MANAGEMENT AND PREVENTION OF IATROGENIC BILE DUCT INJURY

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Introduction

Major bile duct injury (BDI) is the most devastating complication of biliary surgery. Management of this complication is a challenging task. Given that the majority of such injuries occur following cholecystectomy performed for gallbladder stones, a common benign condition makes this injury more significant. It is widely believed that such injuries are under-reported (1). The reported short and long term outcomes of surgical and endo-therapeutic interventions vary between centres. Mortality following injury and after attempted surgical repair have been reported (2, 3). Much is published on the quality of life and medico-legal aspects of such injuries (4, 5, 6).

Bile duct injuries in Sri Lanka

There are no data on the prevalence of bile duct injuries in Sri Lanka. Only few published data on iatrogenic bile duct injuries exist in the Sri Lankan literature (7,8,9). In 2010, we analysed and presented the patient profiles, injury mechanisms, management issues and outcome of 65 patients referred to one tertiary care facility from 2002 to 2010. During the said period we observed the significant morbidity and mortality associated with major bile duct injuries. We also witnessed the physical and psychological impact of this injury on the patients, their families and the emotional impact on surgeons. This experience highlighted the importance of re-visiting the issue of iatrogenic bile duct injuries in Sri Lanka, in a setting of changing global perceptions of such injuries.

Bile duct injuries during the era of open cholecystectomy

Bile duct injuries have been in existence since Carl Langenbuch performed the first open cholecystectomy in 1882. In more recent times, multi centre series, national surveys and single centre series have estimated that the overall prevalence of bile duct injury during the era of open cholecystectomy to be around 0.1-0.2% (10,11, 12). This low incidence has occurred over a century of experience and could be considered as a reference for comparison for other techniques of cholecystectomy. Open surgery was the only approach until the end of eighties and therefore consecutive series of open cholecystectomies represent the true reality of bile duct injury with no selection bias. However, in more recent series of open cholecystectomies during the laparoscopic era, these results remain unchanged despite the fact that more difficult cases are now selected for an open or converted approach (13,14).

Bile duct injuries during the era of laparoscopic cholecystectomy

Introduction of laparoscopic cholecystectomy in 1987 was associated with significantly increased rate of bile duct injury (15,16). This is certainly due in part to the 'learning curve' effect. A survey from USA in 2001 showed that residency training decreases the likelihood of injuring a bile duct, but only by decreasing the frequency of early "learning

curve" injuries. This study concluded that at least one third of injuries are not related to inexperience but reflect fundamental errors in the technique of laparoscopic cholecystectomy (17). In a large series in 1993, Deziel *et al* showed that half the mortality following laparoscopic cholecystectomy was due to operative injury while in open cholecystectomy the mortality was essentially due to medical complications (18).

In 13 European multi-centre series of laparoscopic cholecystectomies, the incidence of bile duct injury was 0.55% and the average rate of bile duct injury from 17 non European centres was 0.49% (19). Approximately the same data were reproduced in USA and in New Zealand (20,21). From all these series it can be estimated that bile duct injury rate is 2.5-4 times higher after laparoscopic cholecystectomy than that with open cholecystectomy.

Changing global perception of bile duct injuries

Historically the bile duct injury was accepted as a recognized complication of cholecystectomy. However, during the last two decades with rapid technological development of surgery and numerous good practice guidelines there appear to be a significant change in the global perception regarding iatrogenic bile duct injury.

Changing perception of surgeons regarding bile duct injuries

Opinions still vary amongst surgeons whether bile duct injury should be considered as a recognized complication or a preventable error although it is universally agreed that outcome of such an injury can be devastating to the patient. Some surgeons believe that the bile duct injury is simply an accident, could happen to the most competent surgeon and therefore is not totally preventable. The rationales for this argument are:

a. Bile duct injuries were a recognised complication even during the era of open cholecystectomy.

b. Injuries could occur during any operation inadvertently and patients have accepted this fact historically, when giving informed consent.

c. If recognised and treated promptly and efficiently, long term outcome is no different to the outcome of an uncomplicated laparoscopic cholecystectomy.

Opponents disagree. They argue that,

a. Bile duct is a vital structure and once injured the adverse outcome is irreversible.

b. Once repaired there is a significant probability of developing a stricture because of the lack of elastin in the bile duct wall.

c. Injuries and outcomes are under reported and therefore true problem is greater than what is reported globally.

d. Defending bile duct injury in a court of law is becoming increasingly difficult in the present era with the patient first, patient centered, evidence based approach and good practice guidelines.

e. The true effect on the surgeon is under reported. Common sense dictates that such incidences must have a significant impact.

Irrespective of perceptions of individual surgeons with regard to bile duct injury, the majority of patients will not consider as an acceptable outcome following surgery for a benign disorder. Judging by the figures of settlements and the outcomes of many trials in the west during the last decade, it is becoming increasingly apparent that the judicial system is not prepared to accept such outcomes except under exceptional circumstances.

It is important to appreciate the fact that unlike in the past, the operating surgeon in many regions of the world is no longer considered as a special breed. Accountability is now judged, critically analyzed and compared with minimum acceptable stands of practice in many countries. No longer there is room for eminence-based complacency in healthcare delivery. The day of the autonomous clinician is gone

with a vogue towards a standardized, evidence based clinical excellence. This is mainly attributed to increasing patient knowledge and expectations and further catalyzed by the parallel increase in litigations (22).

There is ample evidence that the minimal access is the best way forward to provide the best outcome for patients with symptomatic gallstones. Globally the set standards for the overall quality of care in continually changing to reach an ultimate goal of painless safe strictly outcome based surgery. Therefore in the present context, surgeons should be mindful of this disastrous complication and continually monitor the bile duct injury rate as a criterion for the quality of the surgical performance. It is pertinent to note that there are numerous surgeons from all corners of the globe who have performed large numbers of laparoscopic cholecystectomies without a single duct injury. They all follow the basic common sense based, time tested set of rules with patient safety as the foremost factor. The concept is to strictly adhere to the so called "Stop Rules" for surgeons performing this operation.

'Stop rules' for safe laparoscopic cholecystectomy

The first rule is not to stray away from the zone of safety when performing this operation and not to enter the danger zone which may lead to an injury or higher probability of an injury because there is an alternative. The obvious alternative is to convert. The second rule is that after conversion, if the procedure is proving to be difficult even at open surgery, to perform the next best alternative which is to perform a sub total cholecystectomy. The third rule is that if there is an apparent risk of having to compromise the zone of safety in performing a sub total cholecystectomy, not to proceed with the intended procedure but to perform a cholecystostomy, remove the stones and drain the gallbladder. The core issue which should be foremost in the mind of the operating surgeon is that there is a safe alternative to every step in the decision making process and the indication for the procedure is benign disorder.

Mechanisms of bile duct injury

When considering the management of such injuries understanding the mechanism of the injury becomes useful. The global studies on the occurrence of bile duct injuries reveal that the most common reason is the failure to adequately recognize the anatomy of the calot's triangle. The most common mechanism is the so called 'Classic Injury'. This occurs when the operator misidentifies between the cystic duct and the common bile duct during the dissection of Calot's triangle (23,24,25,26). The bile duct is inadvertently transected and common hepatic duct is dissected upwards up to the hilum. The finding of 'another duct' in continuity with the gallbladder is interpreted as an accessory cholecysto-hepatic duct at this stage and is clipped and divided. The injury is therefore associated with a complete transaction together with the loss of a portion of the common hepatic duct. This injury is usually associated with a right hepatic arterial injury. According to Soper *et al* (23) this type of injury is seen in about 67% of bile duct injuries during laparoscopic cholecystectomy. The common step that facilitates the classic injury is the excessive antero-superior retraction of the gall bladder fundus which results in closing the angle between the cystic duct and the bile duct and prevents the adequate appreciation of the location of the common hepatic duct. As a result of the injury, the proximal biliary tree is no longer in continuity with the gastrointestinal tract and surgical reconstruction becomes the only means of the repair.

Simple duct laceration by clips placed across the CBD (24,25) as well as duct injury due to urgent application of clips during attempted control of bleeding is described (23).

Thermal injury due to excessive use of monopolar cautary during dissection of the calot's triangle or during the attempts to control bleeding is also a frequent mechanism for laparoscopy induced bile duct injury (24,25,27). Thermal injury is a mechanism of bile duct injury unique to laparoscopic approach and was very rarely reported during the era of open cholecystectomy. Ischaemic injury could also impair the healing of

the hepatico-jejunal anastomosis and increase the chance of anastomotic stricture.

A survey showed that the classic injury is the most common type. The combined hook and thermal dissector related injury was the second common. Thermal injury due to electro cautery occurred in 1/3 of patients (28). A study reviewing the video scopes found that most bile duct injuries involved a combination of mechanisms such as misidentification of the anatomy, transaction, burn or hepatic arterial injury. They concluded that majority of bile duct injuries seem to be preventable, if surgeons strictly observed the rules of safe surgical dissection (29). Thus the quality of surgical dissection is most important to prevent bile duct injury.

Factors associated with the occurrence of bile duct injury

Many studies have shown that multiple factors are responsible for the occurrence of bile duct injury. The factors related to the patient such as obesity, biliary anatomical abnormalities and pathological changes related to inflammation are common to the open surgical approach as well. However, there are several specific issues unique to laparoscopic surgeries that are recognised. These are,

a. ***Case load of laparoscopic surgery***

This is variable factor between surgeons and hospitals (13).

b. ***Role of the learning curve***

Unlike in open surgery the 'learning curve effect' is seen as a major factor in laparoscopic surgery in general and with laparoscopic cholecystectomy in particular (20,30).

c. ***Individual skills in laparoscopy***

There is evidence that the learning curve is not only number dependant but also operator dependent.

d. ***Changing indications for laparoscopic cholecystectomy***

In the past, acute cholecystitis was considered as a contraindication for laparoscopic cholecystectomy. With the progressive development of technology and skills, this is no longer considered as a contraindication for laparoscopic surgery and surgeons with varying degrees of expertises are attempting more difficult biliary pathologies.

e. ***Rate of conversion to an open approach***

Conversion is considered the way to avoid the probability of bile duct injuries in difficult cases. However, there is a marked variation between the reported conversion rates ranging from 0% to 15%. Other studies have shown that most of the bile duct injuries have occurred before conversion. Also some surgeons have adopted a zero conversion policy with success. This makes the assessment of the impact of conversion rate difficult because it depends on factors such as case selection, individual surgical skill and general surgical policy of the team (31, 32).

f. ***Role of operative cholangiogram***

The routine use of operative cholangiogram as a preventive measure of bile duct injuries (BDI) is controversial (33,34,35,36). However, there is a consenscious that the use of intra operative cholangiogram (IOC) enhances the chance of detection of BDI (18,20,34,37). In a multi-centre study of 177 BDI from 7 hospitals, Wood *et al* reported that the rate of detection and the subsequent conversion was statistically higher if an IOC was performed and correctly interpreted (25% vs 49% p <001) (34). Data support the routine use of IOC in early detection (34,38) but there is no evidence that that knowledge of biliary anatomy pre or peri-operatively would avoid the occurrence of a BDI (28).

g. ***Human error and optical elusion***

Human errors could happen despite all efforts to avoid it and the objective should be to minimize to the extreme. The errors are usually the result of technical, training or knowledge

failures and due to non compliance to the established rules. These are easy to control. However, the two dimensional depth perception which is a phenomenon unique to laparoscopic surgery could result in inducing 'visual errors' in the human brain, that no matter further obvious changes in the visual field, may stay during the whole surgery. Unlike in open surgery where the operator has the images registered in the brain as three dimensional structures, in laparoscopic surgery, the same images are transmitted via the laparoscope on to a two dimensional screen making it difficult to judge the depth and reduce the perceptual clues for identification of anatomical structures. The most common visual error is identifying bile duct as the cystic duct and the brain stores as the correct perception, which eventually lead to crucial iatrogenic lesion. This process is called 'optical elusion'. All these factors lead to a 'paradigms of avoidable error' which poses a challenge to every biliary surgeon. Many injuries could be avoided if the surgeon questions the initial identification of the structures to the point of absolute certainty (39). There is only limited data on the extent to which surgical decision making is linked to risk taking behaviour and surgical judgment (40).

Recognition of the BDI

Most BDI are not recognised at the time of initial injury. A report of 89 patients referred to John Hopkins Hospital with bile duct injuries noted that 31% had injury recognised at the first operation (45). Early presentation of BDI may be mostly non-specific with patient complaining of vague abdominal pain, persistent nausea/vomiting and fever. This is usually the result of bile leak into the peritoneal cavity causing bile ascites. Sepsis will develop subsequently. With a slightest doubt that there is a probability of bile leak, surgeon must have a firm commitment to exclude the possibility by taking steps urgently, to delineate the extra hepatic biliary anatomy. The first step is to arrange an urgent ultrasound or computarised tomogram. A sub-hepatic collection may be observed and in those with biliary obstruction, a degree of biliary dilatation may be noted. Endoscopic retrograde cholangiogram is the next obvious step. If a partial injury such as a lateral duct wall injury is found, placement of a stent would control the leak and provide the definitive treatment for many patients.

In those with bile duct transaction, endoscopic retrograde cholangiogram will demonstrate a 'complete cut off' and delineation of the proximal anatomy is not possible. In this scenario, percutaneous transhepatic cholangiogram will not only delineate the proximal anatomy but also allows placement of trans hepatic biliary catheters to decompress the biliary tree thereby treating and reducing the chances of cholangitis and controlling bile leakage. Stewart and Way noted that 96% of repairs performed without a proper pre-operative cholangiogram were unsuccessful (41). The access to a non dilated or mildly dilated intra hepatic biliary tree poses a challenge to the invasive radiologist if this is to be attempted early before the proximal biliary tree is dilated. Biliary radionucleotide scan can confirm the leakage but such imaging usually lack the detail needed to identify the specific leak site (42). The magnetic resonance cholangio-pancreatogram (MRCP) has evolved into an excellent biliary imaging modality that can rival the detail of direct cholangiography (PTC or ERCP), with negligible morbidity.

Approach after intra-operative detection of bile duct injury

A primary duct-to-duct anastomosis following complete transection has an unacceptably high leak and stricture rate. However, a small lateral duct laceration can sometimes be closed primarily over a T-tube.

There is evidence that immediate re-construction of a complete transaction by an expert is associated with good success but this situation is uncommon. If the surgeon feels uncomfortable to proceed with construction due to the emotional impact after recognising the injury or feel the lack of adequate technical ability and supportive structure to proceed, most experts recommend to position a catheter used for operative cholangiograms to the proximal biliary tree anchored with a clip and

transfer the patient to a centre with facilities and expertise to handle such problems. The catheter can be used to delineate the proximal anatomy of the biliary tree and also prevent bile peritonitis. However, this scenario is rare.

Approach for post-operative detection of bile duct transaction

What is commonly observed is a patient presenting with bile ascites with intra abdominal sepsis within short period following surgery. Once a bile collection is found, biloma should be drained by percutaneous approach or by open surgery. Drainage coupled with broad spectrum antibiotics would control most fistulae. Stricture formation at the site of the leak will soon follow. Final reconstruction is best performed after 6-8 weeks time. The advantages of a delayed repair include resolution of inflammation, demarcation of duct ischemia, time to develop a potentially larger duct which is easy to sew to and enhance the ability to preoperatively define duct anatomy which is easy to access with a variety of imaging techniques.

Definitive treatment of bile duct injuries

In a patient with bile duct injury where the access to the proximal biliary tree is possible, endoscopic stenting will abort the bile leak. Procedure is also useful to alleviate anxiety. After a period of 4-6 weeks, stent is extracted endoscopically and the extent of the occlusion is re-assessed. Endoscopic dilation and stenting is used as the definitive treatment in selected patients. More than one stent may be deployed to maintain the stricture dilation. Stents are extracted once there is evidence of endoscopic resolution of occlusion. It is our experience that some will eventually need excision of the stricture and hepatico-jejunostomy (HJ).

Management of anastomotic strictures following hepatico-jejunostomy (HJ)

Anastomotic site stricture is a recognized complication of HJ. Bismuth level of the injury, revision surgery, and electrocautery damages are implicated in its occurrence (42,43,44). Stricture dilation by jejunal or transhepatic approach has shown good outcomes (46,47,48). However, the expertise's and facilities may not be frequently available in some parts of the world. Gastric access loop is generally not considered by many because of the risk of bile gastritis although there is no documented evidence of morbidity related to such access.

Gastric access loop was first described by Sitaram *et al* in 1998 on 10 patients and access to the HJ site was shown to be possible in five (49). Selvakumar *et al* reported a retrospective analysis of 13 patients. Gastric access loop was accessible in eight and none had clinical or endoscopic evidence of bile gastritis (44). Using a dyspepsia disability score, Jayasundara *et al* in 2010 objectively analysed the morbidity related to gastric access in a cohort of patients who had undergone HJ and gastric access loops. He reported no significant morbidity during a mean study period of two and a half years. He concluded that gastric access loop is a useful adjunct in the surgical treatment of iatrogenic bile duct injuries especially in settings with limited facilities and expertise for radiological manipulations and that the access loop is accessible and safe for stricture dilatation and other endo-therapeutic procedures (9).

Taking into consideration the current global perceptions on iatrogenic bile duct injuries, we recommend the following steps to be performed during and after laparoscopic/open cholecystectomy to minimize, prevent and manage such injuries.

1. Adequate exposure and visualization of the operative field.
2. Opening of the calot's triangle by lateral and inferior traction of the gall bladder neck.
3. Blunt dissection of the calot's triangle avoiding overuse of electro-cautery.
4. Clear identification of the junction between the cystic duct and the gallbladder (infundibulo-cystic duct junction) and gaining circumferential control of the said junction.

5. Avoidance of the excessive cephalic push of the fundus of the gallbladder to minimise closing the calot's triangle and approximating the operating field to common hepatic duct.
6. Avoidance of the excessive traction of the infundibulum of the gallbladder to prevent excessive tenting of the bile duct.
7. Demonstrating that the supero medial wall of the lower 1/3 of the gall bladder is in continuity with the duct which is identified as the cystic duct.
8. Avoidance of the blind use of clips or cautery to control haemorrhage.
9. Liberal conversion to open approach, when the anatomy remains unclear during dissection.
10. Taking undue care during the dissection of the lower medial part of the gallbladder close to the common hepatic duct, during the fundus first approach after conversion.
11. If the anatomy is not clear, to perform a subtotal cholecystectomy by leaving the part of the Hartmann's pouch that is adherent to common hepatic duct or cholecystectomy and drain the gall bladder.

Summary

- Bile duct injury following cholecystectomy is an iatrogenic mishap associated with significant morbidity and mortality, reduced quality of life and reduced long-term survival.
- Increased rates of biliary injury that is reported following laparoscopic approach globally have shown to continue after the 'learning curve'.
- It is a safe practice to question the initial identification of the structure (cystic duct) to the point of absolute certainty before any irreversible step is undertaken.
- There is a safe alternative to each step in the decision making process during the procedure and the indication for the procedure is a benign condition.
- Once a probability of bile duct injury is suspected patient is assumed to have a bile duct injury until the structural integrity of the biliary tree is demonstrated.
- Delayed definitive repair by Roux-en-Y hepatico-jejunostomy is shown as the treatment of choice for major transactions.
- Creation of gastric access loop is shown to be a useful technique in the long term management of such patients and has shown to be safe with minimal morbidity.

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