

Table I Evidence Table of Bariatric Surgery by Type and Effects on Blood Glucose Control in Patients with BMI < 35 kg/m²

	Publication	Study Design	Patient Characteristics	Results	Conclusion/Limitations
1.	<p><i>Surg Endosc.</i> 2008 Mar;22(3):706-16.</p> <p>Laparoscopic treatment of type 2 diabetes mellitus for patients with a body mass index less than 35.</p> <p>DePaula AL, Macedo AL, Rassi N, <i>et al.</i></p>	<p>Background: Type 2 diabetes mellitus (T2DM) is a common disease with numerous complications. Bariatric surgery is an efficient procedure for controlling T2DM in morbidly obese patients. In T2DM, the incretin effect is either greatly impaired or absent.</p> <p>Objective: This study aimed to evaluate the preliminary results from interposing a segment of ileum into the proximal jejunum associated with a sleeve or diverted sleeve gastrectomy to control T2DM in patients with a body mass index (BMI) less than 35 kg/m².</p> <p>Study design: This study aimed to evaluate the results from laparoscopically transposing a segment of ileum to the proximal jejunum associated with either a sleeve gastrectomy or diverted sleeve gastrectomy to control T2DM in patients with a body mass index (BMI) less</p>	<p>N=39 (16 women and 23 men) underwent two laparoscopic procedures comprising different combinations of ileal interposition into the proximal jejunum via a sleeve or diverted sleeve gastrectomy. The mean age of these patients was 50.3 years (range, 36-66 years). The mean BMI was 30.1 kg/m² (range, 23.4-34.9 kg/m²). All the patients had a diagnosis of T2DM that had persisted for at least 3 years and evidence of stable treatment with oral hypoglycemic agents or insulin for at least 12 months. The mean duration of T2DM was 9.3 years (range, 3-22 years). All patients were on prescribed meds for regulation of blood sugar</p> <p>Inclusions The inclusion criteria specified type 2 diabetic patients whose disease had been diagnosed for at least 3 years; documentation of HbA1c exceeding 7.5% for at least 3 months; stable weight, defined as no significant change (>3%) over the 3 months before enrollment; and evidence of stable treatment with oral hypoglycemic therapy or</p>	<p>Four major complications occurred in the short term (30-days), and the mortality rate was 2.6%.</p> <p>The mean percentage of weight loss was 22%. The mean postoperative BMI was 24.9 kg/m² (range, 18.9-31.7 kg/m²).</p> <p>An adequate glycemic control was achieved for 86.9% of the patients, and 13.1% had important improvement. The patients whose glycemia was not normalized were using a single oral hypoglycemic agent. No patient needed insulin therapy postoperatively. Patients with longer duration of disease had less response. Patients who lost more weight had better glycemic control but weight loss was reported to not predict control.</p> <p>All the patients who survived experienced normalization of their cholesterol levels. Targeted triglycerides levels were achieved by 71% of the patients, and hypertension was controlled for 95.8%.</p>	<p>Conclusions The laparoscopic ileal interposition via either a sleeve gastrectomy or diverted sleeve gastrectomy seems to be a promising procedure for the control of T2DM and the metabolic syndrome. The author believes that weight loss is not associated with these outcomes, but that they are due to the neurohormonal changes induced by the surgery.</p> <p>Limitations A longer follow-up period is needed. A replication of the study in a larger sample is needed, a adequate control and randomization process is needed and the mortality rate of 1/39 with major morbidity in an additional 10-20% is considered acceptable for this patient population at high risk population by the authors.</p>

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		<p>than 35 kg/m².</p> <p>Primary endpoints Insulin regulation and blood sugar control</p> <p>Secondary endpoints other metabolic factor and weight loss for each procedure, adverse events</p> <p>Outcomes analyzed elimination of comorbidities especially hyperglycemia and insulin abnormalities post surgically</p>	<p>insulin for at least 12 months. All the patients had a BMI less than 35 kg/m². There were no special criteria for the indication of the two different configurations of the procedures, although it was assumed that the diverted version would be more effective in controlling T2DM.</p> <p>Exclusions The exclusion criteria specified elderly patients (>66 years), previous major upper abdominal surgery, pregnancy, malignant or debilitating diseases, severe pulmonary or cardiac diseases, severe renal disease (glomerular filtration rate < 30 ml/min), use of appetite suppressant medication, eating disorder such as bulimia or binge eating, and obesity due to any other endocrine disorder.</p> <p>Duration The mean operative time was 185 min, and the median hospital stay was 4.3 days. The mean postoperative follow-up period was 7 months (range, 4-16 months),</p>		
2.	<p><i>J Gastrointest Surg</i> 2008;12:945–952</p> <p>Effect of</p>	<p>Objective To determine if mini bypass is effective in management of diabetes in a lower BMI by</p>	<p>201 (24.5%) patients were identified who had impaired fasting glucose or T2DM.</p>	<p>Among the 201 patients, 44 (21.9%) had BMI <35 kg/m², and 114 (56.7%) had BMI between 35 and 45 kg/m², 43 (21.4%) had BMI</p>	<p>Conclusion: Laparoscopic gastric bypass resulted in significant and sustained weight loss with successful</p>

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	<p>Laparoscopic Mini-Gastric Bypass for Type 2 Diabetes Mellitus: Comparison of BMI >35 and <35 kg/m²</p> <p>Lee W-J, Wang W, Lee Y-C, Huang M-T, Ser K-H, Chen J-C.</p>	<p>retrospectively assigned cohort of mildly obese to more severely obese diabetics</p> <p>Study design “From Jan 2002 to Dec 2006, 820 patients who underwent laparoscopic mini-gastric bypass were enrolled in a surgically supervised weight loss program. 201 (24.5%) patients were identified who had impaired fasting glucose or T2DM. All the clinical data were prospectively collected and stored. Patients with BMI <35 kg/m² were compared with those of BMI>35 kg/m².”</p> <p>Primary endpoints: Successful treatment of T2DM was defined by HbA1C <7.0%, and LDL <100 mg/dL, and triglyceride <150 mg/dL.</p>	<p>All the clinical data were prospectively collected and stored. Patients with BMI <35 kg/m² were compared with those of BMI>35 kg/m². Successful treatment of T2DM was defined by HbA1C <7.0%, LDL <100 mg/dL, and triglyceride <150 mg/dL.</p> <p>N 44 of the 201 had BMI <35 kg/m².</p> <p>Inclusions BMI <35 with three comorbidities, abnormal fasting glucose and two lipid levels recorded as abnormal at base lines</p> <p>Exclusions Failure to meet any of the four required criteria</p> <p>Duration measurements at 1, 2, 3, and 5 years post surgery</p>	<p>>45 kg/m². Patients with BMI <35 kg/m² were significantly older, female predominant, had lower liver enzyme and C-peptide levels than those with BMI >35 kg/m². The mean total weight loss for the population was 32.1, 33.4, 31.9, and 32.8% (at 1, 2, 3, 5 years after surgery), and percentage to change in BMI was 31.9, 34.2, 32.2, and 29.5% at 1, 2,3, and 5 years.</p> <p>One year after surgery, fasting plasma glucose returned to normal in 89.5% of BMI <35 kg/m² and 98.5% of BMI >35 kg/m² patients (p=0.087).</p> <p>The treatment goal of T2DM (HbA1C <7.0%, LDL <150 mg/dL and triglyceride <150 mg/dL) was met in 76.5% of BMI <35 kg/m² and 92.4% of BMI >35 kg/m² (p=0.059).</p>	<p>treatment of T2DM up to 87.1%. Despite a slightly lower response rate of T2DM treatment, patients with BMI <35 kg/m² still had an acceptable DM resolution and this treatment option can be offered to this group of patients.</p> <p>Laparoscopic gastric bypass resulted in significant and sustained weight loss with successful treatment of T2DM up to 87.1%. Despite a slightly lower response rate of T2DM treatment compared to gastric bypass in BMI >35 kg/m², patients with BMI <35 kg/m² still had an acceptable DM resolution, and this treatment option can be offered to this group of patients.</p> <p>Limitations Level of Diabetes in the BMI < 35 kg/m² group was relatively mild as minimum entry. Sample is also non randomized and has no control or comparator group.</p>
3.	<p><i>Obesity Surgery.</i> 2007;17, 185-192</p> <p>Long-Term Control of Type 2 Diabetes</p>	<p>Objective To establish that type 2 diabetes mellitus can be effectively treated with BPD Specifically “Bariatric operations are the most</p>	<p>N = 7 patients</p> <p>All T2D obese patients with mean BMI <35 kg/m² underwent BPD between 1976</p>	<p>In all patients, serum glucose was normalized at 1, 2, and 3 years. In 5 patients, a slight increase of serum glucose above 125 mg/dl was observed at or around 5 years, the</p>	<p>Conclusions: T2D patients with BMI <35 kg/m² have very severe metabolic disturbances. Surgical therapy for these patients is</p>

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	<p>Mellitus and the Other Major Components of the Metabolic Syndrome after Biliopancreatic Diversion in Patients with BMI <35 kg/m²</p> <p>Scopinaro N, Papadia F, Marinari G, Camerini G, Adami G.</p>	<p>powerful means of curing type 2 diabetes mellitus (T2D) and the other major components of the metabolic syndrome. Despite the very frequent occurrence of metabolic disturbances in patients with BMI from 30 to 35 kg/m², there is a general reluctance to operate on these patients, as their disease is considered less severe.”</p> <p>Study design: case series report on seven patients with BMI between 30 and 35 kg/m² with type 2 diabetes mellitus</p> <p>Primary endpoints Resolution of diabetes mellitus</p> <p>Secondary endpoints Weight loss , other comorbidities</p> <p>Outcomes analyzed Serum Glucose, Cholesterol , triglycerides, systolic and diastolic blood pressures</p>	<p>and 1996 at the Azienda Universitaria San Martino of Genoa, Italy. Mean age was 49 years, mean body weight 91 kg, and mean waist circumference 115 (M) and 98 (F) cm. The mean follow-up was 13 (10-18) years. All 7 patients had abnormally high values of serum triglyceride,</p> <p>Inclusions not stated Diabetes ranged from “severe” in two patients to latent in two patients and it was discovered at the time of surgery.</p> <p>Exclusions not stated other than lost to follow up</p> <p>Duration Patients followed an average of 13 years, range 10-18 years with yearly observations in the first three years and intermittent observations or transmitted reports in other follow up years. The table of time points appears to have some missing data by this timetable</p>	<p>values being maintained at all subsequent times, with no one value higher than 160mg ever being recorded. The other 2 patients showed full resolution of diabetes at all follow-up times. Both serum cholesterol and triglyceride values fell to normal 1 year after BPD, and remained within the normal range in all 7 patients during the entire follow-up observation. Arterial pressure normalized in 6 cases and was improved in 1 case. No patient had excessive weight loss at any postoperative time.</p>	<p>warranted, and it should be performed as soon as possible, before the rapid evolution of the pattern leads them to a point where even the most effective metabolic surgery operation could be insufficient to yield complete and permanent control of their diabetes.</p> <p>Limitations: Is this a full cohort of available patients to analyze from a series of more than two thousand patients in 1998 paper? Based on graphs presented 5 of 7 patients serum glucose levels appear to parallel changes in body weight while 2 in 7 do not appear to do so. This appears to challenge the claim that diabetes is not related to weight loss.</p>
4.	<p>2006 <i>Ann Intern Med</i> 2006;144(9): 625-634</p>	<p>Study design Randomized, controlled trial</p> <p>Objective To ascertain</p>	<p>N=80 adults with mild to moderate obesity (body mass index, 30 kg/m² to 35 kg/m²) from the general community.</p>	<p>At 2 years, the surgical group had greater weight loss, with a mean of 21.6% (95% CI, 19.3% to 23.9%) of initial weight lost and 87.2% (CI,</p>	<p>Conclusions Surgical treatment using laparoscopic adjustable gastric banding was statistically significantly</p>

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	<p>Treatment of Mild to Moderate Obesity with Laparoscopic Adjustable Gastric Banding or an Intensive Medical Program A Randomized Trial</p> <p>O'Brien PE, Dixon JB, Laurie C, <i>et al.</i></p>	<p>whether surgical therapy for obesity achieves better weight loss, health, and quality of life than nonsurgical therapy.</p> <p>Study design unblinded randomized trial. Patients were assigned to a program of very-low calorie diets, pharmacotherapy, and lifestyle change for 24 months (nonsurgical group) or to placement of a laparoscopic adjustable gastric band (LAP-BAND System) (surgical group).</p> <p>Primary endpoints weight loss by each test group</p> <p>Secondary endpoints control of metabolic syndrome, quality of life at 2 years post surgery</p> <p>Outcomes analyzed Outcome measures were weight change, presence of the metabolic syndrome, and change in quality of life at 2 years.</p>	<p>Inclusions Patients were eligible if they were between 20 and 50 years of age; had a body mass index of 30 kg/m² to 35 kg/m²; had identifiable problems, including an obesity-related comorbid condition (such as hypertension, dyslipidemia, diabetes, obstructive sleep apnea, or gastroesophageal reflux disease), severe physical limitations, or clinically significant psychosocial problems associated with their obesity; had attempted to reduce weight over at least the previous 5 years; could understand the options offered and the randomization process; and were willing to comply with the requirements of each program.</p> <p>Exclusion Criteria Candidates with a history of bariatric surgery or medical problems that contraindicated treatment in either study group, such as impaired mental status, drug or alcohol addiction or portal hypertension were excluded. In addition, participants were excluded if they had undergone an intensive, physician-supervised</p>	<p>77.7% to 96.6%) of excess weight lost, while the nonsurgical group had a loss of 5.5% (CI, 3.2% to 7.9%) of initial weight and 21.8% (CI, 11.9% to 31.6%) of excess weight (<i>P</i> = 0.001).</p> <p>The metabolic syndrome was initially present in 15 (38%) patients in each group and was present in 8 (24%) nonsurgical patients and 1 (3%) surgical patient at the completion of the study (<i>P</i> = 0.002). Quality of life improved statistically significantly more in the surgical group (8 of 8 subscores of SF-36) than in the nonsurgical group (3 of 8 subscores)</p>	<p>more effective than nonsurgical therapy in reducing weight, resolving the metabolic syndrome, and improving quality of life during a 24-month treatment program. Obese diabetes group and obese at risk group could benefit from this analysis</p> <p>Limitations The study included mildly and moderately obese participants, was not powered for comparison of adverse events, and examined outcomes only for 24 months. While metabolic syndrome is resolved no specific diabetic cases are present in the sample.</p>

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			program that used very-low-calorie diets or pharmacotherapy or if they did not attend the 2 initial patient information visits		
5.	<p><i>Surg Obes Rel Dis</i> 2006;2:401–404</p> <p>Laparoscopic Roux-en-Y gastric bypass for BMI ≤35 kg/m²: a tailored approach</p> <p>Cohen R, Pinheiro JS, Correa JL, Schiavon CA</p>	<p>Objective to treat patients with three life threatening comorbidities and BMI between 30 and 30 kg/m² with a gastric bypass procedure</p> <p>Study design observational study post intervention Roux en Y nonrandomized without a control group</p> <p>Primary endpoints observed time points and the resolution of comorbidities, diabetes, lipid disorder and hypertension. and weight loss at those time points</p> <p>Secondary endpoints medication use, other comorbidities GERD sleep apnea</p> <p>Outcomes analyzed primary and secondary measures at 6 12 18 24 36 and 48 months. Data reported when 37 of 37 patients had reached six months and 9 of the 37 had reached 48 months</p>	<p>N = A total of 37 obese patients (30 women and 7 men) had been undergoing clinical treatment with no resolution or improvement of their life-threatening co-morbidities. The mean BMI was 32.5 kg/m². Their age ranged from 28 to 45 years. All patients had type 2 diabetes mellitus, hypertension, and lipid disorder</p> <p>Inclusions diabetes (defined as two fasting blood sugars greater than 120, hyperlipidemia based on total cholesterol TG, HDL or LDL values and hypertension systolic >140 mmHg and or diastolic >90 mmHg and BMI between 30 and 35 kg/m².</p> <p>Exclusion: Any patient with less than the all of the four required conditions</p> <p>Duration Up to 48 months, Mean follow up period is 20 plus or minus 5.4 months</p>	<p>No adverse events reported Authors report no intraoperative or perioperative complications and no deaths</p> <p>36 of 37 had total remission of all three conditions 1 patient resolved diabetes and hypercholesterolemia but still had mild hypertension with preoperative blood pressure meds of three classes needed preoperatively and only one needed postoperatively No anti diabetic meds were required postsurgically. All had HbA_{1c} levels below 6% and normal fasting sugars.</p>	<p>Conclusions Obese patients with a BMI of <35 kg/m² and severe co-morbidities can benefit from laparoscopic Roux-en-Y gastric bypass. This treatment option should be offered to this group of patients.</p> <p>Limitations: Sample size and lack of a control group. Authors state that randomized controlled trial may not be necessary in this population</p>

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6.	<p><i>Obes Surg.</i> 2004;14: 415-418.</p> <p>Italian Group for Lap-Band System®: Results of Multicenter Study on Patients with BMI <35 kg/m²</p> <p>Angrisani L, Favretti F, Furbetta F, <i>et al.</i></p>	<p>Objective: The Lap-Band System® is the most common bariatric operation world-wide. Current selection criteria do not include patients with BMI <35 kg/m². The authors report the Italian multicentre experience with BMI <35 kg/m² over the last 5 years.</p> <p>Study design retrospective analysis of 210 patients of BMI <35 kg/m² after lap band gastric bypass and subset analysis of those with comorbidities</p> <p>Primary endpoints Glucose control in diabetic subset</p> <p>Secondary endpoints other metabolic parameters and their resolution and weight loss, adverse events</p> <p>Outcomes analyzed Data were obtained from 27 centres involved in the Italian Collaborative Study Group for Lap-Band System®. Detailed information was collected on a specially created electronic data sheet (MS Access 2000) on patients</p>	<p>N : 225 (6.8%) out of 3,319 Lap-Band® patients were recruited from the data-base. 15 patients, previously submitted to another bariatric procedure (BIB= 14; VBG= 1) were excluded. 210 patients were eligible for study (34M/176F, mean age 38.19±11.8, range 17- 66 years, mean BMI kg/m² 33.9±1.1, range 25.1-35 kg/m², mean excess weight 29.5±7.1, range 8-41).</p> <p>Inclusions 199 comorbidities were diagnosed preoperatively in 55/210 patients (26.2%). Four of these 55 had diabetes mellitus type 2.</p> <p>Exclusions: prior gastric procedure in BMI under 35 kg/m² (BIB 14 pts and vertical banded gastroplasty 1 patient)</p> <p>Duration: data base searched from 1996 through 2002 to identify patient pool. Follow up for 60 months is reported at intervals of 6, 12, 24, 36, 48, and 60 months post procedure.</p>	<p>Adverse events: 1 patient (0.4%) (35 F) died 20 months postoperatively from sepsis following perforation of dilated gastric pouch. There were no conversions to laparotomy. Postoperative complications presented in 17/210 patients (8.1%).</p> <p>Weight loss follow-up was obtained at 6, 12, 24, 36, 48 and 60 months. At these time periods, mean BMI was 31.1±2.15, 29.7±2.19, 28.7±3.8, 26.7±4.3, 27.9±3.2, and 28.2±0.9 kg/m² respectively. Only one patient had their BMI >30 kg/m² at 60 months</p> <p>Co-morbidity resolution - Co-morbidities completely resolved 1 year postoperatively in 49/55 patients (89.1%). All four patients had their diabetes resolved at 12 months</p>	<p>Conclusions Although surgical indications for BMI <35 kg/m² remain questionable, the Lap-Band® in this study demonstrated that all but 1 patient achieved normal weight, and most lost their co-morbidities with a very low mortality rate.</p> <p>Limitations : Although surgical indications for BMI <35 kg/m² remain questionable, the Lap-Band® in this study demonstrated that all but 1 patient achieved normal weight, and most lost their co-morbidities with a very low mortality rate in a small diabetic sample</p>

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		operated in Italy since January 1996. Items regarding patients with BMI >35 kg/m ² were selected. Data were expressed as mean ± SD except as otherwise indicated.			

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1	<p><i>Obes Surg.</i> 2008; DOI 10.1007/s11695-008-9457-3</p> <p>Improvement of Insulin Resistance After Obesity Surgery: A Comparison of Gastric Banding and Bypass Procedures.</p> <p>Lee WJ, Lee YC, Ser KH, Chen JC, Chen SC.</p>	<p>Objective Insulin resistance (IR) is considered the pathologic link between T2DM and obesity. The mechanism in improving T2DM after bariatric surgery remains speculative. This trial assessed the effect of duodenal jejunal exclusion on the resolution of IR in gastric banding and gastric bypass procedures.</p> <p>Study design: retrospective comparative analysis between two surgical interventions and their effect on insulin resistance</p> <p>Primary endpoints- a wide range of metabolic variables and insulin resistance</p> <p>Secondary endpoints weight loss and time course between procedures</p> <p>Outcomes analyzed: Did insulin resistance alteration occur as a function of procedure or as a function</p>	<p>N=660. There were 544 patients who received laparoscopic gastric bypass, and 116 patients received laparoscopic gastric banding.</p> <p>The mean age was 31.5 years (18-64) and mean BMI was 41.4 (range 32-77).</p> <p>Inclusions A small number of patients are below a BMI of 35 in this sample IR was measured by homeostatic model assessment (HOMA) index (HI), that can be calculated as HI = plasma glucose (mmol/l) x insulin (UI/ml)/22.5.</p> <p>Exclusions none stated for this retrospective analysis</p> <p>Duration HI was measured before surgery and 1, 3, 6, 12, 24, and 36 months after surgery.</p>	<p>Of the 660 individuals, 517 (78.4%) had IR. The mean HI was 7.62 +/- 13.13. The HI was correlated with BMI, waist circumference, insulin resistance, hyperlipidemia, inflammatory indicators, and abnormal liver enzymes. Before surgery, the HI was 7.92 +/- 14.18 for the bypass group and 6.27 +/- 6.47 for the banding group. After surgery, the HI began to lower in both groups, and this reduction was maintained during follow-up. At 36 months after surgery, mean percentage of excess weight loss (%EWL) was 70.5% for the bypass group and 41.9% for the banding group. The HI was 1.00 +/- 0.79 for bypass and 1.51 +/- 1.25 for banding. The bypass patients had a better and faster weight reduction, but the HI was similar between the two groups at the same weight reduction percentage.</p> <p>No specific results for the BMI < 35 kg/m² are given</p>	<p>Conclusions: IR is common in morbidly obese patients. Both gastric banding and gastric bypass are effective for the reverse of IR in these patients. It seems that the effect is related to the absolute weight loss rather than different surgical procedures. There is no duodenal jejunal exclusion effect on IR resolution was observed in this study.</p> <p>Limitations: for purposes of the NCA no specific conclusions can be drawn for the sample of patients where BMI was less than 35 kg/m² which appear to constitute an unknown fraction of each groups being tested. As patients choose which group to enter, selection bias may have occurred relative to the distribution of low weight BMI patients between groups.</p>

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2	<p><i>JAMA</i>. 2008;299(3):316-323.</p> <p>Adjustable Gastric Banding and Conventional Therapy for Type 2 Diabetes A Randomized Controlled Trial</p> <p>Dixon JB, O'Brien PE, Playfair J, <i>et al.</i></p>	<p>of amount of weight lost?</p> <p>Objective : To determine if surgically induced weight loss results in better glycemic control and less need for diabetes medications than conventional approaches to weight loss and diabetes control.</p> <p>Study design Unblinded randomized controlled trial conducted from December 2002 through December 2006 at the University Obesity Research Center in Australia, with general community recruitment to established treatment programs. The two treatment groups 30 patients each received either conventional diabetes therapy with a focus on weight loss by lifestyle change vs laparoscopic adjustable gastric banding with conventional diabetes care. There was a 3 month assessment and run in period prior to randomization.</p> <p>Primary endpoints :</p>	<p>N = Participants were 60 obese patients (BMI 30 to 40 kg/m²)</p> <p>Inclusions Patients were eligible if they were aged between 20 and 60 years, had a body mass index of 30 to 40 kg/m², had been diagnosed with clearly documented type 2 diabetes within the previous 2 years, had no evidence of renal impairment or diabetic retinopathy, and were able to understand and comply with the study process.</p> <p>Exclusions Candidates were excluded if they had a history of type 1 diabetes, diabetes secondary to a specific disease, or previous bariatric surgery; a history of medical problems such as mental impairment, drug or alcohol addiction, recent major vascular event, internal malignancy, or portal hypertension; or a contraindication for either study group. Participants were excluded if they did not attend 2 initial information visits.</p>	<p>Remission of type 2 diabetes was achieved by 22 (73%) in the surgical group and 4 (13%) in the conventional-therapy group.</p> <p>Relative risk of remission for the surgical group was 5.5 (95% confidence interval, 2.2-14.0).</p> <p>Surgical and conventional-therapy groups lost a mean (SD) of 20.7% (8.6%) and 1.7% (5.2%) of weight, respectively, at 2 years ($P<.001$).</p> <p>Remission of type 2 diabetes was related to weight loss ($R^2=0.46$, $P=.001$) and lower baseline HbA_{1c} levels (combined $R^2=0.52$, $P<.001$).</p> <p>There were no serious complications in either group.</p>	<p>Conclusions: Participants randomized to surgical therapy were more likely to achieve remission of type 2 diabetes through greater weight loss.</p> <p>Limitations: For purpose of the NCA the pattern of weight loss and diabetes remission is not analyzed and separately reported for the patients of BMI between 30 and 35 kg/m² since “There were only 13 participants with a baseline BMI less than 35 kg/m²—6 randomized to surgery and 7 to the conventional-therapy group. The mean BMI of those recruited to the study was 37.1 kg/m². As well the authors state that “These results need to be confirmed in a larger, more diverse population and have long-term efficacy assessed.”</p>

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		<p>Remission of type 2 diabetes (fasting glucose level less than 126 mg/dL [7.0 mmol/L] and glycated hemoglobin [HbA_{1c}] value less than 6.2% while taking no glycemic therapy.</p> <p>Secondary endpoints: Secondary measures included weight and components of the metabolic syndrome.</p> <p>Outcomes analyzed: Analysis was by intention-to-treat</p>			
3	<p><i>Obes Surg.</i> 2004;14:1354-1359</p> <p>Duodenal Switch without Gastric Resection: Results and Observations after 6 Years</p> <p>Cossu ML, Noya G, Tonolo GC, <i>et al.</i></p>	<p>Objective: To determine if duodenal switch without gastric resection was effective as a method of control of type 2 diabetes as the primary goal, weight loss was expected to be limited. Specifically the authors state “The results on metabolic effects of the classical biliopancreatic diversion (BPD) have led us to investigate the operation without gastric resection, thus preserving stomach and pylorus, in patients who are not seriously obese but suffer from</p>	<p>N =24 patients. Between March 1996 and March 1999 DS without gastric resection was performed in 24 overweight patients. All the patients underwent DS without gastric resection with either end-to-end or end-to-side duodeno-ileostomy (in 14 cases with a biodegradable ring, and in the others with manual sutures).</p> <p>Mean preoperative BMI 36.2 kg/m² (range 24.7-46.7); mean preoperative weight 94.9 kg (range 64-136) and mean percentage of excess weight</p>	<p>Two individual using insulin to control their diabetes with starting BMIs of 24 kg/m² needed additional surgical conversion to a classic BP procedure due to failure to control their diabetes at 12 and 18 months respectively. Authors attribute the failure to insufficiency of beta cells in the pancreas in each patient.</p> <p>Two additional patients converted to the classic BP approach at two years post initial surgery due to ulcers. Ulceration rate was 29% in this series and the type of ulcers are reported to</p>	<p>The long-term results suggest the following:</p> <p>1) Regarding glycemic metabolism, DS without gastric resection seems to be less efficacious than the classical BPD in controlling diabetes type 2, especially in cases of longstanding disease with serious insufficiency of pancreatic cells.</p> <p>2) The procedure presents as an effective method in controlling abnormalities in lipid metabolism.</p>

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		<p>hypercholesterolemia, often associated with type 2 diabetes and hypertriglyceridemia.”</p> <p>Study design: To determine if Duodenal switch without gastric resection, with prospective data collection in an open unblinded and unrandomized observational trail produces results that would demonstrate the surgery is an effective intervention.</p> <p>Primary endpoints Not specified</p> <p>Secondary endpoints Not specified</p> <p>Outcomes analyzed: change in fasting blood glucose levels, hypertension, hypercholesterolemia and body weight.</p>	<p>60.2% (range 41.9-119.5). Note that the weight range includes at the extremes normal weight and morbidly obese individual(s)</p> <p>The patients consisted of 13 males and 11 females; mean age was 49.6.</p> <p>Seventeen patients (70.8%) suffered from type 2 diabetes: 13 were being treated with oral antidiabetic drugs and/or insulin, and 4 (16.6%) had impaired glucose tolerance. The others were hyperglycemic at fasting and were on a hypocaloric diet.</p> <p>In 20 patients (83.3%), hypercholesterolemia and alterations in the lipid profile were present.</p> <p>Also 20 patients were taking drugs for arterial hypertension.</p> <p>The pluri-metabolic syndrome was present in 41.6% of cases. (10 patients)</p> <p>Inclusions- none stated apparently type 2 diabetes or a</p>	<p>be difficult to treat (relapsing and chronic anastomotic ulcer)</p> <p>Authors report weight loss as minimal as expected but the table 1 shows values of 7 BMI kg/m² at 1 year on average and 5- 6 BMI kg/m² reduced overall. Authors state that the classic approach with resection produced more weight loss and controlled diabetes better (presumably including the individuals with BMI kg/m² of 24 initially).</p> <p>The authors report positive effects on blood glucose, and total cholesterol a slight drop in HDL and a sharp drop in LDL over the 6 year period. Some tendency to lowered albumin levels is evident by year 6.</p>	<p>3) DS without gastric resection induces a very slight weight loss: BMI fell 4-5 kg/m² and stabilized at values of 30 kg/m² at 6 years. This operation is not indicated for morbid obesity.</p> <p>4) Protein absorption is better than in classical BPD and no case of protein malnutrition was observed. The patient’s compliance is also important here.</p> <p>5) Anastomotic ulcer has a high incidence in this group of 29%, and it not easy to resolve.</p> <p>6) DS without gastric resection could be indicated only in patients with BMI 35-40 kg/m², suffering from hypercholesterolemia, sometime associated with diabetes type 2 with a sufficient pancreatic insulin reserve. In these selected cases, the procedure improved or resolved the metabolic alterations.</p> <p>Limitations The observations are without</p>

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			<p>related syndrome was an inclusion criterion</p> <p>Exclusions none explicitly stated</p> <p>Duration: follow up is reported to be an average of 4 years minimum of 2 years and maximum of 6 years</p>		<p>control groups.</p> <p>The conclusions reached i.e. limiting the procedure to BMI 35-40 kg/m² does not match the group treated BMI 24 – 46 kg/m²</p> <p>The results are not adequately separated by initial BMI for a complete analysis in relation to the NCA</p>
4	<p><i>Dig Surg</i> 2003;20:18-23.</p> <p>Plasma Lipids and Lipoprotein Changes after Biliopancreatic Diversion for Morbid Obesity</p> <p>Brizzi P, Angius MF, Carboni A, <i>et al.</i></p>	<p>Objective: To evaluate the modifications in LDL composition and LDL density after biliopancreatic surgery. The aim of our study was to investigate the effects of biliopancreatic diversion on plasma lipids and in particular on LDL composition and [3] size in light of the previously reported [9] marked decrease in LDL cholesterol.</p> <p>Study design: 29 patients (17 type 2 diabetics and 12 patients without diabetes (ND)) with BMI < 35 kg/m², who failed previous attempts to decrease weight</p>	<p>N= 28 patients (16 type 2 diabetics and 12 non-diabetics (ND))</p> <p>Inclusions: BMI > 30 kg/m² mean\pmSD 40\pm10 for the Diabetic subgroup, BMI > 40 kg/m² mean 49\pm4 for the morbidly obese nondiabetic patients. Failed prior attempt at dietary control of weight</p> <p>Exclusions: None stated</p> <p>Duration: 6 months post surgical intervention. Time points for data collection are only 2 pre surgery and 6 months post surgery</p>	<p>After surgery a significant reduction of all circulating lipids, including apolipoprotein (Apo) B was observed. After surgery, all lipid parameters decreased significantly to the same degree in both diabetics and non-diabetics. Diabetes was confirmed by a glucose tolerance test with > 200 mg% the cut off for the diagnosis. Blood glucose fasting was 162 pre surgery and 90 mg% post surgery.</p> <p>Diabetic lipid profiles become more like ND after surgery</p> <p>After surgery, LDL presented a marked decrease in the percentage of cholesterol (from 36 to 32%) with a marked</p>	<p>Conclusions: After biliopancreatic diversion, the plasma lipid profile improves along with improvement of plasma glucose and insulin sensitivity. However, the LDLs become richer in triglycerides and HDL declines.</p> <p>It is possible that the greater atherogenicity of these LDLs is compensated by an improvement in the general metabolic condition.</p> <p>Limitations:</p> <p>Sample size is small</p> <p>Duration is only 6 months</p>

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		<p>by diet, were studied before and 6 months after biliopancreatic diversion for morbid obesity.</p> <p>Twenty-eight subjects who underwent biliopancreatic diversion for severe obesity were studied immediately before and 6 months after surgery and compared to a group of non-diabetic, non-obese(BMI >25 kg/m²) subjects (control). BMI was >40 kg/m² in non-diabetic patients, while in type 2 diabetes, because of the correlated comorbidity, BMI >30 kg/m² was selected.</p> <p>Primary endpoints In all subjects, LDL and VLDL composition were determined and LDL density was evaluated pre surgery and six months post surgery. Fasting plasma glucose and insulin were also determined.</p> <p>Secondary endpoints: fasting circulating lipids, glucose and insulin were also evaluated at the same</p>		<p>increase in the percentage of triglycerides (from 13 to 18%), without appreciable modification of ApoB in both diabetics and non diabetics.</p> <p>A decrease in HDL and ApoAI was evident in all the subjects with an increase in the VLDL-1</p>	<p>Cannot separate out effect on BMI < 35 kg/m²</p>

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		<p>time points.</p> <p>Outcomes analyzed: Changes in the post surgical circulating levels of glucose insulin and lipids from presurgical measurements. LDL and VLDL composition and LDL density were compared pre and post surgical intervention.</p>			
5	<p><i>World J. Surg.</i> 22, 936–946, 1998</p> <p>Biliopancreatic Diversion</p> <p>Scopinaro N, Adami GF, M. Marinari GM, <i>et al.</i></p>	<p>Objective To describe the state of the BPD procedure in 1999</p> <p>Study design: observational retrospective analysis of a nonrandom sample</p> <p>Primary endpoints: appear to be remission of type 2 diabetes</p>	<p>N Of the 2241 patients operated on since May 1976, 1356 (438 men, 918 women) underwent the present “ad hoc stomach” (AHS) type of BPD performed by the same surgical team between June 1984 and April 1997. The patients’ mean age was 37 years (range 11–70 years), mean weight 128 kg (range 73–236 kg), and mean excess weight was 69 kg (range 20–156 kg), corresponding to 117% (range 41–311%) and to a mean body mass index (BMI) of 47kg/m² (range 29–87 kg/m²). Maximum follow-up was 155 months, and the follow-up rate was 98%.</p> <p>The number of patients</p>	<p>The observed beneficial effects are obviously not attributable to the BPD itself but to the weight loss or the reduced nutrient absorption, the only two exceptions being the effects on glucose and cholesterol metabolism. In fact, of the 1773 (total series) AHS BPD patients with a minimum follow-up of 1 year, not only the 248 (14%) with preoperative simple hyperglycemia, or only the 108 (6.1%) with type II diabetes mellitus manageable with oral hypoglycemics, but also the 32 (1.8%) patients with preoperative type II diabetes mellitus requiring insulin therapy 1 year after BPD and permanently thereafter had normal serum glucose levels without medication</p>	<p>Conclusions “Comprehensibly, this picture is accompanied by serum insulin level normalization, as demonstrated by us in a cross-sectional study and a longitudinal study as well as normalization of insulin sensitivity.</p> <p>Considering that about 20% of type II diabetes mellitus patients are not obese, and about 20% of formerly obese patients with type II diabetes mellitus still require insulin therapy after weight normalization by dieting, it must be concluded that simple weight loss or intra abdominal fat reduction cannot account for the</p>

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			<p>between BMI 29 kg/m² and BMI 35 kg/m² is not specified.</p> <p>Inclusions - not specifically stated most are morbidly obese patients presenting for weight loss</p> <p>Exclusions none explicitly stated</p> <p>Duration: author reports up to 13 years of follow up as maximum</p>	<p>and on totally free diet.</p>	<p>observed 100% recovery from type II diabetes mellitus after BPD.</p> <p>Our preoperatively diabetic patients had, on average, a normal serum glucose concentration as early as 1 month after operation, when the excess weight was still more than 80%; this finding indicates a specific action of BPD on glucose metabolism. The latter could be identified with the virtual annulment of the entero-insular axis. “</p> <p>Limitations There is no statement of preoperative levels of blood glucose The number of diabetic patients below BMI 35 kg/m² and their response rates to the procedure in regard to diabetes are not specified</p>