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BRIEF COMMUNICATION

Laparoscopic One-Anastomosis Gastric Bypass with Band-Separated Gastric Pouch (OAGB-BSGP): a Randomized Controlled Trial

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Abstract

Background One-anastomosis gastric bypass with band-separated gastric pouch (OAGB-BSGP) is a novel "staplerless" version of OAGB. This randomized controlled trial (RCT) compared 2-year outcomes for OAGB-BSGP and standard OAGB.

Methods The parallel-group RCT randomly allocated patients to group A, staplerless OAGB-BSGP, or group B, stapled OAGB.

Results Respective mean values for groups A and B ($n = 40$ each): baseline body mass index (BMI, kg/m^2), 40.6 ± 5.6 vs 41.2 ± 6.4 ($p = 0.64$); abdominal bleeding (mL), 5.9 ± 8.0 vs 31.1 ± 30.5 ($p < 0.0001$). Two-year outcomes: BMI, 26.3 ± 3.2 vs 29.0 ± 4.7; %TWL, 34.1 ± 9.0 vs 29.3 ± 10.6, $p < 0.03$; %EBMIL, 94.3 ± 23.6 vs 77.9 ± 29.3, $p < 0.007$; bile reflux, $n = 1$ (2.5%) vs $n = 7$ (17.5%) ($p = 0.05$); revisions, $n = 0$ vs $n = 4$ (10.0%), $p = 0.12$.

Conclusions At 2-year RCT follow-up, staplerless OAGB-BSGP patients had fewer complications, no revisions, and greater weight loss than stapled OAGB patients.

Trial Registration ISRCTN56106651 (OSPAN-RCT)

Keywords Obesity · Laparoscopic · One-anastomosis gastric bypass · Mini gastric bypass · Band-separated gastric pouch · Staplerless gastric pouch · Ospanov procedure · Randomized controlled trial · RCT

Introduction

The epidemic of obesity is advancing not only through Europe and the USA, but also within central Asia. Kazakhstan, the ninth largest country in the world by area, has the same incidence of obesity as most other developed countries [1, 2]. Bariatric procedures are extremely underutilized in central Asia due to insufficient financing by the health care system and the currently low value of the national currency. The slow uptake of bariatric surgery is also related to the high incidence of complications following procedures that use staplers [3, 4].

The one-anastomosis gastric bypass/mini-gastric bypass (OAGB/MGB) is considered by many a highly effective and technically straightforward operation requiring a relatively short learning curve [5]. However, the procedure has been criticized by some bariatric surgeons for its high rate of bile reflux [6], while others believe that risk to be overstated [7]. Despite the controversy regarding OAGB, there is strong evidence of its value for appropriate patients in the practice of a bariatric surgeon [8].

A novel variant of the OAGB/MGB, the laparoscopic OAGB with band-separated gastric pouch (OAGB-BSGP), has similarly met with controversy since its introduction in 2016 by an author of the current study (OO) [9]. OAGB-BSGP outcomes and those of the original OAGB have never been compared. The aim of this study was to perform a randomized controlled trial (RCT) with 2-year follow-up to evaluate the outcomes of the two procedures head to head.

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Methods

Study Design and Consent

This study was designed as a prospective, interventional, single-center, parallel-group RCT (trial identifier: ISRCTN56106651 [https://doi.org/10.1186/

ISRCTN56106651]; acronym OSPAN-RCT). The ethics committee of the Astana Medical University granted ethics approval for the study (15 July 2015). Recruitment was carried out by bariatric surgeons of the Department of Surgery, National Scientific Center for Oncology and Transplantation, University Medical Center, Astana, Kazakhstan. Informed consent was obtained from each participant before patient enrollment in the study.

Inclusion and Exclusion Criteria

Inclusion criteria stipulated obese patients (BMI ≥ 35 kg/m^2), aged 18–60 years, with American Society of Anesthesiologists (ASA) physical status of I or II, and able to provide written informed consent for randomization and treatment. Patients were excluded if they had a BMI < 30 or > 65 kg/m^2, were < 18 or > 65 years old, had a drug or alcohol addiction, had a mental illness, or were taking antidepressants.

Randomization

Allocation concealment was ensured by use of identical, sequentially numbered, opaque sealed envelopes. A nurse who had no involvement in the enrollment or assessment of patients assigned the intervention, opening the sealed patient envelope during his/her visit before surgery. Participants were allocated to one of two procedures: group A, the "staplerless group," treated with the OAGB-BSGP, or, group B, the "stapler group," treated with standard OAGB.

Outcome Evaluation

Weight

Patient demographics were assessed preoperatively. Ideal body weight was calculated as: 25 × [patient's height in meters]^2. Effectiveness endpoints at 2-year follow-up included body mass index (BMI, kg/m^2), change in BMI (ΔBMI [initial BMI − postop BMI]), excess BMI loss (EBMIL, % [(ΔBMI / initial BMI − 25) × 100]), and total weight loss (TWL, % [initial weight − postop weight / initial weight × 100]).

Comorbidities

Criteria used for diagnosis and remission of hypertension were pre-hypertension (120–140/80–89 mmHg systolic/diastolic), stage 1 hypertension (140–159/90–99 mmHg), and stage 2 hypertension (> 160/> 100 mmHg); for diagnosis and remission of type 2 diabetes mellitus (T2DM), fasting glucose < 126 mg/dL with HbA_{1C} < 6.5% without medication.

Complications

All patients had drainage placed into the abdominal cavity near the gastro-entero-anastomosis for 1 day to assess bleeding. Mild bile reflux (BR) was assessed if the biliary reflux was asymptomatic, detected only by an endoscopic picture of gastritis near the gastro-entero-anastomosis. A grade of average BR was assessed by the presence of pain or total gastritis of the pouch caused by the presence of bile. A grade of severe BR was assessed if BR symptoms of stomach pain or heartburn were intolerable, or by endoscopic verification of esophagitis by presence of bile in the esophagus. Signs of protein malnutrition or vitamin B_{12} deficiency were indicative of BR malabsorption syndrome.

Surgical Technique

The standard OAGB procedure was performed in the manner of Carbajo et al. [10], using a linear cutter stapler to effect the gastric bypass. The technique of OAGB-BSGP defined by Ospanov in 2016 [9] employed staplerless gastric pouch creation (Fig. 1). An adjustable low-pressure gastric band was introduced into the abdomen and retracted through the retrogastric tunnel. The front wall of the stomach below the band was displaced upward through the band, increasing the size of the anterior portion of the stomach pouch so that a gastro-entero-anastomosis could be created. Gastro-gastric sutures were placed to create a plication around the band to secure its position. Band tubing was exteriorized, connected to a port, and secured to the abdominal wall fascia. A jejunal loop was created approximately 200 cm from the ligament of Treitz and anastomosed by hand to the gastric pouch using Vicryl 2/0 sutures. Patients were followed at 1, 3, 6, 12, and 24 months.

For the OAGB-BSGP (staplerless) group, the width of the pouch is 2.5 cm; length of the pouch, 10–12 cm; volume of the pouch, approx. 30–40 cc; and width of the gastroenterostomy, 2.0 ± 0.5 cm. In the OAGB (stapler) group, the width of the pouch is 3 cm; length of the pouch, 15–18 cm; pouch volume, approx. 50–60 cc; and width of the gastroenterostomy, 3.5 ± 0.5 cm [10].

During the OAGB-BSGP procedure, we left only 5 mL in the cavity of the band system. In the postoperative period, after 1 month, we performed an X-ray study of the tightness between the large and small parts of the stomach (pouch). If leaks were seen, we introduced the minimum amount of physiological saline into the port until tightness was created. To do this, as a rule, we injected liquid into the port in 1-mL fractions and performed an X-ray leak test. Patients were followed at 1, 3, 6, 12, and 24 months.

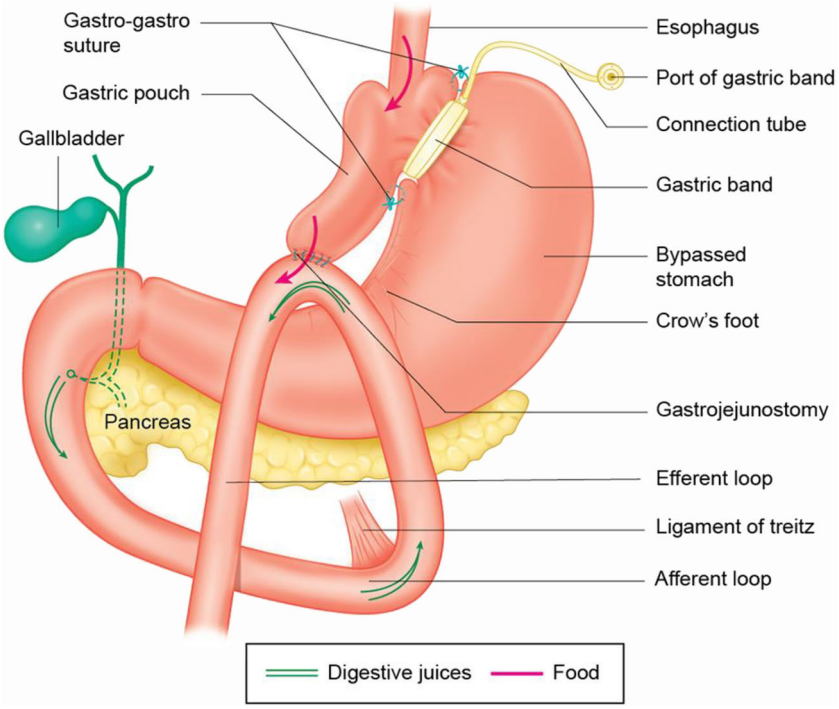

Fig. 1 OAGB-BSGP anatomic configuration: an adjustable band for staplerless creation of the gastric pouch. ©2018 Oral Ospanov

Statistical Analysis

Statistical analysis was performed using Microsoft Excel for Mac (Microsoft Corp., Redmond, WA) and StatPlus: Mac Pro (AnalystSoft Inc., Walnut, CA). Using sample size criteria, a test was performed to determine that a statistically sufficient number of patients were studied to draw safe conclusions based on this new technique. A normality hypothesis test (Kolmogorov-Smirnov) was performed to examine whether or not the observations followed a normal distribution.

Continuous variables are presented using means and standard deviations, and were analyzed using the independent samples *t* test or paired samples *t* test, as appropriate. Categorical variables are presented using counts and percentages, and analyzed using the Fisher's exact test. Statistical significance was set at 0.05, and all tests were two-tailed. Each year of data from April 2015 to December 2016 was included in this analysis.

Results

Patient enrollment started on April 2015 and concluded in December 2016. Surgery was performed between July 2015 and January 2017. Eighty patients met inclusion criteria and agreed to participate in the study with signed informed consent and were randomly allocated into group A ($n = 40$) or B ($n = 40$).

The 2 randomized cohorts were well matched demographically. Patients were predominantly female. Groups A and B baseline height (1.64 ± 0.08 cm vs 1.64 ± 0.072 cm), weight (109.62 ± 18.53 kg vs 111.375 ± 20.05 kg), and BMI (40.55 ± 5.62 kg/m^2 vs 41.18 ± 6.36 kg/m^2) were not significantly different.

No laparoscopic procedure needed to be converted to an open approach. There was no mortality. Early postoperative complications (< 30 days) are presented in Table 1. There was significantly less bleeding in the OAGB-BSGP group (p =

Table 1 Early postoperative complications (< 30 days)

Variable	OAGB-BSGP ("staplerless" group A) $n = 40$	OAGB ("stapled" group B) $n = 40$	p value
Conversions to open, mean ± SD	0	0	0.99*
Operative time (min), mean ± SD	79.45 ± 13.47	81.25 ± 16.92	0.60†
Bleeding (drainage in abdominal cavity, mL), mean ± SD	5.85 ± 8.0	31.12 ± 30.51	0.0001†
Hospital stay (days), mean ± SD	3.67 ± 1.47	4.42 ± 1.61	0.03†

*Fisher's exact test

† Independent samples *t* test

Table 2 Late postoperative complications (> 30 days)

Variable	OAGB-BSGP ("staplerless" group A) $n = 40$ n, %	OAGB ("stapled" group B) $n = 40$ n, %	p value*
Marginal ulcer (at gastroenterostomy)	0 (0.0)	2 (5.0)	0.50
Non symptomatic bile reflux (with gastritis in gastro-entero-anastomosis)	1 (2.5)	3 (7.5)	0.62
Symptomatic bile reflux (with total gastritis of pouch)	0 (0.0)	2 (5.0)	0.50
Intolerant bile reflux (with gastroesophageal reflux disease [GERD])	0 (0.0)	2 (5.0)	0.50
Total biliary reflux	1 (2.5)	7 (17.5)	0.05
Protein malnutrition	1 (2.5)	2 (5.0)	0.99
Vitamin B_{12} deficiency	3 (7.5)	4 (10.0)	0.99

*Fisher's exact test

0.0001) as well as less time spent in hospital ($p = 0.03$). Table 2 demonstrates that, with respect to late complications, the percentage of BR was lower in OAGB-BSGP ($p = 0.05$).

Comparative weight loss for the 2 groups at 2-year follow-up is presented in Table 3. The OAGB-BSGP group showed superior weight loss in TWL ($p = 0.03$) and EBMIL ($p = 0.007$). Table 4 (glycemic changes) and Table 5 (changes in hypertension) show excellent improvement with no significant difference between OAGB-BSGP and OAGB groups. Statistically significant changes in comorbidity markers demonstrated that both procedures were effective in managing all metabolic parameters measured (Table 6).

No revisional procedures were required in the OAGB-BSGP group; whereas, 4 patients (10.0%) of OAGB patients required conversion: 2 OAGB patients were converted to Roux-en-Y gastric bypass (RYGB) due to significant BR; 1 patient experienced significant bleeding requiring diagnostic laparoscopy; and 1 patient had unsatisfactory weight loss (< 50.0% excess weight loss) at 2 years and was converted to a distal RYGB with a shortened alimentary limb length of 400 cm.

Discussion

Standard OAGB provides rapid, excellent weight loss [10]. The procedure is the third most frequently performed bariatric operation in the world [11] and, in 2018, was endorsed by IFSO [12]. Laparoscopic OAGB-BSGP is the first procedure to combine the advantages of OAGB with those of an adjustable gastric band (instead of a stapler and cutter) to create the gastric pouch. OAGB-BSGP is essentially a gastrojejunal loop bypass above an obstructive band in the upper stomach. Operation costs were about $2000 US lower with this method than with standard gastric bypass surgery in which staplers are used [9].

We believe the hospital stay was longer for the OAGB group due to the somewhat more traumatic technique of the stapler-based operation and the presence in the group of one serious bleeding requiring laparoscopic revision of the abdominal cavity. The patient stayed in the hospital for 11 days. Our research team worked to maintain regular contact with patients throughout the current RCT. We were fortunate to be able to maintain 100% follow-up of

Table 3 Weight loss at 2-year follow-up

Variable	OAGB-BSGP ("staplerless" group A) ($n = 40$) mean ± SD	OAGB ("stapled" group B) ($n = 40$) mean ± SD	p value*
Weight loss (kg)	38.15 ± 14.79	33.62 ± 17.19	0.21
BMI (kg/m^2)	26.30 ± 3.2	29.02 ± 4.66	0.003
ΔBMI	14.02 ± 5.05	12.38 ± 5.75	0.18
%TWL	34.06 ± 9.03	29.27 ± 10.59	0.03
%EBMIL	94.29 ± 23.63	77.90 ± 29.25	0.007

BMI, body mass index; *TWL*, total weight loss; *EBMIL*, excess BMI loss

*Independent samples *t* test

Table 4 Glycemic outcomes for patients with diabetes mellitus (T2DM) at 2-year follow-up

Variable	OAGB-BSGP ("staplerless" group A) (n = 40) n (%)	OAGB ("stapled" group B) (n = 40) n (%)	p value*
Type 2 diabetes	21 (52.5)	19 (47.5)	0.82
Complete remission	14 (66.7)	10 (52.6)	0.52
Partial remission	4 (19.0)	5 (26.3)	0.71
Improvement	3 (14.3)	4 (21.1)	0.69
Unchanged	0 (0.0)	0 (0.0)	0.99
Recurrence	0 (0.0)	0 (0.0)	0.99

*Fisher's exact test

both cohorts at 2-year follow-up. The results suggest that, like the standard OAGB, the OAGB-BSGP is both safe and effective. Chevallier et al. cite an OAGB 1.5–2-year follow-up EBMIL of 77.0 ± 22.0% [13]. In the current study, 2-year follow-up OAGB EBMIL was comparable, 77.90 ± 29.25%; however, OAGB-BSGP EBMIL was significantly higher (94.29 ± 23.63%) ($p < 0.007$), as was OAGB-BSGP TWL (34.06 ± 9.03% vs 29.27 ± 10.59%, $p < 0.03$). In addition, OAGB-BSGP may be a safer procedure, as the preconditions for bleeding and suture leak are absent: no staples or sutures in the creation of the gastric pouch—no resulting complications. The superior weight loss of OAGB-BSGP vs OAGB at 2 years may be related to the slightly smaller volume of the gastric pouch [14].

Comorbidities were improved or resolved in most patients following both procedures. The lower incidence of biliary reflux in the OAGB-BSGP group may be related to the smaller diameter of the gastrojejunostomy. Another possible reason for the lower rate of biliary reflux found in the OAGB-BSGP group may be the maintenance of intersection between stomach wall muscle fibers, as well as the absence of a scar on the gastric pouch. In addition, creating the gastric pouch near the esophagogastric junction forms an angle by the antireflux fold of the stomach wall, as in the case of fundoplication.

The use of a gastric band can cause complications. In long-term follow-up, attention should focus on band erosion, band migration, and esophageal dilatation, which seem to be rare at 3 years [15]. We managed to avoid possible band complications perhaps by the use of a wide-profile, low-pressure band ("MedSil" band, CSC, Russia), which has been shown to reduce the likelihood of band erosion and migration [16]. We used the pars flaccida technique [15] and fixed the band with gastro-gastric sutures, reducing the tendency for the band to migrate. Gastric band use may also induce GERD [17]. However, our use of a band with a gastro-entero-anastomosis reduced intragastric pressure and appeared

Table 5 Hypertension at baseline and 2-year follow-up

Variable	OAGB-BSGP ("staplerless" group A) (n = 40) n (%)	OAGB ("stapled" group B) (n = 40) n (%)	p value*
Preoperative			
No hypertension	2 (5.0)	4 (10.0)	0.68
Pre-hypertension (120–140/80–89 systolic/diastolic)	3 (7.5)	4 (10.0)	0.99
Stage 1 hypertension (140–159/90–99)	26 (65.0)	24 (60.0)	0.82
Stage 2 hypertension (> 160/> 100)	9 (22.5)	8 (20.0)	0.99
Postoperative			
No hypertension	25 (62.5)	24 (60.0)	0.99
Pre-hypertension (120–140/80–89 systolic/diastolic)	13 (32.5)	12 (30.0)	0.99
Stage 1 hypertension (140–159/90–99)	2 (5.0)	4 (10.0)	0.68
Stage 2 hypertension (> 160/> 100)	0 (0.0)	0 (0.0)	0.99

*Fisher's exact test

Table 6 Comorbidity outcome markers at baseline and 2-year follow-up

Variable (mean ± SD)1.	OAGB-BSGP ("staplerless" group A) (n = 40) mean ± SD		p value*	OAGB ("stapled" group B) (n = 40) mean ± SD		p value*
	Before surgery	After surgery		Before surgery	After surgery	
Fasting blood glucose (mmol/L)	8.31 ± 4.13	5.4 ± 3.23	< 0.001	7.91 ± 6.11	5.5 ± 2.39	< 0.001
HbA1c ()	9.02 ± 1.4	5.71 ± 1.4	< 0.001	8.82 ± 1.6	5.84 ± 1.2	< 0.001
Systolic blood pressure (mmHg)	141.0 ± 32.0	120.0 ± 19.0	< 0.001	138.0 ± 23.0	120.0 ± 24.0	< 0.001
Diastolic blood pressure (mmHg)	93.0 ± 7.0	74.0 ± 8.0	< 0.001	92.0 ± 11.0	78.0 ± 14.0	< 0.001
LDL cholesterol (mg/dL^{-1})	127.0 ± 26.0	94.0 ± 12.0	< 0.001	131.0 ± 31.0	97.0 ± 16.0	< 0.001
HDL cholesterol (mg/dL^{-1})	44.0 ± 16.0	64.0 ± 23.0	< 0.001	46.0 ± 17.0	61.0 ± 22.0	< 0.001
Total cholesterol (mg dL^{-1})	238.0 ± 54.0	187.0 ± 27.0	< 0.001	235.0 ± 61.0	194.0 ± 34.0	< 0.001
Triglycerides (mg/dL^{-1})	157.0 ± 22.0	89.0 ± 17.0	< 0.001	162.0 ± 21.0	91.0 ± 26.0	< 0.001
Cardiovascular risk (total cholesterol/HDL ratio)	5.4 ± 0.9	2.9 ± 0.4	< 0.001	5.1 ± 1.1	3.1 ± 0.32	< 0.001

*Paired samples t test

H_bA_{1C}, glycosylated hemoglobin; *LDL*, low-density lipoprotein; *HDL*, high-density lipoprotein

to preclude de novo GERD. Also, using gastric bypass for morbid obesity with GERD improves symptoms of GERD postoperatively [18]. Proponents of the procedure advocate its acceptable complication rate when used correctly in selected and well-supported patients.

Conclusion

At 2-year RCT follow-up, staplerless OAGB-BSGP patients had a lower incidence of early postoperative bleeding and biliary reflux, fewer complications, no revisions, and greater weight loss than stapled OAGB patients. Further research is needed to confirm this finding.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Informed Consent Informed consent was obtained from all participants.

Human and Animal Rights The study was conducted in accordance with the ethical standards of the 1964 Helsinki Declaration and its later amendments, and with the approval of the regional ethics committee of Astana, Kazakhstan.

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