

# A Study to Evaluate the Use of Harmonic Scalpel in Laparoscopic Cholecystectomy. A Progressive Study.

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## ABSTRACT

**Background:** Cholecystectomy, surgical removal of the gallbladder, is one of the most common elective procedures performed by general surgeons (McMahon A, Fishbacher C, Frame S et al. 2000). Since Langenbuch performed the first Open cholecystectomy (DC), this technique has remained the “gold standard” for the treatment of symptomatic cholelithiasis and acute cholecystitis for more than 100 years. Advances in laparoscopic techniques have made it possible to remove gallbladder through tiny incisions on abdomen. A young German surgeon, Erich Muhe, working in the Department of Surgery of the Boblingen Hospital, was fascinated by Semm’s technique and Lukichev’s method of minimally invasive cholecystectomy. He developed the idea of laparoscopic removal of gallstones. In 1984, Muhe had already worked out the former details of an operative laparoscope, calling it the “Galloscope”. On September 12th 1985, Prof. Erich Muhe of Boblingen, Germany, carried out the first laparoscopic cholecystectomy. Aims & Objectives: This study was conducted with the following aims and objective. 1. To evaluate the use of Harmonic scalpel as a safe, feasible alternative to use of titanium clips for cystic duct occlusion. 2. To compare post-operative outcome of patients in whom laparoscopic cholecystectomy was done by clips with those in whom Harmonic scalpel was used. **Methods:** This study was conducted in the Department of Surgery, GMC, Jammu over a period of one year on 100 patients suffering from cholelithiasis. The patients were equally divided in two groups of 50 patients each after matching parameters like age group and comorbid condition. In one group of patients undergoing laparoscopic cholecystectomy, cystic duct was occluded with clips and in other group harmonic scalpels were used to occlude cystic duct. Inclusion Criteria: All patients undergoing elective cholecystectomy for various reasons Normal body weight, Exclusion Criteria: Acute Cholecystitis Patients above 80 yrs of age Patients having history of upper abdomen laparotomy. Patient with wide, short, abnormal cystic duct, dilated cbd choledocholithiasis, mirrizi syndrome assessed intra operatively. **Results:** Results of this study demonstrate that cystic duct occlusion with harmonic scalpel as a safe, effective, quicker alternative to clips. Safety of using harmonic scalpel is similar to clips as is evident from our study. **Conclusion:** There is significant decrease in duration of surgery, intra operative and postoperative complication, and duration of hospital stay with the use of harmonic scalpel besides providing effective hemobiliary stasis.

**Keywords:** comorbid, cholecystectomy, laparoscopic.

## INTRODUCTION

Cholecystectomy, surgical removal of the gallbladder, is one of the most common elective procedures performed by general surgeons (McMahon A, Fishbacher C, Frame S et al. 2000). Since Langenbuch performed the first Open cholecystectomy (DC), this technique has remained the “gold standard” for the treatment of symptomatic cholelithiasis and acute cholecystitis for more than 100 years.

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The speed with which laparoscopic cholecystectomy has been developed and introduced into routine practice is unprecedented in the history of surgical procedures. The introduction of laparoscopic cholecystectomy induced a significant growth in cholecystectomy rates (Urbach D and Stukel T 2005). In particular, regarding the dimension of the effectiveness of open and laparoscopic it is possible to distinguish two different kinds of outcome related

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to admission period i.e. intraadmission and post-admission outcomes. Both procedures are associated with complications like common bile duct injury, bile leak, injury to viscera, haemorrhage, spilled gallstone, retained stones, biliary strictures, slippage of ligatures or clips, and others. The spectrum of mishaps has also changed due to involvement of new instruments such as stapling devices, coagulation Sheers, and sealing systems. Related complications like migrating clips or stenosis of common bile duct due to wrongly placed clip were completely unknown in open surgery.

### **Aims and Objectives**

This study was conducted with the following aims and objective

1. To evaluate the use of Harmonic scalpel as a safe, feasible alternative to use of titanium clips for cystic duct occlusion.
2. To compare post-operative outcome of patients in whom laparoscopic cholecystectomy was done by clips with those in whom Harmonic scalpel was used.

## **MATERIALS AND METHODS**

This study was conducted in the Department of Surgery, GMC, Jammu over a period of one year .on 100 patients suffering from cholelithiasis The patients were equally divided in two groups of 50 patients each after matching parameters like age group and comorbid condition. In one group of patients undergoing laparoscopic cholecystectomy, cystic duct was occluded with clips and in other group harmonic scalpels were used to occlude cystic duct.

### **Type of study**

Current study is a randomised controlled prospective study comparing two methods in patients undergoing laparoscopic cholecystectomy.

### **Types of participants**

Participants include patients undergoing laparoscopic cholecystectomy for any reason symptomatic gallstones, acalculous cholecystitis, gallbladder polyp, or any other condition in GMC, Jammu.

### **Inclusion Criteria**

All patients undergoing elective cholecystectomy for various reasons Normal body weight, Elective cholecystectomy No or well controlled hypertension or diabetes No previous upper abdominal surgery Wall thickness of gallbladder less than 6 mm as shown by ultrasound preoperatively with normal biliary passages and normal cystic duct diameter and length. Patient with liver cirrhosis with symptomatic gall bladder stones

### **Exclusion Criteria**

Acute Cholecystitis Patients above 80 yrs of age Patients having history of upper abdomen laparotomy. Patient with wide, short, abnormal cystic duct, dilated cbd choledocholithiasis, mirrizi syndrome assessed intra operatively. Pregnant females Type of intervention essentially two methods of lap cholecystectomies (cystic duct occlusion) is with traditional lap cholecystectomy (titanium clips) and harmonic scalpel in patients undergoing laparoscopic cholecystectomy.

### **Types of outcome measures Primary outcomes**

- (a) Mortality
- (b) Re-operation for any reason (0) Bile duct injury
- (c) Biliary peritonitis
- (d) Bile leak requiring ERCP
- (e) Bile collection requiring re-operation or image guided drainage

### **Secondary outcomes**

- (a) Operating time
- (b) Hospital stay a written informed consent shall be obtained from all patients for participation in the study as well as surgical procedure. A thorough explanation of the diagnosis and therapeutic alternatives shall be presented to the patients. A thorough explanation of the diagnosis and therapeutic alternatives shall be presented to the patients. Patients shall be subjected to: Detailed history and examination. Baseline investigations like complete blood counts, bleeding time, clotting time, renal function tests, liver function tests, serum electrolytes, Chest X-Ray, Electrocardiography. Ultrasonography of abdomen.

## **RESULTS**

In the Clip Group, maximum patients were in 41-50 yrs age group and in Harmonic scalpel Group, largest group was 31-40 yrs. But the mean age of patients in clip and harmonic scalpel group were nearly equal. Mean age in clip group 43.6 yrs and in harmonic scalpel was 42.6 yrs.

Gender Wise Distribution In both groups majority of the patients were females. Male: Female ratio in clip group was 1:45. Male: Female ratio in Harmonic scalpel group was 1:23. Total Male: Female ratio was 1.13.76. Distribution of cases according to past History There were 8 patients with history of cholecystitis 1 with pancreatitis in clip group and 4 and 3 respectively in harmonic scalpel group .

### **Operative Time Taken**

The mean operative time taken ( in min) to perform cholecystectomy in harmonic group was 52.14 minutes as compared to 61.88 minutes in clip group. On applying paired t test it was observed that Harmonic group took less time as compared with the

clip group with p value= 0.0008 which was highly statistically significant.

Distribution of cases according to peritoneal Drain Intraoperative Drainage in Clip Group Drain kept in 18 which was 36% and in harmonic group was 18 which was 36%. Drain not kept were same in both cases which were 32 patients amounting to 64%.

#### **Bile Duct Injuries**

There were no bile duct injuries reported in both group. 0 vs 0.

#### **Bile Leak**

There was 1 patient with bile leak in Clip group vs 1 In Harmonic Scalpel group.

#### **Port Site Infection**

There were 3 cases in clip group as compared to 1 in harmonic scpel group.

#### **Mean Hospital stay**

The mean hospital stay in clip group was 2.82 days vs 2.12 days in HS group.

#### **Return to Work**

Return to work was far less in harmonic group 6.79 days in harmonic group vs 8.18 days in clip group with a significant p value of 0.0477

## **DISCUSSION**

Laparoscopic surgery is a well-established alternative to open surgery across all disciplines. Although positive magnitude of impact varies by the procedure, generally the benefits of laparoscopic surgery on postoperative pain, cosmetics, hospital stay and convalescence are recognized widely. Many surgeons have attempted to use alternatives to non-absorbable clips such as absorbable clips, locking clips, absorbable harmonic scalpels or more recently ultrasonic dissectors for cystic duct occlusion. So far, many studies are available which favour use of harmonic scalpels over clips in terms of safety, feasibility and cost effectiveness.

The technique of cystic duct occlusion with clips and harmonic scalpels/ligatures are well established. The safety of harmonic scalpels over clips can be gauged from the study of Kandil T'El Nakeeb A (2004). They conducted study comparing clips and harmonic scalpels and found harmonic scalpels as safe alternatives to clips.

We took up the study with aim to compare clips and harmonic scalpels for cystic duct occlusion in terms of safety, cost effective and post-operative morbidity. In our study, the patients were randomly allocated into two groups of 50 patients each. In one group of patients undergoing laparoscopic cholecystectomy, cystic duct was occluded with clips and in other group harmonic scalpels or ligatures were used to occlude cystic duct. Similar parameters were observed in study conducted by James Westervelt (2004).

Inclusion criteria in our study was symptomatic gallstones, acalculous cholecystitis, gall bladder polyp

or any other condition warranting laparoscopic cholecystectomy.

Mean age in our study was 43.68 yrs in clip group and 42.64 yrs in harmonic scalpel group. In the Clip Group, maximum patients were in 41-50 yrs age group and in harmonic Group, largest group was 31-40 yrs. There is a female predominance in both clip (82%) and harmonic scalpel groups (70%) in our study with Total Male: Female ratio was 13.76. Similar female predominance is seen in study by Ayman F. ElRamah, Al-Metwaly R. Ibrahim, (2010) the ratio of males to females in the trials conducted by Shahid Alaml, Munir Ahmad 2014 was

1: 6.66. In the present work, operative time ranged from 24 to 80 minutes with a statistically significant decrease in operative time in HS group in comparison to traditional group (52.14 min vs 61.88 min respectively). These results are supported by different previous studies that reported that, HS provides complete hemobiliary stasis and is a safe alternative to the standard clipping of the cystic duct and artery (Janssen et al., 2003; Bessa et al., (2008).

In our study, no bile duct injury was detected intra-operatively in either of the two groups. There was no previous study which has reported such an outcome. Regarding bile leak requiring, in our study both groups had one case of bile leak which were managed conservatively requiring no surgical intervention. Bile leaks in the harmonic group could be explained by the fact that the first application of scalpel occurs on visual basis. The surgeon doesn't have any feedback regarding the sealing status of the scalpel and could be only gauged by the experience. A similar finding was reported by A. ZANGHI, A. CAVALLARO (2014) and Huscher et al. (2003), bile leaks were encountered in 7 of 331 patients (2.1%) Our study had no cases of biliary peritonitis following laparoscopic cholecystectomy in either group. None of previous trials comparing clips and harmonic scalpel for cystic duct occlusion also did not report any cases of biliary peritonitis following laparoscopic cholecystectomy.

Summary and conclusion since its introduction in 1987, laparoscopic Cholecystectomy rapidly gained popularity in modern times to the extent that it is now being regarded as the gold standard for treating symptomatic gallstones disease. As the number of surgeons performing Laparoscopic Cholecystectomy are increasing, therefore efforts are being carried out to minimize the hazards related to laparoscopic Cholecystectomy by introduction of newer and advanced technologies. Cystic duct occlusion and dissection remains central to the concern for surgeons which have been accomplished by using clips, absorbable suture, ligatures and more recently by harmonic shear. It is essential to determine the extent of difference in morbidity and mortality when comparison is made between different methods of cystic duct occlusion. This study was undertaken to compare the safety, cost effectiveness, post-

operative morbidity and mortality of cystic duct occlusion with clips versus harmonic scalpel.

### CONCLUSION

Results of this study demonstrate that cystic duct occlusion with harmonic scalpel as a safe, effective, quicker alternative to clips. Safety of using harmonic scalpel is similar to clips as is evident from our study. There is significant decrease in duration of surgery, intra operative and postoperative complication, and duration of hospital stay with the use of harmonic scalpel besides providing effective hemobiliary stasis. However the major drawbacks of its use are the high cost of the equipment and inability to occlude cystic ducts more than 6mm wide securely but with the evolving use of the modality and advancement in research the drawbacks are likely to be overcome thereby turning it into a superior alternative.

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