Adil Shaker Al Tamimi/J. Pharm. Sci. & Res. Vol. 11(1), 2019, 159-162

ISSN:0975-1459
Journal of Pharmaceutical Sciences and Research
www.jpsr.pharmainfo.in

An Additional Step in the Technique of Laparoscopic Cholecystectomy can Minimize the Incidence of Major Bile Duct Injury

Adil Shaker Al Tamimi
Department of Surgery, College of Medicine, University of Al-Qadisiyah, Iraq.

Abstract

The safety of laparoscopic cholecystectomy sometimes compromised by the rare complication of major bile duct injury, with a devastating sequel of higher mortality and morbidity. Many factors can lead to the occasional insult of visual misinterpretation of the ductal anatomy. From October 2005 to June 2016, 2240 patients were subjected to laparoscopic cholecystectomy. In 985 patients a step of fundal and infundibular traction release before attempting any clip application, was added to the technique , its role in minimizing the incidence of major bile duct injury was assessed, and compared to 1255 patients in whom the new step was not adopted. The overall conversion rate to open surgery was 5.1%. No single major bile duct injury was documented in the study group as compared to 8 patients in the control group. The visual documentation of tenting in the common bile duct from lateral gall bladder traction appeared to be protective against bile duct injury. Traction release may realign the traction induced distorted bile duct structure and hence may minimize the risk of bile duct injury.

Key words: Laparoscopic cholecystectomy. Additional step. Biliary injury.

INTRODUCTION

Iatrogenic bile duct injury (BDI) regarded by many as a devastating complication following cholecystectomy which showed a significant rise in the incidence after the introduction of laparoscopic approach , and has been linked to the experience level (learning curve) [1,2], in addition, the rise in the incidence was coupled with increasing severity of the injury[3,4]. Variable incidence of BDI has been documented, ranging from 0.1- 0.9 % in most series [5-7]. The short and long term sequel of BDI is the associated high morbidity and mortality together with poor quality of life and higher cost of the management [8-11] . The long term mortality of major bile duct injury has been estimated as high as 20.8% [12]. The exact etiology and mechanism of common bile duct injury is considered to be complex , many factors interplay with each other to produce the tragedy of bile duct injury, among these factors , the technical faults are the predominant factor , it usually results from a misinterpretation of the biliary anatomy [13,14], when the common bile duct or the right hepatic duct is misidentified as the cystic duct with the subsequent clipping and division with variable degree of ductal loss, also termed by Divid off as a classical injury. Overzealous use of energy in the vicinity of common bile duct with the resulting devascularization and stricture is another source of the catastrophe. [15-17] Several factors have been linked to this sequel , lack of surgeon experience [18], common bile duct tenting [7], However the technical factors are usually intermingled with the patient factors and cannot be separated [19-21]. Among the commonly assessed patient factors are age, gender, anatomical anomalies , the degree and chronicity of inflammation and local complications related to the gall stones, all are also important players. [22,23] The extent of injury to the extrahepatic bile ducts has been assessed and progressively underwent more sophisticated classification in order to include all the varieties of injuries, each one by itself represent a specific architectural form of ductal disruption and needs specific corrective treatment, each has specific design and standards with the respect to the length of the duct lost in relation to the hepatic confluence, the presence of concomitant arterial injury, completeness of the injury and whether the injury is minor or major and the time elapse between the initial insult and the discovery of bile duct injury, each classification has its own disadvantages. Strasberg classification has included all anatomical variations of ductal injury with the disadvantage of exclusion of associated arterial injury[24]. However the European Association for the Study of the Liver (EAES)-classification creates a more sophisticated classification which include all the parameters related to the duct injury [25].

From the time the laparoscopic cholecystectomy gained its popularity on the cost of the original open counterpart carrying with it a synchronized increase in the incidence of biliary injury [17], Hence, experts started to investigate the safest technical steps to minimize the risk of the injury, among many attempts, including the fundal approach and safety zone[26], the critical view of safety(CVS) described by Strasburg gained the worldwide acceptance as the most useful technical approach[24,27], Which is highly recommended by many international societies EAES and EASL guidelines[5,28]. The technical aspects and the benefits of the CVS has been well established in most centers to minimize but not yet abolish the risk.

Our study aimed to assess the role of a possibly helpful final additional step, in minimizing the incidence common bile duct injury.

MATERIALS AND METHODS

During the period from October 2005 to June 2016, a randomized controlled clinical trial was conducted on a total of 2240 patients, complained from symptomatic cholelithiasis were subjected to laparoscopic cholecystectomy in Al Diwaniya teaching hospital . The surgery was conducted through classical 4 port surgery .The principles of the critical view of safety were followed in all patients , the operations were conducted under general anesthesia by authorized specialist surgeon with an acceptable- high level experience in laparoscopic cholecystectomy. Patients were categorized into two groups the first group 1255 patients (ranked as a control group) operated by a surgeon who didn't adopt the new step of concern in the technique. The second group of patients (study group) 985 patients were managed by the author, adopting the principle of CVS and fulfilled in most of the cases. The cystic artery was managed first, clipped and divided usually more distally on or near the gallbladder wall with an additional final step that entails the following: Before any attempt to clip and divide any presumed cystic duct, fundal and infundibular traction is completely or partially released with camera view kept on the dissected duc,t while the hepatoduodenal ligament stretched by applying gentle downward pressure on the duodenum to straighten the common bile duct, if the duct to be clipped (transversely or obliquely placed with traction, i.e. presumed cystic duct) remain in this direction, traction then reapplied and then it is safe to clip the duct usually at the infundibulum-cystic duct junction, or if it attain vertical position, then this duct is still questionable and further assessment and dissection with 360 degree view , and clipping in that cases placed on more distal structure i.e. the infundibulum

itself or if the stump is too wide to adapt the clip it can be divided and closed with running absorbable suture .Data were collected by reviewing the operative notes and questionnaire sheet information from the operating surgeon. Both groups were compared regarding patients demographic characteristics , the presence of sever local inflammation and fibrosis in the Calot triangle , conversion rate, documented visual tenting of the common bile duct, the incidence of minor and major ductal injury. Intraoperative cholangiogram facilities are not available in our center.

Strasburg classification was used to assess the severity of biliary injury and bile leakage owing to its simplicity of application and can cover most of the injury spectrum except concomitant arterial injury which was not apparent in our study[24,29], accordingly bile leakage from the cystic duct stump or accessory ducts were graded as minor (type A), whereas leakage and or strictures of main bile ducts were graded as major (type E). All cases with suspected or documented bile leakage /biliary injury (minor and major) was subjected to post operative MRCP or ERC, including 3 cases(type E) of intra operatively discovered major injury which was repaired immediately by the author team, the other 5 cases (type E) discovered post operatively, 2 patients presented with persistent bile leakage, the other 3 patients presented with abdominal pain and jaundice, who all were referred to the tertiary hepatobiliary center for further biliary reconstruction. Type A injury (significant postoperative bile leakage)10 patients were managed by endoscopic stenting , the other 7 patients , the bile leakage ceases without further intervention. One year post operative follow up of 2232 patients was complete, including clinical assessment, biochemical liver function test and abdominal ultrasound examination at 3, 6 and 12 months interval. Patients with major bile duct injury were followed up with a special program in the hepatobiliary center. All patients participating in the study were informed about the details, risk of the surgery and the planned follow up.

The data were analyzed using the SPSS version 21. The chi square test for categorical variables and approximate Odds ratio for risk estimate.

RESULTS

Patients mean age was 46.5 year (Range 16-77 year) . There were 356 male and 1884 female with male – female ratio 1: 5.3. The overall conversion rate to open surgery 5.1% (115 patients) including cases of identified major bile duct injury injury at the time of surgery, 46 patients (40%) in the study group and 69 patients (60%) in the control group, the results was statically not significant between both groups p value = 0.37. (Table 1).

Table 1: Conversion rate

Conversion	New step				Total	
	adopt		Not adopt			
	No.	%	No.	%	No.	%
Positive	46	4.7	69	5.5	115	5.1
Negative	939	95.3	1186	94.5	2125	94.9
Total	985	100	1255	100	2240	100

The frequency of complicating local factors in the study group was 86 versus 112 in the control group , the results were statistically insignificant. using Pearson Chi- square test . Asymp.Sig.(2-sided) P value = 0.9 (Table 2).

Table 2: The frequency of complicating local factors.

Complicating local factors	new step				Total	
	adopt		not adopt			
	No.	%	No.	%	No.	%
Positive	96	9.7	122	9.7	218	9.7
Negative	889	90.3	1133	90.3	2022	90.3
Total	985	100	1255	100	2240	100

The gender differences in the presence of patient complicating local factors were statistically insignificant. using Pearson Chi- square test . Asymp.Sig. (2-sided) P value = 0.94. (Table 3).

Table 3: Gender differences in relation to the complicating local factors.

Gender	Complicating local factors				Total	
	Positive		Negative			
	No.	%	No.	%	No.	%
Male	35	16	321	15.9	356	16.3
Female	183	84	1701	84.1	1884	83.7
Total	218	100	2022	100	2240	100

Gender differences in cases of major bile duct injury 2 males vs. 6 females. The difference was statistically insignificant. using Pearson Chi- square test . Asymp.Sig.(2-sided) P value = 0.48 (Table 4).

Table 4: Gender differences in cases of major bile duct injury.

Gender	major bile duct injury				Total	
	Positive		Negative			
	No.	%	No.	%	No.	%
Male	2	25	354	15.9	356	16.3
Female	6	75	1878	84.1	1884	83.7
Total	8	100	2232	100	2240	100

The incidence of minor postoperative bile leakage was not significantly different between both groups, (11 patients in the study group Vs 6 in the control group) using Pearson Chi-square test. Asymp.Sig. (2-sided) P value =0.08 (Table 5).

Table 5: the frequency distribution of minor bile leakage in both groups.

Minor post operative bile leakage	new step				Total	
	adopt		Not adopt			
	No.	%	No.	%	No.	%
Positive	11	1.1	6	0.5	17	0.75
Negative	974	98.9	1249	99.5	2223	99.25
Total	985	100	1255	100	2240	100

Table 6. showed that the incidence of major bile duct injury was almost exclusively in the control group (8 cases) as compared to the study group in which no single major ductal injury was documented. The statistical difference was very significant using Pearson Chi- square test . Asymp.Sig.(2-sided) P value = 0.012.

Table 6: the incidence of major bile duct injury in both groups

Major bile duct injury	new step				Total	
	Adopt		not adopt			
	No.	%	No.	%	No.	%
Positive	0	0	8	0.6	8	0.4
Negative	985	100	1247	99.4	2232	99.6
Total	985	100	1255	100	2240	100

The common bile duct tenting was visualized in 41 cases in the study group as compared to 8 cases in the control group , the difference was highly significant, using Fishers Exact test. Exact. Sig.(2-sided) p value < 0.0001 (Table 7).

Table 7: The frequency distribution of visualized tenting of the common bile duct In both groups.

Common bile duct tenting	new step				Total	
	adopt		not adopt			
	No.	%	No.	%	No.	%
positive	41	4.2	8	0.6	49	2.2
negative	944	95.8	1247	99.4	2191	97.8
Total	985	100	1255	100	2240	100

DISCUSSION

In spite of its rare occurrence , injury of the extra hepatic bile duct injury after laparoscopic cholecystectomy remained regrettable event for its associated high mortality ,morbidity and poor quality of life in addition to the litigation problems.[30]

Attempts have been tried to minimize this sequel by negotiating what has been proposed for its causality, among the most preventable causes of the injury is the visual misperception in which the misidentification of the biliary anatomy can occur.[5,19,20, ,31]

Several technical aspects have been suggested to decrease the incidence of this complication , but the most widely accepted technique of defining the Calot triangle structures is the critical view of safety which developed by Strasburg.[24], even so, this view is sometimes is difficult to be obtained in the presence of intense fibrosis or inflammation rendering its fulfillment very difficult to be achieved and further judgment cannot be decided without hesitation, upon which conversion to open surgery remain the only possible safe choice. In addition, Strasburg himself did not deny the possibility of injury during dissection of the Calots in attempt to obtain the CVS specially in cases of sever inflammation , and the possibility of tenting injury in the presence of forceful lateral traction.[27]

The present data revealed that, female was five times more prevalent than males. In contrary to many researches which propose that, male is a risk factor for rate bile duct injury or complications associated with gallstones , no gender differences in relation neither to presence of complicating local factors nor to the incidence of bile duct injury was found in our study.[32]

The conversion rate (4.6% vs. 5.5%) was comparable with that of most published series 5-10% considered by the most as an acceptable rate.[33] Except for cases of bile duct injury discovered during surgery, most of the conversions were due to failure to progress to identify the calots anatomy due to the presence of local complicating factor including intraoperative bleeding.

The presence of patient local factors (acute cholecystitis, sever fibrotic process in the region of the calots scleroatrophic gall bladder, large stone impaction in the Hartman's pouch and anomalous anatomy) that associated with an added technical difficulty was not different in both groups.[34]

No literature was found to estimate the frequency of visual documentation of common bile duct tenting and its possible protective effect that may decrease the frequency of bile duct injury, a finding suggested that traction on the gall bladder might distort the anatomical alignment of the bile ducts. A similar suggestion was made by Olsen.[35]

The documented visual tenting was obviously more in the study group in which we use the added technical step of traction release. Our data revealed that, visually documented tenting of the common bile duct appeared to be protective against bile duct injury by 61%, using approximate Odds ratio= 0.39.

Moreover, this step of traction release does not protect against bile duct injury in cases of disturbed calots anatomy by excessive fibrosis and inflammation for which we obliged to use an alternative approach of subtotal cholecystectomy or division of the gall bladder at the infandibulum with closure of the remnant with running absorbable suture, for instance we have 4.8 % conversion rate for cases of similar scenario.[36-38]

However, application of this step to all cases of laparoscopic cholecystectomy , can redirect the surgeon heuristic processes and visual perception [39], toward new events and anatomical information that may terminate the visual illusion , and not to proceed with the deliberate clip application and division, should any doubt persist that the dissected duct may be a common bile duct i.e. attains vertical alignment.

CONCLUSION

Strict adherence to the steps of safe laparoscopic cholecystectomy, accurate identification and interpretation of the dissected biliary structures, fulfillment of the critical view of safety , the release of fundal and infundibular traction for a moment before clipping and division of any tubular structure and frequent revision of the dissected area, all can minimize the risk of major bile duct injury. However, if all these attempts failed to obtain unquestionable anatomy then, hesitation to convert is a matter of fanaticism.

REFERENCES

1. Shea JA, Berlin JA, Bachwich DR, et al. Indications for outcomes of cholecystectomy: a comparison of the pre and post laparoscopic eras. Ann Surg. 1998; 227: 343-350.
2. Barkun AN, Rezieg M, Mehta SN, et al. Postcholecystectomy biliary leaks in the laparoscopic era: risk factors, presentation, and management. McGill Gallstone Treatment Group. Gastrointest Endosc. 1997;45:277-82.
3. Misawa T, Saito R, Shiba H, et al. Analysis of bile duct injuries (Stewart-Way classification) during laparoscopic cholecystectomy. J Hepatobiliary Pancreat Surg 2006; 13: 427-434.
4. Strasberg M. and Helton W. S., "An analytical review of vasculobiliary injury in laparoscopic and open cholecystectomy," HPB, 2011; 13, 1, 1–14,.
5. Eikerman M, Siegel R, Broeder I, et al. European Association for Endoscopic Surgery. Prevention and treatment of bile duct injuries during laparoscopic cholecystectomy: the clinical practice guidelines of the European Association for Endoscopic Surgery (EAES). Surg Endosc. 2012; 26(11):3003-39.
6. Connor S, Garden OJ. Bile duct injury in the era of laparoscopic cholecystectomy. *Br J Surg.* 2006; 93:158 –168.
7. Al-Kubati, W.R. Bile Duct Injuries Following Laparoscopic Cholecystectomy: A Clinical Study:_Saudi J Gastroenterol. 2010; 16(2):100-104.
8. Flum DR, Cheadle A, Prela C, et al. Bile duct injury during cholecystectomy and survival in Medicare beneficiaries. JAMA 2003; 290:2168–2173.
9. Kaman L, Behera R, Katariya RN. Management of major bile duct injuries after laparoscopic cholecystectomy. Surg Endosc.2004; 18(8):1196-9.
10. Boerma D, Rauws EA, Keulemans YC, et al. Impaired quality of life 5 years after bile duct injury during laparoscopic cholecystectomy: a prospective analysis. *Ann Surg*. 2001; 234:750-757.
11. Carroll BJ, Birth M, Phillips EH. Common bile duct injuries during laparoscopic cholecystectomy that results in litigation. Surg Endosc.1998; 12:310.
12. Halbert C, Altieri MS, Yang J, et al. Long-term outcomes of patients with common bile duct injury following laparoscopic cholecystectomy. Surg Endosc 2016; 30(10):4294-9.
13. Hugh TB. New strategies to prevent laparoscopic bile duct injuries – surgeons can learn from pilots. Surgery 2002; 132:826–35.
14. Shallaly GEl and Cuschieri A. Nature, aetiology and outcome of bile duct injuries after laparoscopic cholecystectomy. HPB 2000, 2(1): 3- 12.
15. Callery MP. Avoiding biliary injury during laparoscopic cholecystectomy: technical considerations. Surg Endosc 2006; 20: 1654-1658
16. Abbasoğlu O, Tekant Y, Alper A et al .Prevention and acute management of biliary injuries during laparoscopic cholecystectomy: Expert consensus statement. Ulus Cerrahi Dereg. 2016; 8:16127-16131.
17. Davidoff AM, Pappas TN, Murray EA, et al Mechanisms of major biliary injury during laparoscopic cholecystectomy. Ann Surg. 1992; 215:196–202.
18. Oslen DO. Bile duct injuries during laparoscopic cholecystectomy: a decade of experience. J Hepatobiliary Pancreat Surg 2000; 7:35–9.
19. Sinha S, Hofman D, Stoker DL, et al. Epidemiological study of provision of cholecystectomy in England from 2000 to 2009: retrospective analysis of Hospital Episode Statistics. Surg Endosc 2013; 27: 162-175.

20. Krähenbühl L, Sclabas G, Wente MN, et al. Incidence, risk factors, and prevention of biliary tract injuries during laparoscopic cholecystectomy in Switzerland. World J Surg 2001; 25: 1325-1330
21. Stewart L, Way LW. Bile duct injuries during laparoscopic cholecystectomy: factors that influence the results of treatment. *Arch Surg.* 1995; 130:1123.
22. Giger UF, Michel JM, Opitz I, et al. Risk factors for perioperative complications in patients undergoing laparoscopic cholecystectomy: analysis of 22,953 consecutive cases from the SwissAssociation of Laparoscopic and Thoracoscopic Surgery database. J Am Coll Surg 2006; 203:723–728.
23. Buddingh, K.T., Nieuwenhuijs, V.B., van Buuren, L, et al. Intraoperative Assessment of Biliary Anatomy for Prevention of Bile Duct Injury: A Review of Current and Future Patient Safety Interventions. *Surgical Endoscopy*. 2011; 25: 2449-2461
24. Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Coll Surg 1995; 180:101-25.
25. Fingerhut A, Dziri C, Garden OJ et al. ATOM, the all-inclusive, nominal EAES classification of bile duct injuries during cholecystectomy. Surg Endosc. 2013; 27(12):4608-19.
26. Taniguchi Y, Ido K, Kimura K, et al. Introduction of a "safety zone" for the safety of laparoscopic cholecystectomy. Am J Gastroenterol. 1993; 88(8): 1258-61.
27. Strasberg SM, Brunt LM. Rationale and use of the critical view of safety in laparoscopic cholecystectomy. J Am Coll Surg 2010; 211: 132-138.
28. European Association for the study of the liver(EASL). EASL Clinical Practice Guidelines on the prevention, diagnosis and treatment of gallstones.J Hepatol. 2016 Jul; 65(1):146-181.
29. Lau WY, Lai EC. Classification of iatrogenic bile duct injury. *Hepatobiliary Pancreat Dis Int.* 2007; 6 (5): 459-63.
30. Kapoor VK. Bile duct injury repair: when? What?, who?. J Hepato-biliary Pancreat Surg 2007; 14: 276-279.
31. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: building a safer health system. Washington DC: The National Academy of Sciences; 2000.
32. Ambe PC, Weber SA, Wassenberg D. Is gallbladder inflammation more severe in male patients presenting with acute cholecystitis? BMC Surgery. 2015; 15:48.
33. Livingston EH, Rege RV. A Nationwide study of conversion from laparoscopic to open cholecystectomy. Am J Surg. 2004; 188: 205–211.
34. Strasberg SM. Acute calcolous cholecystitis. N Engl J Med. 2008; 358:2804–11.
35. Olsen DO. Avoiding common bile duct injury during laparoscopic cholecystectomy.Surg Technol Int 1995; IV:137-42.
36. Ansaloni L, Pisano M, Coccolini F, et al. WSES guidelines on acute calculous cholecystitis .World Journal of Emergency Surgery 2016, 11: 25; 1-23.
37. Strasberg SM, Pucci MJ, Brunt LM, Deziel DJ. Subtotal cholecystectomy-"fenestrating" vs "reconstituting" subtypes and the prevention of bile duct injury: definition of the optimal procedure in difficult operative conditions. Am Coll Surg 2016; 222: 89-96.
38. Lo CM, Fan ST, Liu CL, et al. Early decision for conversion of laparoscopic to open cholecystectomy for treatment of acute cholecystitis. Am J Surg 1997; 173:513-7.
39. Way LW, Stewart L, Gantert W, et al. Causes and Prevention of Laparoscopic Bile Duct Injuries: Analysis of 252 Cases From a Human Factors and Cognitive Psychology Perspective. Annals of surgery. 2003; 237(4):460-9.