VILNIUS UNIVERSITY

Tomas Abalikšta

BARIATRIC SURGERY USING DIFFERENT ADJUSTABLE GASTRIC BANDS: THE RESULTS OF PROSPECTIVE RANDOMISED STUDY

Summary of Doctoral Dissertation
Biomedical Sciences, Medicine (06B)

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VILNIAUS UNIVERSITETAS

Tomas Abalikšta

NUTUKIMO CHIRURGINIS GYDYMAS NAUDOJANT SKIRTINGAS SKRANDĮ APJUOSIANČIAS REGULIUOJAMAS JUOSTAS: PERSPEKTYVIOJO ATSITIKTINĖS ATRANKOS IMČIŲ BIOMEDICININIO TYRIMO REZULTATAI

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ABBREVIATIONS

LAGB	-	laparoscopic adjustable gastric banding
AGB	-	adjustable gastric band
SAGB	-	Swedish Adjustable Gastric Band
BW	-	body weight
IBW	-	initial body weight
IFM	-	initial fat mass
%IFM	-	percent of initial fat mass
BMI	-	body mass index
IBMI	-	initial body mass index
IFMI	-	initial fat mass index
IEW	-	initial excess weight
IEBMI	-	initial excess body mass index
WL	-	weight loss
BMIL	-	body mass index loss
FML	-	fat mass loss
FMIL	-	fat mass index loss
%IWL	-	percentage of initial weight loss
%IBMIL	-	percentage of initial body mass index loss
%IEWL	-	percentage of initial excess weight loss
%IEBMIL	-	percentage of initial excess body mass index loss
%IFML	-	percentage of initial fat mass loss
%IFMIL	-	percentage of initial fat mass index loss
QoL	-	quality of life
M-A QoLQII	-	updated (second) Moorehead-Ardelt Quality of Life Questionnaire
BAROS	-	Bariatric Analysis and Reporting Outcome System
VAS100	-	visual analogue scale
ATP-III	-	Adult Treatment Panel III guidelines

INTRODUCTION

LAGB is one of the methods for surgical treatment of morbid obesity (BMI >40 or >35 with obesity associated co-morbidities). This method introduced by Kuzmak (1985) and Hallberg has been performed laparoscopically since 1993. It is estimated that LAGB represents about 42% of bariatric operations performed worldwide. The high efficiency of this procedure has been proved in numerous studies, but for some patients the results of this operation are unsatisfactory. Until now there are no accepted criteria for choosing this particular operation. There are a number of different AGBs available on the international market for performing LAGB. These AGBs differ in size, filling volume, internal pressure (and possibly pressure on the gastric wall), fixation method and materials they are made of. Few attempts have been made to compare the influence of these AGB design differences for efficiency and complication rate and conflicting results have emerged from comparative studies that have significant shortcomings: usually nonrandomised or retrospective small studies with short follow up.

THE AIM OF THE STUDY

The aim of our study is to evaluate the influence of AGB design differences for efficiency and complication rate of LAGB and to determine preoperative outcome predictors.

OBJECTIVES

1. To evaluate LAGB results in terms of weight loss, complication rate, correction of co-morbidities and improvement of QoL;
2. To compare LAGB results using different AGBs: SAGB (Obtech Medical, Switzerland) and MiniMizer Extra **(**Bariatric Solutions GmbH, Switzerland);
3. To evaluate the influence of multiple preoperative factors on the results of LAGB and to determine possible outcome predictors.

DEFENSIVE STATEMENTS

1. LAGB is effective and safe bariatric procedure.
2. The compared AGBs do not differ in efficiency and complication rate.
3. Patients at the age ≥ 40 years achieve better results using MiniMizer Extra AGB.
4. Patients with IBMI ≤ 47 kg/m^2 achieve better results using MiniMizer Extra AGB.

SCIENTIFIC NOVELTY OF THE STUDY

Only few usually nonrandomised or retrospective small comparative AGB studies with short follow up are accomplished worldwide and the effects of differences in AGB design are not properly estimated. Until now there are no accepted criteria for choosing this particular operation, only general indications for bariatric surgery are stated. The factors allowing to choose the most suitable AGB for the particular patient are not studied yet.

The history of bariatric surgery in Lithuania is very short. Only few publications about the results of bariatric surgery in Lithuania are published.

It is the first time different AGBs have been compared in prospective randomised study in Lithuania.

LITERATURE REVIEW

A review of literature presents definition, epidemiology and pathology of obesity, overview of modern obesity treatment principles and treatment result evaluation methods. It contains systematic analysis of comparative studies of different AGBs and different subcutaneous injection ports. It also presents data of studies dealing with bariatric surgery outcome predictors or with factors influencing treatment results.

MATERIALS AND METHODS

Study protocol was approved by Lithuanian Bioethics Committee on November 6, 2008. Patients between 18-70 years of age with BMI more than 40 kg/m^2 and patients with BMI between 35 and 40 kg/m^2 with associated co-morbidities were considered eligible for LAGB. Exclusion criteria were contraindications for laparoscopy, previous bariatric surgery, pregnancy and patient's refusal. Signed informed consent was obtained from all patients. Patients were randomly assigned to groups by choosing from two

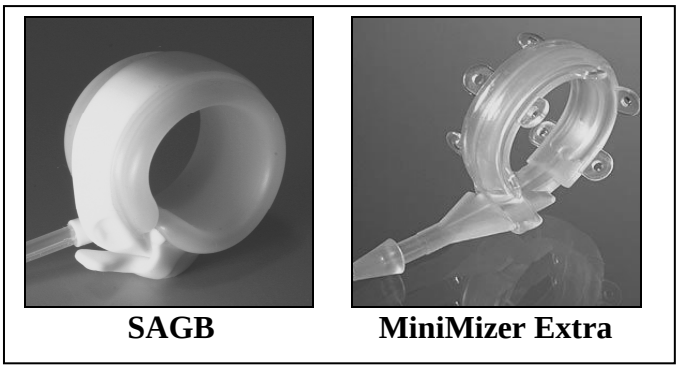
identical sealed envelopes with different AGB name inside. All operations were performed by the same surgeon with prior experience of more than 400 LAGB operations using SAGB and MiniMizer Extra AGBs.

Preoperative data. Extensive preoperative evaluation was done by multidisciplinary team, consisting of endocrinologist, gastroenterologist, dietician, cardiologist and bariatric surgeon. Broad laboratory blood tests, upper gastrointestinal tract endoscopy, abdominal and cardiac sonoscopy and upper gastrointestinal tract radiography were performed to all included patients according to the study protocol. IBW was measured and body composition analysis (hand-to-foot bioelectrical impedance analysis) for IFM and %IFM evaluation was performed. IBMI and IFMI (IFMI = IFM / (height in meters)^2, kg/m^2) were counted from these data. IFM evaluation was possible only if %IFM did not exceed 50% (technical limitation of the bioelectrical impedance analysis device), thus all patients with %IFM more than 50% were included in statistical analysis as if they had 50% of %IFM. IEW was calculated using the formula: IEW = (preoperative body weight) – (upper limit of normal body weight). Upper limit of normal body weight would be the BW if patient's BMI were 25 kg/m^2 and is calculated using the formula: upper limit of normal body weight = (height in metres)^2 × 25. IEBMI was calculated by taking 25 kg/m^2 from IBMI. Metabolic syndrome was diagnosed by ATP-III guidelines. QoL was evaluated by M-A QoLQII in points from -3 to +3. According to the M-A QoLQII scoring key the QoL is stated as *very poor* from -3 to -2.1 points, *poor* from -2 to -1 point, *fair* from -1 to +1 point, *good* from +1.1 to +2 points and *very good* from +2.1 to +3 points. Thromboembolic prophylaxis was provided using low-molecular-weight heparin (nadroparin) 12 hours before operation and on the first postoperative day until mobilization was achieved. Furthermore, mechanical calf compression was also used for the prevention of deep venous thrombosis during surgery. One dose of 2 g cefuroxime was administered intravenously 10 – 15 minutes before the operation for infection prophylaxis. All patients underwent general anaesthesia and nasogastric suction.

Surgical technique. All patients underwent LAGB. Two different AGBs were used: the SAGB and the MiniMizer Extra (Figure 1.). *Pars flaccida* technique was used for both AGBs. The fixation of the AGB on the anterior gastric wall was achieved by creating the gastric fold over the AGB with four nonabsorbable gastro-gastric sutures in

the case of SAGB (*fixation with plication*) or directly suturing the fixation loops of the MiniMizer Extra AGB to the stomach wall (*fixation without plication*). The AGB was left empty at the end of the procedure. The MiniMizer Extra AGB was closed either in the first (wider) or second (tight) position according to the stomach diameter inside the band. At the end of the intraperitoneal part of operation two hepatic needle biopsies were performed according to the study protocol. The SAGB-Velocity Port and Applier were used in case of SAGB AGB and MiniMizer Port Medium was used in the case of MiniMizer Extra AGB.

Figure 1. Compared AGBs



Postoperative care. Early mobilization occurred 3-4 hours after operation. Next day after the surgery patients could drink liquids. Pain and other unpleasant symptoms such as nausea, discomfort feeling in the epigastric region, shoulder pain, tachycardia and others were evaluated using a special questionnaire by VAS100. Patients with normal conditions were discharged on the second postoperative day getting the instruction to follow semi liquid diet for the first postoperative month. Patients were also provided with the written diet instructions.

AGB adjustment. AGB adjustment rate was not influenced by the study protocol and was performed according to the accepted standards of our clinic. The AGBs were left empty in the widest possible position at the end of operation. Patients were asked to arrive for AGB adjustment in case of stopping to lose weight for more than two weeks but not earlier than four weeks after the operation. All other adjustments were also performed in case of stopping to lose weight for more than two weeks but not earlier than four weeks after the previous adjustment. The access to the port was detected sonoscopically. The average filling volume of SAGB was 2.5 ml (not more than 4 ml) of saline solution for the first adjustment, 1.5 ml for the second adjustment, 1 ml for the

third adjustment and 0.5 ml for all following adjustments. The average filling volume of MiniMizer Extra AGB was 1.2 ml (not more than 2 ml) of saline solution for the first adjustment, 0.6 ml for the second adjustment and 0.3 ml for all following adjustments. The degree of restriction was usually controlled by clinical signs only (patient's ability to drink liquids). Upper gastrointestinal tract radiography was performed in cases when two consecutive AGB adjustments were unsuccessful to reach sufficient restriction or if AGB leak or overfilling was suspected.

Follow up and evaluation. Patients were evaluated one year after operation by the same multidisciplinary team. The same laboratory blood tests, upper gastrointestinal tract endoscopy, cardiac sonoscopy, upper gastrointestinal tract radiography, body composition analysis and the evaluation of the QoL were repeated. Primary endpoints were %IEWL, %IEBMIL, %IFML and %IFMIL. Secondary endpoints were early and late complications, reoperations, the proportion of patients with %IEWL of at least 50% (Reinhold's criterion), changes in QoL and co-morbidities. Early complications were complications arising during the first postoperative month. Major early complications were life-threatening and/or led to reoperation. Major late complications were life-threatening and/or led to band removal. Patients whose band had to be removed were excluded from further weight loss analysis; however, they remained included in the analysis regarding the percentage of patients achieving 50% of %IEWL, in which they were considered as failures. Final evaluation of the results was done by BAROS. Outcome groups by BAROS scoring key are: for patients with co-morbidities: *failure* in case of 1 point or less, *fair* in case of >1 to 3 points, *good* in case of >3 to 5 points, *very good* in case of >5 to 7 points and *excellent* in case of > 7 to 9 points; for patients without co-morbidities: *failure* in case of 0 points or less, *fair* in case of >0 to 1.5 points, *good* in case of >1.5 to 3 points, *very good* in case of >3 to 4.5 points and *excellent* in case of > 4.5 to 6 points. Only four co-morbidities (hypertension, cardiovascular diseases, dyslipidemia and type II diabetes) from BAROS major co-morbidity list were included in BAROS evaluation. We did not include changes in sleep apnoea, osteoarthritis and infertility because there was no possibility to perform formal sleep study, osteoarthritis imaging evaluation and infertility/hormonal studies for diagnosis of these conditions as required by BAROS.

Statistical analysis. All data analysis was performed using a software program SPSS Statistics 17.0. Descriptive statistics were mean ± SD and range for parametric continuous variables (after confirmation of normal distribution with one-sample Kolmogorov-Smirnov test) and frequencies for categorical variables. The Student's *t* test or Mann-Whitney U test for continuous variables and chi-squared or Fisher exact test for categorical variables were used to analyze differences between groups. Differences were considered significant if $p<0.05$.

RESULTS

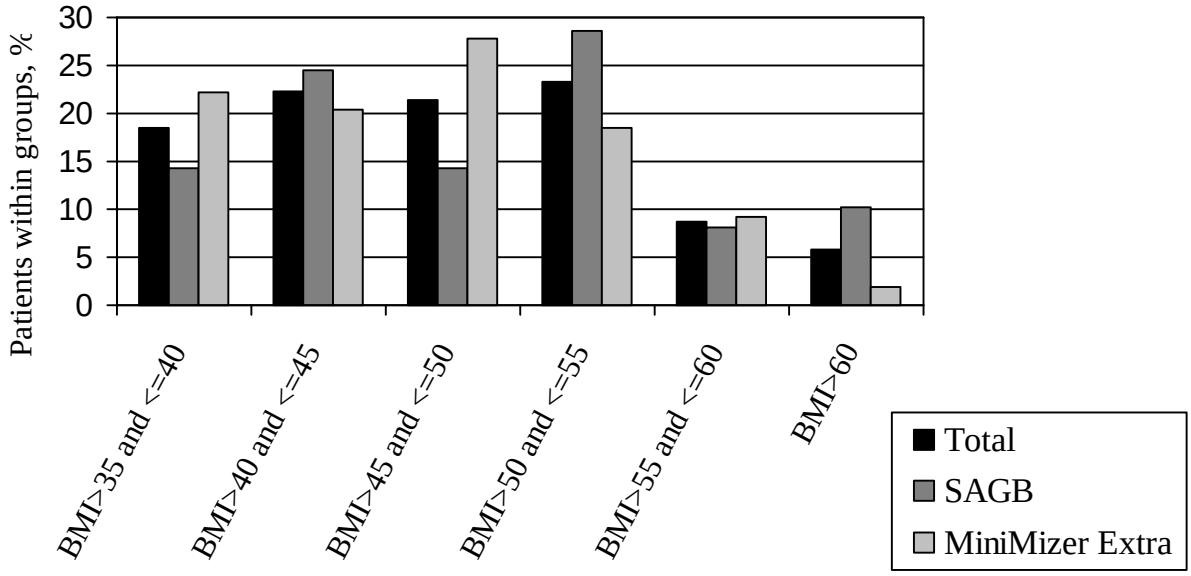
Preoperative data. A total of 103 patients were included in this study between January 1, 2009 and January 31, 2010. There were 69 women (67%) and 34 men (33%). Patients' mean age was 46.1 ± 11.5 years and weight was 141.9 ± 24.2 kg. The SAGB was used in 49 cases and MiniMizer Extra in 54 cases. The preoperative characteristics of the patients did not differ between groups (table I, figure 2).

Table I. Preoperative characteristics of the patients.

Variable	All patients	Comparative groups		*p*
		SAGB	MiniMizer Extra	
Number of patients	103	49	54	0.622
Females/Males, n (%)	69/34 (67/33)	31/18 (63.3/36.7)	38/16 (70.4/29.6)	0.530
Age, yrs	45.9 ± 11.7 (21 – 70)	46.1 ± 11.5 (21 – 67)	45.8 ± 11.9 (22 – 70)	0.869
IBW, kg	137.6 ± 24.4 (87.4 – 199.3)	141.9 ± 24.2 (87.4 – 199.3)	133.8 ± 24.1 (88.5 – 196.5)	0.093
IFM, kg	60.4 ± 12.9 (33.4 – 95.5)	61.5 ± 13.3 (37.3 – 95.5)	59.4 ± 12.7 (33.4 – 85)	0.417
%IFM, %	43.9 ± 5.5 (30 – 50)	43.3 ± 5.7 (31 – 50)	44.5 ± 5.3 (30 – 50)	0.273
IBMI, kg/m^2	47.5 ± 7.3 (35 – 68.3)	48.6 ± 7.9 (35 – 68.3)	46.5 ± 6.7 (35 – 62.4)	0.157
IFMI, kg/m^2	21.1 ± 4.9 (11.8 – 34.1)	21.3 ± 5.3 (13.1 – 34.1)	20.9 ± 4.6 (11.8 – 31.2)	0.703
IEW, kg	64.9 ± 21.2 (24.9 – 116.5)	68.5 ± 22.1 (24.9 – 116.5)	61.8 ± 20.0 (25.3 – 114.6)	0.107
IEBMI, kg/m^2	22.5 ± 7.4 (10 – 43.3)	23.6 ± 7.9 (10 – 43.3)	21.5 ± 6.7 (10 – 37.4)	0.157

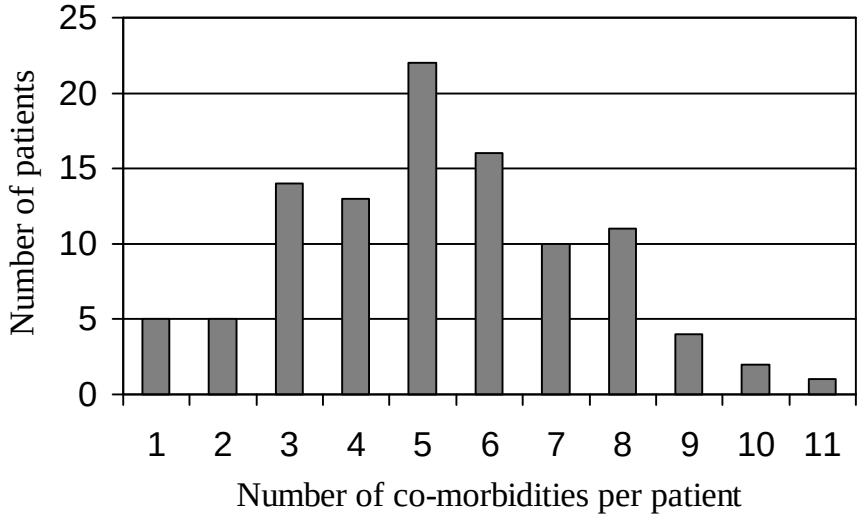
Data are given as mean ± SD (range) unless otherwise indicated.

Figure 2. Distribution of patients by preoperative BMI.



All patients had co-morbidities and most of them had multiple co-morbidities (5.2 ± 2.2 (range 1 – 11) co-morbidities per patient). 37 (35.9%) patients had type II diabetes mellitus, 44 (43.2%) were suffering from heartburn and in 17 (16.8%) of them gastroesophageal reflux was diagnosed during upper gastrointestinal tract radiography, 82 (79.6%) had arterial hypertension, 29 (28.2%) respiratory diseases (chronic obstructive lung disease, bronchial asthma), 28 (27.2%) sleep apnoea (diagnosed by clinical signs only), 21 (20.4%) cardiac pathology (arrhythmia, ischemic heart disease, cardiac insufficiency), 19 (18.4%) genital disorders (polycystic ovary syndrome, infertility, menstrual disorders, dysfunctional bleeding), 28 (27%) gall bladder stones, 71 (68.9%) knee pain, 80 (77.7%) spinal pain, 34 (33%) varicose of the leg veins, 6 (5.8%) elephantiasis, 11 (10.7%) psoriasis, 24 (23.3%) thyroid gland diseases, 9 (8.7%) urinary tract diseases (urinary incontinence, renal insufficiency), 13 (12.6%) depression and 6 (5.8%) hernias. Initial frequency of co-morbidities did not differ between groups (figure 3).

Figure 3. Distribution of patients by number of co-morbidities.



Metabolic syndrome was diagnosed in 79 (77.5 %) patients. The frequency of metabolic syndrome diagnostic factors by ATP-III is shown in table II and number of positive diagnostic factors in metabolic syndrome patients is shown in table III.

Table II. The frequency of metabolic syndrome diagnostic factors (ATP-III).

Diagnostic factor	Frequency, n (%)
Waist circumference >102 cm in men and >88 cm in women	102 (100)
Triglycerides ≥ 1.7 mmol/l	54 (52.9)
HDL cholesterol <1 mmol/l in men and <1.3 mmol/l in women	57 (55.9)
Blood pressure ≥ 130/85 mmHg	82 (80.4)
Fasting glucose ≥ 5.6 mmol/l	59 (57.8)

Table III. The number of positive diagnostic factors in metabolic syndrome patients.

The number of positive diagnostic factors	Frequency, n (%)
3	27 (34.2)
4	28 (35.4)
5	24 (30.4)
Total	79 (100)

The initial BMI of metabolic syndrome patients was significantly higher than that of nonmetabolic syndrome patients (48.4 and 44.5 kg/m^2 respectively, p=0.007). The difference in age of these patient groups was not statistically signifcant.

Hepatic biopsy findings are shown in figures 4 - 6. No statistically significant difference between groups was stated.

Figure 4. Hepatic stetosis.

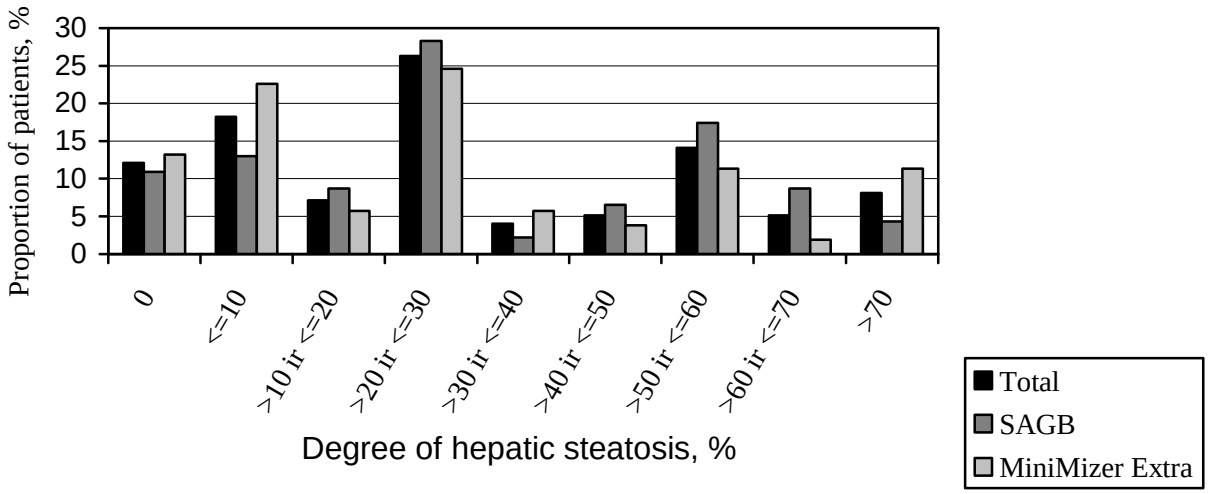


Figure 5. Hepatic fibrosis.

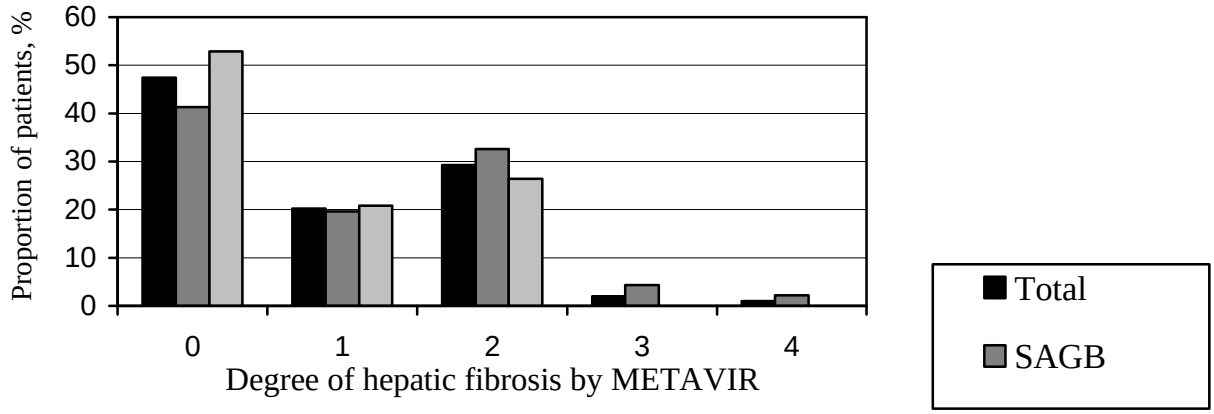
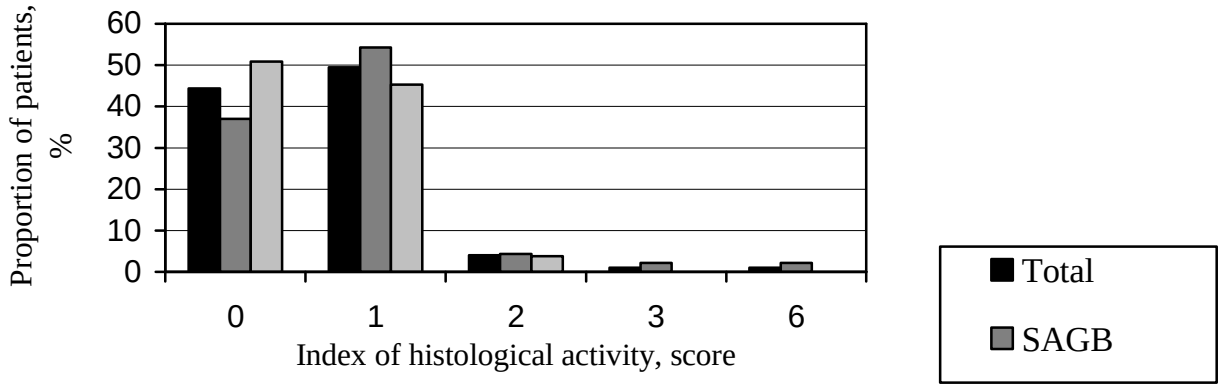


Figure 6. Steatohepatitis



Initial QoL was 0.02 ± 1.2 points by M-A QoLQII. Initial QoL did not differ between groups.

Operation. The operative time was 64.6 ± 18.7 minutes. In 8 cases additional procedures were performed during operation: four small previously undiagnosed formations were removed from anterior gastric wall (two gastrointestinal stroma tumours (GIST), one fibroadenoma and one ectopic pancreatic tissue formation), extensive dissection of massive adhesions after previous operations was performed in two cases, diaphragmatic crura were sutured to repair large hiatal hernia in one case and cystectomy of the ovarian cyst was performed in one case. We encountered five minor intraoperative complications: gastric lesion in one case, bleeding from gastric vessel in one case, hepatic lesions caused by hepatic retractor in two cases and loss of the needle in one case. All complications were diagnosed and solved during the same operation. The time of these additional procedures was excluded from the whole operative time for comparative reasons, because this additional time was not associated with either of the AGBs. Operative time, duration of pneumoperitoneum (i.e. AGB placement and fixation time) and injection port implantation time are shown in table IV.

Table IV. Operative times.

Variable	All patients	Comparative groups		*p*
		SAGB	MiniMizer Extra	
Operative time, min	64.6 ± 18.7 (40 – 160)	67.7 ± 21.9 (40 – 160)	61.8 ± 14.8 (45 – 120)	0.110
The duration of pneumoperitoneum, min	51.6 ± 18.5 (30 – 150)	**56.2 ± 21.5** (30 – 150)	**47.3 ± 14.1** (30 – 105)	**0.016**
Injection port implantation time, min	13.0 ± 2.9 (10 – 20)	**11.4 ± 2.5** (10 – 20)	**14.4 ± 2.5** (10 – 20)	**< 0.001**

Data are given as mean ± SD (range).

Postoperative feeling. Pain level and the rate of other unpleasant symptoms do not differ between groups (figures 7 - 9).

Figure 7. Postoperative pain.

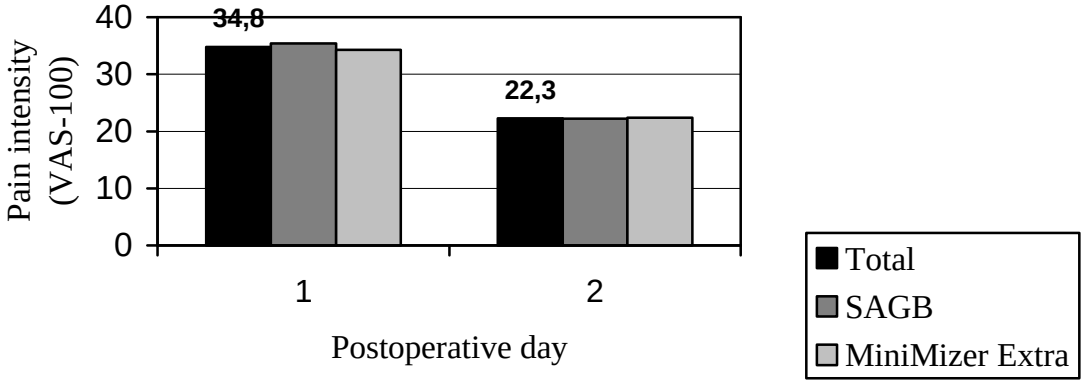


Figure 8. Postoperative nausea.

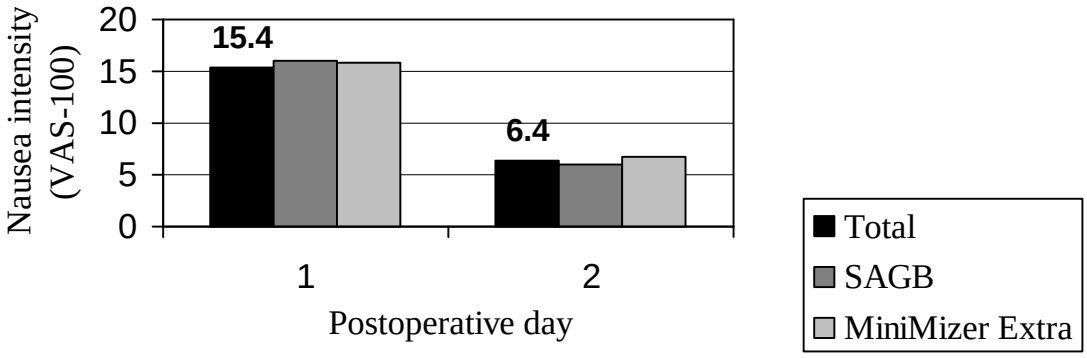
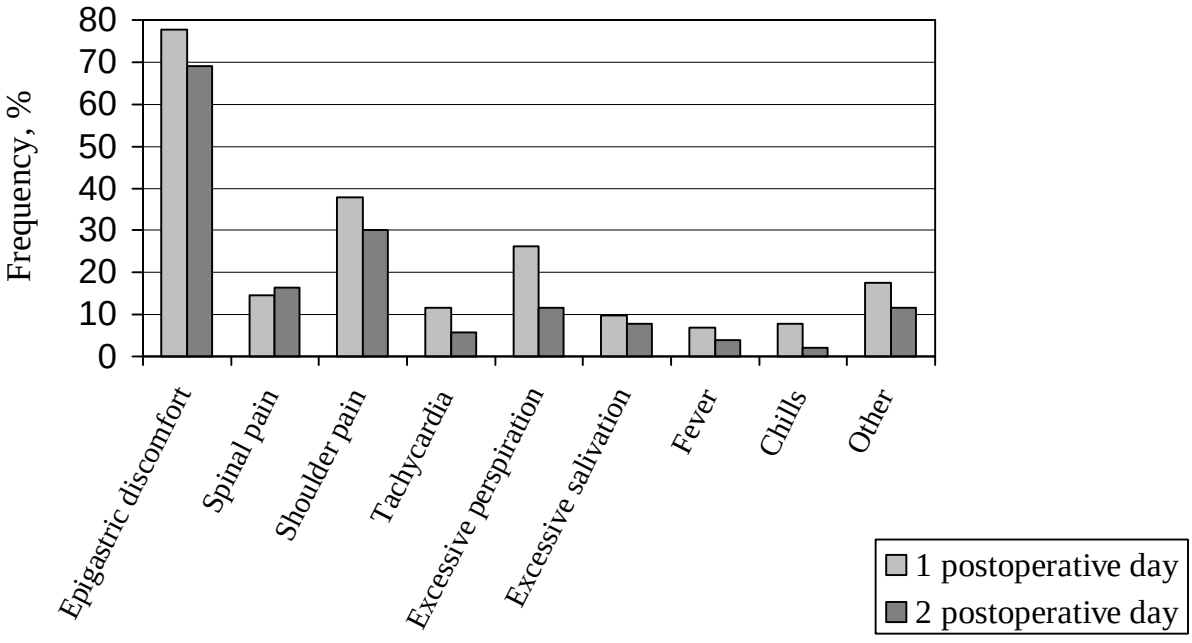


Figure 9. Other unpleasant postoperative symptoms.



AGB adjustment frequency. The AGBs were adjusted 2.7 ± 2.2 times (range 0-10) in SAGB group and 2.4 ± 1.2 times (range 0-5) in MiniMizer Extra group (p=0.514).

Early complications and lost follow-up analysis. There were three transient gastric stenoses in early postoperative period in MiniMizer Extra group that resolved spontaneously during the first postoperative week. There were no early complications and early postoperative deaths. There was one early AGB penetration in MiniMizer Extra group 6 months after operation. The AGB was removed laparoscopically and this patient was excluded from further weight loss analysis. One patient died due to acute myocardial infarction 4 months after LAGB operation in SAGB group. One woman was excluded from weight loss analysis in one year period because of pregnancy. Ten patients could not come for evaluation in one year period after LAGB: one emigrated, one was after orthopaedic operation, one after trauma and seven could not come because of other reasons. All these ten patients were contacted by phone and weight loss was registered. Eventually, 90 (41 SAGB and 49 MiniMizer Extra) patients arrived for one year follow-up evaluation. Fourteen (9 SAGB and 5 MiniMizer Extra) refused the upper gastrointestinal tract endoscopy.

Weight loss. Weight loss parameters are shown in table V. No statistically significant difference could be noted in any of primary weight loss parameters.

Table V. Weight loss parameters.

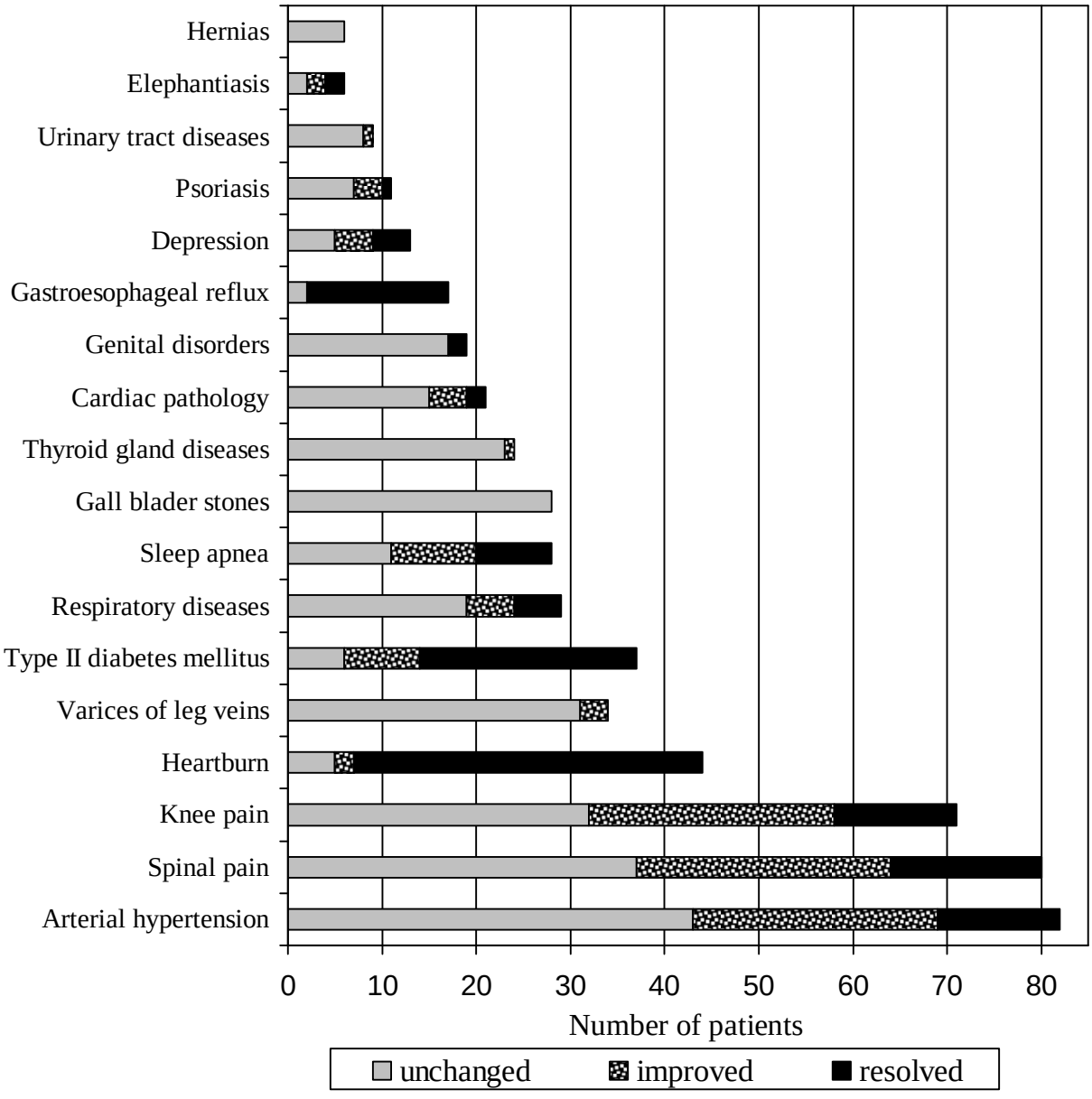
Variable	All patients	Comparative groups		*p*
		SAGB	MiniMizer Extra	
WL, kg	19.5 ± 11.9 (-4.3 – 60)	18.2 ± 12 (0 – 60)	20.7 ± 11.9 (-4.3 – 54)	0.321
BMIL, kg/m^2	6.7 ± 3.9 (-1.4 – 19.9)	6.2 ± 3.9 (0 – 18.1)	7.1 ± 4.0 (-1.4 – 19.9)	0.259
%IWL, %	14.4 ± 8.5 (-2.6 – 37.9)	12.9 ± 8.1 (0 – 35.4)	15.7 ± 8.7 (-2.6 – 37.9)	0.112
%IBMIL, %	14.4 ± 8.5 (-2.6 – 37.9)	12.9 ± 8.1 (0 – 35.4)	15.7 ± 8.7 (-2.6 – 37.9)	0.112
FML, kg	12.3 ± 7.6 (-0.7 – 37.7)	10.7 ± 6.9 (-0.4 – 31.4)	13.5 ± 7.9 (-0.7 – 37.7)	0.090
FMIL, kg/m^2	4.3 ± 2.7 (-0.2 – 14.7)	3.7 ± 2.4 (-0.1 – 11.5)	4.71 ± 2.8 (-0.2 – 14.7)	0.094
%IFML, %	21.0 ± 12.7 (-1.2 – 58.0)	18.1 ± 11.9 (-0.7 – 58.0)	23.3 ± 12.9 (-1.2 – 56.1)	0.062
%IFMIL, %	21.0 ± 12.7 (-1.2 – 58.0)	18.1 ± 11.9 (-0.7 – 58.0)	23.3 ± 12.9 (-1.2 – 56.1)	0.062
%IEWL, %	33.1 ± 21.9 (-4.9 – 124.1)	28.9 ± 21.3 (0 – 124.1)	36.8 ± 22.1 (-4.9 – 91.1)	0.075
%IEBMIL, %	33.1 ± 21.9 (-4.9 – 124.1)	28.9 ± 21.3 (0 – 124.1)	36.8 ± 22.1 (-4.9 – 91.1)	0.075

Data are given as mean ± SD (range).

A significant difference in the proportion of patients who have reached good or excellent weight loss results (i.e. %IEBMIL ≥50 %; Reinhold's criterion) was found in favour of the MiniMizer Extra group (**29.6 % vs. 8.2 %, *p*=0.006**).

Resolution of co-morbidities. Changes in the frequency of co-morbidities are shown in figure 10. The most radical changes are noted in the frequency of gastric disorders (heartburn and gastroesophageal reflux) and type II diabetes mellitus – 85 % of them improved or resolved. Significant changes are also stated in the frequency of arterial hypertension, spinal and knee pain, sleep apnoea, depression and elephantiasis – about a half of these co-morbidities improved or resolved. No significant differences were found between groups.

Figure 10. Changes in frequency of co-morbidities after 1 year (total width of the columns indicates initial frequency of co-morbidities)



Frequency of metabolic syndrome decreased from 77.5 % to 57.8 %. The decrease in the frequency of separate metabolic syndrome diagnostic factors is shown in figure 11 and the decrease in the number of positive diagnostic factors in metabolic syndrome patients is shown in figure 12. No significant differences were found between groups.

Figure 11. Decrease in the frequency of separate metabolic syndrome diagnostic factors.

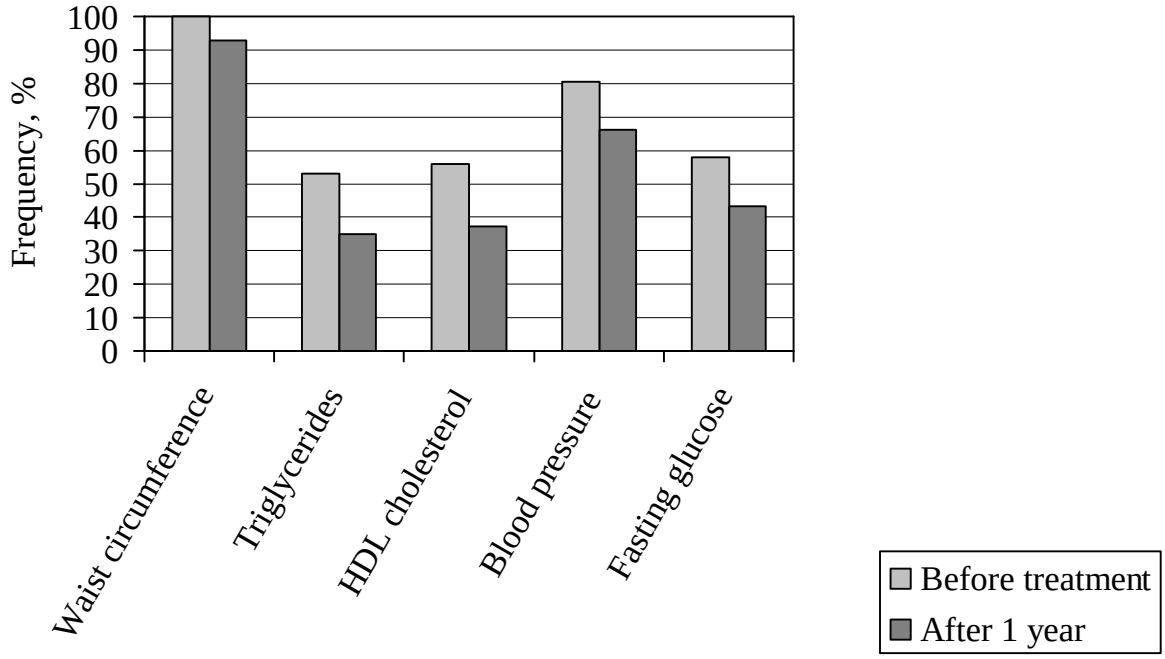
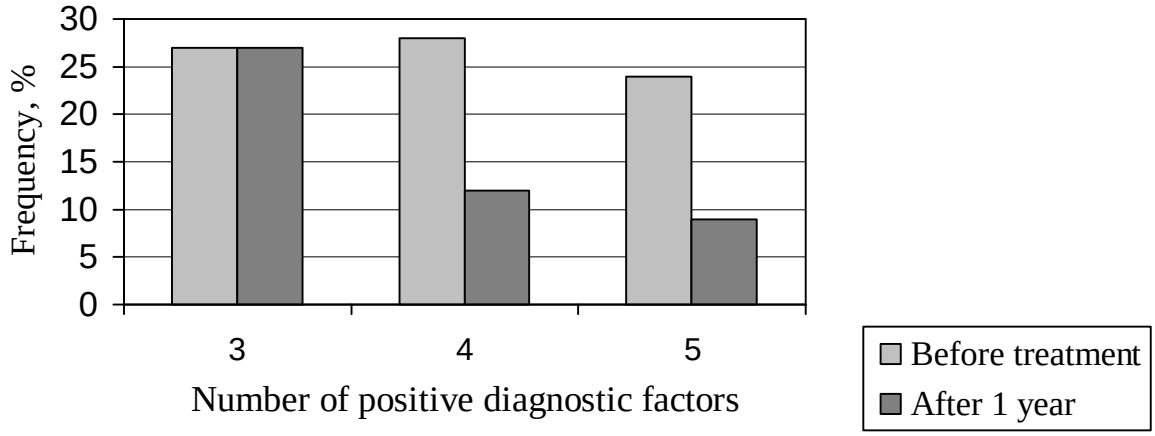
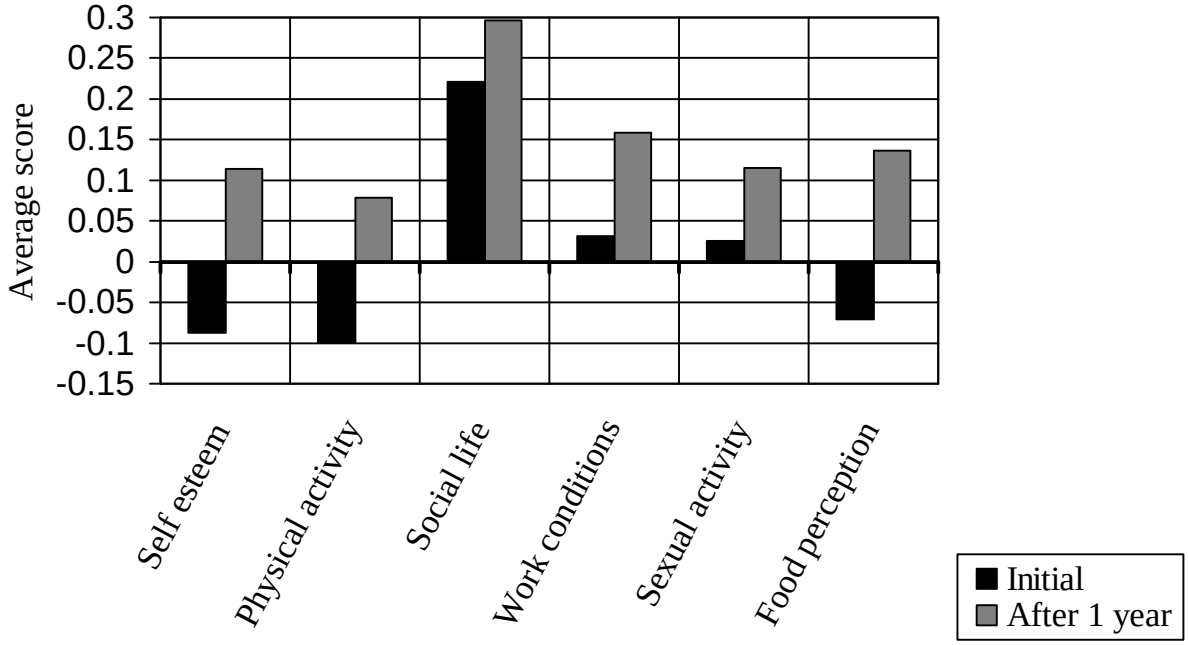


Figure 12. Decrease in the number of positive diagnostic factors in metabolic syndrome patients.



Changes in QoL. The QoL improved from 0.02 ± 1.2 (range -3 – 2.7) to 0.894 ± 1.1 (range -2 – 3) points and though this is a significant improvement (p<0.01), QoL is still stated as *fair* by M-A QoLQII. Changes in different aspects of QoL are shown in figure 13. No significant differences were found between groups.

Figure 13. Changes in general self esteem, activity levels and food perception by M-A QoLQII



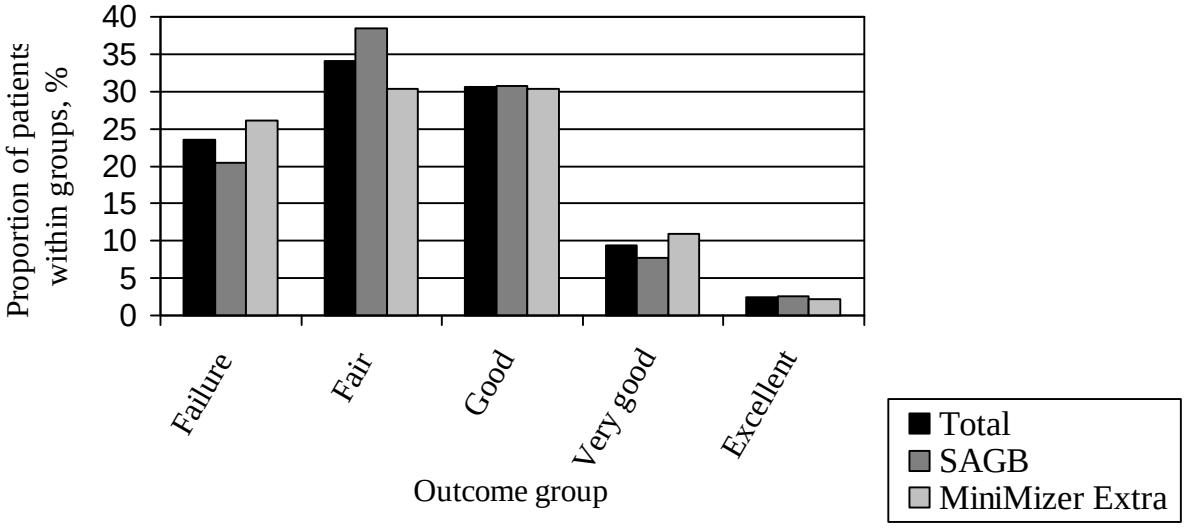
Complications. Oesophageal dilatation caused by over inflation of the AGB was diagnosed by upper gastrointestinal tract radiography in one case in MiniMizer Extra group. The AGB was deflated for a period of two months and oesophageal motility restored. One leakage was diagnosed from the ruptured connecting tube near subcutaneous injection port in MiniMizer Extra. The port was reconnected. Five cases (9.3 %) of AGB penetration were diagnosed endoscopically in MiniMizer Extra group and no penetrations in SAGB group (p=0.069). Four of these penetrations were asymptomatic. One of the penetrated AGBs was removed laparoscopically, while other four patients were left under observation. As it was mentioned above, one death was registered in SAGB group not associated with LAGB. No other complications were registered. All complications are summarized in table VI.

Table VI. Complications.

Complications			All patients	Comparative groups		*p*
				SAGB	MiniMizer Extra	
AGB related	Intraoperative		0	0	0	-
	Early	Minor	3 (2.9%)	0	3 (5.6%) (transient postoperative gastric stenoses)	0.244
		Major	0	0	0	-
	Late	Minor	2 (1.9%)	0	2 (3.7%) (Oesophageal dilatation caused by over inflation of the AGB and leakage from the ruptured connecting tube)	0.496
		Major	5 (4.9%)	0	5 (9.3%) (AGB penetrations)	0.069
	Reoperations		2 (1.9%)	0	2 (3.7%) (reconnection of ruptured connecting tube and removal of penetrated AGB)	0.496
AGB unrelated	Intraoperative		5 (4.9%) (gastric lesion, bleeding from gastric vessel, two hepatic lesions, loss of the needle)			
	Early		0			
	Late		1 (1%) (acute myocardial infarction)			
Deaths			1 (1%) (due to acute myocardial infarction)			

Evaluation by BAROS. The average BAROS score was 2.5 ± 2.1 in SAGB group and 2.6 ± 2 in MiniMizer Extra group (p=0.811). The distribution of patients in BAROS outcome groups is shown in figure 14. No significant differences were found between groups.

Figure 14. The distribution of patients in BAROS outcome groups.



Outcome predictors. In the searching process for possible outcome predictors we evaluated correlation of %IEBMIL with multiple preoperative data: AGB type, gender, age, height, IBW, IEBW, IFM, BMI, FMI, education, dwelling place, working capacity, nature of work, obesity duration and possible obesity cause, co-morbidities and their number, waist, hips and upper arm circumference, waist to hip ratio, lean body mass, muscle mass and various blood test findings. Regression models were constructed from factors strongly correlating with %IEBMIL and noncorrelating with each other.

- Predictors of LAGB outcomes with any AGB used:

%IEBMIL depends on IBMI and uric acid content in the blood (R^2 = 0.265). Final regression model:

%IEBMIL = 114.287 – 1.414 × BMI – 0.035 × uric acid.

- Predictors of LAGB outcomes when SAGB is used:

%IEBMIL depends on IBMI, uric acid content in the blood and age (R^2 = 0,327). Final regression model:

%IEBMIL = 114.451 – 0.804 × BMI – 0.532 × age – 0.033 × uric acid.

- Predictors of LAGB outcomes when MiniMizer Extra is used:

%IEBMIL depends on IBMI (R^2 = 0,309). Final regression model:

%IEBMIL = 122.858 – 1.847 × BMI.

According to the strongest predictors of %IEBMIL we aimed to decide which of the AGBs suit better for a certain patient. We found that patients at the age ≥ 40 years and patients with initial BMI ≤ 47 kg/m^2 achieved better results using MiniMizer Extra AGB (table VII).

Table VII. Influence of BMI and age on %IEBMIL.

		%IEBMIL, %		*p*
		SAGB	MiniMizer Extra	
BMI	≤ 47 kg/m^2	**33.6 ± 24%** (N = 22)	**46.4 ± 20%** (N = 27)	**0.048**
	> 47 kg/m^2	24.5 ± 17.9% (N = 24)	26.5 ± 19.8% (N = 25)	0.716
Age	< 40 years	43.8 ± 38.8% (N = 12)	35.7 ± 24.7% (N = 20)	0.419
	≥ 40 years	**23.6 ± 13.8%** (N = 34)	**37.5 ± 20.8%** (N = 32)	**0.002**

CONCLUSIONS

1. LAGB is effective and safe bariatric procedure: the average %IEBMIL was 33.1 ± 21.9%; 34.1% of patients achieved fair, 30.6% - good, 9.4% - very good and 2.4% - excellent results according to BAROS; only 5 (4.9%) major complications were diagnosed.
2. No radical differences were stated between the efficiency and complication rate of the compared AGBs: the average %IEBMIL in SAGB and MiniMizer Extra groups was 28.9 ± 21.3% and 36.8 ± 22.1% respectively, p=0.075; major complication rate was 0 (0%) and 5 (9.3%) respectively, p=0.069. A significant difference in the proportion of patients who have reached %IEBMIL ≥50 % (Reinhold's criterion) was found in favour of the MiniMizer Extra group (29.6 % vs. 8.2 %, p=0.006).
3. Patients at the age ≥ 40 years achieved better results using MiniMizer Extra AGB - the average %IEBMIL was 37.5 ± 20.8% versus 23.6 ± 13.8% in SAGB group, p=0.002.
4. Patients with IBMI ≤ 47 kg/m^2 achieved better results using MiniMizer Extra AGB - the average %IEBMIL was 46.4 ± 20% versus 33.6 ± 24% in SAGB group, p=0.048.

RECOMMENDATIONS

1. One year results suggest that MiniMizer Extra AGB should be preferred for LAGB for patients at the age ≥ 40 years and for patients with IBMI ≤ 47 kg/m^2.
2. Longer follow up of ≥ 5 years is mandatory for validation of IBMI and age as reliable outcome predictors and for search of other possible predictors.

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1. Abalikšta T, Brimas G, Kuliavas J, Strupas K. Skrandį apjuosiančių reguliuojamų juostų palyginimas: sisteminė literatūros apžvalga *(Comparison of the AGBs: Systematic Review).* Medicinos teorija ir praktika 2011; 17(3): 332-344.
2. Abalikšta T, Brimas G, Strupas K. Laparoscopic Adjustable Gastric Banding A Prospective Randomized Study Comparing the SAGB and the MiniMizer Extra: one year results. Accepted for publication in Videosurgery and Other Miniinvasive Techniques.

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PUBLICATIONS	
1. Abalikšta T, Brimas G, Strupas K. Laparoscopic Adjustable Gastric Banding A Prospective Randomized Study Comparing the SAGB and the MiniMizer Extra: one year results. Accepted in Videosurgery and Other Miniinvasive Techniques.	
2. Abalikšta T, Brimas G, Kuliavas J, Strupas K. Skrandį apjuosiančių reguliuojamų juostų palyginimas: sisteminė literatūros apžvalga *(Comparison of the Adjustable Gastric Bands: Systematic Review)*. Medicinos teorija ir praktika 2011; 17(3): 332-344.	

3. Abalikšta T, Gaidamonis E, Stanaitis J, Lunevičius R. Blužnies sužalojimai dėl uždaros pilvo traumos *(Blunt Splenic Injury)*. Lietuvos chirurgija 2007; 5(2): 152–160.

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1. Abalikšta T, Brimas G, Strupas K. Metabolic Syndrome after Laparoscopic Adjustable Gastric Banding: one year results. 16th World Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders. August 31 – September 3, 2011, Hamburg, Germany.
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5. Abalikšta T, Brimas G, Brimienė V, Lipnickas V, Strupas K. Laparoscopic Adjustable Gastric Banding in Vilnius University Hospital „Santariškių klinikos“. The 6th Meeting of the Baltic Association of Surgeons. 24-26 May, 2009, Druskininkai, Lithuania.
6. Abalikšta T, Gaidamonis E, Stanaitis J, Lunevičius R. Blužnies sužalojimai dėl uždaros pilvo traumos *(Blunt Splenic Injury).* Meeting of Lithuanian Association of Surgeons. 1 June, 2007, Vilnius, Lithuania.
7. Abalikšta T, Stanaitis J, Stašinskas A, Verbickas G. 11 metų patirtis gydant perforacinį apendicitą Vilniaus greitosios pagalbos universitetinėje ligoninėje *(The Treatment of Perforated Appendicitis in Vilnius University Emergency Hospital: 11 Year Experience)*. The 5th Meeting of the Lithuanian Minimally Invasive Surgery Association. 26–27 March, 2004, Šiauliai, Lithuania.

SANTRAUKA

Darbo tikslas

Įvertinti skrandį apjuosiančių reguliuojamų juostų (SARJ) skirtumų įtaką gydymo rezultatams bei nustatyti priešoperacinius gydymo išeičių rodiklius.

Darbo uždaviniai

1. Įvertinti laparoskopinės skrandžio apjuosimo erguliuojama juosta oeracijos (SARJO) gydymo rezultatus ir komplikacijų skaičių;
2. Palyginti nutukimo chirurginio gydymo rezultatus, naudojant skirtingas SARJ;
3. Įvertinti įvairių priešoperacinių duomenų įtaką gydymo rezultatams ir nustatyti priešoperacinius prognostinius gydymo išeičių rodiklius.

Darbo naujumas

Pasaulyje tėra pavieniai tyrimai, lyginantys skirtingas SARJ ir labai trūksta atsitiktinės atrankos tyrimų. Kol kas nėra nustatyti pacientų atrankos SARJO-ai kriterijai (yra tik bendri kriterija nutukimo chirurginiam gydymui), visiškai netyrinėti faktoriai, leidžiantys pasirinkti vieną ar kitą SARJ. Lietuvoje nutukimo chirurginio gydymo istorija yra labai trumpa. Yra tik pavienės publikacijos apie šio gydymo rezultatus. Lietuvoje ir Baltijos šalyse pirmą kartą atsitiktinės atrankos būdu lyginama skirtingų SARJ įtaka gydymo rezultatams bei komplikacijų skaičiui.

Ginamieji disertacijos teiginiai

1. SARJO yra efektyvus ir saugus nutukimo gydymo būdas;
2. Esminių skirtumų tarp lygintų SARJ efektyvumo ir komplikacijų skaičiaus po vienerių metų po operacijos nėra;
3. 40 metų ir vyresni pacientai geresnių rezultatų pasiekia naudojant MiniMizer Extra juostą.
4. Pacientai, kurių pradinis KMI $\leq$ 47 kg/m^2, geresnių rezultatų pasiekia naudojant MiniMizer Extra juostą.

Tyrimo metodika

Disertacija – perspektyvusis atviras atsitiktinės atrankos imčių palyginamasis biomedicininis tyrimas, lyginantis nutukimo chirurginio gydymo rezultatus naudojant skirtingas SARJ. Tyrimo atlikimui 2008.11.06 gautas Lietuvos bioetikos komiteto leidimas Nr. 62. Tyrimo pradžia – 2009.01.01. Visi tyrimo dalyviai pasirašė asmens sutikimo formoje. Į tyrimą įtraukti patologiniu nutukimu (KMI $\geq$ 40 kg/m^2 kai nėra gretutinių ligų arba KMI $\geq$ 35 kg/m^2 kai yra gretutinių ligų) sergantys ne jaunesni nei 18 ir ne vyresni nei 70 metų pacientai. Atmetimo kriterijai: kontraindikacijos laparoskopinei operacijai, nėštumas, anksčiau darytos kitos nutukimo gydymo operacijos ar paciento atsisakymas dalyvauti tyrime.

Visus pacientus prieš operaciją ir praėjus 1 metams nuodugniai ištyrė multidisciplininė gydytojų tyrėjų komanda: endokrinologas, gastroenterologas, kardiologas, chirurgas ir dietologas.

Visi tyrime dalyvaujantys pacientai buvo gydomi chirurginiu būdu pagal VšĮ VUL „Santariškių klinikos“ priimtą metodiką („Skrandžio apjuosimo reguliuojama juosta operacija“, M 173 – 2007) naudojant skirtingas SARJ:

- SAGB, Obtech Medical, Šveicarija.
- MiniMizer Extra, Bariatric Solutions GmbH, Šveicarija.

Visas operacijas atliko vienas chirurgas, turintis daugiau nei 400 SARJO patirtį.

Vertinant rezultatus ir lyginant skirtingas SARJ, pirminiu gydymo tikslu laikytas procentinis perteklinio kūno masės indekso sumažėjimas (%PKMIS). Antriniai tikslai – pacientų, pasiekusių %PKMIS $\geq$ 50%, skaičius („Reinhold” kriterijus), gretutinių ligų ir gyvenimo kokybės pokyčiai, ankstyvųjų ir vėlyvųjų komplikacijų bei pakartotinių operacijų skaičius. Pacientai, kuriems dėl komplikacijų ar kitų priežasčių per pirmus metus teko pašalinti SARJ, neįtraukti į kūno masės mažėjimo, tačiau jie įtraukti į pacientų, pasiekusių %PKMIS $\geq$ 50%, analizę. Galutinis gydymo rezultatų vertinimas atliktas naudojantis BAROS sistema, tačiau vertintos tik keturios gretutinės ligos (arterinė hipertenzija, širdies ir kraujagyslių ligos, dislipidemija ir 2 tipo CD) iš BAROS didžiųjų gretutinių ligų sąrašo (neįtraukėme obstrukcinės miego apnėjos, osteoartrito ir nevaisingumo vertinimo, nes neturėjome galimybės atlikti BAROS rekomenduojamų tyrimų šioms ligoms diagnozuoti: miego studijos, rentgenologinio stuburo ir sąnarių tyrimo bei nevaisingumo/hormoninių tyrimų).

Statistinė analizė atlikta statistikos programų paketu SPSS Statistics 17.0 (*angl.* Statistical package for Social sciences). Aprašant grupes pateiktos kategorinių kintamųjų absoliučios ir procentinės vertės, o intervalinių kintamųjų - vidurkiai ir standartiniai nuokrypiai, prieš tai Kolmogorov-Smirnov testu patvirtinus normalųjį kintamųjų pasiskirstymą. Intervalinių kintamųjų su normaliu skirstiniu skirtumo tarp dviejų nepriklausomų imčių įvertinimui naudotas Student *t* testas, o tarp priklausomų imčių – poruotų duomenų Student *t* testas. Intervalinių kintamųjų su nenormaliu skirstiniu skirtumo tarp dviejų imčių įvertinimui naudotas Mann – Whitney U testas. Kategorinių kintamųjų skirtumo tarp dviejų imčių įvertinimui naudotas Chi kvadrato testas arba Fisher tikslusis testas. Skirtumas tarp dviejų imčių laikytas statistiškai reikšmingu, kai $p < 0,05$. Ryšiams tarp kintamųjų nustatyti apskaičiuotas Spearman koreliacijos koeficientas. Koreliuojančių faktorių įtakai įvertinti naudota tiesinė regresija.

Tyrimo rezultatai

Nuo 2009 sausio 1 iki 2010 sausio 31 į biomedicininį tyrimą įtraukti 103 pacientai - 69 (67%) moterys ir 34 (33%) vyrai. Vidutinis pacientų amžius buvo 46,1 ± 11,5 metai, vidutinė KM buvo 141,9 ± 24,2 kg. SAGB juosta naudota 49 pacientams, MiniMizer Extra - 54 pacientams. Visi pacientai turėjo dar iki tyrimo nustatytų gretutinių ligų. Vidutiniškai vienam pacientui teko 5,2 ± 2,2 (1 – 11) gretutinės ligos. 37 (35,9%) pacientas sirgo 2 tipo CD, 44 (43,2%) pacientus vargino rėmuo, 17 (16,8%) pacientų buvo rentgenologiškai diagnozuotas gastroezofaginis refliuksas, 82 (79,6%) arterinė hipertenzija, 29 (28,2%) kvėpavimo sistemos ligos, 28 (27,2%) miego apnėja, 21 (20,4%) širdies ligos, 19 (18,4%) lytinės sistemos ligos, 28 (27%) tulžies pūslės akmenligė, 71 (68,9%) sąnarių skausmai, 80 (77,7%) nugaros skausmai, 34 (33%) kojų venų varikozės, 6 (5,8%) dramblialigė, 11 (10,7%) psoriazė, 24 (23,3%) skydliaukės ligos, 9 (8,7%) urologinės ligos, 13 (12,6%) depresijos atvejų ir 6 (5,8%) pilvo sienos išvaržos. Metabolinis sindromas buvo nustatytas 79 (77,5 %) pacientams. Pacientų gyvenimo kokybė pagal antrąjį Moorehead – Ardelt gyvenimo kokybės klausimyną (M-AQoLQII) buvo 0,02 ± 1,2 balai. Statistiškai reikšmingo skirtumo pagal įvairius priešoperacinius duomenis tarp grupių nenustatyta.

Vidutinė visos operacijos trukmė buvo 64,6 ± 18,7 minutės, statistiškai reikšmingo skirtumo tarp grupių nenustatyta. Pneumoperitoneumo trukmė MiniMizer

Extra grupėje buvo 9 minutėmis trumpesnė nei SAGB grupėje (p = 0,016). Injekcinio poodžio rezervuaro implantavimo laikas buvo trumpesnis SAGB grupėje (11,4 prieš 14,4 minutes, p < 0,001).

Statistiškai reikšmingo skirtumo pagal pooperacinio skausmo ir pykinimo intensyvumą bei kitų nemalonių pojūčių dažnį pirmąją ir antrąją pooperacinę parą tarp palyginamųjų grupių nebuvo.

Trims ligoniams MiniMizer Extra grupėje diagnozuota pooperacinė tranzitorinė skrandžio okliuzija, savaime praėjusi per pirmąją pooperacinę savaitę. Nenustatyta jokių kitų ankstyvųjų komplikacijų ar ankstyvųjų pooperacinių mirčių atvejų.

Vidutinis %PKMIS buvo 33,1 ± 21,9%, statistiškai reikšmingo skirtumo tarp palyginamųjų grupių nenustatyta. Vertinant pagal „Reinhold" kriterijų (t.y. pacientų, pasiekusių %PKMIS ≥ 50%, dalis, procentais) nustatytas statistiškai reikšmingas skirtumas tarp grupių: 29,6% MiniMizer Extra grupėje ir 8,2% SAGB grupėje (p = 0,006).

Praėjus metams po SARJO ryškiausiai pakito gastroezofaginio refliukso, rėmens ir 2 tipo CD dažnis – apie 85% šių ligų išnyko arba pagerėjo. Ženkliai pakito ir arterinės hipertenzijos, nugaros bei sąnarių skausmų, miego apnėjos, depresijos bei dramblialigės eiga – beveik pusė šių gretutinių ligų išnyko arba pagerėjo. Metabolinio sindromo dažnis sumažėjo nuo 77,5% iki 57,8%. Statistiškai reikšmingo gretutinių ligų eigos skirtumo tarp palyginamųjų grupių nenustatyta.

Gyvenimo kokybė pagerėjo nuo 0,02 ± 1,2 (-3 – 2,7) balų iki 0,894 ± 1,1 (-2 – 3) balų pagal M-AQoLQII. Tačiau nors šis pagerėjimas ir statistiškai reikšmingas (p < 0,01), gyvenimo kokybė, kaip ir prieš operaciją, išlieka patenkinama. Gyvenimo kokybės pokyčių skirtumo tarp grupių nenustatyta.

MiniMizer Extra grupėje diagnozuotas vienas stemplės išsiplėtimas dėl perpildytos ir per daug užveržtos SARJ, vienas jungiančiojo vamzdelio nesandarumas šalia injekcinio poodžio rezervuaro ir penki (9,3%) SARJ penetracijos į skrandį atvejai. Statistiškai reikšmingo komplikacijų skaičiaus skirtumo tarp palyginamųjų grupių nenustatyta. Užregistruotas vienas mirties atvejis SAGB grupėje, mirties priežastis nesusijusi su SARJO (ūminis miokardo infarktas).

Vidutinis BAROS balas buvo 2,5 ± 2,1 SAGB grupėje ir 2,6 ± 2 MiniMizer Extra grupėje (p = 0,811).

Pacientams, kurių KMI ≤ 47 kg/m^2, naudojant MiniMizer Extra juostą %PKMIS buvo 46,4 ± 20%, o naudojant SAGB juostą %PKMIS buvo 33,6 ± 24% (p = 0,048). Pacientams, kurių KMI > 47 kg/m^2, %PKMIS naudojant skirtingas SARJ nesiskyrė.

40 metų ir vyresniems pacientams naudojant MiniMizer Extra juostą %PKMIS buvo 37,5 ± 20,8%, o naudojant SAGB juostą %PKMIS buvo 23,6 ± 13,8% (p = 0,002). Jaunesniems pacientams %PKMIS naudojant skirtingas SARJ nesiskyrė.

Darbo tąsos kryptys

1) Planuojama periodiškai (po 3, 5 ir 10 metų) sekti tyrime dalyvaujančius pacientus;
2) Ypač svarbu įvertinti gydymo rezultatus bei komplikacijų skaičių po 5 metų;
3) Vertinant vėlesnius rezultatus, ieškoti naujų prognostinių gydymo efektyvumo rodiklių ir patikrinti jau nustatytų rodiklių patikimumą.

Išvados

1) SARJO yra efektyvus ir saugus nutukimo gydymo būdas: jau po 1 metų vidutinis %PKMIS = 33,1 ± 21,9%, vertinant pagal BAROS 34.1% pacientų pasiekė patenkinamą, 30,6% - gerą, 9,4% – labai gerą ir 2,4% – puikų gydymo rezultatą; per pirmus metus pasitaikė 5 (4,9%) „didžiosios" komplikacijos;
2) Esminių skirtumų tarp lygintų SARJ efektyvumo ir komplikacijų skaičiaus po vienerių metų po operacijos nėra: vidutinis %PKMIS SAGB ir MiniMizer Extra grupėse buvo atitinkamai 28,9 ± 21,3% ir 36,8 ± 22.1%, p=0.075, o „didžiųjų" komplikacijų skaičius atitinkamai 0 (0%) ir 5 (9.3%), p=0.069; tačiau vertinat pagal „Reinhold" kriterijų efektyvesnė buvo MiniMizer Extra juosta (29.6 % prieš 8.2 %, p=0.006);
3) 40 metų ir vyresni pacientai geresnių %PKMIS rezultatų pasiekia naudojant MiniMizer Extra juostą (37,5 ± 20,8% prieš 23,6 ± 13,8 %, p=0.002)
4) Pacientai, kurių pradinis KMI ≤ 47 kg/m^2, geresnių %PKMIS rezultatų pasiekia naudojant MiniMizer Extra juostą (46,4 ± 20% prieš 33,6 ± 24%, p=0,048) .

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