First-year Analysis of the Operating Room Black Box Study

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Objective: To characterize intraoperative errors, events, and distractions, and measure technical skills of surgeons in minimally invasive surgery practice.
Background: Adverse events in the operating room (OR) are common contributors of morbidity and mortality in surgical patients. Adverse events often occur due to deviations in performance and environmental factors. Although comprehensive intraoperative data analysis and transparent disclosure have been advocated to better understand how to improve surgical safety, they have rarely been done.
Methods: We conducted a prospective cohort study in 132 consecutive patients undergoing elective laparoscopic general surgery at an academic hospital during the first year after the definite implementation of a multiport data capture system called the OR Black Box to identify intraoperative errors, events, and distractions. Expert analysts characterized intraoperative distractions, errors, and events, and measured trainee involvement as main operator. Technical skills were compared, crude and risk-adjusted, among the attending surgeon and trainees.
Results: Auditory distractions occurred a median of 138 times per case [interquartile range (IQR) 96–190]. At least 1 cognitive distraction appeared in 84 cases (64%). Medians of 20 errors (IQR 14–36) and 8 events (IQR 4–12) were identified per case. Both errors and events occurred often in dissection and reconstruction phases of operation. Technical skills of residents were lower than those of the attending surgeon ($P = 0.015$).
Conclusions: During elective laparoscopic operations, frequent intraoperative errors and events, variation in surgeons' technical skills, and a high amount of environmental distractions were identified using the OR Black Box.

Keywords: adverse events, health services research, patient safety, quality improvement, surgery

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Surgical errors resulting in adverse events are significant causes of morbidity and mortality in the United States.[1,2] The majority of surgical adverse events occur in the operating room (OR), and about half are preventable.[3–7] The OR is a complex system in which small deviations in performance and environmental factors can accumulate to result in patient harm.[8,9] Industry sectors associated with high risk of accidents, such as the oil and aviation industries, have long identified both performance-related and systemic deviations as important contributory factors resulting in accidents.[10] Further, they have implemented a structured policy of risk analysis and management, which includes comprehensive data capturing and monitoring strategies to identify hazards before accidents could occur. In contrast, most surgical communities still rely on retrospective analysis of self-reported data from morbidity and mortality rounds, incident reports, and patient charts when evaluating adverse outcomes. However, this type of analysis is limited by recall bias, low compliance, and a lack of details.[11] Also, surgical teams often compensate for errors and system vulnerability before resulting in adverse events, but fail to disclose the errors after the operation. To fully evaluate the overall safety, intraoperative data should be continuously collected, analyzed, and discussed irrespective of whether adverse outcomes occurred.

Safety improvements depend on the ability to learn from previous mishaps. Yet, the process of operative care and the environment in which care is delivered often lack robust monitoring and evaluation, which has created a critical knowledge gap on how to improve safety in the OR. The purpose of intraoperative analysis is to facilitate open discussions among stakeholders to discover more effective ways to identify errors and prevent them from recurring.[12] This exchange of information, in turn, can help foster more responsible attitudes and heightened awareness towards safety among healthcare providers. A recent study demonstrated that patients who underwent surgery at hospitals with higher levels of safety attitude had better clinical outcomes.[13]

To facilitate this objective, our group developed the OR Black Box (Surgical Safety Technologies Inc., Toronto, ON, Canada), which continuously captures and synchronizes several sources of intraoperative data.[14] This technology allows a "fly on the wall" assessment of surgical operations without the intrusiveness of physically being present in the OR. Further, analysts perform accurate and detailed assessments postoperation without the limitations imposed by traditional retrospective analysis. The overall goal of this initiative is to identify factors that contribute to adverse events in the OR, implement targeted interventions to mitigate their harmful effects, and achieve improvements in patient safety. The objective of the present prospective cohort study during the first year after the definite implementation of the OR Black Box is to identify intraoperative errors, events, and distractions.

METHODS

Study Design

This prospective cohort study was conducted from May, 2015 to April, 2016, during which we examined data from consecutive laparoscopic general surgery performed at an academic center. A pilot period from April, 2014 to April, 2015 was used to optimize data capturing technique and allow time for healthcare providers to familiarize with the changed surroundings. The objectives were to characterize intraoperative distractions, errors, and events, and to compare technical skills of the attending surgeon to those of the trainees. The research ethics board at St. Michael's Hospital approved this study.

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Study Subjects

All elective laparoscopic general surgery procedures performed on adult patients (≥18 years old) that involved 1 surgeon (TG) during the study period were considered for inclusion. Cases with invalid or missing informed consent from the OR team members or patients were excluded. The surgical team included 1 attending surgeon, fellows, and residents.

Data Collection

Baseline patient characteristics were obtained from admission notes, preoperative anesthesia notes, and previous admission records through the electronic medical records. A piloted, standardized data abstraction form was used. The OR Black Box captures data from multiple sources.[14] During the present study period, only the audiovisual data were used. Audio feeds from microphones and video feeds from a laparoscopic and 2 panoramic wall-mounted room cameras were obtained. The data streams were then synchronized, encrypted, and stored in a secure server. Recording began when patients were fully draped and ended before the drapes were removed. The completed recording was assigned a random 5-digit case number linked to the patient log, which was kept in a secure server for 30 days, after which both the recording and the log were deleted. Two expert analysts, both board-certified surgeons who received at least 3 months of training to administer the protocol and had at least 2 years of experience in analyzing the intraoperative data, reviewed the recordings and identified intraoperative factors according to the standardized protocol.

Outcomes

Five types of intraoperative factors were identified, listed as follows:

1. Each case was divided into procedural phases, including access, exposure, dissection, resection, reconstruction, inspection, delay, secondary procedure, and closure (Fig. S1, http://links.lww.com/SLA/B438).
2. The analysts identified when the main operator role changed from the attending surgeon to a surgical trainee or vice versa.
3. Distractions were identified according to a modified version of the framework proposed by Sevdalis et al.[15]
4. Objective Structured Assessment of Technical Skills (OSATS) was used to measure 7 categories of surgeon's technical skills.[16] Each category was rated on a 5-point scale to give a total score out of 35. Raters provided an OSATS score for any significant time period (at least 15 minutes) in which 1 assumed the role of main operator.
5. Generic Error Rating Tool (GERT) was used to characterize intraoperative errors, events, and rectification measures.[17] Only laparoscopic video feeds were used to rate OSATS and GERT so that the analysts were blinded to the identity of surgeons.

Statistical Analysis

Descriptive statistics were performed on patient and procedure-level characteristics at baseline and intraoperative distractions using mean [standard deviation (SD)] and median [interquartile range (IQR)] for continuous data and frequency (%) analysis for categorical data. To report intraoperative errors and events, we first calculated the percentage of cases with at least 1 error or event over the number of eligible cases. Then, we determined the frequency of errors or events per eligible case and rates of errors or events per eligible procedure-hour, and summarized their distributions across cases using medians and IQRs. We used a linear mixed model[18,19] with random intercepts for individual surgeons and cases to compare OSATS scores among attending surgeon, fellows, and residents, crude and adjusted, for procedure type (eg, gastric bypass, cholecystectomy, etc), the patients' age, previous history of abdominal surgery, body mass index, and Charlson comorbidity index. We selected this model to accommodate for the complexities involved in clustered data, specifically to account for both within and between-surgeon type variability. We also used a univariable linear mixed model to determine differences in the percentage contribution of attending surgeon, fellows, and residents as main operator to cases. *P* values and 95% confidence intervals (CIs) are all 2-sided. Analyses were conducted using SAS 9.4 (SAS Institute Inc., Cary, NC) and R software version 3.4.2 (R foundation, Vienna, Austria).

TABLE 1. Patient and Procedure Characteristics

Patient characteristics	n = 132
Age, yrs, mean (SD)*	51 ± 14
Female sex, n (%)	98 (74)
Body mass index, median (IQR)†	41 (29–41)
Previous abdominal surgery, n (%)	76 (58)
Smoker, n (%)	55 (42)
Current smoker, n (%)	5 (4)
Missing, n (%)	2 (2)
Obstructive sleep apnea, n (%)	53 (40)
Diabetes, n (%)	24 (18)
With complication(s), n (%)	5 (4)
Solid tumor, n (%)	10 (8)
Metastatic, n (%)	1 (2)
Liver disease, n (%)	2 (2)
Peptic ulcer disease, n (%)	2 (2)
Myocardial infarction, n (%)	2 (2)
Congestive heart failure, n (%)	1 (1)
Peripheral vascular disease, n (%)	1 (1)
ASA physical status classification	
1, n (%)	3 (2)
2, n (%)	29 (22)
3, n (%)	90 (68)
4, n (%)	10 (8)
Charlson comorbidity index	
0, n (%)	54 (41)
1, n (%)	32 (24)
2, n (%)	17 (13)
3, n (%)	10 (8)
4, n (%)	9 (7)
≥5, n (%)	10 (8)
Procedure types	
Roux-en-Y gastric bypass, n (%)	52 (39)
Sleeve gastrectomy, n (%)	18 (14)
Oncologic gastrectomy, n (%)	7 (5)
Paraesophageal hernia, n (%)	6 (5)
Anti-reflux surgery, n (%)	5 (4)
Cholecystectomy, n (%)	24 (18)
Exploratory laparoscopy, n (%)	16 (12)
Other, n (%)‡	4 (3)

*Age at the time of operation expressed as mean years ± standard deviation.
†Body mass index expressed as the weight in kilograms divided by the square of the height in meters.
‡Other category includes 2 median arcuate line release cases, 1 Heller myotomy case, and 1 ventral hernia repair.
ASA indicates American Society of Anesthesiologists.

RESULTS

During the study period, 168 consecutive patients underwent elective laparoscopic surgery and were considered for inclusion. Eight patients (4.8%) did not consent to the study, 7 cases (4.2%) had missing consents from at least 1 member of the OR team, and in 21

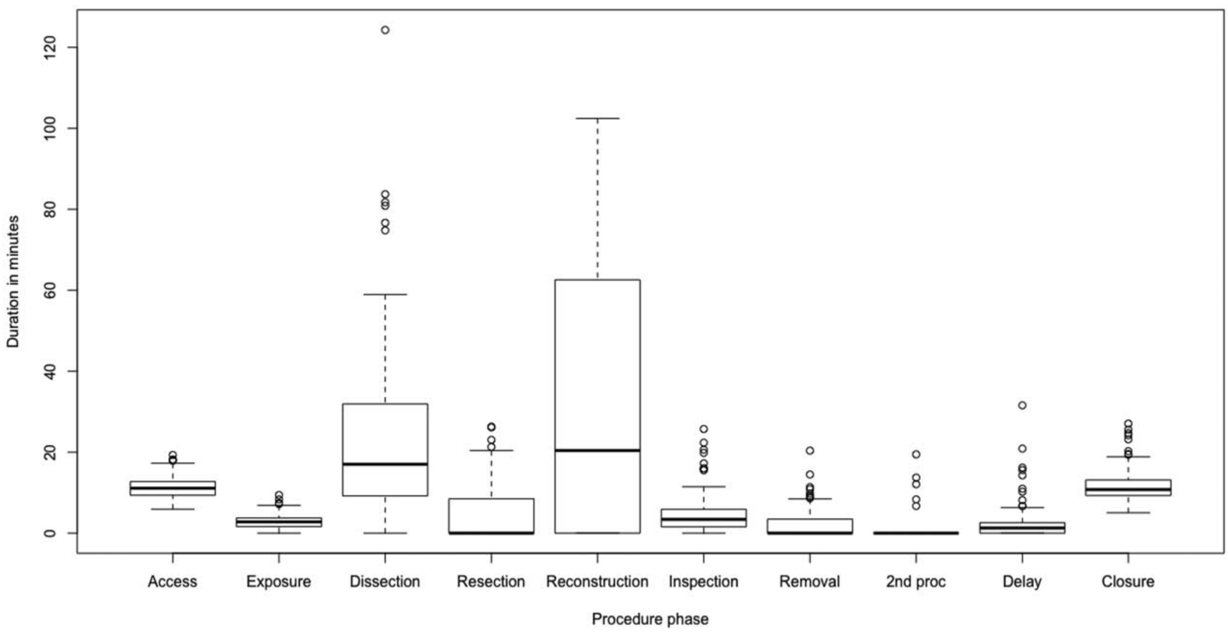

FIGURE 1. Distributions of the durations of different phases in individual procedures. The distributions of procedure phase duration in minutes across the 132 cases are presented as box-and-whisker plots. The median values are presented as horizontal bars and interquartile (25%–75%) ranges are presented as boxes. The whiskers depicted as vertical dotted lines cover a maximum of 1.5 times the interquartile range and the circles represent outliers beyond the maximum range.

cases, the recordings failed to transfer to the server. Thus, 132 OR Black Box recordings were included for analysis, in which 1 attending surgeon, 3 fellows, and 25 residents were involved in surgical care. Table 1 presents characteristics of patients and procedures. The patients had a mean age of 51 years and comprised of more females (74%). More than half of the patients had a history of previous abdominal surgery (58%) and a Charlson comorbidity index score of 1 or above (59%). The most frequent comorbid condition was obstructive sleep apnea (40%), followed by diabetes (18%) and presence of solid tumor (8%).

Eight types of procedures were performed during the study period (Table 1). The median duration of overall procedures was 94 (IQR 73–115) minutes. Oncologic gastrectomy had the longest median duration of 209 (IQR 144–216) minutes, whereas cholecystectomy had the shortest median duration of 64 (IQR, 50–80) minutes (Table S1, http://links.lww.com/SLA/B438). Figure 1 presents the distributions of the durations of different phases in individual cases. The reconstruction and dissection phases had the longest median duration of 20 (IQR 0–63) and 17 (IQR 9–32) minutes, respectively. Table S2 (http://links.lww.com/SLA/B438) presents comparisons of percentage contributions of attending surgeon and trainees to the cases. The attending surgeon's procedure duration per case as the main operator was not significantly different from that of fellows or residents. The median procedure duration as the main operator per case was 24 minutes for the attending surgeon (IQR 6–42 minutes), 35 minutes for fellows (IQR 11–56), and 13 minutes for residents (IQR 3–43). Figure 2 presents OSATS scores of attending surgeon, fellows, and residents as measures of technical skills. The attending surgeon had the highest mean OSATS score (32.0, 95% CI 29.0–34.9), followed by fellows (30.1, 95% CI 28.0–32.2, $P = 0.33$ as compared with attending surgeon) and residents (27.9, 95% CI 26.9–28.9, $P = 0.015$). Adjusted analyses of OSATS scores yielded similar results (Table S3, http://links.lww.com/SLA/B438).

Distractions

Table 2 shows characteristics of distractions during procedures. The OR door opened a median of 42 times per case or approximately once every 2 minutes. Machine alarm occurred a median of 67 times and loud noise occurred 18 times. Pagers or telephones rang a median of 6 times. Together, auditory distractions occurred a median of 138 times per case (IQR 96–190), or once every 40 seconds. Devices in the OR, such as surgical instruments and laparoscopic consoles, were absent or malfunctioning in 43 cases (33%). The surgical team was engaged in at least 1 irrelevant conversation in 34 cases (26%). In 18 cases (14%), the surgical team was involved in managing another case while operating. Time pressure, or an inquiry about the estimated time of case completion, was communicated in 14 cases (11%). Other types of cognitive distraction included teaching activity and late or absent team member. Collectively, at least 1 type of cognitive distraction occurred in 84 cases (64%).

Intraoperative Errors and Events

Table 3 shows characteristics of intraoperative errors and events. A median of 20 errors per case or 3435 errors in total were identified. Among the 4 types of mechanisms, errors most frequently occurred due to the application of insufficient force or underestimation of distance to target tissue when performing surgical tasks. Errors often took place during dissection (median of 18 errors per hour), resection (13 per hour), and reconstruction phases (18 per hour), and when performing a grasping or dissecting task (6 per

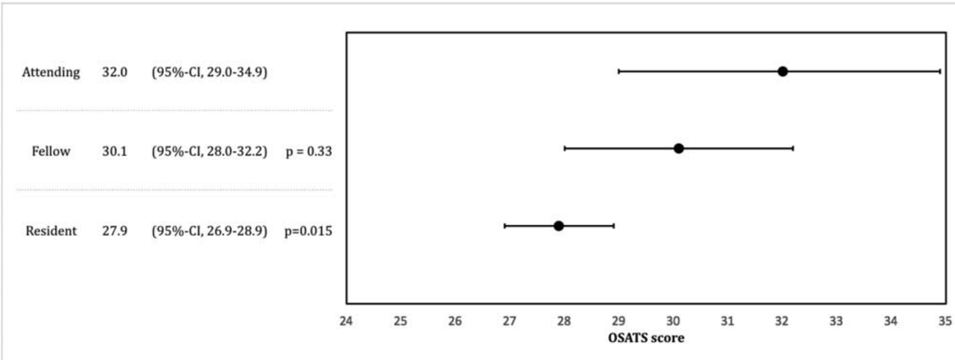

FIGURE 2. . Comparison of OSATS scores among the attending surgeon, fellows, and residents. A univariable linear mixed model with random intercepts for cases and individual surgeons was used to estimate OSATS scores and the 95% CI values. *P* values are for differences between OSATS scores of fellows or residents as compared with OSATS scores of the attending surgeon.

hour). A total of 1258 intraoperative events, or a median of 8 events per case, was identified, and bleeding (6 events per case) was the most common of the 5 event categories. Surgeons attempted to rectify 510 events during the same operation. The measures to rectify events required a median of 160 seconds per case (IQR 21–388), which took up median of 3% of the case duration (Table S4, http://links.lww.com/SLA/B438).

DISCUSSION

This prospective cohort study of consecutive elective laparoscopic operations using the novel OR Black Box demonstrated that the surgical teams committed errors and events frequently and encountered high amounts of auditory and cognitive distractions. The attending surgeon, fellows, and residents performed surgery as the main operator for similar durations of procedures, whereas their global ratings of technical skills varied. To better understand the risks, patterns, and effects of surgical errors and events, intraoperative data capture and analysis have been advocated in the past, but were rarely conducted.[10] Findings from the present study serve as the groundwork for ongoing investigations aimed at determining whether surgeon performance and distractions are linked to intraoperative errors and events. Further, they will facilitate risk analysis and management, and help formulate policies to systematically improve patient safety in the OR.

TABLE 2. Characteristics of Distractions During Procedures

Overall number of cases, N (%)	132 (100)
Case duration, min, median (IQR)	94 (73–115)
Cognitive distraction	
Case with any teaching activity, n (%)	74 (56)
Case with any absent or malfunctioning device, n (%)	43 (33)
Case with any irrelevant conversation, n (%)	34 (26)
Case with any management of another case, n (%)	18 (14)
Case with any time pressure, n (%)*	14 (11)
Case with any surgical team member late, n (%)†	10 (8)
Case with any surgical team member absent, n (%)	7 (5)
Auditory distraction	
Door opening per case, count, median (IQR)	42 (32–54)
Machine alarm per case, count, median (IQR)	67 (42–102)
Loud noise per case, count, median (IQR)	18 (9–31)
External communication per case, count, median (IQR)‡	6 (3–8)

*Time pressure defined as any inquiry received regarding the estimated time of case completion.

†A surgical team member is considered late if arrived after the surgical checklist is performed.

‡External communication includes telephone or pager ring.

Recently, the American College of Surgeons Committee on Perioperative Care emphasized the growing body of evidence, suggesting that distractions in the OR are associated with deleterious effects on patient safety.[20] The present study demonstrated that distractions were frequently observed. Actions categorized as auditory distractions occurred once every 40 seconds. In simulated settings, surgeons faced with auditory distractions exhibited lower surgical skill proficiency, speed, and accuracy.[21–23] The OR door opened a mean of 33 times per hour, whereas other smaller studies reported 13 and 37 per hour.[24,25] Door opening is not only an auditory distraction, but also may be linked to increased risk of surgical site infections. One study reported that in 77 of 191 (40%) joint arthroplasty cases, the OR door was left open long enough to reverse positive room pressure.[26] Further, open doors increased the inflow of larger particles, which were more likely to be microorganisms.[24] Cognitive distractions also occurred frequently in our study. For instance, 33% of the cases had at least 1 device-related interruption—a type of cognitive distraction. It was demonstrated that device-related interruptions were associated with high levels of stress among the OR team members.[27] Further, cognitive distractions had more negative impact than auditory distractions on surgical task speed and accuracy in experimental settings.[21,28] Based on these findings, the ongoing research aims to determine the effects of distractions on surgical team performance in their naturalistic settings and subsequently on patient outcomes.

In addition to distractions, our study also characterized intraoperative errors and events. Errors occurred at a median rate of 13 per hour of operating. While not all, but some errors led to events, defined as tissue injuries caused by healthcare providers that have potential to cause patient harm.[17,29] Events, like errors, often took place during dissection, resection, and reconstruction phases. A median rate of 5 events per hour was detected. Other studies that deployed human observers in the OR on smaller sample sizes of cases demonstrated similar rates of intraoperative events.[8,9,30,31] We hypothesize that intraoperative events, especially when not rectified adequately, accumulate their likelihood of resulting in patient harm. Our ongoing research aims to address this hypothesis in a larger cohort.

The OR Black Box created a timeline that tracked individuals who performed as the main operator and for how long, which allowed accurate measurement of trainee's level of involvement in the operation. In the overall analysis, the attending, fellows, and residents contributed similar durations to the cases as main operator.

TABLE 3. Characteristics of Intraoperative Errors and Events

	Eligible cases n	Cases With ≥1 Error/Event n (%)	Count Per Case Median (IQR)	Rate Per Hour Median (IQR)
Intraoperative errors	132	132 (100)	20 (14–36)	13.4 (9.1–19.6)
Error mechanism				
Excessive force/distance	132	125 (94.7)	6 (3–11)	3.8 (2.1–6.4)
Inadequate force/distance	132	130 (98.5)	8 (4–12)	4.9 (2.9–7.7)
Inadequate visualization	132	107 (81.1)	2 (1–4)	1.3 (0.5–2.7)
Wrong orientation	132	98 (74.2)	2 (0–5)	1.2 (0–2.9)
Surgical task with error				
Abdominal access	132	41 (31.1)	0 (0–1)	0 (0–0.5)
Clipping	132	37 (28.0)	0 (0–1)	0 (0–0.5)
Cutting/stapling	132	45 (34.1)	0 (0–1)	0 (0–0.5)
Use of energy device	132	109 (82.6)	2 (1–5)	1.4 (0.6–3.7)
Grasping/dissection	132	129 (97.7)	10 (6–16)	6.4 (4.1–10.4)
Retraction	132	23 (17.4)	0 (0–0)	0 (0–0)
Use of suction	132	39 (29.5)	0 (0–1)	0 (0–0.5)
Suturing	132	84 (63.6)	3 (0–9)	2.0 (0–4.9)
Other	132	5 (3.8)	0 (0–0)	0 (0–0)
Procedure phase with error				
Access	132	52 (39.4)	0 (0–1)	0 (0–5.98)
Exposure	119	28 (23.5)	0 (0–0)	0 (0–0)
Dissection	127	120 (94.5)	6 (2–12)	18.2 (10.7–29.2)
Resection	51	39 (76.5)	3 (1–4)	12.8 (2.5–24.2)
Reconstruction	80	80 (100)	15.5 (9–24.2)	18.2 (13.2–27.0)
Inspection	126	56 (44.4)	0 (0–1.8)	0 (0–0.4)
Specimen removal	56	13 (23.2)	0 (0–0)	0 (0–0)
Secondary procedure	5	5 (100)	3 (2–4)	17.5 (14.9–17.9)
Delay	92	3 (3.3)	0 (0–0)	0 (0–0)
Other	24	16 (66.7)	0 (0–1.2)	0 (0–0.2)
Closure	132	13 (9.8)	0 (0–0)	0 (0–0)
Intraoperative events	132	130 (98.5)	8 (4–12)	5.0 (3.5–7.1)
Event category				
Bleeding	132	127 (96.2)	6 (3–9)	3.8 (2.1–4.9)
Mechanical injury	132	85 (64.4)	1 (0–2)	0.6 (0–1.1)
Ischemic injury	132	6 (4.5)	0 (0–0)	0 (0–0)
Thermal injury	132	60 (45.4)	0 (0–1)	0 (0–1.0)
Inappropriate anastomosis	63	18 (28.6)	0 (0–1)	0 (0–0.4)
Procedure phase with event				
Access	132	108 (81.8)	1 (1–2)	6.5 (4.4–13.2)
Exposure	119	25 (21.0)	0 (0–0)	0 (0–0)
Dissection	127	102 (80.3)	2 (1–4)	6.4 (2.8–12.3)
Resection	51	31 (60.8)	1 (0–2)	5.0 (0–13.0)
Reconstruction	80	66 (82.5)	3 (1–6)	3.2 (1.7–6.2)
Inspection	126	7 (5.6)	0 (0–1)	0 (0–0.1)
Specimen removal	56	1 (1.8)	0 (0–0)	0 (0–0)
Secondary procedure	5	5 (100)	1 (1–2)	9.0 (7.2–9.9)
Delay	92	4 (4.3)	0 (0–0)	0 (0–0)
Other	24	5 (20.8)	0 (0–0)	0 (0–0)
Closure	132	25 (18.9)	0 (0–0)	0 (0–0)

However, when we analyzed each procedure type, we showed that trainees contributed longer durations as main operator in less technically challenging cases, such as sleeve gastrectomy and antireflux procedures (Table S2, http://links.lww.com/SLA/B438). In addition, we were able to assess technical skills of individual surgeons in their naturalistic setting. Birkmeyer et al[32] provided evidence that attending surgeons' technical skill levels influenced patient outcomes. In most academic hospitals, significant durations of operations are performed by trainees. Therefore, we aim to examine the relationship between technical skills of surgeons and patient outcomes after adjusting for the level of trainee involvement and trainee's technical skills.

Our study has limitations. All procedures during this study were performed at a single center with involvement of a single attending surgeon, and all cases were laparoscopic general surgeries. Thus, our results may not be generalizable to different types of operations performed at other centers. We plan to expand our study to include other surgical specialties in various centers, both domestic and international. In our experience, the raters need to be trained and calibrated for at least 3 months to provide reliable rating of the OR Black Box data. For an outside institution to perform analyses as described in this manuscript on their own, significant resources will be required. Thus, in our current research collaboration model with other institutions, all encrypted data will be sent to our center for analysis. As a general limitation of any study that includes an intervention at the system level, our subjects may have altered their behavior based on their awareness of being observed—a phenomenon known as the Hawthorne effect. We attempted to minimize this effect by installing small recording devices in nonconspicuous locations and undergoing a 1-year pilot period, during which healthcare providers were familiarized with the changed environment before the prospective cohort study began. A systematic review suggested that the Hawthorne effect generally existed for less than 1 year.[33] Accurate characterization of intraoperative factors is challenging. However, all analysts received thorough structured training and used validated frameworks to characterize readily identifiable variables. Any questionable characterization was reviewed by a committee of experts in surgery, measurement, and human factor analysis.

CONCLUSIONS

Our study presents a uniquely comprehensive and transparent quantitative analysis of surgical procedures and the environment in which patient care is provided. Our research will continue to identify pertinent intraoperative factors and variations in surgical practices to better understand how and why adverse outcomes occur. Through transparent reporting of our findings, we hope to encourage the establishment of a more formidable "just culture" among healthcare providers and organizations, where nonpunitive and constructive discussions promote safe surgical practices.[12] Several centers in North America and Europe have already adopted the OR Black Box to join in this commendable endeavor. In conclusion, frequent intraoperative errors and events, variation in surgeons' technical skills, and a high amount of environmental distractions were identified during elective laparoscopic operations in this prospective cohort study.

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