

# Treatment of severe obesity with laparoscopic Roux Y gastric bypass operation

Doctoral (PhD) – dissertation

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University of Pécs, Medical Faculty, Pecs  
2011.

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## Contents

### **1. Introduction, Objectives of my paper**

### **2. Definition, Grades of Obesity**

### **3. The most often performed metabolic surgical intervention and their description**

### **4. Laparoscopic Roux Y Gastric Bypass (LRYGB)**

- 4.1. Indication
- 4.2. Preoperative check-up
- 4.3. Preoperative treatment
- 4.4. Positioning of the patient, advised instruments
- 4.5. Details of the surgical steps
  - 4.5.1. Preparation of the Y anastomosis
  - 4.5.2. Preparation of the gastric pouch
  - 4.5.3. Preparation of the gastro-jejunal-anastomosis (GJA)
- 4.6. The postoperative period
- 4.7. The most frequent complications

### **5. Clinical aspects of the leakage of the GEA and the gastric pouch**

- 5.1. Frequency of the leakage of the GJA and the gastric pouch
- 5.2. Risk factors of the leakage of the GJA and the gastric pouch
- 5.3. Diagnosis of the leakage of the GJA and the gastric pouch
- 5.4. Prevention of the leakage of the GJA and the gastric pouch

### **6. Examination of the efficacy and safety of intraoperative gastroscopic test in our patients and in animal model**

- 6.1. Examination of the efficacy of the intraoperativ gastroscopy applying retrospective analysis of the data of our patients
  - 6.1.1. Data of our patients
  - 6.1.2. Method
  - 6.1.3. Results of the intraoperative gastroscopy in the investigated group of patients
  - 6.1.4. The efficacy of the intraoperative gastroscopy – discussion
- 6.2. Examination of the safety of the intraoperativ gastroscopy
  - 6.2.1. Examination of the safety of the intraoperativ gastroscopy I.  
Measurement of the intraluminal pressure developed during the intraoperative gastroscopy in our patients – results of the human experiment
  - 6.2.2. Examination of the safety of the intraoperativ gastroscopy II.  
Measuring the intraluminal pressure leading to positive air test – results of the animal experiment
  - 6.2.3. Examination of the safety of the intraoperativ gastroscopy III.  
Evaluation of the histological results
  - 6.2.4. Discussion of the examination of the safety of the intraoperative gastroscopy – comparison of the results of the human and animal experiments
  - 6.2.5. Discussion of the localisation of the positive air test

## **7. Comparison of the results after LRYGB and after Laparoscopic Gastric Sleeve Resection (LGS) in aspects of quality of life parameters, weight change and improvement of co-morbidities**

- 7.1. Introduction
- 7.2. Patients and method
  - 7.2.1. Data of our patients
  - 7.2.2. The applied questionnaires
  - 7.2.3. Statistical analysis
- 7.3. Results
  - 7.3.1. Change of the body weight, patients' satisfaction and additional surgical procedures in the postoperativ period
  - 7.3.2. Quality of life parameters
  - 7.3.3. Rate of resolution of the co-morbidities after LRYGB and LGSR
- 7.4. Evaluation of the results - discussion
  - 7.4.1. Discussion of the results of weight loss
  - 7.4.2. Discussion of the results of the QLQ tests
  - 7.4.3. Discussion of the results with diabetes type 2
  - 7.4.4. Discussion of the results with gastro-oesophageal reflux
  - 7.4.5. Discussion of the results with hypertension
- 7.5. Conclusion

## **8. Results of the operations performed in Hungary**

### **9. Summary of the new statements**

- 9.1. Details of the surgical steps
- 9.2. Statements based on conclusions of the examination of efficacy and safety of intraoperative gastroscopy
  - 9.2.1. Statements concluded from examination of the efficacy of intraoperative gastroscopy
  - 9.2.2. Statements concluded from examination of the safety of intraoperative gastroscopy
- 9.3. Statements concluded from the comparison of the results after laparoscopic Roux Y gastric bypass and laparoscopic gastric sleeve resection
  - 9.3.1. Difference in aspect of weight loss
  - 9.3.2. Difference in aspect of quality of life parameters
  - 9.3.3. Difference in aspect of resolution of co-morbidities (diabetes type 2, hypertension, gastro-esophageal reflux)

## **List of own publications and presentations related to the theme of the paper**

### **Acknowledgements**

## 1. Introduction

In the last decades the prevalence of morbid obesity and diabetes mellitus type 2 (DMT2) is growing continually in the majority of the developed countries of the world. In Hungary 1,5 million people are obese and another 2,7 million has overweight.

Patients with severe obesity suffer not only from the problems of the every-day life reducing their quality of life, but the occurrence of severe co-morbidities is also more often (cardiovascular disease, DMT2 and its complications, GER and its associated respiratory complications and different locomotor disorders). According to new data, -probably owing to hormonal and metabolic disorders- the rate of malignant breast, colon and gynaecological tumours is also higher<sup>(1)</sup>. As a consequence the mortality is also higher in case of severe obesity<sup>(1,2,3)</sup>. As in the cases of second and third degree obesity the conservative treatment has long term good results only in 5 % of the patients, more and more metabolic surgical interventions are performed all over the world. Gastric banding is carried out also in our country for decades with good results, but considering the complication rate and the favourable results of different studies involving great number of patients, the laparoscopic Roux Y gastric bypass (LRYGB) seems to be the most suitable solution in the majority of the patients. Undoubtedly it is a more complicated intervention, but the data of weight loss and resolution of co-morbidities are much better after this type of operation<sup>(4,5,6)</sup>. The results are especially good in connection with the rate of the resolution of DMT2, 80-90 % of the patient can leave out the antidiabetic and/or insulin therapy, used before the operation.

### Objectives of the paper

Investigation of the clinical aspects of laparoscopic Roux Y gastric bypass, focusing on the following topics:

1. Detailed description of the technical steps of the operation, emphasising the technical difficulties and their solutions.
2. Investigation of the importance of the intraoperative gastroscopy (IOG) in point of view of the reduction of the leakage rate of the gastric pouch (GP) and of the gastro-jejunal-anastomosis (GJA) experienced in the postoperative period,
  - 2/1. investigation of the efficacy of IOG based on the retrospective analysis of the data of 252 patients operated by us,
  - 2/2. investigation of the safety of IOG based on human and animal experimental model,
3. Presentation of the results of the operation based on the data of the questionnaires filled in by our patients and comparison of them with the results reached after laparoscopic gastric sleeve resection, applying match pair analysis focusing
  - 3/1. on loss of weight,
  - 3/2 on quality of life and
  - 3/3 on resolution of the obesity related more often co-morbidities (DMT2, hypertension, GER).

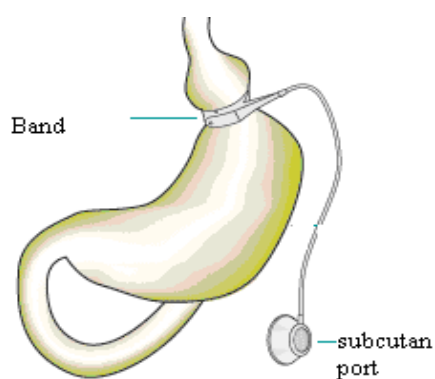
## 2. Definition, Grades of Obesity

Body Mass Index, (BMI) = body weight/ height x height  
Unit: kg/m<sup>2</sup>

20 < Body Mass Index < 25	normal weight	
25 < Body Mass Index < 30	overweight	
30 < Body Mass Index < 35	1. grade obesity	
35 < Body Mass Index < 40	2. grade obesity -	Indication for metabolic surgery in case of severe co-morbidities
40 < Body Mass Index	3. grade obesity -	Morbid obesity - Indication for metabolic surgery
60 < Body Mass Index	megalo-obesity -	Restrictive type of operation (banding, sleeve) is advised

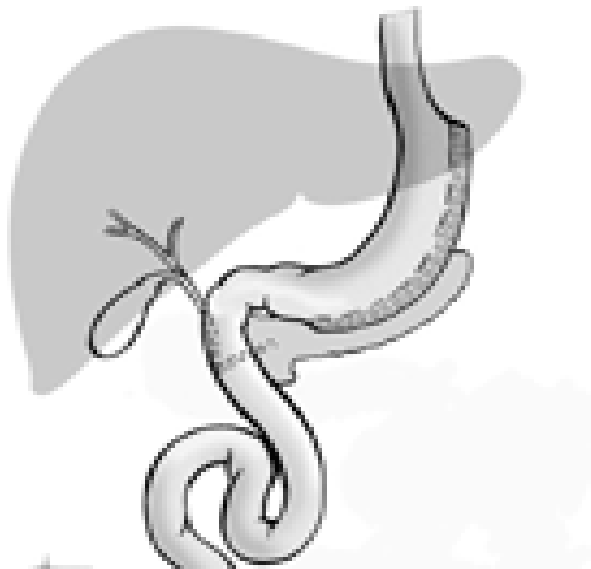
## 3. The most often performed metabolic surgical intervention and their description

The rate of laparoscopic gastric banding (picture 1.) is growing in the last years in the USA, but in Europe, where this type of operation was earlier more often performed, the number of the interventions is decreasing. It is a quick and easy operation. The proportion of weight loss is acceptable, but in 20-30 % of the patients the implanted device should be removed from different reasons (compliance, arrosion, dislocation, infection, etc.) some years after the operation. After that a second intervention –most often gastric bypass- is technically more difficult because of the scar formation caused by the band and the complication rate is significantly higher compared with the primary interventions. Resolution rate of DMT2 and of hypertension is 40-60 %.



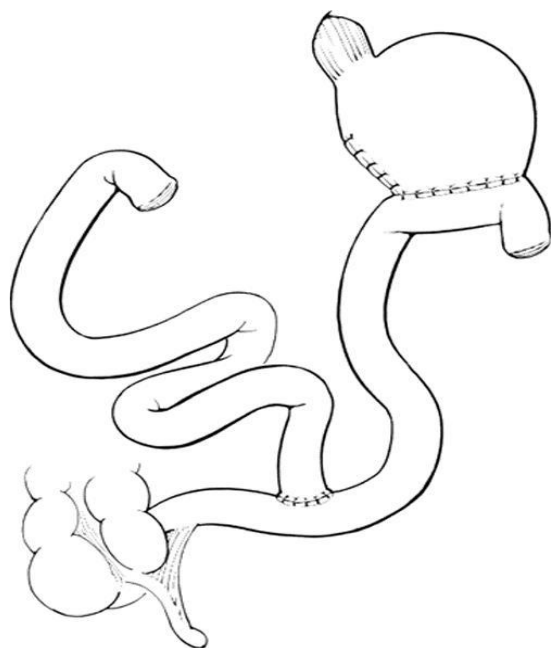
Picture 1. Schematic picture of gastric banding

The rate of the laparoscopic gastric sleeve resection (picture 2.) is progressively increasing. Its advantage are the relative easy operative technique and the effective loss of weight. The main disadvantage is, that 20-30 % of the patients gain again weight 2-3 years after the operation, owing to the dilatation of the gastric tube. In this cases the sleeve resection can be switched to gastric bypass without substantial technical difficulties. Resolution rate of DMT2 and hypertension is 40-60 %.



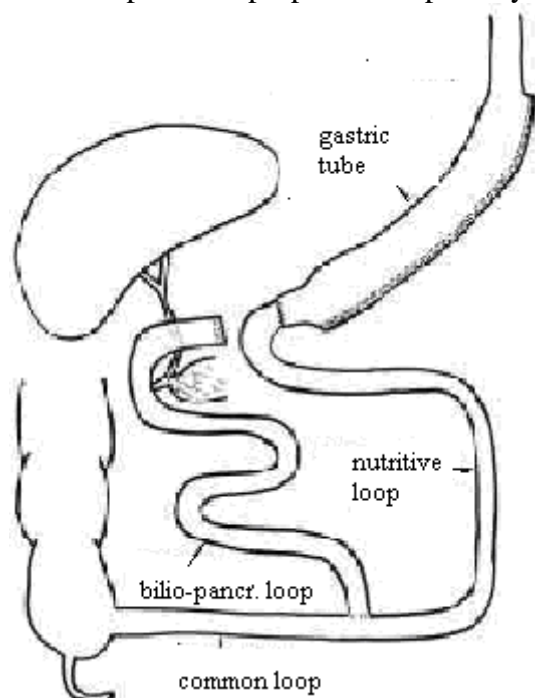
Picture 2. Schematic picture of gastric sleeve resection.

The weight loss reached after bilio-pancreatic diversion (picture 3.) is moderate, but the rate of resolution of DMT2 is above 80 %. Its disadvantage is, that regular vitamin and element level control and substitution are necessary owing to the short common loop (pronounced malabsorption). This type of operation is advised first of all for patient with DMT2 under BMI 40<sup>(45)</sup>.



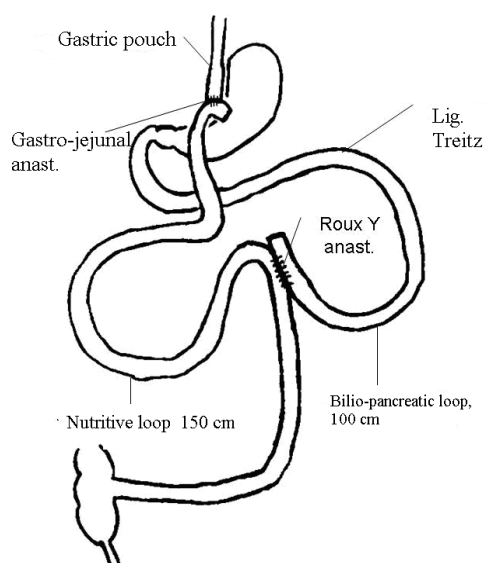
Picture 3. Schematic picture of bilio-pancreatic diversion.

Duodenal switch (picture 4.) is the most effective metabolic surgical intervention in aspect of weight loss and resolution of co-morbidities (picture 4.). But owing to the 5-10 % leakage rate of the duodeno-ileal anastomosis, the rate of mortality and of sever complications are also the highest. Most vitamins and elements should be substituted because of the pronounced malabsorption. Its proportion in primary metabolic surgical operations is under 5 %.



Picture 4. Schematic picture of duodenal switch.

After LRYGB (picture 5.) the patients loose 80-90 % of their extra weight, the resolution rate for DMT2 80-90 %, for hypertension is 75% and for GER is 90 %. The complication rate is relatively low and the grade of malabsorption is mild, which means, that in 50 % of patients vitamin B 12 should be substituted and one third of the patients should take iron regularly. (Table 1.)



Picture 5. Schematic picture of LRYGB.



Considering the effective body weight reduction, the high resolution rate of the co-morbidities and the relatively low rate of complications, our team is trying to perform LRYGB, whenever it is possible. If the patient is high risk in cardio-respiratory point of view, or in case of megalobesity (BMI above 60), when the gastric pouch can't be correctly performed owing to massive hepatomegaly, or the length of the Roux loop would be inappropriate because of massive mesenterial fatty tissue deposition, or intrabdominal adhesions caused by previous operations make impossible the laparoscopic preparation of the small bowels, we carry out a gastric sleeve resection. If the patient gains weight 2-3 years after the sleeve resection, which occurs in 20-30 % of the cases, a switch operation to gastric bypass is carried out by us. If the patient so obese, or has so high anaesthesiological risk, that even gastric sleeve resection can't be carried out, then a gastric balloon will be implanted by us. In 6-12 months, depending on the extent of the body weight reduction, a sleeve resection or a gastric bypass will be performed.

	Gastric banding	Gastric sleeve	Duodenal switch	Gastric bypass
Frequency	45-50 %	5-10 %	under 5 %	45-50 %
Way of action	Restrictive	Restrictive (hormonal)	Restrictive and malabsorptive	Restrictive and malabsorptive
Extra weight loss	50-60 %	70-80 %	above 90 %	80-90 %
Resol. – DMT2	50-60 %	50-60 %	above 90 %	80-90 %
Operat. stress	+	++	++++	+++
Complications	Under 5 %	5-10 %	5-10 %	5-10 %
Mortality	0,1%	0,2-0,5 %	1-2 %	0,2-0,5 %
Vitamins and elements substitution	-	-	Almost all elements and vitamins	Individually vitamin B 12, folic acid, vitamin D
Indication	high risk pat.	High risk pat., BMI > 60	Normal risk pat., DMT2	Normal risk pat., GER, DMT2

Table 1. Characterization of the most often applied metabolic surgical procedures.

#### 4. Laparoscopic Roux Y Gastric Bypass (LRYGB)

##### 4.1. Indication

Indication for LRYGB is a BMI above 40 kg/m<sup>2</sup>. If the patient suffers from any obesity associated co-morbidities (first of all DMT2, severe gastro-oesophageal reflux, severe locomotor disorder, etc.), then the operation is above BMI 35 indicated.

#### 4.2. Preoperative check-up

The aims of the preoperative check-up are to estimate the surgical and the anaesthesiological risk factors and to exclude those types of obesity, they shouldn't be treated by metabolic surgery (endocrinological, psychiatric reasons). Gastroscopy is unavoidable.

#### 4.3. Preoperative treatment

Thrombosis prophylaxis (60 mg enoxaparin and elastic stockings), a single shot antibioticum and proton pump inhibitor (40 mg pantoprazol) are included in preoperative treatment.

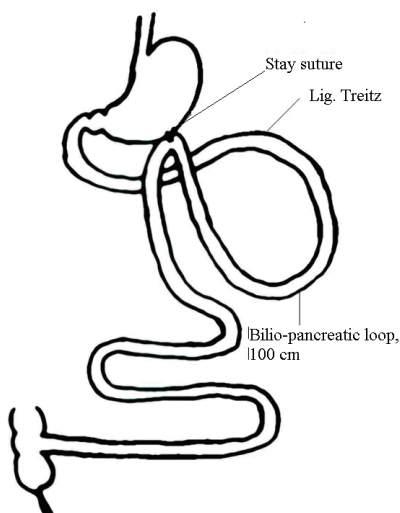
#### 4.4. Positioning of the patient, advised instruments

The procedure is performed with patient in supine, antiTrendelenburg position with both legs abducted. The surgeon stays between the legs. High energy cutting and coagulating device, staplers and instruments for laparoscopic suture are essential for the operation.

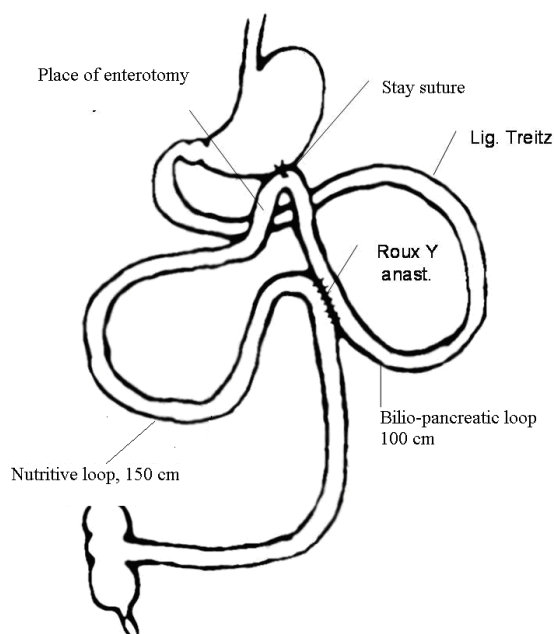
#### 4.5. Details of the surgical steps

##### 4.5.1. Preparation of the Y anastomosis

The ports will be introduced, and after adhaesiolysis the omentum will be turned up to find the ligament of Treitz. Starting from here 100 cm of jejunum will be measured, this will be the bilio-pancreatic loop. At this point the small bowel will be marked and fixed provisionally to the big curvature of the stomach. Then we go on another 150 cm in aboral direction along the jejunum, it will be the Roux loop. The bilio-pancreatic and the Roux loop will be fixed together with stay sutures, and a side to side Y anastomosis will be performed applying three stapler technique (picture 6. and 7.). The mesenterial gap will be closed with a running, non absorbable suture.



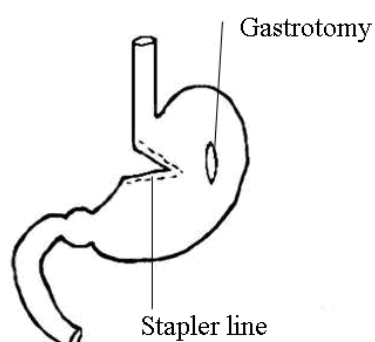
Picture 6. Determining of the bilio-pancreatic loop.



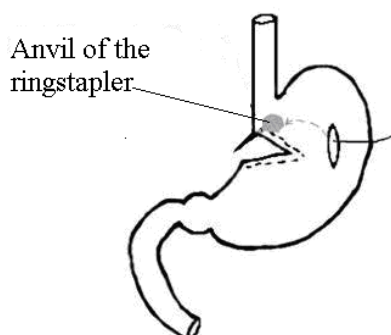
Picture 7. Determining of the Roux loop

#### 4.5.2. Preparation of the gastric pouch

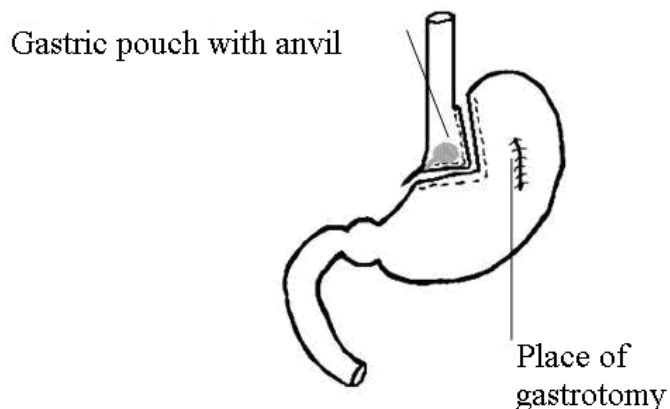
In upper part of the abdominal cavity another ports will be introduced, and the left liver lobe will be elevated. The membrana phrenico-oesophagea will be incised and the left crus and the angle of His will be prepared. The lesser sac will be entered at the small curvature of the stomach, 6 cm below the cardia. The preparation goes on along the left crus up to the big curvature of the stomach. In this way a tunnel will be created behind the stomach, between the small curvature and the left side of the esophago-gastric junction, it will be the suture line of the gastric pouch. The first stapler will be introduced from right and fired perpendicularly on the small curvature. A 2 cm long gastrotomy will be performed, here will be introduced the anvil of the ring stapler into the stomach, and it will be pierced out at the right end of the suture line. The vertical line of the gastric pouch will be performed applying another two cartridges to make the gastric pouch with the inserted anvil ready (picture 8.9.10.).



Picture 8. The first stapler line and the localization of the gastrotomy.



Picture 9. The anvil of the ringstapler is inserted into the gastric pouch.



Picture 10. The ready gastric pouch with the inserted anvil.

#### 4.5.3. Preparation of the GJA

Enterotomy will be performed on the oral part of the Roux loop, where the bowel was marked in the first phase of the operation (picture 7.). The ring stapler will be introduced in the Roux loop, pierced out on the antimesenteric side of the bowel and connected with the anvil, placed previously in the gastric pouch. The stapler will be fired to create the GJA. About 15 cm long portion of the small bowel, involving the enterotomy will be skeletonized in aboral direction up to the GJA and in oral direction up to the Y anastomosis, then it will be resected applying two cartridges and removed from the abdominal cavity. This way the Roux Y gastric bypass with 100 cm bilio-pancreatic loop and with 150 cm nutritive (Roux) loop will be carried out. (picture 5.). On the both sides of the GJA stay sutures will be placed applying Vicryl 3-0, which involve the anterior wall of the rest stomach, the gastric pouch and the small bowel creating the anastomosis, to reduce the tension of the suture line and to cover the posterior wall of the GJA. Intraoperative gastroscopy and air test will be performed. Penrose drains will be left at both anastomosis, and the left lower port side (15 mm) will be closed with a “U” suture under laparoscopic vision.

#### 4.6. The postoperative period

On the second postoperative day a gastrograffin study of the upper gastrointestinal tract will be performed, if it is negative, the patient will be put on oral diet and will be discharged on the fifth postoperative day. The patients will be controlled in our out patient department in every three months in the first year, after that in every six months. By half of them vitamin B12, by one third of them iron and by some of them vitamin D should be substituted regularly.

#### 4.7. The most frequent complications

(The results will be presented in chapter 7.)

According to studies involving hundred thousands of patients, the mortality rate of the procedure is 3-5 /thousand. The most frequent mortal complication is the leakage, followed by pulmonary embolism and myocardial infarction<sup>(17)</sup>. The leakage rate is 0-6 %, and 4-17 % of the leakages are fatal. Typical complications of the procedure are the small bowel obstruction and the stenosis of the GJA, which can be resolved by dilatation (Bougie, balloon) in majority

of the cases. The occurrence of both complications is under 5 %. The rate of the intraabdominal bleedings is 1-2 %, mostly can be controlled laparoscopically. The most frequent localisation is one of port sites, in particularly along the epigastric artery. The most common complication is the inflammation of a port site, with a rate of 20 %. The conservative treatment leads to healing in the overwhelming majority of cases <sup>(29,44)</sup>.

## **5. Clinical aspects of the leakage of the GJA and the gastric pouch**

### **5.1. Frequency of the leakage of the GJA and the gastric pouch**

The leakage of the GJA is the most frequent mortal complication of the LRYGB <sup>(17)</sup>. According to different studies the leakage rate is 0-6 %. If it is late discovered, leads to generalized sepsis and the mortality rate can reach 50 % <sup>(14,15,16)</sup>. The consequences are long hospitalization, intensive care, CT guided percutan drainage, stent implantation and reoperation in 10-25 % of the patients. That is why it is important to prevent this serious complication, whenever it is possible.

### **5.2. Risk factors of the leakage of the GJA and the gastric pouch**

Risk factors are: high age (above 55 years), any kind of metabolic surgical procedure in the anamnesis, higher BMI and male sex. <sup>(17)</sup>. The higher risk of the men can be explained by the visceral type of obesity, which generally typical for males.

### **5.3. Diagnosis of the leakage of the GJA and the gastric pouch**

The diagnosis is often not easy, while the local symptoms and the physical signs are not remarkable, the gastrografin study is false negative in 50 % of the cases and abdominal CT often can't be performed, owing to the extreme body volume of the patient. For this reason, in case of general symptoms (fever, tachycardia, oliguria) and labour results (leucocytosis, high C reactive protein, sings of multiorgan disease) of a possible leakage the patient should be laparoscopically explored.

### **5.4. Prevention of the leakage of the GJA and the gastric pouch**

In favour of prevention of the suture line leakage it is important to respect the classical surgical principles (tension free anastomosis, good blood supply). Good results were also presented, when the anastomosis was covered with omentum, or it was reinforced with glycolid polymer <sup>(11)</sup>.

The intraoperative control of the suture lines applying metilen blue or air test is also advantageous. The air is more suitable for this purpose compared to fluids, owing to its properties, typical generally for gases (compressible, good diffusion capacity, fills in the disposable space at the same level of pressure). The air test can be carried out through nasogastric tube or with gastroscope. The intraoperative gastroscopy makes possible the visual control of the GJA and the gastric pouch at the same time, that's why, this method is routinely applied also by our team.

## 6. Examination of the efficacy and safety of intraoperative gastroscopic (IOG) test in our patients and in animal model

It is proved also in other studies, that the intraoperative gastroscopy is more effective in aspect of the leakage rate of the postoperative period, compared to metilen blue test or to air test, performed through nasogastric tube <sup>(21,23)</sup>. But it can supposed, that the higher intraluminal pressure, developing during the IOG can also lead to mechanical destruction of the newly performed anastomosis. For this reason we performed an experimental study to investigate the effectivity and the safety of the IOG, which consisted of four parts:

1. investigating the effectivity of the IOG we analysed retrospectively the data of our patients (6.1.),
2. we measured intraoperative the intragastric pressure, developing during gastroscopy (6.2.),
3. using animal model, we measured the intragastric pressure, which leads to mechanical destruction of the suture lines, indicated by positive air test (6.3.),
4. the stomach and small bowel samples from the experimental animals without pressure strain, exposed to the pressure strain reached in humans during IOG (32 Hgmm, 3,8 min), and exposed to the pressure strain leading to positive air test (150 Hgmm) were histologically examined in the search for structural disintegration (6.4.).

6.1. Examination of the efficacy of the intraoperativ gastroscopy applying retrospective analysis of the data of our patients

6.1.1. Data of our patients

The dates of 252 patients undergoing LRYGB surgery in our department during a two-year period of time between 01.01.2008 and 01.01.2010 were retrospectively analysed.

The data of the patients are summarized in table 2.

Number of patients (n)		
	Primary operation	209 (83 %)
	After gastric sleeve resection	28 (11 %)
	After gastric banding	12 (5%) )
	After vertical banded gastroplasty	3 (1%)
	Total	252 (100%)
Mean age	(SD)	39.2 years (10,49)
Mean BMI	(SD)	48.2 kg/m <sup>2</sup> (5,72)
Female/male		212/40 84/16 %

Table 2. Clinical characteristics of our patients.

6.1.2. Method

The GP and the GJA are routinely controlled with IOG to check for leakage and for intraluminal bleeding. The Roux limb is clamped and the upper part of the abdomen is filled with saline. The gastroscope (Olympus GIF-Q 145) is introduced through the GJA into the Roux loop and the insufflation was set on high. If a leakage is detected, after its correction the gastroscopic test is repeated so as to make sure, that it has been successfully repaired.

### 6.1.3. Results of the intraoperative gastroscopy in the investigated group of patients

In 6 cases (2.3%) of our 252 patients undergoing LRYGB revealed the IOG positive air test. The leakage was found in 4 patients on the frontal staple line of GJA, 3 of them at the jejunal site of the stay sutures (the posterior staple line is routinely covered with the anterior wall of the rest stomach) and in 1 patient on the vertical suture line of the GP, which were repaired with laparoscopic seromuscular sutures. In the sixth case the leakage occurred on the mesenterial side of the Roux loop. As the edges of dehiscence under the meso-covering cannot be perfectly visualized and the seromuscular sutures in this localisation can destroy the blood supply of the bowel wall, we created a new anastomosis applying orvil technique. In one patient (0.4%) a bleeding artery in the frontal line of the GJA was revealed by IOG, the control of the haemorrhage was achieved by laparoscopic sutures. The results of IOG are summarized in table 3.

No. of patients	Type of detected complications	No. of detected complications leak:6, bleeding:1	Localisation	Surgical treatment	No. of postop. leaks
252	leakage	3	GJA – jejunal site of the stay sutures	seromusc. sutures	0
		1	GJA – anterior wall	seromusc. sutures	
		1	GP – vertical suture line	seromusc. sutures	
		1	Roux loop – mesenterial side	reanastomosis	
	intraluminal bleeding	1	GJA – anterior wall	seromusc. sutures	

Table 3. Results of IOG in the investigated group of patients.

### 6.1.4. The efficacy of the intraoperative gastroscopy – discussion

The air, owing to its high diffusion capacity and ability to penetrate through the narrowest spaces, breaks through easily the smallest dehiscence. Probably that is the physical background of the high sensitivity of the air test combined with gastroscopy. It seems to be justified also by our study: positive air test was detected in 6 cases during the operation and anastomosis insufficiency didn't occur in the postoperative period in our series of 252 patients. That's why we think, that IOG with air test is an effective method to detect the dehiscence of the GJA and the GP in LRYGB surgery. The further advantage of the method is the intraoperative detection of intraluminal bleedings, and this way they can be controlled during the procedure.

## 6.2. Examination of the safety of the intraoperativ gastroscopy

### 6.2.1. Examination of the safety of the intraoperativ gastroscopy I.

Measurement of the intraluminal pressure developed during the intraoperative gastroscopy in our patients – results of the human experiment

The intraluminal pressure developing during IOG and the duration of the examination was estimated applying Spiegelberg probe in 15 patients of us. The pressure values were continuously monitored and registered every 10 seconds. The mean values for each patients were calculated. The maximal pressure value in each cases were registered, and the mean of the maximal values were also calculated. The mean values, the mean maximal values, the standard deviation and the extremities are given in table 4.

	Mean	Standard deviation	Extremities
Intraluminal pressure (Hgmm)	32	(8.26)	25 - 47
Mean maximal pressure (Hgmm)	43	(2.55)	37 - 47
Duration of the examination (min)	3.8	(0.6)	3,0 – 5,1

Table 4. The measured pressure values in the gastric pouch during IOG and the duration of the examination.

### 6.2.2. Examination of the safety of the intraoperative gastroscopy II.

Measuring the intraluminal pressure leading to positive air test – results of the animal experiment

Two animals (meat-type, hybrid pigs, 85 and 102 kg in weight) were operated on under intratracheal narcosis. 6 cm below the cardia was the small curvature sclerotized, the esophago-gastric junction at the angle of His was prepared and the same size of gastric pouch as in our patients was performed and it was connected with a Roux loop applying the identical surgical technique and types of staplers as used in humans. The gastroscope was placed in the GP through the mouth of the animal. An elastic band was applied around the intrabdominal part of the esophagus and the Roux loop was clamped under the anastomosis to prevent the escape of the insufflated air. The work channel of the device was connected with an insufflator and with a manometer. The GP and GJA were immersed in saline. The air was insufflated in the GP through the gastroscope and the pressure was continuously detected and registered. The intraluminal pressure was gradually increased by 30 Hgmm and kept on the same value for 3.8 minutes, in an attempt to try to mimic the pressure strain reached by gastroscopy in humans. Up to 120 Hgmm the GP and the GJA remained intact. At a pressure level of 150 Hgmm by the first animal after 2,2 minutes and by the second animal after 3,1 minutes positive air test from the GJA was detected, in both cases at the point, where the seromuscular stay suture entered to the wall of jejunum (Roux loop). The site of the leakage was repaired with seromuscular sutures and the air test was repeated at 150 Hgmm. This time the air test became positive in 1,2 minutes by the first animal and after 1,1 minutes by the second one, the localisation was the same, as previously. The results are summarized in table 5.



Pressure value (Hgmm)	30	60	90	120	150
Duration of pressure strain (minutes)	3.8	3.8	3.8	3.8	
Animal No.1, first air test	Negative	Negative	Negative	Negative	Positive after 2.2 min
Animal No.1, air test after repair					Positive after 1.2 min
Animal No.2, first air test	Negative	Negative	Negative	Negative	Positive after 3.1 min
Animal no. 2, air test after repair					Positive after 1.1 min
Animal No.1, localisation of leakage	Site of the stay suture, jejunal side				
Animal No. 2, localisation of leakage	Site of the stay suture, jejunal side				

Table 5. Results of testing the GP and the GJA in the animal model.

### 6.2.3. Examination of the safety of the intraoperativ gastroscopy III.

#### Evaluation of the histological results

The stomach and small bowel samples from the experimental animals without pressure strain, exposed to the mean pressure strain reached in humans during IOG (32 Hgmm, 3,8 min), and exposed to the pressure strain leading to positive air test (150 Hgmm) were histologically examined in the search for structural disintegration. Haematoxilin-eosin, Van Gieson, Gömöri silver impregnation and orcein staining methods were applied. After pressure strain of 150 Hgmm a remarkable histological structural disintegration of the jejunum and stomach wall was observed. We could not detect any disintegration in the stomach and jejunum wall samples without pressure strain and after pressure strain of 30 Hgmm for 3.8 minutes (pressure strain developed during the gastroscopy in our patients) applying the above staining methods and light microscope.

### 6.2.4. Discussion of the examination of the safety of the intraoperative gastroscopy – comparison of the results of the human and animal experiments

Comparing the results listed in table 4. and 5. it was found, that during IOG develops an intraluminal pressure of 35-45 Hgmm, as it was measured in our human experiment. On the other hand, the intraluminal pressure, disintegrating the suture lines and leading to positive air test is 150 Hgmm, as it was found in our animal experiment. The 100-120 Hgmm difference between the two values makes unlikely the possible disintegration of the otherwise intact suture lines during IOG. That's why we think, that IOG results in positive air test only in cases of flawed suture line, making possible its intraoperative detection and repair and this way avoiding a serious postoperative complication.

Applying the above staining methods any structural disintegration of the stomach and jejunum samples from the experimental animals after pressure strain of 30 Hgmm for 3.8 minutes (pressure strain developed during the gastroscopy in our patients) could not be detected. It can be concluded, that IOG is a safe method of testing the integrity of the GJA and GP in LRYGB surgery.

IOG has an additional advantage: not only the flawed suture lines, but the intraluminal bleedings of the GP and the GJA can also be detected and controlled intraoperative.

#### 6.2.5. Discussion of the localisation of the positive air test

It was remarkable, that the positive air test occurred most frequently exactly at the point, where the seromuscular Vicryl 3-0 stay sutures, fixing the anterior wall of the rest stomach to the gastric pouch and to the Roux loop on the both side of the GJA, entered the wall of the jejunum. It is evident, that the universal question of the gastrointestinal surgery, if the staple lines should be covered with seromuscular sutures, can't be answered based upon our work. Our results rather indicate, that the seromuscular sutures, covering the staple lines are not always clearly advantageous.

### **7. Comparison of the results after LRYGB and after Laparoscopic Gastric Sleeve Resection (LGS) in aspects of quality of life parameters, weight change and improvement of co-morbidities**

#### 7.1. Introduction

In the Surgical Department of the Territory Hospital Oberwart bariatric surgical operations have been performed regularly since 2004. In the first part of the study period (2004-2009) we have performed predominantly laparoscopic gastric sleeve resections (LGS), then after 2007 the proportion of the LRYGB procedure was continuously growing, and now this type of operation comes to more than 90 % of our bariatric surgical interventions.

Generally it can be stated, that LGS is a rapid and less traumatic surgical intervention with an effective weight loss. The LRYGB is a more invasive and more complex procedure, but it is associated with more effective weight loss and with better control of co-morbidities <sup>(26,27,28)</sup>.

The main disadvantage of the LGS, that 1,5-2 years after the procedure the gastric tube is dilated in 20-30 % of the patients and they put on again weight, making necessary to carry out a second operation (more often LRYGB or seldom duodenal switch).

In our study we attempted to analyse the end results of these two types of bariatric surgical interventions performed regularly by us focusing on the quality of life, on the loss of weight and on the improvement of co-morbidities.

## 7.2. Patients and method

### 7.2.1. Data of our patients

The data from the date-base of our hospital and from the questionnaires filled in by the patients were retrospectively analysed, applying a match pair study of 47 patients after LGS and 47 patients after LRYGB. The characteristics of the patients are summarized in table 6.

	LRYGB	LGS	p
n	47	47	
Age mean (SD)	38,8 (10,42)	46 (9,22)	0,0013
Gender female/male n	35/12	35/12	
Preoperative BMI kg/m <sup>2</sup> mean (SD)	46.1 (5,78)	50,3 (9,70)	0,0471
Preoperative weight kg mean (SD)	132,8 (20,77)	141,0 (29,69)	0,229
Follow up period (months)	15,7	38,3	
Co-morbidities			
Diabetes n (%)	10 (21 %)	13 (28 %)	
Hypertension n (%)	19 (40 %)	23 (49 %)	
Gastro-oesophageal reflux n (%)	24 (51 %)	24 (51 %)	

Table 6. Patient characteristics

### 7.2.2. The applied questionnaires

We have used two standardized, internationally adapted quality of life (SF 36 and Moorehead-Ardelt II.) and one department specific questionnaires. The SF 36 estimates the following 8 aspects of the life quality: general health, physical functioning, role-physical, role-emotional, social functioning, bodily pain, vitality and mental health. The Moorehead-Ardelt II QLQ test surveys and evaluates six different areas of the everyday life: general self-esteem, physical activity, social contacts, satisfaction concerning on work, pleasure related to sexuality and focus on eating behaviour. The third, department specific questionnaires, drawn up by us, focused on the weight change, on the satisfaction of the patients with the result achieved after the surgical procedure, on the accidental operations in the postoperative period, and on the improvement of the most frequent obesity associated co-morbidities (diabetes type 2, hypertension, gastro-oesophageal reflux, degenerative joint disease, sleep apnoea).

### 7.2.3. Statistical Assessment

The data of the patients were collected and computed (Microsoft Excel) from the previous hospital documentation and from the returned questionnaires, filled in by the patients. The scores of SF 36 were calculated using the handbook and the standard software of the questionnaire. To compare the data (continuous variables) of the two patient's group and to calculate the p value the Mann-Whitney U test was applied. The different data are expressed as mean values and the standard deviations (SD) are given too. The p value under 0,05 was accepted to sign significant statistical difference.

### 7.3. Results

#### 7.3.1. Change of the body weight, patients' satisfaction and additional surgical procedures in the postoperative period

The patients lost 88 % of their extra weight after gastric bypass and 70 % after gastric sleeve resection. 94 % of the patients were satisfied with the postoperative results in the bypass group and 90 % in the sleeve group (table 7.).

	Bypass n=47	LGS n=47	p
Preoperative BMI mean kg/m <sup>2</sup> (SD)	46,1 (5,9)	50,3 (9,7)	0,471
Postoperative BMI mean kg/m <sup>2</sup> (SD)	28,1 (4,9)	33,5 (7,6)	0,001
Reduction of BMI (preop.BMI – postop.BMI) kg/m <sup>2</sup> (SD)	18 (4,2)	16,8 (6,9)	0,074
Preoperative weight mean kg (SD)	132,8 (20,8)	140,0 (29,7)	0,229
Postoperative weight mean kg (SD)	80,9 (16,6)	94,0 (21,9)	0,001
Reduction of weight (preop.weight–postop.weight)kg(SD)	51,9 (12,8)	47,3 (19,5)	0,062
Excess weight loss (SD)	88 % (0,21)	70 % (0,25)	0,0001
Satisfaction with the postoperative result	yes: 94 %	yes: 90 %	
Operations in the postop. period (sum)	15 (32%)	4 (8%)	
Laparoscopic sublay mesh implantation	4 (8%)	3 (6%)	
Laparoscopic cholecystectomy	7 (15%)	1 (2%)	
Small bowel ileus - adhesiolysis	4 (8%)		

Table 7. Results of weight change, Patient satisfaction, Operations in the postop. period.

#### 7.3.2. Quality of life parameters

The SF 36 questionnaire resulted in 671 points from the maximal 800 points in the gastric bypass group and 602 points in the gastric sleeve group (mean total scores, p= 0,0615). This result corresponds with the score of the representative panel of the European population <sup>(1)</sup> (table 8.).

	Bypass n=47	Sleeve n=47	p
General health	82	70	
Physical function	94	81	
Role physical	93	80	
Bodily pain	84	73	
Role emotional	87	80	
Social functioning	87	83	
Vitality	76	62	
Mental health	68	73	
Total score	671	602	0,0615

Table 8. Results of SF 36 questionnaire.

In respect of the questionnaire of Moorhead-Ardelt II the patients after gastric bypass achieved a mean total score of 2,09 and after gastric sleeve 1,70 points from the maximal 3 points (p=0,1301). It corresponds to a “good” result in both groups of patients (2. grade in a scale of five grades) (table 9.).

	Bypass n=47	Sleeve n=47	p
General self-esteem	0,38	0,31	
Physical activity	0,37	0,28	
Social contacts	0,42	0,34	
Satisfaction concerning on work	0,35	0,32	
Pleasure related to sexuality	0,24	0,17	
Focus on eating behaviour	0,42	0,28	
Total score	2,09	1,70	0,1301

Table 9. Results of Moorhead-Ardelt II questionnaire.

### 7.3.3. Improvement of Co-morbidities

The changes in diabetes type 2, in hypertension, in gastro-oesophageal reflux, in degenerative joint disease and in sleep apnoea were analysed before and after the two surgical procedures. 90 % of the bypass patients and 55 % of the sleeve patients with diabetes type 2 became without treatment and diet normoglycaemic in the postoperative period. The data are summarized in table 10.

Table 10. The improvement of co-morbidities after LRYGB and LGS.

		Bypass n=47	Sleeve n=47
Diabetes type 2	Number of patients	10	13
	Resolved	9 (90 %)	7 (55 %)
	Th. reduction	1 (10 %)	4 (30 %)
	No change	-	2 (15 %)
Hypertension	Number of patients	19	23
	Resolved	14 (73 %)	10 (43 %)
	Th. reduction	5 (27 %)	7 (30 %)
	No change	-	6 (27 %)
Gastro-oesoph. reflux	Number of patients	24	24
	Resolved	22 (92 %)	6 (25 %)
	Th. reduction/Alleviation	1 (4 %)	5 (21 %)
	No change	1 (4 %)	5 (21 %)
	Progression	-	8 (33 %)
Degenerative joint disease	Number of patients	29	31
	Resolved	-	-
	Th. reduction/Alleviation	28 (97 %)	22 (71%)
	No change	1 (3 %)	9 (29 %)
Sleep apnoea	Number of Patients	7	16
	Resolved	5 (72 %)	1 (6 %)
	Alleviation	1 (14 %)	9 (56 %)
	No change	1 (14 %)	6 (38 %)

## 7.4. Evaluation of the results – discussion

### 7.4.1. Discussion of the results of weight loss

The two types of surgical intervention lead different ways to weight change: the gastric sleeve resection is a restrictive method reducing eating abilities, the gastric bypass procedure is a restrictive and at the same time a malabsorptive method to lose weight and thus influences the overeating in two ways. Probably that is the reason behind, that after gastric bypass the weight loss is more effective: extra weight loss after bypass is 88 % and after sleeve resection is 70 % ( $p=0,0001$ ).

### 7.4.2. Discussion of the results of the QLQ tests

Our patients achieved a relatively high score in both study groups and in both QLQ tests. The SF 36 questionnaire resulted in 671 points in the gastric bypass group and 602 points in the gastric sleeve group (mean total scores,  $p=0,0615$ ). This result corresponds to the score of the representative panel of the normal, healthy European population. In respect of the questionnaire of Moorhead-Ardelt II, the patients after gastric bypass achieved a mean total score of 2,09 and after gastric sleeve 1,70 points ( $p=0,1301$ ). It corresponds to a “good” result (2. grade in a scale of five grades).

Obesity patients can expect, that their quality of life will remarkably improve or in most cases reach the level of the life quality of the normal population after the bariatric procedure, according to the results of SF 36 and Moorhead-Ardelt II QLQ tests applied in our patients. The results are better in the gastric bypass group, but the difference doesn't reach statistical significance.

### 7.4.3. Discussion of the results with diabetes type 2

In case of LRYGB the rearrangement of the small bowel tract –beside the decreased calorie intake and the reduction of the fat mass of the body- plays an important role in the resolution of the diabetes type 2. The insulin demand of the patient decreases remarkably in 1-2 weeks after the procedure, while in case of the restrictive types of bariatric operations it can be expected only some months latter, after the significant reduction of the body weight. There are some –in every details not yet cleared- theories, explaining this clinical experience. One of them is the so called “foregut” hypothesis. It says, if the consumed food doesn't contact the mucus membrane of the duodenum and of the first jejunal loops, the glucagon secretion and as a result the glucose resistance will be decreased, resulting the improvement of the blood glucose level of the patient.

Another theory is the “hindgut” hypothesis. According to this, if the carbohydrate content of the small bowel is high in the ileum, the “L” cells of the bowel wall secrete greater amount of glucagon like peptid 1 (GLP-1). This gastrointestinal peptid hormone increases the insulin synthesis, decreases the glucagon synthesis, decreases the gluco-neogenesis in the liver and leads –proved only in animal studies- to beta cell proliferation.

Probably both, the foregut and the hindgut hypothesis contribute to the result, experienced also in the study performed by us, that 80-90 % of the patients with diabetes type 2 will be normoglycaemic without antidiabetic drugs and diet after LRYGB. 9 from our 10 patients with diabetes type 2 became normoglycaemic without using insulin and antidiabetic drugs, and without keeping diet (besides the diet, which belongs to the postoperative way of living

after gastric bypass surgery). The tenth patient of us left out the insulin regimen, used before the operation, and he takes now antidiabetic drugs.

#### 7.4.4. Discussion of the results with gastro-oesophageal reflux

After LRYGB high rate of the gastro-oesophageal reflux disease (GER) will be resolved. The minimal acid production of the gastric pouch of 50 ml results in no acidic esophagitis and the Roux loop of 100-150 cm inhibits the biliary reflux. 92 % of our patients with GER became free of symptoms without using any type of treatment after the operation. After gastric sleeve resection 25 % of the patients became free of reflux symptoms, but 33 % of the patients experienced progression of the complaints, that may be caused by the slowed emptying of the gastric tube.

#### 7.4.5. Discussion of the results with hypertension

73 % of the patients with hypertension in the gastric bypass group, and 43 % in the sleeve resection group became normotensive after the surgical procedures without the previously used antihypertensive drugs. The resolution of the hypertension is associated first of all to the degree of weight loss, so the experienced difference between the two groups of patients can be explained with the more effective weight reduction after LRYGB<sup>(28)</sup>.

#### 7.5. Conclusion

The patients in both groups reached a remarkable weight loss and a good level of the quality of life. After LRYGB the loss of weight and the resolution rate of the obesity associated most frequent co-morbidities (diabetes type 2, GER, hypertension) were significantly higher. Therefore our first choice in obesity surgery is the LRYGB, if it is technically possible. We indicate gastric sleeve resection for patients with considerable anaesthesiological risk factors or in case of megal-obesity (BMI > 60 kg/m<sup>2</sup>). If the gastric tube dilates after the sleeve resection and the patient gains once again weight, not waiting for the grade of severe obesity, it can be switched laparoscopically to gastric bypass without technical difficulties in vast majority of the cases.

### **8. Results of the operations performed in Hungary**

In the Surgical Department of the County Hospital Veszprém 14 LRYGB procedures were performed since February 2010. The results are not highly informative yet, because the number of patient is too low and the follow-up period is short, but it seems to be justified, that the data of our patients follow the trends of weight loss, of life quality and of resolution rate of the co-morbidities, reached in other studies with large number of patients and with long follow up period. Serious complication didn't develop in this group of patients.

## 9. Summary of the new statements

### 9.1. Details of the surgical steps

The surgical steps of the procedure were presented in details, describing the most frequent causes of the technical troubles and the way, how to avoid them. The elimination of the technical difficulties is also discussed.

### 9.2. Statements based on conclusions of the examination of efficacy and safety of intraoperative gastroscopy

#### 9.2.1. Statements concluded from examination of the efficacy of intraoperative gastroscopy

In the retrospective study performed in our series of 252 patients was found, that the intraoperative gastroscopy with air test detected positive air test in 6 cases during the operation and any anastomosis insufficiency didn't occur in the postoperative period. That's why IOG with air test proved to be an effective method to detect the deficiencies of the suture lines of the GJA and GP, making possible the repair during the LRYGP procedure. The further advantage of the method is the intraoperative detection of intraluminal bleedings, and this way they can be controlled during the operation.

#### 9.2.2. Statements concluded from examination of the safety of intraoperative gastroscopy

It was found based upon the intraoperative measurement in 15 patients of us, that the mean intraluminal pressure, which develops in the gastric pouch –caused by different physical and physiological reasons- was 32 Hgmm, the mean of the maximal pressure values was 43 Hgmm and the developed highest pressure was 47 Hgmm during the intraoperative gastroscopy.

In the other hand, it was proved in the performed animal study, that the intact suture lines were disintegrated at intraluminal pressure of 150 Hgmm. It means, that there is 100 – 120 Hgmm difference between the pressure leading to disintegration of the suture lines and to positive air test and the pressure developing during the IOG in humans.

The applied histological staining methods didn't prove any structural disintegration of the stomach and jejunum samples from the experimental animals after pressure strain of 30 Hgmm for 3.8 minutes (pressure strain developed during the gastroscopy in our patients).

On the basis of the results found in three studies listed above (human experiment 6.2.1., animal experiment 6.2.2., histological results 6.2.3.) it is proved, that IOG with air test is a safe method to examine the integrity of the staple lines of GJA and GP in LRYGB surgery. It is highly probable, that IOG results in positive air test only in cases of flawed suture line, making possible its intraoperative detection and repair and this way avoiding a serious postoperative complication.



### 9.3. Statements concluded from the comparison of the results after laparoscopic Roux Y gastric bypass and laparoscopic gastric sleeve resection

#### 9.3.1. Difference in aspect of weight loss

Our patients reached effective weight loss after both types of surgical procedures. Gastric bypass was more effective in point of view of weight loss, the difference was statistically significant ( $p=0,0001$ ).

#### 9.3.2. Difference in aspect of quality of life parameters

After both procedures the patients reached a mean score in both QLQ tests, which corresponds to the representative panel of the European normal, healthy population. After gastric bypass the results of each questionnaires were better, but the differences didn't reach statistical significance ( $p=0,0615$  and  $p=0,1301$ ).

#### 9.3.3. Difference in aspect of resolution of co-morbidities (diabetes type 2, hypertension, gastro-esophageal reflux)

-9 patients from 10 with diabetes type 2 became normoglycaemic without diet and any types of treatment after gastric bypass (90 %), the resolution rate of diabetes type 2 was 55% after sleeve resection.

-73 % of the patients with hypertension became normotensive without medical treatment after gastric bypass, and 43 % after gastric sleeve resection.

-92 % of the patients with gastro-esophageal reflux became free of symptoms without treatment after gastric bypass. After gastric sleeve resection the resolution rate of GER was 25 %, but 33 % of the patients scored progressive complaints.

That's why LRYGB should be preferred to gastric sleeve resection.

The technically easier, not so demanding gastric sleeve resection is indicated, when gastric bypass can't be performed from any reasons (megalo-obesity, high risk patient, interintestinal adhesions, etc). If the gastric tube dilates after the sleeve resection and the patient gains once again weight, not waiting for the grade of severe obesity, it can be switched laparoscopically to gastric bypass without technical difficulties in vast majority of the patients.

## List of own publications and presentations related to the theme of the paper

### Publications:

1. Mohos E., E. Schmaldienst, M. Prager: Quality of Life Parameters, Weight Change and Improvement of Co-morbidities after Laparoscopic Roux Y Gastric Bypass and Laparoscopic Gastric Sleeve Resection - Comparative Study – Obesity Surgery 21/3, 288-294; 2011.

**Impact factor: 2,93**

2. Mohos E., D.Richter, E. Scmaldienst, M. Prager: Examination of the Efficacy and Safety of Intraoperative Gastroscopic Testing of the Gastrojejunal Anastomosis in Laparoscopic Roux Y Gastric Bypass Surgery DOI: 10.1007/s11695-011-0428-8, Obesity Surgery, online 2011. 04.

**Impact factor: 2,93**

3. Mohos E., Nagy A., E. Schmaldienst, M. Prager: Laparoscopos Roux Y Gastric Bypass (LRYGB) műtéttel szerzett tapasztalataink és az alkalmazott műtéti módszer leírása. Magyar Seb. 2011. 64(1):12-17.

4. Mohos E., E. Schmaldienst, D. Richter, M. Prager: Welche Möglichkeiten gibt es, welche sind die Selektionskriterien ? „Weight Loss Surgery”; Gyn-Aktiv , 70-73; 3/2011.

5. Mohos E., M.Prager: Adipositas bei Jugendlichen: Ein Problem chirurgischer Dimension ? Journal für Ernährungsmedizin 22-25; 1/.2011.

6. Mohos E.:

Laparoscopos Roux Y gastric bypass műtéttel kapcsolatos kezdeti hazai eredményeink a kóros adipositas és a 2-es típusú diabetes gyógyításában. Medical Tribune. IX.évf. 9. 2011.

7. Mohos E.,<sup>1,2</sup> Vándorfi Gy.,<sup>3</sup> M. Prager<sup>2</sup>., Rakk E.,<sup>3</sup> Miléder M.,<sup>3</sup> Fulcz Á.,<sup>3</sup> Szabados Gy.,<sup>4</sup> Szabó L.,<sup>4</sup> Vereczkei A.,<sup>5</sup> Nagy Attila dr.,<sup>1</sup>  
Laparoscopos Roux Y gastric bypass műtéttel szerzett kezdeti hazai eredményeink a kóros adipositas és a 2-es típusú diabetes kezelésében Diabetologia Hungarica. Közlésre elfogadva.

**Sum of impact factors: 5,86**

**Presentations:**

1. Mohos E., E.Schmaldienst, P.Heuberger, G.Koller, M.Prager:  
Laparoscopic Roux Y Gastric Bypass (L-RYGB). Early results and Videopresentation. Endoscopic Surgical Congress – Szeged -2009
2. Mohos E., János Z., Kurán Gy., Nagy A.:  
Our Experiences with Laparoscopic Roux Y Gastric Bypass (LRYGB). Videopresentation. Hungarian Congress of Surgery. – Siófok- 2010.
3. Mohos E., M. Prager:  
Gastric Sleeve and/or Gastric Bypass: Focusing on Quality of Life, on Weight Loss and on Co-morbidities. Videopresentation. World Congress of Endocrinology and Metabolism – Xiamen (China) - 2011.
4. Mohos E., M. Prager:  
Gastric Bypass, Gastric Sleeve and Gastric Balloon. Policy of Indication. Videopresentation. Central European Congress of Surgery – Budapest - 2011.
5. Mohos E., M.Prager, Vándorfi Gy., Szabados Gy., Szabó L., Kurán Gy., Nagy A.:  
Our Results with Laparoscopic Gastric Bypass in Treatment of Severe Obesity and DMT2. Congress of Diabetology - Tihany – 2011.

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