Effects of a Preoperative well-balanced energetic diet.

A prospective, double-blind, randomize 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 Morbidly 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. Methods: 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 carbohydrates or fat. The last eight days prior to surgery both groups took only clear liquids.

We studied the evolution of weight loss, BMI, as well as behavior of co-morbidities such as systolic blood pressure, diastolic blood pressure, glucose controls and tolerance in the research. Results: The study shows that patients undergoing a balanced energy formula diet significantly improved their co-morbidities statistically 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 improved their weight loss and co-morbidities with better surgical results. Conclusion: An adequate correct preparation of the MO patient’s prior to surgery can reduce the operative risks improving the overall results. Our study shows that a preoperative treatment with a balanced energy formula diet as was included in our protocol in patients undergoing bariatric surgery statistically improves their overall conditions, lowers cardiovascular risk and metabolic diseases than in patients who used a regular calorie diet alone.

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

Introduction

Obesity has become one of the largest health issues especially in developed countries in the last couple of decades. It is a major risk factor for the appearance of chronic diseases such as type II diabetes (DM2), high blood pressure, sleep apnea, fat liver, dislipidemia, 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 obese (MO) and super morbidly obese (SO).

Nowadays, bariatric surgery is considered the only therapeutic alternative for morbid obesity and its co-morbidities, when other strategies have failed. Likewise we have known that these kind of patients have higher incidence of difficulties and complications in both preoperative and postoperative processes. Their morbid status and co-morbid conditions can cause an aggressive inflammatory tissue response damaging the normal organ function and the excess of intra-abdominal fat can 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 of 10% of their excess weight cardiovascular risk and co-morbidities improves; it also decreases visceral fat, above all the steatosis hepatic and liver volume. 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” was published, concluding that weight loss before surgery will drastically reduce complications, operating time, blood loss, shorter hospital stay and may even help lose more weight in the long run.

Hypothetically, significant preoperative weight loss before bariatric surgery can reduce morbidity and mortality of the procedure. We consider an efficient preoperative weight loss (WL) to be at least 10% of body weight excess (EWL) in MO and a minimum of 20% in SO patients.
There are different non-invasive strategies we can use to obtain this efficient preoperative WL. One alternative is substituting meals with specially designed very low-calorie diets. These diets provide an easy way to limit daily calorie intake between 400 and 800 kcal containing while still containing all the essential nutrients for the correct nutritional status. These products are designed for special medical treatment; 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 WL, 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 gets 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 helps reduce operative time and complications, and also helps with preservation of lean body mass and resting energy expenditure.

The objective of our study is to evaluate the efficiency and tolerance of a specially formulated, complete high-protein and balanced-energy drink, during preparation for bariatric surgery (laparoscopic gastric bypass) compared to a group of patients who prepared for surgery using a very low calorie diet during regular meals. The main variable analyzed was EWL 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 at the European Center of Excellence for Bariatric Surgery at Campo Grande Hospital in Valladolid, Spain, 120 MO and SO patients, (80 female and 40 male) were selected, in preparation for Laparoscopic Single Anastomosis Gastric Bypass (LSAGB) bariatric surgery and they agreed to be part of the study by signing an informed consent waiver. We excluded patients who did not sign waiver and those who abandoned the study protocols. We also excluded patients, who did not adhere to the nutritional plan, as well as anyone who developed a health problem or required additional nutritional supplements during the study period.

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

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 hyper protein meals with no carbohydrates or fat during 12 days. The remaining 8 days were the same as group A.

Study design
Observational, prospective and randomized in 2 groups study.

Studied data
The following data was collected: Sex, age, weight, height, BMI, 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 is 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 included 120 patients, 60 in each group, Group A 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).

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 menarche or menstrual rhythm (table IV).

**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% during 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 group A had a higher average initial body weight and height 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 previously had had multiple, medically supervised, ineffective past weight loss attempts. 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 WL.

**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 WL achieved by group A with statistical significance (table VIII).

Due to the design model of the study, the difference in WL 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 have achieved a greater weight loss. In order to compensate for the difference, 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 WL between groups, when comparing it with the raw numbers in 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 WL, BMI changes seem less dramatic, but there is still a statistically important difference (table XI). After applying a covariance analysis of data similar to the used for WL, BMI changes seem less dramatic than in the raw numbers, but there is still a statistically important difference (table XI).

<table>
<thead>
<tr>
<th>Group</th>
<th>Weight loss</th>
<th>95% confidence limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>-8.218256</td>
<td>-9.010794 -7.425718</td>
</tr>
<tr>
<td>B</td>
<td>-5.870564</td>
<td>-6.684026 -5.057101</td>
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</tbody>
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**Table X**

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>120</td>
<td>46.57</td>
<td>4.79</td>
<td>34.57</td>
<td>56.69</td>
<td>46.48</td>
<td>7.02</td>
<td>45.32</td>
<td>47.82</td>
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<td>4.90</td>
<td>35.18</td>
<td>53.15</td>
<td>43.27</td>
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<td>42.01</td>
<td>44.39</td>
<td>0.0045</td>
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<tr>
<td>Group B</td>
<td>60</td>
<td>43.94</td>
<td>4.85</td>
<td>31.23</td>
<td>57.07</td>
<td>40.42</td>
<td>10.50</td>
<td>39.30</td>
<td>41.94</td>
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<tr>
<td>Total</td>
<td>120</td>
<td>45.55</td>
<td>5.04</td>
<td>32.46</td>
<td>59.93</td>
<td>44.10</td>
<td>7.65</td>
<td>43.57</td>
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<tr>
<td>Final</td>
<td>120</td>
<td>41.89</td>
<td>4.93</td>
<td>31.23</td>
<td>57.07</td>
<td>41.39</td>
<td>6.79</td>
<td>41.00</td>
<td>42.78</td>
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<tr>
<td>Group A</td>
<td>60</td>
<td>43.20</td>
<td>4.57</td>
<td>31.48</td>
<td>53.15</td>
<td>43.02</td>
<td>6.81</td>
<td>42.01</td>
<td>44.39</td>
<td>0.0045</td>
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<tr>
<td>Group B</td>
<td>60</td>
<td>40.67</td>
<td>4.93</td>
<td>31.23</td>
<td>57.07</td>
<td>40.42</td>
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<tr>
<td>Total</td>
<td>120</td>
<td>41.89</td>
<td>4.93</td>
<td>31.23</td>
<td>57.07</td>
<td>41.39</td>
<td>6.79</td>
<td>41.00</td>
<td>42.78</td>
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<tr>
<td>Difference</td>
<td>120</td>
<td>-2.61</td>
<td>1.29</td>
<td>-8.64</td>
<td>0.00</td>
<td>-2.34</td>
<td>1.71</td>
<td>-2.85</td>
<td>-2.37</td>
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</table>

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Adjusted BMI difference</th>
<th>95% confidence limits</th>
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<tr>
<td>A</td>
<td>-3.320518</td>
<td>-3.467537 -2.942825</td>
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<td>B</td>
<td>-2.174989</td>
<td>-2.476610 -1.871568</td>
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**Table XII**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Avg.</th>
<th>Std. Dev.</th>
<th>Min.</th>
<th>Max.</th>
<th>P value</th>
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<td>14.0</td>
<td>120</td>
<td>190</td>
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<td>60</td>
<td>147.2</td>
<td>13.8</td>
<td>120</td>
<td>190</td>
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<tr>
<td>Group B</td>
<td>60</td>
<td>142.7</td>
<td>14.3</td>
<td>120</td>
<td>190</td>
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<tr>
<td>Total</td>
<td>120</td>
<td>143.1</td>
<td>13.6</td>
<td>110</td>
<td>180</td>
<td></td>
</tr>
<tr>
<td>Final</td>
<td>120</td>
<td>132.2</td>
<td>13.6</td>
<td>110</td>
<td>180</td>
<td>0.04760</td>
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<tr>
<td>Group A</td>
<td>60</td>
<td>132.3</td>
<td>13.6</td>
<td>110</td>
<td>180</td>
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<tr>
<td>Group B</td>
<td>60</td>
<td>133.8</td>
<td>14.0</td>
<td>120</td>
<td>170</td>
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</tr>
<tr>
<td>Total</td>
<td>120</td>
<td>133.1</td>
<td>13.0</td>
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<td>180</td>
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<tr>
<td>Difference</td>
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<td>-9.6</td>
<td>9.1</td>
<td>-40</td>
<td>0</td>
<td>&lt;0.0001</td>
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<tr>
<td>Group A</td>
<td>60</td>
<td>-14.3</td>
<td>8.8</td>
<td>-40</td>
<td>0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Group B</td>
<td>60</td>
<td>-5.3</td>
<td>7.0</td>
<td>-20</td>
<td>0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total</td>
<td>120</td>
<td>-6.3</td>
<td>6.2</td>
<td>-20</td>
<td>0</td>
<td></td>
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</tbody>
</table>
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 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 showed 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 had to respond to an evaluation with 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 satisfactory results.

Discussion

Traditionally, the need for pre-surgery WL 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 who are MO [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 anesthesiology problems, derivative of the large volume of intra-abdominal fat, peri visceral and enlarged liver, which may lead to increased operative time, increased bleeding, possibility of restructuring, severe complications and even death. Using this line of thought, everything we do in preparation for our patients for surgery, for example, 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 pre operative preparation of the MO patients, 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 MO and a 20% like minimum in the S.O. In addition, psychological and nutritional attendance, forlorn smoking, alcohol or any other type of drugs, strict medicinal control and a weekly follow up when entering the surgical waiting list and daily 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 operation in MO and SO patients. It is worth noting that the same is reflected in the analysis of Tarnoff and some of the consulted studies, with evidence level of III [4].

The dietetic project was designed specifically for the pre operative preparation time 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 attitude is based on WL and lessening visceral and intra abdominal 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 low caloric liquid diet.

In 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 pre operative process.

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

The preoperative WL to a great extent stimulate and improves the self-esteem of the patient, adapts them better psychologically for surgery and their immediate future, and to a great extent it facilitates the fast recovery of the patient and diminish 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]. A special importance is required to decreasing liver size in the left liver lobe size in the laparoscopic approach to bariatric surgery. A fatty and hypertrophic liver, can make surgical gestures much more difficult, cause injuries and 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 hepatocytes and a considerable improvement in the degree of non-alcoholic steatohepatitis [2,3,11,10] having improved considerably the risk of intra and post-operative bleeding [16]. Similarly, the physical training of the patient is important to avoid conversions 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, demonstratives that a high protein and balanced energy formula diet of low calorie content during the pre operative stage, compared to a regular high protein diet, obtained statistically greater results in lowering arterial pressure, serum glucose, WL and BMI, which resulted in a smaller cardiovascular risk and therefore better preparation for surgery, improvement in co-morbidities, major WL and reduction in 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 [9].

Certainty, when we analyze the crude data of systolic arterial tension, it can be seen that in spite of existing percentage differences in the levels of arterial tension from the beginning 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), in the end these differences balanced out, appearing that the average values tend to be lower for the patients treated with formula diets, because of the greater normalization values (fig. 1).
If we look at 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 normal caloric 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 initial moment, after treatment, the patients dealt with balanced energy formula diet obtain lower values than the patients treated with a low-calorie regular diet (fig. 2).

Another parameter measured in our study were changes in the serum glucose levels, in both groups of patients who used a balanced energy formula diet and those who used a low-calorie regular diet. The results were similar. 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).

In the own experience of our Center of a total of 1,350 patients operated with a robotic LSABP 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 % significant EWL of at least 10-20%, showed a smaller index statistically of
operative serious complications (6.9% versus 0.6%), compared to the patients that did not lose weight before surgery. It is necessary to review the anesthetic complications that forced previous tracheotomy or definitively disabled the intubation that switched from 3.5% to 0% after a suitable pre operative preparation and weight loss presented in the protocol set out in this study (fig. 4).

In conclusion, we can remember that at this moment a suitable preparation of the obese patient for surgery is absolutely essential and inseparable from the surgical process. To reduce a minimum 10% of the %EWL in patients with MO and 20% in those with SO, and/or metabolic syndrome with central obesity, considerably reduces the peri operative complications, dangerous intubations, tracheotomies, surgical time and hospital stay.

Acknowledgements

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References