



COMPARISON OF LAPAROSCOPIC CHOLECYSTECTOMY USING HARMONIC SCALPEL WITH CONVENTIONAL LAPAROSCOPIC CHOLECYSTECTOMY IN PATIENTS OF SYMPTOMATIC GALLSTONES.

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INTRODUCTION

Formation of stones in the gall bladder is termed as Cholelithiasis. It is one of the common presentations of middle age adult's on the surgical floor. Patients can present with right sub costal pain with nausea, vomiting, postprandial fullness and abdominal discomfort, disturbing the daily routine activities. In developed countries its prevalence is about 15%.¹ Among the non-modifiable risk factors, Age is on the top. Patients of age 20 to 40 years are mostly affected.² Complications include acute cholecystitis, chronic cholecystitis, choledocholithiasis, cholangitis and pancreatitis. The choice of treatment of gall stones is removal of gallbladder (i.e. cholecystectomy).³

Laparoscopic cholecystectomy has now become common in the management of cholelithiasis with shorter hospital stay and post-operative complications. Traditionally calot's triangle and gall bladder are dissected with monopolar cautery

ABSTRACT... Objectives: To compare the laparoscopic cholecystectomy using harmonic scalpel with conventional laparoscopic cholecystectomy in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss. **Study Design:** Randomized Control trial. **Setting:** Department of Surgical at Allied Hospital Faisalabad. **Period:** 6 months Oct 2017 to Mar 2018. **Material & Methods:** Eighty (80) patients (forty in one group) divided randomly into A (harmonic scalpel group) and B (conventional) group, done under general anesthesia. Total time of operation and blood loss during procedure was noted. **Results:** Our study showed that mean operative time in Harmonic group (A) was 38.07±5.28 minutes and in Conventional group (B) 63.75±7.62 minutes, (p-value = 0.0001), blood loss in Harmonic group (A) 32.93±8.86ml and 55.53±8.96ml in Conventional group (B), (p-value = 0.0001). **Conclusion:** It is concluded that the laparoscopic cholecystectomy using harmonic scalpel is significantly better when compared with conventional laparoscopic cholecystectomy in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss.

Key words: Harmonic Scalpel, Symptomatic Gallstones, Laparoscopic Cholecystectomy, Mean Operative Time, Intraoperative Blood Loss.

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but there is always risk of bleeding, collateral damage, smoke production, compromised vision hence prolonged operative time.⁴

In advance techniques, Harmonic scalpel is now used during laparoscopy to prevent these complications.⁵ The scalpel enables synchronous cutting, coagulation, and cavitation of the thicker tissue by a high-frequency (55,500 Hz) vibration, which generates heat by tissue stress and friction to degenerate tissue protein. This technique transfers minimal energy to the tissues in proximity and thereby minimizes the risk of collateral thermal damage. In addition, using a Harmonic scalpel can securely close and seal the biliary ducts and vessels with a diameter of ≤5 mm without requiring vessel clipping.⁶

As there is controversy in literature regarding the effectiveness of use of harmonic scalpel technique in comparison of conventional

technique of laparoscopic cholecystectomy in terms of intraoperative time and blood loss. So the objective of this study was to determine the mean operative time and mean intra-operative blood loss in the two techniques in LC and my study will be helpful in selecting the better treatment modality for symptomatic gallstones.

MATERIAL & METHODS

Randomized control trial at Surgical Department of Allied hospital Faisalabad conducted six months after approval from the hospital ethical review committee. Patient with symptomatic gall stones including both male and female patients age ranges from 20-70 years with duration of symptoms > 6 months and patients having ASA status I and II were included in the study.

Symptomatic Gallstones defined as pain in the upper part of abdomen and radiating to back and right shoulder tip and confirmed on ultrasound if gallbladder showed a hyper-echoic mass with clear acoustic shadow. Operative Time was defined as the time from skin incision to skin approximation measured in minutes. Intra-Operative Blood Loss was defined as estimated by measuring blood aspirated from the operative field. Patients having common bile duct stones, patients with suspicion of gall bladder malignancy, patients having acute cholecystitis and patients with of previous upper abdominal surgery were excluded from the study. Sample size of 80 (40 in each group) calculated using WHO sample size calculator for 2 mean Test value of population mean = 50.17⁷ with pooled deviation of 40.58, power of study 90%, level of significance 5% and anticipated population mean of 100.08.⁷ After explaining the study to the cases informed consent was taken.

Eighty (80) patients (forty in one group) divided randomly into A (harmonic scalpel group) and B (conventional) group. Total time of operation and blood loss during procedure was noted. All procedures were done under general anesthesia by a consultant having more than 5 years post fellowship experience using 4 ports. In Group A Calot's triangle dissected with Harmonic and Maryland forceps, cystic duct & artery separated, clipped and cut with Harmonic Scalpel while same

instrument used for dissection of gall bladder from its bed. In Group B Monopolar Cautery and Maryland forceps used to dissect cystic duct and artery. Cystic duct was cut with scissor after clipping & clipped cystic artery was cut with monopolar cautery followed by dissection of gall bladder from its bed with the same instrument. Data collected was noted according to a pre-designed proforma.

Data entered and analyzed in SPSS version 20 with mean and standard deviation calculated for quantitative variables (age, duration of disease, operative time and intra-operative blood loss) and frequency with percentage calculated for qualitative variables like gender. Both major outcome variables (operative time and intra-operative blood loss) were compared using independent sample t-test. P-value ≤ 0.05 was considered significant. Effect modifiers like age, gender and duration of disease were controlled by stratification. Post-stratification independent sample t-test was applied.

RESULTS

Eighty (80) patients (forty in one group) divided randomly into A (harmonic group) and B (conventional) group, done under general anesthesia. Total time of operation and blood loss during procedure was noted.

Age distribution shows 67.5% (n=27) in Harmonic group (A) and 72.5% (n=29) in conventional group (B) were 20-50 years whereas 32.5% (n=13) in Harmonic Group (A) and 27.5% (n=11) in conventional group (B) were 51-70 years, mean \pm SD calculated as 44.33 \pm 10.06 years in Harmonic Group (A) and 44.56 \pm 11.47 years in conventional group (B).

Gender distribution shows 42.5% (n=17) in Harmonic group (A) while 40% (n=16) in Conventional group (B) were of male gender whereas 57.5% (n=23) in Harmonic group (A) and 60% (n=24) in Conventional group (B) were of females gender.

Mean duration of disease was calculated as 11.42 \pm 2.75 months in Harmonic group (A) and

10.98±3.14 months in Conventional group (B).

Comparison of laparoscopic cholecystectomy using harmonic scalpel with conventional laparoscopic cholecystectomy in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss shows that intraoperative time in Harmonic group (A) was 38.07±5.28 minutes and in

Conventional group (B) 63.75±7.62 minutes, p value was 0.0001, blood loss in Harmonic group (A) and 32.93±8.86ml and 55.53±8.96ml in Conventional group (B), p value was 0.0001. (Table-I)

The data was stratified for age, gender and duration of disease and presented in Table No. II-IV respectively.

Variables	Group-A (n=40)		Conventional Group (B) (n=40)		P-Value
	Mean	SD	Mean	SD	
Intra operative time (minutes)	38.07	5.28	63.75	7.62	0.0001
Blood loss (ml)	32.93	8.86	55.53	8.96	0.0001

Table-I. Comparison of laparoscopic cholecystectomy using harmonic scalpel (group A) with conventional laparoscopic cholecystectomy (Group B) in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss (n=80)

20 to 50 Years

Variables	Group-A (n=40)		Conventional group (B) (n=40)		P-Value
	Mean	SD	Mean	SD	
Intra operative time (minutes)	36.81	5.32	63.41	7.61	0.0001
Blood loss (ml)	32.67	8.40	56.52	7.70	0.0001

Table-II. Stratification for age regarding comparison of laparoscopic cholecystectomy using harmonic scalpel (group A) with conventional laparoscopic cholecystectomy (group B) in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss (n=80)

51 to 70 Years

Variables	Group-A (n=40)		Conventional group (B) (n=40)		P-Value
	Mean	SD	Mean	SD	
Intra operative time (minutes)	36.81	5.32	63.41	7.61	0.0001
Blood loss (ml)	32.67	8.40	56.52	7.70	0.0001

Male

Variables	Group-A (n=40)		Conventional group (B) (n=40)		P-Value
	Mean	SD	Mean	SD	
Intra operative time (minutes)	39.29	5.35	64.44	8.36	0.0001
Blood loss (ml)	33.88	9.73	56.38	10.51	0.0001

Table-III. Stratification for gender regarding comparison of laparoscopic cholecystectomy using harmonic scalpel (group A) with conventional laparoscopic cholecystectomy (group B) in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood (n=80)

Female

Variables	Group-A (n=40)		Conventional group (B) (n=40)		P-Value
	Mean	SD	Mean	SD	
Intra operative time (minutes)	37.17	5.17	63.29	7.23	0.0001
Blood loss (ml)	32.22	8.31	54.96	7.96	0.0001

7-12 Months					
Variables	Group-A (n=40)		Conventional Group (B) (n=40)		P-Value
	Mean	SD	Mean	SD	
Intra operative time (minutes)	37.31	5.74	63.88	8.13	0.0001
Blood loss (ml)	32.08	8.23	55.00	7.93	0.0001

Table-IV. Stratification for duration of disease regarding comparison of laparoscopic cholecystectomy using harmonic scalpel (group A) with conventional laparoscopic cholecystectomy (group B) in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss (n=80)

> 12 Months					
Variables	Group-A (n=40)		Conventional group (B) (n=40)		P-Value
	Mean	SD	Mean	SD	
Intra operative time (minutes)	39.50	4.13	63.50	6.85	0.0001
Blood loss (ml)	34.50	10.05	56.50	10.88	0.0001

DISCUSSION

Laparoscopic cholecystectomy has now become common in the management of cholelithiasis with shorter hospital stay and post-operative complications. Traditionally calot's triangle and gall bladder is dissected with monopolar cautery, cystic duct and vessels are sealed using metallic clips, but risk of bleeding, smoke production, compromised vision, prolonged operative time, collateral damage, direct coupling & capacitive coupling, clip dislodgement and biliary leakage is always there further increasing the morbidity and making the case unsuccessful.

In advance techniques, Harmonic scalpel is now used during laparoscopy to prevent these complications. There is controversy in literature regarding the effectiveness of use of harmonic scalpel technique in comparison of conventional technique of laparoscopic cholecystectomy in terms time of the operation and intra-operative blood loss. So, aim and objective of this study was to determine the mean operative time and mean intra-operative blood loss in the two techniques in LC and my study will be helpful in selecting the better treatment modality for symptomatic gallstones.

In this study, out of 80 cases (40 in each group), mean age was calculated as 44.33 ± 10.06 years in Harmonic group (A) and 44.56 ± 11.47 years in Conventional group (B), 42.5%(n=17) in Harmonic group (A) and 40%(n=16) in Conventional group (B) were male whereas

57.5%(n=23) in Harmonic group (A) and 60%(n=24) in Conventional group (B) were females, comparison of clip less laparoscopic cholecystectomy using harmonic scalpel with conventional laparoscopic cholecystectomy in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss shows that intraoperative time in Harmonic group (A) was 38.07 ± 5.28 minutes and in Conventional group (B) 63.75 ± 7.62 minutes, p value was 0.0001, blood loss in Harmonic group (A) and 32.93 ± 8.86 ml and 55.53 ± 8.96 ml in Conventional group (B) , p value was 0.0001.

We compared our results with a study, where the mean intra-operative blood loss in laparoscopic cholecystectomy using harmonic scalpel was 50.17 ± 35.97 ml and intra-operative blood loss in conventional laparoscopic cholecystectomy 100.08 ± 44.72 ml. Mean operative time for laparoscopic cholecystectomy using harmonic scalpel was 40 ± 4.42 min and operative time for conventional laparoscopic cholecystectomy was 80 ± 17.02 min.⁷ Our findings are close to the above study.

In another study, mean intra-operative blood loss in laparoscopic cholecystectomy using harmonic scalpel was 14.2 ± 10.6 ml and intra-operative blood loss in conventional laparoscopic cholecystectomy 13.7 ± 9.1 ml. Mean operative time for laparoscopic cholecystectomy using harmonic scalpel was 54.9 ± 13.1 min and operative time for conventional laparoscopic

cholecystectomy was 51.7 ± 9.6 min.⁶

Though there is a significant difference in operative and blood loss in our results and the above study, however, in both studies, it is justified that laparoscopic cholecystectomy is better than conventional.

Another study⁸ compared LC done using harmonic scalpel technique with LC done using conventional use of metallic clips. This study reported that harmonic technique is safe and effective in sealing off the biliary tract and vessels suspected to cause complications and increase morbidity in patients with cholelithiasis and it is also a better alternate of high frequency monopolar technology, our results are supported with this study.

Kandil T and others⁹ compared the conventional technique of laparoscopic cholecystectomy (LC) with harmonic scalpel (HS) technique used now a days because of its safety and efficacy. HS technique had shorter time of procedure compared to conventional technique (33.21 ± 9.6 vs. 51.7 ± 13.79 , respectively, $p = 0.001$), with lesser complications like gallbladder perforation (7.1% vs. 18.6, $p = 0.04$) and ending-up in open procedure (not statistical significant). Post-operative drainage measured in amount is also lesser in group A (29 ± 30 vs. 47.7 ± 31 , $p = 0.001$) and is statistically significant. None of the patient in the harmonic group showed any post-operative bile leakage, but it was seen in 2.9% patients in the other group. Pain measured on visual analogue scale in group A at 12 hours post-operative was 3.25 ± 1.84 vs 5.01 ± 1.2 ($p = 0.001$) and at 24 h postoperative was 3.12 ± 1.64 vs. 4.48 ± 1.89 ($p = 0.001$). It was concluded that using harmonic scalpel secures the vessels and bile ducts and it is safer than the conventional use of clips, along with significant decrease in the operative time with lesser complications like perforation, pain and rate of opening-up of abdomen for removal of gall stone.

Considering the results of our study and other above studies, the hypothesis of this trial "laparoscopic cholecystectomy using harmonic

scalpel is better than conventional laparoscopic cholecystectomy in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss" is justified.

This was a single center study and limited local and regional data is available regarding this topic. This study didn't compare other the postoperative complications possible related with the use of harmonic scalpel. Many controlled trials should be done comparing the two techniques in our region and in our country so that complications can be minimized and a better technique should be promoted.

CONCLUSION

We concluded that the laparoscopic cholecystectomy using harmonic scalpel is significantly better when compared with conventional laparoscopic cholecystectomy in patients of symptomatic gallstones in terms of mean operative time and mean intra-operative blood loss.

CONFLICT OF INTEREST

All authors declare that there is no conflict of interest.






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3	M. Hasan Anwaar	Literature review, Compilation of results, Referencing.	
4	Shahbaz Ahmad	Literature review, Referencing, compilation of results.	
5	M. Kamran	Data collection, Referencing, Interpretation.	
6	Saddaqt Hayat	Literature review, Interpretation, compilation of results.	