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CLINICAL REPORT

A Novel Distal Very Long Roux-en Y Gastric Bypass (DVLRYGB) as a Primary Bariatric Procedure—Complication Rates, Weight Loss, and Nutritional/Metabolic Changes in the First 355 Patients

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Abstract Proximal Roux-en Y gastric bypass (RYGB) representing the most frequently performed bariatric procedure yields a weight loss failure rate of around 20 %. In order to reduce failure rates, we established a novel distal RYGB variant characterized by a very long alimentary (Roux) limb and a short common channel. Up to 5 years, follow-up data (complication rates, weight loss, nutritional/metabolic changes) of the first 355 patients (mean±SD preoperative age, 41.4±10.8 years; BMI, 48.5±11.5 kg/m^2) who underwent the novel Distal Very Long Roux-en Y Gastric Bypass (DVLRYGB) were analysed. Overall follow-up rate was 98.9 %, mean follow-up time 1.6±1.4 years. Limb lengths were as follows: common channel 76±7 cm, biliopancreatic limb 79±14 cm, and alimentary (Roux) limb 604±99 cm. The operation was performed laparoscopically in 95.2 % of the cases. Thirty-day mortality was zero; major and minor complication rate was 4.5 % and 10.4 %, respectively. Average excess weight loss (EWL) was >74 % 3, 4, and 5 years after the operation and failure rate defined by an EWL<50 % remained<6 %. Annually blood measurements revealed a relatively low incidence rate of severe nutritional deficiencies, but mild anaemia and hypoproteinemia were frequently observed. Laparoscopic revision with a proximalization of the lower anastomosis was required in 4 (1.1 %) patients. Data indicate that our DVLRYGB leads to excellent weight loss results. Furthermore, within the setting of a structured multidisciplinary follow-up program, the incidence of severe malnutrition states was relatively low.

Keywords Weight loss failure · Malnutrition · Limb length · Supplementation

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Introduction

Bariatric surgery currently represents the most effective weight loss therapy for patients with severe obesity. According to international guidelines, bariatric surgery is indicated in patients with a body mass index (BMI) of 40 kg/m^2 or higher as well as in patients with a BMI above 35 kg/m^2 in conjunction with obesity-associated co-morbidities such as type 2 diabetes, hypertension, or obstructive sleep apnea syndrome [1]. In such patients, bariatric surgery has been shown to increase quality of life and to reduce obesity-related co-morbidities as well as overall mortality [2–5].

The term “bariatric surgery” covers a broad range of different surgical procedures that distinctly differ in their effectiveness to reduced body weight [6]. Mechanical restriction of food intake and malabsorption of macronutrients are traditionally believed to represent the principle mechanisms by which bariatric operations reduce body weight. Some bariatric procedures, however, additionally lead to an altered secretion of gastrointestinal hormones which in turn affect central nervous networks that regulate energy metabolism and eating behavior [7]. In particular, Roux-en Y gastric bypass (RYGB) surgery, i.e. the currently most frequently performed bariatric procedure [8], has consistently been shown to enhance the postprandial release of several satiety hormones such as glucagon-like peptide (GLP) 1 and polypeptide (P) YY [9]. While such hormonal effects of the surgery enhance satiety, reduce hunger, and probably even ameliorate the hedonic drive to consume palatable food [10], some patients still have an inappropriately high caloric intake that limits the extent of achieved weight loss or causes body weight regain in the long run.

High rates of treatment failure, as defined by an excess body weight loss (EWL) of less than 50 %, have been reported in many RYGB cohort studies [11, 12]. For instance, in the large cohort of Christou et al. [12] including more than 1,000 patients the long-term failure rate was 20 % in patients with a preoperative BMI between 40 and 49 kg/m^2 and 35 % in patients with a preoperative BMI between 50 and 60 kg/m^2. In order to reduce failure rates, Sanchez-Santos et al. [11] systematically varied the length of the Roux, also called alimentary, limb according to the patient's preoperative BMI. By establishing a Roux limb length of 100 cm in patients with a BMI below 50 kg/m^2 and a length of 150 cm in patients of BMI above 50 kg/m^2, they achieved relatively low failure rates of 18.5 % and 12.5 %, respectively, 5 years after the operation. Of note, the relevance of the Roux limb length in regard of weight loss had been demonstrated long before this study by Brolin et al. [13] who found a greater weight loss after establishing a Roux limb length of 150 cm compared with a Roux limb length of 75 to 100 cm. However, performing a similar systematic variation in Roux limb length (150 cm in BMI>48 kg/m^2 patients and 100 cm in BMI<48 kg/m^2 patients), Suter et al. reported on even higher failure rates, i.e. 40–50 % in BMI>48 kg/m^2 patients and 25 % in BMI<48 kg/m^2, in a Swiss cohort of severely obese patients [14].

In order to further improve weight loss outcomes, Brolin et al. [15] performed a procedure called "distal RYGB" in patients with a BMI above 50 kg/m^2 and compared the effects of this procedure with that of proximal RYGB operations displaying a Roux limb length between 50 and 150 cm [15]. In their distal RYGB variant, the Roux limb was very long but the common channel, i.e. the distance between the lower anastomosis to the ileocolic junction, was only 75 cm. As expected, results of the study clearly revealed a greater weight loss after the distal than proximal RYGB surgery. However, since the distal RYGB variant frequently also provoked severe metabolic problems, in particular anaemia, the procedure did not become widely accepted in the bariatric community. Similar experience was made by Sugerman et al. when they performed different distal RYGB variants in 27 patients who had previously been failed to lose enough body weight upon a proximal RYGB with a Roux limb length of 45 cm [16]. In the first 5 patients, a common channel of only 50 cm was established resulting in such a very severe malnutrition that all patients required an operative revision. In the subsequent 22 patients, a common channel of 150 cm was established but patients still showed relatively high rates of severe malnutrition. Of note, however, in both of these two distal RYGB variants, the Roux limb length was only 145 cm allowing the ingested food only a relatively short contact with the gut resulting in a distinctly reduced absorption of nutritions.

Müller et al. [17] recently performed a non-randomized study in which they compared the effects of distal vs. proximal RYGB in a total of 50 patients with an average BMI of about 45 kg/m^2. While the authors did not report on relevant nutritional problems, they could not detect any differences in the amount of weight loss achieved after a median follow-up period of 4 years between the two bariatric procedures. However, their distal RYGB variant displayed a common channel length between 100 and 150 cm which presumably is too long to establish a significant degree of malabsorption and thus, is unable to improve the weight loss outcome. Also, this study was obviously underpowered since the detection of a reduction of the failure rate from 20 % to 15 % with a power of 0.8 requires a sample size of more than 900 patients per group.

In clinical practice, bariatric surgeons are increasingly confronted with a substantial number of patients who have undergone RYGB surgery but are not satisfied with or even frustrated about their long-term body weight loss result. In such situations, secondary bariatric operations which establish a stronger degree of malabsorption may be offered in order to achieve a greater reduction of excess body weight. However, classic malabsorptive procedures such as duodenal switch or Scopinaro's procedure, both of which establish a biliopancreatic diversion (BPD), also carry the risk of severe nutritional deficiencies, in particular hypoproteinaemia, and chronic diarrhea [18]. Also, it must be considered that any secondary operation puts the patient on an additional risk of perioperative complications. Thus, every patient with an insufficient weight loss after RYGB brings the question into mind whether patients with an anticipated high risk of weight loss failure, e.g. due to a very high preoperative BMI or a particularly unfavorable eating behavior, should to be offered an alternative, putatively more effective procedure than a 150-cm Roux limb length proximal RYGB as a first line bariatric operation.

Addressing this question in 2002, we established a novel variant of distal RYGB as a primary bariatric procedure at our institution for patients that were assumed to have a high risk for insufficient weight loss after a proximal RYGB operation. The principle idea was to establish a strong malabsorption of nutritional fat by creating a relatively short common channel but leaving a very long alimentary limb for the transit of ingested foods that allows for a proper absorption of micronutrients and proteins being digested by proteases locally expressed by the small bowel mucosa. Here we report up to 5-year follow-up results of the first 355 patients who have undergone this so called Distal Very Long Roux-en Gastric Bypass (DVLRYGB) as a primary bariatric procedure in our institution.

Materials and Methods

Patients' Selection

A total of 355 patients were selected for offering the DVLRYGB as a primary bariatric procedure and gave written informed consent to undergo the operation. Selection criteria included a high BMI, unfavorable eating behavior characterized by a high intake of nutritional fat, and an assumed or self-reported low level of cognitively controlled eating behavior. Also, severe medical problems related to obesity such as type 2 diabetes or sleep apnea syndrome favored the offering of the DVLRYGB. Medical conditions, eating behavior, and psycho-social circumstances were carefully assessed by a multidisciplinary team comprising internists, nutritionists, psychologists, and the surgeon. However, the selection of the patient did not rely on a clear-cutely defined algorithm but rather reflected the overall clinical impression of the patient's individual situation. The final decision for offering the distal RYGB variant was made by the chief bariatric surgeon (MT) and intensively discussed with the patients.

Surgical Procedure

All operations were performed by MT. The operation was performed laparoscopically whenever possible by using 6 ports of 12 mm (in the case of concurrent cholecytectomy, an additional port of 7 mm was used). Like in proximal RYGB procedures, the largest part of the stomach was transected thereby creating a small gastric pouch of approximately 20–30 ml which was anastomized to the proximal jejunum. The pouch-jejunal anastomosis was standardized by using a 25-mm-round stabler (ECS 25 mm; Ethicon Endo-Surgery^{TM}). The biliopancreatic limb was side-to-side anatomized to the ileum 60 and 100 cm proximal from the ileocolic junction thereby establishing the common channel. The exact length of an individual's common channel was designed to count 10 % of the total length of the small bowel as measured in 5 cm intervals from the ileocolic junction to the ligament of Treitz. However, the minimal common channel length was set to be at least 60 cm. The length to the biliopancreatic limb, as measured from the ligament of Treitz to the lower anastomosis, was 60 to 100 cm depending on the individual anatomical situation. Thus, our DVLRYGB, in contrast to classical BPD procedures or the distal RYGB procedures previously performed by Sugerman [16], displays a very long alimentary limb for the passage of food and absorption of nutritions.

Preoperative Preparation

Before the surgery, all patients were carefully informed on how to adjust their eating behavior to the postoperative situation. This was done by providing at least two structured nutritional counseling sessions. Each session lasted 45 to 60 min and mainly focused on adequate protein intake and the avoidance of the consumption of foods containing high amounts of fat and simple carbohydrates after the surgery. Also, special cooking and shopping courses were offered to the patients, but participation in such courses was not a prerequisite for undergoing the surgery.

All patients were advised to lose some weight prior the operation but they did not have to follow a particular diet. Patients were also advised to do some exercise before the surgery in order to improve their physical condition. From July 2005 on, we offered the patients the participation in a special exercise program taking place within our Interdisciplinary Obesity Center (IOC). Medical conditions were improved as much as possible before the operation, e.g. by establishing an optimal blood pressure, glycemic, and lipid control by the implementation of respective pharmacological therapies or by establishing positive airways pressure ventilation in patients with newly diagnosed sleep apnea syndrome.

Follow-up Program

After the surgery, all patients were included in a structured multidisciplinary follow-up program taking place on an outpatients basis in the IOC. This included repeated consultations with the surgeon or internist 1, 3, 6, 9, 12, 18, and 24 month after the surgery. From the third postoperative year on the follow-up, intervals were extended to 12 months provided a stable clinical and psychosocial situation. In the case of any medical problem, additional consultations were offered. Apart from the consultations with the doctor, all patients had at least three nutritional counseling sessions within the first year after the surgery. Additional sessions with the nutritionist as well as psychological support by trained psychotherapists were offered whenever necessary during the follow-up.

Metabolic and nutritional blood parameters were measured before and at least once per year after the operation. A standardized supplementation regime (see below) was prescribed to all patients with individual adjustments according actual results of nutritional blood measurements. Compliance with the supplementation regime was checked by the doctors at every visit of the patients in the ICO and patients were motivated to improve their compliance whenever necessary.

Supplementation Regime

To prevent nutritional deficiencies, a standard supplementation therapy regimen including 100 mg iron/day p.o. (iron (II) fumarate or iron(III) hydroxid-polymaltose both without additional vitamin C) or 500 mg ferric carboxymaltose i.v. every 6 to 18 months, 1.5 g calcium/day p.o. (calcium carbonate, since calcium citrate is not available in Switzerland), 1,500 IU vitamin D_3/day p.o., one multivitamin pill containing trace elements per day, and one tablet of vitamin B-complex (twice a week) was prescribed to the patient. In addition, 1,000 mycro g vit B_{12} was injected i.m. every 3 months. In the case of zinc deficiency, 30 mg/day p.o. was prescribed. In the case of vitamin D_3 deficiency, additional i.m. injections of 300,000 IU were given every 3 months. Dose adjustments were made whenever necessary upon respective values of blood measurements.

Body Weight Assessment

Body height and weight were measured in all subjects while they were wearing light clothes but no shoes. The percent body weight loss (%BWL) was calculated by the formula $[((\text{preoperative weight(kg)} - \text{current weight}) / \text{preoperative weight})^{*}100]$ and percent excess weight loss (%EWL) was calculated by the formula $[(\text{preoperative weight} - \text{current weight})/(\text{preoperative weight} - (\text{height(cm)} - 100)) * 100]$ and percent excess BMI loss (%EBL) was calculated by the formula $[((\text{preoperative BMI} - \text{current BMI}) / (\text{preoperative BMI} - 25))^{*}100]$.

Metabolic and Nutritional Blood Parameters

In all patients, blood samples were drawn in the morning (8:00–11:00) after an overnight fast. Metabolic parameters were classified according to following cutoff values: glucose >126 mg/dl for patients being in the diabetic range and >100 mg/dl for patients being in the impaired fasting glucose or diabetic range. Dyslipidemia was defined as triglycerides >150 mg/dl, total cholesterol >193.0 mg/dl, LDL cholesterol >100 mg/dl, HDL cholesterol <46.0 mg/dl for women and <38.7 mg/dl for men or total/HDL cholesterol >5.0. However, it should be noted that no reliable data on the use of glucose or lipid lowering drugs were available and thus, not analysed.

Nutritional deficiencies were defined as follows: serum total protein <63.0 g/l; serum albumin <34.0, <30.0, or <25 g/l; serum vitamin B_{12} <180.0 ng/l; serum folate <2.0 μg/l; serum 25-OH vitamin D_3 <10.0 ng/ml; serum calcium <8.0 mg/dl; serum zinc <720.0 μg/l; serum ferritin <10.0 μg/l for women and <25.0 μg/l for men; hemoglobin <120 g/l and <100 g/l for women and <140 g/l and <120 gl/l for men. A serum iPTH level >65 ng/l indicated hyperparathyroidism.

Statistical Analysis

This study represents a retrospective analysis of a prospectively maintained database which was approved by the local ethic committee. Data are reported as mean±SD and percentages of the total number of included patients in the study unless otherwise indicated. Data were analysed by using SPSS 12.1 for Windows (SPSS Inc., Chicago, IL). Changes in metabolic and nutritional blood parameters over time were assessed by linear mixed models. For pair-wise comparisons, Student's *t* tests were used. A *P* value of less than 0.05 was considered significant.

Results

Patient's Characteristics and Follow-up Rates

Between February 2002 and October 2010, a total of 355 severely obese patients underwent a DVLRYGB operation as a primary bariatric procedure in our institution. The preoperative characteristics of these patients are provided in Table 1. Average follow-up time was 1.6±1.4 years and the overall follow-up rate was 98.9 %. Table 2 shows the number of patients and the follow-up rates over the 5-year course of the study. Although the follow-up rates decreased over time, they were still higher than 91 % 5 years after the surgery.

Characteristics of the Operation and Complication Rates

The characteristics of the operation are summarized in Table 3. The majority of operations (>95 %) could be performed

Table 1 Preoperative patients' characteristics

N	355
Age (years)	41.4±10.8
Women (%)	72.4
Height (cm)	165.4±11.1
Weight (kg)	131.4±22.9
BMI (kg/m^2)	48.5±11.5
BMI 35–<40 kg/m^2	9.3 % (*n*=33)
BMI 40–<50 kg/m^2	61.4 % (*n*=218)
BMI 50–<60 kg/m^2	22.8 % (*n*=81)
BMI ≥60 kg/m^2	6.5 % (*n*=23)
Diagnosis of	
Diabetes	18.6 % (*n*=66)
Arterial hypertension	49.3 % (*n*=175)
Dyslipidemia	27.3 % (*n*=97)
Obstructive sleep apnea syndrome	19.4 % (*n*=69)
Depression	17.5 % (*n*=62)
Other psychiatric disorders[a]	7.3 % (*n*=26)

Data are mean ± SD or percentages (number) of patients

BMI body mass index

[a] Other than depression

Table 2 Eligible and available patients during the follow-up

Year after surgery	Eligible patients (% of total)	Available patients (% of eligible)
0	355 (100)	355 (100)
1	213 (60.0)	213 (100)
2	171 (48.2)	168 (98.3)
3	93 (26.2)	89 (95.7)
4	40 (11.3)	37 (92.5)
5	12 (3.4)	11 (91.7)

laparoscopically. Limb length varied from patient to patient depending on the individual's total bowel length which was on average impressively long, i.e. about 760 cm. Mortality upon the DVLRYGB surgery was zero, but one patient died during the follow-up, i.e. 4.3 years after the surgery, upon progressive pulmonary cancer. Major surgical complications are summarized in Table 4 and minor surgical complications in Table 5. General complications occurred in 11 patients (3.1 %), one (0.3 %) cardiac, and 10 (2.8 %) pulmonary (3 (0.9 %) peripheral pulmonary embolism and 6 (1.7 %) pneumonia) complication.

During the follow-up, a proximalization of the lower anastomosis was required in 4 (1.1 %) patients, in two cases due to severe hypoproteinemia resulting from malcompliance with nutritional recommendations (case 1 and 2), in one case due to persistent cholegenic severe diarrhea (case 3), and in another case due to persistent chylascites of unknown origin (case 4). All of these revisions could be performed laparoscopically without any complications and the preexisting symptomatology remitted in all cases postoperatively. The time interval between the initial DVLRYGB

Table 3 Operations' characteristics

Surgical technique	
Laparoscopic	n=338 (95.2 %)
Open	n=17 (4.8 %)
Conversion[a]	n=12 (3.4 %)
Operation time	
Overall operation time (min)	139.8±42.1
Laparoscopic operation time (min)	139.1±41.9
Open operation time (min)	162.9±48.0
Limb length	
Total small bowel length (cm)[b]	759±101
Alimentary limb length (cm)[c]	604±99
Biliopancreatic limb length (cm)[d]	78.6±14.1
Common channel length (cm)	76.1±7.2

Data are mean±SD or number (percentages) of patients

[a] Started laparoscopic with intra operative conversion to open surgery

[b] Measured from the ileocecal junction to the ligament of Treitz

[c] Measured from the upper anastomosis to the lower anastomosis

[d] Measured from the ligament of Treitz to the lower anastomosis

Table 4 Major surgical complications

Number of patients with major complications	n=16 (4.5 %)
Patients with one major complications	n=14 (3.9 %)
Patients with two major complications	n=2 (0.6 %)
Onset of major complications	
Early (<30 days after surgery)	n=10 (2.8 %)
Late (>30 days after surgery)	n=10 (2.8 %)
Specific major complications	
Remnant stomach	n=1 (0.3 %)
Gastric fistula, blind	n=2 (0.6 %)
Gastrojejunostomy leak	n=2 (0.6 %)
Stapleline rupture (pouch)	n=3 (0.8 %)
Bleeding (intraabdominal)	n=2 (0.6 %)
Bowel obstruction	n=4 (1.1 %)
Small bowel (adhaesion)	n=1 (0.3 %)
Lower anastomosis	n=1 (0.3 %)
Internal hernia	n=2 (0.6 %)
Perforation (stomach)	n=2 (0.6 %)
Treatment	
Operative revision	n=17 (4.8 %)
Laparoscopic revision	n=9 (2.5 %)
Conservative treatment	n=2 (0.6 %)

Data are number (percentages) of patients

Table 5 Minor surgical complications

Total number of minor complications	n=37 (10.4 %)
Onset of minor complications	
Early (<30 days after surgery)	n=11 (3.1 %)
Late (>30 days after surgery)	n=26 (7.3 %)
Specific minor complications	
Cutis/subcutis infection	n=4 (1.1 %)
Bridge/adhaesiolysis/subileus	n=6 (1.7 %)
Blindloop (jejenunoileostomy)	n=1 (0.3 %)
Hematoma	n=2 (0.6 %)
Bleeding (intraluminal)	n=8 (2.3 %)
Gastrojejenunostomy	n=5 (1.4 %)
Jejunoileostomy	n=3 (0.8 %)
Internal hernia	n=1 (0.3 %)
Ulcus gastrojejunostomy	n=7 (2.0 %)
Stenosis (gastrojejunostomy)	n=8 (2.3 %)
Hiatal hernia	n=2 (0.6 %)
Treatment	
Operative revision	n=14 (3.9 %)
Laparoscopic revision	n=10 (2.8 %)
Conservative treatment	n=24 (6.8 %)

Data are percentages (number) of patients

Table 6 Changes in body weight parameters after surgery

Time	Weight (kg)	BMI (kg/m^2)	%BWL	% EWL	% EBL	Failure rate[a]
Pre OP	131.4±22.9	48.5±11.5		–	–	–
1-year Follow-up	87.6±18.1	32.0±6.8	34.2±8.6	69.7±18.3	73.8±19.7	9.4 % (*n*=20)
2-year Follow-up	82.3±16.1	30.0±6.2	39.0±8.4	78.4±17.2	82.6±18.4	5.4 % (*n*=9)
3-year Follow-up	84.5±16.1	29.9±4.6	38.7±8.0	77.6±17.0	81.2±18.0	3.4 % (*n*=3)
4-year Follow-up	87.3±14.9	31.1±4.3	39.4±8.9	74.6±15.4	77.6±15.9	5.4 % (*n*=2)
5-year Follow-up	92.9±19.2	32.2±5.7	41.9±8.5	75.9±14.3	78.2±15.2	0 % (*n*=0)

Data are mean±SD or percentages (number) of patients

BMI body mass index, *%BWL* percentage body weight loss, *%EWL* percentage excess weight loss, *%EBL* percentage excess BMI loss

[a] Defined as a EWL of less than 50 %

operation and the revisional proximalization was in all case less than 1 year (case 1, 4 months; case 2, 9 months; case 3, 6 months; case 4, 10 months). The length of the common channel and the Roux (alimentary) limb before and after the proximalization were as follows: Case 1: before 70 and 505 cm, and after 130 and 445 cm, respectively. Case 2: before 70 and 560 cm, and after 480 and 150 cm, respectively. Case 3: before 80 and 630 cm, and after 560 and 150 cm, respectively. Case 4: before 75 and 505 cm, and after 110 and 470 cm, respectively.

Body Weight Course

The course of body weight, BMI, %BWL, %EWL, and %EBL as well as the failure rates during the 5-year follow-up are listed in Table 6 and illustrated in Fig. 1. In most cases (85.1 %), body weight continued to decrease during the second postoperative year reaching an overall failure rate, defined as an EWL of less than 50 %, of 3.4 % 3 years after the operation. During the following follow-up years, the failure rate remained below 6 %.

Metabolic and Nutritional Blood Parameters

Table 7 summarizes levels of metabolic blood parameters before and after the surgery. Overall, there was a marked improvement of glucose and lipid levels after the surgery, with the number of patients showing abnormal glucose or lipid levels being distinctly reduced.

The course of nutritional blood parameters is shown in Table 8. Mean serum protein as well as albumin levels decreased and the number of hypoproteinemic and hypoalbuminemic patients increased after the surgery. Severe hypoproteinemia or hypoalbuminemia, however, was rarely

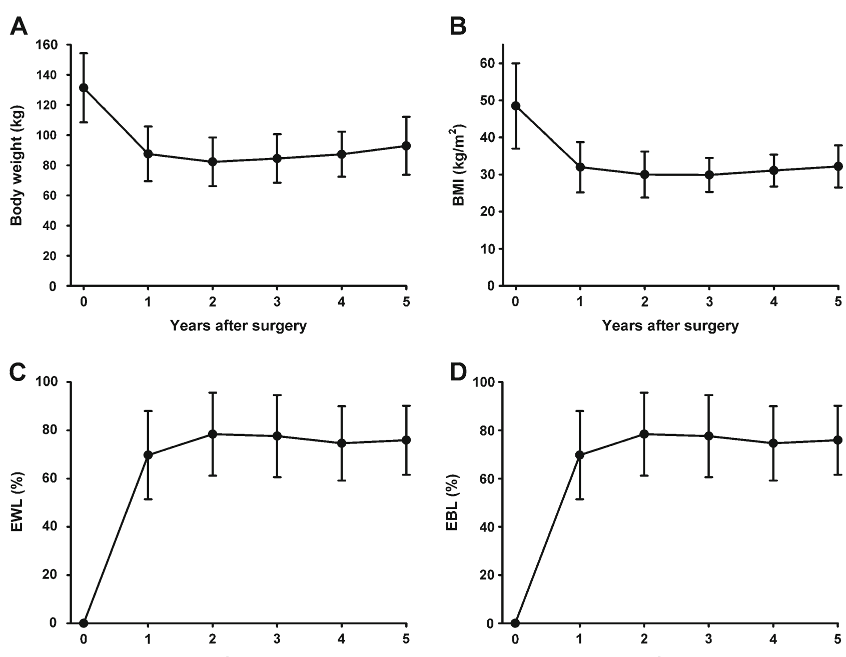

Fig. 1 Mean±SD weight (**a**), BMI (**b**), %EWL (**c**), and %EBL (**d**) course after the novel distal very long Roux-en Y gastric bypass variant

Table 7 Metabolic parameters before as well as up to five years after distal very long Roux-en Y gastric bypass

	Preoperative n=355	1 year after DVLRYGB n=213	2 years after DVLRYGB n=168	3 years after DVLRYGB n=89	4 years after DVLRYGB n=37	5 years after DVLRYGB n=11	P value overall
Glucose							
Mean±SD, mg/dl	108.1±34.2	84.7±16.2***	84.7±14.4***	88.3±21.6***	93.7±27.0**	84.7±9.0**	<0.001
Elevated levels (>126 mg/dl; %)	15.9	2.8***	2.3***	2.3	7.4	0***	<0.001
Elevated levels (>100 mg/dl; %)	42.6	6.1***	7.0***	6.3*	14.8***	0***	<0.001
Triglycerides							
Mean±SD, mg/dl	166.6±96.5	96.5±43.5***	105.2±52.6***	96.5±52.6***	114.0±78.9***	87.7±43.9***	0.024
Elevated levels (>150 mg/dl; %)	51.1	11.7***	13.1***	10.5***	20.0**	11.1**	<0.001
Total cholesterol							
Mean±SD, mg/dl	197.2±42.5	139.2±220.4***	131.5±27.1***	131.5±30.9***	135.4±23.2***	135.4±23.2***	<0.001
Elevated levels (>193.0 mg/dl; %)	51.5	3.1***	4.7***	2.6***	4.0	4.0	<0.001
LDL cholesterol							
Mean±SD, mg/dl	116.0±34.8	54.1±19.3***	58.0±19.3***	61.9±19.3***	65.7±34.8***	69.6±30.9***	<0.001
Elevated levels (>100.0 mg/dl; %)	70.1	4.1***	3.9***	8.1***	4.0***	22.2**	<0.001
HDL cholesterol							
Mean±SD, mg/dl	46.4±11.6	50.3±15.5	54.1±15.5**	54.1±15.5**	54.1±19.3	58.0±15.5	<0.001
Low values[a] (%)	41.5	38.4	27.1**	29.7*	32.0	11.1*	0.015
Cholesterol/HDL cholesterol							
Mean±SD	4.3±1.2	2.6±0.7***	2.6±0.7***	2.6±0.8***	2.9±1.1***	2.6±0.8***	<0.001
Elevated levels (>5.0; %)	27.4	2.2***	0***	1.3***	4.0***	0***	<0.001

Data are mean±SD or percentages of patients

[a] HDL <46.0 mg/dl for women and <38.7 mg/dl for men

*P<0.05; **P<0.01; ***P<0.001 vs preoperative data

observed and in most case recovered after a temporary supplementation with protein powder. However, 4 (1.1 %) patients had to be hospitalized for temporary tube feeding and, as stated above, 2 (0.6 %) patients even required surgical revision with proximalization of the lower anastomosis due to refractory severe hypoproteinemia. After this revision surgery, protein levels rapidly recovered and remained stable thereafter.

In both men and women, haemoglobin levels decreased and the prevalence of anaemia distinctly increased after the operation. However, the degree of anaemia was generally moderate and did not provoke any clinical consequences. As expected, men showed higher serum ferritin levels than women before the surgery (P<0.001). After the operation, ferritin levels increased in women while they decreased in men. The prevalence of hypoferritinemia appeared to be increased during the first two to three postoperative years in both sexes but was reduced thereafter. Mean serum zinc levels remained essentially unchanged after the operation but number of patients showing a below cut-off serum zinc concentration was found to be increased 1 year after the operation.

Serum levels of folic acid, vitamin B_{12}, and 25-OH vitamin D_3 increased after operation and deficiency rates were generally lower than before the operation. Mean serum PTH levels were reduced 1 year after the operation but tended to increase thereafter. Also, the number of patients showing a secondary hyperparathyreoidism was reduced 1 year after the operation as compared with the preoperative state, but slightly increased thereafter. Serum calcium levels slightly decreased over time but stayed well within the reference range.

Discussion

In the present study, we analysed complication rates and the course of body weight as well as of metabolic and nutritional blood parameters in the first 355 patients who have undergone our novel DVLRYGB as a primary bariatric

Table 8 Nutritive parameters before as well as up to 5 years after distal very long gastric bypass

	Preoperative n=355	1 year after DVLRYGB n=213	2 years after DVLRYGB n=168	3 years after DVLRYGB n=89	4 years after DVLRYGB n=37	5 years after DVLRYGB n=11	P value overall
Protein							
Mean±SD, g/l	69.8±8.2	64.3±5.1***	64.0±5.1***	64.0±5.5***	63.5±6.0***	60.3±9.0**	<0.001
Deficiency (<63.0 g/l) rate (%)	2.7	36.7***	35.8***	29.9***	40.7**	55.6	<0.001
Albumin							
Mean±SD, g/l	40.9±4.3	38.9±4.9***	39.8±4.2*	39.8±4.2*	38.9±11.9*	31.7±11.9*	<0.001
Deficiency (<34.0 g/l) rate (%)	4.0	13.3	6.8	7.7	4.2	22.2	0.28
Deficiency (<30.0 g/l) rate (%)	1.2	4.0*	3.0	3.9	0**	11.1	0.016
Deficiency (<25.0 g/l) rate (%)	0.3	1.3	0.8	0	0	11.1	0.18
Vitamin B_{12}							
Mean±SD, ng/l	271±114	318±249**	347±300**	317±232	474±396**	424±218*	0.004
Deficiency (<180 ng/l) rate (%)	18.5	16.6	21.2	28.0	20.0	11.1	0.12
Folic acid							
Mean±SD, μg/l	5.4±3.0	12.8±6.3***	13.6±9.9***	13.3±5.5***	13.3±4.7***	12.9±6.9**	<0.001
Deficiency (<2.0 μg/l) rate (%)	2.2	0.5	0.8	0	0	0	0.17
25(OH)Vit D_3							
Mean±SD, ng/ml	20.2±14.7	30.7±14.4***	28.8±14.4***	29.7±14.4***	27.1±11.3**	33.2±8.7**	<0.001
Deficiency (<10.0 ng/ml) rate (%)	18.4	7.2***	5.5***	4.0***	0***	0***	<0.001
Parathormone							
Mean±SD, ng/l	55.7±29.8	45.2±21.4***	56.4±40.4	56.3±25.5	60.9±27.3	61.2±20.8	<0.001
Hyperparathyroidism (>65 ng/l)	24.9	14.1**	24.8	29.7	50.0*	33.3	0.003
Total calcium							
Mean±SD, mg/dl	9.3±0.04	9.0±0.04	9.8±0.04	9.0±0.04	9.0±0.08	8.9±0.12	<0.001
Deficiency (<8.0 mg/dl) rate (%)	0.7	0.4	0	0	0	0	0.556
Albumin adjusted calcium							
Mean±SD, mmol/l	2.28±0.01	2.26±0.01	2.23±0.01	2.24±0.01	2.28±0.002	2.31±0.03	0.017
Zinc							
Mean±SD, μg/l	908.6±196.1	849.8±222.3	941.3±353.0	960.9±261.5	928.3±163.4	895.7±183.0	0.05
Deficiency (<720.0 μg/l) rate (%)	14.7	32.9***	19.9	6.7*	12.0	33.3	<0.001
Ferritin women							
Mean±SD, μg/l	62±52	101±83***	89±92**	102±172	84±107	191±111*	<0.001
Deficiency (<10.0 μg/l) rate (%)	5.2	3.1	2.3	10.0	6.3	0***	<0.001
Ferritin men							
Mean±SD, μg/l	174±128	139±118	104±72***	100±122**	124±119	161±165	<0.001
Deficiency (<25.0 μg/l) rate (%)	2.3	9.8	6.8	7.7	0	0	0.01
Hemoglobin women							
Mean±SD, g/l	140±20	130±11***	132±30*	127±21***	120±12***	126±11**	<0.001
Deficiency (<120 g/l) rate (%)	2.5	17.3***	21.6***	20.0**	57.9***	42.9	<0.001
Deficiency (<100 g/l) rate (%)	0.4	0.6	0	2.0	5.3	0	0.16
Hemoglobin men							
Mean±SD, g/l	151±19	140±21**	136±23***	139±14***	141±21	129±35	0.018
Deficiency (<140 g/l) rate (%)	14.3	39.7**	46.7***	40.7*	44.4	50.0	0.034
Deficiency (<120 g/l) rate (%)	1.1	6.4	4.4	7.4	11.1	50.0	0.98

Data are mean±SD or percentages of patients

DBG distal gastric bypass

*P<0.05; **P<0.01; ***P<0.001 vs. preoperative data

procedure in our institution. While the average follow-up time was still relatively short (i.e. 1.6 years), the number of patients displaying a follow-up of 4–5 years was still sufficient to obtain reliable midterm results. Importantly, the follow-up rate in our study was extraordinary high, thereby excluding a strong biasing influence of follow-up drop outs. Overall surgical and general complication rates after our DVLRYGB appear to be comparable with those reported after proximal RYGB surgery [19–24]. Even more important, in our series the occurrence of severe nutritional problems was relatively low compared with nutritional complication rates previously reported after different distal RYGB variants [15, 16]. Weight loss results characterized by an EWL of more than 74 % and a failure rate of less than 6 % over 5 years as well as the marked improvement of metabolic blood parameters are obviously excellent and underscore the effectiveness of the operation.

Nutritional problems were relatively mild in most cases and seldom required medical interventions. However, it is important to note that we observed some alterations in nutritional blood parameters that definitively call for attention. In particular, a substantial number of patients showed an, albeit mild, anemia, and hypoprotein/albuminemia. While such a state may not provoke any adverse symptoms, its long-term consequences remain to be explored. Furthermore, it needs to be emphasized that results in our study were obtained within a setting of a structured multidisciplinary follow-up program which included a standardized supplementation regime. It appears questionable whether similar results can be obtained in less intensive follow-up settings. However, our study might be regarded as a “proof of principle” in the view that within an optimal follow-up program excellent weight loss results can be achieved by our DVLRYGB without provoking severe nutritional problems.

As expected, metabolic variables such as fasting glucose and lipid levels greatly improved after the DVLRYGB surgery. However, these data need to be interpreted with caution since we did not systematically monitor the medication of the patients. While this shortcoming could certainly have biased our results, it should also be mentioned that in our experience most patients rather reduce than increase the intake of glucose or lipids lowering drugs after DVLRYGB.

The relevance of the amount of weight loss achieved by bariatric operations has been taken into question by several bariatric surgeons since even suboptimal weight loss appear to be associated with an improvement in quality of life [4, 14]. On the hand, however, analyses of carefully assessed psychometric data in the Swedish Obese Subjects (SOS) study clearly indicated that the improvement in most psychometric parameters correlate with the amount of achieved lost weight in the long-term [25]. Unfortunately, we did not systematically assess quality of life in our patients so that in conjunction with the lack of an adequate control group it remains unknown whether our excellent weight loss results were associated with an even greater improvement in quality of life.

Patient selection in our study did not follow a clear-cutely predefined algorithm which clearly represents a weakness of our study. The decision to offer the novel DVLRYGB to a patient was mainly based on results of a multidisciplinary evaluation, which took into account the degree of obesity, comorbidities, eating behavior, and the psychosocial situation of the patients. Obviously, such a selection regime is highly vulnerable to personal experiences and attitudes which could have biased our results. While our approach to allocate patients to distinct bariatric procedures likely represents the clinical practice performed in most bariatric institutions, i.e. decisions being mainly based on personal experiences, there is clearly a great need to establish and validate objective allocation algorithms. However, the fact that strong and reliable predictors for the outcome after distinct bariatric procedures have not been identified yet makes it very difficult to set up evidence-based algorithm at this point.

In conclusion, our study demonstrates that excellent weight loss results in conjunction with acceptable risks can be achieved with the DVLRYGB. However, we also want to emphasize that in our view a structured follow-up program carried out by a multidisciplinary team represents a prerequisite for offering such an operation to severely obese patients. Also, a longer follow-up period will be required to assess the long-term efficacy and safety of the DVLRYGB procedure.

Conflict of Interest No conflicts of interest were declared by any of the authors: MT, PB, BE, BS.

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