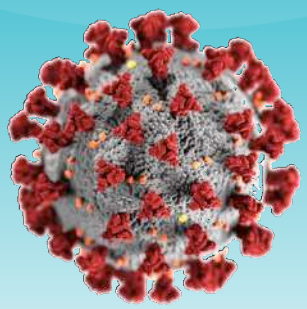
GUIDELINES FOR COVID19 ERA



OSSI

Bariatric & Metabolic Surgery 2020

Severity of illness due to the Covid19 virus is very high in the obese. Bariatric Surgery has to be carefully started in a graded fashion in the current scenario.

Key points to be considered are:

1. Emergency surgery as indicated to continue.
2. Elective to be prioritized as urgent, semi urgent and others.
3. PPE familiarization for OPD, Wards and OT
4. Covid19 workup including RTPCR and Chest CT
5. OT preparation with pressure settings, availability of smoke evacuators
6. Safe anesthesia, handling of GCT and equipments
7. Safe laparoscopy with reduced leak of CO2 and smoke management
8. Post operative ERAS protocols
9. Follow up management including Covid19 awareness
10. Dietary modifications to improve immunity and home based physical activity and exercise

Covid19 in Obese

A pro-inflammatory state coupled with malnutrition may lead to impaired immune response in patients suffering from obesity and increased susceptibility to all influenza viruses including COVID-19.

GUIDELINES

Considering obesity and bariatric surgery to be of equal importance as other chronic life threatening diseases and cancer, OSSI formulated the guidelines for the resumption of bariatric procedures.

These recommendations are mostly based on the opinion of experts given the paucity of data on this subject. The aim is to accord the highest priority to the safety of patients and healthcare workers

Annexure

Preoperative

Patient selection, COVID workup, additional investigations, consent.

Inpatient & OT

OT facility requirements, OT management, Personnel, PPE,

Post operative

Discharge planning, Diet & Exercise, OSSI registry & research

OSSI Recommendations for Bariatric and Metabolic Surgery Practice in the Covid era

The Covid 19 pandemic has had a huge impact on the healthcare services worldwide. All planned elective procedures and operations have been put on hold. Unfortunately, bariatric and metabolic surgery took the worst brunt of the pandemic with most centres putting a complete halt to new referrals and operations. Worryingly, the severity of Covid 19 infection is worse in patients suffering from obesity, and as bariatric surgeons we will need to incorporate specific measures in operating theatre practices to minimise risk of Covid 19 infection to patients as well as healthcare professionals (1).

Obesity is an underlying factor for type 2 diabetes, hypertension, cardiovascular disease, renal disease, and venous thromboembolism and has a detrimental effect on lung function. A pro-inflammatory state coupled with malnutrition may lead to impaired immune response in patients suffering from obesity and increased susceptibility to all influenza viruses including Covid 19. While the world battles with Covid 19 pandemic, obesity pandemic continues to have a huge impact on general health and mortality. Weight loss is extremely important to reduce the health risks in obese, and surgery is one of the important ways to do so. (2)

Considering obesity and bariatric surgery to be of equal importance as other chronic life threatening diseases and cancer, OSSI formed a committee of expert bariatric surgeons who formulated the guidelines for the resumption of bariatric procedures. Published IFSO (3) and ACS (4) recommendations were taken into account in compiling these.

The essential requirements for resumption included a reduction in rate of new Covid 19 cases. However resumption of bariatric surgery has to be a calibrated approach guided by available National and State health authority policies, availability of resources including Covid testing and PPE as well as health personnel.

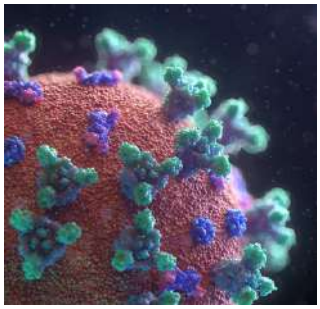
These recommendations are mostly based on the opinion of experts given the paucity of data on this subject. The aim is to accord the highest priority to the safety of patients and healthcare workers (HCW). This will mandate induction of safety measures in all SOPs involving the journey of the patient from admission to discharge from the hospital as well as post discharge care.

Annexures

1. Preoperative Preparation of a Patient : Patient selection, Covid workup, additional investigations, consent.
2. Indoor and OT protocols : OT facility requirements, OT management, Personnel, PPE, Anesthesia, Minimal Access Surgery guidelines, Smoke evacuation, Bariatric Surgery specific points.
3. Post operative protocols, Discharge planning, Diet & Exercise
4. OSSI registry, Conclusion, References.

ANNEXURE I

Preoperative Preparation of a Patient



A : General Points

● Obese patients have a higher risk of morbidity/mortality should they develop Covid 19 infection (4)

● This will hold true for the perioperative period too (5) as the patient is still obese after surgery. There is insufficient data available to comment that obese patient post bariatric has increased risk of infection because of surgery.

● Consider use of Prearrival Screening and preoperative patient evaluation preferably using Telemedicine

● Patients should preferably self-isolate for 2 weeks before the operation

● All Investigations including tests for Covid 19 (if possible) must be complete as far as possible before admission.

● Special attention and re-evaluation needed if patient has had Covid 19

B: Patient Selection

● Because of the progressive nature of obesity and diabetes, delaying surgery increases risks for morbidity and mortality, thus requiring strategies to mitigate harm. The risk of harm, however, varies among patients, depending on the type and severity of their co-morbidities. A planned strategy is therefore needed.

● Emergency surgeries for bleeding, perforations, strictures, obstructions etc need to proceed with all precautions.

● Elective surgery can be planned in advance as below. (7)

- Urgent elective surgery is required for conditions that might deteriorate like dysphagia, vomiting, those needing reversal etc.
- Semi-urgent conditions are likely to deteriorate, if delayed for long like worsening of diabetes and its complications, awaiting renal transplants, joint replacements etc.
- Non-urgent elective surgery is planned for conditions that are unlikely to cause harm if delayed.

● Well Informed and Motivated patient

● **For non urgent elective surgery**, to restart the practice, patient deemed to be straightforward should be selected. Younger patients with few comorbidities may be ideal. It may be best to avoid those with a Body Mass Index of 50 kg/m2 or more to start with.

● Avoid complex revisional bariatric operations initially as it may take longer to perform.

● Avoid high risk patients initially like those with severe obstructive sleep apnea (OSAS) and patients > 60 years, history of VTE etc

• Good control of comorbidities is desirable especially in patients with diabetes mellitus, hypertension and OSAS

C: Detailed Covid 19 Related History

History of fever, cough, travel, contact etc as per the government and hospital protocols

D: Initial Approach

• Admit in Isolation room with only one attendant

• Surgical Masks for all HCW, patient and attendant

• Body Temperature with Non-Contact method

• Re evaluation by the operating surgeon

F: Additional Investigations Required

• **Covid Testing**: Testing for Covid 19 should be guided by the national and state health policies. If available, both Antibody and RT-PCR should be done. All patients should have negative results for Covid 19 antigen test 48-72 hours before the operation. The tests should be done preferably prior to admission for surgery.

• **Imaging**: If required, Imaging should be focused on Portable Radiographs and Bedside portable Ultrasound/ POCUS – Point of Care USG to avoid unnecessary patient transport. In one study, Chest CT scan had sensitivity of 98% compared with RT-PCR sensitivity of only 71% (8). CT chest can be done as a routine screening method or can be done selectively in high-risk patients e.g. those with pre-existing cardio-respiratory comorbidity. CT Chest should be done preferably in the morning of the surgery or a day prior to further reduce the risk of operating on patients with active infection.

G: Consent Form:

A consent form to include the following salient points

• Patient should give consent that he/she is willing to get operated while the pandemic situation has not subsided

• Hospital will not be held responsible if patient develops Covid19

• He/She has been explained that there is evidence that surgery in infected but asymptomatic patients is associated with a more severe disease manifestation in the post-operative period and an increased mortality

ANNEXURE II

Indoor Protocols

● General guidelines about hand hygiene, physical distancing, cough etiquettes, cleaning and disinfection protocols are well known and and should be adhered to at all times. (9)

● Injection and medication safety precautions should be followed

● Risk assessment for appropriate use of PPE: (10)

● All healthcare personnel must be assessed and monitored daily.

● Training programs for all healthcare personnel

● Transportation of patients from ward to the OR and back by a green corridor and a safe transfer route.

Operation Theatre Protocols

A: Facility Requirements

● Elective bariatric operations should ideally be carried out on a cold, Covid negative site.

● If such a separate hospital is not available, then all elective operations should be carried in a different area / wing of the main hospital.

B: OT management;

● Operation theatre protocols, SOP and nursing, anaesthesia, surgery checklists regarding Covid 19 should be revised

● Allow longer than usual time per case e.g. add 50% to 75% of total theatre time required. The extra time would be required for adequate checks to be performed, PPE donning and doffing safely, and cleaning theatre space in between cases.

● It is desirable to consider changing the pressure with the OT from positive to negative (11).

● If that is not possible, switch off the positive pressure 30 minutes before induction and start 30 minutes after sanitisation at end of surgery.

● It is recommended to use smoke evacuation devices if possible to protect health care works (no sufficient evidence available for covid 19 to be present in smoke but there is sufficient evidence of virus like HCV, HPV, HIV to be present is smoke.

C: OT personnel

● All staff in OT should definitely be asymptomatic and ideally tested for antibodies when a reliable antibody test becomes available (check

MOHFW guidelines). They should work only in a non-Covid OT.

● All staff in OT should undergo fit testing for FFP3 masks and should be trained in donning and doffing PPE (12).

● Staff should ensure safety checklists cover that patients have had adequate screening as detailed

above including specific consent form covering Covid 19 infection risk.

D: Personal Protective Equipment
To be worn in OPD too while seeing patients

PPE to be used in all cases by all staff based on the guidelines of MOHFW for Operation theatre staff (10).

- FFP3 mask/N 95 respirator mask
- Eye protection – Goggles or face shield. For longer cases, a respirator hood
- Fluid proof shoe cover
- Fluid resistant double gown
- Double gloves

E: Anaesthetist (intubation protocols)

● Endotracheal intubation is a high-risk procedure for cross-contamination both to the anaesthetist and patient. Limited

number of staff with PPE should be present in the room during tracheal intubation. Surgical and Nursing team should enter 15 minutes after intubation.

● Anesthesia guidelines are available (13, 14).

F: Intra-operative precautions

● Minimum number of theatre staff and all staff should wear PPE.

● Surgeons may be out of practice. So, it may be important to develop procedure specific "time out" checklists that reduce errors and ensure surgeons finish all steps of the operation. In the beginning, it may be worth two trained surgeons pairing up to facilitate surgery and reduce chances of errors and complications.

● The following practical measures for use of filtration during laparoscopy must be followed (15-17):

1. Avoid Open technique for entry into the abdomen as that can cause leak of CO2. Initial entry should be considered with optical trocar or balloon ports can also be used. The skin incision for ports should also be kept as small as possible.

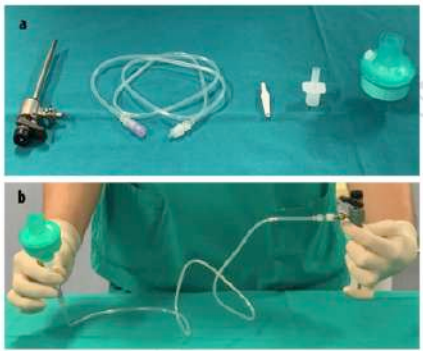
3. Reduce the intra-abdominal pressure to as low as possible without compromising surgical exposure or patient safety.

4. If the surgeon decides to change to another port for insufflation; the original port should be closed prior to disconnecting the tubing and the new port should be closed until the tubing is connected. The insufflator should be 'on' before the new port is opened to prevent gas from back flowing into the insufflator.

5. Surgeons should aim to reduce smoke / vapour generation.

Electrosurgery units should be set at lowest possible settings.

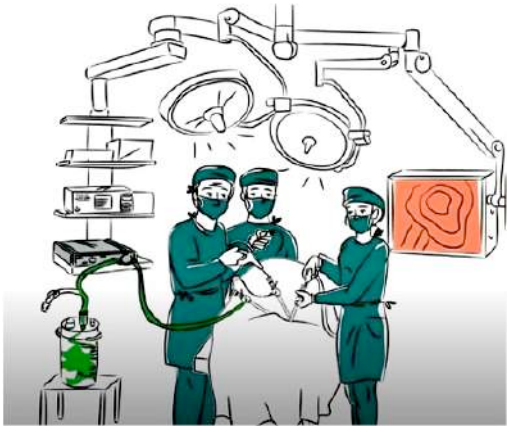
6. Monopolar diathermy with attached smoke evacuator may be



preferable. Ports should NOT be vented during the procedure. Bipolar, ligasure and enseal safer than harmonic and sonicision.

7. During desufflation the insufflator should be switched off and the port connected to the insufflator closed.

8. If possible, all CO2 gas and smoke should be captured with an ultra-filtration system. A number of



commercial devices are available including Virovac (Conmed), Rapidvac (Medtronic), Pneumoclear (Stryker), MegaVac Plus (Ethicon), S-PILOT (Karl Storz) and it is recommended to procure one such system during the preparation period.

9. Pneumoperitoneum should be evacuated from port attached to filtration device before trocar removal, specimen extraction, declamping of drain or conversion to open.

10. The patient should be flat and the least dependent port should be used for desufflation.

11. Surgical drains and NG tubes should be avoided. If used, the drain should be clamped until complete desufflation.

G : Intraoperative special points for bariatric surgery

1. Entry into obese abdomen by muscle splitting optical trocar.

2. Leaks around trocars, Nathanson etc during surgery need to be minimised by additional purse string skin sutures when needed.

3. One extra 5 mm port for suction cannula to suck simultaneosusly during energy usage.

4. Careful and swift introduction of staplers and suture material to reduce leaks.

5. Careful Gastric calibration tube handling with all precautions that were taken during intubation.

6. Port closures in deflated obese abdomen to be done carefully and if need be, incision extended by a few mm for this.

7. Robotic surgeon at console also to wear basic PPE and take precautions. Experienced person by patient table who can handle leakage and smoke evacuation.

ANNEXURE III

Postoperative Care

● Adhere to standardized ERAS protocols for early discharge.

● Cough and/or fever after surgery: Differential diagnosis for postoperative cough/ fever/ breathlessness should include Covid 19. RT-PCR for Covid and /or CT chest may be needed to confirm the diagnosis..

● In patients with suspected or confirmed Covid 19, there is a greater risk of complications such as deep vein thrombosis (DVT) and secondary pulmonary infections (18). Strict VTE prophylaxis, close laboratory monitoring, and appropriate imaging monitoring is indicated.

Diet and Exercise

• Special advice on immunity boosting diet. Vit D, Vit C and Zinc rich food to be stressed.

• There may be difficulty in procuring supplements, hence more stress on nutritious home food.

• Regular zoom or whatsapp video interactions with patients to ensure compliance.

• Low impact home exercises, you tube exercises, Yoga to be suggested in the absence of any gym program these days.

Discharge Protocols:

● Patients should be discharged as early as possible. Discharge should be “only discharge at home” as the default pathway.

● Patients should be discharged with instructions to stay close or have ready access to the treating hospital especially in the initial days.

● General Covid prevention advice and symptoms and signs suggestive of bariatric complications and Covid should be clearly explained to the patient.

● Any respiratory symptoms in the postoperative period should be treated urgently and Covid 19 pneumonia must be considered in the differential diagnosis.

● Patients should be provided an emergency 24X7 contact number. Patients should call the operating surgeon directly for any problem rather than going through their own general practitioner.

ANNEXURE IV

Reporting of Data to OSSI

OSSI encourages all bariatric surgeons in India to submit data regarding any serious adverse events (SAE) as soon as possible following resumption of bariatric surgery. A SAE form with separate questions for Covid will be created and put on the OSSI website soon.

Conclusion

Covid 19 Pandemic in India is still in rising phase and the situation is still evolving. As such it is not possible for OSSI to predict any time frame for resumption of bariatric surgery. It may be prudent to initiate BMS when the pandemic curve shows a deceleration in a region. The safety of patients and HCW is extremely important. The local, state and national advisories and guidelines should be adhered to for resumption of surgery and rational use of resources. Currently, the best practice for mitigating possible infectious transmission during laparoscopic and endoscopic procedures is proper patient and HCW screening and use of a multi-faceted approach, which includes proper room filtration and ventilation, appropriate personal protective equipment (PPE), and smoke evacuation devices with a suction and filtration system, as available.

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