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eDiabetes Review
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MANAGEMENT OF OVERWEIGHT/OBESE PATIENTS WITH T2DM

In this Issue...

The "diabesity" epidemic – the rising number of obese and overweight patients attempting to control their type 2 diabetes – continues to present a conundrum to treating clinicians. Weight loss will improve glycemic control, but patient adherence to effective diets is very often difficulty to maintain. A further complication is that often-prescribed pharmacotherapies are known to induce weight gain.

In this issue, we review the recent evidence describing how GLP–1 agonists may be appropriate at many different stages of T2DM.

In this issue, we review the current literature describing:

- The cardiovascular effects of intensive lifestyle intervention
- The comparative success of weight loss among named diet programs
- Current pharmacotherapies available to treat overweight or obese patients with type 2 diabetes
- The MGI (metformin, GLP-1, insulin) approach to glycemic and weight control
- The latest evidence regarding bariatric surgery as treatment for diabetes in overweight or obese patients.

LEARNING OBJECTIVES

After participating in this activity, the participant will demonstrate the ability to:

- Discuss the impact of healthy lifestyle in improving diabetes in overweight or obese adults.
- Describe pharmacological approaches to obesity treatment in adults with type 2 diabetes for intensifying diabetes medications without inducing weight gain.
- Evaluate surgical approaches to obesity treatment in adults with type 2 diabetes.

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COMMENTARY

With rising diabetes and obesity rates around the world, clinicians often face the challenge of treating patients with both diseases. Against this "diabesity" epidemic, we have made important strides within the past several decades to better understand the roles of lifestyle modification, pharmacotherapy and surgery. Healthy lifestyle focused on low-carbohydrate and/or low-fat diet plus regular exercise is vital in promoting overall health as well as in improving both diabetes and obesity.

In a large longitudinal study of over 5000 adults followed over 10 years, the Look AHEAD research group demonstrated that obese adults with type 2 diabetes (T2DM) can lose weight and maintain modest weight loss through intense lifestyle intervention. Regarding the optimal diet for overweight and obese individuals, a recent meta-analysis by Johnston et al in JAMA showed no evidence to support one type of major named diet over another. Rather, it appears that any diet that a patient will adhere to with the intention of losing weight will be the best diet for weight loss.

The number of medications recently approved to treat diabetes and/or obesity alone speaks to the speed at which our medical community is tackling these problems; between 2006 to the present, a total of 16 diabetes medications and 4 obesity medications (either new or combinations of previously approved medications) were approved by the Food and Drug Administration.[1]

Given this exciting pace of development in pharmacotherapy to treat T2DM and obesity, clinicians now have a selection of choices for initiating a pharmacotherapy in a patient with T2DM whose glycemic control remains off-target despite healthy lifestyle. The (reviewed herein) Bray and Ryan article provides a detailed review of available pharmacotherapies to treat obesity and separately discusses pharmacotherapies available to treat obesity in those with T2DM. Nadeau provides an endocrinologist's perspective in prioritizing the pharmacotherapies for T2DM that are weight-neutral or weight-loss promoting. Specifically, metformin, glucagon-like peptide (GLP)-1 receptor agonists, and DPP4 inhibitor are pharmacotherapies that do not promote weight gain and should be considered strongly in overweight or obese patients with T2DM. Yet another new pharmacotherapy to consider, albeit with limited longitudinal data, are the sodium-glucose cotransporter (SGLT)-2 inhibitors, which lower hemoglobin A1c with modest weight loss benefit. While the increasing number of pharmacotherapy choices available for T2DM may provide new challenges for clinicians, metformin should be considered first-line whenever possible, followed by a GLP-1 agonist or DPP4 inhibitor in T2DM patients who are overweight or obese.

When healthy lifestyle and pharmacotherapy are insufficient to treat overweight or obese patients with T2DM, weight-loss surgery such as Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG) should be considered. Over the past several decades, we have increasing data suggesting the role of weight-loss surgery as the most effective treatment for obesity and T2DM. Currently, the NIH criteria to undergo weight-loss surgery include body mass index (BMI) ≥ 40 kg/m2 or ≥ 35 kg/m2 with comorbidities such as T2DM, sleep apnea, or hypertension.[2] In a systemic review of 33 human studies, Yip et al reported similar T2DM remission rates between RYGB and SG at up to three years after surgery (defining diabetes remission as hemoglobin A1C > 6% without the use of diabetes medications). T2DM remission was observed in over 80% of the patients at 36 months for both surgical interventions.

It is important to note that while these results are quite impressive, only three of the 33 studies included in this review were randomized trials. A more recent study by Schauer et al reported the results of the randomized trial of bariatric surgery versus intensive medical therapy at year 3.[3] The authors of this study confirmed a significantly greater number of individuals with hemoglobin A1C of 6% or less in the surgical group (38% in RYGB and 24% in SG) compared to the intensive medical therapy group (5% at year 3. Similarly, patients in the surgical group lost more weight (24.5% in RYGB, 21.1% in SG) compared to those in the intensive medical therapy group (4.2%) at year 3. More rigorous studies focused on longitudinal outcomes of bariatric surgery are needed to elucidate the long-term benefits and risks related to bariatric surgery.

The cornerstone of treatment of both T2DM and obesity is healthy lifestyle, through which low-carbohydrate, low-fat diet, daily regular exercise should be emphasized. When these efforts fail, metformin should be considered first-line therapy, given its efficacy in lowering the hemoglobin A1c, modest weight-loss benefit, and low cost. Next, GLP-1 agonists or DPP4 inhibitors should be considered, given their efficacy in improving glycemic control and weight-neutral or modest weight-loss benefits. In those who qualify, bariatric surgery is an effective treatment that should be considered, especially in those with extreme obesity and subsequent comorbidities such as lack of mobility, sleep apnea, and hypertension. The mechanisms behind effective and durable improvement in diabetes after bariatric surgery may be partly mediated by changes in gut hormones.[4] In turn, understanding the mechanisms of how bariatric surgical intervention achieves metabolic improvement may provide future targets of medical therapy for treatment of diabetes and obesity.

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CV EFFECTS OF INTENSIVE LIFESTYLE INTERVENTION IN T2DM

Look AHEAD Research Group, Wing RR, Bolin P, et al. Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. *N Engl J Med*. 2013;369(2):145-154.

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In this article, the authors discuss the findings of the landmark "Look AHEAD" (Action for Health in Diabetes) study, which examined the impact of intensive lifestyle intervention on cardiovascular disease among obese adults with type 2 diabetes. In overweight or obese individuals without diabetes, weight loss was shown to be a strong predictor of reduced diabetes risk, thus highlighting the important metabolic benefits of weight loss.[1] Studies on short-term benefits of weight loss on diabetes led to the recommendation of weight loss for overweight or obese adults with type 2 diabetes.[2]

The Look AHEAD study addresses the critical gap in our knowledge about the long-term effect of weight loss on cardiovascular risk in adults with type 2 diabetes. The authors conducted a multicenter, randomized clinical trial with median follow up of 9.6 years in 5145 overweight or obese adults with type 2 diabetes to investigate the impact of weight loss through intensive lifestyle intervention based on caloric restriction and increased physical activity.

Eligible patients were randomly assigned to either the intensive lifestyle intervention group or the control group. The intensive lifestyle group (2570 participants) focused on reduced caloric intake goal of 1200-1800 kcal per day and physical activity of at least 175 minutes per week. The program included both individual and group counseling sessions weekly in the first six months and less frequently thereafter. The goal of this group was to achieve at least 7% weight loss. The control group (2575 participants) received diabetes support and education provided through three group sessions per year in the first four years and less frequent sessions in subsequent years.

The primary end point was the first occurrence of predefined cardiovascular outcome such as death from cardiovascular causes, nonfatal myocardial infarction, and nonfatal stroke, as well as hospitalization for angina. The secondary end points also included death from any cause, myocardial infarction, stroke, coronary artery bypass grafting, percutaneous coronary intervention, and hospitalization for heart failure or peripheral vascular disease. Although the authors anticipated a maximal follow-up period of 11.5 years, the study was stopped early at median follow up of 9.6 years on the basis of futility analysis.

In the study, the intervention group achieved more weight loss and greater fitness compared to the control group with mean weight loss of 7.9% at one year and 2.5% at the end of the study over the control group. Surprisingly, however, there were no significant differences in cardiovascular outcomes between the two groups.

In summary, this study showed that an intensive lifestyle intervention did not reduce the risk of cardiovascular disease, as compared with a control regimen of diabetes support and education among overweight or obese patients with type 2 diabetes. The lack of significant between-group difference may be because weight loss in the intervention group was inadequate to reduce the cardiovascular risk, or the rigorous medical management of cardiovascular risk in the control group making the between-group difference too small to detect.

While the authors failed to show that the reduction of cardiovascular risk in the intervention group was greater than in that of the control group, they succeeded in demonstrating various other important benefits of sustained weight loss through intensive lifestyle intervention, such as improvement in glycemic control, quality of life, physical function, and mobility, as well as reduction in urinary incontinence, sleep apnea, and depression. Therefore, weight loss through healthy lifestyle remains a cornerstone of treatment of type 2 diabetes in overweight or obese adults.

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COMPARISON OF WEIGHT LOSS AMONG NAMED DIET PROGRAMS

Johnston BC, Kanters S, Bandayrel K, et al. Comparison of weight loss among named diet programs in overweight and obese adults: A meta-analysis. *JAMA*. 2014;312(9):923-933.

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In this 2014 publication, the authors sought to determine weight loss outcomes for major named diets. While named weight loss programs in the United States represent a multibillion-dollar industry (with each program claiming superiority over the others), there is a paucity of rigorous studies comparing these programs for the benefit of the consumers. Therefore, the authors of this article aimed to evaluate the effect of each named diet through network meta-analysis of available randomized clinical trial (RCT) data.

In the study design, authors included in the meta-analysis RCTs that assigned overweight or obese adults to a popular branded diet or an alternative with at least three months' follow up thereafter. The primary outcomes were weight loss at six- and 12-month follow-up, and secondary outcomes were BMI and adverse events. The authors searched six electronic databases using keywords such as RCTs, diets, adults, and weight loss. Pairs of reviewers independently screened articles and independently extracted data and assessed selected studies for risk of bias associated with each trial.

The authors selected 48 RCTS in this meta-analysis, which included a total of 7286 individuals with median age of 45.7 years and median BMI of 33.7. A total of 12 trials among the 48 RCTs included patients with type 2 diabetes. Overall, the authors found that a low-carbohydrate and low-fat diet led to more weight loss (up to 4 kg) than no dietary intervention at one year. They also found no significant difference in weight loss between individual diets. Combined with the fact that people tolerate different diets variably, there is no evidence to support one diet over the other. The strengths of this review include the use of network meta-analyses, a comprehensive literature search, assessment of risk of bias, and systematic review of the potential harms of named diets. The study's weaknesses include substantial heterogeneity between studies, limited data on calorie restriction, and high risk of bias in 19 RCTs related to missing participant outcome data.

The important lesson in this study is that any diet that a patient will adhere to with the intention of losing weight appears to be the best diet. In agreement with prior studies by American Heart Association and the Obesity Society, this review did not find adequate evidence to recommend a particular diet.[1,2]

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UPDATE ON OBESITY PHARMACOTHERAPY

Bray GA, Ryan DH. Update on obesity pharmacotherapy. *Ann N Y Acad Sci*. 2014;1311:1-13.

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In this 2014 review article, Bray and Ryan provide a comprehensive overview of pharmacotherapy agents to treat obesity. The authors discuss the use of medications approved for obesity as well as a subset of medications approved for obese patients with chronic diseases such as diabetes.

The authors divide into two categories the medications approved as of 2013 by the US Food and Drug Administration (FDA) for treating patients with obesity: those approved for long-term and those approved for short-term use. The medications approved for long-term use against obesity include orlistat, lorcaserin, phentermine-topiramate and naltrexone/bupropion:

- Orlistat is a selective inhibitor of pancreatic lipase that reduces the intestinal absorption of fat. In a randomized clinical trial, the orlistat-treated group achieved weight loss of 5% over treatment with placebo at one year. Common side effects of orlistat are gastrointestinal symptoms related to fecal fat loss.
- Lorcaserin is a selective serotonin-2C receptor agonist leading up to 3.7% weight loss compared to placebo at one year. Unlike its predecessors, lorcaserin was not associated with valvulopathy. Lorcaserin is well tolerated, with the most common side effects being headache, nausea, dizziness, and constipation.
- Phentermine-topiramate is a combination drug that reduces appetite. The phentermine-topiramate group led to a mean weight loss of 6% over treatment with placebo at two years. Common side effects in this study included dizziness, altered taste, insomnia, and dry mouth. Topiramate is contraindicated in glaucoma.
- Naltrexone/bupropion was approved by the FDA in September 2014 (after this article was published) as treatment option for chronic weight management with average weight loss of 4.1% over treatment with placebo at one year.[1] Bupropion is associated with increased risk of suicidal thoughts and seizure. The naltrexone/bupropion combination was associated with elevated blood pressure, which led to the FDA post-marketing requirement for cardiovascular risk assessment. The most common side effects include nausea, headache, constipation, and insomnia.

Regarding drugs approved for short-term use in treating the patients with obesity, the authors discuss the sympathomimetic drugs such as benzphetamine, diethylpropion, phendimetrazine, and phentermine. The phentermine group achieved a mean weight loss of 2.5% over treatment with placebo at six months. Common side effects include dry mouth, insomnia, and increased heart rate and blood pressure.

For treating obesity in patients with type 2 diabetes, the authors discuss metformin, glucagon-like peptide-1, pramlintide, and sodium-glucose cotransporter (SGLT)-2 inhibitors.

- Metformin is the cornerstone of type 2 diabetes treatment, and its effect on weight loss was established in the Diabetes Prevention Program study (DPP). In this study, the metformin group lost on average 4 kg over the placebo group at two years.
- Liraglutide, a glucagon-like peptide (GLP)-1 agonist, was voted favorably by an FDA panel for treatment of obesity in September 2014 (after publication of this
- Pramlintide is a modified form of amylin that produced weight loss similar to that of the GLP-1 agonists. However, it has not been in wide use because it requires frequent dosing.
- The SGLT2 inhibitors approved by the FDA for diabetes treatment (at this time) are dapagliflozin, canagliflozin, and empagliflozin. These SGLT2 inhibitors led to weight loss of up to 2.3 kg compared to placebo. Side effects included urinary tract infections and hypoglycemia.

Of note, it is important to remember that all weight-loss medications are contraindicated in pregnancy. Topiramate use requires a negative pregnancy test before use because of its association with oral clefts.

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PHYSIOLOGICAL AND WEIGHT-FOCUSED TREATMENT STRATEGIES FOR MANAGING T2DM WITH METFORMIN, GLP-1 RA, AND INSULIN (THE MGI APPROACH)

Nadeau DA. Physiologic and weight-focused treatment strategies for managing type 2 diabetes mellitus: The metformin, glucagon-like peptide-1 receptor agonist, and insulin (MGI) approach. *Postgrad Med*. 2013;125(3):112-126.

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In this review, Dr. Daniel Nadeau presents strategies to effectively treat type 2 diabetes in patients who are overweight or obese.[1] Despite the increasing number of effective treatments available for treating diabetes, many patients do not achieve their glycemic control targets. Guidelines from various professional organizations do not provide a clear direction to clinicians for tailoring diabetes treatments specifically for those who are overweight or obese. All too often, patients with uncontrolled T2DM are started on medications that may help with their diabetes but may also promote weight gain, such as

sulfonylureas and insulin. Fortunately, several diabetes medications are weight-neutral or weight-loss promoting, and they should be strongly considered when clinicians want to intensify treatment of T2DM in patients with obesity.

The cornerstone of T2DM treatment and prevention consists of healthy lifestyle. Healthy diet and exercise have tangible impacts on type 2 diabetes and can delay the initiation of diabetes medications or allow dose reduction or elimination of current pharmacotherapies. Regarding healthy diet, plant-based diets rich in whole grains, fruits, vegetables, and nuts have shown benefits in weight loss and improved insulin sensitivity. In one study, a low-fat, vegan diet lowered the hemoglobin A1c by 0.4% and weight by 1.4 kg at 74 weeks over a diet following the 2003 American Diabetes Association guidelines.[1] While a vegan diet may not be realistic for many patients, the study is useful in highlighting the impact of healthy diet in glycemic control and weight loss.

When starting medications in patients whose glycemic control remains off-target despite adherence to a healthy lifestyle, the author recommends metformin first, followed by a glucagon-like peptide (GLP)-1 agonist and insulin. Metformin is the first-line treatment for T2DM, as recommended by many professional organizations because of its effectiveness in lowering the hemoglobin A1c, low cost, and its weight-neutral or modest weight-loss promoting properties. If a patient with T2DM needs further therapy intensification, the author recommends GLP-1 agonist as the next line of treatment, given its dual roles in glycemic control and weight loss. For those who require further intensification of therapy, the author recommends the addition of basal insulin, which is an effective therapy, albeit promoting weight-gain, to rapidly lower the hemoglobin A1c. Alternatively, clinicians may consider adding a sodium-glucose cotransporter 2 (SGLT2) inhibitor, a newly approved class of medications for T2DM that work by inhibiting glucose reabsorption in the renal proximal tubule. This medication has the added benefit of a modest weight-loss promoting property, which should be taken into consideration, especially for patients who would like to delay using insulin. However, as these are newer agents, their long-term effects on cardiovascular or microvascular outcomes and their safety profile are not well-defined.[2]

In conclusion, clinicians should consider diabetes medications that are weight-neutral or weight-loss promoting when initiating pharmacotherapy in overweight or obese patients with T2DM. Specifically, clinicians should consider metformin, GLP-1 receptor agonists, and most recently, SGLT2 inhibitors as treatment options to help avoid further weight gain in these patients.

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GASTRIC BYPASS AND SLEEVE GASTRECTOMY FOR TYPE 2 DIABETES

Yip S, Plank LD, Murphy R. Gastric bypass and sleeve gastrectomy for type 2 diabetes: A systematic review and meta-analysis of outcomes. *Obes Surg*. 2013;23(12):1994-2003.

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In this article, the authors compared the effectiveness of two popular bariatric surgery procedures: Roux-en-Y gastric bypass (GBP) and sleeve gastrectomy (SG) in T2DM remission and weight loss. Bariatric surgery, especially GBP, is the most effective and durable treatment for both T2DM and obesity. In GBP, a small stomach is created and anastomosed to the jejunum, thus creating both restriction and malabsorption of food.

SG is a newer procedure involving the creation of a gastric sleeve tube without rerouting of the small intestine. T2DM remission was defined in this paper as being off diabetes medications with normal fasting glucose or a hemoglobin A1c of < 6%. Weight loss was assessed by percent excess weight loss and percent excess BMI loss.

The goal of this paper was to determine whether GBP is superior to SG in achieving T2DM remission and weight loss. The authors performed a systematic review and meta-analysis of the current evidence in the literature, searching the PubMed and Embase databases to find clinical studies that reported both of the relevant outcomes. The authors analyzed in detail a total of 33 studies, which included three randomized controlled trials and 30 nonrandomized studies. Only five studies had both GBP and SG as treatment arms, while the rest of the other studies reported outcome either on GBP or SG. The follow up in these studies ranged from three to 36 months following surgery.

The main findings of this meta-analysis were that there were no significant differences in diabetes remission rates or weight loss between GBP and SG at one year. Both procedures caused substantial and rapid improvement in T2DM, which led to T2DM remission rate of 67% for GBP and 56% for SG at three months and 76% and 68%, respectively, at 12 months. For weight loss outcome, the authors found a mean excess weight loss of 65% after GBP and 66.8% after SG at 12 months. The strengths of this study include strict definition of diabetes remission after bariatric surgery, which is in agreement with the latest recommendation of the American Diabetes Association (ADA), as well as rigorous methods to minimize the selection bias and attrition bias.[1] The weaknesses of this study include the paucity of randomized controlled studies comparing GBP and SG and the lack of consensus on the definition of T2DM remission across the literature, which led to a reduction in the number of eligible studies.

This review confirms the potent effect of GBP and SG in T2DM remission and weight loss. Although the longitudinal data on the outcome of SG are lacking (because it is a newer bariatric procedure), it appears that SG has metabolic benefits comparable to that of GBP at one year. Therefore, both GBP and SG are reasonable surgical treatment options in obese individuals with T2DM. More studies directly comparing these two procedures focused on long-term outcome are needed to better tailor bariatric surgery procedures to meet individual patient needs.

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1. American Diabetes Association. Standards of medical care in diabetes--2014. *Diabetes Care*. 2014;37 Suppl 1:S14-80.

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