ΜΕΤΑΠΤΥΧΙΑΚΟ ΠΡΟΓΡΑΜΜΑ ΣΠΟΥΔΩΝ: "ΕΛΑΧΙΣΤΑ ΕΠΕΜΒΑΤΙΚΗ ΧΕΙΡΟΥΡΓΙΚΗ, ΡΟΜΠΟΤΙΚΗ ΧΕΙΡΟΥΡΓΙΚΗ ΚΑΙ ΤΗΛΕΧΕΙΡΟΥΡΓΙΚΗ"

ΕΘΝΙΚΟ ΚΑΙ ΚΑΠΟΔΙΣΤΡΙΑΚΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΑΘΗΝΩΝ ΙΑΤΡΙΚΗ ΣΧΟΛΗ

ΔΙΠΛΩΜΑΤΙΚΗ ΕΡΓΑΣΙΑ

OEMA:

Laparoscopic Sleeve Gastrectomy: Complications and Short-Term Results.

ΜΕΤΑΠΤΥΧΙΑΚΗ ΦΟΙΤΗΤΡΙΑ: ΚΡΙΒΑΝ ΣΥΛΒΙΑ ΑΜ: 2009613

ΑΘΗΝΑ, ΙΑΝΟΥΑΡΙΟΣ 2013

ΠΡΑΚΤΙΚΟ ΚΡΙΣΕΩΣ

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Η Επιτροπή διαπίστωσε ότι η Διπλωματική Εργασία της κας Κριβάν Σύλβιας με τίτλο: «Laparoscopic Sleeve Gastrectomy: Complications and Short-Term Results».

είναι πρωτότυπη, επιστημονικά και τεχνικά άρτια και η βιβλιογραφική πληροφορία ολοκληρωμένη και εμπεριστατωμένη.

Η εξεταστική επιτροπή αφού έλαβε υπ' όψιν το περιεχόμενο της εργασίας και τη συμβολή της στην επιστήμη, με ψήφους προτείνει την απονομή του Μεταπτυχιακού Διπλώματος Ειδίκευσης (Master's Degree), στον παραπάνω Μεταπτυχιακό Φοιτητή.

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Dedications

To Miranda for all the influence... To Mrs. Lambrini Konstantou for insisting till the bitter end...

Acknowledgments

I would like to thank doctor Georgios Spiliopoulos for letting me assist and participate in his practice and for sharing his knowledge and experience in bariatric surgery with me. This study was based on data retrieved by his personal files.

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Introduction

Obesity is a medical condition. It needs to be diagnosed and treated accordingly. It has currently reached epidemic proportions worldwide. There are more than 600 million overweight adults, of which at least 400 million are clinically obese. Morbid obesity is associated with increased morbidity and mortality. (1)

Bariatric surgery is a promising solution offering morbidly obese individuals weight loss and reduction in obesity-related comorbidities when other conservative treatments have failed. The guideline highlights a strong consensus among surgeons, internists, and psychotherapists to the effect that surgery is now an established component of a multimodal treatment concept. Surgery is indicated only if conservative treatment has no prospect of helping the patient or has already been exhausted. In surgical treatment of obesity there are three main categories according to their main mechanism of action described: restrictive (e.g. Laparoscopic adjustable gastric banding (LAGB), vertical banded gastroplasty, laparoscopic sleeve gastrectomy (LSG)); malabsorptive (e.g. Biliopancreatic diversion and duodenal switch (BPD-DS)); and a combination of both (e.g. laparoscopic Roux-en-Y gastric bypass (LRYGBP)). (2)

There are a numerous health consequences attributed to obesity such as physical, psychological, and social consequences. After bariatric surgery, patients have shown an improvement or a complete resolution of their comorbidities. Bariatric surgery reduces the risk of death, hospital admission, and long term cost to the health service. A systematic review has concluded that surgery is superior to conventional treatment in reducing weight. (3)

LSG involves subtotal gastric resection of the body and fundus in order to create a long, tubular gastric conduit along the lesser curve of the stomach. It was originally described by Marceau et al in 1993 (4) as the restrictive part of a duodenal switch malabsorptive operation, aiming to improve the results of biliopancreatic diversion without performing a distal gastrectomy. This procedure is efficient due to restriction and reduction of ghrelin by removing the orexigenic cells and accelerating gastric emptying (5,6). LSG has been proposed as the first step in the treatment of extremely obese patients or in patients with high operative risk, before performing more complicated procedures such as laparoscopic BPDDS or LRYGBP (7,8,9). Recently, it has been stated that LSG may be a potential 'stand-alone' procedure for morbid obesity, mainly because of its promising early results (10,11). The authors present a sample of obese patients that underwent LSG since 2005. We describe our surgical technique, complications as well as early and long term postoperative results. By discussing and stating these statistics we wished to evaluate whether this method proved to be efficacious and with few complications. Therefore, if the complications rate proved to be higher than acceptable, the technical success of the procedure could be assessed and special circumstances that could have contributed to such outcome discussed and taken into consideration.

1. Patients and methods

1.1 Data collection

The survey refers to a 4 year period (September 2005 - May 2009) of laparoscopic sleeve gastrectomy operations performed by a single surgeon in a private hospital (Bariatric Surgery Center of Excellence). Patients included in this study were only those who matched the predefined selection and exclusion criteria (Table 1, 2). Patient data were retrieved from their medical records and retrospectively reviewed.

1.2 Inclusion criteria

All patients who underwent laparoscopic sleeve gastrectomy in the time period we are referring to were considered eligible to enter this study. Completion of an at least 6 month to 1 year follow – up schedule after surgery was also mandatory.

Table 1.	Selection	Criteria	for	Bariatric	Surgery
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Selection criteria
Able to adhere to postoperative care (e.g., follow-up visits and tests, medical
management, use of dietary supplements)
BMI \ge 40 kg per m ²
BMI \ge 35 kg per m ² with obesity-related comorbidity
Previous failed nonsurgical attempts at weight reduction, including nonprofes-
sional programs

1.3 Exclusion criteria

In case of inadequate data an effort of telephone contact or a personal interview was made. Patients who did not answer back were excluded from the study.

Table 2. H	Exclusion	Criteria	for	Bariatric	Surgery
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Exclusion criteria		
Cardiopulmonary disease that would make the risk prohibitive		
Current drug or alcohol abuse		
Lack of comprehension of risks, benefits, expected outcomes, alternatives, and required lifestyle changes		
Reversible endocrine or other disorders that could have caused obesity		
Uncontrolled severe psychiatric illness		

1.4 Patient data and characteristics

A total of 178 patients were included in this study. Characteristics such as gender, age and weight in the form of BMI were monitored. Refering to gender, 73 were male and 105 female. They all underwent a laparoscopic sleeve gastrectomy performed by a single surgeon and with the same surgical technique.

1.5 Surgical technique

LSG involves a longitudinal resection of the stomach on the greater curvature from the antrum up to the angle of His, starting opposite of the nerve of Latarjet. The first step of the procedure is the division of the vascular supply of the greater curvature of the stomach, by disecting the gastro-colic and gastro-splenic ligaments. The greater curvature is completely exposed up to the left crus of the diaphragm in order to resect the gastric fundus completely. Next we procede with the longitudinal gastrectomy that "sleeves" the stomach to reduce it to a narrow tube. (Picture 1) A rhinogastric tube is used to obtain a precise calibration and to avoid stenosis of the gastric plasty. The staple line can then be reinforced with sutures and has been in a number of cases, even in our patients, to reduce the rate of staple line leak or bleeding (12). Possible leaks are identified intraoperatively using the saline submersion test. The stomach specimen is extracted through an extended left upper quadrant trocar site. (3, 13, 14)



Picture 1. Surgical technique of sleeve gastrectomy: Longitudinal gastrectomy that "sleeves" the stomach to reduce it to a narrow tube.

1.6 Follow- up

Patients remained in the postanesthesia care unit (PACU) for a few hours and then were transferred to the surgery ward. On postoperative day 1 liquid diet was initiated, approximately 100ml of fluids, after perfoming a blue de methylene test. Patients were discharged when mobilized, not in pain and able to eat liquid diet. (14) All participating subjects were reexamined at 1, 6 and 12 months and every following year. The initial goal was a loss in weight of at least 3 kg per month and achieving ideal BMI by third year. Postoperative treatment by a psychologist, a physician specializing in psychosomatic medicine, or a psychiatrist was strongly recommended for patients who had a food obsession before surgery, and for those who developed eating attacks afterward. If mental illness was diagnosed after surgery, the patient was reffered to specialized treatment. Participation in self-help groups was also recommended, as it allegedly reinforces weight loss. (15)

1.7 Statistical Analyses

Comparison of qualitative variables was performed by Chi- square test and of quantitative variables by Student's t-test. For quantitative correlations ANOVA (Ana-

lysis of Variances) was performed. We used the STATA statistical software, SE 8.2. A p-value less than 0.05 was considered significant.

Initial outcome measures for this trial was mean total weight loss (TWL) over time. Weight loss was also expressed as the percentage of excess weight loss (%EWL), percentage of excess of body mass index (BMI) loss (%EBMIL), and percentage of the initial body weight loss (%BWL) over time. The percentage of EWL was calculated as the ratio between excess weight over the ideal body weight (IBW) and postoperative TWL. BMI was estimated as the ratio between weight and height squared. The IBW was obtained according to the published medium size data from the Metropolitan Life Tables. Last but not least outcome measures included mean operative time, length of hospital stay (LOS), hospital readmissions, reoperation rates, minor and major morbidity, and mortality. Minor morbidity was defined as that one not requiring readmission to hospital. Major morbidity was defined as the one requiring any reoperation or other invasive or endoscopic intervention or extensive hospital resource utilization.

Tables

	No. of patients (%)					
Total	At 1 mth	At 6 mths	At 1y	At 2 yrs	At 3 yrs	
sample						
178	170(95.5%)	158(88.8%)	140(78.6%)	122(68.5%)	98(55%)	

Table A. Number of patients for each year of follow-up

Table B. Patients' characteristics

	No.	%
Female/male	105/73	58.9%/41.1%
Average age (years)	39.4	22.00%
Average BMI	45.6	25.60%
(kg/m2)		

Table C. Percentage of excess weight loss

		%1	EWL		
Total	At 1 mth	At 6 mths	At 1 yr	At 2 yrs	At 3 yrs
178	21.85%	47.45%	60.53%	68.27%	75.47%

Table D. Complications

Minor	No. of patients (%)	Major	No. of patients (%)
nausea	5(2,8%)	leakage	4(2,24%)
gastroesopha-	2(1,12%)	Fluid collection	1(0,56%)
geal reflux			
cholelithiasis	8(4,5%)	dehydration	1(0,56%)
ventral hernia	1(0,56%)	abscess	3(1,68%)
wound infection	3(1,68%)	hemorrhage	2(1,12%)
		Re-operation	10(5,6%)
		Pulmonary	1(0,56%)
		embolism	
		death	3(1,68%)

LSG	laparoscopic sleeve gastrectomy
LAGB	laparoscopic adjustable gastric banding
BPD-DS	biliopancreatic diversion and duodenal
	switch
LRYGBP	laparoscopic Roux-en-Y gastric bypass
BMI	body mass index
%BMI	percentage of body mass index
PACU	postanesthesia care unit
TWL	total weight loss
EWL	excess weight loss
%EWL	percentage of excess weight loss
EBMIL	excess of body mass index loss
%EBMIL	percentage of excess of body mass index
	loss
BWL	initial body weight loss
%BWL	percentage of the initial body weight loss
IBW	ideal body weight
LOS	length of hospital stay
ICU	intensive care unit

2. Results

All 178 cases were completed laparoscopically with an average operative time of 72 minutes (range, 52–180). No iatrogenic injuries occurred in this series of patients. No surgical bleeding occurred within the peritoneal cavity. No clinical leaks were identified intraoperatively using the saline submersion test.

2.1 Weight loss

The average excess weight loss percentage were 21.85% (range, 6.6 to 42) and 47.45% (range, 22 to 67) at 1 and 6 months respectively and 60.53%, 68.27% and 75.47% at 1, 2 and 3 year follow up respectively. Average BMI at 1 and 6 months, 1, 2 and 3 years was 41.2, 36.3, 32.4, 27.3 and 26.2 respectively. This corresponded to a resolution of morbid obesity (BMI<35kg/m2) in 42% of patients by 6 months. In all patients the weight loss progressed over the first year excessively and continued on a lower pace during the second and third year.

2.2 Complications

Complications recorded during the follow-up, are illustrated on table D. The overall complication rate was 11% with 3 mortalities in our 178 patients.

Minor complications included nausea with intermittent vomiting that occurred in 5 patients. All 5 patients had a normal gastroscopy. Three of them were later diagnosed with cholelithiasis. The other two had a preoperative history of gastroesophageal reflux. Eight patients developed symptomatic cholelithiasis. All 8 patients underwent successful laparoscopic cholecystectomy. Three patients developed superficial wound infection. These patients were treated with oral antibiotics. One patient developed recurrence of a ventral hernia and underwent a laparoscopic ventral hernia repair with mesh.

Major complications occurred in 11 patients. Postoperative bleeding occurred in 2 patients, both of whom required a blood transfusion. Both patients were discharged home on postoperative day 4. One patient developed severe dehydration with acute renal failure which responded to intravenous fluids. The patient's dehydration was caused by vomiting and diarrhea. She was discharged home, tolerating the standard bariatric diet. Four patients developed a gastric fistula and a left upper quadrant abscess with no evidence until the 10th week after surgery, when they presented with fever and anorexia. CT scan showed a fluid collection in the left upper quadrant. This was percutaneously drained and parenteral nutrition and intravenous antibiotics were administered. In two of them a follow-up endoscopy approximately one month after drainage visualized extravasation of contrast at the superior aspect of the staple line. With the aid of the gastroenterologist, a covered stent was placed. A total of 10 patients underwent a reoperation, 6 of them proceding with the Switch, 3 of them undergoing a reconstruction of a narrower sleeve gastrectomy due to inadequate weight loss and 2 of them decided to procede with LAGB. Two patients developed a postoperative leakage from the suture line of the stomach on postoperative day 3 and 5 respectively, which resolved in sepsis and death after many interventions and hospitalization in the ICU. One patient died of massive pulmonary embolism on postoperative day 2.

3. Discussion

The rising prevalence of obesity is associated with an increase in the prevalence of obesity-related comorbidities (e.g. diabetes mellitus, hyperlipidaemia, hypertension, obstructive sleep apnoea, heart disease, stroke, asthma, back and lower extremity osteoarthritis, several cancers and depression). (16,17,18) These comorbidities are responsible for more than 2.5 million deaths per year worldwide. Unfortunately, diet therapy, medical treatment and exercise regimes are relatively ineffective in treating morbid obesity in the long term. (19) In 1991, the National Institutes of Health established guidelines for the surgical therapy of morbid obesity (BMI > 40 or > 35 in the presence of significant comorbidities), which is now referred to as bariatric surgery. (20) Laparoscopic sleeve gastrectomy is one of the most preferable bariatric procedures used worldwide.

LSG has gradually attracted considerable interest in the bariatric community since its introduction, as it does not require an anastomosis or intestinal bypass. (21) It also avoids the implantation of an artificial device. The mechanisms of action of LSG are via mechanical restriction and hormonal modulation.

First, it serves to work as a restrictive operation that reduces the size of the gastric reservoir to 60–200 mL (22, 23, 24) and restricts distension, thus permitting the intake of only small amounts of food, resulting in a feeling of early satiety during a meal. There is no consensus as to where to start the gastrectomy, and which calibre of the rhinogastric tube to use. We started the gastrectomy 1 cm proximal to the pylorus and used a 34 Fr rhinogastric tube (23). The purpose for starting closer to the pylorus and using a small calibre bougie to fashion the gastric tube is to increase the restrictive character of the procedure. The final volume of the gastric tube has been reported to be approximately 120 mL in our study.

Second, evidence has suggested that attenuation of endogenous ghrelin levels may also contribute to the success of LSG. (13, 25) The fundus is the place harbouring the ghrelin secreting cells of the stomach and the part of the stomach that we resected completely along with the greater curvature in order to have a better outcome.

However, the disadvantages of the procedure are its amputatory aspect and irreversibility. Although the procedure is relatively safe, the complications, when they do occur, can be serious. Our early experience has taught us several valuable learning points. Preoperative counselling to select the most suitable procedure, psychiatric assessment, risk optimisation and diet modification (commenced preoperatively) are essential. Perioperative considerations include logistical issues such as a dedicated operating table rated to withstand the weight of such patients and advanced laparoscopic instrumentation appropriate for bariatric surgery (i.e. longer instruments). This has previously been reported by others. (2)

In our study, all operations were carried out laparoscopically and a specific surgical technique was followed. The ability to complete all operations laparoscopically with no need to convert reveals special surgical experience in association with a moderate learning curve, appropriate instrumentation and a relatively safe and reproducible bariatric procedure. The mean operative time, obtained from the time of the first skin incision until the last wound was closed (14), was 72 minutes. This also reveals a relatively safe and efficacious procedure, at least technically. All patients were hospitalized for 3-5 days (mean hospital stay 3.5 days), monitored postoperatively for complications and submitted to a 1 and 6 month, 1, 2 and 3 year follow up and body weight measurement.

The study population that fit the inclusion criteria to undergo a LSG, after all necessary testing and psychiatric counseling, revealed a higher precentage of female obesity versus male, 59% versus 41%. The average BMI was 45.6 stating that in most cases no obesity-related comorbidities were necessary. It also reveals that extreme obesity tends to be treated with this certain surgical procedure as a stand-alone operation.

The average excess weight loss percentage were 21.85% and 47.45% at 1 and 6 months respectively and 60.53%, 68.27% and 75.47% at 1, 2 and 3 year follow up respectively. Average BMI at 1 and 6 months, 1, 2 and 3 years was 41.2, 36.3, 32.4, 27.3 and 26.2 respectively. These numbers reveal excellent weight loss achieved at the 6 month and 1 year follow up. In all patients the weight loss progressed over the first year excessively and continued on a lower pace during the second and third year with only sporadical cases of weight gaining. The latest refers to individuals that developed eating attacks and eventually proceeded to reoperation. In our series, resolution of morbid obesity (BMI<35kg/m2) occurred in 42% of patients by 6 months, reached normal BMI levels by the end of the second year and was maintained during the third year of follow up. This explains also the gradually reduced number of patients presenting annually for follow up, resulting in only 55% of appearance at year 3. Patients undergoing a steady weight loss until reaching the ideal BMI and then maintaining it in time seem to feel cured and unattached to their surgeon. In conclu-

sion our early and limited numerically experience shows that this novel procedure is safe and promising in terms of weight loss and patient acceptance.

The complication rates for laparoscopic sleeve gastrectomy range from 0% to 24% with an overall mortality rate of 0.5%. (26) In our study the overall complication rate was 11% with 3 mortalities (1,68%) in our 178 patients. One patient suffered a massive pulmonary embolism in the early postoperative period (postop day 2) resulting in death and 2 out of 4 patients with a postoperative leakage from the suture line of the stomach on postoperative day 3 and 5 respectively, developed a high fistula output, likely due to the patients' noncompliance with diet restrictions, which resolved in sepsis and death after many interventions and hospitalization in the ICU. Patients' compliance plays a very significant role not only in postoperative period but more importantly in treating any possible complications. Massive complications, irreversible in most of the cases, add to statistics and percentages, increase mortality rates, but cannot be prevented in majority.

All minor complications, such as nausea, gastroesophageal reflux, cholelithiasis, ventral hernia and wound infection were treated succesfully and without the need of hospitilization, at least immediately. From the variety of major complications the 2 most important and serious ones during bariatric surgery include bleeding and anastomotic or staple line leaks. The complication of gastric fistula is a serious concern. While it occurred in only four patients (2,25%) in our series, it has been reported as high as 5.1%. (27) We did not identify a specific cause for gastric fistula formation in our patients. These patients had a negative saline submersion test intraoperatively, but presented with clinical signs of an abscess approximately 10 weeks after surgery. Body habitus would suggest that the morbidly obese patient is well nourished. However, this is not true as evident by micronutrient deficiency reported in multiple studies. (28) Perhaps ulceration plays a factor and would account for the late leak. Different methods have been utilized including over-sewing of the staple line, buttressing with Surgicel strips or with other absorbable polymers. (29) Management of gastric fistula remains a dilemma. Surgical reintervention remains at the forefront and should be used for any patient with abdominal sepsis. It should be at the surgeon's discretion and based on intraoperative findings whether simple drainage is appropriate or a more definitive procedure can be attempted. (30,31) We decided to perform percutaneous drainage in all three cases due to the easy accessibility of the abscess and no radiological evidence of a leak. With interval development of a gastric fistula, we attempted

nonoperative management with parenteral nutrition and antibiotics. However, our patients continued to have high fistula output likely due to the patient's noncompliance with diet restrictions. We placed a covered stent, a method utilized by others, which was successful in two of these patients. Although they did not require any further surgical intervention, other methods such as over-sewing the gastric leak site, injecting fibrin glue, simple drainage, and total gastrectomy have been described. (32) The other 2 patients, one with an abcess that evovled into a high output fistula on postop day 5 and one with a leakage that revealed on postop day 3, underwent many interventions such as drainage, stenting, reoperating and over-sewing the gastric leak site, injecting fibrin glue, reoperating and performing total gastrectomy but with poor outcomes and resulting eventually, as mentioned above, to death. Although gastric fistula is a significant complication of LSG, its low occurrence rate is an acceptable risk for this procedure.

In conclusion, LSG is rather safe, reproducible and effective in the short term to achieve a substantial weight loss. There is no evidence so far that weight loss obtained with LSG can be maintained in the long term. These results should be interpreted with caution. Definitive conclusions on the superiority of laparoscopic sleeve gastrectomy require further investigation.

Abstract

Background: In recent years laparoscopic sleeve gastrectomy has become one of the most frequently performed bariatric operations in Europe. This procedure can be used as a stand alone procedure for treatment of malignant obesity or as a first step in the attempt of accomplishing a massive weight reduction. In this retrospective study we evaluated the complications and 3 year results obtained in patients that underwent laparoscopic sleeve gastrectomy.

Methods: A total of 178 patients were included in this retrospective study. Patients fullfilled the inclusion criteria and were all informed of the probable complications. All patients were operated laparoscopically with a standardized surgical technique.

Results: All patients were operated laparoscopically. The mean operative time was 72 minutes. No surgical bleeding occurred within the peritoneal cavity. No clinical leaks were identified intraoperatively using the saline submersion test. The percentage of excess weight loss ranged from 21.85% to 75.47% in the follow up period. Complications were categorized to minor and major, hemorrhage, abscess, fluid collection and leakage being among them. Ten re-operations and three deaths were reported.

Conclusion: Results from this series of patients indicate laparoscopic sleeve gastrectomy to be rather safe, reproducible, and efficacious as a stand-alone bariatric procedure in achieving and maintaining weight loss in short term follow up. However, the disadvantages of the procedure such as its irreversibility and its major complications place under discussion the common practice and need to be associated with thourough patient update and consent.

Key words: Morbid obesity, Laparoscopic sleeve gastrectomy, excess weight loss, postoperative complications

Περίληψη

Εισαγωγή: Η λαπαροσκοπική κάθετη διαμερισματοποίηση στομάχου έχει γίνει μια από τις πιο δημοφιλείς βαριατρικές επεμβάσεις στην Ευρώπη. Η τεχνική αυτή μπορεί να χρησιμοποιηθεί για την αντιμετώπιση της νοσογόνου παχυσαρκίας μόνη της ή σαν μια πρώτη επέμβαση σε μια σειρά χειρουργείων για την επίτευξη υπερβολικής απώλειας βάρους. Σε αυτή την αναδρομική μελέτη αναλύσαμε τις επιπλοκές και σε βάθος τριετίας τα αποτελέσματα της λαπαροσκοπικής κάθετης διαμερισματοποίησης στομάχου.

Μέθοδος: Πρόκειται για μία αναδρομική μελέτη στην οποία μελετήθηκαν συνολικά 178 ασθενείς. Οι ασθενείς πληρούσαν τα κριτήρια επιλογής και είχαν ενημερωθεί για τους πιθανούς κινδύνους και τις πιθανές επιπλοκές μιας τέτοιας επέμβασης. Όλοι οι ασθενείς χειρουργήθηκαν λαπαροσκοπικά και εφαρμόστηκε η ίδια συγκεκριμένη τεχνική.

Αποτελέσματα: Όλοι οι ασθενείς υποβλήθηκαν σε λαπαροσκοπική επέμβαση. Ο μέσος χειρουργικός χρόνος ήταν 72 λεπτά. Δεν παρατηρήθηκε ενδοκοιλιακή διεγχειρητική αιμορραγία ούτε διαφυγή από τη γραμμή συρραφής κατόπιν ελέγχου. Το ποσοστό της περίσσειας απώλειας βάρους κυμάνθηκε από 21.85% εως 75.47% στην μετεγχειρητική περίοδο. Οι επιπλοκές χωρίστηκαν σε ελλάσσονες και μείζονες, π.χ. αιμορραγία, απόστημα, συλλογή και διαφυγή. Παρατηρήθηκαν 10 επανεπεμβάσεις και 3 θάνατοι.

Συμπεράσματα: Τα αποτελέσματα αυτής της μελέτης δείχνουν ότι η λαπαροσκοπική κάθετη γαστρεκτομή είναι μια μέθοδος σχετικά ασφαλής, εύκολη και αποτελεσματική ακόμη και μόνη της για την αντιμετώπιση της νοσογόνου παχυσαρκίας. Ωστόσο τα μειονεκτήματα της επέμβασης όπως η μη αναστρεψιμότητά της και οι επιπλοκές της, θέτουν υπό συζήτηση την ευρεία εφαρμογή της και πρέπει να σχετίζονται με μια λεπτομερή ενημέρωση και συναίνεση του ασθενούς.

Λέξεις – κλειδιά: Morbid obesity, Laparoscopic sleeve gastrectomy, excess weight loss, postoperative complications

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