

Bariatric Surgery: Should it be the First Choice of Treatment for Diabetic Obese?

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The Study: Schauer PR, Kashyap SR, Wolski K, Brethauer SA, Kirwan JP, Pothier CE, Thomas S, Aboud B, Nissen SE, Bhatt DL. *Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes. N Engl J Med. 2012 Apr 26;366(17):1567-76. PubMed ID: 22449319.*

BACKGROUND

With rising incidence and prevalence of obesity and diabetes mellitus type 2, effective interventions are needed to stop the epidemics [1]. Type 2 diabetes is due to increased insulin resistance requiring increasing amount of insulin production by the islet cells of pancreas. Ultimately, pancreas is unable to produce enough insulin requiring pharmacological agents and ultimately exogenous insulin administration. Obesity is intimately associated with the development of insulin resistance and weight control is one of the most important interventions for the prevention of type 2 diabetes. However, once type 2 diabetes has developed, the risk of diabetes-related complications remains high, irrespective of the glycemic control.

Why was this study done?

Several studies have shown that weight loss, whether through exercise, diet control, or bariatric surgery, is associated with improved glycemic control in type 2 diabetic patients. While the effect of weight loss with diet control and exercise on type 2 diabetes has been studied in randomized controlled clinical trials, such trials had not been for bariatric surgery. Observational studies had suggested that the effect of bariatric surgery-induced weight loss will produce marked improvement in glycemic control than exercise and diet control [2]. This is very attractive since, despite advances in pharmacological therapy of diabetes, less than 50% of patients achieve and maintain adequate glycemic control [3]. However, before its wide use for management of type 2 diabetes, bariatric surgery needed to be studied in a randomized controlled trial; gold standard to show the efficacy of a treatment modality.

How was this study done?

Objective: The very name of the trial delineates the objectives it aims to achieve - Surgical Treatment and Medications Potentially Eradicate Diabetes or STAPMED in short. The study was designed to compare the efficacy of intensive medical therapy alone versus medical therapy with one of the two bariatric surgery procedures, i.e., Roux-en-Y gastric bypass and sleeve gastrectomy. The primary end point was the proportion of patients with a glycated hemoglobin level of less than 6% or less at 12 months of follow up.

Study type: This was a single center (Cleveland Clinic), non-blinded, block randomized trial.

Study population: 150 middle aged (mean age=49±8 years) obese patients (BMI=27 to 43) with poorly controlled type 2 diabetes (mean HbA1C>7%) were enrolled and 12-month follow-up information was available on 93%.

What did this study find?

At 12 months of follow-up, reduction of glycated hemoglobin levels in all the three groups, with a mean glycated hemoglobin level of 7.5±1.8% in the medical group, 6.4±0.9% (P<0.001) and 6.6±1.0% in the sleeve-gastrectomy group (P=0.003) was found.

Another interesting finding was that the surgical group patients who needed pharmacotherapy needed significantly lesser amounts of anti-diabetic drugs than the exclusively medical group. In fact, in the latter, the requirement for drugs was noted to increase throughout the duration of the study. Insulin use remained high at 12 months (38%) in the medical-therapy group and was reduced to 4% in the gastric-bypass group and to 8% in the sleeve-gastrectomy group. The results of the secondary end points of the study were also encouraging. Expectedly, both the gastric bypass and sleeve gastrectomy groups (-27.5±7.3% and -24.7±6.6%, respectively) showed significantly more weight loss than the medical group (-5.2±7.7%) reduction in weight and BMI was more marked with gastric bypass than with sleeve gastrectomy. Though there was significant reduction in the occurrence of metabolic syndrome following either of the two surgical methods, gastric bypass reduced LDL

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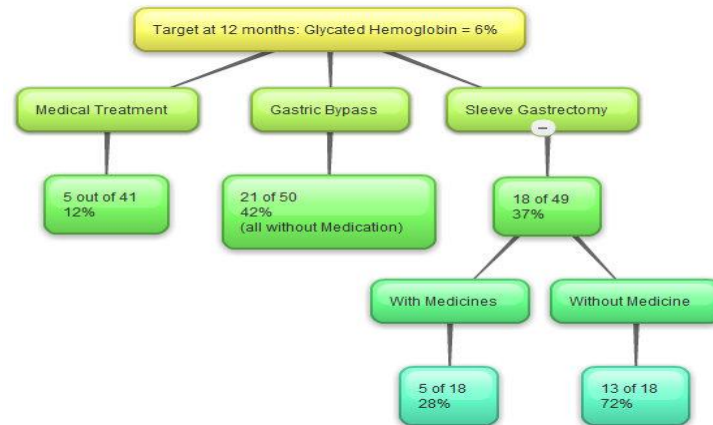


Figure 1: Flow diagram of the results of the study

levels by a more significant level. Another important finding is that the index for homeostasis model assessment of insulin resistance (HOMA-IR) improved significantly after metabolic surgery. HOMA-IR is used to quantify insulin resistance. $HOMA-IR = (\text{glucose} \times \text{insulin}) / 22.5$; here glucose is expressed in mmol/L. This mathematical equation describes glucose regulation as a feedback loop, using data from physiological studies [4].

Implication of the study

This study has direct relevance to patient care and important clinical implications. First, it confirms that bariatric surgery results in significant amount of weight loss. Second, weight loss results in improved glycemic control confirming the hypothesis that increased body fat stores has causal relevance to insulin resistance in type 2 diabetes. Third, the need for antidiabetic agents to maintain optimal glycemic control can be reduced with large amounts of weight loss. Thus, bariatric surgery results in dual benefit for obese diabetic patients; weight loss and better glycemic control with fewer drugs.

Where are the limitations?

The study has a surrogate endpoint, improvement in glycemic control as measured by HbA1C. While this is an accepted measure of glycemic control, HbA1C cannot replace hard clinical endpoints such as cardiovascular disease, retinopathy, or peripheral neuropathy. The short follow-up of only 12 months limits our

ability to evaluate long-term risks associated with bariatric surgery. In this study, the immediate operative risks were minimal and 4 patients needed re-operation. During follow-up, no major complications were noted. Bariatric surgery results in major change in gastrointestinal anatomy and there is a risk of long-term complications such as anastomotic leak, ulcer, stricture, fistula, nutritional deficiency and metabolic bone diseases.

If bariatric surgery is the answer to diabetes, then it is essentially a “developed world” solution. With the burgeoning numbers of diabetics in the developing world, feasibility of widespread bariatric surgery is a rather doubtful proposition. Limited duration of follow-up also precludes us from observing whether the improved glycemic control and weight loss are also associated with a decrease in long-term diabetic complications. A long-term study with hard endpoints (such as myocardial infarction, stroke or death) can answer the clinical utility of bariatric surgery in the management of type 2 diabetics. Therefore, the implications of this treatment are difficult to fathom.

What is the way forward?

Data from longer follow up with hard clinical endpoints, including survival benefits would be necessary to justify the expense, the manpower and the consumption of healthcare resources that would be mandated if bariatric surgery were to be taken up on a larger scale for management of type 2 diabetes.

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