

## Protocol version 1

### Abstract

**Aim:** To define benchmark outcomes in minimally-invasive esophagectomy

**Design:** Multicenter retrospective cohort study

**Primary outcome measure:** Morbidity as defined by the Clavien-Dindo classification for surgical complications and the comprehensive complication index at discharge and after 3 months

**Hospital eligibility:** High volume centers (> 20 esophagectomies / year), conducting a prospective database as well as previous publications critically reporting on their outcome

**Study population:** Adult patients who underwent totally minimally-invasive (laparoscopic / thoracoscopic) Ivor Lewis or McKeown esophagectomy from 01.06.2011 to 31.05.2016.

### Exclusion criteria:

- Open procedures
- Hybrid procedures

**Data collection Deadline:** to be announced

### Introduction

With the growing complexity and cost of modern surgical practice, quality assessment becomes mandatory. The notion of quality and quality assessment is widely recognized and used in the world of business and manufacturing. A possible tool of quality assessment is benchmarking. Benchmarking is a process of measuring performance in order to enable for outcome comparison and improvement within a specific domain. In the surgical community, however, such standard outcome measures and multicenter comparison of results are not available and benchmarking for the best possible results for specific procedures is lacking.

Recently, a first landmark study defining benchmark outcomes for liver resection has been presented at the 2016 ASA meeting in Chicago (1).

Since esophagectomy is a high-risk procedure with a significant morbidity and an accepted perioperative mortality rate of about 5%, quality assessment is of major importance. Up to date no data is available on best achievable results in major esophageal procedures. To identify the best possible outcome (i.e. benchmarking), data from high-volume centers in low risk patients will be thoroughly analyzed. These benchmark outcomes will serve as “negative controls” for comparison with single center outcomes, high-risk patients and future developments.

## Policy Securing

Confidential center specific data: No center-specific data will be published. Instead, all complications or adverse outcomes will be anonymously reported, as fractions of the total study population. Each center, of course, will be free to publish their own data, as they wish.

Authorship: No data will be submitted or published without authorization from each participating center. Each center will be represented by two co-authors. In the ideal case, there will be one junior author who will coordinate data collection with Dr. Henner Schmidt (coordinator of the study from Zurich). If necessary, three authors may be included for one center in the authorship list.

Further use of cohort data: Future studies based on the collected data will hopefully emerge from this multicenter study e.g. comparing outcomes in patients undergoing open or hybrid esophagectomy techniques with the benchmark outcomes.

## Methods

### Objective:

To conduct a retrospective multicenter cohort study to define benchmark criteria for best achievable outcomes in minimally-invasive esophagectomy to serve as controls in quality assessment. The benchmark criteria will be derived from postoperative mortality and morbidity as well as patient survival.

### Aims:

The **primary aim** is to define benchmark outcomes by identifying post procedural complications according to the Clavien-Dindo classification for surgical complications (2,3) and the comprehensive complication index CCI (4) at discharge and after 3 months.

### ***Secondary aim:***

- Patient survival

### Time period:

- The study will cover a 5-year period, from 01.06.2011 to 31.05.2016.

### Hospital inclusion criteria

- Single centers performing > 20 esophagectomies per year (minimally-invasive and other procedures)
- Centers having a prospective database from which most of the data can be extracted

## **Patient eligibility**

### *Inclusion criteria*

- Patients who underwent totally minimally-invasive (laparoscopic / thoracoscopic) transthoracic Ivor Lewis or McKeown esophagectomies.

### *Exclusion criteria*

- Open and hybrid procedures

## **Outcome Measures**

### *Primary outcome measure*

The primary outcome measure is identifying post procedural complications according to the Clavien-Dindo classification for surgical complications (2,3) and the comprehensive complication index (CCI) (4) at discharge and three months. In order to focus on the most frequent complications, investigators should focus on the complications basic platform as published by the esophagectomy complications consensus group (ECCG) (5). This requires the patient to have a documented 3-months follow-up in the center conducting the study. Every complication has to be assessed according to the Clavien-Dindo classification. The corresponding CCI will be calculated by the coordinating center in Zurich.

## **Governance**

Data will be collected via a secure online webpage, provided by the University Hospital of Zurich. This website uses a data entry management system (DEMS) to meet international standards for online databases including fully anonymized data. Data will not be published with hospital identifiers.

## **Collecting data**

**Local collaborators:** Most hospitals will have two local investigators. **A senior and a junior investigator.** The junior collaborator will be in regular contact with the study coordinator in Zurich. The junior investigator will be responsible for:

- Gaining local research ethics approval
- Identifying and including all eligible patients
- Accurately collect baseline and follow-up data
- Submit data to the online DEMS database

## References

1. Rössler F, Sapisochin G, Song G, et al. Defining Benchmarks for major liver surgery. A multicenter analysis of 5202 living liver donors. Ann Surg in press.
2. Dindo D, Demartines N, Clavien PA. Classification of Surgical Complications. A New Proposal with Evaluation in a Cohort of 6336 Patients and Results of a Survey. Ann Surg. 2004;240:205-213.
3. Clavien PA, Barkun J, de Oliveira ML, et al. The Clavien-Dindo classification of surgical complications: five-year experience. Ann Surg. 2009;250:187-196.
4. Slankamenac K, Graf R, Barkun J, et al. The comprehensive complication index: a novel continuous scale to measure surgical morbidity. Ann Surg. 2013;258:1-7.
5. Low DE, Alderson D, Ceconello I, et al. International consensus on standardization of data collection for complications associated with esophagectomy. Ann Surg. 2015;262:286-294

*The esoBenchmark.org Team*



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## Case Report Form (CRF)

Submitted by Dimitri Raptis on Sat, 07/02/2016 - 10:33

### Case Identification

Case ID \*

Please assign above a case identification number related to this case submission. Please ensure that you keep this number in your records (excel file or any other database) if you would like to access this case in the future and perform changes. For each case there should be a unique ID assigned to it.

### Demographics

Age \*  years

Height \*  cm

Weight \*  kg

Gender \*  Male  Female

### Health status

WHO / ECOG performance status

ASA status score

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Indication for esophagectomy

Indication for esophagectomy \*

If other type of malignancy, indicate:

If benign, indicate:

Tumor characteristics (if applicable)

Tumor location

Preoperative therapy

pT Stage

pN Stage

pM Stage

Resection Margin

Total number of resected lymph nodes

Number of positive lymph nodes

Operation characteristics

Patient position during thoracoscopy

Surgical approach \*

Open and hybrid procedures are excluded.

Robotic approach

Postoperative complications

Type and grade of complication according to Clavien-Dindo \*

	None	I	II	IIIa	IIIb	IVa	IVb	V
Anastomotic leak *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Conduit necrosis *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Conduit leak *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chyle leak *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Gastrointestinal *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pulmonary *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cardiac *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thromboembolic *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Urologic *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Infection *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neurologic *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wound infection *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The first column above indicates the most common types of complications after esophageal surgery. The top row lists the different grades of complications according to the Clavien-Dindo classification. Please rate each type of complication according to Clavien-Dindo. If there were no complications encountered, please indicate "None" for all types and grades of complications. "I" indicates "Grade I", "II" indicates "Grade II", "III" indicates "Grade III", and so on. If this grid is not clear to you, please read the protocol of the study and the Clavien-Dindo Classification page available on the right sidebar of this platform. This field is mandatory as it is the primary endpoint of this study!

If there were additional types of complications encountered not listed above, please indicate below:

Additional complication 1: Type: _____, Grade _____.
Additional complication 2: Type: _____, Grade _____.
Additional complication 3: Type: _____, Grade _____.
Additional complication 4: Type: _____, Grade _____.
Additional complication 5: Type: _____, Grade _____.

E.g.: Additional complication 1: Type: Hiatal hernia with bowel strangulation, Grade IIIb (treated with laparotomy, hernia reduction and approximation of hiatal defect with mesh).

## Outcome and quality measures

Change in level of care If admission to the intensive care unit, total number of days admitted   
daysBlood product utilization Postoperative length of stay  days

Re-admission to the hospital

Patient status \* 

The patient status indicates whether the patient was last seen alive or dead at the hospital, followed up at the outpatient clinic, family doctor, or confirmed after being contacted by phone. Below you are requested to indicate the number of days from operation until last follow up or death.

Days from esophagectomy to last follow up or death \*  days

i.e. number of days from operation until the last time the patient was seen alive in the hospital, outpatient clinic, contacted by phone, reviewed by the family doctor or confirmed dead due to carcinomatosis or any other cause. Please feel free to use the date duration calculator link available on the right sidebar of our platform to calculate precisely the duration in days between two separate dates.

Comments (optional)

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