Instilling a culture of safety for laparoscopic cholecystectomy

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Laparoscopic cholecystectomy (LC) is the preferred and most widely used method for removal of the gallbladder in patients with symptomatic cholelithiasis. Modern laparoscopic equipment provides better illumination and definition with the most recent generation processors and cameras offering the possibility of 3D visualization. The minimal access approach results in smaller wounds, less postoperative pain, faster recovery, shorter hospital stay and ultimately a better cosmetic result.[1] The major disadvantage of LC, however, is the biliary complications associated with the procedure, the most serious of which is a major bile duct injury (BDI).[2] Although the technique was introduced more than two decades ago, the incidence of BDIs has not decreased and still occurs in 0.4% of operations, a figure twice as high as recorded during the era of open cholecystectomy.[3] A recent Swedish population-based study reporting a BDI rate of 1.5% suggests that the rates in the literature may be an underestimation, or more alarmingly, that BDI rates are increasing.[4]

While cystic duct leaks or minor injuries with duct continuity can usually be treated successfully with endoscopic stenting without recourse to operation, major injuries with duct division or excision are potentially life-threatening and often require complex reconstructive biliary surgery.[5] The implications of a major BDI can be devastating for the patient, with the spectre of protracted hospitalisation and invasive investigations, the anxiety of major reconstructive surgery, a lengthy rehabilitation period, decreased quality of life, loss of income and, in some cases, prolonged and unpleasant litigation.[6]

Studies, some of them population-based, have shown significantly lower survival in patients with a BDI with overall 1 year mortality rates as high as 20.8% and a 4-fold increased life-time risk of dying of liver disease.[7,8,9] The financial medical burden implicit in the treatment of a major injury and the consequences for the patient are substantial with a mean cost of definitive bile duct reconstruction of R215 711, but which can be as high as R980 800 as documented in a recent cost analysis from Cape Town.[10] Equally, the consequences of litigation may have a detrimental effect on the injuring surgeon's life with marked overall implications for the practice as well as reputation which may suffer with worry, anxiety, loss of confidence, uncomplimentary media coverage and protracted litigation.[11] Ultimately, both parties, the patient and the surgeon, may become victims as two legal teams wrangle and joust for a favourable verdict.[12]

Specific problems associated with laparoscopic BDI are a higher incidence of severe hepatic duct bifurcation injuries as well as associated vascular injuries.[13] In particular, the right hepatic artery is at risk but indiscriminate use of diathermy or energy devices may also damage the delicate blood supply of the bile duct,[14,15] resulting in late ischaemic strictures.[16] It is crucial that the complexity of BDIs and the level of difficulty are not underestimated.[2,3] There is consensus that the optimal evaluation of a major injury requires careful and coordinated multidisciplinary assessment by a knowledgeable group of surgeons, endoscopists and interventional radiologists who have the experience, expertise and the full range of advanced endoscopic, radiologic and hepatobiliary skills necessary to manage the diverse injury patterns and their sequelae.[1-3] Definitive reparative biliary surgery is technically demanding and should be undertaken only by a surgical team with expertise and established credentials. Accurate reconstruction of a major high BDI is taxing and the most important prognostic factor influencing morbidity and long-term functional outcome is the experience of the operating surgeon.[17] The level of complexity escalates with hilar injuries which may require central hepatic resection to expose ducts suitable for reconstruction, often necessitating separate anastomoses to left and right hepatic ducts.[18] Prior attempts at repair, multifocal intrahepatic strictures, sclerosing cholangitis, associated lobar atrophy and hypertrophy, secondary biliary cirrhosis and portal hypertension further compound the operative risks and complexity of the repair.[19]

Anatomical, pathological and operator factors may increase the risk for BDI during LC.[1] Anatomical variations, for example a short cystic duct or a cystic duct joining the right hepatic or a right-sided sectorial duct, increase the risk of misinterpretation of structures. Interpretation can be further

compromised by pathology, such as chronic cholecystitis, where a small stone-filled shrunken gallbladder results in adherence of the gallbladder to the bile duct. Errors leading to BDI during LC most commonly result from surgical misinterpretation of the prevailing anatomy.[20] However, imperfect operative technique, such as alignment of the cystic and bile ducts due to excessive upward retraction on the gallbladder fundus or insufficient lateral retraction on the infundibulum or excessive tenting of the bile duct from exaggerated lateral retraction on the infundibulum may confound correct anatomical identification.[21] The combination of the above factors may set the stage for a "perfect storm" with the risk for a LC-associated BDI approaching a *fait accompli*. The most commonly seen BDI, namely resection of a portion of the bile duct en-bloc with the gallbladder, occurs when the surgeon, convinced that the cystic duct has been conclusively identified, continues dissection upwards, often to the level of the hepatic duct, resulting in a more proximal hepatic duct or hilar injury.[22]

Unexpected leakage of bile from the liver or soft tissue adjacent to the porta hepatis or persistent bile leakage after transection of an apparent cystic duct should raise suspicion of a BDI. Encountering a "second cystic duct" during cholecystectomy which requires clipping cannot simply be dismissed or disregarded as an incidental anomaly. The appropriate action should be cessation of dissection, placement of sufficient drains and referral to a hepato-pancreato-biliary (HPB) team with experience in the repair of BDI.[23,24,25] Conversion to an open laparotomy procedure simply to confirm an obvious BDI is not indicated if immediate repair is not envisaged.

Unfortunately most laparoscopic BDIs are not recognised intra-operatively and early post-operative recognition rates are low.[26] Clinical presentation is influenced by the immediate consequences of the injury, namely leakage of bile, bile duct obstruction or a combination of both. Any deviation from the expected uncomplicated postoperative course must raise the suspicion of a BDI and be investigated expeditiously, as late recognition of a BDI or cystic duct leak delays appropriate treatment and may result in increased morbidity and mortality.[26] It is important to be aware that patients may present with nonspecific symptoms, such as vague abdominal pain, nausea and vomiting or low-grade fever, usually resulting from uncontrolled bile leakage into the peritoneal cavity. Abdominal distension is a frequent finding often without overt signs of peritonitis. Laboratory tests may show a raised white blood cell count, normal or mildly raised serum bilirubin level with minimally deranged liver enzyme levels. Some patients may present with sepsis from severe bile peritonitis, jaundice or intra-abdominal infection. Patients with a ligated bile duct may present with jaundice or cholangitis. Therefore, appropriate investigations must include an ultrasound or when in doubt a CT scan. Any free peritoneal or located fluid collections in the sub-hepatic space should raise the suspicion of a bile leak. It is important to note that ultrasound may miss or under-call fluid collections and that a CT scan, which has a significantly higher sensitivity, should be done. Percutaneous ultrasound catheter drainage confirms the presence of bile in the collection and is the mainstay of initial treatment. Complete drainage is crucial and if percutaneous drainage is inadequate either laparoscopic drainage or laparotomy is essential to achieve optimal drainage, as persistent intra-abdominal sepsis is the most serious immediate threat to life.[27] Once adequate drainage and control of sepsis have been achieved, the extent of the injury must be assessed in detail. A magnetic resonance cholangiopancreatography (MRCP) scan should be performed to define continuity of the bile duct and will direct further intervention. If there is ductal continuity, an endoscopic retrograde cholangiogram and placement of a temporary plastic biliary stent is the treatment of choice for a cystic duct leak.[28] If complete division of the proximal bile duct is present, a percutaneous transhepatic cholangiogram is necessary to further define the proximal biliary anatomy and allow placement of an external biliary drain to decompress the biliary system.

A number of intra-operative manoeuvres and methods have been proposed for safe cholecystectomy, including a variety of dissection techniques, landmark identification based on naturally visible (Rouvière's sulcus, cystic node) or dissected (Calot's triangle) features and bile duct imaging. The "critical view of safety" and intraoperative cholangiogram (IOC) are the most commonly used methods.[29,30,31] However, successful achievement of both these techniques require Calot's triangle dissection and conversely a BDI can be caused rather than prevented by the relentless pursuit of the critical view of safety or attempting to isolate the cystic duct for an IOC in the presence of a severely inflamed or fibrotic gallbladder. Recently there has been renewed focus on methods to accurately identify the biliary structures without dissection, for example, near-infrared fluorescence cholangiography.[32] A number of checklists derived from expert opinion have been proposed for safer LC.[33-36] To our knowledge, no published safety checklists have been based on wider consensus.

It is incumbent on the surgical fraternity to instil a culture of safety by providing clear rules and strategies to prevent LC-associated BDIs. Disappointingly, the incidence of BDI following LC has not decreased in recent times despite the issue continuously being given prominence on national and international scientific and clinical platforms. Ensuring prevention at a national level requires that every general surgeon is adequately trained to perform a safe LC.[37] Instruction must emphasize recognition of the difficult gallbladder based on preoperative risk factors and intraoperative findings. Safe surgical technique must incorporate a standardised method based on stepwise intraprocedural check points to facilitate the safe progression of an LC, with exit strategies when this cannot be achieved.[33,34] In general, the application of perioperative surgical checklists has been shown to reduce both the morbidity and mortality of surgery.[38]

Comparisons have been made between risk reduction procedures in the aircraft cockpit and the operating room.[39] Checklists and protocols used in the aviation industry ensure that crucial steps are cross-checked in order to guarantee passenger safety.[39] A pilot landing an aircraft in unfavourable

circumstances is guided by red flags, stopping rules and, when appropriate, alternative strategies. Similarly, the surgeon performing an LC should be alerted to possible danger and have clear instructions on when to stop and embark on a safer alternative strategy. In analogy with the aviation industry where there are pre-flight, in-flight and pre-landing checks, there should be a preoperative checklist performed by the surgeon to identify the high risk cholecystectomy ("dangerous patient, dangerous pathology, dangerous anatomy") and an intraoperative checklist, with tick boxes to be completed by the anaesthetist, documenting important landmarked milestones during the procedure, fundamental to a safe LC.[34,35,36] Finally, vital structures should be identified by the surgeon and positively acknowledged and agreed on by the assistant before definitive clipping and dividing. Inability to fully comply positively with each task or step would initiate a review and a safe exit strategy.[40,41,42]

In South Africa the surgical population performing laparoscopic cholecystectomies is small and accessible.[37] The development, dissemination and implementation of structured checklists in surgery is therefore a practical and realistic method to standardise performance and enhance the safety of procedures.[43] A checklist for LC, designed to avoid injuries, must be based on national consensus and tailored to the realities of South African conditions. Such an envisaged consensus meeting will take place as a dedicated session at the HPBASA Congress in October 2016 in Stellenbosch.

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