

Mini-Abstract:

Utilizing a standardized dataset based on 27 univocally defined complications, we analyzed clinical, oncological, surgical, and outcome data obtained from European referral centers for gastric cancer belonging to the Gastrectomy Complications Consensus Group in order to provide a benchmark for complications and outcomes associated with gastrectomy for cancer.

ABSTRACT

Objective: Utilizing a standardized dataset based on a newly developed list of 27 complications, this study analyzed data to provide a western benchmark for evaluating complications and outcomes associated with gastrectomy for cancer.

Summary Background Data: The absence of a standardized system for recording gastrectomy-associated complications makes it difficult to compare results from different hospitals and countries.

Methods: Using a secure online platform (www.gastrodata.org), referral centers for gastric cancer in 11 European countries belonging to the Gastrectomy Complications Consensus Group recorded clinical, oncological, and surgical data, and outcome measures at hospital discharge and at 30 and 90 days postoperatively. This retrospective observational study included all resections over a 2-year period.

Results: A total of 1349 gastrectomies performed between January 2017 and December 2018 were entered into the database. Neoadjuvant chemotherapy was administered to 577 patients (42.8%). Total (46.1%) and subtotal (46.4%) gastrectomy were the predominant resections. D2 or D2+ lymphadenectomy was performed in almost 80% of operations. The overall complications incidence was 29.8%; 402 patients developed 625 complications, with the most frequent being non-surgical infections (23%), anastomotic leak (9.8%), other postoperative abnormal fluid from drainage and/or abdominal collections (9.3%), pleural effusion (8.3%), postoperative bleeding (5.6%), and other major complications requiring invasive treatment (5.6%). The median Clavien-Dindo score and Comprehensive Complications Index were IIIa and 26.2, respectively. In-hospital, 30-day, and 90-day mortality were 3.2%, 3.6%, and 4.5%, respectively.

Conclusions: The use of a standardized platform to collect international data on perioperative complications allows for meaningful comparisons across institutions and countries.

Incidence and Grading of Complications after Gastrectomy for Cancer Using the GASTRODATA

Benchmark: A European Retrospective Observational Study

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Short running head: Benchmarking Gastrectomy Complications

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INTRODUCTION

Gastric cancer is the fifth most frequently diagnosed cancer and the fourth cause of cancer-related death globally.¹ Limited progress has been made with non-surgical therapies, and surgical resection enhanced by standardized lymphadenectomy is still the gold standard in the therapeutic pathway.^{2, 3, 4} However, radical gastrectomy with lymphadenectomy is a complex intervention. Many clinical series indicate that postoperative courses differ significantly between eastern and western centers, with 30-day mortality rates being around 1%^{5, 6} and 5%, respectively.^{7, 8} The driving factors behind this difference have not been clarified, being possibly due to both patient- and surgeon-related features.⁹ While mortality is easier to quantify, the reporting of morbidity rates has notably suffered from the lack of a standardized system, with morbidity rates ranging from 10% to 40%.^{9, 10} Clearly, the absence of a standardized system for recording perioperative complications associated with radical gastrectomy generates wide variations in evaluating the impact of complications on outcomes.^{11, 12, 13}

To address this issue, in 2015, the European Chapter of the International Gastric Cancer Association (IGCA) launched the EGCA-1 project entitled: “Complications after gastrectomy for cancer. European perspective”. The Gastrectomy Complications Consensus Group (GCCG) was established with an initial group of 34 gastric cancer referral centers in 13 European countries. Centers were invited based on the volume of gastric cancer surgery, the availability of a data collection system, and a proven scientific interest in the field. After two rounds of online Delphi consensus meetings and four main meetings (Verona, Lisbon, Leiden, Forlì) of the GCCG in 2017 and 2018, a standardized list comprising 27 perioperative complications associated with gastrectomy for cancer was developed and published.¹⁴ Next, a secure online platform for entering clinical, oncological, and surgical data, the incidence and relevant features of the complications and clinical outcomes, was set up in 2018 and launched in early 2019.

The EGCA-1 project consists of two main studies – a retrospective study comprising all resections for gastric cancer performed at participating centers in 2017 and 2018, and an observational prospectively collected database that is currently ongoing and will include all gastrectomies performed in

2019 and 2020. This article presents the main findings from the retrospective study. The final goal is the definition of a western benchmark for complications and outcomes associated with radical gastrectomy for cancer.

METHODS

Participating Centers

Table 1 lists the 27 centers in 11 European countries that entered the data using the standardized GastroData platform; these centers belong to the Gastrectomy Complications Consensus Group.

[TABLE 1 HERE]

Ethics / Study Approval

The study conforms to the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008) as reflected in the IRB approvals that were obtained from the participating centers. The study also meets the guidelines for clinical research required by the institutions with which all the authors are affiliated.

GastroData Online Platform

A secure web-based platform (www.gastrodata.org) was developed by a specialized software firm (www.Fluxedo.com) to facilitate uniform data collection. The GCCG members provided the critical input for building the platform, which was then tested severally with a few retrospective and prospective cases for each center before its official launch in early 2019. Each study participant was then given personal login credentials to enter data. All data, including center, surgeon and patient data, were strictly anonymous and managed through secure codes. Each center only had access to its patient episodes.

The GastroData online platform consists of six sections reporting the following data:

A. Clinical Data

Patient demographics, body mass index (BMI), American Society of Anesthesiologists (ASA) score, Charlson Comorbidity Index, Prognostic Nutritional Index, weight loss, pharmacological therapy at admission, previous supramesocolic surgeries, other major surgeries, Karnofsky Performance Score (KPS), and Eastern Cooperative Oncology Group (ECOG) Performance Status.

B. Oncological and Surgical Data

Preoperative histology (WHO classification), cTNM, diagnostic methods, neoadjuvant chemotherapy, radiotherapy, and chemoradiotherapy, surgical approach, timing, duration, type of procedure, associated resections, lymphadenectomy, reconstruction, duodenal stump closure, anastomoses, drains, feeding jejunostomy, hyperthermic intraperitoneal chemotherapy, final histology, pTNM or ypTNM, number of harvested and pathological nodes, and Enhanced Recovery After Surgery (ERAS) accomplishment.

C. Twenty-seven Perioperative Complications

Detailed clinical (e.g., postoperative day, presentation, transfer to ICU), radiological (e.g., diagnostic tools), and therapeutic (e.g., type of treatment) data on each of the 27 complications previously published by the GCCG,¹⁴ as well as the complication grading according to the Clavien-Dindo scale.¹⁵

D. E. F. Outcomes at Discharge and at 30 and 90 days Postoperatively

Comprehensive Complications Index (CCI),^{16,17} adjuvant chemotherapy, radiotherapy, chemoradiotherapy, number of hospital readmissions, number and types of re-interventions (gastrectomy-related or not), escalation of level of care, blood products utilization, postoperative hospitalization (days), discharge location, survival, causes of death, KPS, and ECOG Performance Status.

Study Design

This was a retrospective observational study that included all resections for gastric cancer performed at participating centers in 2017 and 2018. The primary endpoints of this study were as follows: (i) incidence and grading of the 27 perioperative complications; (ii) number and type of re-interventions; (iii) number of hospital re-admissions; (iv) mortality (total and cause-specific) during hospital stay and at 30 days and 90 days postoperatively; (v) blood product utilization; and (vi) escalation in level of care.

Statistical Analysis

Data entry was checked at each center to ensure consistency and avoid biases. Missing entries affected mainly the information on pharmacological therapy at admission, KPS, and ECOG Performance Status,

which were not considered in the statistics. Continuous variables are reported as mean, median, and range. Frequencies and percentages are reported for categorical variables. Statistical analysis was performed using STATA software (version 12, StataCorp LLC, College Station, Texas).

RESULTS

A total of 1349 patient episodes, referring to all gastric resections for gastric cancer performed in 2017 and 2018 at the 27 participating centers, were entered into the database. The median and mean patient episodes per center were 47 and 52. Detailed clinical, oncological, and surgical data are presented in Table 2 (Table A1 in the Supplemental Digital Content provides similar data by splitting the group into complicated and non-complicated cases).

[TABLE 2 HERE]

Our findings revealed a male patient predominance (60.9%), with almost half of cases (49.2%) having BMI >25 kg/m², 91.3% with almost one comorbidity, 1 of 4 patients with a Charlson Comorbidity Index of ≥ 5 , and 1 of 3 (36.2%) patients with an ASA score of ≥ 3 . Weight loss was observed in 40.8% of cases (in 16.2% of cases, severe weight loss [$>10\%$] was recorded).

Clinical staging was T1 in only 8.9% of cases, whereas advanced gastric cancers were clinically diagnosed in more than 80% of cases. Preoperative chemotherapy was administered to 42.8% of patients. Open surgery was performed in 80.2% of cases, with total and subtotal gastrectomy being almost equally reported (46.1% and 46.4%). D2 or D2+ lymphadenectomy was performed in 79.7% of patients. Surgical drains were used in 69.3% of cases, and more than 70% ERAS items were accomplished in 46.4% of patients. Final pathological reports showed pT ≥ 2 in 74.9% and N ≥ 1 in 55.6% of cases, whereas 12% of cases were classified as metastatic. Median and mean harvested nodes were 31.0 and 32.9. R0 resection was performed in 92.1% of patients.

Table 3 presents the relevant statistics regarding the 27 complications recorded. A total of 402 patients (29.8%) developed at least one complication. A total of 625 episodes of complication were reported. A Clavien-Dindo grade of ≥ 3 was reported in 63.9% of complicated cases. Surgical re-

intervention was necessary in 105 cases (7.8%) and transfer to ICU in 84 cases (6.2%). Mortality rates were 3.2% during the hospital stay, 3.6% at 30 days postoperatively, and 4.5% at 90 days postoperatively.

[TABLE 3 HERE]

Table 4 shows the incidence and median grading of the 27 complications grouped by three categories: intraoperative, postoperative general, and postoperative surgical.

[TABLE 4 HERE]

Intraoperative complications were rare (about 2% of cases). The most frequent complications with an incidence greater than 5% were non-surgical infections (23%), anastomotic leak (9.8%), other postoperative abnormal fluid from drainage and/or abdominal collections without gastrointestinal leak(s) (9.3%), pleural effusion requiring drainage (8.3%), postoperative bleeding requiring urgent transfusions or invasive treatment (5.6%), other major complications requiring re-interventions or invasive procedures (5.6%), and respiratory failure requiring reintubation (5.4%).

The four most frequent surgical complications (anastomotic leak, abdominal collections unrelated to leaks, postoperative bleeding, and other major complications) accounting for 30.3% of adverse events are analyzed in detail in Table 5.

[TABLE 5 HERE]

Mortality rates associated with these four most frequent surgical complications were 32.8%, 5.2%, 22.8%, and 11.4%, respectively. In 73.6%, 67.2%, 65.7%, and 71.4% of anastomotic leak, abdominal collections unrelated to leaks, postoperative bleeding, and other major complications, a total or extended total gastrectomy was performed. An invasive procedure was necessary to treat these four complications in 68.9%, 31.9%, 100% and 100% of cases. A surgical re-intervention was necessary in 42.6%, 13.7%, 57.1%, and 62.8% of cases. Finally, the median postoperative hospital stay was 32, 20, 19, and 22.5 days, whereas the median CCI was 45.4, 26.2, 42.7, and 39.7, respectively.

DISCUSSION

As shown by a few national surveys, radical surgery for gastric cancer is still surprisingly associated with high morbidity and mortality rates (2% to 7%) in western centers.^{18, 19, 20} These data are significantly different from those reported by eastern centers, where mortality rates are always lower or around 1%.^{5, 6} Beyond likely differences in histological features and patient-related risk factors, there may be notable differences pertaining to surgical, and hence, improvable, factors.

Yet, comparing eastern and western results requires foremost a common language. Indeed, whereas mortality rates come from usually undisputable data, morbidity is defined in different ways across centers, countries, studies and in the literature. The universally employed classification system for complications, the Clavien-Dindo score, is particularly useful for assessing the severity grade of a complication based on the therapeutic needs in each adverse event. At the same time, since the score applies to any surgical field, it is not meant to define univocally whether a certain postoperative clinical picture in a specific surgical subfield, such as surgery for gastric cancer, should be considered a complication or not.²¹

Whereas there is a standardized taxonomy to record and study complications associated with esophagectomy based on the works of Low et al,^{22, 23} to date, there is no comparable uniform taxonomy to record and analyze complications associated with gastrectomy. This study is the first study that uses a newly developed and standardized list of 27 gastrectomy-associated complications and the online GastroData platform to record data in a uniform way.¹⁴ The retrospective phase of the study involved 27 gastric cancer referral centers in 11 European countries (Table 1). The centers entered data on all 1349 gastric resections for gastric cancer performed in 2017 and 2018.

Three main findings emerge. First, the postoperative morbidity rate was 29.8%, with 62.9% of the 625 complications having a Clavien-Dindo grade III or higher (Table 3). Second, the participating centers had lower in-hospital (3.2%), 30-day (3.6%), and 90-day (4.5%) postoperative mortality rates compared to rates reported in European national surveys. These rates can help to establish a reliable benchmark in

the West for gastrectomy-associated mortality. Third, the gap between mortality and morbidity rates in eastern and western centers remains evident.

The patient group analyzed in this study is a typical western population, in which 70-year-old, stout patients, with various comorbidities were predominant. Young patients with BMI <20 kg/m², an ASA score of 1, and a Charlson Comorbidity Index of 0 comprised less than 10% of the study population, whereas these characteristics are typically present, on average, in 50% of patients in eastern series.^{24, 25} The clinical and oncological features of the 1349 patients analyzed in this study were also typically western; at least half of patients had lost weight, half of them underwent neoadjuvant chemotherapy, 60% had T3/T4 cancer, while only 20% of patients had early gastric cancers; corresponding values of these parameters in the eastern series are 20%, 20%, 30%, and 60%.²⁵ The proximal localization of the tumor or linitis plastica was reported in 60% of cases, against an average of 30% in the eastern series. Finally, 80.2% of patients in this series underwent open surgery, and 79.7% underwent D2 or D2+ lymphadenectomy, contrasting with the eastern series in which the most frequent intervention was laparoscopic gastrectomy, the percentage of D1 lymphadenectomy was at least 40%, and the percentage of D2+ lymphadenectomy was lower than 5%.²⁵

Understanding the factors associated with these higher mortality and morbidity rates in the West is thus critical.²⁶ The list of the most frequent complications presented in this study can help address this issue. As evident from Table 4, general (49.4%) and surgical (48.5%) complications equally contributed to morbidity. One out of 5 patients with complications had non-surgical infections (renal/urinary, pulmonary, and gastrointestinal), with symptoms and germ isolation, and 1 patient out of 7 had respiratory complications needing pleural drainage or re-intubation. In contrast, cardiovascular events were surprisingly rare (1.6% in total). These figures are similar to those recently reported by Gertsen et al. from the DUCA registry.⁷ There is no obvious line of action regarding some of the most frequent postoperative general complications, such as infections and major respiratory problems. One suggestion would be to collect preoperative swabs from the cutis, mouth, stool, and urine from pre-hospitalized patients undergoing surgery as a way to reduce postoperative infections. The frequency of respiratory

complications may be lowered by boosting the minimally invasive approach, imposing abstinence of smoking before surgery, providing adequate pain management and ERAS programs, and planning respiratory pre-habilitation for all patients undergoing gastric resection.²⁷

In contrast, the most frequent surgical complications were anastomotic leaks, abdominal collections unrelated to anastomotic leaks, postoperative bleeding, and other complications such as evisceration, diaphragmatic hernia, and feeding jejunostomy-related complications. One out of 3 patients with complications had one of these conditions, which were associated with 35 of the 43 in-hospital deaths (81.4%).

Anastomotic leaks was the most frequent surgical complication (reaching 13.3% of the adverse events if duodenal stump leak is taken into account). Mortality associated with leaks is notably high (32.8%). About 90% of anastomotic leaks were at the esophagojejunal anastomosis, and 83.6% occurred after total or extended total gastrectomy. Many patients with anastomotic leak (68.9%) required re-intervention, and outcomes for these patients measured with different indicators were notably poor (Table 5). The data from this multicenter western series suggest the need for a deeper reflection on anastomotic techniques.²⁸ A portion of leaks may be due to patient-related factors that cannot be easily modified (e.g., comorbidities) or are only partially modifiable (nutritional status). However, a significant portion of leaks was evidently linked to the employed surgical technique, calling for action regarding the improvement in the learning of surgical techniques.^{29, 30, 31} The remaining three most frequent surgical complications were also associated with poor outcome: abdominal drain were removed, on average, at postoperative day 12, ICU transfer was necessary in 10.3%, 31.4%, 31.4% of cases, and hospitalization and CCI were significantly higher than in non-complicated cases.

One recurring risk factor for surgical complication is the total or extended total gastrectomy.³² Total or extended total gastrectomy were performed in about 60-70% of complicated cases in our series. Actions toward quality improvement of the surgical techniques seem mandatory. Prominent international scientific organizations can clearly play a major role on this issue. As shown in Table 3, and previously

reported, the impact of postoperative surgical complications on a variety of outcomes is notable, even in high-volume centers.^{33, 34, 35, 36, 37}

The present study does have limitations. Other than requiring participating centers to check data entry accurately, there was no method in place for auditing individual institutional data. In addition, the study was not designed and did not include cancer survival.

During the 12th World Congress of the International Gastric Cancer Association held in Beijing in 2017, the Gastrectomy Complications project received the endorsement of the Executive Committee of the IGCA to disseminate this standardized list of complications worldwide. The ultimate goal of the project is to develop a risk factor model. As shown in Table A1 (Supplemental Digital Content) that provides statistics comparing complicated versus non-complicated patients, the richness of the GastroData study can help assess modifiable risk factors and the best treatment options.

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TABLE 1: Gastrectomy Complications Consensus Group (GCCG): Data Contributing Centers

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	Milano	IEO	Uberto Fumagalli
		San Raffaele Hospital	Riccardo Rosati
	Torino	University of Torino	Maurizio Degiuli
	Roma	Policlinico Gemelli	Domenico D’Ugo
	Verona	University of Verona	Giovanni De Manzoni
			Simone Giacomuzzi
The Netherlands	Amsterdam	Academic Medical Center	Suzanne S. Gisberz
		Netherlands Cancer Institute	Johanna W. van Sandick
	Leiden	Leiden Univers. Medical Center	Wobbe O de Steur
			Henk Hartgrink
	Rotterdam	Erasmus Medical Center	Bas Wijnhoven
Poland	Krakow	Jagiellonian University	Piotr Kołodziejczyk
	Lublin	Medical University of Lublin	Wojciech Polkowski
	Wroclaw	Wroclaw Medical University	Wojciech Kielan
Portugal	Lisbon	University of Lisbon	Paulo Matos da Costa
	Porto	Portuguese Institute of Oncology	Lucio Lara Santos
Spain	Barcelona	Hospital Universitario del Mar	Manuel Pera
Switzerland	Geneva	University Hospital of Geneva	Stefan Mönig
	Zurich	Hirslanden Medical Center	Paul M. Schneider
United Kingdom	London	Royal Marsden NHS	William Allum

TABLE 2: Patient's Clinical, Oncological and Surgical Data (N = 1349)

	Number	Percentage	Median	Mean
Patients per center	---	---	47.0	52.0
Female	528	39.1	---	---
Male	821	60.9	---	---
Age	---	---	69.0	67.3
BMI	---	---	24.9	25.4
< 18.5	58	4.8	---	---
≥ 18.5, < 25	556	46.0	---	---
≥ 25, < 30	411	34.0	---	---
≥ 30, < 35	142	11.7	---	---
≥ 35, < 40	31	2.6	---	---
≥ 40	11	0.9	---	---
ASA	---	---	2.0	2.2
I	190	14.8	---	---
II	629	49.1	---	---
III	438	34.2	---	---
IV	25	2.0	---	---
Charlson comorbidities index	---	---	3.0	3.4
0	118	8.7	---	---
1-4	888	65.8	---	---
5-8	311	23.1	---	---
9-13	32	2.4	---	---
Prognostic nutritional index	---	---	53.5	58.7
< 40	66	9.5	---	---
≥ 40, < 45	86	12.4	---	---
≥ 45, < 50	109	15.7	---	---
≥ 50	434	62.4	---	---
Weight loss (Yes)	551	40.8	---	---
≤ 10%	332	24.6	---	---
> 10%	219	16.2	---	---
Previous supramesocolic surgeries	204	15.1	---	---
Previous major surgeries	278	20.6	---	---
Pre-operative tumor histology known	1190	88.2	---	---
Tumor site (multiple answers allowed)				
Upper	228	17.3	---	---
Middle	358	27.1	---	---
Lower	638	48.3	---	---
Cardias Siewert 2	72	5.5	---	---
Cardias Siewert 3	97	7.3	---	---
Linitis Plastica	42	3.2	---	---
Tumor size				
< 3 cm	493	46.6	---	---
[3 - 6 cm]	366	34.6	---	---
> 6 cm	199	18.8	---	---
cT				
Tx	126	9.5	---	---
T1	118	8.9	---	---
T2	268	20.2	---	---
T3	565	42.5	---	---

	Number	Percentage	Median	Mean
T4	251	18.9	---	---
cN				
Nx	190	14.5	---	---
N0	481	36.6	---	---
N+	643	48.9	---	---
cM				
Mx	309	23.3	---	---
M0	906	68.4	---	---
M+	110	8.3	---	---
Pre-operative chemotherapy (Yes)	577	42.8	---	---
Patient completed more than 80% (Yes)	529	91.7	---	---
Pre-operative radiotherapy (yes)	16	1.2	---	---
Patient completed more than 80% (Yes)	16	100.0	---	---
Pre-operative chemoradiotherapy (Yes)	15	1.1	---	---
Patient completed more than 80% (Yes)	15	100.0	---	---
Timing --- Elective	1317	97.6	---	---
Surgical approach				
Open	1081	80.2	---	---
Laparoscopy	245	18.2	---	---
Conversion to open (Yes)	26	10.8	---	---
Robotic	19	1.4	---	---
Conversion to open (Yes)	3	15.8	---	---
Surgical procedure type				
Extended total gastrectomy	84	6.2	---	---
Total gastrectomy	621	46.1	---	---
Subtotal gastrectomy	624	46.4	---	---
Proximal gastrectomy	17	1.3	---	---
Surgical procedure duration	---	---	244.5	261.2
Lymphadenectomy				
D0	46	3.5	---	---
D1	82	6.2	---	---
D1+	140	10.6	---	---
D2	889	67.1	---	---
D2+	167	12.6	---	---
HIPEC (Yes)	60	4.5	---	---
Type of reconstruction				
Roux-ex-Y	1263	90.3	---	---
Billroth I	22	1.6	---	---
Billroth II	86	6.4	---	---
Other	23	1.7	---	---
Duodenal stump suture				
Manual	52	4.0	---	---
Mechanical	1263	96.0	---	---
Manual reinforcement (Yes)	457	36.2	---	---
Surgical drains (Yes)	934	69.3	---	---
Number of surgical drains	---	---	1.0	1.7
Feeding jejunostomy (Yes)	206	15.3	---	---
ERAS (more than 70% items completed)	625	46.4	---	---
Postoperative tumor histology (WHO class.)				
Adenocarcinoma	1205	90.9	---	---

	Number	Percentage	Median	Mean
Adenosquamous	16	1.2	---	---
Carcinoma with lymphoid stroma	9	0.7	---	---
Hepatoid carcinoma	0	0.0	---	---
Squamous cells carcinoma	2	0.2	---	---
Undifferentiated	34	2.6	---	---
Other ¹	59	4.5	---	---
Resection margin				
R0	1242	92.1	---	---
R1	91	6.7	---	---
R2	16	1.2	---	---
Number of resected lymph nodes	---	---	31.0	32.8
Number of positive lymph nodes	---	---	1.0	4.9
Patients without positive lymph nodes	598	44.3	---	---
Patients with positive lymph nodes	751	55.7	---	---
Pathological staging				
Tis	42	3.1	---	---
T0	49	3.7	---	---
T1a	103	7.7	---	---
T1b	142	10.6	---	---
T2	166	12.4	---	---
T3	419	31.3	---	---
T4a	354	26.4	---	---
T4b	64	4.8	---	---
N0	598	44.3	---	---
N1	220	16.3	---	---
N2	212	15.7	---	---
N3	319	23.6	---	---
M0	1178	88.0	---	---
M1	161	12.0	---	---

¹ In the postoperative tumor histology, “Other” includes benign diseases (8), complete response to neoadjuvant chemo, radio, or chemoradiotherapy (13), neuroendocrine tumors (12), GIST (9), no tumors found on the surgical specimen (7), lymphoma (5), gastric metastases from tumors in other organs (3), small cells tumors (1), and collision tumors (1).

TABLE 3: Gastrectomy Complications and Outcomes at Discharge, 30-days and 90-days Postoperatively

Total patient episodes = 1349	Number	Percentage		
Patients with no complications	947	70.2		
Patients developing at least one complication	402	29.8		
Clavien-Dindo grading of individual complications ¹				
Grade I	40	6.4		
Grade II	192	30.7		
Grade IIIa	135	21.6		
Grade IIIb	119	19.0		
Grade Iva	53	8.5		
Grade IVb	23	3.7		
Grade V	63	10.1		
All	625	---		
Complications per patient	1.5	---		
Patients requiring blood products	216	16.0		
Patients requiring surgical re-interventions	105	7.8		
Patients requiring endoscopic and/or radiological Interventions	40	2.9		
Escalation in level of care (mostly to ICU)	84	6.2		
In-hospital mortality	43	3.2		
Discharge location				
Home	1240	91.9		
Secondary medical facility / Rehab	66	4.9		
Patients with adverse events during 30-d postop				
Re-admissions related to gastrectomy	93	7.1		
Re-admissions unrelated to gastrectomy	47	3.6		
Re-interventions	46	3.5		
Escalation in level of care	9	0.7		
Patients alive at 30-d postoperatively				
No	48	3.6		
Yes	1301	96.4		
Patients with adverse events during 90-d postop				
Re-admissions related to gastrectomy	40	3.1		
Re-admissions unrelated to gastrectomy	39	3.0		
Re-interventions	31	2.4		
Escalation in level of care	11	0.8		
Patients alive at 90-d postoperatively				
No	61	4.5		
Yes	1288	95.5		
	Mean	Median	Min	Max
Comprehensive Complications Index (CCI) ²	37.3	26.2	8.7	100
Blood products utilization ³	4.2	2.0	0	65
Postoperative hospitalization (days)	13.5	9.0	1	142

¹ Median Clavien-Dindo score = IIIa.

² Values are calculated over the 402 patients who had one or more complications.

³ Values are calculated over the 216 patients who needed blood products.

TABLE 4: Incidence of Complications by Category with Grading

		Number of adverse events	% of adverse events	Clavien- Dindo score (median)
Intraoperative				
18.	Unintended intraoperative damage to major vessels and/or organs requiring reconstruction or resection	7	1.1	---
19.	Intraoperative bleeding requiring urgent transfusion	6	0.9	---
24.	Unexpected medical conditions interrupting or changing the planned procedure	0	0	---
Postoperative General				
1.	Non-surgical infections ¹	144	23.0	II
4.	Pleural effusion requiring drainage	52	8.3	IIIa
6.	Respiratory failure requiring reintubation	34	5.4	IVa
10.	Acute renal insufficiency/renal failure requiring CVVH / dialysis	18	2.9	IIIa
11.	Need for prolonged intubation (> 24 hours after surgery)	16	2.6	II
15.	Need for tracheostomy	9	1.4	IVa
16.	Need for CPR	9	1.4	V
17.	Pulmonary embolism	8	1.3	II
18.	Pneumothorax requiring treatment	7	1.1	IIIa
20.	Myocardial infarction	5	0.8	IIIa
21.	Acute myocardial failure with acute pulmonary edema	3	0.5	II
22.	Cardiac dysrhythmia requiring invasive treatment	2	0.3	IIIb
23.	Stroke causing patient's permanent deficit	1	0.2	V
23.	Acute liver dysfunction (Child-Pugh > 8 for 48+ hours)	1	0.2	I
Postoperative Surgical				
2.	Anastomotic leak	61	9.8	IIIb
3.	Other postoperative abnormal fluid from drainage, abdominal collections without gastrointestinal leak(s) preventing drainage removal and/or requiring treatment	58	9.3	IIIa
5.	Postoperative bleeding requiring invasive treatment	35	5.6	IIIb
5.	Other major complications requiring re-intervention or other invasive procedures ²	35	5.6	IIIb
7.	Postoperative bowel obstruction	30	4.8	II
8.	Postoperative pancreatic fistula	25	4.0	II
9.	Duodenal leak	22	3.5	IIIb
12.	Delayed gastric emptying (by 10th postoperative day)	14	2.2	IIIa
13.	Postoperative pancreatitis	12	1.9	II
14.	Postoperative bowel perforation or necrosis	11	1.8	IVa
Total		625		

Precise complication definitions according to the taxonomy agreed upon by the GCCG.¹⁴

The number next to each complication indicates the rank of the 27 major complications according to their incidence (e.g., “non surgical infections” is the top major complication with 23% of all recorded adverse events being due to a non-surgical infection).

¹ They include gastrointestinal, respiratory, renal / urinary and other infections.

² They include evisceration, diaphragmatic hernia, feeding jejunostomy-related complications, and other major complications requiring re-interventions and/or other invasive procedures.

TABLE 5: Features of Four Most Frequent Surgical Complications

	<i>Anastomotic Leak</i>				
	Number	Percentage	Median	Mean	Range
Patients with anastomotic leak	61	9.8	---	---	---
Grade I-II	10	16.4	---	---	---
Grade IIIa-IVb	41	67.2	---	---	---
Grade V	10	16.4	---	---	---
Pod	---	---	6	7.6	[1, 24]
Anastomosis					
Esophago-jejuno	50	89.3	---	---	---
Gastro-jejuno	5	8.9	---	---	---
Jejuno-jejuno	1	1.8	---	---	---
Surgical procedure					
Extended total gastrectomy	11	18.0	---	---	---
Total gastrectomy	40	65.6	---	---	---
Subtotal gastrectomy	8	13.1	---	---	---
Proximal	2	3.3	---	---	---
Patients requiring re-interventions	42	68.9	---	---	---
Treatment (multiple options allowed)					
Surgical	26	42.6	---	---	---
Endoscopic	17	27.9	---	---	---
Percutaneous drainage	10	16.4	---	---	---
Nasogastric tube	12	19.7	---	---	---
Feeding jejunostomy	8	13.1	---	---	---
Fasting & parenteral nutrition	14	23.0	---	---	---
No treatment	9	14.8	---	---	---
Outcome					
Complete leak closure	38	62.3	---	---	---
No leak closure	12	19.7	---	---	---
Unknown	11	18.0	---	---	---
Leak duration (days)	---	---	17.0	23.8	[1, 100]
Postoperative hospitalization (days)	---	---	32.0	40.5	[1, 142]
CCI	---	---	45.4	57.9	[20.9, 100]
Dead patients having this complication	20	32.8	---	---	---
<i>Other postoperative abnormal fluid from drainage, abdominal collections without gastrointestinal leak(s) preventing drainage removal and/or requiring treatment</i>					
	Number	Percentage	Median	Mean	Range
Patients with this complication	58	9.3	---	---	---
Chylous ascites at pod	14	---	4.5	4.6	[0, 15]
Other abnormal fluid at pod	34	---	9.0	10.3	[0, 52]
Biliary drain at pod	6	---	1.0	2.0	[0, 7]
Severity score					
Grade I-II	28	48.3	---	---	---
Grade IIIa-IVb	29	50.0	---	---	---
Grade V	1	1.7	---	---	---
Drainage removed at center's protocol	15	25.9	---	---	---
Drainage removed at pod	---	---	11.0	12.7	[7, 23]
Surgical procedure					
Extended total gastrectomy	5	8.6	---	---	---

Total gastrectomy	34	58.6	---	---	---
Subtotal gastrectomy	19	32.7	---	---	---
Proximal	0	0.0	---	---	---
Patients requiring re-interventions	18	31.0	---	---	---
Treatment (multiple options allowed)					
Surgical	8	13.7	---	---	---
Endoscopic	2	3.4	---	---	---
Percutaneous drainage	23	39.6	---	---	---
Postoperative hospitalization (days)	---	---	20.0	24.5	[7, 120]
Escalation in level of care (ICU)	6	10.3	---	---	---
CCI	---	---	26.2	30.7	[8.7, 100]
Dead patients with this complication	3	5.2	---	---	---

<i>Postoperative bleeding requiring both urgent transfusions and invasive treatment</i>					
	Number	Percentage	Median	Mean	Range
Patients with postoperative bleeding	35	5.6	---	---	---
Grade I-II	0	0.0	---	---	---
Grade IIIa-IVb	32	91.4	---	---	---
Grade V	3	8.6	---	---	---
Pod	---	---	7.0	8.4	[0, 70]
Surgical procedure					
Extended total gastrectomy	7	20.0	---	---	---
Total gastrectomy	16	45.7	---	---	---
Subtotal gastrectomy	12	34.3	---	---	---
Proximal	0	0.0	---	---	---
Hemorrhagic shock	13	37.1	---	---	---
Source of bleeding					
Abdominal wall	4	11.4	---	---	---
Intraluminal	11	31.4	---	---	---
Peritoneal	19	54.3	---	---	---
Unknown	1	2.8	---	---	---
Patients requiring re-interventions	35	100	---	---	---
Treatment					
Surgical	20	57.1	---	---	---
Endoscopic	9	25.7	---	---	---
Endovascular	3	8.6	---	---	---
Incomplete information	3	8.6	---	---	---
Escalation in level of care	11	31.4	---	---	---
Postoperative hospitalization (days)	---	---	19.0	26.2	[1, 95]
CCI	---	---	42.7	57.6	[26.2, 100]
Dead patients with this complication	8	22.8	---	---	---

<i>Other major complications requiring re-intervention or other invasive procedures</i>					
	Number	Percentage	Median	Mean	Range
Patients with other major complications	35	5.6	---	---	---
Evisceration at pod	6	17.1	7.0	6.2	[2, 9]
Diaphragmatic hernia at pod	1	2.8	5.0	5.0	---
Feeding jejun. complication at pod	2	5.7	9.5	9.5	[5, 14]
Other major complications at pod	26	74.3	7.5	13.4	[1, 50]
Severity score					

Grade I-II	0	0.0	---	---	---
Grade IIIa-IVb	32	91.4	---	---	---
Grade V	3	8.6	---	---	---
Surgical procedure					
Extended total gastrectomy	7	20.0	---	---	---
Total gastrectomy	18	51.4	---	---	---
Subtotal gastrectomy	10	28.6	---	---	---
Proximal	0	0.0	---	---	---
Patients requiring re-interventions	35	100.0	---	---	---
Treatment (multiple options allowed)					
Surgical	22	62.8	---	---	---
Endoscopic	3	8.6	---	---	---
Postoperative hospitalization (days)	---	---	22.5	28.8	[4, 83]
Escalation in level of care (ICU)	11	31.4	---	---	---
CCI	---	---	39.7	50.6	[26.2, 30]
Dead patients with this complication	4	11.4	---	---	---
Top four major surgical complications (incidence > 5%)	189	30.2	---	---	---
All 27 complication categories	625	---	---	---	---

SUPPLEMENTAL DIGITAL CONTENT

TABLE A1: Complicated vs Uncomplicated Patient's Clinical, Oncological and Surgical Data

	Percentage		Median	
	C	NC	C	NC
Female	32.1	42.1	---	---
Male	67.9	57.9	---	---
Age	---	---	69.0	67.3
BMI	---	---	25.0	24.8
ASA	---	---	2.0	2.0
Charlson comorbidities index	---	---	4.0	3.0
Prognostic nutritional index	---	---	50.6	56.1
Weight loss (Yes)	48.8	43.2	---	---
Previous supramesocolic surgeries	17.4	14.3	---	---
Previous major surgeries	22.2	20.1	---	---
Pre-operative tumor histology known	86.6	88.9	---	---
Tumor site (multiple answers allowed)				
Upper	18.7	14.6	---	---
Middle	23.8	25.5	---	---
Lower	36.8	48.0	---	---
Cardias Siewert 2	6.2	4.5	---	---
Cardias Siewert 3	11.0	4.8	---	---
Linitis Plastica	3.5	2.7	---	---
Tumor size				
< 3 cm	42.3	48.3	---	---
[3 - 6 cm]	34.2	34.7	---	---
> 6 cm	23.5	17.0	---	---
cT				
Tx	8.8	9.8	---	---
T1	6.3	10.0	---	---
T2	18.3	21.0	---	---
T3	45.4	41.3	---	---
T4	21.3	17.9	---	---
cN				
Nx	12.8	15.1	---	---
N0	34.7	37.4	---	---
N+	52.6	47.5	---	---
cM				
Mx	21.8	24.0	---	---
M0	66.6	69.1	---	---
M+	11.6	6.9	---	---
Pre-operative chemotherapy (Yes)	41.5	43.6	---	---
Patient completed more than 80% (Yes)	91.1	92.8	---	---
Timing --- Elective	96.8	98.1	---	---
Surgical approach				
Open	82.5	79.5	---	---
Laparoscopy	16.0	19.1	---	---
Conversion to open (Yes)	20.0	7.7	---	---

	Percentage		Median	
	C	NC	C	NC
Robotic	1.5	1.4	---	---
Conversion to open (Yes)	16.7	15.4	---	---
Surgical procedure type				
Extended total gastrectomy	9.7	4.8	---	---
Total gastrectomy	54.4	42.6	---	---
Subtotal gastrectomy	35.2	51.1	---	---
Proximal gastrectomy	0.7	1.5	---	---
Surgical procedure duration	---	---	270	240
Lymphadenectomy				
D0	3.8	3.3	---	---
D1	5.8	6.3	---	---
D1+	10.7	10.5	---	---
D2	67.8	66.9	---	---
D2+	11.9	12.9	---	---
HIPEC (Yes)	9.7	2.2	---	---
Type of reconstruction				
Roux-ex-Y	90.0	90.7	---	---
Billroth I	0.5	2.1	---	---
Billroth II	7.5	6.0	---	---
Other	2.0	1.2	---	---
Duodenal stump suture				
Manual	4.3	3.8	---	---
Mechanical	95.7	96.2	---	---
Manual reinforcement (Yes)	41.1	34.4	---	---
Surgical drains (Yes)	76.0	68.6	---	---
Number of surgical drains	---	---	2	1
Feeding jejunostomy (Yes)	24.9	11.2	---	---
ERAS (more than 70% items completed)	31.8	52.5	---	---
Resection margin				
R0	89.1	93.3	---	---
R1	8.7	5.9	---	---
R2	2.2	0.7	---	---
Number of resected lymph nodes	---	---	30.0	31.0
Number of positive lymph nodes	---	---	1.0	1.0
Patients without positive lymph nodes	42.5	45.2	---	---
Patients with positive lymph nodes	57.5	54.8	---	---
Pathological staging				
Tis	1.5	3.8	---	---
T0	3.0	4.0	---	---
T1a	4.5	9.0	---	---
T1b	9.3	11.2	---	---
T2	9.5	13.6	---	---
T3	37.3	28.7	---	---
T4a	28.3	25.6	---	---
T4b	6.8	3.9	---	---
N0	42.5	45.2	---	---
N1	16.7	17.4	---	---
N2	15.4	15.7	---	---
N3	25.4	21.6	---	---

	Percentage		Median	
	C	NC	C	NC
M0	84.5	89.5	---	---
M1	15.5	10.5	---	---

C = Patients with at least one complication; NC = Patients with no complications.

¹ In the postoperative tumor histology, “Other” includes benign diseases (8), complete response to neoadjuvant chemo, radio, or chemoradiotherapy (13), neuroendocrine tumors (12), GIST (9), no tumors found on the surgical specimen (7), lymphoma (5), gastric metastases from tumors in other organs (3), small cells tumors (1), and collision tumors (1).