Increasing Awareness and Consideration of Bariatric Surgery Treatment Option in Obese Type 2 Diabetes Mellitus Patients

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Presented to

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In partial fulfillment of the requirements of

N6621 DNP II

THE UNIVERSITY OF TEXAS AT ARLINGTON

COLLEGE OF NURSING AND HEALTH INNOVATION

November 30, 2016
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Abstract

Background:

Current research indicates the efficacy of bariatric surgery (BS) in the treatment of obese Type 2 Diabetes Mellitus (T2DM) patients, but only a few actually get this treatment option. This is evident when a comparison of the prevalence of T2DM and obesity is compared to the actual number of surgeries conducted. The American Society of Metabolic and Bariatric Surgery (ASMBS) states that less than 1% of eligible patients (general) have access to BS. The option most frequently considered to manage obesity and T2DM (i.e. lifestyle modification), is ineffective and results in weight regained in an average of 4 years.

Method/Data source:

The purpose of this quality improvement project was to increase provider awareness regarding BS for the treatment of obese individuals with T2DM. An evidence based protocol was implemented that included offering information and the option of BS to treat adult obese patients with T2DM. Documentation of patient education regarding BS was obtained from a random sample of medical records pre and post intervention.

Results:

Forty-four (44) and forty-one (41) charts were reviewed pre and post intervention respectively. Pre-intervention none of the charts reviewed had evidence of documentation of BS as a treatment option. Post intervention 83% (34/41) of the charts had BS education documented. Of the patients offered the BS option 56% (19) opted for BS. Of the 44% (15) who refused, more than half (8) was due to the fear of surgery. Of note is that the diagnosis of obesity was not documented in 80% of the charts reviewed pre-intervention and post-intervention 49% of the charts reviewed did not have obesity as a listed diagnosis.

Conclusion and implications:

Current evidence shows BS results in significant improvement of T2DM, compared to current medical therapy with lifestyle modification. Despite this evidence, the option of BS is often not included in provider patient education. This QI project suggests that if patients are given the option more than half of the patients will consider BS as their treatment option. Based on the epidemic nature of T2DM, increased awareness is necessary among clinicians for the consideration of BS to treat obese T2DM patients, and help improve patient access.
Increasing Awareness and Consideration of Bariatric Surgery Treatment Option in Obese Type 2 Diabetic Mellitus Patients.

Diabetes Mellitus (DM) is a chronic, progressive and debilitating disease affecting approximately 422 million people worldwide, and it is the leading cause of death in the world. In 2012 diabetes was the direct cause of 1.5 million deaths and another 2.2 million deaths from less than optimal blood glucose levels. (World Health Organization – WHO, 2016). In 2012 there were approximately 29.1 million Americans with Diabetes Mellitus, the majority (90-95%) of whom have Type 2 Diabetes Mellitus (T2DM) (Center for Disease Control and Prevention - CDC, 2014. Diabetes is listed as the 7th leading cause of death in the United States (US) American Diabetes Association – ADA. (2015). ADA reports suggest that this statistic may be this low due to underreporting of Diabetes as a cause of death in as much as 60 to 65% of the time.

Studies indicate that obesity is associated with an increased risk of diabetes (Mokdad et al., 2001). Data from the National Health and Nutrition Examination Surveys (NHANES) completed during the years 1976 to 2006 of representative samples of the U.S. population between the survey periods 1976-1980 and 2005-2006, indicated that there was a 141 percent increase in the rate of morbid obesity among adults with Type 2 diabetes (CDC/National Center for Health Statistics, 2016).

Obesity and Type 2 Diabetes Mellitus

Dixon, Le Roux, Rubino and Zimmet (2012) reported that more than 60% of T2DM patients are obese. Obesity is defined as a medical condition in which body fat is accumulated to the extent that it produces an adverse effect on health. It is usually measured using the body mass index.
(BMI) of 30.0 or higher; and "extreme" or "severe" obesity is a BMI of 40 or greater (CDC, 2014). Lifestyle interventions with diet therapy, exercise and pharmaco-therapeutics have only shown a modest improvement in both diabetes and weight loss, and most times the successes both in weight and glucose control are not sustained (Rubino, Moo, Rosen, Darkin and Pomp, 2009). Some hypoglycemic medications such as Insulin and Thiazolidinedione have been shown to contributes to weight gain (Yadgar – Yalda, Colman, Fourlanos, and Wentworth, 2016) hence the difficulty in the management of these comorbid diseases.

Bariatric Surgery (BS) is a relatively new addition to clinical practice guidelines for the treatment of obese T2DM patients. It was added in the year 2011, as evidence showed that BS led to significant improvement of hyperglycemia and in some case remission of T2DM. Current research also indicated that very few providers consider this treatment option. The evidence prompted the development and implementation of a quality improvement protocol to heighten awareness of BS as a treatment option (increase stakeholder buy-in) and ultimately increase the number of patients who opt for this treatment, resulting in improved patient outcomes.

Purpose

This project involved the development and implementation of an evidence-based quality improvement protocol for obese T2DM patients seen in a primary care outpatient setting (a family practice clinic). The protocol offered information to patients in the target group, providing them the option for consultation for BS. The goal was to increase provider buy-in and patient knowledge by creating a heightened awareness with stakeholders on the efficacy of BS in the treatment of T2DM and obesity. Heightened awareness was to encourage providers to consider/recommend this treatment option, increase patient referrals for BS and aid compliance
BARIATRIC SURGERY TO TREAT OBESE T2DM PATIENTS

with both the American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association (ADA) current clinical practice guidelines.

Literature review

A review of the literature shows that BS is an effective treatment of T2DM resulting in improved glycemic control and in some cases remission of DM. BS has also been shown to result in benefits such as weight reduction, improved blood pressure, and improved lipid levels in patients, with a subsequent improvement in the rates of cardiovascular disease, and mortality.

Bariatric Surgery versus Medical Therapy

Studies which compared BS with medical therapy for the treatment of obese T2DM establish that BS is more effective than medical therapy for the treatment of obese patients with uncontrolled T2DM. Mingrone et al. (2012), studied 60 T2DM patients ages 30 to 60 with BMI of 35 or higher, who were randomized to undergo either BS (gastric bypass or biliopancreatic diversion) or conventional medical therapy (oral hypoglycemic agents, diet and lifestyle modifications, and increased physical activity). At the end of 2 years, no diabetes remission occurred in the medical treatment group compared to 75% in the gastric-bypass group and 95% in the biliopancreatic-diversion group.

Schauer et al. (2014), studied 150 obese T2DM in the Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) trial. Participants were between ages 20 to 60 years, randomized to intensive medical therapy alone versus intensive medical therapy (exact treatment not specified) plus BS (Roux-en-Y gastric bypass or sleeve gastrectomy). Glycated hemoglobin level (A1c) of 6.0 was considered to be evidence of T2DM remission. After 12 months, of the 93% of the patients who completed the study, 12% in the medical
therapy group had A1c less than 6.0 compared to 37% in the sleeve gastrectomy and 42% in the gastric bypass group. At 3 years, 5% were in remission in the medical therapy group, 24% in the sleeve gastrectomy group and 38% in the gastric bypass group. The trial showed that participants in the two BS groups had a greater remission rate than intensive medical therapy alone.

In a randomized control trial of 667 potential participants who were screened, 69 participants were randomized to BS versus medical therapy options. Participants were between the ages of 25 to 55 years, and were obese (BMI between 30 and 40) with T2DM. The study evaluated the two dominant bariatric surgery procedures Roux-en-Y gastric bypass (RYGB) and Laparoscopic Adjustable Gastric Banding (LAGB) against an Intensive Lifestyle Weight Loss Intervention (LWLI) for managing obese T2DM patients. Remission (partial and complete) of T2DM was based on 2009 ADA guideline. At 1 year, partial and complete remission of T2DM were 50% and 17% respectively in the RYGB group, 27% and 23% respectively in the LAGB group; no remission was found in the LWLI group. The study noted difficulty in completing a large randomized control trial (RCT) that randomized patients to surgery versus no surgery. Of the 69 randomized patients 7 refused to underdo their allotted intervention (3 RYGB, 1 LAGB, 3 LWLI). Courcoulas et al. (2014).

The Look AHEAD (Action for Health in Diabetes) study of 5,145 adults with T2DM and BMI > 25, tested an intensive lifestyle modification program that included sessions with nutritionists and trainers (Curtis et al, 2010). Participants in the intervention group lost over ten times as much weight on average versus non-participants (mean 8.6% versus 0.7%). However almost all the participants had regained the weight after four years.
Long term effects of Bariatric Surgery on Type 2 Diabetes Mellitus

Brethauer et al., (2013) studied the clinical outcomes of 217 patients with T2DM who underwent BS (2004 to 2007) and had at least five years of follow-up. An improvement of A1c of 1% from baseline was found in 34% of the patients. Remission of T2DM occurred in 24% and no change was noted in 16% of the patients. This study suggested that long-term rate of T2DM remission with bariatric surgery may not be as high as suggested in prior short-term studies.

Pignone (2011) conducted a retrospective times series study of 2,235 obese patients who underwent BS between 2002 and 2005. Prior to surgery 85.8% were on at least one diabetic medication. After BS, the patients needing at least one diabetic medication had reduced to only 15.5 % at 24 months.

The Swedish Obese Subjects (SOS) study, compared 2,010 obese patients who underwent BS against 2,037 comparable patients receiving conventional treatment therapy (standard Swedish nonsurgical obesity treatment); namely active lifestyle interventions that included patient counseling. Patients included had varying BMI levels. Patient ages ranged from 37 to 60 years. Mean changes in weight and incidence of T2DM were evaluated at 2, 10, 15 and 20-year intervals. The SOS study found BS to be effective in reducing the incidence of T2DM compared to conventional treatment therapy. Percent of reduction in T2DM in the BS group was 73% in patients with BMI ≥ 35, and 67% in patients with BMI <35, after 15 years of the study. This result compared with 58% in the active lifestyle modification group after 4 years which had reduced to 36%, three years after counseling had stopped. The results of this study also suggested that high BMI is not the optimal basis for eligibility for BS as significant improvement was found in BMI less than 35 (Sjöholm et al., 2013).
Systemic Reviews and Meta-Analysis

A meta-analysis by Cummings, Overduin, Shannon and Foster-Shubert (2005), reviewed 5 large studies with a total of 35,568 diabetic patients who had Roux-en-Y gastric bypass (RYGB). Results of the analysis indicated that patients experienced complete disease remission at rates of ~83% of the cases (82% to 98%) compared with a small weight gain in the control group.

Another systematic review and meta-analysis of 621 studies conducted by Buchwald et al. (2009), included 135,246 patients with multiple BS treatments. The researchers concluded that manifestations of T2DM were resolved or improved in the majority of the obese patients after weight loss surgery. Report findings indicated 78.1% had complete resolution, and 86.6% had improved glycemic control. It is worthy to note that these results were sustained long term up to 16 years regardless of the type of surgical procedure.

Clinical Practice Guidelines

Table 1 below compares the 2015 guidelines of AACE and ADA for BS as a treatment for obese T2DM patients. The guidelines are similar with the exception of baseline BMI. The AACE recommends BS for T2DM patients with BMI > 30 while ADA recommends it for BMI >35. The ADA stance is that there is insufficient evidence to support recommending surgery for BMIs <35.
Table 1. ADA and AACE guidelines comparison table.

<table>
<thead>
<tr>
<th>2015 ADA GUIDELINES</th>
<th>2015 AACE GUIDELINES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consider for adults with BMI &gt; 35 kg/m(^2)</strong></td>
<td>Consider for adults with BMI &gt;30 kg/m(^2) who have not achieved optimal medical regimen especially cardiovascular risks (international DM foundation IDF)</td>
</tr>
<tr>
<td>Insufficient evidence to recommend surgery for BMI&lt;35 kg/m(^2) outside of a research protocol</td>
<td>Consider for patients with BMI &gt;40 kg/m(^2) unless surgery would pose significant risk (AACE, ASMBS, TOS)</td>
</tr>
</tbody>
</table>

**Advantages**
Achieves near or complete normalization of glycemic control 2 years post-surgery 72% compared to 16% in the control group treated with lifestyle and pharmacological intervention

**Advantages**
Marked reduction in A1c and need for DM medications and can result in DM remission. 72% remission rate at 2 years and 30% at 15 years post-surgery. AHEAD trial. In the STAMPEDE (Surgical Therapy and Medications potentially eradicate Diabetes Efficiently) trial. Glycemic control in subjects with T2DM was improved compared with medically treated patients

**Disadvantages**
Cost
Osteoporosis
Associated risk
Variable outcomes depending on procedure
Long term vitamin/mineral deficiencies
Severe hypoglycemia from insulin

**Disadvantages**
High mortality risk due to surgical and nutritional complications. (However recent surgical improvements including laparoscopic approaches have improved outcomes)

Lifelong lifestyle support and medical monitoring are necessary post-surgery

Lifelong medical follow-up and adherence to ongoing lifestyle modifications for optimal outcomes.
Clinician perspective on Bariatric Surgery as treatment for obese Type 2 Diabetes Mellitus

BS is a recent addition to the T2DM treatment guidelines. One study was found that addressed provider perspectives regarding BS as a treatment for T2DM. Physicians were surveyed from two clinic settings, a medical center and a community-based clinic. A total of 339 physicians were surveyed about their attitudes and the efficacy of BS for treating obesity and T2DM. Although the survey response was low at 27.4%, 67% of the respondents reported a positive outlook on BS as a treatment for T2DM. However only 20.8% recorded a likelihood of referring their patients for BS (Sarwer et al., 2012).

Public Perception of BS as treatment of obesity and Type 2 Diabetes Mellitus

A study by Sarwer et al. (2013) evaluated the general public's attitudes toward BS for the treatment of obesity and T2DM. Of the 513 obese T2DM patients surveyed, 130 responded. The patients were surveyed about their perception of the safety and efficacy of BS as a treatment for obesity and T2DM, and their willingness to receive a surgical procedure. Only 20.3% of the respondents had a positive view of BS, 14.3% considered it safe and 28.5% considered BS an effective treatment for T2DM. Only 16% of the respondents were willing to undergo BS for the treatment of T2DM.

Another study (a German study) evaluated the general public attitudes towards BS for weight loss/obesity management. The study was conducted by computer-assisted telephone interview of 1008 persons. Results indicated that 50% of the persons interviewed had “an effective” view of BS for weight loss, but 72% would not recommend it or undergo the procedure (Sirkorski et al., 2013).
Project Framework

The W. K. Kellogg Foundation logic model (2014), was used to develop a framework for this project. A progressive logic model that follows the format below:

Project input includes the stakeholders, namely the providers in the primary care outpatient setting, its clinical administrators, clinic support staff, patients and their family members, local bariatric surgeons and insurance companies. The project activity involved the implementation of a Quality Improvement protocol that focused on increased provider buy-in, for educating and
recommending BS as treatment option for obese T2DM patients, as recommended by the AACE and ADA clinical practice guidelines.

Output was heightened awareness both with clinicians and patients alike on the efficacy of BS in treating obesity and T2DM and referrals for consultation with a Bariatric Surgeon. It is hoped that this goal would ultimately lead to improved patient outcomes including improvement and/or remission of T2DM and obesity and other commodities such as hypertension, hyperlipidemia, kidney disease and mortality as indicated by the evidence. The Kellogg logic model includes a fifth impact step which was not address in this project due to time limitations.

Project Aims

This project had three specific aims.

1. To create an evidence-based protocol that would allow for bariatric surgery to be considered as a treatment option for obese T2DM patients (BMI 35 or greater) in an outpatient setting

2. Have providers educate patients on the efficacy of bariatric surgery and consider it as treatment option for obese T2DM patients

3. Increase compliance with AACE and ADA clinical practice guideline for the treatment of obese T2DM patients with the ultimate goal of improved patient outcomes.

Design and Method

This was a pre and post intervention evaluation of obese T2DM patient chart review to determine if education had been provided with information about the efficacy of BS and given an opportunity to opt for BS as a treatment option. Adult patients, ages 18 and older with BMI ≥ 35 and A1c of 6.5 or greater who were seen in the month of September 2016 were compared with
same demographic seen at the same clinic in the same month the year before (September 2015). Participants were excluded if they were in the clinic for acute episodic issues where DM was not discussed or no recent lab had been completed at the visit that month.

The quality improvement (QI) protocol was established according to ADA and AACE clinical practice guidelines to educate patients and provide them the option to treat their uncontrolled DM and obesity with BS. Permission to conduct the study was obtained from the clinic’s medical director (Appendix A). IRB approval was not required as this is a quality improvement project that did not require investigator direct contact with patients, and no personal patient data was used.

An education material was developed, which explained current medical treatment (including medication therapy and lifestyle modifications), and its limitations. The document also emphasized the efficacy of BS based on current evidence and provided the patient the opportunity to opt for BS (Appendix B). The document was translated to Spanish (from clinic staff feedback) because of the high proportion of non-English speaking Hispanics in the patient population (Appendix C). Post intervention a random sample of patients who met the target group and had been seen in Sept 2016 was reviewed. Charts were reviewed to determine if the patients had been educated on the efficacy of BS and provided the option to opt for it. A chart audit tool was used (Appendix D). The patients’ responses or reasons for not choosing this option was noted as well.

Providers and medical assistants who staff the clinic were educated on the QI protocol. Three Nurse Practitioners (NP) and 4 medical assistants (MA) were educated before the implementation of the QI protocol. Educational documents used included the introduction to the
project document (Appendix E), Protocol for obese T2DM (Appendix F), Project Data Points
document (Appendix G) and Patient education documents (Appendices B and C). The clinic is
usually staffed by one provider when open. The three providers included all providers who
rotate coverage on the clinic schedule.

The chart reviews evaluated whether the patients had been educated on the benefits and
effectiveness of bariatric surgery and offered the option of referral for a consultation for BS with
a bariatric surgeon. Consideration for bariatric surgery was determined to be complete if the
educational material was in the chart and provider documented that it was addressed and patient
was referred for BS if appropriate. Additional data including patient age, sex, insurance
coverage and diagnosis of DM or obesity were collected for analysis.

Clinic setting, Administration and Staffing

The setting was an outpatient family practice clinic with three rotating NPs, 4 medical assistants
and a clerk. One provider, two Medical Assistants and a clinic clerk were on duty at a time. The
medical assistants completed patient vital signs, screenings, labs and injections. Current practice
included patients having routine vital signs measured, as well as having their BMI calculated and
documented before the provider visit. The provision of the BS education document to patients
who met the target group was added to the MA responsibilities during completion of vital sign
measurement. Providers were responsible for the appropriate diagnosis of the patient with
T2DM and obesity, educating them on the benefits of bariatric surgery, and the efficacy of
weight loss surgery as a treatment option. After a patient received a recommendation for
consultation the clinic clerk was responsible for considering local bariatric surgeons in the
vicinity that accept patient’s insurance and referring them as appropriate.
Population and sampling

The target group consisted of adult patients with BMI of 35 and greater with uncontrolled T2DM (HbA1c > 6.5). Fifty (50) random charts were sampled pre and post intervention before exclusions. After exclusions 44 charts pre intervention and 41 post intervention were reviewed. Pre intervention the clinic was staffed by two NPs and a Physician Assistant (PA). Post intervention, staff included 3 NPs. The two NPs from the pre intervention chart audits were included in the post intervention chart audits.

Measurement

The investigator conducted pre and post protocol implementation chart reviews. The review evaluated whether obese T2DM patients were educated and given the option of BS for treatment of their obesity and T2DM. Data was collected on the Chart Audit Tool (Appendix D) and entered into Excel spreadsheets for analysis and comparison. The charts compared were from the same patient population. No attempt was made to follow the same patients or to match patient characteristics.

Data collection and analysis

Data from the chart review addressed the items on the protocol (Appendix F). The data collected was assigned a weighted score of (e.g., 0, 1 or 2) and entered into an Excel spreadsheet for analysis. Patient personal information such as name, date of birth, social security numbers and contact information were not collected.
Project timeline

Staff meetings and trainings occurred in July and August of 2016 and the protocol was implemented in September 2016. Post implementation sample data was obtained in the third and fourth weeks of October 2016. Project results including findings and recommendations were presented in November 2016.

Results and Findings

Population

All charts reviewed were of adult obese T2DM patients with BMI equal or greater than 35 and A1c of 6.5 or higher. The patients were between the ages 19 to 78 years old. The highest percentage of patients were in the 49 - 58 years old range, with 48% in the pre intervention and 54%, in the post intervention group (Table 2). Race distribution included 75% to 76% Hispanics, 14% to 17% Black and 11% to 7% White in the pre and post intervention groups respectively. There were more females than males in both groups. The pre intervention group was 59% female (26) and 41% male (17). The post intervention group was 66% (30) female and 34% (14) male. Table 2 shows the age distribution and demographic characteristics of the patients in the groups pre and post intervention.
Table 2: Socio Demographic Characteristics of Groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pre Intervention Group</th>
<th>Post Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>AGE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 - 28</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>29 - 38</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>39 - 48</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>49 - 58</td>
<td>21</td>
<td>48</td>
</tr>
<tr>
<td>59 - 68</td>
<td>11</td>
<td>25</td>
</tr>
<tr>
<td>69 - 78</td>
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<td>2</td>
</tr>
<tr>
<td>79 +</td>
<td>1</td>
<td>2</td>
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<tr>
<td>Total</td>
<td>44</td>
<td>100</td>
</tr>
</tbody>
</table>

GENDER

<table>
<thead>
<tr>
<th></th>
<th>Pre Intervention Group</th>
<th>Post Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Male</td>
<td>18</td>
<td>41</td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>59</td>
</tr>
<tr>
<td>Total</td>
<td>44</td>
<td>100</td>
</tr>
</tbody>
</table>

RACE

<table>
<thead>
<tr>
<th></th>
<th>Pre Intervention Group</th>
<th>Post Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Blacks</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td>Hispanics</td>
<td>33</td>
<td>75</td>
</tr>
<tr>
<td>Whites</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>44</td>
<td>100</td>
</tr>
</tbody>
</table>

Pre intervention patients’ A1c ranged from 6.5 to 13.7 with an average A1c of 8.39 (7 charts had A1c higher than 10.0). Post intervention A1c range was between 6.5 and 12.5 with an average A1c of 8.07 (9 charts had A1c values higher than 10.0). Patient BMI ranges also varied. Pre intervention patient BMI ranged from 35-48 with an average BMI of 39 (10 patients had BMI over 40). Post intervention BMI ranges were from 35-74 with an average BMI of 42, (7 in the 40s, 4 in the 50s and one BMI of 74). Table 3 provides BMI data with associated A1c pre and post interventions. The 35 to 39 BMI range was the most prevalent in both groups. The most prevalent A1c was 6.5 – 8.0 range, followed by 8.1 – 10.
Table 3: Patient BMIs with Associated A1cs

<table>
<thead>
<tr>
<th>Pre Intervention Group</th>
<th>Post Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI A1c n</td>
<td>BMI A1c n</td>
</tr>
<tr>
<td>35-39 6.5-8.0 19</td>
<td>35-39 6.5-8.0 18</td>
</tr>
<tr>
<td>8.1-10.0 11</td>
<td>8.1-10.0 4</td>
</tr>
<tr>
<td>10.1-12.0 4</td>
<td>10.1-12.0 5</td>
</tr>
<tr>
<td>12.1-14.0 0</td>
<td>12.1-14.0 1</td>
</tr>
<tr>
<td>40-44 6.5-8.0 0</td>
<td>40-44 6.5-8.0 4</td>
</tr>
<tr>
<td>8.1-10.0 5</td>
<td>8.1-10.0 0</td>
</tr>
<tr>
<td>10.1-12.0 0</td>
<td>10.1-12.0 0</td>
</tr>
<tr>
<td>12.1-14.0 2</td>
<td>12.1-14.0 1</td>
</tr>
<tr>
<td>45-49 6.5-8.0 3</td>
<td>45-49 6.5-8.0 2</td>
</tr>
<tr>
<td>8.1-10.0 0</td>
<td>8.1-10.0 0</td>
</tr>
<tr>
<td>10.1-12.0 0</td>
<td>10.1-12.0 0</td>
</tr>
<tr>
<td>12.1-14.0 0</td>
<td>12.1-14.0 0</td>
</tr>
<tr>
<td>50+ 6.5-8.0 4</td>
<td>8.1-10.0 1</td>
</tr>
<tr>
<td></td>
<td>10.1-12.0 0</td>
</tr>
<tr>
<td></td>
<td>12.1-14.0 1</td>
</tr>
<tr>
<td>Total 44</td>
<td>41</td>
</tr>
</tbody>
</table>

Protocol Implementation

Charts reviewed included 44 pre protocol implementation and 41 post implementation. Pre implementation, none of the 44 charts reviewed reflected that patients had been informed of the efficacy of BS or had been considered for that option in the treatment of T2DM or obesity. Only 14 of the 44 charts reviewed had documentation reflecting that the patient had received recommendations for lifestyle modification.

Post intervention 83% of the patient charts reviewed (34), had documentation that patients received education and consideration for the option of BS. Of these patients 56% (19) agreed to
be referred for a consultation to a bariatric surgeon. Of the remaining 44% (15) who received the education and BS option, 8 patients refused the option because of the fear of surgery; 2 reported a concern regarding the cost of the procedure or not being able to afford it. The remaining 5 patients who refused did not believe they were “that big” or felt that they were already losing weight on their own even though their BMIs were elevated (between 38 and 48).

In addition, 80% of the patients (35) pre implementation did not have a documented diagnosis of obesity in the chart, meaning only 20% had been correctly diagnosed as obese. Post intervention appropriate diagnosis of obesity documentation had increased from 20% to 51%. (Table 4).

Table 4: Documentation of Diagnosis of Obesity and Diabetes

<table>
<thead>
<tr>
<th></th>
<th>Pre Intervention</th>
<th>Post Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Obesity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9</td>
<td>20</td>
</tr>
<tr>
<td>No</td>
<td>35</td>
<td>80</td>
</tr>
<tr>
<td>Total</td>
<td>44</td>
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Limitations

This project had several limitations. The first being the small sample size, and the specific demographic of the sample. The project site was located in a middle to low income neighborhood, and it has a relatively high percentage of Hispanics (75%) which may limit the generalization of the results. Secondly, sample data was obtained over a short timeframe. Third, data could not be matched, because of time limitation and variance in clinic visits. Lastly, follow up could not be done with the patients referred for bariatric surgery consultation, to establish the
effectiveness of the protocol and whether or not a resultant improvement had occurred in patient outcomes. This is because direct contact was not made with patients, and no personal data was collected limiting the possibility of patient follow up.

Discussion

The results of this QI project emphasize the need to heighten provider awareness on the efficacy of BS and to increase provider consideration of this option for treatment of obese T2DM patients. Results reflect that obese T2DM patients are not being provided the treatment option per current treatment guidelines. The current evidence indicates that BS is significantly effective for improvement and sometimes remission of both disease T2DM and obesity, but the option is not being considered even though the clinical practice guideline was implement more than five years ago. Pre intervention, 100% of the patients, had not been considered for this option and 80% of the time these diabetic patients had not even been diagnosed with obesity when indicated. This seems to agree with data from the America Society of Bariatric and Metabolic Surgery – ASBMS (2015) which states that less than 1% of patients eligible for BS therapy have access to it.

A review of three major insurance company’s policies on BS for treating obese T2DM revealed the unlikely approval of the procedure for most of the eligible patients. One of the companies does not have coverage for the procedure at all; the other two require documented proof of treatment failure after 6 to 9 months of intensive medical therapy (including lifestyle modifications). If obesity is not addressed or documented up to 80% of the time (pre intervention data), the likelihood of the patient being able to obtain insurance coverage even
when it is an available option is poor, due to lack of needed documentation. The lack of
documentation limits patient access to the BS option.

Another limiting factor was the issue of patient fear of surgery, which can be addressed with
better education at the clinic level and by the BS clinics. Recent advancements in surgical
procedures have resulted in significant improvements and limited complications. An example is
the introduction of the mini sleeve gastroplasty with no mortality noted and documented
complications as low as 2%. Providing patient education on advancements in BS procedures and
reduced rate of complication would likely alleviate patient fears and increase the number of
patients who would opt for this treatment.

Conclusion

With the rate of increase in the co-morbid diagnosis of T2DM and obesity, it is imperative that
more clinicians change their mindset and make a concerted effort to improve clinical practices to
align with current evidence and clinical practice guidelines, making BS more accessible for
treating obese T2DM patients. Without a change in practice, access to an evidence based
effective treatment option, will continue to be limited either through the lack of consideration by
their clinician or inability to access due to cost or perceived risk.

Implications

Practice

It is imperative that clinicians take concrete steps to stay current with clinical practice guidelines
that apply to their patient population. Developing protocols and standards of operation (SOP)
that ensure the best available care options contributes to the best possible patient outcomes. It
might be helpful to secure the services of practice facilitators in developing clinical SOP and
protocols that would help clinicians keep abreast of applicable practice guidelines. Practice
Facilitators are healthcare professionals who serve as a resource to primary care clinicians in the
development of evidence based interventions. They function in the practice level
implementation phase of research projects enhancing continuous quality improvement projects
that help raise awareness, and improve knowledge for proper implementation of practice
guidelines (Nagykaldi, Mold & Aspy, 2005). Routine follow up by these facilitators would also
help to keep clinicians updated on applicable clinical practice guidelines and of any needed
service improvements is their clinical practice.

For Policy

The project shows that it is not enough to have established evidence-based clinical practice
guidelines. Additional efforts are needed to ensure compliance with them. Coleman and Nicholl
(2001) suggested that evidence based guidelines were more likely seen to have contributed to
decisions of public health specialists and commissioners than to clinicians in the primary care
setting. Appropriate information and dissemination systems that increase awareness and use of
evidence based guidelines in the primary care setting should be developed.

The provision of necessary resources at policy-making levels to require compliance with
evidence based practice guidelines is indicated. An example of such was the policy that
changed Medicare reimbursement for hospital-acquired conditions (HAC). It increased
awareness for the prevention of HACs, and encouraged the quality of care provided to Medicare
patients. The policy had the desired effect as it reduced the incidence of two of the HACs
pulmonary embolism and deep vein thrombosis (Gidwani and Bhattacharya, 2015). Insurance
company policies also need to be reviewed to ensure that the patients’ healthcare needs are a
priority for coverage considerations and that effective treatments are included in payment
coverage.
BARIATRIC SURGERY TO TREAT OBESE T2DM PATIENTS

References


May 10, 2016

Reference: Cynthia Bolaji

To Whom It May Concern;

Please be advised that Cynthia Bolaji has authorization to implement her Project Protocol focused on obese diabetics at two of our clinics and is allowed to access and review the chart documentation for evaluation as needed.

She is also allowed to relate with the providers and clinic staff as necessary to conduct activities needed for completion of the project.

We are a family practice outpatient clinic with four locations throughout Houston and Rosenberg.

I hope this letter is sufficient for your purposes. If there are any questions, please feel free to contact our clinic.

Regards,

David P. Schwartz, D.O.

David P. Schwartz, D.O.
Medical Advisor
Med-Cure Primary Care Physicians
Appendix B

Type 2 Diabetes Mellitus and Obesity

Type 2 diabetes is often associated with excess weight gain which is medically referred to as obesity. Obesity means having too much body fat, and a high body mass index (BMI) (>30). The BMI is calculated as a measure of weight related to height.

Both Diabetes and Obesity increase the risk of heart disease, stroke, high blood pressure, high cholesterol, arthritis and cancer. The American Diabetes Association (ADA) recommends weight loss and increased physical activity for the management of Type 2 Diabetes. Lifestyle modification is recommended meaning you have to make some permanent changes to help you lose weight and keep it off for the long term.

Recommended lifestyle modifications include:

1. Reducing caloric intake (how much you eat), reducing portion sizes and eating the rights types of foods (low fat and low carbohydrates).
2. Increased physical activity of moderate intensity exercise 30 to 60 minutes 3 to 4 times a week.
3. Maintaining a healthy weight is necessary, which takes a long term commitment and continuing action.

Current research has found that it is difficult for many people to maintain the necessary lifestyle modification over the long term. Only a few patients are able to lose and maintain weight loss. Over the long term, a lot of people actually regain the initial weight lost from dieting and lifestyle modifications in less than a year.

Weight loss surgery is an option that has been shown to be effective over the long term in managing diabetes and obesity. Weight loss surgery has led to improved diabetes control in about 86% of the patients. After weight loss surgery, 75% of patients have been able to stop taking any diabetes medication, they are cured of diabetes over the long term.

Based on your current weight and your diagnosis of Type 2 diabetes you may qualify for the option of weight loss surgery to manage your diabetes and obesity.

Would you be interested in talking with a Bariatric surgeon to see if this could be an option for you? Yes/No __________

If no, can you tell us why or what would help you consider this option.

________________________________________________________________________

________________________________________________________________________

Please feel free to ask your provider more about any information on this sheet. Thank you.

www.health.harvard.edu/thefirstlinetreatmentweightloss
Appendix C

Diabetes Mellitus Tipo 2 y Obesidad

Diabetes tipo 2 es frecuente asociado con el excess de aumento de peso, que es medicamente referido como obesidad. Obesidad significa tener mucha grasa del cuerpo y alto índice de masa corporal, es igual oh mas alto que 30 (BMI>30). El BMI se calcula como una medida de peso relacionado con la altura.

Ambos, diabetes y obesidad incrementan el riesgo de problemas en el Corazon, derrame cerebral, alta pression, alto colesterol, artritis y cancer. La asociacion Americana de diabetes (ADA) recomienda la perdida de peso y incrementar la actividad fisica para el control de diabetes tipo 2.

Las recomedaciones del estilo de vida incluye:

1. Reduccion de la ingesta caloric (cuanto usted come) reduciendo el tamaño de las porciones y comer los tipos adecuados de alimentos (bajo en grasa en carbohidratos.
2. Incrementar actividad fisica en intensidad moderada, hacer ejercicios por 30 a 60 minutos 3 a 4 veces por semana.
3. Mantener un peso saludable si es necesario, el cual toma compromise a largo pazo y accion continua.

La investigacion actual ah encontrado que es dificil para muchas personas mantener un estilo de vida modificado a largo plazo. Solo ciertos pacientes pueden perder y mantener lo que an perdido de peso. Muchas personas actualmente vuelven al peso que tenian al principio antes de las dietas y del estilo de vida en menos de un año.

Cirugia de perdida de peso es una opcion que ah sido mostrado ah ser effective a un largo plazo en la gestion de diabetes y obesidad. Cirugia de perdida de peso ha llevado a una mejora al control de diabetes en 86% de los pacientes. Despues de la cirugia el 75% de los pacientes an podido dejar de tomar medicamento de diabetes an sido curados de diabetes a un largo pazo.

Basado en su actual peso y su diagnostic de diabetes tipo 2 puede calificar para la opcion de la cirugia de perdida de peso para controlar su diabetes y obesidad.

Estaria interesado en hablar con un cirujano bariatrico para ver si esto puede ser una opcion para ustd? Si/No__________

Si, no nos puede decir por que o que ayudaria para que usted considere este opcion.

Porfavor sientase libre de precuntarle a su proveedor medico acerca de esta informacion. Gracias

www.health.harvard.edu/thefirstlinetreatmentweighloss
## Chart Audit Tool

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<th>A1c</th>
<th>Age</th>
<th>Sex M/F</th>
<th>Race</th>
<th>BS Pt education Y/N</th>
<th>Pt agrees Y/N</th>
<th>Diag. O/D</th>
<th>Has insurance Y/N</th>
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1 = Yes, 0 = No, 2 = N/A

BMI in chart of 35 or greater

A1c actual number

Diagnoses = (O/D: Obesity/Diabetes II)

Race: 1 = white, 2 = Black, 3 = Hispanic, 4 = Asian, 5 = Other
Type II diabetes mellitus (T2DM) is a challenging health problem in the world today, affecting more than 300 million people worldwide (WHO). Obesity presents a significant risk to the development of T2DM, and many of the current diabetic medications also cause weight gain. Bariatric surgery (surgical procedures performed on the stomach or intestines to induce weight loss) has been shown to be efficacious in the improvement and in a lot of cases the remission of diabetes. It is a recommended option for the treatment of severely obese T2DM patients with BMI of 35 and greater.

Obesity and diabetes are chronic diseases frequently linked together. Durable weight loss is uncommon with medical/behavioral approaches. For severe obesity, bariatric surgery is the only treatment resulting in sustained weight loss.

According to the American Association of Certified Endocrinologist (AACE) and the American Diabetes Association (ADA) patient who meet the criteria of BMI of 35 or greater and have uncontrolled T2DM should be considered for bariatric surgery. Current research reflects that 78% of patients in this target group who get bariatric surgery have a remission of the diabetes and as many as 92% have improvement in the disease process evidenced by a 1-2 percent reduction in their HbA1c. (Mingrone et al., 2012)

As a provider do you consider or recommend your severely obese T2DM patient for bariatric surgery? What barriers prevent you from recommending it?

1. Discipline: MD/ DO/ NP/PA
2. Clinical Area or specialty __________________________
3. How long have you been in practice ________________

Comments _________________________________________

The following websites and research articles provide more in-depth information on this topic.
References for review


Appendix F

Protocol for Obese Type 2 Diabetes Mellitus Patients

1. Vital signs including BMI documented in chart for the visit

2. Current labs including patient’s glycated Hemoglobin A1c

3. Correct diagnosis established of obesity and T2DM for each patient

4. All uncontrolled T2DM patient (HbA1c > 6.5) who are obese (BMI > 35) must receive education and counseling on the benefits of weight loss and the efficacy of bariatric surgery compared to conventional medical therapy.

4. Obese T2DM patients (BMI > 35) must be offered the option of bariatric surgery

5. Refer patients who are agreeable for consultation with a local bariatric surgeon.
Appendix G

Project Data Points

BMI $\geq 35$

$A1c > 6.5$

Discuss wt. reduction options including surgery

$A1c \leq 6.5$

Discuss wt. reduction options Interested in surgery

Document response related to Patient interest

Yes

Provide Surgery Consultation referral

No

No further action