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Laparoscopic bariatric surgery is safe during phase 2–3 of COVID-19 pandemic in Italy: A multicenter, prospective, observational study

Gianfranco Silecchia^{a,*}, Cristian E. Boru^a, Giuseppe M. Marinari^b, Paolo Gentileschi^c, Mario Morino^d, Stefano Olmi^e, Mirto Foletto^f, Paolo Bernante^g, Riccardo Morganti^h, Carlo Tasciniⁱ, Marco Anselmino^j, Emanuela Bianciardi^c, Michela Campanelli^c, Luigi Fiorello^f, Rudj Mancini^j, Alberto Oldani^e, Matteo Rottoli^g, Antonio Salzano^d, Manuela Trotta^b, and the cooperative RESTART group

^a Division of General Surgery and Bariatric Center of Excellence IFSO-EC, Department of Medico-Surgical Sciences and Biotechnologies, University “La Sapienza” of Rome, Via Corso della Repubblica 79, Latina, LT 04100, Italy

^b Bariatric Unit, Humanitas Clinical and Research Hospital, IRCCS Rozzano, Milan Via A. Manzoni 56, Rozzano, MI 20089, Italy

^c Department of Bariatric and Metabolic Surgery, San Carlo of Nancy Hospital and “Tor Vergata” University of Rome, Via Aurelia 275, Roma, RM 00165, Italy

^d General Surgery, Department of Surgical Sciences, University of Turin, Via Corso Bramante 88, Turin, TO 10126, Italy

^e Department of General and Oncological Surgery, Center of Bariatric Surgery, Policlinico San Marco di Zingonia, Bergamo Corso Europa 7, Zingonia, BG 24040, Italy

^f Bariatric Surgery Unit, Azienda Ospedaliera of University of Padova, Via Nicolò Giustiniani 2, Padova, PD 35128, Italy

^g Metabolic and Obesity Surgery Unit, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Centre for the Study and Research of Treatment for Morbid Obesity, Department of Medical and Surgical Sciences, Alma Mater Studiorum University of Bologna, Via Giuseppe Massarenti 9, Bologna, BO 40138, Italy

^h Section of Statistics, University Hospital of Pisa, Via Roma, 67, Pisa, PI 56126, Italy

ⁱ Infectious Diseases Clinic, DAME, University of Udine, P.le S. Maria della Misericordia, 15, Udine, UD 33100, Italy

^j Bariatric and Metabolic Surgery Unit, Azienda Ospedaliera at University of Pisa, Via Roma, 67, Pisa, PI 56126, Italy

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ABSTRACT

Background: Sars-Cov-2 epidemic in Italy caused one of the greatest 2020 European outbreaks, with suspension of elective bariatric/metabolic surgery (BMS). From May 2020 a significant decline of the epidemic has been observed (phase 2); National Health Service protocols permitted elective BMS' resumption. A new, more severe COVID-19 surge, the “second wave”, started on October 2020 (phase 3).

Aim: The primary end point was to analyze the outcomes of any Sars-Cov-2 infection and related morbidity/mortality within 30 POD after laparoscopic BMS during phase 2–3; secondary end points were readmission and reoperation rates.

* Corresponding author at: Division of General Surgery & Bariatric Center of Excellence-IFSO EC, Department of Medico-Surgical Sciences and Biotechnologies University La Sapienza of Rome, Via Corso della Repubblica, 79, Latina, LT 04100, Italy.

E-mail addresses: gianfranco.silecchia@uniroma1.it (G. Silecchia), cristian.boru@uniroma1.it (C.E. Boru), giuseppe.marinari@humanitas.it (G. M. Marinari), gentileschi.paolo@gmail.com (P. Gentileschi), mario.morino@unito.it (M. Morino), stefano.olmi@gmail.com (S. Olmi), mirto.foletto@unipd.it (M. Foletto), paolo.bernante@aosp.bo.it (P. Bernante), r.morganti@ao-pisa.toscana.it (R. Morganti), c.tascini@gmail.com (C. Tascini), m.anselmino@me.com (M. Anselmino).

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Keywords:

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 Safety
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 Guidelines
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 Sars-Cov-2 infection

Methods: Study design prospective, multicenter, observational.

Setting: Eight Italian high-volume bariatric centers. All patients undergoing BMS from July 2020 through January 2021 were enrolled according to the following criteria: no Sars-Cov-2 infection; primary procedures; no concomitant procedure; age > 18 < 60 years; compensated comorbidities; informed consent including COVID-19 addendum; adherence to specific admission, in-hospital and follow-up protocols. Data were collected in a prospective database. Patients undergone BMS during July-December 2019 were considered a control group.

Results: 1258 patients were enrolled and compared with 1451 operated on in 2019, with no differences for demographics, complications, readmission, and reintervention rates. Eight patients (0.6%) tested positive for Sars-Cov-2 infection after discharge, as well as 15 healthcare professionals, with no related complications or mortality.

Conclusions: Introduction of strict COVID-19 protocols concerning the protection of patients and health-care professionals guaranteed a safe resumption of elective BMS in Italy. The safety profile was, also, maintained during the second wave of outbreak, thus allowing access to a cure for the obese population.

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1. Introduction

A temporary suspension of the bariatric surgical programs all over the world was one of the immediate consequences of the Sars-Cov-2 virus generated pandemics, especially in Italy, the first European country seriously affected by the Coronavirus disease 2019 (COVID-19). The first indigenous person-to-person Sars-Cov-2 transmission in Italy was reported on February 2nd, and by March 3rd, 2020 all elective bariatric and metabolic surgical procedures (BMS) were suspended. Due to the rapid spread and the aggressive nature of the virus it was considered safer to postpone all elective surgical procedures, in order to preserve the resources and significantly curb the viral transmission/circulation [1]. BMS is a highly demanding resource field, both human and logistics, involving activities at high risk of transmission, such as airway management [2]. One year later more than 3,900,000 coronavirus cases, and over 127,000 related deaths, have been registered in Italy (<http://www.salute.gov.it/portale/home.html>).

Obesity represents a chronic disease, a pro-coagulant and pro-inflammatory state which may increase the risk of thrombosis and exaggerated cytokines and oxidative stress

response [3]. The role of obesity during the outbreak has not been ignored, being independently associated with increased risk for intensive care unit (ICU) admission and intubation [4]. Obesity, an already recognized pandemic itself, being associated with a higher risk of infectious diseases, in particular of the respiratory tract [5,6], plays an important role in a more serious outcomes from Sars-Cov-2 infection, with a higher risk of developing severe pneumonia, especially in men [7,8]. Furthermore, obesity is associated with, and responsible for, comorbid conditions that may represent an increased risk of unfavorable Sars-Cov-2 infection outcomes [9,10].

So far, BMS represents the most effective treatment in obtaining a long-term meaningful weight loss [11], and resolution of related comorbidities, including respiratory disorders [12–14]. Recent findings suggests that BMS is associated with a lower rate of mortality and hospital admission in patients with obesity who, afterwards become infected with SARS-CoV-2 [2,15]. In May 2020, a slight decrease of the pandemic was observed in Italy and a gradual and progressive decrease of the lockdown restrictions was started (phase 2), when the virus was supposed to be under control and protocols and regulations were guiding National Healthcare Sys-

Table 1 – Participating centers to the study and regional location in Italy.

Center	Italian Region
Division of General Surgery and Bariatric Center of Excellence IFSO-EC, Department of Medico-Surgical Sciences and Biotechnologies, University “La Sapienza” of Rome	Central
Bariatric Unit, Humanitas Clinical and Research Hospital, IRCCS Rozzano, Milan	North
Department of Bariatric and Metabolic Surgery, San Carlo of Nancy Hospital & “Tor Vergata” University of Rome	Central
General Surgery, Department of Surgical Sciences, University of Turin	North
Department of General and Oncological Surgery, Center of Bariatric Surgery, Policlinico San Marco di Zingonia, Bergamo	North
Bariatric Surgery Unit, Azienda Ospedaliera of University of Padova	North
Bariatric & Metabolic Surgery Unit, Department of Medical and Surgical Sciences, Azienda Ospedaliera Universitaria Policlinico di Sant’Orsola Bologna	Central
Bariatric and Metabolic Surgery Unit, Azienda Ospedaliera at University of Pisa	Central Backspace

tem (SSN) in order to restart elective surgical practice, including BMS.

In a previous paper we reported the results of a multicenter retrospective study, evaluating the risk of infection during 840 BMS procedures, performed without specific precautions during January-February 2020 (when the circulation of the virus has been subsequently demonstrated) [16]. We found five infections (5.9 cases of 1000 inhabitants), two had mild symptoms requiring home treatment, and three were hospitalized for fever and dyspnea; none died, all made a full recovery. In the same group of patients, the rate of postoperative complications was similar in comparison to the rate recorded in patients undergoing BMS in the eight centers during the same period of 2019: 14 severe complications (Clavien-Dindo III-IV grade classification) [17] vs. 12 grade III in 2019, showing a similar outcome ($p = 0.701685$). With a view to a progressive and prudent restart of elective BMS, while fully respecting patient safety, the need for the curative surgery, and the prioritization criteria, an expert panel of bariatric surgeons and infectious disease specialists agreed on the criteria for patient selection, protocols, both in and out of hospital, to minimize the risk of Sars-Cov-2 infection in phase.

Unfortunately, in October 2020 a third phase of the pandemic started, with a new wave of infection spreading in Europe and Italy, forcing the selective closure of elective bariatric activity, for a temporary period (2–4 weeks) based on epidemiological data and the government's strategy.

Primary end point: Mortality and morbidity over 30 postoperative days (POD) from Sars-Cov-2 infection, in order to check the effectiveness of the hospitals' protocols in minimizing the risk of postoperative infection after elective BMS. **Secondary end points:** perioperative readmission rate (30 days), reoperations for any reason, and infection rate among healthcare professionals.

2. Methods

This was a multicenter, prospective, observational study carried out in eight Italian, SSN's high-volume bariatric centers (Table 1). The study was conducted in accordance with the

principles of Good Clinical Practice, as well as with the study's protocol registered within clinicaltrials.gov (NCT04480034 Unique Protocol ID: 0008758/27.05.2020). The study was approved by the Local Ethical Committee (Lazio 2 Rome, Protocol no. 0104898/2020 of 26/06/2020) as well as by the local Boards and Ethical Committee of each participating center. The protocol respects the STROBE statement and checklist [18] and did not change during the study's period: July 2020 – January 2021. Candidates were enrolled according to the following criteria: no previous Sars-Cov-2 infection; primary bariatric surgery; no concomitant procedure, excluding hiatal hernia repair; no previous major abdominal surgery; >18 < 60 years old; compensated comorbidities; BMI < 60 kg/m²; laparoscopic standard bariatric procedure endorsed by Italian Society for Obesity Surgery (SICOB); estimated procedure duration < 120 min; official SICOB's surgical informed consent given, including COVID-19 and participation to the study addendums.

All the participating centers followed the standard recruitment, ambulatory (including telemedicine) and in-hospital, OR and after discharge protocols, updated to the national and regional guidelines [19,20,21]. Patients with obesity were considered eligible for surgery, maximizing equity of access and minimizing the harm from delayed access [22,23].

3. Hospital admission, in-hospital and OR management and after discharge protocols

3.1. Hospital admission protocol

The patient was checked 2–3 days before admission by telephone interview (Table 2), to rule out fever (threshold value > 37.5 °C/99.5°F), respiratory symptoms, vomiting, diarrhea, conjunctivitis, changes in smell or taste, osteoarticular pain, excessive fatigue, or contact in the previous two weeks with a confirmed case (clinical diagnosis - positive swab for Sars-Cov-2); a PCR/antigenic swab Sars-Cov-2 test was performed in all enrolled patients 24–48 h prior to hospital admission. The medical staff repeated the above interview on admission and the patient received and signed a specific

Table 2 – Patients' COVID-19 questionnaire over the phone: preoperative (2 days before hospital admission) and postoperative (7th & 14th postoperative day and directly at the outpatient visit on the 30th).

Patients preoperative and postoperative COVID-19 survey
Preoperative (2 days before admission, over the phone)
During the 30 days prior to the surgery did you travel abroad or outside your region or were you exposed to people that travelled abroad/outside your region?
During the 30 days prior to the surgery were you exposed to people who were diagnosed with COVID-19? Yes/ no. How, how long?
During the 30 days prior to the surgery did you experience any symptoms concerning of COVID-19, including: respiratory symptoms, vomiting, diarrhea, conjunctivitis, changes in smell or taste, osteoarticular pain, excessive fatigue? Yes/ no. Which?
Postoperative (over the phone on the 7th & 14th postoperative day and direct on the 30th)
During the 7/14/30 days after the surgery did you experience any symptoms concerning of COVID-19, including: respiratory symptoms, vomiting, diarrhea, conjunctivitis, changes in smell or taste, osteoarticular pain, excessive fatigue? Yes/ no. Which?
During the 7/14/30 days after the surgery were you exposed to people who were diagnosed with COVID-19? Yes/ no. How?
During the 7/14/30 days after the surgery were you diagnosed or hospitalized with COVID-19? Yes/ no. How?

COVID-19 consent, together with specific bariatric operation consent and participation in the study. Further screening before admission consisted of a chest X-ray or CT-scan, and blood analysis.

3.2. Operating Room (OR) protocol

Standard personal protective equipment (PPE) plus N95 masks for the surgeons, while for the anesthesiologists and nurses who managed the airways and gastric bougie positioning, the N99 mask was recommended, using face shields, single-use waterproof gowns, and double gloves; restricted access in the OR; expert surgeons and anesthesiologists performed the procedures to minimize the OR occupation time; a smoke evacuator system was employed to avoid air-borne contamination; in the alternative, a filter was connected to the exsufflation system. A negative pressure in the OR was not mandatory, but it was crucial to allow enough time between consecutive cases for a change of air in the room. When the OR was used for intensive care during phase 1 of the pandemic, proper sanitization was a necessity.

3.3. Management of in-hospital patients

No COVID-19 hospital/section was used for elective BMS; standard PPE for staff was mandatory; social distancing had to be respected even in the case of post-surgical mobilization; patients had to wear a surgical mask at all times. Each patient received a single room, however in the case of a larger ward being used, he/she was assigned a suitable space in compliance with social distancing regulations. ERAS (Enhanced Recovery After Surgery) protocol was used whenever possible. Where >48 h hospitalization was needed, Sars-Cov-2 tests were performed on discharge. No visitors were allowed. All caregivers were required to wear masks at all times. Policies were implemented to transfer COVID-19 patients to other facilities.

3.4. After discharge

In the case of intra-hospital contact with Sars-Cov-2 positive patient or healthcare professional, 14 days self-quarantine after discharge was mandatory. After 7 and 14 POD patients received a follow-up phone call, with specific questions about COVID-19 (Table 2) to quantify the number of symptomatic patients, who were tested and diagnosed with COVID-19. First outpatient visit was scheduled for the 30th POD, when the same data acquiring protocol was used.

3.5. Patients and public involvement

Patients were not involved in designing the research questions, outcome measures, or interpretation or writing up of results of this study. Patients' representatives, in our ethics committee, were asked for comments on general comprehensibility. The patients' representatives of each participating hospital were informed about the study and its start. Results will be presented to patients and public as part of regular information events.

Table 3 – Demographics of the study participants; bariatric/metabolic operation types and numbers; number of obese patients presenting comorbidities. Participants were enrolled July 15, 2020–January 31, 2021 (study group); control group was consisted of patients operated between July,1 2019–December 31, 2019.

Factor	2019	2020–21	p-value
N	1451	1258	
Age (y)	42.1 (11)	42.7 (10.5)	0.174
Height (m)	1.66 (0.09)	1.66 (0.09)	0.575
Weight (Kg)	120.9 (20.4)	121.2 (20.1)	0.738
BMI (Kg/m ²)	43.6 (5.3)	43.6 (5.4)	0.910
Operation time (min)	60.3 (19.4)	58.9 (22)	0.160
Gender			
Female	1012 (69.7)	889 (70.7)	0.599
Male	439 (30.3)	369 (29.3)	0.599
Operation type			
Sleeve gastrectomy	1225 (84.4)	1109 (88.2)	0.005
R-en-Y gastric bypass	166 (11.4)	97 (7.7)	0.001
OAGB/MGB	60 (4.1)	52 (4.1)	0.923
Comorbidity	867 (59.7)	711 (56.5)	0.005

Information on patient demographics including age, sex, Body Mass Index (BMI) and co-morbidities, operation details such as the type and duration of BMS, were collected. Perioperative outcomes including length of stay, ICU admissions, Emergency Department (ED) visits, re-admissions, re-operation, complications, and mortality within 30 days were also analyzed. For the 2020 cohort, pre- and post-operative Sars-Cov-2 PCR testing results and the development of any related symptoms were included.

The Rt index, or the R number, describes the average number of secondary infections generated by an infected person on a certain date. It was used by the Italian Government to monitor the progression of the epidemic. A value of Rt above the threshold (Rt 1), even in presence of a low number of cases, was interpreted as an alarming sign of the escalating trend of the epidemic.

All data were collected from a prospectively maintained, online registry. In this prospective observational longitudinal study, categorical data were described by absolute and relative frequency, continuous data by mean, standard deviation and range. To compare qualitative and quantitative clinical/anthropometric factors between the two groups of study (2019; 2020–21) z-test for two proportions and t-test (two-tailed) were used, respectively. Significance was fixed at 0.05 and all analyses were carried out by SPSS v.27 software.

4. Results

Elective laparoscopic BMS in the eight participating centers, was made up on a cohort of 1258 patients, vs. 1451 patients operated during June - December 2019, with no difference in demographics, complications, readmission, and reintervention rates (Table 3). Follow-up was completed in 100% of the cases for each center. No conversion to open surgery was encountered, with only one perioperative death registered, due to pulmonary thromboembolism (0.07%) in the study

Table 4 – Comorbidities encountered in both groups of morbid obese patients that undergone bariatric/metabolic surgery during the study period (2020–2021) and control period (2019).

Comorbidity	2019 (n: 1451)	2020–21 (n: 1258)
Hypertension	386 (26.6)	351 (27.9)
OSAS	271 (18.7)	225 (17.9)
Diabetes	219 (15.1)	172 (13.7)
Hypothyroidism	32 (2.1)	34 (2.7)
Venous insufficiency	8 (0.5)	9 (0.7)
Hypertriglyceridemia/Hypercholesterolemia	218 (15)	157 (12.5)
GERD	49 (3.4)	47 (3.7)
Hiatal hernia	19 (1.3)	19 (1.5)
Arthropathy	131 (9)	100 (7.9)
IGT	37 (2.5)	32 (2.5)
Cholelithiasis	0 (0)	4 (0.3)
Hepatic steatosis	51 (3.5)	35 (2.8)
Others	87 (0.6)	68 (5.4)

Table 5 – Prevalence (expressed as number of Sars-Cov-2 positive cases at the given time point/1000 people) and Regional Rt values (the average number of secondary infections generated by an infected person on a certain date) for the study period. Data was extrapolated according to the date of study initiation (July 1st, 2020) and end (Jan 31st, 2021) according to the participants' origin (province or region). Rt data was only available according to region for the specific time points [24,25].

Province	Regional Rt ^{1, 2}		Prevalence (n/1000) ³		Overall population ³
	29th Jun-5th July 2020	25th Jan-31st Jan 2021	1st July 2020	31st Jan 2021	
Torino	1.06 (CI 0.87-1.31)	0.82 (CI 0.72-0.99)	7.07	66.49	2,247,780
Rome	1.07 (CI 0.45-2.05)	0.82 (CI 0.7-1.06)	1.47	46.09	3,997,465
Pisa	1.12 (CI 0.35-2.9)	1.02 (CI 0.87-1.31)	2.26	54.60	411,190
Padova	1.2 (CI 0.39-2.28)	0.65 (CI 0.58-0.8)	4.29	73.72	921,361
Bergamo	0.92 (CI 0.66-1.26)	0.9 (CI 0.77-1.03)	13.23	37.2	1,088,284
Milano	0.92 (CI 0.66-1.26)	0.9 (CI 0.77-1.03)	8.03	74.09	3,038,420
Bologna	1.2 (CI 0.76-1.88)	0.84 (CI: 0.72-1.06)	5.36	50.1	976,243
Mean	5.96	57.47	12,680,743
National Mean	18th Jun 2020-1st Jul 2020 Approx. 0.8 ⁵	20th Jan-2nd Feb 2021 0.95 (CI 0.86-1.06) ⁴	3.97	42.08	59,433,744

group. Sleeve gastrectomy (LSG) was the most common procedure (88.2%); more LSGs were performed in 2020, while more R-en-Y gastric bypasses were performed in 2019, when statistically compared. All related comorbidities were registered, hypertension, obstructive sleep apnea and diabetes being most frequent, and were more associated in the control group, without showing any significant difference (Table 4).

Eight patients (0.6%), 6 females/2 males, with a mean BMI 44.1 kg/m² ± 4.9, a mean age 37 years ± 6.2, tested positive for Sars-Cov-2, predominantly undergoing LSG. Diagnosis was established after hospital discharge (asymptomatic patients, Sars-Cov-2 swab negative tests), from which only one required admission to the Infective Disease Unit. No complications, no pneumonia, no admission to the ICU, nor mortality relating to Sars-Cov-2 were registered. At the same time, 15 cases of Sars-Cov-2 infections were registered among bariatric healthcare professionals: 5 surgeons, 2 nutritionists, 3 residents, 5 nurses and auxiliaries. All had asymptomatic to mild forms, with no complications registered, and all were submitted to compulsory home quarantine, symptomatic treatment and further testing until a double negative swab test was met. The registered values of Rt index during the

study, in the regions of the participating hospitals, as well as national values, are reported in Table 5 [24,25].

More grade IIIb Clavien-Dindo complications related to surgery, requiring surgical, endoscopic, or radiological intervention were encountered in 2020–21 compared to 2019, without showing a statistically significant difference (see Table 6). The majority of complications encountered were leaks (5 in the study group vs. 8), bleeding (12 vs. 19), anastomotic bleeding (1 vs. 2, $p < 0.001$). All complications were successfully treated, with no further complications.

5. Discussion

This is the first multicenter, prospective, observational study on the safety and feasibility of BMS during the COVID-19 Italian epidemic, performed during two distinct periods: the so-called phase 2, low incidence phase (June–September 2020), and phase 3 or second wave (October 2020 – January 2021), the latter still ongoing as we proffer this manuscript. As a matter of fact, during the second Italian wave 1,822,841 positive cases were registered vs. 236,134 registered during the first wave of the pandemic. Among over 100,000 Italian vic-

Table 6 – Complications by Clavien-Dindo (CD) classification after bariatric/metabolic procedures; Sars-Cov-2 tested positive patients during the first 30 postoperative days; all adverse events from time of surgery up to 30 POD for all patients, both in the study group (operated between July 2020–January 2021) and control group (operated between July 2019–December 2019).

	2019 (n-1451)	2020 (n-1258)	p-value
Complication by CD classification system grade			
CD grade I	21 (1.45)	8 (0.64)	0.064
CD grade II	27 (1.86)	17 (1.35)	0.371
CD grade IIIA	3 (0.21)	1 (0.079)	0.702
CD grade IIIB	11 (0.76)	16 (1.27)	0.255
CD grade IVA	1 (0.069)	1 (0.079)	0.359
CD grade IVB	0 (0)	0 (0)	1
CD grade V	0 (0)	1 (0.079)	0.948
Total	63 (4.34)	44 (3.50)	0.307
COVID-19			
Sars-Cov-2 positive	Non tested	8 (0.6)	0.01
Specific complication			
Leak (sleeve)	8 (0.6)	5 (0.4)	0.646
Bleeding	22 (1.7)	11 (1)	0.163
Anastomotic bleeding	2 (0.14)	1 (0.07)	<0.001
Wound infection	6 (0.4)	6 (0.4)	0.760
Deep vein thrombosis	1 (0.07)	1 (0.07)	0.817
Pulmonary embolism	0 (0)	1 (0.07)	0.004
Respiratory	3 (0.2)	4 (0.3)	0.893
Abscess	1 (0.07)	2 (0.1)	0.692
Occlusion	1 (0.07)	2 (0.1)	0.692
Others	10 (1.1)	6 (0.5)	0.130

tims of COVID-19, obesity was identified as a risk factor in 10.8%, for both genders [26].

Nevertheless, resuming elective BMS was mandatory given the uncertainty regarding the effects and duration of the outbreak, combined with the progressive nature of obesity and related conditions, while delaying BMS could have increased the risk of morbidity and mortality in surgical candidates [23]. The risk of harm during the surgical process, however, is different for each patient, depending on the type and severity of disease and their suitability for BMS. Patients undergoing BMS are not at increased risk of Sars-Cov-2 infection compared to the general surgery population. The 30-day morbidity and mortality following BMS performed during the phase 2–3, with appropriate perioperative protocols, appeared to be similar to the pre-pandemic levels, as shown in a recent retrospective, observational, international cohort study on 2116 adult patients who underwent primary BMS in 133 hospitals from 35 countries [27]. There were ten (0.5%) symptomatic cases diagnosed after BMS, similar to the one reported in our study, both before and during the pandemic.

Patients who had BMS would have a decrease in their fat stores, improvement of their comorbidities, and hence make them less susceptible to severe outcomes if they catch Sars-Cov-2 infection [28]. A nationwide French study was conducted on 8286 individuals with a previous diagnosis of obesity, admitted for COVID-19 between January 1st and May 15th, 2020; 541 patients had a history of BMS [15]. The need for invasive mechanical ventilation and death occurred in 7% and 3.5% of the BMS group versus 15% and 14.2% of the control group, respectively, so BMS is independently associated with a reduced risk of death and invasive mechanical ventilation.

The restart of elective BMS, performed under strict, updated in-hospital and ambulatory regulations, based on

national and international guidelines [19–23,29] was analyzed for the first 30 POD Sars-Cov-2 incidence, its mortality, and complications, as well as the perioperative readmission or reoperation rate. Only 8 patients (0.6%) tested positive for Sars-Cov-2 postoperatively, and diagnosis was established after hospital discharge. The 0.6% rate Sars-Cov-2 infection at 30 days seems to be related to the family/environment link, without excluding the possibility that infections occurred during the hospitalization, and patients became positive or symptomatic after discharge, at home. Five of these patients were located in North Italy, the area most affected during this pandemic, while the rest are located in Rome metropolitan area, highly affected, as well, during the second wave. No specific conditions were registered for these 8 patients, nor for their morbid obesity or associated conditions. No concomitant patients and health professionals were recorded or could be demonstrated. The 15 healthcare professionals infected were involved in a greater variety of in-hospital and ambulatory activities, not restricted to the bariatric area, and we could not find a direct connection between them and the patients who tested positive after hospital discharge. We consider that infections among patients or personnel were completely unrelated.

There was no difference for bariatric surgery's complications, perioperative readmission or reoperation rate between the 2 analyzed periods, except for anastomotic bleedings and postoperative pulmonary embolism (only one event registered in 2020). The lower number of procedures performed in 2020 in the eight centers (13.5% reduction compared to 2019, without reaching a significant cutoff) is easy to comprehend: all the involved centers faced serious difficulties in this period, determined by the reduction in available ORs, allocated hospital admissions, more complicated in-hospital patients management. Additionally, all centers faced tempo-

rary closure (for 2–3 weeks or even more) during the second wave of the pandemic (October 20 – January 21). Nevertheless, the cohorts were similar, with no difference in characteristics.

This is the first multicenter prospective observational study, on a large scale, demonstrating the safety of elective BMS in selected patients when strict protective protocols are adopted. The results of the present study, first to our knowledge in Europe, demonstrate that the bariatric surgical program can guarantee a safe standard of care for selected bariatric patients, thus, avoiding the postponement of surgical treatment. On the basis of the current epidemiological data in Italy we consider that maintaining strict protective protocols, the vaccination of the professional and the priority of vaccination of the obese patients as fragile subpopulation can guarantee a safe standard of care, thereby, avoiding a further BMS suspension. Continuing to deliver surgical treatment to the obese population represents a preventive and protective strategy in the long term. The selection of the patients in our study excluded super-super-obese and estimated time-consuming procedures to minimize the need for postoperative ICU. At least in our country a balance between hospital resources and severely obese patients was needed, allowing a safe delivery of surgical care even during the second wave. The results of the present study allow patients, on waiting list, to be informed about the risk of Sars-Cov-2 infection after surgery and add data to the informed consent. A significant cooperation between hospital governance and professionals, helped in achieving these results. Respect of the protocols, the monitoring of the local epidemiological events, and the resilience of the multidisciplinary team are our key points.

6. Conclusions

The selection criteria of the patients, the strict, protective protocols adopted by the participating hospitals allowed the prevention of in-hospital Sars-Cov-2 infection and guaranteed a safe resumption of bariatric surgery, with a view to continuing the fight against obesity during the outbreak. Considering the pandemic situation and Italian epidemiology, the present data support the weight loss surgery program, not only, in Italy but worldwide. The vaccination of health professionals, telemedicine, in-hospital protective and preventive tools, enhance the safe profile of bariatric surgery, considering that obesity, per se, represents a negative prognostic factor in case of Sars-Cov-2 infection.

7. Data sharing

The metadata will be available through the dedicated online platform <https://test-3mstudy.pantheonsite.io/user/login> and will be available for secondary analysis once the study has completed.

CRedit authorship contribution statement

Gianfranco Silecchia: Conceptualization, Funding acquisition, Methodology, Investigation, Resources, Supervision, Writing - review & editing. **Cristian E. Boru:** Project adminis-

tration, Data curation, Formal analysis, Methodology, Software, Visualization, Validation, Writing - original draft, Writing - review & editing. **Giuseppe Maria Marinari:** Resources, Validation. **Paolo Gentileschi:** Data curation, Resources, Validation, Writing - review & editing. **Mario Morino:** Resources, Validation. **Stefano Olmi:** Resources, Validation. **Mirto Foletto:** Resources, Validation, Writing - review & editing. **Paolo Bernante:** Resources, Validation. **Riccardo Morganti:** . **Carlo Tascini:** Conceptualization, Validation. **Marco Anselmino:** Conceptualization, Resources, Validation, Writing - review & editing. **RESTART group:** Resources and data collection.

Role of the funding source

The funder of the study had no role or support in the study design, data collection, data analysis, data interpretation, or writing of the report.

RESTART group

Resources and data collection.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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