

ORIGINAL ARTICLE

Are we getting the critical view? A prospective study of photographic documentation during laparoscopic cholecystectomy

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Abstract

Background: At laparoscopic cholecystectomy, most surgeons have adopted the operative approach where the 'critical view of safety' (CVS) is achieved prior to dividing the cystic duct and artery. This prospective study evaluated whether an adequate critical view was achieved by scoring standardized intra-operative photographic views and whether there were other factors that might impact on the ability to obtain an adequate critical view.

Methods: One hundred consecutive patients undergoing a laparoscopic cholecystectomy were studied. At each operation, two photographs were taken. Two independent experienced hepatobiliary surgeons scored the photographs on whether a critical view of safety was achieved. Inter-observer agreement was calculated using the weighted kappa coefficient. The Cochran–Mantel–Haenszel test was used to analyse the scores with potential confounding clinical factors.

Results: The kappa coefficient for adequate display of the cystic duct and artery was 0.49; 95% confidence interval (CI) 0.33 to 0.64; $P = 0.001$. No bias was detected in the overall scorings between the two observers (χ^2 1.33; $P = 0.312$). Other clinical factors including surgeon seniority did not alter the outcome [odds ratio (OR) 0.902; 95% confidence interval 0.622 to 1.264].

Conclusion: Heightened awareness of the CVS through mandatory documentation may improve both trainee and surgeon technique.

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Introduction

Since the introduction and routine use of laparoscopic cholecystectomy in the 1990s, the reported incidence of biliary injuries has doubled to 0.4%.^{1,2} Many factors have been shown to influence the risk of biliary injury including patient factors (obesity, older age, male gender and adhesions), local factors (severe gallbladder inflammation/infection, aberrant anatomy and haemorrhage) as well as surgeon volume.³ Given that most of these are beyond the surgeon's control, heightened alertness to the increased risk of

injury is an important consideration when any of these factors are present.

Identifying the common bile duct as the cystic duct is the commonest cause of major bile duct injury;^{4–7} active identification of cystic structures within Calot's triangle is the key to a reduction in biliary injury. Strasberg first coined the term 'critical view of safety' (CVS) in 1995⁸ and this approach of identification of cystic structures has been adopted by many surgeons as the standard of operative technique to reduce the incidence of biliary injury.

To fulfil the criteria for a CVS requires Calot's triangle to be cleared free of fat and fibrous tissue ('fat cleared'), for the lowest part of the gallbladder to be dissected free from the cystic plate ('liver visible') and for there to be only two structures entering the gallbladder ('2 structures').⁸ The published rate of bile duct injury

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is low and prohibitively large numbers would be needed to conduct a randomized trial to ascertain whether Strasberg's approach actually decreases the rate of major bile duct injury.⁹

A quality audit in surgery involves reviewing surgical performance and comparing this with accepted standards of what this performance should be.¹⁰ Most often, surgical outcomes such as complication and mortality rates are measured. However, surgeons should also be scrutinizing their actual practices and processes, and auditing how well they are performing these in order to improve patient care. The steps taken to achieve the CVS may in fact be more important than the actual final view obtained. To take aviation safety as an example, monitoring of how often the pre-flight check is performed, rather than the frequency of airplane crashes.

Aim

The aim of this study was to prospectively audit how often an adequate CVS during a laparoscopic cholecystectomy was achieved and if there were other potential confounding factors that might impact on the ability to obtain an adequate critical view.

Methods

One hundred consecutive patients undergoing a laparoscopic cholecystectomy at a metropolitan tertiary teaching hospital were prospectively studied. Patients undergoing both elective and emergency laparoscopic cholecystectomy were included. Demographic data, indication for surgery, operative diagnosis, clinical data and operative time were collected.

The surgeon was instructed to take two photos once the critical view had been obtained and when no further dissection is to be performed prior to clipping/division of the cystic duct and artery. These were scanned and de-identified, then reviewed by two independent examiners (both specialist hepatobiliary surgeons). They scored each photo on the three criteria set by Strasberg,⁸ as well as an overall mark of adequate, borderline or inadequate. Confounding factors that might potentially influence the difficulties of the procedure [age, gender, body mass index (BMI), diabetic status, white cell count, gallbladder wall thickness, 'American' (supine) or 'French' (low lithotomy) approach] were recorded. Operator experience – whether the primary operator was a consultant or trainee – was also recorded. The consultant surgeon, although available, did not physically participate during the trainees' procedures.

Statistical analysis

All analyses were performed using STATA v12 (StataCorp, College Station, TX, USA). Inter-observer agreement for scores of the CVS was assessed using the weighted kappa (κ_w) statistic (quadratic weighting) for ordered categories. A minimum sample size of 38 patients for two observers was calculated to achieve a power of 80% (two-sided alpha = 0.05) to detect $\kappa_w > 0.4$. For analysis of

bias between the two observers (one giving consistently higher or lower scores than the other), an exact single binomial test was used to calculate a χ^2 where two-sided $P < 0.05$ indicates bias between observers.¹¹ A three-way tabulation for the operator, the scores ('borderline' and 'inadequate' combined as 'inadequate') and potential confounding factors was analysed using the Cochran–Mantel–Haenszel test. A significant P -value implies that clinical factors might have influenced the scores of the operators. Two-sided $P < 0.05$ was chosen to be statistically significant.

Ethics approval was obtained from the institution's Low Risk Ethics Panel according to the requirements of the National Health and Medical Research Council of Australia and assigned the project number QA2012.75.

Results

Data on the 100 patients undergoing a laparoscopic cholecystectomy are shown in Table 1. An intra-operative cholangiogram was successfully completed in 91 of the operations. There were no conversions to open operation and one bile leak which settled without the need for further intervention. The only other major complication was an infected collection requiring computed tomography-guided percutaneous drainage.

The frequencies of the two observers' scores are listed in Table 2a. The weighted kappa coefficient (κ_w) was strongest for the display of '2 structures' (0.49) and weakest for 'fat cleared' (0.18) (Table 2b). There was no bias detected in the overall ratings of the two observers (χ^2 1.33; 1 d.f. $P = 0.312$). An example of a CVS with an 'adequate' overall score is seen in Fig. 1a, and an 'inadequate' overall score in Fig. 1b.

There was no difference in achieving adequate CVS scores with operator experience (consultant vs. trainees) when analysed against potential clinical confounding factors. An odds ratio (ORs) Forest Plot did not favour consultants or trainees [combined OR: 0.902; 95% confidence interval (CI) 0.622 to 1.264].

Discussion

Inter-observer agreement using photographic documentation of the critical view of safety was better than one would expect by chance in this prospective study. Furthermore, there was no bias detected in the overall ratings between the two observers. The measured rate of an adequate critical view of safety was 52% and 45% from two experienced observers. This is similar to a recent study by Buddingh *et al.*¹² The highest agreement and largest numbers of adequate score for the critical view was in the 'two structures' category. Arguably, definitive demonstration of the cystic duct and artery entering the gallbladder is the most objective of the three criteria for a CVS as defined by Strasberg.⁸

In the analyses of potential clinical factors that might impact on the ability to achieve an adequate critical view, a conservative approach was adopted by combining the 'borderline' and 'inad-

Table 1 Demographic and clinical data for 100 patients undergoing a laparoscopic cholecystectomy

Gender	
Male	35
Female	65
Age (years)	
Median (IQR)	49 (33–70)
Diabetic (%)	13
BMI	
Median (IQR)	28 (25–33)
Timing of Surgery	
Elective	72
Emergency	28
Gallbladder wall	
>3 mm	39
≤3 mm	61
Positioning	
French	30
American	70
WCC (×10 ⁶)	
Median (IQR)	7.20 (6.08–8.93)
Surgeon	
Consultant	20
Trainee	80
Indication	
Biliary colic	51
Gallstone pancreatitis	18
Acute cholecystitis	15
Gallbladder polyps	7
Choledocholithiasis/cholangitis	6
Other ^a	3

IQR, inter-quartile range.

^a1 idiopathic pancreatitis, 1 acalculous cholecystitis, 1 not documented.

equated' scores as 'inadequate' as it was not possible to gauge how many 'borderline' scores belong to either the 'adequate' or 'inadequate' categories.

There are limitations to this study. Awareness of being 'observed' (the Hawthorne effect¹³) could very well have influenced the performance of the operators. It may be argued that this is a positive effect of the study. Perhaps in future all surgeons should document the critical view at all laparoscopic cholecystectomies: to remind the surgeon to take a small moment to assess the structures on the screen and be certain the critical view is in fact adequately displayed prior to any division of structures. These could then be randomly audited for quality control purposes. Comments from the two observers highlighted that the photo quality affected the scoring for some patients and previous studies have suggested that taking a short video may provide a more accurate documentation of the CVS.¹⁴

Table 2a Frequencies of observers' scores for the critical view of safety (CVS) photos ($n = 100$)

Two structures				
Observer 2	Observer 1			Total
	Adequate	Borderline	Inadequate	
Adequate	42	2	1	45
Borderline	23	2	3	28
Inadequate	9	5	13	27
Total	74	9	17	100
Fat cleared				
Observer 2	Observer 1			Total
	Adequate	Borderline	Inadequate	
Adequate	30	7	3	40
Borderline	26	6	5	37
Inadequate	13	3	7	23
Total	69	16	15	100
Liver visible				
Observer 2	Observer 1			Total
	Adequate	Borderline	Inadequate	
Adequate	37	7	6	50
Borderline	17	8	2	27
Inadequate	5	8	10	23
Total	59	23	18	100
Overall score				
Observer 2	Observer 1			Total
	Adequate	Borderline	Inadequate	
Adequate	30	11	4	45
Borderline	15	10	5	30
Inadequate	7	6	12	25
Total	52	27	21	100

Table 2b Inter-observer agreement and bias of CVS scores

	κ_w	95% CI	P	Bias _{y2}	p _{bias}
Two structures	0.49	0.33 to 0.64	0.001	22.35	0.001
Fat cleared	0.18	0.01 to 0.36	0.020	12.79	0.001
Liver visible	0.39	0.20 to 0.58	0.001	5.00	0.036
Overall	0.38	0.19 to 0.57	0.001	1.33	0.312

95% CI, 95% confidence interval.

Examples of audits already used for quality assessment in surgery are: monitoring the caecal intubation rate as a surrogate for completeness of a colonoscopy;^{15,16} determining how often the recurrent laryngeal nerves are identified at thyroidectomy¹⁷; and documenting lymph node counts in bowel cancer surgery.¹⁸ A laparoscopic cholecystectomy is a common operation, but can

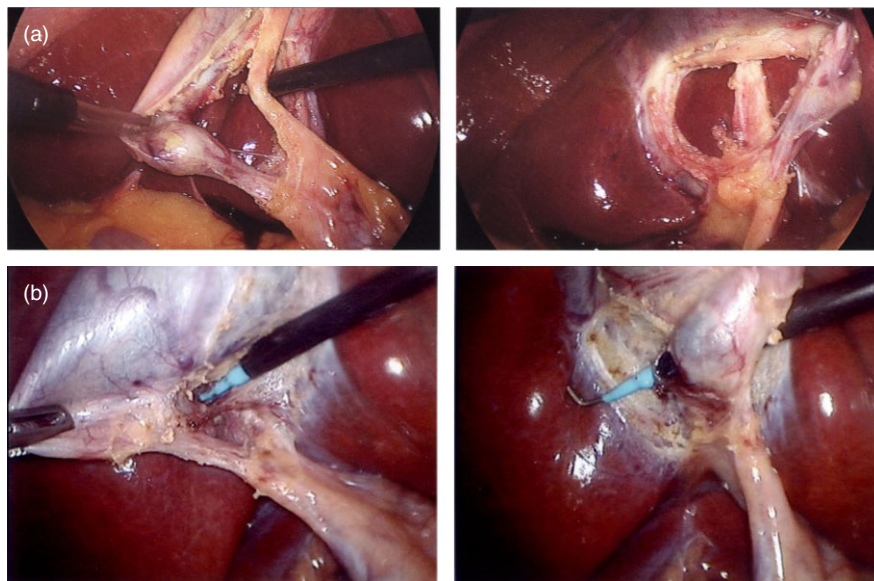


Figure 1 (a) Example of an 'adequate' critical view of safety photo. (b) Example of an 'inadequate' critical view of safety photo

incur the potentially devastating complication of major bile duct injury. Given this, ongoing scrutiny of a surgeon's practice is important to ensure the best outcomes are achieved for patients. In the future, mandatory documentation of the CVS will be performed in this unit for audit and educational purposes. A recent publication has created a proposed laparoscopic cholecystectomy checklist to attempt to create a standard approach to the operation.¹⁹ Perhaps not only the CVS, but also the key steps leading to this should be documented. These and scoring systems such as that described by Eubanks *et al.*²⁰ would potentially make for more structured and reliable methods of teaching trainees or auditing surgeons.

A further prospective study of the documentation of the steps during a laparoscopic cholecystectomy and exploring more accurate ways to document the CVS (such as with a short video clip) is planned. It is probable that using photos alone to document the adequacy of the CVS may not provide the medico-legal protection that some surgeons may believe these pictures confer.

Within the limitations of the photographic documentation used in the current study an adequate CVS was achieved only approximately half of the time. Although the true rate is likely to be higher owing to the varying quality of the photographs, it can still be improved upon. It does not appear there were any particular factors that correlated with a lower likelihood of achieving a CVS – including operator experience. Ongoing scrutiny of this common operation is required to provide continuing improvement.

In summary, this study has demonstrated that an adequate and safe display of the cystic duct and artery was achieved as assessed by photographic documentation with good inter-rater agreement. Factors including seniority of the operator did not affect the per-

formance; however, this study was not powered to specifically examine this. A heightened awareness of the CVS through mandatory documentation may improve both trainee and surgeon technique in laparoscopic cholecystectomy.

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Conflicts of interest

None declared.

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