ORIGINAL ARTICLE



International consensus on a complications list after gastrectomy for cancer

Gian Luca Baiocchi^{1,2} Simone Giacopuzzi³ · Daniele Marrelli⁴ · Daniel Reim⁵ · Guillaume Piessen⁶ · Paulo Matos da Costa^{7,8} · John V. Reynolds⁹ · Hans-Joachim Meyer¹⁰ · Paolo Morgagni¹¹ · Ines Gockel¹² · Lucio Lara Santos¹³ · Lone Susanne Jensen¹⁴ · Thomas Murphy¹⁵ · Shaun R. Preston¹⁶ · Mikhail Ter-Ovanesov¹⁷ · Uberto Fumagalli Romario¹⁸ · Maurizio Degiuli¹⁹ · Wojciech Kielan²⁰ · Stefan Mönig²¹ · Piotr Kołodziejczyk²² · Wojciech Polkowski²³ · Richard Hardwick²⁴ · Manuel Pera²⁵ · Jan Johansson²⁶ · Paul M. Schneider²⁷ · Wobbe O. de Steur²⁸ · Suzanne S. Gisbertz²⁹ · Henk Hartgrink²⁸ · Joanna W. van Sandick³⁰ · Nazario Portolani^{1,2} · Arnulf H. Hölscher³¹ · Maristella Botticini³² · Franco Roviello⁴ · Christophe Mariette⁶ · William Allum³³ · Giovanni De Manzoni³

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Abstract

Background Perioperative complications can affect outcomes after gastrectomy for cancer, with high mortality and morbidity rates ranging between 10 and 40%. The absence of a standardized system for recording complications generates wide variation in evaluating their impacts on outcomes and hinders proposals of quality-improvement projects. The aim of this study was to provide a list of defined gastrectomy complications approved through international consensus.

Methods The Gastrectomy Complications Consensus Group consists of 34 European gastric cancer experts who are members of the International Gastric Cancer Association. A group meeting established the work plan for study implementation through Delphi surveys. A consensus was reached regarding a set of standardized methods to define gastrectomy complications.

Results A standardized list of 27 defined complications (grouped into 3 intraoperative, 14 postoperative general, and 10 postoperative surgical complications) was created to provide a simple but accurate template for recording individual gastrectomy complications. A consensus was reached for both the list of complications that should be considered major adverse events after gastrectomy for cancer and their specific definitions. The study group also agreed that an assessment of each surgical case should be completed at patient discharge and 90 days postoperatively using a Complication Recording Sheet. **Conclusion** The list of defined complications (soon to be validated in an international multicenter study) and the ongoing development of an electronic datasheet app to record them provide the basic infrastructure to reach the ultimate goals of standardized international data collection, establishment of benchmark results, and fostering of quality-improvement projects.

Keywords Perioperative complications \cdot Gastric cancer \cdot Gastrectomy \cdot International consensus \cdot Clavien–Dindo classification \cdot Comprehensive Complications Index

Introduction

Although its incidence is stabilizing, gastric cancer still represents a major cause of cancer deaths worldwide [1–5]. The foundation of gastric cancer care is surgery, which is currently performed in hospitals with different procedure volumes. Centralization of gastric cancer surgery to a small

number of high-volume centers occurs in only a few countries and has not been widely accepted.

The overall estimated mortality rate of gastrectomy for cancer is surprisingly higher than the reported mortality for liver and pancreatic cancer surgeries. The mortality rates in high-volume Western centers range from 3 to 5%, which are in contrast with the rates for low-volume centers that range from 10 to 20% [6–8]. Postoperative morbidity rates are reported as major or minor, but these reports vary and use inconsistent descriptive terminology. As a result, studies

☐ Gian Luca Baiocchi gianluca.baiocchi@unibs.it

Extended author information available on the last page of the article



have reported a wide range of incidence rates varying from 11 to 46% [9–14].

Understanding postoperative complications is of paramount importance, because these adverse events can have major impacts on critical outcomes. However, the wide variation in the definitions and recording of postoperative complications after gastrectomy across different institutions and countries makes establishing causal links between these complications and critical outcome measures almost impossible. A systematic review published in 2001 retrieved a total of 41 different definitions of and 13 grading scales for surgical wound infections from 82 studies. The review also found 56 separate definitions of anastomotic leaks from 107 studies reporting the outcomes of gastrointestinal surgery [15]. A recent study investigating the incidence rates of postoperative hemorrhage, respiratory failure, deep vein thrombosis, and sepsis derived from three data sources (administrative, a national clinical registry, and an institutional clinical registry) reported remarkable discordance, with Cohen's kappa coefficients ranging from 0.02 to 0.60 [16].

These data highlight an unmet need to establish a common language to ensure consistency in the definitions of postoperative gastrectomy complications not only to create standards of care but also to facilitate outcome comparisons. Recent Asian studies have shown the benefits of standardized reporting for conducting detailed comparisons of the differences between Western and Eastern surgeons [17, 18].

The most common and universally recognized classification of postoperative complications is the Clavien–Dindo (C–D) classification, which is a treatment-related severity grading system [19–21]. Since a patient may develop more than one postoperative complication, C–D grading has been expanded into the Comprehensive Complications Index (CCI). The CCI is a web-based calculator that combines multiple complications and produces a final score ranging from 0 to 100 [22, 23]. Both the C–D classification and the CCI are general scores and do not provide definitions of specific postoperative complications for particular operations.

This study reports the first step of a project launched in November 2015 by a large group of gastric cancer experts who are members of the International Gastric Cancer Association (IGCA). The project aimed to define a comprehensive list of surgery-related and gastric cancer-specific complications and adverse events deemed to be essential items that should be included in multicenter studies and international databases. The list will help standardize outcome reporting after gastric resection for cancer worldwide. Recent pioneering studies by Low et al. [24, 25] have shown that standardization of data collection for complications associated with esophagectomy is the building block for achieving the ultimate goal of proposing quality-improvement projects that can benefit patient survival, quality of life, and long-term

outcomes. In other words, quality improvement must start with quality measurements [26–28].

The road map for this study envisaged two steps. In the first step (presented here), European gastric cancer experts created and reached a consensus on a list of defined complications using Delphi surveys. This method was used by Low and coauthors in their study of esophagectomy complications [24]. The second step involves validation of the proposed list and the establishment of a large global database. The multicenter study will be fully international; many gastric cancer experts and members of the IGCA from high-volume centers in Brazil, Canada, China, Japan, Korea, and the US have all agreed to participate.

Methods

Design and assembly of the Gastrectomy Complications Consensus Group (GCCG)

The research project was developed within the portfolio of studies sponsored by European members of the IGCA. A project working group consisting of 3 gastric cancer experts was established. The project working group identified high-volume specialist gastric surgical centers in Europe from the participants of the EURECCA (EUropean REgistry of Cancer CAre) project and the members of the Italian Research Group on Gastric Cancer (GIRCG) to form the Gastrectomy Complications Consensus Group (GCCG). The GCCG was designed to include a widely heterogeneous set of gastric cancer specialists who could represent different individual institutions within a country and different health systems across Europe. Thirty-one experts from 13 European countries agreed to take part in addition to the 3 members of the project working group (Table 1).

Delphi surveys

The project used Delphi surveys designed to be mainly web-based and coordinated by the project working group [29]. The working group thoroughly reviewed the most recent knowledge on how perioperative complications related to gastrectomy for cancer were defined and recorded in the literature. Next, the group invited the study participants to agree on the proposed methodology that would deliver an initial list of complications with their definitions. The group also proposed that (1) the project should focus on transabdominal gastrectomy with curative intent for gastric cancer; (2) Siewert type II and III esophago-gastric junctional cancers should be included, and (3) open and minimally invasive (laparoscopic or robotic) operative procedures should both be included in the scope of the project.



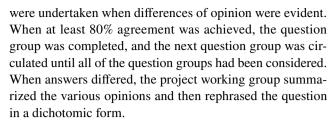
Country	Members	Location
Denmark	Lone Susanne Jensen	Aarhus
France	Christophe Mariette Guillaume Piessen	Lille Lille
Germany	Ines Gockel Arnulf H. Hölscher Hans-Joachim Meyer Daniel Reim	Leipzig Frankfurt Berlin Munich
Ireland	Thomas Murphy John V. Reynolds	Cork City Dublin
Italy	Gian Luca Baiocchi* Maurizio Degiuli Giovanni De Manzoni Uberto Fumagalli Simone Giacopuzzi* Daniele Marrelli* Paolo Morgagni Franco Roviello	Brescia Torino Verona Brescia Verona Siena Forlì Siena
The Netherlands	Wobbe O. de Steur Suzanne S. Gisbertz Henk Hartgrink Johanna W. van Sandick	Leiden Amsterdam Leiden Amsterdam
Poland	Wojciech Kielan Piotr Kołodziejczyk Wojciech Polkowski	Wroclaw Krakow Lublin
Portugal	Paulo Matos da Costa Lucio Lara Santos	Lisboa Porto
Russia	Mikhail Ter-Ovanesov	Moscow
Spain	Manuel Pera	Barcelona
Sweden	Jan Johansson	Lund
Switzerland	Stefan Mönig Paul M. Schneider	Geneva Zurich
United Kingdom	William Allum Richard Hardwick Shaun R. Preston	London Cambridge Guilford

The GCCG comprises the 3 members of the project working group (listed with an * above) who developed and coordinated the Delphi surveys and the 31 gastric cancer experts who answered the questions

A series of questions were designed and circulated electronically to the study participants. A total of 10 groups of questions addressed the initial study design, intraoperative complications, general and surgical postoperative complications, outcome measures, and severity scores (Table 2). The project working group analyzed 660 answers. Each study participant provided a mean of 21 (range 11–36) answers.

For each group of questions, the study participants were asked to give their opinions on each topic. They were requested to base their views on their clinical and surgical experiences rather than referencing the literature. For select cases that were deemed particularly relevant, each expert was invited to provide remarks on a specific topic.

The responses for each group of questions were collated. Blinded discussion rounds using a modified Delphi approach



Confirmation rounds were conducted to approve the final complications list (displayed in Table 3). A consensus was also reached for the definition of each complication (Table 4). The definitions were kept precise but simple and focused on the critical features of each complication determined by the study participants (i.e., the type and level of the clinical response to the complication itself rather than its severity grade). A preliminary version of the list was presented and thoroughly discussed in Lisbon, Portugal, on June 16, 2016, at the "Esophageal and Gastric Cancer Initiative" conference, which was attended by several GCCG members. The final version of the list was presented at two invited sessions at the 12th International Gastric Cancer Congress in Beijing on April 21, 2017, which were attended by most of the GCCG members.

Results

Following initial agreement on the project design, a list of 27 complication topics was identified, including 3 intraoperative, 14 postoperative general, and 10 postoperative surgical complications. The main findings of the Delphi surveys (Table 2) were as follows.

In Question group 1, most experts agreed that general complications, including medical diseases, should be included. The optimal timing to document the postoperative assessment was initially contentious. After lengthy discussions and several blinded re-submissions, study participants agreed that this assessment should be made electronically via an app at both discharge and 90 days postoperatively.

In Question groups 2, 3, and 4, the term "general" was preferred to "medical" for non-surgical complications, which should include all major neurologic, cardiovascular, respiratory, liver, kidney, and infectious events (Table 3). A precise definition was offered for each of these complications (Table 4), and a consensus was reached.

In Question group 5, the study participants agreed that intraoperative damage to vessels and organs and intraoperative major bleeding should be included. These adverse events may also influence medium- to long-term outcomes. The details of each intraoperative complication were also defined (Table 4), and a consensus was reached. Unexpected adverse events (e.g., cardiac arrest) were also included within this category.



 Table 2
 Results of the Delphi surveys

	Question	Round 1	Round
Question grou	up 1—preliminary questions and study design		
1.a	General complications (cardiovascular, respiratory, renal, etc.) should be included in the Complications Recording Sheet for each patient episode	95.2	-
1.b	The Complications Recording Sheet should be filled in		
	(i) At discharge	26.3	_
	(ii) 30 days postoperatively	31.5	_
	(iii) 90 days postoperatively	0.0	_
	(iv) More than one answer	42.1	_
	(v) Electronically through an electronic application at both discharge and 90 days postoperatively	_	87.1
1.c	Complications should be categorized into three subgroups intraoperative, postoperative general, and post- operative surgical	88.8	-
1.d, 1.e, 1.f	Study participants were invited to provide remarks on an initial list of complications	_	_
1.g	Study participants were invited to provide remarks on any topic discussed in Question group 1	_	_
_	ups 2, 3, and 4—postoperative general complications		
2.a	Preference should be given to the taxonomy "general" vs. "medical" complications	77.3	100
2.b	A simple list of generic dysfunctions subdivided by system should be preferred over a detailed list of all	76.2	100
2.0	complications for each system	70.2	100
2.c	Sepsis and infection should be recorded in		
	(i) The postoperative general complications subgroup	52.4	_
	(ii) The postoperative surgical complications subgroup	23.8	_
	(iii) Both subgroups	23.8	100
.a, 3.b, 3.c	Study participants were invited to provide remarks on 2.a 2.b, 2.c	_	_
.a	Study participants were invited to provide remarks on the list of postoperative general complications and their definitions	-	-
uestion grou	pp 5—intraoperative complications		
5.a	Intraoperative complications should be included in the list of complications	100	_
5.b	Intraoperative complications should include		
	(i) Damage to vessels and organs	77.3	100
	(ii) Intraoperative bleeding	95.4	100
uestion grou	up 6—postoperative surgical complications: list		
6.a	The list of postoperative surgical complications should include		
	(i) Postoperative bleeding	100	_
	(ii) Postoperative occlusion	100	_
	(iii) Postoperative bowel perforation	100	_
	(iv) Duodenal leak	100	_
	(v) Anastomotic leak	100	_
	(vi) Postoperative pancreatic fistula	100	_
	(vii) Postoperative pancreatitis	62.5	_
	(viii) Collections without fistula	37.5	_
	(ix) Postoperative biliary leakage	75.0	_
	(x) Postoperative offiary readage (x) Postoperative chylous ascites	25.0	
	(xi) Postoperative chyrous ascites (xi) Postoperative lymphorrhea	25.0	
	(xii) Delayed gastric emptying	91.6	_
	up 7—postoperative surgical complications: definitions. Agreement on the proposed definition for each of the 1 regical complications:		d post-
7.a	Postoperative bleeding	80.7	92.3
7.a 7.b		61.5	92.3 88.5
	Postoperative occlusion Postoperative bowel perforation or necrosis	84.6	92.3
		A4 D	94.5
7.c	•		
	Duodenal leak Anastomotic leak	65.4 55.7	100 100



Table 2 (continued)

	Question	Round 1	Round 2
7.g	Postoperative pancreatitis	53.9	88.5
7.h	Other postoperative abnormal fluid from drainage and/or abdominal collections without gastrointestinal leak(s)	26.9	96.1
7.i	Delayed gastric emptying	73.1	80.7
7.j	Other complications (requiring re-intervention or other invasive procedures)	38.5	100
Question g	roup 8—other outcome measures		
8.a	Study participants were invited to provide remarks on additional outcome measures to be recorded in the Complications Recording Sheet	_	_
8.b	Complication grading should be recorded		
	(i) For each individual complication/subgroup of complications	45	_
	(ii) Only once for the clinical case as a whole	55	_
Question g	roup 9—complication grading system		
9.a	Complications should be graded according to		
	(i) The Clavien–Dindo scale	62.5	_
	(ii) The Comprehensive Complications Index (CCI)	37.5	_
Question g	roup 10—final consensus on complications list		
10.a	Final approval of the list of 27 complications with precise definitions	_	100

The figures indicate the percentages of study participants who agreed on the proposed statement (i.e., answered "Yes")

The project working group submitted a total of 36 questions to the 31 study participants, who provided a total of 660 answers. On average, each expert gave 21 answers (range 11–36)

In Question groups 6 and 7, the study participants were asked to comment and agree on 12 postoperative surgical complications that were previously defined by the Italian Research Group on Gastric Cancer (GIRCG) [30]. Ten complications were agreed upon, and a consensus was reached about the definition of each complication (Tables 3, 4).

In Question groups 8 and 9, the study participants were asked to comment on a list of additional quality measures to be added to the end of the Complication Recording Sheet, including in-hospital mortality (yes/no), length of ICU stay (days), length of postoperative hospitalization (days), discharge (home/other facilities), and the Clavien–Dindo complication grade(s) (considering the highest level). They were also asked to provide remarks on which grading system should be adopted (the Clavien–Dindo scale or the Comprehensive Complication Index). Given the wide disagreement on these questions, a consensus was drawn that both topics should be studied more in depth in the next step of the project during the international multicenter validation of the complications list.

In Question group 10, the project working group invited the study participants to reach a final consensus on the complications list (Table 3) and the precise definition of each complication (Table 4). A unanimous consensus was reached.

To summarize, despite disagreement on some questions, the Delphi surveys delivered a strong consensus on the most critical issues (Table 2), especially the list of complications and their specific definitions (Tables 3, 4).

Discussion

A consensus study is not without limitations. The opinions of those involved are based on varying levels of evidence and on clinical and surgical experience. Although this situation can introduce bias, the breadth of practices and health systems covered by the consensus group should minimize any bias. Needless to say, neither the GCCG nor any other single group can determine the ideal international standards for defining and recording gastrectomy complications. However, this project represents a starting point for generating a wider international consensus for standardization of data collection for cancer-related gastric resections. To facilitate the adoption of the proposed list across institutions and countries, Table 5 briefly summarizes the discussions that occurred among the GCCG members and reports the main rationales that guided them in the choice of a given definition for each complication.

Key features of the complications list

First, in contrast to previous reports, this study has included intraoperative complications, which are often unreported because their effects are corrected during procedures.



Table 3 Gastrectomy for cancer: the complications list

Intraoperative complications

- 1. Unintended intraoperative damage to major vessels and/or organs requiring reconstruction or resection
- 2. Intraoperative bleeding requiring urgent treatment
- 3. Unexpected medical conditions interrupting or changing the planned procedure

Postoperative general complications

- 4. Stroke causing patient's permanent deficit
- Need for CPR
- 6. Myocardial infarction with patient's transfer to CCU/ICU/other critical care facility
- 7. Cardiac dysrhythmia requiring invasive treatment
- 8. Acute myocardial failure with acute pulmonary edema or drop in EF>50%
- 9. Pulmonary embolism with symptoms confirmed by urgent CT scan
- 10. Respiratory failure requiring reintubation
- 11. Need for tracheostomy
- 12. Pleural effusion requiring drainage
- 13. Pneumothorax requiring treatment
- 14. Need for prolonged intubation (> 24 h after the surgical procedure)
- 15. Acute liver dysfunction (the Child–Pugh score > 8 for longer than 48 h)
- Acute renal insufficiency (postoperative creatinine twice its preoperative value)/renal failure requiring CVVH or dialysis
- 17. Infections (gastrointestinal, respiratory, urinary, or other) with both symptoms and germ isolation

Postoperative surgical complications

- Postoperative bleeding requiring both urgent transfusions and invasive treatment
- 19. Postoperative bowel obstruction (clinical/radiological signs of obstruction, inability to enteral feed, longer need for NG suction)
- 20. Postoperative bowel perforation or necrosis requiring surgical treatment (or cause of death)
- 21. Duodenal leak (irrespective of presentation, method of identification, clinical consequences, and treatment)
- 22. Anastomotic leak (irrespective of presentation, method of identification, clinical consequences, and treatment)
- 23. Postoperative pancreatic fistula
- 24. Postoperative pancreatitis diagnosed both clinically and radiologically
- Other postoperative abnormal fluid from drainage and/or abdominal collections without gastrointestinal leak(s) preventing drainage removal or requiring treatment
- 26. Delayed gastric emptying (by 10th postoperative day) requiring treatment or delaying discharge
- 27. Other major complications requiring re-intervention or other invasive procedures

All complications occurring during the in-hospital stay and within 90 days after surgery should be included and recorded in the Complications Recording Sheet for each patient episode

CPR cardiopulmonary resuscitation, CCU coronary care unit, ICU intensive care unit, EF ejection fraction, CVVH continuous veno-venous hemofiltration, NG nasogastric

However, these interventions, such as unplanned splenectomies or pancreatic resections, portal vein/hepatic artery reconstructions, and bile duct repairs, may also have medium- to long-term clinical consequences. The consensus group also agreed that unplanned blood transfusions should be documented as a marker of an unexpected intraoperative event, because they can adversely affect the oncological outcome [32]. One novel feature of this project is the inclusion of unexpected medical conditions other than intraoperative damage and bleeding in the intraoperative group. Despite being rare, these life-threatening events (e.g., anaphylactic shock, cardiac arrest, myocardial infarction) can occur and have dire consequences if they are not dealt with swiftly and ably.

Second, only major gastrectomy-related complications were included in the list. The difference between major and minor adverse events can be quite confusing and arbitrary, which may be one of the most compelling reasons for the different rates of complications reported in the published literature. Whether a given complication should be defined as "major" or "minor" has not been definitively stated. On the one hand, the grading severity cannot ignore the Clavien–Dindo classification system, which refers to the treatment needed for each adverse event. Hence, for several items in the proposed list, a grade equal to or greater than 3 from the C–D classification system is also considered major. On the other hand, this basic principle does not cover all of the items on the list. For example, the consensus group considered major complications to be those that required



Table 4 The gastrectomy complications list: definitions

Intraoperative complications

Unintended intraoperative damage to major vessels and/or organs requiring reconstruction or resection

DEFINITION

- i. Complete section of or major damage to hepatic artery requiring reconstruction
- ii. Complete section of or major damage to splenic artery requiring reconstruction
- iii. Complete section of or major damage to portal vein requiring reconstruction
- iv. Complete section of or major damage to cava vein requiring reconstruction
- v. Complete section of or major damage to bile duct requiring reconstruction
- vi. Damage to spleen requiring splenectomy
- vii. Any unplanned bowel resection (not for oncological reasons)
- viii. Partial or complete section of pancreas requiring resection (not for oncological reasons)
- 2. Intraoperative bleeding requiring urgent treatment

DEFINITION: Acute major bleeding requiring urgent transfusions

3. Unexpected medical conditions interrupting or changing the planned procedure

DEFINITION: Life-threatening intraoperative events other than intraoperative damage and bleeding, which determine the interruption or complete change of the planned procedure, such as anaphylactic shock, cardiac arrest, myocardial infarction, etc.

Postoperative general complications

4. Stroke causing patient's permanent deficit

DEFINITION: Stroke that determines a patient's permanent disability

Need for CPR

DEFINITION: Regardless of the underlying cause, patient needs cardiopulmonary resuscitation

6. Myocardial infarction with patient's transfer to CCU/ICU/other critical care facility

DEFINITION: Myocardial infarction recorded as major complication if the patient needs to be transferred to CCU/ICU/other critical care facility, irrespective of the treatment

7. Cardiac dysrhythmia requiring invasive treatment

DEFINITION: Dysrhythmia atrial or ventricular, which requires invasive treatment (e.g., pace-maker, automatic implantable cardioverter defibrillator, etc.)

8. Acute myocardial failure with acute pulmonary edema or drop in EF > 50%

DEFINITION: Acute myocardial failure that causes acute pulmonary edema or a large (> 50%) drop in EF. Acute pulmonary edema clinically detected. Drop in EF measured through echocardiogram

9. Pulmonary embolism with symptoms confirmed by urgent CT scan

DEFINITION: Pulmonary embolism recorded as major complication if (i) symptoms confirmed by CT scan, and (ii) CT scan required in urgency and not simply as a routine check for other reasons

10. Respiratory failure requiring reintubation

DEFINITION: Self-explanatory definition

11. Need for tracheostomy

Definition: Self-explanatory definition

12. Pleural effusion requiring drainage

DEFINITION: Self-explanatory definition

13. Pneumothorax requiring treatment

DEFINITION: Self-explanatory definition

14. Need for prolonged intubation (>24 h after the surgical procedure)

DEFINITION: Self-explanatory definition

15. Acute liver dysfunction (the Child–Pugh score > 8 for longer than 48 h)

DEFINITION: Liver dysfunction recorded as major complication if the Child-Pugh score is greater than 8 for longer than 48 h

16. Acute renal insufficiency (postoperative creatinine twice its preoperative value)/renal failure requiring CVVH or dialysis

Definition: Self-explanatory definition

Infections (gastrointestinal, respiratory, urinary, or other) with both symptoms and germ isolation

DEFINITION: Infections affecting (i) the gastrointestinal tract, (ii) the respiratory tract, (iii) the urinary tract, (iv) other systems, or (v) a combinations of systems. There should be both symptoms of an infection and germ isolation



Table 4 (continued)

Postoperative surgical complications

18. Postoperative bleeding requiring both urgent transfusions and invasive treatment

DEFINITION: Bleeding requiring both urgent transfusions and other invasive treatment (endovascular or endoscopic or surgical)

19. Postoperative bowel obstruction (clinical/radiological signs of obstruction, inability to enteral feed, longer need for NG suction)

DEFINITION: Postoperative bowel obstruction considered a major complication if these conditions occur simultaneously: (i) there exist clinical and/or radiological signs of mechanical obstruction or paralytic ileus, (ii) a patient's inability to enteral feed occurs, and (iii) there exists the need for nasogastric suction beyond the normal postoperative course

20. Postoperative bowel perforation or necrosis requiring surgical treatment (or cause of death)

DEFINITION: Postoperative bowel perforation or necrosis requiring surgical treatment, or being (post-mortem) diagnosed as the cause of death

21. Duodenal leak (irrespective of presentation, method of identification, clinical consequences, and treatment)

DEFINITION: Full thickness duodenal defect irrespective of (i) presentation, (ii) method of identification, (iii) clinical consequences, and (iv) treatment. An abscess close to the duodenal stump should also be recorded in this group

22. Anastomotic leak (irrespective of presentation, method of identification, clinical consequences, and treatment)

DEFINITION: Full thickness defect of esophago-jejunal, gastro-jejunal, jejuno-jejunal anastomoses irrespective of (i) presentation, (ii) method of identification, (iii) clinical consequences, and (iv) treatment. An abscess close to the anastomosis should also be recorded in this group

23. Postoperative pancreatic fistula

DEFINITION: A drain output of any measurable volume of fluid with an amylase level > 3 times the upper limit of institutional normal serum amylase activity, associated with a clinically relevant development/condition related directly to the postoperative pancreatic fistula (2016 International Study Group of Pancreatic Fistula's definition) [31]

24. Postoperative pancreatitis diagnosed both clinically and radiologically

DEFINITION: Postoperative pancreatitis is considered a major complication if two conditions are met: (i) there exists a postoperative increase in serum amylases/lipases more than 3 times the normal value, and (ii) there are radiological signs of postoperative pancreatitis (e.g., edema or necrosis at CT scan)

 Other postoperative abnormal fluid from drainage and/or abdominal collections without gastrointestinal leak(s) preventing drainage removal and/or requiring treatment

DEFINITION: Postoperative biliary drain, postoperative chylous ascites, and other abnormal fluid from drainage, preventing or significantly delaying drainage removal (5 days or longer after the date set by a center's protocols), as well as abdominal collections requiring invasive treatment

26. Delayed gastric emptying (by 10th postoperative day) requiring treatment or delaying discharge

DEFINITION: Failure to tolerate oral intake by the 10th postoperative day in the absence of bowel obstruction. This failure should (i) require endoscopic or surgical intervention, or (ii) delay a patient's discharge for longer than 5 days with respect to the date set by a center's protocols

27. Other major complications requiring re-intervention or other invasive procedures

DEFINITION: Other major complications, including evisceration, diaphragmatic hernia, feeding jejunostomy-related complications, etc., which require re-intervention or other invasive procedures

the patients to be transferred to a higher level of care (e.g., myocardial infarction should be considered a major complication only when the patient is transferred to the ICU/CCU irrespective of the treatment). In addition, complications that may not necessarily require significant intervention in the C–D system have been classified as major in this study. For example, the consensus group agreed that duodenal and anastomotic leaks after gastrectomy were sufficiently significant and thus should be considered major events irrespective of how they manifested, the method of identification, their clinical consequences, and the required treatment. Other major postoperative complications, such as bowel obstruction, pancreatic fistula, severe pancreatitis, abdominal collections without leakage and delayed gastric emptying, were also included in the proposed list irrespective of the need for treatment.

Third, several common yet minor complications, such as deep venous thrombosis, prolonged urethral catheterization and wound opening at the bedside, have been excluded.

Fourth, the list of postoperative surgical complications also included events such as acute evisceration from wound dehiscence, feeding jejunostomy-related complications, and diaphragmatic hernia. Since these events require re-intervention, they have been considered sufficiently important for inclusion in the list.

Fifth, a consensus among the study participants was also reached on precise yet simple definitions for the proposed complications, which should help improve uniform recording across institutions and countries (Tables 4, 5).



Table 5 Executive summary of consensus group's discussions

Intraoperative complications

Unintended intraoperative damage to major vessels and/or organs requiring reconstruction or resection

RATIONALE: The consensus group agreed that it is important to specify the individual complications for each organ and/or major vessel involved. This would make the comparison across medical centers easier and meaningful. Moreover, the consensus group agreed that the required treatment (reconstruction, resection, etc.) should be included in order to provide a precise definition for each complication

2. Intraoperative bleeding requiring urgent treatment

RATIONALE: The consensus group agreed that intraoperative bleeding should be acute and transfusion should be urgent for this complication to be included in the list. If a patient is given a blood transfusion because his/her blood count was low before the surgical procedure or is slowly losing blood during the intervention, the list will not include this type of adverse events

3. Unexpected medical conditions interrupting or changing the planned procedure

RATIONALE: This complication and its precise definition are one of the main novel features of this study with respect to the literature. The existing studies neither take into consideration nor classify these events among the intraoperative complications (e.g., anaphylactic shock, cardiac arrest, myocardial infarction). Despite being rare, they may happen. When they occur, they can cause dire consequences if not swiftly and ably taken care of

Postoperative general complications

4. Stroke causing patient's permanent deficit

RATIONALE: The international definition of stroke is based on morphological criteria during the study of the encephalon through an MRI. The consensus group agreed that the key feature of this complication is the final outcome, that is, whether the patient develops a permanent disability

Need for CPR

RATIONALE: If a patient needs CPR, a major complication has clearly occurred and immediate intervention is required. The consensus group agreed that the need for CPR should be recorded as a major complication

6. Myocardial infarction with patient's transfer to CCU/ICU/other critical care facility

RATIONALE: The consensus group agreed that not all myocardial infarctions should be recorded as major complications. For example, a minor acute infarction that damages small areas of the heart with no major negative consequences should not be recorded. Myocardial infarction will be recorded in the list if the patient needs to be transferred to a higher level of care unit, such as CCU or ICU or a similar unit irrespective of the treatment performed

7. Cardiac dysrhythmia requiring invasive treatment

RATIONALE: The consensus group agreed that the need for invasive treatment (e.g., pace-maker, automatic implantable cardioverter defibrillator, etc.) is the critical feature in the definition of this complication. For example, in the postoperative course a patient frequently develops symptomatic atrial fibrillation (AF), which sometimes is a signal of an upcoming complication. However, if the postoperative AF resolves without the need for invasive treatment, it should not be recorded in the list

8. Acute myocardial failure with acute pulmonary edema or drop in EF > 50%

RATIONALE: The consensus group agreed that acute myocardial failure together with acute pulmonary edema, or a large (>50%) drop in ejection fraction, should be recorded as a major complication. Acute pulmonary edema should be clinically detected. The drop in EF should be measured through an echocardiogram

9. Pulmonary embolism with symptoms confirmed by urgent CT scan

RATIONALE: The consensus group agreed that pulmonary embolism should be recorded as a major complication if two conditions occur: (i) symptoms need to be confirmed by a CT scan; and (ii) a CT scan needs to be required in urgency and not as a routine check for other reasons (e.g., because of fever, intestinal obstruction, restaging before chemotherapy, etc.)

10. Respiratory failure requiring reintubation

RATIONALE: The consensus group agreed to include this univocal definition

11. Need for tracheostomy

RATIONALE: The consensus group agreed to include this univocal definition

12. Pleural effusion requiring drainage

RATIONALE: The consensus group agreed to include this univocal definition

13. Pneumothorax requiring treatment

RATIONALE: The consensus group agreed to include this univocal definition

14. Need for prolonged intubation (> 24 h after the surgical procedure)

RATIONALE: If a patient needs intubation for longer than 24 h after the surgical procedure, this indicates that the surgical procedure and the patient were complicated cases. Therefore, the consensus group agreed that the need for prolonged intubation should be recorded as a major complication

15. Acute liver dysfunction (the Child-Pugh score > 8 for longer than 48 h)



Table 5 (continued)

RATIONALE: The consensus group agreed that acute liver dysfunction should be considered a major complication if the Child-Pugh score is greater than 8 for longer than 48 h

16. Acute renal insufficiency (postoperative creatinine twice its preoperative value)/renal failure requiring CVVH or dialysis

RATIONALE: The consensus group agreed to include this univocal definition

17. Infections (gastrointestinal, respiratory, urinary, or other) with both symptoms and germ isolation

RATIONALE: The consensus group agreed that infections (gastrointestinal, respiratory, urinary, or other) should be considered major complications if two conditions occur: (i) there are symptoms of one or more infections, and (ii) germ isolation has been performed and recorded

Postoperative surgical complications

18. Postoperative bleeding requiring both urgent transfusions and invasive treatment

RATIONALE: The consensus group agreed that postoperative bleeding should require both transfusions and other invasive (endovascular, endoscopic, or surgical) treatment to be recorded in the list. The transfusions need to be required urgently. Transfusions performed as a planned postoperative therapy should not be recorded in the list

19. Postoperative bowel obstruction (clinical/radiological signs of obstruction, inability to enteral feed, longer need for NG suction)

RATIONALE: The consensus group agreed that bowel obstruction should be recorded as a major complication if three conditions are met: (i) signs (either clinical or radiological) of mechanical obstruction or paralytic ileus occur, (ii) a patient is unable to receive enteral feed, and (iii) a patient needs nasogastric suction beyond the standard postoperative course

20. Postoperative bowel perforation or necrosis requiring surgical treatment (or cause of death)

RATIONALE: The consensus group agreed that bowel perforation or necrosis should require surgical treatment or should be diagnosed post-mortem as the cause of death to be included in the list

21. Duodenal leak (irrespective of presentation, method of identification, clinical consequences, and treatment)

RATIONALE: The study group recognized that there is wide variation in the way this complication (one of the most significant adverse events after gastric resection) is recorded across different centers, including their own. To enhance standardized data collection, the study group agreed to record duodenal leak as a major complication irrespective of (i) the way the leak manifests, (ii) the method of identification, (iii) the clinical consequences it brings, and (iv) the required treatment (endoscopic, percutaneous drainage, surgical, etc.). This broad but precise definition should encompass the largest number of situations in which a duodenal leak exists. Additionally, the consensus group agreed that an abscess close to the duodenal stump should be recorded as a major complication in this group

22. Anastomotic leak (irrespective of presentation, method of identification, clinical consequences, and treatment)

RATIONALE: The consensus group recognized that this complication (one of the most significant adverse events after gastric resection) is recorded with great variability across different centers, including their own. Hence, the consensus group agreed to record anastomotic leak as a major complication irrespective of (i) the way the leak manifests, (ii) the method of identification, (iii) the clinical consequences it causes, and (iv) the required treatment. This broad but precise definition should encompass the largest number of situations in which an anastomotic leak occurs. Additionally, the consensus group agreed that an abscess close to the anastomosis should be recorded as a major complication in this group

23. Postoperative pancreatic fistula

RATIONALE: The consensus group agreed to use the international definition and grading of postoperative pancreatic fistula recently updated by the International Study Group of Pancreatic Fistula, which provides very clear guidelines [31]

24. Postoperative pancreatitis diagnosed both clinically and radiologically

RATIONALE: The consensus group agreed that it is not enough to check blood enzymes. There should be also radiological signs of postoperative pancreatitis (e.g., edema and/or necrosis at the CT scan)

 Other postoperative abnormal fluid from drainage and/or abdominal collections without gastrointestinal leak(s) preventing drainage removal and/or requiring treatment

RATIONALE: Postoperative abnormal fluid from drainage or abdominal collections are frequent complications after gastrectomy for cancer. The consensus group agreed that these events should be recorded as major complications if (i) it is impossible to remove the drainage, or its removal occurs 5 days or longer after the date set by each center's protocols; and/or (ii) invasive treatment (percutaneous or surgical) is required to remove the abnormal fluid or collections

26. Delayed gastric emptying (by 10th postoperative day) requiring treatment or delaying discharge

RATIONALE: The date when different centers let a patient resume eating and check if he/she tolerates oral intake varies a lot. The consensus group agreed to choose the 10th postoperative day. Additionally, one of the following two conditions (or both) should occur: (i) a patient requires endoscopic or surgical treatment to solve this complication, (ii) his/her discharge from the hospital is delayed for longer than 5 days with respect to the date set by a center's protocols

27. Other major complications requiring re-intervention or other invasive procedures

RATIONALE: The consensus group agreed that this residual group should record additional major complications that require re-intervention or other invasive procedures



Comparison of the gastrectomy complications list with other complication lists

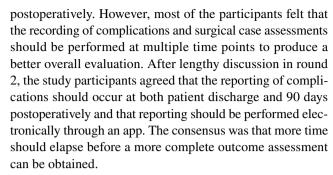
In the studies of complications after esophagectomy by Low et al. [24, 25], 49 items subdivided into 9 groups were determined using the Delphi process with specialist esophageal surgeons. These groups included both general and specific postsurgical adverse events. Esophagectomy-specific complications were fully defined, because variations in descriptions were present across the different participating centers. Although severity was not graded, the study recommended that complications should be recorded in conjunction with their Clavien–Dindo classifications, because this approach would allow recording of multiple complications in one patient.

Several conditions (atelectasis secondary to mucus plugging, *Clostridium difficile* infection, urinary retention, peripheral thrombophlebitis, and acute delirium) included in that study were not included as specific gastrectomy complications in this study. These complications can and do occur in patients undergoing gastric resection, but they are not specific to gastrectomy. Additionally, acute aspiration and atrial fibrillation are not included in this study, because they are more commonly related to the thoracic phase of esophagectomy.

A broad study was conducted by the Japanese Clinical Oncologic Group (JCOG) that assessed complications across 9 cancers to ensure consistency of reporting of adverse events in clinical trials [33]. The Clavien-Dindo general rules were used as the guiding principles for grading the severity of each complication. A total of 72 complications were described. A number of complications that were not formally defined could be associated with gastrectomy. The JCOG group included the severity of the complications. However, clear descriptions of the complications were not fully included, which could result in variability in interpretations. Furthermore, events that might be considered fairly minor in terms of severity could actually be specific events after gastrectomy, such as delayed gastric emptying. Finally, although comprehensive, completing the JCOG assessment is not straightforward, since it covers both gastrectomy-related and other abdominal procedures. The assessment also includes six possible grades for 72 adverse events for a total of more than 400 possible combinations.

Optimal timing of complication reporting and implementation of data collection

The wide variation in reporting complications in the literature also pertains to the optimal timing of this reporting. Indeed, as shown in round 1 of the Delphi survey (Table 2), the study participants had strong disagreements on this topic. One-quarter of the experts preferred to report complications at the patient discharge, whereas more than one-third recommended that complications be reported 30 days



Additionally, although no formal agreement was reached during the Delphi surveys, informal discussions identified the surgeon leading the team performing the surgical procedure as the ideal candidate to complete the Complications Recording Sheet for each patient episode. The GCCG members intend to conduct a more rigorous and thorough discussion to reach a decision on this important point before starting the multicenter validation of the complications list.

Outcome measures and complication severity grading

Although the consensus group discussed which additional quality and outcome measures should be included in the surgical case assessment, they concluded that this topic required more discussion and analysis. Similarly, there was wide disagreement on which grading system to adopt [Clavien–Dindo, Comprehensive Complications Index or other(s)] for recording complications after gastrectomy for cancer. Hence, these two issues, which are clearly important and relevant, will be discussed and studied in depth in the next step of the study.

In conclusion, international comparisons of complications after gastrectomy are unreliable due to differences in the definitions proposed in the literature. These inconsistencies significantly hamper the determination of standards of care and the proposals of quality-improvement initiatives. Therefore, establishment of a common language should be considered a priority. Furthermore, there are indicators (e.g., during esophagectomy for cancer) that perioperative complications have a greater effect on postoperative quality of life than the surgical technique [34].

A consensus approach has identified and rigorously defined a series of 27 complications specific to gastric resection for cancer. At the 12th International Gastric Cancer Congress in Beijing (April 2017) the study received the endorsement of the IGCA executive committee to expand the project from a Europe-based study to an international initiative: surgeons from high-volume centers worldwide will participate in multicenter validation of the comprehensive list of defined complications and collaborate on the development of a large, international database of gastric cancer complications.



 Table 6
 Complications Recording Sheet (CRS)—preliminary template

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(to be decided who will fill in this section)

-	Patient (unique identifier number) Patient Last Name						
	Surgical procedure: Type Total gastrectomy Subtotal gastrectomy Proximal gastrectomy Lymphadenectomy D1 D2 D2 D2 plus Other operation						
	Surgical procedure: Approach ☐ Open ☐ Minimally invasive (lapar	rosco	opic or r	obot	ic)		
-	Surgical procedure: Length F	Iours	3		Mir	nutes	
(R	Other relevant information related COMPLICATIONS LIST AT	d to t	An he patie	ntibic nt's	otics da overall	ily dosa clinica	nge for days
	In	NTR A	OPERA	TIVE	е Сом	PLICAT	IONS
1.	Unintended intraoperative damage to major vessels and/or organs requiring reconstruction or resection		No		Yes	i. ii. iii.	Type of damage (from proposed list) Treatment (from proposed list) Problem solved (yes/no)
2.	Intraoperative bleeding requiring urgent treatment		No		Yes	i. ii.	Red blood packages number Complication solved (yes/no)
3.	Unexpected medical conditions interrupting or changing the planned procedure		No		Yes	i. ii. iii. iv. v.	Description (from proposed list) Surgery interrupted (yes/no) Surgery changed (yes/no) New procedure (description) Complication solved (yes/no)
							ICATIONS
4.	Stroke causing patient's permanent deficit		No		Yes	i. ii.	Pod Permanent disability type (from list)
5.	Need for CPR		No		Yes	i. ii.	Pod Complication solved (yes/no)



Table 6 (continued)

6.	Myocardial infarction with patient's transfer to CCU / ICU/other critical care facility	No	Yes	i. ii. iii.	Pod Critical care facility type (from list) Complication solved at pod
7.	Cardiac dysrhythmia requiring invasive treatment	No	Yes	i. ii. iii. iv.	Pod Dysrhythmia type (atrial/ventricular) Treatment (from proposed list) Complication solved at pod
8.	Acute myocardial failure with acute pulmonary edema or drop in EF > 50%	No	Yes	i. ii. iii. iv. v.	Pod Clinical diagnosis (description) Echocardiogram outcome (EF value) Treatment Complication solved at pod
9.	Pulmonary embolism with symptoms confirmed by urgent CT scan	No	Yes	i. ii. iii. iv. v.	Pod CT scan urgently required (yes/no) CT scan: brief report Treatment Complication solved at pod
10.	Respiratory failure requiring reintubation	No	Yes	i. ii.	Pod Complication solved at pod
11.	Need for tracheostomy	No	Yes	i. ii.	Pod Complication solved at pod
12.	Pleural effusion requiring drainage	No	Yes	i. ii. iii.	Pod Treatment Complication solved at pod
13.	Pneumothorax requiring treatment	No	Yes	i. ii. iii.	Pod Treatment Complication solved at pod
14.	Need for prolonged intubation (> 24 hours after the surgical procedure)	No	Yes	i. ii.	Pod Complication solved at pod
15.	Acute liver dysfunction (Child-Pugh score > 8 for longer than 48 hours)	No	Yes	i. ii. iii.	Pod Child-Pugh score Complication solved at pod
16.	Acute renal insufficiency (postoperative creatinine twice its preoperative value) / renal failure requiring CVVH or dialysis	No	Yes	i. ii. iii. iv.	Acute renal insufficiency at pod Acute renal failure at pod Treatment (from proposed list) Complication solved at pod
17.	Infections (gastrointestinal, respiratory, urinary, or other) with both symptoms and germ isolation	No	Yes	i. ii. iii. iv.	Pod Type of infection (from list) Treatment (description) at pod Complication solved at pod



 Table 6 (continued)

	Posto	PER	ATIVE S	URG	ICAL (COMPLI	CATIONS
18.	Postoperative bleeding requiring both urgent transfusions and invasive treatment		No		Yes	i. ii. iii. iv.	Pod Red blood packages number Invasive treatment (from list) Complication solved at pod
19.	Postoperative bowel obstruction (clinical / radiological signs of obstruction, inability to enteral feed, longer need for NG suction)		No		Yes	i. ii. iii. iv. v. vi.	Clinical signs at pod Radiological signs at pod Inability to enteral feed at pod Longer need for NG suction at pod Treatment (from list) Complication solved at pod
20.	Postoperative bowel perforation or necrosis requiring surgical treatment (or cause of death)		No		Yes	i. ii. iii. iv.	Pod Surgical treatment (from list) Complication solved at pod Complic. cause of death (yes/no)
21.	Duodenal leak (irrespective of presentation, method of identification, clinical consequences, treatment)		No		Yes	i. ii. iii. iv. v. vi.	Pod Presentation (from list) Identification method (from list) Clinical consequences (from list) Treatment (from list) Complication solved at pod
22.	Anastomotic leak (irrespective of presentation, method of identification, clinical consequences, treatment)		No		Yes	i. ii. iii. iv. v. vi.	Pod Presentation (from list) Identification method (from list) Clinical consequences (from list) Treatment (from list) Complication solved at pod
23.	Postoperative pancreatic fistula		No		Yes	i. ii. iii. iv. v.	Pod Amylase level Clinically relevant development (description) Treatment (from list) Complication solved at pod
24.	Postoperative pancreatitis diagnosed both clinically and radiologically		No		Yes	i. ii. iii. iv. v.	Pod Postop amylases/lipases level Radiological signs (from list) Treatment (from list) Complication solved at pod
25.	Other postoperative abnormal fluid from drainage, and/or abdominal collections without gastrointestinal leak(s), preventing drainage removal or requiring treatment		No		Yes	i. ii. iii. iv. v. vi. vii.	Biliary drain at pod



(co	ntinued)							
. (001								
26.	Delayed gas	tric emptying (by	√ □ No	D 7	es i.	Endosc	opic int	ervention at poo
	10th postope							intervention)
	requiring tre				ii.			ention at pod
	delaying dis	charge						surgical interver
					iii	. Compli	cation s	solved at pod
27.	Other major	complications	□ No		es i.	Pod		
		intervention or			ii.	- L		najor complicat
	other invasiv	e procedures				(from p	-	
					iii			mplications not
					;			description)
					iv.			n (description) t (description)
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	☐ Metab		Descrip	otion				
	☐ Endoc	rine system	Descrip	otion				
		tive tract	Descrip	tion				
	☐ HBP		Danamin	tion				
	☐ Infect:							
		ions	Descrip	tion				
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	☐ Immu ☐ Rare o ☐ Repro ☐ Major	ne system liseases ductive system	Descrip Descrip Descrip Descrip Descrip Descrip	otion otion otion				

..... BMI at admission

Other relevant information concerning the patient's medical history



Comorbidities index at admission

ASA score

Table 6 (continued)

■ Tumor Site □ Pylorus □ Antrum □ Body □ Proximal Stomach □ Linitis Plastica □ Siewert 3
■ Tumor Histology □ Adenocarcinoma
■ Pre-operative Stage (TNM8) □ Tis □ N0 □ M0 □ T1a □ N1 □ M1 □ T1b □ N2 □ T2 □ N3 □ T3 □ T4a □ T4b
Chemotherapy regimen:Chemotherapy duration: (months)
 Comorbidities index at discharge BMI at discharge Patient alive at discharge Yes □ No □
Admission date Date of surgery Discharge date
At 90 days postoperatively:
 Comorbidities index at 90 days postoperatively

In the next step of the project, which is already underway, a Complications Recording Sheet based on a user-friendly electronic application will be developed (a preliminary version of the complications recording sheet is included in Table 6). The incidence of these complications across specialized centers worldwide will be assessed. The study plans to develop a risk model specific to gastrectomy that can be recorded simply using the list of complications on the electronic application. This approach will allow the determination of a benchmark for complications that is both

standardized and comparable across institutions and countries. An international assessment of the impact of complications on patient survival, quality of life, and long-term outcomes, as well as that on cost-effectiveness of a novel technology will then be feasible.

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Compliance with ethical standards

Human and animal rights statement This article does not contain any studies with human or animal subjects performed by any of the authors.

Conflict of interest All authors declare that there are no conflicts of interest.

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Affiliations

Gian Luca Baiocchi^{1,2} Simone Giacopuzzi³ · Daniele Marrelli⁴ · Daniel Reim⁵ · Guillaume Piessen⁶ · Paulo Matos da Costa^{7,8} · John V. Reynolds⁹ · Hans-Joachim Meyer¹⁰ · Paolo Morgagni¹¹ · Ines Gockel¹² · Lucio Lara Santos¹³ · Lone Susanne Jensen¹⁴ · Thomas Murphy¹⁵ · Shaun R. Preston¹⁶ · Mikhail Ter-Ovanesov¹⁷ · Uberto Fumagalli Romario¹⁸ · Maurizio Degiuli¹⁹ · Wojciech Kielan²⁰ · Stefan Mönig²¹ · Piotr Kołodziejczyk²² · Wojciech Polkowski²³ · Richard Hardwick²⁴ · Manuel Pera²⁵ · Jan Johansson²⁶ · Paul M. Schneider²⁷ · Wobbe O. de Steur²⁸ · Suzanne S. Gisbertz²⁹ · Henk Hartgrink²⁸ · Joanna W. van Sandick³⁰ · Nazario Portolani^{1,2} · Arnulf H. Hölscher³¹ · Maristella Botticini³² · Franco Roviello⁴ · Christophe Mariette⁶ · William Allum³³ · Giovanni De Manzoni³

- Department of Clinical and Experimental Sciences, Surgical Clinic, University of Brescia, Brescia, Italy
- ² 3rd Division of General Surgery, Spedali Civili di Brescia, P.le Spedali Civili 1, 25127 Brescia, Italy
- Department of Surgery, General and Upper G.I. Surgery Division, University of Verona, Verona, Italy
- Department of Medicine, Surgery and Neurosciences, Unit of General Surgery and Surgical Oncology, University of Siena, Siena, Italy
- Surgical Department, Klinikum Rechts der Isar, Technical University Munich, Munich, Germany
- Department of Digestive and Oncological Surgery, Univ. Lille, and Claude Huriez University Hospital, Lille, France
- Faculdade Medicina, Universidade Lisboa, Lisbon, Portugal
- 8 General Surgery Department, Hospital Garcia de Orta, Lisbon, Portugal
- Department of Surgery, St. James's Hospital and Trinity College Dublin, Dublin, Ireland
- Generalsekretär, Deutsche Gesellschaft für Chirurgie, Berlin, Germany
- GB Morgagni-L Pierantoni Surgical Department, Forlì, Italy
- Department of Visceral, Transplant, Thoracic and Vascular Surgery, University Hospital of Leipzig, Leipzig, Germany
- Experimental Pathology and Therapeutics Group and Surgical Oncology Department, Portuguese Institute of Oncology, Porto, Portugal
- Department of Surgery, Aarhus University Hospital, Aarhus C. Denmark
- Department of Surgery, Mercy University Hospital, Cork City, Ireland
- Oesophageal Gastric Unit, Royal Surrey County Hospital NHS Foundation Trust, Guilford, UK
- Oncological and Haematological RUPF, Moscow Municipal Oncological Hospital, Moscow, Russia

- ¹⁸ 2nd Division of General Surgery, Spedali Civili, Brescia, Italy
- Department of Oncology, Head, Digestive and Surgical Oncology, University of Torino, and San Luigi University Hospital, Orbassano, Italy
- 20 2nd Department of General and Oncological Surgery, Wroclaw Medical University, Wrocław, Poland
- Division of Abdominal Surgery, University Hospital of Geneva, Geneva, Switzerland
- Department of Surgery I, Jagiellonian University, Krakow, Poland
- Department of Surgical Oncology, Medical University of Lublin, Lublin, Poland
- ²⁴ Spire Cambridge Lea Hospital, Cambridge, UK
- Department of Surgery, Section of Gastrointestinal Surgery, Hospital Universitario del Mar, Universitat Autònoma de Barcelona, and Hospital Universitario del Mar Medical Research Institute (IMIM), Barcelona, Spain
- Department of Clinical Sciences, Surgery, Faculty of Medicine, Lund University, Lund, Sweden
- ²⁷ Center for Visceral, Thoracic and Specialized Tumor Surgery, Hirslanden Medical Center, Zurich, Switzerland
- Department of Surgery, Leiden University Medical Center, Leiden, The Netherlands
- Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands
- Department of Surgery, Netherlands Cancer Institute, and Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands
- 31 German Center for Esophageal and Gastric Surgery, Agaplesion Markuskrankenhaus, Frankfurt, Germany
- 32 IGIER, Università Bocconi, Milan, Italy
- 33 Department of Surgery, Royal Marsden NHS Foundation Trust, London, UK

