

# State-of-the-Art Consensus Conference on Prevention of Bile Duct Injury During Cholecystectomy: Consensus Recommendations

**PICO 1: Should critical view of safety (CVS) vs other techniques (e.g. infundibular, top down, or Intraoperative cholangiography) be used to mitigate the risk of bile duct injury during laparoscopic cholecystectomy?**

Recommendation A: In patients undergoing laparoscopic cholecystectomy, we suggest that surgeons use the critical view of safety (CVS) for anatomic identification of the cystic duct and artery. ([conditional recommendation, very low certainty of evidence](#))

**PICO 2: Should the top down technique vs subtotal cholecystectomy be used to mitigate the risk of bile duct injury when the CVS cannot be achieved during laparoscopic cholecystectomy?**

Recommendation A: When the CVS cannot be achieved and the biliary anatomy cannot be clearly defined by other methods (eg imaging) during laparoscopic cholecystectomy, we suggest that surgeons consider subtotal cholecystectomy over total cholecystectomy by the top down approach. ([conditional recommendation, very low certainty of evidence](#))

**PICO 3: How should the CVS be documented during laparoscopic cholecystectomy (still doublet photos vs operative notes vs video vs no documentation)?**

Recommendation A: When performing laparoscopic cholecystectomy, we suggest that surgeons incorporate documentation of the critical view of safety by doublet photography or video in addition to written documentation. ([conditional recommendation, very low certainty of evidence](#))

**PICO 4: Should intraoperative biliary imaging (e.g. intraoperative cholangiography, US) vs no intraoperative biliary imaging be used for mitigating the risk of bile duct injury during laparoscopic cholecystectomy?**

Recommendation A: In patients with uncertainty of biliary anatomy or suspicion of bile duct injury during laparoscopic cholecystectomy, we recommend that surgeons use intraoperative biliary imaging (in particular intraoperative cholangiography) to mitigate the risk of bile duct injury ([strong recommendation, low certainty of evidence](#)).

In patients with acute cholecystitis or history of acute cholecystitis, we suggest the liberal use of intraoperative cholangiography during laparoscopic cholecystectomy to mitigate the risk of bile duct injury ([conditional recommendation, low certainty of evidence](#))

Surgeons with appropriate experience and training may use laparoscopic ultrasound imaging as an alternative to IOC during laparoscopic cholecystectomy.

**PICO 5: Should near infrared vs IOC or white light be used in mitigating the risk of BDI during laparoscopic cholecystectomy?**

Current evidence is insufficient to make a recommendation regarding use of near infrared cholangiography for identification of biliary anatomy during cholecystectomy compared to intraoperative cholangiography or white light. The evidence should be reassessed once results of the large randomized trial become available (FALCON trial: NCT02702843)

### **Recommendations for future study/ type B recommendation:**

Recommendation B: Near infrared cholangiography should be assessed in large trials compared to white light and/or intraoperative cholangiography with risk stratification and risk adjustment. In particular, this technology should be studied in difficult cholecystectomy patient populations that includes those with acute cholecystitis or history of acute cholecystitis, severe chronic cholecystitis, and obese patients.

### **PICO 6: Should surgical (complexity) risk stratification vs alternative or no risk stratification be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?**

Recommendation A1: We suggest that surgeons use the Tokyo Guidelines 18 (TG18) for grading and management of patients with acute cholecystitis ([conditional recommendation, low certainty of evidence](#)).

Recommendation A2: During operative planning of laparoscopic cholecystectomy and intraoperative decision-making, we suggest that surgeons consider factors that potentially increase the difficulty of laparoscopic cholecystectomy (such as male gender, increased age, chronic cholecystitis, obesity, liver cirrhosis, adhesions from previous abdominal surgery, emergency cholecystectomy, cystic duct stones, enlarged liver, cancer of gallbladder and/or biliary tract, anatomic variation, biliodigestive fistula, and limited surgical experience). ([conditional recommendation, very low certainty of evidence](#))

### **PICO 7: Should risk stratification that accounts for cholelithiasis vs no/alternate risk stratification be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?**

A specific recommendation cannot be provided as no risk prediction models exist that incorporate the presence or absence of gallstones as a factor that increases bile duct injury or difficulty of laparoscopic cholecystectomy.

### **PICO 8: Should immediate cholecystectomy (within 72 hrs from symptom onset) vs cholecystectomy performed 72 hours-10 days, 10 days- 6 weeks, >6 weeks be used for patients with acute cholecystitis?**

Recommendation A: In patients presenting with mild acute cholecystitis (according to Tokyo Guidelines), we suggest surgeons perform laparoscopic cholecystectomy within 72 hours of symptom onset ([conditional recommendation, very low certainty of evidence](#))

For patients with moderate and severe cholecystitis there is insufficient evidence to make a recommendation, particularly as it relates to the outcome of bile duct injury.

### **Recommendations for future study/ type B recommendation:**

Recommendation B1: Studies that examine the relationship between bile duct injury and acute cholecystitis should match patients at baseline both for severity grade of acute cholecystitis and history of prior attacks of acute cholecystitis. This recommendation is based on the finding that the incidence of major bile duct injury is significantly higher in moderate grade acute cholecystitis than in mild grade acute cholecystitis and the finding that the incidence of bile duct injury is higher in patients who have had prior attacks of acute cholecystitis than those who have not.

Recommendation B2: The diagnosis of acute cholecystitis should be documented in future studies following well accepted clinical criteria such as TG18 diagnostic criteria **or** histologic findings of acute inflammation **or both**. If documentation of acute cholecystitis is based on ICD codes, investigators should ensure that the ICD codes were based on the preceding criteria.

Recommendation B3: In acute cholecystitis for the purposes of reporting standardization and ability to compare results among studies, we suggest that the interval between onset of symptoms and time of operation should be defined in 4 phases (P1-4): P1: Symptom onset to 72 hrs; P2: 72 hours to 10 days; P3: 10 days to 6 weeks; P4: > 6 weeks. We also recommend that studies define the onset of AC from the onset of patient symptoms rather than from the arrival of the patient to the hospital.

**PICO 9: Should subtotal cholecystectomy vs total laparoscopic or open cholecystectomy be used for mitigating the risk of BDI in marked acute inflammation or chronic biliary inflammatory fusion (BIF)?**

Recommendation A: When marked acute local inflammation or chronic cholecystitis with biliary inflammatory fusion (BIF) of tissues/tissue contraction is encountered during laparoscopic cholecystectomy that prevent the safe identification of the cystic duct and artery, we suggest that surgeons consider subtotal cholecystectomy either laparoscopically or open depending on their skill set and comfort with the procedure (conditional recommendation, very low certainty of evidence).

**PICO 10: Should standard 4-port laparoscopic cholecystectomy vs single-port/ single incision laparoscopic cholecystectomy be used for mitigating the risk of BDI?**

Recommendation A: For patients requiring cholecystectomy, we suggest using a multi-port laparoscopic technique instead of single port/single incision technique (conditional recommendation, very low certainty of evidence).

**PICO 11: Should interval/delayed lap chole vs no additional treatment be used for patients previously treated by percutaneous cholecystostomy?**

Recommendation A: In low risk surgical candidates with acute calculous cholecystitis previously treated by percutaneous cholecystostomy, we suggest interval cholecystectomy after the inflammation has subsided. For high risk candidates, we suggest a non-surgical approach that may include percutaneous stone clearance through the tube tract or tube removal and observation if the cystic duct is patent. (conditional recommendations, very low certainty of evidence).

**PICO 12: Should conversion of laparoscopic to open cholecystectomy vs no conversion be used for mitigating the risk of BDI in the difficult laparoscopic cholecystectomy?**

Current evidence is insufficient to make a recommendation in the difficult laparoscopic cholecystectomy regarding conversion vs no conversion to open cholecystectomy to limit/avoid bile duct injury.

**Recommendations for future study/ type B Recommendation:**

Recommendation B1: We suggest the conduct of prospective and retrospective comparisons of clinical outcomes of various ‘bail-out’ options for the difficult cholecystectomy that include conversion to open, subtotal cholecystectomy, and procedure abandonment.

Recommendation B2: We suggest the development and establishment of valid evidence for a ‘procedure difficulty score’ for laparoscopic cholecystectomy.

**PICO 13: Should a time out to verify the CVS vs no time out be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?**

Current evidence is insufficient to make a recommendation. However, as best practice, we suggest that during laparoscopic cholecystectomy, surgeons conduct a momentary pause for the surgeon to confirm in his/her own mind that the criteria for the critical view of safety have been attained before clipping or transecting ductal or arterial structures.

**Recommendations for future study/ type B Recommendation:**

Recommendation B: We suggest incorporation of a 'critical view time-out' in all prospective studies of laparoscopic cholecystectomy.

**PICO 14: Should two vs one surgeon(s) be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?**

Current evidence is insufficient to make a recommendation regarding two vs one surgeons for limiting/avoiding bile duct injury in cholecystectomy.

**PICO 15: Should CVS coaching of surgeon vs no coaching be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?**

Recommendation A: We suggest continued education of surgeons regarding the critical view of safety during laparoscopic cholecystectomy that may include coaching. ([Conditional recommendation, very low certainty of evidence](#))

**PICO 16: Should training by simulation or video-based education vs alternative surgeon training be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?**

Current evidence is insufficient to determine the benefit of simulation vs video-based vs alternative surgeon training modalities on limiting/avoiding bile duct injury.

**Recommendations for future study/ type B:**

Recommendation B: We suggest the conduct of prospective large-scale multi-center studies to determine the role of simulation vs video-based vs alternative surgeon training modalities on limiting/avoiding bile duct injury.

**PICO 17: Should more vs less surgeon experience be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?**

Recommendation A: We suggest that surgeons have a low threshold for calling for help from another surgeon when practical in difficult cases or when there is uncertain of anatomy ([conditional recommendation, low certainty of evidence](#)).

**Recommendation for future studies/Type B Recommendation:**

Recommendation B: We suggest the conduct of prospective research studies to develop evidence-based guidelines for physicians who are in transition in practice/from residency/fellowship to independent practice, in order to mitigate the risk of BDI associated with laparoscopic cholecystectomy.

**PICO 18: Should immediate reconstruction by the operating surgeon vs referral to a specialty center be used for patients with BDI during cholecystectomy?**

Recommendation A: When a bile duct injury (BDI) has occurred or is highly suspected at the time of cholecystectomy or in the post-operative period, we suggest that surgeons refer the patient promptly to a surgeon with experience in the management of BDI in an institution with a hepato-biliary disease multispecialty team. When not feasible to do so in a timely manner, prompt consultation with a surgeon experienced in the management of BDI should be considered. (strong recommendation, low certainty of evidence)

**Additional Panel Recommendation: Type B Recommendation**

**19.** We suggest the development of national quality improvement initiatives for the prevention of bile duct injuries following cholecystectomy. The initiative(s) should be capable of identifying and characterizing bile duct injuries in the population under study.