Review of NEJM article, "Bariatric Surgery versus Conventional Medical Therapy for Type 2 Diabetes" by Mingrone et al.

Corresponding Author:
Mr. Kamal K Mahawar,
Consultant General and Upper GI Surgeon, Department of General Surgery, Sunderland Royal Hospital, Kayll Road, SR4 7TP - United Kingdom

Submitting Author:
Mr. Kamal K Mahawar,
Consultant General and Upper GI Surgeon, Department of General Surgery, Sunderland Royal Hospital, Kayll Road, SR4 7TP - United Kingdom

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Competing Interests:
I am a shareholder, director, and CEO of Webmed Limited, UK (the company that owns this web portal WebmedCentral)
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Author(s): Mahawar KK

Citation of the Article Reviewed


Review

This article establishes that surgery (laparoscopic roux-en-Y gastric bypass and open biliopancreatic diversion) is more effective than medical treatment in causing resolution of type 2 diabetes mellitus at 2 years. It will hence add more credibility to the increasing body of evidence supporting the claims that certain bariatric procedures are more effective than medical treatment for controlling hyperglycaemia in patients with advanced obesity and type 2 diabetes in short term. Authors must be congratulated on this well carried out randomised controlled trial, which provides welcome level one evidence to support bariatric surgeons.

This study, along with the other study published by Schauer et al in NEJM last month, thus provides stronger evidence for what we already know. Whereas study by Schauer et al examined people with lower BMI than commonly subjected to bariatric surgery, this study adds little new information to what is now common knowledge.

I would like to share my following observations on this study with you.

1. There is some ambiguity regarding the primary end point as per the protocol and that reported in the study. In the protocol, authors lay down primary end point of the study as, "Diabetes full remission (HbA1c 6% or below, on free diet and with no antidiabetic medical therapy); diabetes partial remission (HbA1c between 7% and 6.1%, under the same conditions) at 2 years."

In the abstract, authors say, "the primary end point was the rate of diabetes remission at 2 years (defined as a fasting glucose level of <100 mg/decilitre and a glycated hemoglobin level of <6.5% in the absence of pharmacologic therapy."

Within the paper in the methods section, authors say, "The primary end point was the difference in the rate of remission of type 2 diabetes among patients undergoing either gastric bypass or biliopancreatic diversion, as compared with medical therapy. Remission of diabetes was defined as a fasting plasma glucose level of less than 100 mg per decilitre and a glycated hemoglobin level of less than 6.5% for at least 1 year without active pharmacologic therapy."

Authors talk about full and partial remission in their protocol and also mention these definitions in the paper, but for the purpose of this study, they have adopted a middle approach and used a unified definition of remission as above. It creates some confusion as readers can misconstrue remission in this study to be full remission, even though in reality it is only partial remission (even according to the recommendation they quote from the consensus meeting organised by the American Diabetes Association).

2. One of the secondary end point of this study as per the protocol was, "Number of patients achieving HbA1c<6.5%". I did not find this number for individual groups in the paper. Furthermore, authors report that at 2 years, diabetes remission occurred in none of the medical group patients, 15 out of 20 gastric bypass patients, and 19 out of 20 biliopancreatic diversion patients. It is worth noting that the average glycated haemoglobin level in bypass group was 6.35%. It would be worth knowing how many patients in the bypass group had values < 6.5% and also how many had values less than 6.0%. Since the sole purpose of this paper is to establish a stronger evidence for what is common knowledge, at least amongst the bariatric community, I think we need to be really careful with numbers. Our physician and GP colleagues are unlikely to be persuaded otherwise.

3. Examining any potential treatment for type 2
diabetes without looking at its risks is only addressing half the picture. I am aware that this was beyond the scope of this study but one must not ignore the widely accepted complication rates of 2-3% for these procedures and a mortality of 1:300 for bypass and 1:150-200 for BPDs. Results are likely to be better in experienced hands and high volume units. In this study, there were no deaths in 40 patients subjected to surgery (20 each for gastric bypass and biliopancreatic diversions). There were two major late complications reported- one each for gastric bypass (intestinal obstruction at 6 months) and biliopancreatic diversion (incisional hernia). There were other nutritional consequences.

4. Conclusion of the abstract states, “In severely obese patients with type 2 diabetes, bariatric surgery resulted in better glucose control than did medical therapy. Preoperative BMI and weight loss did not predict the improvement in hyperglycemia after these procedures.”

I am a bit surprised as to how authors got away with making this statement. “Bariatric Surgery” includes a number of procedures, some of which are not as effective as gastric bypass and biliopancreatic diversions in patients with type 2 diabetes mellitus. Moreover, this study was so small that it could not have been powered to evaluate the impact of preoperative BMI and weight loss on improvement in hyperglycaemia. Indeed, these were not even the end points, authors set out to study in their study protocol as well as the paper itself. If these were chance findings, they should be stated as such in results section but not in the conclusion of the abstract. I emphasise this point because a lot of casual readers (who are short of time) may sometimes only read the abstract conclusion and it is hence imperative on a study published in a journal as prestigious as NEJM that conclusions are supported by results.

Conclusion section at the end of the paper, “Our findings indicate that bariatric surgery, specifically gastric bypass and biliopancreatic diversion, may be more effective than conventional medical therapy in controlling hyperglycemia in severely obese patients with type 2 diabetes.” is slightly more justified in its claims.

5. Though beyond the scope of this study, it would have been useful to examine quality of life of study subjects and preferably also a cost analysis.

6. Most importantly, we need to know what happens to these patients in the longer term and the impact on end organ damage.

7. Finally, authors deserve to be congratulated on this landmark study, which will go a long way in establishing bariatric and metabolic surgery firmly in the management algorithm of severely obese patients with type 2 diabetes mellitus.
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