystic duct was dealt in following

Figure 1

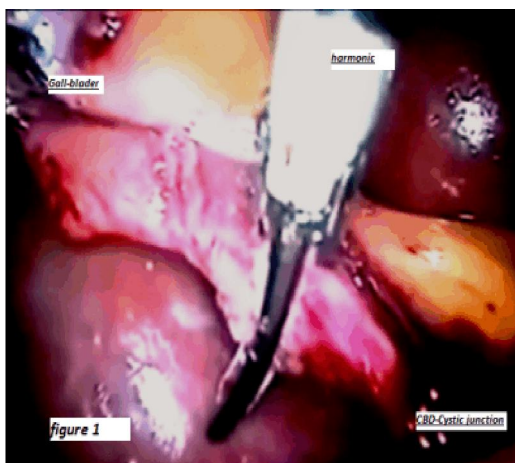
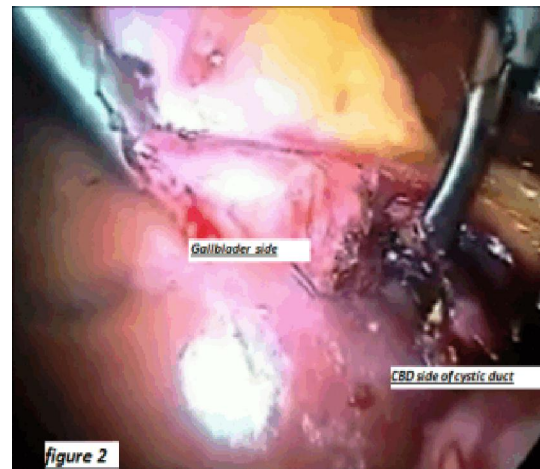


Figure 2



manner (A) Toward CBD side: At safe distance from CBD, till browning of tissues occurred. (B) Toward gallbladder side: till browning of tissues occurred. (C) In last, in between of previous applications (between A and B) and was continued till cystic duct was cut as show in figure 1 & 2. Ultrasonic scalpel was used to dissect GB from liver bed at power level 2/5 setting. Sub-hepatic 16 F drain was kept in all cases.

Mean operative time, Mean time taken for dissecting gallbladder from liver bed and Intrao-perative complications and Postoperative complications was compared in both groups. Postoperative pain score (at 6 hours, 12 hours, 24 hours, 48 hours and 1 week) using VISUAL ANALOG SCALE after giving same analgesia) & mean duration of Hospital stay were also compared in both arms. Abdominal USG was routinely performed after 24 hours of surgery. Patients were discharged after removing drain and were followed up for six weeks.

Results

The demographic data of study population was comparable in both groups. The Mean age in study group (SG) was 41.16 ± 12.80 years and in control group (CG) was 42.13 ± 12.35 years. The age range was between 19-68 years.

Table 1: Mean operative time in minutes

In Minutes	Study Group (SG)	Control Group (CG)	p value
Mean operative time	63.17±9.72	74.23±16.10	0.002
Standard error of mean	1.78	2.94	
Mean time taken for GB dissection	6.13±1.68	10.37±2.96	<0.05
Standard error of mean	0.31	0.54	

Table 2: Intra-operative complications

	Study Group	Control Group
Biliary tract injury	0	0
Hemorrhage	0	1
Bowel injury	0	0
Solid organs injury	0	0
Gallbladder perforation	3	5
Cystic duct stump leak	0	0
Conversion to open	1 (Difficult anatomy)	2 (1 Hemorrhage, 1 Difficult Anatomy)

Male to Female ratio (1:9) was also comparable in both groups.

The mean operative time in SG was 63.17 minutes with standard deviation of ±9.72 and in CG was 74.23 minutes with standard deviation of ±16.10. This difference was statistically significant (p value = 0.002). Mean time required for gallbladder dissection from liver bed was 6.13 minutes (SD± 1.68) in SG and 10.37 minutes (SD± 2.96) in CG. This difference was statistically significant (p value< 0.05). Incidence of gallbladder perforation was 10% (3 cases) in SG and was 16.67% (5 cases) in CG. Incidence of gall bladder perforation decreased on using ultrasonic shears, however difference was statistically insignificant (p value=0.58). No other significant intra-

Chart 1: Pain score comparison (Visual Analogue Scale)

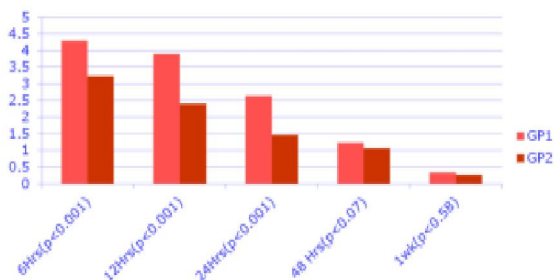


Table 3: Mean hospital stay

	SG	CG	p value
Mean hospital stay	1.30 ± 0.60 days	1.40 ± 0.72 days	0.56
Standard error of mean	0.11 day	0.13 day	

operative complications were observed in both groups.

Port site wound infections were noticed in 3(10%) patients of CG and 2(6.66%) patients of SG. Intra-abdominal collection was noted post-operatively at 24 hours in 2 patients of each group diagnosed by abdominal ultrasonography. Collection was less than 50 ml in all the 4 patients. Other than this, no major postoperative complications like biliary tract injury and bowel injury were encountered in either group. There was no statistically significant difference in both groups regarding postoperative complications.

Discussion

The introduction of ultrasonic device in laparoscopy has been made the procedures more attractive and soothing for the operators and viewers.[6] In addition, it also decreases the inadvertent and unrecognized electrical injuries associated with the use of electro cautery.[7] Ultrasonic scalpel is a potentially safer instrument for tissue dissection. A total ultrasonic scalpel dissection in laparoscopic cholecystectomy is well described in the European literature.[8,9] A statistically significant shorter mean operative time mainly because of the ultrasonic dissector used as a multifunctional instrument that replaces four instruments routinely used in laparoscopic cholecystectomy, namely the dissector, clip applier, scissors, and hook or spatula. Its use, therefore, prevents the frequent extraction and reinsertion of these different instruments with subsequent avoidance of time loss.[19,20] Secondly, the ultrasonic dissector forms less smoke, therefore allowing the surgeon to work in a clear operative field throughout the operation. Finally, the use of ultrasonic dissector has been shown to be associated with lower incidence

of gallbladder perforation,[20] which resulted in subsequent avoidance of time loss in abdominal lavage and spilled stones retrieval.[10,11] The reason for decrease pain scores in early post-operative period is minimal lateral thermal damage and minimal charring of tissue, resulting in minimal damage to surrounding nerves which lead to decreased release of inflammatory mediators and less inflammation and pain.[12] One additional benefit of ultrasonic scalpel is the more effective closure of the ducts of Luschka during dissection of the liver bed preventing bile leakage from the liver bed and therefore, less postoperative pain.[13,14] Less pain is reason for fast recovery and early discharge from hospital. Ultrasonic dissector is a effective sole working instrument[15] with High sealing capacity (x3 times of normal systolic pressure) [16], less collateral damage,[17] and dangers of coupling and tissue charring are necessarily obviated, but the great disadvantage with ultrasonic scalpel is that it is very costly and its effectiveness in closure of cystic duct more than 6 mm is questionable.[18] It may be safe instrument for beginners.

Conclusion

The ultrasonic dissector is a safe, efficient and practical instrument to use during laparoscopic cholecystectomy especially if used as a sole working instrument, with complete haemobiliary stasis. Moving from standard laparoscopy to single port or single incision laparoscopy, CLLC may become procedure of choice in future but before labelling, a large multicentric randomise trails needed to prove safety and efficacy of CLLC.

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