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Study protocol

Laparoscopic single-anastomosis duodeno-ileal bypass with gastric plication (SADI-GP) in the management of morbid obesity

LASAGNE trial

Protocol number: KDK-2071-2/2019

Funding: Kanizsai Dorottya Hospital, Hospital of Nagykanizsa

Introduction

Morbid obesity is in a correlation with hypertension, dyslipidemia, prediabetes (hyperinsulinemia, impaired fasting glucose) and type II diaebetes mellitus [1,2,3]. If lifestyle modifications (behavioral and dietary recommendations, pharmacotherapeutical modalities) failed, bariatric surgery would be advised to patients with BMI over 40 (without comorbid conditions) or over 35 (with comorbid condition, especially glucose metabolism). It is a fact that bariatric surgery is more effectiv in the management of morbid obesity and related comorbidities than conservative therapy. However, there are differences regarding complications and weight loss outcomes depending on the type of the method [4-8].

There are two main groups of bariatric surgery, restrictive and malabsorptive procedures. Laparoscopic adjustable gastric banding (LAGB), laparoscopic gastric sleeve resection or laparoscopic sleeve gastrectomy (LSG) and laparoscopic gastric plication or greater curvature plication (LGP or LGCP, respectively) are restrictive procedures [4,5,8-20]. Bilio-pancreatic diversion (BPD) introduced by Scopinaro, laparoscopic pylorus preserving single-anastomosis duodeno-jejunal or -ileal bypass with sleeve gastrectomy (SADJ-S or SADI-S, respectively), laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic one-anastomosis/single-anastomosis/omega-loop gastric bypass are malabsorptive surgical technics [21-42]. LGP combined with omega loop duodenal switch (duodeno-jejunal or -ileal) was described by Karcz et al. To our knowledge, there are no clinical data available about the latter procedure [43].

In this field, randomized controlled trials (RCTs) are available in a very low number with small sample sizes due the complexity of surgical procedures. Therefore, strong recommendations are lacking [8]. Due to restrictive procedures, the volumen of the stomach is decreased. After LSG, satiety emerge faster and lasts longer because the fundus of the stomach is resected that results in lower ghrelin levels [43]. Malapsorptiv procedure affect more complex the effect of gut hormones. The changes in cholecystokinin (CCK), protein YY (PYY) mechanism have more effect in satiety than ghrelin alone. Incretins (the most important is glucagon like peptide - GLP1) have a serious role in glucose metabolism - GLP1 is an antagonist to glucagon, its higher levels increase insulin effect - and gastric emptying. [44-47].

Enteral bipartition without duodenal exclusion introduced by Santoro et al. is an optional treatment modality without blind segments and exluded parts of the upper gastrointestinal pathway to treat metabolic disorders. Side-to-side anastomosises (duodeno-enteral or gastro-enteral and jejuno-ileal) are made to obtain the favourable effects of biliopancreatic diversion but some part of the food passes the anatomical way, therefore, the common complications due to the lack of physiological duodeno-jejunal functions are missing. The favourable enterohormonal effects (GLP1, PPY) of the upper gastrointestinal pathway are boosted to help evolving satiety. Enteral bipartition may be an evolution of classical bariatric procedures [47-52].

There are no definite dietary recommendations prior to and after bariatric surgery. It is a challenge to reverse obesity due to the weight loss and regain trajectory („jo-jo" phenomenon), therefore, realistic weight loss goals must be determined which can be maintained over a year. Personalized setting would be the best option in dietary and behavioral advisements [53]. Extreme diets (low carbohydrate, low fat, very low calorie) are promising modalities but not on the long term. A balanced diet combined with adequate weekly physicial activity (150 min) can lead to permanent weight loss and remission of comorbidities [54-58].

The main goal of psychologic testing before obesity management is to determine if a candidate is able and willing to make the necessary lifestyle changes required for sustainable weight loss. Psychologic assessment will also identify significant psychiatric disorders (eg, bipolar disorder, major depression, antisocial personality disorder), which can then be managed to minimize challenges to weight loss initiatives and to reduce risk for psychiatric complication [59-61]. The American Society of Metabolic and Bariatric Surgery (ASMBS) suggests assessing eating behaviors, congitive function, current life situtation, motivation, life style, expectations and nutrition [62]. Behavior modification or behavior therapy is an essential component of managing the patient with overweight or obesity. The goals are to help patients make long-term changes in their eating behavior. Comprehensive lifestyle interventions usually provide a structured behavioral program that includes a number of components as setting initial goals, self-monitoring (keeping food diaries and activity records), controlling or modifying the stimuli that activate eating, eating style (slowing down the eating process), behavioral contracting and reinforcement, nutrition education and meal planning, increasing physical activity, social support, cognitive restructuring, problem-solving. [63-78]

Type of research

Medical treatment (psychological, dietary and surgery) performed on human beings by matched cohorts and randomized controlled trials.

Interval of research

Patient recruitment will begin in October of 2018 and end in June of 2019. Last operation is planned to preform in December of 2019.

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Aim of this research

Our aim is to find an efficient bariatric procedure (laparoscopic single-anastomosis duodeno-ileal bypass with gastric plication - SADI-GP) with low complication rates and more physiological conversion in function of the upper gastrointestinal pathway.

Funding

The trial is funded by the Kanizsai Dorottya Hospital.

Conflict of interest

The insvestigators report no conflict of interest.

Organization

The principal investigator (PI) is responsible for the overall study authorized by the Local Ethical Committee. The preoperative evaluation, the surgery and postoperative follow-up visits (1-3-6-12 months) will be carried out and evaluated by the operating surgeon who is the PI.

Study design

This is a safety study designed as a cohort. Enrolment had started on Oct 16, 2018. The last patient will be included in Autumn, 2019. The first surgery was performed on Jan 15, 2019. The end of study could not be predicted this time.

Study population

Taking into account a normal distribution with a statistical power of 80% and a type I error of 5%, the sample size was calculated to 32 patients. Considering 10% drop out rate, 35 cases are planned to be enrolled to the study. All of them will give their informed consent after an advanced examination. The process of the procedures are discussed well with the patients as well as the study purpose, risks and benefits.

Eligibility criteria

Inclusion criteria:

1. Age over 18 and below 65 years
2. BMI over 40 (without comorbidity related to morbid obesity) and 35 (with comorbidity related to morbid obesity, especially glucose metabolism)
3. Patient aggreement for follow-ups
4. Obtained informed consent

Exlusion criteria:

1. Age below 18 or over 65 years
2. BMI less than 40 (without comorbidity related to morbid obesity) and 35 (with comorbidity related to morbid obesity, especially glucose metabolism)
3. Bariatric surgery in previous history
4. Severe mental disorders (drug addiction, alcohol consumption, the use of antipsychotics)
5. Socially vulnerable patients
6. Complete immobilization
7. Patients who did not understand the purpose of the study and bariatric surgery
8. Lack of informed consent

Withdrawal criteria

1. If duodeno-ileal bypass is not performed during surgery
2. Patient drop out before the 6th month follow-up
3. Patients withdraw their informed consent
4. Serious violation of the study protocol

Patient assessment

1. Previous history including the presence of hypertension, prediabetes (hyperinsulinemia, impaired fasting glucose), diabetes mellitus, dyslipidaemia, gout, cardiovascular disease, pulmonary disease, chronic venous disorder, policystic ovarian syndrome, obstructive sleep apnoe, gastrooesophageal reflux disease, peptic ulcer, osteoarhtritis, mental disorders
2. Body weigth, height, BMI adjusted to age-gender-ethnics-physical activity, ideal weight, weight excess, BMI excess
3. Preoperative examinations (transthoracal cardiac ultrasound, abdominal ultrasound, carotid duplex ultrasound, spirometry, esophago-gastro-duodenoscopy)

4. Blood tests: blood count, ionogram, serum protein, glucose, HgA1C, iron binding capacity, lipid profile, kidney and liver function, hemostasis
5. Quality of life measurement by BAROS-Moorehead-Ardelt II and Weiner et al. questionnaires.

Procedure

The patient is operated in the French position. The operating surgeon stay between the patient's leg and the two assistant surgeons on each side. Under combined (general and peridural) anesthesia, a skin incision is made one span (15-20 cm) under the xyphoid process, then the abdominal wall is prepared and directly lifted to prepare CO2-peritoneum with a Veres-needle and an optic trocar (15 mm) is placed into the intraabdominal cavity. Laparoscopy is performed. Under visualization, ports are created left (5 to 10 mm) and rigt (5 to 12 mm) to the umbilicus in the mid-clavicular line, under the xyphoid process (10 mm) and under the left ribarc in the front axillar line (5 mm). Liver retractor is placed through the epigastrial port, and the left upper abdomen is explored. The gastrocolic and gastrolienal ligament is dissected besides the stomach by electrosonic cutting-coagulation device (Thunderbeat, Olympus Co., Japan). 40 F bougie is placed into the gastric lumen through the pylorus. Depending on the anatomical situation, a two layer three fold 2/0 polidioxanon (Polydox, Chirana, Czech Republic) running suture is made from the fundus to the antrum or a 2/0 polidioxanon (Polydox, Chirana, Czech Republic) running suture is made from the fundus (one layer - one fold) through the corpus (two layers - three fold) to the antrum (one layer - one fold). The line is knotted by hand with laparoscopic manipulators. The bougie is changed to a common nasogastric tube. The cholecyst is lifted, then the cystic duct is dissected and closed by two hem-o-lok clips (Teleflex Inc., USA), finally cutted between them. The cystic artery is closed by Thunderbeat. The cholcyst is exstirpated from the liver bed. The posterior wall of the duodenum is dissected from the pancreas till the line of the gastroduodenal artery. The duodenum is dissected 3-4 cm-s after the pylorus by cutting-closing laparoscopic tri-stapler (Endo GIA 60, Covidien, Ireland). The viability of the duodenal stump must be preserved. The omentum maius is dissected vertically. The ileum (counted 300 cm-s backwards from the ileocoecal junction orally) is positioned tension-free antecolic and tied to the posterior wall of the duodenal stump by some 2/0 poliglactin sutures (Surgicryl, SMI AG, Belgium). The proximal duodenal staple line is removed. A lenghtwise ileotomy is made. A running hand sewn end-to-side duodeno-ileostomy is prepared by a 2/0 polidioxanon barbed suture (V-Loc, Covidien, Ireland), the line is secured by Ligamaxx clips (Ethicon Inc., USA) if neccessary. Air-water proof is performed. The oral part of the sewn ileum is connected to the stomach by some 2/0 poliglactin sutures (Surgicryl, SMI AG, Belgium) to protect the anastomosis and reduce alkaline reflux. Intraabdominal drainage is placed through the right upper abdominal port. The cholecyst is taken out of the abdomen. During trocar removal, abdominal wall sanguination is visualized. After desufflation, skin wounds are closed.

Perioperative period

The patients spend the first 36-48 hours after operation at the ICU routinely. On the first postoperative day, a swallowing X-ray is performed with Gastrografin (Bayer Pharma AG, Germany). If there is no leak, the nasogastric tube will be removed. The patients are advised to drink by gulps until they reach 200 ml on the first postoperative day, 500 ml on the second postoperative day and so on to reach 2000 ml finally. Routinely, 6000NE 0,6ml enoxaparine (Clexane, Sanofi, France) shots are administerred during the first month. Compression I elastic graduated stockings are applied perioperatively. Analgetics, antiemetics are part of the routine course. The patients are advised to take vitamins (complex B and D), iron supplementation and oral PPI (routinely a type of pantoprazol). Postoperative diet is adapted to the change of upper gastrointestinal tract anatomy. Nutrition is set up depending on consistency of meal during the first 8 weeks. Appropriate fluid (1500-2000 ml distributed to 200-300ml portions per hour) and protein intake are emphasized. Intially, daily calorie intake is advised to be kept at 900-1000 kcal (protein: 73g, carbohydrate: 73g, fat: 43g) after the third week raising to 1200 kcal (protein: 87g, carbohydrate: 87g, fat: 51,6g) and 1500 kcal (protein: 109g, carbohydrate: 109g, fat: 64,5g) for women and men, respectively. Later on, the patients are advised to keep a standardized diet containing equal quantities of carbohydrate and protein (30-30%) and 40% of fat (1200 kcal for women, 1500 kcal for men). No additive sugar is permitted. During the first 1-3 weeks, fat intake is calculated of the natural content of the dishes. Afterward, 5-10g of fat is advised to add to food daily. Five meals should be kept every day. If necessary, meal replacers (Fresubin Protein Energy Drink, Fresenius Kabi, Ireland) or additive protein (Protifar , Nutricia, Netherlands) are permitted to complete suggested carbohydrate, protein and fat intake. Appropriate vitamin, trace element replacement is necessary. After the first 8 weeks, the patients are advised to keep a balanced weight loss diet containing equal quantities (around 30-40%) of carbohydrate, protein and fat to maintain a negative energy balance providing a deficit of 500-1000 kcal daily. The calorie requirement of each patient will be calculated by the Millfin St. Jeor basal metabolic rate (BMR) estimation formula corrected to age, gender, height, weight and activity level. Adequate weekly physicial activity (around 150 min, 3x50 min or 5x30 min) will be advocated.

Follow-up

At discharge, the patients are educated about the appropriate diet by a specialist. Follow-up visits are performed by the operating surgeon at 2 weeks, 1-3-6-12 months postoperatively. The patients are examined, complications, weight loss outcomes and QoL is assessed, laboratory tests are performed (blood count, serum protein, glucose, HgA1C, ionogram, iron binding capacity, lipid profile, kidney and liver function). At 1 year, personality is planned to assess by MMPI-2 (Minnesota Multiphasic Personality Inventory 2).

Hypothesis

Laparoscopic single-anastomosis duodeno-ileal bypass with gastric plication is expected to be a safe procedure and have low complication rates and favourable weight loss outcomes.

Endpoints

Primary:

Assessing the safety of the method, evaluating risks due to surgery.

Secondary:

Weight loss outcomes.

Complications

Grade	Definition
I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, or radiological interventions Permitted therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. The grade also includes wound infections opened at the bedside
II	Requiring pharmacological treatment with drugs other than those permitted for grade I complications Blood transfusions and total parental nutrition are also included
III	Requiring surgical, endoscopic, or radiological intervention
IIIa	Intervention not under general anaesthesia
IIIb	Intervention under general anaesthesia
IV	Life-threatening complication (including complications of the central nervous system)[a] that requires management in a high dependency, or intensive therapy unit
IVa	Single organ dysfunction (including dialysis)
IVb	Multiorgan dysfunction
V	Death
Suffix "d"	If the patient suffers from a complication at the time of discharge the suffix "d" (for "disability") is added to the respective grade of complication. It indicates the need for follow-up to fully evaluate the complication

[a] Brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks.

Clavien-Dindo classification [79,80].

Laparoscopic gastric plication

Nausea and vomiting (CD1) is expected with higher rates (20-90%) but it is the part of the routine course. Further early complications are wound healing disorder (CD1), bleeding (CD2-3), gastric prolapse or perforation (CD3-4), ileus (CD2-4), venous thromboembolic events (CD4), different organ failure (CD4) and death (CD5). Late complications are malabsorption (CD2), abdominal wall hernia (CD3), gastro-esophageal reflux (CD2), gastric stenosis or dilatation (CD3).

CD 1 (minor complication): 20-90%

CD 2-3a (minor complication): 1-4%

CD 3b-4ab (major complication):1-3%

CD 5: <0,1%

Laparoscopic single-anastomosis duodeno-ileal bypass

About a 10% complication rate is expected (early: 1-5%, late: 1-6%). The most important risks are wound healing disorder (CD1), bleeding (CD2-3), leakage (CD2-4), ileus (CD2-4), venous thromboembolic events (CD4), different organ failure (CD4) and death (CD5). Late complications are malabsorption (CD2), abdominal wall hernia (CD3), gastro-esophageal reflux (CD2), alkaline reflux to the stomach or esophagus (CD2), anastomosis stenosis (CD3).

CD 1-3a (minor complication): 1-5%

CD 3b-4ab (major complication):1-3%

CD 5: 0,1-0,2%

Statistical analysis

Variables with normal distribution will be presented by the mean and standard deviation (SD), non-normally distributed variables will be expressed as the median and interquartile range. Categorical variables will be presented as the number and percentage. Continouos normally distributed records will be examined by ANOVA. Continouos non-normally distributed data will be tested by the Mann-Whitney U test. Categorical variables will be compared with the $\chi 2$ test or Fisher's exact test, when appropriate. The p value will be set of 0.05.

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