

Reporting National Outcomes After Esophagectomy and Gastrectomy According to the Esophageal Complications Consensus Group (ECCG)

Leonie R. van der Werf, MD,* Linde A. D. Busweiler, MD, PhD,† Johanna W. van Sandick, MD, PhD,‡
Mark I. van Berge Henegouwen, MD, PhD,† and Bas P. L. Wijnhoven, MD, PhD*, the Dutch Upper GI Cancer
Audit (DUCA) group

Objective: This nation-wide population-based study aimed to report postoperative morbidity and mortality after esophagectomy and gastrectomy in the Netherlands according to the definitions of the Esophagectomy Complications Consensus Group (ECCG).

Background: To standardize international outcome reporting in esophageal surgery, the ECCG developed a standardized outcomes set.

Methods: For this national cohort study, all patients undergoing esophagectomy or gastrectomy for cancer between 2016 and 2017 were selected from the Dutch Upper gastrointestinal Cancer Audit. In a random sample of hospitals, data completeness and accuracy were validated by reabstraction of the data. The investigated outcomes in the present study were postoperative complications, major complications (Clavien–Dindo grade \geq III), and 30-day mortality, according to definitions of the ECCG.

Results: A total of 2545 patients from 22 hospitals were included. The completeness of the Dutch Upper gastrointestinal Cancer Audit was estimated at 99.8%. Data accuracy on different items was 94% to 100%. After esophagectomy, 1046 of 1617 patients (65%) had a postoperative complication including 468 patients (29%) with a major complication. Most common complications were pneumonia (21%), esophago-enteric leak from anastomosis, staple line or localized conduit necrosis (19%), and atrial dysrhythmia (15%). The 30-day mortality was 1.7%. After gastrectomy, 397 of 928 patients (42%) had a postoperative complication including 180 patients (19%) with a major complication. Most common complications were pneumonia (12%), esophago-enteric leak from anastomosis, staple line or localized conduit necrosis (9%), and acute delirium (5%). The 30-day mortality was 4.4%.

Conclusions: Reporting complications according to the ECCG platform is feasible in the Netherlands and facilitates international benchmarking.

Keywords: clinical auditing, esophagectomy, esophagectomy complication consensus group, gastrectomy, outcomes-set

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For resectable nonmetastatic esophageal and gastric cancer, resection is as yet the cornerstone of treatment. Both esophagectomy and gastrectomy are associated with high postoperative morbidity rates. To evaluate quality of care, in several European countries

clinical audits are used.^{1–3} Feedback of audit data to the specialist may improve outcomes by stimulating best practices and the initiation of improvement programs for health care pathways. For a reliable comparison of outcomes between hospitals on a national level and to compare patterns of care and outcomes between countries, it is important to use uniform definitions.

To standardize outcome reporting in esophageal surgery, the Esophagectomy Complications Consensus Group (ECCG) developed a standardized outcomes-set.⁴ In 2017, in 24 hospitals in different countries the outcomes after esophagectomy were collected according to the definitions of the ECCG.⁵

In January 2016, the definitions of the ECCG were introduced in the Dutch Upper gastrointestinal Cancer Audit (DUCA).¹ The outcomes including postoperative complications, readmission, and 30-day mortality were registered according to the definitions of the ECCG platform for both esophagectomy and gastrectomy. At that time, an international standardized outcomes-set for gastrectomy was lacking. Hence, the ECCG outcomes-set was applied for patients who underwent esophagectomy and gastrectomy also because the type and severity of complications that occur after both procedures is somewhat comparable.

The primary aim of this study was to report postoperative morbidity and mortality after esophagectomy and gastrectomy in the Netherlands according to the ECCG definitions and to report the completeness and accuracy of the DUCA data. Second, the outcomes after esophagectomy in the DUCA were compared with the reported outcomes of the initial ECCG dataset.⁵

METHODS

Study Design

For this national cohort study, patient data were retrieved from the DUCA database. Dutch hospitals are mandated to register all esophageal (including gastro-esophageal junction) or gastric cancer patients undergoing surgery with the intent of a resection.

Data Verification

Before evaluation of the DUCA data, it is important to test whether the outcomes are valid. The reliability of data of the data was verified in 2016. Participation of hospitals in this data verification process was voluntary. Outcomes of this data verification were the completeness and accuracy of registered data. A random sample of 15 participating hospitals was visited by an external data verification employee and a random sample of operated patients with esophageal or gastric cancer was checked for inclusion in the DUCA database. Per hospital, 30 patients operated in 2016 were selected. If less than 30 patients were operated, all available patients were selected. Reabstraction of data from the electronic

From the *Erasmus University Medical Center, Rotterdam, The Netherlands; †Cancer Center Amsterdam, Amsterdam UMC, Amsterdam, The Netherlands; and ‡Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands.

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Reprints: Leonie R. van der Werf, MD, Erasmus University Medical Centre, *Postbus 2040,3000 CA Rotterdam, The Netherlands.

E-mail: L.R.vdwerf@gmail.com.

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patient dossier took place for all selected patients. The original data was compared with data registered in the DUCA.⁶ In the present study, the accuracy with regard to registration of postoperative complications, 30-day mortality, reinterventions, readmissions, number of lymph nodes, resections margin, and ASA score (the physical status classification according to the American Society of Anesthesiologists) was tested. The accuracy was estimated by the number of discrepancies found against the total number of patients in the sample.

Patients

All patients undergoing an esophagectomy of gastrectomy in the Netherlands between January 2016 and December 2017 for esophageal or gastric cancer were included in this study. Patients with a palliative bypass procedure were excluded. Also, patients with missing data regarding complications or other essential elements of the registration including date of birth, survival status at 30 days after surgery or date of discharge (in case of a hospital stay of >30 d) were excluded.

Outcomes

The primary outcome was frequency of postoperative complications. The severity of the complications was defined according to Clavien–Dindo.⁷ Complications grade IIIa or higher were defined as major complications. The secondary outcomes were hospital stay, duration of stay at the intensive care unit, the frequency of reinterventions, 30-day and/or in-hospital mortality, readmissions, the number of retrieved lymph nodes, surgical resection margins, and the ASA score. For all patients who underwent an esophagectomy, the outcomes were compared with the outcomes of the ECCG as recently reported.⁵

Statistical Methods

Patient and tumor characteristics of all included patients were reported according to the type of resection (esophagectomy or gastrectomy) using frequencies and percentages. Also, all postoperative outcomes were described using frequencies and percentages. The outcomes after esophagectomy in the DUCA were compared with the reported outcomes of the ECCG dataset⁵ using chi-square analyses. Statistical analyses of the present study were performed

using Microsoft Excel for Mac (version 15.41). Statistical significance was defined as $P < 0.05$.

RESULTS

Data Verification

The completeness of the DUCA was estimated at 99.8% (Table 1). In a sample of 408 patients, 1 patient who should have been registered according to the inclusion criteria of the DUCA was not registered. Complications were accurately registered in 382 of 407 patients (94%). In 25 patients (6%) no complication was registered in the DUCA, whereas in the electronic patient file a complication was reported. Thirty-day and/or in-hospital mortality was accurately registered in 406 of 407 patients (98.8%). In 13 of 407 patients (3%), a complicated postoperative course (defined as a complication leading to prolonged hospital stay (>21 d), reintervention or death) was not registered in the DUCA database but was extracted from the electronic patient files. All verified variables are shown in Table 1.

Patients

From January 2016 to December 2017, a total of 1617 patients undergoing an esophagectomy and 928 patients undergoing a gastrectomy were registered in the DUCA. Eight patients were excluded due to missing data. Patient, disease, and treatment characteristics are summarized in Tables 2 and 3. Minimally invasive techniques were used in 86% of patients undergoing an esophagectomy and in 58% of patients undergoing a gastrectomy. Fifty-two percent of esophagectomies was performed via a transthoracic approach. In 43% of all gastrectomies, a total gastrectomy was performed.

Outcomes After Esophagectomy

Sixty-five percent of patients who underwent an esophagectomy had a postoperative complication (Table 4). Clavien–Dindo grade III or higher complications occurred in 29% of all patients (Table 5). Most common complications were pneumonia (21%), leak from the anastomosis, staple line or localized conduit necrosis (19%), and atrial dysrhythmia (15%). All complications are presented in Supplementary Table 1 (Supplemental Digital Content, <http://links.lww.com/SLA/B561>). The median stay at the intensive care unit was 2 days (interquartile range: 1–4), and median hospital stay was

TABLE 1. Results of External Data Verification

	Completeness of Data			Completeness
	Registered	Wrongly Not Registered		
Sample Size: 408	n	n		%
Included in DUCA	407	1		99.8%
	Accuracy of Data			
	Correctly Registered	Wrongly Registered	Missing	Accuracy
Sample Size: 407	n	n	n	%
Complications	382	25	0	94%
30-d/in-hospital mortality	406	1	0	99.8%
Reinterventions	394	13	0	97%
Complications leading to prolonged hospital stay (>21 d), reintervention or death	394	13	0	97%
Readmission	390	12	5	97%
Number of lymph nodes	394	13	0	97%
Resection margins	394	11	2	97%
ASA score	379	28	0	93%

TABLE 2. Patient and Disease Characteristics, According to Type of Resection: Esophagectomy (for ECCG¹ and DUCA) and Gastrectomy DUCA only Are Shown

	ECCG Esophagectomy ¹		DUCA Esophagectomy		DUCA Gastrectomy	
	n	%	n	%	n	%
Total			2704		1617	928
Sex						
Male	2096	78%	1228	76%	561	61%
Female	607	22%	388	24%	367	40%
Unknown			1	0%	0	0%
Age (in yr)						
40 or less	66	2%	6	0%	25	3%
41–50	217	8%	76	5%	53	6%
51–60	721	27%	316	20%	129	14%
61–70	1100	41%	739	46%	227	25%
71–80	532	20%	451	28%	355	38%
more than 80	67	3%	29	2%	139	15%
Body mass index						
<18.5	184	7%	47	3%	34	4%
18.5–25	1085	40%	657	41%	420	45%
25–30	908	34%	642	40%	329	36%
30+	526	20%	265	16%	136	15%
Unknown			6	0%	9	1%
ASA score						
I	412	15%	255	16%	113	12%
II	1249	46%	1012	63%	526	57%
III	992	37%	340	21%	273	29%
IV	49	2%	7	0%	15	2%
V	1	0%	0	0%	0	0%
Unknown			3	0%	1	0%
Charlson Comorbidity Score						
0			754	47%	411	44%
1			385	24%	191	21%
2+			478	30%	326	35%
Comorbidities						
Myocardial infarction	146	5%	86	5%	66	7%
Congestive heart failure	124	5%	12	1%	19	2%
Chronic Pulmonary Disease	285	11%	326	20%	155	17%
Peripheral Vascular Disease	185	7%	73	5%	53	6%
Diabetes Mellitus (uncomplicated)	348	13%	221	14%	160	17%
Diabetes Mellitus (end-organ damage)	16	1%	13	6%	5	3%
Moderate to Severe Renal Disease	35	1%	21	1%	29	3%
Pathology (indication for surgery)						
Benign	97	4%				
Malignant	2585	96%				
Other, including perforations	21	1%				
Location (ECCG)						
At the GE junction	762	28%				
Proximal 1/2 of esophagus	304	11%				
Distal 1/2 of esophagus	1519	56%				
Location (DUCA)						
Cervical (C15.0)			1	0%	0	0%
Proximal (C15.3)			14	1%	0	0%
Mid (C15.4)			226	14%	0	0%
Distal (C15.5)			1087	67%	3	0%
Gastro-esophageal junction (C16.0)			261	16%	32	3%
Fundus (C16.1)			18	1%	69	7%
Corpus (C16.2)			1	0%	281	30%
Antrum (C16.3)			0	0%	365	39%
Pylorus (C16.4)			0	0%	80	9%
Total stomach			0	0%	44	5%
Rest stomach/anastomosis			0	0%	34	4%
Unknown (stomach)			6	0%	1	0%
Missing			3	0%	19	2%
Unknown			2	0%	2	0%

1. Low DE, Kuppusamy MK, Alderson D, et al. Benchmarking Complications Associated with Esophagectomy. *Ann Surg* 2017.
 ASA indicates American Society of Anaesthesiologists.

TABLE 3. Pathological- and Treatment Characteristics, According to Type or Resection: Esophagectomy (for ECCG¹ and DUCA) and Gastrectomy DUCA only Are Shown

	ECCG Esophagectomy ¹		DUCA Esophagectomy		DUCA Gastrectomy	
	N	%	n	%	n	%
Total	2704		1617		928	
Pathological tumor stage						
pT0–2	1242	65%	966	60%	341	37%
pT3	1075	42%	592	37%	327	35%
pT4	78	3%	21	1%	236	25%
Missing	0	0%	38	2%	24	3%
Pathological node stage						
pN–	1477	57%	957	59%	421	45%
pN+	1101	42%	622	39%	485	52%
pNx	7	0%	4	0%	7	1%
Missing			34	2%	15	2%
Pathological metastases stage						
pM–	2170	84%	1528	95%	796	86%
pM+	46	2%	23	1%	61	7%
Not applicable	0	0%	48	3%	54	6%
pMx	369	14%	18	1%	17	2%
Timing of surgery						
Elective	2680	99%	1610	100%	895	96%
Urgent			3	0%	25	3%
Emergency	23	1%	3	0%	8	1%
Unknown			1	0%	0	0%
Neoadjuvant therapy						
No	545	21%	105	7%	379	42%
Chemotherapy	763	30%	86	5%	502	55%
Chemoradiotherapy	1192	46%	1417	88%	28	3%
Radiotherapy	5	0%	6	0%	0	0%
Unknown			0	0%	1	0%
Definitive chemoradiotherapy	80	3%				
Surgical approach						
Open	1407	52%	229	14%	394	43%
MI	1296	48%	1388	86%	534	58%
Esophagectomy (open)						
Transhiatal	283	20%	109	48%		
Transthoracic	1124	80%	120	52%		
Esophagectomy (MI)						
Abdomen only	521	40%	222	16%		
Chest only	144	11%	60	4%		
Abdomen and chest	631	49%	1106	80%		
Gastrectomy (open and MI)						
Total					402	43%
Partial					526	57%
Site of anastomosis						
Chest	1641	61%	876	54%	65	7%
Neck	1025	38%	696	43%	2	0%
Abdomen			7	0%	807	87%
Other/none	37	1%	38	2%	54	6%
Conduit/reconstruction						
Stomach	2564	95%	1567	99%	4	0%
Colon	34	1%	4	0%	1	0%
Small bowel	72	3%	0	0%	2	0%
Esophagojejunostomy (Roux-Y)			5	0%	394	44%
Gastroenterostomy (BII or Roux-Y)			0	0%	483	54%
Other/none	33	1%	9	1%	12	1%
Resection margins						
R0 Microscopic radical	2414	93%	1532	95%	820	89%
R1 microscopic irradical	157	6%	65	4%	83	9%
R2 Locoregional residual tumor	14	1%	1	0%	4	0%
Not applicable			8	1%	8	1%
Unknown			2	0%	2	0%

1. Low DE, Kuppusamy MK, Alderson D et al. Benchmarking Complications Associated with Esophagectomy. *Ann Surg* 2017. MI indicates minimally invasive.

TABLE 4. Outcomes of the DUCA (Dutch Upper Gastrointestinal Cancer Audit) According to Type of Resection

Total (n =)	Esophagectomy		Gastrectomy	
	1617		928	
	Median	[IQR]	Median	[IQR]
Hospital stay (d)	11	[9–18]	8	[6–13]
ICU stay (d)	2	[1–4]	0	[0–1]
	n	%	n	%
Intraoperative complication	89	5.5%	34	3.7%
Postoperative complication	1046	65%	397	43%
Reintervention	420	26%	186	20%
Radiological	170		51	
Endoscopic	187		54	
Reoperation	208		121	
In-hospital/30-d mortality	38	2.4%	49	5.3%
30-d mortality	27	1.7%	41	4.4%
Readmission	233	15%	123	14%
Postoperative complication Clavien Dindo grade III or more	468	29%	180	19%

ICU indicates intensive care unit.

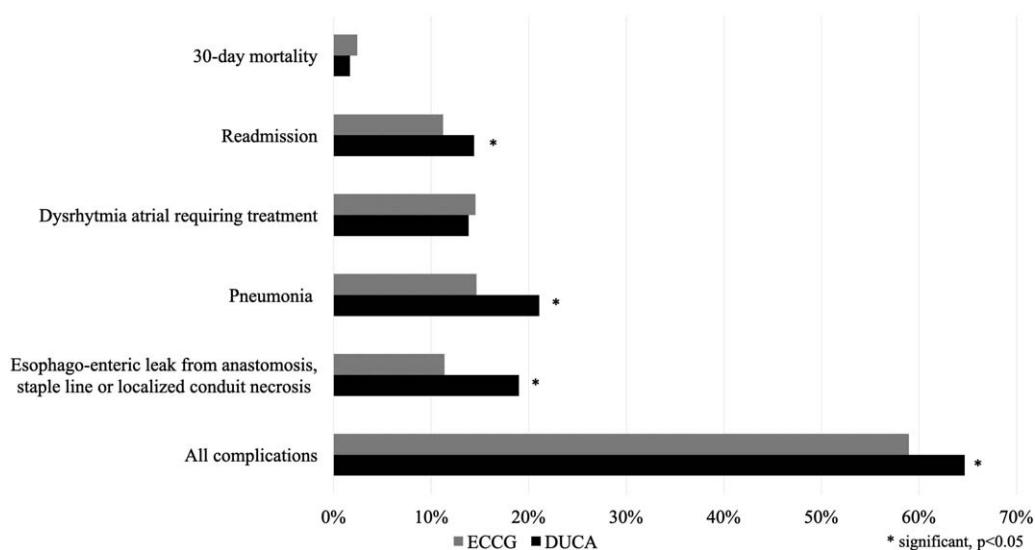
TABLE 5. Severity of Complications in the DUCA (Dutch Upper Gastrointestinal Cancer Audit) According to Type of Resection

Complication Severity	Esophagectomy				Gastrectomy			
	n	%	95%	CI	n	%	95%	CI
No complications	605	37%	35%	40%	562	61%	57%	64%
Grade I	150	9%	8%	11%	39	4%	3%	6%
Grade II	379	23%	21%	26%	130	14%	12%	16%
Grade IIIa	192	12%	10%	14%	51	6%	4%	7%
Grade IIIb	128	8%	7%	9%	66	7%	6%	9%
Grade IVa	110	7%	6%	8%	23	3%	2%	4%
Grade IVb	11	1%	0%	1%	5	1%	0%	1%
Grade V	27	2%	1%	2%	35	4%	3%	5%
Grade unknown	15	1%	1%	2%	17	2%	1%	3%

11 days (interquartile range: 9–18). The 30-day mortality rate was 1.7% and the 30-day/in-hospital mortality rate was 2.4%.

In comparison with the reported outcomes of the ECCG,⁵ the overall complication rate was significantly higher in the DUCA (65%

vs 59%, $P < 0.001$). Also, pneumonia and leak from anastomosis, staple line, or localized conduit necrosis, occurred more often (respectively, 21% vs 15%, $P < 0.001$ and 19% vs 11%, $P < 0.001$) (Fig. 1). Hospital readmission within 30 days after discharge

**FIGURE 1.** Comparison of outcomes after esophagectomies, DUCA versus ECCG.

occurred in 15% of patients, significantly more often compared with the ECCG cohort (11%, $P < 0.001$). The 30-day mortality rate was 1.7% versus 2.4% in the ECCG cohort ($P=0.10$).

Outcomes After Gastrectomy

Forty-three percent of patients who underwent a gastrectomy experienced a postoperative complication (Table 4). Clavien–Dindo grade III or higher complications occurred in 19% of patients (Table 5). Most common complications were pneumonia (12%), esophago-enteric leak from anastomosis, staple line or localized conduit necrosis (9%), and acute delirium (5%). All complications are presented in Supplementary Table 1 (Supplemental Digital Content, <http://links.lww.com/SLA/B561>). The severity of 4 outcome measures according to the ECCG⁴ is presented in Supplementary Table 2, Supplemental Digital Content, <http://links.lww.com/SLA/B561>. The median stay at the intensive care unit stay was 0 days (interquartile range: 0–1), and median hospital stay was 8 days (interquartile range: 6–13). Hospital readmission within 30 days after discharge occurred in 14% of patients. The 30-day mortality rate was 4.4%, and the 30-day/in-hospital mortality was 5.3%.

DISCUSSION

This study with DUCA data shows that reporting complications according to the ECCG definitions can be achieved on a national level. Data verification showed that the completeness and accuracy of data in the DUCA were high. Overall, complications after esophagectomy and gastrectomy occurred in 65% and 43% of patients, respectively. Major complications (Clavien–Dindo grade III or higher) occurred in 29% and 19% of patients, respectively. The most common complications after esophagectomy were pneumonia, esophago-enteric leak, and dysrhythmia atrial. After gastrectomy, pneumonia, esophago-enteric leak, and acute delirium were the most common complications.

Recently, the outcomes of 24 high volume hospitals participating in the ECCG were published.⁵ Compared with these data, overall complication rates, pneumonia rates, and esophago-enteric leakage rates were significantly higher in the DUCA. Different explanations may exist for these discrepancies.

First, differences in patient and treatment characteristics exist between the ECCG cohort and DUCA cohort which might have influenced the occurrence of complications. From previous studies with DUCA data, it is known that higher age, ASA score, body mass index, N+ status, proximal-mid esophageal tumor location, and open transthoracic procedures are associated with an increased risk for postoperative complications.^{8,9} Some of these factors were more frequently present in the DUCA, for example, 30% of patients were older than 70 years old (vs 23% in the ECCG cohort). However, in the ECCG cohort, patients with ASA III or higher were more frequently present than in the DUCA (39% vs 21%).

The second difference was the percentage of patients that was treated with neoadjuvant chemoradiotherapy. In the DUCA, 88% of patients were treated with neoadjuvant chemoradiotherapy, versus 46% in the ECCG cohort. In the literature, some studies regarding neoadjuvant chemoradiotherapy have reported no significant differences in complication rates between neoadjuvant chemoradiotherapy and neoadjuvant chemotherapy alone or no neoadjuvant therapy.^{10–12} However, Klevebro et al¹² reported a higher frequency of severe complications after neoadjuvant chemoradiotherapy in comparison with neoadjuvant chemotherapy alone. It has been suggested that radiotherapy affects the lung tissue and may increase pulmonary complications.¹³ The difference in type and frequency of neoadjuvant therapy could be an

explanation of the higher pneumonia rate in the DUCA versus the ECCG cohort. A study with combined datasets and correction for differences in case-mix could potentially answer this issue.

Another difference between both cohorts was the type of esophagectomy. In the DUCA 86% of patients underwent a minimally invasive esophagectomy versus 48% in the ECCG. The TIME trial, a randomized trial evaluating minimally invasive versus open transthoracic esophagectomy, showed that in-hospital pulmonary infections occurred significantly less frequent after minimally invasive esophagectomy (12% vs 34%).¹⁴ A previous Dutch study showed that during the implementation of minimally invasive esophagectomies in the Netherlands there were no differences in pulmonary complications and 30-day/in-hospital mortality between minimally invasive versus open gastrectomy. However, the same study showed higher anastomotic leakage rates and reintervention rates after minimally invasive gastrectomy.¹⁵ The introduction of minimally invasive surgery and the associated learning curve that goes with it,¹⁶ might have influenced the complication rate. Nonetheless, in 2015, 84% of the registered esophagectomies in the DUCA was performed with minimally invasive techniques and, since the current study only reports data of 2016 and 2017, it could be that most surgeons might already have completed their learning curve in this period. However, it is important to keep in mind that learning curve until proficiency might be much longer than initially was expected.¹⁶ Future studies are needed to evaluate the “real” length of the learning curve.

Also the approach of esophagectomy differed between the DUCA and ECCG cohorts. The transhiatal approach was more favourite in the DUCA cohort than in the ECCG cohort: 48% versus 20%, respectively. As reported in a meta-analysis of Hulscher et al,¹⁷ the transhiatal approach and cervical anastomosis is associated with a higher frequency of anastomotic leakage and vocal cord paralysis. In the transthoracic group in this meta-analysis, there was more perioperative blood loss, pulmonary complications, chyle leak, and wound infections. Thus, the difference in favored approaches between the DUCA and ECCG might explain the higher anastomotic leakage rate in the DUCA database. Nonetheless, the higher pneumonia rate in the DUCA could not be explained by the differences in surgical approach.

The annual hospital volume of the participating hospitals in the ECCG has been described as all “high volume.” In the DUCA, in 2016, the annual hospital volume varied each year. In 2016, 9 of 22 hospitals performed 40 or more resections and 5 hospitals performed less than 20 resections.¹⁸ Differences in annual hospital volume may influence outcomes. However, further studies are needed to evaluate whether these differences can explain the variation in outcomes between the cohorts.

Due to the use of a standardized outcomes set, the DUCA outcomes after esophagectomies could be compared with the ECCG outcomes fairly. For outcomes after gastrectomies, at the time of the implementation of the ECCG outcomes, there was no standardized international consensus set and the ECCG outcomes were also incorporated for patients after gastrectomy. To our knowledge, the ECCG outcomes set has not been used for reporting outcomes after gastrectomy in other cohorts. Recently, a specific standardized outcomes set for gastric cancer surgery was published with the intent to facilitate international comparison.¹⁹ The intent is to implement this standardized set of definitions in the DUCA because it potentially facilitates international comparison.

An international comparison of Dutch results after esophagectomy and gastrectomy has been done previously. The results of the DUCA were compared with the results of the Swedish NREV (Nationellt Kvalitetsregister matstrups-och magsäckscancer).²⁰ However, the results of the registries at that time were not standardized, which makes comparison not really reliable.

The 30-day mortality in the DUCA database was 1.7% after esophagectomy and 4.4% after gastrectomy. In comparison with the outcomes of the ECCG cohort, the mortality after esophagectomies was not significantly different. The 30-day mortality after gastrectomy and esophagectomy was also reported in the annual report of the British “National Oesophago Gastric Cancer Audit.” Between 2007 and 2009 and between 2013 and 2015, the 30-day mortality after esophagectomies was 3.8% (95% confidence interval: 3.1%–4.7%) and 1.6% (95% confidence interval: 1.2%–2.1%), respectively. After gastrectomy it was 4.5% (95% confidence interval: 3.4%–5.7%) and 1.9% (95% confidence interval: 1.3%–2.7%), respectively. In the annual report of the National Oesophago Gastric Cancer Audit, no clarification was given for this improvement in 30-day mortality after esophagectomy and gastrectomy. It would be interesting to evaluate the underlying processes; to direct a strategy to also improve 30-day mortality after gastrectomy in the Netherlands.

In conclusion, evaluation of quality of care is important, especially for high complex, low-volume procedures such as esophagectomy and gastrectomy. Reporting outcomes using standardized definitions is an essential step toward reliable results. Furthermore, it enables international comparisons that could help to reveal significant differences in outcomes and to identify factors which could be improved. A more widespread adoption of the ECCG platform could be recommended to improve international benchmarking in esophageal surgery.

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