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Controversies in Bariatric Surgery

Bariatric and metabolic surgery during COVID-19 outbreak phase 2 in Italy: why, when and how to restart

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Abstract

In Italy elective bariatric and metabolic surgery was cancelled on February 21, 2020 at the beginning of the so-called phase 1 of the SARS-CoV-2 outbreak. Gradually it was restarted on May 4, 2020 at the beginning of the so-called phase 2, when epidemiological data showed containment of the infection. Before the outbreak in eight high-volume bariatric centers 840 patients were surgically treated developing a Covid-19 infection, during phase 1, in only 5 cases (0.6%) without mortality. The post-operative complication rate was similar when compared to the 836 subjects submitted to bariatric surgery the year before. Since the high prevalence of infection in subjects with BMI > 30, it was argued that early intervention on obesity during phase 2 could help to minimize the effects of the disease in the event of a possible reversion to a SARS-CoV-2 outbreak phase 1. At the same time a prospective observational study from July 1 till the WHO declaration of the end of the pandemic has started in the eight high volume centers to monitor the post-operative outcome and its effect on SARS-CoV-2 infection. (Surg Obes Relat Dis 2020;16:1614–1618.) © 2020 American Society for Bariatric Surgery. Published by Elsevier Inc. All rights reserved.

Since its first isolation in Wuhan, China in December 2019, the novel coronavirus 2 (SARS-CoV-2) responsible for the coronavirus disease 2019 (COVID-19), has become

a pandemic in just a few months. In Italy, the first person-to-person transmission was reported on February 21, 2020, in Lombardia region, causing so far one of the most extensive outbreaks in Europe. As of May 4, 2020, the total number of cases in Italy was 211,938, with 29,079 deaths and the estimated percentage of infected persons was 4.76% (4.28%–5.37%), that means almost 5,000,000 people [1,2]. The near totality of elective nononcologic procedures

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has been postponed by the end of February to increase capacity for inpatient beds and acute care [3].

The elderly, especially those with a higher rate of comorbidities, were the most severely affected population [4]. It seems that the increased prevalence of obesity in older adults in Italy compared with Chinese population may account for the differences in mortality between the 2 countries. Thus, the rising prevalence of obesity in the United States and prior experience of the impact of obesity on mortality from H1N1 flu should increase the sensitivity of clinicians caring for patients with obesity and COVID-19 for the need for aggressive treatment [5].

However, epidemiologic studies conducted up to now have indicated obesity as severe co-morbidity in patients with age <60 years. Young people with obesity have required intensive admission more often than healthy weight people with related higher mortality. In New York, of 3615 patients with SARS-CoV-2–positive swab between March 4 and April 4, 2020, 21% had body mass index (BMI) of 30 to 34 and 16% had BMI >35. Robust data show a link between the BMI and the need for hospitalization and intensive care unit (ICU) admission in positive patients younger than 60 years [6]. The Intensive Care National Audit & Research Centre reported that 72.1% of 775 patients were overweight or obese and that among patients with BMI >30 who had undergone ICU admission, 60.9% of them died (www.icnarc.org, April 3, 2020).

A French study on 124 patients in ICU reports that obesity and morbid obesity affected 47.6% and 28.2% of COVID-19 cases, respectively. [7]. The data from previous outbreaks, attributable to different viral agents, also show a correlation between obesity and the severity of the clinical manifestation of viral disease [8,9].

The largest European prospective observational cohort study with rapid data gathering and near real-time analysis, using a preapproved questionnaire adopted by the World Health Organization carried out in 166 U.K. hospitals between February 6 and April 18, 2020 and involving 16,749 people with COVID-19, reported that obesity was associated with a higher probability of mortality [10].

In a prospective, observational cohort of critically ill patients with confirmed SARS-CoV-2 infection admitted to ICU in Brescia (Lombardia, Italy) between March 2 and March 13, 2020 obesity was present in 31% of patients, with an additional 58% being overweight [11].

High-volume Italian bariatric center network data

Throughout the months of January and February 2020, no special protocol was adopted to contain the infection (period immediately before the lockdown).

The primary aim of the present multicenter retrospective report was to evaluate the impact of operating on a bariatric population at risk of infection without specific precautions. We gathered a group of 8 high-volume Italian bariatric

centers, which during January and February 2020 performed 840 bariatric procedures. Of the 8 centers, 5 were in regions with high infection rates (Lombardia [2 centers], Veneto, Piemonte, and Emilia Romagna), and 3 in areas with an infection rate closer to the national average (Toscana and Lazio [2 centers]). A structured phone interview was administered to all the patients operated during that period. We found 5 infections (5.9 cases of 1000 inhabitants), 4 in Lombardia and 1 in Veneto. In the 2 regions, the overall rate of infection on May 2, 2020, was similar (7.2 of 1000 inhabitants) [1]. Among infected patients, 2 had mild symptoms with home care management, and 3 were hospitalized for fever and dyspnea; none died. Four of 5 cases were >60 years, and 3 of 5 cases, reported an extrahospital contact with positive COVID-19 people. The 5 cases made a full recovery with a negative swab.

In the same group of patients, we recorded the rate of postoperative complications comparing it with the same rate of patients undergone to bariatric procedures in the 8 centers during the same period of the year before (2019). Of the 840 patients in 2020, we registered 14 severe complications (Clavien-Dindo III: 12 cases, Clavien-Dindo IV: 2 cases). In 2019, of the 836 patients submitted to bariatric surgery, 12 developed postoperative complications, all class III according the Clavien-Dindo classification, showing a similar outcome compared with 2020 results (χ^2 test = .1467, P value = .701685)

Similarly, oncologic and emergency patients operated in Northern Italy during the peak of the outbreak on March and April, did not experience an increase in the morbidity and mortality rates compared with the 2019 rates of the same period [12]. Therefore, it seems that keeping the COVID/non-COVID pathways separate is a safe approach, supported by the fact that the complication rate was overlapping.

All the patients in the waiting list (phone interview) confirmed consent to bariatric surgery, despite the warning on the risk of COVID-19 infection, as well as on the eventual postoperative quarantine.

What is the next step?

There are little data on patients with morbid obesity contracting COVID-19 after bariatric surgery. Four gastric bypasses, performed between February 24 and March 4, 2020 in Tehran, Iran, have developed COVID-19 as a perioperative complication. The authors stated that performing elective surgical procedures on patients with an undetected hidden or mild form of COVID-19 may lead to hospital transmission of COVID-19. Another small series of surgical patients reported higher morbidity and mortality in COVID-19 patients. The practice guidelines from the national and international society strongly recommend performing the COVID-19 screening test before any elective surgery [13–16].

In Italy on May 4, 2020, the so-called “phase 2” had started (virus outbreak under control status $R_0 < 1$); the phase was characterized by maintaining the strategies adopted to minimize COVID-19 infection (social distancing, respiratory hygiene, face and nose coverings in public settings, school and university closings, and a ban of all public events) while there is still no specific antiCOVID-19 medications and while still waiting for a vaccine.

To delay patients with morbid obesity in the waiting list who are seeking surgery could worsen associated diseases [17,18].

The rapid weight loss after bariatric surgery improves the multiple obesity co-morbidities, including obstructive sleep apnea [19]. In a self-controlled case series study on a population of 56,277 bariatric surgery patients, the risk of respiratory infection significantly decreased during the first 12 months after surgery [20].

As a result, we can argue that early intervention on obesity can help minimize the effects of the disease in the event of a second SARS-CoV-2 outbreak. Moreover, obesity not only increases the risk of infection and of complications for the single obese person, but robust evidence indicates that a large obese population increases the chance of more virulent viral strain, prolongs the virus shedding throughout the total community and eventually may increase overall mortality rate of a pandemic [21].

It seems, therefore, reasonable to address the problem of when and how to restart the elective bariatric surgery in Italy.

How to and why restart

Any resumption of elective bariatric surgery should be prudent and selective, to minimize the risks to patients and healthcare staff [16]. Recently, a panel of experts highlighted the risk of bariatric surgery, especially if out of metabolic control [22]. A prudent restart should not forget the higher risk in patients >60 years of age or with type 2 diabetes out of metabolic control [23].

An expert panel involving 9 bariatric surgeons with proven experience and responsible of high volume/bariatric center of excellence in Italy and 1 infectious diseases specialist involved in the management of severe SARS-CoV-2-infected obese patients was established, and a 2-step modified Delphi method conducted online between April 14 and April 30, 2020 was used to reach consensus.

The secondary aim of the paper was to present the proposal of selection criteria for elective obesity surgery in the phase 2 based on Delphi modified process [24].

The proposed patient’s selection criteria for obesity surgery during phase 2 in Italy is as follows:

1. No previous Sars-CoV-2 infection
2. No concomitant procedure
3. >18 and <60 years old

4. Avoid long procedure (estimated >120 min)
5. Type 2 diabetes must be compensated
6. Hypertension must be controlled
7. Patients with obstructive sleep apnea can only be admitted if therapy with home continuous positive airway pressure is effective
8. Postpone surgery in patients who may need an extended stay or intensive care
9. Signature of the informed consent, including COVID-19 section proposed by the national bariatric society [16]

The following considerations have been emphasized by the expert panel to support why elective bariatric surgery should be unlocked:

1. The average age of the patients on the waiting list ranged between 40 and 50 years
2. Usually short-duration procedures adopted
3. Short hospital stay
4. Limited need for ICU in such selected population
5. The rate of Sars-CoV-2 infection in bariatric patients in the period between January 7 and March 6, 2020, is very low (.6%), despite the absence of lockdown and specific measures against Sars-CoV-2 infection
6. The surgical complications rate does not seem to be affected by the pandemic in a series of oncologic and emergency digestive surgery patients
7. The surgical complications rate does not seem to have changed even in bariatric patients

Hospital admission protocol

Two to 3 days before admission, the patient should be interviewed by telephone with the following questionnaire:

1. Have you been experiencing fever (threshold value $>37.5^\circ\text{C}$), especially in the last 48 hours?
2. Do you have any new respiratory symptoms?
3. Do you have any other symptoms, such as vomiting, diarrhea, conjunctivitis, changes in smell or taste, osteoarticular pain, or excessive fatigue?
4. Have you been exposed to someone with clinical diagnosis—positive swab COVID-19 in the last 2 weeks?

The patient should arrive at the hospital 24 to 48 hours before hospitalization, outside the hospital, the medical staff must repeat the interview as above and swab the patient. In the case of a positive swab, surgery must be suspended. In the case of negativity, the patient must sign a specific consent, after which the operation can be carried out with hospitalization on the same day of the procedure.

These procedures are in line with international and national guidelines for the screening of patients before entry the hospital [13–17,22,25]

Operating room protocol

The centers participating to the network are committed to following national (Ministry of Health, Regional Health Authority) and international guidelines recommendations [1,12–17,23,25]. Moreover, the procedures should be possibly performed by expert surgeons and anesthesiologists to minimize the operating room occupation time.

Management of in-hospital patients

The following guidelines will apply to manage in-hospital patients:

1. Social distancing must be respected even in case of post-surgical mobilization
2. The patient should always wear a surgical mask
3. The patient should have a single room, or in the case of a large room, a suitable space between the patients should be assigned to comply with the laws in force on social distancing.

After discharge

The following guidelines will apply to after discharge:

1. In the case of intrahospital contact with COVID-19 patient or healthcare staff, a period of 14-days self-quarantine after discharge is mandatory
2. Home physical activity
3. Implement oral supplementation
4. Low-dose heparin for at least 3 weeks
5. After 7 and 15 days the patients will receive a follow-up phone call.

Discussion

In Italy, the phase 2 presents the same epidemiologic aspects observed in January and February before the outbreak, when the incidence of postoperative COVID-19 infection was .6% without mortality in a cohort of 840 bariatric surgery patients. The restart of elective bariatric surgery should be progressive and prudent, with proper patient selection based on the lesson learned during the phase 1. An expert panel of bariatric surgeons and infectious disease specialist agree on the patient's selection criteria, in and out of hospital protocol, to minimize the risk of COVID-19 infection in phase 2. From July 2020, all the data of the bariatric cases performed in the 8 centers will be collected in a prospective database, to monitor the postoperative course of the patients until the World Health Organization will declare the end of the pandemic. Nonetheless, high-volume centers must take responsibility to plan the new scenario to continue their surgical and clinical activity, respecting the patient safety and

the need for the cure of morbid obesity, which was considered, before the COVID-19 pandemic, the pandemic of the Third Millennium. Nevertheless, criteria of prioritization of access to diabetes surgery are matter of debate [17].

Conclusion

In summary, the deliverance of transparent information to the patients and the introduction of the COVID-19 protocol concerning patients and health-professionals protection, seem to guarantee in Italy a safe restart of elective laparoscopic bariatric surgery. The establishment of a network of high-volume centers sharing information and protocol in this “unexplored” period is a guarantee for the safety of patients.

Patients with severe obesity usually have multiple comorbid conditions, which would make them vulnerable to a severe form of COVID-19. Bariatric surgery induces a postoperative amelioration of those co-morbidities reducing the risk in case of a second outbreak while waiting for the antiCOVID-19 vaccination.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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