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Original Research Article

A Clinical Study to Evaluate 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 2 years undertaken in Department of General Surgery, It included 200 patients undergoing laparoscopic cholecystectomy.

Results: The mean±SD of age (years) in group A was 40.65±7.43 and while in group B was 42.28±9.71. There was no significant difference between the groups in terms of age (years). There was no significant difference between the various groups in terms of distribution of age. The majority of the patients in both the groups were females. In group B (harmonic scalpel) 70% were females and 30% were males while, in group A (electrocautery) 76% were females and 24% were males. The p value for sex distribution was found to be statistically insignificant. The mean±SD of operative time (minutes) in the group A was 50.20±11.88 while in group B was 39.21±11.21. There was a significant difference between the 2 groups in terms of operative time (minutes). The mean±SD of number of times lens cleaning done in group A was 3.16±1.35and in group B was 2.06±0.88. There was a significant difference between the 2 groups in terms of number of times lens cleaning done. 7% of the participants in the group A had gall bladder perforation while 24% 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. 7% 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. None of the participants in either of the groups had Common bile duct and bowel injury. 5% 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. The mean±SD of duration of hospital stay (days) in the group A was 1.20±0.74 while in group B was 1.06±0.22. Hence, there was no significant difference between the groups in terms of duration of hospital stay (days).

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.

Introduction

Since 1987, laparoscopic cholecystectomy has evolved to become the gold standard for management of symptomatic gallstones. [1] Electrocautery remains the main energy form used during laparoscopic dissection. However, because of its documented risks, especially those related to visceral injury, search for alternative forms of energy that can be used in laparoscopic dissection and even coagulating and sealing vessels and ducts began very early during the evolution of laparoscopic cholecystectomy itself, specifically in 1992 by researchers such as Wetter. [2]

The standard laparoscopic cholecystectomy is commonly performed by means of specialized instruments. For gallbladder dissection, the electrosurgical hook, spatula, and/or scissors, using high-frequency monopolar technology, have been used in most centers. Occlusion by simple metal clips was the most frequently used technique to achieve both cystic duct and artery closure. [3] In laparoscopic surgery, instruments using a variety of energy sources to cut and coagulate tissue have been used, including monopolar and bipolar cautery, CO2 laser, and the ultrasonic scalpel. The exact incidence of collateral injury is difficult to be assessed;

however, 18% of physicians responding to a survey from the society of monopolar electrocautery use have been directly associated with 90% of visceral injuries and 15% of biliary tract injuries during laparoscopic cholecystectomy. [4]

Electrosurgical devices can also cause injury owing to insulation failure of the active electrode, direct coupling between the active electrode and metal instruments or tissue, and stray electrical currents. Because of these risks for patient injury, alternative devices such as ultrasonic scalpels have been investigated further. [5] The ultrasonically activated scalpel (Harmonic; Ethicon Endo-Surgery Inc., Johnson and Johnson Medical SPA, Somerville, New Jersey, USA) was introduced into clinical use more than a decade ago. Its technology relies on the application of ultrasound within the harmonic frequency range to tissues and allows three effects that act synergistically: coagulation, cutting, and cavitation. The temperature obtained and the lateral energy spread are lower than those detected when the monopolar hook is used, thus reducing the risk of tissue damage. The harmonic scalpel is also an effective tool for closure of biliary ducts and vessels whose diameter is 4–6 mm. [6] Applied with sufficient power, ultrasound waves fragment tissue. Fragmentation is strictly related to the water content of tissue: the higher the water content, the easier the fragmentation. [7]

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 2 years undertaken in Department of General Surgery, SKMCH, Muzaffarpur ,Bihar ,India. It included 200 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 anesthesia. 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 suing 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 [8] 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=100) (%)	**Group B (harmonic scalpel) (N=100) (%)**	
Age (years)	40.65±7.43	42.28±9.71	0.812
Age (years)			0.420
Gender			
Male	24 (24)	30 (30)	0.105
Female	76 (76)	70 (70)	
<40	55 (55)	52 (52)	
40-60	45 (45)	44 (44)	
>60	0 (0)	4 (4)	
Operative time (minutes)	50.20±11.88	39.21±11.21	<0.001
No. of times lens cleaning done	3.16±1.35	2.06±0.88	<0.001
Gall bladder perforation (present)	24 (24)	7 (7)	0.018
Biliary leak (present)	7 (7)	0	0.460
Common bile duct injury (present)	0	0	1.000
Bowel injury (present)	0	0	1.000
Drain output/nature			1.000
Bile	5 (5)	5 (5)	
Nil	95 (95)	95 (95)	
Duration of hospital stay (days)	1.20±0.74	1.06±0.22	0.832

The mean±SD of age (years) in group A was 40.65±7.43 and while in group B was 42.28±9.71. There was no significant difference between the groups in terms of age (years). There was no significant difference between the various groups in terms of distribution of age. The majority of the patients in both the groups were females. In group B (harmonic scalpel) 70% were females and 30% were males while, in group A (electrocautery) 76% were females and 24% were males. The p value for sex distribution was found to be statistically insignificant. The mean±SD of operative time (minutes) in the group A was 50.20±11.88 while in group B was 39.21±11.21. There was a significant difference between the 2 groups in terms of operative time (minutes). The mean±SD of number of times lens cleaning done in group A was 3.16±1.35and in group B was 2.06±0.88. There was a significant difference between the 2 groups in terms of number of times lens cleaning done. 7% of the participants in the group A had gall bladder perforation while 24% 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. 7% 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. None of the participants in either of the groups had Common bile duct and bowel injury. 5% 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. The mean±SD of duration of hospital stay (days) in the group A was 1.20±0.74 while in group B was 1.06±0.22. Hence, there was no significant difference between the groups in terms of duration of hospital stay (days).

Discussion

Laparoscopic cholecystectomy (LC) is the gold standard operation for benign gallbladder diseases.[9] There are two main dissecting devices used in the procedure, including the ultrasonic and electrosurgical energy dissectors. The electrosurgical 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. [9,10] The potential risks and benefits related to ultrasonic dissection compared with the electrosurgical dissection for cholecystitis or cholecystolithiasis are not fully understood. Symptomatic Cholelithiasis is a common disease with incidence of 10-25%. [11] 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. [12] 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. [13,14]

The mean±SD of age (years) in group A was 40.65±7.43 and while in group B was 42.28±9.71. There was no significant difference between the groups in terms of age (years). There was no significant difference between the various groups in terms of distribution of age. The majority of the patients in both the groups were females. In group B (harmonic scalpel) 70% were females and 30% were males while, in group A (electrocautery) 76% were females and 24% were males. The p value for sex distribution was found to be statistically insignificant. The mean±SD of operative time (minutes) in the group A was 50.20±11.88 while in group B was 39.21±11.21. There was a significant difference between the 2 groups in terms of operative time (minutes). In the studies conducted by Jain et al (64.7±13.74 vs 50±9.36; p=0.001) and Kandil et al (61.88±16.17 vs 52.14±9.8; p<0.0001) operating time was significantly less in the harmonic group. [10,15]

The mean±SD of number of times lens cleaning done in group A was 3.16±1.35and in group B was 2.06±0.88. There was a significant difference between the 2 groups in terms of number of times lens cleaning done. 7% of the participants in the group A had gall bladder perforation while 24% 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. 7% 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. None of the participants in either of the groups had Common bile duct and bowel injury. 5% 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. The mean±SD of duration of hospital stay (days) in the group A was 1.20±0.74 while in group B was 1.06±0.22. Hence, there was no significant difference between the groups in terms of duration of hospital stay (days). 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). [16] Conversely, Mukesh et al in their study found that, there was no significant risk in gall bladder perforation. [17]

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 electrocauterization, 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.

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