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Research Article

Effect of Bariatric Surgery on Glycemic Control in a Military Training Facility

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Abstract

Background: The objective of the study was to evaluate the effects of gastric bypass surgery on diabetic and pre-diabetic patients. Outcome variables were diabetic status, BMI, and if patients were able to discontinue pre-operative medications.

Methods: At our institution 193 consecutive patients were retrospectively evaluated who underwent gastric bypass surgery between 2007-11. Demographic data was obtained. In addition, diabetic status, BMI, and current medications were recorded pre-operatively and followed for 2 years.

Results: The average weight loss was 12 BMI with the majority of the weight loss occurred in the first 6 months (9.1 BMI). At follow up, 73.9% of diabetic patients were cured, and 83.5% of pre-diabetic patients were cured within 24 months post-operatively ($p<0.01$). Reduction of BMI post-operatively was statistically significant ($p<0.01$) While only 38% of patients who lost 0-5 BMI were able to discontinue their pre-operative medications, 71% of those who lost 11-15BMI were medication free at 2 years.

Conclusions: Patients in all age groups were equally as likely to lose weight. Patients who lost more weight were more likely to discontinue pre-operative antiglycemic medications. This study is the first which demonstrates that surgical intervention is an effective modality in the treatment pre-diabetes.

Keywords: Diabetes mellitus; Pre-diabetes; Bariatric surgery; Obesity

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Introduction

Diabetes is associated with a tremendous disease burden and is the primary cause of limb amputation, kidney failure, and blindness in American adults[1]. Obesity is a significant contributor to the development of Type II Diabetes has recently been classified by a disease by the American Medical Association[2]. Effective management of hyperglycemia decreases healthcare costs, length of hospital stays, incidence of multi-organ failure, systemic infections, and mortality[3].

Diabetes and pre-diabetes (fasting blood glucose of 100-125 mg/dl or Hemoglobin A1c of 5.7-6.4%) are becoming increasingly more prevalent in the United States and world-wide. The CDC recently estimated that 11.3% or 25.6 million U.S. adults had diabetes in 2010. While CDC data from 2005-2008 reported that 35% of U.S. adults, or 79 million, had pre-diabetes[4]. While this enormous disease burden puts tremendous strain on healthcare resources, controversy exists over treatment in the management ofdiabetes.

The Diabetes Prevention Program (DPP) was one of the first large landmark initiatives to focus on pre-diabetes. The DPPhas shown that those at high-risk for developing diabetes can prevent disease by controlling weight and glycemic control with increased physical activity, diet, and Metformin use[1]. These findings of a multimodal approach in treatment were reiterated by the Look AHEAD trial[5]. Despite the increased focus on early treatment, these momentous publications did not specifically address the benefit of bariatric surgery as an early intervention, particularly in the pre-diabetic setting. However, the benefit of bariatric surgery on diabetic patients is well known[6,7].

Our objective is to evaluate the benefits of all patients, diabetic and pre-diabetic, after bariatric surgery. Outcome measures are BMI, need for antiglycemic medication, and diabetic status. Our hypothesis is that bariatric surgery will not only benefit those with diabetes, but those with pre-diabetes as well.

Methods

Patients

This was a retrospective chart review and was approved by the William Beaumont Army Medical Center Institutional Review Board. A list of patients who underwent either laparoscopic gastric bypass surgery or laparoscopic gastric band placement, from the years of 2007-2011 was produced by the Department of General Surgery at the same institution. Inclusion criteria were: having underwent one of the two aforementioned procedures between 2007 and 2011, having 24 month follow up which would include laboratory data, clinical notes to document active medication list, and clinical exam to include BMI. Exclusion criteria included those who did not have these follow up measures, pregnant women, and <18 years age.

Patient BMI, diabetes status, medication list, and demographic data were procured preoperatively. These patients were then followed at 6, 12, and 24 month follow up using the same factors. Clinical notes were reviewed from general surgery and internal medicine clinics for follow up parameters. Any changes to BMI, diabetes status, or active medications were then recorded over the time periods.

Diabetes Status

Patients were put into one of three categories: Diabetics (D), Pre-Diabetics (P), and Non-Diabetics or Cured (C). Patients were given one of these three diagnoses preoperatively as well as at terminal follow up depending on their diabetic status. The Diabetic group included patients with a Hemoglobin A1C of ≥ 6.5% or a fasting blood glucose of ≥126 mg/dl. The Pre-diabetic group included patients with a Hemoglobin A1C o 5.7 to 6.5% or a fasting blood glucose of 100 to 125 mg/dl. The Cured group included patients with a fasting blood glucose of ≤100 or A1C of <5.7%[8].

A patient was given two letters to determine their pre and postoperative diabetic status, D (Diabetic), P (Pre-diabetic), or C (non-diabetic or cured). Therefore there are 9 pre and post operative combinations for patients in this study: DD, DP, DC, PD, PP, PC, CD, CP, CC. Thus a patient who was diabetic before and after surgery was labeled DD, a patient who had diabetes pre-operatively but was pre-diabetic post operatively was labeled DP, a patient who had diabetes pre-operatively and was cured post operatively was DC, a pre-diabetic that progressed to diabetes was PD, a pre-diabetic that remained pre-diabetic was PP, a pre-diabetic that was cured as PC, a non-diabetic that became diabetic was CD, a non-diabetic that progressed to pre-diabetes was CP, and a non-diabetic that remained non-diabetic was CC.

Medication Status and BMI

Clinical notes were reviewed for active medication lists. There were 3 groups based on medication status. First, a group of patients who were on diabetic medication preoperatively then came off the medication at follow up was made. This would involve a patient taking either insulin or metformin or any other type of oral anti-glycemic medication preoperatively, but not at 24 month follow up. Second, a group was formed of patients who were on these medications preoperatively as well as post operatively. Finally, a third group included patients who were never on insulin or any type of anti-glycemic medication. BMI was recorded at all time points. The change in BMI was recorded by calculating the difference in BMI between two time points and recorded as change in BMI.

Statistical methods

Analysis to examine condition (diabetic, pre-diabetic, cured) during pre-intervention versus post-intervention: A McNemar-Bowker test was conducted to examine the change in the proportion of individuals labeled as pre-diabetic, diabetic, or "cured" before and after the surgery.

Analysis of Change in BMI over time by age: An analysis was performed to look at the statistical significance in change in BMI over time, and the significance of this change by age category. This analysis was conducted using a mixed between-within subjects analysis of variance (ANOVA). Age Category was the between subjects factor (looking at different groups of subjects), and BMI Change over the four time points under consideration was the within subjects factor (looking at same subjects at different points in time).

Results

193 patients met inclusion and exclusion criteria. There were 162 females and 31 males, 36 former military service members, 3 active duty service members and 154 military dependents (Table 1). The average age was 41.6 years. Preoperatively 56 patients were on diabetic medication and 39 patients or 69.6% of patients were able to discontinue their diabetic medication post-operatively (Table 2).

Table 1: Demographic data

Male	Female	Military	Dependent	<30 yrs	30-39 yrs	40-49 yrs	50-59 yrs	60-69 yrs
31	162	39	154	35	60	43	38	171

Table 2: Pre and post-operative medication status

Pre: metformin and insulin Post: No medication	Pre: metformin Post: No medication	Pre: insulin Post: no medication	Pre: metformin and insulin Post: metformin and insulin	Pre: metformin Post: metformin	Pre: insulin Post: insulin	No diabetic medication at any time
9	26	4	4	11	2	137

The average total weight loss was 12.0 BMI points. All BMI weight losses were statistically significant between time periods except for between 12 and 24 months follow up (Wilks lambda $p<0.01$) (Table 3). Patients were then grouped into decade of age and evaluated in terms of weight loss at these same four time periods. Overall patients in their 40s lost the most amount of weight, 13.4 BMI points. There was no statistical difference between the age groups in terms of weight loss (Wilks Lambda $p<0.026$) (Table 4).

Table 3: Average BMI loss of all patients in four time points, 0-6 months, 6-12 months, 12-24 months, and 0-24 months. All but 12-24 month time periods showed statistically significant change in BMI ($p<0.5$).

Average BMI loss pre-op-6 months	Average BMI loss 6- 12 months	Average BMI loss 12-24 months	Average BMI loss 0-24 months
9.1*	2.6*	0.3	12.0*

Table 4: Average weight loss in four time periods divided amount age groups. This data is not statistically significant.

	Average BMI loss pre-op6 months	Average BMI loss 6-12 months	Average BMI loss 12-24 months	Average BMI loss 0-24 months
<30 yrs	9.60	1.97	-0.20	11.37
30-39 yrs	9.10	2.35	0.37	11.78
40-49 yrs	8.93	3.67	0.79	13.40
50-59 yrs	9.29	2.38	0.079	11.76
60-69 yrs	7.76	2.47	0.412	10.65

Patients were grouped into categories by weight loss, in increments of 5 BMI points. The ability of these patients to come off of their diabetic medication was then evaluated. At 24 month follow up, 37.5% of the patients who lost 0-5 BMI points and were taking diabetic medication preoperatively were able to come off of their diabetic medication post operatively. 71.4% of the patients who lost 11-15 BMI points discontinued medication post-operatively. This data is not statistically significant (Table 5). 89% of the patients who were PC andtaking a diabetic medication pre-operatively discontinued medication after surgery (Table 6). While this data is not statistically significant, a McNemar-Bowker test was conducted to examine the change in the proportion of individuals labeled as pre-diabetic, diabetic, or "cured" before and after the surgery. The test showed a statistically significant change in the proportion of individuals labeled as "cured" after the surgery as compared to pre-surgery. ($p < .001$).

Table5: Pre and post-operative medication status is compared with the amount of weight loss. This data is not statistically significant.

	0-5 BMI points	6-10 BMI points	11-15 BMI points	16-20 BMI points	>20 BMI points
Pre: metformin & insulin Post: no medication	1	2	5	1	0
Pre: metformin Post: no medication	2	9	9	6	0
Pre: insulin Post: no medication	0	2	1	1	0
Pre: metformin & insulin Post: metformin & insulin	0	3	1	0	0
Pre: metformin Post: metformin	4	3	4	0	0
Pre: insulin Post: insulin	1	0	1	0	0
Pre: no medication Post: no medication	21	21	34	39	12
Number of patients per BMI loss group	29	50	55	47	12
Number of patients per BMI loss group that came off of medication	3	13	15	8	0
Number of patients per BMI loss group that remained on medication	5	6	6	0	0
Number of patients per BMI loss group that were on medicine before surgery	8	19	21	8	0
Percentage of patients per BMI loss group were on medication and came off of medication post-operatively	0.38	0.68	0.71	1	1

Table 6: Pre and post-operative medication status is compared with diabetes status and post-operatively. This data is not statistically significant.

	DD	DP	DC	PD	PP	PC	CD	CP	CC
Pre: metformin & insulin Post: no medication	1	2	2	0	1	3	0	0	0
Pre: metformin Post: no medication	1	3	9	1	1	4	0	1	4
"Pre: Insuli Post: no medication"	1	0	2	0	0	1	0	0	0
Pre: metformin & insulin Post: metformin & insulin	1	0	2	0	1	0	0	0	0
Pre: metformin Post: metformin	1	1	6	2	0	1	0	0	0
Pre: Insulin Post: Insulin	1	0	0	0	0	0	0	0	1
Pre: no medication Post: no medication	0	0	26	3	5	62	0	2	35
Number of patients per Diabetic group that took medication pre-operatively and came off medication post-operatively	3	5	13	1	2	8	0	1	4
Number of patients per Diabetic group that took medication pre-operatively and post-operatively	2	1	8	2	1	1	0	0	1
Number of patients per Diabetic group that never took medication pre-operatively nor post-operatively	1	0	26	3	5	62	0	2	35
Total Number of patients per Diabetic group	6	6	47	3	8	71	0	3	40
Total number of patients per Diabetic group that took medication pre-operatively	5	6	21	3	3	9	0	1	5
Percentage of patients who took medication pre-operatively and came off medication post-operatively	0.6	0.83	0.62	0.33	0.67	0.89	0	1	0.8

Discussion

Successful treatment of diabetes with bariatric surgery is well studied. Renard, et al.[9] reported improved glycemic control, reduced insulin resistance, and weight loss for diabetic patients post bariatric surgery. Arterburn[10] found that 68.2% of

patients experienced complete diabetes remission even 5 years post bariatric surgery, and of these only 35.1% had recurrence of diabetes within 5 years.Furthermore, the milestoneSTAMPEDE trial showed that bariatric surgery in obese Type 2 diabetics resulted in improved glycemic control compared to medications alone. Those patients that underwent bariatric surgery lost more weight and had lower Hemoglobin A1c levels than their counterparts on anti-glycemic medications alone[11].

Our analysis was novel as it captured a cohort of pre-diabetic patients. Private insurance may not often offer bariatric surgery in the United States for this population which may not meet the BMI or comorbid disease requirement. This study was conducted at a large military medicalteaching hospital. Medical care is free to active duty soldiers and dependents alike and surgeons are able operate on any patient who they believe may benefit from bariatric surgery. Thus patients with neither significant co-morbidities nor active diabetes are able to electively undergo surgery in our facility, making our population unique compared to what has previously been reported in the literature.

In addition to the high prevalence of non-diabetics that underwent surgery, our cohort was also quite young. Most patients were wives of active duty soldiers; however one fifth of our population consisted of active duty soldiers or retired servicemembers. Patients in each age category experienced considerable weight loss and there was no statistical difference in weight loss between all of the age groups (Table 4). This finding suggests that patients younger than 30 and older than 60 may benefit tremendously.

The average weight loss was 12 BMI points (Table 3). While 75% of the weight loss occurred in the first six months; there were nearly no gains made in the second year of follow up. We would encourage a team based approach post-operatively with especially close follow up in this time period. Regular visits with the surgeon as well as internal medicine, dieticians, nutritionists, and exercise therapists can maximize the benefit from bariatric surgery. Telephone calls as well as group sessions should be encouraged.

While the correlation between BMI and cessation of diabetic medication was not statistically proven in this study, our data is clinical significant (Table 5). 71% of the patients that lost 11-15 BMI points and who were taking medication pre-operativelydiscontinued their medication post-operatively, while only 38% of patients who lost 0-5 BMI discontinued medication post-operatively. With only 193 total patients, the lack of power inhibits our analysis. However it is clinically relevant that the more weight a patient can lose, the higher likelihood that he or she will be able to discontinue their antiglycemic medication. Additionally, the status of one's diabetes is also a proxy for medication discontinuation (Table 6). Of the patients who went from pre-diabetic to cured, 89% discontinued medication. In addition there was a statistically significant change in the proportion of individuals labeled as "cured" after the surgery as compared to pre-surgery ($p < .001$).

There were several limitations to our study, the most notable of which is lack of power. There was a lack of power necessary to expound statistical differences between BMI and change in medication status (Table 5) and diabetic status and medication status (Table 6). The largest contributing factor to the limited power was that a majority of our patients were not taking medication pre-operatively. Many of our patients may not have received surgery at a civilian medical center as an untreated pre-diabetic. Also contributing to the limited power of our study was the military setting. Patients who are overweight are removed from the military, leaving our cohort dominated by military family members. A second limitation is follow up. Patients who did not complete 2 year follow up were excluded.This is due to the military population that often moves from post to post and may be lost to follow up. Also soldiers and their dependents are often lost to follow up when soldiers leave the active duty service.A third limitation to the study is external validity. Our data may not be completely transferable to general management of a long-standing diabetic in a civilian population. We treated younger, pre-diabetics, often times who were currently taking neither metformin nor insulin. Despite the challenge of external validity, this population allows us insight in the early, aggressive treatment of the young, pre-diabetic patient.

The indications for surgical interventions for gastric bypass are evolving. Maggard-Gibbons, et al.[12] demonstrated that performing gastric bypass in patients with BMI 30-35 resulted in significant weight reduction and improved glucose control. Ikramuddin, et al.[14] recently demonstrated that Roux-en-Y bypass in addition to lifestyle and medical treatment resulted in achieving target weight loss and glycemic control much more frequently than lifestyle and medicine alone[13]. Diet, physical activity, and oral anti-diabetic medications should remain the cornerstone the medical management of diabetes. However, with a rapidly expanding American diabetic and pre-diabetic population, aggressive management of this disease may be warranted in an effort to prolong life, increased quality of life, and reduce health care expenditures by eliminating the need for costly hospitalizations, visits to specialists, and years of diabetes medications.

The results of this study highlight the benefit of bariatric surgery to both diabetic and non-diabetic patients alike. While this study may not have been possible under a private-payer circumstance, the unique military population permitted the study and treatment of pre-diabetic patients with bariatric surgery. Further research should be directed at prospective investigation of pre-diabetic patients, which would provide more specific data analysis. To the best of our knowledge; this is the first study in literature to evaluate using preventative bariatric surgery in pre-diabetic patients. Surgical intervention may benefit patients of all ages, with or without diabetes or comorbidities through significant weight loss, improved glycemic control, and discontinuation of medications. This additional modality may prove a valuable resource in the age of healthcare resource limitations.

Conflicts of Interest: None

Funding source: None

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