




# Metabolic and Bariatric Surgery in Patients with Obesity Class V (BMI > 60 kg/m<sup>2</sup>): a Modified Delphi Study

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## Abstract

**Background** Metabolic and bariatric surgery (MBS) is the preferred method to achieve significant weight loss in patients with Obesity Class V (BMI > 60 kg/m<sup>2</sup>). However, there is no consensus regarding the best procedure(s) for this population. Additionally, these patients will likely have a higher risk of complications and mortality. The aim of this study was to achieve a consensus among a global panel of expert bariatric surgeons using a modified Delphi methodology.

**Methods** A total of 36 recognized opinion-makers and highly experienced metabolic and bariatric surgeons participated in the present Delphi consensus. 81 statements on preoperative management, selection of the procedure, perioperative management, weight loss parameters, follow-up, and metabolic outcomes were voted on in two rounds. A consensus was considered reached when an agreement of ≥ 70% of experts' votes was achieved.

**Results** A total of 54 out of 81 statements reached consensus. Remarkably, more than 90% of the experts agreed that patients should be notified of the greater risk of complications, the possibility of modifications to the surgical procedure, and the early start of chemical thromboprophylaxis. Regarding the choice of the procedure, SADI-S, RYGB, and OAGB were the top 3 preferred operations. However, no consensus was reached on the limb length in these operations.

**Conclusion** This study represents the first attempt to reach consensus on the choice of procedures as well as perioperative management in patients with obesity class V. Although overall consensus was reached in different areas, more research is needed to better serve this high-risk population.

**Keywords** Bariatric surgery · Metabolic surgery · Severe obesity · BMI > 60

## Abbreviations

BMI	Body mass index
BPD/DS	Biliopancreatic diversion with duodenal switch
CPAP	Continuous positive airway pressure
EWL	Excess body weight loss
ICU	Intensive care unit
LAGB	Laparoscopic adjustable gastric band
MBS	Metabolic and bariatric surgery
OSA	Obstructive sleep apnea
OAGB	One anastomosis gastric bypass
RYGB	Roux-en-Y gastric bypass

SADI-S	Single anastomosis duodenal-ileal bypass with sleeve gastrectomy
SG	Sleeve gastrectomy
T2DM	Type 2 diabetes mellitus
TWL	Total weight loss

## Introduction

Over the past decades, there has been a substantial increase in the prevalence of obesity worldwide. This is most concerning for the group of patients with obesity class IV and V (body mass index (BMI) between 50 and 59.9 kg/m<sup>2</sup>,

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and BMI > 60 kg/m<sup>2</sup>, respectively, as the increase has been reported to be 120% in recent years [1]. In fact, between 7 and 16% of all metabolic and bariatric surgery (MBS) procedures are done on patients with obesity class V [2, 3].

Although the safety and efficacy of MBS has been demonstrated in this group, the recently updated guidelines by the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) and the American Society for Metabolic and Bariatric Surgery (ASMBS) acknowledge that there is no consensus regarding the best procedure(s) for individuals with especially high BMI [4]. However, a major concern for this specific population is the higher risk of complications and mortality [5, 6].

Regarding the type of surgery, a recent survey showed that the sleeve gastrectomy (SG) is the most commonly performed procedure in patients with obesity class IV, representing more than 50% of the cases. This includes both 1 and 2-stage approaches [7]. Meanwhile, the percentage increases to 68% of procedures for patients with obesity class V [5]. However, when compared to other procedures such as Roux-en-Y Gastric Bypass (RYGB) and One-Anastomosis Gastric Bypass (OAGB), the SG has been associated with lower short- and mid-term weight loss [8–12]. Also, the SG has been associated with significant weight recurrence after 3 years, showing a decrease in up to 10% of the TWL [10, 13].

On the other hand, in patients with obesity class IV and up, it seems that the SG has a better safety profile than the RYGB, demonstrating lower rates of complications, including surgical site infections, unplanned intubation, prolonged intubation, reoperation, and early readmission [5, 6].

Considering the conflicting data and the severity of the problem, a consensus is needed to designate the best possible approach for patients with severe obesity undergoing MBS. Thus, the current study aim was to achieve a consensus among a global panel of expert bariatric surgeons on the approach and management of patients with severe obesity using a modified Delphi methodology.

## Methods

A Delphi consensus committee, comprised of four bariatric and minimally invasive surgeons as non-voting members (G.P.L.B., S.P., C.P., and G.R.V.), was established. The committee extended invitations to 38 recognized opinion-makers and highly experienced MBS surgeons. They were also known for their expertise for performing MBS on patients with severe obesity and most worked in high-volume practices. The committee included current presidents of national or international bariatric surgical societies, to participate in the consensus-building exercise. Also, the included surgeons were experts from the different regions or IFSO chapters (North American, Latin American, European, Middle East/

North Africa, and Asia/Pacific). Out of the 38 experts invited, 36 (94.73%) agreed to participate in the present study.

The committee drafted 78 statements regarding MBS in patients with obesity class V that experts would vote on. Those statements were organized into 5 categories: pre-operative management, selection of the procedure and/or approach, perioperative management, weight loss parameters and follow-up, and metabolic outcomes (Appendix Table 6). Before proceeding to the voting stage, all of the statements underwent a thorough analysis and modifications based on the recommendations by the expert members.

Statements were submitted for voting in two rounds using Google Forms®. Following other published consensus-building publications, a consensus was considered reached when an agreement of ≥ 70% of experts' votes was achieved [14–16]. No single attempt was made to analyze individual responses. The first round of consensus was carried out between February 27 and March 28, 2023, and the results were shared with all the committee members.

The statements that did not reach consensus were carefully reviewed and adjusted according to the committee's recommendations. Consequently, a total of 33 statements were submitted for a second round of voting, conducted between June 6 and July 26, 2023 (Appendix Table 7).

## Results

A total of 36 experts from 17 countries voted on the 78 statements proposed by the non-voting members committee, corresponding to the first-round voting stage, whereas 34 experts from 16 countries completed the second voting round which consisted of 33 statements.

A consensus was reached on 48 of 78 (64%) statements during the first round. The statements that did not achieve consensus during the first round were voted on a second time. Of these, 5 statements were modified, the answer options were changed or reduced in 10 items, and 2 statements were subsequently subdivided into 2 and 3 statements, respectively. Therefore, a total of 33 statements were submitted to be voted on in the second round. In the second round, only 6 statements (18%) achieved a consensus, whereas 27 (82%) statements did not reach consensus. At the end of the second round of voting a total of 54 of the 81 statements, reached consensus. Tables 1, 2, 3, 4, and 5 summarize the results of the two voting rounds.

After the two voting rounds, consensus of over 90% was achieved on 20 statements.

- i. Preoperative weight loss is needed using the following options (91.7% of the experts vote on using a combi-

**Table 1** Consensus statements voting results. Preoperative management for patients with obesity class V

Statement	First-round, experts' result (%)	Second-round, experts' result (%)	Outcome
1 Preoperative weight loss is needed, irrespective of the percentage	Agree, 83.3% ( <i>n</i> = 30)		Consensus
2 Preoperative weight loss is needed using following options:	Using a combination of medication, dietary and exercise, 91.7% ( <i>n</i> = 33)		Consensus
3 Intra-gastric balloon as a bridge therapy is recommended	Disagree, 55.6% ( <i>n</i> = 20)	Agree, 52.9% ( <i>n</i> = 18)	No consensus
4 The recommended weight loss before surgery in these population should be	> 5%, 52.8% ( <i>n</i> = 19)	> 5%, 47.1% ( <i>n</i> = 16)	No consensus
5 Liver size should be reduced by a very strict protein-only diet for:	Agree, at least 2 weeks, 55.6% ( <i>n</i> = 20)	Agree, 1 – 2 weeks, 67.6% ( <i>n</i> = 23)	No consensus
6 Adherence to a strict preoperative diet should be secured if needed (e.g., in case of T2DM) by preoperative in-hospital stay	Agree, 52.8% ( <i>n</i> = 19)	Disagree, 52.9% ( <i>n</i> = 18)	No consensus
7 First round: Patients with T2DM should have proper glycemic control. Therefore, the recommended HbA1c % should be	< 8%, 44.4% ( <i>n</i> = 16)		No consensus
Second round: Prior to surgery, it is suggested that patients with T2DM maintain an HbA1c level below 8%		Agree, 67.6% ( <i>n</i> = 23)	
8 Patients with T2DM who requires high doses of insulin can be operated even with HbA1c > 8%	Agree, 86.1% ( <i>n</i> = 31)		Consensus
9 First round: Patients should be screened for OSA using at least one score	Any of the questionnaires, 63.9% ( <i>n</i> = 23)		Consensus
Second round: Patients should be screened for OSA using either the STOP-BANG or Epworth scale		Agree, 97.1% ( <i>n</i> = 33)	
10 Patients with moderate to high risk for OSA should have a polysomnography	Agree, 91.7% ( <i>n</i> = 33)		Consensus
11 Patients with moderate to severe OSA (according to polysomnography findings) should use CPAP for at least	1 month before surgery, 88.9% ( <i>n</i> = 32)		Consensus
12 Patients with hypertension should have controlled blood pressure	Agree, 100% ( <i>n</i> = 36)		Consensus
13 Patients with NASH with liver fibrosis (up to F3) may undergo any type of MBS	Agree, 63.9% ( <i>n</i> = 23)	Agree, 50% ( <i>n</i> = 17)	No consensus
14 In patients with compensated liver cirrhosis (F4) hypo absorptive procedures should be avoided	Agree, 91.7% ( <i>n</i> = 33)		Consensus
15 In patients with decompensated liver cirrhosis any type of MBS should be avoided	Agree, 66.7% ( <i>n</i> = 24)	Agree, 58.8% ( <i>n</i> = 20)	No consensus
16 A preoperative evaluation by an expert anesthesiologist in the management of bariatric patients is needed	Agree, 100% ( <i>n</i> = 36)		Consensus
17 Patients should be notified of the greater risk of complications compared to patients with lower BMI	Agree, 97.2% ( <i>n</i> = 35)		Consensus
18 Patients should be notified of the higher risk of surgical related mortality compared to patients with lower BMI	Agree, 86.1% ( <i>n</i> = 31)		Consensus
19 Patients should be notified of the possibility of modifications of the surgical techniques according to intraoperative findings	Agree, 100% ( <i>n</i> = 36)		Consensus

**Table 1** (continued)

Statement	First-round, experts' result (%)	Second-round, experts' result (%)	Outcome
20 The surgeon must consider a longer operative time than usual	Agree, 88.9% ( <i>n</i> = 32)		Consensus
21 Surgeries in patients with obesity class V should be performed by an expert and high-volume bariatric surgeon	Agree, 86.1% ( <i>n</i> = 31)		Consensus
22 Surgeries of patients with obesity class V should be made in high-volume centers with all the facilities (Proper operating room tables, radiology equipment – CT scan, fluoroscopy equipment -, intensive care unit, blood bank, crash carts, weight-rated or supported toilets, appropriately designed beds and doorways)	Agree, 94.4% ( <i>n</i> = 34)		Consensus
23 A specific informed consent including risks, and the necessity for higher supplementation in hypo-absorptive procedures should be made	Agree, 77.8% ( <i>n</i> = 28)		Consensus

*BMI*, body mass index; *CPAP*, continuous positive airway pressure; *OSA*, obstructive sleep apnea; *T2DM*, type 2 diabetes mellitus

- nation of medication, dietary and exercise interventions).
- ii. Patients should be screened for OSA using either the STOP-BANG or Epworth scale (agreed by 97.1% of the experts)
  - iii. Patients with moderate to high risk for OSA should have a polysomnography (agreed by 91.7% of the experts).
  - iv. Patients with hypertension should have controlled blood pressure (agreed by 100% of the experts).
  - v. In patients with compensated liver cirrhosis (F4) hypo-absorptive procedures should be avoided (agreed by 91.7% of the experts).
  - vi. A preoperative evaluation by an expert anesthesiologist in the management of bariatric patients is needed (agreed by 100% of the experts).
  - vii. Patients should be notified of the greater risk of complications compared to patients with lower BMI (agreed by 97.2% of the experts).
  - viii. Patients should be notified of the possibility of modifications of the surgical technique according to intra-operative findings (agreed by 100% of the experts).
  - ix. Surgery on patients with obesity class V should be performed in high-volume centers with all of the proper facilities (Proper operating room tables, radiology equipment – CT scan, fluoroscopy equipment -, intensive care unit, blood bank, crash carts, weight-rated or supported toilets, appropriately designed beds and doorways) (agreed by 94.4% of the experts).
  - x. SG is an appropriate option as the first procedure in a 2-stage approach (agreed by 91.7% of the experts).
  - xi. Single Anastomosis Duodenal-Ileal Bypass with sleeve gastrectomy (SADI-S) is an appropriate option as a stand-alone procedure (agreed by 97.2% of the experts).
  - xii. SADI-S is an appropriate option as the second procedure in a 2-stage approach (agreed by 91.7% of the experts).
  - xiii. SADI-S is an appropriate option for patients with type 2 diabetes and obesity class V (agreed by 91.7% of the experts).
  - xiv. Pneumatic compression sleeves should be worn by the patient during surgery (agreed by 97.2% of the experts).
  - xv. It is recommended to start pharmacological thromboprophylaxis during in-hospital stay (agreed by 100% of the experts).
  - xvi. Postoperative pharmacological thromboprophylaxis could be administered with low molecular weight heparin (agreed by 97.2% of the experts).
  - xvii. For patients with symptomatic gallstone disease, concomitant cholecystectomy should be performed when feasible (agreed by 91.2% of the experts).
  - xviii. CPAP use during the in-hospital stay is recommended in patients with oxygen saturation < 90% (agreed by 94.4% of the experts).
  - xix. Nutritional supplementation should be carried out according to national or international guidelines. With a special interest in patients who undergo OAGB, SADI-S, and Biliopancreatic Diversion with Duodenal Switch (BPD/DS) (agreed by 91.7% of the experts).
- Meanwhile, consensus for disagreement was achieved for 9 statements either during the first or second round.

**Table 2** Consensus statements voting results. Selection of the procedure for patients with obesity class V

	Statement	First-round, experts' result (%)	Second-round, experts' result (%)	Outcome
1	A 2-stage approach is safer than a 1-stage approach	Agree, 58.3% ( <i>n</i> = 21)	Agree, 64.7% ( <i>n</i> = 22)	No consensus
2	LAGB is an appropriate option as a stand-alone procedure	Disagree, 86.1% ( <i>n</i> = 31)		Consensus
3	LAGB is an appropriate option as the first option when using a 2-stage approach	Disagree, 77.8% ( <i>n</i> = 28)		Consensus
4	SG is an appropriate option as a stand-alone procedure	Agree, 77.8% ( <i>n</i> = 28)		Consensus
5	SG is an appropriate option as the first procedure when using a 2-stage approach	Agree, 91.7% ( <i>n</i> = 33)		Consensus
6	RYGB is an appropriate option as a stand-alone procedure	Agree, 83.3% ( <i>n</i> = 30)		Consensus
7	RYGB is an appropriate option as the second procedure when using a 2-stage approach	Agree, 66.7% ( <i>n</i> = 24)	Agree, 70.6% ( <i>n</i> = 24)	No consensus
8	Distal (Type 1) RYGB is preferred after failed primary RYGB (Shortening total alimentary limb length to 3–4 m)	Agree, 58.3% ( <i>n</i> = 21)	Agree, 67.6% ( <i>n</i> = 23)	No consensus
9	Distal (Type 2) RYGB is preferred after failed primary RYGB (Shortening common channel length to 50–150 cm)	Disagree, 80.6% ( <i>n</i> = 29)		Consensus
10	The ideal biliopancreatic limb length in RYGB for these patients should be:	Between 100 and 150 cm, 41.7% ( <i>n</i> = 15)	Between 100 and 150 cm, 50% ( <i>n</i> = 17)	No consensus
11	OAGB is an appropriate option as a stand-alone procedure	Agree, 80.6% ( <i>n</i> = 29)		Consensus
12	OAGB is an appropriate option as the second procedure when using a 2-stage approach	Agree, 77.8% ( <i>n</i> = 28)		Consensus
13	The ideal biliopancreatic limb length in OAGB for these patients should be:	Between 100 and 150 cm, 33.3% ( <i>n</i> = 12)	Less than 250 cm 55.9% ( <i>n</i> = 19)	No consensus
14	SADI-S is an appropriate option as a stand-alone procedure	Agree, 97.2% ( <i>n</i> = 35)		Consensus
15	SADI-S in an appropriate option as the second procedure when using a 2-stage approach	Agree, 91.7% ( <i>n</i> = 33)		Consensus
16	The ideal common channel length in SADI-S for these patients should be:	At least 300 cm, 50% ( <i>n</i> = 18)	At least 300 cm, 64.7% ( <i>n</i> = 22)	No consensus
17	BPD/DS is an appropriate option as a stand-alone procedure	Agree, 77.8% ( <i>n</i> = 28)		Consensus
18	BPD/DS is an appropriate option as the second procedure when using a 2-stage approach	Agree, 86.1% ( <i>n</i> = 31)		Consensus
19	The ideal total alimentary limb length in BPD/DS for these patients should be:	250 cm, 41.7% ( <i>n</i> = 15)	At least 300 cm, 55.9% ( <i>n</i> = 19)	No consensus
20	The ideal common channel length in BPD/DS for these patients should be:	At least 150 cm, 47.2% ( <i>n</i> = 17)	At least 150 cm, 47.1% ( <i>n</i> = 16)	No consensus
21	First round: The placement of non-adjustable bands is an acceptable option to avoid recurrent weight gain Second round: The placement of non-adjustable bands in SG, RYGB or OAGB is an acceptable option to avoid recurrent weight gain	Agree, 52.8% ( <i>n</i> = 19)	Disagree, 70.6% ( <i>n</i> = 24)	Consensus

**Table 2** (continued)

Statement	First-round, experts' result (%)	Second-round, experts' result (%)	Outcome
22 Measurement of the total small bowel length is recommended in these patients, as surgeons are likely to use longer biliopancreatic limbs compared to lower BMI patients	Agree, 75% ( $n=27$ )		Consensus
23 LAGB is an appropriate option in patients with T2DM and obesity class V	Disagree, 97.2% ( $n=35$ )		Consensus
24 SG is an appropriate option in patients with T2DM and obesity class V	Agree, 72.2% ( $n=26$ )		Consensus
25 RYGB is an appropriate option in patients with T2DM and obesity class V	Agree, 77.8% ( $n=28$ )		Consensus
26 OAGB is an appropriate option in patients with T2DM and obesity class V	Agree, 83.3% ( $n=30$ )		Consensus
27 SADI-S is an appropriate option in patients with T2DM and obesity class V	Agree, 91.7% ( $n=33$ )		Consensus
28 BPD/DS is an appropriate option in patients with T2DM and obesity class V	Agree, 80.6% ( $n=29$ )		Consensus

*BMI*, body mass index; *BPD/DS*, biliopancreatic diversion with duodenal switch; *LAGB*, laparoscopic adjustable gastric band; *OAGB*, one anastomosis gastric bypass; *RYGB*, Roux en-Y gastric bypass; *SADI-S*, single anastomosis duodenal-ileal bypass with sleeve gastrectomy; *SG*, sleeve gastrectomy; *T2DM*, type 2 diabetes mellitus

- i. Laparoscopic Adjustable Gastric Band (LAGB) is an appropriate option as a stand-alone procedure (disagreed by 86.1% of the experts).
- ii. LAGB is an appropriate option as the first procedure in a 2-stage approach (disagreed by the 77.8% of the experts).
- iii. Distal (type 2) RYGB is preferred after failed primary RYGB (Shortening common channel length to 50 to 150 cm) (disagreed by 80.6% of the experts).
- iv. LAGB is an appropriate option for patients with T2DM and obesity class V (disagreed by 97.2% of the experts).
- v. Routine intensive care unit (ICU) admission after surgery is recommended (disagreed by 75% of the experts).
- vi. A major cardiovascular event even in the absence of significant recurrent weight gain could be an indication for reoperation (disagreed by 75% of the experts).
- vii. Hypertension relapse even in the absence of significant recurrent weight gain is an indication for reoperation (disagreed by the 83.3% of the experts).
- viii. Hyperlipidemia relapse even in the absence of significant recurrent weight gain is an indication for reoperation (disagreed by the 75% of the experts).
- ix. The placement of non-adjustable bands in SG, RYGB, OAGB is an acceptable option to avoid recurrent weight gain (disagreed by 70.6% of the experts).

## Discussion

Despite the latest guidelines that recommended that MBS should be considered the preferred method to achieve significant weight loss in individuals with obesity class V, there is conflicting data regarding the safety, perioperative morbidity, and long-term outcomes. In addition, there is a lack of consensus for which procedure is best for these individuals [4]. Therefore, the present study was undertaken to generate a consensus between expert bariatric surgeons and after conducting two rounds of voting, 54/81 statements reached consensus. Our study can set a precedent for further research regarding the choice of the procedure in individuals with obesity class V.

## Preoperative Management

As mentioned before, the safety of MBS in this population is one of the major concerns. Different studies have shown

**Table 3** Consensus statements voting results. Perioperative management for patients with obesity class V

	Statement	First-round, experts' result (%)	Second-round, experts' result (%)	Outcome
1	The use of pneumatic compressors is needed during surgery	Agree, 97.2% ( <i>n</i> = 35)		Consensus
2	The use of pneumatic compressors is needed after surgery (During in-hospital stay)	Agree, 72.2% ( <i>n</i> = 26)		Consensus
3	It is recommended to start pharmacological thromboprophylaxis during in-hospital stay	Agree, 100% ( <i>n</i> = 36)		Consensus
4	Postoperative pharmacological thromboprophylaxis is recommended for at least:	2 weeks, 50% ( <i>n</i> = 18)	2 weeks, 67.6% ( <i>n</i> = 23)	No consensus
5	Postoperative pharmacological thromboprophylaxis could be administered with low molecular weight heparin	Agree, 97.2% ( <i>n</i> = 35)		Consensus
6	Postoperative pharmacological thromboprophylaxis dosage with low molecular weight heparin should be BMI-adapted	Agree, 72.2% ( <i>n</i> = 26)		Consensus
7	Postoperative pharmacological thromboprophylaxis could be administered with non-vitamin K antagonist oral anticoagulants (i.e., dabigatran, rivaroxaban, apixaban)	Disagree, 52.8% ( <i>n</i> = 19)	Agree, 73.5% ( <i>n</i> = 25)	Consensus
8	The preferred approach to operate on patients with obesity class V	Either laparoscopically or robotically, 75% ( <i>n</i> = 27)		Consensus
9	Routine use of automatic liver retractor is recommended	Agree, 69.4% ( <i>n</i> = 25)	Agree, 67.6% ( <i>n</i> = 23)	No consensus
10	First round: Regarding concomitant cholecystectomy in this population	Symptomatic gallstone disease should be treated when feasible, 69.4% ( <i>n</i> = 25)		
10 (a)	Second round: Concomitant cholecystectomy in symptomatic gallstone disease should be performed when feasible		Agree, 91.2% ( <i>n</i> = 31)	Consensus
10 (b)	Second round: Concomitant cholecystectomy in asymptomatic gallstone disease should be performed when feasible		Disagree, 58.8% ( <i>n</i> = 14)	No consensus
11	Regarding concomitant umbilical or incisional hernia repair in this population	Hernia repair should be avoided irrespective of the size, 58.3% ( <i>n</i> = 21)	Hernia repair should be avoided irrespective of the size, 55.9% ( <i>n</i> = 19)	No consensus
12	CPAP use during in-hospital stay is recommended in patients with oxygen saturation < 90%	Agree, 94.4% ( <i>n</i> = 34)		Consensus
13	Routinary ICU admission after the surgery is recommended	Disagree, 75% ( <i>n</i> = 27)		Consensus

*BMI*, body mass index; *CPAP*, continuous positive airway pressure; *ICU*, intensive care unit

that patients with obesity class V have more preoperative comorbidities, also, MBS in this group is related to longer operative time, length of stay, and 30-day readmission in comparison to patients with a lower BMI [5, 17–19]. These findings could be related to the greater risk of perioperative complications, including venous thrombosis, reoperation, unplanned intensive care unit (ICU) admission, surgical site infection, number of episodes of hypoxemia, and unplanned intubation. In addition, it includes the challenge

itself of operating on these patients [5, 6, 13, 18, 20]. It is important to highlight that different studies have not shown a significant increase in mortality in this population [5, 17, 19, 21], with the exception of one study in which patients with a BMI > 70 kg/m<sup>2</sup> showed a mortality rate of 0.4% in comparison to 0.1% in patients with a lower BMI [6].

This concern regarding safety was obvious in the present consensus study since more than 90% of the experts agreed that these patients should undergo a preoperative weight loss

**Table 4** Weight loss outcomes and management in patients with obesity class V

	Statement	First-round, experts' result (%)	Second-round, experts' result (%)	Outcome
1	The second stage procedure should be performed based on a time-specific approach	Disagree, 58.3% ( $n=21$ )	Disagree, 52.9% ( $n=18$ )	No consensus
2	Time-specific approach second stage procedure may be performed at:	Between the 1st and 2nd year, 72.2% ( $n=26$ )		Consensus
3	The second stage procedure should be performed once the weight loss has stopped (At the nadir)	Agree, 75% ( $n=27$ )		Consensus
4	First round: The preferred way to define acceptable primary response or optimal weight loss in this population is:	An EWL > 50%, irrespective of the BMI, 33.3% ( $n=12$ )		
4 (a)	Second round: An EWL > 50%, regardless of the reached BMI, is an acceptable way to define primary response or optimal weight loss in this population		Agree, 70.6% ( $n=24$ )	Consensus
4 (b)	Second round: The ideal percentage of TWL to define primary response or optimal weight loss in this population should be:		At least 30%, 58.8% ( $n=20$ )	No consensus
4 (c)	Second round: The ideal BMI target to define primary response or optimal weight loss in this population should be:		A BMI < 40 kg/m <sup>2</sup> , 52.9% ( $n=18$ )	No consensus
5	Nutritional supplementation should be carried out according to national or international guidelines. With a special interest in patients who undergo OAGB, SADI-S, and BPD/DS	Agree, 91.7% ( $n=33$ )		Consensus
6	The indication for revisional surgery according to the BMI should be	A BMI > 40 kg/m <sup>2</sup> , 44.4% ( $n=16$ )	A BMI > 35 kg/m <sup>2</sup> , 58.8% ( $n=20$ )	No consensus
7	Recurrent weight gain greater than 20% from nadir is an indication for surgical reintervention	Agree, 55.6% ( $n=20$ )	Agree, 64.7% ( $n=22$ )	No consensus

*BMI*, body mass index; *BPD/DS*, biliopancreatic diversion with duodenal switch; *EWL*, excess body weight loss; *OAGB*, one anastomosis gastric bypass; *SADI-S*, single anastomosis duodenal-ileal bypass with sleeve gastrectomy; *TWL*, total weight loss

program, be screened for OSA, have proper blood pressure control, use in-hospital pneumatic compression sleeves, and CPAP to maintain oxygen saturation > 90%. In addition, pharmacological thromboprophylaxis should be started during their in-hospital stay. Also, 97% and 100% of the experts agreed to inform the patient of the higher risk of complications in comparison to patients with a lower BMI and the possibility of changing the procedure due to intraoperative findings, respectively. Therefore, in order to increase the safety of MBS in patients with obesity class V, the authors of the current consensus study recommended taking particular considerations into account.

### Selection of Procedure

In regard to the choice of the procedure, the results obtained in the present consensus were slightly different from what was expected, since SG has been reported as the most frequently performed procedure in patients with obesity class

V, corresponding to more than two-thirds of the surgeries in different studies [5, 7, 18]. Interestingly, only 77.8% of the experts included in the present study thought that the SG is a proper stand-alone procedure, while SADI-S was the procedure that more experts agreed as an appropriate stand-alone procedure with 97.2%, followed by RYGB and OAGB with 83.3% and 80.6% of agreement, respectively. LAGB reached consensus for disagreement as an appropriate procedure either as a stand-alone procedure (86.1% of disagreement) or as the first option when using a 2-stage approach (77.8% of disagreement).

On the other hand, 91.7% of the experts thought that the SG is an appropriate procedure as the first stage when using a 2-stage approach. This can be explained by the fact that many surgeons will prefer to perform it, because of the relative simplicity of the procedure and the consequently shorter operative time, length of stay, unplanned ICU admission, and lower risk of complications when compared to other procedures such as RYGB, SADI-S, or BPD/DS [5, 6, 22]



**Table 5** Metabolic outcomes and management in patients with obesity class V

Statement	First-round, experts' result (%)	Second-round, experts' result (%)	Outcome
1 First round: T2DM relapse even in the absence of significant recurrent weight gain is an indication for reoperation	Agree, 58.3% ( $n=21$ )		
Second round: T2DM relapse even in the absence of significant recurrent weight gain could be an indication for reoperation		Agree, 70.6% ( $n=24$ )	Consensus
2 First round: New onset of T2DM even in the absence of significant recurrent weight gain is an indication for reoperation	Agree, 58.3% ( $n=21$ )		
Second round: New onset of T2DM even in the absence of significant recurrent weight gain after primary MBS could be an indication for reoperation		Agree, 61.8% ( $n=21$ )	No consensus
3 A major cardiovascular event even in the absence of significant recurrent weight gain could be indication for reoperation	Disagree, 75% ( $n=27$ )		Consensus
4 Hypertension relapse even in the absence of significant recurrent weight gain is an indication for reoperation	Disagree, 83.3% ( $n=30$ )		Consensus
5 Hypertension relapse even in the presence of significant recurrent weight gain should not be an indication for reoperation	Disagree, 69.4% ( $n=25$ )	Disagree, 67.6% ( $n=23$ )	No consensus
6 Hyperlipidemia relapse even in the absence of significant recurrent weight gain is an indication for reoperation	Disagree, 75% ( $n=27$ )		Consensus
7 Hyperlipidemia relapse even in the presence of significant recurrent weight gain should not be an indication for reoperation	Disagree, 55.6% ( $n=20$ )	Disagree, 64.7% ( $n=22$ )	No consensus

T2DM, type 2 diabetes mellitus

in this high BMI cohort of patients. Also, it can be easily revised into RYGB, OAGB, SADI-S, or BPD/DS in those patients who persist with severe obesity or develop recurrent weight gain.

It is important to note that the statement suggesting the use of a 2-stage approach is safer than a 1-stage approach in this high BMI group of patients did not reach a consensus among the experts included in the present study. However, a recently published consensus by the IFSO recommends adopting a 2-stage approach, which involves performing a technically easier procedure first instead of RYGB, SADI-S, or BPD/DS, as this may be a suitable strategy [23]. The latter is supported by different retrospective series in which the authors found that a 2-stage approach is feasible and effective based on short-term outcomes, with acceptable morbidity and mortality rates [24, 25]. Consistent with this, some of the experts who actively participated in the Delphi consensus recommended that the consideration of the SG in cases where single-stage operations had originally been planned but some technical difficulties or complications arose during surgery. Therefore, it is important to emphasize that these are expert opinions and recommendations, and they should be considered with caution. Furthermore, these recommendations can evolve over time and vary among

surgeons; hence, every practice should be supported by the experience and results of each center to ensure the safety of the patient.

Consistent with the percentage of agreement obtained in the present study, different studies have shown that RYGB has better outcomes in terms of weight loss compared to the SG and LAGB in mid- to long-term [13, 19, 20, 22, 26–28]. Also, OAGB, SADI-S, and BPD/DS have shown good to excellent results in terms of weight loss in similar patients [10, 11, 19, 29]. Of the latter, SADI-S and BPD/DS have shown greater weight loss, however, at the expense of a greater risk of micronutrient deficiencies as well as early and late complications [27, 29]. However, a single institutional series showed that either the SG or the BPD/DS are related to a higher early and late complications rate in comparison to the RYGB [19].

Similar to the results discussed above, the SADI-S was the procedure with greater approval to treat patients with obesity class V and T2DM, showing a 91.7% agreement, followed by OAGB, BPD/DS, and RYGB with 83.3%, 80.6%, and 77.8%, respectively. Meanwhile, the SG was considered a good option for these patients by only 72% of the experts. As in patients without T2DM, the LAGB reached consensus for disagreement as an appropriate procedure to treat

patients with obesity class V and T2DM (97.2%). Again, the BPD/DS has shown better outcomes in terms of T2DM remission as well as in other comorbidities compared to the SG and the RYGB [27]. The T2DM remission rate following BPD/DS has been reported from 75 to 100% [27, 30], whereas this has been reported between 53.9 and 83.3% following the RYGB [22, 27, 31, 32], and 30 to 76.6% following the SG [20, 22, 27].

Interestingly no consensus was reached for standardizing biliopancreatic or common channel limb lengths in operations including RYGB, OAGB, SADI-S and BPD/DS. However, 75% of the experts agreed on routine measurement of the total small bowel length, as longer biliopancreatic limbs are used in this specific population. The latter suggests that experts were in favor of tailoring limb length according to BMI in this high BMI group of patients rather than giving fixed limb lengths.

### Concomitant Procedures

Regarding performing concomitant procedures, a consensus for agreement to perform concomitant cholecystectomy in symptomatic gallstone disease when feasible was reached (91.2% of agreement), whereas no consensus was achieved in terms of the management of abdominal wall hernias during MBS. As expected, there is scarce evidence about performing concomitant procedures in this population. However, several studies have shown that concomitant cholecystectomy during MBS is feasible and safe. Recently, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) published a series of recommendations for the management of abdominal wall hernias in patients with severe obesity. The authors stated that concomitant hernia repair should be discussed with the patient, since these patients carry a higher risk of recurrence and wound morbidity [33].

### Weight Loss and Metabolic Outcomes

Finally, in an attempt to reach a consensus on the most appropriate way to manage and determine weight loss parameters as well as to define primary response, different items were voted on. At the second round, 70.6% of the

experts agreed for consensus that an EWL > 50%, regardless of the reached BMI, is an acceptable way to define primary response in patients with obesity class V, whereas no single cutoff point of TWL or BMI reached consensus. Also, 75% of the experts agreed to perform the second procedure of a 2-stage approach at the nadir of weight loss. No consensus was reached about the indications for revisional surgery according to recurrent weight gain, suboptimal weight loss, or for new-onset comorbidities or recurrence.

### Strengths and Limitations

The biggest strength of this study is that this is the first attempt at providing evidence of the management of patients with obesity class V with MBS. On the other hand, one limitation of the present consensus study is that it is composed solely of expert opinion which is considered the lowest level of scientific evidence. It, therefore, would be important to reinforce the fact that these are expert viewpoints and may not apply to all practices. Therefore, these authors suggest being cautious about the interpretation of the findings of this consensus study. However, the literature to guide the management of these patients is scarce and mainly consists of retrospective cohort studies with limited samples.

### Conclusion

This study represents the first attempt to reach consensus on the choice of procedures as well as perioperative management of patients with obesity class V. Thirty-six worldwide recognized bariatric surgeons from 17 countries participated in this consensus conference and reached consensus on 54 items regarding procedure selection, preoperative, intraoperative, and postoperative management, as well as in terms of weight loss and metabolic outcomes.

The results of this study emphasize the need for special considerations in order to maximize the safety of MBS in this population. This includes the early onset of chemical thromboprophylaxis, the use of pneumatic compression sleeves, in-hospital use of oxygen and CPAP in patients with oxygen saturation lower than 90%, avoidance of hypoabsorptive procedures in patients with liver cirrhosis, and performing concomitant cholecystectomy when symptomatic gallstone disease is present.

**Appendix**

**Table 6** First-round voting stage statements

Statement	Answers
A. Preoperative management for patients with obesity class V	
1. Preoperative weight loss is needed, irrespective of the percentage	Disagree
2. Preoperative weight loss is needed using following options:	Exercise interventions Combination of medication, dietary and exercise is recommended
3. Intra-gastric balloon as a bridge therapy is recommended	Disagree
4. The recommended weight loss before surgery in these population should be	20%
5. Liver size should be reduced by a very strict protein-only diet for:	Agree 4 weeks Disagree
6. Adherence to a strict preoperative diet should be secured if needed (e.g., in case of T2DM) by preoperative in-hospital stay	Disagree
7. Patients with type 2 diabetes should have proper glycemic control. Therefore, the recommended HbA1c % should be	Disagree
8. Patients with type 2 diabetes who requires high doses of insulin can be operated even with HbA1c > 8%	Disagree
9. Patients should be screened for OSA using at least one score	Both of above
10. Patients with moderate to high risk for OSA should have a polysomnography	Disagree
11. Patients with moderate to severe OSA (according to polysomnography findings) should use CPAP for at least	2 months before surgery
	Any of the questionnaires
	Epworth sleeping scale
	STOP-BANG
	Agree
	1 month before surgery

Table 6 (continued)

Statement	Answers
12. Patients with hypertension should have controlled blood pressure	Disagree
13. Patients with NASH with liver fibrosis (up to F3) may undergo any type of bariatric procedure	Disagree
14. In patients with compensated liver cirrhosis (F4) hyp absorptive procedures should be avoided	Disagree
15. In patients with decompensated liver cirrhosis any type of MBS should be avoided	Disagree
16. A preoperative evaluation by an expert anesthesiologist in the management of bariatric patients is needed	Disagree
17. Patients should be notified of the greater risk of complications compared to patients with lower BMI	Disagree
18. Patients should be notified of the higher risk of surgical related mortality compared to patients with lower BMI	Disagree
19. Patients should be notified of the possibility of modifications of the surgical techniques according to intraoperative findings	Disagree
20. The surgeon must consider a longer operative time than usual	Disagree
21. Surgeries in patients with obesity class V should be performed by an expert and high-volume bariatric surgeon	Disagree Should be performed jointly by 2 consultant bariatric surgeons

**Table 6** (continued)

Statement	Answers	Disagree
<p>22. Surgeries of patients with obesity class V should be made in high-volume centers with all the facilities (Proper operating room tables, radiology equipment – CT scan, fluoroscopy equipment -, intensive care unit, blood bank, crash carts, weighted or supported toilets, appropriately designed beds and doorways)</p>	Agree	Disagree
<p>23. A specific informed consent including risks, and the necessity for higher supplementation in hypo-absorptive procedures should be made</p>	Agree	Disagree
<p>B. Selection of the procedure for patients with obesity class V</p>		
<p>1. A 2-stage approach is safer than a 1-stage approach</p>	Agree	Disagree
<p>2. LAGB is an appropriate option as a stand-alone procedure</p>	Agree	Disagree
<p>3. LAGB is an appropriate option as the first option when using a 2-stage approach</p>	Agree	Disagree
<p>4. SG is an appropriate option as a stand-alone procedure</p>	Agree	Disagree
<p>5. SG is an appropriate option as the first procedure when using a 2-stage approach</p>	Agree	Disagree
<p>6. RYGB is an appropriate option as a stand-alone procedure</p>	Agree	Disagree
<p>7. RYGB is an appropriate option as the second procedure when using a 2-stage approach</p>	Agree	Disagree

Table 6 (continued)

Statement	Answers
8. Distal (Type 1) RYGB is preferred after failed primary RYGB (Shortening total alimentary limb length to 3–4 m)	Agree Disagree
9. Distal (Type 2) RYGB is preferred after failed primary RYGB (Shortening common channel length to 50–150 cm)	Agree Disagree
10. The ideal biliopancreatic limb length in RYGB for these patients should be:	Between 50 and 100 cm Between 100 and 150 cm At least 200 cm
11. OAGB is an appropriate option as a stand-alone procedure	Agree Disagree
12. OAGB is an appropriate option as the second procedure when using a 2-stage approach	Agree Disagree
13. The ideal biliopancreatic limb length in OAGB for these patients should be:	Between 150 and 200 cm Between 200 and 250 cm Tailored to 30% bowel length Tailored to 40% bowel length
14. SADI-S is an appropriate option as a stand-alone procedure	Agree Disagree
15. SADI-S in an appropriate option as the second procedure when using a 2-stage approach	Agree Disagree
16. The ideal common channel length in SADI-S for these patients should be:	Less than 200 cm 200 cm At least 300 cm
17. BPD/DS is an appropriate option as a stand-alone procedure	Agree Disagree
18. BPD/DS is an appropriate option as the second procedure when using a 2-stage approach	Agree Disagree

Table 6 (continued)

Statement	Answers
19. The ideal total alimentary limb length in BPD/DS for these patients should be:	Less than 200 cm 200 cm At least 250 cm At least 300 cm
20. The ideal common channel length in BPD/DS for these patients should be:	Between 50 and 100 cm Between 100 and 150 cm At least 150 cm
21. The placement of non-adjustable bands is an acceptable option to avoid recurrent weight gain	Disagree
22. Measurement of the total small bowel length is recommended in these patients, as surgeons are likely to use longer biliopancreatic limbs compared to lower BMI patients	Disagree
23. LAGB is an appropriate option in patients with type 2 diabetes and obesity class V	Disagree
24. SG is an appropriate option in patients with type 2 diabetes and obesity class V	Disagree
25. RYGB is an appropriate option in patients with type 2 diabetes and obesity class V	Disagree
26. OAGB is an appropriate option in patients with type 2 diabetes and obesity class V	Disagree
27. SADI-S is an appropriate option in patients with type 2 diabetes and obesity class V	Disagree
28. BPD/DS is an appropriate option in patients with type 2 diabetes and obesity class V	Disagree

Table 6 (continued)

Statement	Answers
C. Perioperative management for patients with obesity class V	
1. The use of pneumatic compressors is needed during surgery	Agree Disagree
2. The use of pneumatic compressors is needed after surgery (During in-hospital stay)	Agree Disagree
3. It is recommended to start pharmacological thromboprophylaxis during in-hospital stay	Agree Disagree
4. Postoperative pharmacological thromboprophylaxis is recommended for at least:	2 weeks 4 weeks 6 weeks
5. Postoperative pharmacological thromboprophylaxis could be administered with low molecular weight heparin	Agree Disagree
6. Postoperative pharmacological thromboprophylaxis dosage with low molecular weight heparin should be BMI-adapted	Agree Disagree
7. Postoperative pharmacological thromboprophylaxis could be administered with non-vitamin K antagonist oral anticoagulants (i.e., dabigatran, rivaroxaban, apixaban)	Agree Disagree
8. The preferred approach to operate on patients with obesity class V	Robotically Laparoscopically Either laparoscopically or robotically
9. Routine use of automatic liver retractor is recommended	Agree Disagree



Table 6 (continued)

Statement	Answers
10. Regarding concomitant cholecystectomy in this population	Symptomatic gallstone disease should be treated when feasible Asymptomatic gallstone disease should be avoided irrespective of symptoms
11. Regarding concomitant umbilical or incisional hernia repair in this population	Hernia repair could be done only when defect is <5 cm and feasible Hernia repair should be avoided irrespective of size
12. CPAP use during the in-hospital stay is recommended in patients with oxygen saturation < 90%	Disagree
13. Routinary intensive care unit admission after the surgery is recommended	Disagree
D. Weight loss outcomes and management in patients with obesity class V	
1. The second stage procedure should be performed based on a time-specific approach	Disagree
2. Time-specific approach second stage procedure may be performed at:	During the first year Between the first and second year After the second year
3. The second stage procedure should be performed once the weight loss has stopped (At the nadir)	Disagree
4. The preferred way to define acceptable primary response or optimal weight loss in this population is:	EWL > 50%. Irrespective of BMI TWL > 20%, irrespective of BMI TWL > 30% irrespective of BMI Reach a BMI < 40 kg/m <sup>2</sup> Reach a BMI < 35 kg/m <sup>2</sup>
5. Nutritional supplementation should be carried out according to national or international guidelines. With a special interest in patients who undergo OAGB, SADI-S, and BPD/DS	Disagree Should be uniform irrespective of the procedure
6. The indication for surgical reintervention according to the BMI should be	A BMI > 30 kg/m <sup>2</sup> A BMI > 35 kg/m <sup>2</sup> A BMI > 40 kg/m <sup>2</sup>

Table 6 (continued)

Statement	Answers
7. A recurrent weight gain greater than 20% from nadir is an indication for revisional surgery	Disagree
E. Metabolic outcomes and management in patients with obesity class V	
1. Type 2 diabetes relapse even in the absence of significant recurrent weight gain is an indication for reoperation	Disagree
2. New onset of type 2 diabetes even in the absence of significant recurrent weight gain is an indication for reoperation	Disagree
3. A major cardiovascular event even in the absence of significant recurrent weight gain could be indication for reoperation	Disagree
4. Hypertension relapse even in the absence of significant recurrent weight gain is an indication for reoperation	Disagree
5. Hypertension relapse even in the presence of significant recurrent weight gain is not an indication for reoperation	Disagree
6. Hyperlipidemia relapse even in the absence of significant recurrent weight gain is an indication for reoperation	Disagree
7. Hyperlipidemia relapse even in the presence of significant recurrent weight gain is not an indication for reoperation	Disagree

**Table 7** Second-round voting stage statements

Statement	Answers
A. Preoperative management for patients with obesity class V	
1. Intra gastric balloon as a bridge therapy is recommended	Disagree
2. The recommended weight loss before surgery in these population should be	10% No preoperative weight loss is needed
3. Liver size should be reduced by a very strict protein-only diet for:	Disagree
4. Adherence to a strict preoperative diet should be secured if needed (e.g., in case of T2DM) by preoperative in-hospital stay	Disagree
5. Prior to surgery, it is suggested that patients with type 2 diabetes maintain an HbA1c level below 8%	Disagree
6. Patients should be screened for OSA using either the STOP-BANG or Epworth scales	Disagree
7. Patients with NASH and liver fibrosis (up to F3) may undergo any type of MBS	Disagree
8. In patients with decompensated liver cirrhosis any type of MBS should be avoided	Disagree
B. Selection of the procedure for patients with obesity class V	
1. A 2-stage approach is safer than a 1-stage approach	Disagree
2. RYGB is an appropriate option as the second procedure when using a 2-stage approach	Disagree
3. Distal (Type 1) RYGB is preferred after failed primary RYGB (Shortening total alimentary limb length to 3–4 m)	Disagree
4. In RYGB, the ideal biliopancreatic limb length should be:	Between 100 and 150 cm Between 150 and 200 cm
5. In OAGB, the ideal biliopancreatic limb length should be:	Tailored (30–40%) according to the small bowel length No opinion
6. In SADI-S, the ideal common channel length should be:	At least 300 cm No opinion
7. In BPD/DS, the ideal total alimentary limb length should be:	At least 300 cm No opinion
8. In BPD/DS, the ideal total common channel length should be:	At least 150 cm No opinion

Table 7 (continued)

Statement	Answers	
9. The placement of non-adjustable bands is an acceptable option to avoid recurrent weight gain	Agree	Disagree
<b>C. Perioperative management for patients with obesity class V</b>		
1. Postoperative pharmacological thromboprophylaxis is suggested for at least:	2 weeks	4 weeks
2. Postoperative pharmacological thromboprophylaxis could be administered with non-vitamin K antagonist oral anti-coagulants (i.e., dabigatran, rivaroxaban, apixaban)	Agree	Disagree
3. Routine use of automatic liver retractor is suggested	Agree	Disagree
4. Concomitant cholecystectomy in symptomatic gallstone disease should be performed when feasible	Agree	Disagree
5. Concomitant cholecystectomy in asymptomatic gallstone disease should be performed when feasible	Agree	Disagree
6. Regarding concomitant umbilical or incisional hernia repair in this population	Hernia repair could be done only when defect is < 5 cm and feasible	Hernia repair should be avoided irrespective of size
<b>Weight loss outcomes and management in patients with obesity class V</b>		
1. The second stage procedure should be performed based on a time-specific approach	Agree	Disagree
2. An EWL > 50%, regardless of the reached BMI, is an acceptable way to define primary response or optimal weight loss in this population	Agree	Disagree
3. The ideal % TWL to define primary response or optimal weight loss in this population should be	At least 20%	At least 30%
4. The ideal BMI targeted to define primary response or optimal weight loss in this population should be	BMI < 40 kg/m <sup>2</sup>	BMI < 35 kg/m <sup>2</sup>
5. The indication for surgical reintervention based on the BMI should be	A BMI > 35 kg/m <sup>2</sup>	A BMI > 40 kg/m <sup>2</sup>
6. A recurrent weight gain greater than 20% from nadir is an indication for reoperation	Agree	Disagree
<b>E. Metabolic outcomes and management in patients with obesity class V</b>		
1. Type 2 diabetes relapse even in the absence of significant recurrent weight gain could be an indication for reoperation	Agree	Disagree

**Table 7** (continued)

Statement	Answers
2. New onset of type 2 diabetes even in the absence of significant recurrent weight gain after primary MBS could be an indication for reoperation	Disagree
3. Hypertension relapse even in the presence of significant recurrent weight gain should not be an indication for reoperation	Disagree
4. Hyperlipidemia relapse even in the presence of significant recurrent weight gain should not be an indication for reoperation	Disagree

**Declarations**

This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed Consent** Not applicable.

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