

## Study Protocol v1.3

### Defining Benchmarks in Bariatric Surgery – A global analysis of laparoscopic Roux-en-Y gastric bypass and sleeve gastrectomy

#### Abstract

**Aim:** To define benchmark outcomes in minimally-invasive primary bariatric surgery.

**Design:** Multicenter retrospective cohort study.

**Assessed outcomes:** Morbidity as defined by the Clavien-Dindo classification for surgical complications, the Comprehensive Complication Index® (CCI®) at discharge, at 3 months and at latest follow-up. Evolution of body mass index (BMI) will be also analyzed.

**Hospital eligibility:** High volume centers (> 200 bariatric operations per year) from at least three continents, maintaining a prospective database, as well as having published previously critically on their outcome.

**Study population:** Adult patients who underwent primary minimally invasive (laparoscopic / robotic) Roux-en-Y gastric bypass or sleeve gastrectomy from 1<sup>st</sup> of June 2012 to 31<sup>st</sup> of May 2017.

#### Patient Exclusion criteria:

- Open surgery
- Previous intra-abdominal surgery (including previous bariatric surgery)
- Pre-operative BMI over 50 kg/m<sup>2</sup>
- Age over 65 years
- Cardiovascular disease (e.g. cardiac arrhythmia, stroke, coronary artery disease) (Hypertension is allowed)
- History of thromboembolic events and/or therapeutic anticoagulation
- Diabetes mellitus (Type I and Type II, as defined by the American Diabetes Association)
- Obstructive sleep apnea (recurrent episodes of upper airway collapse during sleep)
- Chronic obstructive pulmonary disease (FEV<sub>1</sub>/FVC<0.7)
- Chronic kidney disease (eGFR < 30ml/min/1.72 m<sup>2</sup>)
- Inflammatory bowel disease (ulcerative colitis, Crohn's)
- Immunosuppression therapy (e.g. steroids, calcineurin inhibitors, etc)
- Patients who underwent associated procedures (for example: cholecystectomy, hiatoplasty, liver biopsy)
- ASA score > 2

**Data collection Deadline:** 1<sup>st</sup> September 2017 – 30 April 2018 (to meet 2018 IFSO World Congress abstract submission deadline)

## **Background**

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 by comparison to the outcomes achieved by the best “service provider” in a specific domain. Usually, a benchmark describes the “best possible” outcome of a benchmarking subject to whom comparison can be performed. In the surgical community, however, such benchmarks – best possible outcomes - for specific procedures, not just the pooled overall performance, are lacking.

In 2016, a first landmark study defining benchmark outcomes for liver resection was published in *Annals of Surgery* by a group of international authors invited and guided by our department (1). More recently, further surgical outcomes (liver transplantation, minimally invasive esophagectomy) have been benchmarked and have been accepted for publication (2, 3).

Since laparoscopic bariatric surgery has become a standardized and widely performed procedure worldwide, quality assessment is of major importance. To identify the best possible outcomes (i.e. the benchmarks), data from high-volume centers (based on official IFSO criteria; <http://www.eac-bs.com/site/index.php/ifso-endorsed-coe-programs/centre-of-excellence-coe-program/requirements>) in low risk patients will be analyzed. These benchmarks will serve as “optimal outcomes” for comparison with single center outcomes, high-risk patients and future developments.

## **Aim**

The primary aim is to define benchmark outcomes based on assessment of post procedural complications according to the Clavien-Dindo classification for surgical complications (4,5) and the comprehensive complication index CCI™ at discharge and at 90-days (6). The CCI® expresses morbidity on a continuous numeric scale from 0 (no complications) to 100 (death) by weighing all postoperative complications according to the Clavien–Dindo classification for their respective severity. Secondary outcome measure are patient survival and excess BMI loss (EBMIL).

## **Data Security**

This multicenter international study is designed to harvest prospectively collected retrospective data via an encrypted (i.e. Secure Sockets Layer (SSL) protocol) online

platform (<https://bbenchmarks.org/>) that meets Food and Drug Administration (FDA) standards and is accessible only by secured login membership (7).

**Confidential center specific data:** Centers' outcomes will be individually analyzed in a first step to screen for center-specific differences. Benchmarks will be computed from each center's results in a second step. 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.

**Further use of cohort data:** Future studies based on the collected data may emerge from this multicenter study, such as comparing outcomes in patients with or without specific comorbidities with benchmark outcomes. For further data usage, additional ethics approval may be required.

## Authorship

No data will be submitted or published without the authorization of 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. Daniel Gero (coordinator of the study from Zurich). Exceptionally and if necessary, three authors may be included for a particular center in the authorship list. Publication authorship will comply with the International Committee of Medical Journal Editors recommendations.

## Methods

### Study design

This is a multi-centric retrospective cohort study to define benchmark values for best achievable outcomes in primary minimally invasive bariatric surgery. Centers from at least three continents will be included. The benchmark values will be derived from postoperative morbidity and mortality (according to the Clavien-Dindo classification and CCI®), as well as length of surgery, length of stay, rate of ICU use, blood transfusion needs and rate of readmission/reoperation. Most frequent complications of bariatric surgery, such as:

- Staple line leak: gastrojejunostomy / jejunojejunostomy / gastric tube
- Stenosis of anastomosis or of gastric tube
- Postoperative bleeding: intra-abdominal / intra-luminal (inside the GI tract)
- Small bowel obstruction: internal hernia / trocar site hernia / adhesions / other
- Marginal ulcer at the gastrojejunostomy
- Wound infection
- Gastro-esophageal reflux disease (de novo / worsening)

will be benchmarked specifically. Excess body mass index loss (EBMIL) will also be assessed.

## **Data origin**

The data used for this study are routinely assessed during the course of patients' treatment. Data collected are entirely derived from prospectively maintained databases of the participating centers. No additional examinations or tests during the perioperative or postoperative course are required.

## **Time period**

The study will cover a 5-year period, from 1<sup>st</sup> of June 2012 to 31<sup>st</sup> of May 2017.

## **Hospital inclusion criteria**

- Single centers performing > 200 bariatric operations per year (4 times the minimal facility volume requirement defining centers of excellence by IFSO (<http://www.eac-bs.com/site/index.php/ifso-endorsed-coe-programs/centre-of-excellence-coe-program/requirements>) and by ASMBS ([http://www.soard.org/article/S1550-7289\(16\)30051-X/fulltext](http://www.soard.org/article/S1550-7289(16)30051-X/fulltext)).
- Centers having a prospective database from which most of the data can be extracted.
- Centers should have specific interest in bariatric surgery, documented by previous publications critically reporting on their outcomes.
- Opinions of experts and/or of scientific societies on “clinical excellence” will support the selection of centers

## **Patient eligibility**

### ***Inclusion criteria***

- Adult patients of 18-65 years
- Low risk profile (please read “exclusion criteria”),
- Maximum preoperative BMI of 50 kg/m<sup>2</sup>
- Primary laparoscopic/robotic proximal Roux-en-Y gastric bypass or sleeve gastrectomy
- Documented follow-up of at least 90 days

### ***Exclusion criteria***

- Open surgery
- Previous intra-abdominal surgery (including previous bariatric surgery)
- Pre-operative BMI over 50 kg/m<sup>2</sup>
- Age over 65 years

- Cardiovascular disease (e.g. cardiac arrhythmia, stroke, coronary artery disease) (Hypertension is allowed)
- History of thromboembolic events and/or therapeutic anticoagulation
- Diabetes mellitus (Type I and Type II, as defined by the American Diabetes Association)
- Obstructive sleep apnea (recurrent episodes of upper airway collapse during sleep)
- Chronic obstructive pulmonary disease ( $FEV_1/FVC < 0.7$ )
- Chronic kidney disease ( $eGFR < 30\text{ml}/\text{min}/1.72\text{ m}^2$ )
- Inflammatory bowel disease (ulcerative colitis, Crohn's)
- Immunosuppression therapy (e.g. steroids, calcineurin inhibitors, etc)
- Patients who underwent associated procedures (for example: cholecystectomy, hiatoplasty, liver biopsy)
- ASA score  $> 2$

## **Outcome Measures**

### ***Benchmark outcome measures***

The benchmark outcome measures will be derived by identifying and grading post procedural complications according to the Clavien-Dindo classification for surgical complications (4,5) and the Comprehensive Complication Index<sup>®</sup> (CCI<sup>®</sup>) (6) at discharge and three months postoperatively, as well as length of surgery, length of stay, rate of ICU use and rate of readmission/reoperation. Every complication until discharge has to be assessed according to the Clavien-Dindo classification. The corresponding CCI<sup>®</sup> and Clavien-Dindo classification of late complications will be calculated by the coordinating center in Zurich. Most frequent complications will be benchmarked specifically (staple line or anastomotic leak, stenosis of anastomosis or of gastric tube, postoperative bleeding, small bowel obstruction, marginal ulcer at the gastrojejunostomy, wound infection, gastro-esophageal reflux disease (de novo / worsening)).

### **Governance**

Data collection will be performed via the secure online platform <https://bbenchmarks.org/>, provided by the University Hospital of Zurich. This platform uses a data entry management system (DEMS) to meet international standards for online databases including fully anonymized data (7). Data will not be reported 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 Dr. Daniel Gero 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 Data Entry Management System (DEMS).

### **Statistical analysis (2,3)**

We will conduct descriptive statistics for intra- and postoperative parameters to characterize the patient population.

Benchmark cutoffs will be determined for peri- and postoperative morbidity & mortality indicators including length of surgery (skin-to-skin time), intraoperative blood transfusions, most frequent complications as listed in “Outcome measures”, rate of ICU admissions, hospital stay, readmission rate and the CCI® at discharge and 3 months and at latest follow-up. Benchmarks will be defined as the 75<sup>th</sup> percentile of the median outcome parameters of the participating centers representing best achievable results.

For subgroup analyses (i.e., comparison of the surgical technique or benchmark vs non-benchmark groups), continuous variables will be compared using the Mann-Whitney U test. Categorical variables will be compared using the Fischer exact or the Pearson  $\chi^2$  tests, where appropriate. BMI values over time will be compared with the repeated measures ANOVA. Survival curves will be compared by using the log rank test and linear regression analysis will be performed for correlations. A value of  $P < 0.05$  will be considered statistically significant. Statistical analysis will be performed using Stat 10.1 and SPSS 20.

### **References**

(underlined authors are affiliated to the Department of Visceral and Transplantation Surgery, University Hospital Zurich)

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