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1 **Equipment failures in laparoscopic surgery: causes and consequences**

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Abstract

Objective: The aim of this study was to assess incidence, causes and consequences of equipment failures in a high volume, advanced endoscopic surgery department.

Methods: This is a prospectical observational single centre study between April and July of 2019 in the Gynecological surgery department of the Estaing University Hospital of Clermont-Ferrand, France. During the study period, 171 laparoscopies were observed. Data were collected real time by three supernumerary observers.

Results 66 (38.6%) laparoscopies were complicated by equipment failures. The bipolar cable and forceps accounted for 31% of the total amount of malfunctions in laparoscopy. Causes of malfunctions were in 45% due to the instrument per se and in 43% due to the incorrect combination of elements. Less commonly, the equipment was not available or a mismatched was reported. The total length of the surgery increased by 1.35% due to the malfunctions. Human error was identified in 50% of cases. No morbidity, neither mortality was reported in this series; however we observed 34 malfunctions that could have led to serious consequences for the patients and 3 incidents induced a real consequence on the operation workflow.

Conclusions Equipment failure is a common event in endoscopy. On the opposite, time wasted for the malfunctions is low in laparoscopy, as it only accounts for 1.35% of the overall surgical time. Human decisions contributed to malfunctions in almost half of cases. This alarming finding may advise for intensification in training and upgrading of the surgical team.

Key words

endoscopic instruments, equipment failure, human error, improvement

Introduction

The laparoscopic approach relies on advanced technology with the use of more and more sophisticated instruments and the need for more training of the surgical team, as equipment malfunctions accounts for approximately one-fourth of surgical errors in the operating room (1-2).

A good knowledge of the equipment by the surgical team is required, as well as adequate maintenance of the instruments and a prompt intervention in case of failure. In fact, several authors have already demonstrated the impact of distractions and malfunctions, which affect surgical workflow and patient's safety. Several studies have highlighted the negative effects of distractions (such as noise, irrelevant communications, mobile phones and equipment failures) in surgical theaters (3,4). According to S. Forman et al., equipment failures contribute in half of the cases, followed by irrelevant communications (26%), and auditory distractions (9%)(5).

However, endoscopic tools have significantly improved in the last decade, in particular in surgical reference centers.

The aim of this study is to assess the current incidence of equipment failure in a high-volume surgical academic department.

Material and methods

This is a prospective observational single-center study performed in the gynecological surgery department of the Estaing University Hospital of Clermont-Ferrand, France.

All laparoscopic gynecological procedures performed between April and July 2019 were included, with the exclusion of emergency and trial procedures. Written consent was ruled out by the institutional review board for the observational study.

72 Data were collected real time by three supernumerary observers. One observer was
73 the leader, receiving direct training from the senior author, and was the one
74 responsible for discussing unclear cases and intermediate data with the senior author.
75 The other two observers were trained by the leader both with the support of the
76 available literature for the methodology and demonstrative live sessions in the
77 operative room. Then, they collected pilot data for one week under the supervision of
78 the leader, and finally started collecting independently. Data were always
79 cross-checked between the three observers after the surgeries to avoid inter-observer
80 bias. In case of doubt on objective issues, for example the type of instrument involved
81 in the malfunction or the cause of the malfunction, the observer had to ask the
82 scrubbed nurse and/or the first surgeon in order to clarify the doubt. On contrary, to
83 assess more subjective issues, such as human involvement and responsibilities,
84 some cases were discussed with the senior author, who was not directly involved in
85 the surgery. In this way, we tried at best to enhance data accuracy, reducing bias
86 linked to impartiality and distortion of the information.

87 The amount of procedures and failures was calculated in relation to the operator and
88 the difficulty of the surgery, by dividing laparoscopies in 3 groups: (a) low difficulty,
89 such as salpingectomy, annexectomy, ovarian cystectomy, explorative and fertility
90 procedures; (b) medium difficulty, as hysterectomy and myomectomy; (c) high
91 difficulty, including laparoscopic prolapsus surgeries, endometriosis and oncologic
92 surgeries.

93 For each observed procedure the following data were collected: - name and date of
94 the procedure; - name of the first surgeon and first assistant; - duration of the
95 procedure, from the incision to skin closure; - presence of one or more equipment
96 failure, where the equipment failure was defined as a problem of the endoscopic
97 equipment resulting in a waste of time and a consequent measure of correction; -
98 duration of each equipment failure, from the moment it has appeared to its resolution;

- causes and consequences for each failure; - possible human error related to the failure.

To achieve it, an equipment catalogue was created, inspired by the one published by Wattiez et al, 2008 (6), and a specific data collection form was printed and delivered to the observers.

Within the catalogue, equipment was divided into 4 categories: (a) fluid and gas circuit, including connections and fittings which could interfere with the fluid flow; (b) endoscopic instruments, such as forceps, scissors and even the small fittings that are not properly endoscopic but are however functional for the endoscopy, such as suspension/exposition devices and fascia closure devices; (c) electrical circuit, including bipolar forceps failing to conduct the electricity or cables and pedals; (d) video system devices, such as the optic and the camera which could be responsible of a dirty image or even a missed one.

Causes for failure were assessed and divided in 5 groups to improve the uniformity of language: failure of the equipment itself, lack of availability, incorrect assembly, mismatch and other causes, such as the humidity for the camera resulting in image failure.

Whenever the equipment failure rises from an omission or a direct action of the primary surgeon or the operative nurses, this was designated as human error (p.e. the electrical failure caused by the inadequate or missing connection of the cable is a direct responsibility of the operator who set up the operating field).

Consequences of each failure were recorded as follows: none, if the equipment failure does not generate any consequence but the waste of time; potential or “near-miss”, whenever the equipment failure induce an effect that is minimal in the specific case but could have been more severe if it has occurred at a different time (p.e. bipolar failure in the beginning of the adhesiolysis vs. facing a bleeding); real and serious,

when the event induce any consequences related to the patient or the surgical procedure (p.e. interruption of the procedure, deviation of the surgical strategy).

Patients were followed-up during the post-operative days till discharge to identify any deviation from the normal postoperative course. In the department, patients were monitored as usual; no further investigation was required for the study. Readmission or reintervention were monitored for 3 months after discharge.

Results

During the study period, a total of 171 laparoscopies were observed.

At least one equipment failure was reported for 66 (38%) procedures. The total number of equipment failure recorded was 91; however, some surgeries were complicated by more than one equipment failure, as listed in **table 1**.

Procedures were carried out by 8 senior surgeons, 3 junior surgeons and residents in rotation, and were divided according to its difficulty, as explained in the methods section. The incidence of equipment failure increased with the length and the difficulty of the procedure (**table 2**).

As shown in **table 3**, the most common equipment failure was observed in the category of instruments (n 44, 48%); followed by the electric circuit with 22 cases (24%) and video system with 13 malfunctions (14%); the category of fluid and gas circuit was affected by 12 cases (13%).

Notably, the most frequent malfunction was related to the electric circuit with both bipolar forceps and cables dysfunctions (14 cases each), corresponding to the 30.7% of the total amount of malfunctions (**table 3**).

Most often, the failure was due to the instrument per se (n 41, 45%).

149 In 39 cases the malfunction resulted from the incorrect combination of elements
150 (42.8%). Less commonly, in 8 cases (8.7%), the equipment was not available,
151 because not sterilized or kept in storage. Mismatched was reported in only 1 case
152 during one procedure in which two pieces belonging to different boxes were
153 incorrectly assembled together.

154 Human error was identified in the 50.5% of the times. Nurses, because they are in
155 charge most of the times of the setting up of the operative field, were involved in the
156 majority of equipment failure (32.9%).

157 The total duration of the 66 surgeries complicated by equipment failure was 135 hours
158 and 03 minutes. The global estimated delay due to malfunctions was 1 hour, 49
159 minutes and 35 seconds. This results in a total length of the surgery increased by
160 1.35% due to malfunctions.

161 As regards consequences of equipment failure, no morbidity neither mortality was
162 reported in this series; however we observed 34 (37.3%) “near-misses” cases, that
163 could have led to serious consequences for the patients, such as uncontrolled
164 bleeding in case of bipolar failure.

165 Furthermore, incidents induced a real consequence on the operation workflow or on
166 patient well-being in 3 cases; in one report the bipolar forceps broke in several small
167 pieces into the abdomen causing a significant waste of time and modification of the
168 operative strategy, as well as a consistent risk for the patient in case of inadequate
169 recovery of all the pieces; in another case, the suspension device broke while
170 extracting it and a small part of it was lost in the abdominal wall; in one more case, the
171 malfunction caused a modification of the surgical strategy and a significant delay
172 leading to a stressful overload for the surgical team and a non optimal development of
173 the surgery itself.

174

Discussion

This study provides a snapshot on the current state of the endoscopic gynecology, highlighting the incidence of equipment malfunctions and the role of surgeons and nurses in their management.

In fact, risk management principles; such as avoidance of equipment failures, communication and teamwork, training and updating are essential to protect patient safety, as well as to improve surgical performances (7).

Data collection has been performed in a university department with a high volume of laparoscopic surgeries.

There are few papers in literature about this subject. Wattiez et al published in 2008 a paper with a similar methodology to the present study, representing a benchmark for our data (6). Overall incidence of equipment failures reported by Wattiez et al on 116 operative procedures was 38.8%, a value that is very similar to our overall percentage of 38%. The time needed to solve the malfunction is significantly reduced in our study, probably due to a better knowledge of the equipment and improved surgical skills, especially as regards laparoscopic procedures (increase in the length of the intervention of the 1.35%, compared to the 7% of the previous series).

According to both previous and current series, the principal incidents were related to the energy sources, in particular bipolar coagulation devices. This finding was already reported by Borie et al (8) who analyzed 876 adverse events related to health care (AERHC), reporting a persisting misunderstanding of the energy sources appropriate usage within the medical and paramedical teams.

As regards our findings, most of the low difficulty procedures were performed by junior surgeons and/or residents, whose surgical skills and knowledge of the equipment are frequently inferior in comparison to senior surgeons'.

Nevertheless, laparoscopic skills and expertise may not be enough to prevent and treat in a short gap of time the malfunctions; as demonstrated by Marlies P. Schijven et al (2) through a serious game simulating incidents in the operative room, expert laparoscopic surgeons were less skilled in solving malfunctions than laparoscopic equipment specialist (45.0 % vs 68.9, $p=0.01$). Moreover, this study shows that experienced surgeons were unable to outperform novice and intermediate surgeons in dealing with laparoscopic equipment failure. These findings are alarming and show how important is the continuous training throughout the laparoscopic surgeon's careers.

The Federation of Visceral and Digestive Surgery (FCVD) is in charge in France of the continuing medical education of digestive surgeons and propose an interesting program to consolidate knowledge and abilities on the fundamental use of the surgical energy (FUSE). The program was welcomed by the 485 participants and seems to help in achieving objectives (9).

Moreover, the implementation of checklists (10)(11) in the preoperative phase and the assessment of instruments before the operative act may have a impact in reducing equipment failures (7), despite they may be not sufficient to prevent intraoperative malfunctions.

Further investigations are required to assess the impact of a preoperative check-list on the development of equipment failures during the surgery; a clinical audit may be a useful strategy to implement some corrective measures and obtain an improvement.

Another aspect that has to be taken in consideration in future studies is the correlation between equipment failure and declaration of medical device incidents, in order to assess the frequency of instrument's replacement and to enhance device's traceability and safety (12).

In our center, scrubbed nurses are not always involved in the surgery, especially in “easy” procedures. This could lead to an inadequate preoperative check of instruments and to an improper assembling of components. In case of implementation of new check-lists, their extensive application to all procedures must be ensured, even in case of lack of dedicated staff.

We chose not to include emergency procedures in the study in order to follow the methodology. Nevertheless, it could be interesting to investigate the incidence of equipment failure during emergency in further studies.

Patient safety incidents occurring in the gynecology theatre may originate from apparently innocuous incidents, such as a bipolar forceps failure or insufficient knowledge of a new device. Interventions may include investment in continuing medical education (9), assessment and competency of gynecological surgeons, especially consultants and residents, team briefing after the appearance of an incident, implementation of clinical audit, instrument's adequate preoperative check.

Conclusions

Equipment failure is a common event in laparoscopy. Nevertheless, this study shows how time wasted for malfunctions is low in laparoscopy, as it only accounts for 1.35% of the overall surgical time. Human decisions appear to be involved in problems onset in almost half of cases. This alarming finding may advise for intensification in training and upgrading of the surgical team, implementation of check lists and clinical audit.

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250

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289 **Tables**

290 Table 1. Number of equipment failures per surgery

291 Table 2. Surgeons, type of surgery and incidence of equipment failure by type of
292 surgery

293 Table 3. Catalogue of endoscopic equipment and related rate of malfunction

294

Interventions complicated by EF	66
interventions with 1 EF	49
interventions with 2 EF	12
interventions with 3 EF	3
interventions with 4 EF	1
interventions with 5 EF	1
Total of EF	91

Table 1. number of equipment failures per surgery

(EF= equipment failure)

	Laparoscopies (N°)		
	Low difficulty	Medium difficulty	High difficulty
Senior surgeon	19 (4 EF)	27 (16 EF)	56 (42 EF)
Surg 1		7 (7 EF)	20 (21 EF)
Surg 2	5 (1 EF)	5 (1 EF)	15 (6 EF)
Surg 3	3 (0 EF)	7 (5 EF)	
Surg 4	2 (0 EF)	2 (0 EF)	11 (8 EF)
Surg 5	5 (1 EF)	2 (0 EF)	7 (4 EF)
Surg 6	1 (0 EF)	3 (2 EF)	
Surg 7	1 (1 EF)		3 (1 EF)
Surg 8	2 (1 EF)	1 (1 EF)	
Junior surgeon	28 (9 EF)	14 (6 EF)	3 (1 EF)
Surg 9	13 (4 EF)	4 (2 EF)	
Surg 10	10 (3 EF)	5 (3 EF)	
Surg 11	5 (2 EF)	5 (1 EF)	3 (1 EF)
Residents	16 (7 EF)	8 (6 EF)	0
	16 (7 EF)	8 (6 EF)	
TOTAL	63 (20 EF)	49 (28 EF)	59 (43 EF)
% EF	22% (20/91)	31% (28/91)	47% (43/91)

Table 2. Surgeons, type of surgery and incidence of equipment failure by type of surgery

(Surg= surgeon; EF= equipment failure)

	N° of malfunctions	Rate of malfunction (%)
Fluid and gas circuit	12	13%
Laparoscopic suction/irrigation system	10	10.9%
Insufflator	2	2.1%
Instruments	44	48%
Bipolar forceps	14	15.3%
Optical system	0	-
Uterine manipulator	0	-
Laparoscopic morcellator	1	1.1%
Insufflation switch	0	-
Extraction bag	1	1.1%
Sheath	5	5.5%
Niddle holder	10	11%
Monopolar needlepoint or loop	1	1.1%
Forceps for tissue fusion	4	4.4%
Monopolar scissors	1	1.1%
Scissors	1	1.1%
Suspension device	2	2.2%
Fascia closure device	4	4.4%
Electrical circuit	22	24%
Bipolar forceps	1	1.1%
Bipolar cable	14	15.3%
Diathermy foot pedal	1	1.1%
Monopolar scissors	0	-
Monopolar cable	6	6.6%
Generator	0	-
Video circuit	13	14%
Cold light cable	2	2.2%
Monitor	2	2.2%
Optical system	9	9.9%
Digital camera	0	-
Total of EF	91	100%

Table 3. Catalogue of endoscopic equipment and related rate of malfunction
(EF=equipment failures)