REVIEW ARTICLE

Universal culture of safety in Cholecystectomy, how to be safe?

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Abstract:
Although laparoscopic cholecystectomy has brought a huge advancement in the field of biliary surgery in terms of excellent recovery and early return to work, it has a higher risk of biliary ductal and vascular injuries associated with life-threatening complications such as sepsis, multiorgan failure, biliary cirrhosis, portal hypertension and are associated with reduced long term survival and quality of life. The risk of these injuries has decreased over the years but it is still almost twice that of open technique. Mis-identification of common hepatic duct and bile duct as cystic duct is the commonest cause of biliary injury. The concept of obtaining a Critical View of Safety (CVS) was introduced in 1995 in order to correctly define structures in the hepatocystic triangle in an effort to mitigate biliary ductal and vascular injuries. The Society of American Gastroenterologists and Endoscopic Surgeons (SAGES) formed the Safe Cholecystectomy Task Force in 2014 to promote the Culture of Safety in Cholecystectomy (COSIC) including CVS, in a further attempt to prevent such injuries. In this article we shall review the mechanisms of biliary injury and the principles of safe cholecystectomy devised by the SAGES.

Received
date:9th January, 2022
Accepted
date: 28th June, 2022

Keywords: Safe cholecystectomy, laparoscopic cholecystectomy, critical view of safety, hepatocystic triangle, subtotal cholecystectomy

Abbreviations:
CVS: Critical view of safety
COSIC: Culture of safety in cholecystectomy
LC: Laparoscopic cholecystectomy
HCT: Hepato-cystic triangle
STC: Sub-total cholecystectomy
BDI: Bile duct injury, ICG: indocyanine green
NIR: Near-infrared
IOC: Intra-operative cholangiography

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Introduction:
The first Laparoscopic Cholecystectomy (LC) was performed by Professor Eric Mühe of Germany in 1985.[7] laparoscopic cholecystectomy soon became the gold standard of care in gallbladder surgery and is now the most commonly performed laparoscopic procedure by general surgeons around the world today.[8] Between 750,000- 10,00,000 cases are performed in United States annually, most of these being laparoscopic procedures.[9,10] laparoscopic cholecystectomy has established itself as the standard of care for symptomatic gallstones due to its less post-operative pain, reduced risk of surgical site infection, shorter hospital stay, faster recovery, early return to work and superior cosmetic outcome.[11] laparoscopic cholecystectomy has proven to be particularly beneficial in high risk

groups like elderly, cirrhotic and pregnant patients.[12-15]

The afore-mentioned benefits of laparoscopic cholecystectomy do come with a price tag. Despite being the standard of care, laparoscopic cholecystectomy has a higher risk of injury to the biliary ductal and vascular structures as compared to conventional open cholecystectomy. In a classic study of 42,000 patients in 1989 by Roslyn et al., the rate of bile duct injury in open cholecystectomy was reported to be 0.2%.[16] O'Brien et al. reported an incidence of 0.8% in 1,168,288 patients where more that 95% were operated laparoscopically.[17] Nuzzo and Waage reported an incidence of 0.4% in laparoscopic cholecystectomy in Europe.[18,19] Although infrequent, biliary injuries after cholecystectomy are a major cause of morbidity, mortality and cost to the healthcare system. Biliary injuries result in early and late complications requiring readmissions and re-interventions. They compromise the quality of life and are also a common cause of litigation.[17,20] The concept of Critical View of Safety (CVS) in laparoscopic cholecystectomy was introduced in 1995 in an attempt to decrease the incidence of biliary injury.[3,21,22] Achieving the critical view of safety provides a conclusive identification of the cystic duct and artery along with any anatomical variations in the hepatocystic triangle. This eliminates misidentification of the cystic duct as a cause of biliary injury. In 2014, Safe Cholecystectomy Task Force was launched by the SAGES in order to promote a Universal Culture of Safety in Cholecystectomy among residents, fellows and practicing surgeons in a further attempt to minimize biliary injury by bringing forward certain principles for performing safe laparoscopic cholecystectomy.[3,5]

Universal culture of safety in Cholecystectomy:
Laparoscopic Cholecystectomy nearly doubled the rate of biliary duct injuries (BDI) and extensive work has since been done on this subject.[3,23] Mis-identification of structures due to visual misperception is the major cause of biliary duct injuries.[3,24-26] Distortion of structures due to inflammation and anomalous anatomy add to this risk.[27,28] The SAGES launched a safe cholecystectomy task force in 2014 in an effort to lessen the rate of biliary injury during laparoscopic cholecystectomy. A 6-step protocol was devised through a Delphi consensus process for surgeons to adopt and practice as a culture of safety in Cholecystectomy (COSIC) in order to minimize biliary duct injuries.[29,30] Studies have found that implementation of the 6-step protocol resulted in an increase in the achievement of CVS and identification of aberrant anatomy while the rate of intra-operative complications declined.[29,31,32] Efforts to reduce BDI continued and a multi-society consensus conference on the prevention of BDI was convened in Boston in 2018.[9] The aim of the consensus was to identify optimal strategies to not only reduce BDI in cholecystectomy but also propagate evidence-based recommendations to enhance patient safety and improve outcomes.

The SAGES 6-step protocol is described below:

1- Critical View of Safety: Use the CVS as a method of identification of the cystic duct and cystic artery during laparoscopic cholecystectomy.[5] The cystic duct, cystic artery and lower third of the cystic plate should be clearly visible beyond any doubt. The cystic duct and cystic artery should be the only two structures attached to the gallbladder. Once the CVS has been achieved, its completeness is confirmed and documented by photographing a Doublet View of both sides of the dissected hepatocystic triangle (HCT). Two points are given to each of the three components of the CVS. A score of 5-6 is desirable while a score of less than 5 is unsatisfactory.[33] The CVS method of target identification eliminates the misperception or illusion factor in biliary duct injuries as it allows an all-around view of the cystic duct and artery as the only two structures attached to the gallbladder. It is recommended that surgeons use CVS for anatomical identification of cystic duct and artery during laparoscopic cholecystectomy and if CVS cannot be achieved, subtotal cholecystectomy (STC) be performed instead of performing total cholecystectomy via fundus-first technique.[34]

Figure 1: Anterior view of the hepatocystic triangle with the cystic duct, artery and plate clearly visible

Figure 2: Posterior view of hepatocystic triangle in the same patient as in figure 1.

2- Aberrant anatomy: Understand the possibility of aberrant anatomy in all cases. This includes but is not limited to a short or absent cystic duct, aberrant hepatic ducts or vascular anomalies like a right hepatic artery crossing anterior to the bile duct.[35]

3- Imaging of biliary anatomy: Use intra-operative cholangiography (IOC) or another method to image the biliary anatomy. Intra-operative cholangiography is used to define anatomy especially in difficult cases where CVS cannot be achieved and the risk of inadvertent biliary injury is high. It is also indicated in cases of recent choledocholithiasis, jaundice, pancreatitis, a large cystic duct and small gallstones, abnormal pre-operative liver function tests, or dilated biliary ducts on ultrasonography. Studies show a significant reduction in the rate of biliary injury with the use of intra-operative cholangiography but it may not always identify aberrant anatomy.[36] IOC is used selectively or routinely. Studies also indicate that routine use of intra-operative cholangiography not only reduced the rate of biliary injury but also detected injury at operation and reduced the rate of death due to injury.[22,36-38]

Other modalities used for intra-operative imaging the biliary tree include ultrasonography and fluorescent cholangiography. Ultrasonography is non-invasive, non-irradiating, quick to perform and has a high specificity and sensitivity. It identifies biliary anatomy even before starting dissection in the HCT and it can identify stones in the bile duct, a short cystic duct and Mirrizi syndrome. Ultrasonography is not widely practiced due to its long learning curve and operator dependence.[39-41] Near infrared (NIR) fluorescence cholangiography utilizes indocyanine green (ICG) to visualize the biliary tree which is administered intravenously 45 minutes to 2 hours before surgery. It binds to plasma proteins, is taken up by hepatocytes and excreted in the bile. Indocyanine green emits green fluorescence when exposed to the Near infrared light captured by a filter on the laparoscope. The surgeon switches between the standard light and Near infrared light on the laparoscope to identify ductal structures.[42,43] Intra-operative biliary imaging, especially IOC is strongly recommended in case of uncertain biliary anatomy or suspicion of biliary injury.[9]

4- Take time out: It is prudent that the surgeon stops during the procedure after completing dissection in the HCT and before clipping and dividing any structures. All three elements of CVS must be clearly achieved and 'two and only two structures' must enter the gallbladder as cystic duct and cystic artery. Any anomaly in the HCT must be identified.[6,9]

5- Identify the Danger Zone: Recognize when dissection is approaching a zone of significant risk and stop before entering it. Complete the operation by a safer method other than a total cholecystectomy. In case of severe inflammation around the HCT, safe dissection may not be possible due to inflammatory fibrosis, fusion

and bleeding. When dissection is not making progress and achieving a CVS is not possible, the experience surgeon must be alerted to the possibility of an impending biliary injury. The surgeon must stop at this point, use his judgement and think about an alternate 'damage-control' or 'bailout' method to end the procedure. This includes performing STC or placement of a cholecystostomy tube, either laparoscopically or by conversion to an open procedure. Conversion to an open procedure must not be regarded as a failure and must be considered as a sound clinical judgement instead. The sole fact that target identification of cystic structures by achieving CVS is not possible in a difficult situation is the key benefit of this method as it alerts the surgeon to the danger of an impending injury.[34,44-46]

6- Call for help: Call for help in perilous circumstances. An advice by a colleague can be of significant help in case of difficult dissection, bleeding or uncertain anatomy. The surgeon must keep a low threshold for calling for help in in these circumstances. It is also recommended that if a BDI has occurred or suspected at the time of cholecystectomy or in the post-operative period, the surgeon must refer the patient to a surgeon with expertise in management of BDI.[35,45,46]

Conclusion:

Laparoscopic cholecystectomy is a commonly performed procedure. Biliary injuries are uncommon but they have far reaching and serious consequences, converting a day-care procedure into a life threatening condition. The principals of culture of safety in Cholecystectomy must be followed in every case of cholecystectomy and must be strictly adhered to especially in difficult gallbladders to prevent a biliary injury. These principals must be adopted and practiced by surgeons worldwide and must also be taught to residents in an attempt to mitigate the risk of biliary injury and bring about a universal uniformity and improve outcomes in the treatment of gallstone disease.

Conflict of interest: None

Funding source: None

Role and contribution of authors:

Zafar Ullah Khan, collected the data, references and did the writeup.

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