

Comparison of Preoperative Diets Before Bariatric Surgery: a Randomized, Single-Blinded, Non-inferiority Trial

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Abstract

Objective In order to increase weight loss and minimize complications, a preoperative diet before bariatric has been advocated. However, some diets are poorly tolerated by patients and this can lead to low compliance and too little weight loss. In this study, we aim to compare two preoperative diets in order to find the most suitable for this patient population.

Methods Comparison of preoperative diets before bariatric surgery with a randomized non-inferiority trial in order to compare the standard very low calorie diet (VLCD) by protein shakes (Prodimed) with a standard diet using ordinary products. The primary outcome parameter was preoperative weight loss. Secondary outcome parameters were operation time, difficulty of surgery, short-term complications, short-term weight loss and compliance, tolerance, and acceptance of the diets.

Results Two hundred twelve patients suitable for gastric bypass surgery were included and randomized. The Prodimed group contained 105 patients, the standard diet group 107 patients. Preoperative weight loss and 4 weeks after the procedure were not significantly different between the two diet groups. Operation time, difficulty of surgery, short-term complications, and short-term weight loss were also comparable without significant differences between the diet groups. However, most

of the parameters measuring patients' compliance, tolerance, and acceptance of the diets were significantly better in the standard diet group as compared to the patients in the Prodimed group.

Conclusion Protein shakes and standard diets are capable of achieving good and comparable results on preoperative weight loss before bariatric surgery. However, patients' compliance, tolerance, and acceptance were all significantly better after a standard diet. We recommend giving patients a choice in preoperative diets in order to achieve the best possible weight loss and results.

Keywords Bariatric · Gastric bypass · Preoperative diet · Randomized trial · Weight loss · Compliance · Tolerance

Introduction

Morbid obesity, defined as a body mass index (BMI) of >40 or >35 kg/m² with obesity-related comorbidities, is nowadays a worldwide growing problem [1]. At this moment, surgical therapy is the only treatment option that results in sufficient and long-term weight loss. Non-surgical approaches, like low energy diets and behavior modification, are not successful in the long term with respect to maintaining significant weight loss and decreasing obesity-related comorbidities [2–8]. Although mortality is low after bariatric and metabolic surgery, complications are common and percentages range from 5 to 20 % (Table 1) [9]. These complications, e.g., anastomotic leakage, bleeding, and infections, are partly dependent on patient factors like age, sex, and comorbidity, but certain factors can be influenced by the treating physician. In order to increase weight loss and decrease complications, a preoperative diet before bariatric surgery has been

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Table 1 Patient characteristics, weight loss, and operative details

	Prodimed (<i>N</i> = 105)	Diet (<i>N</i> = 107)	<i>P</i> value
Sex (m:f)	20:85	25:82	0.44
Age (years)	40.2	41.7	0.31
Gastric bypass/sleeve (N)	99 / 6	102 / 5	0.73
Preoperative weight (kg)	122.5	125.0	0.42
Preoperative BMI (kg/m ²)	42.8	43.1	0.71
Weight after diet (kg)	115.2	118.3	0.33
BMI after diet (kg/m ²)	40.2	41.1	0.24
Weight loss after diet (kg)	5.9	6.0	0.78
BMI loss after diet (kg/m ²)	2.6	2.0	0.43
Weight after 4 weeks (kg)	110.0	110.7	0.82
BMI after 4 weeks (kg/m ²)	38.4	38.2	0.83
Weight loss after 4 weeks (kg)	12.5	14.2	0.18
BMI loss after 4 weeks (kg/m ²)	4.4	4.9	0.30
Operation time (minutes)	44	43	0.65
VAS score	31	36	0.25
Complications (%)	5.7	4.8	0.76

advocated. It is known from literature that preoperative weight loss by means of a very low calorie diet (VLCD) has beneficial effects. For example, the difficulty of the procedure, blood loss, short-term weight loss, and short-term complications as well as operation time all seem to improve with preoperative weight loss. This has been shown in two randomized trials and a literature review [10–12]. The explanation for this phenomenon lies in the reduction in liver size and, possibly, intra-abdominal fat mass caused by VLCD's with a very low amount of carbohydrates. This in turn makes surgery, and especially laparoscopic procedures, easier. A decrease in blood loss, conversions, and complications is the result. Furthermore, preoperative dieting and weight loss stimulates the patient and helps them to stay focused and prepare for the upcoming procedure. Usually, the diet is prescribed by the bariatric clinic and consists of a VLCD in the form of commercially available protein shakes. This is easy to use and easy to explain to the patient. In our clinic, we oblige our patients to use Prodimed (Prodimed Benelux BV, Valkenswaard, Nederland) for 2 weeks before surgery. However, we noticed compliance is low because protein shakes are poorly tolerated by patients and are also quite expensive (130 euros for 2 weeks). Because the use of a diet is mandatory, we decided to investigate two different diets in a randomized non-inferiority trial, comparing VLCD (protein shakes, Prodimed) with a standard diet (no shakes, regular food low on carbohydrates) in order to rule out any differences in short-term results and compare acceptance and tolerance of the different diet regimes (Table 2).

Table 2 Diet questionnaire

	Prodimed (<i>N</i> = 105)	Diet (<i>N</i> = 107)	<i>P</i> value
Taste	5	8	0.000
Variance	6	8	0.000
Endurance	6	8	0.000
Tolerance	7	8	0.000
Applicability	6	8	0.000
Nausea	3	3	0.552
Hunger	6	5	0.188

Methods

Patients

After referral from the general practitioner, patients were screened by a multidisciplinary team consisting of an internist, a nurse practitioner, dietician, psychologist, and surgeon. During a multidisciplinary meeting, it was discussed if the patient was suitable for gastric bypass surgery. In order to consider inclusion in the present study, patients had to have a BMI >40 or >35 kg/m² with at least two obesity-related comorbidities and suitable for gastric bypass surgery. Exclusion criteria were serious and/or untreated psychiatric disorders, serious cardiopulmonary disease with an American Society of Anesthesiology (ASA) classification of 3 or higher, previous bariatric and/or gastric surgery including gastric banding and age <18 or >60 years. The purpose and procedure of the study was explained to the patient and a patient information form including an informed consent form was given. After a waiting period of at least 48 h, the patient signed the informed consent form together with the principal investigator (R.S.) during one of the preoperative counseling meetings. If the patient decided not to participate, the normal protocol was followed (Prodimed for 2 weeks before surgery).

Randomization and Blinding

Randomization took place after signing the informed consent form and approximately 3 weeks before the planned procedure during a mandatory group meeting. Sealed envelopes were used, containing a piece of paper with the text “Prodimed” or “Standard diet,” prepared by an independent secretary of the clinic. A 1:1 stratification was used with a total of 212 envelopes, 106 for each arm. During the study and data analysis, the intention-to-treat principle was respected. Only the patient and the treating dietician knew what diet the patient was following, the latter because she (I.K.) had to advice and counsel the patient during the diet period. The remaining members of the treating team, including the operating and counseling surgeon and the principal investigator, were blinded.

Diets

All patients had to adhere to one of the two preoperative diets starting 10 days before the planned surgery. Dependent on the randomization, Prodimed or standard diet was used. Both were comparable in amounts of calories, proteins, carbohydrates, and fats (Tables 3 and 4). Details of the Prodimed diet can be found in Table 3.

A typical daily schedule consisted of one breakfast sachet, one lunch sachet with vegetables, fish or meat with vegetables, and one snack sachet. Details of the standard diet can be found in Table 4. A typical daily schedule consisted of a dairy product, meat with vegetables, fish with vegetables, and a salad.

Study Parameters

Several perioperative parameters were investigated during the study. The primary outcome parameter was preoperative weight loss (in kilograms (kg), measured on a standard scale in the clinic at the start of the diet and at the morning of surgery). Secondary outcome parameters were operation time (minutes), difficulty of surgery according to the operating surgeon (visual analogue scale (VAS) with a range of 0 mm (most easy) to 100 mm (most difficult)), short-term complications (30 days), short-term weight loss (in kg, after 30 days) and compliance, tolerance and acceptance of the diets measured by a self-designed questionnaire (Table 5), and a daily diet book filled out by the patient during 10 days (example in Table 6).

Table 3 Prodimed

Breakfast	
1 sachet of hot/cold drink or 1 sachet of oat flakes	
Lunch	
1 sachet soup/omelet with unlimited vegetables per meal of list A or 100 g of list B	
Dinner	
Unlimited vegetables per meal of list A or 100 g of list B with 150 g of lean meat or 200 g of lean fish or 2 eggs, prepared with 1 spoon of sunflower oil	
Snack	
1 sachet of cold/warm drink or dessert sachet	
Daily use of at least 1.5 l of clear fluids is advised plus three multivitamin tablets	
List A: for example, endive, broccoli, and courgette	
List B: for example, aubergine, cauliflower, and tomatoes	
Total daily intake:	
Kcal	650
Protein	101
Carbohydrate	12
Fat	16

Table 4 Standard diet

Breakfast	
200 g lean quark with sweetener	
Lunch	
Unlimited vegetables per meal of list A or 100 g of list B with 100 g of lean meat or 80 g of lean fish or 1 egg, prepared with 1 spoon of sunflower oil	
Dinner	
Unlimited vegetables per meal of list A or 100 g of list B with 100 g of lean meat or 150 g of lean fish or 2 eggs, prepared with 1 spoon of sunflower oil	
Snack	
Cabbage salad with vegetables of list A with 3 slices of lean meat products or 20+ cheese, or 200 g of lean dairy products	
Daily use of at least 1.5 l of clear fluids is advised plus three multivitamin tablets	
List A: for example, endive, broccoli and courgette	
List B: for example, aubergine, cauliflower, and tomatoes	
Total daily intake:	
Kcal	647/657 ^a
Protein	81/86 ^a
Carbohydrate	20
Fat	21/25 ^a

^a Dependent on the snack 20+ cheese or lean meat products

Surgical Procedure

Patients received a daily dose of low molecular weight heparin from 5 days before until 10 days after surgery. Also, a daily dose of oral proton pump inhibitors were prescribed from 2 days before until 6 months after surgery. General anesthesia with endotracheal intubation was used in all cases. Thirty minutes before the incision, a single dose of cefazolin (1000 mg) and metronidazole (500 mg) was administered. All patients underwent standard primary laparoscopic Roux-en-Y gastric bypass with the use of four 12 mm trocars. A gastric pouch of 5 to 7 cm with an estimated volume of 25 ml

Table 5 Preoperative diet questionnaire

1. On a scale of 1 to 10 points, how would you judge the taste of the diet?
2. On a scale of 1 to 10 points, how would you judge the variance of the diet?
3. On a scale of 1 to 10 points, how would you judge the easiness to stick with the diet?
4. On a scale of 1 to 10 points, how would you judge your tolerance of the diet?
5. On a scale of 1 to 10 points, how would you judge the applicability in daily life of the diet?
6. On a scale of 1 to 10 points, how would you judge the intensity of feelings of nausea during the diet?
7. On a scale of 1 to 10 points, how would you judge the intensity of feelings of hunger during the diet?

Table 6 Example of diet book (Prodimed, day 1)

Diary Prodimed diet day 1

Breakfast, time:

Flavor of sachet:

.....

Drinks:

.....

Meal supplements/additives:

.....

Lunch, time:

Flavor of sachet:

.....

Drinks:

.....

Meal supplements/additives:

.....

Vegetables group A:.....

Vegetables group B (including amount in grams):.....

Dinner, time:

Meat/fish/eggs (amount in grams or number):

.....

Drinks:

.....

Meal supplements/additives:

.....

Vegetables group A:.....

Vegetables group B (including amount in grams):.....

Snack, time:

Flavor of sachet:

.....

Drinks:

.....

Meal supplements/additives:

.....

What did you drink in between the meals?

.....

.....

Did you have any extra food in between the meals? If so, please describe here as detailed as possible.

.....

.....

.....

(not calibrated) was created with the use of a stapling device guided by a 34 French nasogastric tube. The major omentum

was always divided. Next, the jejunum was divided at a measured length of 75 cm from the ligament of Treitz and an

antecolic, antegastric end-to-side gastrojejunostomy was created with the linear stapling technique. A double row absorbable suture was used to close the defect. After measuring a standard 150 cm alimentary limb, the continuity was restored by creating a side-to-side stapled jejunojejunostomy. The defect was closed with a single row absorbable suture. Mesenteric defects were never closed. The wounds were closed with absorbable intracutaneous sutures.

Postoperative hospital stay was standard 2 days. On day 0 (day of surgery), the patient was mobilized and received 2500 ml of Ringer's lactate solution. On day 1, the patient was mobilized at least six times and received 2500 ml of Ringer's lactate solution. On day 2, the patient started drinking clear fluids. If this was well tolerated, mobilization was sufficient and the pain easily managed with oral analgesics, the patient was dismissed from the hospital. A fluid diet was advised during the first 2 weeks and after this period, more solid food was slowly introduced with supervision of the dietician. Standard outpatient clinic consultations were planned after 2, 4, and 6 weeks. During these visits, weight loss and complications were analyzed.

Sample Size and Statistical Analysis

Based on the non-inferiority principle of the study, the null hypothesis was that Prodimed leads to more weight loss than the standard diet while the alternative hypothesis was that both diets lead to a comparable weight loss. Based on previous randomized trials, a mean weight loss of 7.8 kg with a standard deviation (SD) of 3.6 kg was expected [11, 12]. A difference in weight loss of less than 1.6 kg ($\approx 20\%$ of the mean weight loss) was regarded as clinically irrelevant. In order to achieve a statistical power of 90 % ($\beta = 0.10$) with a one-sided Alfa of 0.05, a patient group of 88 in both arms was necessary, taking an accepted difference of 1.6, a variance of 12.96, and a delta of 0.01 into account. With an expected high drop-out percentage of 20, both study arms included 106 patients. Therefore, the total study population consisted of 212 patients.

Data analysis was performed with the use of SPSS Statistics 20 (SPSS Inc., Chicago, IL, USA). Weight was expressed in kilograms with an accuracy of 0.1 kg. All data were analyzed with the Shapiro-Wilk test in order to investigate normal distribution. Weight loss in one group was analyzed with the paired *T* test, while weight loss between the groups was analyzed with the unpaired *T* test, in case of normal distribution. The established limit of the confidence interval of the difference in weight was 20 %. Results of postoperative complications and diet questionnaires were all analyzed by use of the unpaired *T* test.

Results

Basic Characteristics

Details on patient characteristics, weight loss, and operative details can be found in Table 1. There were no significant differences between the two groups (Prodimed and standard diet) in male to female ratio, mean age, preoperative weight, and BMI. Preoperative comorbidities were present in many patients and often in combinations: insulin dependent diabetes mellitus (11/5.2 %), non-insulin dependent diabetes mellitus (27/12.8 %), hypertension (78/36.8 %), hyperlipidemia (55/25.9 %), obstructive sleep apnea syndrome (20/9.4 %), and degenerative joint disease (137/67.0 %). All comorbidities were equally present in the diet groups without significant differences. Six patients in the Prodimed group and five in the standard diet group did not have a standard gastric bypass procedure but instead a gastric sleeve resection. In all cases, this was decided during the procedure because of extensive adhesions in the lower abdomen as a result of previous surgery and/or the inability to lift the intended alimentary limb to the intended gastric pouch area. This was also not significantly different in the two groups.

Weight Loss

With 5.9 kg of preoperative weight loss in the Prodimed group and 6.0 kg in the standard diet group, patients did lose weight with both the preoperative diet regimens. Weight loss and BMI loss after the diet period and 4 weeks after the procedure were however not significantly different between the two diet groups. All details can be found in Table 1.

Operative Details and Complications

Operation time (44 versus 43 min) and the VAS score of the difficulty of the operation (31 versus 36 mm) also did not differ significantly between the groups. Complications occurred in 5.7 % of patients in the Prodimed group (6/105) and consisted of a bleeding needing relaparoscopy ($n = 1$), cerebrovascular infarction ($n = 1$), gastrojejunal stenosis which needed endoscopic dilatation ($n = 1$), dehydration treated with intravenous fluids ($n = 1$), abdominal wall hematoma treated conservatively ($n = 1$), and constipation which needed readmission for laxatives ($n = 1$). Complications occurred in 4.8 % of patients in the standard diet group (5/107) and consisted of kidney stone colic ($n = 1$), internal herniation needing relaparoscopy ($n = 1$), early trocar site herniation needing open repair ($n = 1$), and urine tract infection ($n = 2$). However, this was also not significantly different between the two diet groups in terms of total number of complications.

Satisfaction with Diet

The results of the questionnaire evaluating patients' compliance, tolerance, and acceptance of the diets can be found in Table 2. The parameters "taste," "variance," "endurance" (meaning: to stick with the diet as prescribed), "tolerance" (meaning: of the diet ingredients), and "applicability" (meaning: easiness to apply the prescribed diet in daily life) were all significantly better appreciated by the patients in the standard diet group as compared to the patients in the Prodimed group ($P=0.000$ for all parameters). The parameters "nausea" and "feelings of hunger" during the diet period were not scored significantly different in the two diet groups.

Discussion

Surgical therapy is the only treatment option for morbidly obese patients that result in sufficient long-term weight loss [2–8]. However, the number of re-operations varies enormously in literature ranging from 2 to 80 % for gastric banding, 10 to 41 % for gastropasty, and 12 to 33 % for gastric bypass [13–16]. As a consequence, many technical adaptations and perioperative strategies have been put forward in order to improve outcome. One of the strategies is preoperative weight loss. It has been proven in literature that this strategy is safe and leads to better results, for example, shorter length of hospital stay, operation time, and better short-term postoperative weight loss [10–12, 17–20]. Moreover, Alger-Mayer et al. showed in 95 patients that even 4 years after the operation, preoperative weight loss was still positively correlated with percentage excess weight loss (%EWL) [21]. These studies show that preoperative weight loss is a valuable additional preparation in the morbidly obese patient. However, many patients fail to lose weight before the operation, even in a study-controlled environment, because it is usually by means of a VLCD with protein shakes. For example, in the study by Still et al., only 48 % of the patient population lost more than 10 % EWL prior to surgery [22]. In the study by Alger-Mayer et al., this was only 43 % [21]. Because of the success of preoperatively achieved weight loss and the high failure rate of VLCD's in this patient population, a well-balanced and especially well-tolerated diet is of utmost importance. It is also possible to use more invasive techniques and tools to achieve weight loss before the operation, e.g., an intragastric balloon or a duodenal-jejunal bypass sleeve. However, Vargas et al. already showed in a literature review that a VLCD is safer, cheaper, and easier to use compared to intragastric balloons [20]. Furthermore, our own previous data have shown that 1 week after the implantation of a duodenal-jejunal bypass sleeve, weight loss is comparable with results after 10 days of VLCD (BMI loss of 2.6 and 2.1 kg/m², respectively) [23]. Therefore, in our opinion, preoperative

weight loss before bariatric surgery is preferably achieved by means of a VLCD. However, the question remains what kind of diet provides the best results in terms of weight loss and patients' compliance, tolerance, and acceptance. In the present study, two different VLCDs were used, both with an average content of 650 kcal/day. The literature review by Vargas et al. has shown that a LCD (800–1200 kcal/day) is insufficient in 60 % of cases to achieve the intended 10 % EWL, while a VLCD (600 kcal/day) is able to achieve a 10 % EWL in practically all patients [20]. How this 10 % EWL is achieved is probably less important as long as it is by means of a low-calorie, low-carbohydrate diet leading to weight loss, and a reduction in liver size. For example, in the study by van Nieuwenhove et al., preoperative VLCD by use of protein shakes led to a BMI loss of 1.7 kg/m² (compared to 0.1 kg/m² in a patient group without VLCD), but 10.7 % of patients were not able to complete the allocated regimen because of intolerance of the diet, lack of adherence to the diet regimen, or both [11]. On the other hand, in the study by Gonzalez-Perez et al., a VLCD with "home ingredients" (instead of liquid substitution, i.e., protein shakes) 4 to 6 weeks before surgery led to an EWL of 14.4 %, a significant reduction in liver size and high patient satisfaction and adherence [17]. A prospective, double-blind, randomized trial was conducted by Carbajo et al., comparing protein shakes with normal meals (low-calorie, high-protein) during a preoperative period of 12 days followed by 8 days of a strictly liquid diet. Both diets were able to achieve a significant amount of weight loss (BMI loss of 3.2 and 2.2 kg/m², respectively), but protein shakes seemed to do better. However, the initial weight of the first group was significantly higher than the second group (124.8 versus 112.7 kg), and it is not defined how many kcal/day were prescribed with the normal meals [19]. Therefore, it is questionable if the patients and the diets were truly comparable. Tolerance, safety, adverse events, and patients' satisfaction were however all better with the normal meals compared to the protein shakes [19]. The present study confirms the latter findings but also had the same limitations. Both diet groups had the same prescription with unlimited vegetables from list A (see Tables 3 and 4). If the amount of vegetables was limited, the total amount of calories would have been more precise and the mean preoperative weight loss might have been higher. We tried to compensate this limitation by using a large group of 212 randomized patients.

The usefulness of preoperative weight loss before bariatric surgery has been clearly shown in literature, as well as the fact that this should be achieved with a VLCD instead of a LCD or a (minimally) invasive device. The VLCD itself has to be easy to use, cheap, well-tolerated, and leading to an acceptable weight loss. This study shows that both a commercially available protein shake diet and a standard, low-calorie high-protein, home-made diet are capable of achieving good and comparable results on preoperative weight loss. As a direct result

of this, operation time, difficulty of the procedure, and complications were also comparable. However, patients' compliance, tolerance, and acceptance were all significantly better after a standard diet compared to protein shakes. Because of these results, we recommend the use of a standard diet before bariatric surgery instead of the widely used and expensive protein shakes. At least, give your patients a choice in preoperative diets in order to achieve the best possible weight loss and results.

Compliance with Ethical Standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Conflict of Interest The authors declare that they have no competing interests.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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