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TECHNICAL INNOVATION

Sleeve Gastrectomy with Jejunal Bypass for the Treatment of Type 2 Diabetes Mellitus in Patients with Body Mass Index <35 kg/m^2. A cohort study

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Abstract The objective of this study was to evaluate sleeve gastrectomy with jejunal bypass (SGJB) as a surgical treatment for type 2 diabetes mellitus (T2DM) in patients with a body mass index (BMI) <35 kg/m^2. This is a prospective cohort study. Patients with T2DM and BMI <35 kg/m^2 who underwent SGJB between January 2009 and June 2011 at DIPRECA Hospital, in Santiago, and Hospital Base, Osorno, Chile were included. SGJB consists of creating a gastric tube, which preserves the pylorus, and performing a jejunoileal anastomosis 300 cm distal to the angle of Treitz. Excess weight loss (EWL) and complete or partial remission of T2DM were reported. Forty-nine patients met the inclusion criteria. The mean age was 49 years (36–62), and 53 % of patients were female. Mean preoperative BMI was 31.6 kg/m^2 (25–34.9 kg/m^2). Operation time was 123± 14 min, with 94.7 % of operations performed laparoscopically. Mean postoperative hospital stay was 2 days. Mean postoperative follow-up was 12 months. Median EWL at 1, 3, 6, 12, and 18 months postoperatively was 31.9 %, 56.9 %, 76.1 %, 81.5 %, and 76.1 %, respectively. Complete T2DM remission was achieved in 81.6 % of patients (40/49) and partial remission in 18.4 % (9/49). Forty of 41 patients (97.6 %) on oral hypoglycemic agents achieved complete T2DM remission, and 100 % of insulin-dependent patients stopped using insulin but were still being treated for T2DM. One patient experienced postoperative gastrointestinal bleeding. There were no deaths. SGJB is an effective treatment for T2DM in patients with BMI <35 kg/m^2.

Keywords Bariatric surgery · Obesity surgery · Type 2 diabetes mellitus · Body mass index · Metabolic surgery · Sleeve gastrectomy · Jejunal bypass · Cohort studies · New technique

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Introduction

Obesity is closely linked to the development of type 2 diabetes mellitus (T2DM). Both obesity and T2DM are difficult to treat, and result in significant morbidity and mortality. Some recent studies have evaluated the prevention of T2DM through intensive lifestyle intervention, and other studies have examined the impact of bariatric surgery on T2DM with good results in morbidly obese patients [1–6].

A systematic review [7] found that the T2DM remission rate after all types of bariatric surgery in patients with a body mass index (BMI) <35 kg/m^2 was 85.3 %, suggesting that surgery is safe and has good results in patients who are not

morbidly obese. It has been proposed that the mechanism of this high success rate is the increased production of glucagon-like peptide-1 (GLP-1) by the ileum, which occurs after all types of bariatric surgery, whether they are restrictive or malabsorptive [8, 9].

The sleeve gastrectomy (SG) with jejunal bypass (SGJB) was developed in 2004, and creates a more physiological rearrangement of the stomach and small bowel than other bariatric surgery procedures. Preliminary results showed good excess weight loss (EWL) and resolution of comorbidities [10]. In July 2006, this technique was modified to include complete removal of the bypassed portion of the stomach, due to four cases developing gastrojejunal anastomotic ulcers [11].

The main objective of this study was to determine the effectiveness of SGJB in achieving T2DM remission in patients with a BMI <35 kg/m^2. The secondary objectives were to verify reduction in BMI after SGJB and to evaluate surgical and medical morbidity and mortality. This is a prospective cohort study, performed at two surgery departments in two cities of Chile.

This manuscript follows the guidelines of the STROBE declaration for reporting the results of observational studies [12, 13].

Patients and Methods

Study Design

This is a concurrent or prospective cohort study.

Setting

The study was conducted in the Departments of Surgery of DIPRECA Hospital in Santiago and Base Hospital in Osorno, Chile. Patient recruitment and data collection occurred from January 2009 to June 2011.

Participants

Forty-nine consecutive patients who underwent SGJB at one of the two aforementioned institutions, performed by one of the authors, aged from 18 to 65 years, with a BMI of 25.0 to 34.9 kg/m^2, T2DM, and at least 3 months of postoperative follow-up were included. Exclusion criteria were pregnancy and psychiatric illness.

Study Protocol

All patients were evaluated by a multidisciplinary team including a nutritionist, internist, anesthesiologist, psychologist, and other specialists if required. T2DM was diagnosed by a diabetologist according to the American Diabetes Association criteria [14]. All patients were followed prospectively according to the protocol designed by the authors, and EWL, BMI, complications, and T2DM remission were recorded. Data were registered in an electronic database (Microsoft Excel). Follow-up visits were scheduled at 1, 3, 6, 9, and 12 months postoperatively, and yearly thereafter. Follow-up was performed via telephone or e-mail in some cases. Fasting plasma glucose and glycosylated hemoglobin (HbA1c) levels were measured at 1 and 3 months postoperatively, and yearly thereafter.

Medical and surgical complications were evaluated only within 30 days postoperatively, and metabolic complications were evaluated at all follow-up visits. Patients received identical meal regimens and oral vitamins; none received routinely other supplements such as calcium, iron, or folic acid, but only when necessary. All patients were instructed to take proton pump inhibitors for 1 month postoperatively and if they had symptoms of gastroesophageal reflux.

Surgical Technique

Surgery was undertaken under general anesthesia via laparoscopy or laparotomy. A gastric tube was created parallel to the lesser curvature of the stomach, from the prepyloric area of the greater curvature to the angle of His. A jejunoileal anastomosis was formed 300 cm distal to the angle of Treitz (Fig. 1). In patients undergoing laparoscopy, a standard six-port technique was used (one 5-mm port, five 10-mm ports) after insufflation of CO2 through a Veress needle to 15 mmHg. In patients undergoing laparotomy, a midline incision was made. The patient was then placed in the reverse Trendelenburg position.

Sleeve Gastrectomy

The short gastric vessels were ligated using the Harmonic Ace® device (Ethicon Endo-Surgery Inc., Cincinnati, OH, USA). Dissection of the greater omentum 3 cm proximal to the pylorus allowed for the first firing of a linear stapler (Echelon® 60 mm or Endopath® 45 mm, Ethicon Endo-Surgery Inc., Cincinnati, OH, USA). Further firings of the linear stapler were used to divide the stomach longitudinally, from the antrum to the angle of His. Concurrently, the anesthesiologist inserted a 34-French orogastric tube to guide the gastric division. A 2-0 absorbable monofilament (Monocryl®) invaginating running suture was placed to reinforce the staple line. A leak test with methylene blue was performed only in selected cases. The remaining greater omentum was dissected close to the gastric wall, freeing the stomach, which was then removed through the epigastric trocar.

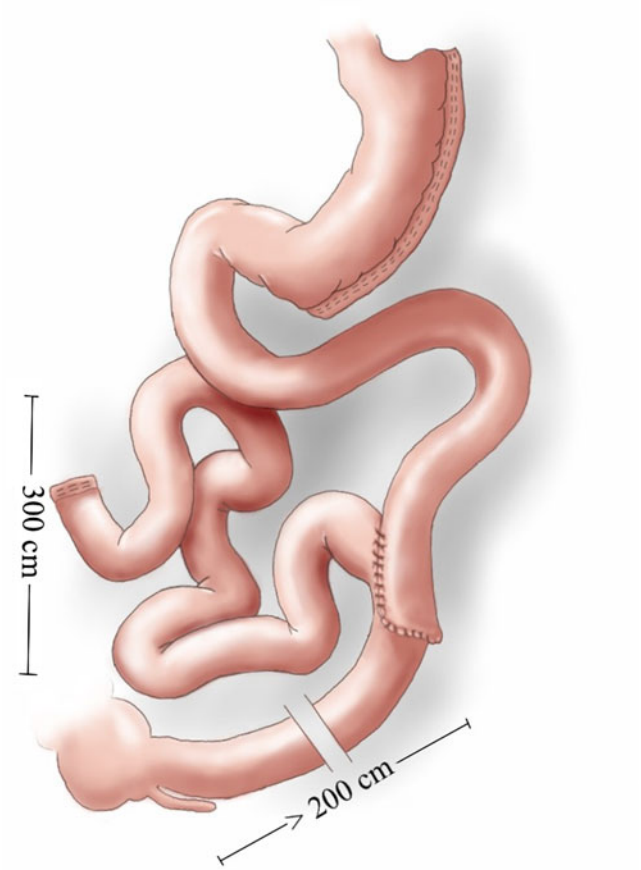

Fig. 1 Sleeve gastrectomy with jejunal bypass. A gastric tube is created parallel to the lesser curvature of the stomach, from the prepyloric area of the greater curvature to the angle of His. Later, a jejunoileal anastomosis is created 300 cm distal to the angle of Treitz

Jejunal Bypass

The jejunum was divided with a white cartridge of the linear stapler 20–40 cm distal to the ligament of Treitz, depending on the mobility of the mesentery. An enteroenterostomy (jejunoileal anastomosis) was performed 300 cm distal to the location of the jejunal division using the same cartridge and stapler, ensuring at least 200 cm of absorptive bowel. The bowel defect was closed with a 3-0 multifilament absorbable (Vicryl®) running suture. The mesenteric defect was closed in the same way. Finally, a silicon drainage tube was placed next to the gastric sutures in all cases.

Variables

Outcome variables were T2DM remission and BMI reduction. Control variables were age, sex, preoperative BMI, T2DM treatment [insulin and oral hypoglycemic agents (OHGA)], associated comorbidities, operation time, length of postoperative hospital stay, morbidity, and mortality.

Definitions

Partial and complete T2DM remission were established as defined by the American Diabetes Association criteria (fasting glucose <100 mg/dL and/or HbA1c <6.5 % without hypoglycemic therapy) [15]. EWL was calculated using the ideal body weight formula as described by Robinson in 1983 [16].

Bias

Potential sources of bias were reduced by comprehensive follow-up of the cohort. Data collection was blinded, and subsequent statistical adjustment to control for confounding factors was performed.

Statistical Methods

Data were analyzed using SPSS statistical software (version 15.0; SPSS Inc., Chicago, IL, USA). Exploratory analysis of the data yielded descriptive statistics as calculated percentage, mean, standard deviation, median, and range. Bivariate analyses used the Pearson Chi^2 and Fisher's exact tests to compare categorical variables, and the *t* test and non-parametric tests to compare continuous variables. Values of $p<0.05$ were considered statistically significant.

Ethics

The ethics committees of DIPRECA Hospital and Hospital Base de Osorno approved the protocol and authorized the study. Written consent was obtained from all patients.

Results

During the study period, 49 consecutive patients with T2DM underwent SGJB, representing 11.8 % of the total number of patients who have undergone SGJB in these institutions to date (mother cohort).

The 49 patients comprising the study cohort had a median (±standard deviation) age of 49 (±10.6) years (range, 36–62 years), and 53 % (26 patients) were female. The mean preoperative BMI was 31.6 (±2.1)kg/m^2 (range, 25.0–34.9 kg/m^2). Eight patients (16.3 %) were treated with insulin, and the rest of the cohort was treated with OHGA. Associated comorbidities included dyslipidemia in 77.8 % of patients and arterial hypertension in 80.0 % of patients (Table 1).

SGJB was performed laparoscopically in 47 cases (95.9 %) with no cases converted to open surgery, and via laparotomy in the remaining two cases. The mean operation time was 123 (±14) min (range, 100–155 min), and the

Table 1 Characteristics of patients (N=49)

Age	49±10.6 (36–62) years
Mean preoperative BMI	31.6±2.1 (25–34.9) kg/m^2
Surgical time	123±14 (90–155) min
Postoperative stay	2±0.2 (2–3) days
T2DM treatment	
OHGA	41 (83.7 %)
Insulin	8 (16.3 %)
Comorbidities	
Arterial hypertension	36 (73.0 %)
Dyslipidemia	35 (71.4 %)
Sleep apnea	1 (2.0 %)
Depression	1 (2.0 %)

mean length of postoperative hospital stay was 2.0 (±0.2) days (range, 2–3 days).

One patient experienced postoperative gastrointestinal bleeding during the follow-up period, which did not require blood transfusion. No other surgical complications were observed. No cases needed reoperation, and there were no postoperative deaths.

The average BMI was reduced from 31.6 (±2.1) kg/m^2 preoperatively to 21.4 (±1.9) kg/m^2 at the 18-month follow-up (Fig. 2). No patients developed a BMI less than 20 kg/m^2. The mean EWL at 18 months was 75.7 % (±8.5 %).

Forty patients (81.6 %) achieved complete T2DM remission after SGJB, and the remaining nine patients achieved T2DM improvement. Forty of 41 patients (97.6 %) taking preoperative OHGA achieved complete remission, and all eight patients with preoperative insulin dependence stopped using insulin but were still being treated for T2DM (Table 2).

Table 2 Partial or complete remission of type 2 diabetes mellitus in patients receiving oral hypoglycemic agents (OHGA) or insulin

	Partial remission (%)	Complete remission (%)	Total (%)
OHGA (%)	1 (2.5)	40 (97.5)	41 (100)
Insulin (%)	8 (100)	–	8 (100)
Total	9 (18.4)	40 (81.6)	49 (100)

Discussion

SGJB is a combined restrictive and malabsorptive procedure developed in February 2004, which creates a more physiological arrangement of the stomach and small bowel than other bariatric surgical procedures, preserving the pylorus and duodenum. The first results were published in 2006 [10, 11].

A vertical gastrectomy is performed, the jejunum is bypassed, and the biliopancreatic loop is anastomosed to the ileum, preserving at least 200 cm of absorptive bowel. This results in early exposure of the ileum to undigested food, resulting in secretion of incretin hormones, especially GLP-1.

GLP-1 is produced by the L cells of the ileum and stimulates insulin secretion by beta cells (incretin effect). GLP-1 reduces beta cell apoptosis and glucagon production by alpha cells [17–20] and, together with peptide YY, induces satiety and slows gastric emptying, an effect known as the "ileal break" [21, 22]. The incretin effect is also the main mechanism responsible for the improvement or remission of T2DM in obese patients during the early stages after bariatric surgery [23].

SGJB permanently adapts the digestive tract to the twenty-first century lifestyle, by eliminating gastric storage

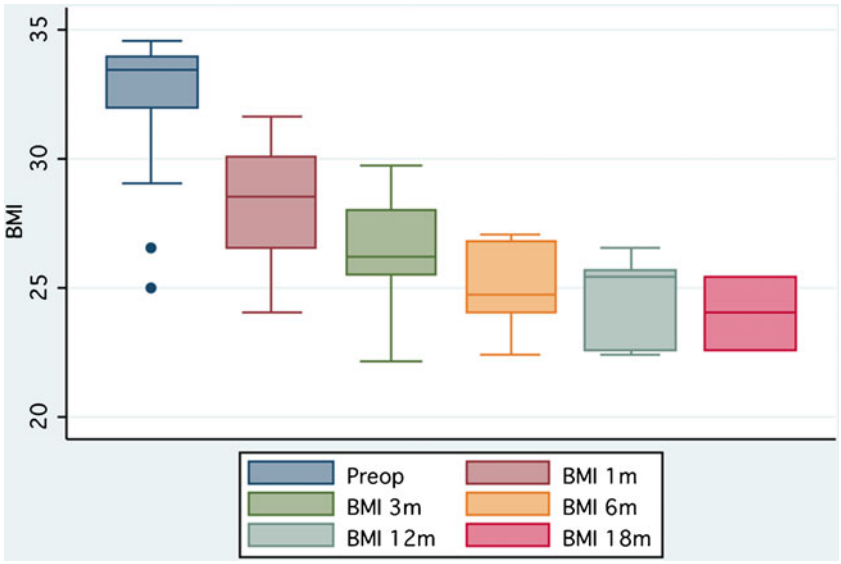

Fig. 2 Changes in body mass index (BMI) during the first 18 months postoperatively

of hypercaloric and excessively processed food, and providing the ileum with the needed stimulus for incretin release.

Some other bariatric surgery procedures also result in early exposure of the ileum to undigested food and therefore stimulate GLP-1 secretion, including procedures with duodenal exclusion. In our opinion, the easiest and most logical way to expose the ileum to undigested food and stimulate GLP-1 secretion is to create a jejunoileal anastomosis. This anastomosis is easy to perform, and has been shown to have minimal metabolic complications compared with other techniques such as Roux-en-Y gastric bypass (RYGB) and biliopancreatic diversion with duodenal switch (BPDDS) [24]. SG with ileal interposition as described by DePaula et al. [9] has the same physiological effects as SGJB, with 84.2 % of patients achieving HbA1c <6.5 % and 68.4 % achieving complete remission of T2DM. However, SGJB is technically easier to perform, requiring only one anastomosis and mesenteric gap closure.

In this series, 100 % of patients had partial or complete T2DM remission. Of patients on OHGA, 97.6 % (40/41) achieved complete remission, with normoglycemia and HbA1c <6.5 % without medication. These results are highly significant when compared with those obtained after other bariatric surgery procedures in the same subgroup of patients. In a recent review, Fried et al. [7] found that in patients with a BMI <35 kg/m^2, combined restrictive and malabsorptive procedures had better results in terms of T2DM remission than procedures which were purely restrictive or purely malabsorptive. Lee et al. [25] reported a randomized controlled trial comparing the T2DM remission rate in patients with non-severe obesity after SG (47 % remission) versus RYGB (93 % remission) and suggested that SG alone may not be sufficient treatment for patients with T2DM. A prospective study comparing RYGB with SG in morbidly obese patients found a T2DM remission rate of 75.8 % and 60 %, respectively [26]. Gill et al. [27] reported a systematic review which found that the T2DM remission rate after SG was 66.2 %. The T2DM remission rate in this study was 97.6 %, which is closer to the rates achieved with BPDDS or SG with ileal interposition [9, 10, 28–30].

The improvement in diabetes observed after duodenal exclusion in rats has not been replicated in humans [31, 32]. There is a slight improvement in patients with an Endobarrier® [33, 34], which is an endoscopically placed plastic barrier that excludes the duodenum. These results may be related to the poor weight loss after this procedure [35]. The recent randomized controlled trial described above which compared RYGB with SG [25] in patients with a BMI of 25–35 kg/m^2 reported T2DM remission in 93 % of patients who underwent RYGB versus 47 % of patients who underwent SG, suggesting that duodenal exclusion plays a role in T2DM remission. However, our study shows that similar results can be achieved while preserving the duodenum, suggesting that the mechanism of T2DM remission is related to GLP-1 secretion when undigested food enters the ileum. Several studies in animal models also show that duodenal exclusion does not seem to be the reason for the results of bariatric surgery [36]. The results of SGJB demonstrate the need to reconsider the role of duodenal exclusion in T2DM remission after bariatric surgery, and that the GLP-1 secretion when food enters the ileum may be responsible for T2DM remission.

The mean postoperative BMI was less than 25 kg/m^2, and mean EWL was 75.7 %. BMI did not decrease to less than 20 kg/m^2 in any patients. We did not measure vitamin or micronutrient levels, so we cannot be sure that there were no deficiencies, but albumin levels remained normal, and there were no cases of anemia, diarrhea, or excessive weight loss. In the 8-year cohort that we have been following since our first publication describing SGJB in 2006 [10], liver function tests have remained completely normal, and no signs of liver dysfunction have been recorded. Some patients in the series developed hair loss during follow-up, which was successfully treated with zinc supplements.

There was only one case with a postoperative complication (gastrointestinal bleeding), demonstrating that SGJB is a relatively safe technique.

None of our patients developed anemia, except for the case with postoperative gastrointestinal bleeding, which was promptly resolved with oral iron supplementation. Preservation of the duodenum leaves the iron absorption surface intact, providing an advantage compared with RYGB, which has a reported mean 36 % rate of chronic anemia (range, 6–50 %) [37–40]. No cases in this series developed dumping syndrome, which is a common complication after RYGB [41].

Bypassing almost 300 cm of small bowel may cause concern about the possibility of developing bacterial overgrowth syndrome (BOS) or blind loop syndrome. However, the development of BOS requires slower bowel food transit as the bacterial substrate, as seen in chronic pancreatitis, intestinal aganglionosis, or stenosis [42, 43]. In SGJB, the bypassed segment has no food transit, and has isoperistalsis and mucosal IgA production [42, 43].

SGJB is not a complete jejunoileal bypass. The bypassed loop is as long as necessary to reach the ileum, approximately 300 cm, leaving more than 200 cm of common limb, which should not produce malabsorption. There are no scientific findings to support the old premise that a functionless or blind loop is a reservoir for bacterial overgrowth. BPDDS carries a high risk of postoperative liver dysfunction, and the mechanism, though multifactorial, is predominantly due to malnutrition [44, 45]. We therefore believe that the main cause of liver dysfunction in complete jejunoileal bypass or BPDDS is not BOS, but rather undernutrition secondary to

malabsorption due to having less than 100 cm of common limb. In 1998, Riordan et al. [46] demonstrated that BOS per se is not a major risk factor for liver dysfunction in humans, even when the overgrowth flora includes obligate anaerobes. Increased small intestinal permeability therefore does not necessarily cause liver dysfunction in this setting [46]. Liver dysfunction secondary to short bowel syndrome has been shown to reverse after lengthening and tailoring of the small intestine [47]. All our patients had normal liver function tests at 3, 6, 12, and 18 months postoperatively, and no signs of BOS, liver dysfunction, or malabsorption were observed. We believe that it is not advisable to perform enterectomy, since this would cause release of GLP-2 and therefore hypertrophy of the remnant intestine, which could lead to regaining of weight [48–50].

This study has some potential limitations that merit comment. One limitation is the heterogeneity of the population, which is addressed by comprehensive follow-up. Another limitation is the relatively small sample size. Further prospective studies should be undertaken to confirm the outcomes of SGJB.

In conclusion, SGJB is an efficient alternative bariatric surgery procedure compared with other procedures which aim to achieve the same physiological response of increasing GLP-1 secretion, such as RYGB, ileal interposition, biliopancreatic diversion, and more recently, SG. SGJB is technically simple and therefore easily reproducible, does not alter iron metabolism or cause liver dysfunction due to malabsorption, and is not associated with gastroenterostomy complications such as bowel obstruction and dumping syndrome.

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