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Original

Effects of a balanced energy and high protein formula diet (Vegestart complet®) *vs.* low-calorie regular diet in morbid obese patients prior to bariatric surgery (laparoscopic single anastomosis gastric bypass): A prospective, double-blind randomized study

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Abstract

Objective: **Bariatric surgery is considered the only therapeutic alternative for morbid obesity and its co-morbidities. High risks factors are usually linked with this kind of surgery. In order to reduce it, we consider that losing at least 10% of overweight in Morbid Obese (MO) and a minimum of 20% in Super- Obese patients (SO) before surgery, may reduce the morbidity of the procedure.**

The aim of our study is to demonstrate the effectiveness and tolerance of a balanced energy formula diet at the preoperative stage, comparing it against a low calorie regular diet.

Method: **We studied 120 patients divided into two groups of 60 each, group A was treated 20 days prior to bariatric surgery with a balanced energy formula diet, based on 200Kcal every 6 hours for 12 days and group B was treated with a low calorie regular diet with no carbs or fat. The last eight days prior to surgery both groups took only clear liquids.**

We studied the evolution of weight loss, the BMI, as well as behavior of co-morbidities as systolic blood pressure, diastolic blood pressure, glucose controls and tolerance at the protocol.

Results: **The study shows that patients undergoing a balanced energy formula diet improved their comorbidities statistically significant in terms of decrease in weight and BMI loss, blood pressure and glucose, compared to the group that was treated before surgery with a low calorie regular diet. Nevertheless both groups improving the weight loss and co-morbidities with better surgical results and facilities.**

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EFECTOS DE UNA DIETA-FORMULA NORMOCALÓRICA E HIPERPROTEICA (VEGESTART COMPLET®) *VS* DIETA NORMAL BAJA EN CALORIAS EN PACIENTES CON OBESIDAD MORBIDA COMO PREPARACION A CIRUGÍA BARIÁTRICA (BYPASS GÁSTRICO LAPAROSCÓPICO DE UNA ANASTOMOSIS): ESTUDIO PROSPECTIVO DOBLE CIEGO ALEATORIZADO

Resumen

Objetivos: **La cirugía bariátrica es considerada la única alternativa terapéutica para el control de la obesidad mórbida y sus co-morbilidades. Dada la complejidad, gravedad y dificultades de estos pacientes, todo lo que hagamos para disminuir los riesgos peri-operatorios debe ser considerado como muy beneficioso para ellos. De este modo consideramos que una disminución como mínimo del 10% en el exceso de peso en los Obesos Mórbidos (OM) y un 20% en los Super-Obesos (SO), antes de la cirugía, puede mejorar los resultados y disminuir la morbimortalidad del procedimiento.**

El objetivo de nuestro estudio es demostrar la eficiencia y tolerancia de una dieta-fórmula hiperproteica y normocalórica como preparación preoperatoria, comparándola con una dieta hipocalórica de comida habitual.

Métodos: **De forma prospectiva y aleatorizada, se estudiaron 120 pacientes divididos en dos grupos de 60 cada uno. Las dietas se administraron 20 días previos a la cirugía. Al primer grupo (A), se le aplicó una dieta-fórmula hiperproteica y normocalórica en bricks, conteniendo 200 kcal cada 6 horas durante los primeros 12 días y al segundo grupo (B), una dieta hiperproteica normal sin carbohidratos o grasas.**

Los últimos 8 días previos a la cirugía se dieron solamente líquidos claros en ambos grupos.

El análisis se efectuó sobre la evolución del peso, del IMC, de la presión arterial y de los niveles de glucemia, así como de la tolerancia al procedimiento.

Resultados: **El estudio demostró que los pacientes pertenecientes al grupo A, mejoraron de forma estadísticamente significativa tanto en la pérdida de peso y del IMC, como de las co-morbilidades estudiadas, frente a los pacientes que integraron el grupo B. Aunque en todo el conjunto, ambos grupos obtuvieron pérdida de peso preoperatoria y mejoría en sus co-morbilidades.**

Conclusion: **A correct preparation of the Morbid Obese patients prior of surgery can reduce the operative risks improving the results.**

Our study show that the preoperative treatment with a balanced energy formula diet as were included in our protocol in patients undergoing bariatric surgery improves statistical better their overall conditions, lowers cardiovascular risk and metabolic diseases that the patients with regular diet alone.

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Key words: *Preoperative weight loss. Low calorie diet. Morbid obesity. Bariatric surgery. Laparoscopic single anastomosis. Gastric bypass.*

Conclusiones: **Una preparación adecuada para los pacientes que vayan a ser sometidos a cirugía bariátrica, puede mejorar los resultados y minimizar los posibles efectos indeseables de la misma.**

Una dieta-fórmula del tipo de la ensayada en nuestro estudio, alcanza los objetivos de pérdida de peso y reducción o control de las co-morbilidades en mejor proporción que las dietas hipocalóricas habituales, mejorando el riesgo cardiovascular y facilitando todo el proceso quirúrgico.

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Palabras clave: *Pérdida de peso preoperatoria. Dieta baja en calorías. Obesidad mórbida. Cirugía bariátrica. Bypass gástrico laparoscópico de una anastomosis. Bypass gástrico.*

Introduction

For the last couple of decades obesity has been one of the largest health issues in the world, especially in developed countries. It is a major risk factor for the appearance of chronic diseases such as type II diabetes, high blood pressure, sleep apnea, fat liver, dyslipidemia, cardiovascular diseases, and many types of cancer. It also has major economical, psychological and social implications that notably affect life expectancy and quality of life in obese people, specifically in the morbidly and super morbidly obese.

Nowadays, bariatric surgery is considered the only therapeutic alternative for morbid obesity and its co-morbidities, when other strategies had failed. Likewise we have known that this kind of patients have higher incidence of difficulties and complications in both perioperative and postoperative processes. The morbid status and co-morbid conditions imply an aggressive inflammatory tissue response damaging the normal organ function and the excess of intra-abdominal fat increase the technical problems jeopardizing the safety and results of the surgical response.

The relationship between weight reduction and improvement of risk factors and associated co-morbidities is well known. By losing, at least, 10% of their overweight improves cardiovascular risk and co-morbidities;[1] also decreases visceral fat, above all the hepatic steatosis and liver volume.[2,3] This conditions can reduce surgical time, potential difficulties and complications (both surgical and anesthetics), probably less blood loss and shorter hospital stay. Recently, an "Evidenced-based Assessment of preoperative weight loss in bariatric surgery" has been published, concluding that weight loss before surgery will drastically reduce complications, operating time, blood loss, shorter hospital stay and may even lose more weight in long time.[4]

Hypothetically, significant preoperative weight loss before bariatric surgery can reduce morbidity and mortality of the procedure, we consider, an efficient preoperative weight loss to be at least 10% of excess body weight in MO and a minimum of 20% in SO patients.

There are different non-invasive strategies we can use to obtain this efficient preoperative weight loss. One alternative is substituting meals with specially designed very low-calorie formulas. These formulas represent an easy way to limit daily calorie intake between 400 and 800 kcal containing at the same time all essential nutrients for the correct nutritional status. These products are designed for special medical requirements; therefore, patients undergoing these strict diets must always remain under medical supervision.

In the context of bariatric surgery, high protein diets are useful because they produce rapid weight loss, with an adequate level of satiety and contribute to less lean body mass loss, and less resting energy expenditure reduction. The formula we use for substituting meals contains 30% of its caloric value from a protein source. We suggest that substituting all meals for this formula in patients prior to laparoscopic bariatric surgery can help us obtain a significant weight loss that translates into less operative time and complications, and preservation of lean body mass and resting energy expenditure.

The objective of our study is to evaluate efficiency and tolerance of a complete high protein and balanced energy specially formulated drink, during preparation for bariatric surgery (laparoscopic gastric bypass) comparing with a group of patients preparing for surgery with a very low-calorie diet with regular meals. The main variable analyzed was excess body weight reduction and BMI. Secondary variables also analyzed were changes in blood pressure, blood glucose levels, and patient satisfaction.

Materials and methods

Patients

From January to June 2006 the Center of Excellence for Bariatric Surgery at Campo Grande Hospital in Valladolid, (Spain), selected 120 obese and super-obese patients, (80 female and 40 male), in preparation for bariatric surgery (Laparoscopic Single Anastomosis Gastric Bypass) that accepted to be part of the study, signing an informed consent. We excluded patients who did not

sign an informed consent and those that abandoning the study protocols. We excluded also the patients who did not adhere to the nutritional plan, as well as any one who developed a health problem and any one who required an additional nutritional support during the study period.

Patients were randomly divided in 2 groups, including 60 patients in each group. The length of the study was 20 days before the surgery for each patient.

Group A: Complete high protein, balanced energy diet with a specially formulated drink (four 200 ml-kcal bricks per day of Vegestart Complet®, Vegenat, Spain) during 12 days. They were allowed to drink other calorie free drinks such as water, tea, coffee and nonfat broth. For the remaining 8 days they were kept on a strictly liquid diet consisting of water, tea, coffee, natural juices, nonfat broth and nonfat milk.

Group B: Normal hyperproteic meals with no carbohydrates or fat during 12 days. The remaining 8 days were the same as in group A.

Study design

The study was observational, prospective, and randomized in 2 groups.

Studied data

The following data were collected: Sex, age, weight, height, body mass index, personal and family history, blood pressure, blood glucose level, chronic illness or co-morbidities, present medication, and previous weight loss attempts.

Statistical analysis

All data are expressed as the mean ± standard deviation and percentage. Statistical Analysis was performed using Statistical Analyzing System software (SAS Version 9.1 for Windows Cary Institute 2002-2003, Cary, NC, USA). Continuous variables were analyzed using the student's *t*-test. Categorical data analysis was conducted using Fisher´s exact test. Comparisons between groups were performed using Chi-Squared parametric and non parametric test (Student *t* and Mann-Whitney *U)*. In order to adjust numbers we applied a Covariance Analysis (ANCOVA). All P values < 0.05 were considered statistically significant.

Results

The study included120 patients, 60 in each group, group an included 23 male and 37 female patients, and group B had 17 male and 43 female patients, finding no statistical difference in sex distribution (table I). Average age was 38 years with no statistical difference between groups (table II).

Table I
Distribution by sex

	Group A		*Group B*		*Total*	
	N	*%*	*N*	*%*	*N*	*%*
Male	23	38.33	17	28.33	40	33.33
Female	37	61.67	43	71.67	80	66.67
Total	60	100.0	60	100.0	120	100.0

Table II
Distribution by age

	N	*Average*	*Min.*	*Max.*
Group A	60	38.18	18.00	58.00
Group B	60	37.86	17.00	75.00
Total	120	38.03	17.00	75.00

Family History: No statistical difference was found. We found that only 5% of patients had no family history of diseases of any kind and 84% had a family history of Obesity (table III).

Personal History: No statistical difference was found in history of allergies, previous surgical procedures, age of menarchy or menstrual rhythm (table IV).

Table III
Family history

	Group A		*Group B*		*Total*		*P value*
	N	*%*	*N*	*%*	*N*	*%*	*(Chi²)*
Negative history	3	5.00	3	4.92	6	4.96	
Obesity	51	85.00	51	83.61	102	84.30	0.8332
Diabetes Mellitus	38	63.33	36	59.02	74	61.16	0.5437
Dyslipidemia	42	70.00	38	62.30	80	66.12	0.3016
Hypertension	45	75.00	41	67.21	86	71.07	0.3449
Cardiac disease	25	41.67	24	39.34	49	40.50	0.7358
Thyroid disease	5	8.33	1	1.64	6	4.96	0.1111

Table IV
Personal history

	Group A		*Group B*		*Total*		*P value*
	N	*%*	*N*	*%*	*N*	*%*	*(Chi²)*
Allergies	10	16.67	4	6.56	14	11.57	0.0763
Surgical procedures	28	46.67	30	49.18	58	47.93	0.6444
Other diseases	18	30.00	21	34.43	39	32.23	0.2937
Normal Menstrual Rhythm	23	62.16	31	72.09	54	67.50	
Menstrual Rhythm disorders	14	37.84	12	27.91	26	32.50	

Table V
Body measurement (anthropometry)

	Initial body weight (kg)						Body height (m)				
	N	*Avg.*	*Std. Dev.*	*Min.*	*Max.*	*Mean*	*Avg*	*Std. Dev.*	*Min.*	*Max.*	*Mean*
Group A	60	124.8	16.51	99.00	179.0	124.00	1.66	0.08	1.50	1.81	1.65
Group B	60	112.7	15.65	78.00	151.0	112.50	1.62	0.07	1.42	1.83	1.59
TOTAL	120	118.2	18.67	78.00	179.0	116.00	1.63	0.08	1.42	1.83	1.62

Table VI
Body Mass Index

	N	*Avg.*	*Std. Dev.*	*Min.*	*Max.*	*Mean*
Group A	60	45.07	4.79	34.57	56.69	45.48
Group B	60	43.56	5.27	34.46	59.93	43.94
Total	120	44.55	5.40	34.46	59.93	44.10

Table VII
Co-morbidities

	Group A		Group B		Total		P value
	N	*%*	*N*	*%*	*N*	*%*	*(Chi²)*
Hypertension	25	41.67	20	33.33	45	37.50	n.s.
Diabetes Mellitus	18	30.00	19	31.67	36	30.00	n.s.
Dyslipidemia	30	50.00	24	39.34	54	44.63	0.2384
Ischemic Heart Disease	3	5.00	2	3.28	5	4.13	0.6343
Arthropathy	38	63.33	39	63.93	77	63.64	0.9452
Sleep Apnea	45	75.00	35	57.38	80	66.12	0.0406
Psychiatric Disorders	13	21.67	20	32.79	33	27.27	0.1697

Obesity history: We collected each patient's birth weight finding that the vast majority had normal weight at birth, with an average of 3.66 kg and no important difference between groups. 41% of patients started developing obesity at early childhood and 37.5% in their puberty, which means that 78.5% of these patients were obese before reaching adulthood and only 21% developed obesity during their adult life. The average body weight at the beginning of our study was 118 ± 18.67 kg with an average body height of 1.63 m. Although an average initial body weight and height was found higher in group A, there was no statistical difference between groups (table V). Body Mass Index (BMI) was slightly higher in group A, but once again with no statistical significance (table VI). We found that all patients had multiple medically supervised ineffective past weight loss attempts, and additionally 19 total patients, 8 from group A (13.3%) and 11 from group B (18.3%), previously had an intragastric balloon with no success in achieving weight loss.

Co-morbidities: We found slightly different prevalence of co-morbidities like hypertension, diabetes mellitus, dyslipidemia, cardiac disease, arthropathy and psychiatric disorders in both groups with no statistical significance for any of them. We found a statistically significant P value for sleep apnea with a higher prevalence in Group A, which can be explained due to the larger number of male patients in this group (table VII).

Weight loss: The following table shows initial and final body weight for both groups, demonstrating a greater weight loss achieved by group A with statistical significance (table VIII).

Table VIII
Initial and final body weight

								IC Med 95%			
		N	*Avg.*	*Std. Dev.*	*Min.*	*Max.*	*Mean*	*IQR*	*Inf.*	*Sup.*	*P value*
Initial	Group A	60	124.8	16.51	99.00	179.0	127.00	24.00	123.55	132.1	N.S.
	Group B	60	118.7	15.65	78.00	151.0	108.50	17.00	104.69	112.8	
	Total	120	121.7	18.67	78.00	179.0	116.00	25.00	114.82	121.6	
Final	Group A	60	115.42	14.55	93.00	151.0	119.00	20.00	114.66	122.5	< 0.0001
	Group B	60	113.85	14.69	74.00	145.0	102.50	19.00	100.09	107.7	
	Total	120	114.74	16.31	74.00	151.0	111.50	20.50	107.97	114.0	
Difference	Group A	60	-9.38	3.92	-28.0	-4.00	-9.00	4.00	-10.42	-8.33	< 0.0001
	Group B	60	-4.85	2.29	-11.0	0.00	-5.00	3.00	-5.44	-4.26	
	Total	120	-7.03	3.90	-28.0	0.00	-6.00	6.00	-7.75	-6.32	

Table IX
Adjusted weight loss

	Weight loss	*95% confidence limits*	
Group A	-8.218256	-9.010794	-7.425718
Group B	-5.870564	-6.684026	-5.057101

weight loss between groups, when comparing it with the raw numbers on table 8, but there is still a significant difference.

Body Mass Index (BMI): Statistically significant differences were found when comparing BMI changes between groups as seen in table X. After applying a covariance analysis of data in the same way as for weight loss, BMI changes seem less dramatic, but there is still a statistically important difference (table XI).

After applying a covariance analysis of data in the same way as for weight loss, BMI changes seem less dramatic that in the raw numbers, but there is still a statistically important difference (table XI).

Table X
Evolution of body mass index

								IC Med 95%			
		N	*Avg.*	*Std. Dev.*	*Min.*	*Max.*	*Mean*	*IQR*	*Inf.*	*Sup.*	*P value*
Initial	Group A	60	46.57	4.79	34.57	56.69	46.48	7.02	45.32	47.82	N.S.
	Group B	60	42.56	5.27	32.46	59.93	41.94	5.54	41.20	43.92	
	Total	120	44.55	5.40	32.46	59.93	44.10	7.65	43.57	45.53	
Final	Group A	60	43.20	4.45	31.48	53.15	43.27	6.81	42.01	44.39	0.0045
	Group B	60	40.67	4.93	31.23	57.07	40.42	5.10	39.39	41.94	
	Total	120	41.89	4.85	31.23	57.07	41.39	6.79	41.00	42.78	
Difference	Group A	60	-3.38	1.23	-8.64	-1.54	-3.16	1.58	-3.71	-3.05	< 0.0001
	Group B	60	-1.89	0.86	-4.46	0.00	-1.75	0.95	-2.12	-1.67	
	Total	120	-2.61	1.29	-8.64	0.00	-2.34	1.71	-2.85	-2.37	

Table XI
Adjusted BMI difference

	Adjusted BMI difference	*95% confidence limits*	
Group A	-3.205181	-3.467537	-2.942825
Group B	-2.174089	-2.476610	-1.871568

Due to the design model of the study, the difference in weight loss can be influenced by the initial body weight. Since group A had a slightly higher initial weight, it is possible for patients in this group to achieve a greater weight loss. In order to adjust numbers we applied a covariance analysis (ANCOVA) to determine a corrected weight loss value as seen in table IX. The adjusted results show a narrower difference in

Blood Pressure Evolution: Changes in both Systolic and Diastolic Blood Pressure were found statistically significant favoring patients in group A as seen in raw numbers in table XII, and in table XIII after adjusting results with covariance analysis.

Blood Glucose Level Evolution: There was an important reduction in blood glucose levels in both groups, but once again the decrease in Group A was

Table XII
Evolution of systolic and diastolic blood pressure

			Sistolic Blood Pressure (SBP)					*Diastolic Blood Pressure (DBP)*				
		N	*Avg.*	*Std. Dev.*	*Min.*	*Max.*	*P value*	*Avg*	*Std. Dev.*	*Min.*	*Max.*	*P value*
Initial	Group A	60	146.5	14.0	120	190	0.0051	90.4	6.0	80	100	0.0010
	Group B	60	139.2	13.8	120	180		86.4	6.5	65	100	
	Total	120	142.7	14.3	120	190		88.3	6.6	65	100	
Final	Group A	60	132.2	13.6	110	180	0.4760	80.8	7.0	60	90	0.0361
	Group B	60	133.8	10.4	120	170		83.3	5.6	65	95	
	Total	120	133.1	12.0	110	180		82.1	6.4	60	95	
Difference	Group A	60	-14.3	8.8	-40	0	< 0.0001	-9.9	5.9	-20	0	<0.0001
	Group B	60	-5.3	7.0	-20	0		-3.1	4.5	-10	0	
	Total	120	-9.6	9.1	-40	0		-6.3	6.2	-20	0	

Table XIII
Adjusted changes in systolic and diastolic blood pressure

	Adjusted decrease in SBP	95% confidence limits		Adjusted decrease in DBP	95% confidence limits	
Group A	-13.29997	-15.19	-11.40	-9.29	-10.63	-7.95
Group B	-6.91138	-9.01	-4.80	-4.38	-5.87	-2.89

Table XIV
Evolution of blood glucose levels

								IC Med 95%			
		N	Avg.	Std. Dev.	Min.	Max.	Mean	IQR	Inf.	Sup.	P value
Initial	Group A	60	118.4	29.51	94	270	115	6	110.67	126.2	0.0227
	Group B	60	108.7	14.00	90	175	111	17	105.05	112.3	
	Total	120	113.5	23.39	90	270	112	17	109.20	117.7	
Final	Group A	60	101.9	19.69	83	190	95	20	96.53	107.2	0.6318
	Group B	60	103.3	10.43	86	140	98	16	100.56	105.9	
	Total	120	102.6	15.51	83	190	98	18	99.72	105.4	
Difference	Group A	60	-16.9	16.02	-11	-80	-20	11	-21.24	-12.6	<0.0001
	Group B	60	-5.42	8.22	-4	-35	-13	6.5	-7.54	-3.29	
	Total	120	-10.9	13.78	-7	-90	-14	15	-13.46	-8.37	

larger finding the difference statistically significant both in raw numbers (table XIV) and after adjustment (table XV).

Safety and tolerance of the dietary plans: Treatment safety was determined by observing how well patients tolerated each dietary plan. We considered any adverse effects or reactions as seen in table XVI.

We found a statistically significant difference regarding the presence of adverse effects favoring Group B, which was better tolerated. Analyzing each of the adverse effects individually, no parameter reached statistical significance. Diarrhea was the most frequent unpleasant effect; however, patients reported it as mild and only at the beginning of the treatment and further on it disappeared.

Dietary satisfaction: Patients from each group evaluated their dietary plans in terms of satisfaction using a scale from 1 to 5 (table XVII). Although both dietary plans were well evaluated, Group B had better grades.

Discussion

Traditionally the need for weight loss before surgery in patients with morbid obesity has been controversial, even considered unjustified and painful for the patient. But everyone recognizes the difficulties that are added to any type of surgical procedure in obese patients, along with its greater rate of complications intra and peri-operative in comparison to non-obese patients, leading even to the contraindication or impossibility to perform multiple operations in patients presenting morbid obesity.[5,6]

Bariatric surgery, and especially the one made by laparoscopy, supports the combination of a wide panorama of serious comorbidities with technical, surgical and anesthetics problems, derivatives of the large volume of intra-abdominal fat, perivisceral and growned liver, which may lead to increased operative time, increased bleeding, possibility of restructuring, severe complications and even death. In this line of thought, everything we

Table XV
Adjusted glucose level difference

	Adjusted glucose difference	95% confidence limits	
Group A	-14.948644	-17.098330	-12.798958
Group B	-8.475937	-10.915958	-6.035917

Table XVI
Tolerance and safety of dietary plans

	Group A		Group B		Total		P value
	N	%	N	%	N	%	
No adverse effects	51	85.00	58	98.36	111	91.74	0.0076
Nausea/Vomit	2	3.33	0	0.00	2	1.65	0.2438
Constipation	1	1.67	2	1.64	3	1.65	1.0000
Headache	1	1.67	0	0.00	1	0.83	0.4959
Diarrhea	4	6.67	0	0.00	4	3.31	0.0574
Other	1	1.67	0	0.00	1	0.83	0.4959

Table XVII
Patient dietary satisfaction

	N	Avg.	Std. Dev.	Min.	Max.	Mean	IQR	Inf.	Sup.
Group A liquid formula									
Taste	56	3.85	1.10	1.00	5.00	4.00	2.00	3.55	4.14
Color	55	4.73	0.68	1.00	5.00	5.00	0.00	4.54	4.91
Texture	56	4.63	0.59	3.00	5.00	5.00	1.00	4.47	4.78
Level of Fullness	56	4.52	0.79	1.00	5.00	5.00	1.00	4.31	4.73
Group B high protein regular diet									
Taste	52	4.92	0.27	4.00	5.00	5.00	0.00	4.85	5.00
Meal Preparation Difficulty	52	4.79	0.64	1.00	5.00	5.00	0.00	4.61	4.97
Easiness to Follow Diet	52	4.44	0.87	2.00	5.00	5.00	1.00	4.20	4.69
Level of Fullness	52	4.41	0.78	2.00	5.00	5.00	1.00	4.20	4.63

do in order to prepare our patients for surgery, improving their co-morbidities, decreasing the liver volume, lowering abdominal pressure and inflammation, will result in benefit of the efficacy and safety of surgery.

This hypothesis of work lead us several years ago to a protocol of preoperative preparation of the morbid obese patient, consisting basically in the accomplishment of respiratory physiotherapy, daily moderate physical exercise during an hour and a half and a 10% minimum weight loss of the initial overweight in the O.M and a 20% like minimum in the S.O.

Next to it, psychological and nutritional attendance, disaccustom of smoking, alcohol or any other type of drugs, strict medicinal control and a weekly follow up when entering the surgical waiting list and daily for the 20 previous days to the surgery.[7,8]

Although there is no evidence of the optimal percentage of weight reduction previous to surgery, our experience indicates that the minimum percentage above indicated is indispensable for the best, safest and correct surgical exercise in obese and great obese patients. In the same sense it is reflected in the analysis of Tarnoff and some of the consulted studies, with a level of evidence III.[4]

The dietetic project was designed specifically for the preoperative preparation lasting of 20 days: twelve days of high protein formula diet, with bricks of 200 kcal each every 6 hours, at the rate of 800 kcal/day (Vegestart-Complet®) and complete liquid diet during eight days previous to the surgery.

Since our philosophy is based on the loss of weight and the lightening in the visceral and intraabdominal fat before surgery, the formula diet should be compared to another model of diet which consist of low caloric content in conventional eating and maintenance of the same eight days of hypocaloric liquid diet.

This way, the result of a random prospective study between the two models of preoperative rules would indicate the best option for the objective of weight loss and improvement of Co-morbidities in the preoperative process.

On the other hand, the establishment of a dietetic discipline and new life habits in patients with OM and SO in a previous phase of surgery is fundamental for their motivation and subsequent adaptation to their new post-operative condition and the changes realized in their digestive tract mainly in any gastrointestinal model of bypass.

The preoperative weight loss to a great extent stimulates and improves self-esteem of the patient, adapts him better psychologically for surgery and his immediate future, and in a great extent facilitates the fast recovery of the patient diminishing the possible adverse effects of the post-operative stage and reduces the possibility of operating complications. Several studies have been realized in this sense agreeing with our own experience.[9-13]

Special interest acquires in some studies the importance of the liver size in its left lobe facing the laparoscopic boarding in bariatric surgery. A greasy and excessively hypertrophic liver, can difficult the surgical gestures to a great extent, cause injuries having the consequence of bleeding and prevent a correct intervention.

Ultrasound and clinical studies in patients who control their weight loss have indicated even a 33% reduction of visceral fat of the left lobe, 50% less hepatocites and a considerable improvement in the degree of non-alcoholic steatohepatitis[2,3,11,15] having improved considerably the risk of intra and post-operative bleeding.[16]

Similarly, the physical training of the patient is important to avoid reconversions to conventional surgery because of the impossibility of finishing it via the laparoscopic route, which intensifies surgical stress, the inflammatory reaction and the possibility of serious complications.[17,18]

Our study is specifically demonstrative that a high protein and balanced energy formula diet of low calorie content during the preoperative stage, against a regular high protein diet, obtained statistically significant advantages lowering the data of arterial tension, glucemia, ponderal evolution and of the BMI, which

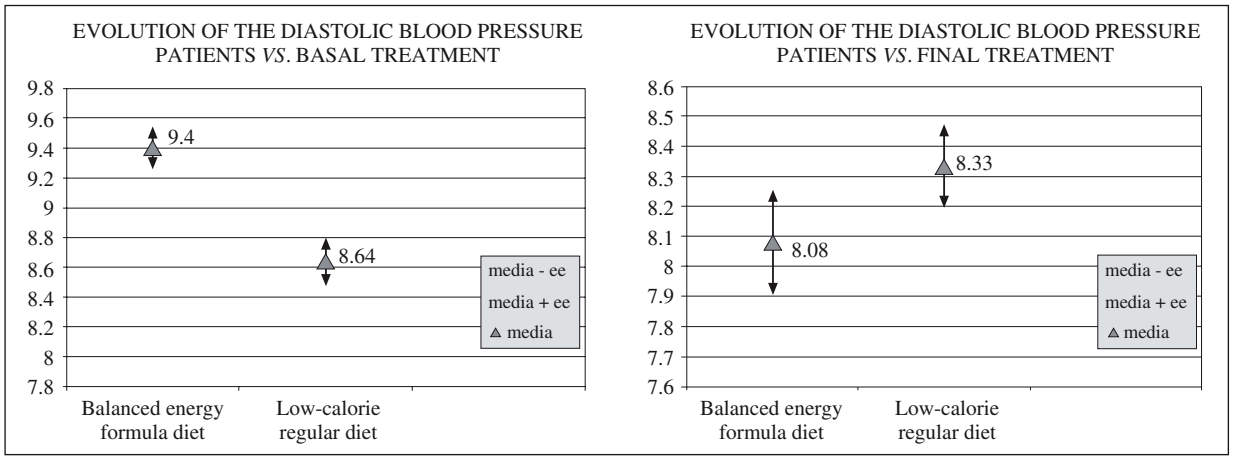

Fig. 1.

was translated in a smaller cardiovascular risk and therefore better preparation for surgery, improvement in co-morbidities, major weight loss and the volume of visceral and intraabdominal fat.

Recently a comparative study between a balanced energy formula diet (introduced replacing a meal during the day), against a low calorie regular diet during six months, obtained better results in weight loss and associated co-morbidities.[19]

Concretely if we analyze our results the crude data of systolic arterial tension, it is observed that in spite of existing percentage differences in levels of arterial tension at the initial moment in both groups (146 mmHg in patients dealing with a balanced energy formula diet versus 139 mmHg in patients treated with a low-calorie regular diet), at the final moment these differences balance, appearing the average values to be lower for the patients treated with formula diets, because of the greater normalization values (fig. 1).

If we value the data of the diastolic arterial tension, a behavior very similar to the precedent is observed. Initially we part from a different situation observing the percentages of both treatment groups, since the patients who were treated with the normocaloric formula-diet displayed higher values of diastolic tension than the group dealing with a regular diet.

Nevertheless after treatment, it is observed that these differences become significant in the opposite order, in spite of having superficially values at the basal moment, after treatment, the patients dealt with balanced energy formula diet obtain smaller values than the patients treated with a low-calorie regular diet (fig. 2).

About the evolution in the seric glucose levels, the difference with other parameters analyzed in our study, the patients who were treated with a balanced energy formula diet part from similar values than the patients which were treated with a regular low-calorie diet, taking place a similarity of these values after the treatment. If we applied the same type of model ANCOVA, the model is statistically significant, detecting as significant the treatment of the study and the basal glucose level (fig. 3).

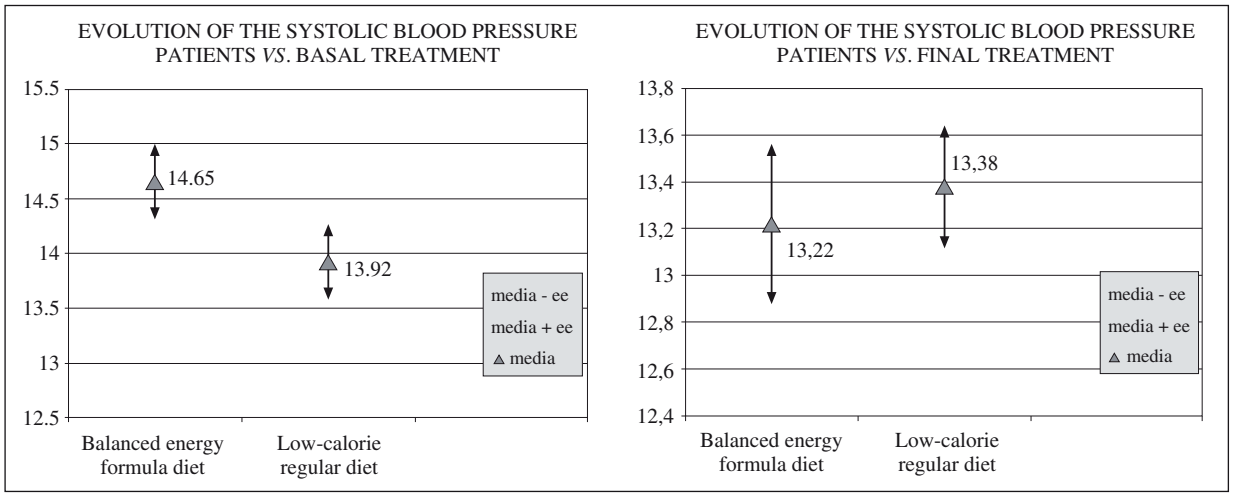

Fig. 2.

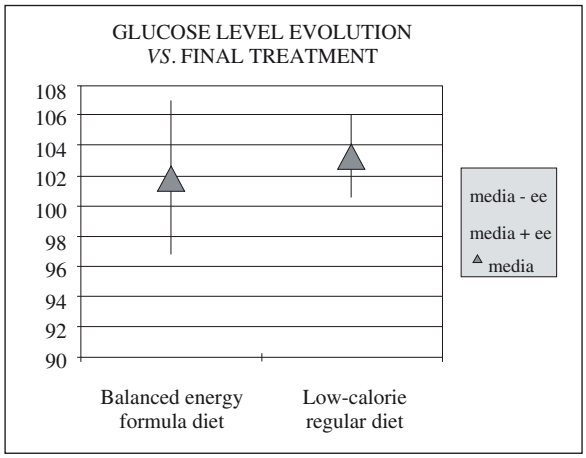

Fig. 3.

index statistically significant of peri-operating serious complications (6,9% *versus* 0,6%), against the patients that did not lose weight before surgery. It is necessary to review the anesthetic complications that forced previous traqueotomy or definitively disabled the intubation that switched from 3.5% to 0% after a suitable preoperative preparation and weight loss presented in the protocol set out in this study (fig. 4).

As a final conclusion, we can review that at the moment a suitable preparation of the obese patient for surgery is absolutely essential and inseparable of the surgical process.

To reduce a minimum 10% of the initial percentage of overweight in patients with MO and 20% in those with SO, and/or metabolic syndrome with víscero-main Obesity, considerably reduces the peri-operating

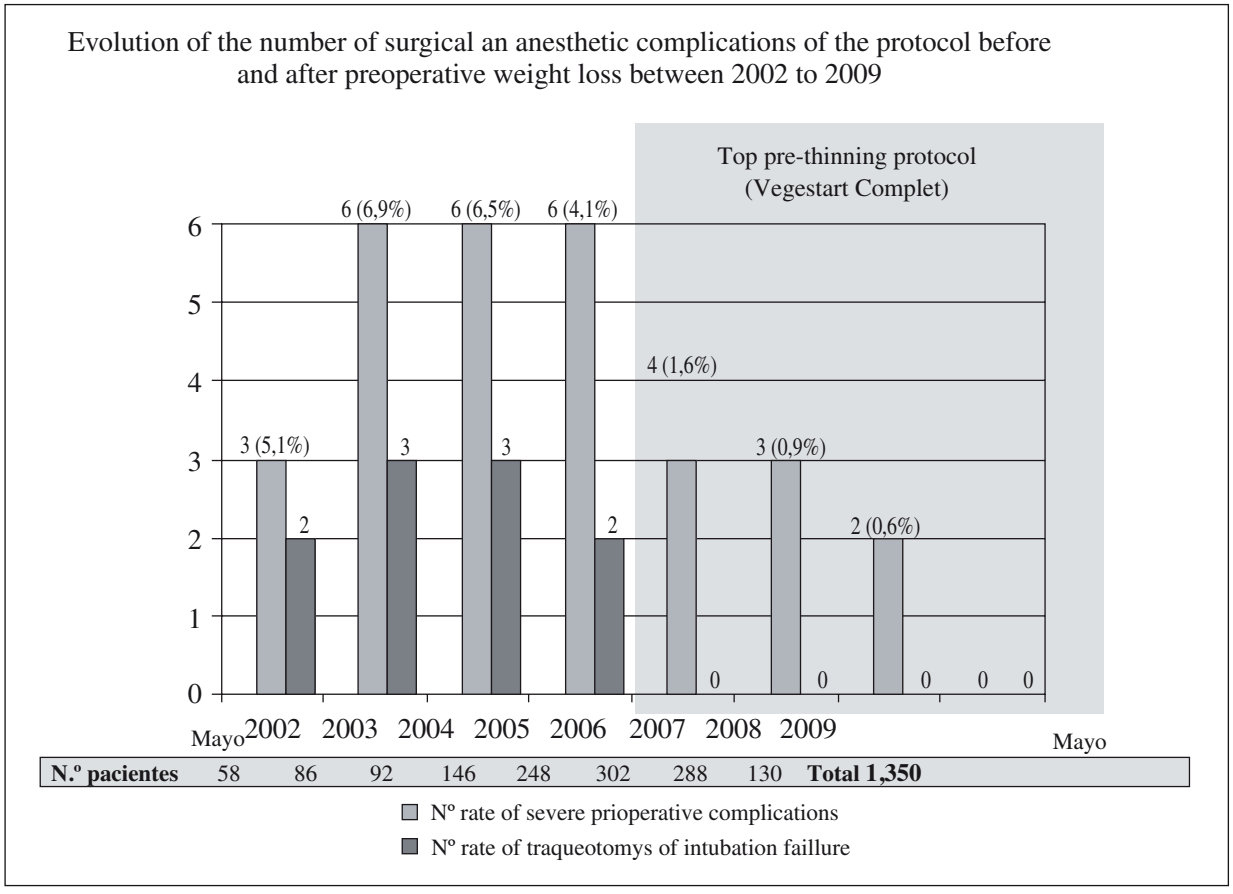

Fig. 4.

In the own experience of our Center of Excellence for the Study and Treatment of the Obesity, of a total of 1,350 patients operated with a robotic-laparoscopic gastric bypass of a single anastomosis between May 2002 and May 2009, the group of 968 patients who were treated with the preoperatively protocol of a balanced energy formula diet here reviewed, and which they presented an index of overweight loss of at least 10-20%, showed a smaller complications, dangerous intubations, traqueotomies, surgical time and hospital stay.

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