Defining Global Benchmarks in Elective Secondary Bariatric Surgery Comprising Conversional, Revisional, and Reversal Procedures

Daniel Gero, MD, PhD,[*] Marie Vannijvel, MD,[†] Sietske Okkema, MD,[‡] Ellen Deleus, MD,[§] Aaron Lloyd, MPH,[¶] Emanuele Lo Menzo, MD,[||] George Tadros, MD,[||] Ivana Raguz, MD,[*] Andres San Martin, MD,[**] Marko Kraljević, MD,[††] Styliani Mantziari, MD, MSc,[‡‡] Sebastien Frey, MD,[§§] Lisa Gensthaler, MD,[¶¶] Henna Sammalkorpi, MD, PhD,[||||] José Luis Garcia-Galocha, MD,[***] Amalia Zapata, MD,[†††] Talar Tatarian, MD,[‡‡‡] Tom Wiggins, MBChB, PhD,[§§§] Ekhlas Bardisi, MD,[¶¶¶] Jean-Philippe Goreux, MD,[||||||] Yosuke Seki, MD, PhD,[****] René Vonlanthen, MD, MHA,[*] Jeannette Widmer, MD,[*] Andreas Thalheimer, MD,[*] Kazunori Kasama, MD,[****] Jacques Himpens, MD, PhD,[¶¶¶||||||††††] Marianne Hollyman, MBChB, PhD,[§§§] Richard Welbourn, MD,[§§§] Rajesh Aggarwal, MD,[‡‡‡] Alec Beekley, MD,[‡‡‡] Matias Sepulveda, MD,[†††] Antonio Torres, MD, PhD,[***] Anne Juuti, MD, PhD,[||||] Paulina Salminen, MD, PhD,[‡‡‡‡] Gerhard Prager, MD,[¶¶] Antonio Iannelli, MD, PhD,[§§] Michel Suter, MD,[‡‡§§§§] Ralph Peterli, MD, PhD,[††¶¶¶¶] Camilo Boza, MD,[**] Raul Rosenthal, MD,[||] Kelvin Higa, MD,[¶] Matthias Lannoo, MD, PhD,[§] Eric J. Hazebroek, MD, PhD,[‡] Bruno Dillemans, MD,[†] Pierre-Alain Clavien, MD, PhD,[*] Milo Puhan, MD, PhD,[||||||||] Dimitri A. Raptis, MD, MSc, PhD,[*****] and Marco Bueter, MD, PhD[*]✉

Objective: To define "best possible" outcomes for secondary bariatric surgery (BS).

Background: Management of poor response and of long-term complications after BS is complex and under-investigated. Indications and types of reoperations vary widely and postoperative complication rates are higher compared to primary BS.

Methods: Out of 44,884 BS performed in 18 high-volume centers from 4 continents between 06/2013-05/2019, 5,349 (12%) secondary BS cases were identified. Twenty-one outcome benchmarks were established in low-risk patients, defined as the 75th percentile of the median outcome values of centers. Benchmark cases had no previous laparotomy, diabetes, sleep apnea, cardiopathy, renal insufficiency, inflammatory bowel disease, immunosuppression, thromboembolic events, BMI $> 50\,kg/m^2$ or age > 65 years.

Results: The benchmark cohort included 3143 cases, mainly females (85%), aged 43.8 ± 10 years, 8.4 ± 5.3 years after primary BS, with a BMI $35.2 \pm 7\,kg/m^2$. Main indications were insufficient weight loss (43%) and gastro-esophageal reflux disease/dysphagia (25%). 90-days postoperatively, 14.6% of benchmark patients presented ≥ 1 complication, mortality was 0.06% (n = 2). Significantly higher morbidity was observed in non-benchmark cases (OR 1.37) and after conversional/reversal or revisional procedures with gastrointestinal suture/stapling (OR 1.84). Benchmark cutoffs for conversional BS were $\leq 4.5\%$ re-intervention, $\leq 8.3\%$ re-operation 90-days postoperatively. At 2-years (IQR 1–3) 15.6% of benchmark patients required a reoperation.

Conclusion: Secondary BS is safe, although postoperative morbidity exceeds the established benchmarks for primary BS. The excess morbidity is due to an increased risk of gastrointestinal leakage and higher need for intensive care.

From the [*]Department of Surgery and Transplantation, University Hospital Zurich, Zurich, Switzerland; †Department of General Surgery, AZ Sint Jan Brugge-Oostende, Bruges, Belgium; ‡Department of Surgery, Rijnstate Hospital/Vitalys Clinics, Arnhem, The Netherlands; §Department of General Surgery, University Hospital Leuven, Leuven, Belgium; ¶Minimally Invasive and Bariatric Surgery, Fresno Heart and Surgical Hospital, Fresno, California; ||The Bariatric and Metabolic Institute, Cleveland Clinic Florida, Weston, Florida; [**]Bariatric and Metabolic Center, Department of Surgery, Clinica Las Condes, Las Condes, Santiago, Chile; ††Department of Visceral Surgery, Clarunis: St.Clara Hosptital, Basel, Switzerland; ‡‡Department of Visceral Surgery, University Hospital Lausanne, Lausanne, Switzerland; §§Digestive Surgery and Liver Transplantation Unit, University Hospital Nice, University Côte d'Azur, Nice, France; ¶¶Department of Surgery, Medical University of Vienna, Vienna, Austria; ||||Department ofGastroenterological Surgery, University of Helsinki, Helsinki University Hospital, Helsinki, Finland; [***]Department of Surgery, Hospital Clínico San Carlos, Complutense University of Madrid, Madrid, Spain; †††Bariatric and Metabolic Surgery Center, Dipreca Hospital, Las Condes, Santiago, Chile; ‡‡‡Department of Surgery, Thomas Jefferson University Hospital, Philadelphia, Pennsylvania; §§§Department of Upper Gastrointestinal and Bariatric Surgery, Musgrove Park Hospital, Taunton, UK; ¶¶¶Department of Surgery, St Blasius Hospital, Dendermonde, Belgium; ||||||Department of Surgery, Delta CHIREC Hospital, Brussels, Belgium; [****]Weight Loss and Metabolic Surgery Center, Yotsuya Medical Cube, Tokyo, Japan; ††††The European School of Laparoscopic Surgery, St Pierre University Hospital, Brussels, Belgium; ‡‡‡‡Department of Surgery, University of Turku, Turku, Finland; §§§§Department of Surgery, Riviera-Chablais Hospital, Rennaz, Switzerland; ¶¶¶¶Department of Clinical Research, University of Basel, Basel, Switzerland; ||||||||Epidemiology, Biostatistics and Prevention Institute, University of Zurich, Zurich, Switzerland; and [*****]Department of Hepatobiliary and Pancreas Surgery and Liver Transplantation, Royal Free Hospital, London, UK.

✉marco.bueter@usz.ch.

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The considerable rate of tertiary BS warrants expertise and future research to optimize the management of non-success after BS.

Keywords: benchmarks, complication, conversion, morbidity, quality, reoperation, reversal, revision, secondary bariatric surgery, surgical outcomes

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Benchmarking refers to a market-based learning process by which an institution seeks to identify best practices that produce superior results compared to competitors, and enhances its own performance by adopting them.[1] This methodology has been recently introduced to surgery with the analysis of intra- and postoperative outcomes in well-defined low-risk patient cohorts operated in high volume centers around the world.[2–7] Our research consortium lately established outcome benchmarks for the 2 most commonly performed primary bariatric surgery (BS) procedures, Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG).[8] The goal was to improve surgical quality by providing best achievable ''goals'' for relevant outcome indicators and thus enable comparability between centers, surgeons and periods of time.[9,10]

As the population of patients with a history of BS is growing, we are increasingly confronted with the long-term complications of these procedures and with patients who do not achieve their intended weight loss.[11] Secondary BS therefore became part of regular procedures in the bariatric surgeons' practice.[12] Although this surgical segment is highly unstandardized, secondary BS procedures may be categorized as follows: emergency, conversional (exchange of one bariatric procedure to another, i.e. SG to RYGB), revisional (modifications of the bariatric anatomy), and reversal operations (primary BS undone with restoration of the original anatomy).[13] Indications and types of reoperations vary widely and secondary BS is typically characterized by higher postoperative complications compared to primary BS.[14,15] Due to lack of clear recommendations, institutional multidisciplinary boards are often left to manage these patients on a case-by-case basis.[13]

Our aim was to identify the highest achievable quality (ie, benchmarks) in elective secondary BS, by assessing clinically relevant patient-centered outcome indicators in patients operated in high-volume bariatric centers. The identified benchmarks are expected to improve surgical quality by providing goals in postoperative outcomes and may therefore assist optimizing procedure selection and ultimately enhance patient care.

METHODS

Study Design

The establishment of benchmarks in secondary BS followed a standardized methodology[2–8] recently refined by a panel of experts via a Delphi consensus-building process.[9] We performed a multicentric retrospective cohort study based on prospective institutional databases of elective secondary BS.

First, the consecutive cohort of secondary BS was collected from international expert centers via invitation of distinguished surgeons. Centers had to meet criteria promoting sufficient experience, surgical safety, and continuous monitoring of outcomes (Table 1)[9,35]. Five centers dropped out after inclusion due to lack of available resources for research amid the COVID-19 pandemic. The final collaborative consortium included 18 centers: 12 from Europe (Arnhem, Basel, Brussels/Dendermonde, Bruges, Helsinki, Lausanne/Riviera-Chablais, Leuven, Madrid, Nice, Taunton, Vienna, Zurich), 3 from USA (Fresno, Philadelphia, Weston), 2 from Southern America (Santiago de Chile) and 1 from Japan (Tokyo).

Second, we defined the ''*benchmark bariatric patient*'' by applying evidence-based criteria associated with a lower postoperative complication rate (Table 1). Each center had to include all

TABLE 1. Criteria Used to Identify Participating Centers and ''Benchmark'' Cases

	Case classification criteria	
Center inclusion criteria	**Low-risk patient criteria (''benchmark'')**	**High-risk patient criteria (''non-benchmark'')**
Annual caseload ≥150 bariatric operations (every year between 2013–2019), out of which ≥40 cases/year performed by the same surgeon [9,35,36]	Age 18–65 yr [37–39]	History of laparotomy [40,41]
Available prospective bariatric database[8,9]	American Society of Anesthesiologists (ASA) score < IV [42]	Cardiovascular disease (e.g. cardiac arrhythmia, stroke, coronary artery disease) [38]
Interest in bariatric outcomes, documented by ≥1 publication(s) on bariatric surgery[8]	Preoperative BMI <50 kg/m^2[43,44]	History of thromboembolic events and/or therapeutic anticoagulation [44]
''Clinical excellence'' or national reference centers with a dedicated bariatric multidisciplinary team (including endocrinologist, gastroenterologist, access to intensive care unit and interventional radiology) [9,45]	Absence of any high-risk patient criteria listed in the next column	Diabetes mellitus (Type 1 and Type 2, as defined by the American Diabetes Association) [46,47]
≥2 board-certified surgeons perform bariatric surgery within the center [9]		Obstructive sleep apnea (recurrent episodes of upper airway collapse during sleep) [43,44]
Ability to offer ≥2 primary bariatric procedures and revisional bariatric surgery [9]		Chronic obstructive pulmonary disease (FEV1/FVC< 0.7) [48]
		Chronic kidney disease (eGFR < 30ml/min/1.72 m^2) [38]
		Inflammatory bowel disease (ulcerative colitis, Crohn's disease) [49]
		Immunosuppression therapy (ie,.: steroids, calcineurin inhibitors, etc) [50]

consecutive cases (low-risk/benchmark and normal-/high-risk), operated over a 6-year period (06/01/2013-05/31/2019), enabling the internal validation of risk criteria by the assessment of the additional morbidity burden related to the non-benchmark patient profile.

Third, relevant outcome indicators for surgical quality were assessed. To adjust for variability, median values of continuous variables and the proportions of categorical variables were calculated for each participating center. Benchmark cutoffs, indicating ''best achievable'' results for each outcome indicator were set at the 75th percentile of the centers' median values. The study protocol was approved by the Cantonal Ethics Committee of Zurich and by the institutional review boards of participating centers.

Outcome Variables of Interest

Local investigators retrieved de-identified patient-specific data into pre-programmed spreadsheets and forwarded them to the principal investigators at the University Hospital Zurich via secured file transfer (https://transfer.usz.ch/). Data were audited and checked for completeness by DG and included baseline characteristics of patients [age, sex, body-mass index (BMI), risk profile], time and type of first BS, indication for secondary BS, characteristics of the index operation, postoperative complications by severity according to the Clavien–Dindo (CD) grading system,[16] length of stay, readmissions (time from operation, reason, and treatment), last follow-up, and postoperative BMI at 1-year. Secondary BS procedures were grouped into 4 categories, as recommended by Patel et al.[13]: 1.) Conversional, 2.) Reversal, 3.) Revisional with gastrointestinal (GI) suture (ie, gastric pouch resizing, limb-length modification) and 4.) Revisional without GI suture (no opening or stapling of the GI tract, i.e. salvage banding RYGB, band removal, closure of mesenteric defect). To enable the assessment of cumulative morbidity over time, the Comprehensive Complication Index (CCI©) was used.[5,7,8,17] The CCI© expresses morbidity on a continuous numeric scale from 0 (no complications) to 100 (death) by weighing all postoperative complications according to the CD classification. Relevant bariatric complications, such as staple line/anastomotic leak, anastomotic stenosis, internal hernia, pain syndrome were additionally analyzed. Postoperative weight loss was expressed as %-total weight loss, ΔBMI and %-excess body mass index loss, with BMI $\leq$25 kg/m^2 considered as normal.

Statistical Analysis

Discrete variables were described using count (percent), and continuous variables were described using medians (with interquartile range). Multivariable logistic regression was used to compute the additional morbidity burden related to procedure type and preoperative risk profile. Statistical analysis and data visualization were performed using the R software 4.0.2 (R Foundation, Vienna, Austria).[18]

RESULTS

Secondary BS Cohort

The proportion of secondary BS within the centers' overall elective bariatric activity varied between 2.6–38% (Supplementary Figure 1, http://links.lww.com/SLA/D317). Out of the 6818 consecutive elective secondary BS cases performed over 6 years in the 18 included centers, sufficient data allowing inclusion to the study were available for 5349 cases. 3143 benchmark cases (59%) were identified based on preoperative risk-factors. Indications for secondary BS showed continental variations (Fig. 1). Overall, main indications included insufficient weight loss/weight regain (45%), gastro-esophageal reflux disease/dysphagia (25%), abdominal pain/internal hernia (13.5%) and technical problems related to gastric bands (10%). Patients underwent secondary BS following gastric banding (46.5%), RYGB (31%), SG (13.4%), various gastroplasties (6.6%), one-anastomosis gastric bypass (0.9%), or bilio-pancreatic diversion (0.9%). Baseline characteristics of benchmark and non-benchmark patients are presented in Supplementary Table 1, http://links.lww.com/SLA/D317.

Benchmark Cohort

Within the benchmark cohort (n = 3143), the mean age was 43.8 ± 10 years and 85.2% were females. The mean BMI before the primary BS, at baseline and at 1-year (follow-up: 70.5%) was 43 ± 10, 35.2 ± 7 and 29.4 ± 5.8 kg/m^2; representing a %-total body weight loss of 17.65 ± 20 at 1-year. The mean operation duration was 93 ± 50 minutes. The rate of conversion to open surgery was 1% (n = 32). The rate of uneventful postoperative course until 90-days varied largely between centers with a median of 82% (IQR 76–90%). Until discharge, 5.2% of patients presented $\geq$1 complication. Readmissions due to CD-grade $\geq$IIIa events occurred in 3%, 6.2%, 13.45%, and 23.8% of cases until postoperative days 30, 90, 365 and last follow-up. 4.9% of benchmark patients underwent a reoperation by the end of the first postoperative year, which represented a cumulative hazard of 20% (Supplementary Figure 2, http://links.lww.com/SLA/D317). Centers with higher caseload showed a trend toward achieving lower mean CCI over 90-days, however, this correlation was not statistically significant (Supplementary Figure 3, http://links.lww.com/SLA/D317).

Benchmark Cutoffs of Quality Indicators

The outcome benchmarks of Revisional BS with GI suture, Revisional BS without GI suture and Conversional BS are shown in Supplemental Digital Content Table 3, http://links.lww.com/SLA/D412. As conversional BS represented the largest group of secondary BS cases, its outcome benchmarks are compared with the previously reported benchmarks for primary RYGB[8] in Supplementary Table 2, http://links.lww.com/SLA/D317. Our database captured only 43 low-risk Reversal cases from 10 centers, which prevented the confident establishment of global benchmark cutoffs for this subgroup.

Common Complications and Causes of Death within the Entire Cohort

At a median follow-up of 2-years (IQR 1–3, Supplementary Figure 4, http://links.lww.com/SLA/D317), the most common complications/reasons of readmission in the study cohort were small bowel obstruction/internal or parietal hernia (cumulative incidence: 7.2%), followed by abdominal or osteoarticular pain (6%), vomiting/diarrhea (5.2%), gastrointestinal leakage (3.5%), and dysphagia (3.5%) (Fig. 2). Only 35 (0.65%) patients had been recorded as having died up to their last follow-up time point. Most frequently, fatalities occurred out of the hospital and their cause remained unknown (n = 21/35), however, the following etiologies have been reported: sepsis with abdominal focus (n = 3), lung cancer (n = 3), suicide (n = 2), cardiac arrest (n = 2), esophageal carcinoma (n = 1), cachexia (n = 1), spontaneous intracranial bleeding (n = 1), and euthanasia after necrotizing fasciitis (n = 1).

Risk-benefit Analysis of Secondary BS Procedures for Insufficient Weight loss and Anorexia

Within the subgroup of benchmark patients undergoing secondary BS for insufficient weight loss (n = 1334), the highest decrease in BMI at 1-year (median: 10 kg/m^2) was achieved by conversional surgery. However, for this indication, the 1-year cumulative complication profile of conversional BS was higher than those of revisional surgeries with or without gastrointestinal suture. Benchmark patients re-operated for anorexia/malabsorption (n = 64)

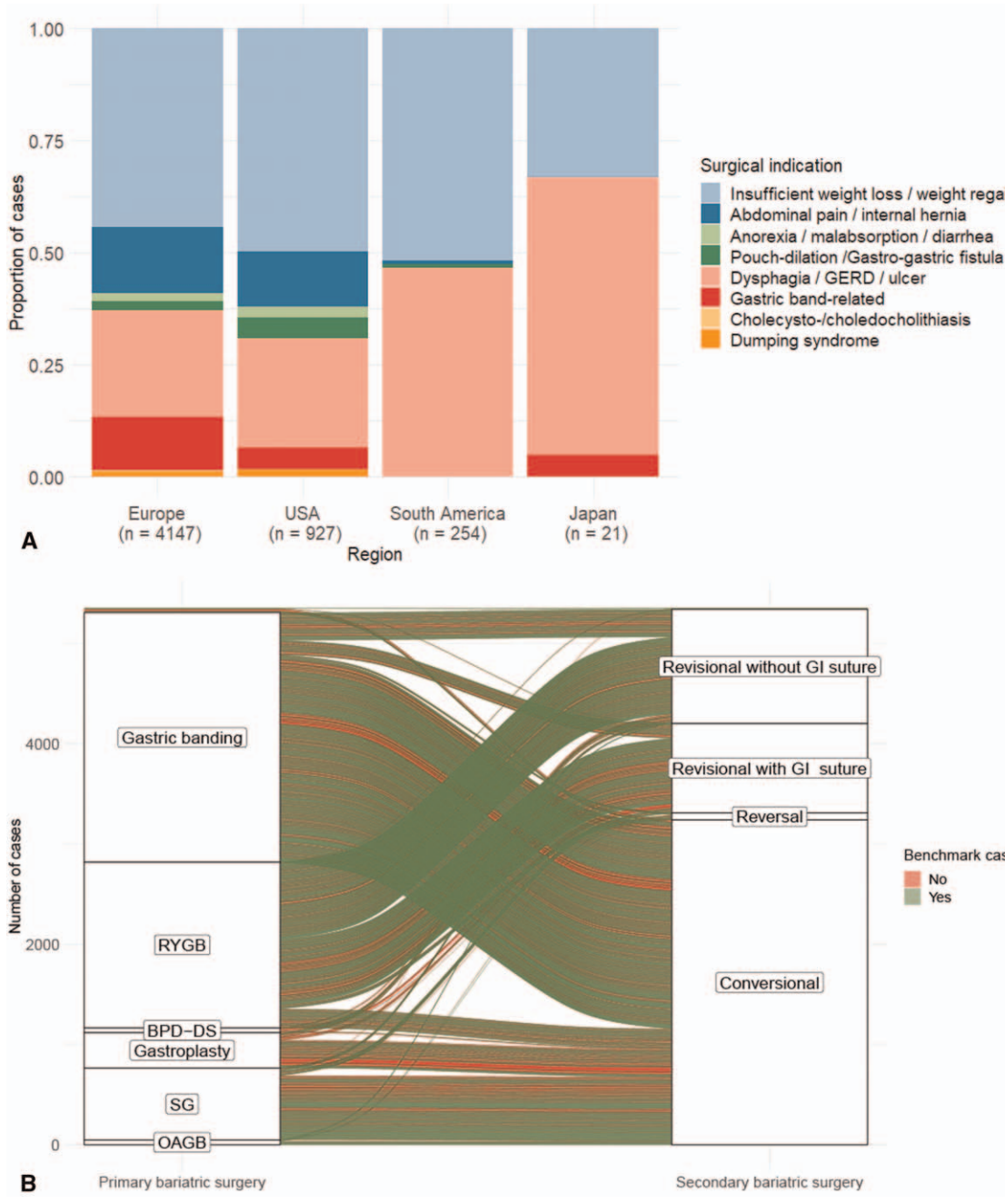

FIGURE 1. A. Regional variations in indications of secondary bariatric surgery. B. Primary bariatric surgeries and categories of secondary bariatric surgery. 1 line = 1 case. BPD-DS, bilio-pancreatic diversion with duodenal switch; GI, gastro-intestinal; OAGB, one-anastomosis gastric bypass; RYGB, Roux-en-Y gastric bypass; SG, Sleeve gastrectomy.

gained 4.11 kg/m^2 in 1-year after reversal, however, CCI© was higher compared to revisional or conversional surgeries (Supplementary Figure 5, http://links.lww.com/SLA/D317).

Internal Validation of the Benchmark Criteria

Although each of the benchmark criteria used to form the low-risk benchmark cohort was selected based on previous findings of large cohort studies, we internally validated the composite "benchmark patient" stratum by comparing 90-day postoperative morbidity between the benchmark and non-benchmark cohorts (Fig. 3). Relative risk for any complication between the different surgical groups in benchmark cases only is shown in Supplementary Figure 6, http://links.lww.com/SLA/D317. The 90-day mortality rate in the benchmark group was 0.06%, whereas in the non-benchmark group it reached 0.14%, representing an odds ratio of 2.14 (95%CI 0.35–16.3, P = 0.4).

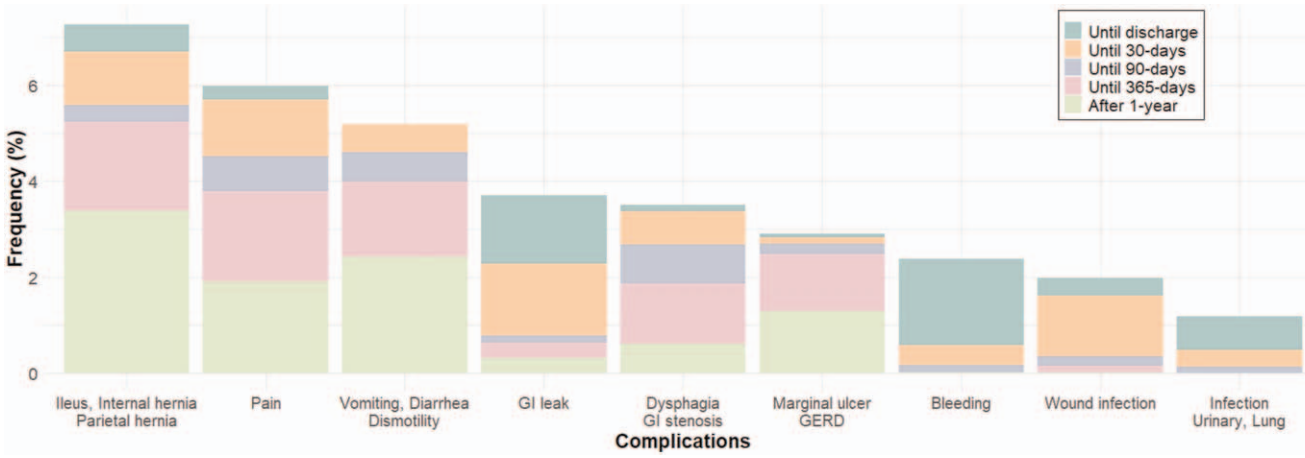

FIGURE 2. Cumulative incidence (%) of the most common types of complications and/or reasons of readmissions in patients after secondary bariatric surgery (n = 5349). Median follow-up: 704 days (IQR: 366–1158). GERD, gastro-esophageal reflux disease; GI, gastro-intestinal.

DISCUSSION

This multicenter study established outcome benchmarks for elective secondary BS procedures by applying a recently developed standardized methodology. The contribution of 18 high-volume bariatric centers located on 4 continents resulted in the largest series of secondary BS reported so far, consisting of 5349 patients. The main findings were a higher 90-day postoperative complication rate compared to the one reported after primary BS,[8] especially due to a higher rate of GI leaks and increased need for intensive care unit

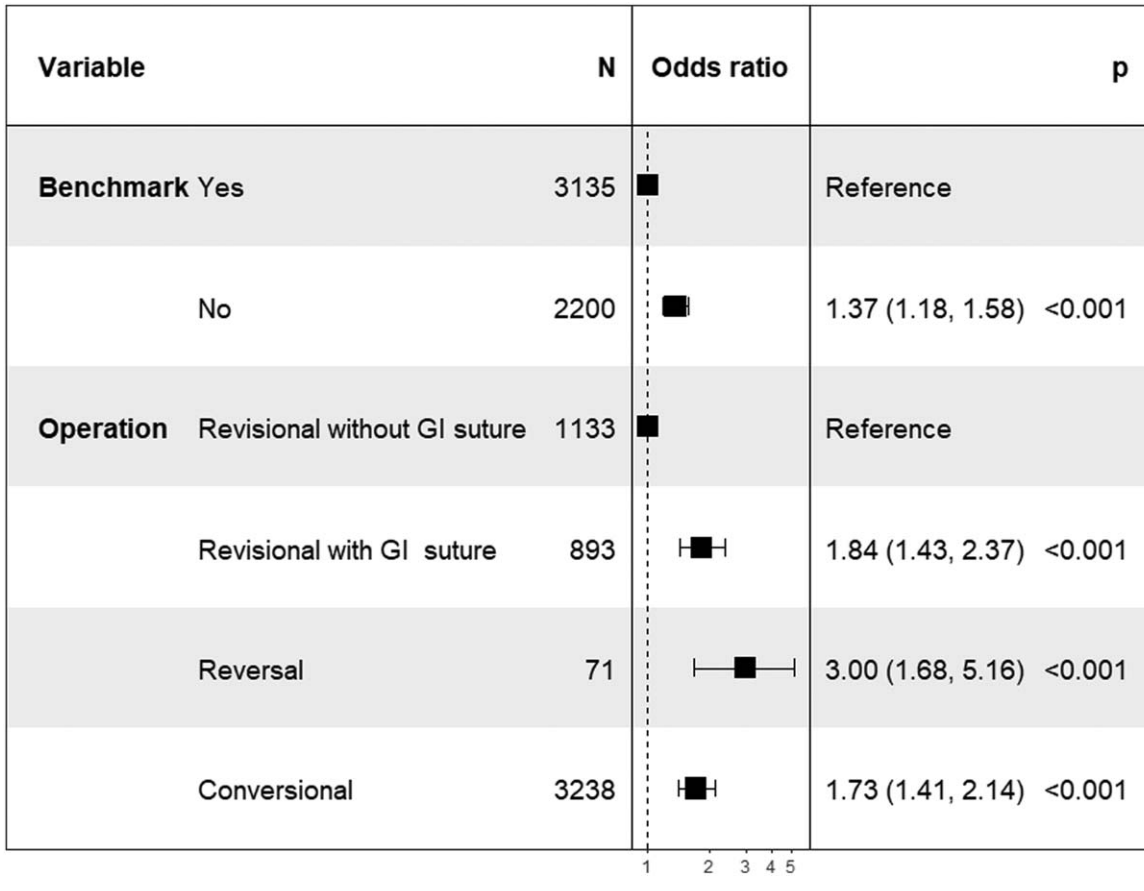

FIGURE 3. Risk factors for the development of any complication at 90-days after secondary bariatric surgery. GI, gastro-intestinal. Benchmark: cases with a pre-defined low-risk profile.

admission. Although several studies suggested that secondary BS may be technically challenging and thus associated with increased morbidity, the proportional contribution of patient-related factors and procedure types to the operative risk remained unclear. Our findings showed that benchmark patients undergoing revisional BS without GI suture had the lowest overall complication rate, whereas non-benchmark patient profile (OR 1.37), revisional surgery with GI suture (OR 1.84), conversional and reversal procedures (OR 1.73; 3.0) were associated with significantly higher morbidity.

Identified outcome benchmarks may serve as a reference for bariatric centers to compare their own outcomes reflecting surgical quality.[9,10] Additionally, they may be used to pre-operatively stratify surgical risk based on patient-related factors and the type of planned secondary BS. In case of identified gaps in a center's performance, action may be taken to improve care. The selection of benchmark patients was obtained by using a strict and evidence-based list of criteria aiming to identify the ''healthiest'' BS candidates with the least expected complications. The validity of this approach has been successfully re-confirmed in this international cohort of patients operated in high-volume centers led by recognized experts in the field of BS.

The regional differences in the indications for secondary BS are likely to mirror the past local trends in procedural choices of primary BS and the lack of international standards. Regional differences in bariatric procedures are well documented in the 5th International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Global Registry report.[19] Based on our study, European centers had to mainly deal with the backlog of gastric bands and vertical banded gastroplasties, while in the USA RYGB and bands, in Chile and in Japan SG represented the most frequent type of BS mandating reoperations.

Overall, most of the benchmark cutoffs for the cumulative 90-day complication and reoperation rates were higher than those reported in primary BS.[8] This confirms the need for a competency-based surgical training along with volume-based requirements of accreditation of centers of excellence.[20] In Switzerland for example, secondary BS can only be performed in referral bariatric centers with in-house intensive care unit and a bariatric surgeon with $\geq$5 years of experience and $\geq$300 bariatric cases.[21] To maintain surgical quality, the new concept of resilience engineering suggests to focus not only on complications but also on how successful outcomes were achieved despite ever-present challenges.[22] To enhance learning from the ratio of successful and unsuccessful outcomes, benchmark cutoffs may assist case selection for morbidity-mortality conferences. Furthermore, a Delphi panel of experts suggested that centers should make their outcomes publicly available to allow comparison with the global benchmarks.[9]

Remarkably, some outcome benchmarks of revisional secondary BS were within the benchmark cutoffs established for primary RYGB.[8] These include operative time, intraoperative blood transfusion rate, hospital stay, small bowel obstruction within 30-days and 90-day mortality. We interpret these surrogates of surgical quality, as a joint result of advanced technical skills, state-of-the-art infrastructure, multidisciplinary efforts and modern perioperative protocols that characterize high-volume referral centers and affect outcomes across a variety of procedures.[23]

Controversy exists about the treatment of choice in case of insufficient weight loss or weight regain after primary BS due to conflicting or partly lacking results in the literature concerning long-term efficacy and safety.[24,25] The palette of suggested treatments includes medical therapy, such as glucagon-like-peptide-1 analogues[26] and surgical approaches, such as gastric pouch resizing,[27–29] salvage banding,[30] limb length modification,[31] and conversion to RYGB[32] or to SG.[33] Our database allowed the comparison of BMI changes at 1-year between different types of secondary BS in benchmark patients who were re-operated for insufficient weight loss. We found that conversional procedures achieved a median reduction of 10 BMI-units, whereas revisional procedures achieved only 5. Each surgical strategy was safe, however, after conversional surgery the proportion of patients with higher cumulative complications was higher. These findings need to be confirmed in dedicated prospective trials.

Several limitations are to be considered when interpreting our results. *First*, the data collection period coincided with the first outbreak of the COVID-19 pandemic, leading to the cancellation of the participation of several prestigious centers from USA, France, The Netherlands, Brazil and Mexico. This emphasizes the need for the broader implementation of automatized data retrieval technologies based on prospective registries, decreasing the logistical burden and high necessity in manpower for the establishment of outcome benchmarks in surgery. *Second*, the retrospective nature of the study may have resulted in under-reporting of complications or imprecision in data-collection, incomplete 1-year follow-up and in lack of data on peri-operative nutritional status. Inter-center variations in definition and severity grading of postoperative negative events may also exist, nevertheless, all centers had a prospective database and were requested to grade complications according the Clavien-Dindo classification,[16] which provides uniformity based on complication severity. Different interval delays between primary and secondary BS and non-standardized surgical techniques and instruments may have introduced further confounders. *Third*, while our study period spanned 6 years, the medium- to long-term follow-up rates were poor (<50% beyond 2-years), therefore we mainly focused on the postoperative morbidity up to 3-months. Furthermore, medically treated complications of BS are frequently managed by non-surgeon healthcare providers outside of bariatric centers and thus, do not obviously appear in institutional databases. Therefore, the long-term differences in obesity-related comorbidities, absorption of vitamins, micronutrients, and other nutritional parameters could not be assessed. Standardized definitions provided by the American Society for Metabolic and Bariatric Surgery guideline may be used in future research to enable comparison of metabolic outcomes.[34] *Fourth*, despite the selection of high-volume referral centers, the proportion of secondary BS within the institutional cohorts showed large variations and there was a lack of robotically-assisted surgeries.

In conclusion, this study established benchmark cutoffs for postoperative surgical outcomes in secondary BS that may be used as a reference for evaluating surgical performance within and among centers worldwide. Secondary BS performed in high-volume centers is safe, however, the need for tertiary BS is non-negligible. There is therefore a need to optimize procedure selection and surgical quality for patients with postbariatric weight regain, refractory comorbidities or late complications.

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Ethical approval: The Swiss Cantonal Ethics Committees of Zurich, Vaud and Northwest- and Central Switzerland approved this study (BASEC-Nr. 2019–02145). Data collection was in accordance with the local instituitional board of each participating center, with the actual version of the Declaration of Helsinki, and was according to the terms of Good Clinical Practice. Centers from the European Union complied with the General Data Protection Regulation (EU

Regulation 2016/679). The Austrian co-authors additionally applied guidelines of the Austrian Data Protection Law (Österreichisches Datenschutzgesetz, DSG 2000). The co-authors from the United Kingdom complied with the NHS Health Research Agency decision making tool for data handling. Co-authors from the United States complied with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Only fully anonymized data without any patient identifiers (such as date of birth, date of operation, date of follow up, name, social security number, address of patient, etc.) were transferred for data analysis.

REFERENCES

1. Camp RC. *Business process benchmarking: finding and implementing best practices.* Milwaukee, Wisconsin, USA: ASQC Quality Press; 1995.
2. Rossler F, Sapisochin G, Song G, et al. Defining Benchmarks for major liver surgery: a multicenter analysis of 5202 living liver donors. *Ann Surg*. 2016; 264:492–500.
3. Schmidt HM, Gisbertz SS, Moons J, et al. Defining benchmarks for transthoracic esophagectomy: a multicenter analysis of total minimally invasive esophagectomy in low risk patients. *Ann Surg*. 2017;266:814–821.
4. Muller X, Marcon F, Sapisochin G, et al. Defining benchmarks in liver transplantation: a multicenter outcome analysis determining best achievable results. *Ann Surg*. 2018;267:419–425.
5. Sanchez-Velazquez P, Muller X, Malleo G, et al. Benchmarks in pancreatic surgery: a novel tool for unbiased outcome comparisons. *Ann Surg*. 2019;270:211–218.
6. Raptis DA, Linecker M, Kambakamba P, et al. Defining Benchmark Outcomes for ALPPS. *Ann Surg*. 2019;270:835–841.
7. Raptis DA, Sanchez-Velazquez P, Machairas N, et al. Defining benchmark outcomes for pancreatoduodenectomy with portomesenteric venous resection. *Ann Surg*. 2020;272:731–737.
8. Gero D, Raptis DA, Vleeschouwers W, et al. Defining global benchmarks in bariatric surgery: a retrospective multicenter analysis of minimally invasive Roux-en-Y Gastric bypass and sleeve gastrectomy. *Ann Surg*. 2019;270: 859–867.
9. Gero D, Muller X, Staiger RD, et al. How to establish benchmarks for surgical outcomes?: A checklist based on an international expert Delphi consensus. *Ann Surg*. 2020.
10. Giudicelli G, Diana M, Chevallay M, et al. Global benchmark values for laparoscopic Roux-en-Y-gastric bypass: a potential new indicator of the surgical learning curve. *Obes Surg*. 2020;31:746–754.
11. Switzer NJ, Karmali S, Gill RS, et al. Revisional bariatric surgery. *Surg Clin North Am*. 2016;96:827–842.
12. Lee Bion A, Le Roux Y, Alves A, et al. Bariatric revisional surgery: what are the challenges for the patient and the practitioner? *J Visc Surg*. 2020;158: 38–50.
13. Patel S, Szomstein S, Rosenthal RJ. Reasons and outcomes of reoperative bariatric surgery for failed and complicated procedures (excluding adjustable gastric banding). *Obes Surg*. 2011;21:1209–1219.
14. Pedziwiatr M, Malczak P, Wierdak M, et al. Revisional gastric bypass is inferior to primary gastric bypass in terms of short- and long-term outcomes-systematic review and meta-analysis. *Obes Surg*. 2018;28:2083–2091.
15. Fournier P, Gero D, Dayer-Jankechova A, et al. Laparoscopic Roux-en-Y gastric bypass for failed gastric banding: outcomes in 642 patients. *Surg Obes Relat Dis*. 2016;12:231–239.
16. 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.
17. 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.
18. Wickham H. ggplot2. Wiley Interdisciplinary Reviews: Computational Statistics, 2011; 2:180–185.
19. Ramos ALK, Brown W, Welbourn R, et al. *5th International Federation for the Surgery of Obesity and Metabolic Disorders Global Registry Report 2019.* Reading, United Kingdom: Dendrite Clinical Systems Ltd; 2019.
20. Telem DA, Jones DB, Schauer PR, et al. Updated panel report: best practices for the surgical treatment of obesity. *Surg Endosc*. 2018;32:4158–4164.
21. SMOB. Directives médicale pour le traitement chirurgical de l'obésité 1.1.2018, 2018. Available at: http://www.smob.ch/fr/component/jdownloads/send/1-root/64-smob-directives-medicales-2018-01-01.
22. Verhagen MJ, de Vos MS, Hamming JF. Taking morbidity and mortality conferences to a next level: the resilience engineering concept. *Ann Surg*. 2020;272:678–683.
23. Lorenz K, Raffaeli M, Barczynski M, et al. Volume, outcomes, and quality standards in thyroid surgery: an evidence-based analysis-European Society of Endocrine Surgeons (ESES) positional statement. *Langenbecks Arch Surg*. 2020;405:401–425.
24. Zhou R, Poirier J, Torquati A, et al. Short-term outcomes of conversion of failed gastric banding to laparoscopic sleeve gastrectomy or Roux-En-Y gastric bypass: a meta-analysis. *Obes Surg*. 2019;29:420–425.
25. Koh ZJ, Chew CAZ, Zhang JJY, et al. Metabolic outcomes after revisional bariatric surgery: a systematic review and meta-analysis. *Surg Obes Relat Dis*. 2020;16:1442–1454.
26. Linke K, Schneider R, Gebhart M, et al. Outcome of revisional bariatric surgery for insufficient weight loss after laparoscopic Roux-en-Y gastric bypass: an observational study. *Surg Obes Relat Dis*. 2020;16:1052–1059.
27. Lee PC, Dixon JB, Sim PY, et al. Treatment options for poor responders to bariatric surgery. *Curr Obes Rep*. 2020;9:364–372.
28. Amor IB, Debs T, Petrucciani N, et al. A simple technique of gastric pouch resizing for inadequate weight loss after Roux-en-Y gastric bypass. *Obes Surg*. 2017;27:273–274.
29. Nguyen D, Dip F, Huaco JA, et al. Outcomes of revisional treatment modalities in non-complicated Roux-en-Y gastric bypass patients with weight regain. *Obes Surg*. 2015;25:928–934.
30. Vijgen GH, Schouten R, Bouvy ND, et al. Salvage banding for failed Roux-en-Y gastric bypass. *Surg Obes Relat Dis*. 2012;8:803–808.
31. Kraljevic M, Kostler T, Susstrunk J, et al. Revisional surgery for insufficient loss or regain of weight after roux-en-y gastric bypass: biliopancreatic limb length matters. *Obes Surg*. 2020;30:804–811.
32. AlSabah S, Alsharqawi N, Almulla A, et al. Approach to poor weight loss after laparoscopic sleeve gastrectomy: re-sleeve vs. gastric bypass. *Obes Surg*. 2016;26:2302–2307.
33. Barrett AM, Vu KT, Sandhu KK, et al. Primary sleeve gastrectomy compared to sleeve gastrectomy as revisional surgery: weight loss and complications at intermediate follow-up. *J Gastrointest Surg*. 2014;18:1737–1743.
34. Burger PM, Monpellier VM, Deden LN, et al. Standardized reporting of comorbidity outcome after bariatric surgery: low compliance with the ASMBS outcome reporting standards despite ease of use. *Surg Obes Relat Dis*. 2020;16:1673–1682.
35. Surgery EACfB. IFSO-EC Accredited Centre of Excellence in Bariatric and Metabolic Surgery: Code of Practice 2018. Available at: https://www.eacbs.com/site/index.php/ifso-endorsed-coe-programs/centre-of-excellence-coe-program/requirements. 2018.
36. Krell RW, Finks JF, English WJ, et al. Profiling hospitals on bariatric surgery quality: which outcomes are most reliable? *J Am Coll Surg*. 2014;219:725–734.e3.
37. Al-Kurd A, Grinbaum R, Mordechay-Heyn T, et al. Outcomes of sleeve gastrectomy in septuagenarians. *Obes Surg*. 2018;28:3895–3901.
38. Quilliot D, Sirveaux MA, Nomine-Criqui C, et al. Evaluation of risk factors for complications after bariatric surgery. *J Visc Surg*. 2018;155:201–210.
39. Buchwald H, Estok R, Fahrbach K, et al. Trends in mortality in bariatric surgery: a systematic review and meta-analysis. *Surgery.* 2007;142:621–632. discussion 632-5.
40. Benois M, Sebastianelli L, Morisot A, et al. Revisional but not conversional gastric bypass surgery increases the risk of leaks: Review of 176 redo out of 932 consecutive cases. *Obes Surg*. 2018;28:2903–2911.
41. Lunardi N, Mehta A, Ezzeddine H, et al. Recurring emergency general surgery: characterizing a vulnerable population. *J Trauma Acute Care Surg*. 2019;86:464–470.
42. ASA. ASA Physical Status Classification System 2014. Available at: https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system. 2018.
43. Fernandez AZ Jr, DeMaria EJ, Tichansky DS, et al. Experience with over 3,000 open and laparoscopic bariatric procedures: multivariate analysis of factors related to leak and resultant mortality. *Surg Endosc*. 2004;18:193–197.
44. Flum DR, Belle SH, et al., Longitudinal Assessment of Bariatric Surgery C,. Perioperative safety in the longitudinal assessment of bariatric surgery. *N Engl J Med*. 2009;361:445–454.
45. Ibrahim AM, Ghaferi AA, Thumma JR, et al. Variation in outcomes at bariatric surgery centers of excellence. *JAMA Surg*. 2017;152:629–636.
46. Kabir A, Mousavi S, Pazouki A. The complications of bariatric surgery patients with type 2 diabetes in the world: A systematic review and meta-analysis. *Curr Diabetes Rev.* 2019;15:49–61.

47. Kumar R, Nandhini LP, Kamalanathan S, et al. Evidence for current diagnostic criteria of diabetes mellitus. *World J Diabetes*. 2016;7:396–405.
48. Husain F, Jeong IH, Spight D, et al. Risk factors for early postoperative complications after bariatric surgery. *Ann Surg Treat Res*. 2018;95:100–110.
49. Shoar S, Shahabuddin Hoseini S, Naderan M, et al. Bariatric surgery in morbidly obese patients with inflammatory bowel disease: a systematic review. *Surg Obes Relat Dis*. 2017;13:652–659.
50. Andalib A, Aminian A, Khorgami Z, et al. Early postoperative outcomes of primary bariatric surgery in patients on chronic steroid or immunosuppressive therapy. *Obes Surg*. 2016;26:1479–1486.

DISCUSSANTS

François Pattou (Lille, France)

I would like to first congratulate our colleagues for this important study, which addresses a very relevant and important topic. Of course, it's a first attempt in a very complex field, where heterogeneity is always a difficult matter. I think it's important to know that we have listened to a derivation study, highlighting the concept, and it is important to also now have validations in other contexts, with other cohorts or other colleagues, who could confirm that we are really seeing the global standard for the benchmark. That said, I think that it is a very important point that you are raising.

I have the following questions: First, 1 intriguing or worrisome result of the study was that, even in expert centers, 15.6% of benchmark patients required a reoperation within 2–3 years. What was the reason(s) for these reoperations – insufficient weight loss or complications? In your opinion, does this unexpected rate reflect the extreme features of the patients concerned or suboptimal management? Could you suggest avenues to reduce this rate?

Second, could you better explain the rationale behind the exclusion criteria used to select benchmark cases, i.e. diabetes is not a clear independent risk factor for postoperative complications?

Finally, one anastomosis gastric bypass (OAGB) represented a very limited subgroup in your study. In France, where this operation used to be performed at an increasing rate, it was officially abandoned last year because of a higher risk of long-term complications and the frequent need for secondary revisions. Do you have any explanation for this apparent difference in your dataset?

Response From Daniel Gero (Zurich, Switzerland)

Thank you very much, Prof. Pattou, for your kind words and interest in our work. Regarding your first question, the reasons for complications and reoperations after secondary bariatric surgery were the focus of our attention. A stacked bar chart has been created to illustrate the main causes. These were typically not related to insufficient weight loss, but to other problems, such as small bowel obstruction, internal hernia, abdominal pain, dysphagia/vomiting, marginal ulcer or gastroesophageal reflux disease. Whether these complications were related to the extreme characteristics of the patients or due to suboptimal management was your next question. Our data cannot precisely answer this question, but we can assume that they were rather related to the underlying diseases of the patients and to their post-bariatric gastrointestinal anatomy. We selected the participating centers based on very strict quality criteria. All of them were high-volume, reference centers, experienced in the treatment of revisional bariatric surgery. Our study does not provide direct information on measures to reduce the rate of postoperative complications. However, we are convinced that our study will indirectly contribute to the enhancement of surgical quality through the precise and objective reporting of the outcomes of revisional/secondary bariatric surgery. We hope that our work will stimulate quality improvement through the sensitization of the bariatric community, so that surgeons and centers may implement solutions to reduce morbidity following secondary bariatric operations.

Concerning your next question, we used criteria that are independently shown to influence surgical outcomes within 90 days post-operatively. We used the same criteria as our previous study, entitled ''Defining Global Benchmarks in Bariatric Surgery: A Retrospective Multicenter Analysis of Minimally Invasive Roux-en-Y Gastric Bypass and Sleeve Gastrectomy.'', published in *Annals of Surgery*, in November 2019 (doi: 10.1097/SLA.0000000000003512). Specifically, with regards to diabetes, based on the evidence we found in the literature (i.e. Ferraz et al. Surgical site infection in bariatric surgery: results of a care bundle. Rev Col Bras Cir. 2019), it has been shown that diabetes mellitus is an independent risk factor for surgical site infection, also in the bariatric cohorts. The surgical site infection rate in diabetics is around 2.2% and it is 0.6% in non-diabetics, according to Ferraz et al. Furthermore, diabetes mellitus has also been identified as a surgical risk factor in systematic reviews and meta-analyses in the field of colorectal surgery. In short, we believe that the criteria used to define benchmark cases were not arbitrary. Each of them was chosen with the goal to define the healthiest bariatric patients, who are not expected to develop postoperative complications.

Finally, regarding the prevalence of OAGB among the primary bariatric surgeries, we have to admit that they were quite underrepresented in our cohort. Only around 100 of OAGBs were captured as primary surgeries in a database of 5,500 secondary bariatric cases. We believe that the reasons are multifactorial. The period of data collection spanned from 2013 to 2019. Secondary bariatric operations are typically performed 5–7 years following the primary ones, and they heavily rely on the trends in primary bariatric surgery in the same geographic region over the last decade. We may have selected centers that did not perform OAGB 5 years before the inclusion period. To keep the outcome benchmarks updated and prevailing, we recommend repeating the process of global benchmark establishment at regular intervals.

Wolf Bechstein (Frankfurt a.M., Germany)

Many thanks for your presentation. I have 2 questions. First, with a follow-up rate of 70%, almost one- third of patients will have been missed. Could it be that some of these could have presented with further complications at other hospitals?

Second, an internal hernia (like Peterson space hernia) and intestinal obstruction were the most common complications. How could these be prevented?

Response From Daniel Gero (Zurich, Switzerland)

Patients undergoing secondary bariatric surgery typically present themselves at their tertiary reference center in the case of any postoperative complaints. Nevertheless, we cannot rule out underreporting at a 70% follow-up rate at 1 year. Therefore, we only established benchmark cut-offs for the 90-day postoperative period.

A minimally invasive surgical approach and systematic closure of all mesenteric windows are proven methods to reduce the risk of an internal hernia and intestinal obstruction after bariatric surgery.