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ORIGINAL CONTRIBUTIONS

Five-Year Outcomes: Laparoscopic Greater Curvature Plication for Treatment of Morbid Obesity

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Abstract

Background Laparoscopic greater curvature plication (LGCP) is a newer metabolic/bariatric surgical procedure that requires no resection, bypass, or implantable device. We report outcomes in a cohort of LGCP patients at 5-year follow-up.

Methods Body mass index (BMI, kg/m^2) evolution, excess weight loss (%EWL), excess BMI loss (%EBMIL), and total weight loss (%TWL) were recorded. Repeated measures analysis of variance (ANOVA) was used to assess BMI change over 5 years. Two-step cluster analysis was used to profile LGCP patients according to significant characteristics relative to successful 5-year weight loss.

Results Of patients entering the study between 2010 and 2011 with complete weight data through 5-year follow-up (86.9%, 212/244), mean age was 45.8 ± 10.9 years; mean baseline BMI, 41.4 ± 5.5 (81.6% women); 58 patients (27.4%) had type 2 diabetes. Mean operative time was 69.0 min; mean hospitalization, 38 h (24–72). ANOVA indicated a significant BMI reduction out to 2 years ($p < 0.001$), a plateau at 3 and 4 years, and a moderate but significant BMI increase at 5 years ($p < 0.01$). EBMIL at 1, 2, 3, 4, and 5 years was as follows: 50.7 ± 9.1%, 61.5 ± 8.1%, 60.2 ± 7.0%, 58.5 ± 7.0%, and 56.8 ± 6.3%. At 5 years, 79.2% (168/212) of patients were successful; 20.8% (44/212) experienced a suboptimal weight outcome; mean weight regain, 9.2%. Cluster analysis identified four distinct LGCP patient profiles. Diabetes improvement rate was 65.5%. There were 12 reoperations (4.9%): 4 emergency (1.6%) and 8 (3.3%) elective. There was no mortality.

Conclusions At 5-year follow-up, LGCP proved to be safe and effective, with 56.8% EBMIL and a low rate of complications.

Keywords Laparoscopic greater curvature plication · LGCP · Obesity · Diabetes

Introduction

Since 1980, worldwide obesity has more than doubled. In most countries today, more people die from obesity than from being underweight [1]. In the USA alone, approximately 78 million adults are obese (35.7%) with associated annual medical costs estimated at $210 billion [2]. Global obesity rates and costs are projected to escalate up to 2034 [3, 4]. Metabolic/bariatric surgery continues to be the most successful treatment for obesity, responsible for the greatest sustained weight loss, resolution of comorbidities, and reduction in health care services [5–7]. Laparoscopic greater curvature plication (LGCP), not yet a standard bariatric procedure, has demonstrated good weight loss with potentially fewer complications and costs below the average for traditional operations [8].

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Gastric plication is a bariatric procedure introduced by Tretbar et al. in 1976 [9, 10] and described by laparoscopic approach by Talebpour and Amoli in 2007 [11]. LGCP reduces stomach volume by infolding of the greater curvature and performing 1–2 rows of sutures or staples [12]. LGCP requires no gastric resection, intestinal bypass, or implantable device [13] and is reversible [14–16]. The operation achieves weight loss and comorbidity improvement similar to that of accepted procedures over the short term [8] with lower mean costs than those for laparoscopic sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass (RYGBP) [14, 17, 18].

Ji et al.'s 2014 systematic review of available LGCP data through 2-year follow-up [8] found LGCP a promising, safe, and effective treatment for obesity in the short term; however, they concluded that most individual studies lacked sufficient numbers of patients for validity, and, with the exception of Talebpour et al.'s long-term study [18], lacked evidence on the durability of LGCP beyond 2 years. In 2012, our group published 18-month findings of a prospective, consecutive case series of 244 morbidly obese patients who underwent LGCP when it was an emerging bariatric procedure [12]. Herein, we report mid-term weight and diabetes outcomes for this LGCP cohort through 5 years of follow-up.

Methods

Study Design and Patient Inclusion

An initial prospective feasibility study (recorded with clinicaltrials.gov, identifier #NCT00721227) was IRB approved in 2009 to test 2-row LGCP in three sites. (Details of this protocol were previously published [12].) Following good early weight loss, the Prague, Czech Republic site, a bariatric surgery center of excellence (BSCOE), received IRB approval to perform LGCP prospectively using a 1- or 2-suture row technique. The American Society for Metabolic and Bariatric Surgery [19] and National Institutes of Health [20] criteria for inclusion were applied (i.e., age 18 to 65; BMI ≥40 or ≥35 with comorbidities). Diabetic patients were not excluded if they were being treated with antidiabetic medication or if they had small hiatal hernias (≤2 cm). All patients provided their informed consent for the procedure. Ethical treatment was ensured under the guidelines of the Declaration of Helsinki [21].

Endpoints, Data Collection

The primary study objective was to assess evolution of BMI over the course of 5 years in 212 LGCP patients with complete weight data. Assessments also included percentage body fat (measured by a standardized bioelectrical impedance instrument (In-Body 720, Biospace Inc., Cerritos, CA)); percentage excess weight loss (%EWL: calculated as [preoperative weight − current weight]/[preoperative weight − ideal weight] × 100 [22] relative to the 1983 Metropolitan Life Insurance tables [23]); percentage excess BMI loss (%EBMIL: calculated as [preoperative BMI − current BMI]/[preoperative BMI − 25] × 100 [24]); and percentage total weight loss (%TWL: calculated as [baseline absolute weight − follow-up absolute weight]/[baseline absolute weight] × 100). Specific focus was given to changes from baseline in absolute weight, excess weight, BMI, and excess BMI at 2 and 5 years. Weight loss outcomes were assessed at 2 and 5 years and operationally defined as "successful" if patients with basal BMI < 50 had a residual BMI < 35 and patients with a basal BMI ≥ 50 had a residual BMI < 40. Proportional changes in outcome status at 2 and 5 years were assessed and cluster profiles of successful LGCP patients were identified.

Secondary endpoints were type 2 diabetes mellitus (T2DM) reduction and complications. Surgically induced T2DM improvement was evaluated at 2 and 5 years following LGCP. Improvement was defined as follows: (1) a reduction from baseline in fasting blood glucose of ≥25 mg/dL; or (2) a reduction in HbA_{1C} > 0.5% (or reaching <7.0%); or (3) a reduction in diabetes medication or dose (i.e., discontinuing one medicine, or 50% reduction in dosage, or 25% reduction in insulin).

Surgical Technique

Our own and other techniques for the LGCP procedure have been described previously [12, 13, 15, 18]. The authors' technique features infolding of the greater curvature from below the angle of His distally to approximately 4 cm of the pylorus, secured with full-thickness bites of polypropylene suture in 1 or 2 rows of plications. Endoscopy was used intraoperatively to verify plication integrity in the first 100 patients. After that, a 38F calibration bougie was used routinely.

Postoperative Care and Follow-Up Program

Postoperatively, visits were scheduled for complications as they arose. Ultrasonography (and upper gastrointestinal (GI) endoscopy when needed) was employed to investigate patient complaints and unusual findings. Patients were required to attend all follow-up visits at ±2 months of yearly visit time points. The costs of visits were covered by the Czech Republic's national health system. Our center coordinated with referring general practitioners, diabetologists, and other specialists closely to ensure that LGCP patients attended their follow-up office visits. In addition, follow-up visit compliance was leveraged by our nursing and administrative staffs' program of regular phone calls and emails to every patient.

Statistical Analysis

Quantitative demographic variables were reported as mean, standard deviation (SD), and 95% confidence intervals (95% CI). Qualitative variables (demographic and outcome variables) were reported as number and percentage; complications were also reported as number and percentage. Within-subject analysis of BMI evolution over 5 years was performed using repeated measures analysis of variance (ANOVA). Additional continuous outcome variables were generally reported as mean, SD, mean change, and 95% CI. Measures of change from baseline along weight parameters at 2 and 5 years were analyzed using the paired samples t test. Also, at 2 and 5 years, patients were classified as attaining successful or suboptimal weight loss based on residual BMI (see "Endpoints, Data Collection," above). McNemar's test was used to assess changes in proportion of patients achieving weight loss success at 2 and 5 years. Two-step cluster analysis (a multivariate analysis technique) was used to profile LGCP patients according to significant characteristics relative to successful 5-year weight loss; ANOVA was used to analyze between-cluster differences. Logistic regression was applied in the development of a weight loss success probability model based on the strongest differentiating predictor identified by cluster analysis. The SPSS software package (version 20, SPSS (IBM), Chicago, IL) was used to perform all statistical analyses. Statistical significance was set at $p < 0.05$.

Results

Baseline Patient Characteristics

The following results are based on 212 LGCP patients with complete weight data out to 5 years (i.e., an 86.9% [212/244] follow-up rate at 1, 2, 3, 4, and 5 years). Patients' mean age was 45.8 ± 10.9 years; 81.6% were women (Table 1). Mean absolute weight was 119.2 ± 21.0 kg and mean excess body weight, 51.1 ± 17.4 kg. Mean BMI was 41.4 ± 5.5 kg/m^2 (91.5% < 50; 8.5% ≥ 50); mean body fat was 51.8 ± 6.3%. Sixty-one percent of patients had at least one comorbidity. Hypertension was the most prominent comorbid illness (98, 46.2%), followed by T2DM (58, 27.4%), and dyslipidemia (38, 17.9%).

Operative Time, Hospital Stay

Mean operative time was 69.0 ± 11.0 min; mean hospitalization, 38.0 ± 8.5 h (range 24–72).

Table 1 Preoperative patient characteristics

Characteristic	Value mean ± SD (95%CI) N = 212
Age (years)	45.8 ± 10.9 (44.3, 47.3)
Height (cm)	169.3 ± 9.2 (168.1, 170.6)
Absolute weight (kg)	119.2 ± 21.0 (116.4, 122.0)
Ideal body weight (kg)	68.1 ± 6.4 (67.2, 69.0)
Excess body weight (kg)	51.1 ± 17.4 (48.7, 53.5)
Waist circumference (cm)	120.0 ± 14.2 (118.1, 121.9)
Waist-to height ratio	0.7 ± 0.1 (0.6, 0.8)
Body fat percentage	51.8 ± 6.3 (50.9, 52.7)
Excess body mass index (kg/m^2)	16.4 ± 5.5 (15.6, 17.1)
BMI (kg/m^2)	41.4 ± 5.5 (40.7, 42.1)
<50, (n, %)	194 (91.5)
≥50, (n, %)	18 (8.5)
Gender (n, %)	
Male	39 (18.4)
Female	173 (81.6)
Comorbidities (n, %)	
At least one comorbidity	129 (60.8)
Hypertension	98 (46.2)
Type 2 diabetes mellitus	58 (27.4)
Dyslipidemia	38 (17.9)
Other	20 (9.4)

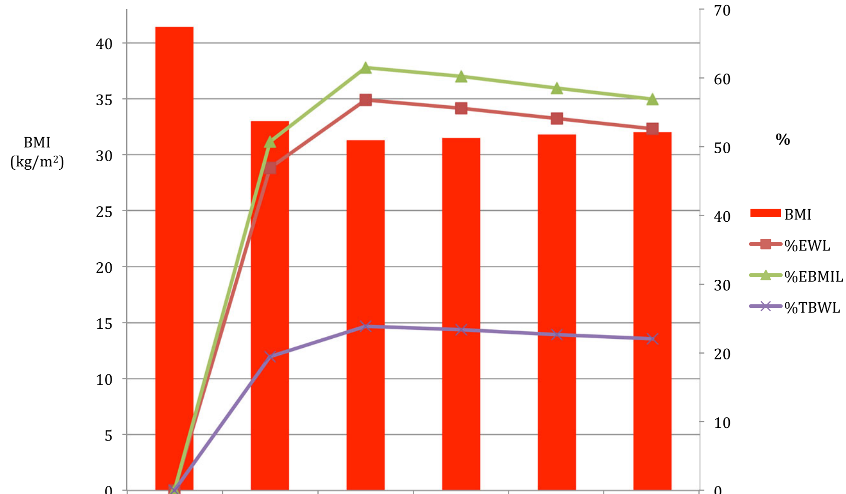
Ideal body weight and excess body weight derived from the Metropolitan Weight Tables for Life Insurance, 1983 [23]

Other = hypothyroidism, asthma, sleep apnea, depression, arthropathy, etc.

Weight Outcomes

Within-subject weight change over time was analyzed by assessing mean BMI at baseline and at 1, 2, 3, 4, and 5 years. One-way repeated measures ANOVA, with Greenhouse-Geisser corrections, indicated that mean BMI differed significantly across time points (F [1.5, 300.6] = 1273.9, p < 0.001). Multiple pairwise comparisons were performed using Bonferroni-adjusted alpha levels. Following LGCP, significant reductions in BMI relative to baseline were achieved at all time points (p < 0.001). As depicted in Fig. 1, mean BMI was reduced from 41.2 ± 5.3 to 33.0 ± 3.1 kg/m^2 at 1 year (p < 0.001). The significant downward BMI trend persisted through 2 years, 31.1 ± 2.3 kg/m^2 (p < 0.001). A relative plateau occurred from 2 to 4 years following LGCP, with no significant change in mean BMI. However, from 4 through 5 years, a moderate but significant increase in BMI was observed, 32.0 ± 2.3 kg/m^2 (p < 0.001). This trend was more evident in patients with baseline BMI > 40 (Fig. 2).

Also presented in Fig. 1 are trends in EWL, EBMIL, and TWL corresponding to BMI changes over the 5 years of follow-up. For example, at 1 year following LGCP, patient BMI had fallen to 33.0 ± 3.1 kg/m^2 and the



Time	Baseline	1 Year	2 Years	3 Years	4 Years	5 Years
BMI (95% CI)	41.4 (40.7, 42.2)	33.0 (32.6, 33.5)	31.2 (30.9, 31.6)	31.4 (31.1, 31.8)	31.7 (31.4, 32.0)	32.0 (31.7, 32.4)
%EWL (95% CI)	–	46.8 (45.8, 47.9)	56.8 (55.9, 57.7)	55.6 (54.8, 56.3)	54.1 (53.3, 54.8)	52.6 (51.9, 53.3)
%EBMIL (95% CI)	–	50.7 (49.5, 51.9)	61.5 (60.4, 62.6)	60.2 (59.2, 61.1)	58.5 (57.6, 59.5)	56.8 (55.9, 57.7)
%TWL (95% CI)	–	19.4 (18.8, 20.1)	23.9 (23.1, 24.7)	23.4 (23.6, 24.1)	22.7 (22.0, 23.5)	22.1 (21.4, 22.8)

Fig. 1 Body mass index (*BMI*, kg/m^2), excess weight loss (*%EWL*), excess BMI loss (*%EBMIL*), and total weight loss (*%TWL*) through 5 years after laparoscopic greater curvature plication

corresponding EWL, EBMIL, and TWL values were 46.9 ± 7.4%, 50.7 ± 9.1%, and 19.5 ± 4.8%, respectively. For comparative purposes, current LGCP EWL data were integrated in Fig. 3 with Talebpour et al.'s [18] 5-year LGCP follow-up data (the only other investigators to date to report 5-year LGCP results) to provide EWL results in the context of other bariatric operations with follow-up out to 5 years (as summarized by O'Brien et al. [25] for RYGBP, long-limb RYGBP (LL-RYGBP), banded RYGBP (Banded RYGBP), laparoscopic adjustable gastric banding (LAGB), and biliopancreatic diversion (BPD), and for LSG by Golomb et al., Hirth et al., Lemanu et al., Sieber et al., and Diamantis et al. [26–30]). For the first 2 years, LGCP EWL results appear to occupy the middle ground of weight loss effectiveness provided by traditional procedures. At 5 years, LGCP weight loss appears comparable to that of LSG, RYGBP, LL-RYGBP, and LAGB.

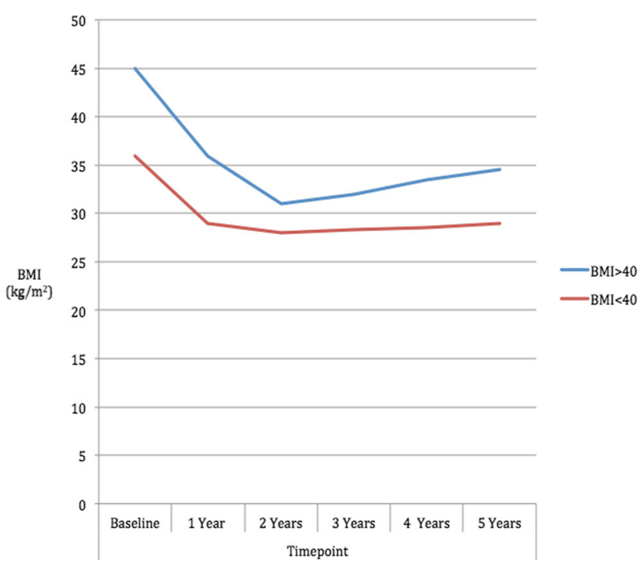


Fig. 2 Body mass index (*BMI*, kg/m^2) evolution of patients with baseline <40.0 vs. >40.0 BMI

Specific weight data for 2-year (the BMI nadir) and 5-year follow-ups are presented in Table 2. Paired samples *t* tests indicated that obesity markers were significantly reduced relative to baseline. At 2 years, absolute weight was 89.8 ± 10.8 compared to 119.2 ± 21.0 kg at baseline, a mean reduction of 29.5 ± 11.9 kg (95% CI: 27.9, 31.1; $p < 0.001$). BMI dropped to 31.3 ± 2.4 from 41.4 ± 5.5 kg/m^2 ($p < 0.001$), a reduction that represents a mean EWL of 56.8 ± 6.5% (55.9, 57.7). EBMIL was 61.5 ± 8.1% (60.4, 62.6), and TWL, 23.9 ± 5.8% (23.1, 24.7). Also at 2 years, 87.3% of LGCP patients (185/212) were classified as having achieved a "successful" outcome (i.e., patients with basal BMI < 50 kg/m^2 who had residual BMI < 35 kg/m^2, and patients with a basal BMI ≥ 50 kg/m^2 who had a residual BMI < 40 kg/m^2). Further, 35.4% (75/212) were classified as having an "excellent" outcome (basal BMI < 50 kg/m^2 with residual BMI < 30 kg/m^2, and patients with a basal BMI ≥ 50 kg/m^2 with residual BMI < 35 kg/m^2) while 51.9% (110/212) had a "good" outcome (basal BMI < 50 kg/m^2 with residual BMI between 30 and 35 kg/m^2, and patients with a basal BMI ≥ 50 kg/m^2 with residual BMI between 35 and 40 kg/m^2). Overall, at 2 years, only 12.7% (27/212) of LGCP patients experienced suboptimal outcomes.

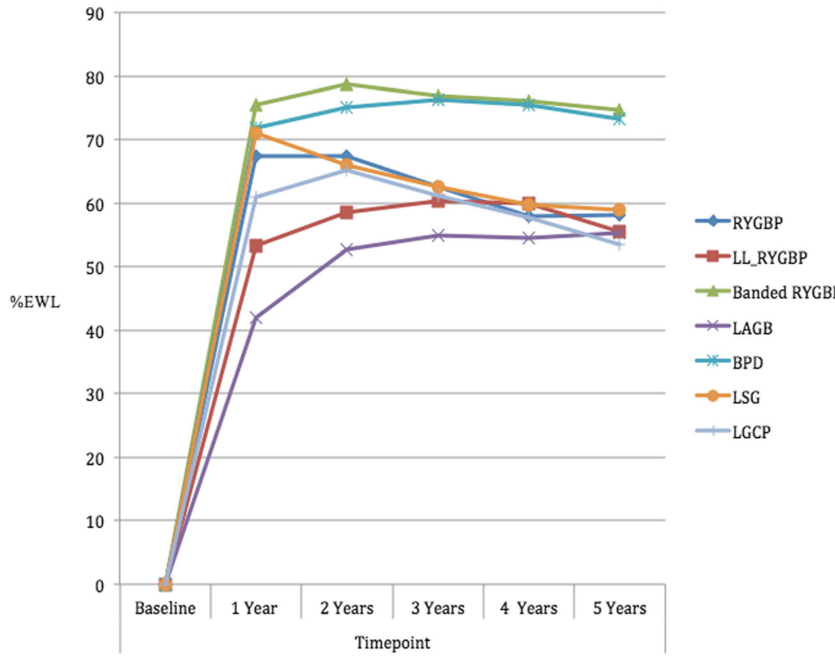


Fig. 3 Laparoscopic greater curvature plication (LGCP) excess weight loss (%EWL) of the current study combined with LGCP results from Talebpour et al. [18] trends out to 5 years compared with those for Roux-en-Y gastric bypass (RYGBP), long-limb RYGBP (LL-RYGBP), banded RYGBP (Banded RYGBP), laparoscopic adjustable gastric banding (LAGB), biliopancreatic diversion (BPD) (as projected by O'Brien et al.'s meta-analysis [25]), and for laparoscopic sleeve gastrectomy (LSG) as projected by the combined results of Golomb et al., Sieber et al., Hirth et al., Lemanu et al., and Diamantis et al. [26–30]

At 5 years, obesity indicators remained significantly reduced relative to baseline measures. For example, absolute weight was 91.9 ± 11.3 compared to 119.2 ± 21.0 kg at baseline, a mean reduction of 27.3 ± 11.0 kg (25.8, 28.8; $p < 0.001$). However, a certain amount of weight regain was evident: EWL was 52.6 ± 4.9% (51.9, 53.3) compared to the

Table 2 Weight loss at 2 and 5 years

Variable	2-year outcomes			5-year outcomes		
	Mean ± SD(95% CI)*	Mean change(95% CI)[a]	p value[b]	Mean ± SD (95% CI)	Mean change (95% CI)	p value[b]
Absolute weight (kg)	89.8 ± 10.8 (88.3, 91.3)	29.5 ± 11.9 (27.9, 31.1)	<0.001	91.9 ± 11.3 (90.4, 93.4)	27.3 ± 11.0 (25.8, 28.8)	<0.001
Excess weight (kg)	21.6 ± 7.0 (20.7, 22.6)	29.5 ± 11.9 (27.9, 31.1)	<0.001	23.8 ± 7.3 (22.8, 24.8)	27.3 ± 11.0 (25.8, 28.8)	<0.001
BMI (kg/m^2)	31.3 ± 2.4 (30.9, 31.6)	10.2 ± 3.8 (9.6, 10.7)	<0.001	32.0 ± 2.4 (31.6, 32.3)	9.4 ± 3.5 (8.9, 9.9)	<0.001
Excess BMI (kg/m^2)	6.2 ± 2.4 (5.8, 6.5)	10.1 ± 3.8 (9.6, 10.7)	<0.001	7.0 ± 2.4 (6.6, 7.3)	9.4 ± 3.5 (8.9, 9.9)	<0.001
EWL (%)	56.8 ± 6.5 (55.9, 57.7)			52.6 ± 4.9 (51.9, 53.3)		
EBMIL (%)	61.5 ± 8.1 (60.4, 62.6)			56.8 ± 6.3 (56.0, 57.8)		
TWL (%)	23.9 ± 5.8 (23.1, 24.7)			22.1 ± 5.2 (21.4, 22.8)		
Successful outcome (n, %)	185 (87.3)			168 (79.2)		<0.001[c]
Excellent (n, %)	75 (35.4)			48 (22.6)		
Good (n, %)	110 (51.9)			120 (56.6)		
Suboptimal (n, %)	27 (12.7)			44 (20.8)		

Calculations based on patients with complete weight data out to 5 years

BMI body mass index, *EWL* excess weight loss, *EBMIL* excess BMI loss, *SD* standard deviation, *CI* confidence interval

*95% CI of the mean

[a] 95% CI of mean difference

[b] Paired samples t test assessing change from baseline

[c] Repeated measures McNemar test

2-year level of 56.8%. Similarly, mean EBMIL and TWL values fell to 56.9 ± 6.3% and 22.1 ± 5.2%, respectively, with a concomitant mean weight regain of 9.2 ± 4.5% (8.5, 9.8) and a range of 0.60–23.3%. Predictably, the weight regain experienced by LGCP patients translated into a significant decrease in the number of patients achieving a successful outcome at the 5-year mark. At that time point, 79.2% (168/212) were classified as having experienced a successful outcome vs. 87.3% at 2 years ($p < 0.001$) (Table 2).

The varying patterns of weight loss/gain characterizing LGCP patients can be further understood by tracking changes in success classification from 2 to 5 years. For example, the majority of patients who had an excellent outcome at 5 years (91.7%, 44/48) also had excellent outcomes at 2 years. A small percentage of LGCP patients (8.3%, 4/48) who were classified as achieving excellent outcomes at 5 years were originally classified as "good" at 2 years, indicating their continued progress from the 2- to 5-year time points in terms of BMI reduction. No patients classified as having excellent outcomes at 5 years fell into the "suboptimal" outcome category at 2 years. The majority of patients with a good outcome at 5 years also had good outcomes at 2 years (71.4%, 85/120). However, 25.2% (30/120) of patients who achieved good outcomes at 5 years fell off from their excellent rating at 2 years. On the other hand, 3.4% of patients (4/120) with good outcomes at 5 years demonstrated significant weight loss from year 2 to year 5, and moved from a suboptimal to a good classification. Finally, slightly more than half of patients classified as suboptimal at 5 years also were classified as suboptimal at 2 years (52.3%, 23/44). However, 47.7% (21/44) of patients classified as suboptimal at 5 years experienced significant weight regain, and fell from a good outcome at 2 years to a suboptimal outcome at 5 years.

Weight Loss Success Profiles

In an attempt to better understand the nature of the long-term "successful" weight loss LGCP patient, data on preoperative patient characteristics (e.g., body fat percentage, BMI, waist circumference, height, waist-to-height ratio, excess weight, age, gender) and 5-year outcomes were entered into a 2-step cluster analysis program. Applying this multivariate method to the data, four distinct LGCP patient cluster profiles were identified. Descriptive statistics characterizing the four cluster profiles are presented in Table 3.

Cluster 1 Less Successful Females

"Less successful females" is the second largest cluster of LGCP patients (32.2%, 68/212), with a mean age of 58.2 ± 4.1 years. Baseline body fat percentage was 55.5 ± 1.8 (highest of all clusters, $p < 0.001$) and BMI, 46.7 ± 4.8 kg/m^2 (highest of all clusters, $p < 0.001$). The group's mean basal waist circumference was 128.9 ± 11.6 cm (highest of all female clusters, $p < 0.001$), and their mean height was 166.5 ± 7.3 cm, resulting in the highest waist-to-height ratio (0.88, $p < 0.001$) observed among the four clusters. Patients in this group experienced a mean weight regain of 9.2 ± 4.3% (highest of all female groups, $p < 0.001$). Most striking is the fact that all of the 68 LGCP patients (100%) comprising this cluster entered the study at ≥45 kg/100 lb over the ideal weight, and subsequently, only 45.1% (31/68) were classified as having had a successful weight loss outcome. In fact, 86.0% (38/44) of all suboptimal outcomes were derived from this cluster. However, the successful patients in this group experienced a mean EBMIL of 59.3 ± 5.6%.

Cluster 2 Successful Males

All male/no female patients fell into this, the second smallest cluster of LGCP patients identified (18.5%, 39/212). The mean age was 47.0 ± 10.1 years, with 56.4% (22/39) <50 years of age. On study entry, mean body fat was 43.3 ± 3.9% (lowest of all clusters, $p < 0.001$), and BMI, 41.7 ± 4.7 kg/m^2 (second highest of all clusters). Also, waist circumference was 131.6 ± 11.6 cm (highest of all clusters, $p < 0.001$) and mean height was 182.3 ± 7.6 cm (highest of all clusters, $p < 0.001$), resulting in the second highest waist-to-height ratio observed (0.72). Patients in this group experienced a mean weight regain of 10.1 ± 5.0% (highest of all clusters, $p < 0.001$). The majority of these males (79.5%, 31/39) entered the study at ≥45 kg over the ideal weight; yet, the success rate for this cluster was 89.7%. At 5 years, the successful male patients experienced a mean EBMIL of 60.0 ± 6.7%. Also, 15.9% (7/44) of all excellent outcomes and 22.6% (28/124) of all good outcomes came from this group.

Cluster 3 Successful Younger Females (<50 yrs)

This is the largest cluster identified (35.4%, 75/212) and the youngest, with a mean age of 38.6 ± 6.0 years. In this LGCP group, 97.3% (73/75) were classified as having had a successful weight loss outcome at 5 years. They entered the study with a mean body fat of 50.4 ± 2.2% and BMI of 38.5 ± 2.7 kg/m^2. The group's mean waist circumference was 109.7 ± 8.9 cm (lowest of all groups, $p < 0.001$), while their mean height was 167.5 ± 6.6 cm (highest of all female groups, $p < 0.001$), resulting in the lowest waist-to-height ratio observed (0.65, $p < 0.001$). Patients in this cluster experienced a mean weight regain (from 2 to 5 years) of 8.6 ± 4.5% (lowest of all groups, $p < 0.001$). Interestingly, 39.0% (29/75) of these patients entered the study at ≥45 kg

Table 3 Cluster profiles of LGCP patient characteristics relative to 5-year weight loss

Variable	C1 Less successful females	C2 Successful males	C2 Successful younger females	C4 Successful older females	*p* value*
Qualitative					
Number (%)	68 (32.2)	39 (18.5)	75 (35.4)	30 (14.2)	<0.001
Age (% ≥50 years)	48.5	43.6	0	100	<0.001
Excess weight (% ≥45 kg)	100	79.5	39.2	0	<0.001
Success (%)	44.1	89.7	97.3	100	<0.001
Quantitative					
Age (years)	47.9	47.0	38.6	58.2	<0.001
% Body fat	55.5	43.3	50.4	49.9	<0.001
Body mass index (kg/m^2)	46.7	41.7	38.4	36.8	<0.001
Waist circumference (cm)	128.9	131.6	109.7	110.7	<0.001
Height (cm)	166.5	182.3	167.5	162.9	<0.001
Waist-to-height ratio	.78	.72	.65	.68	<0.001
% Weight regain	9.2	10.1	8.6	8.9	<0.001

C cluster

*Analysis of variance test (ANOVA)

over the ideal weight, and yet, this cluster experienced a 97.3% success rate. At 5 years, successful patients in this cluster experienced a mean EBMIL of 57.2 ± 6.1%. Also, 56.8% (25/44) of excellent outcomes and 38.7% (48/124) of good outcomes came from this cluster.

Cluster 4 Successful Older Females (50+ years)

This was the smallest (14.2%, 30/212) and the oldest cluster of LGCP patients, with a mean age of 58.2 ± 4.1 years. A successful weight loss outcome at 5 years was attained by 100% of patients, all of whom entered the study with a mean body fat of 49.9 ± 2.5% and BMI of 36.8 ± 3.0 kg/m^2. The group's mean waist circumference was 110.7 ± 6.5 cm (second lowest of all clusters), while their mean height was 162.9 ± 4.2 cm (lowest of all clusters, $p < 0.001$), resulting in the second lowest waist-to-height ratio observed (0.68). Patients experienced a mean weight regain of 8.9 ± 4.1%. Perhaps most significantly, none entered the study at ≥45 kg over the ideal weight. At 5 years, and 100% successful, patients in this cluster experienced an EBMIL of 53.2 ± 6.6%. Also, 25.0% (11/44) of all excellent outcomes came from this cluster.

Logistic Regression Model

The 2-step cluster analysis identified body fat as the strongest predictor of cluster membership. Logistic regression, using body fat percentage as the lone predictor (odds ratio = 0.80, 95% CI: 0.74, 0.87, $p < 0.001$), was applied in the development of an LGCP weight loss success model. Figure 4 depicts results in the form of a probability curve. The logistic model's beta coefficient (−0.22) and associated constant (13.34) were used to develop an equation projecting the likelihood of a successful weight loss outcome (as defined in "Methods") as a function of patient preoperative body fat; model

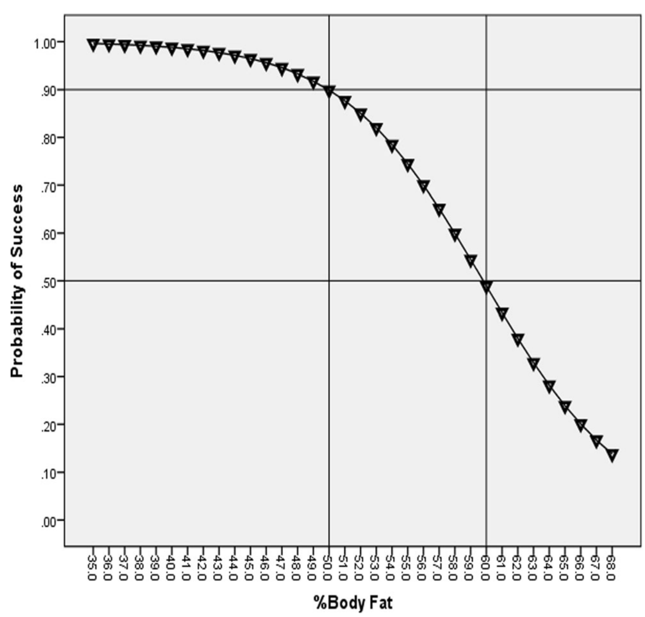


Fig. 4 The probability curve characterizes the likelihood of a patient with a given preoperative body fat percentage experiencing successful weight loss (i.e., residual BMI <35 or <40 if superobese) 5 years following laparoscopic greater curvature plication (LGCP). For example, a patient with a preoperative body fat of 50.0% is predicted to have a 90.0% chance of success following LGCP. On the other hand, a patient with 60.0% basal body fat is predicted to have only a 50.0% chance of success following LGCP

sensitivity, 91.02%. Results indicated that those patients presenting with body fat of <50.0% had a >90.0% chance of experiencing a successful LGCP outcome.

Diabetes Resolution

At 2 years following LGCP, 52 of 58 preoperatively diabetic patients (89.7%) experienced surgically induced improvement. Six patients (10.3%) showed no significant change from baseline. At 5 years, the improvement rate was 65.5% (38/58). Weight loss outcomes did not significantly differ between diabetic and non-diabetic LGCP patients. At 2 years, EBMIL was 61.2 ± 9.0% and 61.6 ± 7.8% ($p = 0.75$) for diabetics and non-diabetics, respectively; at 5 years, 56.4 ± 7.7% vs. 57.0 ± 5.8% ($p = 0.50$). Also at 5 years, 82.8% of diabetics (48/58) and 77.9% of non-diabetics (120/154) reached the BMI success criterion of <35 kg/m^2 (or <40 kg/m^2 if superobese).

Complications

There was no mortality in our series. Early LGCP complications (described in the initial report of 18-month outcomes [12]) included one intraoperative conversion from laparoscopy to laparotomy and postoperative nausea and vomiting in 68 patients (32.1%) that was controlled with the 5-HT3 receptor antagonist, ondansetron. The rate of minor early complications was 27.8% ($n = 68$). Nine patients required hospital readmission but not reoperation. Six of these patients underwent gastroscopy and were diagnosed with gastric mucosal irritations or lesions in the lower third of the plication ridge. Five of them were successfully treated with proton-pump inhibitor (PPI) drugs, and one patient's invaginating sutures that were prominent intraluminally at the area of mucosal irritation were removed endoscopically. The three remaining patients were admitted because of vomiting not correlated to gastroscopy findings (i.e., gastroscopy was essentially normal). These patients were treated with intravenous PPIs and parenteral fluids and their status improved rapidly. They were returned to oral diet in 24–48 h after admission and discharged home on PPI therapy for 3 months. As reported previously [12], there were three emergency reoperations in the initial 18-month period, and four patients who elected for reoperation ($n = 1$ in 2010, $n = 3$ in 2011).

Major complications included one patient who required emergency reoperation due to a gastric diverticulum in the proximal one third of the gastric fundus. The patient presented with vomiting that had lasted for more than 1 week and epigastric pain after every meal. On emergency reoperation, a stomach wall diverticulum (approximately 2 × 3 cm) between invaginating suture bites was found. The diverticulum was deemed viable and was reinvaginated, and the entire greater curvature was replicated with 2/0 Prolene sutures.

Also, in the later stages of the 5-year follow-up, four elective reoperations were performed ($n = 1$ in 2012, $n = 1$ in 2013, $n = 0$ in 2014, $n = 2$ in 2015) due to stomach dilatation and/or suture-line disruption that caused a premature weight loss plateau and/or a reduced feeling of satiety after a small meal. In three patients, replication was elected and was carried out by addition of 1–2 invaginating rows with 2/0 Prolene sutures. In conjunction with multidisciplinary team reassessment, the final patient requested a different procedure at reoperation; thus, the Scopinaro biliopancreatic diversion (BPD) was performed on him with good results, including additional weight loss and resolution of T2DM.

Discussion

LGCP evidence to date has been limited to small series reporting short-term findings [8]. The current study presents outcomes for, we believe, the largest LGCP cohort to date to achieve 5-year follow-up. Our study found that BMI was significantly reduced from 41.4 to 31.3 kg/m^2 at 2 years and to 32.0 kg/m^2 at 5 years, with improvements in diabetes at both 2 and 5 years. Nine patients (3.7%) had major complications, six (2.5%) of whom required reoperation.

Weight

The study's primary focus was to observe and analyze medium-term weight loss in LGCP patients through the 5-year follow-up. We evaluated weight loss trends in terms of BMI evolution, %EWL, %EBMIL, and %TWL. In addition, we used a residual BMI of <35 (or <40 for superobese) as the defining criterion of surgically induced weight loss success. Biron et al. have shown that these BMI cutoff points correspond to metabolic/bariatric patients' beliefs about weight loss success and failure [31]. According to Biron et al., "…to reach patients' 'reasonable goal' and to claim success, a BMI of 35 should be used for morbid obesity (basal BMI<50) and a BMI of 40 for super-obesity (basal BMI≥50)" [31]. Van de Laar et al. also emphasize that %EWL is a relative measure not necessarily indicative of surgically induced success in terms of health risk and quality of life measures [32].

Based on the above criteria, at 2 and 5 years, 87.3 and 79.2%, respectively, of patients were classified as having had a successful weight outcome. Our 5-year BMI reduction of 9.4 kg/m^2 compares favorably to 3-year BMI reductions reported by Coleman et al. [33], i.e., LGCP BMI reduction was somewhat inferior to that of RYGBP (13.3 kg/m^2), but greater than LAGB (7.3 kg/m^2) and equivalent to LSG (9.4 kg/m^2). Although our series demonstrated a mean absolute weight regain of 9.2% (0.3–23.0%), the majority of patients (71.4%, 85/120) with good outcomes at 5 years also had good outcomes at 2 years; further, 91.7% (44/48) of patients with excellent outcomes at 5 years also had excellent outcomes at 2 years. These results suggest that LGCP weight loss can be not only substantial but also enduring.

In LGCP patients with complete weight data, corresponding mean EWL and EBMIL were 56.8 and 61.5% at 2 years and 52.6 and 56.9% at 5 years, respectively. Our 5-year %EWL results were comparable to those of Talebpour et al. (55.0% EWL), the only other group that has published 5-year or greater LGCP outcomes [18]. The current mid-term weight loss findings are also in line with those of accepted metabolic/bariatric procedures as evaluated by meta-analysis: Buchwald et al. reported >2-year mean EWL outcomes ranging from 40.7 to 74.8% [34], and O'Brien et al., in their long-term meta-analytic results, reported a 5-year composite mean 63.4% EWL that encompassed all accepted metabolic/bariatric surgery procedures [25].

When profiling LGCP patients using multivariate analysis, four weight loss clusters relative to 5-year outcomes emerged. The largest cluster profile, "successful younger females <50 years old" (mean age 38.6 years), comprised 35.4% of the LGCP population. Although 39.0% of these patients entered the study at ≥45 kg over the ideal weight, they attained a 97.3% success rate. Younger age seemed to moderate the negative effects of excessive weight prior to undergoing LGCP. In contrast, 100% of the second largest cluster (32.0%), "less-successful females," (mean age 58.2 years) entered the study at ≥45 kg over the ideal weight, and only 45.0% were classified as having a successful weight loss outcome. This group began the study with the highest mean basal body fat percentage (55.5%); further, 86.0% of all suboptimal outcomes derived from this cluster. None of the individuals in the third cluster, profiled as "older successful females >50 years old" (mean age 58.2 years), entered the study at ≥45 kg over the ideal weight. This group achieved a 100% success rate. The final cluster was profiled as "successful males." The majority of these patients (79.5%) entered the study at ≥45 kg/over the ideal weight; yet, their success rate was 89.7%, accounting for 15.9% of all excellent outcomes. Basal body fat was the strongest predictor of cluster membership.

As BMI is based solely on weight and height, it cannot differentiate fat mass from lean body mass or bone. Patients with the same BMI can vary markedly with respect to percentage body fat. Research has suggested that preoperative body fat may be a predictive factor in poor weight loss after bariatric surgery [35]. The current study suggests that percentage body fat may be able to play a key role in LGCP patient selection and counseling.

Diabetes

Metabolic/bariatric surgery is superior to diet therapy, behavior modification, exercise programs, and pharmacotherapy in combatting T2DM [36, 37], although longer-term effects of LGCP on T2DM have not been well studied. The current study appears to provide the only mid-term report of LGCP T2DM results. LGCP-induced T2DM improvement was observed in 89.7 and 65.5% of patients at 2- and 5-year follow-ups, respectively. Of studies reporting early LGCP T2DM outcomes, four out of five described significant T2DM improvement [12, 17, 18, 38, 39], while one stated that LGCP had very little influence on T2DM, noting that HbA_{1C} levels dropped from 7.9% at baseline to only 7.5% at 12 months following LGCP with no patients off T2DM medication [39]; whereas, in our early outcomes, HbA_{1C} dropped from 6.4% at baseline to 5.1% ($p < 0.001$) at 6 months [12]. The current study's mid-term outcomes are in line those from with a meta-analysis that shows significant T2DM improvement (86.6% resolution/improvement) following all accepted metabolic/bariatric procedures at ≥2 years of follow-up [40].

Weight regain after the 2-year weight loss nadir did not appear to be directly or solely related to 5-year diabetes outcomes in our study. The majority of LGCP patients who showed early improvement in their diabetes retained these benefits despite varying amounts of weight regain. Therefore, it is possible that neuroendocrine effects engendered by gastric reconfiguration and disruption of blood supply along the greater curvature (similar to that performed during LSG), rather than the restrictive component of LGCP alone, may influence the maintenance of patients' T2DM improvements. Hormonal mechanisms affecting weight loss and comorbidity resolution following metabolic/bariatric surgery have only begun to be explored [41, 42]. In a related study, we performed an analysis of LGCP-induced changes in glucose homeostasis, postprandial triglyceridemia, and meal-stimulated secretion of selected gastrointestinal hormones in female T2DM patients [43]. Results demonstrated that patients undergoing LGCP experience significant improvement in glucose homeostasis and postprandial hypertriglyceridemia due to significant weight loss from gastric restriction. Postprandial plasma levels of ghrelin were significantly decreased, and meal-induced glucose-dependent insulinotropic polypeptide (GIP) secretion was increased.

These findings, which appear to parallel those of bariatric operations involving more extensive gut rearrangements, cannot be attributed to caloric restriction or to weight loss alone.

Complications

Within the first 30 days following the majority of LGCP operations, nausea and vomiting are a minor but unwelcome complication of LGCP [8, 14, 18, 38]. Though typically of short duration, nausea and vomiting can continue for many days, even weeks, in a row. These are complications to which more research should be devoted so that they can be attenuated.

Over 5 years of follow-up, our elective reoperation rate was 3.3% (8/244), a rate at medium-term (5-year) follow-up comparable to the range of 0–8 reoperations recorded within the first 14 months alone that has been reported in other LGCP studies [12, 13, 17, 18, 38, 39, 44–51]. Reoperation due to complications and/or weight regain resulted in a return to patients' sensation of more rapidly achieved satiety and a return to weight loss. During our regular LGCP gastroscopy follow-up, the plication ridge as viewed endoluminally was typically very prominent, occupying around 70–80% of stomach volume. In patients who elected reoperation, it is interesting to note that after 24 months, 10.0% exhibited a substantially flatter, less bulky plication ridge than appeared on gastroscopy during the early postoperative period. Yet, following elective reoperative surgery, the eight patients who underwent these procedures ceased regaining weight, and all reported a return to the sensation of satiety following meals that they had enjoyed in the initial postoperative period.

Follow-Up Program

The high rate of follow-up (86.9%) in the current study was likely attributable to several factors in addition to our intensive program of regular communication with patients and their primary care providers. All patients had an early consultation evaluation; none of the data were obtained by phone call or email. The Czech Republic is small geographically and well networked with public transportation. As 300 km is the longest distance from the Eastern country border to Prague's center, >50.0% of patients reside within 50 km of our medical center, and 30.0% live within a 150-km range, it is relatively easy for all patients to travel to an annual office visit within 1–2 h. Our center has opened three additional outpatient clinics in the most remote regions, making it feasible for even far-flung patients to attend follow-up visits. Finally, national health insurance covers all patient care and transportation, as needed, which provides an added inducement to maintain visit compliance.

Limitations

The major limitation of this study is that 32 patients were lost to follow-up from the original 244 reported in the initial 18-month publication. The BMIs of these patients were relatively higher than the mean BMI of the remaining cohort of 212. As patients with a higher BMI, traditionally, do not experience successful outcomes with the same regularity and often regain significantly more weight than lower-BMI patients, the current results may be somewhat positively biased.

Conclusion

This report presents the findings for what we believe to be the largest LGCP cohort to date to achieve medium-term (5-year) follow-up. LGCP resulted in a low rate of reoperations and 56.8% EBMIL. Additional longitudinal LGCP research is needed.

Compliance with Ethical Standards

Disclosure The authors state that there was no financial support for the conduct of the study or writing of the manuscript.

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

Ethical Approval Statement All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Statement Informed consent was obtained from all individual participants included in the study.

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