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Incidence and presentation of COVID-19 in the vaccinated and unvaccinated patients undergoing bariatric surgery

Mohamed Hany [a,*], Bart Torensma [b]

[a] Department of Surgery, Medical Research Institute, Alexandria University, Alexandria, Egypt
[b] Clinical Epidemiologist, Leiden University Medical Center (LUMC), Leiden, the Netherlands

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ABSTRACT

Background: This study aimed to describe the incidence and clinical presentation of fully vaccinated and unvaccinated patients who tested positive for COVID-19 in the first year after Madina Women's Hospital in Alexandria, Egypt, resumed bariatric surgery procedures. (The clinic was closed between March 2020 and reopened in mid-October 2020)

Methods: This prospective cohort study was conducted between November 2020 till the end of December 2021. We identified patients undergoing bariatric surgery infected with COVID-19 with and without vaccination. COVID-19 severity was assessed based on the Egypt Ministry of Health guidelines. Some patients were isolated at home, whereas others were hospitalised.

Results: During the one year after the restart of bariatric surgery procedures, 606 patients underwent bariatric procedures (n = 280 fully vaccinated, n = 320 unvaccinated). During follow-up, that period, the incidence of COVID-19 in the vaccinated group was 1.07% (n = 3) versus 14.1% (n = 46) in the unvaccinated group.

Three patients had mild symptoms in the vaccinated group, and no hospital admission was necessary. In the unvaccinated group, 27 patients (60%) were classified as mild, eight (17.8%) as moderate, eight (17.8%) as moderate with risk, and two (4.4%) as severe; the mortality rate was 0%. Of these, 16 (88.9%) were hospitalised, of which six (33.3%) were admitted to the intensive care unit in the moderate to severe groups.

Conclusion: Patients with obesity are at increased risk for COVID-19 infection and adverse consequences. Our findings showed a higher incidence of COVID-19 among those unvaccinated versus vaccinated. Therefore, at least during times and locations of a COVID-19 pandemic, vaccinations may be beneficial for patients against COVID-19 prior to bariatric surgery.

1. Introduction

The coronavirus disease (COVID-19) was declared a global pandemic on 11 March 2020 by the World Health Organization (WHO) after more than 118,000 cases and 4291 deaths were reported in 114 countries [1]. The first case and death were confirmed in Egypt on 14 February and 8 March 2020, respectively. The prevalence peaked by mid-June and fell dramatically by July the same year [2]. The necessity for elective procedures, including bariatric surgeries, has been debated during the pandemic. Patients with obesity have an increased risk of unfavourable outcomes if infected with COVID-19 [3]. Furthermore, bariatric surgeries were briefly put on hold as recommended by the *International Federation for the Surgery of Obesity* and metabolic disorders (*IFSO*) [4].

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in patients undergoing bariatric surgery can present several challenges. Firstly, the clinical presentation of bariatric complications, such as fever, dyspnoea, abdominal pain, and ageusia could mimic COVID-19. Secondly, the anatomical and physiological modifications of the gastrointestinal tract (GIT) could alter drug absorption and bioavailability, leading to pharmacological challenges [5]. Other medications, such as corticosteroids and monoclonal antibodies, may interfere with the GIT healing process [6]. Additionally, bariatric patients with SARS-CoV-2 infection are at increased risk of anxiety, isolation, and fear of death due to the nature of the pandemic and the clinical presentation [7]. There is an increased risk for patients with obesity [8], and surgery is advised to mitigate this risk. However, even after a (bariatric) surgery, living in an environment that may let them catch COVID-19 postoperatively is possible whether the patient is vaccinated or not.

* Corresponding author. Department of Surgery, Medical Research Institute, Alexandria University, 165 Horreya Avenue, Hadara, Alexandria, 21561, Egypt.
E-mail addresses: mohamed.ashour@alexu.edu.eg (M. Hany), bart@torensmaresearch.nl (B. Torensma).

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This study describes the incidence and clinical presentation of vaccinated and unvaccinated patients who tested positive for COVID-19 after the resumption of bariatric surgery during the first year of practice.

2. Methods

2.1. Trial design

This study was a prospective, descriptive cohort study conducted from November 2020, after Madina Women's Hospital in Alexandria, Egypt, resumed bariatric surgery procedures. (The clinic was closed between March 2020 and reopened in mid-October 2020). It ended at the end of December 2021, when the database was closed and included the presentation of patients infected with COVID-19 after bariatric surgery in patients with and without vaccination and the analysis was done during a pandemic period.

All patients provided written and oral informed consent and signed a consent form acknowledging the pandemic and the associated risks. All data were used anonymously. The study was conducted by the principles of the Declaration of Helsinki and approved by the Medical Research Institute's ethical committee.

2.2. Patients

All patients with an American Society of Anaesthesiologist classification of 1–3 class, aged from 18 to 65 years, of either sex, and indicated according to the International Federation of Surgery (IFSO) criteria before bariatric surgery, those with fully vaccinated (minimal 2 months before surgery) or without vaccination, were screened for surgery.

Exclusion criteria included the inability to give informed consent. Patients with comorbidities were not excluded from undergoing the operation; however, patients with surgical complications were excluded from this analysis.

2.3. Trial visits: precautions

Twenty-four hours before surgery, all patients underwent polymerase chain reaction (PCR) testing for SARS-CoV-2. Surgery was performed in COVID-free hospitals as a precautionary measure. Minimized contact with healthcare professionals was performed while following the Enhanced Recovery After Bariatric Surgery protocol and patients were discharged after 1 day in the hospital.

Furthermore, the patient could only be accompanied by one individual. Patients were asked to self-isolate themselves at home with family members for approximately 2 weeks after surgery to conform with IFSO's consensus statement for resuming bariatric surgery [9].

Instructions were given to all patients who underwent bariatric surgery upon discharge to continuously monitor their body temperature and symptoms, such as dyspnoea, abdominal pain, or GIT pain.

2.4. Patients' follow-up

The patients were contacted 48 h after discharge, and outpatient visits were set up at a weekly interval for 1 month by a team of nurses to check and record the measured temperatures. Patients were also provided with a hotline to call physicians and report any of the previously mentioned symptoms as soon as possible. Patients with hypertension and diabetes were monitored closely.

Patients who reported any symptoms were requested to visit the hospital for a clinical assessment and laboratory tests that included PCR testing and chest and abdomen computed tomography (CT) imaging. Patients with a positive PCR test without any surgical complications were included in the study and followed up for at least 2 months after recovery.

Data were collected on demographics, body mass index (BMI), type of surgery, comorbidities, and date of presentation of symptoms.

2.5. Severity assessment

Patients were assessed for severity and categorised into the following groups according to the triage protocol issued by the Egypt Ministry of Health (MOH) [10]: 1) mild, 2) moderate, 3) moderate with risk factors, 4) severe, and 5) critically ill. Patients with mild symptoms and regular imaging scans were asked to isolate at home with symptomatic management and monitoring of oxygen saturation (SpO_2) and pulse rate using a pulse oximeter. Regarding patients with moderate symptoms, the patients with positive imaging scans and $SpO_2 \geq 92\%$ were also asked to isolate at home and monitor themselves. In those with moderate with risk factors symptoms, risk factors such as high age >60 years, $SpO_2 < 92\%$, heart rate >110 bpm, respiratory rate >25/min, uncontrolled comorbidities, and BMI >40 kg/m^2, admitted to a COVID-19 hospital for oxygen mask therapy. Patients with severe symptoms (i.e. respiratory rate >30/min, pulmonary infiltrates >50%, and the ratio of arterial oxygen partial pressure to fractional inspired oxygen <300) were admitted to the intensive care unit (ICU). Patients with acute ill symptoms that had respiratory failure and septic shock were also admitted to the ICU.

2.6. Criteria for convalescence [11]

The following criteria were used to decide when to end home isolation: 1) At least 10 days had passed since the onset of mild and moderate symptoms, or 20 days in case of severe symptoms. 2) At least 24 h had passed since the resolution of fever without antipyretic medications. 3) Other symptoms have improved. 4) Negative PCR test result. Patients isolating at home were asked to visit a physician 1 week after convalescence and as needed.

2.7. Criteria for hospital discharge

The following criteria were used to decide on the discharge of hospitalised patients: 1) Improvement of respiratory symptoms. 2) Two negative PCR test results with 24-h intervals. 3) Body temperature ≤ 37.5 °C for at least 3 days. 4) $SpO_2 > 93\%$ without the need for oxygen. 5) Improvement of lung lesions upon imaging.

2.8. Statistical methods

For analyses, we used descriptive statistics and inferential statistics. All data were first tested for normality by a Kolmogorov-Smirnov test, a Q-Q plot, and Levene's test.

Categorical variables were expressed as n (%). Continuous normally distributed variables were represented by their mean and standard deviation, and not normally distributed data by their median and interquartile range due to their skewed distributions. When appropriate, categorical variables were tested using Pearson's chi-square test or Fisher's exact test. Normally distributed continuous data were tested with the independent-sample Students t-test and in case of skewed data, with the independent-sample Mann-Whitney *U* test. All statistical tests performed were two-sided, and analyses were performed using SPSS v. 27 (IBM Corp, Illinois, USA) [12].

2.9. Data capture

The analysis was performed on a blinded dataset. After the medical/scientific review was completed, all protocol violations were identified, and the data set was declared complete. All data were collected in a data management system (Castor EDC, Amsterdam, The Netherlands; https://www.castoredc.com) and handled according to the Good Clinical Practice guidelines, Data Protection Directive certificate, and complies with Title 21 CFR Part 11. Furthermore, the data centre where all the research data is stored is ISO27001 and ISO9001 certified, and Dutch NEN7510 certified.

3. Results

3.1. Incidence of SARS-CoV-2 infection

During the one year after the restart of bariatric surgery procedures in total, 606 patients underwent bariatric surgery from November 2020, after Madina Women's Hospital in Alexandria, Egypt, resumed bariatric surgery procedures. (The clinic was closed between March 2020 and reopened in mid-October 2020, until the end of December 2021, when the database was closed. This included 280 (47%) in the vaccinated group and 326 (53%) in the unvaccinated group.

The incidence, during that period, of SARS-CoV-2 infection in the vaccinated group was significantly lower, 1.07% (n = 3) versus 14.1% (n = 46) in the unvaccinated group. (p. <0.001) None of the groups had any surgical complications, as assessed by chest and abdomen CT scans (Fig. 1)

3.2. Patient demographics with SARS-CoV-2 infection

The vaccinated group had two females and one male patient; the mean age was 40.67 ± 8.66 years and BMI was 41.60 ± 5.80 kg/m^2. Comorbidities and types of bariatric surgery are presented in Table 1.

The unvaccinated group had 23 (50%) male and 23 (50%) female patients infected with COVID-19 after surgery. The mean age was 44.96 ± 9.66 years and BMI was 47.75 ± 6.80 kg/m^2. Comorbidities and types of bariatric surgery are presented in Table 1.

3.3. Vaccination types

Regarding the vaccination type, 49.6% had two doses of AstraZeneca, 2.1% had a single dose of Johnson & Johnson, 1.1% had two doses of Moderna, 4.6% had two doses of Pfizer, and 42.5% had two doses of Sinopharm. The infected vaccinated group (n = 3) two patients had received two doses of AstraZeneca and one patient, a single dose of Sinopharm and slipped through and still had surgery despite 1 dose and therefore not fully vaccinated.

3.4. Severity results of COVID-19 infected patients

The three patients in the vaccinated group had mild symptoms, and no hospital admission was necessary.

In the unvaccinated group, 27 patients (60%) were classified as mild, eight (17.8%) as moderate, eight (17.8%) as moderate with risk, and two (4.4%) as severe. None of the patients had any complications from their pre-existing comorbidities. One patient dropped out and was excluded from the analysis.

The most common symptoms were fever (71.1%), cough (75.6%), and fatigue (97.8%). Dyspnoea (94.7% vs 0% vs 0%), runny nose (44.4% vs 14.8% vs 0%), and cough (100% vs 59.3% vs 33.3%) were significantly more present in the unvaccinated moderate and severe risk group than in the mild group vs vaccinated mild group.

Table 1
Incidence and demographic characteristics of the infected COVID-19 population.

Characteristics n = 606	Unvaccinated (n = 326)	Vaccinated (n = 280)
Incidence COVID-19 infection % (n)	14.1% (n = 46)	1.07% (n = 3)
Demographic characteristics infected	**Total n=46**	**Total n= 3**
Age, years, mean ± SD	44.96 ± 9.66	40.67 ± 8.66
Sex, *n* (%)		
Female	23 (50)	2 (66.6%)
Male	23 (50)	1 (33.3%)
Body mass index, kg/m^2, mean ± SD	47.75 ± 6.80	41.60 ± 5.80
Associated comorbidities, n (%)		
Diabetes mellitus type 2	22 (47.8)	1 (33.3%)
Hypertension	22 (47.8)	3 (100%)
Osteoarthritis	15 (32.6)	–
Obstructive sleep apnoea	10 (21.7)	–
Hyperlipidaemia	28 (60.9)	1 (33.3%)
Gastroesophageal reflux disease	10 (21.7)	–
Type of surgery, n (%)		
Sleeve gastrectomy	28 (60.9)	2 (66.6%)
One anastomosis gastric bypass	10 (21.7)	–
Roux-en-Y gastric bypass	6 (13.1)	1 (33.3%)
Revision	2 (4.3)	–
Duration before post-operative presentation, days, median (range)	15 (3–42)	12 (6–24)

Furthermore, sleep apnoea and diabetes were significantly more common (p.<.001) among patients with severe risk; the rest of the comorbidities were not significantly different between the groups (Table 2).

3.5. Hospitalisation of COVID-19 infected patients

Among the unvaccinated group, the moderate and severe patients (n = 18), 16 (88.9%) were hospitalised, of which six (33.3%) were admitted to the ICU. Of the group with mild symptoms, zero patients were hospitalised. All patients recovered, and there were no (0%) mortalities in both groups. No hospitalisation in the vaccinated group was necessary (Table 2).

3.6. Vital signs and recovery of COVID-19 infected patients

In the unvaccinated group, respiratory and heart rates were significantly higher, whereas SpO_2 was significantly lower in moderate and severe patients. Among the moderate and severe patients, four were subjected to continuous positive airway pressure, and six required a high-flow nasal cannula. The duration of hospital stay among unvaccinated moderate and severe patients was 12 (10.0–14.75) days. The recovery period was significantly longer in the mild vaccinated group vs the mild unvaccinated and moderate and severe patients in the unvaccinated

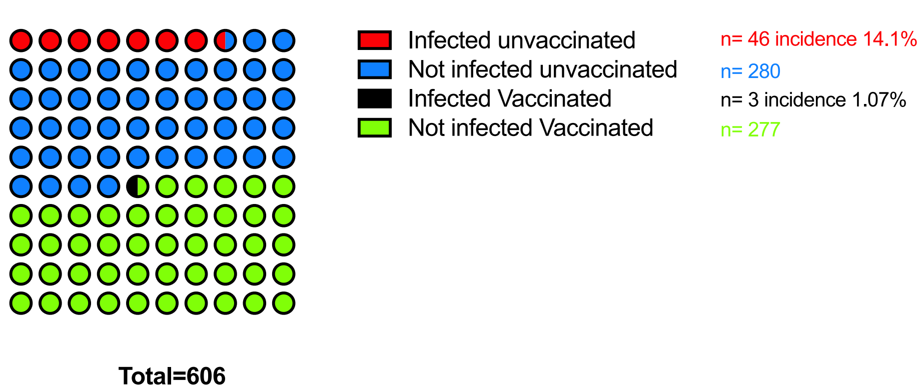

Fig. 1. Dot plot of the vaccinated and unvaccinated patients and the level of incidence.

Table 2
Clinical presentation and outcomes of infected patients stratified by severity.

	Mild symptoms group Vaccinated (n = 3)	Mild symptoms group Unvaccinated (n = 27)	Moderate To severe symptoms Unvaccinated group (n = 18)	*P* value
Symptoms, N (%)				
Fever	2 (66.6)	22 (81.5)	10 (55.6)	.060
Cough	1 (33.3)	16 (59.3)	18 (100)	.001*
Fatigue	3 (100)	26 (96.3)	18 (100)	1
Ageusia	3 (100)	16 (59.3)	8 (44.4)	.329
Diarrhoea	0 (0)	5 (18.5)	4 (22.2)	1
Vomiting	0 (0)	11 (40.7)	6 (33.3)	.252
Dyspnoea	0 (0)	0 (0)	18 (94.7)	<.001*
Runny nose	0 (0)	4 (14.8)	8 (44.4)	.041*
Associated comorbidities,n (%)	Mild symptoms group Vaccinated (n = 3)	Mild symptoms group Unvaccinated (n = 27)	Moderate To severe symptoms Unvaccinated group (n = 18)	*P* value
Diabetes mellitus type 2	1 (33.3)	8 (29.7)	14 (77.8)	<.001*
Hypertension	3 (100)	10 (37.0)	12 (66.7)	.072
Osteoarthritis	–	7 (25.9)	8 (44.4)	0.22
Obstructive sleep apnoea	–	0 (0.0)	10 (55.6)	<.001*
Hyperlipidaemia	1 (33.3)	16 (59.3)	12 (66.7)	0.77
Gastroesophageal reflux disease	–	6 (22.2)	4 (22.2)	1
Vital signs				
Respiratory rate, cycle/min, median (IQR)	16 (15–18)	15 (14–16)	25 (21.75–26.25)	<.001*
Heart rate, beats/min, median (IQR)	76 (65–91)	78 (70–86)	100 (94.25–110.5)	<.001*
SpO_2, %, median (IQR)	97 (94–97)	95 (94–97)	93 (89.5–93)	<.001*
Positive chest CT findings, n (%)	0 (0)	0 (0)	18 (100.0)	<.001*
Laboratory test results				
Elevated LFTs, N (%)	1(100)	1 (3.7)	14 (77.8)	<.001*
CRP, mg/L, median (IQR)	16 (12–20)	17 (13–20)	88 (43.5–101.5)	<.001*
D-dimer, ng/mL, median (IQR)	190 (110–230)	180 (125–221)	550 (497.5–617.5)	<.001*
Elevated IL-6, n (%)	3 (3)	0	4 (40.0)	–
Elevated LDH, n (%)	1 (1)	0	16 (88.9)	<.001*
Ferritin ng/mL, median (IQR)	55 (43–71)	76 (44–98)	250 (195–354.75)	<.001*
WBC, μL^{-1}, median (IQR)	4500 (3500–8000)	4300 (3800–6000)	3900 (3325–4200)	.039*
Lymphopenia, n (%)	1 (100)	26 (96.3)	16 (88.9)	.555
Glycemia, mg/dL, median (IQR)	140 (140–140)	119 (107–135.5)	320 (140–400)	<.001*
Outcomes				
Hospitalisation, n (%)	0 (0)	0 (0)	16 (88.9)	<.001*
Recovery, n (%)	3 (100)	27 (100)	18 (100)	–
ICU admission, n (%)	0 (0)	0 (0)	6 (33.3)	.002*
Ventilation				
Nasal cannula, n (%)	0 (0)	0 (0)	6 (33.3)	
CPAP, n (%)	0 (0)	0 (0)	4 (22.2)	<.001*
None, n (%)	3 (100)	27 (100)	8 (44.4)	
Period until recovery, days, median (IQR)	14 (12–21)	11 (8–12)	12 (11.5–14.75)	.020*
Hospital stay days, median (IQR)	0 (0)	0 (0)	12 (10–14.75)	<.001*
Follow-up days, median (IQR)	150 (147–169)	108 (85–162)	116 (83.75–141)	.659

*Indicates statistical significance ($P \leq 0.05$). CPAP: continuous positive airway pressure; CRP: C-reactive protein; ICU: intensive care unit; IL-6: interleukin 6; IQR: interquartile range; LDH: lactate dehydrogenase; LFT: liver function test; SpO_2: oxygen saturation; WBC: white blood cell.

group; 14 (12–21) vs 12 (11.5–14.75) vs 11 (8–12) (p = 0.020). The mild vaccinated group had all normal signs (Table 2).

CT scan results showed positive findings in the unvaccinated moderate and severe cases group, and nothing on the CT scans was found in the mild vaccinated and unvaccinated groups (Table 2).

3.7. Lab results of COVID-19 infected patients

In the unvaccinated group, liver function test levels, C-reactive protein (CRP), d-dimer, interleukin-6, lactate dehydrogenase (LDH), ferritin, and blood glucose were significantly higher in moderate and severe patients compared to mild patients in the vaccinated and unvaccinated groups (Table 2).

4. Discussion

This was a prospective descriptive cohort study on 606 patients between November 2020, after the resumption of bariatric surgery, until the end of December 2021, when the database was closed, during a pandemic period. It is important to note that vaccination in Egypt was not yet available for everybody in the study period.

We aimed to describe the incidence and clinical presentation of vaccinated and unvaccinated patients who tested positive for COVID-19 during the first year of practice. Forty-six unvaccinated patients (14.1%) and three vaccinated (1.07%) patients were diagnosed with COVID-19 in this period.

Performing bariatric surgery during the COVID-19 pandemic requires special considerations before, during, and after the operation. Early detection and management of SARS-CoV-2 infection in patients undergoing surgery are essential since there was a worldwide stop on operations.

The current total worldwide vaccination rate (two doses) is now 52.8% [1], and in Egypt, it is 25.2%. We would first like to raise a general discussion regarding bariatrics and COVID-19 vaccination for all health politics and decision-makers. The current vaccination rate is low and there is a failure to become vaccinated on time in all countries worldwide in this group of people/patients. Since it is known that overweight and patients with obesity with comorbidities and aged 40–60 years (within the IFSO criteria) are most at risk, this has not been adequately addressed [13–15]. Especially when the ICUs filled up, this group of patients had the most extended hospital stay [15]. With today's knowledge alongside the new rising infections and different kinds of mutations, we would like to plead for the continuation of what has turned out to be essential care and not creating a healthcare landscape whereby it was necessary to stop non-critical care. The clinic started operating again after the IFSO-approved bariatric surgeries. The restart was in a county where adequate vaccination was not possible until the beginning of March 2021.

The COVID-19 incidence in this study of unvaccinated (14.1%) patients is high. The group of vaccinated patients (1.07%) shows that it is possible to significantly decrease the number of incidences and, therefore, create a safer window for operating postoperative care. Nevertheless, even with this fact of high incidence, the mortality was 0%, and all patients recovered in the infected unvaccinated group; we can therefore suggest that bariatric surgery can be seen as safe in pandemic times if enough precautionary measures are taken before, during, and after surgery, even when vaccination is not always available for everybody in the society. In addition, the expected behavior of humans must be considered a natural part of the increased incidence, even with the imposition of restrictions and precautions, and the effect of vaccination. We saw that the expected behavior (for example, visiting family and friends) during the postoperative period was happening. When they got interviewed about the signs and symptoms, the research nurses were told how difficult it was to abide by the rules. In the same period when the vaccination rate was low, it is plausible that vaccination was also not present among friends and family at that time. Therefore, a possible spreader-effect within that group could also happen. After a period of quarantine, the everyday life of this group was also resumed. Therefore, it is also logical that the basis for this is that more infections with COVID-19 would occur, and the incidence would rise. It is important to note that although patients were asked to self-isolate as recommended by the IFSO resumption guidelines [8], this does not eliminate the possibility of patients being infected within the postoperative period if the rules were not followed up. Vaccination in Egypt was initiated in March 2021 [16]. This finding, combined with the incidence of 14.1%, should warn politicians and policymakers that this group of patients requires extra attention to ensure timely vaccination and that vaccinated patients will have a lower incidence of COVID-19 after surgery (1.07%).

Furthermore, other studies showed the efficacy of the immunological response after COVID-19 vaccination in patients with obesity which was found to be decreased. Besides the trend of a negative correlation between obesity and immunogenic response, vaccination generated a lower level of neutralizing antibodies in patients with obesity compared to those who were healthy, underweight, and overweight [17–19]. Also, after bariatric surgery, whereby weight loss is initiated, the immunological response increased 5.33 times more than vaccinated patients with obesity without any bariatric operation [20]. Focus on treatment of patients with obesity should be considered at all times.

The low immune response might be due to obesity-associated comorbidities such as dyslipidemia, which is claimed to cause changes in lymphocyte subsets and dendritic cells, leading to immune dysfunction. Therefore, this implies that vaccinating patients with obesity preoperatively can have a reduced effect, compared to what we hope to achieve with vaccination in patients without obesity. Nevertheless, vaccinating, in general, helps to reduce the incidence of COVID-19 (14.1% vs 1.07%). However, this could be even more effective when combined with weight loss management, like bariatric surgery, to reduce weight and comorbidities.

Based on disease severity in our study, 60% of COVID-19 diagnosed cases in Egypt were mild, 35.6% were moderate, and 4.4% were severe. Patients in this study exhibited symptoms between 4 and 42 days postoperatively. This agrees with the global data from the WHO that showed that mild to moderate symptoms (81%) were more prevalent than severe (14%) or critical ones (5%) [1]. Therefore, this research population is a good sample of the target population.

4.1. Study limitations

This study also had some limitations. Firstly, because we cannot conclude with certainty that all infected patients were included in this study, we could not accurately determine the infection rate since some patients could also witness an infection without symptoms and therefore did not contact us.

Secondly, the study was a descriptive statistics study with a relatively small group of patients. Excellent and extensive inferential and prognostic analyses were not possible since there were too few variables and low incidence in the vaccinated group to test for and correct the data; therefore, correcting for bias was impossible. Third, we did not distinguish outcomes for different bariatric procedures since this would decrease the power of the study vs the low incidence but can be relevant in new studies. Finally, we did not test for prior SARS-CoV-2 infection before surgery with a blood sample for antibody serological testing. This may have interfered in the results and the effect on the incidence ratio between vaccinated and unvaccinated patients, as well as the ability of the body to activate antibodies faster and improve pre-operative immunity.

5. Conclusion

Patients with obesity are at increased risk for COVID-19 infection and adverse consequences. Our findings showed a higher incidence of COVID-19 among those unvaccinated versus vaccinated. Therefore, at least during times and locations of a COVID-19 pandemic, vaccinations may be beneficial for patients against COVID-19 prior to bariatric surgery. Also, appropriate precautionary measures, approaches, and guidelines for the patient before, during, and after surgery with a multidisciplinary team could prove beneficial effects in all groups. Future studies are necessary to investigate the long-term impact of COVID-19 and the vaccine that may be required before surgery.

Disclosures

No competing interests were applicable. Furthermore, the authors declare that they have no conflict of interest. ICMJE disclosure form is signed by all the authors.

Author contribution

Conceptualization: MH. Methodology BT. Formal analysis: BT. Writing: Original Draft: BT. Writing: Review and Editing: MH. Supervision MH. All contributors reviewed, edited, and approved the final submission and publication.

Ethical review

All procedures performed in studies involving human participants were by the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

All patients provided written and oral informed consent.

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N.A.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.obpill.2022.100019.

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