

TIME TO ACHIEVEMENT OF THE CRITICAL VIEW OF SAFETY AS AN OBJECTIVE INTRAOPERATIVE MARKER OF DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE ANALYTICAL STUDY

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ABSTRACT

Objective: To determine the mean time to achievement of the critical view of safety (CVS) and assess its ability to distinguish difficult from non-difficult laparoscopic cholecystectomy.

Study Design: Prospective analytical cross-sectional comparative study.

Settings: Department of Surgery, Jinnah Postgraduate Medical Centre, Karachi.

Period: Five months from December 2025 to April 2026.

Material & Methods: Sixty-four adults undergoing elective or emergency laparoscopic cholecystectomy were enrolled by purposive sampling. Modified Nassar grades I-II were classified as non-difficult and grades III-V as difficult. Time from commencement of hepatocystic-triangle dissection to confirmation of all three CVS criteria was recorded. Welch's t-test was primary; categorical, correlation, censored time-to-event, and receiver operating characteristic (ROC) analyses were complementary.

Results: Twenty-five (39.1%) procedures were difficult. CVS was achieved in 38/39 (97.4%) non-difficult and 20/25 (80.0%) difficult procedures ($p=0.030$). Mean time to CVS was 16.57 ± 5.66 versus 33.55 ± 10.59 minutes; mean difference 16.98 minutes (95% CI 11.75-22.21; $p<0.001$). Time correlated with Nassar grade ($\rho=0.820$) and total operative time ($r=0.918$), both $p<0.001$. Exploratory ROC area was 0.935 (95% CI 0.849-1.000); a ≥ 25.75 -minute threshold yielded 90.0% sensitivity and 97.4% specificity.

Conclusion: Time to CVS was substantially longer in difficult laparoscopic cholecystectomy and showed strong discriminatory performance. A prolonged interval may provide an objective intraoperative prompt for escalation or a bailout strategy, but the proposed threshold requires prospective external validation.

KEYWORDS: Critical View of Safety, Difficult Laparoscopic Cholecystectomy, Laparoscopic Cholecystectomy, Modified Nassar Scale, Operative Time

INTRODUCTION

Laparoscopic cholecystectomy is the standard operative treatment for symptomatic gallstone disease, but distorted anatomy, inflammation, fibrosis, and anomalous biliary structures can convert a routine operation into a high-risk dissection. The critical view of safety (CVS) is intended to prevent misidentification by requiring clearance of the hepatocystic triangle, exposure of the lower cystic plate, and demonstration that only two structures enter the gallbladder before division. Contemporary reviews and technical analyses continue to support disciplined CVS acquisition while emphasizing that apparent completion must be judged anatomically rather than assumed from operative familiarity.¹⁻³ Photographic studies also show that surgeons' declarations of CVS do not always correspond to objective documentation of all three criteria, which has encouraged structured time-outs and image-based verification.^{4,5}

Difficulty is commonly recognized through operative grading, yet the decision to seek senior help, change the dissection plane, or select a bailout procedure may still be subjective. The modified Nassar scale links increasing operative severity with inflammatory change and technical complexity, while time to CVS offers a simple continuous measure available during every case.⁶ Previous work has quantified the interval to CVS and explored fluorescence-assisted identification, but a practical temporal marker of difficult dissection remains insufficiently validated.⁷ Recent studies have examined preoperative predictors, local grading systems, patient and surgeon factors, photographic CVS quality, and the broader consequences of difficult cholecystectomy.⁸⁻¹⁵ A reproducible intraoperative time signal could complement—not replace—anatomic judgment and difficulty grading.

The primary objective of this study was to determine the mean time to achievement of CVS during laparoscopic cholecystectomy and compare this interval between difficult and non-difficult procedures. The secondary objective was to evaluate the association of time to CVS with modified Nassar grade, CVS achievement, total operative time, and operative outcomes. We hypothesized that difficult procedures would require a significantly longer time to CVS and that time to CVS would discriminate modified Nassar grades III-V from grades I-II.

MATERIAL & METHODS

Study Design: Prospective analytical cross-sectional comparative study.

Settings: Department of Surgery, Jinnah Postgraduate Medical Centre (JPMC), Karachi, Pakistan.

Duration: Four months after approval; exact dates must be inserted before submission: [start date] to [end date].

Sample Size: The sample size was calculated from a previously reported standard deviation of 13.6 minutes for time to CVS, using 95% confidence and absolute precision of 3.5 minutes.⁷

Sampling Technique: Non-probability purposive sampling.

Inclusion Criteria: Adults aged 18-70 years of either sex with symptomatic cholelithiasis or acute/chronic calculous cholecystitis scheduled for elective or emergency laparoscopic cholecystectomy and providing written informed consent were eligible.

Exclusion Criteria: Patients were excluded for suspected or confirmed choledocholithiasis, Mirizzi syndrome, gallbladder malignancy, previous upper-abdominal surgery causing unrelated adhesions, conversion before Calot's triangle dissection, deranged coagulation, American Society of Anesthesiologists (ASA) class IV or higher, pregnancy, or refusal of consent.

Data Collection Procedure: Laparoscopic cholecystectomy was performed under general anaesthesia using a standard four-port technique by surgeons with at least three years of post-fellowship experience. Operative difficulty was assigned independently at the start of dissection using the modified Nassar scale. Grades I-II were classified as non-difficult and grades III-V as difficult. A trained observer started a stopwatch when the first dissecting instrument was applied after gallbladder retraction and stopped it when all three CVS criteria were confirmed. The operative field was photographed. Failure to achieve CVS by 60 minutes, conversion, bailout procedure, intraoperative complication, and total operative time were recorded. Six non-achievement observations were right-censored at 60 minutes for time-to-event analysis.

Data / Statistical Analysis: Data were analysed in IBM SPSS Statistics version 26. Continuous variables were summarized as mean±standard deviation or median (interquartile range), and categorical variables as frequency and percentage. The prespecified group comparison used an independent-samples t-test; because variances differed, the Welch result is reported. Categorical outcomes were compared with Fisher's exact test where cell counts were small. Spearman correlation assessed modified Nassar grade and time to CVS, and Pearson correlation assessed time to CVS and total operative time among cases in which CVS was achieved. Stratified comparisons were performed for age, body mass index, ASA class, and admission mode. Complementary Kaplan-Meier/log-rank and ROC analyses treated non-achievement by 60 minutes as censoring and explored discrimination. Two-sided $p \leq 0.05$ was significant. ROC cut-off selection was exploratory and based on the maximum Youden index.

Ethical Approval: Approval was obtained from the institutional review board of JPMC before data collection. Written informed consent was documented for all participants.

RESULTS

All 64 included procedures were analysed; 39 (60.9%) were non-difficult and 25 (39.1%) difficult. Mean age was 44.16 ± 10.38 years, mean body mass index was 26.98 ± 3.57 kg/m², 43 (67.2%) participants were women, and 21 (32.8%) were admitted as emergencies. Difficult cases involved older patients and more hypertension, whereas other measured baseline characteristics did not differ statistically (Table I). Modified Nassar grades were I in 14, II in 25, III in 15, IV in eight, and V in two procedures.

Table I: Baseline and clinical characteristics by operative difficulty (n=64)

Characteristic	Non-difficult (n=39)	Difficult (n=25)	p-value
Age, years, mean±SD	41.15±10.05	48.84±9.25	0.003
BMI, kg/m ² , mean±SD	26.44±3.86	27.81±2.95	0.135
Female sex, n (%)	25 (64.1)	18 (72.0)	0.592
Emergency admission, n (%)	11 (28.2)	10 (40.0)	0.416
ASA class I/II/III, n	23/15/1	13/10/2	0.577
Acute calculous cholecystitis, n (%)	16 (41.0)	13 (52.0)	0.447
Diabetes mellitus, n (%)	8 (20.5)	2 (8.0)	0.292
Hypertension, n (%)	3 (7.7)	8 (32.0)	0.018

Values are n (%) unless stated. ASA: American Society of Anesthesiologists; BMI: body mass index; SD: standard deviation. Independent-samples t-test for continuous variables; Fisher's exact or Pearson chi-square test for categorical variables.

CVS was achieved in 58/64 procedures (90.6%), including 38/39 non-difficult (97.4%) and 20/25 difficult cases (80.0%; Fisher exact $p=0.030$). Among achieved cases, mean time to CVS was 16.57 ± 5.66 minutes in the non-difficult group and 33.55 ± 10.59 minutes in the difficult group. The mean difference was 16.98 minutes (95% CI 11.75-22.21; Welch $t=6.683$, $df=24.861$; $p<0.001$). The distributional comparison was concordant (Mann-Whitney $U=49.5$; $Z=-5.407$; $p<0.001$). The restricted mean time-to-CVS including censored observations was 17.68 minutes (95% CI 14.92-20.44) for non-difficult and 38.84 minutes (95% CI 33.33-44.34) for difficult procedures; log-rank chi-square=36.796, $p<0.001$ (Table II).

Table II: Primary and operative outcomes by difficulty group (n=64)

Outcome	Non-difficult (n=39)	Difficult (n=25)	p-value
CVS achieved, n (%)	38 (97.4)	20 (80.0)	0.030
Time to CVS among achieved cases, min	16.57 ± 5.66	33.55 ± 10.59	<0.001
Restricted mean time to CVS, min (95% CI)	17.68 (14.92-20.44)	38.84 (33.33-44.34)	<0.001
Total operative time, min	67.36 ± 16.31	106.52 ± 23.43	<0.001
Conversion to open, n (%)	0 (0.0)	1 (4.0)	0.391
Any bailout procedure, n (%)	1 (2.6)	5 (20.0)	0.030
Any intraoperative complication, n (%)	2 (5.1)	4 (16.0)	0.199

CVS: critical view of safety; CI: confidence interval. Time-to-CVS means use achieved cases (n=58). Restricted means and log-rank test include six observations censored at 60 minutes. Welch's t-test was used for continuous outcomes with unequal variances; Fisher's exact test for sparse categorical outcomes.

Time to CVS increased strongly with modified Nassar grade (Spearman $\rho=0.820$; $p<0.001$; n=58) and correlated with total operative time (Pearson $r=0.918$; $p<0.001$; n=58). Difficult procedures lasted 39.16 minutes longer on average (95% CI 28.31-50.01; $p<0.001$) and more frequently required a bailout procedure (20.0% vs 2.6%; $p=0.030$), while conversion and intraoperative-complication differences were not statistically significant (Table II). The direction of the primary association persisted across age, ASA, and admission strata; the BMI <25 kg/m² subgroup was small and imprecise (Table III).

Table III: Stratified comparison of mean time to CVS among achieved cases (n=58)

Stratum	Non-difficult n; mean min	Difficult n; mean min	Difference min	p-value
Age ≤ 45 years	27; 17.66	3; 38.53	20.87	0.007
Age >45 years	11; 13.88	17; 32.66	18.78	<0.001
BMI <25 kg/m ²	13; 17.09	4; 25.18	8.08	0.134
BMI ≥ 25 kg/m ²	25; 16.29	16; 35.64	19.35	<0.001
ASA I	23; 18.12	9; 34.38	16.26	<0.001
ASA II-III	15; 14.19	11; 32.86	18.68	<0.001
Elective admission	28; 15.44	13; 31.89	16.45	<0.001
Emergency admission	10; 19.71	7; 36.61	16.90	0.011

ASA: American Society of Anesthesiologists; BMI: body mass index; CVS: critical view of safety. Differences are difficult minus non-difficult. Welch's independent-samples t-test; subgroup analyses are exploratory and were not adjusted for multiplicity.

Exploratory ROC analysis among the 58 procedures in which CVS was achieved produced an area under the curve of 0.935 (95% CI 0.849-1.000; $p<0.001$). A time threshold of ≥ 25.75 minutes maximized the Youden index, with sensitivity 90.0% and specificity 97.4% for classifying modified Nassar grades III-V (Figure 1).

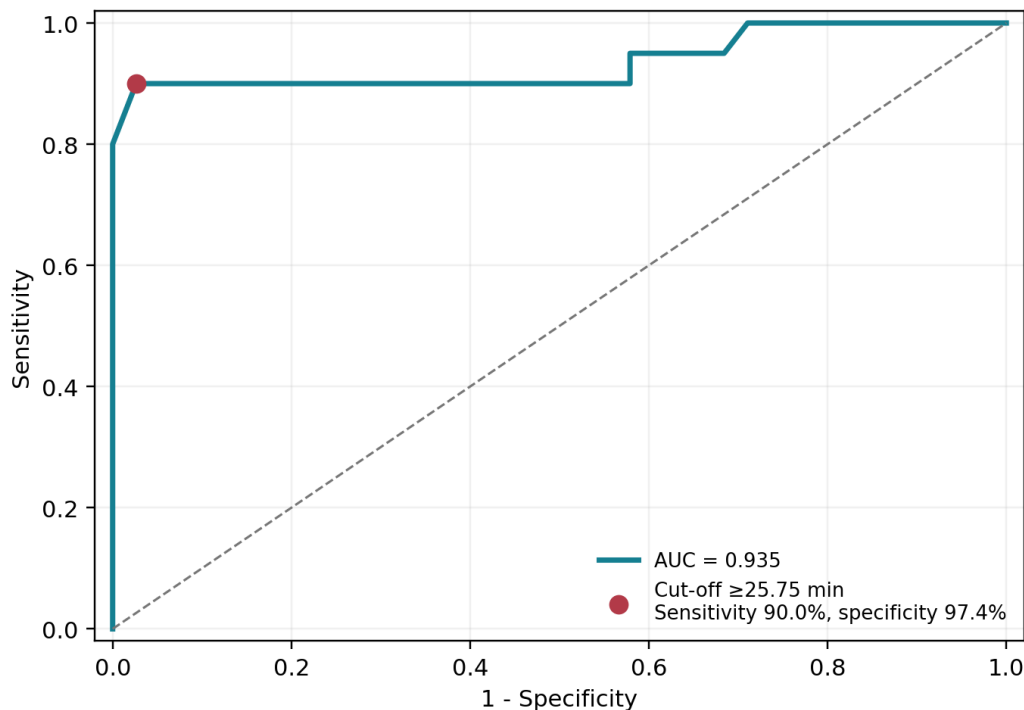


Figure 1: Receiver operating characteristic curve for time to CVS as a marker of difficult laparoscopic cholecystectomy (n=58)

The analysis includes CVS-achieved cases. Difficult laparoscopic cholecystectomy was defined as modified Nassar grade III-V. The cut-off is exploratory.

DISCUSSION

This study found a large and clinically interpretable separation in time to CVS: difficult procedures required approximately 17 additional minutes among cases in which CVS was achieved. The association was supported by a strong rank correlation with modified Nassar grade, a large difference in restricted mean time when non-achievement was censored at 60 minutes, and high exploratory ROC discrimination. These convergent analyses suggest that elapsed dissection time contains information about operative difficulty beyond a binary impression at the start of the case.

The findings are directionally consistent with Nassar and colleagues, who showed that deliberate CVS pursuit can remain feasible in difficult cholecystectomy, and with Koong and colleagues, who treated early identification of CVS as a measurable operative endpoint.^{6,7} More recent work has identified patient, disease, imaging, and surgeon factors related to CVS failure or difficult surgery.^{8-11,13-15} Time differs from these predictors because it is generated dynamically during dissection. It therefore has potential as a process marker: not a substitute for preoperative risk assessment, but a real-time indication that the expected trajectory is being exceeded.

CVS achievement was lower in difficult than non-difficult procedures, and difficult cases more often required bailout. This pattern is compatible with prospective photographic assessments and systematic reviews showing that complete, objectively documented CVS is less frequent than surgeons may assume.^{1,4,12} Photographic documentation and a formal intraoperative time-out can strengthen the distinction between genuine completion and a subjective declaration.^{5,16} In the present study, photographing the final view supported protocolized confirmation; however, the images were not independently re-scored, so observer agreement cannot be inferred. The proposed threshold of 25.75 minutes should be interpreted as an alert point rather than a mandate to continue dissection until that time. A timer cannot determine whether the anatomy is safe, and a high AUC against the modified Nassar classification does not establish that acting on the threshold prevents bile duct injury. Its practical role may be to prompt a pause, senior review, retraction adjustment, alternative imaging, or consideration of a bailout before further hazardous dissection. Automated image assessment and structured video-based instruments are increasingly capable of evaluating CVS quality and could eventually be combined with elapsed time in a multimodal safety system.¹⁷⁻²⁰ Such integration requires prospective human-factors evaluation to ensure that an alert improves decisions without creating false reassurance.

The greater operative duration and bailout rate in difficult cases are expected consequences of inflammatory distortion and limited safe progress. Current reviews advocate early recognition of the difficult gallbladder and timely use of subtotal cholecystectomy or other bailout strategies when safe anatomic identification cannot be achieved.²¹⁻²³ Aberrant anatomy remains an important caveat: even a view that appears technically complete may be misleading if the surgeon has entered an incorrect plane.²⁴ Accordingly, the observed time signal should

reinforce—never override—the principles of anatomic confirmation, avoidance of blind clipping, and willingness to stop or change strategy.

These findings are relevant to high-volume Pakistani public-sector practice, where case mix, emergency workload, imaging access, and training structures may differ from those in many validation cohorts. Pakistani reports have highlighted both the applicability of operative difficulty grading and the association of local disease characteristics with adverse events.^{3,9,25} A simple stopwatch-based measure is inexpensive and auditable, which makes it attractive for quality-improvement and training. External validation across local centres should assess calibration, interobserver reproducibility of timing landmarks, and whether a predefined alert changes escalation behavior or patient outcomes.

This study has several limitations. It was conducted at a single centre with a small purposively sampled cohort, including only 25 difficult procedures and six non-achievements. The primary achieved-case comparison excludes failures and may underestimate the full time burden, although the censored time-to-event analysis was concordant. Difficulty grade and CVS confirmation were not independently blinded or centrally adjudicated. ROC threshold selection was data-driven and optimistically biased, and subgroup analyses were underpowered and unadjusted for multiple testing. Confounding by age, hypertension, disease severity, surgeon, and learning effects was not addressed with multivariable modelling. Finally, modified Nassar grade is an operative reference standard rather than a direct patient-harm endpoint; the study cannot establish that the proposed threshold reduces bile duct injury or complications.

CONCLUSION

Time to achievement of CVS was substantially longer in modified Nassar grade III-V laparoscopic cholecystectomy and correlated strongly with operative difficulty and total operative time. An elapsed time of approximately 26 minutes may be a useful intraoperative prompt for reassessment or escalation, but it requires prospective external validation before clinical implementation.

CONFLICT OF INTEREST / DISCLOSURE

The authors declare no conflict of interest.

FUNDING

No external funding was reported.

DATA AVAILABILITY

A de-identified dataset may be made available by the corresponding author on reasonable request, subject to institutional approval.

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