



# Ten-year Audit of Safe Bail-Out Alternatives to the Critical View of Safety in Laparoscopic Cholecystectomy

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## Abstract

**Background** To prevent vasculobiliary injuries according to the Tokyo Guidelines, Critical View of Safety (CVS) is the recommended method for the identification of the cystic duct and cystic artery. Our aim was to audit laparoscopic cholecystectomies, in order to determine the rate of CVS feasibility and to explore safe bail-out alternatives, when CVS cannot be obtained.

**Methods** Patients who underwent either elective or emergent laparoscopic cholecystectomy, between January 2009 and December 2018, in whom the CVS was attempted, were retrospectively identified from the institutional electronic database. Dissection technique was documented in the operative notes. Bile duct injuries (BDI) were classified by the Strasberg classification, and their management and outcome were reported in the patient files.

**Results** In total, 1226 cases were included in the final analysis. CVS was feasible in 1128 cases (92.0%), whereas 65 patients (5.3%) were managed laparoscopically by a bail-out technique. Of those, 52 (4.3%) underwent a subtotal cholecystectomy, 12 (0.9%) a fundus-first cholecystectomy, and in one patient (0.1%) the operation was concluded by a tube cholecystostomy. Overall conversion rate was 2.7% (33/1226 cases). Male gender, older age, junior surgeons, and acute cholecystitis were significantly associated with higher conversion rates. Post-operatively, 10 patients (0.82%) developed a type A bile leakage. No major BDI (types B–E) were observed, either with CVS or the bail-out techniques.

**Conclusions** Our study showed that CVS and the bail-out alternatives complement each other in preventing major BDI and should belong to the armamentarium of every modern surgeon.

## Introduction

Despite increasing laparoscopic experience, technological advances and improvements in surgical training over the past 25 years, bile duct injuries (BDI) continue to occur almost twice as frequently during laparoscopic

cholecystectomy, compared to open surgery [1–3]. Even more importantly, the pattern of BDI also changed with the advent of laparoscopy. One-third of BDI are complex injuries (e.g., complete bile duct transection, thermal injuries, central injuries towards the hepatic hilum), whereas almost one in four BDI is a combined vasculobiliary injury [4].

Apart from prolonging hospital stay, with concomitant increase in hospitalisation costs, BDI increase post-operative morbidity and occasionally mortality [4]. They impair quality of life in the long term and are a frequent cause of legal claims against surgeons [4, 5].

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The ideal method to prevent BDI should be safe and effective, easily mastered and reproducible, fast and economical. The Critical View of Safety (CVS), described initially in 1995, combines all these merits and has gradually gained wide acceptance, becoming the recommended method of dissection in the hepatocystic triangle [6].

The technique has three requirements. First, the hepatocystic triangle should be completely cleared of all fibrofatty tissue. Second, the lower third of the gallbladder should be dissected off the cystic plate. Third, two and only two structures are seen entering the gallbladder, i.e., the cystic duct and artery. Until *conclusively* identified, the cystic duct and artery should *not* be clipped or divided. No effort is made to expose the common hepatic or common bile ducts.

Several international consensus meetings have published safe clinical practice guidelines, recommending that the CVS should be attempted in every patient, both in straightforward and difficult cases [7–9]. Large cohort studies consistently report rates of CVS feasibility exceeding 85–90% [4, 10]. In those patients, where the CVS cannot be adequately obtained, the 2018 Tokyo Guidelines recommend a bail-out procedure, to avoid secondary damage [1].

Our primary purpose was to audit laparoscopic cholecystectomies, in order to determine the rate of CVS feasibility and to explore safe bail-out alternatives, when CVS cannot be obtained. Our secondary aims were to assess BDI rate and severity, as well as conversion rates.

## Materials and methods

Patients who underwent laparoscopic cholecystectomy between January 2009 and December 2018 at the Department of Surgery, Athens Naval and Veterans Hospital, were retrospectively identified from the institutional electronic database and operating theatre logbooks.

Demographic (gender, age) and clinical data (surgical indication, elective or acute case, bile duct injury and management) were retrieved from patient files. Operative notes were reviewed, to determine the method of dissection in the hepatocystic triangle, documentation of the CVS, and aetiology for resorting to bail-out techniques. These included laparoscopic subtotal cholecystectomy, laparoscopic fundus-first cholecystectomy, laparoscopic tube cholecystostomy and conversion to the open approach [11].

All consecutive patients, aged  $\geq 18$  years, who underwent laparoscopic cholecystectomy for gallstones or polyps, and in whom the CVS was attempted, were included in the analysis. Both elective and acute cases were

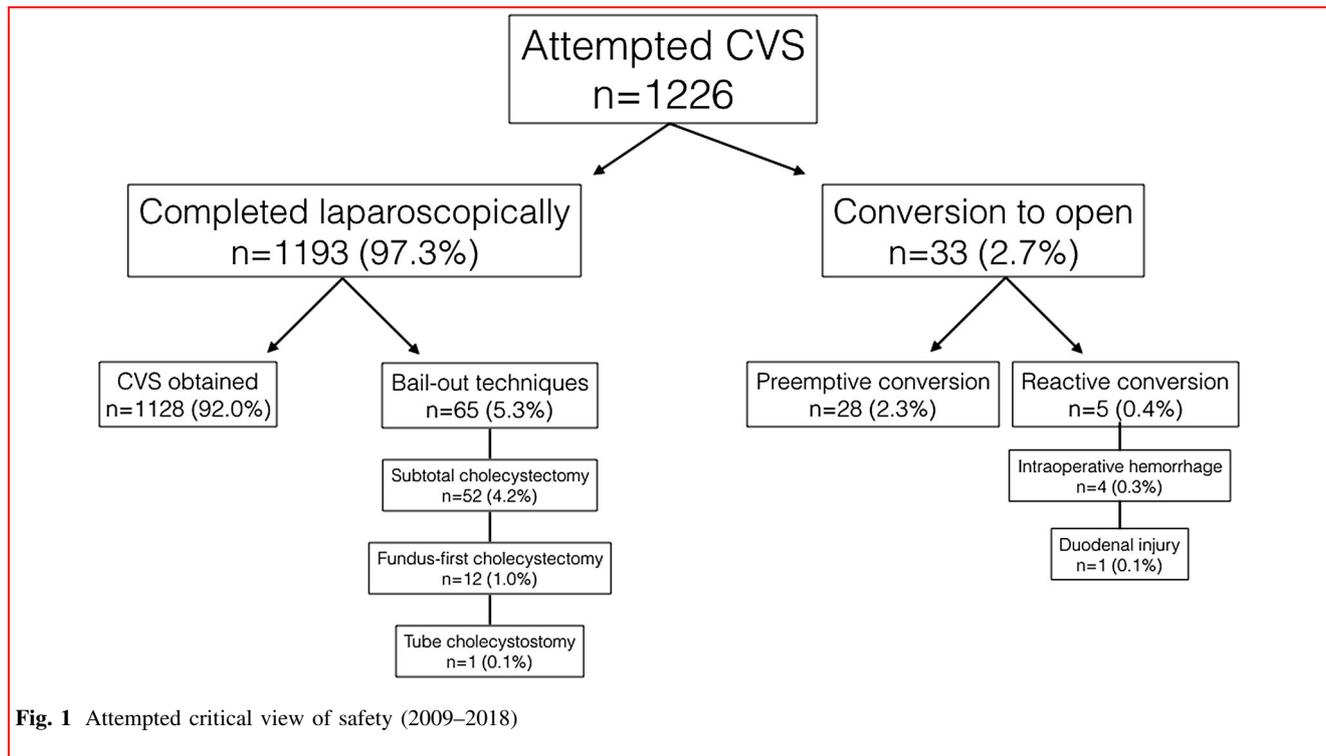
included. Excluded were patients, in whom the CVS was not adequately described in detail and therefore could not be confirmed, or patients in whom the infundibular technique was performed.

Between 2009 and 2013, the CVS was confirmed intraoperatively after discussion among the surgical team during a brief pause. Since 2014, we have employed the six-point scale proposed by Sanford and Strasberg [12]. Two points are awarded for each CVS criterion, if it is immediately obvious, one point when the criterion is fulfilled but the view is less than optimal, and no points for lesser results. A total score of 5 or 6 means that the CVS has been successfully achieved, and it is consequently safe to proceed to ligation and division of the cystic duct and artery. The only exception to this rule, as mentioned by Strasberg et al. [6] is a short cystic artery entering the gallbladder wall higher than usual, making exposure of the triangle more challenging. Scores of  $\leq 4$  require further dissection. However, when the surgeon judges that additional dissection within the triangle is dangerous or beyond their skills, then an alternative bail-out method is chosen.

Overall conversion rate was calculated as the total number of open conversions to the total number of operations. We further distinguished between preemptive conversion (elective conversion before a complication develops) and reactive conversion (emergency conversion due to an intraoperative complication). The conversion rates of individual surgeons were also calculated. Finally, we investigated the impact of age, gender, surgeon experience, and acute cholecystitis on conversion rates [13, 14].

Drains were generally used on a selective basis, depending on surgeons' judgement or preference. Regular post-operative follow-up was clinical, at 15 and 30 days, or in case of unexpected symptoms. Bile duct injuries were classified according to the Strasberg classification (types A–E) [6]. Type A bile leaks are considered a minor complication, whereas types B–E are considered major complications. In case of a suspected BDI, laboratory tests and imaging studies were used in a staged approach and included liver function tests, ultrasound, CT scan, MRI/MRCP and ERCP.

Continuous variables were expressed as mean  $\pm$  standard deviation, while categorical variables were expressed as frequencies or percentages. Statistical analysis was performed on SPSS, version 20.0, using Student's *t* test for continuous variables and Chi-square test for categorical variables. Statistical significance was set to  $p < 0.05$ . The study was approved by the institutional research ethics committee.



## Results

Out of 2168 laparoscopic cholecystectomies registered between 2009 and 2018, 1226 cases (Fig. 1) were performed by four senior and three junior surgeons, who have been routinely attempting the CVS, regardless of indication or intraoperative difficulty (males 543/44.3%, females 683/55.7%, mean age  $55.8 \pm 16.2$  years). Excluded were 894 patients in whom the infundibular technique was applied, and 48 patients, in whose operative notes the three CVS elements were not specifically described. Cholecystectomy was indicated for gallstones in 1201 (98%) patients and for gallbladder polyps in 25 (2%). 1136 patients (92.7%) were operated on an elective basis, whereas 90 patients (7.3%) were acute cases.

The CVS was feasible laparoscopically in 1128 cases (92.0%), whereas 65 patients (5.3%) were managed laparoscopically by a bail-out technique. Of the latter, 52 (4.3%) underwent a subtotal cholecystectomy, 12 (0.9%) a fundus-first cholecystectomy, and in one patient (0.1%), the operation was concluded by a tube cholecystostomy. Intraoperative cholangiography was employed in 12 cases (1%), with a preoperative suspicion of concomitant choledocholithiasis. In these patients, the CVS had been successfully obtained laparoscopically, before cystic duct cannulation.

Overall conversion rate was 2.7% (33/1226 cases), ranging between 0 and 9.4% among individual surgeons. Of those converted, 15.2% (5/33) were reactive

conversions, due to uncontrollable intraoperative haemorrhage or duodenal injury, and 84.8% (28/33) were preemptive conversions, due to doubtful anatomy. Older age, male sex, acute cases and junior surgeons were associated with higher conversion rates (Table 1).

Post-operatively, all patients completed the scheduled follow-up. Ten patients (0.82%) developed a type A bile leakage (8/1128 CVS cases, 1/33 converted cases, 1/65 laparoscopic bail-out cases), presenting either early (bile stained drain) or late after discharge (biloma on CT scan). MRCP revealed inadequate closure of the cystic duct stump in six cases and bile leak from the liver bed in four cases. Four patients were managed conservatively with spontaneous resolution of the leak, five patients underwent ERCP plus stenting and CT-guided percutaneous biloma drainage, while one patient required reoperation with cystic duct stump ligation. There were no major BDI (types B–E), either with the CVS or with the bail-out alternatives. Post-operative mortality was nil.

## Discussion

Errors during a laparoscopic cholecystectomy may be either *technical* (clip failure, wrong dissection plane, thermal injury) or *anatomical* (misidentification of a major bile duct as the cystic duct) [6, 15]. Correct application of the three CVS elements prevents vasculobiliary injuries due to anatomical mistakes [12, 15].

**Table 1** Conversion rates

	Laparoscopic	Conversion	Conversion rate	<i>p</i> value
Age	55.2 ± 15.9	69.4 ± 15.6		< 0.001
Male	522	21	3.9%	0.023
Female	671	12	1.76%	
Elective	1111	25	2.2%	< 0.001
Acute	82	8	8.9%	
Senior surgeon	991	22	2.2%	0.014
Junior surgeon	202	11	5.2%	

Our audit confirmed that the CVS was feasible in > 90% of cases, regardless of operative indication or surgeon expertise. Both CVS and the bail-out techniques were effective in preventing major BDI, while type A bile leaks (0.82%) were comparable to international standards [3, 4, 16]. Based on a reported incidence of 3–4 BDI per 1000 laparoscopic cholecystectomies, we would have expected four to five major injuries (types B–E) in this series.

Laparoscopic subtotal cholecystectomy was the most frequently used bail-out procedure in our cohort (52/65, 80%). It is a valuable operation that we use liberally, when the CVS cannot be achieved. It entails leaving a remnant of the gallbladder in situ, after excising the free peritonealised portion of the gallbladder wall [1]. The cystic duct orifice is closed from the inside with a purse-string suture, while the gallbladder remnant is either left open (fenestrating variant) or oversewn (reconstituting variant) [17]. We generally favour the former and avoid the latter, which is more likely to leave a functional gallbladder stump, resulting in recurrent cholelithiasis and need for reoperation and completion cholecystectomy [18]. Compared to open conversion, laparoscopic subtotal cholecystectomy has lower rates of BDI, post-operative morbidity and mortality [17–19].

Laparoscopic fundus-first cholecystectomy is another option that enables the safe completion of a cholecystectomy (12/65, 18.5% in our series). The procedure involves dissecting the gallbladder off the liver bed in a retrograde manner, from the fundus towards the infundibulum, until the gallbladder hangs from two tubular structures, i.e. the cystic duct and artery. Fundus-first cholecystectomy offers an advantage in cases of acute cholecystitis, cirrhosis, kyphosis, Mirizzi syndrome or severely contracted gallbladders, and can be combined with a subtotal cholecystectomy [20]. We agree, however, that it carries a not-so-theoretically increased risk of haemorrhage, either from the liver bed or the gallbladder wall, the potential migration of gallstones into the common bile duct during handling of the gallbladder and more importantly the risk of “extreme”

vasculobiliary injuries by entering into the wrong dissection plane [21, 22].

Laparoscopic tube cholecystostomy is a damage control procedure for the difficult gallbladder, especially in acute cholecystitis with severe inflammation that obliterates the dissection planes, or in critically ill patients [23–26]. We chose laparoscopic tube cholecystostomy over conversion in an elderly patient with severe acute cholecystitis, who did not tolerate the pneumoperitoneum. Tube decompression of the gallbladder serves as a temporary measure to allow for resolution of sepsis and safe delay of definitive surgery [24–26]. Our patient recovered well and underwent elective cholecystectomy at a later date. When interventional radiology facilities are not available, laparoscopic cholecystostomy is a valid alternative, with the added advantages of intraoperative assessment of disease severity, exclusion of gangrenous cholecystitis, and avoidance of injuries to the hepatic flexure [25].

Open cholecystectomy remained the standard of care for symptomatic gallstone disease for more than a century. In the laparoscopic era, conversion rates for elective cholecystectomy are reported at 4–6% and for acute cholecystitis at 5–10% [3, 13, 27]. Several studies have identified various risk factors for conversion (*patient related*: male gender, older age, anatomical variations, obesity, adhesions due to prior abdominal surgery, liver cirrhosis; *disease related*: acute cholecystitis, impacted gallstone, Mirizzi syndrome, chronic cholecystitis and fibrosis, emergency surgery; and *surgeon related*: experience, teaching hospital) [14, 27–29]. In our series, the overall conversion rate of 2.7% is within international standards. We also observed that conversions were more frequent in older patients, males, in acute cholecystitis and by junior surgeons. Most converted cases (85%) were due to inability to establish the CVS, while the remaining (15%) were due to intraoperative mishaps. However, timing of an elective (preemptive) conversion is still a matter of debate. The old dictum that a quick conversion is better than a prolonged laparoscopic attempt is challenged, as long as the patient tolerates

anaesthesia and pneumoperitoneum and dissection in the hepatocystic triangle proceeds safely [13]. A conversion may not necessarily be the most comfortable option [1, 16]. Converted cases pose a significant technical challenge to junior surgeons, trained primarily in the laparoscopic approach [13, 30]. The decision to convert can be combined with an open subtotal cholecystectomy, if complete resection of the gallbladder is deemed dangerous [1]. In any case, conversion should not be viewed as a complication, but as a sign of sound surgical judgement.

Our study is limited by its single-centre, retrospective nature. However, similar observational studies are most likely the best level of evidence on CVS and the bail-out techniques that we will get in the near future [4, 6]. Furthermore, acute cases represented less than 10% of the study population, which may have limited the overall number of “difficult” cholecystectomies and consequently conversion rates. Another pending issue in the literature is correct evaluation and appropriate documentation of the CVS [31–33]. Indeed, post-operative reassessment of CVS video or photography yields inconclusive results in up to 38% of cases [33]. Interestingly, it has not been established whether the problem lies in the documentation per se, or in poor understanding of what constitutes an appropriate CVS [31, 33]. In our practice, we explicitly document the three CVS elements in the operative notes. Since 2014, we have been additionally obtaining a doublet photography of the medial and lateral aspects of the hepatocystic triangle prior to clipping, as part of a standardised protocol.

## Conclusion

Even though evidence to date is only level 4 (case series), we strongly agree that the CVS should be the preferred method for target identification, to avoid major catastrophes within the hepatocystic triangle [34]. However the CVS should not be viewed in isolation, but rather as an element of an overall culture of safety in laparoscopic cholecystectomy, as described by the SAGES or the Dutch Society of Surgery [35, 36]. Our study shows that both CVS and the bail-out alternatives complement each other in preventing major BDI and should belong to the armamentarium of every modern surgeon.

### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** The study was approved by the institutional research ethics committee.

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