The First Modified Delphi Consensus Statement for Resuming Bariatric and Metabolic Surgery in the COVID-19 Times

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Abstract

The purpose of this study was to achieve consensus amongst a global panel of expert bariatric surgeons on various aspects of resuming Bariatric and Metabolic Surgery (BMS) during the Coronavirus Disease-2019 (COVID-19) pandemic. A modified Delphi consensus-building protocol was used to build consensus amongst 44 globally recognised bariatric surgeons. The experts were asked to either agree or disagree with 111 statements they collectively proposed over two separate rounds. An agreement amongst ≥70.0% of experts was construed as consensus as per the predetermined methodology. We present here 38 of our key recommendations. This first global consensus statement on the resumption of BMS can provide a framework for multidisciplinary BMS teams planning to resume local services as well as guide future research in this area.

Keywords COVID-19 · Resuming elective surgery · Bariatric surgery · Obesity surgery

Introduction

Though many countries now appear to be past their Coronavirus Disease-2019 (COVID-19) peak, the world is still very much in the midst of a pandemic with tens of thousands of new cases being reported globally every day. Not only that the World Health Organisation has also warned that the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus, the causative agent of COVID-19, “may never go away” [1].

Multidisciplinary teams involved in the delivery of Bariatric and Metabolic Surgery (BMS) are trying to find ways to resume their services safely especially because there are expressed concerns that the COVID-19 pandemic might further aggravate the ongoing obesity pandemic [2]. Several guidelines have been published recently [3, 4] on how to safely resume BMS, but there is currently no global consensus on its various aspects.

Modified Delphi methodology for achieving consensus in areas of poor evidence and disagreements amongst professionals is now firmly rooted in clinical medicine including BMS [5–8]. They are recognised to be more robust and cheaper compared with consensus building in an open room setting. The purpose of this study was to achieve consensus amongst a global panel of expert bariatric surgeons on various aspects of resuming BMS during the COVID-19 era using a modified Delphi methodology.

Methods

We constituted a committee of 44 recognised opinion-makers in the field of BMS from 23 countries. These professionals are
recognised leaders in the field and include the current, the incumbent, and several past presidents of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO); presidents or other office-bearers of many national obesity surgery societies; and many others recognised for academic excellence in the field. Sjaak Pouwels and Islam Omar were non-voting committee members.

The committee members collectively proposed a total of 111 statements to vote on in two separate rounds after discussions amongst themselves. The word “must” was used to suggest an essential requirement whereas “should” suggested a desirable requirement. The phrase “initial phase” indicated a period of 3 months upon resumption of BMS in that centre.

The members were asked to either agree or disagree with each statement. Following other published consensus papers [5–8], an agreement amongst ≥ 70.0% of experts was construed as consensus. Voting was conducted virtually on Typeform®, and no attempt was made to identify individual members’ responses.

The first-round voting link was made live on 23 May 2020, and the second-round voting was concluded on 1 June 2020. The committee voted on 88 statements in the first round. In the second round, the committee voted on only those statements where there was an agreement/disagreement of ≥ 60.0% but not enough to reach the consensus threshold of 70.0%. The committee did not vote again on statements with an

Table 1  Key consensus points in general and facility-specific considerations

| Serial no. | Statements                                                                 | Final voting results |
|------------|----------------------------------------------------------------------------|----------------------|
| 1.         | A delayed elective BMS hinders the resolution of obesity and its co-morbidities. | Agree 100% (N = 44)  |
| 2.         | The decision to resume BMS must be tailored to the local circumstances.     | Agree 100% (N = 44)  |
| 3.         | Fellowship training requirements (caseload) should be altered during the pandemic. | Agree 75% (N = 33)   |
| 4.         | All-cause and COVID-19-specific morbidity and mortality of BMS must be closely monitored in the initial phase (first 3 months after resumption). | Agree 97.7% (N = 43) |
| 5.         | The decision to resume BMS must be reviewed monthly by every institution that routinely performed BMS before the pandemic. | Agree 97.7% (N = 43) |
| 6.         | Hospital’s provisions for Personal Protective Equipment (PPE) must be ensured, and there should be clear policies on how and when to use which type of PPE. | Agree 100% (N = 44)  |
| 7.         | If a separate hospital/clinic is not available, BMS should be carried out on a hospital wing or part, which does not treat patients with Coronavirus Disease-19 (COVID-19). | Agree 100% (N = 44)  |
| 8.         | Screening tests for SARS-CoV-2 should be performed in a designated facility where contact with other patients is minimised. | Agree 100% (N = 44)  |

Table 2  Key consensus points in patient- and staff-specific testing and isolation considerations

| Serial no. | Statements                                                                 | Final voting results |
|------------|----------------------------------------------------------------------------|----------------------|
| 1.         | Patients should undergo locally appropriate testing to screen for SARS-CoV-2 infection 24–72 h before BMS. | Agree 84.1% (N = 37) |
| 2.         | Patients must be screened for the symptoms of COVID-19, before arrival into the hospital. | Agree 93.2% (N = 41) |
| 3.         | Patients’ hospitalisation time before BMS should be as short as possible. | Agree 100% (N = 44)  |
| 4.         | Patients must consent for the potential risk of acquiring SARS-CoV-2 infection during the hospital stay. | Agree 93.2% (N = 41) |
| 5.         | Patients must not have had any contact with a SARS-CoV-2 positive patient in the fortnight leading up to the operation. | Agree 95.5% (N = 42) |
| 6.         | BMS must be postponed if the preoperative COVID-19 antigen/PCR test is positive. | Agree 100% (N = 44)  |
| 7.         | Healthcare professionals (involved in delivering BMS) with symptoms suggestive of COVID-19 must self-isolate for 14 days. | Agree 79.5% (N = 35) |
| 8.         | Healthcare professionals with symptoms suggestive of COVID-19 must be tested for SARS-CoV-2 infection before resuming work. | Agree 97.7% (N = 43) |
agreement/disagreement of < 60.0% in the first round, as previous consensus-building exercises have shown that these statements rarely achieve consensus even after the second round of voting [5, 6]. The committee also introduced 23 new statements in the second round to further clarify some of the statements voted on in the first round.

Results

Forty-four globally recognised BMS experts from 23 countries voted on 111 statements on resuming bariatric practice in COVID-19 times. The committee achieved consensus on 72/88 statements voted on in the first round and 14/26 in the second round. Three statements were voted on again in the second round as per our methodology. None of these reached a consensus even after the second round of voting. The committee also added 23 new statements in the second round for further clarification of some of the aspects. In total, a consensus was achieved for 86 statements. Table 1 presents the results of voting on key general and facility-specific considerations. Amongst the important ones, there was a consensus of 97.7% on close monitoring of all-cause and COVID-19-specific morbidity and mortality of BMS in the initial phase after resumption; and with 100% consensus that if a separate hospital/clinic was not available, BMS should be carried out on a hospital wing or part, which does not treat patients with COVID-19.

Table 2 presents the voting results on key patient and staff testing/isolation considerations. Amongst the important ones in this category, the committee agreed with 84.1% consensus that patients should undergo locally appropriate testing to

| Table 3 | Key consensus points in patient selection considerations |
|---------|----------------------------------------------------------|
| Serial no. | Statements | Final voting results |
| 1. | Qualifying criteria for BMS should be the same as before COVID. | Agree 88.6% (N = 39) |
| 2. | The choice of the BMS procedure for an individual patient should not be influenced by the COVID-19 pandemic. | Agree 86.4% (N = 38) |
| 3. | Patients’ co-morbidities must be carefully optimised before BMS. | Agree 100% (N = 44) |
| 4. | Revisional surgery for complication management must not be delayed. | Agree 93.2% (N = 41) |
| 5. | Patients with poorer cardio-pulmonary reserves (such as ischemic heart disease and COPD) should be avoided in the initial phase (first 3 months after resumption). | Agree 72.7% (N = 32) |
| 6. | Patients with > 2 co-morbidities should be avoided in the initial phase (first 3 months after resumption). | Agree 86.4% (N = 38) |
| 7. | Policy regarding routine preoperative endoscopy should be the same as before the COVID-19 pandemic. | Agree 77.3% (N = 33) |

| Table 4 | Key consensus points in operative considerations |
|---------|----------------------------------------------------------|
| Serial no. | Statements | Final voting results |
| 1. | BMS must be performed laparoscopically or robotically. | Agree 86.4% (N = 38) |
| 2. | Surgeons should allow more time for each patient whilst planning their operating theatre schedule. | Agree 90.9% (N = 40) |
| 3. | There should be a minimum number of people present in the operating room. | Agree 95.5% (N = 42) |
| 4. | Surgical teams should wear the full PPE including an FFP3 or N-95 mask when operating on a COVID-positive patient. | Agree 100% (N = 44) |
| 5. | Fully trained bariatric surgeons should perform the operations during the initial phase. | Agree 90.9% (N = 40) |
| 6. | Surgeons should take care to avoid gas leakage during and especially at the end of the operation. | Agree 93.2% (N = 41) |
| 7. | The surgeon should use a closed system to remove pneumoperitoneum at the end of the case | Agree 81.8% (N = 36) |
screen for SARS-CoV-2 infection 24–72 h before BMS; and with 97.7% consensus that healthcare professionals with symptoms suggestive of COVID-19 must be tested for SARS-CoV-2 infection before resuming work.

Table 3 presents the voting results on key patient selection considerations. There was a consensus of 88.6% that qualifying criteria for BMS should be the same as before COVID-19 pandemic; and 86.4% consensus that those with > 2 co-morbidities should be avoided in the initial phase.

Table 4 presents the voting results on key operative considerations. There was an 86.4% consensus that BMS must be performed laparoscopically or robotically and 100% consensus that surgical teams should wear the full PPE including an FFP3 or N-95 mask when operating on a COVID-positive patient.

Table 5 presents the voting results on key postoperative considerations. There was 81.8% consensus that patients should self-isolate with family members at home for approximately 2 weeks after surgery and 95.5% consensus that patients should undergo a telephonic follow-up within a week of discharge.

Discussion

This study represents the first multinational effort at achieving consensus amongst a group of globally recognised BMS experts on resuming bariatric surgery during the COVID-19 pandemic. The committee achieved a consensus on 86 statements they collectively proposed.

IFSO recently issued guidance advising postponement of all elective surgical and endoscopic BMS procedures during the pandemic [9]. However, it is not clear if and when this pandemic will end.

Furthermore, there are concerns that the COVID-19 pandemic may exacerbate the obesity crisis further [2] and some evidence that patients suffering from obesity may have worse outcomes with COVID-19. All these factors have led to a widespread recognition that BMS teams will have to find a way of resuming this surgery whilst the world is still in the middle of this pandemic. However, that task has proved difficult because of the scarce evidence base on the SARS-CoV-2 virus and COVID-19.

Expert advice is often the only tool for clinicians to base their decisions on in areas where robust evidence is lacking. At the same time, experts can also have differences amongst themselves. This makes a consensus amongst experts very useful for routine decision-making whilst the evidence catches up to inform practice. Consensus statements are recognised to be useful for identifying the most pragmatic course of action in areas of a poor evidence base. Modified Delphi consensus-building strategies are known to be more robust than traditional consensus-building approaches, which can often be hijacked by loud voices, and have been successfully used before in a multitude of clinical settings [5, 6].

Rubino et al. [10] recently argued that patients with the greatest risk of morbidity and mortality from their disease should be prioritised in a resource-constrained environment in terms of availability of BMS. Significantly, and in contrast to Rubino et al. [10], our committee recommended avoiding patients with > 2 co-morbidities in the initial phase with an 86.4% consensus. The committee also recommended (72.7%) avoiding patients with poorer cardio-pulmonary in the initial phase. However, similar to Rubino et al., there was no agreement on any BMI cutoff for patient selection.

Several weaknesses of this paper need to be acknowledged. The choice of experts and the threshold of 70% for consensus can be considered arbitrary. A consensus agreement of a large...
number of experts is better quality evidence than the opinion of a single expert. But it is still an opinion that should ideally be confirmed in adequately designed studies. At the same time, one has to recognise that evidence on many of the aspects concerning the safe resumption of any elective surgery, let alone BMS, may take months—if not years—to develop.

**Conclusion**

In this first global attempt at consensus building on the resumption of BMS in COVID-19 times, 44 experts from 23 countries achieved consensus on a number of its aspects. These can provide a framework for BMS multidisciplinary teams working on local guidance as well as guide future research in this area.

**Author Contributions** KM conceived the idea for this exercise, moderated it and wrote some sections of the manuscript. IO helped with manuscript writing, drafting voting statements, analysis of results and submission process. SP helped with drafting voting statements, collecting and analysing votes and wrote the results and some other parts of the manuscript. All other authors helped with determining the methodology of the exercise, provided feedback at every stage, took part in the online voting, critically reviewed the draft of the manuscript and provided robust leadership. All authors have seen the final draft and approve of it.

**Compliance with Ethical Standards**

**Conflict of Interest** Author RB is a consultant for Johnson & Johnson and a consultant for Verb.

Author AA received research grants from Medtronic outside the scope of this project. Author MF is a consultant for Bariatec Corporation.

Author CV is an advisory consultant to Intuitive, Medtronic, and Johnson & Johnson. Author RM is a consultant for Medtronic and Allurion.

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