Original paper

Videosurgery

Laparoscopic gastric plication and its effect on saccharide and lipid metabolism: a 12-month prospective study

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Abstract

Introduction: *Laparoscopic greater curvature plication (LGCP) is a novel restrictive technique that reduces gastric volume by plication of the greater curvature. The advantage of LGCP is its reversibility in comparison to laparoscopic sleeve gastrectomy. Nowadays, the long-term LGCP efficacy, safety and metabolic effect are being investigated.*
Aim: *To assess body composition, clinical complications and metabolic changes in obese patients 6 and 12 months after laparoscopic greater curvature plication.*
Material and methods: *A total of 70 subjects underwent LGCP; 52 of them (33 women and 19 men) completed 1-year follow-up study. Anthropometry and biochemical parameters (glucose, glycated haemoglobin, lipids, ghrelin, leptin, adiponectin and fibroblast growth factor 21 [FGF-21]) were assessed before and 3, 6, and 12 months after surgery.*
Results: *All study participants exhibited statistically significant weight loss at both 6 and 12 months following the LGCP compared to baseline, with significant reductions in body composition – body weight, body mass index, percentage excess weight loss (%EWL), and percentage excess BMI loss (%EBL) ($p \leq 0.001$). Moreover, significant lowering of glucose and glycated haemoglobin, triacylglycerols and leptin was observed 12 months after LGCP. On the other hand, plasma concentrations of ghrelin, adiponectin and LDL cholesterol increased significantly. Total cholesterol, LDL cholesterol and FGF-21 levels did not change significantly.*
Conclusions: *Laparoscopic greater curvature plication appears to be a procedure with good restriction results, which might be mediated through alteration in incretin metabolism. Technical aspects and standardization of the procedure still remain to be worked out.*

Key words: *weight loss, ghrelin, fibroblast growth factor 21, metabolic effect, gastric plication.*

Introduction

Over the past two decades, obesity has become a serious global health problem. The International Association for the Study of Obesity/International Obesity Task Force, a WHO body, has reported that approximately 1 billion adults worldwide are overweight and another 475 million adults are obese [1]. In the countries of Central and Eastern Europe, including the Czech Republic, the prevalence of obesity stands as a forefront issue in all epidemiological studies. Results of the latest large epidemiological study conducted in the Czech Republic reveal that 30% of Czechs are overweight and 25% of them suffer from obesity [2].

There are several therapeutic approaches to obesity. In most cases, the first choice is lifestyle change focused on balanced dietary intake and physical ac-

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tivity. Pharmaceutical therapy, the principal aims of which are to support change in dietary habits and prevent decrease in basal metabolism, is another option. However, since the end of the 1990s, surgical treatment (bariatric/metabolic surgery) has proved to be the most effective obesity treatment [3, 4]. Unlike conservative treatment, which fails in more than 80% of patients in the long term, bariatric surgery results in long-term success in more than 80% of patients [5]. It is the only treatment that produces long-term weight loss in morbidly obese patients [6].

Like all surgical procedures, bariatric surgery requires appropriate training [7] and carries its own risks [8]. Although cure of associated co-morbidities cannot be guaranteed, more than 75% of obese patients experience complete or partial post-operative remission of most obesity-associated health conditions (e.g. type 2 diabetes, dyslipidaemia, and hypertension) [9].

Surgical treatment for obesity is either malabsorptive, or restrictive, or a combination of both. Laparoscopic adjustable gastric banding (LAGB) and laparoscopic sleeve gastrectomy (LSG) are the most popular restrictive procedures for morbid obesity. On the basis of a recent update of the Cochrane Database Systematic Review of 20 randomized controlled trials, LSG is superior to LAGB in terms of weight loss and comparable to the outcome of gastric bypass [10]. Laparoscopic greater curvature plication (LGCP) is a novel restrictive technique that reduces gastric volume by plication of the greater curvature. The mechanism of LGCP is notably similar to that of LSG in that both result in gastric tube formation and elimination of the greater curvature, but LGCP has the advantage of a reversible restrictive technique without the use of gastrectomy [11]. However, its long-term efficacy is under investigation, and there are very few studies that compare it with other bariatric procedures, including LSG.

Aim

The main purpose of this study was to assess body composition, clinical complications and metabolic changes in obese patients 6 and 12 months after laparoscopic greater curvature plication.

Material and methods

Patients

A total of 70 subjects aged 24 to 68 years underwent LGCP. The study was approved by the Ethics Committee of the Faculty of Medicine, University of Ostrava, Czech Republic, in accordance with the ethical standards of the Helsinki Declaration of 1975, as revised in 2000. The subjects were patients of the Gastroenterology Care Centre, Department of Surgery of the Vitkovice Hospital, Czech Republic. Selection of subjects for the surgical treatment of obesity was carried out in accordance with the guidelines of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO). The subjects had either body mass index (BMI) ≥ 40 kg/m^2, BMI ≥ 35 kg/m^2 with associated co-morbidities, or BMI < 35 kg/m^2 with a history of weight loss resulting from intensive therapy followed by regaining of weight. Patients with history of stomach surgery, gastric and duodenal ulcers, thyroid disorders, gastrointestinal disorders associated with intestinal resorption dysfunction and hypolipidaemic and anti-diabetic treatment were excluded.

Out of 70 enrolled subjects, 52 subjects (33 women and 19 men) completed the study. Eighteen subjects were rejected from the study due to loss of follow-up. All patients underwent pre-operative and follow-up examinations (3, 6, and 12 months after surgery). The assessment procedures – anthropometry, monitoring of serum concentrations of fasting glucose and relevant hormones – were identical on each assessment occasion. This was a prospective, non-randomized, open-label, single-centre, observational safety and feasibility study.

Surgical technique

The operations were performed under general anaesthesia, in supine position, with legs apart. A laparoscopic approach with five ports was used. Two 5-mm ports and three 10-mm ports were placed in the upper abdomen according to a standard schema. Dissection of the greater curvature started 4 cm proximally from the pylorus along the whole greater curvature. Two proximal short gastric veins were preserved. Afterwards, the greater curvature was plicated with one or two rows of continuous non-absorbable monofilament suture (18 vs. 34 patients, respectively). The first three procedures were carried out under endoscopic observation (Photo 1); thereafter the procedures were performed without endoscopic guidance or bougie. The anatomic landmarks were free margins of short gastric veins. Tilting of the operating table was used to obtain better vision

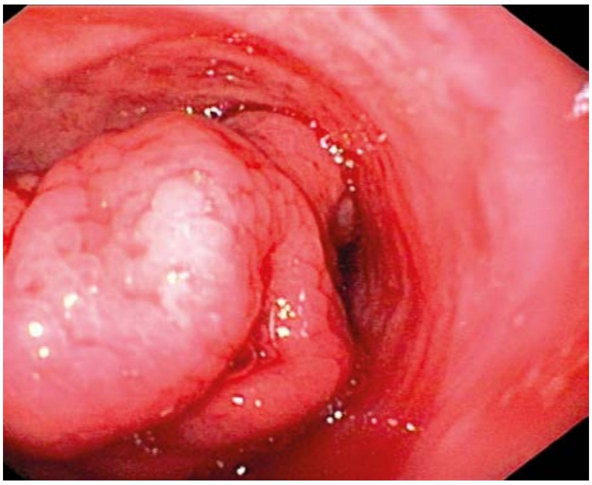

Photo 1. LGCP – endoscopic view

in the operating field. No antibiotic prophylaxis was used. At the end of the procedures, serotonin 5-HT3 receptor antagonist was administered to prevent nausea and vomiting. Proton pump inhibitor was administered before the operation, 20 mg orally and also intravenously after the operation until the resolution of nausea.

Post-operative care

Following the operation, the patients were transferred to the ICU, usually for 24 h. Oral liquids were allowed depending on tolerance from 4 h post-operatively. Early mobilization was forced mostly 6 h after the operation. The special "bariatric diet" called BS 1 to 7, was administered in the next days. Patients were discharged only when they were able to eat a BS 7 diet (solid food).

Anthropometric assessment

A basic anthropometric examination was carried out, including measurements of body weight, height, waist and hip circumference, and calculation of BMI. Body composition was determined by dual-energy X-ray absorptiometry (DXA, Hologic Discovery A, Waltham, USA).

Weight loss

The main study objective was to assess the weight loss after LGCP. The weight loss assessments included absolute weight loss (AWL), percentage of total weight loss (%TWL), percentage of excess weight loss (%EWL), and changes in BMI. Percentage of EWL was calculated using ideal body weight according to the middle of the 1983 Metropolitan Life Insurance tables for median frame. The weight was measured by electronic scales on the day of surgery and at 3, 6, and 12 months after surgery.

Biochemical assessment

Venepuncture was performed in the morning after overnight fasting a week before the planned procedure, and 3, 6 and 12 months after it. Blood samples, except the sample for glycated haemoglobin determination, were centrifuged at 2500 g for 6 min at 4°C. Serum concentrations of the following substances were assayed: glucose, triacylglycerols (TG), total cholesterol (TC), high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol (AU 5420, Beckman Coulter, Inc., USA). To reduce analytical variation of hormones and cytokines of fat tissue, the serum samples were aliquoted into two vials (2 ml each) and stored at –80°C until the time of analysis. Serum levels of leptin, adiponectin and ghrelin were analysed by the ELISA method using the sandwich sets (Biovendor – Laboratorni medicina, Czech Republic) by ELISA technology (DSX, Dynex Technologies, Chantilly, VA, USA). Fibroblast growth factor 21 (FGF21) was determined by multiplex assay developed by Biovendor – Laboratorni medicina using barcoded magnetic beads, and performed on Biocode-100A (Applied Biocode, USA). Glycated haemoglobin (HbA_{1c}) was measured by HPLC (Tosoh G8, Tosoh Bioscience Inc., CA, USA).

Statistical analysis

The anthropometry and body composition measurement results were evaluated by Student paired *t*-test. *F*-test based on a linear mixed model was used to compare concentrations of biochemical parameters pre- and post-operatively. Surgical complications were evaluated by a χ^2 test and two-sample Wilcoxon rank-sum (Mann-Whitney) test. The level of significance was set at 0.05. These statistical data were processed with the Stata v.10 program and statistical software R version 2.14.1. (R Development Core Team 2013).

Results

A total of 70 patients (51 women and 29 men) underwent surgery from January 2011 to December 2013. A total of 18 patients dropped out of the study. Fifty-two patients (33 women and 19 men) finished the study. Their initial mean age and mean weight were 42.1 years and 124.4 kg, respectively. The mean BMI was 43.3 kg/m^2, including 3 patients with a BMI of > 50 kg/m^2. The mean duration of the procedure was 58.1 min (ranging from 45 to 90 min in one-row suture) versus 75 min (ranging from 50 min to 105 min in two-row suture) – a highly significant difference. The length of hospital stay did not differ significantly between one- and two-row plication.

Table I presents the weight loss outcomes and body composition in our cohort study, including the significant reductions noted in body fat mass and in lean body mass. The patients achieved a mean %EWL of 51.5 after 12 months post-operatively, and a mean %EBL of 56.9 during this period. All study participants exhibited statistically significant weight loss both at 6 and 12 months following the LGCP compared to baseline, with significant reductions in body composition – body weight, BMI, %EWL, and %EBL ($p \le 0.001$).

Biochemical variables

Serum concentrations of glucose, triacylglycerols, leptin and blood concentrations of glycated haemoglobin were significantly lower 12 months after LGCP. On the other hand, plasma concentrations of ghrelin and adiponectin increased significantly. Similar to LSG studies, HDL cholesterol levels increased and triacylglycerol levels decreased. Low-density lipoprotein cholesterol, total cholesterol and FGF-21 levels did not change significantly. The changes in biochemical parameters are summarized in Table II.

Complications

All operations were performed laparoscopically without any need for conversion. Laparoscopic greater curvature plication were performed in 18 patients with one row of sutures. The remaining 34 patients received procedure with two rows of sutures. One death was reported one year after the surgery without any connection with the operation. We compared the two subgroups (one-row plication to two-row plication) regarding surgical complications. There were 16 (88.9%) patients without complications in the first subgroup versus 23 (67.6%) patients in the second. In the one-row subgroup one repeated procedure was needed for partial release of the stomach wall plication or stomach dilatation and one gastro-gastric protrusion was recorded (both represent 5.6%) (Photos 2, 3). The two-row subgroup required 5 repeated procedures for stomach dilatation or partial release (14.7%); in 2 cases the plication was completely released after spontaneous partial release (5.9%). The patients will undergo a sleeve gastrectomy later. Gastric wall perforation was observed in 1 (2.9%) case. Partial release without further surgical intervention occurred in 2 (5.9%) patients. An attempt to repair 1 partial release was technically impossible due to dense adhesions of stomach, spleen and liver. There were more complications observed in the two-row subgroup, but due to small numbers there were no statistically significant differences recorded (χ^2 – $p = 0.177$).

Table I. Anthropometric parameter changes 6 and 12 months after surgery (*n* = 52, 33 women and 19 men)

Parameter	Pre-operative examination	6 months after surgery	12 months after surgery
Weight [kg]	124.4 ±19.7	107.2 ±18.2^a	102.0 ±17.8^a
Weight loss [kg]	–	17.9 ±6.9^a	28.5 ±15.5^a
BMI [kg/m^2]	43.3 ±10.6	36.8 ±10.4^a	33.3 ±9.4^a
EWL (%)	–	41.7 ±7.3	51.5 ±12.7^a
EBL (%)	–	45.8 ±14.7	56.9 ±24.3^a
Fat DXA [kg]	55.9 ±10.6	41.6 ±10.2^a	37.8 ±13.1^a
Fat DXA (%)	45.1 ±5.7	40.1 ±6.4^a	37.2 ±7.5^a
LBM DXA [kg]	68.3 ±12.6	62.1 ±12.2^b	62.7 ±12.3^{NS}

^{a}Comparison with pre-operative examination $p < 0.001$, ^{b}comparison with pre-operative examination $p < 0.05$, ^{NS}comparison with pre-operative examination $p > 0.05$, EWL – excess weight loss, EBL – excess BMI loss, LBM – lean body mass.

Table II. Changes in biochemical parameters pre-, 6 and 12 months after the surgery (*n* = 52, 33 women and 19 men)

Parameter	Pre-operative examination	6 months post-operative	12 months post-operative
Glucose [mmol/l]	5.7 ±1.0	5.3 ±0.7[a]	5.1 ±0.8[a]
Glycated haemoglobin (%)	4.3 ±1.1	3.9 ±0.5[a]	3.7 ±0.4[a]
Ghrelin [ng/l]	127.5 ±96.9	190.2 ±98.2[b]	201.8 ±101.1[b]
Leptin [μg/l]	53.6 ±14.9	28.6 ±13.7[a]	23.3 ±12.1[a]
Adiponectin [mg/l]	16.3 ±7.8	17.9 ±3.1[NS]	25.8 ±11.0[a]
FGF 21 [ng/l]	112.2 ±117.9	94.2 ±207.7[NS]	77.5 ±103.1[NS]
TC [mmol/l]	4.9 ±1.2	4.82 ±0.84[NS]	4.9 ±0.8[NS]
TG [mmol/l]	2.4 ±1.6	1.4 ±0.5[a]	1.1 ±0.8[a]
HDL [mmol/l]	1.1 ±0.3	1.3 ±0.3[b]	1.5 ±0.3[a]
LDL [mmol/l]	3.2 ±0.9	3.0 ±0.7[NS]	3.0 ±0.3[NS]

[a]Comparison with pre-operative examination $p < 0.001$, [b]comparison with pre-operative examination $p < 0.01$, [NS]non-significant, TC – total cholesterol, TG – triacylglycerols, HDL – high-density lipoprotein cholesterol, LDL – low-density lipoprotein cholesterol.

Photo 2. Gastro-gastric protrusion

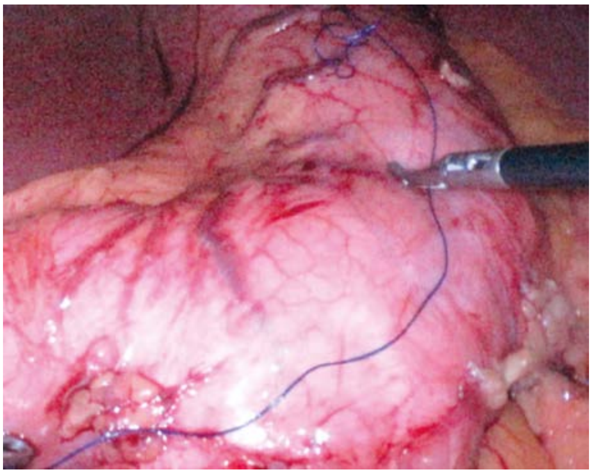

Photo 3. Spontaneous deplication

Discussion

Weight loss results were similar to those of standard restriction procedures (LSG). Our LGCP weight loss results were comparable to other studies. Ramos *et al.* [12] reported a series of LGCP in 42 patients who achieved encouraging weight loss without major complications. The mean %EWL was about 60% EWL at 12 months and 62% EWL at 18 months. Skrekas *et al.* [13] reported early-stage outcome in a series of 135 patients, showing that after a follow-up of 8–31 months (mean: 22.59 months), the mean %EWL was 65.29. Shen *et al.* [11] reported a 58.8% EWL at 12 months in a series of 19 patients. A study combining LAGB with gastric plication conducted with 42 patients resulted in a remarkable final EWL of 62.6% [14]. These were, however, short-term data from 6-month monitoring.

Data from recent studies indicate that LGCP is a method with very good general weight reduction and overweight reduction results. Nevertheless, it is necessary to point out that long-term data regarding evidence based medicine are lacking. So far, the global number of clinical studies is limited. A review of Taiwanese authors [15] presented interesting results. The systematic review covered 14 studies encompassing 1,450 LGCP patients. Mean pre-operative

BMI ranged from 31.2 kg/m^2 to 44.5 kg/m^2, and 80.8% of the patients were female. The %EWL for LGCP varied from 31.8% to 74.4% with follow-up from 6 months to 24 months. Our results are fully comparable in this regard, and can be considered as a successful weight loss. When LGCP and LSG methods are compared as to weight loss, EWL results are slightly lower after LGCP than LSG [16, 17]. Yet the results do not differ very significantly. It is necessary to realize that overall weight loss due to any surgical method incomparably exceeds the weight loss that is achieved by conservative treatment itself [18].

Early reports with LGCP are promising, with a favourable short-term safety profile. However, it remains unclear if weight loss following LGCP is durable in the long term. Additional prospective comparative trials and long-term follow-up are needed to further define the role of LGCP in the surgical management of obesity [15].

Metabolic effect of laparoscopic greater curvature plication

Restrictive bariatric methods were considered as merely weight-reducing for a long time. Recently, studies began to emerge [19, 20], including meta-analyses [21], which have demonstrated a metabolic effect in both surgical and endoscopic restrictive procedures [22]. That is why LSG is no longer registered as an exclusively restrictive surgery, but as a so-called combination method [23]. The LGCP method, on the other hand, is a relative novelty, which has been introduced by a limited number of healthcare providers to date, even on a global scale. Metabolic effects of this method have practically not been studied.

So far, we have found a single reference to a study concerning metabolic outcomes of LGCP in the human organism [24]. This study noted a positive effect of LGCP on the postprandial changes of incretin pathways and hormones of the proximal GIT, as well as a positive effect on saccharide metabolism. Correspondingly, we found a significant decrease of glucose concentration and glycated haemoglobin in our study. Moreover, a significant decrease of total triacylglycerol levels and significant increase of HDL cholesterol levels were also observed in our cohort. Studies evaluating effects of LSG on the lipid spectrum have generated similar effects regarding serum lipids [16]. We consider the increase of total ghrelin levels, which were reported rising throughout the entire 12-month monitoring period, a significant finding. The Brazilian study by Ivano [25] provided similar results. It is known that ghrelin stimulates food intake during fasting because it leads to hunger, being an important hormone of body weight control [26]. But there are other hormones that regulate food intake and satiety, including YY peptide (PYY), glucagon like peptide (GLP-1) and leptin [27]. From this viewpoint, it is relatively difficult to evaluate the role of ghrelin as a single hormone influencing dietary intake. Leptin was another important factor monitored in our study. Leptin produced in white adipose tissue acts on the hypothalamus, leading to satiety and regulation of energetic balance. In our study, leptin showed a significant decrease 12 months after surgery, which is related to a decrease in the amount of adipose tissue after gastric plication. The decline in plasma leptin levels was similarly reported in bariatric surgery studies.

We found a mild, but not significant, decrease in FGF21 levels 12 months following the surgery. FGF21 has been considered a metabolic hormone regulated by nutritional status, with beneficial effects on glucose homeostasis and lipid metabolism in animal models [28]. In humans, increased FGF21 levels are associated with obesity in both children [29] and adults [30], indicating a connection between FGF21 and body fat mass. Studies analysing the response of FGF21 to weight loss in humans had controversial findings. Mai *et al.* [31] found that moderate weight loss (~5 kg) did not induce changes of FGF21 levels in 30 obese subjects following a hypocaloric diet and physical activity regimen for 6 months. The same results were found in 23 non-diabetic, morbidly obese subjects 1 year after laparoscopic Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy [32]. However, a recently published work describes significant decreases in levels of FGF21 in 17 obese females undergoing laparoscopic sleeve gastrectomy [33], which is in accordance with our results.

Conclusions

Considering all results, LGCP appears to be a procedure with good restriction results, which might be mediated through alteration in incretin metabolism. Technical aspects and standardization of the procedure still remain to be worked out.

Bearing in mind the limitations of our study, such as the relatively small size of our cohort, the lack of a controlled comparison group and the relatively short duration of follow-up, our study suggests that LGCP can offer an effective addition to the arsenal of bariatric surgery with effects that may extend beyond gastric volume restriction. Larger and long-term studies are required to further explore the spectrum of metabolic/hormonal effects of LGCP and establish the role of this bariatric technique in the treatment of obesity.

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Conflict of interest

The authors declare no conflict of interest.

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