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ORIGINAL RESEARCH



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

Rishi Singhal^{1,2} | Tom Wiggins¹ | Jonathan Super¹ | Aayed Alqahtani³ | Evan P. Nadler⁴ | Christian Ludwig⁵ | Abd Tahrani^{5,6,7} | Kamal Mahawar⁸

Correspondence

Rishi Singhal, Consultant Bariatric and Upper GI Surgeon, Birmingham Heartlands Hospital, University Hospital Birmingham NHS Foundation Trust, UK. Email: singhal_rishi@hotmail.com

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 \pm 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 \pm 15.92 kg and 43.7 \pm 7.11 kg/m², 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 preoperative testing). The 30-day morbidity rates were similar to those reported prepandemic. 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.

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¹Upper GI Unit, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

²Department of Bariatric Surgery, Medical Director, Healthier Weight, Birmingham, UK

³Department of Bariatric Surgery, New You Medical Center, Riyadh, Saudi Arabia

⁴Department of Bariatric Surgery, Children's National Hospital, Washington, DC, USA

⁵Institute of Metabolism and Systems Research, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK

⁶Department of Diabetes and Endocrinology, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

⁷Department of Diabetes and Endocrinology, Centre for Endocrinology, Diabetes and Metabolism, Birmingham Health Partners, Birmingham, UK

⁸Bariatric Unit, South Tyneside and Sunderland NHS Trust, Sunderland, UK

1 | INTRODUCTION

Metabolic and bariatric surgery (MBS) is a highly effective treatment for adolescent patients with severe obesity resulting in long-term weightloss 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 preoperative 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 preoperative 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 \pm 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 Chisquare 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 preoperative weight was 122.16 ± 15.92 kg, with a mean body mass index (BMI) of 43.7 ± 7.11 kg/m².

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.

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

			Elective Primary Surgery					
		All Primary Procedures		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 A	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 o Pacific Islander		1 (0.6%)	1 (0.8%)	0	0	0		
American Indian o	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	Diet controlled	7 (4.1%)	4 (3%)	0	2 (11.1%)	1 (16.7%)		
Mellitus	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		
Hypercholesterola	aemia	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.

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-

^aOther primary procedures – Patients who underwent additional procedures/non-standard access. Includes 1* banded sleeve, 3* LSG with hiatus hernia repair fundoplication, 4* robotic LSG.

bNon-white: Asian, Black or African American, Hispanic or Latino, Native Hawaiian or other Pacific Islander and American Indian or Alaska Native.

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%)

 $^{\mathrm{a}}$ 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 nonemergent 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 prepandemic (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.

ORCID

Rishi Singhal (1) https://orcid.org/0000-0002-2797-2569

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APPENDIX A:

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Piotr Major Piotr Major 2'nd Department of General Surgery, Jagiellonian University Medical College, Krakow, Poland Piotr Zarzycki Piotr Zarzycki 2'nd Department of General Surgery, Jagiellonian University Medical College, Krakow, Poland Athanasios Pantelis A Pantelis 4th Surgical Department, Evaggelismos General Hospital of Athens, Athens, Greece Dimitris P. Lapatsanis D Lapatsanis 4th Surgical Department, Evaggelismos General Hospital of Athens, Athens, Greece Georgios Stravodimos G Stravodimos 4th Surgical Department, Evaggelismos General Hospital of Athens, Athens, Greece Chris Matthys C Matthys A Z Sint Elisabeth Zottegem, Belgium Marc Focquet M Focquet A Z Sint Elisabeth Zottegem, Belgium Wouter Vieschouwers W Vieschouwers A Sint Elisabeth Zottegem, Belgium Antonio G Spaventa A Spaventa ABC Medical Center Santa Fe, Mexico City, Mexico Carlos Zernweck C Zernweck ABC Medical Center Santa Fe, Mexico City, Mexico Carlos Zernweck A Striello Avanced Biomedical Sciences Department - Naples "Federico II" University - Italy Giovanna Berardi G Berardi Advanced Biomedical Sciences Department - Naples "Federico II" University - Italy Mario Musella Musella Advanced Biomedical Sciences Department - Naples "Federico II" University - Italy Advanced Biomedical Sciences Department - Naples "Federico II" University - Italy Advanced Biomedical Sciences Department - Naples "Federico II" University - Italy Advanced Medicine Institute. Reynosa, MEXICO. Fernando Mora F Mora Advanced Medicine Institute. Reynosa, MEXICO. Fernando Mora F Mora Advanced Medicine Institute. Reynosa, MEXICO. Albishok Katakwar Al Katakwar Al G hospital, Hyderabad, India D Nageshwar Reddy D N Reddy Al G hospital, Hyderabad, India D Nageshwar Reddy D N Reddy Al G hospital, Hyderabad, India D Nageshwar Reddy Al G Namas University Hospitals Mohammad Hassan Al Shams University Hospitals. Cairo, Egypt Albishok Katakwar Al Albana Ali Shams University Hospitals, Cairo, Egypt Albana Al Harkan Ali Shams University Hospitals, Cairo, Egypt Albana Albana Ali Shams U	Full Name	Initial and Surname	Institution
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Abhishek Katakwar D Nageshwar Reddy D N Reddy AlG hospital, Hyderabad, India D Nageshwar Reddy D N Reddy AlG hospital, Hyderabad, India Haitham Elmaleh H Elmaleh Ain Shams University Hospitals Mohammad Hassan M Hassan Ain Shams University Hospitals Abdelrahman Elghandour A Elghandour Ain Shams University Hospitals Mohey Elbanna M Elbanna Ain Shams University Hospitals Ahmed Osman A Osman Ain Shams University Hospitals, Cairo, Egypt Athar Khan A Khan A Khan Al shark hospital fujairah UAE Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin A Velikorechin A Welikorechin A Merican Medical Clinic, Saint Petersburg, Russia Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi Amin University Hospital, Isfahan, Iran	Fernando Mora	F Mora	Advanced Medicine Institute. Reynosa, MEXICO.
D Nageshwar Reddy D N Reddy AlG hospital, Hyderabad, India Haitham Elmaleh H Elmaleh Ain Shams University Hospitals Mohammad Hassan M Hassan Ain Shams University Hospitals Abdelrahman Elghandour A Elghandour Ain Shams University Hospitals Mohey Elbanna M Elbanna Ain Shams University Hospitals Ahmed Osman A Osman Ain Shams University Hospitals, Cairo, Egypt Athar Khan A Khan Al shark hospital fujairah UAE Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin A Velikorechin A Medali Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi Amin University Hospital, Isfahan, Iran	Marco A Cantu	M Cantu	Advanced Medicine Institute. Reynosa, MEXICO.
Haitham Elmaleh H Elmaleh Ain Shams University Hospitals Mohammad Hassan M Hassan Ain Shams University Hospitals Abdelrahman Elghandour A Elghandour Ain Shams University Hospitals Mohey Elbanna M Elbanna Ain Shams University Hospitals Ahmed Osman A Osman Ain Shams University Hospitals, Cairo, Egypt Athar Khan A Khan Al shark hospital fujairah UAE Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin American Medical Clinic, Saint Petersburg, Russia Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi Shahabi Amin University Hospital, Isfahan, Iran	Abhishek Katakwar	A Katakwar	AIG hospital, Hyderabad, India
Mohammad Hassan M Hassan Ain Shams University Hospitals Ain Shams University Hospitals Mohey Elbanna M Elbanna M Elbanna Ain Shams University Hospitals Mohey Elbanna Ain Shams University Hospitals Ahmed Osman A Osman Ain Shams University Hospitals, Cairo, Egypt Athar Khan A Khan A Khan Al shark hospital fujairah UAE Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin A Velikorechin A Welikorechin Maria Solovyeva M Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi Amin University Hospital, Isfahan, Iran	D Nageshwar Reddy	D N Reddy	AIG hospital, Hyderabad, India
Abdelrahman Elghandour A Elghandour Ain Shams University Hospitals Ahmed Osman A Osman Ain Shams University Hospitals Ahmed Osman A Osman Ain Shams University Hospitals, Cairo, Egypt Athar Khan A Khan Al shark hospital fujairah UAE Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin A Welikorechin American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi Amin University Hospital, Isfahan, Iran	Haitham Elmaleh	H Elmaleh	Ain Shams University Hospitals
Mohey Elbanna M Elbanna Ain Shams University Hospitals Ahmed Osman A Osman Ain Shams University Hospitals, Cairo, Egypt Athar Khan A Khan Al shark hospital fujairah UAE Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin American Medical Clinic, Saint Petersburg, Russia Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi S Shahabi Amin University Hospital, Isfahan, Iran	Mohammad Hassan	M Hassan	Ain Shams University Hospitals
Ahmed Osman A Osman Ain Shams University Hospitals, Cairo, Egypt Athar Khan A Khan Al shark hospital fujairah UAE Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin American Medical Clinic, Saint Petersburg, Russia Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi Shahabi Amin University Hospital, Isfahan, Iran	Abdelrahman Elghandour	A Elghandour	Ain Shams University Hospitals
Athar Khan A Khan Al shark hospital fujairah UAE Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin American Medical Clinic, Saint Petersburg, Russia Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi S S Shahabi Amin University Hospital, Isfahan, Iran	Mohey Elbanna	M Elbanna	Ain Shams University Hospitals
Laurent layani L Layani Al shark hospital fujairah UAE Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin American Medical Clinic, Saint Petersburg, Russia Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi S Shahabi Amin University Hospital, Isfahan, Iran	Ahmed Osman	A Osman	Ain Shams University Hospitals, Cairo, Egypt
Nalini kiran N Kiran Al shark hospital fujairah UAE Andrey Velikorechin A Velikorechin American Medical Clinic, Saint Petersburg, Russia Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi S Shahabi Amin University Hospital, Isfahan, Iran	Athar Khan	A Khan	Al shark hospital fujairah UAE
Andrey Velikorechin A Velikorechin American Medical Clinic, Saint Petersburg, Russia Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi S Shahabi Amin University Hospital, Isfahan, Iran	Laurent layani	L Layani	Al shark hospital fujairah UAE
Maria Solovyeva M Solovyeva American Medical Clinic, Saint Petersburg, Russia Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi S Shahabi Amin University Hospital, Isfahan, Iran	Nalini kiran	N Kiran	Al shark hospital fujairah UAE
Hamid Melali H Melali Amin University Hospital, Isfahan, Iran Shahab Shahabi S Shahabi Amin University Hospital, Isfahan, Iran	Andrey Velikorechin	A Velikorechin	American Medical Clinic, Saint Petersburg, Russia
Shahabi Shahabi Amin University Hospital, Isfahan, Iran	Maria Solovyeva	M Solovyeva	American Medical Clinic, Saint Petersburg, Russia
Shahab Shahabi S Shahabi Amin University Hospital, Isfahan, Iran	Hamid Melali	H Melali	Amin University Hospital, Isfahan, Iran
	Shahab Shahabi		Amin University Hospital, Isfahan, Iran
Apport I i Total at Ookalaas Hospital	Ashish Agrawal	A Agrawal	Apoorv Hi Tech at Gokuldas Hospital

Full Name	Initial and Surname	Institution
Apoorv Shrivastava	A Shrivastava	Apoorv Hi Tech at Gokuldas Hospital
Ankur Sharma	A Sharma	Asian Bariatrics, Ahmedabad, India
Bhavya Narwaria	B Narwaria	Asian Bariatrics, Ahmedabad, India
Mahendra Narwaria	M Narwaria	Asian Bariatrics, Ahmedabad, India
Asnat Raziel	A Raziel	Assuta Medical Center, Tel Aviv, Israel
Nasser Sakran	N Sakran	Assuta Medical Center, Tel Aviv, Israel
Sergio Susmallian	S Susmallian	Assuta Medical Center, Tel Aviv, Israel
Levent Karagöz	L Karagöz	Atasam Hospitals,Samsun,Turkey
Murat Akbaba	M Akbaba	Atasam Hospitals,Samsun,Turkey
Salih Zeki Pişkin	SZ Pişkin	Atasam Hospitals,Samsun,Turkey
Ahmet Ziya BALTA	AZ Balta	AZBariatrics Obesity Center, Istanbul
Zafer Senol	Z Senol	AZBariatrics Obesity Center, Istanbul
Emilio Manno	E Manno	Bariatric and Metabolic surgery UnitOspedale A.Cardarelli Napoli Italia
Michele Giuseppe Iovino	MG Iovino	Bariatric and Metabolic surgery UnitOspedale A.Cardarelli Napoli Italia
Ahmed Osman	A Osman	Bariatric Surgery Department, Faculty of Medicine, Ain Shams University, Cairo, Egypt
Mohamed Qassem	M Qassem	Bariatric Surgery Department, Faculty of Medicine, Ain Shams University, Cairo, Egypt
Sebastián Arana-Garza	S Arana-Garza	Bariatric Surgery Experts, Monterrey, Mexico
Heitor P. Povoas	H Povoas	BAROS - Bariatric and Metabolic Surgery, Salvador, Brazil
Marcos Leão Vilas-Boas	M Vilas-Boas	BAROS - Bariatric and Metabolic Surgery, Salvador, Brazil
David Naumann	D Naumann	Birmingham Heartlands Hospital, University Hospital Birmingham NHS Foundation Trust
Alan Li	A Li	BMI Alexandra Hospital, Manchester, UK
Basil J Ammori	BJ Ammori	Burjeel Hospital, Abu Dhabi, UAE
Hany Balamoun	H Balamoun	Cairo University, Cairo, Egypt
Mohammed Salman	M Salman	Cairo University, Cairo, Egypt
Amrit Manik Nasta	A M Nasta	Center of Metabolic Surgery, Wockhardt Hospital, Agripada, Mumbai, India
Ramen Goel	R Goel	Center of Metabolic Surgery, Wockhardt Hospital, Agripada, Mumbai, India
Hugo Sánchez-Aguilar	H Sánchez	Center of Nutrition and Obesity, ABC Medical Center (Observatorio), Mexico City
Miguel F Herrera	M Herrera	Center of Nutrition and Obesity, ABC Medical Center (Observatorio), Mexico City
Adel ABOU-MRAD	A Abou-Mrad	Centre Hospitalier Regional d'ORLEANS
Lucie CLOIX	L Cloix	Centre Hospitalier Regional d'ORLEANS
Guilherme Silva Mazzini	GS Mazzini	Centro de Obesidade do Instituto do Aparelho Digestivo, Porto Alegre, Brazil
Leonardo Kristem	L Kristem	Centro de Obesidade do Instituto do Aparelho Digestivo, Porto Alegre, Brazil
Andre Lazaro	A Lazaro	Centro Hospitalar e Universitario de Coimbra, Coimbra, Portugal
Jose Campos	J Campos	Centro Hospitalar e Universitario de Coimbra, Coimbra, Portugal
Joaquín Bernardo	J Bernardo	Centro Médico de Asturias. Oviedo. Spain
Jesús González	J González	Centro Médico de Asturias. Oviedo. Spain
Carlos Trindade	C Trindade	Centro Multidisciplinar da Doença Metabólica, Clínica Santo Antonio - Lusiadas, Amadora, Portugal
Octávio Viveiros	O Viveiros	Centro Multidisciplinar da Doença Metabólica, Clínica Santo Antonio - Lusiadas, Amadora, Portugal
Rui Ribeiro	R Ribeiro	Centro Multidisciplinar da Doença Metabólica, Clínica Santo Antonio - Lusiadas, Amadora, Portugal

Full Name	Initial and Surname	Institution
David Goitein	D Goitein	Chaim Sheba Medical Center, Affiliated with Sackler School of Medicine, Tel Aviv University, Ramat Gan, Israel
David Hazzan	D Hazzan	Chaim Sheba Medical Center, Affiliated with Sackler School of Medicine, Tel Aviv University, Ramat Gan, Israel
Lior Segev	L Segev	Chaim Sheba Medical Center, Affiliated with Sackler School of Medicine, Tel Aviv University, Ramat Gan, Israel
Tamar Beck	T Beck	Chaim Sheba Medical Center, Affiliated with Sackler School of Medicine, Tel Aviv University, Ramat Gan, Israel
Hernán Reyes	H Reyes	Christus Muguerza Sur, Monterrey, Mexico
Jerónimo Monterrubio	J Monterrubio	Christus Muguerza Sur, Monterrey, Mexico
Paulina García	P García	Christus Muguerza Sur, Monterrey, Mexico
Marine Benois	M Benois	CHU Félix Guyon, la Réunion, France
Radwan Kassir	R Kassir	CHU Félix Guyon, la Réunion, France
Alessandro Contine	A Contine	Città di Castello Hospital, Usl Umbria 1, Città di Castello - Italy
Moustafa Elshafei	M Elshafei	Clinic for Metabolic Surgery, Krankenhaus Nordwest, Frankfurt, Germany
Sueleyman Aktas	S Aktas	Clinic for Metabolic Surgery, Krankenhaus Nordwest, Frankfurt, Germany
Sylvia Weiner	S Weiner	Clinic for Metabolic Surgery, Krankenhaus Nordwest, Frankfurt, Germany
Till Heidsieck	T Heidsieck	Clinic for Metabolic Surgery, Krankenhaus Nordwest, Frankfurt, Germany
Luis Level	L Level	Clínica Santa Sofía, Caracas, Venezuela
Silvia Pinango	S Pinango	Clínica Santa Sofía, Caracas, Venezuela
Patricia Martinez Ortega	P Martinez	Clinica Universidad de Navarra. Pamplona. Spain
Rafael Moncada	R Moncada	Clinica Universidad de Navarra. Pamplona. Spain
Victor Valenti	V Valenti	Clinica Universidad de Navarra. Pamplona. Spain
Ivan Vlahović	I Vlahović	Clinical Hospital Centre Osijek, Osijek, Croatia
Zdenko Boras	Z Boras	Clinical Hospital Centre Osijek, Osijek, Croatia
Arnaud Liagre	A Liagre	Clinique des Cedres, Cornebarrieu, France
Francesco Martini	F Martini	Clinique des Cedres, Cornebarrieu, France
Gildas Juglard	G Juglard	Clinique des Cedres, Cornebarrieu, France
Manish Motwani	M Motwani	COMS, Apollo Spectra Hospital, New Delhi, India
Sukhvinder Singh Saggu	S Saggu	COMS, Apollo Spectra Hospital, New Delhi, India
Hazem Al Momani	H Al Momani	Danat Al Emarat Hospital, Abu Dhabi, UAE
Luis Adolfo Aceves López	L Aceves	Defeat Obesity Bariatric and Metabolic Surgery, CHRISTUS MUGUERZA Hospital Reynosa, Reynosa, Tamaulipas.
María Angelina Contreras Cortez	M Contreras	Defeat Obesity Bariatric and Metabolic Surgery, CHRISTUS MUGUERZA Hospital Reynosa, Reynosa, Tamaulipas.
Rodrigo Aceves Zavala	R Aceves	Defeat Obesity Bariatric and Metabolic Surgery, CHRISTUS MUGUERZA Hospital Reynosa, Reynosa, Tamaulipas.
Christine D'Haese RN	C D'Haese	Delta CHIREC hospital, Brussels Belgium
Ivo Kempeneers	I Kempeneers	Delta CHIREC hospital, Brussels Belgium
Jacques Himpens	J Himpens	Delta CHIREC hospital, Brussels Belgium
Andrea Lazzati	A Lazzati	Department of General Surgery, Center Hospitalier Intercommunal de Créteil, Paris, France
Luca Paolino	L Paolino	Department of General Surgery, Center Hospitalier Intercommunal de Créteil, Paris, France
Sarah Bathaei	S Bathaei	Department of General Surgery, Center Hospitalier Intercommunal de Créteil, Paris, France
Abdulkadir Bedirli	A Bedirli	Department of General Surgery, Gazi University Faculty of Medicine, Turkey
Aydın Yavuz	A Yavuz	Department of General Surgery, Gazi University Faculty of Medicine, Turkey



Full Name	Initial and Surname	Institution
Çağrı Büyükkasap	Ç Büyükkasap	Department of General Surgery, Gazi University Faculty of Medicine, Turkey
Safa Özaydın	S Özaydın	Department of General Surgery, Gazi University Faculty of Medicine, Turkey
Andrzej Kwiatkowski	A Kwiatkowski	Department of General Surgery, Military Institute of Medicine, Szaserów 128, 04–141, Warsaw, Poland
Katarzyna Bartosiak	K Bartosiak	Department of General Surgery, Military Institute of Medicine, Szaserów 128, 04–141, Warsaw, Poland
Maciej Walędziak	M Walędziak	Department of General Surgery, Military Institute of Medicine, Szaserów 128, 04–141, Warsaw, Poland
Antonella Santonicola	A Santonicola	Department of Public Health, "Federico II" University of Naples, Naples, Italy
Luigi Angrisani	L Angrisani	Department of Public Health, "Federico II" University of Naples, Naples, Italy
Paola Iovino	P Iovino	Department of Public Health, "Federico II" University of Naples, Naples, Italy
Rossella Palma	R Palma	Department of Public Health, "Federico II" University of Naples, Naples, Italy
Angelo lossa	A Lossa	Division of General Surgery & Bariatric Center of Excellence IFSO-EC, University La Sapienza of Rome, Italy
Cristian Eugeniu Boru	CE Boru	Division of General Surgery & Bariatric Center of Excellence IFSO-EC, University La Sapienza of Rome, Italy
Francesco De Angelis	F De Angelis	Division of General Surgery & Bariatric Center of Excellence IFSO-EC, University La Sapienza of Rome, Italy
Gianfranco Silecchia	G Silecchia	Division of General Surgery & Bariatric Center of Excellence IFSO-EC, University La Sapienza of Rome, Italy
Abdulzahra Hussain	A Hussain	Doncaster and Bassetlaw Teaching Hospitals
Srivinasan Balchandra	S Balchandra	Doncaster and Bassetlaw Teaching Hospitals
Izaskun Balciscueta Coltell	I Balciscueta	Dr. Lorenzo, Innovación Cirugía Obesidad y Diabetes
Javier Lorenzo Pérez	J Lorenzo	Dr. Lorenzo, Innovación Cirugía Obesidad y Diabetes
Ashok Bohra	A Bohra	East-Midlands Bariatric & Metabolic Institute (EMBMI), Royal Derby Hospital, Derby, UK
Altaf K Awan	AK Awan	East-Midlands Bariatric & Metabolic Institute (EMBMI), Royal Derby Hospital, Derby, UK
Brijesh Madhok	B Madhok	East-Midlands Bariatric & Metabolic Institute (EMBMI), Royal Derby Hospital, Derby, UK
Paul C Leeder	PC Leeder	East-Midlands Bariatric & Metabolic Institute (EMBMI), Royal Derby Hospital, Derby, UK
Sherif Awad	S Awad	East-Midlands Bariatric & Metabolic Institute (EMBMI), Royal Derby Hospital, Derby, UK
Waleed Al-Khyatt	W Al-Khyatt	East-Midlands Bariatric & Metabolic Institute (EMBMI), Royal Derby Hospital, Derby, UK
Ashraf Shoma	A Shoma	Elsafa Private Hospital & Mansoura University Hospital & Eldelta Hospital
Hosam Elghadban	H Elghadban	Elsafa Private Hospital & Mansoura University Hospital & Eldelta Hospital
Sameh Ghareeb	S Ghareeb	Elsafa Private Hospital & Mansoura University Hospital & Eldelta Hospit
Bryan Mathews	B Mathews	ew York Minimally Invasive Surgery PLLC, New York, NY, USA
Marina Kurian	M Kurian	ew York Minimally Invasive Surgery PLLC, New York, NY, USA
Andreas Larentzakis	A Larentzakis	First Department of Propaedeutic Surgery, Hippocration General Athens Hospital, National and Kapodistrian University of Athens, Athens, Greece
Gavriella Zoi Vrakopoulou	G Vrakopoulou	First Department of Propaedeutic Surgery, Hippocration General Athens Hospital, National and Kapodistrian University of Athens, Athens, Greece

Full Name	Initial and Surname	Institution
Konstantinos Albanopoulos	K Albanopoulos	First Department of Propaedeutic Surgery, Hippocration General Athens Hospital, National and Kapodistrian University of Athens, Athens, Greece
Ahemt Bozdag	A Bozdag	Fırat University Hospital, Elazığ. Turkey
Azmi Lale	A Lale	Fırat University Hospital, Elazığ. Turkey
Cuneyt Kirkil	C Kirkil	Fırat University Hospital, Elazığ. Turkey
Mursid Dincer	M Dincer	Fırat University Hospital, Elazığ. Turkey
Ahmad Bashir	A Bashir	Gastrointestinal, Bariatric & Metabolic Center at Jordan Hospital, Amman, Jordan
Ashraf Haddad	A Haddad	Gastrointestinal, Bariatric & Metabolic Center at Jordan Hospital, Amman, Jordan
Leen Abu Hijleh	L Abu Hijleh	Gastrointestinal, Bariatric & Metabolic Center at Jordan Hospital, Amman, Jordan
Bruno Zilberstein	B Zilberstein	GASTROMED-Zilberstein Institute, Sao Paulo, Brazil
Danilo Dallago de Marchi	D D de Marchi	GASTROMED-Zilberstein Institute, Sao Paulo, Brazil
Willy Petrini Souza	W Petrini Souza	GASTROMED-Zilberstein Institute, Sao Paulo, Brazil
Carl Magnus Brodén	C Brodén	GB Obesitas Skaane, Malmö. Sweden.
Hjörtur Gislason	H Gislason	GB Obesitas Skaane, Malmö. Sweden.
Kamran Shah	K Shah	GB Obesitas Skaane, Malmö. Sweden.
Antonio Ambrosi	A Ambrosi	General Surgery, University of Foggia. Italy.
Giovanna Pavone	G Pavone	General Surgery, University of Foggia. Italy.
Nicola Tartaglia	N Tartaglia	General Surgery, University of Foggia. Italy.
S Lakshmi Kumari Kona	K Lakshmi	Glenagles Global Hospital, Lakdikapul, Hyderabad
Kalyan K	KA Kalyan	Glenagles Global Hospital, Lakdikapul, Hyderabad
Cesar Ernesto Guevara Perez	C Guevara	Grammo SAS IPS, Bogotá, Colombia
Miguel Alberto Forero Botero	M Forero	Grammo SAS IPS, Bogotá, Colombia
Adrian Covic	A Covic	Grigore T. Popa University of Medicine and Pharmacy, Iasi, Romania
Daniel Timofte	D Timofte	Grigore T. Popa University of Medicine and Pharmacy, Iasi, Romania
Madalina Maxim	M Maxim	Grigore T. Popa University of Medicine and Pharmacy, Iasi, Romania
Dashti Faraj	D Faraj	Groene Hart Hospital in Gouda & Dutch Obesity Clinic The Hague, Netherlands
Larissa Tseng	LNL Tseng	Groene Hart Hospital in Gouda & Dutch Obesity Clinic The Hague, Netherlands
Ronald Liem	RSL Liem	Groene Hart Hospital in Gouda & Dutch Obesity Clinic The Hague, Netherlands
Gürdal Ören	G Oren	Gürdal Ören Bariatric Surgery Center, İstanbul, Turkey
Evren Dilektasli	E Dilektasli	Hayat Hospital, General Surgery, Bariatric & Metabolic Surgery, Bursa, Turkey
Ilker Yalcin	I Yalcin	Hayat Hospital, General Surgery, Bariatric & Metabolic Surgery, Bursa, Turkey
Hudhaifa AlMukhtar	H AlMukhtar	Healthpoint Hospital, Abu Dhabi, UAE
Mohammed Al Hadad	M Alhadad	Healthpoint Hospital, Abu Dhabi, UAE
Rasmi Mohan	R Mohan	Healthpoint Hospital, Abu Dhabi, UAE
Naresh Arora	N Arora	HOPE OBESITY CENTRE, AHMEDABAD, INDIA
Digvijaysingh Bedi	DS Bedi	HOPE OBESITY CENTRE, AHMEDABAD, INDIA
Claire Rives-Lange	C Rives-Lange	Hôpital Européen Georges Pompidou, AP-HP, Université de Paris, Paris, France
Jean-Marc Chevallier	J-M Chevallier	Hôpital Européen Georges Pompidou, AP-HP, Université de Paris, Paris, France
Tigran Poghosyan	T Poghosyan	Hôpital Européen Georges Pompidou, AP-HP, Université de Paris, Paris, France



Full Name	Initial and Surname	Institution
Hugues Sebbag	H Sebbag	Hôpital Privé de Provence (HPP), Aix-en-Provence, France
Lamia Zinaï	L Zinaï	Hôpital Privé de Provence (HPP), Aix-en-Provence, France
Saadi Khaldi	S Khaldi	Hôpital Privé de Provence (HPP), Aix-en-Provence, France
Charles Mauchien	C Mauchien	Hôpital Ste Musse Centre Hospitalier Toulon
Davide Mazza	D Mazza	Hôpital Ste Musse Centre Hospitalier Toulon
Georgiana Dinescu	G Dinescu	Hôpital Ste Musse Centre Hospitalier Toulon
Bernardo Rea	B Rea	Hospital Ángeles Lomas, Estado de México, México
Fernando Pérez-Galaz	F Pérez-Galaz	Hospital Ángeles Lomas, Estado de México, México
Luis Zavala	L Zavala	Hospital Christus Muguerza Sur - Monterrey México
Anais Besa	A Besa	Hospital Clínic de Barcelona, Barcelona, Spain
Anna Curell	A Curell	Hospital Clínic de Barcelona, Barcelona, Spain
Jose M Balibrea	JM Balibrea	Hospital Clínic de Barcelona, Barcelona, Spain
Carlos Vaz	C Vaz	Hospital CUF Tejo, Lisbon, Portugal
Luis Galindo	L Galindo	Hospital CUF Tejo, Lisbon, Portugal
Nelson Silva	N Silva	Hospital CUF Tejo, Lisbon, Portugal
José Luis Estrada Caballero	JL Estrada	Hospital General Universitario Alicante Spain
Sergio Ortiz Sebastian	S Ortiz	Hospital General Universitario Alicante Spain
João Caetano Dallegrave Marchesini	JC Marchesini	Hospital Marcelino Champagnat, Curitiba, Brazil
Ricardo Arcanjo da Fonseca Pereira	R Arcanio	Hospital Marcelino Champagnat, Curitiba, Brazil
Wagner Herbert Sobottka	W Sobottka	Hospital Marcelino Champagnat, Curitiba, Brazil
Felipe Eduardo Fiolo	F Fiolo	Hospital Privado de Comunidad - Mar del Plata - Argentina
Matias Turchi	M Turchi	Hospital Privado de Comunidad - Mar del Plata - Argentina
Antonio Claudio Jamel Coelho	A Coelho	Hospital Rios D'Or, Rio de Janeiro, Brazil
Andre Luis Zacaron	A Zacaron	Hospital Rios D'Or, Rio de Janeiro, Brazil
André Barbosa	A Barbosa	Hospital Unimed Natal, Natal, Brazil
Reynaldo Quinino	R Quinino	Hospital Unimed Natal, Natal, Brazil
Gabriel Menaldi	G Menaldi	Hospital Universitario Austral, Bariatric and Metabolic department. Buenos Aires Argentina
Nicolás Paleari	N Paleari	Hospital Universitario Austral, Bariatric and Metabolic department. Buenos Aires Argentina
Pedro Martinez-Duartez	P Martinez Duartez	Hospital Universitario Austral, Bariatric and Metabolic department. Buenos Aires Argentina
Gabriel Martínez de Aragon Ramírez de Esparza	G Martínez de Aragon	Hospital Universitario de Álava, Vitoria- Gasteiz. Spain
Valentin Sierra Esteban	V Sierra	Hospital Universitario de Álava, Vitoria- Gasteiz. Spain
Antonio Torres	A Torres	Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos.
		Madrid
Jose Luis Garcia-Galocha	JL Garcia-Galocha	
Jose Luis Garcia-Galocha Mlguel Josa	JL Garcia-Galocha M Josa	Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos.
		Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos.
Mlguel Josa	M Josa	Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid
MIguel Josa Jose Manuel Pacheco-Garcia	M Josa JM Pacheco-Garcia	Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Puerta del Mar. Cadiz. Spain
MIguel Josa Jose Manuel Pacheco-Garcia Maria Angeles Mayo-Ossorio	M Josa JM Pacheco-Garcia MA Mayo-Ossorio	Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Puerta del Mar. Cadiz. Spain Hospital Universitario Puerta del Mar. Cadiz. Spain Institute of Minimal Access, Metabolic & Bariatric Surgery, Max Super-
MIguel Josa Jose Manuel Pacheco-Garcia Maria Angeles Mayo-Ossorio Pradeep Chowbey	M Josa JM Pacheco-Garcia MA Mayo-Ossorio P Chowbey	Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Puerta del Mar. Cadiz. Spain Hospital Universitario Puerta del Mar. Cadiz. Spain Institute of Minimal Access, Metabolic & Bariatric Surgery, Max Super- Speciality Hospital, Saket, New Delhi, India Institute of Minimal Access, Metabolic & Bariatric Surgery, Max Super-
MIguel Josa Jose Manuel Pacheco-Garcia Maria Angeles Mayo-Ossorio Pradeep Chowbey Vandana Soni	M Josa JM Pacheco-Garcia MA Mayo-Ossorio P Chowbey V Soni	Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Madrid Monteprincipe. Hospital Clinico San Carlos. Madrid Hospital Universitario Puerta del Mar. Cadiz. Spain Hospital Universitario Puerta del Mar. Cadiz. Spain Institute of Minimal Access, Metabolic & Bariatric Surgery, Max Super- Speciality Hospital, Saket, New Delhi, India Institute of Minimal Access, Metabolic & Bariatric Surgery, Max Super- Speciality Hospital, Saket, New Delhi, India

Full Name	Initial and Surname	Institution
Thiago Alvim Barreiro	TA Barreiro	Instituto Campineiro de Tratamento da Obesidade, Campinas, Brazil
Alexandros Charalabopoulos	A Charalabopoulos	Interbalcan Medical Center
Elias Sdralis	E Sdralis	Interbalcan Medical Center
Spyridon Davakis	S Davakis	Interbalcan Medical Center
Benoit Bomans	B Bomans	International School Reduced Scar Laparoscopy, Brussels, Belgium
Giovanni Dapri	G Dapri	International School Reduced Scar Laparoscopy, Brussels, Belgium
Koenraad Van Belle	K Van Belle	International School Reduced Scar Laparoscopy, Brussels, Belgium
MazenTakieddine	M Takieddine	Isppc chu -André Vésale, metabolic & Bariatric surgery
Pol Vaneukem	P Vaneukem	Isppc chu -André Vésale, metabolic & Bariatric surgery
Esma Seda Akalın Karaca	ES Akalın Karaca	İstanbul Bilgi University, Turkey,(first author), Department of Pulmonary Medicine, Istanbul Yedikule Chest Diseases and Thoracic Surgery Education and Research Hospital, Zeytinburnu, Turkey(for sekond author)
Fatih Can Karaca	FC Karaca	İstanbul Bilgi University, Turkey,(first author), Department of Pulmonary Medicine, Istanbul Yedikule Chest Diseases and Thoracic Surgery Education and Research Hospital, Zeytinburnu, Turkey(for sekond author)
Aziz Sumer	A Sumer	Istinye University, School of Medicine, Istanbul, Turkey
Caghan Peksen	C Peksen	Istinye University, School of Medicine, Istanbul, Turkey
Osman Anil Savas	OA Savas	Istinye University, School of Medicine, Istanbul, Turkey
Elias Chousleb	E Chousleb	Jackson North Medical Center, Miami Fl
fahad Elmokayed	F Elmokayed	king Abdul aziz hospital, Alhasa,saudi arabia
islam fakhereldin	F Islam	king Abdul aziz hospital, Alhasa,saudi arabia
Hany Mohamed Aboshanab	H Aboshanab	king Abdul aziz hospital, Alhasa,saudi arabia
Talal swelium	T Swelium	king Abdul aziz hospital, Alhasa,saudi arabia
Ahmad Gudal	A Gudal	King Abdullah Medical Complex, Jeddah, KSA
Lamees Gamloo	L Gamloo	King Abdullah Medical Complex, Jeddah, KSA
Ayushka Ugale	A Ugale	Kirloskar Hospital, Hyderabad, India
Surendra Ugale	S Ugale	Kirloskar Hospital, Hyderabad, India
Clara Boeker	C Boeker	Klinikum Region Hannover- Klinikum Nordstadt
Christian Reetz	C Reetz	Klinikum Region Hannover- Klinikum Nordstadt
Ibrahim Ali Hakami	I Hakami	Klinikum Region Hannover- Klinikum Nordstadt
Julian Mall	J Mall	Klinikum Region Hannover- Klinikum Nordstadt
Andreas Alexandrou	A Alexandrou	Laiko General Hospital, National and Kapodistrian University of Athens, Greece
Efstratia Baili	E Baili	Laiko General Hospital, National and Kapodistrian University of Athens, Greece
Zsolt Bodnar	Z Bodnar	Letterkenny University Hospital, Letterkenny, Ireland
Almantas Maleckas	A Maleckas	Lithuanian University of Health Sciences, Surgery Department, Kaunas, Lithuania
Rita Gudaityte	R Gudaityte	Lithuanian University of Health Sciences, Surgery Department, Kaunas, Lithuania
Cem Emir Guldogan	CE Guldogan	Liv Hospital Ankara, Turkey
Emre Gundogdu	E Gundogdu	Liv Hospital Ankara, Turkey
Mehmet Mahir Ozmen	MM Ozmen	Liv Hospital Ankara, Turkey
Deepti Thakkar	D Thakkar	Livlife Hospitals, Hyderabad, India
Nandakishore Dukkipati	N Dukkipati	Livlife Hospitals, Hyderabad, India
Poonam Shashank Shah	P Shah	LOC Healthcare LLP, Pune, India
Shashank Subhashchandra Shah	S Shah	LOC Healthcare LLP, Pune, India
Simran Shashank Shah	SS Shah	LOC Healthcare LLP, Pune, India



Full Name	Initial and Surname	Institution
Md Tanveer Adil	MT Adil	Luton and Dunstable Hospital
Periyathambi Jambulingam	P Jambulingam	Luton and Dunstable Hospital
Ravikrishna Mamidanna	R Mamidanna	Luton and Dunstable Hospital
Douglas Whitelaw	D Whitelaw	Luton and Dunstable University Hospital
Md Tanveer Adil	MT Adil	Luton and Dunstable University Hospital
Vigyan Jain	V Jain	Luton and Dunstable University Hospital
Deepa Kizhakke Veetil	Deepa KV	Manipal Hospital, New Delhi, India
Randeep Wadhawan	R Wadhawan	Manipal Hospital, New Delhi, India
Antonio Torres	A Torres	Max Medical, centro de cirugía bariátrica/robótica, Hospital Metropilitano de Quito/Ecuador
Max Torres	M Torres	Max Medical, centro de cirugía bariátrica/robótica, Hospital Metropilitano de Quito/Ecuador
Tabata Tinoco	T Tinoco	Max Medical, centro de cirugía bariátrica/robótica, Hospital Metropilitano de Quito/Ecuador
Wouter Leclercq	W Leclercq	Máxima Medical Center, Veldhoven, The Netherlands
Marleen Romeijn	M Romeijn	Máxima Medical Center, Veldhoven, The Netherlands
Kelly van de Pas	K van de Pas	Máxima Medical Center, Veldhoven, The Netherlands
Ali K. Alkhazraji	A Alkhazraji	Mediclinic Hospital Airport Road, Abu Dhabi, UAE.
Safwan A. Taha	S Taha	Mediclinic Hospital Airport Road, Abu Dhabi, UAE.
Murat Ustun	M Ustun	Memorial Hospital, Istanbul, Turkey
Taner Yigit	T Yigit	Memorial Hospital, Istanbul, Turkey
Aatif Inam	A Inam	Metabolic, Thoracic & General Surgery Team III, Department of General Surgery, Pakistan Institute of Medical Sciences (PIMS), Islamabad, Pakistan.
Muhammad Burhanulhaq	M Burhan UlHaq	Metabolic, Thoracic & General Surgery Team III, Department of General Surgery, Pakistan Institute of Medical Sciences (PIMS), Islamabad, Pakistan.
Abdolreza Pazouki	A Pazouki	Minimally Invasive Surgery Research Center, Division of Minimally invasive and Bariatric surgery, Department of Surgery, Rasool-e Akram Hospital, Iran University of Medical Sciences, Tehran, Iran
Foolad Eghbali	F Eghbali	Minimally Invasive Surgery Research Center, Division of Minimally invasive and Bariatric surgery, Department of Surgery, Rasool-e Akram Hospital, Iran University of Medical Sciences, Tehran, Iran
Mohammad Kermansaravi	M Kermansaravi	Minimally Invasive Surgery Research Center, Division of Minimally invasive and Bariatric surgery, Department of Surgery, Rasool-e Akram Hospital, Iran University of Medical Sciences, Tehran, Iran
Amir Hosein Davarpanah Jazi	AH Davarpanah Jazi	Minimally Invasive Surgery Research Center, Isfahan University of Medical Sciences, Isfahan, Iran
Mohsen Mahmoudieh	M Mahmoudieh	Minimally Invasive Surgery Research Center, Isfahan University of Medical Sciences, Isfahan, Iran
Neda Mogharehabed	N Mogharehabed	Minimally Invasive Surgery Research Center, Isfahan University of Medical Sciences, Isfahan, Iran
Gregory Tsiotos	G Tsiotos	MITERA Hospital, Athens, Greece
Konstantinos Stamou	K Stamou	MITERA Hospital, Athens, Greece
Francisco J. Barrera Rodriguez	F Barrera-Rdz	Monterrey Gastro & Bariatric Group, Monterrey Mexico
Marco A. Rojas Navarro	MA Rojas-Navarro	Monterrey Gastro & Bariatric Group, Monterrey Mexico
Omar MOhamed Torres	O Mohamed-Torres	Monterrey Gastro & Bariatric Group, Monterrey Mexico
Sergio Lopez Martinez	S Lopez-Mtz	Monterrey Gastro & Bariatric Group, Monterrey Mexico
Elda Rocio Maltos Tamez	E Maltos	MtyBariatrics, Monterrey, Nuevo Leon, Mexico
Gustavo A. Millan Cornejo	G Millan	MtyBariatrics, Monterrey, Nuevo Leon, Mexico
Jose Eduardo Garcia Flores	J Garcia-Flores	MtyBariatrics, Monterrey, Nuevo Leon, Mexico



Full Name	Initial and Surname	Institution
Diya Aldeen Mohammed	D Mohammed	Najjar Hospital, Beirut, Lebanon
Mohamad Hayssam Elfawal	M Elfawal	Najjar Hospital, Beirut, Lebanon
Asim Shabbir	A Shabbir	National University Hospital Singapore
Kim Guowei	G Kim	National University Hospital Singapore
Jimmy BY So	J So	National University Hospital Singapore
Elif Tuğçe Kaplan	ET Kaplan	NCR International Hospital, Gaziantep, Turkey
Mehmet Kaplan	M Kaplan	NCR International Hospital, Gaziantep, Turkey
Tuğba Kaplan	T Kaplan	NCR International Hospital, Gaziantep, Turkey
DangTuan Pham	DT Pham	Niagara Falls Memorial Medical Center, Niagara Falls, NY, USA
Gurteshwar Rana	G Rana	Niagara Falls Memorial Medical Center, Niagara Falls, NY, USA
Mojdeh Kappus	M Kappus	Niagara Falls Memorial Medical Center, Niagara Falls, NY, USA
Riddish Gadani	R Gadani	NOBESITY BARIATRIC CENTRE, K D HOSPITAL, AHMEDABAD, INDIA
Manish Kahitan	M Khaitan	NOBESITY BARIATRIC CENTRE, K D HOSPITAL, AHMEDABAD, INDIA
Koshish Pokharel	K Pokharel	NOBESITY BARIATRIC CENTRE, K D HOSPITAL, AHMEDABAD, INDIA
Alan Osborne	A Osborne	North Bristol NHS Trust
Dimitri Pournaras	DJ Pournaras	North Bristol NHS Trust
James Hewes	J Hewes	North Bristol NHS Trust
Errichetta Napolitano	E Napolitano	Obesity and Metabolic Surgery Unit, Ospedale Evangelico Betania, Naples,
	·	Italy
Sonja Chiappetta	S Chiappetta	Obesity and Metabolic Surgery Unit, Ospedale Evangelico Betania, Naples, Italy
Vincenzo Bottino	V Bottino	Obesity and Metabolic Surgery Unit, Ospedale Evangelico Betania, Naples, Italy
evelyn dorado	E Dorado	obesity and stethic surgery clinic clinica med cali colombia
Axel Schoettler	A Schoettler	Obesity Center, Municipal Hospital Karlsruhe, Germany
Daniel Gaertner	D Gaertner	Obesity Center, Municipal Hospital Karlsruhe, Germany
Katharina Fedtke	K Fedtke	Obesity Center, Municipal Hospital Karlsruhe, Germany
Francisco Aguilar-Espinosa	F Aguilar-Espinosa	Obesity Clinic: Los Altos Obesity Surgery, Tepatitlan, Mexico
Saul Aceves-Lozano	S Aceves-Lozano	Obesity Clinic: Los Altos Obesity Surgery, Tepatitlan, Mexico
Alessandro Balani	A Balani	Ospedale di Gorizia, Italy. Struttura Complessa Chirurgia Generale
Carlo Nagliati	C Nagliati	Ospedale di Gorizia, Italy. Struttura Complessa Chirurgia Generale
Damiano Pennisi	D Pennisi	Ospedale di Gorizia, Italy. Struttura Complessa Chirurgia Generale
Andrea Rizzi	A Rizzi	Ospedale Galmarini Tradate, Varese, Italy
Francesco Frattini	F Frattini	Ospedale Galmarini Tradate, Varese, Italy
Diego Foschi	D Foschi	Ospedale San Giuseppe IRCCS Multimedica, University of Milan, Milan, Italy
Laura Benuzzi	L Benuzzi	Ospedale San Giuseppe IRCCS Multimedica, University of Milan, Milan, Italy
CHIRAG PARIKH	C Parikh	PARUL INSTITUTE OF MEDICAL SCIENCES & RESEARCH, PARUL UIVERSITY, WAGHODIA, VADODARA, INDIA
HARSHIL SHAH	H Shah	PARUL INSTITUTE OF MEDICAL SCIENCES & RESEARCH, PARUL UIVERSITY, WAGHODIA, VADODARA, INDIA
Enrico Pinotti	E Pinotti	Policlinico San Pietro, Bergamo, Italy, Unitá di Chirurgia Bariatrica
Mauro Montuori	M Montuori	Policlinico San Pietro, Bergamo, Italy, Unitá di Chirurgia Bariatrica
Vincenzo Borrelli	V Borrelli	Policlinico San Pietro, Bergamo, Italy, Unitá di Chirurgia Bariatrica
Jerome Dargent	J Dargent	Polyclinique Lyon-Nord, 69 140 Rillieux, France
Catalin A COPAESCU	CA Copaescu	PONDERAS ACADEMIC HOSPITAL, Bucharest, ROMANIA
Ionut HUTOPILA	l Hutopila	PONDERAS ACADEMIC HOSPITAL, Bucharest, ROMANIA
Bogdan SMEU	SMEU Bogdan	PONDERAS ACADEMIC HOSPITAL, Bucharest, ROMANIA
-	<u> </u>	,



Full Name	Initial and Surname	Institution
Bart Witteman	B Witteman	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Eric Hazebroek	E Hazebroek	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Laura Deden	L Deden	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Laura Heusschen	L Heusschen	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Sietske Okkema	S Okkema	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Theo Aufenacker	T Aufenacker	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Willem den Hengst	W den Hengst	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Wouter Vening	W Vening	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Yonta van der Burgh	Y van der Burgh	Rijnstate Hospital/Vitalys Clinics, Arnhem, the Netherlands
Ahmad Ghazal	A Ghazal	Saint Louis Hospital - Aleppo, Syria
Hamza Ibrahim	H Ibrahim	Saint Louis Hospital - Aleppo, Syria
Mourad Niazi	M Niazi	Saint Louis Hospital - Aleppo, Syria
Bilal Alkhaffaf	B Alkhaffaf	Salford Royal NHS Foundation Trust
Mohammad Altarawni	M Altarawni	Salford Royal NHS Foundation Trust
Giovanni Carlo Cesana	GC Cesana	San Marco Hospital GSD, Zingonia (BG), Italy
Marco Anselmino	M Anselmino	San Marco Hospital GSD, Zingonia (BG), Italy
Matteo Uccelli	M Uccelli	San Marco Hospital GSD, Zingonia (BG), Italy
Stefano Olmi	S Olmi	San Marco Hospital GSD, Zingonia (BG), Italy
Christine Stier	C Stier	Sana Obesity Center Northrhine Westphalia, Clinic for General, Visceral,
	5 5 t. 6.	and Transplantation Surgery, RWTH University Aachen.
Tahsin Akmanlar	T Akmanlar	Sana Obesity Center Northrhine Westphalia, Clinic for General, Visceral, and Transplantation Surgery, RWTH University Aachen.
Thomas Sonnenberg	T Sonnenberg	Sana Obesity Center Northrhine Westphalia
Uwe Schieferbein	U Schieferbein	Sana Obesity Center Northrhine Westphalia
Alejandro Marcolini	A Marcolini	Sanatorio Britanico de Rosario, Rosario, Santa Fe, Argentina
Diego Awruch	D Awruch	Sanatorio Britanico de Rosario, Rosario, Santa Fe, Argentina
Marco Vicentin	M Vicentin	Sanatorio Britanico de Rosario, Rosario, Santa Fe, Argentina
Eduardo Lemos de Souza Bastos	E Bastos	Santa Casa de Marilia, Marilia, Brazil
Samuel Azenha Gregorio	S Gregorio	Santa Casa de Marilia, Marilia, Brazil
Anmol ahuja	A Ahuja	sir ganga ram hospital delhi india
Tarun mittal	T Mittal	sir ganga ram hospital delhi india
Roel Bolckmans	R Bolckmans	Somerset NHS Foundation Trust
Tom Wiggins	T Wiggins	Somerset NHS Foundation Trust
Clément Baratte	C Baratte	Sorbonne Université, Institute of Cardiometabolism and Nutrition ICAN, Assistance Publique-Hôpitaux de Paris, Departments of Digestive surgery and Nutrition, Pitié-Salpêtrière University Hospital, Paris, France.
Judith Aron Wisnewsky	J Aron Wisnewsky	Sorbonne Université, Institute of Cardiometabolism and Nutrition ICAN, Assistance Publique-Hôpitaux de Paris, Departments of Digestive surgery and Nutrition, Pitié-Salpêtrière University Hospital, Paris, France.
Laurent Genser	L Genser	Sorbonne Université, Institute of Cardiometabolism and Nutrition ICAN, Assistance Publique-Hôpitaux de Paris, Departments of Digestive surgery and Nutrition, Pitié-Salpêtrière University Hospital, Paris, France.
Lynn Chong	L Chong	St Vincent's Hospital Melbourne
Lillian Taylor	L Taylor	St Vincent's Hospital Melbourne
Salena Ward	S Ward	St Vincent's Hospital Melbourne
Lynn Chong	L Chong	St Vincent's Hospital, Melbourne, Australia
Lillian Taylor	L Taylor	St Vincent's Hospital, Melbourne, Australia
Michael W Hi	MW Hii	St Vincent's Hospital, Melbourne, Australia
		. ,

Full Name	Initial and Surname	Institution
Naomi Fearon	N Fearon	St Vincent's University Hospital, Dublin, Ireland
Andreas Plamper	A Plamper	St. Franziskus Hospital, Cologne, Germany
Karl Rheinwalt	K Rheinwalt	St. Franziskus Hospital, Cologne, Germany
Helen Heneghan	H Helenghan	St. Vincent's University Hospital, Dublin, Ireland
Justin Geoghegan	J Geoghegan	St. Vincent's University Hospital, Dublin, Ireland
Kin Cheung Ng	KC Ng	St. Vincent's University Hospital, Dublin, Ireland
Naomi Fearon	N Fearon	St. Vincent's University Hospital, Dublin, Ireland
Krzysztof Kaseja	K Kaseja	State Clinical Hospital No 2 of the Pomeranian Medical University in Szczecin, Poland
Maciej Kotowski	M Kotowski	State Clinical Hospital No 2 of the Pomeranian Medical University in Szczecin, Poland
Tarig A Samarkandy	T Samarkandy	Sutter Gould Medical Foundation, Dameron Hospital - Ca, USA
Adolfo Leyva-Alvizo	A Leyva-Alvizo	Tecnologico de Monterrey, Monterrey, MX
Lourdes Corzo-Culebro	L Corzo-Culebro	Tecnologico de Monterrey, Monterrey, MX
Cunchuan Wang	C Wang	The First Affiliated Hospital of Jinan University, Guangzhou, China
Wah Yang	W Yang	The First Affiliated Hospital of Jinan University, Guangzhou, China
Zhiyong Dong	Z Dong	The First Affiliated Hospital of Jinan University, Guangzhou, China
Manel Riera	M Riera	The Shrewsbury and Telford Hospital, Shrewsbury, UK
Rajesh Jain	R Jain	The Shrewsbury and Telford Hospital, Shrewsbury, UK
Hosam Hamed	H Hamed	Truelife bariatric and digestive surgery center, Mansoura, Dakahleyya, Egypt
Mohammed Said	M Said	Truelife bariatric and digestive surgery center, Mansoura, Dakahleyya, Egypt
Katia Zarzar	K Zarzar	Tu Opcion Bariatrica
Manuel Garcia	M Garcia	Tu Opcion Bariatrica
Ahmet Gökhan Türkçapar	AG Türkçapar	Türkçapar Bariatrics Obesity Center, İstanbul, Turkey
Ozan Şen	O Şen	Türkçapar Bariatrics Obesity Center, İstanbul, Turkey
Edoardo Baldini	E Baldini	U.O. Chirurgia, Ospedale "Guglielmo da Saliceto", Piacenza, Italy
Luigi Conti	L Conti	U.O. Chirurgia, Ospedale "Guglielmo da Saliceto", Piacenza, Italy
Cacio Wietzycoski	C Wietzycoski	Unimed Vale do Caí Hospital, Montenegro, BR. Maicé Hospital, Caçador, BR
Eduardo Lopes	E Lopes	Unimed Vale do Caí Hospital, Montenegro, BR. Maicé Hospital, Caçador, BR
Tadeja Pintar	T Pintar	University Medical Center Ljubljana, Slovenia
Jure Salobir	J Salobir	University Medical Center Ljubljana, Slovenia
Cengiz Aydin	C Aydin	University of Health Sciences Tepecik Training and Research Hospital, Department of General Surgery, Izmir, Turkey
Semra Demirli Atici	SD Atici	University of Health Sciences Tepecik Training and Research Hospital, Department of General Surgery, Izmir, Turkey
Anıl Ergin	A Ergin	University of Health Sciences, Fatih Sultan Mehmet Training and Research Hospital, General Surgery Department, Istanbul, Turkey
Huseyin Ciyiltepe	H Ciyiltepe	University of Health Sciences, Fatih Sultan Mehmet Training and Research Hospital, General Surgery Department, Istanbul, Turkey
Mehmet Abdussamet Bozkurt	MA Bozkurt	University of Health Sciences, Kanuni Sultan Süleyman Training and Research Hospital, Istanbul, Turkey
Mehmet Celal Kizilkaya	MC Kizilkaya	University of Health Sciences, Kanuni Sultan Süleyman Training and Research Hospital, Istanbul, Turkey
Nezihe Berrin Dodur Onalan	NB Dodur Onalan	University of Health Sciences, Kanuni Sultan Süleyman Training and Research Hospital, Istanbul, Turkey
Mariana Nabila Binti Ahmad Zuber	MNB Ahmad Zuber	University of Malaya Medical Centre, Kuala Lumpur, Malaysia



Full Name	Initial and Surname	Institution
Wei Jin Wong	WJ Wong	University of Malaya Medical Centre, Kuala Lumpur, Malaysia
Amador Garcia	A Garcia	Vall d'Hebron University Hospital, Barcelona, Spain
Laura Vidal	L Vidal	Vall d'Hebron University Hospital, Barcelona, Spain
Marc Beisani	M Beisani	Vall d'Hebron University Hospital, Barcelona, Spain
Jorge Pasquier	J PAsquier	Vall Hebron Hospital Campus - Hospital de Barcelonoa-SCIAS
Ramon Vilallonga	R Vilallonga	Vall Hebron Hospital Campus - Hospital de Barcelonoa-SCIAS
Sharad Sharma	S Sharma	Vinamra Swaraj Hospital, Navi Mumbai, India
Chetan Parmar	C Parmar	Whittington Health NHS Trust, London, United Kingdom
Lyndcie Lee	L Lee	Whittington Health NHS Trust, London, United Kingdom
Pratik Sufi	P Sufi	Whittington Health NHS Trust, London, United Kingdom
Hüseyin Sinan	H Sinan	www.metabolistsurgery.com Istanbul Turkey
Mehmet Saydam	M Saydam	www.metabolistsurgery.com Istanbul Turkey