

Documentation of the Critical View of Safety in Laparoscopic Cholecystectomy: Frequency, Quality, and Association with Biliary Complications in a Secondary-Level Hospital

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Abstract

Background: Iatrogenic bile duct injury (BDI) is the most serious complication of laparoscopic cholecystectomy. The Critical View of Safety (CVS), introduced by Strasberg in 1995, is the principal technical strategy for preventing the misidentification of biliary anatomy. Although CVS adoption has been endorsed in international guidelines, the quality of its documentation in operative notes at secondary-level institutions in Mexico has not been systematically evaluated, and local data to inform future research designs are lacking.

Objective: To characterize the frequency and quality of CVS documentation in operative notes, compare baseline characteristics between patients with complete versus incomplete documentation, analyze the crude association between documentation status and biliary complications

within 30 days, and estimate the sample size for a confirmatory prospective study.

Methods: A retrospective single-center cohort study of 406 adults who underwent laparoscopic cholecystectomy for cholecystitis between January 2023 and December 2024 at Clínica Hospital “Mérida” Susulá Commisary, ISSSTE, Mérida, Yucatán, Mexico. CVS documentation was designated as complete only if all three Strasberg criteria were clearly articulated. Inter-rater reliability was evaluated using Cohen’s kappa. Biliary complications at 30 days were analyzed using odds ratios (OR) with exact 95% confidence intervals and Fisher’s exact test. The STROBE guidelines were followed.

Results: Complete CVS documentation was found in of 359/406 cases (88.4%). The inter-rater agreement was close to perfect (kappa = 0.84; 95% CI: 0.71–0.97).

There were five biliary complications (1.23%; all bile leaks or post-operative cholangitis; no major ductal injuries). The crude OR for biliary complications was 0.19 (95% CI: 0.031–1.165; $p = 0.105$). The post-hoc statistical power was 32%.

Conclusions: CVS documentation was present in most operative notes, exceeding the rates in several international series. This non-significant result reflects the low event count and insufficient statistical power. These results create an institutional reference point for quality auditing and parameters for a confirmatory prospective study with objective intraoperative validation.

Keywords: laparoscopic cholecystectomy; critical view of safety; bile duct injury; operative documentation; biliary complications; patient safety; surgical quality.

Introduction

Laparoscopic cholecystectomy is among the most commonly performed surgical procedures worldwide and is the standard of care for patients with symptomatic cholelithiasis and acute cholecystitis^{1,2}. Despite decades of refinement, iatrogenic bile duct injury (BDI) remains the most consequential complication, with notable functional, medicolegal, and economic consequences^{3,4}. The current series reports an incidence between 0.3% and 1.5%, with an increased risk due to severe inflammation, anatomical variants, and intraoperative technical error^{5,6}. Current evidence suggests that the predominant mechanism behind BDI is anatomical misidentification, that is, confusion between the cystic duct and the common hepatic duct or the right hepatic duct caused by inflammation, excessive traction, and perceptual errors during dissection^{8,9}.

This realization has led to the adoption of systematic anatomical confirmation protocols prior to clipping and division as a preventive measure. The Critical View of

Safety (CVS), formulated by Strasberg et al. in 1995, operationalizes this principle by three mandatory criteria: complete dissection of the hepatocystic triangle, separation of the lower third of the gallbladder from the cystic plate, and visual observation that only two structures enter the gallbladder prior to division¹⁰. Approved by several global multi-society guidelines, CVS is the cornerstone of safe cholecystectomy^{1, 11, 12, 13}. Widespread advocacy has not been associated with comparable reductions in BDI rates, indicating a continuing disconnect between knowledge, execution, and documentation^{14,15}. Photographic or video graphic validation studies have found that CVS written in operative notes overestimates adherence to these criteria^{16, 17, 18}.

As this limitation persists, the operative note represents a valuable process marker, reflecting the culture of institutional safety and actual guideline compliance^{19, 20}. Local information on CVS documentation quality in secondary-level Mexican hospitals is missing from the literature. The aim of the current study was to (1) investigate the frequency and quality of CVS documentation in operative notes, (2) compare clinical and surgical features by documentation status, (3) examine the crude association of complete CVS documentation with 30-day biliary complications, and (4) estimate the sample size for a sufficiently powered confirmatory study.

Materials and Methods

Design and report

An observational, analytical, retrospective, non-concurrent cohort study was conducted. Reporting was performed according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for cohort studies. The research protocol was approved by the Research Committee, Biosafety

Committee, and Research Ethics Committee of Clínica Hospital “Mérida” Susulá Commisary, ISSSTE (approval Folio 168/02/2026, February 2026). A waiver of individual informed consent was obtained based on the retrospective nature of our study and anonymized data-handling procedures, following NOM-012-SSA3-2012 and the Declaration of Helsinki. This study was considered to involve no risk.

Setting and period

The study was conducted at Clínica Hospital “Mérida” Susulá Commisary, ISSSTE in Mérida, Yucatán, Mexico, a secondary-level public hospital that conducts approximately 200 laparoscopic cholecystectomies annually. All procedures done from 01 January 2023 to December 31, 2024, were eligible for inclusion.

Eligibility criteria

The following were included in the final evaluation: age ≥ 18 years, laparoscopic cholecystectomy (elective or urgent) after acute or chronic cholecystitis diagnosed according to the Tokyo Guidelines 2018 diagnostic criteria, operative note in the institutional electronic health record, and documented follow-up ≥ 30 days at the same institution or verifiable referral documentation.

Exclusion criteria

(i) no record, and no possibility of omission, in order to prevent exposure classification; (ii) elective conversion to open surgery before laparoscopic initiation; (iii) intraoperative recognized BDI followed by immediate reconstruction; (iv) concurrent major operations changing baseline risk; and (v) requirement of a second abdominal surgery in follow-up.

Exposure variable CVS documentation

The CVS documentation was complete for the operative note to clearly indicate the completion of all three Strasberg criteria: (1) complete dissection of the hepatocystic triangle; (2) separation of the lower third of

the gallbladder from the hepatic bed; and (3) visual verification that only two structures accessed the gallbladder. Missing criteria or an absolute CVS score without specifying components (where that was not available) were deemed incomplete. A random 15% subsample ($n = 61$) was examined by two skilled assessors independently and the inter-rater agreement was measured using Cohen’s kappa (Landis and Koch criteria: $\text{kappa} > 0.80 = \text{near-perfect agreement}$).

Descriptive outcome

The main outcome determined by the examination included any biliary complication within 30 post-operative days, such as bile leak determined by cholangiography, CT, or reoperation; main or major BDI defined via imaging or surgery; early biliary stricture with radiological confirmation; and other complications reported by the treatment provider. Case identification was achieved through a systematic review of medical records with no active extramural follow-up.

Covariates

Age, sex, BMI, ASA physical status classification (basically classification with ASA I versus ASA II or greater), type of cholecystitis, elective or urgent procedure, conversion to open surgery, time to surgery, and post-operative length of stay were collected for descriptive and comparative analyses.

Statistical analysis

Analyses were performed using SPSS v28.0 (IBM Corp., Armonk, NY, USA) followed by validation in R v4.3.0 (R Foundation, Vienna, Austria). Continuous variables are presented as mean \pm SD or IQR, according to the normal distribution normality test with Shapiro-Wilk. Categorical variables are expressed as frequencies and proportions. Between-group comparisons were performed using Welch’s t-test, Mann-Whitney U test, or chi-square/Fisher’s exact test, where appropriate ($\alpha =$

0.05). The relationship between CVS documentation and biliary complications was estimated as an OR with a 95% CI (Cornfield method) and Fisher's exact test. The low number of events ($n = 5$) eliminated the possibility of multivariate adjustment. The statistical power of both the observed OR and sample allocation was calculated post-hoc. Sensitivity analyses included deleted cases and subgroup analyses of acute cholecystitis. The sample size for future confirmatory studies was calculated using the Kelsey formula (two-sided $\alpha = 0.05$; target power: 80% and 90%).

Results and Discussion

Study population

Between January 2023 and December 2024, 480 laparoscopic procedures were performed at the study institution. After exclusions for incomplete records ($n = 34$), pre-laparoscopic elective conversion ($n = 8$), intraoperative BDI with immediate reconstruction ($n = 3$), concomitant major procedure ($n = 7$), and loss to 30-day follow-up ($n = 22$), 406 patients were included in the final analysis (Figure 1). The overall exclusion rate was 15.4%.

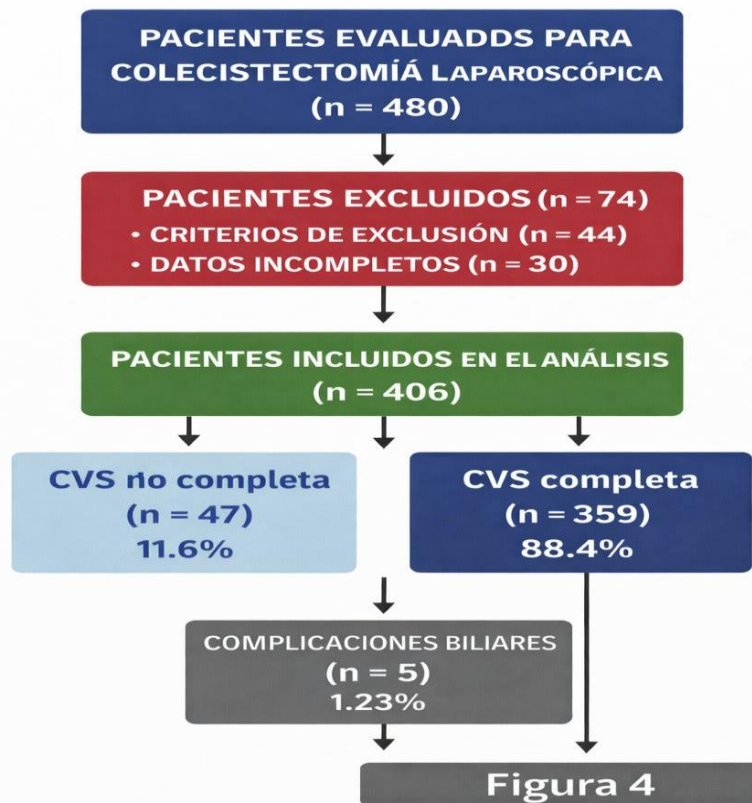


Figure 1: Study flow diagram. A total of 480 patients were assessed for laparoscopic cholecystectomy; 74 were excluded (44 by exclusion criteria, 30 due to incomplete data), yielding a final analytical cohort of 406 patients. Of these, 359 (88.4%) had complete CVS documentation and 47 (11.6%) had incomplete documentation of CVS. CVS, Critical View of Safety.

Inter-rater reliability

In the validation subsample ($n = 61$), Cohen's kappa for CVS documentation categorization was 0.84 (95% CI:

0.71–0.97), indicating near-perfect agreement and supporting the reliability of the exposure classification.

CVS documentation frequency and quality

Of the 406 procedures, 359 (88.4%) had complete CVS documentation, while 47 (11.6%) were incomplete or absent (Figure 2). The most frequently omitted criterion was separation of the lower third of the gallbladder from

the hepatic bed (31 cases; 66.0%), followed by the absence of any mention of the number of structures visualized (21 cases; 44.7%). Some operative notes lacked more than one criterion.

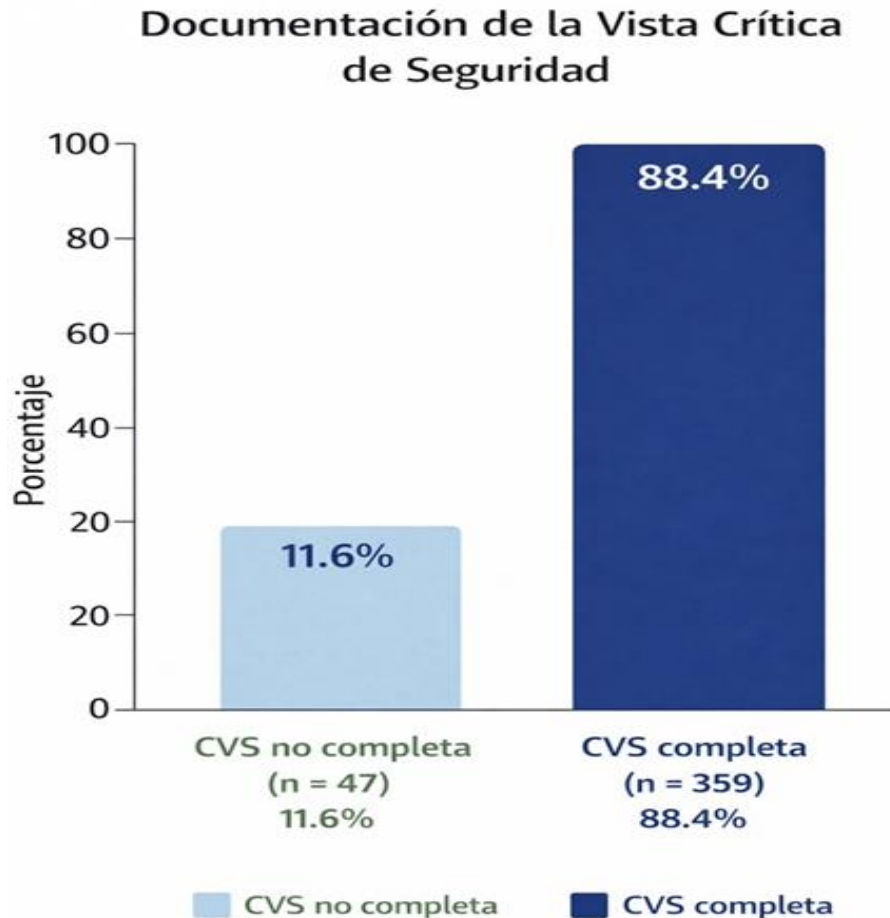


Figure 2: Frequency of Critical View of Safety (CVS) documentation in operative notes. Complete CVS documentation (all three Strasberg criteria explicitly described) was present in 88.4% of the cases (n=359), and incomplete or absent documentation was recorded in 11.6% of the cases (n=47).

The documentation rate (88.4%) exceeded figures from international series: Nijssen et al.¹⁶ reported 48%–76% in Dutch academic hospitals, and Lam et al.²³ found approximately 55% in an Australian tertiary center. This variation may reflect differences in operative note culture, institutional templates, or the definitional criteria. Importantly, high documentation rates do not certify high technical compliance; multiple studies have shown that written CVS descriptions overestimate actual

achievement verified by intraoperative video review^{16,17,18}. Documentation is therefore treated here as a process indicator, not as evidence of correct execution. The pattern of omissions — with lower gallbladder separation being the most frequently missing element — is consistent with videographic validation studies²⁴ and may reflect a genuinely vulnerable technical point.

Baseline characteristics by documentation status

The baseline clinical and surgical characteristics are summarized in Table 1 and Figure 5. Patients with incomplete CVS documentation were significantly older (mean 59.0 vs. 54.0 years; $p = 0.030$), more frequently ASA II or higher (68.1% vs. 50.1%; $p = 0.031$), had

higher conversion rates (8.5% vs. 0.6%; $p = 0.002$), longer operative times (median 80 vs. 60 min; $p < 0.001$), and longer hospital stays (median 2 vs. 1 days; $p < 0.001$). No significant differences were found in sex, BMI, or acute cholecystitis.

Table 1: Baseline characteristics of patients according to CVS documentation status

Variable	Complete CVS (n=359)	Incomplete CVS (n=47)	p-value
Age, years — mean (SD)	54.0 (15.1)	59.0 (14.7)	0.030
Female sex — n (%)	234 (65.2)	30 (63.8)	0.857
BMI, kg/m ² — mean (SD)	28.3 (4.6)	29.1 (5.1)	0.303
ASA II or higher — n (%)	180 (50.1)	32 (68.1)	0.031
Acute cholecystitis — n (%)	46 (12.8)	5 (10.6)	0.817
Urgent procedure — n (%)	48 (13.4)	8 (17.0)	0.642
Conversion to open — n (%)	2 (0.6)	4 (8.5)	0.002
Operative time, min — median (IQR)	60 (45–80)	80 (60–110)	< 0.001
Hospital stay, days — median (IQR)	1 (1–2)	2 (1–3)	< 0.001

SD: standard deviation; IQR: interquartile range; BMI: body mass index; ASA: American Society of Anesthesiologists. P-values were calculated using Welch’s t-test, Mann-Whitney U test, or Fisher’s exact test, as appropriate.

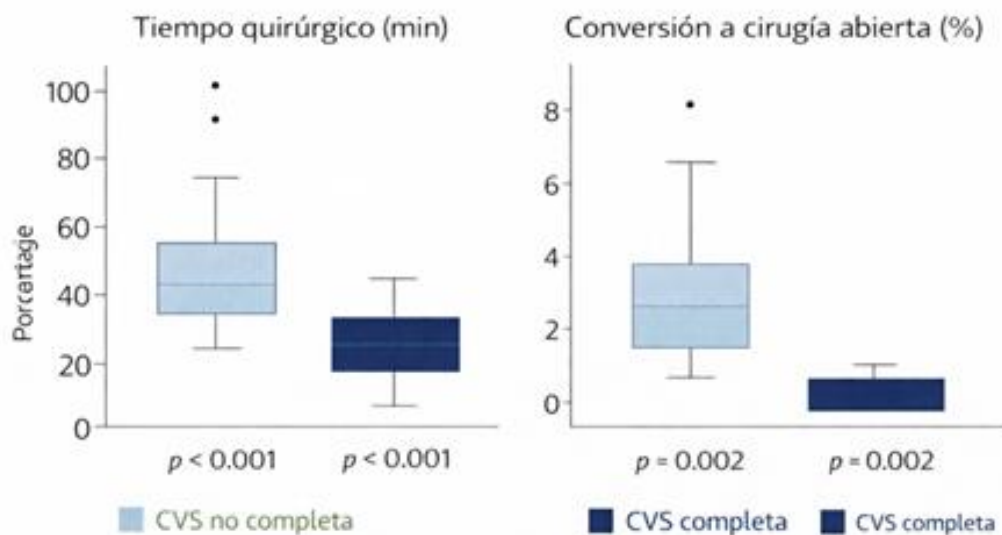


Figure 3: Comparison of operative time (minutes) and conversion to open surgery rate (%) according to CVS documentation status. Patients with incomplete documentation had significantly longer operative times (median 80 vs. 60 min; $p < 0.001$) and higher conversion rates (8.5% vs. 0.6%; $p = 0.002$). CVS, Critical View of Safety.

These systematic differences confirm that the incomplete documentation group comprised disproportionately complex cases and patients with a less favorable baseline

profile, which was the primary interpretive challenge of the study. This baseline imbalance prevents causal attribution of any outcome differences to documentation

status and introduces confounding by indication, as greater clinical and technical complexity independently elevates BDI risk^{5, 6, 25}.

Biliary complications

Five biliary complications were recopost-operative0 postoperative days (1.23% of patients). Four patients had bile leaks (0.98%post-operated postoperative

cholangitis without evidence of major ductal injury (0.25%). No Strasberg types C, D, or E injuries were identified. All five patients required hospitalization, and two required percutaneous CT-guided drainage. No mortality was observed during the follow-up period. The overall rate is consistent with the 0.3%–1.5% range reported in contemporary series^{5, 14}.



Figure 4: Absolute count of biliary comppost-operativehin 30 postoperative days by CVS documentation. Incomplete documentation: 2 events in 47 patients (4.26%); complete documentation: 3 events in 359 patients (0.84%). CVS, Critical View of Safety.

Association between CVS documentation and biliary complications

The incidence of biliary complications was 3/359 (0.84%) in the complete documentation group and 2/47 (4.26%) in the incomplete documentation group (Table 2; Figure 3). The crude OR by Fisher’s exact test was 0.19 (exact 95% CI: 0.031–1.165; p = 0.105). The CI included

unity, and p exceeded 0.05; no statistically significant association was identified.

Table 2: Association between CVS documentation status and biliary comppost-operativehin 30 postoperative days

Group	Complications / Total	Incidence (%)	OR (95% CI); p
Complete CVS documentation	3 / 359	0.84	Reference
Incomplete CVS documentation	2 / 47	4.26	0.19 (0.031–1.165); p=0.105
Total	5 / 406	1.23	—

OR: odds ratio; CI: confidence interval. OR and 95% CI using the Cornfield exact method. P-value was calculated using Fisher’s exact test.

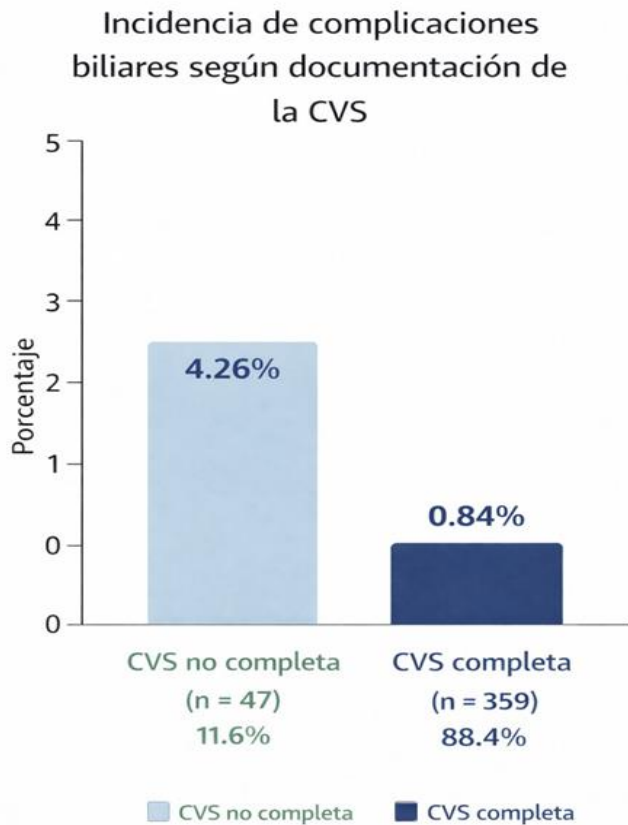


Figure 5: Incidence of biliary post-operatives within 30 postoperative days according to CVS documentation status. The incomplete documentation group had a complication rate of 4.26% (2/47), compared with 0.84% (3/359) in the complete-documentation group. CVS, Critical View of Safety.

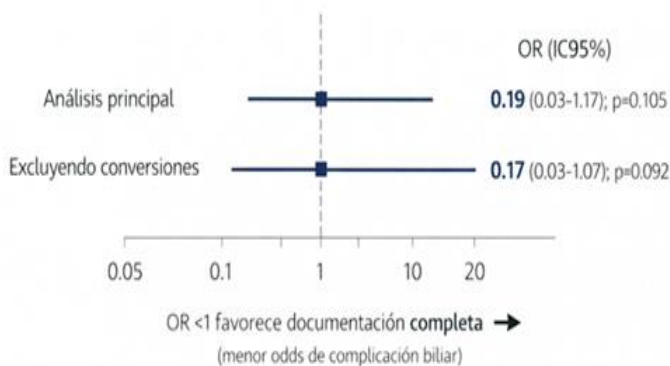


Figure 6: Odds ratios (OR) with 95% confidence intervals (CI) for biliary complications according to CVS documentation status (complete vs. incomplete), main analysis (n=406), and sensitivity analysis excluding

conversions to open surgery (n=400). OR <1 favors complete documentation (lower odds of biliary complications). Both estimates were non-significant, the and results were exploratory. CVS, Critical View of Safety.

The post-hoc statistical power was 32%, which was far below the conventional 80% threshold. Therefore, the non-significant result must be interpreted as uninformative with respect to the null hypothesis, not as evidence of the absence of an association. Additionally, the baseline imbalance precludes causal interpretation: the incomplete documentation group concentrated patients with older age, higher ASA status, and greater surgical complexity, all of which are independently associated with higher BDI risk^{5,6,25}. Without multivariable adjustment, residual confounding cannot be excluded due to the scarcity of events.

Sensitivity analyses

Exclusion of the six converted cases (analytical n = 400) did not alter the primary direction of effect (OR = 0.17; 95% CI: 0.028–1.070; p = 0.092), confirming robustness. In the acute cholecystitis subgroup (n = 51), only one biliary event occurred, and formal inferential analysis was not performed.

Sample size for a confirmatory study

Using the observed baseline complication rate in the incomplete documentation group (4.26%), observed OR (0.19), and observed allocation ratio (1:7.6), a confirmatory prospective study with 80% power (two-sided $\alpha = 0.05$) would require 42 patients with incomplete documentation and 322 with complete documentation (total n = 364). With a balanced 1:1 design, 214 patients per group are required (total n = 428). At 90% power, the unbalanced design required a total of 483 participants (Table 3).

Table 3: Sample size estimates for a confirmatory prospective study under different effect size and power scenarios

Target OR	Power (%)	Incomplete CVS (n)	Complete CVS (n)	Total N
0.19 (observed)	80	42	322	364
0.19 (observed)	90	57	426	483
0.30 (attenuated)	80	107	813	920
0.19 (1:1 design)	80	214	214	428

Calculations were based on the Kelsey formula. Reference complication rate: 4.26% (incomplete CVS group). Alpha: 0.05 (two-sided). The exposed: unexposed ratio was 1:7.6 unless otherwise specified. OR: odds ratio.

Discussion

The main contribution is not to establish a protective effect of CVS documentation, which simply cannot be done at this level of evidence, but to generate a quantitative institutional baseline describing what codification of CVS looks like in operative notes at a Mexican secondary-level hospital and the formulation of rational design parameterizations necessary for future confirmatory studies. The high rate of documentation (88.4%) is promising from the process-monitoring perspective of an institution. However, ^{16, 17, 18} point out the established discordance between documentation and technical execution, making caution in interpreting this number important. As shown in videographic validation studies, merely having a written statement that the CVS was achieved is not valid proof of correct anatomical realization. This is a driving force to plan a prospective study with objective intraoperative photographic or videographic documentation. Nonetheless, documentation quality remains a legitimate institutional quality metric. The failure of this particular set of omissions, where the most commonly missing element was lower gallbladder separation, is in keeping with other video-validated observations from other centers ²⁴, and is likely indicative of a real technical weakness. Targeted

interventions (e.g., standard operative notes, planned surgical teaching, and frequent audits of documentation) represent practical quality enhancement strategies. The global complication rate of 1.23% is within the acceptable error rate for current laparoscopic cholecystectomy series ^{5,14}. The fact that there were no major biliary injuries (Strasberg C–E) during the duration of the study is good, but the passive follow-up method may have contributed to the under-recognition of minor events controlled for outside the protocol. This research project has several limitations: (1) retrospective (due to the quality of operative notes), (2) no photographic or videographic validation at the intraoperative level, (3) a low event count limiting statistical power and multivariable adjustment, (4) baseline imbalance causing indication confounding, (5) use of passive follow-up limiting outcome capture, and (6) a single-center research design may limit generalizability. Strengths include ongoing case counting, a predefined set of operational classifications of the study participants, a formalized inter-rater reliability test (kappa = 0.84), prespecified sensitivity analyses, and clear reporting of analytical limitations.

Conclusions

In this retrospective institutional cohort of 406 laparoscopic cholecystectomies performed at Clínica Hospital “Mérida” Susulá Commisary, ISSSTE, full documentation of the Critical View of Safety was available in 88.4% of operative notes, exceeding several international benchmarks. Incomplete patient

documentation was a subset of patients with the highest clinical complexity and procedural difficulty; therefore, causality was not a direct comparison of the outcomes.

A reduced biliary complication rate was found in those with sufficient documentation, but in a non-significant manner, which should be an exploratory finding limited by a low number of events, poor post-hoc statistical power (32%), and the impossibility of controlling for key confounders. These findings are important at three levels: they set an institutional baseline for surgical quality auditing, highlight opportunities for enhanced operating note quality through templates and educational reinforcement, and provide empirical parameters to enable the establishment of a well-powered prospective study.

The next logical step is a prospective study based on objective intraoperative documentation to determine whether obtaining the CVS and systematically documenting it is independently associated with a lower incidence of biliary complications.

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