

## A Prospective Randomized Controlled Trial Evaluating Ultrasonic Verses Monopolar Electrocautery Dissection of Gall Bladder in Laparoscopic Cholecystectomy

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### Abstract

**Aim:** The aim of the present study was to compare the use of monopolar electrocautery and ultrasonic dissection of gall bladder in laparoscopic cholecystectomy in terms of intra-operative and post-operative parameters.

**Material & Methods:** A prospective randomized controlled trial within the duration of 1 year undertaken in Department of General Surgery, Bhagwan Mahavir institute of medical science, Pawapuri, Nalanda, Bihar, India. It included 100 patients undergoing laparoscopic cholecystectomy.

**Results:** There was no significant difference between the groups in terms of age (years) ( $p=0.840$ ). There was no significant difference between the various groups in terms of distribution of age ( $p=0.414$ ). The  $p$  value for sex distribution was found to be 0.115 which was statistically insignificant. There was a significant difference between the 2 groups in terms of operative time (minutes) ( $p\leq 0.001$ ). There was a significant difference between the 2 groups in terms of number of times lens cleaning done ( $p\leq 0.001$ ). 6% of the participants in the group A had gall bladder perforation while 22% of the patients in group B had gall bladder perforation. There was a significant difference between the various groups in terms of distribution of gall bladder perforation ( $p=0.012$ ). There was no significant difference between the various groups in terms of distribution of biliary leak ( $p=0.484$ ). None of the participants in either of the groups had Common bile duct and bowel injury. 4% of the participants in the group A and group B had drain (output nature: bile). Hence, there was no significant difference between the groups in terms of duration of hospital stay (days) ( $W=1258.000$ ,  $p=0.920$ ).

**Conclusion:** Ultrasonic dissection is safe and effective, and it improves the operative course of laparoscopic cholecystectomy by reducing the incidence of gallbladder perforation.

**Keywords:** Ultrasonic dissection, Electrocautery, Electrosurgical energy.

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### Introduction

Gallstones are still one of the most common routinely encountered surgical problem in the developed world. [1] Symptomatic Cholelithiasis is a common disease with incidence of 10-25%. [2] The aim was to remove the diseased gall bladder completely and to ensure a patent channel for biliary drainage into the gastrointestinal tract. Laparoscopic cholecystectomy is the "gold standard" for treatment of uncomplicated acute or chronic cholecystitis with cholelithiasis due to its minimal invasiveness and swift post-operative recovery. [3] It has the advantages of less post-operative pain, better cosmetic results, shorter hospital stay, early return to work and is cost effective. [4]

There are two main dissecting devices used in the procedure, including the ultrasonic and electrosurgical energy dissectors. In-conventional laparoscopic cholecystectomy, especially for dissection and coagulation of Calot's triangle and gall bladder bed monopolar electrocautery is used, mainly using an electrosurgical hook and spatula. [5] Though laparoscopic cholecystectomy is considered a safe procedure, local thermal injuries and distant tissue damage caused by monopolar electrocautery are common problems. During dissecting gall bladder from the liver bed by monopolar electrocautery, the incidence of gall bladder perforation during Laparoscopic cholecystectomy is 20-40% Gallbladder perforation during dissection from the liver bed with spillage of

bile and loss of stones in the peritoneal cavity is a common operative problem during laparoscopic cholecystectomy. [6] Also, there is risk of insulation failure of the active electrode and there might be direct coupling between the active electrode and tissue or metal instruments which can cause injury. [7]

Furthermore, thermal side effects of electrocauterization can lead to iatrogenic injury to adjacent solid organs and vessels such as small intestine and common bile duct. [8] Ultrasonic dissection is an alternative to monopolar electrocautery during laparoscopic cholecystectomy. It generates less thermal injury, produces a smaller zone of tissue damage and more precise dissection. The incidence of gallbladder perforation is also low with ultrasonic dissection as compared to monopolar electrocautery during laparoscopic cholecystectomy. Ultrasonic dissection produces a minimal amount of smoke and char resulting in faster dissection and also provides an enhanced vessel sealing capacity and is less traumatic to the patient. [9,10]

Hence, the present study was conducted to compare the use of monopolar electrocautery and ultrasonic dissection of gall bladder in laparoscopic cholecystectomy in terms of intra-operative and post-operative parameters.

### Material & Methods

A prospective randomized controlled trial within the duration of 1 year undertaken in Department of General Surgery, Bhagwan Mahavir institute of medical science, Pawapuri, Nalanda, Bihar, India. It included 100 patients undergoing laparoscopic cholecystectomy.

### Inclusion Criteria

- Adult patients with uncomplicated acute or chronic cholecystitis with cholelithiasis disease who were eligible for laparoscopic cholecystectomy.

### Exclusion Criteria

- Patients with common bile duct stones, suspicion of gallbladder malignancy based on ultrasonography and subsequent computed tomography findings and patients not fit for laparoscopic surgery were excluded.

Patients were randomly assigned into two groups using the envelope method to either monopolar electrocautery or ultrasonic dissection just before the operation.

Group-I: In the ultrasonic dissection group, dissection of the gallbladder was performed using Harmonic Ace curved shears (Ethicon Endo-Surgery, Johnson & Johnson Co.).

Group II: Patients undergoing laparoscopic cholecystectomy in whom gall bladder dissection was done by monopolar electrocautery

### Methodology

All patients underwent successful completion of laparoscopic cholecystectomy with one of the dissection techniques, as per random assignment. Preoperative data of each patient, including age, sex, body mass index (BMI), presenting symptoms, comorbidities if any, previous abdominal surgeries and ultrasonography findings, were recorded. Complicating factors, such as acute cholecystitis, shrunken fibrotic gallbladder, impacted stones in the gallbladder neck and dense adhesions with the gallbladder, visualized on laparoscopy were also recorded. The primary outcome of this study was the incidence of gallbladder perforation during dissection of the gallbladder from its liver bed, and the secondary outcomes were bile leak (defined as leak of any amount of bile from the ruptured gallbladder site visualized intraoperatively), spillage of stones (macroscopic loss of gallstones through the ruptured gallbladder into the peritoneal cavity), the number and type (intracorporeal or extracorporeal) of lens cleaning during the surgery and the duration of surgery (defined as time between incision and closure). In addition, we estimated the risk of gallbladder perforation in the presence of complicating factors. All patients received prophylactic antibiotics before induction and underwent general anaesthesia. Patients were taken up for laparoscopic cholecystectomy and the surgery was performed by consultants using a uniform technique of laparoscopic cholecystectomy involving 4 ports, with the surgeon and assistant positioned as in the standard North American approach.

In Group 1 patients, dissection of calot's triangle and gall bladder from liver bed was done using harmonic scalpel.

In Group 2, monopolar electrocautery was used for calot's dissection and gall bladder dissection from liver bed done using hook/spatula

The following parameters were recorded in each group

#### 1. Intra-operative parameters

1. Operative findings – status of gall bladder, adhesions, calot's triangle anatomy, gall bladder perforation leading to bile or stone spillage, bleeding, use of Haemostat.
2. (Spongostan/Surgicel) and number of times lens was cleaned.
3. Duration of surgery.
4. Bleeding – assessed by gauze visual analogue method and
5. Use of drain.

## 2. Post-operative parameters.

1. Post-operative pain at 6 hour and 24 hours – pain score from Modified Early Warning System [11] used.
2. Duration of hospital stay (days)
3. Nature and amount of drainage in drain (when used)
4. Any post-operative complication

**Statistical analysis**

The statistical analysis was carried out using Statistical Package for Social Sciences software version 15.0 for Windows (SPSS Inc.). All quantitative variables were estimated using measures of central location (mean, median) and measures of dispersion (standard deviation and

standard error). Normality of data was checked using measures of skewness and Kolmogorov–Smirnov tests of normality. For normally distributed data, we compared means using the Student t test for both groups. For skewed data, we used the Mann–Whitney U test. Qualitative or categorical variables were described as frequencies and proportions. Proportions were compared using the  $\chi^2$  or Fisher exact test as applicable. The risk of gallbladder perforation in the presence of complicating factors was also estimated by calculating odds ratios. All statistical tests were 2-sided and performed at a significance level of  $\alpha = 0.05$ .

**Results****Table 1: Comparison of parameters in two groups**

	Group A (electrocautery) (N=50) (%)	Group B (harmonic scalpel) (N=50) (%)	
Age (years)	38.72±8.42	40.30±10.72	0.840
Age (years)			0.414
<b>Gender</b>			
Male	11 (22)	14 (28)	0.115
Female	39 (78)	36 (72)	
<40	27 (54)	27 (54)	
40-60	23 (46)	21 (42)	
>60	0 (0.0)	2 (4)	
Operative time (minutes)	52.18±12.82	38.26±10.20	<0.001
No. of times lens cleaning done	4.16±1.32	2.08±0.84	<0.001
Gall bladder perforation (present)***	11 (22)	3 (6)	0.012
Biliary leak (present)	3 (6)	0 (0)	0.484
Common bile duct injury (present)	0 (0.0)	0 (0.0)	1.000
Bowel injury (present)	0 (0.0)	0 (0.0)	1.000
<b>Drain output/nature</b>			
Bile	2 (4)	2 (4)	
Nil	48 (96)	48 (96)	
Duration of hospital stay (days)	1.18±0.72	1.06±0.24	0.920

The mean±SD of age (years) in group A was 38.72±8.42 and while in group B was 40.30±10.72. There was no significant difference between the groups in terms of age (years) ( $p=0.840$ ). There was no significant difference between the various groups in terms of distribution of age ( $p=0.414$ ). The majority of the patients in both the groups were females. In group B (harmonic scalpel) 72% were females and 28% were males while, in group A (electrocautery) 78% were females and 22% were males. The p value for sex distribution was found to be 0.115 which was statistically insignificant. The mean±SD of operative time (minutes) in the group A was 52.18±12.82 while in group B was 38.26±10.20. There was a significant difference between the 2 groups in terms of operative time (minutes) ( $p\leq 0.001$ ). The mean±SD of number of times lens cleaning done in group A was 4.16±1.32 and in group B was 2.08±0.84.

There was a significant difference between the 2 groups in terms of number of times lens cleaning done ( $p\leq 0.001$ ). 6% of the participants in the group A had gall bladder perforation while 22% of the patients in group B had gall bladder perforation. There was a significant difference between the various groups in terms of distribution of gall bladder perforation ( $p=0.012$ ). 6% of the participants in group A had biliary leak. There was no significant difference between the various groups in terms of distribution of biliary leak ( $p=0.484$ ). None of the participants in either of the groups had Common bile duct and bowel injury. 4% of the participants in the group A and group B had drain (output nature: bile). There was no significant difference between the various groups in terms of distribution of drain output/nature ( $p=1.000$ ). The mean±SD of duration of hospital stay (days) in the group A was 1.18±0.72 while in

group B was  $1.06 \pm 0.24$ . Hence, there was no significant difference between the groups in terms of duration of hospital stay (days) ( $W=1258.000$ ,  $p=0.920$ ).

### Discussion

Laparoscopic cholecystectomy (LC) is the gold standard operation for benign gallbladder diseases. [12] There are two main dissecting devices used in the procedure, including the ultrasonic and electro-surgical energy dissectors. The electro-surgical device is widely used in LC, and the ultrasonic device has increasingly been used in wider and deeper operative fields. The former can easily fragment soft tissues, such as adipose or hepatic tissues, by producing shearing forces, while the latter can cut harder tissues such as fibrous tissues by delivering heat energy. It is controversial on the advantages and disadvantages of different devices. [12,13] The potential risks and benefits related to ultrasonic dissection compared with the electro-surgical dissection for cholecystitis or cholelithiasis are not fully understood. Symptomatic Cholelithiasis is a common disease with incidence of 10-25%. [14] Laparoscopic cholecystectomy is the "Gold Standard" for the treatment of symptomatic gallstone disease. It has the advantages of less post-operative pain, better cosmetic results, shorter hospital stay, early return to work and is cost effective. [15] Though laparoscopic cholecystectomy is considered a safe procedure, local thermal injuries and distant tissue damage caused by monopolar electrocautery are common problems. During dissecting gall bladder from the liver bed by monopolar electrocautery, the incidence of gall bladder perforation during Laparoscopic cholecystectomy is 20-40%. Perforation of gall bladder and spillage of bile and stones disrupts the flow of surgery and prolongs its duration. [16,17]

The mean $\pm$ SD of age (years) in group A was  $38.72 \pm 8.42$  and while in group B was  $40.30 \pm 10.72$ . There was no significant difference between the groups in terms of age (years) ( $p=0.840$ ) was similar to the study conducted by Mahabaleswar et al ( $45.30 \pm 9.32$  vs  $47.36 \pm 10.42$ ;  $p=0.55$ ). [18] There was no significant difference between the various groups in terms of distribution of age ( $p=0.414$ ). The majority of the patients in both the groups were females. In group B (harmonic scalpel) 72% were females and 28% were males while, in group A (electrocautery) 78% were females and 22% were males. The p value for sex distribution was found to be 0.115 which was statistically insignificant. The mean $\pm$ SD of operative time (minutes) in the group A was  $52.18 \pm 12.82$  while in group B was  $38.26 \pm 10.20$ . There was a significant difference between the 2 groups in terms of operative time (minutes) ( $p \leq 0.001$ ). In the studies conducted by Jain et al ( $64.7 \pm 13.74$  vs  $50 \pm 9.36$ ;

$p=0.001$ ) and Kandil et al ( $61.88 \pm 16.17$  vs  $52.14 \pm 9.8$ ;  $p < 0.0001$ ) operating time was significantly less in the harmonic group. [12,19]

The mean $\pm$ SD of number of times lens cleaning done in group A was  $4.16 \pm 1.32$  and in group B was  $2.08 \pm 0.84$ . There was a significant difference between the 2 groups in terms of number of times lens cleaning done ( $p \leq 0.001$ ). 6% of the participants in the group A had gall bladder perforation while 22% of the patients in group B had gall bladder perforation. There was a significant difference between the various groups in terms of distribution of gall bladder perforation ( $p=0.012$ ). 6% of the participants in group A had biliary leak. There was no significant difference between the various groups in terms of distribution of biliary leak ( $p=0.484$ ). None of the participants in either of the groups had Common bile duct and bowel injury. 4% of the participants in the group A and group B had drain (output nature: bile). There was no significant difference between the various groups in terms of distribution of drain output/nature ( $p=1.000$ ). The mean $\pm$ SD of duration of hospital stay (days) in the group A was  $1.18 \pm 0.72$  while in group B was  $1.06 \pm 0.24$ . Hence, there was no significant difference between the groups in terms of duration of hospital stay (days) ( $W=1258.000$ ,  $p=0.920$ ). Kandil et al in their study, showed that the risk of gall bladder perforation was significantly higher in the electrocautery group as compared to the harmonic group (18.6% vs 7.1% respectively;  $p=0.04$ ). [19] Conversely, Mukesh et al in their study found that, there was no significant risk in gall bladder perforation. [20]

In our study, none of the patients had any intraoperative complications like bleeding, bile duct injury, etc. Laparoscopic cholecystectomy using harmonic scalpel as compared with conventional monopolar electrocautery is recorded to be safer and associated with infrequent iatrogenic injury, such as postoperative bleeding, common bile duct damage and bowel perforation, mainly because of the effect of collateral damage from electro cauterization, contrary to minimal energy transfer while using ultrasonic vibration. [18] Overall, the ultrasonic harmonic scalpel has been emerging as a better method for dissection during laparoscopic cholecystectomy and has almost replaced electrocautery in modern era laparoscopic surgeries.

### Conclusion

Laparoscopic Cholecystectomy is the gold standard for treatment of gall stones. Since its inception the energy sources used for dissection have evolved in form of monopolar electrocautery to ultrasonic harmonic scalpel. It was concluded in our study that harmonic scalpel has a significant advantage over electrocautery in terms of operative time and

incidence of gall bladder perforation. Further randomized trials are required to prove a definite advantage of the harmonic scalpel over conventional electrocautery for laparoscopic cholecystectomy.

### References

1. Nakeeb A, Steven A, Hency A. Calculous biliary disease. Greenfield surgery.
2. Stinton LM, Shaffer EA. Epidemiology of gallbladder disease: cholelithiasis and cancer. Gut and liver. 2012 Apr;6(2):172.
3. Keus F, de Jong J, Gooszen HG, van Laarhoven CH, Cochrane Hepato-Biliary Group. Laparoscopic versus small-incision cholecystectomy for patients with symptomatic cholelithiasis. Cochrane database of systematic reviews. 1996 Sep 1;2010(1).
4. Polychronidis A, Karayiannakis AJ, Simopoulos C. 'Laparoscopic Cholecystectomy' or Simply 'Cholecystectomy'? Medical Principles and Practice. 2003 Sep 12;12(4):276.
5. Soper NJ, Barteau JA, Clayman RV, Becich MJ. Safety and efficacy of laparoscopic cholecystectomy using monopolar electrocautery in the porcine model. Surgical Laparoscopy Endoscopy & Percutaneous Techniques. 1991 Mar 1;1(1):17-22.
6. Diez J, Arozamena C, Gutierrez L, Bracco J, Mon A, Almeyra RS, Secchi M. Lost stones during laparoscopic cholecystectomy. HPB Surgery. 1998;11(2):105-9.
7. Westervelt J. Clipless cholecystectomy: broadening the role of the harmonic scalpel. JSLS: Journal of the Society of Laparoendoscopic Surgeons. 2004 Jul;8(3):283.
8. Humes DJ, Ahmed I, Lobo DN. The pedicle effect and direct coupling: delayed thermal injuries to the bile duct after laparoscopic cholecystectomy. Archives of Surgery. 2010 Jan 1;145(1):96-8.
9. Power C, Maguire D, McAnena OJ, Calleary J. Use of the ultrasonic dissecting scalpel in laparoscopic cholecystectomy. Surgical endoscopy. 2000 Nov; 14:1070-3.
10. Wetter LA, Payne JH, Kirshenbaum G, Podoll EF, Bachinsky T, Way LW. The ultrasonic dissector facilitates laparoscopic cholecystectomy. Archives of Surgery. 1992 Oct 1;127(10):1195-9.
11. Gardner-Thorpe J, Love N, Wrightson J, Walsh S, Keeling N. The value of Modified Early Warning Score (MEWS) in surgical in-patients: a prospective observational study. The Annals of The Royal College of Surgeons of England. 2006 Oct;88(6):571-5.
12. Jain SK, Tanwar R, Kaza RC, Agarwal PN. A prospective, randomized study of comparison of clipless cholecystectomy with conventional laparoscopic cholecystectomy. Journal of Laparoendoscopic & Advanced Surgical Techniques. 2011 Apr 1;21(3):203-8.
13. Sista, F., Schietroma, M., Abruzzese, V., Bianchi, Z., Carlei, F., De Santis, G., Cecilia, E.M., Pessia, B., Piccione, F. and Amicucci, G., 2014. Ultrasonic versus standard electric dissection in laparoscopic cholecystectomy in patients with acute calculous cholecystitis, complicated by peritonitis: influence on the postoperative systemic inflammation and immune response. A prospective randomized study. Journal of Laparoendoscopic & Advanced Surgical Techniques, 24(3), pp.151-158.
14. Stinton LM, Shaffer EA. Epidemiology of gallbladder disease: cholelithiasis and cancer. Gut and liver. 2012 Apr;6(2):172.
15. Polychronidis A, Karayiannakis AJ, Simopoulos C. 'Laparoscopic Cholecystectomy' or Simply 'Cholecystectomy'? Medical Principles and Practice. 2003 Sep 12;12 (4): 276-.
16. Peters JH, Gibbons GD, Innes JT, Nichols KE, Roby SR, Ellison EC. Complications of laparoscopic cholecystectomy. Surgery. 1991 Oct 1;110(4):769-7.
17. Soper NJ, Dunnegan DL. Does intraoperative gallbladder perforation influence the early outcome of laparoscopic cholecystectomy? Surgical Laparoscopy Endoscopy & Percutaneous Techniques. 1991 Sep 1;1(3): 156-61.
18. Mahabaleshwar V, Kaman L, Iqbal J, Singh R. Monopolar electrocautery versus ultrasonic dissection of the gallbladder from the gallbladder bed in laparoscopic cholecystectomy: a randomized controlled trial. Can J Surg. 2012;55(5):307-11.
19. Kandil T, Nakeeb A, Hefnawy E. Comparative study between clipless laparoscopic cholecystectomy by harmonic scalpel versus conventional method: a prospective randomized study. J Gastrointest Surg. 2010; 14(2):323-8.
20. Mukesh KS, Vijayata S, Mohinder KG, Deepak S. Triple ligation technique of clipless laparoscopic cholecystectomy: a spanner especially for complicated cholecystitis. Int J Adv Med. 2017; 4:1358-63.