Review Article

ESODATA: benchmarking esophagectomy complications

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Abstract: With the aim to improve the quality of esophagectomy research, the Esophageal Complications Consensus Group (ECCG) was created in 2011. The group performed a Delphi process to reach consensus regarding a basic platform of complications that should be reported in all outcome studies reporting of esophagectomy, and developed an infrastructure defining the four critical individual complications. This group also reached a consensus on what other quality measures should be routinely reported in outcome studies on esophagectomy. The ECCG then performed a study of the defined outcomes in a prospective multicenter international cohort study with the acronym: "ESODATA". Postoperative results and demographic data about all esophagectomies for benign or malignant indications were collected. Participating centers included 19 of the original institutions with addition of five high volume esophagectomy units. The study provides an international contemporary standard for complication incidence and assessment, and a framework for audit and quality improvement projects for esophagectomy units worldwide. A large contemporary multicenter international dataset with standardized outcomes, like the ESODATA study cohort, provides the best opportunity for precise information about contemporary practice in the management of esophageal disease, and is likely to become gold standard for future clinical oncologic research.

Keywords: Esophagectomy; postoperative complications; ESODATA

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Introduction

Esophagectomy is associated with significant risk for postoperative complications (1,2). Countless studies have been performed evaluating patient and treatment factors related to adverse outcomes after esophagectomy, however, standardized definitions have not historically been available which prevents meaningful comparisons between studies and high-quality meta-analyses to be performed. A meta-analysis showed that 60 of 122 previous studies of complications after esophagectomy did not include any definitions for the reported complications (3).

Esophageal Complications Consensus Group (ECCG)

With the aim to improve the quality of esophagectomy research, the ECCG was created in 2011. The initial ECCG comprised 21 high-volume esophageal surgeons from 14 countries and was sponsored by all the major UGI and Thoracic surgical societies including ESTS, STS, SSAT, OESO, and ISDE (*Table 1*). The group performed a Delphi process via email and three face-to-face full day meetings to reach consensus regarding a basic platform of complications that should be reported in all outcome studies reporting of

Table 1 Members of the original Esophageal Complications Consensus Group

Region	City	Member
Australia	Brisbane	Mark Smithers
China	Hong Kong	Simon Law
Europe	Barcelona, Spain	Manuel Pera
	Cologne, Germany	Arnulf Hölscher
	Dublin, Ireland	John V. Reynolds
	Edgbaston, Birmingham, UK	Derek Alderson
	Leuven, Belgium	Toni Lerut
	Marseille, France	Xavier Benoit D'Journo
	Newcastle, UK	Michael Griffin
	Oxford, UK	Nick Maynard
	Rotterdam, Netherlands	Jan van Lanschot/Wijnhoven
Japan	Tokyo, Japan	Yuko Kitagawa
North America	Ann Arbor, MI	Andrew C. Chang
	Houston, TX	Wayne Hofstetter
	Philadelphia, PA	John Kucharczuk
	Pittsburgh, PA	Blair Jobe
	Rochester, NY	Jeffrey H Peters
	Seattle, WA	Donald E Low
	Toronto, Canada	Gail Darling
South America	São Paulo, Brazil	Ivan Cecconello
South Asia	Mumbai, India	C. S. Pramesh

esophagectomy, and developed an infrastructure defining the four critical individual complications (*Table 2*). This group also reached a consensus on what other quality measures should be routinely reported in outcome studies on esophagectomy. The result of this process was published in 2015 (4).

The group recommends routine recording of 30-day and in-hospital mortality. There was strong agreement for also recording 90-day mortality. Reports of 30-day mortality should include:

(I) All deaths within 30 days, regardless of cause, during the initial hospitalization including those transferred to other acute care facilities.
(II) All deaths regardless of cause, after discharge up to 30 days post-operatively

The most appropriate individuals for data collection/recording were ranked:

(I) Cancer coordinators;
(II) Data managers;
(III) Surgeons.

Trainees were not recommended.

Concerning comorbidity routine recording of:

(I) ASA;
(II) Zubrod/ECOG;
(III) Charlson comorbidity index.

Blood Transfusions should be recorded in two settings:

(I) Intra-operative transfusions;
(II) Post-operative transfusions.

Number of units transfused should be recorded.

Transfers of patients to higher level of care, e.g., Ward to ICU/HDU should be recorded.

Complication data recording should include scoring with either Clavien-Dindo classification or Accordion classification, with the Clavien-Dindo Score being

Table 2 Standardized definitions for reporting complications after esophagectomy

Data entry: ideally by surgeon, data manager or nurse specialist
Mortality: 30–90 day mortality
Co-morbidity scoring system: Charlson, Zubrod, ASA
Severity grading: Clavien-Dindo or Accordion
Timeframe for readmissions: 30 days
Change in level of care should be recorded, i.e., return to Stepdown Unit, HDU or ICU
Blood transfusions should be recorded as routine
Blood transfusions should be distinguished between intra-operative and postoperative transfusions
Recording of blood transfusions should include the number of units transfused
Discharge location should be routinely recorded

recommended.

All readmissions to primary or secondary hospital within 30 days of discharge should be recorded including information about timing and cause of readmission.

Discharge location should also be reported, and should discriminate between:

(I) Discharge home;

(II) Discharge to any other medical facility, e.g., secondary hospital, rehab center, or nursing facility.

Benchmarking esophagectomy complications

Once the basic ECCG platform was developed and published, the ECCG moved forward to beta test the system in high volume international centers. The goals of the project included documentation of contemporary incidence of complications and other esophagectomy quality measures, testing relevance of outcome definitions, and assess the ability to carry out international prospective web-based studies. It was decided that the best way to carry out the project was to construct a secure online dataset that could be accessed by all contributing centers and would simplify data entry. This format would also allow contributing centers to access their institutional data anywhere internet access is available.

The ECCG then decided to continue the collaboration and perform a study of the defined outcomes in a prospective multicenter international cohort study with the acronym: "ESODATA". Postoperative results and demographic data about all esophagectomies for benign or malignant indications were collected in a secure online database. Participating centers included 19 of the original institutions with addition of five high volume esophagectomy units (*Table 2*). The database and the web portal were hosted in a high-performance, dedicated web server and the database interface was accessible only via authenticated and encrypted secure network connections. Data collection was performed between January 2015 and December 2016, 1,500 esophagectomies were targeted but 2,704 esophagectomies were accrued over 24 months and the results were published in 2017 (5). There is no clear definition of how many resections are required for the definition of a high-volume surgical center. Previous esophagectomy studies have used cutoffs from nine resections per year to >300 per year (6,7). Regardless of this, an institutional database from a single center doing 50 resections/year would have to collect data over 50 years to reach a sample of 2,704, which makes the information collected susceptible to a multiplicity of changes in technique and peri-operative management over time.

The publication of the short-term results of this very large sample of contemporary esophagectomies from high volume international esophagectomy centers is completely unique. No international oncologic dataset has utilized an "online" format. Never before has a study of postoperative outcomes after esophagectomy used a predefined set of complications with clear definitions, and never before has a study had the statistical power to study rare exposures or outcomes. The study provides an international contemporary standard for complication incidence and assessment, and a framework for audit and quality improvement projects for esophagectomy units worldwide. All participating centers were high volume esophagectomy units with established history of data collection. The study

collected international data with clear definitions. The dataset was designed to specifically address the goals of the study. The ESODATA project provides high volume "short-term" data accrual, which makes the results contemporary and highly relevant.

ESODATA project

The assembly and maintenance of the dataset offers several challenges. National protocols for protecting patient information require adapting the methodology of collecting information. The ESODATA dataset has to date been supported by the work of individual researchers without external funding. In order to secure the future for the dataset, a stable and funded infrastructure for maintaining and expanding the dataset is crucial. Advantages with the ESODATA website include easy to use interface, no local IT-support required, data entry can be performed anywhere Internet access is available, there is no institutional maintenance, and there is no current cost for entering data. All data fields in the dataset are mandatory and conditional fields are applied only as appropriate, which makes all the included variables complete. Data entry is performed by clicking the appropriate box or selecting from the dropdown menu. There are no free text data fields. Entry of a patient with esophageal cancer treated with esophagectomy and with postoperative complications requires a maximum of 49 data fields, whereas a benign esophagectomy patient with no complications only requires 24 fields. This is made possible by minimizing the data fields according to the details of each individual patient. The data fields in ESODATA are labeled and include essential data for analyses. When data is exported, it is complete and does not require any cleaning before analyses. Institutional reports are instantly available for all ESODATA contributors, which can be utilized for quality improvement projects and provides an opportunity to compare institutional results to international outcomes.

The national register for esophageal cancer in the Netherlands; the Dutch Upper Gastrointestinal Cancer Audit have included the ECCG complication definitions. A recent publication showed that high completeness and accuracy of data was achieved (8). The five centers currently performing esophagectomies in Ireland have also started reporting their national data according to the ECCG complication definitions. Implementation of the ECCG platform in prospective national registers increases the opportunities for future high-quality studies and makes international comparisons between studies feasible.

New services now provided through the Esodata dataset include the opportunity for contributing centers to apply to carry out a focused study. In addition, it is planned that Esodata is capable of providing data collection on a national rather than just an institutional level. The initial example of this will be Ireland where the Esodata database will provide a venue for collecting and auditing the outcomes of all five Irish esophagectomy units. A large contemporary multicenter international dataset with standardized outcomes, like the ESODATA study cohort, provides the best opportunity for precise information about contemporary practice in the management of esophageal disease, and is likely to become gold standard for future clinical oncologic research.

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