



# The first consensus statement on revisional bariatric surgery using a modified Delphi approach

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#### **Abstract**

**Background** Revisional bariatric surgery (RBS) constitutes a possible solution for patients who experience an inadequate response following bariatric surgery or significant weight regain following an initial satisfactory response. This paper reports results from the first modified Delphi consensus-building exercise on RBS.

**Methods** We created a committee of 22 recognised opinion-makers with a special interest in RBS. The committee invited 70 RBS experts from 27 countries to vote on 39 statements concerning RBS. An agreement amongst  $\geq$  70.0% experts was regarded as a consensus.

Results Seventy experts from twenty-seven countries took part. There was a consensus that the decision for RBS should be individualised (100.0%) and multi-disciplinary (92.8%). Experts recommended a preoperative nutritional (95.7%) and psychological evaluation (85.7%), endoscopy (97.1%), and a contrast series (94.3%). Experts agreed that Roux-Y gastric bypass (RYGB) (94.3%), One anastomosis gastric bypass (OAGB) (82.8%), and single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) (71.4%) were acceptable RBS options after gastric banding (84.3%). OAGB (84.3%), bilio-pancreatic diversion/duodenal switch (BPD/DS) (81.4%), and SADI-S (88.5%) were agreed as consensus RBS options after sleeve gastrectomy. lengthening of bilio-pancreatic limb was the only consensus RBS option after RYGB (94.3%) and OAGB (72.8%).

**Conclusion** Experts achieved consensus on a number of aspects of RBS. Though expert opinion can only be regarded as low-quality evidence, the findings of this exercise should help improve the outcomes of RBS while we develop robust evidence to inform future practice.

**Keywords** Bariatric surgery  $\cdot$  Revisional bariatric surgery  $\cdot$  Gastric banding  $\cdot$  Sleeve gastrectomy  $\cdot$  Roux-en-Y gastric bypass  $\cdot$  One anastomosis gastric bypass  $\cdot$  Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy  $\cdot$  Obesity surgery  $\cdot$  Conversion  $\cdot$  Weight regain  $\cdot$  Band to sleeve  $\cdot$  Band to bypass  $\cdot$  Sleeve to bypass

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RBS Revisional bariatric surgery
IFSO International Federation for the Surgery of

Obesity and Metabolic Disorders

OAGB/MGB One anastomosis (mini) gastric bypass

RYGB Roux-en-Y gastric bypass

SADI-S Single-anastomosis duodeno-ileal bypass

with sleeve gastrectomy

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SG Sleeve gastrectomy BPL Bilio-pancreatic limb

Algorithms, where next line treatment is offered to patients who do not respond to their original treatment strategies, are commonplace in medicine. After all, it cannot be realistically expected from any complex disease that all patients will behave in a similar fashion and that each of the available treatment modalities will have a similar effect on all the patients. The same is true of obesity (and diabetes) and bariatric (and metabolic) surgery. It is generally accepted



that obesity is a chronic relapsing condition and that not all bariatric surgery patients achieve a satisfactory clinical response in terms of weight loss and co-morbidity resolution following their first line surgery [1]. Yet another significant group of patients experiences a gradual waning of an initially satisfactory clinical response [2].

These patients seek further bariatric surgery [3], often loosely labelled as revisional bariatric surgery (RBS). Though riskier than primary bariatric surgery, RBS can be expected to bring additional clinical benefits [4]. Notwithstanding these clinical arguments, RBS is not automatically funded in many countries [5], making it difficult for patients to access this option. Despite these challenges, RBS is growing and it now accounts for a significant proportion of overall bariatric activity [6].

Given that we do not fully understand the mechanism (s) of action of the different bariatric procedures, there is significant variation in the choice of revisional procedures after the different primary procedures [3]. Furthermore, there is a lack of high-quality studies and an almost complete lack of randomised data [4] on various aspects of RBS. These factors make it difficult for individual surgeons looking after these patients to know which RBS procedures to recommend to their patients. This may also affect the clinical outcomes of patients having RBS. There is, therefore, a need to identify best practice.

A consensus amongst experts [7] is a recognised strategy to guide patient management in areas of clinical practice where there is a relative lack of high-quality evidence. It can help clinicians with practical day-to-day decisions while research continues to inform future practice. A consensus amongst experts is further necessary as individual experts may hold different opinions. Modified Delphi method of consensus building is regarded as superior to face-to-face meetings for consensus building as it prevents the loud voices from hijacking the exercise and prevailing upon the group [8].

There is currently no published consensus amongst experts on RBS. The aim of this exercise was to develop consensus amongst a group of international RBS experts on a range of practices and principles concerning this procedure following a Modified Delphi protocol. For the purpose of this exercise, RBS was defined as surgery for inadequate weight loss (or co-morbidity resolution) OR weight regain (or recurrence of co-morbidities) after bariatric surgery. This exercise does not deal with revisions of bariatric procedures carried out for management of complications as that is a very different clinical problem where the objective of management is the resolution of the complication rather than weight loss or co-morbidity resolution.

### **Methods**

A committee (Table 1) of recognised opinion-makers in bariatric surgery with a special interest in RBS was created to oversee the modified Delphi consensus-building exercise (Table 1). No prior Institutional Review Board approval or Consent was deemed necessary for this type of consensus-building exercise.

The committee invited RBS experts (Table 2) from around the world to take part in the consensus-building exercise. The experts were required to meet the following criteria for inclusion.

- 1. Nomination by either a member of the Consensus-Building Committee or President of a national bariatric society affiliated to the International Federation for the surgery of obesity and metabolic disorders (IFSO).
- Self-confirmation of RBS expert status for further confirmation that the nominated member also felt him/herself to be an expert in RBS.
- 3. Working knowledge of English language.
- 4. Participation in both rounds of voting as per the agreed modified Delphi protocol.

 Table 1
 Members of RBS-modified Delphi consensus-building committee (in alphabetical order)

Name	Country
Marco Adamo	United Kingdom
Luigi Angrisani	Italy
Jean-Marc Chevallier	France
Pradeep Chowbey	India
Jerome Dargent	France
Maurizio DeLuca	Italy
Bruno Dillemans	Belgium
Jan Willem M Greve	Netherlands
Jacques M Himpens	Belgium
Lilian Kow	Australia
Muffazal Lakdawala	India
Kamal Mahawar	United Kingdom
Abdelrahman Nimeri	United Arab Emirates
Gerhard Prager	Austria
Almino C Ramos	Brazil
Nasser Sakran	Israel
Scott Shikora	United States of America
Peter Small	United Kingdom
Shaw Somers	United Kingdom
Antonio Torres	Spain
Ramon Vilallonga	Spain
Rudolf Weiner	Germany

RBS revisional bariatric surgery



 Table 2
 Revisional bariatric surgery experts (in alphabetical order)

S. Number	Name	Institution	Country
1	Subhi Abu Abeid	Tel Aviv Sourasky Medical Center	Israel
2	Marco Adamo	University College London Hospital	United Kingdom
3	Salman Alsabah	Kuwait University	Kuwait
4	Ahmad Aly	Austin Health, Melbourne	Australia
5	Ali Aminian	Cleveland Clinic	United States of America
6	Luigi Angrisani	University of Naples "Federico II"	Italy
7	Sergio Aparicio	Clinica "Los Olivos"	Bolivia
8	Ahmad Assalia	Rambam Health Care Campus, Haifa	Israel
9	Sarfaraz Baig	Belle Vue Clinic, Kolkata	India
10	Ahmad Bashir	GBMC-Jordan Hospital	Jordan
11	Nahum Beglaibter	Hadassah Mount Scopus Medical Center, Jerusalem	Israel
12	Frits Berends	Rijnstate Hospital Arnhem	Netherlands
13	Vincenzo Bruni	Campus Biomedico University	Italy
14	Robert Caiazzo	Lille CHU	France
15	Stefano Cariani	University of Bologna	Italy
16	Miguel Carbajo	Center of Excellence for the Study and Treatment of the Obesity and Diabetes, Valladolid	Spain
17	Jean-Marc Chevallier	Université Paris 5	France
18	Pradeep Chowbey	Max Hospital, Saket, New Delhi	India
19	Daniel Cottam	Bariatric Medicine Institute, Lake City, Utah	United States of America
20	Jerome Dargent	Polyclinique Lyon-Nord, Lyon	France
21	Maurizio De Luca	Castelfranco and Montebelluna Hospitals, Treviso	Italy
22	Bruno Dillemans	AZ Sint Jan AV, Brugge -Oostende	Belgium
23	Mohamad Hayssam Elfawal		Lebanon,
24	Mathias A L Fobi	SAIMS Indore	India
25	Pierre Fournier	Pierre Fournier, Soffco-mm	Switzerland
26 26	David Goitein	Chaim Sheba Medical Center, Tel Aviv	Israel
27	Tito Grágeda Soto	Elizabeth Seton Hospital/Santa Maria Clinic	Bolivia
28	Jan Willem M Greve	Zuyderland Medical Center, Heerlen, The Netherlands and Maastricht University (MUMC+), Maastricht	Netherlands
29	Caroline Gronnier	Bordeaux university hospital	France
30	Eric Hazebroek	Rijnstate Hospital, Arnhem	Netherlands
31	Jacques Himpens	St Pierre University Hospital, Brussels	Belgium
32	George Hopkins	Royal Brisbane and Women's Hospital	Australia
33	Niculae Iordache	Saint John Emergency Clinical Hospital, Bucharest	Romania
34	Michal Janik	Military Institute of Medicine	Poland
35	Andrei Keidar	Assuta Ashdod Public Hospital	Israel
36	Lilian Kow	Flinders Private Hospital	Australia
37	Jon Kristinsson	Oslo University Hospital, Aker	Norway
38	Muffazal Lakdawala	Digestive Health Institute, Saifee Hospital, Mumbai	India
39	Kamal Mahawar	Sunderland Royal Hospital, Sunderland	United Kingdom
40	Tarek Mahdy	Mansoura University Hospital	United Arab Emirates
41	Vinod Menon	University Hospitals Coventry & Warwickshire NHS Trust	United Kingdom
42	M Khalid Mirza	King Fahad University Hospital, Dammam	Kingdom of Saudi Arabia
43	Mario Musella	Advanced Biomedical Sciences Department—"Federico II" University, Naples	Italy
44	Abdelrahman Nimeri	Bariatric & Metabolic Institute (BMI) Abu Dhabi	United Arab Emirates
45	Francesco Saverio Papadia	Ospedale Policlinico San Martino, Genova	Italy
46	Luigi Piazza	Società Italiana di Chirurgia dell'Obesità	Italy
47	Alfons Pomp	Weill Cornell Medicine/New York Presbyterian Hospital	United States of America



Table 2 (continued)

S. Number	Name	Institution	Country
48	Gerhard Prager	Medical University of Vienna	Austria
49	Rana C Pullatt	Medical University of South Carolina	United States of America
50	Ramon Vilallonga	Universitary Hospital Vall Hebron	Spain
51	Marco Raffaelli	Policlinico Universitario A. Gemelli, Università Cattolica del Sacro Cuore, Rome	Italy
52	Almino C Ramos	Gastro-Obeso-Center Metabolic Optimisation Institute	Brazil
53	Karl Peter Rheinwalt	St. Franziskus Hospital, Cologne	Germany
54	Bassem Safadi	American University of Beirut Medical Center	Lebanon
55	Nasser Sakran	Emek Medical Center, Afula	Israel
56	Marc Schiesser	Hirslanden Klinik St. Anna, Lucerne	Switzerland
57	Rishi Singhal	Birmingham Heartlands Hospital	United Kingdom
58	Scott Shikora	Brigham and Women's Hospital	United States of America
59	Peter K Small	Sunderland Royal Hospital, Sunderland	United Kingdom
60	Shaw Somers	Portsmouth Hospitals NHS Trust	United Kingdom
61	Rudolf Steffen	Center for bariatric surgery, Berne	Switzerland
62	Adrien Sterkers	CHP Saint Gregoire, Vivalto Santé recherche	France
63	Osama Taha	Assuit University Hospital, Assuit	Egypt
64	Antonio Torres	Hospital Clinico San Carlos, Complutense University, Madrid	Spain
65	Villy Vage	Haraldsplass Deaconess Hospital	Norway
66	Nicolas Veyrie	International Obesity Center of Paris	France
67	Rudolf Weiner	Sana-Klinikum Offenbach	Germany
68	Simon Wong	The Chinese University of Hong Kong	China
69	Mariusz Wylezol	Medical University of Warsaw	Poland
70	Yury Yashkov	Centre of Endosurgery and Lithotripsy (CELT-clinic), Moscow	Russia

The RBS consensus-building committee agreed on 39 statements for experts to vote on. All the members of the committee also voted as experts. Experts were asked to either agree or disagree with each statement and were not allowed to skip any statement. Following other published bariatric surgery consensus papers [7, 9] an agreement amongst ≥ 70.0% of experts was considered to indicate consensus. Voting was conducted virtually on Survey Monkey® and no attempt was made to identify individual experts' responses. Where possible, experts were also encouraged to provide justification for their choices. The first round voting link was made live on 7th May 2018 and was closed on 27th May 2018. The cumulative first round results including anonymised individual responses were then shared with all the voting members before the committee invited a second round of votes from experts on statements with < 80.0% consensus after the first round. A higher cut-off of 80.0% was chosen so that the consensus still remained valid if some experts were not able to help with the second round.

The second round of voting began on 6th June 2018 and the voting was closed for analysis on 14th July 2018. The voting was concluded after the two rounds as the consensus-building committee felt a saturation point had been reached and that there was no need to force a consensus on the remaining seven statements without any consensus. The committee further noted that there was no hard recommendation regarding a minimum number of rounds of voting with Delphi consensus-building exercises in the literature [7, 8].

# Results

A total of 70 experts from 27 countries voted on both the rounds of 39 statements on various aspects of RBS proposed by the consensus-building committee. Twenty invited experts either did not respond to the invitation (n=13) or were unable to help (n=7) with this exercise. They were not involved in the exercise.

Table 3 presents the results of both rounds of voting on each of the 39 statements. The committee decided to only have a second round of voting for statements with < 80.0% consensus in the first round. After two rounds, the experts reached a consensus agreement on 29 of the proposed statements and a consensus disagreement on 3 statements. Consequently, a consensus (of either agreement or disagreement) was achieved for 32 statements. Of these, 18 statements achieved a consensus of  $\ge 90.0\%$  and 30



 Table 3
 Voting results for modified Delphi consensus-building exercise on RBS

Serial No.	Statements	First round voting results (%), $N = 70$	Second round voting results (%), $N=70$	Consensus
1	RBS is a justified treatment option for some patients	100.0 (71/71)	NA	Consensus Agreement
2	A second RBS may be justified for some patients	95.7 (67/70)	NA	Consensus Agreement
3	A third RBS may be justified for some patients	<u>77.1 (54/70)</u>	90.0 (63/70)	Consensus Agreement
4	A fourth RBS may be justified for some patients	55.7 (39/70)	61.4 (43/70)	No consensus achieved
5	RBS is technically more challenging to perform compared to PBS	98.5 (69/70)	NA	Consensus Agreement
6	For a procedure that can be carried out as both RBS and PBS, RBS carries a lower efficacy	70.0 (49/71)	87.1 (61/70)	Consensus Agreement
7	For a procedure that can be carried out as both RBS and PBS, RBS carries a higher complication rate	87.1 (61/70)	NA	Consensus Agreement
8	Patients should undergo a dietetic evaluation, where applicable, before an RBS	95.7 (67/70)	NA	Consensus Agreement
9	Patients should undergo a psychological evaluation, where applicable, before an RBS	85.7 (60/70)	NA	Consensus Agreement
10	Patients should undergo a contrast series, where applicable, before an RBS	94.3 (66/70)	NA	Consensus Agreement
11	Patients should undergo an upper gastrointestinal endoscopy, where applicable, before an RBS	97.1 (68/70)	NA	Consensus Agreement
12	It is not possible to lay down specific criteria for RBS in terms of body mass index for RBS at the current time	<u>78.5 (55/70)</u>	95.7 (67/70)	Consensus Agreement
13	It is not possible to lay down specific criteria for RBS in terms of weight loss after PBS at the current time	87.1 (61/70)	NA	Consensus Agreement
14	It is not possible to lay down specific criteria for RBS in terms of weight regain from the nadir weight after PBS at the current time	91.4 (64/70)	NA	Consensus Agreement
15	The decision for an RBS should be individualised for every patient	100.0 (70/70)	NA	Consensus Agreement
16	The decision for an RBS should be taken in a multi-disciplinary setting	92.8 (65/70)	NA	Consensus Agreement
17	RYGB is an acceptable RBS option after gastric banding.	94.3 (66/70)	NA	Consensus Agreement
18	OAGB is an acceptable RBS option after gastric banding	82.8 (58/70)	NA	Consensus Agreement
19	SADI-S is an acceptable RBS option after gastric banding	65.7 (46/70)	71.4 (50/70)	Consensus Agreement
20	RBS after gastric banding can be carried out in either 1 or 2-stage	91.4 (64/70)	NA	Consensus Agreement
21	OAGB is an acceptable RBS option after SG	84.3 (59/70)	NA	Consensus Agreement
22	BPD/DS is an acceptable RBS option after SG	81.4 (57/70)	NA	Consensus Agreement
23	SADI-S is an acceptable RBS option after SG	88.5 (62/70)	NA	Consensus Agreement
24	Surgical pouch size reduction is an acceptable RBS option after RYGB	61.4 (43/70)	67.1 (47/70)	No consensus achieved
25	Surgical Stoma size reduction is an acceptable RBS option after RYGB	61.4 (43/70)	55.7 (39/70)	No consensus achieved
26	Endoscopic Pouch size reduction is an acceptable RBS option after RYGB	55.7 (39/70)	41.4 (29/70)	No consensus achieved



Table 3 (continued)

Serial No.	Statements	First round voting results (%), $N=70$	Second round voting results (%), $N=70$	Consensus
27	Endoscopic stoma size reduction is an acceptable RBS option after RYGB	60.0 (42/70)	57.1 (40/70)	No consensus achieved
28	Prolongation of bilio-pancreatic limb is an acceptable RBS option after RYGB	74.3 (52/70)	94.3 (66/70)	Consensus Agreement
29	Secondary banding using an adjustable band is an acceptable RBS option after RYGB	44.3 (31/71)	34.3 (24/70)	No consensus achieved
30	BPD is an acceptable RBS option after RYGB	45.7 (32/70)	32.8 (23/70)	No consensus achieved
31	Prolongation of bilio-pancreatic limb is an acceptable RBS option after OAGB	62.8 (44/70)	72.8 (51/70)	Consensus Agreement
32	Secondary banding using a fixed band is an acceptable RBS option after OAGB	31.4 (22/70)	14.3 (10/70)	Consensus Disagreement
33	Secondary banding using an adjustable band is an acceptable RBS option after OAGB	27.1 (19/70)	10.0 (7/70)	Consensus Disagreement
34	BPD is an acceptable RBS option after OAGB	34.3 (24/70)	14.3 (10/70)	Consensus Disagreement
35	Surgeons should measure the total small bowel length while prolonging bilio-pancreatic Limb for patients needing RBS after RYGB or OAGB	94.3 (66/70)	NA	Consensus Agreement
36	RBS should, where possible, be only carried out by dedicated bariatric surgeons	98.5 (69/70)	NA	Consensus Agreement
37	RBS should, where possible, be only carried out in high volume centres	87.1 (61/70)	NA	Consensus Agreement
38	Clinical response to a PBS or RBS depends on a number of patient-related and procedure-related factors	91.4 (64/70)	NA	Consensus Agreement
39	It is undesirable to have strict definitions of "success" (responders) or "failure" (non-responders) after revisional bariatric surgery	60.0 (42/70)	84.3 (59/70)	Consensus Agreement

RBS revisional bariatric surgery, PBS primary bariatric surgery, RYGB Roux-en-Y gastric bypass, SG sleeve gastrectomy, OAGB one anastomosis gastric bypass, BPD/DS bilio-pancreatic diversion/duodenal switch, SADI-S single anastomosis duodeno-ileal bypass with sleeve gastrectomy

statements achieved a consensus of  $\geq 80.0\%$ . There was no consensus on 7 statements.

# Expert disagreement with the committee statements

Of the 32 statements where experts achieved a consensus, there was a consensus of disagreement for three. These have been clearly identified in Table 3 and are as follows:

- i. Secondary banding using a fixed band is an acceptable RBS option after one anastomosis gastric bypass (OAGB). (Disagreed by 85.7% experts).
- ii. Secondary banding using an adjustable band is an acceptable RBS option after OAGB. (Disagreed by 90.0% experts).
- iii. BPD is an acceptable RBS option after OAGB. (Disagreed by 85.7% experts).

# Change in opinion in second round

The committee invited expert votes on 17 of the 39 statements in the second round. These were the statements where there was < 80.0% consensus after the first round. These statements are clearly identified in Table 3. Some experts changed their position on each of these statements in the second round.

Five of these statements had already achieved consensus (4 consensus agreement, 1 consensus disagreement) of  $\geq 70.0\%$ . The first round voting results of these statements are italicised and underlined in Table 3 for ease of identification. For each of these statements, the consensus majority increased as experts changed their position in the second round and the consensus (of agreement/disagreement) was even stronger after the second round. Out of the 12 statements that the experts voted on in the second round where there was no consensus after the first round, experts reached a further consensus on 5 statements (3 of agreement and 2



of disagreement) leaving only 7 statements after the second round with no consensus. The second round results of these 5 statements have been highlighted using the bold fonts in Table 3.

#### No consensus achieved

Even after two rounds of voting, there was no consensus on 7 statements. These have been clearly identified in Table 3 and are as follows.

- i. A fourth RBS may be justified for some patients. Agreed by 61.4% (43/70) in the second round.
- ii. Surgical pouch size reduction is an acceptable RBS option after Roux-en-Y gastric bypass (RYGB). Agreed by 67.1% (47/70) in the second round.
- iii. Surgical stoma size reduction is an acceptable RBS option after RYGB. Agreed by 55.7% (39/70) in the second round.
- iv. Endoscopic pouch size reduction is an acceptable RBS option after RYGB. Agreed by 41.4% (29/70) in the second round.
- Endoscopic stoma size reduction is an acceptable RBS option after RYGB. Agreed by 57.1% (40/70) in the second round.
- vi. Secondary banding using an adjustable band is an acceptable RBS option after RYGB. Agreed by 34.3% (24/70) in the second round.
- vii. BPD is an acceptable RBS option after RYGB. Agreed by 32.8% (23/70) in the second round.

# Discussion

RBS has been described as a natural escalation of therapy by some [4] and a moral obligation by others [10]. Though the benefits of RBS are probably lower than the benefits obtained by the respective primary bariatric procedures [4, 11], they are real and currently, RBS may be the only durable treatment option available to many of these patients. It is, therefore, an important consideration for these patients and their treating teams. At the same time, there is currently insufficient evidence on various aspects of RBS. This poses challenges for clinical teams and can explain the variation in practice observed in a recent survey of 460 RBS surgeons [3]. A consensus amongst experts is a recognised strategy to guide clinical practice [8] in areas of clinical practice with scant evidence and can overcome some of the weaknesses of the opinion of individual experts.

As expected, 100.0% of the experts in this exercise agreed that RBS was a "justified treatment option" for some patients. But when it came to further revisional surgeries, the numbers declined to 95.7% for the second RBS

and 90.0% for the third RBS. Remarkably, however, there was no consensus on a fourth RBS suggesting perhaps that there is a limit to the number of surgical procedures that patients can be offered and that other factors may be at play if a patient does not achieve a satisfactory response even after four surgeries. At the same time, a majority 61.4% of the experts felt even a fourth RBS could be a justified option for some patients. Thus, even a fourth RBS cannot be automatically excluded.

Experts in this exercise agreed that RBS is technically more challenging to perform (98.5%) and carries lower efficacy than respective primary procedures (87.1%). This is probably why there was consensus on a preoperative nutritional evaluation (95.7%), psychological evaluation (85.7%), upper gastrointestinal endoscopy (97.1%), and a contrast series (94.3%) prior to embarking on an RBS. These findings are similar to those published in a recent survey of RBS surgeons [3]. It is only logical to attempt to identify any obvious nutritional or psychological factors responsible for the poor response before attempting the riskier RBS [4]. Similarly, the anatomy in patients presenting for RBS, even when the primary surgery was carried out by the same surgical team, cannot be expected to be constant. It would, therefore, seem reasonable to define it using endoscopic and radiological means prior to embarking on the RBS.

There is currently no agreement amongst the medical fraternity on what is an adequate response after bariatric surgery and for which patient groups the higher risks of an RBS would be justified [3]. These decisions can indeed be very difficult in clinical settings and that is probably why 100.0% of the experts in this exercise agreed that the decision for RBS should be individualised and 92.8% of them agreed that the decision should be taken in a multi-disciplinary setting. There was a further consensus in this exercise that it was not possible to create specific criteria for RBS in terms of body mass index (95.7%), weight loss after primary surgery (87.1%), and weight regain from nadir weight (91.4%).

Experts in this study achieved consensus that RYGB (94.3%), OAGB (82.8%), and single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) (71.4%) were all acceptable RBS options after gastric banding. There was also a consensus that such revisions can be safely carried out in either one or two stages (91.4%). A recent systematic review [12] examining RBS options after gastric banding noted a lack of evidence from randomised trials on this issue. When it came to revisions after sleeve gastrectomy (SG), experts agreed that OAGB (84.3%), BPD-DS (81.4%), and SADI-S (88.5%) were all acceptable RBS options. Once again, randomised studies comparing various approaches are lacking [13]. It will indeed be very difficult to organise such studies with a sufficiently large sample size that will provide statistically robust answers to relevant questions about

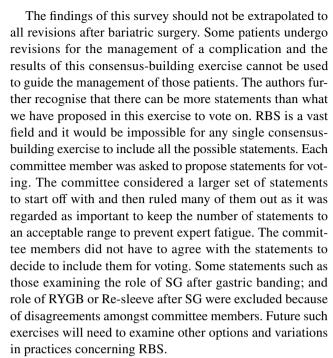


long-term safety and efficacy, without a major national/international multi-centre collaboration.

When it came to RBS after RYGB and OAGB, there was no consensus on most of the proposed statements and there was even a consensus of disagreement for some of them. The only RBS option experts agreed with consensus after both RYGB and OAGB was lengthening of the bilio-pancreatic limb (BPL). Experts further achieved a consensus of 94.3% that the total small bowel length should be measured when such lengthening of the BPL is carried out. This consensus is significant especially since a number of surgical options are in use for RBS after RYGB [3, 14]. At the same time, though lengthening of BPL is gaining traction [15], high-quality evidence comparing different options over a sufficient period of time is lacking.

Experts agreed with a consensus that RBS should only be carried out by dedicated bariatric surgeons (98.5%) in high volume centres (87.1%). This is probably in recognition of the increased complexity and higher complication rates associated with this type of surgery. Finally, experts agreed that the clinical response to a primary or revisional bariatric surgery depends on a number of patient and procedure-related factors (91.4%) and that it was undesirable to have strict definitions for "success" (responders) or "failure" (non-responders) after RBS (84.3%). Such definitions do not exist in other areas of medical science and carry a significant risk of blaming the patients for what may simply be our inability to effectively treat the disease at the current time. There is generally a need for bariatric surgeons to avoid measuring response in these terms. Furthermore, what is often regarded as a suboptimal response in terms of weight loss may well be regarded as a good response when viewed in terms of reduced cardiovascular risk or improved quality of life.

The authors believe that the results of this consensusbuilding exercise have the potential to influence clinical practice, and therefore, improve the outcomes of patients undergoing RBS. At the same time, one has to recognise that expert opinion is regarded as a low level of evidence and the strength of the recommendations that can be made from it will likely be weak. The opinion of experts in this exercise, therefore, needs to be confirmed in carefully designed clinical studies. The advantages and disadvantages of a Modified Delphi virtual consensus-building exercise have been discussed elsewhere [7, 8]. It is believed that anonymous voting allows experts to contribute equally without any peer pressure and it also encourages them to shift their positions without loss of face that could happen in an open forum setting. At the same time, a virtual, anonymous setting may lead to a diminished personal sense of responsibility. The authors hope that the naming of all of the committee members and the experts in this paper, would at least partially overcome these limitations.



Though the exercise involves a large number of experts from around the world, authors acknowledge that there might be experts out there who have not been able to contribute to this exercise and that since most of the committee members are from Europe, groups from other parts of the world may not be adequately represented. Moreover, bariatric surgery is new in certain parts of the world such as Asia where there may not be many experts in RBS. In that sense, the results of this exercise can only indicate the opinion of this group.

The choice of committee members and experts in any such exercise is by definition somewhat arbitrary [16, 17] but we did try to broaden our expert panel by writing to the presidents of all IFSO endorsed national societies and included more experts than previous consensus-building attempts in the field of bariatric surgery [16, 17]. The authors hope that the relatively large number of experts in this exercise would help reduce any potential for bias. We did not ask individual experts to mention the numbers of revisional procedures that they have carried out as such information is difficult to verify. Instead, experts had to be nominated followed by self-confirmation that s/he is an expert in RBS. It is hoped that these efforts would help minimise the chances of a non-expert being included as an expert without compromising their geographic spread.

Indeed, many of the statements (statements 5, 8, 9, and 10 for example) that the experts voted on are routine practice in many centres. The committee agreed to vote on them simply because even these practices are not universally adopted by bariatric surgeons [3] and we felt that a consensus on these aspects of RBS would help improve standards.

It is further possible that even with Delphi protocols, participants may change their opinion in line with the group



thinking but at the same time, this technique is much less prone to forced change in opinion in comparison to open group setting where the whole exercise remains at risk of being hijacked by the loud voices. The Delphi protocol guarantees anonymity to individual experts and reduces the tendency for them to fall in line with the most assertive members of the group. In our exercise, individual experts only had access to group results and only the moderator of the exercise (KM) had access to individual responses.

At the same time, we have to recognise that the results of any such consensus-building exercise are merely the opinion of the experts and though it does overcome the limitations of the opinion of individual experts, it cannot replace the need for robust evidence. Viewed in this manner, the results of this exercise are only meant to help clinicians care for patients needing RBS in their practices until we can develop sufficient evidence to inform practice in this area. This is all the more important given that RBS now accounts for an increasing proportion of bariatric activity around the world [18, 19].

#### **Conclusion**

This paper reports the findings from the first Modified Delphi consensus-building exercise on various aspects of RBS. Seventy experts from 27 countries achieved a consensus on a number of statements concerning RBS. The experts achieved consensus that in suitable patients even a third RBS can be justified (90.0%) and that RBS is technically more challenging than respective primary bariatric procedures (98.5%). There was a further consensus that strict definitions of "success" and "failure" were undesirable (84.3%) and that it was not possible to have strict criteria for RBS in terms of body mass index (95.7%), weight loss after primary bariatric surgery (87.1%), and weight regain from the nadir weight (91.4%). The experts also achieved consensus on acceptable RBS options after different bariatric procedures. Though the opinion of experts, even a group of them, can only be regarded as limited (low)-quality evidence, authors believe the findings of this consensus-building exercise should help improve the outcomes of RBS while further evidence accumulates. The authors would also like to emphasise the need for confirming the findings of this exercise in adequately designed scientific studies.

Author contributions KKM conceived the idea for this exercise, moderated it, analysed 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.

# Compliance with ethical standards

**Disclosures** Dr. Mahawar has been paid honoraria by Medtronic, Gore, and Olympus for educational activities, outside the submitted work. Dr. Himpens is a consultant with Medtronic and Ethicon. Dr. Torres reports personal fees from Ethicon, personal fees from Medtronic, outside the submitted work. Dr. Dillemans is a consultant with Medtronic and with Ethicon. Dr. Greve reports personal fees from GI Dynamics, outside the submitted work. Dr. Adamo reports grants from Ethicon, grants from Gore, personal fees from Olympus, personal fees from Gore, and personal fees from Stryker. Drs. Shikora, Ramos, Somers, Angrisani, Chevallier, Chowbey, De Luca, Weiner, Prager, Vilallonga, Sakran, Kow, Lakdawala, Dargent, Nimeri, and Small have no conflicts of interests or financial ties to disclose.

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