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Characterization of device-related interruptions in minimally invasive surgery: need for intraoperative data and effective mitigation strategies

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Abstract

Background The burden of device-related interruptions is expected to increase as modern surgical practices adopt complex minimally invasive surgery devices. Currently, there is a paucity of empiric data that examined the nature of device-related interruptions using comprehensive intraoperative data.

Methods We performed a cross-sectional study of consecutive elective laparoscopic general surgery cases performed in one operating room (OR) at a referral center between April 2014 and April 2016. The included cases were directly observed using a comprehensive multiport data recorder called the OR Black Box. The data were synchronized, encrypted, and reviewed by expert surgeon assessors. The assessors characterized device-related interruptions that occurred during operations. The prevalence of the cases with device-related interruptions was calculated. Device-related interruptions were classified into a priori categories of (1) absent/wrong device; (2) improper assembly; (3) loss of sterility; (4) disconnection; and (5) device failure.

Results In a cohort of 210 cases, 64 (30%) had at least one device-related interruption. Sleeve gastrectomy (52%) and oncologic gastrectomy (43%) procedures experienced the highest prevalence of device-related interruptions. Device failure was the most frequently chosen category with laparoscopic staplers implicated in more than half of these failures. Three failure modes were described for laparoscopic stapler, of which stapler malfunction (46%) was the most common.

Conclusions Device-related interruptions occurred frequently in the OR and could be characterized into one of the five categories. Understanding the nature of the device-related interruptions can help guide implementation of safety interventions and user training in the future.

Keywords Surgical safety · Education · Interruption · Distraction · Surgery

Since the publication of "To Err is Human" from Institute of Medicine [1] that highlighted staggering number of adverse events in healthcare, there has been a growing interest in improving surgical safety [2]. A systems approach from other high-risk industries prone to adverse events, such as aviation [3, 4] and nuclear energy industries [5], has revealed that workflow interruptions negatively affected overall performance [6, 7]. Interruptions are prevalent in the operating room (OR), occurring as often as once every 3 min [8]. They cause significant stress to the OR team and increased risk of intraoperative errors [6, 9]. Also, studies in simulated settings demonstrated that interruptions were associated with higher frequency of major surgical errors and lower performance on memory tasks [10]. Thus, it is imperative to better understand the epidemiology and nature of interruptions in the OR.

Emergence of minimally invasive surgery has introduced an increased burden of device-related interruptions in the OR [11]. Complexity of surgical care in minimally invasive surgery necessitates the use of several laparoscopic devices, each representing a potential source of interruption. Compared to open surgery, laparoscopic surgery had longer and more frequent device-related interruptions [12–14]. Furthermore, device-related interruptions related to laparoscopic surgery were associated with more interference with team performance and generated the most surgical delays [15, 16].

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Previous studies presented incidence of device-related interruptions, but they did not characterize the nature of these events [6, 9, 17].

Characterizing the nature of device-related interruptions can help guide implementation of safety interventions, such as checklists and staff training programs [18]. It can also guide future development of targeted interventions and provide a framework to assess their effectiveness. Therefore, the objective of this study was to assess the incidence and characterize the nature of device-related interruptions during consecutive laparoscopic surgery cases for a 2-year period.

Materials and methods

Subjects, setting, and data source

All elective laparoscopic adult (≥ 18 years of age) general surgery cases performed in one OR at a referral center between April 2014 and April 2016 were considered for inclusion. The OR was equipped with a comprehensive intraoperative recording platform called the OR Black Box® (Surgical Safety Technologies, Toronto, ON) [19]. This platform continuously captures data from multiple sources in the OR, including, but not limited to, laparoscopic and room video and audio feeds, patient physiology data from anesthetic monitoring equipment, and healthcare provider's physiology data from wearable devices. During the study period, only the audio-visual data were analyzed. The captured data are then synchronized, encrypted, and stored in a secure server for review. Two assessors identified and characterized device-related interruptions using the OR Black Box recordings. One assessor (AK) was a board-certified general surgeon undergoing fellowship training in minimally invasive surgery and the other assessor (SS) was a medical student. Both assessors underwent 2 months of comprehensive training to administer the measurement protocol. The curriculum included didactic lectures and multimedia-based training on the framework to measure device-related interruptions. Both assessors analyzed all cases and reached consensus on characterization of device-related interruption when discrepancy existed. Cases were excluded if informed consents were not obtained from patients or any member of the healthcare team, or if OR Black Box recording was not available. The research ethics board approval was obtained.

Outcomes

Device-related interruptions were identified by expert surgeon assessors and classified to one of the five categories. The categories are absent/wrong device; improper assembly; loss of sterility; disconnection; and device failure ("Appendix"). Laparoscopic stapler-associated device failures are further divided into subcategories: stapler misfire, stapler malfunction, and tissue sticking ("Appendix"). Definitions of the categories and the stapler-specific subcategories were either directly derived or modified from other studies in the literature [18, 20–23]. Devices that caused interruptions were identified and classified into the following: visual (e.g., laparoscope and monitors), stapler, advanced energy device (e.g., bipolar energy device and ultrasonic dissector), monopolar energy device, suction/irrigation, and other.

Patient- and procedure-based characteristics

A trained research assistant used a pilot-tested standard data form to abstract relevant variables from patient charts. Age, gender, body mass index (BMI), history of previous abdominal surgery, and Charlson comorbidity index score were collected. Also, procedure type and operating time were included.

Statistical analysis

Descriptive statistics were performed and included frequency (%) analysis for categorical variables and means [standard deviation (SD)] for continuous variables. All statistical analyses were performed using SAS 9.4 package (SAS Institute, Cary, NC).

Results

Subjects (Table 1)

A total of 210 cases were included for analysis. There was one patient with missing BMI. This patient was included in the analysis. Otherwise, the data were complete. The cohort had a mean [SD] age of 50 [14] years and predominantly female gender (75%). More than half of the cohort had morbid or super obesity (50%), previous abdominal surgery (57%), and at least one comorbidity (59%). Bariatric procedures were the most frequently performed procedures (52%), followed by cholecystectomy (20%) and exploratory laparoscopy (10%).

Outcomes

Cases with device-related interruptions (Table 2)

In a cohort of 210 cases, 64 (30%) had at least one device-related interruption. Thirty-nine cases (61%) had one interruption, whereas 25 cases (39%) had two or more interruptions. Device-related interruptions were the most frequent

Table 1 Patient characteristics and procedure types

Patient characteristics	
Age, mean years (SD)	50.3 (13.5)
Female sex—no. (%)	157 (74.8)
BMI < 40—no. (%)[a]	102 (48.8)
BMI 40–59—no. (%)	97 (46.4)
BMI ≥60—no. (%)	10 (4.8)
Previous abdominal surgery—no. (%)	119 (57.0)
Charlson comorbidity index	
0—no. (%)	86 (40.9)
≥1—no. (%)	124 (59.1)
Procedure types	
Total—no. (%)	210 (100)
Roux-en-Y gastric bypass—no. (%)	86 (41.0)
Cholecystectomy—no. (%)	41 (19.5)
Sleeve gastrectomy—no. (%)	23 (11.0)
Exploratory laparoscopy—no. (%)	21 (10.0)
Paraesophageal hernia—no. (%)	12 (5.7)
Antireflux surgery—no. (%)	12 (5.7)
Other—no. (%)[b]	8 (3.8)
Oncologic gastrectomy—no. (%)	7 (3.3)

no. number, *SD* standard deviation, *BMI* body mass index

[a]One patient's BMI was missing

[b]Other procedure types included two median arcuate ligament release procedures, one splenectomy, one laparoscopic sigmoid resection, one incisional hernia repair, one ventral hernia repair, one Heller myotomy, and one gastric wedge resection

Table 2 Frequency of device-related interruptions by procedure type

Procedure type	Number of cases—no. (%)	Cases with device-related interruption—no. (%)
Roux-en-Y gastric bypass	86	34 (39.5)
Cholecystectomy	41	8 (19.5)
Sleeve gastrectomy	23	12 (52.1)
Exploratory laparoscopy	21	4 (19.1)
Paraesophageal hernia	12	3 (25.0)
Antireflux surgery	12	0 (0)
Other[a]	8	0 (0)
Oncologic gastrectomy	7	3 (42.9)

no. number

[a]Other procedure types included 2 median arcuate ligament release procedures, 1 splenectomy, 1 laparoscopic sigmoid resection, 1 incisional hernia repair, 1 ventral hernia repair, 1 Heller myotomy, and 1 gastric wedge resection

in sleeve gastrectomy (52%), followed by oncologic gastrectomy (43%) and Roux-en-Y gastric bypass (40%).

Characteristics of device-related interruptions (Tables 3, 4)

A total of 110 device-related interruptions was observed. Almost half (49%) was classified as device failure, half (52%) of which was related to laparoscopic stapler. Improper/challenging assembly was the second most frequent category (24%) and was associated with several types of device. Disconnection category (13%) was mostly related to visual devices, such as laparoscope and monitors. Examples of device-related interruption categories are presented in Table 4. Distribution of device-related interruption occurrence throughout the four temporal quarters of procedures was examined. It was generally widespread with 30, 23, 34, and 14% of the interruptions taking place in the 1st, 2nd, 3rd, and 4th temporal quarter of procedures, respectively.

Characteristics of stapler device failure (Table 5)

There were 28 device-related interruptions associated with stapler device failure. This represented more than half of device failure category and a quarter of all device-related interruptions. Thirteen (46%) were subcategorized to stapler malfunction, such as defected rotation, opening, and closing. Ten (36%) failed to completely separate stapler components from tissue. Five (18%) failed to fire staples despite correct use.

Discussion

In a cohort of 210 consecutive elective laparoscopic general surgery cases, device-related interruptions occurred frequently and were classified into five distinct categories. Of the categories, device failure was the most common type of device-related interruptions. Further, laparoscopic stapler contributed to over half of device failures. Accelerated innovation and development and lack of systematic data collection after the implementation of surgical devices has increased the burden of device-related interruptions. In our cohort, 30% of the cases experienced at least one device-related interruption. A systematic review of adverse events in the OR demonstrated that > 20% were related to surgical devices [18]. Verdaasdonk et al. found that 87% (26/30) of laparoscopic cholecystectomy cases had at least one device-related interruption [24]. Also, Courdier et al. reported 42% (26/62) prevalence of device-related interruption in laparoscopic gynecology cases [25]. Both studies demonstrated a higher prevalence of device-related interruptions than our cohort. This difference might be due to the discrepancy in the definition of device-related interruption and the larger sample size that our study adopted. For instance, our cohort contained 210 cases in a 2-year period. Also, positioning of

Table 3 Frequency of device-related interruptions by device type

Device type	Device-related interruption classification					
	Absent/wrong device	Improper/challenging assembly	Loss of sterility	Device failure	Disconnection	Subtotal—no. (%)
Visual	1	5	2	8	12	28 (25)
Stapler	6	5	0	28	0	39 (35)
Advanced energy device	1	4	0	2	0	7 (6)
Monopolar energy device	0	7	0	7	1	15 (14)
Suction/irrigation	0	2	1	0	1	4 (4)
Other[a]	4	3	1	9	0	17 (16)
Subtotal—no. (%)	12 (11)	26 (23)	4 (4)	54 (49)	14 (13)	110 (100)

no. number

[a]Other device types included laparoscopic scissors, laparoscopic grasper, retractor, endoscopic bag, needle driver, trocar, and hemostatic clips

Table 4 Examples of device-related interruption categories

Category	Examples
Absent/wrong device	Regular stapling device not in room and causes delay Delay in starting the operation because a wrong angled laparoscope present
Improper/challenging assembly	Team waits for advanced energy device to be assembled and tested Failure to progress in operation due to struggle to install a cartridge to a stapling device
Loss of sterility	A suction tip fell on the ground and team waits for a new suction tip to arrive from central sterile core A camera light cord is dropped to the floor, requiring extended time for a replacement to arrive to the OR
Device failure	Stapler jaws fail to close and open despite correct handling Stapling device fails to fire staples despite pressing on the correct button Laparoscope monitors turn to purple color for an extended period of time
Disconnection	Camera head is easily disconnected from cord Irrigation tube is disconnected forcefully when turned on and distracts surgical team

Table 5 Subcategories of stapler device failure

Stapler device failure subcategory	Frequency—no. (%)
Tissue sticking	10 (36)
Stapler misfire	5 (18)
Stapler malfunction	13 (46)

no. number

patients and monitors was considered device-related interruptions in other studies, but not in the present study.

Device failure occurring in laparoscopic stapler contributed to 25% of all device-related interruptions. Stapler malfunction and incomplete separation from tissue were common problems that were previously documented in other empiric studies and FDA reports. In the decade from January 2006 to 2016, 75% (9972/13,312) of all reported stapler-related events involved device malfunction and more than a quarter (3340/13,312) resulted in injury or death [26]. Further, a recent survey of minimally invasive surgery program directors revealed that 66% experienced incomplete separation from tissue events while using stapler in their practice and 25% had to change their planned procedure as a result of stapler malfunction [27]. Several reports, including the present study, demonstrated that laparoscopic staplers were frequently associated with device-related interruptions. It is imperative to fully understand the patterns, risk factors, and clinical impact related to stapler device failures in order to guide future improvements in design and user training.

Improper or challenging assembly represented 23% of the device-related interruptions recorded. This category encompassed interruptions caused by improper configuration of wires and device components. Improper device assembly is a recognized cause of medical device incidents and patient mortality [20, 28]. However, there is a paucity of data investigating the frequency with which it occurs in the OR. Disconnection and absent or wrong device categories have also been featured in other studies that examined device-related interruptions. Disconnection represented 13% of the events recorded in our cohort. In a similar study, faulty connections contributed to 18% (9/49) of device malfunctions recorded

over 30 laparoscopic cholecystectomies [24]. More intuitive design of devices and their connections may reduce these types of device-related interruptions. Discussions about device-related issues with manufacturers will help identify faulty design and improve device function.

Missing or absent device category comprised 11% of device-related interruptions in our cohort. A 9-month study in vascular and endovascular procedures found that 47% (127/269) of device-related interruptions were due to unavailability [29]. Further, an investigation of device-related interruptions conducted in The Netherlands found device unavailability was implicated in 44.6% [30]. Incidents of missing or absent devices were shown to cause intraoperative delay and higher operating costs [14]. Further, they were associated with increased case-irrelevant communication and distracting door-openings [8]. Loss of sterility due to device falling only occurred four times in our study. Another study reported 39 total falls during a study of 120 orthopedic procedures [31]. Unlike the other study, our cohort did not include emergency cases and documented only the device falls that required subsequent replacement. Further, the setting of laparoscopic surgery where device holsters were readily available might have prevented some device falls.

There were potential limitations to our study. Categorization of device-related interruptions was based on a novel classification tool. As such, there is no evidence of reliability or validity for this tool. In order to address for this limitation, two assessors underwent extensive training on using the tool before categorizing device-related interruptions. When there were discrepancies, meetings were held to reach consensus. Another potential limitation was a relatively small sample size of subjects from one urban center. This might limit generalizability of our results. Lastly, this study represents an exploratory phase in an ongoing effort to understand the true impact of device-related interruptions in the OR. The current results are descriptive and present the prevalence and nature of such interruptions. Future studies will explore the patterns, risk factors, and relationship of device-related interruptions to clinical outcomes and costs.

Characterization of device-related interruptions can help guide future safety interventions [6, 17, 32]. For example, implementation of a preoperative checklist for devices that were frequently missing produced a 53% reduction in device-related interruptions [33]. Further, careful discussions of device failures with manufacturers can help improve device design and functionality. New devices then must be implemented with close monitoring through systematic intraoperative data capture and analysis. These interventions, in turn, can help reduce unnecessary interruptions in the OR and ultimately improve patient safety and reduce costs.

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Compliance with ethical standards

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Appendix

See Table 6.

Table 6 Definitions of device-related interruptions and stapler-specific device failure subcategories

Term	Definition	References
Absent/missing device	Device unavailable at the point of clinical need or incorrect device prepared	[6, 19]
Improper assembly	Device was incorrectly assembled, or there was a challenge in assembly that caused additional OR time	–
Loss of sterility	Instrument falling that necessitates replacement of equipment and subsequent delay in surgery	–
Disconnection	Issue associated with the linking of device and/or device components	[20]
Device failure	Malfunction means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed	[21]
Subcategories of device failure associated with laparoscopic stapler		
Tissue Sticking	Failure of device or one of its components to separate from tissue as intended	[22]
Device Misfire	Failure of device to fire	–
Device Malfunction	Failure of device to move or adhere to tissue as expected	[22]

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