

SAFETY OF ULTRASONIC DISSECTION VERSUS CONVENTIONAL ELECTROCAUTERY DISSECTION DURING LAPROSCOPIC CHOLECYSTECTOMY IN TERMS OF GALL BLADDER PERFORATION

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ABSTRACT

Objective: To compare the safety of ultrasonic and electrocautery method of dissection in terms of gall bladder perforation.

Methodology: This randomized controlled trial included 128 patients, which were divided into two groups, ultrasonic dissection (A) and electrocautery dissection (B). GB perforation (if any) was noted intraoperatively, and all the data was recorded on a structured questionnaire. Data was analyzed using SPSS.

Results: The incidence of GB perforation was significantly lower in ultrasonic dissection (10.9%) than electrocautery methods of dissection (29.7%), hence the safety of ultrasonic dissection in terms of gall bladder perforation, was significantly higher than electrocautery dissection (89.1% vs. 70.3% p-value= 0.007).

Conclusion: ultrasonic dissection is safer modality of dissection in terms of gall bladder perforation and its use should be encouraged as routine method of dissection during LC.

Key Words: Symptomatic gall stones, Gall bladder perforation, Ultrasonic dissection, Electrocautery dissection, Laproscopic cholecystectomy.

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INTRODUCTION

Gall stones are the most common of biliary diseases throughout the world, accounting for about 12 % of population in United States and 18 % in Europe¹. Majority of people harboring gall stones are asymptomatic but there are chances of developing complications (1-2%)².

Laposcopic cholecystectomy (LC) was first performed in 1988 in united states³. Laproscopic cholecystectomy (LC), is now

considered the gold standard for symptomatic gall stone disease^{1,3-5}. LC though less invasive is still commonly complicated by the Gall Bladder perforation and spillage of stones into peritoneal cavity^{4,6}. These complications occur during dissection of the gall bladder off its bed, grasping and retrieval of Gall Bladder^{4,6}.

The incidence of GB perforation ranges from 6 to 40% and about 13 to 32% of patients develop late complications due to spillage of infected bile and spilled gall stones⁷. These complications include intraabdominal and subcutaneous abscesses, fistulas, liver abscess and intestinal obstruction etc⁷. Also Gall Bladder perforation during laproscopic cholecystectomy causes an undue prolongation of the operation^{8,9}.

Gall bladder dissection off its bed, an important step in LC with regards to perforation, is routinely performed with conventional electrocautery¹⁰. LC being a commonly performed operation for gall stone disease is undergoing rapid improvement with the advent of newer technologies^{11,12}. Furthermore the association of

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conventional electrocautery with some potential hazards like inadvertent and unrecognized intra abdominal and biliary tract injuries, and electrical arcing injuries has led to the popularization of ultrasonic method of dissection^{6,12,13}.

The primary use of ultrasonically activated shears in LC is for division of cystic artery and dissection of GB off its bed¹². Ultrasonic dissection is safe, effective and efficient modality of dissection^{6,12}. Use of ultrasonic dissection is associated with less chance of bile spillage (GB perforation)^{12,14}. Ultrasonically activated shears work by three synergistic actions i.e. cavitation, coaptation/ coagulation and cutting¹⁰. Cavitation effect is important for dissection, as it causes separation of tissue planes by cellular destruction and is because of low pressure at the blade^{10,13}. A review article showed GB perforation in 11% and 32% patients undergoing LC using ultrasonic and electrocautery dissection respectively⁵. Another study reported GB perforation rate of 16% and 36% using ultrasonic and electrocautery method of dissection respectively¹¹. Despite the advantages the use of ultrasonic shears in LC as method of dissection is still under debate such as lack of sufficient clinical trials in its support, fear of use, and scarce regional data^{6,11}. Mahabaleshwar and colleagues reported that the incidence of Gall Bladder perforation is 40% in Electrocautery dissection whereas 16.7% in Ultrasonic dissection⁸.

Symptomatic gall stone disease is not uncommon in our population and the best modality of treatment for these patients is LC. GB perforation during laproscopic cholecystectomy can result in serious post operative complications and may increase hospital stay and add financial burden to the patient. The current study was designed to compare the safety of ultrasonic dissection with electrocautery dissection in terms of GB perforation, so as to know the safer method of dissection, which will be used as routine method of dissection during LC and also to contribute to the local literature regarding these two methods of dissection in LC.

METHODOLOGY

This randomized trial was conducted on patients with symptomatic gall stone disease at surgical A unit Lady Reading Hospital Peshawar, Pakistan, from November 2011 to May 2012. The study included all the patients above 18 years, of either gender and with symptomatic gall stones. Exclusion criteria excluded all the patients with CBD stones (USS detected), acute or chronic cholecystitis (diagnosed on history, clinical examination and USS), emphyema gall bladder, hydrophic gall bladder, previous abdominal surgery

and pregnant women.

Approval of the study was obtained from the institutional medical ethical committee. All patients with symptomatic gallstones were admitted in surgical A unit through OPD. All cases had thorough history (pain right hypochondrium), physical examination (tender right hypochondrium in case of acute biliary colic without acute cholecystitis) investigations such as US abdomen (calculi in GB), and also all base line blood tests such as full blood count, serum urea and creatinine, serum electrolytes, LFTS and hepatitis B and C screening were done.

Consecutive Non Probability Sampling technique was used. A written informed consent explaining the risks and benefits of the two procedures was obtained from the patients fulfilling the selection criteria. Total numbers of patients (cases) were 128. Patients were randomly allocated into two groups A & B using lottery method before the operation. In group A the method of dissection was by ultrasonic device (Harmonic) whereas in group B conventional monopolar electrocautery method of dissection was used for dissection of the gall bladder from its bed. The sample size was calculated by WHO sample size calculator using 89% safety of ultrasonic method and 68% safety of electrocautery method⁷, 95 % confidence level and 90% power of testing.

All the patients were operated under general anesthesia by a single consultant surgeon having minimum of 5 years of experience and well versed with LC and the two modalities of dissection. The number of cases operated per day varied from one to four, but never exceeded 4 cases. There was standard working hours from 8 am to 1 pm, during which all the operations were performed. No operation was performed beyond 1pm to minimize the exhaustion factor of surgeon. All the operations were performed laproscopically through standard video laproscopic four port technique, pneumoperitonuem was created through open technique and pressure kept at 12mmHg. In group A ultrasonic device (harmonic) was used for GB dissection from its bed, while in group B electrocautery hook was used for GB dissection off its bed. Intraoperatively bile leak or stone spillage was looked for suggesting GB perforation to determine intervention safety. After GB delivery, it was further examined with naked eye to exclude perforation.

The primary outcome was safety of ultrasonic dissection as compared to electrocautery dissection. The safety was determined in terms of GB perforation. The intervention was considered safe when there was no GB perforation during

dissection off its bed, in LC. GB perforation was defined as any visible rent (any size) in GB wall with bile leak (irrespective of amount) and/or spillage of gall stone into the peritoneal cavity, observed intra-operatively.

Exclusion criteria were strictly followed to control confounders and bias in the study. The demographic and clinical (intraoperative) data of the all the patients such as name, age, gender, GB perforation and safety of intervention was recorded in a proforma.

The data was analyzed with SPSS version 15. Frequency and percentages were computed for categorical variables such as gender and safety while numerical variables such as age was presented with Mean \pm SD. Chi square test was used to compare the safety between the two groups. Also safety was stratified among the age and gender to see the effect modifiers. P 0.05 was considered significant. All results were presented in the form of Tables.

RESULTS

We included total of 128 patients in our study, assigned into two groups, Group A underwent Electrocautery dissection & Group B underwent Ultrasonic dissection, each having 64 patients. Of the 128 patients 89 were female and 39 were male shown in Table 1.

The age distribution among the two groups is shown in the Table 2. The mean age was 37.28 \pm 14.4 (SD) in ultrasonic group (A) and 35.98 \pm 13.29 (SD) in electrocautery group (B). The age and gender had no statistically significant effect on the safety of the two methods of dissection in terms of Gall Bladder perforation, which signifies that the age and gender do not act as effect modifier. Table 3 & 4.

The primary outcome of our study was to look for Gall Bladder perforation during dissection of the Gall Bladder from the liver bed. In our study the overall incidence of gall bladder perforation was 20.3%, 29.7% in electrocautery group and 10.9% in ultrasonic group, which is

Table 1: Gender distribution among the two groups

		Method of dissection(intervention)	
		Ultrasonic(A)	Electrocautery(B)
Gender	Male	19(39)	20(39)
		29.7%	31.2%
	Female	45(89)	44(89)
		70.3%	68.8%
Total		64(128)	64(128)
		100.0%	100.0%

Table 2: Age distribution among the two groups

		Method of dissection(intervention)	
		Ultrasonic(A)	Electrocautery(B)
Age (in years)	18-25	17(n=33)	16(n=33)
		26.6%	25.0%
	26-40	28(n=61)	33(n=61)
		43.8%	51.6%
	41-55	6(n=11)	5(n=11)
		9.4%	7.8%
	56-65	13(n=23)	10(n=23)
		20.3%	15.6%
Total		64(n=128)	64(n=128)
		100.0%	100.0%

Table 3: Stratification of the safety of intervention among the age groups

		Intervention Safe	
		Yes	No
Age (in years)	18-25	27(33)	6(33)
		81.8%	18.2%
	26-40	50(61)	11(61)
		82.0%	18.0%
	41- 55	9(11)	2(11)
		81.8%	18.2%
56-65	16(23)	7(23)	
	69.6%	30.4%	
Total		102(128)	26(128)
		79.7%	20.3%

Table 4: Stratification of the safety of intervention among the gender

		Intervention Safe	
		Yes	No
Gender	Male	30(39)	9(39)
		76.9%	23.1%
	Female	72(89)	17(89)
		80.9%	19.1%
Total		102(128)	26(128)
		79.7%	20.3%

Table 5: Frequency of gall bladder perforation among the two groups

		Method of dissection (intervention)		p-value
		Ultrasonic(A)	Electrocautery(B)	
Gall bladder Perforation	Yes	7(26)	19(26)	0.007
		10.9%	29.7%	
	No	57(102)	45(102)	
		89.1%	70.3%	
Total		64(128)	64(128)	
		100.0%	100.0%	

Table 6: Comparison of the safety of the two methods of dissection

		Method of dissection (intervention)		p-value
		Ultrasonic(A)	Electrocautery(B)	
Intervention Safe	Yes	57(102)	45(102)	0.007
		89.1%	70.3%	
	No	7(26)	19(26)	
		10.9%	29.7%	
Total		64(128)	64(128)	
		100.0%	100.0%	

highly statistically significant ($p=0.007$). From the incidence of gall bladder perforation in the two groups, safety of the two methods of dissection was calculated, which showed that the safety of ultrasonic dissection in terms of gall bladder perforation was significantly higher than electrocautery method of dissection, i.e. 89.1% vs. 70.3 % ($p=0.007$) {Table 5 & 6}.

DISCUSSION

Gallbladder perforation is reported to be the most frequent complication occurring intra-operatively during laparoscopic cholecystectomy⁸. Various Studies have reported that ultrasonic dissection is effective and safe modality, for the dissection of Gall Bladder from the liver and there is less chances of accidental GB perforation and hence bile spillage^{14,15}. The reason being that there is minimal lateral energy spread and lower distant tissue damage than with conventional Electrocautery¹⁵. In our study, we found that the incidence of GB perforation was significantly lower in ultrasonic group than in electrocautery group (10.9% vs. 29.7% $p=0.007$). Hence the safety of ultrasonically activated shears (ultrasonic dissection) in terms of GB perforation, while dissecting GB of its bed, was significantly higher than conventional electrocautery dissection (89.1% vs. 70.3). These findings are consistent with majority of the studies conducted so far regarding this issue. Elnakeeb and colleagues, reported that GB perforation was higher in electrocautery group than ultrasonic group (18.3% vs. 10% $p=0.03$)¹⁵. Besa and colleagues reported significantly lower rate of GB perforation in ultrasonic group than electrocautery group (10% vs 30 $p=.002$)¹⁶. A review article showed statistically significant results, with incidence of GB perforation to be 11 and 32% in ultrasonic and electrocautery group respectively, making the safety Ultrasonic dissection to be 89% and that of Electrocautery dissection 68% safe¹⁰. An Indian study reported the incidence of GB perforation to be significantly higher in electrocautery dissection (40 %) than Ultrasonic dissection. From the results of the above mentioned studies, we can say that our study yielded results that are comparable to the results of these international studies, which showed that ultrasonic dissection is more safer and effective than electrocautery dissection in terms of gall bladder perforation.

There is one study which showed comparable results, regarding incidence of GB perforation in the two modalities of dissection , 10% in Ultrasonic group and 13% in Electrocautery group, $p=0.46$. Although its results are statically not significant but still ultrasonic (harmonic) group has lower incidence of GB

perforation than electrocautery group¹². There are very few local studies on this problem, one study that was conducted in CMH Rawalpindi, had reported surprisingly very low incidence of GB perforation about 2.72%, with ultrasonic dissection¹⁹. This is much lower incidence of GB perforation using Ultrasonic dissection than the incidence of GB perforation in our study. In addition they have not compared the two methods of dissection but only studied the Ultrasonic method of dissection. However majority of the studies reported that Ultrasonic dissection has much lower incidence of GB perforation than conventional Electrocautery dissection^{12,16, 20, 21}.

In our study we have compared the safety of the two modalities of dissection only in terms of GB perforation, which clearly showed that ultrasonic dissection is a safer modality than conventional electrocautery. But there is some other factors which also significantly correlate with GB perforation, such as surgeon skill and experience, acute cholecystitis and hydropic gall bladder^{17,18}. But in our study we have excluded all these confounding factors and all the surgery were performed by a single surgeon having 5 years experience and well versed with both modalities of dissection in laproscopic cholecystectomy.

Apart from the primary outcome, in the results we have stratified safety among the age and gender, to see effect modifiers. We found no statistically significant effect of age and gender on GB perforation and so as on safety of the intervention. Kamal et al have shown similar results with no statistical significant effect of age and gender on GB perforation²². One recent study showed that male gender have significant effect on GB perforation irrespective of the method of dissection ($p=0.017$) but no effect of age on GB perforation²³. Another study also showed significant effect of male gender and age on iatrogenic GB perforation²⁴. Although the data regarding the effect of age and gender on GB perforation is conflicting but still more studies have reported increased incidence of iatrogenic GB perforation in male gender^{23,24}. Our study also shows increased incidence of GB perforation in male (23%) than in female (19%) $p=0.607$, though statistically not significant. One Pakistani study reported that male gender is not a significant risk factor for gall bladder perforation²⁵.

CONCLUSION

Ultrasonic dissection (Harmonic) is safe and effective modality of dissection and its use in laproscopic cholecystectomy should be encouraged specially in our part of the world where its availability is still limited despite its potential

advantages over electrocautery. But due to small number of patients, this study does not advocate that the use of conventional electrocautery should be abandoned in laproscopic cholecystectomy, rather it provides data in favor of the potential benefit of ultrasonic dissection.

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CONTRIBUTORS

NK conceived the idea, planned and wrote the manuscript of the study. MA & ZA did the data collection and helped in the write up of the study. All the authors contributed significantly to the research that resulted in the submitted manuscript.