Bariatric Surgery Significantly Decreases the Prevalence of Type 2 Diabetes Mellitus and Pre-Diabetes among Morbidly Obese Multiethnic Adults: Long-Term Results

Nestor de la Cruz-Muñoz, MD, FACS, Sarah E Messiah, PhD, MPH, Kristopher L Arheart, EdD, Gabriela Lopez-Mitnik, MS, Steven E Lipshultz, MD, Alan Livingstone, MD, FACS

BACKGROUND: Type 2 diabetes (T2DM) and obesity are codependent epidemics that disproportionately affect ethnic minorities. Recent studies have shown that in non-Hispanic whites, bariatric surgical procedures successfully reverse or improve abnormal glucose metabolism, yet little is known about the results of bariatric surgery in Hispanic and other ethnic minority adults with T2DM.

STUDY DESIGN: A retrospective analysis of 1,603 adults (77% female, 66% Hispanic, mean age at surgery 45.1 years [SD 11.6 years]) who underwent bariatric surgery from 2002 to 2010 was conducted. A total of 377 subjects had diagnosed T2DM, 107 had fasting plasma glucose (FPG) <126 mg/dL but were not on T2DM medication, 276 were pre-diabetic (FPG 100 to 125 mg/dL), and 843 had normal FPG. Pre-surgery and 6, 12, 24, and 36 months post-surgery comparative-means analyses of weight, body mass index, estimated weight loss, hemoglobin A1c, and FPG were conducted via repeated-measures analysis.

RESULTS: By 1 year and through 3 years post-surgery, all groups had normal FPG. Patients with undiagnosed diabetes had a 43% FPG decrease followed by diagnosed diabetics (33%). Patients with diagnosed diabetes showed a slightly greater loss in hemoglobin A1c (2.30%) versus undiagnosed diabetics (2.13%). Patients with pre-diabetes saw the most dramatic loss in weight (47.00 kg), followed by patients with undiagnosed diabetes (46.62 kg), normal FPG (43.14 kg), and patients with diagnosed diabetes (41.39 kg) (p < 0.0001 for all up to 24 months).

CONCLUSIONS: Bariatric surgery results in significant long-term weight loss and improvement in FPG levels among ethnically diverse adults. Bariatric surgery has the potential to be an effective treatment option for weight loss and chronic disease risk improvements in this demographic. (J Am Coll Surg 2011;212:505–513. © 2011 by the American College of Surgeons)
Patients with pre-diabetes, or those with impaired fasting glucose (IFG; fasting blood sugar level of 100 to 125 mg/dL after overnight fast) and/or impaired glucose tolerance (blood sugar level of 140 to 199 mg/dL after 2-hour oral glucose tolerance test) have an increased risk of developing T2DM, heart disease, and stroke. In 2003 to 2006, 25.9% of US adults 20 years or older had IFG (35.4% of adults 60 years or older). Applying this percentage to the entire US population in 2007 yields an estimated 57 million American adults 20 years or older with IFG, suggesting that at least 57 million American adults had pre-diabetes in 2007. After adjustment for population age and sex differences, IFG prevalence among US adults 20 years or older in 2003 to 2006 was 21.1% for non-Hispanic blacks, 25.1% for non-Hispanic whites, and 26.1% for Mexican Americans.

In addition to the high burden of T2DM among Hispanics, uncontrolled T2DM is highly prevalent and contributes to higher rates of T2DM-related complications and worse overall T2DM outcomes among Hispanics compared with other ethnic groups.

Currently there are 5 commonly performed surgical procedures to treat morbid obesity: Roux-en-Y gastric bypass (RYGB), adjustable gastric banding, biliopancreatic diversion, duodenal switch, and sleeve gastrectomy. In the US, RYGB is the most frequently performed procedure. One meta-analysis showed complete resolution of T2DM among 78% of adults who underwent bariatric surgery, and even 2 years post-surgery more than 85% reported continued improvement in their condition. However, little is known about the long-term weight and glucose regulation results of bariatric surgery in Hispanic and other ethnic minority groups with diagnosed and undiagnosed T2DM as well as pre-diabetes. Therefore, in a large cohort of multiethnic adults with T2DM, undiagnosed T2DM, and pre-diabetes, we examined pre- versus post-surgery mean weight, estimated weight loss (EWL), body mass index (BMI), fasting plasma glucose (FPG), and hemoglobin A1c (HbA1c) values to examine the improvement in glucose metabolism and weight.

METHODS

A retrospective medical chart analysis of 1,603 adults (77% female, 66% Hispanic, mean age at surgery 45.1 years [SD 11.6 years]) who met NIH criteria for bariatric surgery (BMI >35 kg/m² with ≥1 existing comorbidity or BMI ≥40 kg/m²) and underwent gastric bypass/banding surgery in a single surgeon’s practice from 2002 to 2010 was conducted. A total of 377 subjects had T2DM (determined by previous diagnosis and/or medication usage), 107 had FPG ≥126 mg/dL but were not on medication and were labeled as undiagnosed T2DM, 276 had pre-diabetes (FPG = 100 to 125 mg/dL), and 843 had normal FPG pre-surgery.

Pre-surgery and 6 months, 1, 2, and 3 years post-surgery comparative-means analyses of weight (kg), EWL, BMI, HbA1c, and FPG were conducted among all 4 groups. Blood work (complete blood count; comprehensive metabolic panel; vitamin B12, calcium, parathyroid hormone, and uric acid levels; and iron studies) was performed every 6 months for the first 2 years and then yearly thereafter, but those results are not reported here. This study was approved by the University of Miami IRB.

Measurements

Pre- and post-surgery height and weight were measured during routine clinical visits by practice nursing staff. Weight was measured to the nearest 0.1 kg using a digital scale with the participants wearing light clothing and no shoes. Height was measured to the nearest 0.5 cm using an Accustat Genentech stadiometer. The BMI was calculated as body weight in kg divided by height in m². Weight loss was expressed as EWL in kg.

On the basis of American Diabetes Association (ADA) criteria, FPG, measured by a modified hexokinase enzymatic method, of 100 to 125 mg/dL was used to identify those who had pre-diabetes and those with FPG ≥126 mg/dL as frank T2DM patients. The HbA1c (glycated hemoglobin), used primarily to identify the average plasma glucose concentration over prolonged periods of time, was measured by immunoassay and was included as a component of the standard pre- and post-surgery laboratory measurements.

Surgical criteria

All patients met NIH criteria for bariatric surgery. All patients underwent group and individual education with a practice interdisciplinary group about the potential surgical and nonsurgical options, outcomes, complications, and necessary lifestyle changes. Additionally, all patients underwent pre-surgery psychologic and nutritional evaluation and testing.

Abbreviations and Acronyms

ADA = American Diabetes Association
BMI = body mass index
EWL = estimated weight loss
FPG = fasting plasma glucose
HbA1c = hemoglobin A1c
IFG = impaired fasting glucose
RYGB = Roux-en-Y gastric bypass
T2DM = type 2 diabetes mellitus
Surgical procedure

The laparoscopic approach was used in all but 5 patients. Patients who underwent gastric bypass had a Roux limb length that was either 125 cm or 150 cm depending on the patient’s baseline BMI. The Roux limb was brought up in an antecolic, antegastric manner. The jejunal–jejunal mesenteric defect was closed with a running permanent suture. The entire gastrojejunostomy was oversewn with a circumferential running permanent suture. All patients went to the bariatric floor post-operatively and were started on liquids after undergoing an upper gastrointestinal study on post-operative day 1. All patients were discharged home on our standard bariatric liquid diet for 1 week.

Patients that underwent a gastric band had the band placed through a pars flaccida technique. The procedures were generally done on an outpatient basis. These patients were scheduled for monthly visits for the first year, then every 3 months in year 2, and then at least yearly after the second year.

Statistical analysis

Analysis of variance was used to test for baseline differences in all demographic variables: weight, BMI, EWL, HbA1c, and FPG. For assessment of longitudinal change in weight and BMI, separate repeated-measures mixed linear models were fit using the MIXED procedure in SAS (version 9.2, SAS Institute). A variance–covariance matrix was selected for each model to account for the correlation of within-patient repeated observations. Age at surgery, sex, ethnicity, and time were the covariates considered for potential inclusion in each model. The interaction between time and ethnicity and time and sex was also assessed. Within-group contrasts of mean values of weight, BMI, EWL, FPG, and HbA1c for each time period were conducted to test for mean differences by group via least square means analysis. Statistical tests resulting in a probability of 0.05 or less were considered significant.

RESULTS

The majority of the sample was female (76.92%), and 65.88% identified their ethnicity as Hispanic, 17.16% as African American, 9.05% as white, and 7.92% as other (eg, mixed race, Asian, American Indian). The mean age of the sample was 45.1 years (SD 11.7 years) with a range of 20 to 74 years.

Almost one-quarter of the sample (23.52%) consisted of those diagnosed as having T2DM pre-surgery, 6.67% of the sample was undiagnosed T2DM, 17.22% had pre-diabetes, and 52.59% had normal glucose levels pre-surgery. The majority of the sample underwent gastric bypass surgery (90%), followed by adjustable gastric band (9.5%), and sleeve (0.5%) (Table 1).

Table 2 shows changes in weight, BMI, and EWL for each diabetic group and those with normal FPG from pre-surgery to 3 years post-surgery. Patients with pre-diabetes saw the most dramatic loss in weight (47.00 kg), followed closely by undiagnosed T2DM (46.62 kg), normal IFG (43.14 kg), and T2DM (41.39 kg) at 3 years post surgery. For all groups, the most weight was lost in the first 12 months following surgery. All 4 groups had very similar BMI measures (range of 2.7 mg/dL) and were within 6.96 EWL% of each other at 3 years post-surgery (Table 2).

Similar to pre–post changes in weight, dramatic decreases in FPG and HbA1c were seen for all groups. By 1 year post-surgery, all groups were within the normal FPG range according to ADA criteria*, and this was maintained through 3 years post-surgery. Undiagnosed T2DM patients saw the most dramatic decrease (70.20 mg/dL

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Table 1. Pre-Surgery Characteristics of Patients with Diagnosed Diabetes and Those with Impaired Fasting Glucose, Pre-Diabetes, and Normal Fasting Glucose

<table>
<thead>
<tr>
<th></th>
<th>Total (N = 1,603)</th>
<th>Diabetes (n = 377)</th>
<th>Undiagnosed diabetes* (n = 107)</th>
<th>Pre-diabetes† (n = 276)</th>
<th>Normal fasting glucose (n = 843)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>370 (23.08)</td>
<td>114 (30.24)</td>
<td>35 (32.71)</td>
<td>56 (20.29)</td>
<td>165 (19.57)</td>
</tr>
<tr>
<td>Hispanic, n (%)</td>
<td>1056 (65.88)</td>
<td>235 (62.33)</td>
<td>64 (59.81)</td>
<td>188 (68.12)</td>
<td>569 (67.50)</td>
</tr>
<tr>
<td>African American, n (%)</td>
<td>275 (17.16)</td>
<td>61 (16.18)</td>
<td>16 (14.95)</td>
<td>47 (17.03)</td>
<td>151 (17.91)</td>
</tr>
<tr>
<td>White, n (%)</td>
<td>145 (9.05)</td>
<td>48 (12.73)</td>
<td>12 (11.21)</td>
<td>24 (8.70)</td>
<td>61 (7.24)</td>
</tr>
<tr>
<td>Other, n (%)</td>
<td>127 (7.92)</td>
<td>33 (8.76)</td>
<td>15 (14.02)</td>
<td>17 (6.16)</td>
<td>62 (7.35)</td>
</tr>
<tr>
<td>Age at surgery, y (SD)</td>
<td>41.18 (11.73)</td>
<td>48.15 (11.21)</td>
<td>43.32 (10.58)</td>
<td>41.48 (11.58)</td>
<td>37.69 (10.65)</td>
</tr>
<tr>
<td>BMI, kg/m² (SD)</td>
<td>46.77 (7.62)</td>
<td>47.22 (8.17)</td>
<td>47.97 (7.92)</td>
<td>46.49 (7.72)</td>
<td>46.50 (7.28)</td>
</tr>
<tr>
<td>Weight, kg (SD)</td>
<td>129.28 (26.79)</td>
<td>131.54 (27.19)</td>
<td>134.79 (27.52)</td>
<td>128.84 (27.22)</td>
<td>127.70 (26.26)</td>
</tr>
<tr>
<td>Glucose, mg/dL (SD)</td>
<td>103.71 (46.84)</td>
<td>149.02 (62.64)</td>
<td>163.22 (75.74)</td>
<td>105.51 (8.22)</td>
<td>81.04 (16.55)</td>
</tr>
<tr>
<td>Hemoglobin A1c, % (SD)</td>
<td>6.46 (1.48)</td>
<td>8.11 (1.92)</td>
<td>7.33 (1.47)</td>
<td>6.10 (0.69)</td>
<td>5.78 (0.54)</td>
</tr>
</tbody>
</table>

*Fasting glucose ≥126 mg/dL and not on medication for type 2 diabetes mellitus.
†Fasting glucose 100–125 mg/dL.
BMI, body mass index.
followed by diagnosed T2DM patients (49.09 mg/dL [33%]). Conversely, diagnosed T2DM patients showed a slightly greater loss in HbA1c (2.30%) versus undiagnosed T2DM (2.13%) (Table 3).

Within-group comparisons of mean values of weight, BMI, EWL, FPG, and HbA1c between each time period showed significant decreases in weight, BMI, and EWL from pre-surgery to post-surgical assessments at 6 months, 6 to 12 months, and 12 to 24 months (p < 0.0001 for all). No significant decrease in BMI was seen for any group from 24 to 36 months post-surgery (data not shown in tables).

All 4 groups showed a significant decrease in FPG in the first 6 months post-surgery (p < 0.0001 for all) (Fig. 1).

### Table 2. Weight, BMI, and Estimated Weight Loss Changes from Pre-Operative to Post-Operative for Patients with Diagnosed Diabetes and Those with Impaired Fasting Glucose, Pre-Diabetes, and Normal Fasting Glucose

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>Weight, kg (SE)</th>
<th>BMI, kg/m² (SE)</th>
<th>EWL, kg (SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diabetes</td>
<td>130.53 (1.37)</td>
<td>47.19 (0.44)</td>
<td>−13.67 (0.38)</td>
</tr>
<tr>
<td>6 mo</td>
<td>Undiagnosed diabetes *</td>
<td>132.13 (2.40)</td>
<td>47.74 (0.77)</td>
<td>−13.80 (0.65)</td>
</tr>
<tr>
<td>1 y</td>
<td>Pre-diabetes †</td>
<td>130.48 (1.64)</td>
<td>46.81 (0.49)</td>
<td>−13.98 (0.35)</td>
</tr>
<tr>
<td>2 y</td>
<td>Normal fasting glucose</td>
<td>127.77 (0.83)</td>
<td>46.44 (0.26)</td>
<td>−13.57 (0.23)</td>
</tr>
<tr>
<td>3 y</td>
<td></td>
<td>116.11 (1.26)</td>
<td>42.09 (0.41)</td>
<td>−33.92 (0.81)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>117.68 (2.15)</td>
<td>42.62 (0.69)</td>
<td>−43.47 (1.51)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>116.42 (1.55)</td>
<td>41.75 (0.47)</td>
<td>−37.39 (0.93)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>114.18 (0.76)</td>
<td>41.54 (0.24)</td>
<td>−35.72 (0.58)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>95.26 (1.27)</td>
<td>34.55 (0.40)</td>
<td>−38.76 (1.09)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>86.54 (1.91)</td>
<td>32.81 (0.43)</td>
<td>−45.68 (2.48)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>88.40 (1.50)</td>
<td>32.42 (0.53)</td>
<td>−46.69 (1.79)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>84.31 (0.84)</td>
<td>31.32 (0.94)</td>
<td>−41.54 (1.19)</td>
</tr>
</tbody>
</table>

*Fasting glucose ≥126 mg/dL and not on medication for type 2 diabetes. †Fasting glucose 100–125 mg/dL. BMI, body mass index; EWL, estimated weight loss.

[43%]) followed by diagnosed T2DM patients (49.09 mg/dL [33%]). Conversely, diagnosed T2DM patients showed a slightly greater loss in HbA1c (2.30%) versus undiagnosed T2DM (2.13%) (Table 3).

Within-group comparisons of mean values of weight, BMI, EWL, FPG, and HbA1c between each time period showed significant decreases in weight, BMI, and EWL from pre-surgery to post-surgical assessments at 6 months, 6 to 12 months, and 12 to 24 months (p < 0.0001 for all). No significant decrease in BMI was seen for any group from 24 to 36 months post-surgery (data not shown in tables).

All 4 groups showed a significant decrease in FPG in the first 6 months post-surgery (p < 0.0001 for all) (Fig. 1).

### Table 3. Fasting Glucose and Hemoglobin A1c Changes from Pre-Operative to Post-Operative for Patients with Diagnosed Diabetes and Those with Impaired Fasting Glucose, Pre-Diabetes, and Normal Fasting Glucose

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>Fasting Glucose, mg/dL (SD)</th>
<th>Hemoglobin A1c, % (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diabetes</td>
<td>146.34 (3.71)</td>
<td>8.05 (0.19)</td>
</tr>
<tr>
<td>6 mo</td>
<td>Undiagnosed diabetes *</td>
<td>161.97 (7.35)</td>
<td>7.35 (0.34)</td>
</tr>
<tr>
<td>1 y</td>
<td>Pre-diabetes †</td>
<td>104.53 (8.11)</td>
<td>5.88 (0.15)</td>
</tr>
<tr>
<td>2 y</td>
<td>Normal fasting glucose</td>
<td>91.12 (2.31)</td>
<td>5.10 (0.09)</td>
</tr>
<tr>
<td>3 y</td>
<td></td>
<td>86.38 (1.14)</td>
<td>5.53 (0.13)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>84.74 (1.43)</td>
<td>5.76 (0.26)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>85.07 (1.31)</td>
<td>5.61 (0.08)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>84.63 (1.52)</td>
<td>5.60 (0.07)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>83.31 (0.89)</td>
<td>5.52 (0.05)</td>
</tr>
</tbody>
</table>

*Fasting glucose ≥126 mg/dL and not on medication for type 2 diabetes mellitus. †Fasting glucose 100–125 mg/dL.
The IFG continued to significantly decrease from 6 to 12 months among patients with T2DM (p = 0.05) and those with undiagnosed T2DM (p = 0.001), whereas those with a normal initial FPG saw a significant rise in FPG (p < 0.0001). Patients with diagnosed and undiagnosed T2DM and those with pre-diabetes all showed a significant decrease in HbA1c in the first 6 months post-surgery (p < 0.0001 for all) (data not shown in tables).

The 3 most common post-operative complications were iron deficiency anemia, post-operative gastrointestinal bleeding, and internal hernias. Most of the patients who developed anemia were menstruating women. Several were noncompliant with their vitamin regimen. Three were given blood transfusions at other institutions for severe anemia, and all others underwent either intravenous or oral replenishment of their iron stores. Most bleeding episodes resolved with discontinuation of prophylactic anticoagulation, with a transfusion rate of 0.5% and reoperation rate of 0.1%. The majority of internal hernias that were found in this analysis occurred earlier (2000 to 2005); more recently the number of internal hernias has been significantly decreased with a change in our surgical technique.12

**DISCUSSION**

This analysis shows that bariatric surgery results in significant and dramatic weight loss and improvement in FPG and HbA1c levels as far as 3 years post-surgery among ethnically diverse adults with diagnosed and undiagnosed T2DM and pre-diabetes. Almost one-third of the sample had either diagnosed or undiagnosed T2DM pre-surgery, a significantly higher proportion than reported elsewhere,8,13-15 perhaps because of the ethnic diversity of this sample. Three years post-surgery all patients with T2DM were within the normal FPG range. Our results indicate that bariatric surgery has the potential to be an effective treatment option for weight loss and chronic disease risk improvements in this demographic, and for Hispanic and other ethnic minority adults in particular.

Type 2 diabetes mellitus is one of the major diseases that impacts the health, quality of life, costs, and survival of obese persons. Type 2 diabetes is accepted as a global world health crisis, with 240 million people currently afflicted.1 Within 15 years, this number may be expected to rise to 380 million people worldwide. This figure is supported by studies that have reported that prevalence rates of the met-
abiotic syndrome, a precursor to T2DM, continue to increase even in pediatric populations and among those who are obese and morbidly obese in particular.\textsuperscript{16-18}

Inadequate control of hyperglycemia is common despite expanding options for pharmacotherapy and more intensive approaches to disease management overall. Bariatric surgery has repeatedly demonstrated that it can provide control of hyperglycemia, frequently eliminating the need for diabetes medications,\textsuperscript{19,20} prompting some to call it a “cure” or a method of inducing “remission” of diabetes.\textsuperscript{20-22}

The ADA’s Standards of Medical Care in Diabetes 2009\textsuperscript{9} states, “bariatric surgery should be considered for adults with a BMI $\geq 35$ kg/m$^2$ and T2DM, especially when the T2DM is difficult to control with lifestyle and pharmacologic therapy.” This is the first time that the ADA has declared bariatric surgery as a treatment option that should be considered for a population of patients with T2DM. Our results support this idea, particularly among adults of Hispanic origin.

Others have reported that bypass-type bariatric procedures offer improved T2DM resolution over nonbypass procedures (84% to 95% vs 48%).\textsuperscript{8} Specifically, studies have shown that RYGB can help prevent patients with impaired glucose tolerance from progressing to frank T2DM by improvement in peripheral insulin resistance.\textsuperscript{22} Moreover, the improvement in glycemic control has been shown to last for years; in some studies, RYGB and biliopancreatic diversion have shown sustained improvement in T2DM for up to 2 decades.\textsuperscript{14,15,19}

Interestingly, the bypass-type procedures demonstrate an immediate improvement in T2DM, before any significant weight loss has occurred, leading many to speculate that mechanisms other than overt weight loss are responsible for the improvement.\textsuperscript{23,24} Specifically, studies have reported a significant normalization of insulin sensitivity, enhanced $\beta$ cell sensitivity to glucose,\textsuperscript{22} and significant changes in the production of incretins post-operatively.\textsuperscript{25,26}

Other studies have shown that with improved glycemic control, each 1% decrease in HbA1c decreases T2DM-related deaths by 21%.\textsuperscript{27} Bariatric surgery has been shown to cause a 92% decrease in T2DM-related deaths compared with nonoperated obese-matched controls.\textsuperscript{28} The effectiveness of bariatric surgery in inducing remission is related to the number of years of T2DM duration and the level of control pre-operatively, supporting the argument for early surgical intervention in patients with T2DM.\textsuperscript{29}

Overall, the direct health care costs of diabetes range from 2.5% to 15% of annual health care budgets, depending on local T2DM prevalence and the sophistication of the treatments available. The annual costs of treating a patient with T2DM are 4 times the expense of a patient without T2DM.\textsuperscript{30} Bariatric surgery has been shown to be more clinically effective and less expensive than standard nonsurgical therapy for T2DM in appropriate patients.\textsuperscript{31} A typical surgery’s expenses are recouped in 26 months.\textsuperscript{30}

A recent analysis estimated the burden of T2DM in the US adult population in the year 2050.\textsuperscript{32} To overcome previous studies’ limitations and to provide contemporary realistic estimates of the growth of the national T2DM burden, Boyle and colleagues\textsuperscript{32} incorporated the percentage of the population with both diagnosed and undiagnosed T2DM as well as pre-diabetes to generate their estimates. The projections showed that annual diagnosed T2DM incidence will increase from approximately 8 new cases per 1,000 in 2008 to approximately 15 in 2050. Based on these estimates, Boyle and colleagues\textsuperscript{32} concluded that the US will need to engage in effective strategies, especially among high-risk subgroups of the population, to moderate the impact of their projected T2DM burden. Our results here showed that bariatric surgery results in the normalization of FPG levels in patients with pre-diabetes as well as patients with diagnosed and undiagnosed T2DM from a variety of ethnic backgrounds, including some that are considered particularly high risk, namely Hispanics. Thus, bariatric surgery might be considered as a realistic future strategy to combat T2DM in this country and beyond.

Limitations
The main study limitation was not having medication information available post-surgery for the T2DM group, making it impossible to attribute the normal IFG and HbA1c levels to weight loss or bariatric surgery alone. However, the patients with undiagnosed T2DM were known to be on no T2DM medications pre- and post-surgery and showed maintenance of normal levels of both parameters as far as 3 years post-surgery.

CONCLUSIONS
Results from this study show that bariatric surgery results in significant weight loss and improvement in FPG and HbA1c levels as far as 3 years post-surgery among ethnically diverse adults. Bariatric surgery has the potential to be an effective treatment option for weight loss and chronic disease risk improvements in this demographic.

Author Contributions
Study conception and design: de la Cruz-Muñoz, Messiah, Arheart, Lopez-Mitnik, Lipshultz, Livingstone
Acquisition of data: de la Cruz-Muñoz, Messiah, Arheart, Lopez-Mitnik
Analysis and interpretation of data: Messiah, Arheart, Lopez-Mitnik, Lipshultz, Livingstone
REFERENCES


Discussion

DR PATRICK O’LEARY (Miami, FL): My election to this august organization occurred about 3 decades ago, despite the fact I did bariatric surgery. Now, bariatric surgery is mainline general surgery, and it includes some of the most commonly performed procedures in the United States. The first presentation of a bariatric surgical paper at the Southern was in the early 1990s, by Sugerman.

The effects of bariatric surgery have been clearly demonstrated in this study by Drs Muñoz and Livingstone. They have validated other studies that have been reported both here and elsewhere. This presentation was straightforward, true, honest, and clear. It does not raise many questions, although some clarifications might help. You did not tell us how many patients started the study or what percent of patients were followed up. Do you have those data? In your manuscript, you mentioned iron deficiency anemia. How do you treat iron deficiency anemia in patients with bypass? Finally, I would like your opinion on how this improvement in glucose control occurs. The insulin levels drop and yet the insulin seems to be more effective.

We did a study in the late 1970s, which was reported at the American College of Surgeons Surgical Forum. When a surgeon performed an intestinal bypass, diabetes improved remarkably. We performed preoperative IV and PO glucose tolerance tests, measuring both insulin and glucose, and calculated insulin’s effectiveness in controlling plasma glucose levels. We observed the same type of effect you report here. The diabetes improved before weight loss occurred and the improvement persisted up to a year. All 25 of these patients were studied preoperatively, immediately postoperatively, and at 3 months, 6 months, and a year after surgery. In these patients the upper gastrointestinal (GI) tract, including the duodenum, was still in the flow of the food. How does this insulin become so much more potent in controlling plasma glucose and in what part of the GI tract is this modulated? Is this phenomenon of improvement really a fortuitous event, as proposed by various authors?

DR BRUCE SCHIRMER (Charlottesville, VA): This paper confirms, in the Hispanic population, what has been previously observed and published in Caucasian populations—that bariatric surgery is a highly effective treatment for type 2 diabetes. I have 2 questions and a comment for the authors. What is your opinion on extending the indications for doing a gastric bypass for diabetics with a body mass index of 30 to 35 kg/m²? The second question is: at 3 years after surgery, what percentage of the patients were treated with banding, what percentage of the bands were removed, what was the weight loss that you saw in the bands, and how effective were the bands compared with the bypass in the treatment of type 2 diabetes?

DR CLIVE O CALLENDER (Washington, DC): I just wanted to ask if they had looked at all at the glomerular filtration rates in these patients, because in some of our experiments, we did identify that there was a high glomerular filtration rate. And I wondered if you found that in your patients.

DR THOR SUNDT (Rochester, MN): This may be a bit far afield, but I wonder if you have got any experience in using this in patients with ventricular-assist devices or heart transplantation. The obesity problem in those individuals is an enormous one.

DR FRANK MOODY (Houston, TX): I wonder if you might comment on the recent work going on in South America and the experimental models in America in terms of the role of glucose-1 peptide and the glucagon-1 peptide. There’s very extensive literature and there’s a movement toward applying these types of procedures in nonobese patients.

DR NESTOR DE LA CRUZ-MUNOZ (Miami, FL): In response to Dr O’Leary, we performed operations in just under 2,900 patients over the last 9 years. The patients we included in this analysis had at least 2 laboratory data points postoperatively out to at least 3 years. Roughly 1,600 patients met the criteria.

For Dr Schirmer, at our center, our 3-year follow-up was approximately 55% in these patients. So, you are correct; it is too early to say that diabetes resolution and weight loss are permanent. But at the 3-year mark, we were happy to see a sustained plateau of both diabetes and weight improvement.

How do we treat iron deficiency anemia in these patients? All patients were given oral supplementation. The American Society for Metabolic and Bariatric Surgery recently came out with supplementation recommendations for all bariatric procedures. We follow laboratory work for patients every 6 months for up to 2 years, and then once a year thereafter. We make supplementation adjustments based on any deficiencies. Most of the men do just fine. Some of the women with very heavy menses may need additional iron. Sometimes they also require gynecologic consults to help with their menses.

Our standard iron supplementation is usually with a multivitamin BID in the beginning, and then supplemented with additional ferrous fumarate later, if needed. Occasionally, if the patient develops significant microcytic anemia, we’ll send them for IV iron infusions to build up their baseline iron stores. How does it make diabetes improve? I’m going to discuss that at the end because it was asked by several discussants.

Dr Richards asked about the laparoscopic adjustable gastric banding patients and their outcomes. Yes, based on intention to treat, they were included in our analysis and consisted of approximately 9% of our sample. Unfortunately, I do not have the exact data with me, but as expected, the percent excess weight loss was less and the percent resolution of diabetes was less. We believed it was important to include them in the analysis rather than exclude them. In terms of the
removal of the bands and conversion to gastric bypasses, we have removed bands in 2% of our patients, and converted another approximately 3% of our bands to bypasses.

Dr Callender, as to the glomerular filtration rates, unfortunately, we have not looked at that. At the recent American Heart Association meeting we had an interesting discussion with an endocrinologist, who convinced me that we do need to look into it because the expected renal function difficulties in our diabetic patients may be anywhere from 40% to 50%, and potentially even higher, in the 50% to 55% range. So that’s something I’m anticipating looking at over the next year.

In terms of cardiac patients, we have not operated on any postcardiac transplant patients. We have operated on 4 pretransplantation patients, who have been sent to us with ejection fractions anywhere from 10% to 15%, who have done very well. A couple of them are not on the transplant list, because their ejection fractions improved significantly. We do not have enough data to give any recommendations on that.

Getting back to Dr Schirmer’s remark about expanding the indications of bariatric surgery for type 2 diabetes, for me, it’s an easy answer. I think the current challenge is the need for better long-term data. We need more prospective data, out several years, in multiple national and international sites, and that is not yet available. But I think that we will be doing gastric bypasses on patients with body mass indices of 30 to 35 kg/m² in the near future. It makes sense from a diabetes-resolution perspective, certainly. We have all seen the excellent results of the diabetes resolution in the literature. If you are doing gastric bypasses every day, the idea of expanding the criteria to include thinner patients is not nearly as scary as if you aren’t familiar with bariatric surgery and haven’t seen the miraculous results. So it does make a lot of sense to do it in this population of people. At the end of the Diabetes Surgical Summit in 2007 in Rome, even some of the world leading endocrinologists were hinting that they would potentially be okay with patients with lower body mass indices getting bariatric procedures for uncontrollable type 2 diabetes. These doctors discussed their difficulties with this group of patients as well.

This brings me to the last point that was brought up a couple of times about metabolic surgery. It is currently being done around Latin America, and around the world. Japan has a few studies that have been published. The interesting aspect involves looking into how these procedures work.

The bypass procedures improve diabetes even before significant weight loss has occurred. So the question has been around awhile. A couple of different theories have evolved. Some speculate that it is a foregut mechanism in which bypassing the duodenum may decrease the production of a yet unknown, anti-incretin, which improves insulin resistance. Others believe a hindgut hypothesis, which states that getting the nondigested food down to the terminal ileum more quickly seems to stimulate GLP-1 and other incretin production and its subsequent improvement in insulin resistance.

No one is really sure. I’m not sure if either one of these theories is exactly correct. There are scientists looking into neurologic mechanisms that involve the liver as well as bile as a potential mechanism. I believe that if both foregut and hindgut procedures are having results and both are being done clinically around the world already, then neither theory should be 100% correct because they are essentially mutually exclusive.