



ASMBS guidelines/statements

American Society of Metabolic and Bariatric Surgery consensus statement on laparoscopic adjustable gastric band management

Sue Benson-Davies, Ph.D., D.C.N., M.P.H., R.D.N., F.A.N.D.^a,
 Ann M. Rogers, M.D., F.A.C.S., F.A.S.M.B.S.^b, Warren Huberman, Ph.D., A.B.P.P.^c,
 Nathaniel Sann, M.S.N., F.N.P.-B.C.^d, William F. Gourash, Ph.D., C.R.N.P., C.B.N.^e,
 Karen Flanders, M.S.N., C.N.P., C.B.N.^f,
 Christine Ren-Fielding, M.D., F.A.C.S., F.A.S.M.B.S.^{g,*}

^aDepartment of Surgery, Sanford School of Medicine, University of South Dakota, Vermillion, South Dakota

^bDepartment of Surgery, Division of Minimally Invasive and Bariatric Surgery, Penn State Milton S. Hershey Medical Center, Hershey, Pennsylvania

^cDepartment of Psychiatry, New York University Grossman School of Medicine, New York, New York

^dAdvanced Surgical Partners of Virginia, Richmond, Virginia

^eDepartment of Surgery, Division of Minimally Invasive Bariatric and General Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania

^fMassachusetts General Hospital Weight Center, Boston, Massachusetts

^gNew York University Langone Medical Center, Division of Bariatric Surgery and Weight Management, New York, New York

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Abstract

Background: Laparoscopic adjustable gastric band (LAGB) management continues to be an important part of many metabolic and bariatric surgery practices.

Objectives: To replace the existing American Society for Metabolic and Bariatric Surgery (ASMBS) LAGB adjustment credentialing guidelines for physician extenders with consensus statements that reflect the current state of LAGB management.

Setting: ASMBS Integrated Health Clinical Issues Committee.

Methods: A modified Delphi process using a 2-stage consensus approach was conducted on LAGB management. Thirty-four consensus statements were developed following a literature search on a wide range of LAGB topics. A 5-point Likert scale was implemented to measure consensus agreement with a Delphi panel of 39 expert participants who were invited and agreed to participate in 2 rounds of Delphi questionnaires. Consensus was set a priori at 75% agreement, defined as the proportion of participants responding with agreement (i.e., 4 or 5) or disagreement (i.e., 1 or 2) on the Likert scale.

Results: Consensus was reached on 74% (25 of 34) of the LAGB management statements. In Delphi round 1, 95% (37 of 39) of the participants responded to 34 consensus statements; 21 of the statements (62%) met the 75% criteria for consensus. Thirty-one participants (80%) responded in round 2, shifting the agreement on 4 more statements to the 75% threshold.

Conclusion: The ASMBS consensus statement on LAGB management is intended to guide practice with current evidence-based knowledge and professional experience. The ASMBS is not a credentialing body and does not seek to guide credentialing with this document. (Surg Obes Relat Dis 2022; ■:1–14.) © 2022 Published by Elsevier Inc. on behalf of American Society for Metabolic Bariatric Surgery.

Keywords:

Adjustable gastric band; Bariatric surgery; Weight loss surgery; Postoperative care

* Correspondence: Christine Ren-Fielding, M.D., New York University, Langone Medical Center, Division of Bariatric Surgery and Weight Management, 530 First Avenue, Suite 10S, New York, NY 10016.

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E-mail address: christine.ren-fielding@nyulangone.org (C. Ren-Fielding).

Laparoscopic adjustable gastric band (LAGB) management continues to be an important part of many metabolic and bariatric surgery (MBS) practices. Although laparoscopic LAGB placement has declined over the past several years, >161,000 LAGBs were placed in the United States from 2011 through 2019 [1]. In 2001, the U.S. Food and Drug Administration (FDA) approved the Lap-Band (Allergan, Inc, Irvine, CA, USA) [2] as a novel and safe procedure to treat severe obesity at that time. Thousands of LAGBs were placed in the earlier decade. Therefore, there remains a strong demand for guidance regarding LAGB management within the United States.

The purpose of this publication is to replace the existing American Society for Metabolic and Bariatric Surgery (ASMBS) LAGB credentialing guideline for physicians and physician extenders [3] with a consensus statement that reflects the current state of LAGB management. A comprehensive analysis of the existing evidence-based literature, in addition to examining practice opinions from a group of clinical experts, was conducted to develop this consensus statement. This consensus statement issued by the ASMBS Integrated Health Clinical Issues Committee acknowledges a lack of rigorous scientific evidence. Therefore, this document is based on current clinical knowledge, expert opinion, and published peer-reviewed scientific evidence available at this time. It is not intended to establish local, regional, or national standards of care. This publication may be revised in the future should more evidence become available.

Methods

Delphi team, literature search, consensus statements

A modified Delphi process using a 2-stage consensus-building approach was conducted. Seven multidisciplinary clinicians (2 surgeons, 3 nurse practitioners, 1 registered dietician, and 1 psychologist) with clinical experience and knowledge in LAGB management served as the core team leading the Delphi study. Each stage of the Delphi process was discussed by video conferencing, phone calls, and e-mail communications. A wide range of LAGB management topics were identified and described in an operational definition. Inclusion criteria for a literature search were set and consisted of postoperative LAGB studies with 10 or more human subjects, English-language, peer-reviewed, scientific evidence-based studies. Records excluded were those that addressed nonadjustable gastric bands or other types of band mechanisms, animal studies, and preoperative LAGB management. A literature search was conducted in MEDLINE from January 1, 2006, to June 30, 2021. The following MEDLINE search resulted in 604 abstracts: band* AND “Gastroplasty/adverse effects”[Mesh] AND English [lang] AND (2006:2022[pdat]) AND English[Filter] NOT (letter [Publication Type]) NOT (editorial [Publication Type]). A total of 179 full-text records from the scientific literature were reviewed by the Delphi team.

References of the papers were screened for other relevant articles where applicable.

The LAGB evidence was transformed into questions using the population, intervention, control, and outcomes (PICO) format when possible. For each question, supporting literature was used to draft consensus statements. This process resulted in a list of 34 consensus statements finalized by the Delphi team. The final list of consensus statements was uploaded into SurveyMonkey software (Momentive, Inc, San Mateo, CA, USA) by ASMBS administrative staff to gather results of the Likert scale from the panel of experts.

Likert scale, predefined consensus agreement, Delphi rounds

A Likert scale was implemented to measure consensus agreement with the following anchors: strongly agree = 5; agree = 4; neutral = 3; disagree = 2; strongly disagree = 1; and no opinion = 0. Consensus was set a priori at 75% agreement, which is consistent with previous Delphi studies reported in the literature [4–6]. Seventy-five percent consensus is defined as the proportion of participant responses rated with agreement (i.e., 4 or 5) or disagreement (i.e., 1 or 2) on the Likert scale.

The Delphi method included 2 rounds of electronic questionnaires. Consensus statements that did not reach 75% agreement were repeated in Delphi round 2. Two weeks were provided for participants to complete each Delphi round.

Selection of the Delphi panel

The consensus statement participants were MBS providers identified by the Delphi team. A knowledgeable participant for the Delphi panel was defined as any licensed healthcare provider (i.e., physicians, nurses, dieticians, behavioral health specialists, nurse practitioners, and physician assistants) currently working with LAGB patients or who have had extensive experience in treating LAGB patients in the past. All Delphi panel participants were active ASMBS members. Individuals who work directly or indirectly with the LAGB industry and the manuscript authors were excluded from questionnaire participation.

Prior to Delphi round 1, 49 MBS providers were invited to participate in the questionnaire of consensus statements through an e-mail invitation. All responses were anonymous. Thirty-nine of the invited participants (80%) responded and were e-mailed Delphi round 1 consensus statements. The Delphi panel was instructed to score each consensus statement as described earlier. A free-text option also was available for participants to provide comments to each statement. The completed questionnaires were electronically submitted to the ASMBS administrative staff, deidentified, and collated with the raw data. The data were analyzed by the Delphi team and summarized accordingly. After round 1, 13 of the consensus statements (38%) did not reach 75% agreement. The Delphi team slightly

modified 4 of the 13 statements by eliminating nonessential words. In Delphi round 2, 13 statements with the results from Delphi round 1 were sent to 39 participants with the same instructions as for the first round. The raw data were collected by ASMBS staff and collated in the same manner as for round 1. Both quantitative and qualitative data were summarized from the Delphi rounds.

Results and discussion

Thirty-nine of 49 ASMBS experts (80%) identified in LAGB management agreed to take part in the Delphi process (Fig. 1). In Delphi rounds 1 and 2, most participants were physicians (72%), and the remainder were integrated health members (28%).

In Delphi round 1, 95% of the participants (37 of 39) responded to 34 consensus statements (Table 1). Twenty-one statements (62%) met the 75% criteria for consensus. These statements were eliminated from Delphi round 2 (Table 2). Consensus statements in round 1 receiving the highest scores (95%–100%) for LAGB management included (1) provider training and experience; (2) awareness of multiple factors that may contribute to weight recurrence or insufficient weight loss (i.e., dietary, behavioral, medications, and device-related problems); (3) adding antiobesity medication when indicated; (4) suggesting fluid removal from the LAGB with dysphagia, vomiting, or regurgitation; and (5) postoperative therapy including a behavioral health specialist with support group attendance for behavioral-related symptoms or diagnoses.

Ten of 13 statements not meeting the 75% threshold fell within 50%–74% of agreement, suggesting that most providers in Delphi round 1 recognized similar LAGB management. Thirty-one participants (80%) responded in round 2. In this round, 4 more statements met the 75% agreement

criterion. The responses shifted agreement from round 1 to round 2, respectively: (1) fluid removal with chest pain, 73%–90% agreement; (2) fluid removal with maladaptive eating behaviors, 73%–84% agreement; (3) preoperative psychopathology may predict postoperative psychopathology, 73%–81% agreement; and (4) symptoms of vomiting, dysphagia, and other eating challenges may delay diet progression, 57%–77% agreement.

Finally, 2 opposing statements of interest were included in the questionnaire. These statements compared nonoperative LAGB management with LAGB removal as the optimal treatment for long-term ABG complications such as band slip/gastric prolapse, gastroesophageal reflux disease (GERD), and esophageal dilatation. Regarding long-term ABG complications, more participants disagreed with nonoperative LAGB management between round 1 (51%) and round 2 (71%). Furthermore, the statement regarding LAGB removal as the optimal treatment for long-term complications moved from 43% agreement in round 1 to 58% in round 2.

Our literature review found insufficient evidence to support graded guideline recommendations for LAGB management. Therefore, we relied on expert opinion to establish a consensus via the Delphi methodology. After 2 Delphi rounds, consensus was reached on 74% of the statements (25 of 34) representing 6 domains across the spectrum of LAGB management. We briefly discuss each domain below.

Domain: Behavioral health

Consensus among 81% of LAGB experts agreed that preoperative psychopathology may predict postoperative psychopathology. Up to 70% of the general population have psychiatric disorders, most commonly depression, anxiety, and binge eating disorder (BED) [7,8]. Although studies

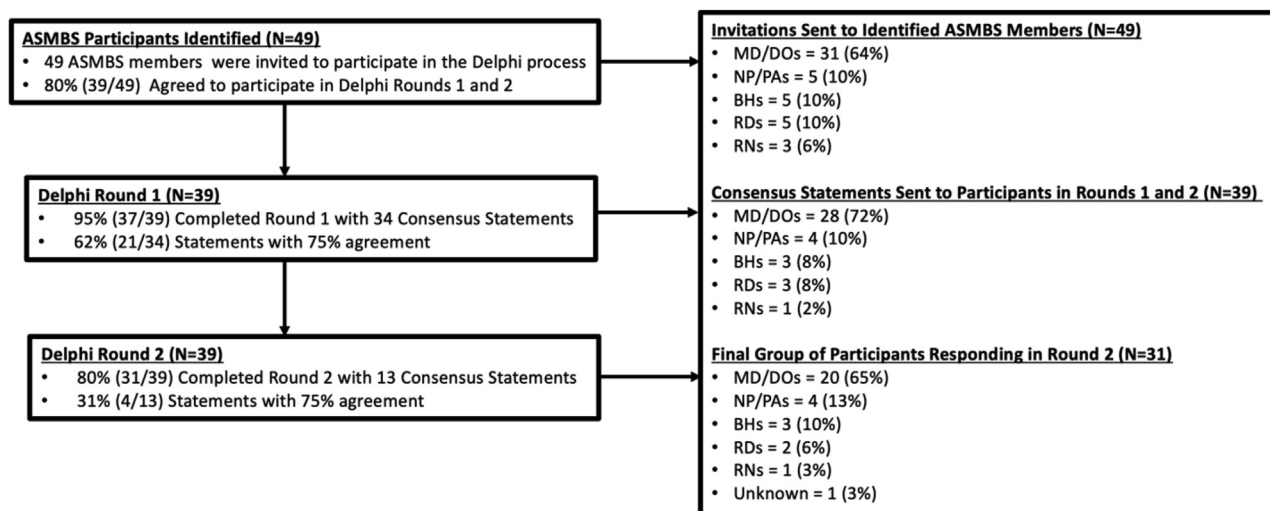


Fig. 1. Delphi process described by participants and completion of rounds 1 and 2. ASMBS = American Society of Metabolic and Bariatric Surgery; MD = doctor of medicine; DO = doctor of osteopathic medicine; NP = nurse practitioner; PA = physician assistant; BH = behavioral health; RD = registered dietician; RN = registered nurse; Unknown = individuals who opted not to identify their healthcare credentials according to the categories in this list.

Table 1
Delphi round 1 consensus statements and level of agreement

Adjustable gastric band round 1 consensus agreement (n = 37)	Agree	Neutral	Disagree	No opinion
1. Providers responsible for LAGB management should have training and experience with recommended fluid volumes and adjustment schedules.	100%			
2. Weight regain or insufficient weight loss after LAGB can be caused by dietary, behavioral, medications, or device-related mechanical problems.	97%			3%
3. LAGB patients with behavior-related symptoms or diagnoses should undergo postoperative therapy with appropriate medication and counseling, in combination with support groups.	97%			3%
4. Providers should evaluate patient medications that may lead to weight regain (mood stabilizers, antipsychotic and antiseizure medications, steroids, antihistamines, beta-blockers, diabetes medications).	97%	3%		
5. Antiobesity medications may assist with weight loss after LAGB surgery and help prevent weight regain.	95%	5%		
6. Fluid should be removed from the LAGB when a patient experiences significant dysphagia, vomiting/regurgitation.	95%		3%	3%
7. Fluid should be added to the LAGB when a patient tolerates large portions of dense solid foods.	92%	5%		3%
8. LAGBs can be removed and converted to either sleeve gastrectomy or Roux-en-Y gastric bypass in either 1 stage or 2 stages.	92%	5%	3%	
9. Device-related complications of the LAGB (device leak, band erosion, disconnected tubing, port infections) require replacement of LAGB components or band removal.	89%	8%		3%
10. Signs or symptoms of maladaptive and disordered eating behaviors among individuals with an LAGB include grazing/nibbling, loss of control, eating in response to emotional or situational triggers, perceived hunger, lack of dietary restraint, and purging.	86%	11%		3%
11. Fluid should be added to the LAGB when a patient feels a lack of satiety.	86%	11%		3%
12. After LAGB surgery, psychosocial issues (disordered eating, substance-use disorders, suicide, depression, lack of social support, and body image/excess skin) can have a negative impact on outcomes.	84%	8%	5%	3%
13. LAGB patients should be managed by only surgical teams familiar with LAGB adjustments and potential complications.	84%	8%	8%	
14. LAGB-induced weight loss may lower the risk of pregnancy-induced hypertension, gestational diabetes, preeclampsia, and eclampsia.	84%	11%		5%
15. Fluid should be removed from the LAGB when a patient experiences an inability to tolerate solid-food textures.	84%	8%	5%	3%
16. LAGB management requires multidisciplinary teams with experienced providers including surgeons, primary care physicians, registered dietitians, behavioral health specialists, nurse practitioners, nurses, and physician assistants.	81%	8%	11%	
17. My practice has the resources and training to manage LAGBs well.	81%	11%	5%	3%
18. Fluid should be removed from the LAGB when a patient experiences new or increasing heartburn or reflux symptoms.	78%	14%	5%	3%
19. Providers managing LAGBs should be competent in understanding physiologic mechanisms affected (vagus nerve, hormones, gut motility) by LAGB placement and fluid volume adjustments.	76%	19%	3%	3%
20. Fluid should be added to the LAGB when a patient senses that hunger/appetite is not well controlled.	76%	19%	3%	3%
21. Fluid should be removed from the LAGB when a patient experiences feelings of uneasiness with eating.	76%	24%	5%	3%
22. Preoperative psychopathology may predict postoperative psychopathology.	73%	16%	11%	
23. After LAGB surgery, adolescents may show early improvement in psychological health.	73%	16%		11%
24. Fluid should be removed from the LAGB when a patient experiences new onset or persistence of chest pain.	73%	16%	8%	3%
25. Fluid should be removed from the LAGB when a patient experiences maladaptive eating behavior.	73%	22%	3%	3%
26. During pregnancy, LAGBs should be evaluated for possible deflation in the third trimester to prevent potential complications (risk of LAGB slippage, nutrition deficiencies, low birth weight).	68%	11%	8%	13%
27. LAGBs should be assessed regularly by upper gastrointestinal radiologic study to evaluate for complications (i.e., every 5 years).	65%	16%	14%	5%
28. Postoperative nutrition follow-up visits should be conducted by a registered dietitian.	59%	22%	19%	
29. Vomiting, regurgitation, reflux with saliva, dysphagia, and food intolerances are common LAGB surgery complications that may delay diet progression or lead to maladaptive eating behaviors.	57%	22%	22%	

(continued on next page)

Table 1 (continued)

Adjustable gastric band round 1 consensus agreement (n = 37)	Agree	Neutral	Disagree	No opinion
30. Providers should consult a registered dietician when patients with an LAGB experience adverse symptoms with eating behaviors, diet progression, food intolerances, nutrient deficiencies, excessive or insufficient weight loss, and weight regain.	54%	24%	22%	
31. LAGB removal is the best treatment option for long-term complications such as band slip/gastric prolapse, GERD, and esophageal dilatation.	43%	22%	32%	3%
32. Fluid should be added to the LAGB when a patient experiences a minimal weight loss or weight gain.	38%	41%	19%	3%
33. During pregnancy, LAGBs should be evaluated for possible inflation to prevent excessive weight gain during the first and second trimesters.	32%	16%	41%	11%
34. Nonoperative management of LAGB is the best treatment option for long-term complications such as band slip/gastric prolapse, GERD, and esophageal dilatation.	24%	22%	51%	3%

LAGB = laparoscopic adjustable gastric band; GERD = gastroesophageal reflux disease.

Key: Green = 75%–100% consensus agreement; yellow = 50%–74% consensus agreement; blue = 0%–49% consensus agreement.

have shown a reduction in depression after LAGB surgery [9,10], longer-term studies suggest that initial reductions in depression may deteriorate over time [7,9]. Results of studies on anxiety after LAGB are inconclusive [7,10]. Pre-operative psychological evaluations by experienced mental health providers should identify psychological risk factors that may impact postoperative LAGB outcomes. Mental health providers should be part of the MBS team to minimize or prevent psychiatric disorders postoperatively.

Consensus among 84% of the Delphi panel agreed that psychosocial issues (e.g., disordered eating, substance abuse, suicide, depression, lack of social support, and body image/excess skin) can have a negative impact on outcomes. True BED, which includes both the consumption of excessively large amounts of food (objective binge eating) and loss of control (LOC) of eating episodes, is physically difficult after LAGB surgery because of the limited gastric capacity [11]. However, LOC eating can continue after LAGB in the form of continuous grazing or nibbling on small amounts of food within a 24-hour period. Furthermore, LOC eating is the most common maladaptive eating behavior associated with poor outcomes in the LAGB literature [11]. Another possible acquired or problematic LAGB eating behavior is chewing and spitting out food contents [8,11]. Maladaptive behaviors have been shown to negatively affect weight loss. MBS providers should refer patients to mental health providers when maladaptive eating behaviors are suspected or identified. Therapy should include a personalized treatment plan with close monitoring of eating behaviors through a combination of psychological and nutrition counseling.

MBS providers also should routinely screen patients for substance abuse, emotional stability, and social support. Although substance abuse and suicide are not common among LAGB patients, awareness of behavior change and emotional stability, including psychosocial situations and relationships, is critical. For example, body image dissatisfaction associated with sagging skin is a psychological concern that can adversely impact physical and

psychosocial functioning and the activities of daily living among LAGB patients [8,12]. Therefore, any potential or identified psychosocial concerns should be referred to mental health professionals who work with MBS patients.

Consensus experts (97%) agreed that LAGB patients with behavior-related symptoms or diagnoses should undergo postoperative therapy with counseling and appropriate medication in combination with support groups. Support group attendance has been shown to improve outcomes postoperatively [8,12]. Psychological and behavioral interventions can promote long-term success after MBS by slowing or preventing weight recurrence [8]. Furthermore, access to mental health providers with MBS expertise should be provided to all MBS personnel who manage LAGB patients.

Domain: Nutrition

Consistent with the evidence and with the majority of agreement in Delphi rounds 1 and 2, clinical nutrition assessments and evaluations should be conducted by a registered dietician for routine follow-up care and in situations where individuals are experiencing dietary complications associated with LAGB management [13–16]. As mentioned earlier, maladaptive eating behaviors, whether identified prior to LAGB placement or postoperatively, are common, often complex, and can be multifactorial. Grazing behaviors, binge eating, or LOC eating in response to emotional and situational triggers, perceived hunger, and lack of dietary restraint may be unrecognized by patients with LAGBs [17–19]. Eating disorders are defined by very specific diagnostic criteria, frequency, and severity. However, the onset or continuation of abnormal eating patterns may become a habit and progress to meet the diagnostic criteria for disordered eating behavior [19]. As new LAGB eating experiences evolve, self-monitoring of eating patterns and behaviors should be reported during nutrition counseling and corrected when maladaptive behaviors are identified. LAGB adjustment may be part of the treatment plan for maladaptive eating behaviors. In

Table 2
Delphi round 2 consensus statements and level of agreement

Adjustable gastric band round 2 consensus agreement (n = 31)	Agree	Neutral	Disagree	No Opinion
1. In general, fluid should be removed from the LAGB when a patient experiences new onset or persistence of chest pain. (Round 1 response: 73% agreement, 16% neutral, 8% disagree)	90%		6%	3%
2. In general, fluid should be removed from the LAGB when a patient experiences maladaptive eating behavior. (Round 1 response: 73% agreement, 22% neutral, 3% disagree)	84%	13%		3%
3. Preoperative psychopathology may predict postoperative psychopathology. (Round 1 response: 73% agreement, 16% neutral, 11% disagree)	81%	16%	3%	
4. Vomiting, regurgitation, reflux with saliva, dysphagia, and food intolerances are common LAGB surgery complications that may delay diet progression or lead to maladaptive eating behaviors. (Round 1 response: 57% agreement, 22% neutral, 22% disagree)	77%	16%	6%	
5. During pregnancy, LAGBs should be evaluated for possible deflation in the third trimester to prevent potential complications (risk of LAGB slippage, nutrition deficiencies, low birth weight). (Round 1 response: 68% agreement, 11% neutral, 8% disagree)	74%	13%	10%	3%
6. After LAGB surgery, adolescents may show early improvement in psychological health. (Round 1 response: 73% agreement, 16% neutral, 11% no opinion)	74%	16%		10%
7. LAGBs should be assessed regularly by upper gastrointestinal radiologic study to evaluate for complications (i.e., every 5 years). (Round 1 response: 65% agreement, 16% neutral, 14% disagree)	71%	13%	13%	3%
8. Providers should consult a registered dietician when patients with an LAGB experience adverse symptoms with eating behaviors, diet progression, food intolerances, nutrient deficiencies, excessive or insufficient weight loss, and weight regain. (Round 1 response: 54% agreement, 24% neutral, 22% disagree)	68%	19%	13%	
9. In general, postoperative nutrition follow-up visits should be conducted by a registered dietician. (Round 1 response: 59% agreement, 22% neutral, 19% disagree)	58%	26%	16%	
10. LAGB removal is the best treatment option for long-term complications such as band slip/gastric prolapse, GERD, and esophageal dilatation. (Round 1 response: 43% agreement, 22% neutral, 32% disagree)	58%	16%	23%	3%
11. Fluid should be added to the LAGB when a patient experiences a minimal weight loss or weight gain. (Round 1 response: 38% agreement, 41% neutral, 19% disagree)	35%	61%		3%
12. During pregnancy, LAGBs should be evaluated for possible inflation to prevent excessive weight gain during the first and second trimesters. (Round 1 response: 32% agreement, 16% neutral, 41% disagree)	26%	16%	48%	10%
13. Nonoperative management of LAGB is the best treatment option for long-term complications such as band slip/gastric prolapse, GERD, and esophageal dilatation. (Round 1 response: 24% agreement, 22% neutral, 51% disagree)	13%	13%	71%	3%

LAGB = laparoscopic adjustable gastric band; GERD = gastroesophageal reflux disease

Key: Green = 75%–100% consensus agreement; yellow = 50%–74% consensus agreement; blue = 0%–49% consensus agreement.

addition, behavioral health counseling with support group attendance is critical for successful therapy [13].

Diet quality and adequacy should be evaluated by a registered dietician when symptoms of vomiting, regurgitation, reflux, dysphagia, or food intolerances delay diet progression [13,14,20–23]. This includes micronutrient status, macronutrient composition, energy requirements, food choices, fiber content, and food textures and intolerances related to diet progression and weight change [14–16]. Advancement to solid foods 2 months after LAGB placement increases satiety and nutritional quality [14]. Some patients, however, may hesitate to advance their diet because of weight gain, pain, nausea, or vomiting [14]. A daily multivitamin and mineral supplement is recommended for patients with LAGBs to cover potential micronutrient insufficiencies [13]. Additional supplementation may be needed depending on biochemical analyses [13]. Patients with persistent vomiting should be evaluated for thiamine deficiency and electrolyte replacement in addition to LAGB adjustment

[13,14]. Most important, prescribing multivitamin and mineral supplements in a powder, liquid, or chewable formulation may prevent pill esophagitis. Proper LAGB device management, nutrition, and mental health counseling have been shown to decrease or eliminate adverse symptoms of regurgitation, reflux, dysphagia, and many food intolerances that impact diet progression and eating behaviors [13,14,20–23].

As part of ongoing LAGB management, excessive or insufficient weight loss and weight recurrence should include a comprehensive nutrition assessment by a registered dietician [13]. A detailed appraisal of the percentage of protein, fat, and carbohydrate intake compared with total energy requirements is the cornerstone of a successful treatment plan. Macronutrient recommendations are 15%–35% protein and 20%–25% fat, with the remainder of calories from complex carbohydrates [13,24]. Energy requirements should be adjusted based on goals, weight change, and weight maintenance over time. Prediction equations are available for estimating

energy requirements. Indirect calorimetry remains the “gold standard” to measure resting metabolic rate. This metric provides invaluable insight into a patient’s progress over time [25].

Domain: Identification and management of complications

Table 3 summarizes the most common complications (i.e., band slip/prolapse, GERD, esophageal dilatation associated with LAGB management, band erosion, device failure, and leak). No consensus was reported (51% round 1, 71% round 2) regarding nonoperative management of LAGBs as the best treatment option for long-term complications such as band slip/prolapse, GERD, and esophageal dilatation. Similarly, no consensus was reached (43% round 1, 58% round 2) regarding LAGB removal as the best option for band slip/prolapse, GERD, and esophageal dilatation. There are several reasons why the Delphi panel may have reported a mixed response in treatment options. For example, grouping the complications together into a single consensus statement may have biased the results as opposed to individually identifying each LAGB complication and treatment option. In addition, the treatment options for LAGB complications may include a spectrum from conservative treatment (i.e., medication for GERD, band loosening, nutrition counseling, and behavioral therapy) as opposed to band removal. Furthermore, the consensus statement questionnaire did not differentiate between initial and definitive LAGB treatment. Finally, we also acknowledge that the questionnaire responses may be subject to selection bias because only ASMBS members were eligible and invited to participate in this study.

Domain: Medical management

Consensus among 97% of the Delphi panel indicated that pharmacology is important to review and manage in patients with LAGBs. Consistent with the evidence, MBS providers should evaluate patient medications that may lead to weight gain, such as mood-stabilizing medications, antidepressants, antipsychotic medications, seizure medications, steroids, antihistamines, beta-blockers, and diabetic medications [47]. The benefit of these medications should be weighed against the likelihood of weight gain. When there are alternative medications that are equally efficacious in treating the medical or psychiatric problem and are also weight neutral or enhance weight loss, these should be considered. Some examples of these alternative medications include bupropion for depression and diabetic medications such as glucagon-like peptide-1 agonists [48]. MBS providers should consult with the patient’s other healthcare providers to discuss the risks versus benefits of using alternative medications that are less likely to cause weight gain. A complete medication review should be part of every patient encounter.

Long-term follow-up data indicate that some degree of weight recurrence in the years following MBS is common [49]. Although this is expected, early intervention is important to minimize the amount of weight recurrence and optimize weight loss. Adjunct pharmacotherapy is one consideration for treating weight recurrence after LAGB surgery, which is consistent with the 95% consensus among those participating in our Delphi study [49]. Data suggest that patients are more likely to be prescribed antiobesity medications after weight recurrence than at their plateau [50]. However, patients receiving antiobesity medications at their plateau show more weight loss than patients prescribed medication after weight recurrence [50]. Furthermore, patients with LAGBs should be evaluated for psychosocial, environmental, and eating behavior changes that may contribute to weight recurrence. Optimizing medical management of patients is critical to LAGB management and preventing weight-related complications.

Domain: Special populations

Pediatric patients. We observed that 74% of LAGB experts in Delphi rounds 1 and 2 agreed that pediatric patients show early improvement in psychological health after LAGB surgery. Despite a lack of FDA approval for LAGB surgery in the pediatric population, evidence in several investigational studies under institutional review board protocols and internationally have shown safety and efficacy after LAGB surgery in young patients [51–56]. Potential advantages of LAGB treatment for pediatric patients with obesity involve band adjustability, low anatomic complication rates, preservation of the gastrointestinal track, improved overall health status, and the option of band removal, if indicated [53,55,56]. Long-term evidence has consistently shown improvement in such patients’ quality of life, psychological health, nonalcoholic fatty liver disease, and resolution of metabolic syndrome by successfully lowering body mass index [51,54–56].

On the contrary, LAGB treatment for young patients is not universally supported by some in the medical community [57–59]. Insufficient weight loss compared with other MBS procedures (i.e., sleeve gastrectomy and Roux-en-Y gastric bypass), patient dissatisfaction with LAGB weight loss outcomes, and other complications resulting in reoperation are cited in the evidence [57–59]. Thus, severity of obesity and co-morbid complications must be factored into decisions regarding patient selection and timing of LAGB intervention for young patients [56]. Additionally, pediatricians, surgeons, behavioral health clinicians, and registered dietitians must work together with patients and families for ongoing support, education, and LAGB management. Dissatisfaction with LAGB outcomes may result from not fully understanding the functionality of the LAGB or adherence with routine follow-up care for

Table 3
Potential complications and weight recurrence associated with LAGB placement and management

Complication	Prevalence, symptoms, diagnostics, and treatment
Band slip/gastric prolapse [26–31]	<p>Prevalence: The rate of gastric prolapse varies, with a reported occurrence between 1% and 14% of patients at an average of 10 months after surgery. It remains one of the main indications for reoperation after gastric banding. Symptoms: Symptoms of gastric prolapse commonly include nocturnal reflux, regurgitation or cough, inability to tolerate oral intake, increased ability to tolerate food with vomiting 2–3 hours later, and heartburn. Occasionally, patients can be asymptomatic. Acute onset of epigastric pain is a rare symptom of gastric prolapse and may represent a more severe complication such as strangulation leading to gastric ischemia, perforation, or volvulus, which are surgical emergencies requiring immediate operation. Diagnostics: Gastric prolapse can be subdivided into 3 varieties: anterior, posterior, and concentric. These subtypes are determined by the portion of the stomach that has prolapsed cephalad up through the band and whether the enlarged resulting pouch is asymmetric (AP) or symmetric (concentric) [32,33]. This also has been referred to as <i>symmetric pouch dilatation</i>. The size of the gastric pouch typically should be equal to or less than, in height and diameter, the length of the band seen on a radiograph. Band slippage/gastric prolapse is diagnosed by an esophagram. This barium study can readily demonstrate slippage, with the presence of a dilated gastric pouch or displacement of the band to the lower gastric fundus, body, or even antrum. Often a flat-plate x-ray of the upper abdomen is useful in screening for slippage. In an AP projection of an abdominal x-ray, the band normally lies about 3–5 cm below the diaphragm, and the phi angle of the band is 45 degrees (phi angle corresponds to the angle between the spinal column and the gastric band—normal range, between 4 and 58 degrees). A slipped band tends to be more horizontal in orientation, with a phi angle >58 degrees. Additionally, a common radiologic presentation known as the <i>O-shaped sign</i> can be seen when the slipped band tilts along its horizontal axis and resembles the letter O [32]. If a patient has an obstruction from a slipped band, an air–fluid level may be present in the dilated pouch as well. Treatment: Initial treatment requires complete deflation of the gastric band. If symptoms resolve, a repeat esophagram should be performed. Sometimes a small band slip will correct itself after the band is emptied. In this case, the band can be retightened gradually, but both the patient and clinician should be aware that if symptoms recur, it is highly likely that the gastric prolapse or symmetric pouch dilatation has recurred, and surgery should be scheduled electively after the band is emptied again. If liquids are not tolerated despite fluid removal from the band, prolapse or symmetric pouch dilatation has recurred, and surgery should be scheduled electively after the band is emptied again. If liquids are not tolerated despite fluid removal from the band, the patient should be rehydrated with intravenous crystalloid and taken for surgery. Persistent epigastric pain in the presence of gastric prolapse despite band loosening is suspect for gastric strangulation and ischemia and is a surgical emergency; this requires immediate surgical intervention. Surgical intervention involves either band revision, band replacement, or band removal. Band unlocking is another alternative, particularly in a pregnant patient, in whom time under anesthesia and fetal health are most important; the patient then can return for a definitive operation when she is postpartum. Although rarely a surgical emergency, band revision should be performed in a timely manner to avoid development of complications such as aspiration pneumonia or gastric strangulation. Concomitant conversion surgery to sleeve gastrectomy or gastric bypass should not be performed at the time of acute band slip because of the presence of inflamed, thickened, or distorted gastric wall that may contribute to compromised staple-line creation.</p>
Gastroesophageal reflux disease [23,34–37]	<p>Prevalence: Gastroesophageal reflux disease, a common disorder in the population with obesity, often can be improved after gastric banding, particularly if a preexisting hiatal hernia is identified and repaired. However, the incidence of GERD can be as high as 70% in LAGB patients. Symptoms: Symptoms can vary from mild heartburn to very severe nocturnal reflux, which may be accompanied by aspiration pneumonia or even new-onset asthma. Diagnostics: Postoperative reflux after LAGB placement has multiple causes, and an esophagram may aid in diagnosis. If the esophagram shows gastric pouch dilatation, the band is likely too tight and should be treated with loosening. Gastric prolapse may be the culprit, and it can be corrected surgically. Esophagram also can reveal a concentric pouch extending into the mediastinum consistent with a hiatal hernia. An upper endoscopy or a computed tomography scan can be more specific at identifying a hiatal hernia. Esophagogastroduodenoscopy is most useful in diagnosing the presence of esophagitis. Treatment: Symptoms should be managed with antacids and proton-pump inhibitors; however, definitive treatment should be dictated by the physiologic cause of reflux. GERD caused by a hiatal hernia may be addressed by repair of the hiatal hernia with repositioning of the gastric band if necessary. GERD can be a symptom of esophageal dysmotility, the most common causes being regurgitant esophagitis and pill esophagitis. Behavioral counseling consists of 2 primary types: (1) eating slowly with thorough chewing of a food bolus to avoid regurgitation and (2) avoiding swallowing large pills. As such, it is helpful to assist the patient in finding medications in crushable, chewable, or liquid formulation. In both cases, esophagitis is best treated with temporary band loosening plus either sucralfate elixir or proton-pump inhibitor for 2–4 weeks. The band can be retightened subsequently.</p>
Esophageal dilatation [38,39]	<p>Prevalence: Prevalence of esophageal dilatation reported in the literature varies widely from .5% to 77.8%. Symptoms: Although esophageal dilatation has been implicated in exacerbating GERD symptoms, the presentation of esophageal dilatation and its associated symptoms is quite broad. Some patients remain asymptomatic, some have decreased satiety, and others may develop reflux. Diagnostics: Esophageal dilatation can be diagnosed initially by esophagram, as shown by an esophageal diameter wider than the width of the vertebrae. Definitive diagnosis is made by esophageal manometry showing decreased or lack of esophageal motility. Treatment: Esophageal dilatation is at least partly reversible by removing fluid from the lap band. It is advisable to wait at least 8 weeks to begin band reinflation. If esophageal dilatation and dysmotility fail to resolve, the band should be removed and possibly converted to a Roux-en-Y gastric bypass for weight control. Conversion to sleeve gastrectomy is not recommended because of the increased intraluminal pressure, which would exacerbate esophageal dysmotility and reflux.</p>

(continued on next page)

Table 3 (continued)

Complication	Prevalence, symptoms, diagnostics, and treatment
Band erosion [40]	<p>Prevalence: Band erosion is characterized by intragastric band migration, either partial or complete, due to the band eroding through the gastric wall over time. It is a rare complication occurring in <1% of cases. Symptoms: Erosions may present with nonspecific upper abdominal discomfort, weight gain, increased hunger, or loss of satiety despite band adjustment. In some cases, the first indication is a late infection at the port site presenting as cellulitis.</p> <p>Diagnostics: If band erosion is suspected, upper endoscopy confirms the diagnosis. Band erosion also can be identified on a computed tomography scan or upper gastrointestinal study by passage of barium around the intraluminal portion of the band or around all sides of the band if it has eroded completely into the gastric lumen. Treatment: Although rarely an emergency, an eroded band must be removed to avoid potential complications such as intraluminal bleeding, port infection with cellulitis, and obstruction. The band can be removed laparoscopically with subsequent repair of the stomach wall. An intraoperative leak test is recommended along with placement of a drain. Replacing a new band or performing another bariatric procedure such as a Roux-en-Y gastric bypass or sleeve gastrectomy at the time of gastric repair is not recommended because of the inflammation of tissue that may compromise wound healing. Although endoscopic removal of the band has been described, it has many limitations that may make this strategy challenging.</p>
Device leak [41,42]	<p>Prevalence: The rate of port and tubing leak has a reported frequency of .6%–1%. Symptoms: Leakage should be suspected when filling volumes do not correspond with deflating volumes, the fluid appearance is altered, or the patient experiences loss of restriction. Diagnostics: Leakage can occur from a variety of locations: (1) break in the tubing, (2) needle perforation of the nonmembrane portion of the port due to attempted adjustments, and (3) cored section of silicone membrane due to prior use of a hyperdermic needle rather than noncoring Huber needle. Radiographic studies such as an abdominal x-ray can be helpful in showing tubing disconnection, but injecting contrast material into the device and performing an x-ray do not typically provide optimal visualization of the defect. Treatment: A port leak can be rectified by simple port replacement and reconnection to the existing band. Leakage caused by tubing disconnection or break can be corrected by laparoscopic retrieval of the tubing, mobilization of the access port, and reconnection of the tubing with a new access port. Leakage also can occur from the band itself. This is usually due to an inadvertent needle puncture of the band in the operating room. Occasionally, a defect in the band material itself can give way to a crease defect in the balloon or a fractured seal between the balloon and band shell, resulting in leak. Leakage can occur from anywhere in the tubing, particularly if there is any angulation due to adhesions. Intraoperative methylene blue injection into the access port can be helpful in revealing the location of the leak. Device leakage from either the band or the tubing warrants replacement of the gastric band component only, with reconnection to the existing access port. Regardless of which component is replaced, the corrected system should be checked to ensure that the source of the leak has been addressed by injecting and retrieving the same amount of saline. It is important to note that since the band was first introduced, it has gone through multiple iterations. Many devices and components that have been discontinued may still be in situ in patients, potentially presenting a challenge for replacement and management.</p>
Weight recurrence [42–46]	<p>Prevalence: Mean excess weight loss at 10–20 years postoperatively has been reported to be approximately 47%. Weight loss is typically gradual and constant over the course of 18–30 months, with a target loss of 1–2 lb/week. The distribution of weight loss is heterogeneous and has been shown by the Longitudinal Assessment of Bariatric Surgery group to be the following at 7 years postoperatively: 62% of patients have 15% TWL, with 19% having 35%+ TWL and 19% having <5% TWL. Symptoms: Insufficient weight loss or weight recurrence after LAGB surgery occurs for a variety of reasons, and management must be based on the cause of failure. Sometimes it can be a symptom of a band complication. Primary malfunction of the band can cause failure to lose weight or weight recurrence; these complications include device leakage (port, tubing, or band) and band erosion. Band slippage, gastric pouch, or esophageal dilatation, which may present with food intolerance, may lead to maladaptive eating of soft high-calorie foods and subsequent weight gain. Diagnostics: Insufficient weight change or weight gain. Treatment: One of the most common reasons for poor weight loss is suboptimal band tightness. Weight loss after LAGB is contingent on band adjustments, which necessitate frequent postoperative visits. Band adjustments should begin 4–6 weeks after surgery when the patient is tolerating regular food and can be reassessed every 4–6 weeks until the rate of weight loss is at goal levels. Titration of the band's compression around the stomach will result in appetite suppression and satiety. A band that is too loose will not be effective in portion control, and conversely, a band that is too tight will result in solid food intolerance with subsequent maladaptive eating of soft high-calorie foods such as ice cream, chocolate, and sugary beverages. It is important to note that in addition to patient compliance, the surgical practice also must have resources to accommodate the frequent patient follow-up necessary for successful weight loss after gastric banding. Incorporating an interdisciplinary program with LAGB patients can result in greater weight loss and fewer complications.</p>

LAGB = laparoscopic adjustable gastric band; AP = anterior/posterior; GERD = gastroesophageal reflux disease; TWL = total weight loss.

LAGB management. Therefore, pediatric patients must be involved with their own healthcare and LAGB management to optimize band effectiveness and to prevent LAGB complications [51–53].

Pregnancy. Approximately 50% of female individuals with LAGBs are of reproductive age [60]. During pregnancy, LAGB management is critical because of the

anatomic and physiologic changes that occur during each trimester. We report no consensus on LAGB management during pregnancy within either Delphi round 1 or 2 among the Delphi panel (Table 1). This supports the literature that shows mixed opinions on LAGB adjustments during pregnancy [60–63]. Over the years, some providers have reported removing all LAGB fluid at the beginning of

pregnancy, whereas others removed all LAGB fluid at delivery [60,61]. In the case of severe nausea, vomiting, gastroesophageal reflux, or other symptomatic concerns, fluid removal or loosening of the LAGB is supported in more recent practice [62–64]. A tailored approach to LAGB adjustments is the most common method of LAGB management during pregnancy. This allows patients and providers to monitor weight gain, nutritional adequacy, and fetal growth for a healthy pregnancy outcome [60–65]. Regarding device-related complications, band slippage is one risk that should be discussed with patients prior to conception, during pregnancy, and postpartum [63]. In sum, this evidence supports LAGB placement as safe and well tolerated during pregnancy with close LAGB monitoring [62,63].

Domain: Follow-up assessment of LAGB patients

A Delphi panel consensus of 80% acknowledges that experienced providers (i.e., surgeons, primary care physicians, registered dietitians, behavioral health specialists, nurse practitioners, nurses, and physician assistants) should be part of the multidisciplinary team in LAGB management [13]. Providers should have training and experience with the specific LAGB fluid volumes, adjustment schedules or algorithms, and potential complications [3,66]. Management of LAGBs also requires provider competency in understanding physiologic mechanisms (i.e., vagus nerve, hormones, and gut motility) affected by LAGB placement and fluid volume adjustments [3,66].

Assessment of LAGBs should occur at least yearly, and more often as needed (e.g., active adjustment for weight loss or complications) [13,67]. ASMBS credentialing guidelines for physician extenders outline the responsibilities for LAGB management [3]. Briefly, providers who manage patients with LAGBs should conduct a detailed assessment prior to any LAGB adjustment, including knowledge of the band size and type, date of and response to last adjustment, and review of current band fluid volume [3]. Evaluation of dietary patterns, behaviors, and nutrient composition is paramount to discern symptoms of hunger, dysphagia, dehydration, reflux, or vomiting prior to LAGB adjustments [3]. For patients who had LAGBs placed, it is important to consider a regular diagnostic assessment of the LAGB for complications, which may or may not be associated with symptoms. At 71% Delphi panel agreement, it seems reasonable for clinicians to consider some regularly scheduled diagnostic evaluation (i.e., upper gastrointestinal radiologic study) of patients with long-term LAGB management [68].

Skilled providers recognize when fluid in the LAGB should be titrated (i.e., increased or decreased) or remain constant based on the patient's assessment of weight, symptoms associated with the LAGB placement, the

patient's ability to adopt positive eating behaviors, and emotional stability. There was Delphi consensus and literature agreement that it is reasonable to consider fluid addition when a patient tolerates large portions of solid foods, feels a lack of satiety, or senses that hunger and appetite are not well controlled [69]. There was only 40% (round 1) and 35% (round 2) agreement that LAGB adjustment should be considered when a patient experiences minimal weight loss or weight gain. However, there is literature support to consider the addition of fluid with minimal weight loss or weight gain given that weight loss is an important and desired outcome, in addition to the consideration or context of other factors [66,69].

Furthermore, the Delphi results indicated consensus that fluid removal and a referral to an MBS surgeon should take place when a patient experiences significant dysphagia, vomiting, regurgitation, reflux, or symptoms of heartburn. Fluid removal also should be considered with new onset or persistence of chest pain, in addition to potential work-up for evaluating the onset of chest pain symptoms in reference to Delphi panel comments. Maladaptive eating behaviors, feelings of uneasiness with eating, and an inability to tolerate solid-food textures are also considerations for LAGB fluid removal, in addition to referrals for nutrition and mental health counseling [69]. The key points of each domain are summarized in [Table 4](#).

Limitations

Although a modified Delphi technique is a popular method of defining consensus when there is insufficient or conflicting scientific evidence, there are several considerations involving participant selection, validity, and reliability. Potential bias exists in the selection of expert participants. We reported underrepresentation of behavioral health specialists, registered dietitians, nurses, nurse practitioners, and physician assistants compared with the number of physicians who responded to the Delphi invitation and completed both Delphi questionnaires. As a result, the conclusions may underreport opinions and experiences of members of the multidisciplinary surgical team. Another limitation is the possible lack of reliability or reproducibility by a different group of MBS clinicians. Furthermore, we acknowledge that some of the consensus statements may have been drafted with stronger or persuasive language. In addition, a combination of symptoms or complications may have been confusing or unintentionally influenced a participant's response to a statement. Retrospectively, each of the potential LAGB complications should have been listed in separate statements rather than as subparts of an overall question to allow for clarity in the interpretation of both the questions and responses.

Table 4
Key points summarized within each domain

Domain	Key points summarized within each domain
Behavioral health	Preoperative psychopathology identified by mental health professionals may predict postoperative psychopathology. Mental health professionals should address pre- and postoperative psychosocial issues (e.g., disordered eating, substance abuse, suicide, depression, lack of social support, and body image/excess skin). Proper LAGB device management, nutrition, and mental health counseling may decrease or eliminate maladaptive eating behaviors. Patients with behavior-related symptoms or diagnoses should undergo postoperative therapy with counseling and appropriate medication, in combination with support groups. Support group attendance should be encouraged for postoperative behavioral and emotional changes.
Nutrition	Clinical nutrition assessments and evaluations should be conducted by an RD for routine follow-up care and in situations where individuals are experiencing dietary complications, excessive or insufficient weight loss, and weight recurrence. RDs should evaluate diet quality and adequacy when symptoms of vomiting, regurgitation, reflux, dysphagia, or food intolerances delay diet progression. RDs should monitor micronutrient status, macronutrient composition, energy requirements, food choices, fiber content, food textures and intolerances related to diet progression and weight change. Prescribing multivitamin and mineral supplements in powder, liquid, or chewable formulations may prevent pill esophagitis. Patients with persistent vomiting should be evaluated for thiamine deficiency and electrolyte replacement.
Identification and management of complications and weight recurrence	The most common complications of LAGBs are band slip/prolapse, GERD, esophageal dilatation, band erosion, device, and leak (see Table 3). Treatment options for LAGB complications may include conservative treatment (i.e., medication for GERD, band loosening, nutrition counseling, and behavioral therapy) or band removal. Weight recurrence or insufficient weight loss after LAGB can be caused by dietary, behavioral, medication, and device-related mechanical problems. Device-related complications of LAGB (i.e., device leak, band erosion, disconnected tubing, and port infections) require replacement of LAGB components or band removal. LAGBs can be removed and converted to either sleeve gastrectomy or Roux-en-Y gastric bypass in 1 or 2 stages.
Medical management	Metabolic and bariatric surgery providers should evaluate patient medications that may lead to weight gain (i.e., mood-stabilizing medications, antidepressants, antipsychotic medications, seizure medications, steroids, antihistamines, beta-blockers, and diabetic medications). Alternative medications that are weight neutral or enhance weight loss and are equally efficacious in treating the medical and psychiatric problem should be considered (i.e., bupropion for depression and glucagon-like peptide -1 agonists for diabetes). A complete medication review should be part of every patient encounter. Adjunct pharmacotherapy may be considered for treating weight recurrence after LAGB surgery. Prescribing antiobesity medications when a patient's weight plateaus as opposed to after weight recurrence has been shown to prevent further weight gain.
Special populations	Pediatric population: LAGB surgery is not approved for use in the pediatric population by the Food and Drug Administration despite evidence in several investigational studies showing safety and efficacy after LAGB surgery in young patients. Potential advantages of LAGB treatment for pediatric patients with obesity involve band adjustability, low anatomic complication rates, preservation of the gastrointestinal track, improved overall health status, and the option of band removal, if indicated. Pregnancy: A tailored approach to LAGB management during pregnancy allows patients and providers to monitor weight gain, nutritional adequacy, and fetal growth for a healthy pregnancy outcome. Evidence supports LAGB placement as safe and well tolerated during pregnancy with close LAGB monitoring. One risk that should be discussed with patients prior to conception, during pregnancy, and postpartum is band slippage.
Follow-up assessment of LAGB patients	Experienced providers (i.e., surgeons, primary care, RDs, mental health professionals, nurse practitioners, nurses, and physician assistants) should be part of the multidisciplinary team in LAGB management. Providers should have training and experience with the specific LAGB fluid volumes, adjustment schedules or algorithms, and potential complications. Management of LAGBs requires provider competency in understanding physiologic mechanisms (i.e., vagus nerve, hormones, and gut motility) affected by LAGB placement and fluid volume adjustments. Fluid removal and a referral to a metabolic and bariatric surgery provider should take place when a patient experiences significant dysphagia, vomiting, regurgitation, reflux, or symptoms of heartburn. Fluid removal and referrals for nutrition and behavioral health counseling should be considered when patients experience maladaptive eating behaviors, feelings of uneasiness with eating, or an inability to tolerate solid-food textures. Additional fluid may be considered when a patient tolerates large portions of solid foods, feels a lack of satiety, or senses that hunger and appetite are not well controlled. Providers may consider regularly scheduled diagnostic evaluation (i.e., upper gastrointestinal radiologic study) of patients with long-term LAGB management.

LAGB = laparoscopic adjustable gastric band; RD = registered dietitian; GERD = gastroesophageal reflux disease.

Conclusion

The ASMBS is not a credentialing body. This Delphi process review is intended to replace the existing ASMBS credentialing guideline with current opinion on LAGB patient management, which has evolved over time based on practitioner experience. This document is primarily a review of expert opinion and is grounded on the limited existing scientific evidence. This consensus statement is intended to guide LAGB management and practice with current evidence-based knowledge and professional experience. Future research would be helpful in preventing potential mechanical, anatomic, maladaptive eating, and behavioral health symptoms and complications.

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