




Restarting Elective Bariatric and Metabolic Surgery Under a Security Protocol During the COVID-19 Pandemic—a Prospective Observational Cohort Study

Marcio P. M. Balieiro^{1,2,3}  · Michel M. da Silva⁴ · Antônio C. J. Coelho³ · Fernando de Barros^{5,6} · Carlos Saboya^{3,7} · Leonardo R. Ferraz^{1,3,8} · Mauricio E. G. Vieira³ · Dyego Sá Benevenuto³ · Luiz G. de Oliveira e Silva⁵ · Marcio Lucas⁴ · Fernando Valente³ · Fabio Viegas³ · Fernando J. Kaddoum³ · Luciana J. El-Kadre⁶ · Fernanda Vaisman^{2,9}

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Abstract

Background During the SARS-CoV-2 pandemic, in order to protect the patient and to save hospital beds, cancelation of elective surgeries has become a great challenge. Considering that obesity is a chronic disease and the possible effect imposed by quarantine on weight gain with worsening rates of obesity and metabolic comorbidities, the creation of a protocol for a safe return to bariatric surgery became essential.

Objective The aim of this study was to identify the incidence of new-onset severe acute respiratory syndrome coronavirus (SARS-CoV-2) symptoms in patients who underwent bariatric procedures during the declining curve period.

Setting Private practice

Methods A prospective observational cohort study was conducted and included patients with indications for bariatric surgery during the decreasing curve period of the SARS-CoV-2 pandemic who underwent surgery under a hospital security protocol. Patients were asked to answer a questionnaire and had a swab PCR test for SARS-CoV-2 detection. The primary outcome measure was the presence of 14-day and 30-day postoperative symptoms associated with COVID-19. Mortality was also analyzed.

Results Three hundred patients with negative RT-PCR were operated on from May to June 2020. Seventeen patients had their surgery postponed because of a positive RT-PCR test or close contact. None of the patients developed new-onset SARS-CoV-2 symptomatic infection after 30 days of observation. No deaths were reported. Eleven had complications not related to SARS-CoV-2.

Conclusions Even though this population may have a poorer outcome when infected with SARS-CoV-2, this security protocol has shown that the procedure can be safely performed during the outbreak.

Keywords COVID-19 · Bariatric surgery · Obesity

✉ Marcio P. M. Balieiro
marciobalieiro@hotmail.com

¹ Surgery Service- Hospital Federal de Bonsucesso, Rio de Janeiro, Brazil

² Faculdade de Medicina, Universidade Federal do Rio de Janeiro (UFRJ), Rio de Janeiro, Brazil

³ Surgery Service- Rede D'or/São Luis- Rio de Janeiro, Rio de Janeiro, Brazil

⁴ Private Practice, Rio de Janeiro, Brazil

⁵ Surgery Service- Universidade Federal Fluminense, Rio de Janeiro, Brazil

⁶ Surgery Service- Centro Metabólico da Gávea, Rede Ímpar, Rio de Janeiro, Brazil

⁷ Surgery Service- Hospital de Ipanema, Rio de Janeiro, Brazil

⁸ Surgery Service- Universidade Federal do Estado do Rio de Janeiro (UNIRIO), Rio de Janeiro, Brazil

⁹ Endocrinology Service, Instituto Nacional do Cancer, Rio de Janeiro, Brazil

Introduction

China and Europe were strongly affected by one of the worst known pandemics at the beginning of 2020, causing considerable mortality and rapid spread of SARS-CoV-2 worldwide. The first cases of SARS-CoV-2, also called coronavirus disease (COVID-19), in Brazil were reported in March 2020, and the outbreak exploded exponentially [1–5]. Since then, the need of protecting susceptible people and staff as well as saving equipment and hospital beds for the supposedly increased influx of COVID-19 patients became an issue [6]. Therefore, all elective surgeries were temporarily canceled, including bariatric and metabolic procedures [7]. Moreover, in the following months, the medical literature suggested poor outcomes in postoperative patients with different surgeries affected by COVID-19 [8]. The COVIDSurg Collaborative report provided 30-day results of an international cohort study assessing postoperative outcomes in 1128 adults with COVID-19 who were undergoing a broad range of surgeries. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection was diagnosed postoperatively in more than two-thirds of the patients (806 [71.5%]). The overall 30-day mortality was 23.8%, with pulmonary complications in 51.2%, and the mortality in those patients was 38%, accounting for 82.6% of all deaths [9]. Even with those figures, obesity-related societies emphasized the need to postpone bariatric surgery during the worst period of the pandemic but were also radically opposed to defining these surgeries as elective, supporting them as “medical necessary not emergent surgery” and that they should be restarted as soon as it was safe to do so [10, 11]. Another factor was the confirmation of poor outcomes for patients with obesity when infected with SARS-CoV-2, with increased mortality rates [8, 12, 13]. Moreover, a gradual worsening of comorbidities and of obesity itself, with forced social distancing and compulsory confinement, and the benefit of bariatric surgery to decrease hospitalization and mortality in infected patients induced a strategy for a safe restart [14, 15].

Some services and hospitals created secure protocols with questionnaires, RT-PCR tests, and segregated areas, demonstrating good results preventing postoperative COVID-19 infection [16–18].

The ideal time to return to bariatric surgery remains unclear. Therefore, the aim of this study was to report COVID-19-related symptoms and mortality within the first month after bariatric surgery in patients who underwent a COVID-19 infection prevention protocol.

Methods

After institutional review board approval under the number CAAE 34749320.4.0000.5249, every patient scheduled to

have bariatric surgery within the study period was invited to participate. Informed consent was also obtained.

Tests

Real-time polymerase chain reaction (RT-PCR) was performed using Allplex, Seegene, target E gene, N gene and RdRP gene, Charité protocol, and U.S. CDC.

Serologic tests were performed using an Elecsys® Anti-SARS-CoV-2 electrochemiluminescence immunoassay (Roche Diagnostics, reagent lot number 49025801) for the qualitative detection of SARS-CoV-2 antibodies in human plasma.

COVID-19 Infection Prevention Protocol

Six to four days before the procedure, all patients were scheduled to undergo nasopharyngeal swab/RT-PCR at a drive-through in the parking lot of the hospital, at a preindicated laboratory, or through home collection to prevent exposure to the general population. All patients were strictly advised to have self-quarantined with social distance before that time, which was reinforced after testing.

The symptomatic questionnaire was completed at least twice: once at the office when the date of the procedure was confirmed, and the other when the patient arrived at the hospital. It included the most frequent symptoms related to coronavirus in adults, which might have occurred within the 2 weeks before surgery was scheduled, such as fever, cough, myalgia or fatigue, headache, dyspnea, diarrhea, sore throat, cough, anosmia, and ageusia, in addition to previous close contact with suspected or confirmed cases.

Data regarding social distancing, security behavior (mask and hygiene), and avoidance of crowds were collected.

Serologic tests and further imaging such as chest computed tomography were allowed to be performed outside the routine protocol if a clinical history or physical examination was suggested or if the surgical team found it necessary for further confirmation.

Follow-up was carried out for 30 days postoperatively; the electronic medical records from hospitals and general practitioners were searched on a daily basis to assess whether there were complications, hospital reattendances, or general practitioner visits.

The primary outcome measure was 14-day postoperative symptoms associated with COVID-19. The secondary outcome measure was 30-day postoperative symptoms or mortality related to SARS-CoV-2 with any positive test confirming the diagnosis, their complications and relationship to any surgery complication, increased operative time, or length of hospital stay. Those information were actively collected by the surgeons responsible for each patient during routine visits and any unexpected symptom not routinely seen postoperatively (e.g., local pain) was considered suspicious

for COVID 19 and a new test was performed. The questionnaire was created in Google Forms and their outcomes with all detailed information analyzed in the results.

Participants

The study demographics of the operated patients are summarized in Table 1. In total, 300 patients underwent an elective operation at a median body mass index (BMI) of 41.52 kg/m². The mean age (\pm standard deviation) of the patients was 38.1 \pm 8.7. A total of 222 (74.0%) were women, and 78 (26.0%) were men. Comorbidities were recorded during the preoperative period in the medical setting. Fatty liver was the most common comorbidity reported in 217/300 patients, followed by hypertension, diabetes/glycemic alterations, and dyslipidemia. In 202 patients, gastric by-pass was performed, and in 98, sleeve gastrectomy; 244 procedures were laparoscopic, and 56 were robotic.

Statistical Analysis

Statistical analysis was performed using SPSS for MAC version 20.0 (SPSS Inc., Chicago, IL, USA). Continuous variables are described as the mean and median. Categorical variables are presented as numbers and percentages. Parametric variables were evaluated with chi-square and Student's *t* tests. Nonparametric variables were evaluated by the Mann-Whitney *U* test. The confidence interval was 95%, and a *p* value less than 0.05 was considered significant. Effect size analysis was performed in all statistics. In that study, with a sample size of 11 (with rehospitalization) and 289 (without rehospitalization) patients in the groups, the effect sizes (ES) for the Student *t* test for independent samples (ES = 0.86) and for Mann-Whitney (ES = 0.88) were relatively large. For the

chi-square test with 1 gl (degree of freedom), the effect size (ES = 0.16) was relatively low to moderate.

Results

This study was carried out in seventeen private hospitals in Rio de Janeiro. Only one hospital had no COVID-19 inpatients during the period. The others had predefined "COVID-free" areas, including room floors and intensive unit care, if necessary. An inclusion diagram is shown in Fig. 1. From 317 patients selected for bariatric and metabolic surgery, 300 underwent surgery by 12 different surgical teams from May 25 to June 31, 2020, with RT-PCR negative status performed routinely as part of the nosocomial COVID-19 infection prevention protocol. Fifteen surgeries were postponed because of RT-PCR test positivity, and 2 were postponed because of close contact (spouses) with recently infected patients. All of these patients were asymptomatic, as symptomatic patients were not even considered for surgery. Serologic evaluation was not part of the nosocomial COVID-19 infection prevention protocol; however, some surgeons also chose to do so before surgery, and the results are shown in Fig. 1.

Thirty-nine patients underwent double testing combining swab PCR and serologic evaluation for COVID-19, in 3 only serologic and in 258 only swab PCR (Table 2). Two patients had IgM positivity, but both were IgG positive and negative for PCR, so surgery was performed. Six patients had to stay longer than 1 day at the hospital, 3 because of bleeding, 2 because of liquid diet intolerance, and 1 which was due to fever but unrelated to COVID-19. Patients were readmitted to the hospital because of the following complications: 1 anastomosis stenosis (D 28) and 2 surgical wound infections, which were both due to umbilical hernia surgery as open surgery. However, one had stayed just a few hours at the emergency and was discharged with oral antibiotics. One was due to urinary infection, 1 epiploic appendage, 2 bleeding, 1 fistula, 1 small bowel obstruction, 1 pulmonary embolism, and 1 intolerance to liquid diet. All patients were rescreened for COVID-19 with PCR swabs and tested negative. Details on the risk factors for surgical complications and readmissions were analyzed and are shown in Table 3. This table also shows that complications occurred more frequently in patients with type 2 diabetes, sleep apnea, and hepatic steatosis, and in whom the surgical procedure took a long time. The type of surgery, serologic background, age, BMI, and high blood pressure were not significantly different regarding the risk of complications.

There were no reports of COVID-19 infection symptoms within the first 14 and 30 days, postoperatively. All symptomatic patients were readmitted to the hospital and rescreened with swab PCR and chest computed tomography scans. All tested negative and did not have images that suggested COVID-19 infection. All

Table 1 General characteristics

	N=300	%
Age (median–range)	38.1 \pm 8.7 (19–62)	–
Sex F:M	222:78	74:26
BMI (median–range)	41.52 \pm 4.4 (35–60)	–
Comorbidities		
HBP	151	50.3
T2D/glycemic alterations	108	36
Fatty liver	217	72.3
Dyslipidemia	68	22.7
Arthrosis/joint problems	50	16.7
Sleep apnea	25	8.3
Reflux	29	9.6

F, female; M, male; BMI, body mass index; T2D, type 2 diabetes; HBP, high blood pressure; COVID-19, coronavirus infection disease 19

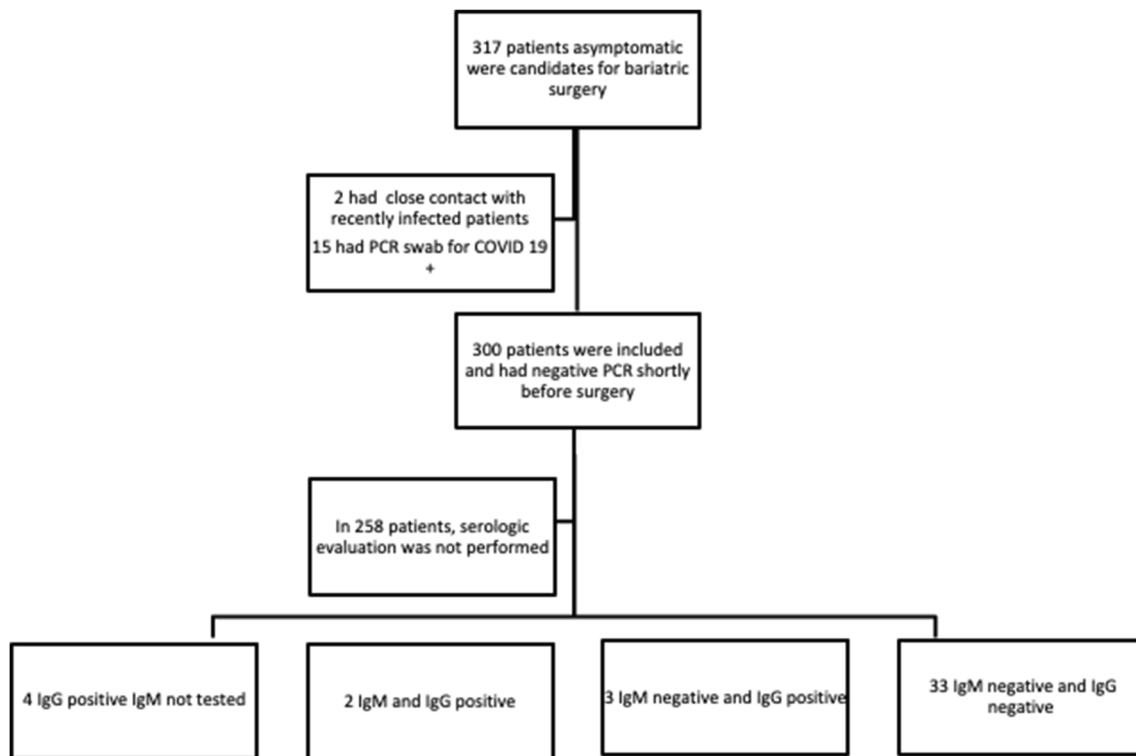


Fig. 1 Diagram of inclusion and testing for COVID-19

symptoms were explained by other ordinary causes as reported above. There were also no reports of COVID-19-related deaths or deaths because of other causes.

Discussion

After a literature review, we found that this is the first study to prospectively evaluate the risk of COVID-19 nosocomial infection, 14 and 30 days later in patients who underwent a single uniform safety and testing protocol and underwent bariatric surgery during the decline curve of newly infected patients in Rio de Janeiro. As shown in the results, we were able to demonstrate the efficacy and safety of rigid preoperative screening protocols mainly based on questionnaires and RT-PCR tests. Only expected surgical complications were reported, and even with readmissions, none of the patients tested positive. Furthermore, within the first month after surgery, there was no report of symptoms related to SARS-COV-19. There was no difference between the hospital totally dedicated to no COVID-19 patients and segregated hospitals.

Brazil has the second highest number of infected patients, with 6,290,272 cases of COVID-19 until December 2020 and 172,561 deaths. It has been estimated that 28,404,603 surgeries worldwide were canceled or postponed during the peak 12 weeks of the COVID-19 outbreak, and it could take a long time to normalize the demand [19].

The COVIDSurg Collaborative group described how bad postoperative recovery could be if the patient was infected with SARS-CoV-2, with a high grade of pulmonary complications and mortality [9]. However, it included not only elective surgeries but also patients who were not preoperatively tested or were segregated in different places. Doglietto et al. [20] identified the same results with higher mortality when compared with no infection, just to emphasize the importance and terrible outcome when major surgery patients were infected during the recovery. On the other hand, Singhal et al. [21] published an international cohort study, with 30-day outcomes of 2001 bariatric surgeries during the COVID-19 outbreak, with different results from the previous two. Only ten patients (0.5%) had symptomatic infection, and one death was unrelated. Seven patients had no special treatment, none needed intensive care or ventilation, and none died. Two of the ten patients had no perioperative test for SARS-CoV-2, and 20.4% had no preoperative test. This is the main difference in our cohort, which included only patients with preoperative RT-PCR tests and rigid protocols. However, these results and outcomes corroborate ours [21].

There were two important factors with the return of bariatric surgery: the occupation of hospital beds or ICU places with elective surgeries that could be requested for a possible urgent inflow of COVID-infected patients. Other concerns were regarding complications and mortality related to the bariatric patients if they were infected just previously or during the postoperative period. The first was solved with great control

Table 2 Description of operative details, testing, outcomes, readmissions, and complications

	N=300	%
Type of surgery		
Gastric bypass	202	67.3
Sleeve gastrectomy	98	32.7
Surgical access technique		
Laparoscopic	244	81.3
Robotic	56	18.7
Time of hospitalization (h)	33.41±18.5 (18–148)	–
Surgical time (median–range)	1 h 30 min±25 min (35 min–3 h 20 min)	–
Postoperative complications		
Early	6	2
Late	11	3.6
Preoperative COVID-19 PCR swab		
Negative	297	99
Not performed*	3	1
Serologic evaluation for COVID-19		
Preoperative		
IgM negative	36	12
IgM positive	2	0.6
IgG negative	33	11
IgG positive	9	3
Not performed	258	86
New COVID-19-PCR swab within the first months after bariatric surgery **		
Negative	8	2.7
Positive	0	0
Not performed	292	97.3
Surgeons volume (surgeries in 2 months), median–range	27.2 (5–150)	–

COVID-19, coronavirus infection disease 19

*Three patients who did not undergo PCR had IgG positivity before surgery, previous COVID-19 symptoms, and RT-PCR positive

**A new COVID-19 PCR swab test was performed for every patient who needed hospital readmission and/or presented with any symptoms that could be related to COVID-19, such as fever, shortness of breath, gastrointestinal abnormalities unexpected in bariatric postoperative patients

of the occupancy of the participating hospitals, digital meetings with the managers, and observations of the declining curve of deaths and infections in the region. It was possible to let sectors and ICUs be “free” of infected patients, and sometimes the whole hospital was just “no COVID patients,” targeting any possible cases for another sector, or even another institution. Therefore, the recommendation to cancel every procedure was not unanimously followed around the globe. The COVID Collaborative group also showed in a recent review that some countries, instead of suspending surgeries, selected some areas that had fewer reported cases and kept them as a so-called COVID-free environment and kept the procedures [16]. Second, we could reproduce good results as other surgery specialties with no COVID infections during the

postoperative period, performing a similar security protocol. Ferenczi et al. [17], from Virginia Medical Center, tested 840 patients during the preoperative period with 3 positive tests that were rescheduled, demonstrating the utility of preoperative screening as a safe way to prevent surgery in asymptomatic COVID patients. Gammeri et al. [22] reported excellent results of performing RT-PCR tests for every patient scheduled for surgery during the outbreak in the UK at a COVID-19-free hospital. Of the 309 patients operated on, no one had COVID-19 infection, but at least 1 patient had a positive test. However, these were minor or intermediate surgeries with a maximum length of 24 h, and it was a single institution [22]. Other single institutions have published their results, testing every oncological patient who had previously undergone

Table 3 Risk factors associated with postoperative complications requiring rehospitalization

Variable	Yes (n = 11)	No (n = 289)	p value	Effect size
Sex (male)	6 (54.5%)	72 (24.9%)	0.038	0.16
Age (years) ^a	35.8±10.0 (26–57)	38.2±8.7 (14–62)	0.62	0.86
T2D	8 (72.7%)	189 (65.4%)	0.02	0.16
HBP	6 (54.5%)	144 (49.8%)	0.50	0.16
DLP 2	(18.2%)	66 (22.8%)	0.52	0.16
Sleep apnea	4 (36.4%)	268 (92.7%)	0.01	0.16
Steatosis	11 (100%)	83 (28.7%)	0.03	0.16
BMI (kg/m ²) ^a	40.0±2.8 (37–46)	41.6±8.7 (35–60)	0.94	0.86
Surgical time (min) ^b	135 (80–210)	65 (42–173)	0.05 0.50	0.88 0.16
Sleeve	4 (36.4%)	94 (32.5%)		
Bypass	7 (63.6%)	195 (67.5%)		
IgG and/or IgM positive with PCR negative	3 (27.2%)	26 (9.0%)	0.08	0.16

T2D, type 2 diabetes; HBP, high blood pressure; DLP, dyslipidemia; COVID-19, coronavirus disease 2019. The effect size was obtained with the following parameters: alpha error $\alpha = 5\%$, power $(1-\beta) = 80\%$, and bilateral test (two-tailed)

In Bold, variables with statistical significance, $p < 0.05$

^a Continuous data were expressed by the mean \pm standard deviation (minimum–maximum)

^b By the median and interquartile range (Q1–Q3)

elective surgery in Brazil. Aguiar et al. [18] from AC Camargo Cancer Center, São Paulo, performed a very similar prevention protocol. From 454 patients with negative tests who underwent surgery, no COVID-related symptoms or complications were observed during the in-hospital postoperative period, and no readmission that was due to COVID-19 was identified [18].

The DDS (Diabetes Surgery Summit) group claimed that the worsening of comorbidities, which is directly related to the degree of the obesity class and quality of medical treatment and patient adherence to therapy, can lead to complications and permanent damage. Thus, they should have priority to restart [23]. Our results showed that the presence of type 2 diabetes, sleep apnea, hepatic steatosis, and longer surgical time were related to an increased complication rate, consequently extending the hospital stay or readmissions, increasing exposure and contamination rates with possible worst outcomes. However, there was no significance because there were no symptomatic COVID-19 patients during the observation time, even in those patients.

Perhaps one of the major concerns is the relationship between obesity and the worst outcomes, considering this group of patients when they develop SARS-CoV-19 [24]. Less published or not well established is the bariatric surgery paper, and the positive benefits decreasing the complications and mortality of this group after surgery. Aminiam et al. published a retrospective comparative study between postoperative

bariatric patients after weight loss and obese patients who tested positive for COVID-19. The worst outcomes were shown in the nonsurgery group, with higher hospitalization, UCI admission, and death rates [25].

The two main limitations of this paper are the efficacy of RT-PCR tests and serology and the confidence of quarantine with severe social distance before surgery, principally after RT-PCR testing; however, RT-PCR is still the gold standard for the diagnosis of COVID infection, so this was the choice to screen our patients. Another limitation worth mentioning is that active rescreening (serology or RT-PCR test) after 30 days was not performed, and some asymptomatic cases might have been missed; however, none of the patients reported symptoms, and even more importantly, they did not have any complications related to SARS-COV-19. Society was forced to come back to normal life. Sometimes, it was impossible to isolate patients at the preoperative time at the same moment they were being called back to work.

Conclusion

In conclusion, these results demonstrate that this protocol is efficient and safe and could be used similarly worldwide, thus minimizing the delay in the benefit that bariatric surgery can promote in resolving comorbidities, improving quality of life and prolonging life expectancy [26].

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Declarations

Conflict of Interest The authors declare no competing interests.

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