For a Better Evaluation of Intraoperative Adverse Events in Laparoscopic Surgery: The Club Cœlio Experience

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ABSTRACT

Aim: To assess the incidence of intraoperative events during laparoscopic surgery according to a new 5-grade classification based on the Satava approach to surgical error evaluation and the Kazaryan classification.

Material and Methods: This prospective and multicentric study was performed by 24 surgeons*, members of the Club Cœlio. All their patients who had an abdominal laparoscopic operation during a 3-month period were included in the study. The major analysed outcomes were the intraoperative incidents and accidents.

Results: The series consisted of 1674 consecutive patients and an intraoperative adverse event was noted in 118 (7 %). Creation of pneumoperitoneum and port placement were specifically responsible for 29 events (1,73 %): 4 mild emphysemas, 13 mild vascular injuries (0,78 %) and 12 visceral injuries (0,72 %). During the surgical procedure itself, 3 major vascular injuries (0,17%) and 14 visceral injuries (0,83%) were reported.

According to our classification, uneventful operation was observed in 1556 patients (93%), an incident without intraoperative consequence (Grade I) in 68 (4 %) and an incident with consequence treated by laparoscopy (Grade II) in 14 (0,8 %). A conversion (Grade III) was required in 35 patients (2,1%). Surgery of the colon and rectum were associated with the highest rate of conversion. Only one patient had an event not recognized during operation with postoperative consequence (Grade IV).

Conclusion: The prevalence of intraoperative events is not well known in the literature. We propose a simple classification of the intraoperative adverse events appropriate for abdominal laparoscopic surgery that appears to be an effective tool for a better assessment of surgical outcomes.

Keywords: Laparoscopic surgery; Classification; Intraoperative adverse events

INTRODUCTION

In 1992, Clavien and al. proposed a classification for postoperative complications [1]validated for open and laparoscopic surgery. In a previous study concerning more than 4000 laparoscopic procedures [2], we pointed out the need to report intraoperative events especially conversion. Even if the postoperative course is uneventful, such adverse event is a deviation from the expected postoperative course. Recently, Rosenthal and al. [3]underlined the lack of consensus on the statement of intraoperative complications in the prospective and randomized studies. The aim of this trial is to assess the incidence of intraoperative adverse events occurring during laparoscopic abdominal surgery according to a new classification based on the Satava approach to surgical error evaluation [4]and the Kazaryan classification [5].

MATERIAL AND METHODS

Twenty-four surgeons* members of the Club Cœlio, a group of French and Belgian surgeons specialised in laparoscopy, participated at that multicentre prospective study. All consecutive patients having a laparoscopic abdominal surgery between January and April 2015 were included in the study. Both patients with emergency or scheduled laparoscopic surgery were eligible. Previous abdominal surgery by laparotomy or laparoscopy was not a cause of exclusion.

For the data processing, we used a spreadsheet Excel (Microsoft XP, Redmond service, WA, USA).

The following parameters were recorded: names of patient and surgeon, patient gender, age, weight, height and body mass index (BMI), the site of previous scars, emergency and/or elective and/or ambulatory surgery, the disease or the organ involved and the modalities of pneumoperitoneum creation. Any adverse event occurring at any time of the surgery was noted and graded according to a new classification (Table 1). Grade 0 corresponds to an operation without any incident or accident. Grade I corresponds to an event without any change in the operative

approach and without expected further consequences for the patient (for example bleeding from a minor abdominal wall vessel or mesenteric emphysema). Grade II corresponds to an event with possible further consequence for the patient that can be managed by laparoscopy (for example suture of a small bowel injury). The need for peroperative blood transfusion is also considered as a Grade II adverse event. Grade III corresponds to the need for conversion that is defined as unplanned abdominal wall incision or an incision significantly larger than initially planned [6]. Furthermore, was specified if it was a pre-emptive conversion (IIIp), decided by the surgeon before any incident (for example a dissection considered as too hazardous by laparoscopy), or a reactive conversion (IIIr) to handle a not approachable difficulty in a reliable way under laparoscopy (for example injury of a major blood vessel) [7]. Grade IV corresponds to an event unrecognized during the surgical procedure and responsible of postoperative complications (for example an ignored injury of the common bile duct).

Table 1: New 5-grade Classification of intraoperative adverse events.

Grade 0	No intraoperative event
Grade I	Incident without intraoperative consequence
Grade II	Intraoperative incident with consequence treated by laparoscopy (including operative transfusion)
Grade III	Intraoperative incident requiring conversion
	IIIp: Preemptive conversion
	IIIr: Reactive conversion
Grade IV	Intraoperative event not recognized during operation with postoperative consequence

For the assessment of the postoperative complications, we used the Clavien's classification [1] at the day of the hospital discharge and one month postoperatively.

RESULTS

The study group consisted in 1674 patients; 803 women and 871 men with a mean age of 54 ± 17 years and a mean BMI of 29 ± 8. There were 1472 elective operations (88 %) (among which 510 (30 %) were performed in one-day clinic) and 202 emergency operations (12 %). The different procedures were: 32 gastroœsophagal reflux disease repair (2 %), 280 bariatric surgery (17 %), 399 biliary tract surgery (24 %), 16 small bowel surgery (1 %), 97 appendectomies (6 %), 135 colectomies (8 %), 39 rectal resection (2 %), 447 groin hernia repair (27 %), 137 ventral hernia repair (8 %) and 92 miscellaneous (5 %), among which 23 gynaecological interventions and 20 diagnostic laparoscopies. On total, intraoperative adverse events were reported in 118 patients (7,05 %). Globally, 16 vascular injuries (0,96 %) and 26 visceral injuries (1,55 %) were noted. All these lesions are listed in the Appendix A in which the setting, the devices incriminated in injury and the classification are included.

Events Related to the Creation of Pneumoperitoneum or Trocar Insertion

Creation of the pneumoperitoneum was performed with a Palmer or Veress needle in 1261 cases (75 %) and the Hansson technique was used in 331 (20 %). Two surgeons used the direct trocar technique placement in 82 cases (5 %).

Pneumoperitoneum creation was associated with 19 adverse events. The Veress needle generated 16 incidents (0,96 %): 3 persistent emphysemas without consequence among which one in the mesentery and also 13 minor injuries : 6 of another parietal vessel than the epigastric artery, 4 hepatic injuries, 2 mesenteric injuries and 1 gastric puncture. Only one patient had a median scar with risk of underestimated adhesions. With the Hansson technique, one mild emphysema and two gut injuries (small bowel and caecum) due to adhesions were noted. No gaseous complication was observed in the patients who had direct trocar placement before pneumoperitoneum.

Trocar insertion caused 10 adverse events (0,60 %). One mild liver injury occurred with direct trocar placement before pneumoperitoneum, for a cholecystectomy, recognized and dabbed itself quickly. Insertion of the following trocars was responsible for 9 injuries : 7 of another parietal vessel than the epigastric artery, 1 epiplooic injury and 1 bladder injury during appendectomy, not seen and thus recognized at the reoperation.

On total, creation of pneumoperitoneum and trocar insertion were responsible for 29 events(1,73 %): 4 mild emphysemas, 13 mild vascular injuries (0,78 %) and 12 visceral injuries (0,72 %).

Intraoperative Events After Creation of the Pneumoperitoneum

Three vascular injuries (0,18 %) were recorded: one injury of the left iliac vein with a ultrasonic device during in the course of recurrent colonic cancer justifying a reactive conversion, one injury of the upper left colonic artery during the extraction of the colonic specimen and one injury of the epigastric arterywith the hook coagulator during a groin hernia repair.

Eight digestive tract injuries (0,48 %) were noted. A calibration tube was responsible for an oesophageal perforation during a sleeve gastrectomy, with reactive conversion. A gastric wound with ultrasonic device was recorded. Five small bowel injuries were recorded : three times by soft graspers, one by scissors without coagulation and one by a calibration tube. Two of them (bariatric and rectal surgery) were treated after reactive conversion. For every case, diagnosis and treatment were immediate and postoperative course was not complicated (one Clavien I). No secondary injury by electric arc was observed. A colonic injury with scissors without coagulation was reported and treated by laparoscopic suture.

Two injuries of the main bile duct were recorded: one was immediately recognized and sutured with secondary endoprosthesis, the other one required an hepaticojejunal anastomosis after reactive conversion.

Four other visceral injuries were recorded : 1 mild hepatic injury with the hook, 1 splenic injury by soft graspers (haemostasis), 1 epiplooic injury with scissors and one opening of the left pleura during a gastroœsophagal reflux repair without any consequence.

Adverse Events' Classification

The operation was totally uneventful in 1556 patients (93%). GradeI adverse events were noted 68 times (4%): 4 emphysemas, 2 optic dysfunctions, 2 failures of direct trocar insertion before pneumoperitoneum (creation of the pneumoperitoneum with needle and then insertion of the first trocar), 14 parietal vessel injuries, 18 visceral injuries and 28 other intraoperative events reported by the surgeon, in particular ruptured of the bag used for the extraction of the gallbladder.Grade II events were recorded 14 times (0,84 %): 8 intra operative findings inducing a modification (n=6) or cancellation (n=2) of the planned procedure, 3 small bowel injuries sutured laparoscopically, onesuture of the common bile duct injury, one drained pneumothorax, one redo ileocolic anastomosis, one nasogastric tube section by the linear staplers during a by-pass and the tearing of the upper left colonic artery at the time of specimen extraction. The global rate of conversion (Grade III) was 2 %:25 patients (1,5 %) benefited from a pre-emptive conversion (Grade IIIp) and 10 from a reactive conversion (0,6 %) (GradeIIIr) (Table 3). Surgery of the colon or rectum was associated with the highest rate of conversion. One Grade IV event was recorded (0,06 %): a bladder injury by secondary trocar in the course of an appendectomy, not seen immediately and requiring a reoperation.

Table 2: Details of Grade III adverse events.

	Type of surgery	Reason for conversion
25 pre-emptive conversions (1,5%)	2 VHR	Strangulated umbilical hernia, adhesions
	1 GHR	Adhesions
	2 bariatric	Adhesions, obesity
	2 biliary	Pseudoneoplasic cholecystitis, unclear anatomy of the CBD
	1 small bowel	Occlusion following bypass
	3 appendix	2 plastrons, 1 peritonitis
	11 colonic	5 adhesions, 3 large lesions, 1 operative difficulty, 1 abscess, 1 cirrhosis
	2 rectal	2 adhesions
	1 other	Intractable intrathoracic stomach
10 reactive conversions (0,6%)	3 rectal	Large lesion, small bowel injury, iliac vein injury
	2 bariatric	Oesophageal injury, small bowel injury
	2 biliary	Severe cholecystitis, Hepaticojejunostomy for CBD injury
	2 colonic	Colovesical fistula, non planned total colectomy
	1 small bowel	Small bowel injury

VHR: ventral hernia repair; GHR: groin hernia repair; CBD: common bile duct.

Table 3: Intraoperative event's classification and Clavien's classification by type of surgery.

	N	Intraoperative event's classification						No complication at discharge		Clavien I or II at discharge	Clavien III, IV or V at discharge	
		0	I	II	IIIp	IIIr	IV					
GER disease repair	32	30	1	1				27	84%	1	4	12%
Bariatric surgery	280	256	16	4	2	2		254	91%	17	9	3%
Biliary tract surgery	399	364	29	2	2	2		372	93%	27	0	0%
Small bowel surgery	16	13	1		1	1		13	81%	1	2	12%
Appendectomy	97	92	1		3		1	93	98%	3	1	1%
Colectomies	135	116	5	1	11	2		104	77%	22	9	7%
Rectal resection	39	33		1	2	3		27	69%	9	3	8%
Groin hernia repair	447	435	10	1	1			439	98%	6	2	1%
Ventral hernia repair	137	134	1		2			132	97%	4	0	-
Miscellaneous	92	83	4	4	1			89	97%	2	1	1%
TOTAL	1674	1556	68	14	25	10	1	1551	93%	92	31	2%

Postoperative Complications

Postoperative course was uneventful in 1551 patients at the discharge day and 123 patients (7.3%) had a postoperative complication. According to the Clavien's classification, 92 patients had a type I or II postoperative complication and 31 a type III,IV or V complication. One month later, the number of complication increased slightly: 216 patients (13.3%) with 53 lost for follow up. The intraoperative adverse events and postoperative complications by type of surgery are reported in Table 3. The possible correlation between the intraoperative adverse events and the postoperative complications according to the Clavien's classification is shown in table 4.

Table 4: Possible consequences of the intraoperative course according to the Clavien's classification.

	Clavien at the discharge						Clavien 1 month later Lost for follow-up: 53					
	Clavien I	Clavien II	ClavienIIIa	ClavienIIIb	ClavienIVa	Clavien V	Clavien I	Clavien II	ClavienIIIa	ClavienIIIb	ClavienIVa	Clavien V
1556 Grade 0	35	22	1	23	1	2	97	32	3	33	1	5
68 Grade I	14			1			21			1		
14 Grade II	3	1					2	1		1		
25 Grade IIIp	4	3		1			5	3	1	2		
10 Grade IIIr	3	3		1			3	3		1		
1 Grade IV				1						1		

DISCUSSION

As already reported by the authors [2], this prospective study on consecutive patients confirms that intraoperative adverse events are not uncommon and that they are not limited to the creation of the pneumoperitoneum and insertion of trocars or due to coagulation devices. It also indicates that the intraoperative events are badly described and much more frequent than usually reported. A recent study [8]underlines that for 46 randomized studies published in international reviews, no intraoperative event is reported in 18 and no postoperative event is reported in 3 of them. This report illustrates that the exhaustive statement of the intraoperative events is perfectible. The reasons of this gap were analyzed [9]: lack of consensus on the definitions, lack of systematized report and lack of neutral observer; documentation of the occurrence of intraoperative event relying solely on the willingness of the surgeon.

In conclusion of the first study of the Club Cœlio, we suggested to complete the Clavien 's classification with 2 added prefixes : " I " for incident and "C" for conversion. Recently, Platz and al. [10]reported prospective series in which the intraoperative events for any surgery are reported in 9 grades. Kaafarani and al. [9]proposed a classification of the intraoperative events in 6 grades, without specifying the need for conversion. Kazaryan and al. [5]proposed the Oslo classification, grading the intraoperative adverse events on the basis of Satava approach to surgical error evaluation [4]. Satava primarily used this approach to grade errors occurring during simulation of a laparoscopic operation. In our study, the adverse events were reported not for what and they are factually but rather for their immediate or predictable consequences. Furthermore, the concepts of preemptive or reactive conversion and their consequences were already specified by Yang and al. [7]. We also consider useful to specify conversion (grade III) and the circumstances of a possible conversion because it was demonstrated that the post-operative morbidity is increased in case of intraoperative event and in case of reactive conversions[8,11].

Within the Club Cœlio, we observed that an additional approach is accepted and followed all the more easily as it is simple to implementand familiar in its conception. We propose a classification answering this project with only 5 grades and following on the same concept as the Clavien's classification, which is known by every surgeon. To do so, we benefit of simplicity, allowing to put into grades the intraoperative course, uneventful procedures included, and to authorize comparisons over the time and between surgical teams independent from the type of concerned surgery.

Hundred and eighteen intraoperative adverse events were recorded (7,05 %), among which 35 conversions (2 %). If the surgical team may consider that these are percentages brought back in the literature, the event remains major for the patient. This number of intraoperative events is nearby of the number of postoperative complications(123 patients, 7,35 %). The modesty of our sample does not still allow us to study the possible correlations between the arisen of unwanted intraoperative events and the rate of post-operative complications. Our first goal is to stimulate

the surgeons to mention in their operating protocol any adverse event occurring during the procedure because the clinical consequences of those events can be delayed and unpredictable.

If some publications reporting those events are immerging in the literature [8], there are few specific information on this subject about laparoscopic surgery, the existing publications dealing with the subject in a general way doesn't consider the precise number of patients[12,13]. At the same time, the incidence of these events in the course of laparoscopy does not decrease, even if their treatment improved [8].

In spite of the effort made in this study, the prevalence of all intraoperative events is likely still underestimated. First of all, anesthesiological events were not listed in the grid. Besides, only two surgeons indicated that the gallbladder had been torn or morcellated during dissection or extraction despite the recommendation of the French Federation of Visceral and Digestive tract surgeons. Undoubtedly, this reflects the surgeon's thought that it was more important to indicate "major" or "significant" intraoperative events rather than those considered as "minor".

CONCLUSION

This second prospective trial of the Club Cœlio underlines the incidence of intraoperative incidents and accidents and their consequences. In addition to the classic evaluation of post-operative complications, a better assessment of the perioperative unfavourable events appears mandatory. Evaluation of surgical practice should not only consider the consequences of the operation but also any event that can interfere with the surgery performance or the expectation of the patient. A new classification of intraoperative adverse events is proposed for a better knowledge of the course of the patient and for an adequate evaluation of current laparoscopic procedures.

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Appendix A: Vascular and digestive tract injuries.

Injured vessel	Type of surgery	Injuring agent	Modality creation PNP	Emergency/ elective	Previous scars	Grade	Reoperation	Clavien stage one month after discharge
Iliac vein	Rectal	Ultrasonic device	Needle	Elective	Other	IIIr	yes	IIIb
Epigastric artery	GH	Scissors or hook w/o coagulation	1st trocar	Elective		I		
Other AWV	Bariatric	Other trocar	Needle	Elective	Other	I		Ib
Other AWV	Bariatric	Other trocar	Needle	Elective	IM	I		Ib
Other AWV	Bariatric	Other trocar	Needle	Elective	IM	I		Ib
Other AWV	Bariatric	Other trocar	Needle	Elective	IM	I		Ib
Other AWV	Bariatric	Palmer	Needle	Elective		I		
Other AWV	Bariatric	Palmer	Needle	Elective		I		Ia
Other AWV	Biliary	Other trocar	Needle	Elective	Other	I		Ib
Other AWV	Biliary	Other trocar	Needle	Elective	Other	I		Ib
Other AWV	Biliary	Other trocar	Needle	Elective		I		Ib
Other AWV	Biliary	Palmer	Needle	Elective	Other	I		
Other AWV	Biliary	Palmer	Needle	Elective		I		
Other AWV	Biliary	Palmer	Needle	Elective		I		
Other AWV	Colonic	Palmer	Needle	Elective		I		Ia
Upper left colic artery	Rectal	Traction	Needle	Elective		II		
Injured organ								
Esophagus	Bariatric	Calibration probe	Open	Elective		IIIr		Ia
Stomach	GERD	Ultrasonic device	Needle	Elective		I	yes	IIIb
Stomach	Biliary	Palmer	Needle	Elective		I		
Small bowel	Small bowel	Flat-jawed grasper	Open	Emergency	Other	I		
Small bowel	Bariatric	Flat-jawed grasper	Needle	Elective	Other	IIIr		
Small bowel	Rectal	Scissors or hook w/o coagulation	Open	Elective	XPM	IIIr		II
Small bowel	Bariatric	Calibration probe	Needle	Elective		II		Ib
Small bowel	Biliary	Open technique	Open	Elective	IM	II		Ia
Small bowel	Colonic	Flat-jawed grasper	1st trocar	Elective		I		
Colonic	Biliary	Scissors or hook w/o coagulation	Needle	Elective	SM	I		
Colonic	Colonic	Open technique	Open	Elective		I		
Liver	VAW	Palmer	Needle	Elective	SM	I		
Liver	Bariatric	Palmer	Needle	Elective		I		
Liver	Biliary	1er trocar	1st trocar	Elective	IM	I		Ib
Liver	Biliary	Palmer	Needle	Elective	Other	I		Ia
Liver	Biliary	Palmer	Needle	Elective	Other	I		Ib
Liver	Biliary	Scissors or hook w/o coagulation	Needle	Elective		I		Ia
CBD	Biliary	Scissors or hook w/o coagulation	Needle	Elective	Other	II	yes	IIIb

CBD	Biliary	Cisx/crochet+coag	Needle	Elective		IIIr		Ia
Spleen	Bariatric	Flat-jawed grasper	Needle	Elective	Other	I		
Bladder	Appendix	Other trocar	Needle	Emergency		IV		IIIb
Mesentery	Biliary	Palmer	Needle	Emergency		I		
Mesentery	Biliary	Palmer	Needle	Elective		I		
Omentum	IFH	Scissors or hook w/o coagulation	Needle	Elective	Other	I		
Omentum	Other	Other trocar	Needle	Elective	Other	I		
Pleura	GERD	NP	Needle	Elective		II		

PNP: pneumoperitoneum; GH: groin hernia; CBD: common bile duct; VAW: ventral abdominal wall; w/o coag: without coagulation; w coag: with coagulation; SM: supraumbiical midline; IM: infraumbilical midline; XPM: xiphopubic midline; GERD: gastroesophageal reflux disease; NP: not provided.

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