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# Bile Duct Injury: Prevention Entails Analysis of Why It Happens, Not Only How It Happens

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**Abstract**

Bile duct injury (BDI) during cholecystectomy is a devastating complication that can lead to severe short-term and long-term morbidity and mortality. It can be responsible for prolonged hospitalization and readmissions, multiple redo and drainage procedures,[1] impaired quality of life,[2] and increased costs and workload burdens for health care facilities and providers. At the same time, it is a vast source of legal liability (and consequently, additional costs) for the health care profession (high assurance premiums and compensation). In this narrative review, we analyze how and why BDI occurs, thus paving the way to better prevention.

**Keywords:** Bile duct injury (BDI), prevention, analysis

**Incidence**

The incidence of BDI has doubled, if not more so, increasing from 0.1 to 0.3% of operations in the open era to 0.3% or more in the laparoscopic era. The incidence of biliary duct injury (BDI) during laparoscopic cholecystectomy has been reported to range from 0.5% to as high as 1.5% without signs of decreasing over the years, or slightly so [1,2,3,4,5-9]; the unadjusted pooled outcomes in one recent overview found a modest (and not statistically significant) decrease in reported BDI rates over the past 30 years. However, today, there is little evidence that this rate is decreasing.[10] Likewise, the outcome of a Japanese national survey suggested little change in BDI rates over the past decade, the mean incidence being 0.66%.[9] Even if we consider the lowest estimate of 0.3%, and that approximately 1 million cholecystectomies (750,000-1.2 million) are performed each year in the United States alone, the annual rate would be at least 2250 such bile duct injuries.[10] Considering the 1.5% rate of Tornqvist,[1] the rate could be as high as 18,000. The current world population as of October 2021 is 7.9 billion according to the most recent United Nations estimates elaborated by Worldometer.[11] Approximately, 15% of the world population live in "developed" countries.[12] If we estimate that 1/330 people undergo cholecystectomy per year, this means we are looking at 3,800,000 BDI per year in these developed countries,[12] and who knows how many in the other 85%. The overall medical, psychological, social, and financial burdens attributed to BDI are enormous.

However, it is difficult to have a precise idea of the incidence because many of these reports do not use the same classification system or take into account the BDIs that lead to an open operation and, therefore, are no longer classed as BDI occurring during a laparoscopic cholecystectomy.

**Risk Factors and Mechanisms**

Several authors have looked at the risk factors for BDI occurring during laparoscopic cholecystectomy: 70%-80% of all BDI are a consequence of misidentification of biliary anatomy before clipping, ligating, and/or dividing structures.[13-17] The surgeon's learning curve has been highlighted as a major cause in many papers, although these accidents also occur in series of experienced surgeons. In the Belgian national survey in 1997, for instance, the incidence of BDI was 1.3% for surgeons having performed less than 50 cases,[18] and, in more than half of these cases, the procedure was even described as an "easy cholecystectomy" without any predisposing local risk factors for BDI. Additionally, in this same study, one third of the patients with BDI were operated on by surgeons with more than 100 cases of experience.[18] A prospective survey in the US confirmed the concept of a "permanent" risk for BDI at any time during laparoscopic cholecystectomy, even in experienced hands.[19] Of note, half of BDI seems to occur on a normal extrahepatic biliary tract, without any local anatomical risk factors, which clearly demonstrates a lack of correct surgical exposition and adequate dissection of Calot's triangle.[19] Excessive dissection along the common bile duct margins during open cholecystectomy can lead to biliary stricture because of damage to the three o'clock and nine o'clock axial arteries and their branches to the pericholedochal plexus. According to the literature, distal BDI are accompanied by damage of axial arteries (10%-15%) and proximal BDI are usually associated with damage to the hepatic artery and its branches (40%-60%).[4,20-23]

**Mechanisms (How They Happen)**

The mechanisms of injury can be divided into several categories which we will call 1) misidentification of structures (ducts and arteries), often integrated with human errors; 2) absence of recognized safety measures; and 3) technical errors.

Misidentification, the most widely described mechanism, stems essentially from the fact that the surgeon dissects what she thinks is the cystic duct (CD). But, in fact, one or both structures are the common bile duct (CBD). Much more rarely, it is the common (CHD) or right hepatic duct, or an aberrant right sectoral hepatic duct that is mistakenly thought to be the cystic duct.

The most common dissection and visual error has been named the Davidoff injury.[24] Of particular note, Eisendrath described the so-called "Davidoff" injury in his princeps paper in 1920.[25] The surgeon, usually after identifying the junction between the gallbladder and the cystic duct (proximal end) ("infundibular technique"), places the proximal clip. Next the "distal" clip is placed, but if the cystic duct has not been dissected free (part of the critical view of safety), which is often the case, or at least along the medial (left) border, the distal clip can be placed either partially or completely on the common bile duct. Next, depending on whether the surgeon performs an intraoperative cholangiogram (IOC) or not, two scenarios are possible. If an IOC is performed, the surgeon should see the mistake. This is clearly one of the advantages and positive aspects of IOC. If the surgeon does not perform an IOC, the surgeon will divide the CBD, believing it to be the cystic duct, and then pursue the procedure by dissecting back up toward the gallbladder on the medial (left) side of what he or she believes should be the cystic duct, though it is in fact the common hepatic duct. Here, again, anatomical variations ("hidden cystic duct"), inflammation, or too much lateral traction on the gallbladder lead the surgeon to the cystic artery and the cystic plate. Injury to the right hepatic duct is the second most frequent event.[26] The duct is usually not seen before it is reached. Either the surgeon does not recognize it and cuts it and bile appears, or the surgeon believes that this is a "normal" variation (aberrant or Luschka duct) and, either ignores it, or clips it. The loss of substance of the hepatic duct depends on the level of dissection cephalad along the left (medial) hepatic duct. Possible cues that should alert the surgeon that something is wrong include the diameter of the "distal" end of the "cystic duct," seeming larger than the proximal end; the cholangiogram, not appearing normal; or, if the surgeon has performed an IOC, clear contrast material and/or bubbles may appear (air injected during the cholangiography). All of these cues should alert that something is not normal.

However, most of the literature today concerns ***how*** they happened, and few concentrate on ***why*** they happen.

Human errors or behavior intervenes in these injuries as the surgeon often under-estimates the risk of being wrong and does not pay attention to certain cues that should provide an alert.[27] Under-estimating the risk is usually based on past success in avoiding the error; "never had one" and the relative rarity of such an event. As a general surgeon would, on average, incur a BDI at most once every 5 years,[3] experienced surgeons may have a false sense of "this can't happen to me," unaware that past success is no guarantee of future safety.[28] The surgeon has a preconceived impression of what is "normal anatomy" and "sees" what she believes should be there.[27] Improper traction and inflammation are often adjunctive underlying causes.[25,29] Superior or cephalad traction tends to align the cystic duct parallel to the hepatic duct, increasing the risk of misidentification, while excessive lateral traction tends to bring the right hepatic artery into the field of dissection.[29] Once the error has occurred and the structure has been clipped (and divided), the surgeon plunges further into the assumption that she cannot be wrong and continues. This is called "cognitive fixation."

Another sequence of events that may lead to BDI is when the surgeon does not pay attention to the "cues" that something is wrong.[13] Some of these cues are found in Table 1.

**Preventive Measures**

There are several methods described to avoid, or prevent, bile duct injuries during cholecystectomy, whether performed during traditional or open surgery or *via* the laparoscopic approach. These include (however, not exclusively), the so-called critical view of safety, infundibular technique, antegrade dissection, subtotal cholecystectomy, using landmarks such as Rouvière's sulcus, Calot's node or the B-SAFE method,[30] intra-operative cholangiography, laparoscopic ultrasound (LUS), and, more recently, near-infrared fluorescent cholangiography (NIRF-C). Despite the plethora of publications and debates, there is still no consensus as to which method is best, although most surgeons would agree that the "critical view of safety" and intraoperative cholangiogram are among the most widely used. Nonetheless, evidence is lacking as to whether they are effective (other than a stimulated "Hawthorne effect") as there are no correctly performed controlled comparative trials. Both of these methods can be used either *via* laparotomy or laparoscopy. Of note, both methods, as well as other methods, require initial (blind) opening of the peritoneum covering the bile structures and/or cystic plate, not knowing where the underlying bile duct structure lie.

Moreover, the popularity of the critical view of safety seems to stem more from the excellent reputation of its author than from its performance status. Several studies have reported very low rates of application of the method (44%, 10.8%, 3.6-12.5%).[31-33] One, not very often cited, reason might be the confusion between the hepatocystic triangle and the Calot triangle.[34]

The bile duct is well-recognized as having one of the most variable anatomical patterns in the human body, and when disease exists (acute or chronic cholecystitis, cholangitis, Mirizzi syndrome (calculi in the gallbladder infundibulum jousting, abutting and sometimes eroding the main bile duct), the exact location of the structures that have to be identified for the operation (cystic duct and artery, and gallbladder bed), as well as, those to be avoided (hepatic and common bile ducts) are difficult to find. The surgeon, therefore, has to rely on visual identification, but only after dissection of the Calot triangle area. It is obvious that under these conditions, and especially when the cystic duct is short, or in the wake of infection and inflammation, the risk of BDI is increased.

Avoidance (prevention) of BDI requires a method that allows identification of the bile structures ***before*** any dissection takes place. Up until now, three methods fill these requirements: ultra-sound, identification of Calot's node, and Rouvière's sulcus (RS) (*i.e.*, incisura hepatis dextra, Gans incisura). Ultrasound, however, is not widely available intra-operatively, and has been reported to be highly operator dependent for the identification of the bile duct structures. Identification of the two anatomic landmarks (Calot's node and RS) and dissection remaining to the right and anterior to these two landmarks, respectively, are thought to be safe, easily reproducible, and effective means of avoiding the vital bile structures. However, Calot's node is not always easy to find, especially, in the wake of infection and inflammation. Additionally, Rouvière's sulcus is not constant.

Sutherand *et al.* recommended five subhepatic landmarks, summarized mnemonically as "B-SAFE": "B" for Bile duct base segment 4; "S" for (Rouvière's) sulcus, "A" for (hepatic) artery; "F" for (umbilical) fissure; and "E" for enteric structure (duodenum).[30] The R4U line is an imaginary line drawn between the base of segment 4 to the right. All the dissection during the LC must be done ventral and cephalad to the line joining the roof of this sulcus and base of segment 4 (*R4U line*).[35]

Another method that can be used, ***before any dissection takes place,*** is cholangiography by laser-excited or near-infra red (NIR) excited dyes. Intravenous injection of indocyanine green (ICG) and use of specific equipment, a NIR light-emitting xenon-based light source and a camera that is capable of detecting the NIR fluorescence emitted by ICG-dyed bile. Neither the dye (at normal doses) nor the equipment is dangerous (no irradiation) for the patient or surgeon.[17,36] Depending on the timing of the injection of ICG, the liver parenchyma remains fluorescent for several hours. If too strong, the bile duct structures might be difficult to distinguish from the liver parenchyma. While some surgeons dissect under the NIR light, it is also possible to use different filters to obtain contrasting colors to distinguish between the structures and the liver. Technical advances now optimize the NIR system in a way that both the fluorescent and white light can be seen at the same time without the costs and safety measurements of a laser-based NIR system; therefore, the surgeon can perform the dissection, clearly observing what lies beneath the peritoneal cover with just a step on the pedal.

Understandably, as has been the case with the critical view of safety or intraoperative cholangiogram, we need solid evidence that this method will indeed prevent bile duct injuries during cholecystectomy. BDI should be avoided using this method in all situations (acute cholecystitis), in all hands, and ideally under controlled experimental conditions compared with the existing methods, before it can be claimed to be the gold standard.

Several studies have compared ICG to IOC for identification of biliary structures. In one propensity score matched comparison,[37] 44 patients with acute or chronic cholecystitis who underwent NIR-ICG fluorescent cholangiography during LC were compared to 44 matched (age, sex, body mass index, and diagnosis) patients who underwent LC with routine IOC. Due to no adverse events having been registered, and according to the mean operative time difference (86.9 ± 36.9 (30-180) min vs. 117.9 ± 43.4 (40-220)) ($p = 0.0006$), the authors concluded that NIR-ICG fluorescent cholangiography was safe and effective for early recognition of anatomical landmarks, even when residents were the first operator. A meta-analysis of seven studies, which included 481 patients, five (n=275 patients) reported higher CD and CBD visualization rates with ICG-FC, four (n=223 patients) reported higher CD-CBD junction visualization rates, and another four (n=210 patients) reported higher CHD visualization rates compared to IOC.[38] Only the last comparison was statistically significant ($p=0.03$). Of note, none of the seven studies included were randomized; all were case-controlled studies. In the only randomized trial to date (n=120 patients), the authors found that fluorescent cholangiography was non-inferior in identifying the junction between the cystic common hepatic and common bile ducts, but was more efficient to perform than traditional cholangiography.[39] Dip *et al.*[40] reported that the median cost of ICG fluorescence cholangiography was much less than that of IOC. Of note, it was not clear whether the authors were referring to the mean or median costs. Moreover, they found that NIRF-C should be possible to perform in all cases (*vs.* 93% rate for IOC).

While many authors laud the CVS as an identification method, the procedure still requires dissection to recognize the structures; therefore, the risk of injury is always present. ICG cholangiography might help the surgeon to achieve the CVS quickly and safely. However, in a recent single center randomized study, the time taken to achieve the CVS was slightly (but not statistically significant) shorter when ICG cholangiography was performed before dissection in various settings of increasing difficulty.[41] Dip *et al.*[41] conducted a multicenter single-blind, randomized trial comparing the efficacy of NIF-C (n=321) to white light (WL) alone (n=318) during laparoscopic cholecystectomy, identifying the main bile duct structures before and after surgical dissection. Pre-dissection detection rates were significantly superior in all seven biliary structures (cystic duct (CD), right hepatic duct (RHD), common hepatic duct, common bile duct, cystic common bile duct junction, cystic gallbladder junction (CGJ), and accessory ducts)). Nevertheless, only the identification of the seven structures was mentioned; there was no mention of obtaining the critical view of safety. Moreover, it is not recommended to try to dissect the CGJ. Of note, the only two patients that sustained a bile duct injury were in the white light group.

Prevention can be defined as actions taken “to reduce the frequency and severity of health impairments of individuals and of the populations they comprise”.[43] William Haddon, former president of the Insurance Institute for Highway Safety in Washington DC elaborated what is commonly called the “Haddon matrix,” commonly used to mitigate road traffic crash injury. The matrix considers the human, vehicle and equipment, physical environment, and socio-economic environment factors in three different time periods: before (“pre-crash”), during (“crash”), and after (“post-crash”) the accident.[43] Applying such a matrix to bile duct injury considering the pre-BDI, BDI, and post-BDI phases on one hand and the human (patient and surgeon) OR (operation procedure) and equipment, surgical team, and postinjury periods on the other, a BDI matrix can be constructed.

Prevention also stems from the surgeon’s mind set: the surgeon should be vigilant, always conscient that an accident can occur, and combine all the preventive measures at his or her disposal to avoid a disastrous complication.

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**Table 1:** Cues that the structure seen and interpreted as the cystic duct a) might not be the cystic duct or b) is wrong and that the common bile duct is under imminent danger or has already been injured.

| | 1a: | | 1b: |
|---|---|---|---|
| 1) | duct cannot be fully encompassed by a 9-mm clip | 1) | presence of "white" or "clear" bile in operative field, especially when the color of bile changes from "dirty" or "dark" to "white" or "clear" |
| 2) | diameter of "distal" end of the "cystic duct" is larger than the proximal end, | 2) | smooth and thin (bile duct) mucosa as opposed to villous and thick (cystic duct) mucosa |
| 3) | extra lymphatic and vascular structures in close proximity, and especially behind what is believed to be the cystic duct | 3) | Non-opacification of proximal ducts on cholangiography |
| 4) | structure traced without interruption to course behind the duodenum | 4) | Presence of air bubbles escaping from clipped "cystic duct", after it has been partially opened to perform cholangiogram |
| 5) | presence of another unexpected ductal structure after identification of what the surgeon believes to be the cystic duct | | |
| 6) | presence of large artery (probably the right hepatic) behind the structure | | |