Global 30-day outcomes after bariatric surgery during the COVID-19 pandemic (GENEVA)

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Title: Global 30-day outcomes of bariatric surgEry iN thE coVid-19 erA (The GENEVA Cohort Study)

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Bariatric and Metabolic surgery (BMS) is the most effective weight loss intervention. But the high morbidity and mortality associated with peri-operative Coronavirus Disease 2019 (COVID-19),[1] has led to the cancellation of millions of surgical procedures including BMS. There are concerns that obesity treatment, including BMS, may be overlooked in the COVID-19 recovery era due to obesity stigma[2], which has led to the BMS community proactively developing consensus statements on its various aspects.[3]

There is a paucity of data on the safety of BMS performed with the full knowledge of the pandemic. We, therefore, conducted a global multicentre, cohort study to evaluate the 30-day morbidity and mortality of primary BMS performed in adults (≥ 18 years) between 1/05/2020 and 10/07/2020. Complications were recorded using the Clavien-Dindo (CD) Classification system, widely regarded as the accepted method for reporting surgical complications. Please see the Appendix for full Methods.

A total of 2116 adult patients (from 133 hospitals in 38 countries) underwent primary BMS during the study period. Of these, complete 30-day morbidity and mortality data were available for 2001 (94.6 %) by the 15th of August 2020.

Two hundred and eighteen surgeons from 127 hospitals in 35 countries entered data with a complete 30-day follow-up (Appendix Figure 1). Of the 35 countries, 12 had their peak of COVID-19 before 1st May 2020 (883 patients; 44.1%); another 12 had their peak during the data collection period (811 patients; 40.52%) and the remaining 11 had their peak after the 10th August (307 patients; 15.34%) (https://www.worldometers.info/coronavirus/ accessed 20/08/2020 at 14:00 BST; Appendix Table 1). Baseline Demographics including types of surgery performed are summarised in Appendix Table 2.

There was one death in a patient who had a leak following sleeve gastrectomy (SG). This patient was COVID-19 negative. At 30 days, 138 complications were reported in 137/2001 patients (6.8%) including 10 cases of COVID-19 (Table 1). Most complications (n=83, 60.6%) were mild (CD grade I & II). Patients who developed complications were older, more likely to be current or ex-smokers (vs. non-smokers). Fewer complications occurred with more experienced surgeons (Appendix Table 3).

There were 10 (0.5%) symptomatic COVID-19 diagnosed during the 30-day follow up. These were from Egypt (4), Brazil (2), Mexico (2), Argentina (1) and India (1) (Appendix Table 4). Eight of these patients were from countries (Brazil, Egypt and Mexico) that had their COVID-19 peak during the study period. Two (out of 10) of these patients had no preoperative testing for SARS-CoV-2, 7 required no treatment, and none needed intensive care. A total of 1593 (79.6%) patients in this study underwent some preoperative testing. Peri-operative COVID-19 protocols are summarised in Appendix Table 5.

The 30-day mortality of 0.05% (1/2001) seen in this study is consistent with the pre-pandemic figures reported in BMS studies (0.04–0.1%).[4,5,6] The 30-day mortality of 0.09% (1/1142) with SG in this study is similar to 0.1% reported in a study of 29,588 patients.[7] In a recent systematic review, 30-day complications occurred in 10.1% (319/3155) and 5.4% (155/2876) of patients who had Roux-En-Y Gastric bypass (RYGB) and SG respectively, which is similar to our study (8.4% and 5.7% respectively).[8] Similarly, Stenberg et al reported 7.8% (196/2503) 30-day complications with RYGB.[6] The 30-day severe complications (CD grade III, IV, or V) rate with RYGB and SG in this study (3.2% and 2.1% respectively) are also similar to those reported in previous studies.[4,6,7]

Out of the 10 patients with symptomatic post-operative COVID-19, none needed ventilation and none died. They were all CD grade I or II complications. This is at odds with the findings by COVIDSurg collaborators[1] who observed pulmonary complications in half the patients and even more remarkably 23.8% of all their patients died within 30-days. This is interesting because obesity is associated with an increased risk of severe COVID-19. However, unlike our study, COVIDSurg was performed during a time where local peri-operative COVID-19 protocols where not well established, which might explain the lower morbidity and mortality observed in our study

This study included countries with variable timing of COVID-19 peak in relation to the time of the study. Local heterogeneity in COVID-19 prevalence might have contributed to the small number of symptomatic COVID-19 reported in this study. However, the COVID-19 cases reported were from countries with widespread COVID-19 (based on the country-specific

COVID-19 maps), and other countries that have not reported any symptomatic COVID-19 cases in this study also had widespread COVID-19. So, our findings of a low number of symptomatic COVID-19 are likely to reflect the presence and efficacy of local peri-operative COVID-19 protocols.

Because of the time gap between BMS and getting infected with SARS-CoV-2, developing symptoms, requiring ventilation/mortality; there is a possibility that some adverse outcomes that developed after 30-days may have not been captured. However, the study population is at high risk of severe COVID-19 (obesity, diabetes, hypertension, Cardiovascular Disease) and the median incubation period for COVID-19 is approximately four days. Hence, it is likely that our data has picked up the majority of the symptomatic COVID-19 that developed in the study population. Further follow up regarding COVID-19 mortality is ongoing.

Unsurprisingly, SG, RYGB, and One Anastomosis Gastric Bypass (OAGB) accounted for >95% of all primary procedures. This is in keeping with the last two International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) global reports.[9,10] The mean Body Mass Index of 42.4kg/m^2 in this cohort is also comparable to a median of 41.7kg/m^2 reported in the Fourth IFSO Global Registry report.[9] Although we cannot rule out selection bias caused by the health care professionals choosing lower-risk patients for BMS in the view of the pandemic, our study baseline characteristics were similar to other global BMS studies.

Our study has limitations. It only included data of participating centres and may therefore not represent the complete global picture. Also, though we had taken all care to ensure our collaborators knew the importance of submitting all consecutive patients during the study period, we cannot be certain of that.

Our study lacks a contemporary control cohort. However, it is not possible to have a control cohort from a place that does not have COVID-19 during our study period, and comparing the safety of BMS to other surgical procedures during the pandemic was not the aim of our study. Besides, comparing with other surgical procedures is challenging considering the different population characteristics for patients undergoing BMS. An ideal study would collect outcomes for BMS before and through the COVID-19 pandemic from the same

centres. However, this would have been challenging due to the unpredictability and the fast spread of COVID-19 at the time. Despite this, our findings show low rates of adverse events following BMS.

The study has several strengths including the large sample size, the global reach of the study, the high data completion rate, and extensive data profiling. Besides, the data represented different phases of the COVID-19 pandemic across the 35 countries (pre-, during, or post-COVID-19 peak).

In conclusion, this study shows that 30-day morbidity and mortality of BMS during the COVID-19 pandemic with locally appropriate peri-operative COVID-19 protocols in place seemed to be similar to that reported in the literature prior to the pandemic. However, with the evolving pandemic situation, BMS teams need to continually monitor the data.

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Author Contribution:

Concept: RS and KM

Manuscript writing and reviewing: all authors

Figures: CL

Analysis: RS and AT

Data collection and conduct: RS

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Table 1: 30-day Morbidity and Mortality* for all patients and different procedures (*includes all adverse events from time of surgery to 30-days post-operatively)

COMPLICATIONS ACCORDING TO CLAVIEN-DINDO CLASSIFICATION SYSTEM					
	ALL PATIENTS	**LSG**	**RYGB**	**OAGB**	**Others**
Complication Grade/ Category	2001	1142 (57.1%)	557 (27.8%)	215 (10.7%)	87 (4.3%)
Clavien Dindo Grade I	42 (2.1%)	20 (1.8%)	17 (3.1%)	3 (1.4%)	2 (2.3%)
Clavien Dindo Grade II	41 (2%)	21 (1.8%)	12 (2.2%)	5 (2.3%)	3 (3.4%)
Clavien Dindo Grade IIIa	10 (0.5%)	3 (0.3%)	3 (0.5%)	4 (1.9%)	0 (0%)
Clavien Dindo Grade IIIb	29 (1.4%)	14 (1.2%)	9 (1.6%)	6 (2.8%)	0 (0%)
Clavien Dindo Grade IVa	12 (0.6%)	5 (0.5%)	6 (1.1%)	1 (0.5%)	0 (0%)
Clavien Dindo Grade IVb	2 (0.1%)	1 (0.1%)	0 (0%)	0 (0%)	1 (1.1%)
Clavien Dindo Grade V	1 (0.05%)	1 (0.1%)	0 (0%)	0 (0%)	0 (0%)
All Complications	137 (6.8%)	65 (5.7%)	47 (8.4%)	19 (8.8%)	6 (6.9%)
Clavien Dindo Grade I and II	83 (4.1%)	41 (3.6%)	29 (5.2%)	8 (3.7%)	5 (5.7%)
Clavien Dindo Grade III, IV, V	54 (2.7%)	24 (2.1%)	18 (3.2%)	11 (5.1%)	1(1.2%)
COVID INFECTION					
COVID-19	10 (0.5%)	8 (0.7%)	1(0.2%)	0 (0%)	1(1.1%)
SPECIFIC COMPLICATIONS					
Bleeding	36 (1.8%)	19 (1.7%)	11 (2%)	6 (2.8%)	0 (0%)
Leak from Gastrointestinal Tract	16 (0.8%)	9 (0.8%)	2 (0.4%)	5 (2.3%)	0 (0%)
Wound Infection	10 (0.5%)	4 (0.4%)	4 (0.7%)	0 (0%)	2 (2.3%)
Postoperative Pneumonia (not otherwise specified)	5 (0.2%)	0 (0%)	4 (0.7%)	1 (0.5%)	0 (0%)
DVT	1 (0.05%)	1 (0.1%)	0 (0%)	0 (0%)	0 (0%)
PE	1 (0.05%)	1 (0.1%)	0 (0%)	0 (0%)	0 (0%)
Other	59 (2.9%)	24 (2.1%)	25 (4.5%)	7 (3.3%)	3 (3.4%)