Early Postoperative Outcomes of Metabolic Surgery to Treat Diabetes From Sites Participating in the ASMBS Bariatric Surgery Center of Excellence Program as Reported in the Bariatric Outcomes Longitudinal Database

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Objective: Small case series suggest bariatric surgery may be an effective treatment for type 2 diabetes mellitus in patients who do not meet body weight criteria for morbid obesity (body mass index [BMI], <35 kg/m^2), but large multi-institutional series, which allow better assessment of the safety and efficacy of treatment, have not been reported.

Methods: Data from 66,264 research-consented patients with a primary bariatric surgery encounter in the Bariatric Outcomes Longitudinal Database from June 2007 to June 2009 were queried to identify patients with a BMI $\geq$30 but $<$35 kg/m^2 (1.2%, n = 794) and diabetes requiring any medication (29%).

Results: A total of 235 patients met inclusion criteria. The 2 most common procedures, adjustable gastric banding (n = 109) and gastric bypass (n = 109), were compared. Laparoscopic access was used in 92% of procedures. Gender (76.6% female), race (80.4% White), and age (mean 52.6 ± 10.4 years) did not differ between procedure groups. Gastric bypass provided superior weight loss and diabetes remission but demonstrated more frequent complications (90-day complications: 18% vs. 3%, $P < 0.05$). No mortalities were reported, and most complications were minor.

Conclusions: The data suggest early effectiveness of surgical treatment of diabetes in patients who do not meet criteria for morbid obesity. Gastric bypass provides more effective treatment for diabetes than adjustable gastric banding within 6 to 12 months.

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All forms of bariatric surgery provide significant improvement or resolution of type 2 diabetes mellitus (T2DM).[1–3] Although this effect has been presumed to be secondary to weight loss, investigations recognized more than 2 decades ago that some forms of gastrointestinal bypass improve insulin resistance before significant surgically induced weight loss occurs, and have begun to unlock the physiologic mechanisms.[4] The concept of metabolic surgery has been advanced to focus on the metabolic effect of bariatric procedures and differentiate these effects from weight loss effects. Metabolic comorbidities frequently develop in overweight and obese patients who do not meet traditional criteria for morbid obesity. Therefore, surgical investigators have examined the effects of metabolic surgery on the severity of metabolic diseases, such as T2DM, systemic hypertension, and hyperlipidemia, in patients with body mass index (BMI) $<$35 kg/m^2.[5,6]

Current published series of nonmorbidly obese and overweight patients undergoing metabolic surgery to treat T2DM provide small number of cases at single centers. To date, no large multicenter study has been reported in the surgical literature. A recent review of published literature on various surgical treatments in diabetic patients with BMI $<$35 collected only 343 patients from 16 studies around the world.[5] Only 2 of these studies were performed in the United States,[7,8] reporting a combined total of 22 surgically treated diabetic patients. The largest reported series outside the United States reported the results of surgical treatment in 69 patients with T2DM.[9]

In the current study, the Bariatric Outcomes Longitudinal Database (BOLD) was queried to identify patients undergoing bariatric surgery with BMI $\geq$30 but $<$35 who were being treated with medications for diabetes to evaluate the safety and early ($\leq$12 months) efficacy of surgical treatment for nonmorbidly obese patients with diabetes.

METHODS

Database

BOLD was created by Surgical Review Corporation as a tool to monitor and track outcomes of surgeries performed by participants in the American Society for Metabolic and Bariatric Surgery Bariatric Surgery Center of Excellence (BSCOE) program. Data are entered into BOLD prospectively on all patients who have their bariatric surgery performed by a BSCOE participant surgeon. These surgeons are required to enter pre, intra-, and postoperative data on all patients as well as long-term follow-up information for a minimum of 5 years. BOLD is used to ensure compliance with the requirements of the BSCOE program and to support quality improvement for bariatric and metabolic surgery. The use of BOLD data for research to develop general knowledge about optimal bariatric surgery practices was approved by the University and Medical Center Institutional Review Board at East Carolina University. As of September 22, 2009, approximately 63% of patients treated by surgeons participating in the BSCOE program had signed an informed consent document to allow their data to be used for research. The demographic characteristics of patients who provided this consent are similar to those of patients who did not.

Participants

For the current report, data entered into BOLD from 66,264 research-consented patients who had a surgery performed between June 2007 and June 25, 2009, were queried to identify all patients with BMI $\geq$30 and $<$35 kg/m^2 who were diabetic requiring medication. A total of 794 (1.2%) patients met BMI inclusion criteria at their last preoperative visit before surgery. Of these, 235 (29%)

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indicated in their comorbidity assessment were diabetic being treated with oral medication, insulin, or both drugs.

Data Definitions

A description of the data entered into BOLD from all patients during pre- and postoperative encounters and during the facility stay has been previously reported.[10] The principal data used in this study include age, gender, race, BMI, excess body weight (EBW), diabetes status, and diabetes medication status. Diabetes status is assessed using a modified version of the comorbidity scale developed by Ali et al.[11] The 6-point scoring system assigns a numerical value (0–5) to each level to objectively quantify the severity of the disease. A value of "0" indicates no symptoms of diabetes; 1, elevated fasting glucose; 2, diabetes controlled with oral medication; 3, diabetes controlled with insulin; 4, diabetes controlled with insulin and oral medication; and 5, diabetes with severe complications. For the purpose of this study, patients were considered diabetic if they had a score of 2 or higher.

Statistical Analysis

Baseline patient characteristics are reported by bariatric procedure using means and standard deviations for continuous variables and frequency and percentage distributions for categorical variables. Using 2-sample *t* tests for continuous variables and χ^2 tests for categorical variables, baseline characteristics were compared across procedure groups.

Follow-up numbers are based on the number of patients who had a postoperative visit where weight, comorbidity status, and medications were assessed during the given time frame. Follow-up percentages are calculated using only those patients who were eligible for follow-up within each time frame.

Postoperative outcomes are summarized for adjustable gastric banding (AGB) and gastric bypass patients at the following 4 time points: 0 to 3 months, 3 to 6 months, 6 to 12 months, and 12 to 14 months. At each time point, 2-sample *t* tests were used to compare the means between the 2 procedures. In addition, for each procedure, the mean change from baseline was tested using a 1-sample *t* test.

RESULTS

A total of 235 diabetic patients with BMI $\geq$30 and $<$35 kg/m^2 were identified and comprise the study population. These patient records were reported from 135 hospitals participating in BOLD data entry.

AGB and gastric bypass were the most commonly reported surgical procedures in the study population, with 109 cases of each. The remaining surgical procedures were sleeve gastrectomy (7 cases), biliopancreatic diversion (1 case), and "other" (9 cases). Further analysis was focused on the patients who underwent AGB and gastric bypass procedures.

Of the 218 cases of AGB and gastric bypass, 92% used laparoscopic access and 6% used open access. Other techniques were used in the remaining cases.

Baseline demographic data are presented in Table 1 and demonstrate typical age, race, and gender characteristics for a population of patients undergoing bariatric surgery. Comparisons of patients undergoing AGB and gastric bypass revealed no differences between groups in age, racial distribution, or gender.

Table 2 provides a list of all complications reported after surgery in AGB and gastric bypass patients. No mortalities were

TABLE 1. Baseline Characteristics of Population

	N	% of Total		*P*
Gender				
Female	180	76.6		0.3476
Male	55	23.4		
Race				
White	189	80.4		0.5695
African-American	20	8.5		
Other	26	11.1		
	Gastric Bypass		**Adjustable Gastric Banding**	***P***
No. procedures	109		109	0.6033
Mean age at surgery (yr)	52.8 ± 9.5		52.0 ± 11.2	
	N	**% of Total**	**N**	**% of Total**
Diabetes status				
Diabetes controlled with oral medication (score = 2)	58	53.3	72	66.1
Diabetes controlled with insulin (score = 3)	16	14.7	9	8.3
Diabetes controlled with insulin and oral medication (score = 4)	31	28.4	27	24.8
Diabetes with severe complications (score = 5)	4	3.7	1	0.9
		N		**N**
Medication status				
Mean no. all medications		5.8		5.0
Mean no. diabetes medications		1.5		1.3

TABLE 2. Number of Complications Through 90 Days

Complication	Gastric Bypass	Adjustable Gastric Banding
Anastomotic leakage	1	0
Arrhythmia	1	0
Atelectasis	1	0
Bleeding/hemorrhage, intra-abdominal	1	0
Common bile duct obstruction	1	0
Internal hernia	1	0
Nutritional support feeding tube	1	0
Nausea/vomiting	4	1
Paralytic ileus	0	1
Pneumonia	2	0
Slippage, adjustable gastric band	0	1
Stricture	4	0
Surgical wound infection/abscess	1	0
Vitamin K deficiency	1	0
Other	1	0
	=20 in 16 pts (18%)	=3 in 3 pts (3.3%)

Complications occurring during surgery, prior to discharge and post-discharge through 90 day in patients undergoing gastric bypass and adjustable gastric banding. There were no mortalities. Complications were frequently minor.

TABLE 3. Surgical Outcomes

Variable	Procedure	Time Frame				
		Baseline	0–3 mo	3–6 mo	6–12 mo	12–24 mo
Follow-up: N (%)	Bypass	109	88 (80.4%)	44 (55.4%)	29 (61.9%)	4 (N/A)
	Band	109	90 (83.3%)	63 (71.8%)	40 (69.2%)	11 (N/A)
BMI (stdev)	Bypass	33.7 (1.1)	30.6 (3.0)*	27.2 (3.8)*	27.1 (4.5)*	23.0 (2.0)*
	Band	33.9 (1.1)	31.6 (2.5)†	31.0 (2.7)†	30.9 (2.9)†	29.9 (2.2)†
	P	0.2483	0.0181	<0.0001	0.0002	<0.0001
% EBW (stdev)	Bypass	56.3 (8.7)	41.7 (15.0)†	26.8 (17.4)†	26.9 (19.7)†	7.6 (7.6)‡
	Band	57.9 (7.8)	40.6 (46.8)†	45.5 (12.9)*	45.4 (13.6)*	41.8 (10.2)†
	P	0.1501	0.8290	<0.0001	<0.0001	<0.0001
Total no. meds (stdev)	Bypass	5.9 (3.6)	3.9 (3.2)*	3.5 (3.2)*	3.0 (2.5)†	1.5 (1.9)
	Band	5.1 (4.1)	4.2 (3.8)*	3.5 (3.7)*	3.1 (3.7)‡	3.0 (3.3)
	P	0.1745	0.5136	0.9645	0.8752	0.4150
No. T2DM meds (stdev)	Bypass	1.6 (1.2)	0.8 (1.0)*	0.4 (0.7)*	0.5 (0.7)‡	0 (0)
	Band	1.3 (1.1)	1.0 (1.1)*	0.8 (1.0)*	0.6 (0.8)†	0.8 (1.1)§
	P	0.1294	0.2257	0.0243	0.5300	0.0306
% off T2DM meds	Bypass	N/A	37.5	50.0	55.2	75.0
	Band	N/A	21.1	31.8	27.5	36.4
	P	N/A	0.0161	0.0579	0.0199	0.2115

Outcomes of gastric bypass and adjustable gastric banding patients with BMI ≥30 and <35 kg/m^2, including the number of patients with available follow-up, BMI, calculated EBW, total number of medications, number of medications to treat T2DM, and the proportion of patients able to discontinue medications for T2DM at each interval.

Follow-up percentage is calculated using only those patients who had a follow-up encounter beyond the end of the time frame.

P values indicated in the table were calculated by comparing the 2 procedures at a given point using 2-sample *t* tests.

Symbols indicate the significance of the change from baseline at a given point using a 1-sample *t* test.

*Change from baseline $P < 0.0001$.

†Change from baseline $P < 0.001$.

‡Change from baseline $P < 0.01$.

§Change from baseline $P < 0.05$.

N indicates number of patients; BMI, body mass index; stdev, standard deviation; EBW, excess body weight; T2DM, type 2 diabetes mellitus; Bypass, gastric bypass; Band, adjustable gastric banding.

reported for patients in the series. Complications were reported in 16 gastric bypass patients (18%) and 3 AGB patients (3.3%). The difference in the incidence of complications between the 2 procedures was significant ($P < 0.05$). The most commonly reported complications were minor in nature, including nausea/vomiting and stricture. Serious complications, including anastomotic leakage, intra-abdominal bleeding, and internal hernia, were reported in 1 patient each after gastric bypass. One AGB patient developed gastric band slippage.

Table 3 provides surgical outcomes for AGB and gastric bypass patients. For the purposes of this study, outcomes are reported at the following postoperative time intervals: 0 to 3 months, 3 to 6 months, 6 to 12 months, and 12 to 24 months. A postoperative encounter was reported in BOLD for 69.2% of AGB patients and 61.9% of gastric bypass patients at 6 to 12 months following surgery.

There was no preoperative difference in BMI or EBW between the 2 surgical procedure groups at baseline. Both BMI and EBW decreased significantly from baseline at every postoperative time interval following both procedures. BMI was significantly lower after gastric bypass than after AGB at each postoperative time point ($P < 0.02$) (Table 3 and Fig. 1).

Changes in the severity of T2DM as a result of AGB or gastric bypass surgery were assessed as changes in the diabetes comorbidity score (Fig. 2) and the number of medications used to treat diabetes (Fig. 3 and Table 3). Both parameters showed a significant reduction from baseline for both surgical procedures at all postoperative time points. Figure 4 displays changes over time in the proportion of patients not requiring medications for diabetes within the first postoperative year as a function of the baseline preoperative diabetes comorbidity score (ie, baseline score of 2, 3, or 4) and by procedure (ie, AGB or gastric bypass). Among patients with a baseline diabetes score of 2 (diabetes controlled with oral medication), 38.5% undergoing AGB and 60.9% undergoing gastric bypass showed improvements in their T2DM such that their diabetes medication was discontinued within 3 to 6 months following surgery. The proportion of patients no longer requiring diabetes medication did not significantly change in the 6- to 12-month postoperative interval. Among patients with a baseline diabetes score of 4 (diabetes controlled with insulin and oral medication), 11.1% undergoing AGB demonstrated no need for diabetes medications within 3 to 6 months following surgery, whereas 50% undergoing gastric bypass were able to discontinue their medications.

DISCUSSION

The American Diabetes Association's (ADA) Standards of Medical Care in Diabetes 2009[12] states, "Bariatric surgery should be considered for adults with BMI ≥35 kg/m^2 and type 2 diabetes, especially whether the diabetes is difficult to control with lifestyle and pharmacologic therapy." This is the first time the ADA declared bariatric surgery as a treatment option that should be considered for a population of diabetic patients. Diabetes is one of the most common major diseases that impact the health, quality of life, costs, and survival of obese persons. Diabetes is accepted as a global world health crisis, with 240 million people currently afflicted.[13] Within 15 years, this number is expected to rise to 380 million people worldwide. T2DM is the predominant issue in the diabetes epidemic,

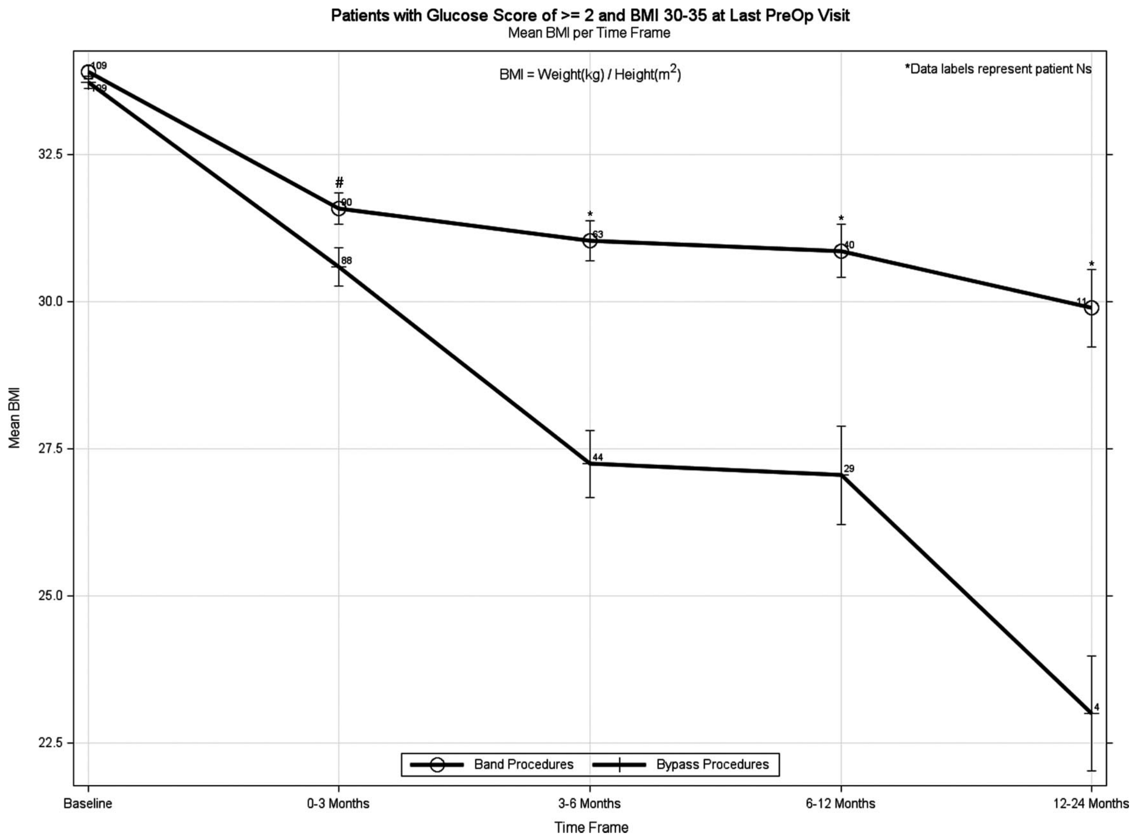

FIGURE 1. BMI at preoperative baseline and postoperative intervals comparing patients treated with AGB to those treated with gastric bypass. BMI decreased significantly following surgery in both procedure groups at each postoperative time interval. BMI was significantly lower following gastric bypass at 0 to 3 months ($^{\#}P < 0.02$) and at 3 to 6 months, 6 to 12 months, and 12 to 24 months ($^{*}P < 0.001$).

affecting 90% to 95% of all patients with diabetes. 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 whereas frequently eliminating the need for diabetes medications,[14] prompting some to call it a "cure" for diabetes.

Improvement in insulin resistance, reduction in systemic hypertension, and amelioration of hyperlipidemic states, among other changes, typically precede significant weight loss after some bariatric procedures via physiologic mechanisms that have yet to be defined.[4] Such observations have prompted many to propose that surgical treatment of metabolic disease may be appropriate in patients who do not require substantial weight loss. In fact, the concept of "metabolic" surgery rather than "bariatric" surgery was advanced decades ago.[15] Bariatric surgery developed in the category of "weight-loss surgery," and patient selection using body weight criteria was therefore widely accepted, particularly after the NIH issued its 1991 Consensus.[16] However, despite well-proven health and quality of life benefits for weight loss in the morbidly obese population, only 200,000 (approximately 2%) of the estimated 9 million Americans who suffer from morbid obesity (BMI, ≥40) undergo surgical treatment. A further indictment of the BMI qualifications for surgical intervention include the observation that metabolic system comorbidities occur frequently in nonmorbidly obese patients, leading many to argue that BMI qualifications for surgery should be revised or even eliminated. For example, 45% of type 2 patients with diabetes worldwide demonstrate a BMI <30 and would not qualify for surgical treatment based on traditional criteria.[12]

Early reports of full remission of T2DM in nonmorbidly obese and nonobese patients following duodenojejunal bypass and other forms of gastrointestinal surgery[5–10,17] triggered the organization of an international Diabetes Surgery Summit,[14] which concluded that surgery to treat diabetes should be considered in carefully selected moderately obese patients with BMI ≥30 and <35 who are inadequately controlled by conventional medical/behavioral therapies. This conclusion is controversial and not likely to become generally accepted without further study, including large clinical studies such as the current report, and randomized controlled trials, which are critical to address outcomes of surgical versus medical management of patients with diabetes in the BMI <35 range. The current study is the largest to date in the scientific literature regarding outcomes of bariatric surgery in a population of obese patients with BMI ≥30 and <35. The only larger compilation of data regarding the surgical treatment of patients with diabetes with BMI <35 kg/m^2 are an extensive review of the 16 available studies published in the literature.[5] The concept of utilizing surgery to treat diabetes in patients who fall short of traditional BMI criteria for bariatric surgery is new and rapidly evolving, as demonstrated by the fact that 10 of the 16 available studies in this collected review were published since 2008. For the current report, data are drawn from querying BOLD. Data are self-reported by participating centers, which include 673 hospitals and 906 surgeons. The current series of 235 patients represents only 0.35% of the overall 66,264 research-

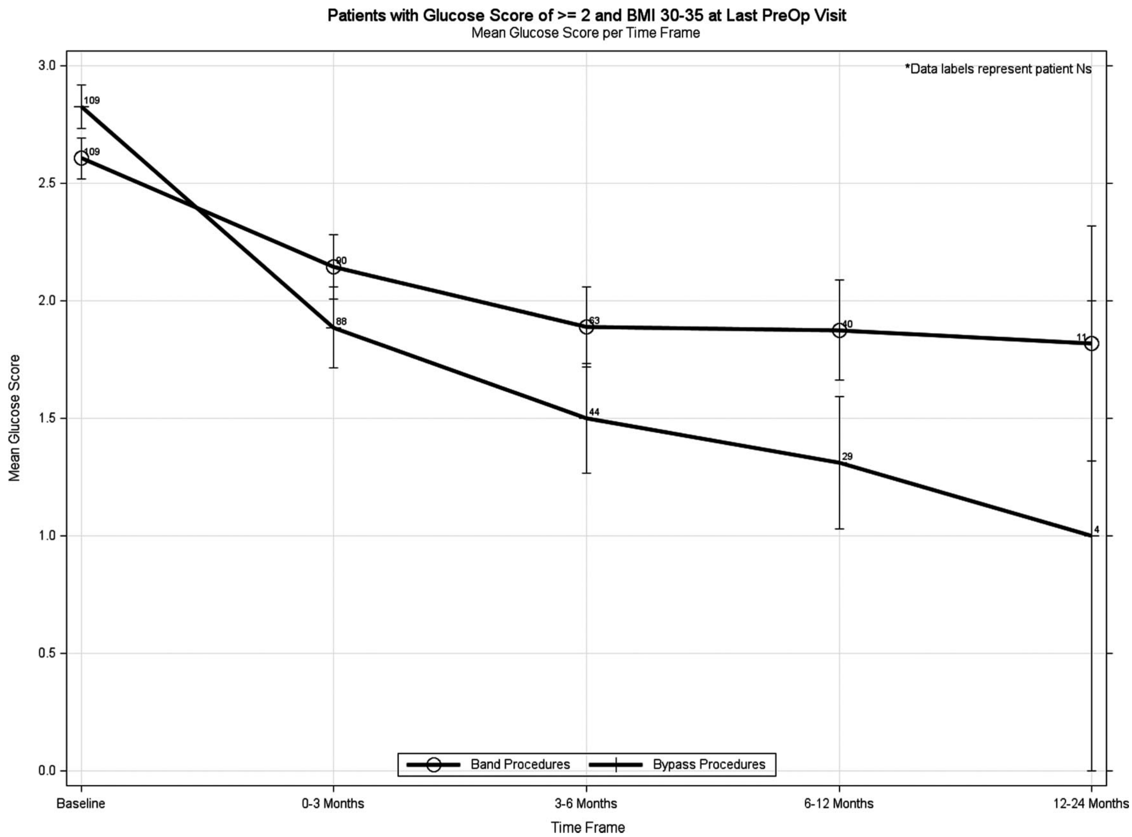

FIGURE 2. Changes in diabetes comorbidity score from preoperative baseline through follow-up interval in AGB and gastric bypass patients. Diabetes comorbidity score decreased significantly from baseline at every postoperative time interval following both surgical procedures.

consented surgically treated population reported in BOLD at the time of the research query, demonstrating the potential application of large, prospective data collection efforts.

The results demonstrate a significant, favorable impact on diabetes following AGB and gastric bypass surgery. Overall, both procedures demonstrate a significant reduction in diabetes comorbidity score (Fig. 2), number of medications required to treat diabetes (Fig. 3), and the proportion of patients able to discontinue medications to treat diabetes (Fig. 4). The results of treatment are similar to those reported in other series that include low BMI patients with diabetes[5–9] and to the favorable impact on diabetes repeatedly observed when morbidly obese patients are treated with bariatric surgery.[1–3] This initial report is an important step in evaluating the benefits and risks of bariatric surgery in the BMI <35 group, but similar work must be done to provide long-term follow-up data on these patients.

A major limitation of the current study is the short-term nature of the available follow-up, explained primarily by the limited time that BOLD has been available for data entry (ie, 2 years as of the query date in June 2009). At the time of the data query, only 15 of 218 AGB and gastric bypass patients had data entered between 12 and 24 months after surgery, but all patients with missing data entry at 12 to 24 months were found to still fall within the 12 to 24 month window for data entry. The low absolute number of patients at 12 to 24 months suggests less reliability in examining results beyond 12 months at this time. In contrast, at 6 to 12 months after surgery, the follow-up rate (percentage of patients with data entered between 6 and 12 months of the total number of patients known to be 6 months or more from the surgery encounter date) was much higher (69.2% for AGB and 61.9% for gastric bypass). Although this observation may lead to the conclusion that approximately one-third of patients at 6 to 12 months are lost to follow-up, this is deceptive because at the time of the query, the majority of postoperative subjects were still within the 6 to 12 month window for data entry and therefore not lost to follow-up. However, since data in the 6- to 12-month postoperative period were available in a significantly higher absolute number of patients (69/218 or 31.7% of the total number of AGB and gastric bypass patients), it is clear that more reliable conclusions can be drawn from the current report within the 6- to 12-month interval following surgery. The reported short-term clinical outcomes regarding diabetes appear beneficial, as 55.2% of patients after gastric bypass and 27.5% of patients after AGB were reported to have discontinued medications to treat diabetes within 6 to 12 months of surgery for an overall medication cessation rate of 39.1%. Overall, 47.8% of patients (58.6% after gastric bypass and 40% after AGB) at 6 to 12 months were reported to have a lower diabetes comorbidity score based on their medication requirements. Another shortcoming in the current report is that clinical improvement in diabetes severity is assessed using diabetes comorbidity score and number of medications to treat diabetes. Biochemical markers of diabetes severity are not collected in BOLD.

Perhaps the most significant result of the current analysis is the reporting of enough patients to allow for an assessment of the risks and complications occurring in the subgroup of patients with BMI ≥30 and <35. Although life-threatening complications and mortality following bariatric surgery are uncommon in the current

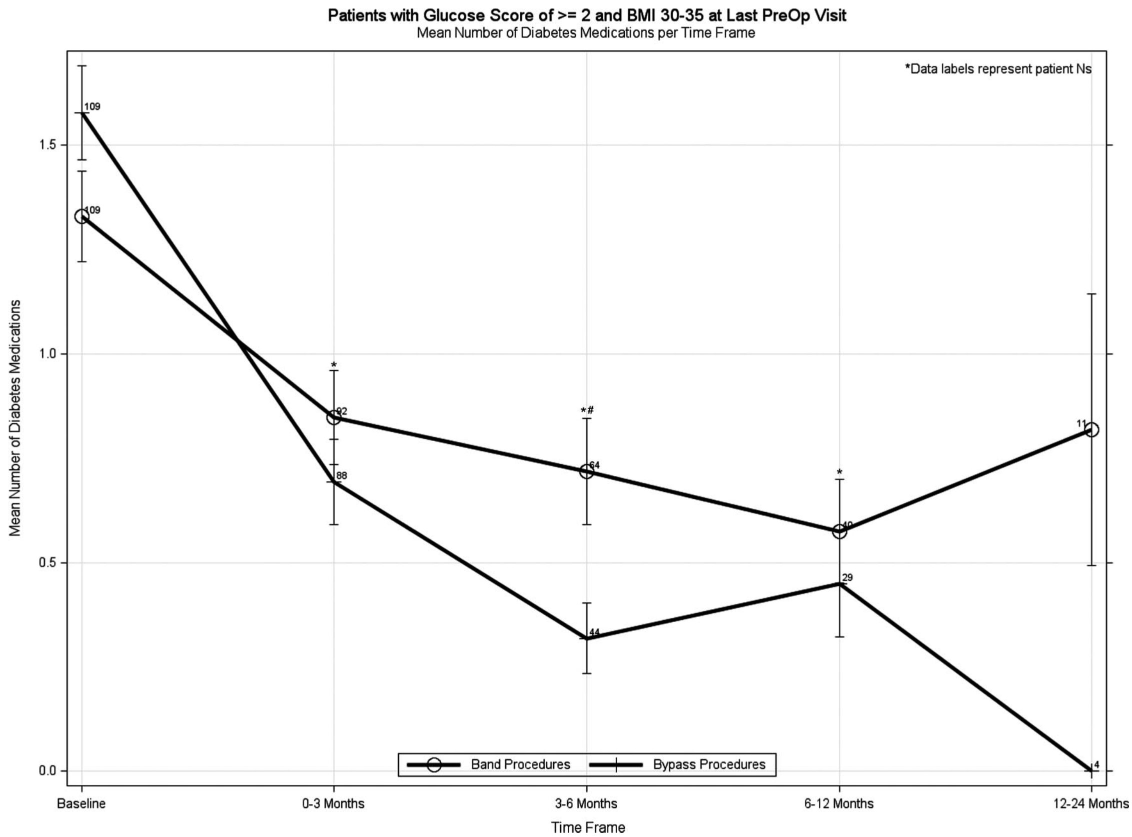

FIGURE 3. Number of medications to treat diabetes at baseline and postoperative intervals. The baseline number of medications for diabetes did not differ between groups but did decrease significantly at each postoperative time point up to 1 year of follow-up (*$P < 0.002$) following each precedure. At the 3- to 6-month postoperative interval, gastric bypass patients required significantly fewer medications for diabetes than AGB patients ($^{\#}P < 0.05$). Limited follow-up appears to explain the lack of significance found at 12 to 24 months.

era, a single bad outcome may discourage the publication of data on a small series. Importantly, no mortality was reported within 90 days after surgery in this series, and overall, potentially life-threatening complications, such as anastomotic leakage (1 case), intra-abdominal hemorrhage (1 case), internal hernia (1 case), and band slippage (1 case), were uncommon. The most common complications are typically viewed as minor, including nausea/vomiting (5 cases) and gastrointestinal anastomotic stricture (4 cases). Overall, as is typically reported in series that compare the 2 procedures, gastric bypass patients developed complications more frequently than patients treated by AGB (18% vs. 3.3%, $P < 0.05$).

Many unanswered questions remain regarding the application of bariatric surgery for patients who do not meet criteria for morbid obesity. It is not known how often bariatric surgery to treat nonmorbidly obese patients may lead to excessive weight loss and malnutrition. Because of this concern, some investigators have proposed novel surgical procedures to try and reduce or eliminate the weight loss effect of surgery for the nonmorbidly obese diabetic population. It is not known whether these types of novel procedures (eg, duodenojejunal bypass or ileal interposition) are advantageous or whether the surgical complication profile will justify their potential role in diabetes treatment. These questions are not addressed in the current report where more traditional bariatric procedures (AGB and gastric bypass) were used for treatment in the study population. It is not known whether surgery to treat diabetes can be considered a "cure" for the disease or whether it simply provides better control of hyperglycemia, often without medications. Finally, it is not known whether surgical control of hyperglycemia without medications will have a significant impact on the frequency or severity of long-term health consequences of diabetes, including atherosclerotic disease, neuropathy, blindness, and renal failure. These and other questions must be answered in the coming years to determine whether metabolic surgery has a role in the treatment of diabetes and other diseases in the nonmorbidly obese patient.

The findings of this study further question whether BMI is an appropriate gateway to determine access to bariatric surgery. The BMI is unigender, uniracial, and fails to distinguish patients in terms of fat distribution, body composition, age, and fitness.[18] The continued imposition of the BMI "35/40 rule" despite the evident differences in body composition between males and females and its discrimination against Asians and African-Americans demands prompt review as well.

Bariatric surgery has evolved over a 50-year span to become a treatment modality characterized by a high degree of safety and efficacy.[10] The current report demonstrates safety and short-term efficacy in a nonmorbidly obese population of diabetic patients who require medications. Both AGB and gastric bypass provided improvement in the severity of diabetes, including the diabetes comorbidity score, number of diabetes medications, and the proportion of patients reportedly discontinuing medications for diabetes. Confirmation of these results, which must include large clinical studies with long-term follow-up, may lead to broad acceptance of surgical

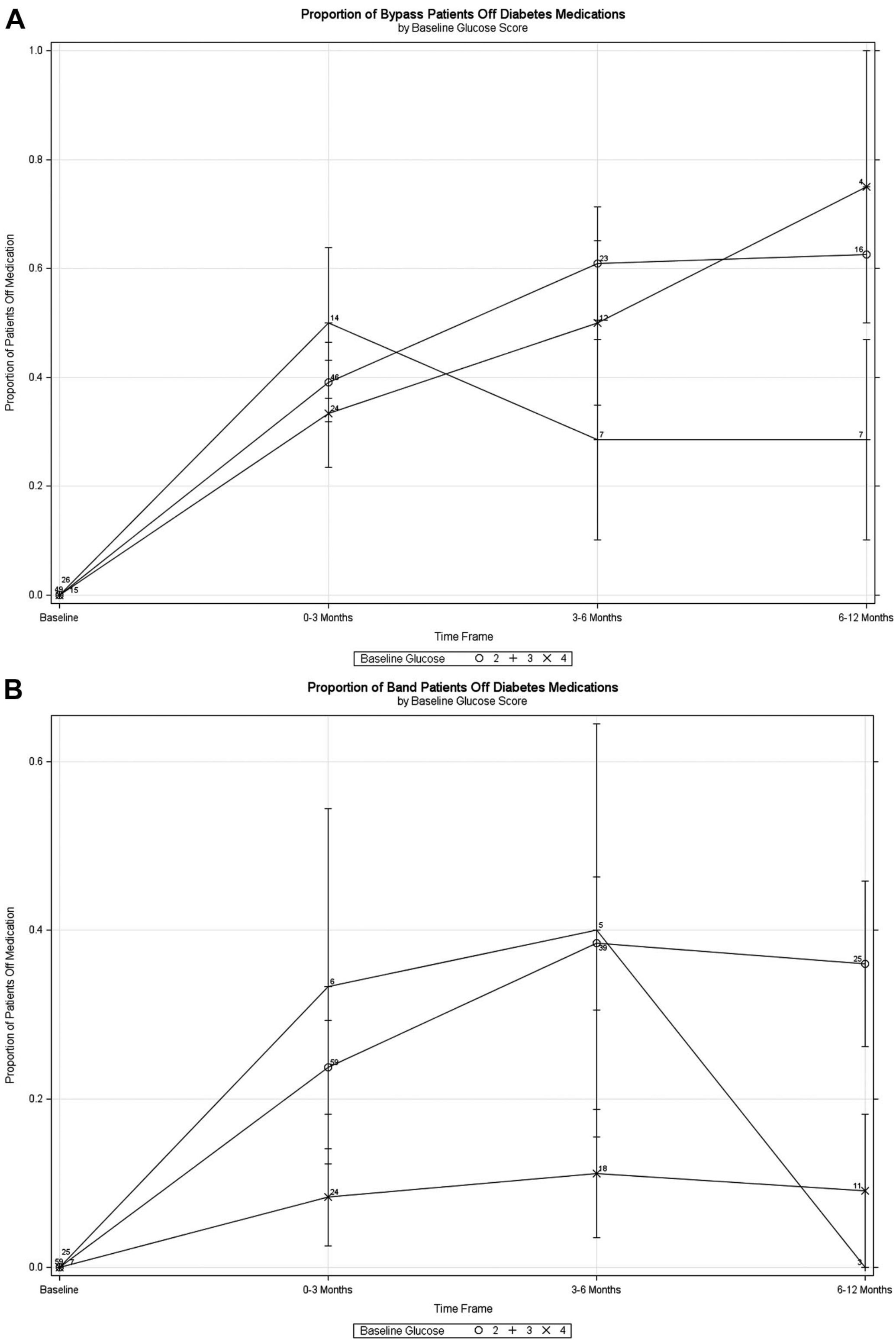

FIGURE 4. Proportion of patients off medications for diabetes in subgroups based on preoperative diabetes comorbidity score and procedure performed. No data are shown at 12 to 24 months, as the available number of patients was too small in the various subgroups. A, Depicts gastric bypass patients; and B, depicts AGB patients.

interventions as treatment for diabetes in nonmorbidly obese and nonobese populations.

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Discussions

Dr. Henry Buchwald (Minneapolis, Minnesota): Surgery evolved from an incisional science to extirpative to reconstructive, and now it is metabolic. We, in metabolic surgery, operate on normal organs or organ systems to achieve a secondary or metabolic effect.

With the coming of the age of metabolic surgery, we have entered an era where we treat diseases that we have never treated before, such as diabetes, hypertension, hyperlipidemia, and so on. The entire metabolic syndrome can be treated by metabolic surgery, and bariatric surgery has become metabolic surgery.

The article presented by Dr. DeMaria and his colleagues is an organized assessment of metabolic/bariatric surgery in the treatment of type 2 diabetes in a large series of patients with a BMI >30 and <35. There are 2 takeaway messages. First, metabolic/bariatric surgery in this population with a BMI more than 30 but less than 35 is safe. Second, metabolic/bariatric surgery in type 2 diabetic patients with a BMI over 30 but under 35 is effective.

There is an unstated third message in this article: Namely, that metabolic/bariatric surgery in treating diabetes in this low BMI range is nowhere as effective as in a high BMI range.

We published 2 meta-analyses on this topic, in 2004 in "JAMA" and in 2009 in the "American Journal of Medicine." In the truly morbidly obese we are achieving 86% resolution. Dr. DeMaria and colleagues are not achieving these same findings in the patients who are not as obese.

Why are we more successful in the higher weight range? There may well be a spectrum of type 2 diabetes or there might be a spectrum of causative factors of type 2 diabetes, and the weight factor may be the easiest one to manage.

This was not my perspective. Nicola Scopinaro of Genoa, Italy, 2 years ago speculated that as the BMI range decreases, controlling diabetes grows more difficult. Yet, we do so much better than with anything else that is available.

Can the BOLD database from the SRC be combined with the American College of Surgeons' database to make a true national registry and can this lead to a conciliation of these different perspectives?

Second, a scientific question, how do you explain the action of metabolic/bariatric surgery? None of us believe it is truly just weight loss related. Is it related to duodenal exclusion and the decrease in the GIP hormone? Is it related to earlier contact with the terminal ileum and an increase in GLP 1 and PYY? Why does it work? This is a question that our endocrinology friends always ask us. It is a question that we should try to answer.

Dr. Philip Schauer (Cleveland, Ohio): These studies are difficult to conduct because current payers will not pay for these operations with a BMI of 35 or less, regardless of the comorbidity profiles.

Recently, the ADA met for an historic meeting to define remission and cure of diabetes. Presumably, this was driven by recent reports in "Surgery," where remission was achieved. They define remission as normoglycemia, with a hemoglobin A1c of 6.0 or less on no medication. They define cure as remission lasting 5 years or more, and by their definition, currently, the only way to remit or cure diabetes is with surgery.

Given your results demonstrating the safety and efficacy of this operation and a fairly high remission rate, do you think organizations like the ADA will augment their current guidelines to recommend surgery for patients with a BMI of less than 35?

One major criticism of your study is your definition of remission. You use primarily clinical means without biochemical evidence of remission. Some would argue that this is fairly inaccurate. Do you think this may weaken your conclusions?

I presume your patients were self-pay, because no payers will cover the operation with a BMI of 35 or less. Do you think that their socioeconomic status may have affected these very good results?

Finally, this is a relatively new database. What measures have been taken to ensure that the data are accurate and valid, particularly with omission of potential remission of major morbidity and mortality?

Dr. Eric J. DeMaria (Durham, North Carolina): Dr. Buchwald, I think you started with a political challenge for me to determine whether we could somehow merge center of excellence accreditation between the college's efforts and the American Society for Metabolic and Bariatric Surgery SRC efforts. I agree that it is a tremendous frustration for many practitioners that we do not have a single credentialing entity. However, I must point out that the BOLD and SRC data collection initiative are mammoth in comparison to the college's current status with data collection in this area, and therefore offers the opportunity to potentially address many more research questions in the short-term.

You also asked me about the mechanism. As a simple surgeon, I do not know that I can answer that question. I offer the same conjecture that many people have regarding differences in gut hormones; the effect of the bypass of the duodenum, which is one proposed mechanism versus the ileal break mechanism, and how these physiologically interact to change insulin resistance.

My group also published a series in the morbidly obese population, drawing a direct line between the success of weight loss and the improvement of diabetes. Therefore, I think this puzzle will prove to be much more complex than anyone would have guessed entering the arena for treatment of diabetes, because, as you pointed out, there does appear to be a significant difference in the effectiveness or treatment in the lean population of diabetics undergoing treatment for type 2 diabetes, particularly in other countries around the world. This is a question that will unlock many secrets, I suspect, to diabetes.

Dr. Schauer asked about the ADA and their recommendations regarding treatment. This, hopefully, is one step forward in helping to gain a better understanding of the effect of surgery to specifically treat type 2 diabetes in a lower-than-typical body weight population for bariatric surgery. I do not think that a single study, in and of itself, will make much difference to ADA guidelines, but the accumulation of evidence over the course of time will lead to guideline changes.

You also asked about the self-pay status of these patients, which is certainly true. The vast majority of insurance programs do not cover bariatric surgery for BMI below 35, and this, of course, could represent a socioeconomic form of bias. Patients who can afford a surgical procedure may be more motivated and may possess a better understanding of what they need to do, but I do not have any data regarding that.

Finally, in answer to your question and comment about data validation, it is no less important for the BOLD database than it is for any initiative involving the collection of data. There are different ways to validate data including internal mechanisms and external mechanisms. Internal mechanisms have been accomplished in this data set. For example, when we looked for a clinical diabetes remission in this population, we were also able to cross-check and make sure there were no medications reported for diabetes. Therefore, we utilized some internal controls in the population. The SRC is just beginning the process of external validation, where they would use their system to go to the source documents and confirm that the data entered in the BOLD was in fact the accurate information. That process is likely to take many years of hard work going forward.