Review

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Formulation and interpretation of the Chinese Guidelines for Surgical Treatment of Obesity and Type 2 Diabetes Mellitus

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SUMMARY Obesity and related metabolic diseases have become one of the world's most serious public health problems. Bariatric surgery has gone through a long and difficult development process, from being rejected to gradually recognized, then widely accepted, and finally becoming the "gold standard" for the treatment of morbid obesity with metabolic diseases. Procedures have constantly been improving and evolving as the concept of bariatric surgery has been reappraised. The comparison and selection of different procedures, the emergence of new technologies and treatment methods, and the in-depth study of the mechanism of metabolic weight loss surgery are effectively promoting the rapid development of bariatric surgery. This article looks at both the 2014 and 2019 editions of the Guidelines for Diagnosis and Treatment of Obesity and Type 2 Diabetes Mellitus from the Chinese Society of Metabolic and Bariatric Surgery (CSMBS), its review the development of bariatric surgery, and it describes surgical indications and contraindications, the mechanism of weight loss, and tailored selection of the surgical procedure in order to serve as a reference.

Keywords Chinese Society of Metabolic and Bariatric Surgery (CSMBS), obesity, bariatric surgery, Chinese guidelines

1. Introduction

The Chinese Society for Metabolic & Bariatric Surgery (CSMBS) organized domestic metabolic and bariatric experts in 2014 and formulated its first guidelines – the Chinese Guidelines for Surgical Treatment of Obesity and Type 2 Diabetes Mellitus (2014 edition). Specified and standardized by the Guidelines, bariatric surgery in China has made great progress, particularly after the Chinese Medical Association created its Division of Thyroid and Metabolic Surgery in 2017 (*1*). Clinical study centers have been established successively in various regions of the country, and multi-center cooperation has been promoted to constantly accumulate multi-center hard clinical data. The number of bariatric surgeries performed has increased from 4000 cases in 2014 to more than 12,000 cases, but there were no obvious differences in the procedures compared to Europe and the US (*2*). In 2017, the American and European guidelines for metabolic and bariatric surgery were correspondingly updated; procedures such as adjustable gastric banding (AGB) are now gone from the pages of history. In 2019, the CSMBS formulated its second guidelines, the Chinese Guidelines for Surgical Treatment of Obesity and Type 2 Diabetes Mellitus (2019 edition) (Figure 1), to better reflect developments in bariatric surgery.

2. Surgical Indications and Contraindications

Surgical indications for patients with simple obesity: if BMI ≥ 37.5, bariatric surgery is highly recommended; if 32.5 ≤ BMI < 37.5, bariatric surgery is recommended; if 27.5 ≥ BMI < 32.5, obesity cannot be readily controlled with lifestyle changes and medical treatment, and the candidate has at least 2 components of metabolic syndrome or complications of obesity, surgery may be considered pursuant to a comprehensive assessment. For males with a waist circumference ≥ 90 cm, and females with a waist circumference ≥ 85 cm, if an imaging study suggests central obesity, the level of recommendation may be increased. The recommended age is 16-65 years.

Surgical indications for patients with type 2 diabetes mellitus: (1) If a patient with type 2 diabetes mellitus still secretes insulin to an extent. (2) If BMI ≥ 32.5, bariatric surgery is strongly recommended; if 27.5 ≤ BMI < 32.5, bariatric surgery is recommended; if 25 ≤ BMI < 27.5, obesity cannot be readily controlled with lifestyle changes and medical treatment, and the candidate has at least 2 components of metabolic syndrome or

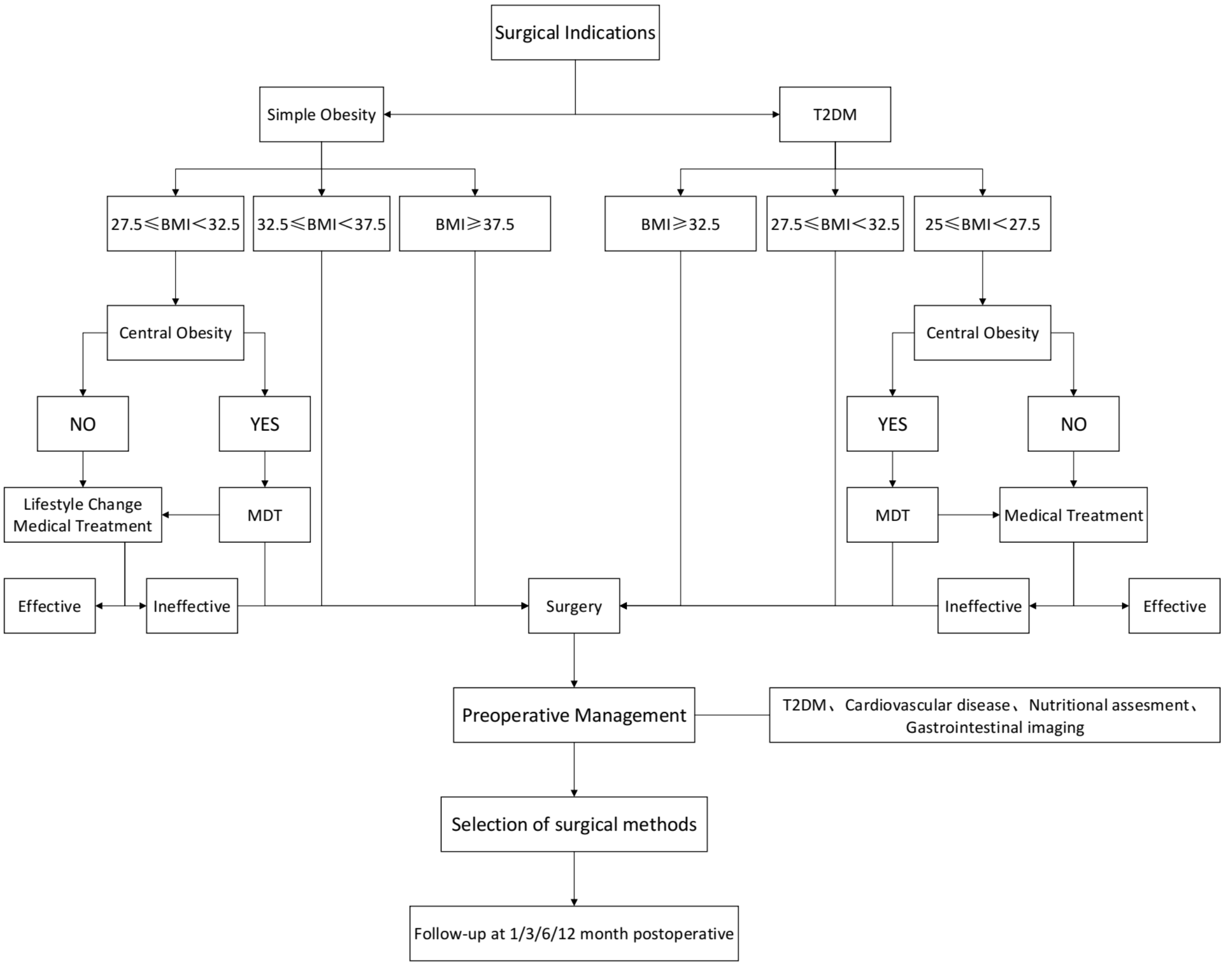

Figure1. The Chinese algorithm for treatment of obesity and metabolic disease.

complications of obesity, surgery may be considered pursuant to a comprehensive assessment. (3) For patients with 25 ≤ BMI < 27.5 (males with a waist circumference ≥ 90 cm, and females with a waist circumference ≥ 85 cm), if an imaging study suggests central obesity, the level of recommendation may be increased. (4) The suggested age for surgery is 16-65 years. For patients < 16 years of age, a multidisciplinary discussion involving a nutritionist and pediatrician should be conducted to comprehensive assess the feasibility and risks, surgery should be performed with informed consent, and surgery should not be heavily promoted. For patients > 65 years of age, their health status, concomitant diseases, and treatment profile should be seriously considered, a multidisciplinary discussion should be conducted to evaluate the patient's cardiopulmonary function and tolerance to surgery, and then surgery should be performed with informed consent.

Compared to the 2014 Guidelines, the 2019 Guidelines are more proactive in recommending surgery for patients with diabetes mellitus and a BMI ranging from 27.5-32.5. Two comorbidities of obesity were required in the 2014 edition of the guidelines but not in the 2019 edition. According to the 2014 Guidelines, bariatric surgery has demonstrated effectiveness in treating type 2 diabetes mellitus associated with obesity and is therefore also called metabolic surgery. Surgery is superior to diet therapy or drug therapy in treating type 2 diabetes mellitus and may be effective long-term. In 1991, the National Institutes of Health Consensus Development Panel recommended that nonsurgical treatment such as dietary and lifestyle changes and exercise should first be considered for patients with severe obesity and that surgery be considered for those with type 2 diabetes mellitus and a BMI ≥ 35 (class II). Although surgery is effective in treating patients with type 2 diabetes mellitus and a BMI ≥ 35, a large proportion of patients with type 2 diabetes mellitus have a BMI < 35 (class I), they are excluded as surgical candidates, and remission is difficult to achieve with medication or lifestyle changes alone. Surgery is an option for patients with type 2 diabetes mellitus and a BMI < 35, and studies have indicated that the remission of type 2 diabetes mellitus achieved by metabolic surgery is independent of weight loss and that the type 2 diabetes mellitus response rate after metabolic surgery was not statistically associated with the preoperative BMI. Surgery also resulted in remission of diabetes in patients who are slightly obese (low BMI, class I). Since, European and American guidelines on metabolic surgery have changed the indications from severe obesity (BMI ≥ 40) or they recommend that this approach be considered for patients with diabetes mellitus and a BMI ≥ 30 (or ≥ 25.7 for Asians) (*3*). In 2014, the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) issued a statement that surgery should be considered for patients with class I obesity and serious complications after the failure of proper nonsurgical treatment and that it should be based not only on the BMI but also on comorbidities. In 2017, the second Diabetes Surgery Summit issued a statement: Metabolic surgery to treat type 2 diabetes mellitus is recommended for patients with class III obesity (body mass index, BMI ≥ 40) regardless of glycemic control and for patients with class II obesity (BMI 35.0-39.9) with inadequately controlled hyperglycemia despite lifestyle changes and optimal medical therapy. Metabolic surgery should also be considered to treat type 2 diabetes mellitus in patients with class I obesity (BMI 30.0-34.9) and inadequately controlled hyperglycemia despite optimal medical treatment with oral or injectable medications (including insulin) (*4*). In 2018, the American Society for Metabolic & Bariatric Surgery (ASMBS) highly recommended surgery for patients with diabetes mellitus and class I obesity (BMI 30-35 kg/m^2), and the currently recommended age ranges from 18 to 65 years (*5*). In 2018, the Korean Society for the Study of Obesity (KSSO) Guidelines stated that metabolic surgery is indicated for obese patients with a BMI ≥ 35 (Class II) and for patients with diabetes mellitus and a BMI ≥ 30 (Class I) who have comorbidities (*6*). In light of the particular characteristics of Asians, the 2019 Chinese Guidelines recommend surgery for patients with type 2 diabetes mellitus and a BMI ≥ 27.5.

The 2019 Guidelines indicate that obese patients with diabetes who are < 16 or > 65 years of age may undergo surgery if they provide informed consent. At present, the main concerns regarding metabolic surgery in adolescents are surgical complications, uncertainty about long-term outcomes, and probable and possible ethical considerations. However, some of the existing literature has reported that metabolic surgery in adolescents was not associated with a significantly higher complication rate than that in adults and that it achieved a satisfactory outcome in terms of weight loss. Although adolescent patients who are obese are less likely to have diabetes, those with diabetes would face earlier failure of drug treatment and require insulin earlier. In 2018, the Pediatric Metabolic and Bariatric Surgery Guidelines of the ASMBS stated that bariatric surgery can be considered for adolescents with a BMI > 40 or a BMI > 35 and complications (*7*). A point worth noting is that bariatric surgery is not currently considered to be frontline treatment for adolescent obesity and surgery should be considered only after nonsurgical approaches fail to achieve weight control. For obese patients > 65 years of age, the overall complication rate after bariatric surgery does not significantly from that in adults, and laparoscopic sleeve gastrectomy (LSG) is relatively much safer than Roux-en-Y gastric bypass (RYGB). According to the Chinese guidelines, randomized controlled trials with a larger sample size and a longer follow-up period need to demonstrate the safety and efficacy of bariatric surgery in obese patients < 16 or > 65 years of age. Bariatric surgery should be performed on adolescent or elderly patients who are obese with their informed consent.

3. Mechanism of Weight Loss

Although bariatric surgery is effective at alleviating type 2 diabetes mellitus, the mechanism by which it does so is not completely clear at the moment. Initially, Kalam *et al.* speculated that energy intake control may play an important role in regulating blood glucose, and in addition, changes in bile acid metabolism, GI tract nutrient sensing and glucose utilization, incretins or anti-incretin(s), and intestinal microbiome may all participate in blood glucose regulation after bariatric surgery (*8*). The more likely conjecture is that multiple mechanisms work simultaneously to generate liver glycogen and to promote the uptake of blood glucose in tissues, lead to greater insulin sensitivity, improved β-cell function, and according regulation of blood glucose.

Previous studies contended that the mechanism by which bariatric/metabolic surgery treats type 2 diabetes mellitus is through a combination of the "foregut hypothesis" and "hindgut hypothesis" (*9*). The "foregut hypothesis" posits that the duodenum and proximal jejunum secrete special hormones by excluding the duodenum-jejunum bypass, whilst the "hindgut hypothesis" posits that surgery affects the secretion of glucagon-like peptide-1 (GLP-1) by distal ileal L cells, thus improving blood glucose metabolism. As further studies have been conducted, however, both the "foregut hypothesis" and "hindgut hypothesis" have failed to explain all of the clinical phenomena. Therefore, this mechanism is still a topic of interest for clinical and basic research on bariatric surgery (*10,11*). Any breakthrough may generate a new target for the treatment of obesity and metabolic disorders and facilitate the evidence-based development of metabolic surgery.

In addition, a recent study found that neurocircuits located within a brain-centered glucoregulatory system work cooperatively with pancreatic islets to promote glucose homeostasis, and the authors put forward the concept of the "gut-brain-liver axis" for blood glucose regulation (*12*). After eating, enteral nutrition will induce complex neural and hormonal changes. Neural signs submitted upwards from the gut to the brain, together with peptide hormones produced in the gut, act on the brain and regulate blood glucose through the negative feedback pathway, which is mainly achieved by affecting the generation of liver glycogen. This could be another potential mechanism by which metabolic surgery treats diabetes mellitus.

At present, the gut microbiota has also attracted attention due to its role in the control of obesity. Studies have indicated that the gut microbiota is closely associated with obesity and that in the obese population; gut microbes colonize in an unhealthy manner to uptake and store more energy as fat, and there is less species richness of the gut microbiota than that in the healthy population (*13*). The species richness of the gut microbiota increases in patients after metabolic surgery, and the change in the gut microbiota is considered to be closely associated with insulin resistance, which may be a potential mechanism by which metabolic surgery treats diabetes mellitus. A study has indicated that after RYGB surgery (*14*) the numbers of Prevotellaceae, Archea, Firmicutes, and Bacteroidetes decreased while there was an increase in the Bacteroidetes:Prevotella ratio and the number of γ-proteobacteria. This may occur due to changes in the composition of the diet or changes in bile acid metabolism. However, Murphy *et al*. found that differences in the postoperative diet contributed to the different changes in the gut microbiota (*15*). Interestingly, Depommier *et al*. found that the supplementation of beneficial bacteria such as Akkermansia muciniphila effectively reduced body weight, increased insulin sensitivity, and alleviated insulin resistance (*16*). Ascertaining the postoperative changes in the gut microbiota and developing gut microbiota supplements accordingly could provide insight into the nonsurgical treatment of metabolic syndromes.

4. Tailored Selection of the Procedure

Compared to the 2014 Chinese guidelines on bariatric surgery, the 2019 guidelines removed AGB. The long-term weight loss outcomes of AGB were unsatisfactory. Band slippage and esophageal dilatation, fistulae, and infections were common reasons for the removal of gastric banding. By 2020, AGB accounted for about 3% of all surgical procedures worldwide (*17*) and 0% in China, indicating its disappearance from the pages of history. In light of the satisfactory outcomes achieved by LSG in terms of weight loss and remission of diabetes mellitus, the frequency of LSG has increased in recent years. According to the Fourth IFSO Global Registry Report 2018 (*18*), LSG has surpassed RYGB (46% *vs.* 38.2%) on a global scale and it has become the most commonly adopted surgical procedure for metabolic syndrome, accounting for 67% of all such procedures in China. Therefore, the Chinese Guidelines have listed LSG as the procedure of choice. According to the Guidelines, currently recommended surgical procedures include LSG, LRYGB, BPD/DS, OAGB, and SG + JJB, SG + DJB.

LSG is mainly indicated for patients with moderate to severe simple obesity and those with minor symptoms of metabolic syndrome. Since LSG may aggravate GERD and GERD-induced Barrett esophagus, moderate to severe GERD is a relative contraindication. Now, there is an expert consensus on reinforcing sutures to reduce gastric stump bleeding.

Compared to LSG, LGB is more advantageous in terms of postoperative long-term weight control and remission of diabetes mellitus, so gastric bypass may be a better option for patients with severe metabolic symptoms. At present, LGB has been performed less frequently each year. Since LSG can achieve the same outcomes in terms of weight loss and metabolic remission with fewer complications, LGB may be gradually replaced by LSG. LGB could be used as salvage surgery in the event of LSG failure, and it will still account for a certain proportion of surgeries on a long-term basis. LGB is indicated for patients with moderate to severe GERD or those with severe metabolic syndrome. Because gastroscopy is difficult to perform after LGB surgery, this procedure should be considered for patients with gastric precancerous disease and a family history of gastric cancer.

BPD/BS has a higher complication and mortality rate, its proportion has continued to decrease, and it only accounted for 0.5% of metabolic surgeries in 2020 (*19*). BPD/DS is mainly used in patients in whom sleeve gastrectomy fails to achieve a satisfactory outcome in terms of weight loss and therefore should be selected with caution.

Dr. Robert Rutledge performed a duodenal exclusion with an anastomosis in 2001, which he termed the "mini gastric bypass." In 2018, the procedure was re-named the one anastomosis gastric bypass (OAGB) by the IFSO. A possible risk of OAGB is bile regurgitation, which may induce gastritis and esophagitis and possibly induce subsequent gastric cancer and esophageal cancer, but such speculations have not yet been corroborated by existing studies. OAGB achieves satisfactory outcomes in terms of long-term weight loss and diabetes remission, so it is being performed more frequently (*20*). In the Asian-Pacific region, OAGB is performed more often than gastric bypass. Its complications mainly include afferent loop obstruction, anastomotic bleeding, an anastomotic leak, anastomotic stenosis, and wound infection. Clinical studies still need to be conducted to evaluate the procedure and its long-term nutritional implications.

Other procedures include SG+JJB and SG+DJB. At present, more clinical studies need to be conducted and more results of long-term follow-up need to be compiled to confirm long-term weight loss by and complications due to different procedures.

Metabolic surgery is now accepted for the treatment of type 2 diabetes mellitus. However, there is still no unified standard for personalized treatment based

Table 1. DiaRem scoring system

Factor	Score
Age	
< 40	1
40-49	1
50-59	2
≥ 60	3
HbA1c (%)	
< 6.5	0
6.5-6.9	2
7.0-8.9	4
≥ 9.0	6
Other diabetic drugs	
No sulfonylureas or insu-lin-sensitizing agents other than metformin	0
Sulfonylureas and insu-lin-sensitizing agents other than metformin	3
Treatment with insulin	
No	0
Yes	10
Total Score	0-22

Table 2. ABCD scoring system

Factor	Score
Age	
< 40	0
≥ 40	1
BMI	
< 27	0
27-34.9	1
35-41.9	2
≥ 42	3
C-peptide (ng/mL)	
< 2	0
2-2.9	1
3-4.9	2
≥ 5	3
Duration of DM (years)	
> 8	0
4-8	1
1-3.9	2
< 1	3
Total Score	0-10

Table 3. DRS scoring system

Factor	Score
Age	
30-60	1
< 30 or > 60	2
BMI	
< 27	1
> 27	2
Duration of T2DM (years)	
< 10	1
> 10	2
Microvascular complications	
No	1
Yes	2
Macrovascular complications	
No	1
Yes	2
Pre-operative insulin use	
No	1
Yes	2
Stimulated C-peptide (ng/mL)	
≥ 4	1
< 4	2
Total score	7-14

on the patient's condition. Today, three preoperative scoring methods are available: the ABCD score (*21*), the DiaRem score (*22*), and the IMS score (*23*). In the current literature, no studies have clearly demonstrated which scoring method is more accurate, and there is no significant difference in the preoperative prediction of the rate of diabetes mellitus remission among the three scoring methods.

According to DiaRem scoring, early remission was achieved in 88% (95% CI 83-92%) of patients with a score of 0-2 points, 64% (58-71%) of those with a score of 3-7 points, 23% (13-33%) of those with a score of 8-12 points, 11% (6-16%) of those with a score of 13-17 points, and 2% (0-5%) of those with a score of 18-22 points (Table 1). The DiaRem score was used to predict the rate of diabetes rate at 1 year post-RYGB, but it was not accurate for long-term predictions such as 5 years post-operatively or for other procedures (*24*).

The predictors of the ABCD score are age, BMI, C-peptide level, and duration of diabetes mellitus, and the predicted rate of diabetes remission ranges from 33-100% (0-10 points), that is, the rate of remission increases by 6.7% per point (Table 2). ABCD is a model established based on the Asian population is probably more suitable for use in the Chinese population. Although the ABCD score does not recommend surgery based on specific scores, a statistical analysis suggested that LSG may be more suitable for patients with an ABCD score higher than 7 and that RYGB may be more suitable for those with an ABCD score lower than 7 (*25*).

The IMS score consists of four predictors: preoperative duration of type 2 diabetes mellitus, preoperative number of diabetes medications, insulin use, and glycemic control (HbA1C < 7%). In mild type 2 diabetes mellitus (IMS score ≤ 25), both procedures significantly alleviated type 2 diabetes mellitus (Table 3). In severe type 2 diabetes mellitus (IMS score > 95), when clinical features suggest limited functional β-cell reserve, both procedures were similarly ineffective at diabetes remission. There was an intermediate group, however, in which RYGB was significantly more effective than SG, but this is likely related to its more pronounced neurohormonal effects. The IMS score can not only be used to predict the remission of diabetes mellitus after LSG and RYGB, it can also be used to preoperatively guide the selection of a procedure. If the IMS score ≤ 25, both sleeve gastrectomy and gastric bypass both result in a satisfactory outcome in terms of remission. If the IMS score > 25, gastric bypass should be selected. If the IMS score > 95, neither procedure will result in a satisfactory outcome in terms of weight loss. A point worth mentioning is that procedures are recommended based on the preoperative IMS score (*26*).

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