Obesity Surgery (2020) 30:4159–4164
https://doi.org/10.1007/s11695-020-04733-8

BRIEF COMMUNICATION

A Structured Approach for Safely Reintroducing Bariatric Surgery in a COVID-19 Environment

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Published online: 26 May 2020

Abstract

Due to the profound effect of novel coronavirus disease 2019 (COVID-19) on healthcare systems, surgical programs across the country have paused surgical operations and have been utilizing virtual visits to help maintain public safety. For those who treat obesity, the importance of bariatric surgery has never been more clear. Emerging studies continue to identify obesity and several other obesity-related comorbid conditions as major risk factors for a more severe COVID-19 disease course. However, this also suggests that patients seeking bariatric surgery are inherently at risk of suffering severe complications if they were to contract COVID-19 in the perioperative period. The aim of this protocol is to utilize careful analysis of existing risk stratification for bariatric patients, novel COVID-19-related data, and consensus opinion from multiple academic bariatric centers within our organization to help guide the reanimation of our programs when appropriate and to use this template to prospectively study this risk-stratified population in real time. The core principles of this protocol can be applied to any surgical specialty.

Keywords Bariatric surgery · COVID-19 · Coronavirus · Complications · Safety · Pneumonia

Introduction

In the USA, non-urgent surgical procedures have been postponed due to the novel coronavirus disease 2019 (COVID-19) pandemic with the hopes of preserving much-needed equipment and minimizing exposure to patients and staff. For this reason, bariatric programs across the country have paused surgical operations and have been utilizing virtual visits to maintain multidisciplinary care pathway momentum and fulfill insurance requirements. Superimposed on this historic public health threat is a looming economic disaster stemming from essential social distancing and the effective interruption of the global economy. The resulting economic and political pressures are forcing Federal and State officials to consider reopening the country, including phasing back in elective, non-urgent surgery [1, 2].

For those who treat obesity and associated metabolic disease, the importance of bariatric surgery has never been more clear. Emerging studies continue to identify obesity and several other obesity-related comorbid conditions as major risk factors for a more severe COVID-19 disease course, suggesting yet another addition to the long list of afflictions related to the global obesity epidemic [3–5]. However, this also suggests that patients seeking bariatric surgery are inherently at risk of suffering severe complications if they were to be undiagnosed asymptomatic or pre-symptomatic carriers of COVID-19 at the time of surgery or contract it in the perioperative period. While it is reasonable to assume that the beneficial effects of surgical therapy for obesity and related conditions could significantly mitigate the severity of COVID-19 infection, that must be carefully balanced against many unknown perioperative variables in a truly novel and dynamic situation.

There is no established playbook for this. There is no litany of research to help guide our field through the inevitable challenges we will collectively face as we try to carefully usher our

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patients back to the critical therapies they need. A simple reopening of the floodgates without careful attention to triaging based on perceived risk could be disastrous for patients, staff, and local hospital infrastructure. To our knowledge, there are currently no reports helping to establish safe practice guidelines for reintroducing bariatric surgery to our communities in a COVID-19 environment. The aim of this protocol is to utilize careful analysis of existing risk stratification for bariatric patients, novel COVID-19-related data, and thoughtful consensus opinion from multiple bariatric centers within the Cleveland Clinic Ohio Health System to help guide the reanimation of our programs when appropriate. This template will then be used to prospectively study this risk-stratified population in real time. We hypothesize that the core principles of such a protocol are useful for any surgical specialty considering careful reintroduction of surgical therapies.

Methods

In developing our proposed tiered protocol (Table 1), we aimed to align with established bariatric risk data and prediction models, recent guidance principles from the American College of Surgeons, and consensus among eight bariatric surgeons in the four Ohio bariatric programs within our organization, including Cleveland Clinic Main Campus, Fairview Hospital, Hillcrest Hospital, and Akron General [2, 6–8]. The consensus opinion was important as previously established risk prediction models and calculators do not account for COVID-19 risk nor the important effects of certain outcomes on healthcare resource utilization during a pandemic. The goal of the safety-centered tiered approach is to adhere to the following key principles, understanding that these recommendations will have to be individualized in each practice setting based on resources and the status of patients, surgeons, centers, and regions:

- Break down local patient population into reasonable risk tiers based on local patient and resource characteristics, as suggested in Table 1
- Start cases in the lowest risk group (tier 1) with reasonable expectation of rapid discharge from the inpatient setting and having less risk of protracted postoperative course if they develop COVID-19
- Consider slower than average case volumes initially (for example, ~ 50% typical volume) to ensure real-time safety analysis and mitigate unknown risk
- Suggest strict social distancing for 2 weeks before bariatric surgery to limit exposure
- Preoperative COVID-19 testing in all prospective patients (depending on local availability) as close to surgery as possible with strict quarantine between testing date and surgery date
- Consider adjunctive preoperative chest CT scan if COVID-19 status, interval exposure risk, or clinical picture is unclear
- Constant monitoring and analysis of real-time data before transitioning to the next tier or continuing with the current tier if outcome data is of concern
- Heavy reliance on outpatient-based postoperative care (virtual or in-person), including preemptive hydration clinics, to avoid unnecessary postoperative emergency room visits or inpatient admission

All patients with pre-existing insurance approval for bariatric surgery from the four participating centers were then partitioned into one of the three tiers based on the criteria in Table 1. Demographic data of the cohort in each tier were extracted and analyzed to help predict the surgical risk and resource utilization needs. Categorical and continuous variables were reported as frequencies (%) and mean ± standard deviation (SD), respectively.

Results

We identified 98 patients between our four Ohio bariatric programs who had already obtained insurance approval for their bariatric procedure and were ready to schedule. The cohort had a mean age of 47.8 ± 11.3 years, mean body mass index (BMI) of 45.8 ± 7.6 kg/m^2, and 80.6% ($n = 79$) were female. Planned primary procedures included Roux-en-Y gastric bypass ($n = 52$), sleeve gastrectomy ($n = 39$), and duodenal switch ($n = 2$). There were 2 cases of gastric bypass with associated hiatal hernia repair and 4 revisional procedures. Detailed results of the specific tiered variables and the effect that had on the allocation of the cohort can be found in Table 1. Patients were categorized to tier 1 (low risk, 39%), tier 2 (intermediate risk, 25%), and tier 3 (high risk, 37%) based on their perioperative risk for future surgical scheduling.

Discussion

There is still much that remains unknown about COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). What we do know is that the pathogen typically has a median incubation period of 4 days (range, 2–7), patients needing medical attention tend to present to hospital 7 days after onset and need for intensive care unit (ICU) level care is at around day 10. Patients in the ICU require much longer periods of time than typical ICU patients and carry staggering mortality rates, especially once they require invasive ventilation. SARS-CoV-2 is a highly

Table 1 Risk stratification for reintroducing bariatric surgery after the peak of COVID-19 at the Cleveland Clinic

Condition	Tier 1 Low risk Must meet all conditions below	Tier 2 Intermediate risk If not considered as tier 1 and tier 3 Other eligibility criteria are listed below	Tier 3 High risk If meets any of these conditions below
Type of surgery	Primary bariatric procedure without other major concurrent procedures	Lower risk revisional procedures: - Conversion of gastric band or sleeve to other procedures	- Revisional surgery in patients with prior open bariatric surgery - Conversion of VBG to other procedures - Concurrent procedures such as paraesophageal hernia repair - Procedures with higher than average risk for conversion to open surgery, blood transfusion, and prolonged length of stay (e.g., hostile abdomen)
Suggested age cutoff	< 60 years		≥ 60 years
Suggested BMI cutoff	< 55 kg/m^2		≥ 55 kg/m^2
ASA class	No ASA class 4		
Mobility	No mobility restriction		
Diabetes	No diabetes or controlled type 2 diabetes	- Poorly controlled diabetic (HbA1c > 8%) - Need for high-dose insulin - Type 1 diabetes	
Hypertension	No hypertension or controlled (< 140/90 mmHg) with one or two antihypertensive agents		
Cardiac disease	No underlying heart disease	Stable heart disease: - Stable coronary artery disease - Controlled atrial fibrillation or other arrhythmias	Significant history of heart disease: - Previous myocardial infarction - Heart failure - Ejection fraction < 40% - Previous cardiac stents requiring continuing perioperative antiplatelet medications
Lung disease	No underlying lung disease	Mildly impaired pulmonary function tests (FEV1 ≥ 80% predicted value)	- Moderately or severely impaired pulmonary function tests (FEV1 < 80% of predicted value) - Need for home oxygen
Obstructive sleep apnea	No severe OSA (AHI ≥ 30)		
Renal disease	No CKD stage 3, 4, or 5		On dialysis
Liver disease			Cirrhosis ± portal hypertension
Immunosuppression including steroids	Not on immunosuppressive medications		On immunosuppressive medications
Anticoagulant	Not on anticoagulant		
Cleveland clinic cases to be scheduled (N = 98)*			
N (%)	38 (39%)	24 (25%)	36 (37%)
Age (years), mean ± SD	41.1 ± 8.4	48.3 ± 7.9	54.5 ± 12.0
BMI (kg/m^2), mean ± SD	44.4 ± 4.4	43.3 ± 5.1	49.0 ± 10.1

Table 1 (continued)

Condition	Tier 1 Low risk Must meet all conditions below	Tier 2 Intermediate risk If not considered as tier 1 and tier 3 Other eligibility criteria are listed below	Tier 3 High risk If meets any of these conditions below
Bariatric procedures			
SG	15	5	19
RYGB	23	15	14
DS	0	1	0
SG to RYGB	0	3	0
RYGB and HHR	0	0	2
Open reversal of RYGB	0	0	1

AHI apnea hypopnea index, *ASA* American Society of Anesthesiologists, *BMI* body mass index, *CKD* chronic kidney disease, *DS* duodenal switch, *FEV1* forced expiratory volume in 1 s, *HbA1c* glycated hemoglobin, *HHR* hiatal hernia repair, *OSA* obstructive sleep apnea, *RYGB* Roux-en-Y gastric bypass, *SG* sleeve gastrectomy, *VBG* vertical banded gastroplasty

*As of April 20, 2020

contagious pathogen with significant asymptomatic carrier rates and emerging opinion that people are likely highly contagious before ever exhibiting symptoms. For this reason, COVID-19 has rapidly become a once-in-a-generation global pandemic capable of quickly overrunning public health infrastructure [9–12]. Initial reports out of China suggested high sensitivities for CT chest in diagnosing COVID-19 (98% sensitivity) but subsequent reviews of the literature have brought that practice into question. Diagnosis can be confirmed using nasal and pharyngeal swab specimens to perform sequencing or reverse transcriptase–polymerase chain reaction (RT-PCR) for SARS-CoV-2 and sensitivities in these developing protocols continue to improve [13–15]. The accuracy of the RT-PCR in the postoperative period is unknown.

The profound metabolic effects of bariatric surgery are well known [16]. It is easy to imagine a scenario where the benefits of surgery could feasibly mitigate some of the reported major COVID-19 risk factors that are so prevalent in bariatric patient populations, like type 2 diabetes, hypertension, chronic lung disease, and the pro-inflammatory obesity state itself. However, emerging reports demonstrate significant mortality rates in patients who underwent elective surgery during the early phases of the pandemic and unknowingly had COVID-19. Furthermore, it is unknown if surgical stress or perioperative physiological changes can increase the risk of contracting or exacerbating COVID-19 infection and management of higher BMI patients with multiple cardiopulmonary comorbidities who develop COVID-19 pneumonia postoperatively would be extremely challenging [17, 18]. Although the current practice of bariatric surgery is very safe, known complications, such as postoperative bleeding, anastomotic leak, or pulmonary embolism, could significantly increase resource utilization, length of hospital stay, and thus, absolute time for possible exposure to COVID-19 in the hospital. Elective surgery on patients with undetected asymptomatic and pre-symptomatic COVID-19 may lead to transmission of COVID-19 to healthcare providers and contamination of crucial operating room infrastructure. Similarly, bariatric surgical patients may acquire the infection during their hospital stay [10, 18, 19].

There are many approaches to prioritizing bariatric patients once the time comes for restarting surgical practices. One approach would emphasize on prioritizing the highest cardio-metabolic risk populations chasing protective metabolic and cardiovascular effects of bariatric surgery. According to this approach, patients with uncontrolled diabetes, on high-dose insulin, with macro- and micro-vascular complications of diabetes, heart failure, severe sleep apnea, or BMI > 60 kg/m^2 should have expedited access to bariatric surgery. On the other hand, the cornerstone of our approach is based on safety concerns considering the potential risk of poor outcomes if a patient were to develop postoperative COVID-19 infection. Our group believes a more aggressive approach assumes a

safety profile we have yet to establish and may overlook the effect this could have on infrastructure that still continues to struggle with resources to combat COVID-19 despite the widespread cessation of elective procedures. Our structured approach focuses on slow and selective restarting of surgical practice until we learn more about the impact of COVID-19 on bariatric surgical patients.

Another point of view taken by some is questioning the current timing of reinstituting bariatric surgery in certain places. Given the heterogeneous approach in opening up states and healthcare infrastructure across the USA, this tends to be a more challenging and existential argument. This question gets to the very core of what bariatric and metabolic surgery achieves in its patients, mainly improvement of metabolic derangements and the effects on end-organ dysfunction through comprehensive, surgical-driven weight loss strategies. Many states are still experiencing significant COVID-19 hospitalization numbers and strains on their systems. Other states, like Ohio, are moving into phased approaches of reintroducing healthcare functions. In Ohio, recent guidelines by the governor recommended proceeding with already delayed non-emergent cases if they met any of a list of conditions, including the threat of permanent dysfunction of an organ system, risk of rapidly worsening or severe symptoms, or presence of severe symptoms causing an inability to perform activities of daily living [20]. These types of definitions are also core principles in how these patients were insurance approved based on medical necessity. Regardless, based on definitions in our state, programs are now starting to move forward with bariatric cases and this calls for thoughtful approaches with real-time data analysis. We recommend that all surgical programs across the USA familiarize themselves with their local and state COVID-19 data reports, case projections, resource analyses, and government-mandated orders and protocols as these data will help guide them through the programmatic reintroduction process.

As seen in Table 1, the application of the proposed tiered safety protocol split the current cohort of approved patients into three very manageable groups from an institutional resource utilization standpoint. Currently, we have 38 patients comprising the tier 1 group and we feel this will be a useful number of patients to analyze as we consider the safety profile of bariatric surgery in the midst of the COVID-19 pandemic. This will allow us to assess for suitability of transition to the next tier based on tier 1 perioperative outcomes, local epidemiological factors, and hospital resources when that time arrives.

Herein, we present a practical protocol for the triage of bariatric surgery patients as we aim for the safe reintroduction of non-urgent surgery in the USA in an active COVID-19 environment. This protocol contains core principles and considerations that should be useful for all surgical specialties as they consider similar paths toward programmatic reanimation and can serve as a template in analyzing tiered outcomes in real time.

Acknowledgments We acknowledge Eileen Arnold, Helene Hamulak, Beth Janssen, Jamie Sarver, and Kathy Smolenski from the Cleveland Clinic Main Campus, and Tracy Akers and Angela Smoleny from the Cleveland Clinic Akron General for their assistance with data collection

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethics Approval For this type of study, formal consent is not required.

Informed Consent Statement Informed consent does not apply in this study.

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