



## Use of Harmonic Scalpel (Clipless) Versus Conventional Laparoscopic Cholecystectomy (Titanium Clips) – A Prospective Study

### KEYWORDS

laparoscopic cholecystectomy, Harmonic Scalpel (clipless), Conventional Laparoscopic Cholecystectomy (titanium clips) .

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**ABSTRACT** *Aims and Objective-*This study was conducted To evaluate the use of Harmonic scalpel as a safe, feasible alternative to use of titanium clips for cystic duct occlusion and to compare post operative outcome of patients in whom laparoscopic cholecystectomy was done by clips with those in whom Harmonic scalpel was used.

*Material and Method* This study is randomised controlled prospective study conducted in the Department of Surgery, GMC, Jammu over a period of one year w.e.f 1st November 2014 to 31st October 2015 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 and Wall thickness of gallbladder less than 6 mm as shown by ultrasound preoperatively with normal biliary passages and normal cystic duct diameter and length.

*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, mirizzi syndrome assessed intra operatively.
- Pregnant females

*Conclusion:* Results of this study demonstrate that cystic duct occlusion with harmonic scalpel as a safe, effective, quicker alternative to clips.

### Introduction

Cholecystectomy, surgical removal of the gallbladder, is one of the most common elective procedures performed by general surgeons. The spectrum of mishaps has changed due to involvement of new instruments such as stapling devices, coagulation sheers, and sealing systems. During laparoscopic cholecystectomy, it is necessary to occlude cystic duct permanently in order to prevent leakage of bile into the peritoneal cavity. Traditionally this has been through the application of non-absorbable metal clips. One reason for the bile leak is laceration of the cystic duct by metal clips resulting in bile leakage from cystic duct (Kennedy 1995). This is because of ability of the metal clips to conduct electricity causing a cut in cystic duct (Hamer 1996) or causing necrosis of clamped tissue (Hawsali 1994). Clips can also cause occlusion & stenosis of the common bile duct without causing any laceration (Bektas 2007). Rarely the metal clips can erode into the cystic duct & migrate into common bile duct (Hawsali 1994). Such migration of the clip into the common can act as nidus for stone in common bile duct.

In view of these concerns regarding the use of metal clips

other alternatives to non absorbable metal clips for cystic duct occlusion have been suggested. These include:-

Absorbable Clips (Hawsali 1994)

Locking Clips (Rohatgi 2006)

Absorbable Knots (Ligatures Saha 2000 Seenu 2004).

Ultrasonic dissectors have been used to occlude cystic duct, cystic artery and also for dissection of gallbladder from liver bed. Combined with electrocautery problem of lateral tissue thermal damage. Concerns regarding use of Harmonic Scalpel. My study is prospective randomised study in which I had compared outcomes of patients in whom Cystic Duct Occlusion was done by clips with those in whom Harmonic scalpel was used.

James Westervelt (2004) studied a new technique of clipless laparoscopic cholecystectomy in a personal prospective series involving 100 consecutive patients undergoing laparoscopic cholecystectomies.<sup>9</sup> In all but 2 cases, closure and division of the cystic duct and artery as well as mo

bilization of the gallbladder from the liver bed were accomplished solely with the Harmonic scalpel equipped with an LCS-C5 curved blade tip at a level 2 setting. Result was no patient developed post-operative bile leakage or haemorrhage. Except for the 2- to 3-minute interval required for cystic duct division, use of the Harmonic-scalpel did not adversely affect the length of procedures. In fact, properties intrinsic to the Harmonic scalpel (cavitation and smokeless coagulation) seem to provide an advantage over electrocautery in the dissection of the gallbladder and may enhance surgeon performance. One additional benefit of Harmonic scalpel dissection of the liver bed is the more effective closure of the ducts of Luschka. The harmonic scalpel provided complete hemobiliary stasis for most patients and an effective alternative to standard clip and ligation closure of cystic duct. The only disadvantage was the cost factor associated with it.

In our study all patients were evaluated up to 4 weeks postoperatively in the office. This study clearly demonstrated that the Harmonic scalpel provides complete and reliable hemobiliary stasis in most patients undergoing laparoscopic cholecystectomies. In all patients who underwent division of the cystic duct and artery by harmonic scalpel alone, there were no clinically apparent immediate or remote postoperative bile leaks or hemorrhages.

#### Aims and Objective-

This study was conducted with the following aims and objective

To evaluate the use of Harmonic scalpel as a safe, feasible alternative to use of titanium clips for cystic duct occlusion.

To compare post operative outcome of patients in whom laparoscopic cholecystectomy was done by clips with those in whom Harmonic scalpel was used.

#### Material and Method

This study is randomised controlled prospective study conducted in the Department of Surgery, GMC, Jammu over a period of one year w.e.f 1<sup>st</sup> November 2014 to 31<sup>st</sup> October 2015 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 comorbidity. 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

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#### Type of intervention

Essentially two methods of lap cholecystectomies (cystic duct occlusion) i.e. with traditional lap cholecystectomy (titanium clips) and harmonic scalpel in patients undergoing laparoscopic cholecystectomy.

A written informed consent shall be obtained from all patients for participation in the study as well as surgical procedure.

#### Equipments

The equipment required for laparoscopic cholecystectomy includes a high-flow insufflator, light source, high-resolution camera, high-resolution video monitor, irrigation device, and electrocautery unit and ultrasonic scalpel. Lasers are used rarely, if ever.

#### Observation and result

**Table 1: Distribution of cases according to the age in Harmonic and clip groups.**

##### AGE DISTRIBUTION

AGE GROUPS	No. of Patients in Clip group(n=50)	%age	No. of Patients in Harmonic scalpel group(n=50)	%age
0-10	-	-	-	-
11-20	-	-	1	2%
21-30	1	2%	5	10%
31-40	19	38%	20	40%
41-50	25	50%	12	24%
>50	5	10%	12	24%
Total	50	100%	50	100%

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 was 43.68 years and in harmonic scalpel group was 42.64 years

**Table 2 : Distribution of cases gender wise in Harmonic and Clip group undergoing laparoscopic cholecystectomy.**

##### SEX DISTRIBUTION

SEX	No. of patients in Clip group (n=50)	%age	No. of patients in Harmonic scalpel group (n=50)	%age
Males	9	18%	15	30%
Females	41	82%	35	70%
Total	50	100%	50	100%

In both groups majority of the patients were females.

**Male: Female ratio in clip group was 1:4.5.**

**Male: Female ratio in Harmonic scalpel group was 1:2.3.**

**Total Male: Female ratio was 1:3.76.**

**Table 3- Distribution of cases according to past history in both groups.**

**PAST HISTORY**

Past History	No. of Patients in Clip Group (n=50)	%age	No. of Patients in Harmonic scalpel Group (n=50)	%age
H/O cholecystitis	8	16%	4	8%
H/O Pancreatitis	1	2%	3	6%
H/O ERCP for CBD Calculi	0	0%	0	0%

**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 .

**Table 4: Mean operative time in performing laparoscopic cholecystectomy in Harmonic and Clip group.**

**Operating Time**

Operative time	Harmonic Group	Clip Group
Mean	52.14	61.88
SD	9.82	16.17

Paired t test value = 3.57 .

P value comes to be statistically significant.

**Table 5 :Distribution of cases according to peritoneal Drain Intraoperative Drainage**

	Clip Group n= 50	%age	Harmonic scalpel Group n=50	%age
Drain kept	18	36%	18	36%
Drain not kept	32	64%	32	64%

**Table 6: Table showing bile duct injuries in both groups. Bile Duct Injury detected intra- operative period**

	Clip Group n=50	Harmonic scalpel Group N=50
Bile Duct Injury	0	0

**Table 7: Table showing bile leak developed in Harmonic scalpel and clip group. Bile – Leak**

	Clip Group n=50	%age	Harmonic scalpel Group n=50	%age
Bile leak	1	2%	1	2%

**Table 8: Bile collection requiring re-operation or image guided aspiration**

	Clip Group n=50	%age	Harmonic scalpel Group n=50	%age
Bile collection requiring re-operation	0	0%	0	0%

**Table 9: Table demonstrating port site infections in both group postoperatively.**

**Port site infections**

Port Site Infection	Number	Mean	SD	P value = 0.1594
Harmonic	1	0.02	0.14	
Clip	3	0.06	0.24	

**Table 10: Table showing development of obstructive jaundice postoperatively in both groups.**

**Obstructive Jaundice**

	Clip Group n=50	%age	Harmonic scalpel Group n=50	%age
Obstructive Jaundice	0	0%	0	0%

**Table 11: Mean hospital stay in Harmonic and clip group.**

**Hospital Stay**

	Clip Group n=50	Harmonic scalpel Group n=50	P value = 0.0361 significant
Mean Hospital stay	2.82 days	2.12 days	

**Table 12: Mean time taken for return to work in both groups. Return to work/ Routine**

	Clip Group n=50	Harmonic scalpel Group n=50	P value = 0.0477 significant
Mean no of days	8.18 days	6.79 days	

**Discussion**

Laparoscopic surgery is a well established alternative to open surgery across all disciplines. 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.

Many surgeons have attempted to use alternatives to non absorbable clips such as absorbable clips, locking clips, 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 sealers/clips can be gauged from the study of [Saito et al \(2004\)](#).<sup>2</sup> They conducted study comparing clips and harmonic scalpels and found harmonic scalpels as safe alternatives to clips.

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; Janssen et al., (2008)).<sup>3</sup> 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. ZANGHÌ, A. CAVALLARO (2014)<sup>4</sup> and Huscher et al. (2003),<sup>5</sup> 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 occlusion also did not report any cases of biliary peritonitis following laparoscopic cholecystectomy. Bile collection requiring re-operation. In our study we had no patients in either group which required re-operation before bile collection.

re-operation reported in the trials included in this review in clip group as reported by A. ZANGHÌ, A. CAVALLARO, (2014).<sup>4</sup> This was not statistically significant on Fisher's exact test ( $p=0.50$ ) Regarding port site infections or surgical site infections, three (6%) patients out of fifty developed port site infections in the clip group. In harmonic scalpel group, one patients (2%) patients out of fifty developed infections at the port site. The result was statically insignificant ( $p=0.524$ ) In the similar study by Nazih Salameh Amarin (1994) no patients in either group develop port site infections.<sup>6</sup>

Another secondary outcome in our study was hospital stay after surgery. Mean hospital stay in clip group was 2.82 days while it was 2.12 days in harmonic group which was statistically significant ( $p=0.0361$ ). A similar trial done by Huseyin Yilmaz\*, Husnu Alptekin (2014) however reported no such difference.<sup>7</sup> Ayman F. El-Ramah (2010) reported a significant decrease in post operative duration of stay in harmonic group.<sup>8</sup>

Return to work/routine is another outcome calculated in our study. Mean time taken for patients to get back to routine in clip group is 8.22 days in comparison to 6.86 days in harmonic group patients. The results were statically significant ( $p=0.047$ ) which is significant.

in clip group and 2% of the patients in the harmonic group developed minor bile leak for which no intervention was required. Regarding the outcome of return to routine/work, patients in the clip group took more time as compared to the patients in the harmonic group. Patient in clip group took 8.18 days as compared to harmonic group patients who took 6.79 days to get back to routine.

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.

**Conclusion:** Results of this study demonstrate that cystic duct occlusion with harmonic scalpel as a safe, effective, quicker alternative to clips.

#### References:

1. James Westervelt et al. Clipless cholecystectomy : Broadening the role of Harmonic Scalpel *JLS. 2004 Jul-Sep; 8(3): 283-285.*
2. Kandil T, El Nakeeb A and El Hefnawy E et al. Comparative study between clipless laparoscopic cholecystectomy by harmonic scalpel versus conventional method: A prospective randomized study. *J Gastrointest Surg. 2010 Feb;14(2):323-8.*
3. Janssen IMC, Swank DJ et al. Randomized clinical trial of ultrasonic versus electrocautery dissection of the gallbladder in laparoscopic cholecystectomy. *Br J Surg 90:799-803*
4. A. ZANGHÌ, A. CAVALLARO et al. Laparoscopic cholecystectomy: ultrasonic energy versus monopolar electrosurgical energy. *European Review for Medical and Pharmaceutical Sciences 2014;18(Suppl2):54-59.*
5. Huscher CGS, Lirici MM et al. Laparoscopic cholecystectomy by ultrasonic dissection without cystic duct and artery ligation. *Surg Endosc 17:442-451.*
6. Nazih Salameh Amarin et al. Harmonic Scalpel and clipless laparoscopic cholecystectomy. *World Journal of Laparoscopic Surgery, May-August 2008;1(2):6-8*
7. Huseyin Yilmaz, Husnu Alptekin et al. Closure of the Cystic Duct: Comparison to Harmonic Scalpel Versus Clip Application in Single Incision Laparoscopic Cholecystectomy. *Yilmaz et al., J Gastroint Dig Syst 2014, 4:1.*
8. Ayman F. El-Ramah, Al-Metwaly et al. Clipless Laparoscopic Cholecystectomy using harmonic scalpel versus conventional laparoscopic cholecystectomy. *AAMJ, 2010. Vol.8, N. 3:314-330*
9. James Westervelt et al. Clipless cholecystectomy : Broadening the role of Harmonic Scalpel *JLS. 2004 Jul-Sep; 8(3): 283-285.*