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30-Day morbidity and mortality of bariatric metabolic surgery in adolescence during the COVID-19 pandemic – The GENEVA study

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Summary

Background: Metabolic and bariatric surgery (MBS) is an effective treatment for adolescents with severe obesity.

Objectives: This study examined the safety of MBS in adolescents during the coronavirus disease 2019 (COVID-19) pandemic.

Methods: This was a global, multicentre and observational cohort study of MBS performed between May 01, 2020, and October 10,2020, in 68 centres from 24 countries. Data collection included in-hospital and 30-day COVID-19 and surgery-specific morbidity/mortality.

Results: One hundred and seventy adolescent patients (mean age: 17.75 ± 1.30 years), mostly females (n = 122, 71.8%), underwent MBS during the study period. The mean pre-operative weight and body mass index were 122.16 ± 15.92 kg and 43.7 ± 7.11 kg/m^2, respectively. Although majority of patients had pre-operative testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (n = 146; 85.9%), only 42.4% (n = 72) of the patients were asked to self-isolate pre-operatively. Two patients developed symptomatic SARS-CoV-2 infection post-operatively (1.2%). The overall complication rate was 5.3% (n = 9). There was no mortality in this cohort.

Conclusions: MBS in adolescents with obesity is safe during the COVID-19 pandemic when performed within the context of local precautionary procedures (such as pre-operative testing). The 30-day morbidity rates were similar to those reported pre-pandemic. These data will help facilitate the safe re-introduction of MBS services for this group of patients.

KEYWORDS
bariatric surgery, COVID-19, pandemic, SARS-CoV-2

On behalf of the GENEVA Collaborators

Rishi Singhal and Tom Wiggins contributed equally to this study.

1 | INTRODUCTION

Metabolic and bariatric surgery (MBS) is a highly effective treatment for adolescent patients with severe obesity resulting in long-term weight-loss maintenance alongside improvements in co-morbid conditions and quality of life.[1–3] The safety of MBS in this age-group has been well established with extremely low complication rates reported by international specialist centres.[4,5] Rates of childhood obesity have been consistently increasing globally. For example, 20.2% of 11-year-old children in the United Kingdom suffer with clinical obesity (4.4% having severe obesity).[6] Despite these increasing rates of children and adolescent patients with obesity, the clinical utilization of MBS in this population remains very limited,[7] and there is significant disparity in the utilization of surgery in patients of different ethnic backgrounds and socioeconomic status.[8,9]

All programmes for MBS internationally have been severely affected by the coronavirus disease (COVID-19) pandemic with services largely paused initially followed by a graduated resumption of services. However, there has been a wide variability in the resumption of procedures worldwide. There have been significant concerns regarding the potential risks of peri-operative infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in all patient groups but particularly in those patients who may have risk factors for severe COVID-19 such as obesity.[10–12] During the initial phase of the COVID-19 pandemic, recommendations were produced to identify factors that could be associated with a safe reintroduction of MBS services in adults,[13] but there is no such guidance for adolescents.

This study aimed to analyse data from adolescent patients undergoing MBS during the COVID-19 pandemic. The utilization of pre-operative isolation and testing programmes internationally will be reported alongside short-term complication rates following surgery.

2 | METHODS

2.1 | Study design and population

The GENEVA study represents an international, multicentre and observational cohort study of MBS (elective primary, elective revisional and emergency) during the COVID-19 pandemic.[14] This includes data from patients receiving MBS between 1 May 2020 and 31 October 2020. For the purposes of the current analysis, only data from the adolescents as defined by the World Health Organization (aged from 10 years to 19 years 11 months) were included. The study start date was 1st May to exclude patients who underwent MBS before the full scale of the pandemic, and its effect on surgical patients became widely known.

In this study, we included all consecutive adolescent patients (<20 years) undergoing MBS between 1 May and 31 October 2020, regardless of the surgical approach, procedure or the patient's pre-operative COVID-19 status. The participating centres and surgeons were contacted using personal networks and national professional MBS societies (via newsletters, email and social media groups) and bariatric professionals' networks on social media platforms.

This project was registered as a multinational audit (reference number: 5197) at the University Hospitals Birmingham NHS Foundation Trust, UK. Each site project lead was responsible for obtaining local governance approvals and data sharing agreements before entering data into the registry. Approval of the patients and/or their legal guardian (as appropriate) to share their anonymized data was obtained by the individual collaborators, and it was the responsibility of the site leads to ensure that such approval was in place and documented before entering data into the registry. The site leads had to agree to these terms electronically before they were allowed access to the registry to enter data.

2.2 | Data collection and handling

Data collection included patients' demographics, details of surgery performed, pre-operative testing protocols and outcomes, in-hospital and 30-day mortality as well as surgery-specific morbidity and mortality. If a patient developed more than one complication, additional questions were completed for each complication. This information was collected using a questionnaire with 77 datapoints, which has been published previously.[14]

Complications were categorized using the Clavien-Dindo (CD) Classification system for reporting surgical complications.[15] This allowed for easier comparison of complication data and captured all complications irrespective of their severity. We further assessed individual complications that would be important to the bariatric community, such as bleeding and leak rates, as well as complications such as chest infection/pneumonia that would be relevant in the context of the COVID-19 pandemic. In cases where more than one complication occurred in an individual patient, the highest CD score was reported.

Data collected regarding the centre and the surgeon were organized into 73 questions and included extensive profiling of the centre, the surgeon and the impact and handling of COVID-19 in that centre. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Birmingham, UK. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies.[16,17] Data entered in REDCap were examined weekly for any missing or erroneous data throughout the study period, and site leads were contacted for clarification. Collaborators were routinely contacted at 32 days following surgery when the 30-day follow data had not been completed. The final dataset was downloaded on the 10 December 2020, once data queries had been resolved. Data were subsequently re-examined for omissions or abnormalities.

2.3 | Statistical methods

Continuous data were presented as mean ± standard deviation (SD). Frequencies were used to summarize categorical variables. Independent *t*-test or Mann–Whitney *U*-test was used to examine differences

between continuous variables depending on data distribution. A Chi-square test was used to compare categorical variables. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) statistical software, version 27.0 (SPSS Inc).

To examine the relationship between the community incidence of COVID-19 and symptomatic post-operative COVID-19, daily cumulative infection data were downloaded from John's Hopkins University git repository and differentiated to obtain daily numbers of new infection cases.[18] To analytically define peak maxima of new infections, data curves for each country were fed through a low-pass Butterworth filter. Maxima were automatically detected if local maxima had a width of at least 7 days and reached at least 15% of the maximum number of infections of the country.

3 | RESULTS

A total of 171 adolescent patients underwent primary bariatric surgery at 68 centres in 24 countries during the study period (Table 1). In total, complete 30-day follow-up data were available for 170 patients (99.4%). Basic demographic details are provided in Table 2. The majority of patients were female (n = 122, 71.8%). The mean age was 17.75 ± 1.3 years. The youngest patient receiving surgery during this period was 14 years' old. The mean pre-operative weight was 122.16 ± 15.92 kg, with a mean body mass index (BMI) of 43.7 ± 7.11 kg/m^2.

Seventy-eight patients (45.9%) had pre-existing co-morbidities including type 2 diabetes (T2D) (7.1%,n = 12), hypertension (7.6%, n = 13) and obstructive sleep apnoea (12.4%, n = 21). The most commonly performed surgical procedure was laparoscopic sleeve gastrectomy (LSG; n = 132, 77.6%) followed by one-anastomosis gastric bypass (n = 18, 10.6%) and Roux-en-Y gastric bypass (RYGB; n = 14, 8.2%).

There were differences in pre-procedure quarantine protocols with 42.4% (n = 72) of patients asked to self-isolate before surgery. The majority of patients had some form of pre-operative testing for the presence of SARS-CoV-2 (n = 146, 85.9%), mostly reverse-transcriptase polymerase chain reaction (RT-PCR) tests (71.2%; n = 121 patients). In terms of radiological screening, half of the patients (n = 85) had a pre-operative chest X-ray performed, and 25.3%

TABLE 1 Country-wise reporting of cases and the relationship of the peak incidence of coronavirus disease 2019 (COVID-19) to the study period (1 May – 30 Nov)

Country	Continent	No. of BMS	Percentage of Cases	Peak	Timing of Peak
Australia	Australia	1	0.6	30/07/20	During
Belgium	Europe	5	2.9	25/10/20	During
Brazil	South America	1	0.6	02/08/20	During
China	Asia	4	2.4	09/02/20	Before
Colombia	South America	1	0.6	12/08/20	During
Egypt	Africa	4	2.4	17/06/20	During
France	Europe	7	4.1	31/10/20	During
Germany	Europe	3	1.8	01/04/20	Before
Greece	Europe	5	2.9	14/11/20	During
India	Asia	11	6.5	13/09/20	During
Iran	Asia	8	4.7	>30/11/20	After
Israel	Asia	8	4.7	23/07/20	During
Italy	Europe	14	8.2	12/11/20	During
Jordan	Asia	1	0.6	15/11/20	During
Malaysia	Asia	1	0.6	>30/11/20	After
Mexico	North America	32	18.8	24/07/20	During
Netherlands	Europe	9	5.3	25/10/20	During
Poland	Europe	1	0.6	11/11/20	During
Romania	Europe	1	0.6	12/08/20	During
Saudi Arabia	Asia	9	5.3	23/06/20	During
Spain	Europe	1	0.6	01/11/20	During
Syria	Asia	2	1.2	22/08/20	During
Turkey	Europe/Asia	29	17.1	>30/11/20	After
United Arab Emirates (UAE)	Asia	12	7.1	19/05/20	During

Note: Based on https://github.com/CSSEGISandData/COVID-19/tree/master/csse_covid_19_data/csse_covid_19_time_series accessed 01/12/2020 at 14:00 GMT. Shaded lines represent countries that did not have a peak of COVID-19 incidence during the study period.

TABLE 2 Basic demographic details of all patients undergoing primary metabolic and bariatric surgery (MBS) in adolescence

		Elective Primary Surgery				
		All Primary Procedures	LSG	RYGB	OAGB	Others[a]
Total number		170	132	14	18	6
Age		17.75 ± 1.3	17.77 ± 1.3	18.21 ± 0.9	17.17 ± 1.4	17.83 ± 0.9
Sex (M:F)		48 (28.2%):122 (71.8%)	34 (25.8%):98 (74.2%)	7 (50%):7 (50%)	6 (33.3%):12 (66.7%)	1 (16.7%):5 (83.3%)
Weight (in kg)		122.16 ± 25.4	121.46 ± 24.5	132.85 ± 31.6	120.38 ± 27.4	117.86 ± 22.8
BMI		43.68 ± 7.1	43.48 ± 7	44.51 ± 7.9	44.01 ± 7.4	45.25 ± 7.7
Ethnicity data						
White		119 (70%)	97 (73.5%)	10 (71.4%)	7 (38.9%)	5 (83.3%)
Non-white[b]		51 (30%)	35 (26.5%)	4 (28.6%)	11 (61.1%)	1 (16.7%)
Asian		16 (9.4%)	11 (8.3%)	0	4 (22.2%)	1 (16.7%)
Black or African American		0	51 (1·28%)	0	0	0
Hispanic or Latino		34 (20%)	23 (17.4%)	4 (28.6%)	7 (38.9%)	0
Native Hawaiian or Other Pacific Islander		1 (0.6%)	1 (0.8%)	0	0	0
American Indian or Alaska Native		0	7 (0·18%)	0	0	0
Co-morbidity data						
Any co-morbidity		78 (45·9%)	60 (45.5%)	6 (42.9%)	9 (50%)	3 (50%)
Type 2 Diabetes Mellitus	Diet controlled	7 (4.1%)	4 (3%)	0	2 (11.1%)	1 (16.7%)
	Oral medication	4 (2.4%)	3 (2.3%)	0	0	1 (16.7%)
	Insulin dependent	1 (0·6%)	1 (0.8%)	0	0	0
Hypertension		13 (7.6%)	12 (9.1%)	1 (7.1%)	0	0
Sleep apnoea	Not on CPAP	15 (8·8%)	8 (8.1%)	1 (7.1%)	5 (27.8%)	1 (16.7%)
	on CPAP	6 (3.5%)	5 (3.8%)	1 (7.1%)	0	0
Hypercholesterolaemia		10 (5.9%)	10 (7.6%)	0	0	0
Other		45 (26.5%)	36 (27.3%)	3 (21.4%)	6 (33.3%)	0
Smoking status						
Current smoker		17 (10%)	13 (9.8%)	1 (7.1%)	1 (5.6%)	2 (33.3%)
Ex-smoker		6 (3.5%)	4 (3%)	1 (7.1%)	0	1 (16.7%)
Non-smoker		147 (86.5%)	115 (87.1%)	12 (5.7%)	17 (94.4%)	3 (50%)

Abbreviations: CPAP, continuous positive-airway pressure; LSG, laparoscopic sleeve gastrectomy.
[a]Other primary procedures – Patients who underwent additional procedures/non-standard access. Includes 1* banded sleeve, 3* LSG with hiatus hernia repair fundoplication, 4* robotic LSG.
[b]Non-white: Asian, Black or African American, Hispanic or Latino, Native Hawaiian or other Pacific Islander and American Indian or Alaska Native.

TABLE 3 Peri-operative protocols

		Pre-operative Testing for SARS-CoV2	
		No	Yes
Self-isolation	No	23 (95.8%)	68 (48.9%)
	Yes	1 (4.2%)	71 (51.1%)

(n = 43) had a computed tomography thorax. Patients who were recommended self-isolation were significantly more likely to have undergone pre-operative testing to rule out active SARS-CoV-2 infection (Table 3; Fisher's exact test <0.001).

Overall, 128 (75.3%) cases were performed in countries that had at least one peak of COVID-19 during the study period (Table 1). Following surgery, only two patients developed symptomatic COVID-19 within 30 days of surgery (1.2%). Both of these patients had self-isolated for 2 weeks prior to surgery and had a negative pre-operative RT-PCR result. They were diagnosed as SARS-CoV-2-positive on post-operative days 10 and 18, respectively. Although these do represent a deviation from the normal post-operative course, one patient did not require any additional pharmacological treatment and was therefore categorized as CD I. The second patient required re-admission and in-hospital quarantine prior to discharge (CD II).

There were no peri-operative mortalities. The overall complication rate was 5.3% (n = 9) (Table 4). Seven of these were CD I. This included one of the patients who tested positive for SARS-CoV-2 post-operatively. Only one patient had a CD II complication, and this was the other patient who tested positive for SARS-CoV-2 post-

TABLE 4 30-Day morbidity and mortality of elective primary metabolic and bariatric surgery (MBS) in adolescents

	All Primary Procedures
	170
Highest grade	
Clavien Dindo Grade I	7 (4.1%)
Clavien Dindo Grade II	1 (0.6%)
Clavien Dindo Grade IIIa	0
Clavien Dindo Grade IIIb	0
Clavien Dindo Grade IVa	1 (0.6%)
Clavien Dindo Grade IVb	0
Clavien Dindo Grade V	0
All complications	9 (5.29%)
Clavien Dindo Grade I and II	8 (4.7%)
Clavien Dindo Grade III, IV, V	1 (0.59%)
Covid infection	
COVID-19	2 (1.17%)
Specific complications	
Bleeding	2 (1.17%)
Leak from gastrointestinal tract	0
Wound infection	0
Post-operative pneumonia (not otherwise specified)	1 (0.6%)
DVT	0
PE	0
Other[a]	3 (1.76%)
Unspecified	2 (1.17%)

[a]Other complications: 1* pyrexia of unknown origin, 1* drug-induced fever, 1* dehydration.

operatively and required re-admission. Within this group of CD I and II patients, two patients had post-operative bleeding. Both of these patients had undergone an LSG. One of these patients required 3 units of blood transfusion. Neither of these patients were on any anti-coagulants. Finally, there was one patient who had a CD IVa complication. This patient had an oesophageal intubation during index procedure, followed by endo-bronchial intubation. This led to bronchospasm and, subsequently, pneumonia. The patient was thus managed in intensive care unit for 3 days and received antibiotics for 7 days. This patient was subsequently discharged. This patient did not test positive for SARS-CoV-2 at any stage. There were no re-operations or mortality within 30 days of surgery in this series.

4 | DISCUSSION

This study has demonstrated that MBS within the adolescent population can be performed safely in the setting of the present COVID-19 pandemic in the presence of local COVID-19 protocols. There were only two incidences of peri-operative SARS-CoV-2 infection (1.2%), and the overall complication rate in this series was low (5.3%). The majority of these complications were minor in nature with only two being CD II or greater. There were no peri-operative mortalities.

The current study is the only international study providing safety data for adolescent patients undergoing any type of elective or non-emergent surgery. The overall complication rate of MBS reported in this study (5.3%) is comparable to those widely reported for such procedures from specialist centres performing adolescent MBS pre-pandemic (reported complication rates of 3.7% to 5.6%).[4,5,19,20] These complication rates are also lower than that reported for adult patients undergoing MBS during the COVID-19 pandemic (overall complication rate 6.8% for adult patients).[14] The complication rate in this series is greater than that identified from a recent analysis of data from the National Surgical Quality Improvement Program (NSQIP) (surgical complication rate 2.6%), which included data from adolescent patients undergoing MBS prior to the COVID-19 pandemic.[21] However, complications may have been classified differently between the two studies, and given the NSQIP study had a larger cohort of patients ($n = 2625$) albeit over a 10-year period, it is difficult to directly compare results.

The low rates of peri-operative SARS-CoV-2 infection identified in this study (1.2%) are thought to be likely due to the rigorous use of pre-operative screening for COVID-19 prior to surgery. Although there was variability in specific testing protocols across this international cohort study, the majority of patients had some form of pre-operative screening to ensure they did not have asymptomatic COVID-19 prior to surgery (85.9%). The two COVID-19 cases had been screened as SARS-CoV-2 negative prior to surgery and developed symptoms with a positive test more than 10 days following surgery. This implies they may have become exposed to SARS-CoV-2 during their post-operative course and highlights the potential need to encourage patients to adhere to strict self-isolation protocols following surgery in order to avoid post-operative exposure and the potential risks of associated complications.

MBS for adolescent patients remains a highly specialized field with a limited number of centres performing such procedures internationally. However, MBS still represents an important treatment option for adolescent patients with severe obesity or associated co-morbidities as there is a lack of other effective treatment options. For adolescent patients with T2D, MBS has been demonstrated to be superior to medical treatment alone in terms of glycaemic control, weight reduction and improvement in other co-morbidities.[22] This is particularly relevant, given the long-term risks of cardiovascular disease associated with the presence of obesity during adolescence.[23] These patients have a cumulative cardiovascular and metabolic risk, and if left untreated, the presence of obesity during adolescence has been associated with the risk of cardiovascular death during adulthood being more than tripled compared to control patients (Hazard ratio 3.5 (95% confidence interval, 2.9–4.1)).[24] Patients with obesity during adolescence are also at significant risk of T2D during adulthood with between 56% and 61% of cases of adult-onset T2D being

projected to be attributable to obesity during adolescence.[25] This further highlights the need for timely intervention in this patient group in order to reduce the long-term effects of these co-morbid conditions upon long-term mortality and cardiovascular risk.[26]

In adult patients, the presence of obesity has been associated with increased risk of poor outcomes from COVID-19 including need for in-hospital admission or invasive mechanical ventilation, as well as increased mortality risk.[27–29] The link between the presence of obesity and poor COVID-19-related outcomes in children and adolescent patients is less clear, but the presence of obesity is still considered a significant risk for severe disease by the Centres for Disease Control and Prevention.[30] In adult patients, there are also data to suggest that a history of previous MBS is protective for patients in terms of outcomes from COVID-19 compared to propensity-matched controlled patients.[31] This further reinforces the need to continue to increase the provision of services to deliver MBS in order to reduce potential risks to patients living with obesity.

The primary strengths of this study are that it provides international data from the largest collaborative study regarding outcomes of MBS during the COVID-19 pandemic. This study has been specifically designed to capture data regarding pre-operative precautions taken for all patients to mitigate the risk of peri-operative SARS-CoV-2 infection and measure outcomes. Despite this, there are a number of limitations. Due to the nature of this study, results were self-reported by the practicing clinicians, and there was no external validation of data accuracy. However, steps were taken to ensure data completeness at the point of analysis as evidenced by 99.4% 30-day follow-up data completion. There is also an absence of an equivalent cohort of adolescent patients who received MBS prior to the COVID-19 pandemic at the same institutions as contributed to the current study. Therefore, it is not possible to complete a direct comparison of outcomes before and during the COVID-19 pandemic. There was also some differences in screening methods for the presence of COVID-19 with the majority of centres utilizing RT-PCR screening (71.2%) but others offering radiological testing with chest radiographs or cross-sectional imaging. These differences in screening methods are likely to be largely due to the worldwide nature of the data presented herein and potential difficulties with access to RT-PCR testing during the early phases of the pandemic in some countries. Cross-sectional thoracic imaging has been demonstrated to have a high sensitivity due to the presence of COVID-19.[32] Plain chest radiographs were also utilized pre-operatively but have lower sensitivity for SARS-CoV-2 infection.[33] However, such tests have an associated radiation exposure making the use of RT-PCR testing now the preferred choice for pre-operative diagnostic screening.[34]

In conclusion, this study has identified that MBS has been performed safely for adolescent patients during the COVID-19 pandemic. Low rates of peri-operative SARS-CoV-2 infection are likely to be due to strict protocols of patient isolation and screening for presence of SARS-CoV-2 pre-operatively. Although MBS for adolescent patients remains a highly specialized service, the results demonstrated here highlight the importance of developing specific recommendations for peri-operative isolation and screening as services are re-introduced internationally.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

Conceptualization: RS and KM
Manuscript writing and reviewing: all authors
Analysis: RS, CL and JS
Data collection and conduct: RS

ETHICS STATEMENT

The project was registered as a multinational audit (reference number: 5197) at the University Hospitals Birmingham NHS Foundation Trust, UK.

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