



The first modified Delphi consensus statement on sleeve gastrectomy

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Abstract

Introduction Sleeve gastrectomy (SG) is the commonest bariatric procedure worldwide. Yet there is significant variation in practice concerning its various aspects. This paper report results from the first modified Delphi consensus-building exercise on SG.

Methods We established a committee of 54 globally recognized opinion makers in this field. The committee agreed to vote on several statements concerning SG. An agreement or disagreement amongst $\geq 70.0\%$ experts was construed as a consensus.

Results The committee achieved a consensus of agreement ($n = 71$) or disagreement ($n = 7$) for 78 out of 97 proposed statements after two rounds of voting. The committee agreed with 96.3% consensus that the characterization of SG as a purely restrictive procedure was inaccurate and there was 88.7% consensus that SG was not a suitable standalone, primary, surgical weight loss option for patients with Barrett's esophagus (BE) without dysplasia. There was an overwhelming consensus of 92.5% that the sleeve should be fashioned over an orogastric tube of 36–40 Fr and a 90.7% consensus that surgeons should stay at least 1 cm away from the angle of His. Remarkably, the committee agreed with 81.1% consensus that SG patients should undergo a screening endoscopy every 5 years after surgery to screen for BE.

Conclusion A multinational team of experts achieved consensus on several aspects of SG. The findings of this exercise should help improve the outcomes of SG, the commonest bariatric procedure worldwide, and guide future research on this topic.

Keywords Bariatric surgery · Obesity surgery · Sleeve gastrectomy · Gastric sleeve

Abbreviations

SG Sleeve gastrectomy

GERD Gastro-esophageal reflux disease

BE Barrett's esophagus

GEJ Gastro-esophageal junction

IFSO International Federation for the Surgery of Obesity and Metabolic Disorders

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Sleeve gastrectomy (SG) is now the most common bariatric procedure worldwide [1]. Few consensus statements have been published on this procedure, with the last one published in 2016 [2]. Despite these, significant variations in practices persist concerning various aspects of this procedure [3]. Developing robust evidence to identify the best choice from amongst a range of practices can be a time consuming and laborious process. This often leads to individual clinicians

relying on authoritative and expert advice to base their clinical decisions on.

This is even though expert advice is graded as Level 5 evidence which is the lowest level of quality of evidence, and the recommendations that can be issued from such evidence are graded as D, the lowest possible grade [4]. Not only this, the experts can themselves have opposed views, leaving room for confusion. Consensus building amongst experts can help reduce this confusion, and also somewhat improve the quality of the recommendations. This is probably why consensus-building exercises are now commonplace in a variety of clinical situations.

Delphi consensus-building approach was first developed by Olaf Helmer–Hirschberg and Norman Dalkey of the RAND (Research and Development) Corporation, an American non-profit think tank [5]. Modifications of this approach to consensus-building are increasingly replacing traditional protocols in all walks of medicine including bariatric surgery [6, 7]. They are recognised to be more robust and cheaper compared to consensus building in an open room setting [8]. To the best of our knowledge, no attempt has been made to perform a consensus-building exercise using a modified Delphi protocol for SG.

The purpose of this study was to achieve consensus on a number of preoperative, intraoperative, and postoperative considerations concerning SG using a modified Delphi protocol.

Methods

We constituted a committee (Supplemental Data 1) of 54 recognized opinion makers in the field of bariatric and metabolic surgery (from 32 countries) with a working knowledge of the English language and a special interest in SG. The committee members voted twice on several aspects of SG.

Members agreed on several statements to vote on after discussion amongst themselves. The voting for each round was only started when the whole committee was satisfied with the language of the statements to be voted on. The members were asked to either agree or disagree with each statement and were not given the choice to skip any. Following other published bariatric surgery consensus papers [4, 5], an agreement amongst $\geq 70.0\%$ of experts was regarded as consensus. Voting was conducted virtually on online survey platforms and no attempt was made to identify individual members' responses.

The first-round voting link was made live on the 12th of January 2020 and the second-round voting was concluded on 22nd April 2020. The committee voted on 84 statements in the first round. In the second round, the committee voted on only those statements where there was an agreement/disagreement of $\geq 60.0\%$ but not enough to reach the consensus

threshold of 70.0%. The committee did not vote again on statements with an agreement/disagreement of $< 60.0\%$ in the first round as previous consensus-building exercises have shown that these statements rarely achieve consensus even after a second round of voting [6, 7]. The committee also introduced 13 new statements in the second round to further clarify some of the statements voted on in the first round.

Statement of informed consent not applicable.

IRB approval not applicable.

Results

A total of 54 SG recognized global bariatric surgery experts (Supplemental Data 1) from 32 countries voted on a total of 97 statements concerning various aspects of SG.

Table 1 presents the results of voting on some of the key preoperative considerations of SG. In total, there was a consensus of agreement on 28 of these statements and a consensus of disagreement on 6 statements. There was no consensus on six statements proposed. Out of six statements that the committee voted on again in the second round, four achieved a consensus in the second round (Supplemental Data 2).

Table 2 presents the results of voting on key perioperative considerations of SG. The committee agreed with a consensus on 21 of the 26 statements voted on in this category. There was a consensus of disagreement on two statements and an inability to reach consensus on the remaining three. Both of the statements that the committee voted on again reached a consensus in the second round (Supplemental Data 3).

Table 3 presents the results of voting on key postoperative considerations of SG. The committee achieved a consensus of agreement on 6 out of 13 statements voted on in this category (Supplemental Data 4).

Table 4 presents the results on the management of complications and revisional bariatric surgery in the context of SG. There was a consensus of agreement on 16 out of 18 statements voted on in this category and that of disagreement on one statement (Supplemental Data 5).

In total, the committee agreed with a consensus on 71 out of the 97 proposed statements. There was a consensus of disagreement for 7 proposed statements and no consensus was achieved for the remaining 19 statements.

Discussion

The last consensus statement to be published on SG came out in 2016; and in recent years, there have been significant controversies on several preoperative, perioperative, and postoperative considerations involving this procedure.

Table 1 Results of voting on key preoperative considerations concerning sleeve gastrectomy (see Supplemental Data 2 for full results)

Serial nos	Statements	Final voting results
1	Sleeve gastrectomy (SG) works through as yet incompletely understood neurohormonal mechanisms	Agree 88.9%
2	The characterization of SG as a purely restrictive procedure is inaccurate	Agree 96.3%
3	SG is a suitable surgical weight loss option for appropriate patients with a body mass index (BMI) of ≥ 60 kg/m ² as part of a staged approach	Agree 94.44%
4	SG is a suitable standalone, primary, surgical weight loss option for patients with BMI ≥ 50 kg/m ²	Agree 73.6%
5	SG is a suitable, primary, surgical weight loss option for appropriate patients with insulin-dependent type 2 diabetes mellitus with a BMI of > 35 kg/m ²	Agree 73.6%
6	SG is an acceptable surgical option for suitable patients with moderate hiatal hernia (> 2.0 to ≤ 4.0 cm) with concomitant hiatal hernia repair	Agree 81.1%
7	SG is an acceptable surgical option for suitable patients with mild hiatal hernia (≤ 2.0 cm) with or without concomitant hiatal hernia repair	Agree 85.2%
8	SG patients should undergo a mandatory, routine preoperative upper gastro-intestinal endoscopy	Agree 79.2%
9	SG is an acceptable surgical option for suitable patients with Barrett's esophagus (BE) if patient can commit to undergoing lifelong annual Barrett's surveillance	Disagree 83.3%
10	SG is an acceptable surgical option for suitable patients with severe gastro-esophageal reflux disease (GERD) requiring daily medication if patient can commit to lifelong endoscopic surveillance	Disagree 83.3%
11	SG is a suitable standalone, primary, surgical weight loss option for patients with Barrett's esophagus (BE) without dysplasia	Disagree 88.7%
12	SG is a suitable standalone, primary, surgical weight loss option for patients with Barrett's esophagus (BE) with dysplasia	Disagree 98.1%

Table 2 Results of voting on key perioperative considerations concerning sleeve gastrectomy (see Supplemental Data 3 for full results)

Serial nos	Statements	Final voting results
1	Construction of the sleeve should start within 4–5 cm from the pylorus to avoid leaving behind a large antrum	Agree 85.2%
2	The sleeve should be fashioned over an orogastric tube of 36–40 Fr	Agree 92.5%
3	The sleeve should be fashioned over an orogastric tube of at least 36 Fr	Agree 74.1%
4	When performing a sleeve gastrectomy (SG), care must be taken to not narrow the sleeve at the incisura	Agree 98.2%
5	When performing a SG, care must be taken to maintain equal anterior and posterior walls and symmetric traction to avoid twisting of the sleeve	Agree 100.0%
6	There is currently insufficient evidence to recommend routine use of staple line buttressing	Agree 81.5%
7	There is currently insufficient evidence to recommend routine use of fibrin glue for the staple line	Agree 100.0%
8	Surgeons should stay at least 1 cm away from the angle of His	Agree 90.7%
9	The pre-cardial fat pad should be routinely dissected to avoid leaving behind a large fundus	Agree 71.7%
10	When performing a SG, care must be taken to avoid leaving behind a large posterior fundus by ensuring visualization of left crus of the diaphragm	Agree 98.2%
11	The merits and demerits of routine hiatal dissection to identify occult hiatal hernia need to be further examined inadequately designed studies	Agree 94.4%
12	Patients with preoperatively or intraoperatively diagnosed hiatal hernia should undergo a concomitant hiatal repair with SG	Agree 92.6%
13	Posterior crural approximation is the recommended technique for approximating diaphragmatic crura in patients with hiatus hernia	Agree 87.0%
14	Omentopexy should be performed routinely with a SG	Disagree 77.4%
15	Sleeve specimen should be retrieved in a specimen retrieval bag	Disagree 81.1%

A recent survey [3] of 863 surgeons from 67 countries showed considerable variation in a range of practices concerning this procedure. Moreover, none of the previous consensus statements have appeared to follow a rigorous modified Delphi protocol. All these factors, coupled with the enormous popularity of SG, led us to embark on

this modified Delphi consensus-building exercise on this procedure.

When it came to preoperative considerations, we attempted to challenge the traditional restrictive/malabsorptive paradigm by voting on the purported mechanisms of action of SG. The committee agreed with a significant

Table 3 Results of voting on key postoperative considerations concerning sleeve gastrectomy (see Supplemental Data 4 for full results)

Serial nos	Statements	Final voting results
1	Sleeve gastrectomy (SG) patients should be advised to take over the counter multivitamin/mineral supplement tablets daily for the rest of their life	Agree 77.8%
2	Patients should be advised to take proton pump inhibitors (or H2 blockers) for 3–6 months	Agree 79.6%
3	Patients should be advised to have annual screening for anemia and secondary hyperparathyroidism for the rest of their life	Agree 74.1%
4	Patients should be advised to have annual follow-up with appropriate hematological monitoring for the rest of their life	Agree 83.3%
5	Studies investigating Barrett's esophagus (BE) after SG should account for migration of the gastro-esophageal junction and gastric cardia (where intestinal metaplasia is very common) into the chest following SG	Agree 96.3%
6	SG patients should undergo a screening endoscopy every 5 years after surgery to screen for BE	Agree 81.1%

Table 4 Results of voting on key aspects of management of complications and revisional bariatric surgery in the context of sleeve gastrectomy (SG) (see Supplemental Data 5 for full results)

Serial nos	Statements	Final voting results
1	Patients developing symptomatic GERD unresponsive to maximal medical therapy after SG can be offered surgical correction in the form of conversion to Roux-en-Y gastric bypass (RYGB)	Agree 100.0%
2	SG strictures may be successfully managed with balloon dilatation	Agree 83.3%
3	SG strictures may be successfully managed with a conversion to RYGB	Agree 100.0%
4	SG leaks may be managed by laparoscopic drainage +/- re-suture +/- t-tube placement +/- feeding jejunostomy as appropriate depending on the clinical circumstances	Agree 88.9%
5	SG leaks may be managed by stent placement in appropriate patients	Agree 92.6%
6	SG leaks may be managed by conversion to RYGB in appropriate patients	Agree 77.8%
7	SG is an acceptable revisional surgery option after gastric banding for suitable patients seeking further bariatric/metabolic benefits if they do not suffer from severe symptoms of GERD requiring daily medication	Agree 79.6%
8	One anastomosis gastric bypass (OAGB) is an acceptable revisional surgery option after SG for suitable patients seeking further bariatric/metabolic benefits if they do not suffer from severe symptoms of GERD requiring daily medication	Agree 79.6%
9	Bilio-pancreatic diversion/duodenal switch (BPD/DS) is an acceptable revisional surgery option after SG for suitable patients seeking further bariatric/metabolic benefits	Agree 85.2%
10	RYGB is an acceptable revisional surgery option after SG for suitable patients seeking further bariatric/metabolic benefits	Agree 79.6%
11	Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) is an acceptable revisional surgery option after SG for suitable patients seeking further bariatric/metabolic benefit	Agree 94.4%
12	SG can be a suitable revisional procedure for patients who suffer from severe reactive hypoglycemia after RYGB	Agree 85.2%

consensus of 89.0% that SG works through yet incompletely understood neurohormonal mechanisms and an even higher 96.0% felt that the characterization of SG as a purely restrictive procedure was inaccurate.

We then aimed to identify which group of patients SG was considered an option for. Unsurprisingly, the committee endorsed with consensus several clinical situations (Supplemental Data 2) where SG could be considered an option. Remarkably, however, there was no consensus on whether SG was a suitable standalone, primary, surgical weight loss option for patients with BMI ≥ 60 kg/m². There was further no consensus on SG being a suitable, primary, surgical weight loss option for appropriate patients with long-standing (> 5-year duration) type 2 diabetes mellitus with a

BMI of > 35 kg/m². Given that we now know that a gastric bypass offers superior weight loss and metabolic outcomes in comparison to SG in the longer term for this population of patients [9], this may suggest that SG can be considered slightly less popular in those with a more significant metabolic burden, but still favored by a majority.

There is little doubt that a significant number of patients suffer from gastro-esophageal reflux disease (GERD) after SG, and that this number is higher than those undergoing RYGB [10]. This is probably why many surgeons regard the presence of GERD or hiatal hernia as contraindications for undergoing SG [3]. This explains why there was no consensus on performing SG on patients needing daily medication for GERD or > 4.0 cm hiatal hernia. When it

comes to Barrett's esophagus (BE), RYGB can lead to the remission of this condition in a large number of patients [11], while on the other hand, there have been data suggesting that some SG patients can develop BE in the long term [12]. This may be why the committee rejected SG as an option for patients with BE with consensus; irrespective of the presence or absence of dysplasia, or the patient's willingness to undergo lifelong annual surveillance.

There has been much debate in the scientific literature regarding various technical aspects of SG with significant variation in practice [3, 13]. It is, therefore, important that the committee agreed with a consensus of 85.0% that construction of the sleeve should start within 4–5 cm from the pylorus to avoid leaving behind a large antrum and with 92.5% consensus that the sleeve should be fashioned over an orogastric tube of a size 36–40 Fr. The committee achieved a consensus that there was currently insufficient evidence to recommend routine use of staple line reinforcement with sutures (89%), staple line buttressing (81.5%), fibrin glue (100%), routine placement of band (96%), routine fundoplication as in Nissen-sleeve (98%), or single incision sleeve (90%). This should not be viewed as a rejection of these approaches but simply a reminder for development of more evidence to clarify the advantages and disadvantages of each of them.

American Society for Metabolic and Bariatric Surgery recommends [14] that patients undergoing SG be routinely supplemented with iron, vitamin D, and calcium in dosages that are much higher than typical over the counter multivitamin/mineral supplements. It was, therefore, interesting that there was no consensus reached on routine supplementation for these in this exercise. This probably points to a need for more robust evidence in support of these recommendations which were issued on Level 3 evidence.

Studies showing an alarmingly high incidence of BE after SG in the long term [12, 15, 16] show roughly the same incidence of intestinal metaplasia that is seen at the gastro-esophageal junction, GEJ [17] and have therefore been criticised [18] for not accounting for migration of the GEJ and cardia proximally into the thorax following SG. This is probably the reason that the committee agreed with an overwhelming 96.3% consensus that "studies investigating BE after SG should account for migration of the GEJ and gastric cardia (where intestinal metaplasia is very common) into the chest following SG". Though a majority of the committee members (67.9%) felt that SG does not increase the risk of gastro-esophageal junctional adenocarcinoma, this statement did not reach consensus even after two rounds of voting. It would, therefore, be prudent to keep an open mind on this topic and this may be why the committee agreed with 81.1% consensus that "SG patients should undergo a screening endoscopy every 5 years after surgery to screen for BE".

Management of complications and revisional bariatric surgery can be two particularly challenging areas for surgeons. It was, therefore, very helpful that the committee was able to reach a consensus on most of these issues. Unsurprisingly perhaps, re-sleeve did not reach a consensus as long-term data in its support are still lacking.

Strengths and weaknesses

This consensus-building exercise included 54 bariatric surgeons with significant experience and credentials. These surgeons are recognised leaders in the field and include the current, the incumbent, and several past presidents of International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO); editors in chief of two most prestigious journals in the field of obesity surgery—i.e., "Obesity Surgery" and "Surgery for Obesity and Related Diseases"; presidents or other office-bearers of many national obesity surgery societies; and many other surgeons recognized for academic excellence in the field. The exercise can, therefore, genuinely be regarded as a consensus amongst experts. Moreover, a representation of 32 countries means that this consensus statement can genuinely be regarded as a global effort. We, therefore, feel it will reduce variations in global practices concerning SG [11] and nudge individual practitioners toward consensus expert opinion. This should improve clinical outcomes with SG as well as help identify priority areas for future research.

Several weaknesses of this paper need to be emphasized. The choice of experts and the threshold of 70% for consensus have to be regarded as arbitrary. At the same time, as explained above, we genuinely feel a better quality group would be difficult to assemble. The threshold of 70% has been used in several consensus-building exercises in the field of bariatric surgery and elsewhere [6, 7]. Authors, therefore, feel it to be an appropriate cut-off. Understandably, a consensus agreement of a large number of experts would be regarded as stronger evidence than the opinion of a single expert. But it is still an opinion that needs confirmation in adequately designed studies. In that sense, consensus statements are only meant to guide current practice while the evidence develops and should not be considered as a replacement for high-quality evidence.

Conclusion

Fifty-four recognized opinion makers in the field of bariatric surgery from 32 countries around the world took part in this consensus statement on SG. Experts voted on a range of statements concerning various preoperative, perioperative, postoperative and complication management and revisional surgery considerations concerning SG. The findings of this

paper will provide individual surgeons with much-needed clarity on a range of issues and also guide future research.

Author contributions KKM conceived the idea for this exercise, moderated it, analyzed the results, and wrote large sections 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.

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Compliance with ethical standards

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