



How young for bariatric surgery in children?

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KEYWORDS

Obesity;
Treatment;
Bariatric;
Devices;
Surgery;
Weight management
program

Obesity affects 50% of adults and 18% of children in the USA. It has wide-ranging comorbidities with clinical, psychosocial, and economic ramifications. Obesity refers to a condition of excess body fat. The basis for weight gain is a fundamental imbalance between caloric intake and output, but individual variation based on genetics, metabolism, and diverse environmental triggers is seen. Although modifications to our obesogenic society and education about the risks in our environment may lead to a decrease in the incidence of obesity through prevention, treatment for those already obese is critically important. In adults, the most successful treatment programs for obesity include a surgical procedure. This article discusses the problems obesity presents to children and their families, highlights the unique aspects of treating obesity in children, reviews the currently utilized bariatric surgical procedures, and introduces those bariatric procedures that are under development. When considering whether to use bariatric surgical procedures in a multidisciplinary weight management program for children, the special needs and characteristics of children with a severe weight problem must be considered. Development of bariatric surgical techniques and devices and implementation of these tools in multidisciplinary weight management programs need greater attention. This will require the combined efforts of the pediatric health care providers from many specialties and partnerships with industry to facilitate discovery and implementation.

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As the detrimental effects of pediatric obesity are increasingly documented, procedures and devices that can be used in conjunction with other weight management techniques will increasingly be needed. What is the appropriate age to apply effective treatment for obesity? In general, children with health problems receive treatment when either the current disease burden or the projected future disease burden is sufficient to justify treatment. This general paradigm is applicable to children of all ages; however, the interaction between the developmental status of the child and the unique risks and benefits of a particular treatment must be factored into treatment plans. For complex diseases, treatment regimens are frequently multidisciplinary and involve risk—insulin for diabetes, radiation

and chemotherapy for cancer, immunotherapy for inflammatory bowel disease, surgical reconstruction for gastrointestinal tract anomalies, and cardiac surgery for cardiac anomalies. Treatment risks are accepted when the benefits of treatment outweigh the risks of inaction. So, in general, the use of bariatric surgery in pediatric weight management is need-related not age-related.

In this article, the needs that children with obesity have will be addressed in light of the unique characteristics of children. Current surgical techniques as well as some of the devices and procedures that are in development for use in children will also be presented.

The problem

Currently, there is considerable debate around who, at any age, has obesity, when obesity becomes a true health prob-

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lem, how much of a problem obesity presents, and how much risk to take with treatment. Recent guidelines from the American Academy of Pediatrics (AAP) emphasize the identification and treatment of obesity at various ages.¹ Children ages 2-18 years old with a basal metabolic index (BMI) between the 85th and 95th percentile for their age and gender are at risk of obesity and should be the targets of intensive treatment efforts. Children ages 2-18 years old with a BMI over the 95th percentile for their age and gender are obese and need to have their weight gain stopped or reversed.

The impact of excess accumulation of adipose tissue is manifold, with physiological, psychological, and social implications. It is important to identify individuals who have excess adiposity. Due to technical difficulties and limitations in estimating excess accumulation of fat, most experts agree that assessment of weight in relation to height with the BMI is the most efficient and valid method to describe adipose tissue status. BMI is calculated as weight (kg)/height (m²), but the caveat is that all excess weight is certainly not fat weight. For example, high BMI values due to gain of lean weight is seen in athletes. However, in general, high BMI values are assumed to be related to excess adiposity. The AAP guidelines state:

- A BMI between the 85th and 95th percentile based on normals from 1973 for age and gender identifies children who are overweight (at risk for obesity).
- A BMI over 95th percentile based on normals from 1973 for age and gender identifies children who are obese.

Using these guidelines, the USA has seen a threefold increase in the incidence of overweight in children overall (10-30%) in the past 30 years² with a much higher incidence in certain high-risk populations (50-60%).³ Using the BMI percentile-for-age-gender tool, children with obesity can be identified. BMI percentile-for-age-gender can be calculated in the primary care physician's office using the patient's height and weight. Percentile tables and Internet-based applications are readily available to plot the BMI relative to age and gender.

As mentioned, the problems associated with excess percent body fat (obesity) can be divided into clinical, psychosocial, and societal/economic.

Clinical comorbidities

Clinical comorbidities of obesity can be divided into present and future problems. Obese children can develop pseudotumor cerebri,⁴ type 2 diabetes,⁵ hyperinsulinemia,⁵ acanthosis nigricans,⁶ sleep apnea,⁷ polycystic ovarian syndrome (PCOS),⁸ slipped capital femoral epiphysis (SCFE),⁹ tibia vara (Blounts's disease),¹⁰ nonalcoholic steatohepatitis (NASH),¹¹ focal nodular sclerosis of the kidneys,¹² asthma,¹³ obesity-related cardiomyopathy,¹⁴ and gastroesophageal reflux disease (GERD).¹⁵ Research is demonstrating that some of these problems resolve, whereas others certainly improve when obesity is effectively treated.¹⁶⁻¹⁸

Long-term outcome studies of people with obesity demonstrate shortened life spans, increased risks of atherosclerotic cardiovascular disease (heart attacks, strokes, peripheral vascular disease), increased risks of cancer (colon cancer, prostate cancer, and breast cancer),¹⁹ and persistent risks of existing obesity-related comorbidities. Research indicates a decrease in future risks for an individual patient with improvement in their obesity.²⁰

Psychosocial issues

Psychosocial issues associated with obesity range from bullying and discrimination at school and in public places to depression and ADHD.²¹⁻²³ The relationship of these issues to obesity is complex. Bullying and discrimination at school lead to poor school performance, often with the result of homeschooling or dropping out of school.²⁴ Discrimination can also be a causative or contributing factor in the depression and ADHD issues.²⁴ Being out of school, off the playground, or unable to participate in usual types of physical education activities aggravates the problem of need for increased activity in children with obesity. The depression and ADHD can predate the obesity or can develop after the obesity occurs and become aggravating factors.²⁴ Behavioral issues complicate attempts to improve nutrition, increase activity, and modify eating habits. Discrimination from health care workers has been documented.²³ Some health care workers are uncomfortable working with patients and families of children with obesity and are unable to provide a good therapeutic situation for them. "Providers . . . who find themselves annoyed or easily frustrated by obese children or the parents of obese children should refer these patients elsewhere for care because of the potential adverse effect the providers' response may have on the child and family."²⁵

Societal/economic issues

Societal issues strongly impact children with obesity. Obese people are the last legally discriminated against group in the USA.²⁶ The obese (using the rationalization of safety) can be restricted from public places and discriminated against at work.

Society also faces a huge economic problem related to obesity in children. Children with obesity are at risk of not becoming educated.²⁷ Some teachers discriminate and stereotype obese children. Bullying and lack of social opportunities are a problem at school. The physical characteristics of the school—desks, chairs, doors, commodes—are a problem. The expected activities on the playground and at gym class are a problem. As a result, children with obesity receive poor job training and often are not hired for jobs.

Obese people often experience discrimination in the workplace.^{28,29} Job performance can be hindered due to obesity-related health problems and resulting absenteeism.³⁰ If obese people are unable to work due to poor job

skills, chronic illness, or discrimination, earnings are lost, governments are deprived of taxable income, and costs of disabilities and health care must often be born by society. Obesity-related chronic illness often means increased health care utilization and costs. In other words, the obese are often unable to contribute economically and are expensive to our society. Ultimately, the adverse consequences of obesity can be witnessed at the individual as well as the society level. Indeed, the problem of obesity may have very real implications for national defense. In a country with more than two-thirds of its citizens overweight, and a world with increasing conflict, the health and fitness of citizens are increasingly important.

Treatment issues

From a societal/economic point of view, it would seem obvious that treatment of childhood obesity would be a high priority. Hassink has said "Intervention to prevent the development of comorbidities, treatment of existing comorbidities, and reversal of obesity whenever possible are critical tasks that cannot wait."²⁴ Treatment for those children with a BMI over the 85th percentile has been recommended by the AAP in their recommendations from 1998²⁵ and 2007.³¹ However, most efforts by health care providers, communities, the federal government, private organizations, and businesses are aimed at prevention. Efforts that attempt to slow weight gain in children have received much attention because prevention of obesity is seen as being potentially more feasible than treatment. Sadly, there are no prevention or treatment efforts that have proven to be effective and sustainable.³³

Treatment of obesity in general is challenging, due to a number of factors. First, there is a certain frustration on the part of the patient because behaviorally based treatment approaches that focus on dieting and physical activity produce only modest weight loss (about 5% mean weight loss) with a high recidivism rate.^{32,34} Data from moderately overweight pediatric research populations (eg, kids who are recruited to obesity treatment research studies) give us some reason to believe that treatment of pediatric obesity may be somewhat more effective than treatment of obese adults.³⁵ However, when pediatric obesity treatment effectiveness is examined for clinical populations of obese kids (eg, those who seek a treatment program), results are far less impressive.³⁶⁻³⁸

Because obese patients have a chronic disease, often associated with life-compromising or life-threatening comorbidities, proven weight loss surgical procedures should be considered in the treatment armamentarium. Surgery should be considered because it has the best chance of significant weight loss, reversal or improvement of current comorbidities, and reduction of risk for future comorbidities. Indeed, the National Institutes of Health (NIH) recognized these factors in 1991 when they recommended that patients with severe obesity consider adding bariatric surgery procedures to their efforts to control their disease and

improve quality of life.³⁹ Work in adult bariatrics over the past 40 years and in the last 10 years in pediatric bariatrics has demonstrated that bariatric surgical procedures in the context of a multidisciplinary weight management program can lead to sustainable loss of one-third or more of a patient's weight.⁴⁰⁻⁴² Observational studies have demonstrated that weight loss leads to resolution or improvement of many obesity-related comorbidities and prolongation of life.^{16-18,38,43,44}

Second, there is still a widespread belief that obesity is a behavioral, self control problem either on the part of the child or the parent or both. Many assume that all obese people have to do is eat less and exercise more. This belief leads to stereotyping and discrimination. In practice, however, treatment of childhood obesity is time-consuming, frustrating, difficult, and expensive.³¹ Obesity is better understood as a disease caused by a genetically determined pathophysiologic response to environmental triggers²⁴ Obesity is ultimately an imbalance between energy consumption and energy expenditure. Hunger, satiety, and energy utilization are all involved and all poorly understood at a basic science level. Although weight management has a behavioral component, nutritional changes, activity changes, and the physiological changes brought on by a bariatric surgical procedure are also needed to achieve significant weight loss in a majority of people with obesity. Spontaneous remission of the obesity rarely occurs. Most believe that the longer an individual is obese, the less likely spontaneous remissions will occur.³²

Because the obese patient has a chronic incurable disease that has life-threatening present and future comorbidities, there should be no question of providing treatment. The treatment chosen should have the best chance of significant weight loss, reversal or improvement of current comorbidities, and reduction of risk for future comorbidities.

Treatment should be supported professionally, financially, and logistically. Clinicians who care for families of obese children must treat them with sensitivity, compassion, and a conviction that obesity is an important, chronic medical problem that can be treated.²⁵ Treatment should be planned to extend for the whole life of the patient—an important consideration in children.

Unique challenges of children

Children present a number of unique challenges for weight management. The first challenge is that children have a family with siblings, parents, and other care providers. The family will of necessity be involved in any weight management plan. Participation in a weight management program is time-consuming for the whole family. Food availability and nutritional education will affect the whole family. Physical activity routines are best established on a family basis. Much of the weight management plan is centered around a healthful lifestyle for the whole family.

The second challenge is the normal growth and development of all children. Children need calories and good nutrition for growth and development. Weight management plans that cause weight to be lost too fast or that lead to vitamin, mineral, or protein deficiencies require appropriate medical monitoring and adjustment of the program to avoid malnutrition. It is unlikely that controlled weight loss leads to any change in normal growth and maturation.⁴⁵ Controlled weight loss does improve the obese child's health.^{16,46} In some situations with younger children, stopping the weight gain while linear growth occurs will be enough to improve the child's health. This slower process is attractive if there are no current comorbidities.

The third challenge is the current developmental stage of the child. The child's control over food and drink choices along with food availability varies from toddlers to adolescents. The child's success with activity and interest in various activities will also change as they develop. Weight management that requires strict, unpalatable options or schedules will be harder to maintain in a healthy, successful fashion through the developmental stages of childhood.

A fourth challenge is the fact that the child faces a whole lifetime with the possibility for school, work, social relationships, and family relationships. We have an immense responsibility to each child to improve their possibilities for success in each of those areas.

A fifth consideration is that a child being treated for obesity in 2009 may benefit from improvements in our understanding of obesity, and obesity treatment paradigms may change in their lifetime. Better treatments may become available over the years.

Opportunities to individualize treatment

Recommendations regarding bariatric procedures in children have included behavioral screening and family screening to "qualify" the patient and family for a bariatric procedure. To justify surgical intervention, children should be extremely obese and should have some identifiable consequence of the obesity on their medical or psychosocial status. They should understand the nature of the surgical treatment of obesity, understand the important role they will play in their own success (or failure), and demonstrate the ability to adhere to regimen(s).^{41,42} The experience they have with nonsurgical weight management techniques is very important because they will need to continue them after their surgical procedure. Achievable goals should be established as obese children proceed through each phase of their evaluation for surgery. Surgical procedures are not cures, but rather should be seen as "tools" to achieve substantial weight reduction. They work best in combination with nonsurgical weight management techniques. Patients and family members must learn a great deal about nutrition and how to reduce risk factors that relate to weight regain.

Bariatric procedures

Bariatric procedures must be part of a multidisciplinary weight management program that the patient uses long term. Currently, we hypothesize that the best results with bariatric procedures will be achieved only when performed as part of a multidisciplinary long-term weight management program.⁴⁷ The program optimally includes family nutritional education, physical activity education, and behavioral support. Bariatric procedures are not a cure for obesity and need to be considered as one tangible component of a multipronged approach in the context of many long-term changes in the lives of the children and their families.

Pediatric bariatric practice is currently based on observational data and adoption of concepts that have been developed in adult populations. Patients who undergo 95% gastrectomies lose their appetite. Patients with short gut anatomy and malabsorption lose weight. Patients with vagotomies can also lose modest amounts of weight. Surgeons and biomedical engineers have taken these observations into consideration and designed operations and implants to mimic our understanding of these observations. The procedures have been placed into three categories: restrictive, malabsorptive, and mixed.

Restrictive procedures

Restrictive procedures include the vertical banded gastroplasty (VBG), the adjustable gastric band (AGB), and the sleeve gastrectomy. The restrictive operations produce weight loss because they assist the patient in portion control. They produce "early satiety" by mechanisms that are still poorly understood at a basic science level.

VBG and AGB

Whether performing the VBG (a gastric staple line and an unadjustable gastric band) or an AGB, a small proximal pouch is created in the stomach. Although there are limitations in the texture of what the person can eat and the speed with which they can eat, the biggest effect of both of these restrictive procedures is the loss of the sensation of being hungry (satiety) after eating a small amount of food. Patients have to take advantage of "bulky" foods that fill the proximal pouch to feel a good "satiety signal." Foods such as liquids or soft foods that flow rapidly through the proximal pouch do not cause pouch expansion and a good "satiety signal." It is important for the patient to learn the sensation of satiety, how to cause it, how to prolong it, and how to take advantage of it. It is also important for the patient to be knowledgeable of the calories in liquids and soft foods.

The outlet of the proximal gastric pouch is permanent when a VBG is created. The proximal pouch can enlarge by being overstretched with a chronic increase in food volume. Correction of this enlargement involves a surgical revision. The AGB has almost entirely replaced the VBG due to the

ease and safety of placement of the AGB and its adjustability.

The development of the AGB allowed for convenient adjustment of the size of the outlet of the proximal pouch. The size of the outlet is determined by the lumen of the band and the tissue inside the band, including the stomach and adjacent fat tissue. The balloon inside the AGB can be inflated or deflated to decrease or increase the size of the outlet from the proximal pouch. The stomach and adjacent fat tissue can thin out or become thicker making the lumen bigger or smaller, respectively. The AGB balloon adjustability allows response to these changes in the lumen from the upper pouch to the lower pouch.

Typically, adjustments to tighten the band around the stomach occur four to six times during the first year after AGB placement and one to two times per year thereafter. The adjustability allows opening the lumen, if need be, to allow more food intake. If the proximal pouch enlarges, decreasing the AGB's tightness allows the upper pouch to come down to normal size. The AGB's adjustability also allows the opening of the lumen to facilitate the passage of an obstructing bolus of food. The adjustments to the AGB are an essential, recurring part of a weight management program using the AGB. This presents significant financial, professional, and logistical issues.

The operative mortality from placement of the AGB is <0.05% in published series of adult patients.⁴² The morbidity is 10-20%, including pouch enlargement, tubing and port breakage, and band erosion.^{48,49} The resolution of comorbidities is consistent with the amount of weight lost. The weight loss is 1-2 lbs/week and may continue steadily for up to 3 years. The average weight loss after 3 years is 25-30% of the baseline weight.⁴²

There is a considerable learning curve for the patients to understand when to get their AGB adjusted and to accept the necessity of "band habits" (separating eating and drinking along with careful chopping and chewing of food) and continuing their basic tools of weight management (nutrition, activity, and behavior). Short-term reports with small sample sizes have been published on the use of the AGB in morbidly obese adolescents, and they have demonstrated safety and efficacy.^{16,50-56}

The AGB is not currently approved in the USA for use in children younger than 18 years. The device manufacturer and four academic institutions are collecting safety and efficacy data on the LapBand version of the AGB on adolescents from 14 to 18 years old to support an application to the FDA for a change in labeling to approve of use of the device in teenagers <18 years of age.

The use of the AGB in younger age groups may require modifications in current patient management practices as related to discomfort with AGB adjustments and frequency of imaging. It will also require modification by clinicians in the training and support of the younger patients and families. This training will include age-appropriate guidance about basic AGB habits (separation of food and liquids,

chewing well, and eating slowly). In many instances, pediatric surgical practitioners have developed these teaching skills in caring for children after procedures, such as esophageal atresia repair and gastroesophageal fundoplication.

Gastric sleeve resection

The gastric sleeve resection involves resecting a portion of the stomach longitudinally, which leaves a tube along the lesser curvature from the esophagus to the duodenum. This procedure was originally part of a larger procedure known as the biliopancreatic diversion (BPD) with duodenal switch (DS). When the gastric sleeve resection was done as the first stage of this larger procedure, surgeons noted that some patients lost a significant amount of weight without ever undergoing the next stage of their planned procedure. Increasing data support gastric sleeve resection as a stand-alone procedure for some patients.⁵⁷⁻⁵⁹ Long-term results over 5-10 years have not been reported. The mechanism of weight loss maintenance is not fully understood. It may be based on removing a large portion of the stomach and possibly reducing ghrelin production. It may be based on filling the tube of stomach with a small amount of food and thus producing a satiety signal. The patients report early satiety and success with portion control. The gastric sleeve resection involves much less physiological and anatomical derangement than the roux-en-Y gastric bypass (RYGB), the BPD with DS, or the BPD.

Malabsorptive procedures

Malabsorptive (diversionary) procedures are attempts to create a balanced short gut situation. The absorptive capability of the gastrointestinal (GI) tract is limited so that portion control is no longer the issue. Unfortunately, limiting the absorption capability in the GI tract is not selective to calories. It also limits the absorption of important nutrients, such as protein, vitamins, and minerals. These procedures are permanent, not adjustable, and have a high risk of producing deficiency states and their attendant sequelae. They do bypass parts of the GI tract that may be important in the development and progression of obesity-related comorbidities, such as diabetes and dyslipidemias. The malabsorptive procedure may even affect these comorbidities with little or no weight loss.

The first widely used malabsorption procedure was the jejunal-ileal bypass (J-I bypass). It was very successful at creating weight loss, and variations have been used for dyslipidemias. However, the management of the protein, vitamin, and mineral deficiencies proved too difficult. This procedure was abandoned and in many instances reversed due to the risk of complications like kidney stones, liver disease, and liver failure. The J-I bypass remains a good example of the difficulties in developing surgical procedures for the treatment of obesity. It was successful but had to be abandoned due to unacceptable side effects.

The currently used malabsorption procedures are the BPD with DS and the BPD. They are technically demanding

procedures that are successful in producing weight loss and resolution of comorbidities in adults, but they require a lot of expectant management to prevent protein, vitamin, and mineral deficiencies. There is little experience with these procedures in children. They seem unsuited because of the management difficulties, the precipitous weight loss they cause, and the potential effect of protein, vitamin, and mineral deficiencies on growth and development.

Mixed procedures

Mixed procedures use components of restriction and malabsorption. Currently, the most commonly used bariatric procedure in the USA is the RYGB. In this procedure, a small proximal pouch of stomach is created just beyond the gastroesophageal junction and the stomach is divided immediately distal to that point. Then, a roux limb of jejunum measuring 75-150 cm is constructed and anastomosed to the newly formed gastric pouch. Thus, the alimentary stream bypasses most of the stomach, the duodenum, and a short proximal portion of jejunum (the bypassed tissue is also known as the biliopancreatic limb). The length of jejunum in the biliopancreatic limb is not standardized and typically ranges from 15 to 50 cm. The small proximal pouch of stomach mimics a 95% gastrectomy and causes early satiety after a small meal. The bypass of the distal stomach, the duodenum, and the proximal jejunum causes a modest amount of malabsorption, placing the patient at risk for iron deficiency anemia, hypovitaminosis D, deficient calcium absorption, and vitamin B deficiencies. These micronutrient problems are avoided with routine supplementation. Another benefit of the RYGB is that patients may experience "dumping syndrome" if simple sugars are ingested, as there is no opportunity for dilution in a large gastric reservoir before small bowel entry. The early satiety and the malabsorption from this procedure lead to a reliable weight loss of 1.5-2.5 kg/week for the 6 months after the operation, and maximal weight loss is achieved by 12-18 months postoperatively. After the first year, the body seems to adapt and there is some weight regain (5-10% of the lost weight) unless the patient is careful about his/her dietary choices, activity, and behavior.

The effect of RYGB on type 2 diabetes mellitus in normalizing the blood sugar, the HgA1C, and the insulin levels occurs very early in the postoperative period. Recently described is the reversal of type 2 diabetes in adolescents who underwent RYGB.⁴⁶ The early reversal of hyperinsulinemia and blood glucose has led investigators to question whether the main effect of RYGP on type 2 diabetes is related to weight loss or to the bypass of the duodenum and first part of the jejunum. There are numerous research groups engaged in these mechanistic questions.

Clinical management of patients after RYGP is less difficult than after DS or AGB. The RYGP operation is not adjustable, thus there is less burden on the patient and health care system for postoperative adjustment procedures. Although the operation can be reversed, it is not advisable due

to the high likelihood of weight regain, comorbidity re-appearance, and gastroesophageal reflux. The mortality rate is now about 0.5% in published adult series. Complications occur at a rate of approximately 20-30%. These include immediate and late postoperative problems, such as anastomotic leak, anastomotic stricture, stomal ulcers, intestinal bleeding, incisional hernias, and bowel obstruction secondary to adhesions and internal hernias. The average weight loss after 3 years is 30-40%.

There is a growing pediatric experience with RYGB showing similar results in teenagers with excellent resolution of comorbidities. Recent data have demonstrated significant improvements in type 2 diabetes and insulin resistance,⁴⁶ dyslipidemia,^{46,60} sleep efficiency,⁶¹ obstructive sleep apnea,⁶² hypertension and cardiac hypertrophy,⁶³ proteinuria,⁶⁴ depressive symptoms,⁶⁵ quality of life,⁶⁵ and body composition⁶⁶ in extremely obese adolescents following weight loss surgery. The procedure has to be used cautiously in adolescents because of the precipitous weight loss in the first postoperative year and the potential for calcium, folate, vitamin B1, vitamin B12, vitamin D, and iron deficiencies.

New procedures

A number of concepts/procedures are in development as bariatric procedures. These include the intragastric balloon, vagal stimulator, gastric stimulator, endosleeve duodenojejunal bypass, and endoscopic gastroplasty techniques. They can be divided into temporary and semipermanent procedures.

Temporary procedures

The intragastric balloon and the endosleeve are intraluminal devices that need to be removed or changed on a regular basis. These temporary procedures would be attractive if children could be identified whose bodies would revert to a more normal physiology with attainment of a healthy percentage body fat. If the multifaceted problems that lead to exogenous weight gain were corrected, then there might be a time when such devices could even be used temporarily to help a child attain a healthy percentage body fat, and then their use might be discontinued. Clearly, this possibility is not on the horizon today. The greatest use for such temporary devices may be in achieving weight loss that permits a safer definitive weight loss intervention (eg, AGB or RYGB) to occur.

Intragastric balloon

The intragastric balloon is a balloon that is placed endoscopically. It is designed to be in place for about 6 months and then either removed or replaced. The patient has to adapt to having their stomach full all the time. Many patients have considerable vomiting as they adapt. Older versions lost their volume and migrated postpyloric to cause

obstruction. This problem has been largely overcome in modern versions. The device comes in one size at this time. Intra-gastric balloons will need to be adjustable to be used in children. Adjustability will allow the size to be gradually increased by repeated endoscopies, perhaps allowing patients to adapt without vomiting and better tolerate the presence of the device. Adjustability will also allow the balloon size to be titrated to the size of the patient and to effect desired. The intra-gastric balloon has been used in adults and a small number of children outside the USA.^{59,67-70} It appears to be fairly safe and effective for temporary use. The Bioenterics Intra-gastric Balloon (BIB, Allergan Corp, Irvine, CA) has been used outside the USA, but is not approved by the FDA for use in the USA.

Endosleeve

The EndoBarrier Gastrointestinal Liner involves a sleeve of impermeable material placed inside the intestine from the proximal duodenum which extends distally for about 60 cm.⁷¹ The sleeve is placed and removed endoscopically. The gastrointestinal liner creates a mechanical, as opposed to surgical, bypass by diverting the alimentary stream through the inner lumen of the sleeve while the biliopancreatic secretions travel outside the sleeve. Thus, emulsification, digestion, and absorption are impaired. Also, there is limited macronutrient stimulation of gastrointestinal hormones in the bypassed intestine, which has antidiabetic actions and reverses insulin resistance. The length of sleeve necessary for an effective device has been determined in adults, but a pediatric version has yet to be worked out and would probably vary with different ages of children. Current design and early studies on adults plan for the individual gastrointestinal liners to have a lifespan of about 6 months and then require endoscopic retrieval and possible deployment of a new EndoBarrier. A trial of the EndoBarrier (GI Dynamics, Lexington, MA) for FDA approval is ongoing in adults in the USA, and the company is also conducting clinical trials in South America and Europe.

Semi-permanent procedures

The vagal blocking devices, the gastric stimulating devices, and the endoscopic gastroplasty techniques are designed to be more permanent than the intra-gastric balloon and the endosleeve. Although these procedures are designed for long-term usage, they can be removed or reversed and cause no permanent change in anatomy.

Vagal blocking devices

The vagal blocking devices are based on the following observations. Animal studies have shown vagal involvement in areas of the brain that regulate hunger and satiety. After vagotomy, humans can experience a reduction of appetite and experience weight loss. Thus, the vagal blocking devices aim to interrupt vagal signaling and involve placing electrodes around the vagus nerve branches either

laparoscopically or thoracoscopically and attaching the leads to a frequency generator placed subcutaneously. This can be done safely as an outpatient or short stay procedure under general anesthesia. The resumption of normal activity is rapid. There is currently considerable experience in children with phrenic nerve pacing devices⁷² and with cervical vagus nerve stimulating devices for seizures.⁷³ These devices seem to be well tolerated long term. The frequency, amplitude, and waveform of the stimulation provides considerable room for a variety of settings or considerable adjustment of the settings to a given individual. The current subcutaneous generators are about the same size as a pacemaker, but may come down in size and be easier for children to tolerate in the future. Ongoing studies in adults show modest results in terms of weight loss in programs with little or no stress of the other tools of weight management.⁷⁴

Gastric stimulators

Gastric stimulation is based on a number of possible mechanisms. The stimulators might affect ghrelin production, simulate the sensation of a full stomach, or send afferent messages via the vagus nerve. Trials in adults to date have been disappointing, but there is an effect in some patients.⁷⁵⁻⁷⁷ Perhaps patient selection and/or a comprehensive weight management approach would make this effective in children. These devices can be turned on and off via a subcutaneous control box or via a sensor system placed on the proximal part of the stomach. The frequency, amplitude, and waveform of the stimulation provides considerable room for a variety of settings or considerable adjustment of the settings to a given individual. As with the vagal blocking systems, the power/control box remains an awkward aspect of the device, but the placement of the device by laparoscopy would be a safe outpatient or short stay surgery with rapid resumption of normal activity. One gastric stimulation system (Tantalus; MedaCure, Orangeburg, NY) has been used in Europe and is undergoing FDA trial in the USA on patients over 17 years old.

Both vagal stimulating and gastric stimulating devices are removable, adjustable, and do little to the GI structure or function.

Endoscopic gastroplasty

Endoscopic gastroplasty techniques are being developed using endoscopes designed with suturing devices incorporated in the endoscope. The maneuver is done intraluminally. Both formation of a small upper gastric pouch similar to the proximal pouch with an AGB and formation of a tube of stomach along the lesser curvature of the stomach that mimics a gastric sleeve resection are being attempted. Currently, this procedure requires a large gastroscope, which would limit its usage by the size of the patient. The durability of these suturing techniques remains to be determined. These techniques are potentially adjustable, reversible, or repairable endoscopically. They do not cause malnutrition, protein deficiency, vitamin deficiency, or mineral deficiency due to malabsorption or bypass.

The FDA and bariatric procedures

Bariatric procedures can be divided into those with devices and those without devices. Those procedures that involve implanted devices come under the control of the FDA. The AGB, the endosleeve, the gastric stimulators, and the vagal blocker all fall into this category. They will be studied for safety and efficacy before they are FDA-approved.

Typically, medical devices are developed and studied in adults before they are approved for use in human beings by the FDA. For approval in children, appropriate trials in children are usually expected. However, physicians use many devices and pharmaceuticals in pediatric patients without FDA approval for use in children. After devices and drugs are approved by the FDA for use in adults and are on the market, it is difficult to get the manufacturer to do the studies necessary for the device to become labeled for use in children. Frequently, pediatric practitioners use clinical judgment and make the necessary mechanical and dosage adaptations to use drugs and devices "off label." However, such practice does not lead to the rigorous collection of efficacy or adverse event data that the public should be able to see to make informed decisions.

The AGB was approved for use in patients 18 years of age and older in 2001, and the contraindications include "age less than 18 years." This contraindication was based on the lack of inclusion of adolescents in the original early trials in the USA. Since then, pediatric investigators have been working with the FDA and the manufacturer of the AGB to collect data on the device's safety and efficacy in patients younger than 18 years of age. It is likely that by 2010, sufficient pediatric data will have been collected to allow the FDA to evaluate the use of the device in younger adolescents (14-17 years old).

There is a program underway at the federal level to facilitate the development of pediatric drugs and devices.^{78,79} The process needs to facilitate development and approval of devices for children as a primary process. The process needs to be streamlined to reduce the length of approval time and adjusted to encourage industry to invest in developing devices for pediatric use while maintaining the safety of the children.

The procedures that do not involve the implantation of a device do not come under the regulational jurisdiction of the FDA. Practitioners use their best clinical judgment and adapt the procedures to children as they seem clinically indicated. The RYGB, the BPD with DS, the BPD, and the gastric sleeve resection all fall into this category, although the 1991 NIH consensus panel that led to widespread use of bariatric procedures in adults specifically excluded minors as appropriate patients for these procedures. Non-device bariatric procedures are being used in children based on clinical judgment and in many cases without any program of study and evaluation. These practices leave the public with a real knowledge gap around safety and efficacy of these procedures. Rigorously conducted clinical investigations, such as the Teen-LABS study (<http://www.cincinnatichildrens.org/>

Teen-LABS), will permit the objective evaluation of risks and benefits of RYGP and other procedures in adolescents, to help fill this knowledge gap.

Conclusions

Children with obesity are ill with a chronic, incurable disease that threatens their physical health, their psychosocial well being, and the economic future of society. The question is not how young to treat them, but which aggressive, effective treatments can be most safely used to affect a healthy weight. The current generation of children with obesity needs treatment now. The best that medicine has to offer currently for patients with obesity is a surgical procedure combined with a multidisciplinary weight management program. Until pharmacologic, hormonal, or genetic therapy that is more effective and/or safer is developed, the combination of a surgical procedure with a multidisciplinary weight management program is the gold standard, but it must be used cautiously and with good long-term data collection.

When choosing which procedure to use on children in a multidisciplinary weight management program, the special needs and characteristics of children with obesity need to be considered. Careful safeguards need to be used while the techniques and devices are developed and tested. Development of the techniques and devices and how they interact with the multidisciplinary weight management program need to be facilitated both economically and logistically. This will require the cooperation of the pediatric health care providers, the government, and industry. Development of devices and techniques for use in children cannot wait for development of techniques and devices in adults. The current generation of children cannot wait, and the results and the methodologies in children may be quite different from those in adults.

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