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Intraoperative Time-Out to Promote the Implementation of the Critical View of Safety in Laparoscopic Cholecystectomy: A Video-Based Assessment of 343 Procedures

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Brief title: Time-Out for Safe Cholecystectomy

Background: The critical view of safety (CVS) is poorly adopted in surgical practices although it is ubiquitously recommended to prevent major bile duct injuries during laparoscopic cholecystectomy (LC). This study aims to investigate whether performing a short intraoperative time out can improve CVS implementation.

Study design: In this before versus after study, surgeons performing LCs at an academic center were invited to use a 5-second long time out to verify CVS before dividing the cystic duct (5-second rule). The primary aim was to compare the rate of CVS achievement for LCs performed in the year before versus the year after implementation of the 5-second rule. The CVS achievement rate was computed after exclusion of bailout procedures using a mediated video-based assessment made by two independent reviewers. Clinical outcomes, LC workflows, and postoperative reports were also compared.

Results: 343 of the 381 LCs performed between December 2017 and November 2019 (171 before and 172 after implementation of the 5-second rule) were analyzed. The 5-second rule was associated with a significantly increased rate of CVS achievement (15.9 vs. 44.1% before vs. after the 5-second rule, respectively; $P<0.001$). Significant differences were also observed with respect to the rate of bailout procedures (8.2 vs. 15.7%; $P=0.04$), the median [IQR] time to clip the cystic duct or artery (00:17:26 [00:11:48, 00:28:35] vs. 00:23:12 [00:14:29, 00:31:45] duration; $P=0.007$), and the rate of postoperative CVS reporting (1.3 vs. 28.8%; $P<0.001$). Postoperative morbidity was comparable (1.8 vs. 2.3%; $P=0.68$).

Conclusion: Performing a short intraoperative time out was associated with an improved CVS achievement rate. Systematic intraoperative cognitive aids should be studied to sustain the uptake of guidelines.

Key words: Surgical safety; Video-based assessment; Intraoperative time out; Critical view of safety; Bile duct injury; Laparoscopic cholecystectomy.

Abbreviations:

Bile duct injury	BDI
Critical view of safety	CVS
European Association of Endoscopic Surgery	EAES
Interquartile range	IQR
Intraoperative cholangiogram	IOC
Laparoscopic cholecystectomy	LC
Quality improvement	QI
Society of American Gastrointestinal and Endoscopic Surgeons	SAGES
Video-based assessment	VBA

Introduction

Surgical societies are united (1) in promoting research, education, and quality improvement (QI) initiatives to prevent bile duct injuries (BDIs) since this adverse event of laparoscopic cholecystectomy (LC) negatively impacts patients' survival (2) and quality of life (3), surgeons' careers (4, 5), and health systems' expenditures (6).

Achieving a critical view of safety (CVS) (7) in LC is widely recommended to prevent the visual perceptual illusion that causes 97% of major BDIs (8). However, the incidence of BDIs in LC remains stable at 0.3 to 1.5% (2, 9), a frequency at least three times higher than commonly reported for open cholecystectomy 30 years ago (10). In addition, the complexity of BDIs seems to have increased over time, with a trend towards more proximal injuries (11).

The frequently described poor uptake and subjective assessment of formal CVS in surgical practices (12–14) might account for the non-decreasing rate of BDIs (9). To promote the implementation of CVS, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Safe Cholecystectomy Program (15) and the recent multi-society guidelines on BDI prevention suggested using a momentary pause to recall and verify the CVS before clipping and dividing the cystic duct or artery (1). However, this recommendation was based solely on the opinion of experts.

It has been hypothesized that performing an intraoperative time out could serve as a procedural cognitive aid to recall and apply essential safety measures such as CVS, in the same way as the implementation of the surgical safety checklist (16) serves as a cognitive aid in the perioperative setting (17).

The aim of this study was to evaluate the effect of performing a 5-second long intraoperative time out on CVS achievement rate. To this end, a video-based assessment

(VBA) (18) of LC procedures performed in the year before and the year after a quality improvement intervention was performed.

Methods

This QI study was approved by the local medical research and ethical committee (*CE-2020-178*). The study uses a before *vs.* after comparative design. It is reported according to the Standards for QQuality Improvement Reporting Excellence (SQUIRE) guidelines (18).

Participants

To facilitate QI research and education, patients undergoing surgery in the Department of General, Digestive, and Endocrine Surgery of the *Nouvel Hôpital Civil* (Strasbourg, France) are routinely asked to give their informed consent for video data recording. Prospectively collected data from patients over 18 years of age and undergoing a LC for benign conditions between November 2017 and November 2019 were analyzed retrospectively.

Quality improvement intervention

As part of an institution-wide initiative to promote the implementation of best practices to ensure a safe LC (19–24), two authors of the study (PM and NP) were invited to give a short presentation during the morning surgical staff meeting. During this brief intervention, the authors asked surgeons to verify CVS achievement in a 5-second long intraoperative time out before clipping or dividing the cystic duct or artery. To foster attention and reinforce the concept (25), surgical operators were asked to indicate and verbalize CVS criteria to their assistant during the 5-second time out. This procedure was called the “5-second rule”.

Surgeons that were not present on the day of the intervention were informed about the 5-second rule. However, no subsequent meetings were organized in order to assess the long-

term effect of a single QI intervention. In addition, during the study period, surgical operators were not exposed to further education on safe cholecystectomy to prevent the introduction of confounders.

Video-based assessment

Laparoscopic videos were streamed, recorded, and retrieved connecting the OR1™ (Karl Storz, Tuttlingen, Germany), an integration solution for operating rooms, to the hospital information system.

Videos of LC procedures performed in the year before and the year after the 5-second rule were independently reviewed by a surgical trainee (PM) and a hepatobiliary pancreatic surgeon (TU) with over 300 LCs of experience. Video reviewers were not involved in clinical care during the study period and were not informed about the time period (i.e., before or after) from when LC procedures occurred.

Reviewers time-stamped the beginning, the first application of a clip in the hepatocystic triangle, and the end of each procedure. Following extensive training, the two independent reviewers assessed the achievement of CVS criteria according to a previously validated method (21). According to this method, the 3 CVS criteria were assessed analyzing videos of LC procedures, most often showing anterior and posterior views of the hepatocystic triangle, and marked as either achieved or not, in a binary fashion (21); if all 3 criteria were marked as achieved (i.e., 3/3), CVS was then considered achieved. CVS criteria were defined as follows: the view of only 2 tubular structures, the cystic duct and the cystic artery, entering the gallbladder (2-structure criterion, C1); a hepatocystic triangle well dissected from adipose and connective tissues (hepatocystic triangle criterion, C2); and the separation of the lowest part of the gallbladder from the cystic plate (cystic plate criterion, C3) (7). In the event of disagreement on CVS assessment, mediation was conducted by a third study author (BD) with over 3500 LCs of experience. Finally, video reviewers annotated whether an

intraoperative cholangiogram (IOC) was performed and if surgical operators bailed out from a conventional retrograde cholecystectomy to a fundus first cholecystectomy, subtotal cholecystectomy or converted/aborted the laparoscopic procedure (collectively referred to as bailout procedures).

Outcomes and statistical analysis

The primary aim of the study was to compare the rate of CVS achievement in the year before versus the year after implementation of the 5-second rule. The CVS achievement rate was computed using a mediated VBA of CVS criteria, after exclusion of fundus first cholecystectomy, subtotal cholecystectomy, and converted/aborted procedures.

Secondary objectives were to compare the LC procedures performed before versus after the 5-second rule regarding clinical outcomes, bailout procedures, IOC, operating times, and postoperative CVS reporting.

Baseline characteristics, operative reports, and clinical outcomes data were collected for each patient from electronic medical records; all other endpoints were annotated on LC videos.

Major bile duct injuries were defined as the transection or significant laceration of the common hepatic duct or the common bile duct (26).

Duration was reported using the hours:minutes:seconds (HH:MM:SS) format.

Inter-rater agreement between reviewers assessing CVS criteria in videos was quantified in terms of Cohen's *kappa*. The level of agreement was defined as follows: almost perfect ($\kappa > 0.90$); strong ($\kappa 0.80-0.90$); moderate ($\kappa 0.60-0.79$); weak ($\kappa 0.40-0.59$); minimal ($\kappa 0.21-0.39$); or no agreement ($\kappa 0-0.20$) (27).

Categorical variables were reported with integers and frequency (%) and were compared using a two-sided Fisher's exact test. Normally distributed continuous variables were reported with means (\pm standard deviation) and compared using a two-tailed

independent samples t-test whereas not normally distributed continuous variables were reported with medians and interquartile range (IQR, 25th percentile, 75th percentile) and compared using the Mann-Whitney rank test. A complete case analysis was used. Findings with two-sided p values <0.05 were considered statistically significant.

All analyses were implemented in Python using the SciPy library (28) consisting of a package for statistical functions.

Results

The 5-second rule QI intervention took place on December 4, 2018. A total of 381 LC procedures were logged during the 2-year long study period. After exclusion of 6 procedures with incomplete video recordings and 32 procedures for which clinical information could not be collected, 171 and 172 LC procedures performed the year before and the year after the 5-second rule, respectively, by 17 different surgeons were included in the study. The inter-rater agreement between reviewers assessing each of the 3 CVS criteria in the 343 LC videos was moderate, with Cohen's κ ranging from 0.72 to 0.78.

Patient and disease characteristics

After the implementation of the 5-second rule, significantly more patients were operated on for a previous acute cholecystitis (39.2 vs. 51.7% before vs. after the 5-second rule, respectively; $P=0.02$) and had higher aspartate transaminase (22 [18, 28] vs. 24 [19, 34] U/L; $P=0.04$) and gamma-glutamyl transferase (27 [18, 53] vs. 38 [19, 93] U/L; $P=0.02$) levels. A comparison of patients, diseases, and surgical operators characteristics is shown in Table 1.

LC procedures

Overall, surgical operators bailed out from conventional LCs more frequently after the implementation of the 5-second rule (8.2 vs. 15.7% before vs. after the 5-second rule,

respectively; $P=0.04$). Specifically, a greater number of surgeons switched to a fundus first cholecystectomy (4.1 vs. 12.8 %; $P=0.006$) rather than opting for a subtotal cholecystectomy (1.2 vs. 1.7%; $P>0.99$) or to abort the LC (2.9 vs. 1.2%; $P=0.28$). The rate of IOC was comparable between the study groups (7.6 vs. 6.4%; $P=0.68$).

Excluding bailout procedures, the CVS achievement rate increased from 25 of 157 (15.9%) procedures to 64 of 145 procedures (44.1%) after the implementation of the 5-second rule ($P<0.001$). The greatest improvements were noted for the achievement of the cystic plate criterion (26.8 vs. 64.1% before vs. after the 5-second rule, respectively; $P<0.001$). However, the hepatocystic triangle criterion (32.5 vs. 59.3%; $P<0.001$) and the 2-structure criterion (54.1 vs. 71.7%; $P=0.002$) were also significantly more achieved after the implementation of the intraoperative time out. The evolution of the CVS achievement rate over the 2-year study period can be seen in Figure 1.

The CVS achievement rate significantly improved among attending surgeons (30.0 vs. 51.8% before vs. after the 5-second rule, respectively; $P=0.02$) and senior residents (7.2 vs. 39.3%; $P<0.001$) after the implementation of the 5-second rule. In addition, attending surgeons achieved CVS significantly more often than senior residents before the quality improvement intervention (30.0 vs. 7.2% attending surgeons and senior residents, respectively; $P<0.001$). However, this difference was no longer significant after implementing the 5-second rule (51.8 vs. 39.3%; $P=0.17$). These results are shown in Figure 2.

Finally, operating times were comparable (00:46:11 [00:32:37, 01:07:13] vs. 00:53:03 [00:36:09, 01:12:59] duration before vs. after the 5-second rule, respectively; $P=0.09$). However, surgeons spent more time before applying clips in the hepatocystic triangle after the implementation of the 5-second rule (00:17:26 [00:11:48, 00:28:35] vs. 00:23:12 [00:14:29, 00:31:45] duration; $P=0.007$).

CVS reporting

All but 27 missing operative reports were retrieved. After exclusion of operative reports of bailout procedures, 151 and 118 reports respectively from before and after the 5-second rule were analyzed. Most of the operative reports in both study groups described the dissection of Calot's triangle (98.0 vs. 98.3% before vs. after the 5-second rule, respectively; $P>0.99$) and the identification of the cystic artery and the cystic duct, namely the 2-structure criterion of CVS (96.7 vs. 97.5%; $P>0.99$). However, explicit CVS reporting (1.3 vs. 28.8%; $P<0.001$), description of the hepatocystic triangle criterion (0.0 vs. 22.0%; $P<0.001$), and the cystic plate criterion (0.0 vs. 22.0 %; $P<0.001$) increased significantly after the 5-second rule.

LC clinical outcomes

No major BDIs or fatalities occurred during the study period. Length of hospital stay (0 [0, 2] vs. 0 [0, 2] days before vs. after the 5-second rule, respectively; $P=0.97$), readmission rates (0.6 vs. 1.7%; $P=0.62$), and reintervention rates (0.6 vs. 0.6%; $P>0.99$) were comparable among study groups (Table 1). Postoperative morbidity was also comparable (1.1 vs. 2.3%; $P=0.68$), with an overall bile leak rate of 5 in 343 LCs (1.5%). Of note, CVS was not achieved in any of these procedures. Details of patients who experienced postoperative morbidity in the study period can be found in Table 2.

Discussion

The present quality improvement (QI) study compared the before versus after implementation periods for the 5-second rule intraoperative cognitive aid in a series of 343 LC videos using a validated protocol for the assessment of the CVS (21). In this study, implementing a 5-second long intraoperative time out to verify the CVS before dividing the cystic duct led to an approximately threefold increase in the average CVS achievement rate (from 15.9 to 44.1%, as shown in Figure 1). Improvements were consistent across the 3 CVS

criteria and across surgical operators with different levels of experience, with senior residents and attending surgeons achieving CVS at similar rates after the quality improvement intervention (Figure 2). In addition, the more frequent decision to bail out to a fundus first cholecystectomy, the longer time taken to carefully dissect the hepatocystic triangle, and the increased rate of postoperative CVS reporting after implementation of the 5-second rule suggest an increased awareness towards CVS principles and the so-called “Culture of Safety in Cholecystectomy” (29).

These findings are consistent with the results of a previous pilot study evaluating the effect of comprehensive education and a CVS time out in a series of 101 LC cases performed over a 5-month study period (30) and support the recommendations (1, 31) on the importance of performing an intraoperative pause to implement best practices in LC.

Our study results include observations that deserve further investigations. With respect to overall LC safety, the fact that CVS-aware surgeons seem to have a lower threshold to bail out from difficult procedures may be positive, as bailing out is recommended when CVS cannot be safely achieved after reasonable attempts (1, 20). However, in the present series, surgeons have more often opted for a fundus first cholecystectomy rather than a subtotal cholecystectomy. The best strategy to achieve CVS, the right threshold for bailing out and the best alternative to a standard LC are a matter of fervid scientific debate (1, 32–34), and future studies should be designed to address such points.

With respect to the CVS, the achievement rate before the 5-second rule intervention was low, an observation also reported recently (14). Soon after the QI intervention, the rate of CVS achievement peaked to almost 70% but then stabilized at approximately 44% at 1 year (Figure 1). The peak suggests that operating surgeons know how to correctly implement CVS and that performing a short intraoperative time out helps to consistently achieve this safety

view. On the other hand, the reduction in CVS achievement over time may indicate a decline in the application of the 5-second rule. Overall, the inconsistent implementation of CVS together with its subjective assessment and reporting (12–14) might hamper efforts to prevent BDIs in LC. These limitations have traditionally been addressed mostly through education. To favor implementation of best practices in surgical care, cholecystectomy-specific intraoperative checklists (35) and stepwise guidelines for difficult cases (36) have also been developed. Today, surgeons and computer scientists from various institutions including ours have teamed up and embarked on a series of surgical data science studies (37–39). These multidisciplinary collaborations are developing context-aware (40) computer vision solutions using artificial intelligence (AI) to guide towards safe areas of dissection (41), univocally assessing major process measures such as CVS (23) and objectively documenting critical moments of procedures with concise videos (24), with the overall objective of promoting the consistency, efficiency, and safety of surgery.

Finally, this study has some limitations. From a methodological standpoint, the use of VBA is both a merit and a drawback. VBA is increasingly recognized as a valuable approach to objectively study intraoperative surgical performance (42, 43), especially when operative reports are known to be unreliable as in the case of the CVS (12, 44). However, the potential Hawthorne effect (i.e., behavior changes due to the subjects' awareness of being observed, also known as the clinical trial effect) prevents us from knowing to what extent the improvements in CVS achievement rates were either due to the operators' awareness of being recorded or to the 5-second rule. This is especially true since the application of the 5-second rule by surgeons was not appropriately studied through in-person observations in the operating room. The absence of an observer in the operating room and the fact that our institution systematically records surgical procedures for QI and education certainly

decreases the Hawthorne effect. However, the extent to which this is the case is unknown so far (45).

Even though included surgeons are regularly involved in research projects around safe cholecystectomy and were not exposed to further education on CVS during the study period, another limitation of this study lies in the inability to completely exclude or quantify to what extent the positive results were due to an educational effect of 5-second rule intervention.

No randomization or other active strategies to guarantee blinding of video reviewers were implemented. However, the facts that video reviewers were not involved in clinical care during the study period, were not informed about the allocation of the procedures, and systematically assess LC videos for surgical data science studies requiring highly consistent labels, should decrease the changes of unintentional biases of video assessors.

From a clinical perspective, LC difficulty is highly variable and influences the ability to achieve CVS. While it cannot be completely excluded that this variability has influenced our findings, factors known to correlate with difficult cases did not differ between study groups, except for a higher proportion of patients operated on for a previous acute cholecystitis after the implementation of the 5-second rule. In this regard, the more frequent decision to bail out to a fundus first cholecystectomy found after the implementation of the 5-second rule might be related not only to a greater awareness towards the principles of safe cholecystectomy but also to the occurrence of more difficult cases in this study period.

In addition, surgeon experience and attitude might have played a role in the CVS achievement rate. While it was found that senior residents and attending surgeons both improved, it was unfortunately not possible to rigorously study the individual surgeon effect.

A further limitation lies in the fact that this study was not adequately powered to detect a difference in the incidence of major BDI. This is a limitation common to most studies on BDIs in LC, as an impractical large number of patients would be necessary to

identify a statistically significant difference in the incidence of such a rare adverse event (19). However, the CVS achievement rate, which is the primary endpoint of this study, is considered to be an acceptable process measure of LC safety given the widely accepted correlation between this critical view and the prevention of major BDIs. Of note, the fact that other clinical outcomes were comparable between study groups or the observation that CVS was not achieved in the 5 procedures complicated by a bile leak should neither speak against or in favor of CVS, as this critical view was designed and validated to prevent the visual perceptual illusion most often leading to the partial or complete transection of the common hepatic duct or the common bile duct (7, 8), the lesions defined as major BDI in this manuscript.

Lastly, as the vast majority of LC cases included were performed in the elective setting due to video recording constraints, further research is required to confirm the impact of the 5-second rule time out in the acute setting.

Conclusions

The 5-second rule time out was significantly associated with an increased CVS achievement rate. Overall, the findings of the present study provide a practical strategy to improve the uptake of safety principles in LC. Future studies should investigate the use of intraoperative cognitive aids and develop solutions to sustain their positive effect over time.

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References

1. Brunt LM, Deziel DJ, Telem DA, et al. Safe cholecystectomy multi-society practice guideline and state-of-the-art consensus conference on prevention of bile duct injury during cholecystectomy. *Surg Endosc* 2020;34:2827–2855.
2. Törnqvist B, Strömberg C, Persson G, Nilsson M. Effect of intended intraoperative cholangiography and early detection of bile duct injury on survival after cholecystectomy: population based cohort study. *BMJ* 2012;345:e6457.
3. Booiij KAC, de Reuver PR, van Dieren S, et al. Long-term Impact of Bile Duct Injury on Morbidity, Mortality, Quality of Life, and Work Related Limitations. *Ann Surg* 2018;268:143–150.
4. Alkhaffaf B, Decadt B. 15 years of litigation following laparoscopic cholecystectomy in England. *Ann Surg* 2010;251:682–685.
5. Fletcher R, Cortina CS, Kornfield H, et al. Bile duct injuries: a contemporary survey of surgeon attitudes and experiences. *Surg Endosc* 2020;34:3079-3084.
6. Berci G, Hunter J, Morgenstern L, et al. Laparoscopic cholecystectomy: first, do no harm; second, take care of bile duct stones. *Surg Endosc* 2013;27:1051–1054.
7. Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. *J Am Coll Surg* 1995;180:101–125.
8. Way LW, Stewart L, Gantert W, et al. Causes and prevention of laparoscopic bile duct injuries: analysis of 252 cases from a human factors and cognitive psychology perspective. *Ann Surg* 2003;237:460-469.

9. Pucher PH, Brunt LM, Davies N, et al. Outcome trends and safety measures after 30 years of laparoscopic cholecystectomy: a systematic review and pooled data analysis. *Surg Endosc* 2018;32:2175–2183.
10. Anon. A Prospective Analysis of 1518 Laparoscopic Cholecystectomies: The Southern Surgeons Club. *N Engl J Med* 1991;324:1073–1078.
11. Chuang KI, Corley D, Postlethwaite DA, et al. Does increased experience with laparoscopic cholecystectomy yield more complex bile duct injuries? *Am J Surg* 2012;203:480–487.
12. Nijssen MAJ, Schreinemakers JMJ, Meyer Z, et al. Complications after laparoscopic cholecystectomy: a video evaluation study of whether the critical view of safety was reached. *World J Surg* 2015;39:1798–1803.
13. Stefanidis D, Chintalapudi N, Anderson-Montoya B, et al. How often do surgeons obtain the critical view of safety during laparoscopic cholecystectomy? *Surg Endosc* 2017;31:142–146.
14. Korndorffer Jr JR, Hawn MT, Spain DA, et al. Situating Artificial Intelligence in Surgery: A Focus on Disease Severity. *Ann Surg* 2020;272:523–528.
15. Society of American Gastrointestinal and Endoscopic Surgeons. The SAGES Safe Cholecystectomy Program - Strategies for Minimizing Bile Duct Injuries. SAGES. Available at: <https://www.sages.org/safe-cholecystectomy-program/>. Accessed October 8, 2020.
16. van Klei WA, Hoff RG, van Aarnhem EEHL, et al. Effects of the Introduction of the WHO “Surgical Safety Checklist” on In-Hospital Mortality: A Cohort Study. *Ann Surg* 2012;255:44–49.

17. Merry AF, Mitchell SJ. Advancing patient safety through the use of cognitive aids. *BMJ Qual Saf* 2016;25:733–735.
18. Ogrinc G, Davies L, Goodman D, et al. SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. *Am J Crit Care* 2015;24:466–473.
19. Conrad C, Wakabayashi G, Asbun HJ, et al. IRCAD recommendation on safe laparoscopic cholecystectomy. *J Hepato-Biliary-Pancreat Sci* 2017;24:603–615.
20. Felli E, Mascagni P, Wakabayashi T, et al. Feasibility and value of the critical view of safety in difficult cholecystectomies. *Ann Surg* 2019;269:e41.
21. Mascagni P, Fiorillo C, Urade T, et al. Formalizing video documentation of the Critical View of Safety in laparoscopic cholecystectomy: a step towards artificial intelligence assistance to improve surgical safety. *Surg Endosc* 2020;34:2709–2714.
22. Mascagni P, Spota A, Felli E, et al. Conclusive Identification and Division of the Cystic Artery: A Forgotten Trick to Optimize Exposure of the Critical View of Safety in Laparoscopic Cholecystectomy. *J Am Coll Surg* 2019;229:e5–e7.
23. Mascagni P, Vardazaryan A, Alapatt D, et al. Artificial Intelligence for Surgical Safety: Automatic Assessment of the Critical View of Safety in Laparoscopic Cholecystectomy Using Deep Learning. *Ann Surg*. In Press 2020.
24. Mascagni P, Alapatt D, Urade T, et al. A Computer Vision Platform to Automatically Locate Critical Events in Surgical Videos: Documenting Safety in Laparoscopic Cholecystectomy. *Ann Surg*. In Press 2020.

25. Shinohara K, Naito H, Matsui Y, Hikono M. The effects of “finger pointing and calling” on cognitive control processes in the task-switching paradigm. *Int J Ind Ergon* 2013;43:129–136.
26. Melton GB, Lillemoe KD, Cameron JL, et al. Major bile duct injuries associated with laparoscopic cholecystectomy: effect of surgical repair on quality of life. *Ann Surg* 2002;235:888–895.
27. McHugh ML. Interrater reliability: the kappa statistic. *Biochem Medica Medicinska naklada* 2012;22:276–282.
28. Virtanen P, Gommers R, Oliphant TE, et al. SciPy 1.0: fundamental algorithms for scientific computing in Python. *Nat Methods* 2020;17:261–272.
29. Strasberg SM. A teaching program for the “culture of safety in cholecystectomy” and avoidance of bile duct injury. *J Am Coll Surg* 2013;217:751.
30. Chen CB, Palazzo F, Doane SM, et al. Increasing resident utilization and recognition of the critical view of safety during laparoscopic cholecystectomy: a pilot study from an academic medical center. *Surg Endosc* 2017;31:1627–1635.
31. Pucher PH, Brunt LM, Fanelli RD, et al. SAGES expert Delphi consensus: critical factors for safe surgical practice in laparoscopic cholecystectomy. *Surg Endosc* 2015;29:3074–3085.
32. Iwashita Y, Hibi T, Ohyama T, et al. Delphi consensus on bile duct injuries during laparoscopic cholecystectomy: an evolutionary cul-de-sac or the birth pangs of a new technical framework? *J Hepato-Biliary-Pancreat Sci* 2017;24:591–602.

33. Strasberg SM, Pucci MJ, Brunt LM, Deziel DJ. Subtotal Cholecystectomy–“Fenestrating” vs “Reconstituting” Subtypes and the Prevention of Bile Duct Injury: Definition of the Optimal Procedure in Difficult Operative Conditions. *J Am Coll Surg* 2016;222:89–96.
34. Cengiz Y, Lund M, Jänes A, et al. Fundus first as the standard technique for laparoscopic cholecystectomy. *Sci Rep* 2019;9:18736.
35. Connor SJ, Perry W, Nathanson L, et al. Using a standardized method for laparoscopic cholecystectomy to create a concept operation-specific checklist. *HPB* 2014;16:422–429.
36. Wakabayashi G, Iwashita Y, Hibi T, et al. Tokyo Guidelines 2018: surgical management of acute cholecystitis: safe steps in laparoscopic cholecystectomy for acute cholecystitis (with videos). *J Hepato-Biliary-Pancreat Sci* 2018;25:73–86.
37. Maier-Hein L, Vedula SS, Speidel S, et al. Surgical data science for next-generation interventions. *Nat Biomed Eng* 2017;1:691–696.
38. Maier-Hein L, Eisenmann M, Sarikaya D, et al. Surgical Data Science -- from Concepts to Clinical Translation. *ArXiv* 2020;2011.02284.
39. Mascagni P, Padoy N. OR black box and surgical control tower: Recording and streaming data and analytics to improve surgical care. *J Visc Surg*. In Press 2020.
40. Vercauteren T, Unberath M, Padoy N, Navab N. CAI4CAI: The Rise of Contextual Artificial Intelligence in Computer-Assisted Interventions. *Proc IEEE* 2019;108:198–214.
41. Madani A, Namazi B, Altieri MS, et al. Artificial Intelligence for Intraoperative Guidance: Using Semantic Segmentation to Identify Surgical Anatomy During Laparoscopic Cholecystectomy. *Ann Surg*. In Press 2020.

42. Feldman LS, Pryor AD, Gardner AK, et al. SAGES Video-Based Assessment (VBA) program: a vision for life-long learning for surgeons. *Surg Endosc* 2020;34:3285–3288.
43. Jung JP, Zenati MS, Dhir M, et al. Use of video review to investigate technical factors that may be associated with delayed gastric emptying after pancreaticoduodenectomy. *JAMA Surg* 2018;153:918–927.
44. Rawlings A, Hodgett SE, Matthews BD, et al. Single-incision laparoscopic cholecystectomy: initial experience with critical view of safety dissection and routine intraoperative cholangiography. *J Am Coll Surg* 2010;211:1–7.
45. Choi WJ, Jung JJ, Grantcharov TP. Impact of Hawthorne effect on healthcare professionals: a systematic review. *Univ Tor Med J* 2019;96:21–32.
46. Dindo D, Demartines N, Clavien P-A. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004;240:205-213.

Tables

Table 1. Comparison Between Patient and Disease Characteristic, Surgical Operator

Experience, and Clinical Outcomes of Patients Operated on Before Vs After the 5-Second

Rule

Variable	Before (n = 171)	After (n = 172)	p Value
Patient characteristic			
Sex, female, n (%)	104 (60.8)	101 (58.7)	0.74
Age, y, median (IQR)	54 (42, 69)	58 (41, 69)	0.41
BMI, kg/m ² , median (IQR)	27 (24, 32)	28 (25, 32)	0.82
ASA, median (IQR)	2 (1, 2)	2 (1, 2)	0.80
Elective, n (%)	166 (97.1)	167 (97.1)	≥0.99
Previous UGI surgery, n (%)	13 (7.6)	14 (8.1)	≥0.99
Previous ERCP, n (%)	23 (13.5)	27 (15.7)	0.65
Previous percutaneous drain, n (%)	8 (4.7)	15 (8.7)	0.19
Indication for LC[‡], n (%)			
AC	4 (2.3)	4 (2.3)	≥0.99
Previous AC	67 (39.2)	89 (51.7)	0.02
Symptomatic cholelithiasis	80 (46.8)	68 (39.5)	0.19
Previous choledocholithiasis	23 (13.5)	25 (14.5)	0.88
Acute biliary pancreatitis	1 (0.6)	1 (0.6)	≥0.99
Previous pancreatitis	27 (15.8)	19 (11.1)	0.21
Preoperative laboratory finding, median (IQR)			
Leukocytes (cells/μL, x0.001 to 10 ⁹ /L) [§]	7110 (5797, 8663)	6760 (5405, 8570)	0.29
ALT (U/L, x0.0167 to μkat/L)	23 (18, 35)	27 (19, 42)	0.11
AST (U/L)	22 (18, 28)	24 (19, 34)	0.04
ALP (U/L)	76 (61, 92)	77 (63, 97)	0.18
GGT (U/L)	27 (18, 53)	38 (19, 94)	0.02
CRP (mg/dL, x10 to mg/L)	0.4 (0.2, 0.7)	0.4 (0.3, 1.3)	0.13
TB (mg/dL, x17.104 to μmol/L)	0.58 (0.39, 0.77)	0.53 (0.40, 0.76)	0.62
DB (mg/dL)	0.18 (0.12, 0.25)	0.20 (0.13, 0.31)	0.07
IB (mg/dL)	0.36 (0.23, 0.55)	0.37 (0.26, 0.53)	0.84
Surgical operators			
Seniority, senior resident ^l , n (%)	106 (62.0)	108 (62.8)	0.91
Postoperative outcomes*			
Mortality, n (%)	0	0	≥0.99
Morbidity, n (%)	2 (1.2)	4 (2.3)	0.68
Readmission, n (%)	1 (0.6)	3 (1.7)	0.62
Reintervention, n (%)	1 (0.6)	1 (0.6)	≥0.99
LOS, d, median (IQR)	0 (0, 2)	0 (0, 2)	0.97

[‡]Patients may have more than 1 indication for surgery

[§]Laboratory values are reported using conventional units of measure; conversion factors to the relevant Système International (SI) unit are reported at first mention.

[†]The remaining procedures were all performed by attending surgeons.

*Patients were followed-up for 30 days after operation; however, eventual later complaints were noted in electronic health records, the source used to retrieve information on clinical outcomes including morbidity.

Categorical variables were reported with integers and frequency (%) and were compared using a two-sided Fisher's exact test. Normally distributed continuous variables were reported with means (\pm SD) and compared using a 2-tailed independent samples *t*-test, whereas not normally distributed continuous variables were reported with median and interquartile range (25th percentile, 75th percentile) and compared using the Mann-Whitney rank test. AC, acute cholecystitis; ALP, alkaline phosphatase; ALT, alanine aminotransferase; ASA, American Society of Anesthesiologist score; surgery; AST; aspartate transaminase; CRP, C-reactive protein; DB, direct/conjugated bilirubin; ERCP, endoscopic retrograde cholangiopancreatography; GGT, gamma-glutamyl transferase; IB, indirect/unconjugated bilirubin; LOS, length of hospital stay; TB, total bilirubin; UGI, upper gastrointestinal.

Table 2. Description of Patients Who Experienced Postoperative Morbidity During the Study

Period

Study group, indication for LC, CVS, or bailout procedure	Operative time*	Adverse event (if BDI, Strasberg type[†])	Clavien-Dindo grade[‡]	Treatment
Before, previous AC, previous pancreatitis, not achieved	01:30:00	BDI (A)	IIIb	Laparoscopic suture of Luschka's duct
Before, previous AC, previous pancreatitis, converted	02:52:00	BDI (A)	IIIb	Percutaneous drain, ERCP stenting
After, previous AC, previous pancreatitis, not achieved	01:00:00	BDI (A)	IIIb	Percutaneous drain
After, symptomatic cholelithiasis, not achieved	00:32:00	BDI (C)	IIIb	Percutaneous drain, laparoscopic lavage
After, previous AC, previous pancreatitis, previous cholelithiasis, fundus first LC	02:00:00	Intra-abdominal hematoma	IIIb	Percutaneous drain
After, previous AC, previous cholelithiasis, subtotal LC	03:32:00	BDI (A)	IIIb	Percutaneous drain, ERCP stenting

*Operative times are reported using the hh:mm:ss format.

[†]Strasberg classification of bile duct injury (BDI) can be found in (7).

[‡]Dindo-Clavien grade classification of postoperative complications can be found in (46).

AC, acute cholecystitis; CVS, critical view of safety; ERCP, endoscopic retrograde cholangiopancreatography; LC, laparoscopic cholecystectomy; hh,mm,ss, hours, minutes, seconds.

Figure 1. Critical view of safety (CVS) achievement rates over the 2-year study. The vertical dashed red line marks the day of the 5-second rule quality improvement intervention; each dot on the continuous blue line represents the CVS achievement rate averaged over sets of 15 consecutive procedures and the dashed blue line denotes the average value before and after the 5-second rule CVS achievement rate.

Figure 2. Critical view of safety (CVS) achievement rate stratified by attending surgeons vs senior residents. Excluding bailout procedures, attending surgeons performed 60 laparoscopic cholecystectomies (LCs) before and 56 LCs after the QI intervention while senior residents performed 97 LCs before and 89 LCs after the QI intervention. The 5-second rule was associated with a significant improvement in CVS achievement rates among attending surgeons ($p = 0.02$) and senior residents ($p < 0.001$). Additionally, the gap in CVS achievement rates between attending surgeons and senior residents found before the QI intervention ($p < 0.001$) was no longer significant after implementation of the 5-second rule ($p = 0.17$).

Précis

Achieving a critical view of safety in laparoscopic cholecystectomy is recommended but inconsistently performed. This before-and-after study assessed 343 procedural videos and found that performing a short intraoperative time-out drastically increased the implementation of this recommended step for safe cholecystectomy.



