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Long-Term Results of Laparoscopic Roux-en-Y Gastric Bypass: Evaluation After 9 Years

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Abstract This retrospective study aimed to evaluate the long-term results of the laparoscopic Roux-en-Y gastric bypass (LRYGB) procedure performed at our department of bariatric surgery. The 126 consecutive patients treated by LRYGB between January 1, 2001 and December 31, 2002 were analyzed in August 2011. Seventy-seven patients (61.1 %), including 18 who had had previous bariatric surgery, were available for evaluation after 9.4±0.6 years (range, 8.7–10.9 years). Eight patients (10.4 %) suffered from type 2 diabetes mellitus (DMII) at the time of surgery. Initial body mass index (BMI) was 40.3±7.5 kg/m^2 (range, 24.5–66.1 kg/m^2). There was no postoperative mortality, but two patients died of causes unrelated to the surgery. Some 9 % of the patients suffered from internal herniation, despite the closure of potential hernia sites. With time, the patients had the tendency to experience weight regain: percentage of excess BMI lost was 56.2±29.3 % (range, −78.8 to 117.9 %), down from a maximum of 88.0±29.6 % (range, −19.7 to 197.1 %), that had been obtained after a median of 2.0 years (range, 1–8 years). LRYGB was effective for diabetes control in 85.7 % of the affected patients, but, surprisingly, 27.9 % developed new-onset diabetes. The weight regain in this latter patient group was statistically not different from the nondiabetic group. Conversely, four patients required hospitalization for hypoglycemic syndrome. Two patients underwent reversal of their bypass for problems linked to glucose metabolism (one hypoglycemia, one DMII). Patient quality of life was fair. The patient satisfaction remained good in 76 % of the cases.

Keywords Laparoscopic Roux-en-Y gastric bypass · Long-term results · Reoperations · Type 2 diabetes · New-onset diabetes · Hypoglycemia

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Introduction

Due to the obesity epidemic, the search for an adequate surgical option for weight reduction is a priority. In 1999, we decided to surgically treat morbid obesity by laparoscopic Roux-en-Y gastric bypass (LRYGB) in selected cases based on the unsatisfactory long-term results of laparoscopic adjustable band gastroplasty (LAGB) [1] and because laparoscopic gastric bypass was emerging at the time as a valuable bariatric option [2]. After the unavoidable [3] learning curve, we performed LRYGB routinely starting in 2000 and followed the codification of the procedure that we had achieved [4]. The purpose of this retrospective study was to analyze the long-term results of the "mature" LRYGB procedure performed in our department, which is a high-volume bariatric unit. Considering the recent introduction of gastric bypass as a "metabolic" operation [5–7], the outcome of diabetes is also discussed.

Methods

Between January 1, 2001 and December 31, 2002, 126 patients underwent LRYGB in our department of obesity surgery. This group comprised first-time surgical patients (primary LRYGB or PLRYGB) as well as patients who previously had undergone unsuccessful bariatric surgery (secondary LRYGB or SLRYGB). The new surgical patients were selected for this procedure instead of another laparoscopic operation based on an empirically established algorithm (Fig. 1). The preoperative workup consisted of an extensive bloodwork, an abdominal ultrasound, a dietary and psychological evaluation, and an endocrinology consultation.

The LRYGB procedure involved the creation of a very small gastric pouch, a biliary limb of approximately 50 cm, and a Roux limb 150 cm in length, placed in an antecolic, antegastric position. In primary cases, the anastomosis was performed by a circular mechanical technique using a 25-mm anvil introduced perorally [8]. In case of revisional LRYGB, the anastomosis was preferably handsewn [8]. The mesenteric defect and the Petersen defect were both systematically closed using a purse string of nonresorbable suture material. After discharge from the hospital, the patients were advised to refrain from eating fast sugars and to take multivitamins, calcium, and zinc. The patients were urged to come for a checkup, including extensive bloodwork, every 3 months the first year after surgery, every 6 months the second and third years, and once every year thereafter.

In August 2011, the patients were called to the office for clinical evaluation and bloodwork. This study was approved by the ethical committee of the hospital and the costs involved were entirely paid for by one of the authors (JH).

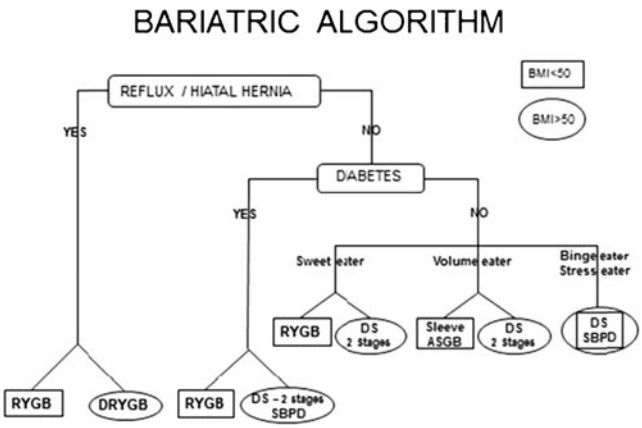

Fig. 1 Empirically established bariatric algorithm as we used in 2001–2002. *RYGB* Roux-en-Y gastric bypass, *DRYGB* distal Roux-en-Y gastric bypass, *DS* duodenal switch, *SBPD* Scopinaro biliopancreatic diversion, *Sleeve* sleeve gastrectomy, *BMI* body mass index

The patients who declined to visit the office were approached by telephone and asked to answer a questionnaire addressing the following important outcomes: weight loss progress, changes in dietary habits, quality of life (QOL) with special attention to procedure-related side effects, satisfaction with the procedure, and finally, the progression of DMII. DMII was diagnosed on clinical grounds when oral antidiabetic agents and/or insulin were taken by the patient and on blood analysis when a value of fasting plasma glucose >105 mg/dl and/or glycated hemoglobin (HbA1c) >6.0 % was documented. The patients were weighed in the office and changes in weight were plotted against previous recordings in their charts. Changes in weight between two recordings were considered linear. In cases of telephone contact, changes in weight were evaluated by recording and plotting the most recent weight reported by the patient with the weight values that were previously recorded.

Patient QOL was evaluated according to the Bariatric Analysis and Reporting Outcome System (BAROS) score, which evaluates the results of obesity treatment by analyzing three psychomedical aspects: weight loss, changes in comorbidities, and QOL [9]. In this system, up to three points are allowed for each category, and points are deducted for reoperations and complications.

Patient satisfaction with the procedure was evaluated by answering “yes” or “no” to the simple question “Would you undergo the operation again?”. This is a straightforward means of evaluation when a variety of continuous and categorical variables intervene to establish a final subjective impression [10].

Statistics

Microsoft Excel was used for data management. The McNemar test for paired variables was used for the statistical analysis of categorical data. The *t* test for paired variables was used for the analysis of changes in weight, body mass index (BMI; calculated as the weight in kilograms divided by the height in meters squared), and percentage of excess BMI lost (%EBMIL; calculated as the difference between the initial and the postoperative BMI divided by the preoperative BMI in excess of 25 (considered the ideal BMI) multiplied by 100). Results are represented as mean values, standard deviation, and range or median values with the range. Statistical significance was reached at $p<0.05$. Statistical analysis was done with the SPSS statistical software (SPSS Inc., Chicago, IL, USA).

Long-Term Results

Complete data were obtained for 77 patients (61.1 %). Sixty-one (79.2 %) of the patients were women. The mean age was 38.9±10.6 years (range, 17–64 years) at the time of surgery, and the initial BMI was 40.3±7.5 kg/m^2 (range, 24.5–66.1 kg/m^2). The low initial BMI of some of the patients can be explained by the fact that 18 of the patients (23.4 %) had previously undergone another bariatric procedure and, while all 18 were showing weight regain, some had not yet reached the 35 or 40 kg/m^2 mark again.

Of the 77 patients, 8 (10.4 %) were diabetic at the time of surgery. All of these patients underwent the LRYGB as a primary procedure. Two (one man) were treated with insulin, and six (one man) were treated with at least one oral antidiabetic agent.

Mean follow-up was 9.4±0.6 years (range, 8.7–10.9 years). Two patients (2.6 %) died of unrelated causes 7 and 9 years after the procedure: one diabetic patient died of metastatic colonic and prostate cancer in his seventh postoperative year and one patient committed suicide in the ninth postoperative year due to marital problems unrelated to her surgery. Fifty-one of the 75 surviving patients (68.0 %) were interviewed and examined in the office by three of the authors (JH, AV, and WE) and complete fasting bloodwork was performed. The remaining 24 patients were evaluated based on answers to the standardized questionnaire obtained over the telephone.

Reoperations

Seven patients (9.3 %) suffered an internal herniation that occurred after a median of 4.8 years (range, 1–9 years) after LRYGB. This condition was approached successfully by laparoscopy in all cases. It was not possible to determine the exact site of the hernia (mesenteric defect or Petersen defect) based on the operative notes.

One patient with primary LRYGB developed a perforated benign ulcer of the gastric remnant 9 years postoperatively and was treated laparoscopically. Two patients underwent laparoscopic hiatal hernia (HH) repair; however, one of them, who previously had been treated by LAGB, required a laparoscopic revision of the hiatal repair and subsequently needed an esophageal plastic stent (Polyflex, Boston Scientific, Natick, MA, USA) for stenosis at the hiatus. The final outcome was good.

One patient developed a gastrogastric fistula 9 years after SLRYGB after LAGB and was treated by laparoscopic subtotal gastrectomy of the remnant. Three patients who had undergone primary LRYGB required reoperation for metabolic issues: one severely diabetic patient was treated by distalization (reimplanting the alimentary limb at some 150 cm proximal to the ileocecal valve); two patients required reversal of their primary bypass after 9 years for glycemia issues, including one with hypoglycemia syndrome and one with new-onset DMII that was extremely difficult to adjust because of noncompliance with the dietary restrictions. A post-reconversion oral glucose tolerance test was normal in both patients.

Long-Term Weight Loss

Overall BMI at the time of the study had reached a plateau at a mean of 30.0±6.0 kg/m^2 (range, 19.7–50.5 kg/m^2) after a nadir at 25.1±5.1 kg/m^2 (range, 17.5–40.1 kg/m^2) that was obtained after a median of 2.0 years (range, 1.0–8.0 years). The maximum %EBMIL was 88.0±29.6 % (range, −19.7 to 197.1 %), while the %EBMIL at the time of the study averaged 56.2±29.0 % (range, −78.8 to 118.0 %). The difference between the maximum and actual %EBMIL was statistically different ($p<0.0001$). The progression of BMI can be found in Fig. 2.

If we analyze the patients who underwent PRYLGB and exclude the patients who had the bypass as a revisional procedure, we find a similar weight loss pattern: the PLRYGB patients' overall BMI at the time of the study was 29.5±5.5 kg/m^2 (range, 21.2–42.8 kg/m^2), after a minimum of 24.4±4.5 kg/m^2 (range, 17.5–39.2 kg/m^2), obtained after 2.0 years (range, 1.0–7 years). The maximum %EBMIL was 90.3±18.7 % (range, 52.0–130.0 %) and the final %EBMIL was 62.9±23.0 % (range, 12.9–104.1 %). The weight loss progression (maximum %EBMIL and final %EBMIL) in the

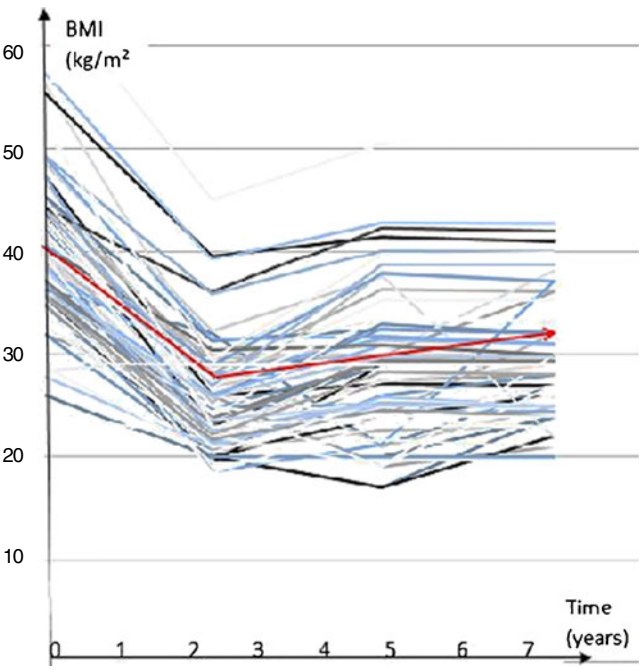

Fig. 2 Progression of the BMI with time after LRYGB in our cohort of 75 surviving patients. The *red arrow* represents the mean BMI

PLRYGB group was statistically not different from the progression in the entire group (p=0.433 and p=0.115, respectively).

Long-Term Results for DMII and Glucose Metabolism

Of the eight preoperatively diabetic patients, one died of cancer. Of the seven survivors, one male insulin-dependent patient was in full remission at the time of evaluation. One female insulin-dependent patient was able to switch to oral antidiabetic agents after distalization of the bypass. Of the five remaining surviving patients initially treated with oral antidiabetic agents, four (80 %) were in remission (HbA1c <6.1 % and/or fasting plasma glucose <105 mg/dl) and off medication.

Of the 68 surviving patients who preoperatively did not suffer from DMII, 19 patients (27.9 %) presented new-onset DMII: 15 of the 45 patients (33.3 %) in whom bloodwork was available and who presented biochemical evidence of new-onset DMII and 4 additional patients for whom bloodwork was not available but who reported being treated for DMII.

- In analyzing the link between the weight changes and the appearance of new-onset DMII in the 19 patients, there appeared to be no link between weight regain and new-onset DMII: final %EBMIL in the subgroup of the "de novo diabetic" patients averaged 57.8±26.0 % (range, 10.9–117.9 %) [maximum %EBMIL was 94.2±34.5 % (range, 48.0–197.1 %)]; this value was not statistically different from the weight progression in the group of 49 individuals who had no history of DMII and who did not develop DMII [%EBMIL 55.0±31.5 % (range, −78.8 to 104.1 %), p=0.7371] [maximum %EBMIL 87.6±28.8 % (range, −19.7 to 130.0 %), p=0.423].
- In analyzing the demographics of the 19 new-onset diabetics, there appeared to be no link between the gender and age distribution and the development of new-onset DMII: in the group of new diabetics, all but 4 patients were women (78.9 %) and the age at operation was 40.1±9.8 years (range, 28.3–57.0 years), whereas in the group who remained disease-free, 39 of the 49 patients were women (79.6 %) and the age was 39.0±11.3 years (range, 17.0–64.0 years) (p=0.921).
- In analyzing the influence of previous weight loss operations on the appearance of new-onset DMII, there appeared to be no difference between the PLRYGB group and the SLRYGB group: 4 patients in the redo group developed DMII (4/18=22.2 %) versus 15 in the primary bypass group (15/50=30.0 %) (p=0.309).

The distribution of patients suffering from new-onset DMII can be found in Fig. 3. Of the 49 patients who never suffered from DMII, 4 required hospitalization for severe symptoms objectively linked to hypoglycemia (glycemic value under 50 mg/dl during the symptoms), including seizures in 3 and invalidating fatigue and fainting in a fourth patient. This latter individual eventually required reconversion of her bypass.

Long-Term QOL and Patient Satisfaction

The BAROS score was 2.03±1.96 (range, −2 to 7), which represents a "fair" result [9]. Fifty-seven of the patients (76.0 %) were happy or very happy with the procedure and indicated that they would opt to have the operation again.

Discussion

Limitations of the Study

1. There was a follow-up rate of approximately 60 % in this cohort, which may seem relatively low. Follow-up rates of over 90 % are typically reached in Sweden [10] and Australia [11], but not in Europe or in the USA. Higa reported a follow-up rate of 26 % after 10 years, but only 7 % of patients were actually seen in the office [12]. Clearly, patient follow-up plays an important role in bariatric surgery, and patients lost to follow-up tend to lose less weight [13]. There is extensive literature emphasizing the need for adequate follow-up to obtain better clinical results after bariatric surgery, particularly for restrictive operations [14, 15]. Recently, the literature has mentioned, however, that compliance with office visits is less important for LRYGB than for LAGB [16].
2. The study is retrospective. Despite the fact that the patients were consecutive and that the database was maintained in a prospective manner, many patients were not seen for a long period of time prior to being seen in the office or interviewed by telephone in August 2011. Because of these factors, changes in weight over time can only be estimated for a number of the patients. In addition, data gathered from telephone interviews must be approached with caution, as patients have the tendency to underestimate their weight [17] or they may underestimate their weight loss and exaggerate possible side effects and complications in cases of animosity towards the surgeon for whatever reason [18]. Concerning the data on DMII and hypoglycemia, we limited the information on the patients interviewed by telephone to objectively verifiable elements, such as the use of antidiabetic agents confirmed by the patient's general practitioner and the data recorded during a hospital stay for symptoms related to hypoglycemia.
3. The initial mean BMI of the patients in our series was lower than the values generally mentioned for LRYGB

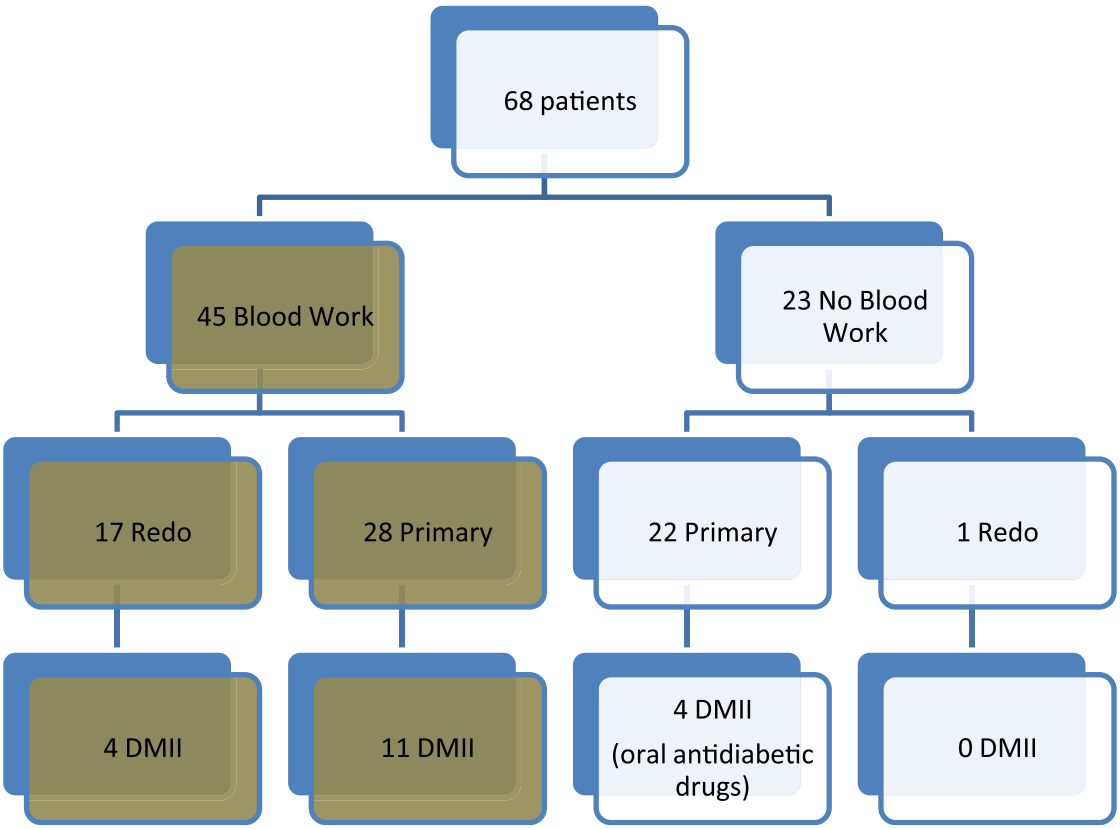

Fig. 3 Progression of de novo DMII in the 68 surviving preoperatively nondiabetic patients some 9 years after RYGB. Distinction is made between the primary and redo cases and between the diagnostic approach: bloodwork (*dark squares*) and history (*white squares*). DMII was diagnosed when HbA1c was >6.0 % and/or fasting plasma glucose was >105 mg/dl on blood analysis or when the patients were taking antidiabetic drugs according to their general practitioner. *DMII* type 2 diabetes mellitus, *Primary* patients who underwent the bypass as a first procedure, *Redo* patients who underwent the bypass after another bariatric procedure

in the literature [19]. This could be an important factor in terms of glucose metabolism. There is evidence that glycemic control by Roux-en-Y gastric bypass (RYGB) is not as good in patients with lower BMIs compared to more obese patients [20]. This might be an indication that we cannot extrapolate our results to the entire morbidly obese community.

4. Our cohort consisted of patients who had undergone primary or revisional LRYGB. It has been advocated by some that patients do less well after redo surgery [21]. However, a growing number of patients in our practice undergo LRYGB as a revision procedure, and the incidence presently reaches 45 %. Our cohort can, therefore, be considered representative of our bariatric practice. In addition, we and others have demonstrated that the results in terms of weight loss do not differ after primary versus redo bypass, despite an increased number of complications [22–24].

Despite our policy of closing the defects, the incidence of internal hernias (IH) after LRYGB (9.3 %) is alarming. Most authors advise the systematic closure of all possible mesenteric defects during the procedure [25, 26]. According to the literature, nonclosure of the defects with the LRYGB technique (antegastric, antecolic), as used in this study, results in an IH rate of 6.9 % [27]. Higa [12] recently demonstrated that, after his team adapted the policy of systematic closure of both the mesenteric defect and the Petersen defect with nonresorbable material, the occurrence of IH after transmesocolic antegastric LRYGB dropped from 16 % to <1 %. Conversely, Rosenthal's team claims that the chances of developing an IH are low and do not justify the additional time and possible complications required for the closure [28]. The series presented in this study had an incidence of IH after antegastric antecolic LRYGB that is considerably higher than previously reported. When patients were reexplored for IH, the polypropylene material that we had used could be seen, but it had obviously cut through the tissues and usually both defects had reopened. Alternative ways of closure are worth investigating [29, 30].

Two patients developed an HH with significant gastroesophageal reflux disease (GERD) and required reoperation,

a finding that somewhat contradicts the paradigm that LRYGB constitutes a preferred treatment for GERD [31]. It is noteworthy that repeated dissection of the hiatus can be hazardous especially after redo bypass [32], as one of our patients experienced. One patient required reoperation for anastomotic ulcers, a condition that has been extensively described in the literature [33–35].

The RYGB is a hybrid restrictive–malabsorptive procedure [36]. The laparoscopic version has become a well-established bariatric operation and produces persistent, positive results [37]. In this series, the overall results of weight loss recorded for some 9 years after PLRYGB and SLRYGB seem to deteriorate after 2 years. Hence, unlike others [21], we found a similar weight loss pattern in primary and revisional LRYGB [22]. In most instances, the development of poor eating habits is an evident suspect for this undesired development [14]. However, gastrogastric fistula must be ruled out in case of substantial weight regain [38], as demonstrated by one of our patients.

The majority of our patients suffering from DMII greatly benefitted from the procedure. The salutary effect of RYGB on DMII has been widely described [39–43] and can be explained by the enhanced secretion of incretins secondary to the duodenal exclusion and to the rapid transition of food stuffs to the distal small bowel [40]. An additional important factor intervening in the remission of DMII is the weight loss induced by the procedure [41, 42]. Actually, one patient experienced improvement of her diabetic condition after benefitting from significant additional weight loss after distalization of the bypass.

Interestingly, none of our patients experienced a recurrence of their condition despite some weight regain, a condition that has been linked to the reemergence of DMII [44, 45]. On the other hand, we found an unexpectedly high incidence of new-onset diabetes. The cause of this evolution is not clear and, according to our data, cannot be explained by weight regain, gender, age, or previous bariatric interventions. One obvious reason, again, could be poor eating habits [14]. Evidently, the number of patients suffering from new-onset diabetes must be weighed against the normal progression of the disease in an obese population over a 9-year period. According to the literature, the incidence of diabetes in an obese population that underwent gastric bypass is comparable to the incidence in the general population [10]. In the Western world, the incidence of new-onset DMII is approximately 4 % over 10 years [46]. For obese and morbidly obese patients, however, this number increases significantly [47, 48], but the odds of developing DMII do not change significantly if the patients' BMI remains below 30 kg/m^2 [46]. In our study, the "new diabetics" reached a final BMI of just 31 kg/m^2. With this value, the incidence of DMII we observed was far more than expected given the odds.

We found that the bypass construction can generate the hypoglycemic syndrome, as was found in at least four of our patients. The exaggerated insulin response to an oral glucose challenge, which is typical for patients following RYGB and might be responsible for the early remission of DMII [49, 50], can result in this condition. The relative risk for developing the hypoglycemic syndrome is seven times higher after bypass than in the general population [51, 52]. The consequences can be devastating in that hypoglycemia-induced loss of consciousness can lead to fatal driving accidents and mishaps on the work floor [53]. Possible treatment modes for the hypoglycemic syndrome are a strict low carbohydrate diet, which is difficult to implement in this population [54], and drugs including acarbose, diazoxide, octreotide and calcium channel blocking agents [55]. When needed, surgical treatment can consist of the addition of a restrictive component [56], reincorporation of the duodenum in the digestive circuit [57], or reconstitution of the gastrointestinal continuity [58]. More radical options include pancreatic resections as initially proposed [59], but the use of such formidable surgery is questionable because neuroglycopenia is usually not caused by a pancreatic cell hyperplasia [60]. We prefer to proceed to laparoscopic reconstitution of the anatomic integrity, as we described previously [61] and as proposed by McLaughlin et al. [62]. We proved the efficacy of this approach in one of our patients suffering from documented invalidating recurrent hypoglycemia and who remained unresponsive to stringent dietary restrictions and to an expensive octreotide treatment.

We successfully extrapolated this therapeutic option to another patient who suffered from poorly adjustable insulin-dependent DMII occurring de novo after PLRYGB. This patient was extremely poorly disciplined in terms of dietary restrictions. We assumed that undoing the duodenal exclusion might result in less postprandial fluctuations in autogenous insulin, hence in a better controllable DMII. Since test-gastrostomy feedings allowed for better glycemic control in this patient, we went ahead and converted the bypass back to normal anatomy. This approach proved useful, as demonstrated by a normal postoperative oral glucose tolerance test.

Patient Satisfaction

The patients' QOL (BAROS) score was 2.03, which indicates a moderate QOL [9]. This score is remarkably less than the score recently reported by Suter [63]. Our less favorable outcome can be explained by the high number of long-term complications and reoperations and by the substantial incidence of fluctuating glucose plasma values, which is a highly symptomatic clinical condition. Overall, patient satisfaction remained high. We found a similar phenomenon in our patients after LAGB [1] and LSG [17], despite modest results in terms of weight loss. Obese

patients appear to be happy with themselves, provided they are convinced that they made a substantial effort to correct their condition [64, 65]. This underscores the social character of obesity as a crippling psychological disease that is lived through the eyes of "the other" [66]. The bariatric patient finds himself/herself more accepted after the surgery, even when the results are not necessarily good [67].

Conclusion

The results from this study suggest that LRYGB, performed as a primary or as a revisional procedure, induces an acceptable long-term weight loss, as expressed by an overall %EBMIL of 56.2. Despite our policy of closing the potential IH defects, 9 % of the patients required laparoscopic reintervention for IH. While LRYGB is salutary for patients suffering from DMII preoperatively, the patients appear to be at significant risk for developing new-onset diabetes several years after LRYGB. In addition, hypoglycemic symptoms may warrant hospital treatment for some additional patients. Overall, the QOL is acceptable and the satisfaction of the patients remains quite high.

Conflict of Interest The authors have no conflict of interest with the materials presented here. Jacques Himpens is a consultant for Ethicon Endosurgery (receives money personally) and receives money personally from Gore for lectures. Anneleen Verbrugghe has no potential conflicts of interest. Wouter Everaerts has no potential conflicts of interest. Guy-Bernard Cadière is a consultant for Covidien, Endogastric Solutions, and Ethicon Endosurgery (receives money personally and for the unit of obesity surgery at Saint-Pierre University Hospital); he personally receives royalties from Intuitive and has stock options of Endogastric Solutions. Jan Willlem Greve is a consultant with Allergan and Johnson and Johnson Endosurgery (receives money personally from both companies); he is a consultant with GI Dynamics and his institution receives money for that; his institution benefits from an open research grant from GI Dynamics.

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