

Monopolar electrocautery versus ultrasonic dissection of the gallbladder from the gallbladder bed in laparoscopic cholecystectomy: a randomized controlled trial

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Background: Ultrasonic dissection has been suggested as an alternative to monopolar electrocautery in laparoscopic cholecystectomy because it generates less tissue damage and may have a lower incidence of gallbladder perforation. We compared the 2 methods to determine the incidence of gallbladder perforation and its intraoperative consequences.

Methods: We conducted a prospective randomized controlled trial between July 2008 and December 2009 involving adult patients with symptomatic gall stone disease who were eligible for laparoscopic cholecystectomy. Patients were randomly assigned before administration of anesthesia to electrocautery or ultrasonic dissection. Both groups were compared for incidence of gallbladder perforation during dissection, bile leak, stones spillage, lens cleaning, duration of surgery and estimation of risk of gallbladder in the presence of complicating factors.

Results: We included 60 adult patients in our study. The groups were comparable with respect to demographic characteristics, symptomatology, comorbidities, previous abdominal surgeries, preoperative ultrasonography findings and intraoperative complications. The overall incidence of gallbladder perforation was 28.3% (40.0% in the electrocautery v. 16.7% in the ultrasonic dissection group, $p = 0.045$). Bile leak occurred in 40.0% of patients in the electrocautery group and 16.7% of patients in ultrasonic group ($p = 0.045$). Lens cleaning time ($p = 0.015$) and duration of surgery ($p = 0.001$) were longer in the electrocautery than the ultrasonic dissection group. There was no statistical difference in stone spillage between the groups ($p = 0.62$).

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

Contexte : La dissection par ultrasons a été proposée comme solution de rechange à l'électrocautère monopolaire dans la cholécystectomie laparoscopique parce qu'elle engendre moins de lésions tissulaires et s'accompagnerait d'une incidence moindre de perforations de la vésicule. Nous avons comparé les 2 méthodes afin de déterminer l'incidence des perforations de la vésicule et ses conséquences peropératoires.

Méthodes : Nous avons réalisé un essai prospectif randomisé et contrôlé entre juillet 2008 et décembre 2009 sur des patients adultes présentant des calculs biliaires symptomatiques et qui étaient admissibles à une cholécystectomie laparoscopique. Avant l'anesthésie, nous avons assigné aléatoirement les patients à une dissection soit par électrocautère, soit par ultrasons. Les 2 groupes ont été comparés sur le plan de l'incidence des perforations peropératoires de la vésicule, des fuites biliaires, de la perte fortuite des calculs dans la cavité abdominale, du nettoyage des lentilles, de la durée de la chirurgie et de l'estimation du risque associé à l'intervention en présence de facteurs de complication peropératoires.

Résultats : Notre étude a regroupé 60 patients adultes. Les groupes étaient comparables en ce qui a trait aux caractéristiques démographiques, à la symptomatologie, aux comorbidités, aux antécédents de chirurgie abdominale, aux résultats d'examen échographiques préopératoires et aux complications peropératoires. L'incidence globale des perforations de la vésicule a été de 28,3 % (40,0 % dans le groupe traité à l'électrocautère c. 16,7 % dans le groupe traité à la dissection par ultrasons, $p = 0,045$). Des fuites biliaires sont survenues chez 40,0 % des patients du groupe traité à l'électrocautère et chez 16,7 % des patients traités à la dissection par ultrasons ($p = 0,045$). Le temps de nettoyage des lentilles ($p = 0,015$) et la durée de la chirurgie ($p = 0,001$)

ont été plus longs dans le groupe traité à l'électrocautère que dans le groupe traité à la dissection par ultrasons. On n'a noté aucune différence statistique quant à la perte de calculs entre les groupes ($p = 0,62$).

Conclusion : La dissection par ultrasons est sécuritaire et efficace et elle améliore le déroulement opératoire de la cholécystectomie laparoscopique en réduisant l'incidence des perforations de la vésicule.

Laparoscopic cholecystectomy is the “gold standard” for treatment of symptomatic gallstone disease. 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.¹ The incidence of gallbladder perforation during laparoscopic cholecystectomy has been reported to be 20%–40%.^{2,3} During surgery, gallbladder perforation with spillage of bile and loss of stones disrupts the flow of surgery and prolongs its duration. At present, monopolar electrocautery is the main cutting method used for gallbladder dissection from the liver bed. It is associated with local thermal and distant tissue damage, which might cause inadvertent perforation of the gallbladder during gallbladder bed dissection.^{4–6} Ultrasonic dissection generates less thermal injury, produces a smaller zone of tissue damage and more precise dissection, and has been suggested as an alternative to monopolar electrocautery in laparoscopic cholecystectomy.^{7–9} The incidence of gallbladder perforation also has been reported to be low with ultrasonic dissection compared to monopolar electrocautery during laparoscopic cholecystectomy.^{7–11} Ultrasonic dissection of the gallbladder bed during laparoscopic cholecystectomy has the potential to improve the quality of surgery by decreasing the incidence of gallbladder perforation and its intraoperative consequences. The present study was designed and conducted to observe the effect of ultrasonic dissection in laparoscopic cholecystectomy and to determine the incidence of gallbladder perforation and its intraoperative consequences.

METHODS

We conducted a prospective randomized controlled trial between January 2009 and December 2009 involving adult patients with symptomatic gallstone disease who were eligible for laparoscopic cholecystectomy. 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 using the envelope method to either monopolar electrocautery or ultrasonic dissection just before the operation. In the ultrasonic dissection group, dissection of the gallbladder was performed using Harmonic Ace curved shears (Ethicon Endo-Surgery, Johnson & Johnson Co.). The study was conducted after institutional ethics committee approval, and we obtained written informed consent from

each patient before enrolment in this study. 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. Surgeries were performed by 2 experienced surgeons using a uniform technique of video laparoscopic cholecystectomy involving 4 ports, with the surgeon and assistant positioned as in the standard North American approach

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 χ^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

We included 60 adult patients in our study: 30 underwent electrocautery and 30 underwent ultrasonic dissection of the gallbladder from the liver bed, as per random assignment. The electrocautery and ultrasonic dissection groups were comparable with respect to age, sex, BMI, presenting symptoms, comorbidities, previous abdominal surgery, preoperative ultrasonography findings and intraoperative complicating factors (Tables 1 and 2).

Gallbladder perforation occurred in 12 (40.0%) patients in the electrocautery group and 5 (16.7%) patients in the ultrasonic dissection group. Bile leak was noted in all patients who had gallbladder perforation (40.0% in the electrocautery group v. 16.7% in the ultrasonic dissection group), with an overall incidence of 28.3% ($p = 0.045$; Table 3). Stone spillage was noted in 7 patients in the electrocautery group and 2 patients in the ultrasonic dissection group. Telescopic lens cleaning was required in 27 patients in the electrocautery group and 19 patients in the ultrasonic dissection group during surgery. The mean number of times that lens cleaning (extracorporeal and intracorporeal) was required per patient was twice in the electrocautery group and once in the ultrasonic dissection group ($p = 0.004$). The mean duration of surgery in was 34.37 minutes the electrocautery group and 27.20 minutes in the ultrasonic dissection group ($p = 0.001$). Ultrasonic dissection reduced the requirement of lens cleaning and the duration of surgery (Table 3).

Of the 21 patients who experienced complications, 13 (61.9%) sustained gallbladder perforation during the procedure. Analysis revealed an odds ratio of 14.23 for complications, which reflected the risk of perforation. It showed that there was a 14.23 times greater risk of gallbladder rupture in the presence of complications. In the electrocautery group, 9 patients had complicating factors, and all of them

Table 1. Demographic and clinical characteristics and complications among patients randomly assigned to electrocautery or ultrasonic dissection

Characteristic	Group; no.*		p value
	Electrocautery, n = 30	Ultrasonic, n = 30	
Age, mean yr	47.36	45.3	0.55
Sex, male:female	1:1.5	1:2.75	0.27
Body mass index, mean	26.38	27.53	0.08
Presenting symptoms			
Heartburn	13	15	0.60
Pain abdomen	13	20	0.07
Dyspepsia	23	23	> 0.99
History of gallstone pancreatitis	2	1	0.55
Comorbidities	8	3	0.32
Previous abdominal surgeries	2	3	0.64
Intraoperative complications	9	12	0.42

*Unless otherwise indicated.

sustained gallbladder perforation ($p = 0.001$). In the ultrasonic dissection group, 12 patients experienced complications, with gallbladder perforation occurring in 4 patients (33.3%; $p = 0.046$). There was no bile duct injury, bleeding or bile leak from gallbladder fossa noted during surgery or the postoperative period. No patients required conversion to open surgery, and the only postoperative complications that occurred were port site infections in 2 patients.

DISCUSSION

Laparoscopic cholecystectomy is the standard of care for patients with symptomatic gallstone disease.¹⁻⁶ This technique, with all its advantages, has almost replaced open cholecystectomy in those with uncomplicated gallstone disease. During laparoscopic cholecystectomy various methods of cutting and coagulation are used, but at present, monopolar electrocautery is the preferred cutting method for laparoscopic surgery.¹² The use of monopolar electrocautery is often associated with inadvertent tissue injury, as it generates intense collateral heat leading to tissue necrosis and ischemia. Most electrocautery injuries go unrecognized during surgery or present late.¹² But injury such as gallbladder perforation during laparoscopic cholecystectomy may greatly hinder the surgical procedure by

Table 2. Comparison of preoperative ultrasonography findings between the electrocautery and ultrasonic dissection groups

Finding	Group; no.		p value
	Electrocautery, n = 30	Ultrasonic, n = 30	
Distended gallbladder	19	19	> 0.99
Gallbladder wall thickness > 3 mm	7	2	0.07
Pericholecystic lucency	2	2	> 0.99
Single calculus	8	6	0.54
Multiple calculi	13	18	0.20
Sludge	9	6	0.37
Stone size > 1 cm	3	3	> 0.99
Common bile duct diameter > 6 mm	4	6	0.49

Table 3. Comparison of outcomes in the electrocautery and ultrasonic dissection groups

Outcome	Group; no. (%)*		p value
	Electrocautery, n = 30	Ultrasonic, n = 30	
Primary			
Gallbladder perforation	12 (40.0)	5 (16.7)	0.045
Secondary			
Bile leak	12 (40.0)	5 (16.7)	0.045
Stone spillage	7 (23.3)	2 (6.7)	0.62
Lens cleaning, no. of patients	27 (90.0)	19 (63.3)	0.015
Lens cleaning, mean no. of times	2 (6.7)	1 (3.3)	0.004
Duration of surgery, min.	34.37	27.20	0.001

*Unless otherwise indicated.

leading to inevitable spillage of bile and stones into the peritoneal cavity. This may prolong the surgical procedure and have serious consequences.¹³

Unlike monopolar electrocautery, ultrasonic dissection instrumentation denatures protein by means of ultrasonic vibrations at a frequency of 55 500 Hz with a vibratory excursion of 50–100 μm .¹⁴ The vibration transfers mechanical energy to the tissue, resulting in simultaneous cutting and coagulation. The vibrating ultrasonic dissector produces a coagulum of denatured protein and blood clot that occludes adjacent blood vessels and reduces bleeding. Vibration of the dissector scalpel blade does not generate as much heat as monopolar cautery or laser cautery, and the vibration in potential spaces results in cavitations, which may facilitate tissue dissection.¹⁴ No smoke is generated, only microaromized water droplets are produced, and no electric current is detected in the surgical field; therefore, this cutting method is also safe for use in patients with implanted pacemakers.¹⁵ The mist produced by the harmonic scalpel is rapidly absorbed by the peritoneal surface, and it does not require suctioning or releasing the smoke that is produced during monopolar electrocautery dissection.

Gallbladder perforation is reported to be the most frequent complication occurring intraoperatively during laparoscopic cholecystectomy.¹⁶ Perforation occurs in 13%–50% of patients who undergo laparoscopic cholecystectomy, and in 10%–40% of these patients, bile leakage and stone spillage are present.¹⁷ Laceration due to grasper traction and electrocautery dissection is the most common mechanism of gallbladder rupture during laparoscopic cholecystectomy.¹⁰ The overall incidence of gallbladder perforation in our study was 28.3% and differed significantly between the 2 groups (40.0% in the electrocautery group v. 16.7% in the ultrasonic dissection group, $p = 0.045$). There was a 23.3% reduction in the perforation rate with the ultrasonic dissector. Reduction of gallbladder perforation during laparoscopic cholecystectomy using the ultrasonic dissector has also been reported in other studies.^{6,12,18,19} Bile leak was noted in all patients who had gallbladder perforation, but the incidence of stone spillage was 58.3% in the electrocautery group and 40.0% in the ultrasonic dissection group, which was not significant ($p = 0.62$). Janssen and colleagues⁶ reported that the gallbladder perforation with stone spillage was 6 times higher in the electrocautery group than the ultrasonic dissection group. However, even if perforation occurred, stone spillage could still be prevented by quickly occluding the perforated site of the gallbladder with a grasper. The incidence of gallbladder perforation during laparoscopic cholecystectomy has been reported more often in patients with complications, such as acute cholecystitis, fibrotic gallbladder and dense adhesions in the Calot triangle.⁶ Ultrasonic dissection is the technique of choice for gallbladder dissection in patients with complications.⁶ Our study revealed a 14.23 times greater risk of

gallbladder rupture in the presence of complications, and gallbladder perforation occurred in all patients with complications in the electrocautery group and in 33.3% of patients in the ultrasonic dissection group. This observation suggests that the ultrasonic dissector is a better device, especially in patients with complicated gallbladder disease.

In our study, 90.0% of the patients in the electrocautery group required lens cleaning during surgery, whereas only 63.3% of the patients required lens cleaning in the ultrasonic dissection group, and the mean number of times that lens cleaning was required per patient was twice in the electrocautery group and once in the ultrasonic dissection group ($p = 0.004$). The number of lens cleanings is very subjective, but the very need for lens cleaning (extracorporeal and intracorporeal) suggests the degree of difficulty and the duration of the surgical procedure.

Duration of surgery in our study was significantly shorter in the ultrasonic dissection group than the electrocautery group (27.20 min v. 34.37 min, $p = 0.001$). The use of the ultrasonic dissector in laparoscopic cholecystectomy provides a superior alternative to monopolar electrocautery, as it is associated with shorter duration of surgery.^{12,18,20} Shorter mean duration of surgery in the ultrasonic dissection group may be attributed to several factors. The Harmonic Ace is a multifunctional instrument; it replaces 4 instruments routinely used in laparoscopic cholecystectomy: namely, the dissector, clip applier, scissors and electrocautery hook or spatula. Finally, the activation of the ultrasonic dissector does not produce smoke and allows the surgeon to work in a clear operative field throughout the operation.

Cost is a concern with the routine use of a Harmonic scalpel in laparoscopic cholecystectomy. Ours is a fully government-funded hospital, and the cost of all surgical procedures is subsidized, so there is no difference in the cost for use of Harmonic scalpel and monopolar cautery dissection. Otherwise, Harmonic scalpel use will be more costly.

CONCLUSION

Ultrasonic dissection is safe and effective, and it improves the operative course of laparoscopic cholecystectomy. It provides a superior alternative to the currently used high-frequency monopolar technology in terms of a lower incidence of gallbladder perforation, especially in patients with complicated gallbladder disease, and a shorter duration of surgery. This being a small study, there is a greater chance of type-II statistical error in the results, so our results must be confirmed by conducting a larger, multicentric randomized trial.

Competing interests: None declared.

Contributors: R. Singh and L. Kaman designed the study. V. Mahabaleswar, L. Kaman and J. Iqbal acquired the data and wrote the article. All authors analyzed the data, reviewed the article and approved its publication.

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