COMPARISON BETWEEN HARMONIC ACE VERSUS CONVENTIONAL MONOPOLAR DIATHERMY IN LAPAROSCOPIC CHOLECYSTECTOMY IN TERMS OF GALLBLADDER PERFORATION

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ABSTRACT

Objective: To compare Harmonic scalpel with conventional Monopolar Electrocautery hook in terms of gallbladder perforation rate in Laparoscopic Cholecystectomy.

Study design: Randomized controlled trial.

Place and Duration of Study: Department of Surgery Combined Military Hospital (CMH) Rawalpindi, Pakistan, from Feb 2013 to Oct 2013.

Methodology: Consecutive 280 patients of cholelithiasis, fulfilling inclusion criteria, were included in this study after taking written informed consent and approval from hospital ethical committee. They were divided into two equal groups of 140 patients i.e. "Group A" who underwent LC by Harmonic scalpel and "Group B" in which conventional Monopolar electrocautery was used for dissection of gallbladder.

Results: An increased incidence of 21.42% gallbladder perforation (GBP) in laparoscopic cholecystectomy (LC), was observed in "Group B" using Monopolar electrocautery for dissection as compared to 8.57% in "Group A" using Harmonic scalpel (p=0.002). Male gender was significantly associated with increased GBP i.e. 33.33% as compared to females 12.29% irrespective of the instrument used.

Conclusion: Harmonic scalpel is better alternative to traditional Monopolar Electrocautery in LC due to decrease incidence of GBP.

Keywords: Bile duct injuries, Conventional monopolar electrocautery, Gallstones, Harmonic scalpel, Laparoscopic cholecystectomy.

INTRODUCTION

Gallstones having a prevalence of 4% in Asian population[1] is the most common biliary disease being encountered in surgical practice. Surgery should be undertaken in patients with symptomatic gallstones[2,3] with the aim to remove gallbladder that is responsible for both formation and complications associated with them. With the advent of laparoscopic cholecystectomy (LC) and continuous improvement in its technique there is evidence of low threshold for operative management of gallstones by each passing day[4-6].

Two methods of dissection being used in LC include Conventional Monopolar Electrocautery and Harmonic scalpel. Harmonic scalpel uses ultrasound energy for dissection, cutting and coagulation at the same time, which results in low temperature, decreased smoke/ lateral tissue damage[7-11] and enables it to replace four instruments that were used in traditional LC12, leading to less complications by avoiding frequent instrumentation and iatrogenic gallbladder perforations (GBP) during dissection[13-15]. Rationale of this study was comparison of Harmonic scalpel with

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Electrocautery in LC, to determine the preferred method of dissection in terms of iatrogenic GBP.

MATERIAL AND METHODS

This randomized controlled trial was conducted after approval of hospital ethical committee, at the Department of General Surgery, Combined Military Hospital Rawalpindi Pakistan, from Feb 2013 to Oct 2013. 280 consecutive patients including both male and female ranging from 18-80 years with symptomatic gallstones i.e. presenting with biliary colic, dyspepsia, post-prandial distress, bloating, fat intolerance along with ultrasound findings of cholelithiasis were included in the study using non-probability consecutive sampling. Exclusion criteria included patients with USG findings of acute cholecystitis, empyema gallbladder, cholangitis, gallstone pancreatitis, choledocholithiasis, patients having coexisting gall bladder malignancy, patients having previous history of upper midline laparotomy and patients with positive Hepatitis B and C serology. WHO calculator was used to calculate sample size with level of significance 5%, power of test 80% and anticipated population proportion percentages 18.6% vs 7.1%[1]. Patients were randomized into two groups "A" and "B" using lottery method which constituted 140 patients in each group (n=140). No subjects were dropped out or lost at any point in the study.

All those patients who met the inclusion criteria were planned for elective laparoscopic cholecystectomy after complete history, physical examination abdominal ultrasonography and baseline investigations (Blood complete picture, Liver function tests, Renal functions tests, Hepatitis B, C screening by ELISA, Chest radiograph and Electrocardiogram). Patients were admitted one day before the surgery when their written informed consent was taken. All the patients received a preoperative prophylactic cefuroxime intravenous injection, which was continued till 18 hours post-surgery. All surgeries were performed under general anesthesia by the same surgical team, which included consultant laparoscopic surgeon who had performed more than 200 laparoscopic cholecystectomies. Patients were discharged from hospital depending upon the individual recovery.

Data was entered and analyzed using SPSS version 20.0. Qualitative variables like Gender and Gallbladder perforations were analyzed by using Frequencies and Percentages whereas, quantitative variables like Age, Mean and Standard Deviations were calculated by using descriptive statistics. "Chi-Square" test was used to compare both instruments in terms of gallbladder perforation rate and a "*p*-value" of < 0.05 was considered significant.

RESULTS

The study population comprised of two hundred and eighty patients fulfilling the inclusion criteria were divided into two groups "A" and "B" that underwent LC by using harmonic scalpel and electro cautery respectively. In Group A mean age was 43.72 years (SD 13.47) while in Group B mean age was 46.56 years (SD 12.62).

In group A, 16.4% patients (n=23) were male while 83.6% (n=117) were female with male to female ratio of 1:5.08.

In group B, 9.3% patients (n=13) were male while 90.7% (n=127) were female with male to female ratio of 1:9.7.

In group A, number of gall bladder perforations were 8.57% (n=12) as compared to 21.42% (n=30) in group B. The overall result in terms of gallbladder perforation rates between two groups i.e. Harmonic versus Monopolar diathermy using Chi square test was highly significant with a *p*-value of 0.002 (less than 0.05). (Table-1).

It was also observed that male gender was associated with increased risk of GBP ie 33.33% in males (12 GBP out of 36 patients) versus 12.29% in females (30 GBP out of 244 patients). The difference was statistically significant with *p*-value of 0.002. (Table-2).

DISCUSSION

Total number of iatrogenic gallbladder perforations (GBP) noted in our study was 15%, which is comparable to the study conducted by Kandil, but it is much smaller then other studies in which GBP ranges from 21.6%[15] to even 36%[16]. GBP by Monopolar Electrocautery dissection constitutes 21.42% (30 patients) out of total 15% GBP in our study which is quite less than 49.5% reported in study conducted by Janssen et al[17]. The reason for this gross difference in GBP is probably because of the patient selection criteria. Our study included elective cases of symptomatic gallstones in which there are less chances of complicating factors whereas the study mentioned included complicated cases. Secondly in our study all the LC were performed by senior consultant surgeon only whereas in the study mentioned LC was performed by both consultant and trainee surgeons making gallbladder more susceptible to perforation during dissection.

Comparison of the two instruments used for dissection in our study showed that 8.57% patients sustained GBP with Harmonic Ace while 21.42% patients sustained GBP when Monopolar Electrocautery was used. These results are comparable to the studies performed by Bessa[15] (10% vs 30%, respectively) and Kandil[1] (7.1% vs 18.6%, respectively). Results of our study are comparable to meta-analysis of five studies published by Sasi[18], in which 30 patients sustained GBP out of 256 in Harmonic group making ultrasound dissection 89% safe, where as out of 263 in Monopolar electrocautery group 86 cases of GBP, with a safety of 68% was reported. Confounding factors present in these studies like active inflammation of gallbladder, complicated cases including empyema gallbladder/ Mirrizi's syndrome, perioperative abnormal anatomy/ dense fibrotic adhesions and variable expertise of the surgical team were all excluded in our study.

In comparison to few local studies, study conducted by Nadim[19] included a total of 128 patients out of which overall, harmonic and electrocautery GBP rates were found to be 20.3%, 10.9% and 29.7% respectively that is comparable

Table-1: Group wise distribution of gallbladder perforation according to the Gender.

Groups	Perforations	Male	Female	Total	*p*-value
Group A	Yes	6	6	12	0.001
	No	10	118	128	
	Total	16	124	140	
Group B	Yes	6	24	30	0.231
	No	14	96	110	
	Total	20	120	140	
Over all in both groups	Yes	12	30	42	0.002
	No	24	214	238	
	Total	36	244	280	

Table-2: Complications among the two study groups.

Groups	Complications	Frequency	Percentage
Monopolar Diathermy	Cystic artery Bleeding	2	0.8
	Biloma (one due to slippage of clip from cystic duct and one from liver bed)	2	0.8
	Gut injury	1	0.4
Harmonic scalpel	Common hepatic duct injury	1	0.4
	Bleeding from cystic artery (which was controlled laparoscopically).	1	0.4
	Port site Hernia	1	0.4

to our results i.e. 15%, 8.57% and 21.42% respectively. Another study comprising of 110 patients revealed similar results in comparison of iatrogenic GBP by Harmonic and Electrocautery. Total of 17 patients (20%) underwent GBP during laparoscopic cholecystectomy out of which 5 (9.1%) were Harmonic induced while 17 cases (30.9%) were attributable to Electrocautery[20]. Sample size of both above-mentioned studies was less then our study, but shared common sample selection criteria and exclusion of similar confounding factors.

Efficacy of harmonic dissection has been described in another local study carried out in military settings, including 110 patients[21]. GBP occurred only in 3 patients (2.72%), which is amazingly low as compared to our study and most of the national and international studies. This may be attributable to the careful selection of study group; better operating facilities or expertise of surgical team but the results cannot be generalized because no comparison was made between harmonic and electrocautery dissection.

However, there is one international study carried out by Redwan[22] in which no statistically significant difference in GBP between the harmonic versus electrocautery was observed (p=0.46), although the incidence of GBP was lesser with harmonic dissection in comparison to electrocautery group.

Besides primary result of this study, risk analysis of gender on GBP was also calculated. Out of 36 males in total, 12(33.33%) sustained iatrogenic GBP in our study, no matter which method of dissection was used, which is much more as compared to 12.29% (30 out of 244 cases) in female patients (p=0.002). This statistically significant effect of gender on GBP has been described in many international studies[23-25]. Results of these studies show similar effect of gender on iatrogenic GBP as evident in our study, however sample size used in these studies are comparatively much larger. Reason behind the phenomenon of higher GBP in males is perhaps the increased tolerability, leading to delayed presentation responsible for comparatively increased adhesions and fibrosis in Calot's triangle as well as between gallbladder and liver bed predisposing iatrogenic GBP during dissection.

Results of our study cannot be generalized to whole population as our study group contained either entitled patients having military backgrounds or non-entitled patients who belongs to the high and middle socioeconomic class.

Selection of study group was narrowed down to include elective cases of symptomatic cholelithiasis only, in which anatomy and dissection of calots triangle is relatively easier with less chances of per operative complications as compared to the complicated cases.

In comparison of both instruments, only one aspect of complication was assessed i.e. gallbladder perforation, which does not, makes an instrument completely safe or superior over the other nor determines its overall efficacy.

It was not possible to blind surgeons and eliminate bias completely as operating team was in picture of instrument being used on the patient.

CONCLUSION

Ultrasonic dissection of gallbladder with Harmonic scalpel reduces the risks of gallbladder perforation and bile spillage, thereby not only keeps the operative field clean but also helps the less experienced surgeon in identification of correct dissection plane and less frequent change of instruments.

RECOMMENDATIONS

Harmonic scalpel is a better alternative to electrocautery with less gallbladder perforations and should be routinely used in laparoscopic cholecystectomy.

Main drawback of presently available ultrasonic devices is their cost, which may outweigh the potential benefits and free availability of this technology especially in third

world countries; further studies are required to determine their cost-benefit analysis.

Existing classification of biliary injuries is inadequate and does not include the associated vascular injuries, an explicit and comprehensive classification of biliary injuries need to formulated in order to educate the upcoming surgeons regarding different possibilities of risks involved in Laparoscopic cholecystectomy.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

REFERENCES

1. Kandil T, El Nakeeb A, El 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.
2. Sandler RS, Maule WF, Baltus ME. Factors associated with postoperative complications in diabetes after biliary tract surgery. Gastroenterology 1986; 91: 157-162.
3. Ransohoff DF, Miller GL, Forsythe SB, Hermann RE. Outcome of acute cholecystitis in patients with diabetes mellitus. Ann Intern Med 1987; 106: 829-832.
4. Legoretta AP, SilberJH, Constantino GN, Kobylinski RW, Zata SL. Increased cholecystectomy rate after the introduction of laparoscopic cholecystectomy. JAMA 1993; 270: 1429-32.
5. C M Lam, F E Murray, A Cuschieri. Increased cholecystectomy rate after the introduction of laparoscopic cholecystectomy in Scotland. Gut. 1996; 38(2): 282-284.
6. Schwesinger WH, Diehl AK. Changing indications for laparoscopic cholecystectomy. Stones without symptoms and symptoms without stones. SurgClin North Am. 1996; 76(3): 493-504.
7. Sietses C, Eijsbouts QAJ, von Blomberg BME, Cuesta MA: Ultrasonic energy vsmonopolarelectrosurgery in laparoscopic Cholecystectomy: influence on the postoperative systemic immune response. SurgEndosc 2001; 15: 69-71.
8. Antonutti R, Fontes-Dislaire I, Rumeau JL. Experimental study of monopolar electrical and ultrasonic dissection. Ann Chir 2001; 126: 330.
9. Carlander J, Johansson K, Lindstrom S .Comparison of experimental nerve injury caused by ultrasonically activated scalpel and electrosurgery. Br J Surg 2005; 92: 772.
10. Barrett WL, Garber SM.Surgical smoke a review of the literature. SurgEndosc 2003; 17: 979.
11. McDonald R, Biswas P. A methodology to establish the morphology of ambient aerosols. J Air Waste Mgmt 2004; 54: 1069.
12. Tebala GD. Three port laparoscopic cholecystectomy by harmonic dissection without cystic duct and artery clipping. Am J Surg 2006; 191: 718–20.
13. MinutoloV, GaglianoG, RinzivilloC, LiDestriG, CarnazzaM, Minutolo O, et al: Usefullness of the ultrasonically activated scalpel in laparoscopic cholecystectomy: our experience and review of literature. 2008; 29(5): 242-5.
14. Altaf K, Huang W, Javed MA, Mukherjee R, Mai G, Hu W, et al, A meta-analysis of randomized clinical trials that compared ultrasonic energy and monopolar electrosurgical energy in laparoscopic cholecystectomy. J Laparoendosc AdvSurg Tech A 2012;22(8): 768-77.
15. Bessa SS, Al-Fayoumi TA, Katri KM, Awad AT. Clipless laparoscopic cholecystectomy by ultrasonic dissection. J Laparoendosc AdvSurg Tech A 2008; 18: 593-8.
16. Ioannis T; Nikolaos N; Nikolaos S; Maria C;IoannaK;Thomas C. Complications of Laparoscopic Cholecystectomy: Our Experience in a District General HospitalSurgical Laparoscopy, Endosc& Percutaneous Tech: 2009; 19: 449-458.
17. Janssen I. M. C, Swank D. J, Boonstra O, Knipscheer B. C, Klinkenbijl J. H. G, van Goor H. Randomized clinical trial of ultrasonic versus electrocautery dissection of the gallbladder in laparoscopic cholecystectomy. B J S2003; 90(7): 799 – 803.
18. Sasi W. Dissection by ultrasonic energy versus monopolar electrosurgical energy in laparoscopic cholecystectomy. JSLS. 2010; 14: 23–34.
19. Khan N, Ahmad M, Ahmad Z, Khan A, Sadiq M. Safety of ultrasonic dissection versus conventional electrocautery dissection during laproscopic cholecystectomy in terms of gall bladder perforation. J Postgrad Med Inst 2013; 27(2): 157-63.
20. Ahmed N, Mian MA, Zaidi SH, Inam S, Rehmani JA. Association of iatrogenic gall bladder perforation in laparoscopic cholecystectomy with harmonic scalpel and electrocautery. Pak Armed Forces Med J. 2013; 63-1.
21. Zaidi AH, Haleem A, Rana S. Use of harmonic scalpel in laparoscopic cholecystectomy. Pak Armed Forces Med J 2011; 61: 20-4.
22. Redwan AA. Single-working instrument, double trocar, clipless cholecystectomy using harmonic scalpel: a feasible, safe, and less invasive technique. J Laparoendosc AdvSurg Tech A 2010; 20(7): 59- 603.
23. Hui TT, Giurgiu DI, Margulies DR, Takagi S, Iida A, Phillips EH.Iatrogenic gallbladder perforation during laparoscopic cholecystectomy: etiology and sequelae. Am Surg. 1999; 65(10): 944- 8.
24. Suh SW, Park JM, Lee SE, Choi YS. Accidental gallbladder perforation during laparoscopic cholecystectomy: does it have an effect on the clinical outcomes? J Laparoendosc AdvSurg Tech A 2012; 22: 40-5.
25. Giger UF, Michel JM, Optiz I, ThInderbitzin D, Kocher T, KrahenbuhlL.Risk factors for perioperative complications in patients undergoing laparoscopic cholecystectomy: analysis of 22,953 consecutive cases from the Swiss Association of Laparoscopic and Thoracoscopic Surgery database. J Am Coll Surg.2006; 203(5): 723-8.