

Preoperative Very Low-Calorie Diet and Operative Outcome After Laparoscopic Gastric Bypass

A Randomized Multicenter Study

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Hypothesis: A 14-day very low-calorie diet (VLCD) regimen before a laparoscopic gastric bypass procedure will improve perioperative and postoperative outcomes.

Design: Multicenter, randomized, single-blind study.

Setting: Five high-volume bariatric centers in Sweden, the Netherlands, Lithuania, Spain, and Belgium.

Patients: Two hundred ninety-eight morbidly obese patients undergoing laparoscopic gastric bypass from March 1, 2009, through December 5, 2010.

Intervention: Patients were randomly allocated to a 2-week preoperative VLCD regimen or no preoperative dietary restriction (control group).

Main Outcome Measures: Operating time, surgeon's perceived difficulty of the operation, liver lacerations, intraoperative bleeding and complications, 30-day weight loss, and morbidity.

Results: Mean (SD) preoperative weight change was -4.9

(3.6) kg in the VLCD group vs -0.4 (3.2) kg in the control group ($P < .001$). Although the surgeon's perceived difficulty of the procedure was lower in the VLCD group (median [interquartile range], 26 [15-42] vs 35 [18-50] mm on a visual analog scale; $P = .04$), no differences were found regarding mean (SD) operating time (81 [21] vs 80 [23] min; $P = .53$), estimated blood loss ($P = .62$), or intraoperative complications ($P = .88$). At the 30-day follow-up, the number of complications was greater in the control compared with the VLCD group (18 vs 8; $P = .04$).

Conclusions: Although weight reduction with a 14-day VLCD regimen before laparoscopic gastric bypass performed in high-volume centers seems to reduce the perceived difficulty of the procedure, only minor effects on operating time, intraoperative complications, and short-term weight loss could be expected. However, the finding of reduced postoperative complication rates suggests that such a regimen should be recommended before bariatric surgery.

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RESULTS WITH CONSERVATIVE modalities for treatment of morbid obesity are often unsatisfactory. In contrast, surgical intervention for severe obesity has been demonstrated to result in long-lasting effects on not only weight but also obesity-associated disease.¹⁻⁴ Therefore, the number of bariatric surgical procedures is increasing rapidly and has become one of the most commonly performed surgical procedures worldwide.⁵ Today, most bariatric surgical procedures are performed laparoscopically.⁶ Although rates of serious complications after laparoscopic bariatric surgery have decreased, varying from 5% to 20%, factors such as case mix, center volumes, definition of complications, and technical and routine aspects to facilitate the surgical procedure and to re-

duce complication rates still constitute important areas for improvement in bariatric surgery.⁷

See Invited Critique at end of article

Excess body fat is known to complicate the technical aspects of surgery and, thus, increase operating time and risk of complications. In particular, excessive intrahepatic deposition of fat^{8,9} has been claimed to increase surgical risk during upper abdominal laparoscopic surgery.¹⁰⁻¹² Indeed, an enlarged liver has been reported to be the most common cause for conversion to an open procedure during laparoscopic gastric bypass and gastric banding.^{13,14}

Several studies have shown a significant reduction in liver volume after a pe-

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riod of low caloric intake by restriction to a very low-calorie diet (VLCD) or by the use of an intragastric balloon.^{13,14} In the presurgical setting, a VLCD has been shown to result in rapid weight loss¹⁵ without compromising immune function¹⁶ or wound healing⁸ and with few adverse effects.⁹ It has been reported that 80% of the decrease in liver volume in response to the intake of a VLCD for 12 weeks is achieved already after the first 2 weeks.¹⁷ Furthermore, because most morbidly obese patients have been shown to be able to satisfactorily adhere to the strict intake of VLCD during such a limited period, it has been suggested that the use of this regimen could be beneficial in the clinical setting in terms of weight loss, operative times, and complication rates.^{15,16} However, potential negative effects of this regimen include increased costs, patient discomfort, and increased morbidity associated with undergoing a surgical procedure in a catabolic state.¹⁸ Although the use of a VLCD has been widely adopted for clinical use in patients about to undergo bariatric surgery, the clinical effects with regard to surgical outcome in terms of perceived difficulty of the procedure, operating time, intraoperative bleeding, and complication rates have not been convincingly demonstrated.

Therefore, the aim of the present study was to evaluate the clinical effects of the use of a preoperative VLCD compared with no dietary regimen in patients undergoing laparoscopic gastric bypass in a randomized international multicenter setting.

METHODS

PATIENTS AND RANDOMIZATION

During the period from March 1, 2009, through December 5, 2010, morbidly obese patients scheduled for laparoscopic gastric bypass at one of the participating centers (Ersta Hospital, Stockholm, Sweden; Kaunas Hospital, Kaunas, Lithuania; Murcia Hospital, Murcia, Spain; Ghent University Hospital, Ghent, Belgium; and Nieuwegein Hospital, Nieuwegein, the Netherlands) were included in the study. Patients were eligible for inclusion if they were 18 to 60 years of age, if previously attempted nonsurgical programs for weight loss had failed, and if their body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) was greater than 40 or greater than 35 in the presence of obesity-related comorbidity. Patients who had undergone previous bariatric or gastric operations, those with severe psychological disorders, and those who could not be expected to adhere to the study protocol because of a language barrier or for any other reason were considered ineligible. All included patients had given their written informed consent to participate after being informed orally and in writing about the purpose and nature of the study. The study protocol was approved by the ethical committees of the different participating centers. Patients were randomly assigned to a 2-week VLCD protocol (VLCD group) or to no dietary restriction (control group). At each center, a computer-generated list with information of group allocation was created, and numbered sealed envelopes in lots of 10 each were opened consecutively after patients had given their written informed consent to participate.

To avoid an uneven distribution between groups, randomization was stratified for BMI. When we reviewed the registries at the different centers retrospectively, patients with a BMI higher than 50 and of 48 or higher represented approximately 10% and

30% of patients, respectively. To enable post hoc analysis of a sufficient number of patients in each group with higher BMI, a BMI of 48 or higher was chosen as the cutoff. Throughout the study, all bariatric surgeons were blinded to patient allocation.

STUDY PROTOCOL

At the preoperative visit 2 to 3 weeks before the surgical procedure, patient characteristics and anthropometric data were recorded together with medication use and medical history, including the presence of comorbidity. Comorbidities were recorded only if they were medically treated. Information regarding the group to which patients were allocated was given to the patients by a designated study nurse who was not otherwise involved in the treatment or postoperative follow-up. Fourteen days before the surgical procedure, patients initiated the dietary regimen to which they were allocated.

On the morning of the procedure, anthropometric data were again recorded by a nurse who was unaware of the regimen to which the patient was allocated. Immediately after the procedure, the operating surgeon recorded the operating time in minutes and any complication occurring during the procedure, including the number and grading of liver lacerations, measured bleeding, and whether a conversion to an open procedure was performed. Blood loss was removed by suction and measured in the suction device container. Swabs were not used intra-abdominally at any center. Also, the perceived difficulty of the procedure was noted on a 100-mm visual analog scale for which 100 and 0 mm represented the highest and lowest degrees of difficulty, respectively.

Grading of liver lacerations, used as a surrogate, objective marker for technical difficulty, was defined using a semiquantitative scale (0 indicates none; 1, bruises; 2, capsular tears; 3, parenchymal tear without need for hemostasis; and 4, parenchymal tear with need for hemostasis).

Four weeks postoperatively, patients again underwent assessment with documentation of anthropometric data and any complications occurring within 30 days postoperatively by a blinded nurse. A definition of complications is given in the eAppendix (available at <http://www.archsurg.com>).

PREOPERATIVE DIET

The VLCD used in the study was a very low-energy diet (Optifast 800; Nestlé HealthCare Nutrition GmbH, Frankfurt, Germany) designed to replace 3 meals per day during a 14-day period. To replace 3 meals, 5 shakes per day were consumed, which provided 1906 kJ (800 kcal, including 70 g of protein, 15 g of fat, and 100 g of carbohydrates) plus the recommended daily allowance of essential vitamins, minerals, and trace elements.

Patients who were allocated to a normal diet were instructed to have their regular diet until the day of the procedure. All patients were instructed to avoid the intake of solids from midnight the day before the procedure. The intake of clear fluids was allowed until 2 hours before the induction of anesthesia.

SURGICAL TECHNIQUE

All patients underwent a laparoscopic Roux-en-Y gastric bypass by an experienced bariatric surgeon who had performed at least 50 procedures independently before operating within the study. The participating centers are high-volume centers, with more than 100 laparoscopic Roux-en-Y gastric bypass procedures performed annually. All technical aspects of the laparoscopic Roux-en-Y gastric bypass were not standardized in detail, but a 5-port technique with a 30° laparoscope was used at all centers. A laparoscopic liver retractor was used for retrac-

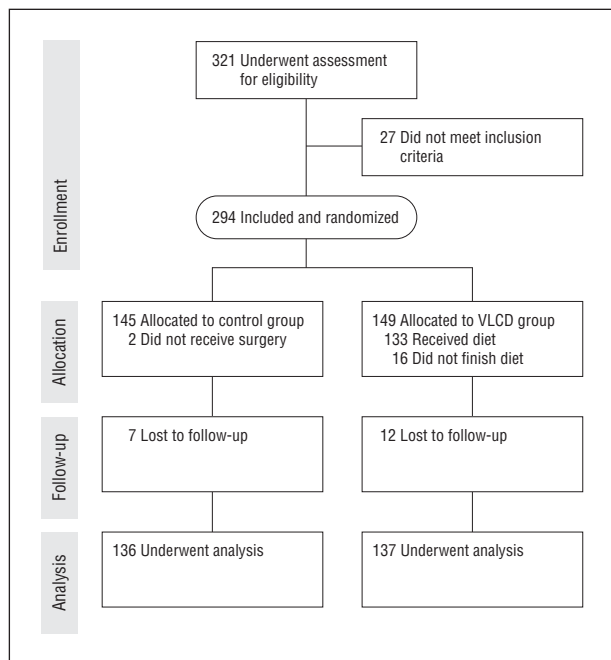


Figure. CONSORT (Consolidated Standards of Reporting Trials) diagram of the study. VLCD indicates very low-calorie diet.

tion of the left lobe of the liver, and a 4- to 5-cm gastric pouch was created by the use of linear staples. The gastroenteroanastomosis and enteroenteroanastomosis were also performed using linear staples, with a running suture for closure of the openings. The length of the Roux limb was typically 120 cm. At the end of the operation, the gastroenteroanastomosis was controlled for leakage by the use of instillation of dye or air through a nasogastric tube. Preoperative intravenous or oral antibiotic prophylaxis was given to all patients, and low-molecular-weight heparin was used as postoperative antithrombosis prophylaxis for 7 to 10 days.

STATISTICAL ANALYSIS

With operating time as the primary end point, randomization of 300 patients would identify a 10-minute difference between the 2 groups, with 80% power and an α of .05. Data are given as median and interquartile range if not stated otherwise. For comparisons within and between groups, parametric (unpaired, 2-tailed *t* test) and nonparametric (Mann-Whitney test) methods were used, as appropriate. The χ^2 test was used to compare frequency distributions. The analysis of the study was based on an intention-to-treat principle throughout.

RESULTS

From March 1, 2009, through December 5, 2010, a total of 321 patients underwent assessment for eligibility at the 5 participating centers according to the inclusion criteria. Of these, 27 did not fulfill the inclusion criteria; therefore, 294 patients were randomized to the control or the VLCD group (**Figure**).

One hundred forty-five patients were allocated to the control group, whereas 149 patients were allocated to the VLCD study group. The groups were similar regarding age, sex, anthropometrics, and the presence of comorbidity as shown in **Table 1**. In the VLCD group, 16 pa-

Table 1. Baseline Characteristics

| Characteristic | Study Group ^a | |
|--|--------------------------|--------------|
| | Control (n=136) | VLCD (n=137) |
| Age, mean (SD), y | 40.3 (9.7) | 39.7 (9.5) |
| Sex, No. of patients | | |
| Male | 41 | 40 |
| Female | 93 | 96 |
| Anthropometric measurements, mean (SD) | | |
| Weight, kg | 127.0 (22.8) | 130.3 (23.7) |
| Height, m | 1.69 (0.09) | 1.70 (0.09) |
| BMI | 43.3 (8.2) | 43.4 (10.0) |
| Waist, cm | 127 (15) | 128 (18) |
| Hip, cm | 133 (14) | 134 (16) |
| Waist to hip ratio | 0.97 (0.12) | 0.97 (0.16) |
| Comorbidity, No. of patients | | |
| DM-2 | 19 | 19 |
| AHT | 60 | 62 |
| OSAS | 15 | 21 |
| Pulmonary disease | 16 | 14 |
| CVD | 14 | 9 |
| GERD | 15 | 7 |
| Joint problems | 23 | 27 |

Abbreviations: AHT, arterial hypertension; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CVD, cardiovascular disease; DM-2, type 2 diabetes mellitus; GERD, gastroesophageal reflux disease; OSAS, obstructive sleep apnea syndrome; VLCD, very low-calorie diet.

^aBoth groups were adequately matched based on age, sex, anthropometric measurements, and comorbidities.

tients (10.7%) were not able to complete the allocated regimen because of intolerance of the diet, lack of adherence to the diet regimen, or both. In the control group, 2 patients did not undergo the procedure: one owing to difficulties associated with endotracheal intubation and the other because the patient changed her mind regarding the decision to undergo the procedure. All patients in the VLCD group underwent gastric bypass as planned. Seven and 12 patients did not show up at the follow-up visit after 4 weeks postoperatively in the control and VLCD groups, respectively. Therefore, on an intention-to-treat basis, it was finally possible to analyze data from 136 patients in the control group and 137 in the VLCD groups. From this latter group, 12 patients underwent operative procedures in Nieuwegein, 30 in Ghent, 37 in Murcia, 81 in Kaunas, and 113 in Stockholm.

PREOPERATIVE WEIGHT LOSS

The mean (SD) weight change during the 2 weeks before the procedure was -0.4 (3.2) kg in the control group and -4.9 (3.6) kg in subjects who followed the VLCD regimen (*t* test, $P < .001$). However, the mean weight the day before the procedure did not differ between the groups. Similarly, although BMI on the day before the procedure was not different between groups, the reduction in BMI was significantly higher in the VLCD (-1.7 [1.3]) compared with the control group (-0.1 [1.1]; *t* test, $P < .001$). On the other hand, no statistically significant differences could be observed in mean waist or hip cir-

Table 2. Intraoperative Variables in Patients Undergoing Laparoscopic Gastric Bypass

| | Study Group ^a | | P Value |
|--|--------------------------|--------------|---------|
| | Control (n=136) | VLCD (n=137) | |
| Operating time, mean (SD), min | 81 (21) | 80 (23) | NS |
| BMI <48 | 78 (22) | 77 (20) | NS |
| BMI ≥48 | 91 (20) | 88 (26) | NS |
| VAS of difficulty, median (IQR), mm ^b | 35 (18-50) | 26 (15-42) | .04 |
| BMI <48 | 25 (15-41) | 30 (14-45) | NS |
| BMI ≥48 | 44 (25-57) | 35 (15-45) | NS |

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IQR, interquartile range; VAS, visual analog scale; VLCD, very low-calorie diet.

^aPatients were randomized to a VLCD or a normal diet for the 14 days before the procedure. The control group included 99 patients with a BMI of less than 48 and 37 with a BMI of 48 or higher. The VLCD group included 107 patients with a BMI of less than 48 and 30 with a BMI of 48 or higher.

^bCalculated as a surgeon-perceived scale of difficulty (range, 0-100 mm). A higher score indicates a greater degree of perceived difficulty.

cumference or waist to hip ratio between the 2 groups on the day before the procedure or in the difference compared with the corresponding values 2 weeks earlier (data not shown).

INTRAOPERATIVE FINDINGS

No conversions to an open procedure occurred. Whereas the mean (SD) operating time of 81 (21) minutes in the control group was not significantly different from the 80 (23) minutes needed to complete the procedure in the VLCD group before surgery (**Table 2**), the median perceived visual analog scale of difficulty encountered by the surgeon during the operation was significantly higher in the control (35 [18-50] mm) compared with the VLCD group (26 [15-42] mm, $P=.04$; Table 2). However, no differences could be observed between groups in median blood loss (30 [10-50] mL for both groups; $P=.62$) the number of intraoperative complications ($P=.88$), or the number or degree of liver lacerations (data not shown). No sequelae were noted as a result of intraoperative liver lacerations.

We also analyzed the possible influence of a higher BMI on these variables. Therefore, the groups were divided into those with a BMI of 48 or higher or lower than 48, respectively. However, there were no statistically significant differences between the groups in operating time, visual analog scale of difficulty (Table 2), blood loss (data not shown), or number and score of liver lacerations (data not shown), irrespective of a BMI of 48 or higher or lower than 48.

FOLLOW-UP AT 30 DAYS

At the 30-day postoperative follow-up, neither mean (SD) body weight (117 [23] vs 116 [22] kg) nor total weight loss compared with baseline (13.4 [20.9] vs 17.9 [21.9] kg) was significantly different between the 2 groups. Similarly, BMI and BMI loss compared with baseline did not

Table 3. Complications Recorded at 30 Days After Surgery in Patients Undergoing Laparoscopic Gastric Bypass^a

| Complication ^b | Study Group, No. of Patients | |
|--------------------------------------|------------------------------|--------------|
| | Control (n=136) | VLCD (n=137) |
| Wound hemorrhage | 1 | 0 |
| Deep wound hemorrhage | 1 | 0 |
| GI tract hemorrhage | 1 | 1 |
| Pulmonary infection | 2 | 1 |
| Urinary tract infection | 1 | 1 |
| Wound infection | 7 | 4 |
| Pyrexia of unknown origin | 3 | 1 |
| Wound dehiscence | 1 | 0 |
| Anastomotic leak | 1 | 0 |
| All Complications^c | 18 | 8 |

Abbreviations: GI, gastrointestinal; VLCD, very low-calorie diet.

^aPatients were randomized to a VLCD or a normal diet during the 14 days before the procedure.

^bNo patient in either group experienced deep infection, sepsis, cardiac failure, renal failure, respiratory failure, rhabdomyolysis, anastomotic stenosis, deep venous thrombosis, or pulmonary embolus.

^c $P=.04$.

differ between the 2 groups at 30 days postoperatively (data not shown).

In-hospital and 30-day morbidity is summarized in **Table 3**. No mortality occurred in any group, but a significantly higher number of complications were observed in the control group compared with the VLCD group (18 vs 8, χ^2 test, $P=.04$).

COMMENT

In the present study, we demonstrated that, with modest preoperative weight reduction induced by the use of a 14-day VLCD regimen, perceived difficulty of the surgical procedure is reduced. Although this does not seem to have a major influence on operating time, risk of intraoperative complications, or short-term weight reduction, the risk of postoperative complications, in particular infections, was found to be reduced.

Despite a lack of convincing evidence of its clinical benefits, the use of a preoperative weight reduction regimen has been widely adopted in most bariatric surgical centers owing to its demonstrated effects on liver volume,¹⁷ abdominal and subcutaneous fat mass, and comorbidity,¹⁹ which has been assumed to improve intraoperative and postoperative outcomes. However, theoretically, an aggressive restriction of preoperative dietary intake might be associated with negative outcomes because malnutrition²⁰ and a short period of preoperative fasting^{18,21} have been shown to negatively affect results after the surgical procedure.^{22,23}

Some earlier studies have addressed the potential benefits associated with low-calorie diet regimens before bariatric surgery. In a small randomized study consisting of 61 patients, Alami et al¹⁵ demonstrated reduced operative times (220 to 258 minutes) without effects on major complications or conversion rates in patients who had 10% preoperative weight loss compared with those who did not. In a follow-up report of the same patients, no

differences were found regarding weight, BMI, excess weight loss, or number of comorbidities.²⁴ A major problem with these reports, apart from the small number of patients, is the very long operating time, suggesting that participating surgeons were not beyond the learning curve and that the circumstances therefore might not be representative of modern bariatric surgery. In a retrospective analysis of 884 patients undergoing open or laparoscopic gastric bypass exposed to an extensive multidisciplinary preoperative program including weight reduction, Still et al²⁵ found a higher probability of 70% excess weight loss at a mean follow-up of 12 months in those who lost more than 10% of their excess weight during the program. In a later report using a logistic regression model in the same cohort,²⁶ the authors reported that increased preoperative weight loss was a predictor of a reduction in postoperative complications and that they hoped that this “will be confirmed by prospective, controlled trials.”^{26(p1155)}

Nevertheless, in the present study, the mean weight reduction of almost 5 kg in the VLCD group compared with the control group reduced the surgeon’s perceived technical difficulty of the procedure. It could be assumed that this improvement should be increased in patients with a higher BMI; however, when we stratified patients with a BMI of 48 or higher or lower than 48, we were not able to statistically confirm this, which might be the result of a type II error.

The fact that subjective reduction of technical complexity did not influence operating time was somewhat surprising. This could be assumed to reflect that all participating surgeons were experienced enough to overcome this difference without delaying the procedure. However, it could not be excluded that, with the use of a VLCD regimen preoperatively, a reduction of operating time might be achieved in the hands of less experienced surgeons. Again, our inability to demonstrate a reduction in operating time in patients with a higher BMI might be explained by the fact that the study was underpowered for such a subgroup of the patients.

We were not able to confirm a difference in total weight loss between groups during the 30-day follow-up. However, the present study protocol was not primarily designed to evaluate any potential increased short-term weight reduction with a preoperative VLCD. Some earlier, noncontrolled data suggest that a better weight loss could be achieved by the use of a preoperative calorie restriction regimen, but whether this is an effect of the diet per se or a result of a better and earlier adaptation to post-surgical dietary habits remains to be elucidated.

Although used as a secondary outcome variable, postoperative complications could be considered even more clinically relevant than operating time. In the present study, we noted a total rate of postoperative complications after 30 days of 9.5% (26 of 273), which could be considered acceptable considering the patient population and the definitions of complications used (eAppendix). In accordance with earlier uncontrolled data,²⁶ we noted a reduced number of complications in the VLCD group (8 vs 18, $P = .04$). The mechanisms behind this reduction in complications are not entirely clear. It does not seem likely that this is a result of a less invasive sur-

gical procedure in the VLCD group because operating time, complications, and blood loss did not differ between groups. A possible explanation could be that an increase in insulin sensitivity preoperatively, induced by the VLCD regimen,²⁷ could render a better glucose control postoperatively, which has been demonstrated to reduce risk of complications in postsurgical patients.²⁸ However, because we did not monitor blood glucose concentrations in the present study, any differences between groups in this respect could not be confirmed but will be an important issue to address in the future.

In conclusion, the data from this randomized, blinded multicenter study show that, by the use of a 14-day VLCD regimen in morbidly obese patients undergoing laparoscopic gastric bypass, perceived difficulty during the operation could be reduced without a proven effect on operating time or intraoperative complications. Moreover, although this regimen does not seem to affect short-term weight reduction, our data strongly suggest a potential for the reduction of postoperative complications. We therefore conclude that a preoperative VLCD regimen should be recommended for morbidly obese patients—and also for modestly obese patients—undergoing bariatric surgical procedures.

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Online-Only Material: The eAppendix is available at <http://www.archsurg.com>.

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INVITED CRITIQUE

Weight Loss Preceding Laparoscopic Gastric Bypass Improves Acute Outcomes

In a prospective, randomized, multicenter study in patients undergoing laparoscopic gastric bypass procedures (LRYGBP), postoperative complications were reduced from 18 in control subjects to 8 in patients who were preoperatively given a diet of 800 kcal/d for 2 weeks. Surgeons, who were blinded as to who received the diet, also rated the operations as easier in those

who received the diet, although operating times were not different between the groups.

To my knowledge, this article¹ is the first to provide class I data regarding the benefits of weight loss on early operative outcomes of LRYGBP. The study was correctly designed and controlled, and therefore, the data should be reliable.