




An Extended Pouch in a Roux-En-Y Gastric Bypass Reduces Weight Regain: 3-Year Results of a Randomized Controlled Trial

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Abstract

Background Although the Roux-en-Y gastric bypass (RYGB) is considered a standard procedure, many variations exist in the basic design. In order to achieve more pronounced and sustainable results after RYGB, factors such as diameter of the gastroenterostomy, limb length, and pouch size are gripping points for improvement of design. Extending the pouch could improve results by altering food passage through the pouch.

Objective The aim of this randomized controlled trial was to evaluate the effect of an extended pouch RYGB (EP-GB) and standard pouch RYGB (S-GB).

Methods In total, 132 patients were randomized in two groups: 68 patients received an EP-GB (pouch length 10 cm) and 64 a S-GB (pouch length 5 cm). Subsequently, weight loss, remission of comorbidities, nutritional status, complications, quality of life, and GERD-symptoms were assessed during a follow-up of 3 years.

Results During the first 2 years of follow-up, no significant differences in terms of weight loss were observed. In the third year of follow-up, the S-GB group regained 3 kg, while in the EP-GB group no weight regain was observed. The mean TBWL after 36 months in the EP-GB group was 31% versus 27% in the S-GB group ($p = 0.023$). Additionally, besides a better remission rate of hypertension in the EP-GB group, no differences in complications, quality of life, and GERD-symptoms were found.

Conclusion Creation of an extended gastric pouch is a safe and effective modification in RYGB design. An EP-GB improves mid-term weight loss, potentially driven by a lower occurrence of weight regain.

Keywords Morbid obesity · Bariatric surgery · Metabolic surgery · Roux-en-Y gastric bypass · RYGB · Pouch size · Pouch composition · Weight loss

Introduction

Since the introduction of the gastric bypass in 1966 by Mason, there only have been a few changes in its basic design. After adding the Roux-en-Y construction in 1977, no other essential alterations are done to the original design [1, 2]. Although the gastric sleeve is currently the most popular bariatric procedure worldwide, over the years, the RYGB has been performed in most patients. Especially when type 2 diabetes is present, the RYGB is often the preferred bariatric treatment [3, 4]. Although the RYGB is considered a standard procedure, many different versions of the same procedure are used. No

international standards or guidelines exist for possibly relevant anatomical features such as stoma size, limb length, pouch size, and volume [5, 6]. The growing awareness about the metabolic rather than mechanical effects of bariatric surgery have warranted a more critical look at gastric bypass construction. In this study, we looked specifically at pouch shape and length.

There are numerous studies regarding pouch size and the influence on weight loss and complications, but the majority are descriptive and observational studies, and it proves hard to draw any conclusions from them [7–11]. Many studies focus on using a smaller pouch, yet mostly without demonstrating a correlation between pouch volume and weight loss [7–9]. Observational studies do report a reduced risk of marginal ulcers in patients with a small pouch, which is attributed to the scarcity of parietal cells proximal in the stomach [12, 13].

In the past, it was postulated that the combination of restriction and malabsorption was the working mechanism of the RYGB. However, further research led to a growing

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awareness of the metabolic effect of the small intestine contributing to weight loss and reduction of comorbidities after bariatric surgery. Duration of pouch passage and gastric emptying seem to affect this metabolic mechanism, since Deden et al. found a relatively fast pouch emptying in patients with poor weight loss after RYGB surgery [14]. Following established laws of physics, a longer pouch may delay passage which in turn could affect intestinal function [6]. In that respect, pouch size could be one of the gripping points for RYGB design improvement.

This article (The Extended Pouch trial) reports the results of a RCT looking specifically at pouch length. It is part of a series of three randomized controlled trials (RCTs) studying the possible gripping points to optimize the RYGB, the other two being: the Elegance trial (limb length) [15] and the Bandolera trial (banded bypass, not yet published). The aim of the present study was to compare the effect on weight loss, reduction of comorbidities, and complications of an extended pouch gastric bypass (EP-GB) with our standard pouch gastric bypass (S-GB) (Fig. 1).

Methods

This study (The Extended Pouch trial) was designed as single (high volume bariatric) center, single-blinded, randomized controlled trial. The study protocol is approved by the Central Medical Committee for Research in humans in Nijmegen and the local ethics committee in Arnhem and is registered at the clinical trials registry of clinicaltrials.gov (NCT02218957). This study was in accordance with the Declaration of Helsinki.

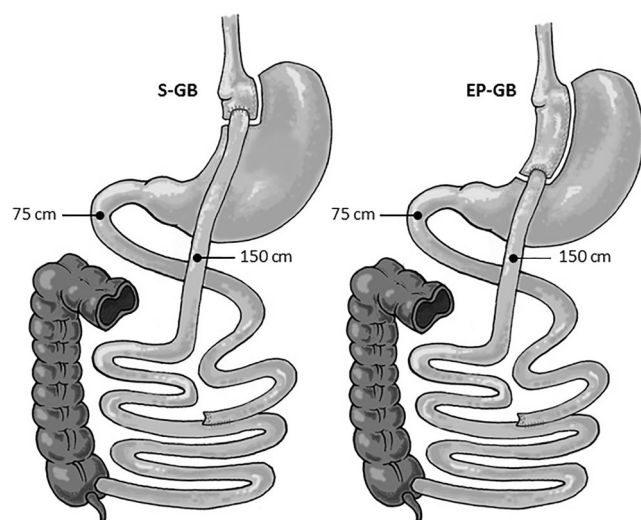


Fig. 1 Surgical procedures. *S-GB* standard pouch Roux-en-Y gastric bypass, *EP-GB* extended pouch Roux-en-Y gastric bypass

Patients

Patients eligible for primary gastric bypass surgery according to the IFSO criteria (BMI > 40 kg/m² or > 35 kg/m² with an obesity related comorbidity) who were referred to our center were approached by the surgeon for participation in the study. A history of bariatric surgery, any form of inflammatory bowel disease, renal dysfunction (GFS < 30 min), and therapy-resistant reflux disease were additional exclusion criteria for this study. When interested, patients received additional information about the study, potential risks, and benefits. Patients had 2 weeks to consider participation. To officially confirm participation in the study, written informed consent was obtained from each patient in twofold.

Surgical Procedures (S-GB and EP-GB)

Four experienced bariatric surgeons (> 500 RYGB cases) performed all procedures. A standardized laparoscopic technique was used for this study. An antecolic antegastric RYGB with an alimentary limb of 150 cm and a biliopancreatic limb of 75 cm was performed. To create the standard gastric pouch, the first blue 60-mm lineal stapler (Echelon, Ethicon, Johnson & Johnson, New Brunswick, NJ, USA) was placed 5 cm below the angle of His at the right angle to the minor curvature of the stomach. The small proximal pouch was finished using two 60-mm staplers placed against a 40 French stomach tube. The extended pouch was created firing the first stapler 10 cm below the angle of His (4 cm proximal of the pylorus) and was finished using three blue 60-mm staplers against a 40 French stomach tube. Oversewing of the staple line was not performed. Both the gastroenterostomy and the enteroenterostomy were created using a linear stapler (35 mm (ETS, Ethicon, Johnson & Johnson, New Brunswick, NJ, USA) and 60 mm respectively) and completed anteriorly using a barbed suture (V-loc™, Medtronic, Minneapolis, MN, USA). Staple lines were tested intraoperatively with an air leak test and mesenteric defects were closed with a double layer of hernia staples (EMS, Ethicon, Johnson & Johnson, New Brunswick, NJ, USA).

Outcomes (Primary and Secondary)

The primary outcome of this study was weight loss over a period of 3 years expressed as percentage total body weight loss (%TBWL) defined as weight loss divided by weight before surgery. It was anticipated that especially the difference in weight regain would make the significant difference. Weight loss was also calculated and expressed as percentage excess weight loss (%EWL) defined as weight loss divided by excess weight before surgery above a normal BMI of 25 kg/m².

Secondary outcomes were reduction of comorbidities (type 2 diabetes, hypertension, and dyslipidemia), complaints of reflux disease, quality of life (QoL), nutritional deficiencies, and complications after surgery. Type 2 diabetes (T2DM) was defined as the use of antidiabetic medication and/or a fasting glucose > 7 mmol/l and/or a HbA1c $\geq 6.5\%$. Remission was defined as discontinuation of antidiabetic medication for at least 1 year with normal laboratory values (HbA1c $< 6.5\%$). Improvement was a reduction of antidiabetic medication and unchanged when no difference to the preoperative situation. Hypertension (HT) and dyslipidemia (DL) were defined, respectively, as the use of antihypertensive drug therapy and the use of lipid-lowering medication. Remission of these comorbidities were a discontinuation of the antihypertensive or lipid-lowering medication. Deficiencies in vitamins were defined as a value under the lower limit. Complaints of gastroesophageal reflux disease (GERD) were assessed using the GERD-Health Related Quality of Life (GERD-HRQL) which contains ten questions concerning reflux and dysphagia. A total score of zero is equal to no complaints and a score of 50 to very severe complaints [16]. In addition, the Bariatric Analysis and Reporting Outcome System (BAROS) and the RAND-36 were used to score QoL [17].

Pre- and Postoperative Care

Preoperatively, all patients underwent screening and counseling at the Dutch Obesity Clinic to prepare them for the lifestyle adjustment before and after surgery. During multiple sessions, patients received dietary, physical, and psychological counseling. During the preoperative consultation at the hospital, patients were screened for nutritional deficiencies and if present they were corrected preoperatively.

In the postoperative phase, the multidisciplinary sessions continue up till 5 years after surgery. During the regular annually medical control sessions, questionnaires (BAROS, RAND-36, and GERD-HRQL) were taken and assessment of patient weight, BMI, medication use, and blood values took place. Patients were advised specialized multivitamin supplements for RYGB patients (FitForMe Forte, Rotterdam, The Netherlands), and 20 mg of omeprazole for 7 months and calcium 1500 mg and 2400 IU vitamin D3 daily lifelong were prescribed.

Sample Size, Randomization, and Blinding

Sample size calculation was based on the assumption that the EP-GB leads to 5% more %TBWL after 2 years. Using a power of 80%, a sensitivity of 95%, a SD of 9.3%, and taking into account a 10% drop out, a minimum of 65 patients were required per group.

Randomization was performed by the hospital epidemiologist using Research Manager (Nova Business Software,

Zwolle, The Netherlands). A 1:1 allocation ratio and concealed carrying permuted blocked size of two and four patients was used.

Patients were blinded during the complete duration of follow-up (single blinded). Due to logistics, researchers and surgeons could not be blinded for group allocation.

Statistical Methods and Monitoring

All parts of the study were monitored by an independent and trained monitor provided by the local ethical committee of the Rijnstate Hospital. Discrepancies or protocol violations were reported to the national ethical board located in Nijmegen. All statistical analyses were performed by the coordinating investigator and an independent statistician from the Rijnstate Hospital. Per protocol analyses were performed to present primary and secondary outcomes. Protocol violations were excluded for these analyses.

Variables were analyzed using an independent Student *t* test for continuous data and a Fisher's exact test for categorical data. Additionally, the difference in weight loss between the groups was analyzed using a linear regression analysis to adjust for the baseline covariates, i.e., age, sex, preoperative BMI, and preoperative diabetes. All tests were two-tailed and a *p* value < 0.05 was considered statistically significant.

Results

Between July 2014 and July 2015, 134 patients were included in the study. Sixty-five patients were randomized to S-GB and 69 to EP-GB. In both groups, one patient withdrew from surgery. Both patients were excluded for all analyses. Baseline characteristics between the groups did not significantly differ (Table 1).

Despite our instant efforts, two patients were lost to follow-up after 2 years and an additional seven after 3 years. In total, nine patients (7%) were lost to follow-up. Two patients in the EP-GB group withdrew participation and in the S-GB group one patient became pregnant in the third year of follow-up. Data of all these patients were used up until the point they

Table 1 Baseline patient characteristics

	S-GB	EP-GB
Number of patients	64	68
Female (%)	51 (80)	54 (79)
Age, years	47 ± 9	47 ± 10
Length, cm	170 ± 8	170 ± 8
Weight, kg	127 ± 17	126 ± 18
BMI, kg/m ²	44 ± 5	44 ± 5

S-GB standard pouch Roux-en-Y gastric bypass, EP-GB extended pouch Roux-en-Y gastric bypass, BMI body mass index, ± standard deviation

were lost to follow-up, withdrew participation, or became pregnant. A follow-up percentage of 98% after 2 years and 90% after 3 years was achieved (Fig. 2).

Weight Loss

During the first 2 years of follow-up, no significant differences in terms of weight loss were seen between the groups. After 24 months, the S-GB group achieved a %TBWL of 30% versus 32% in the EP-GB group ($p = 0.327$). In the S-GB group, patients regained 3 kg in the third year of follow-up. The %TBWL in the EP-GB remained stable. The %TBWL after 36 months in the EP-GB group was 31%, and in the S-GB group, the value dropped to 27% ($p = 0.023$). After adjustment for age, sex, preoperative BMI, and preoperative T2DM, the difference in %TBWL after 36 months between the EP-GB and the S-GB was 3.7% ($p = 0.043$). Results of the weight parameters are shown in Table 2.

Resolution of Comorbidities

The number of patients that achieved remission of the most common obesity related comorbidities are listed in Table 3.

Type 2 Diabetes

In total 54 (41%) patients were diagnosed with T2DM. Despite randomization, more patients in S-GB group, 31 (48%), were diagnosed with T2DM compared to those in the EP-GB group, 23 (34%) ($p = 0.111$). Both these groups included patients with glucose intolerance (a fasting glucose > 7 mmol/l and/or a HbA1c $\geq 6.5\%$ without using antidiabetic medication), seven in the S-GB and two in the EP-GB group. In the S-GB group, 61% achieved remission after 2 years and 71% after 3 years of follow-up compared to 70% and 57% in the EP-GB group. No significant differences between the groups were found.

Hypertension

In the S-GB group 25 (39%) and in the EP-group 28 (41%) suffered from hypertension. Remission rates increased during follow-up to 36% after 36 months in the S-GB and to 61% in the EP-GB group. The difference in remission rate between the groups was significant after 2 years and remained significant after 3 years in favor of the EP-GB group ($p = 0.043$).

Fig. 2 Flow diagram: number of patients during follow-up. *RYGB* Roux-en-Y gastric bypass, *S-GB* standard pouch Roux-en-Y gastric bypass, *EP-GB* extended pouch Roux-en-Y gastric bypass

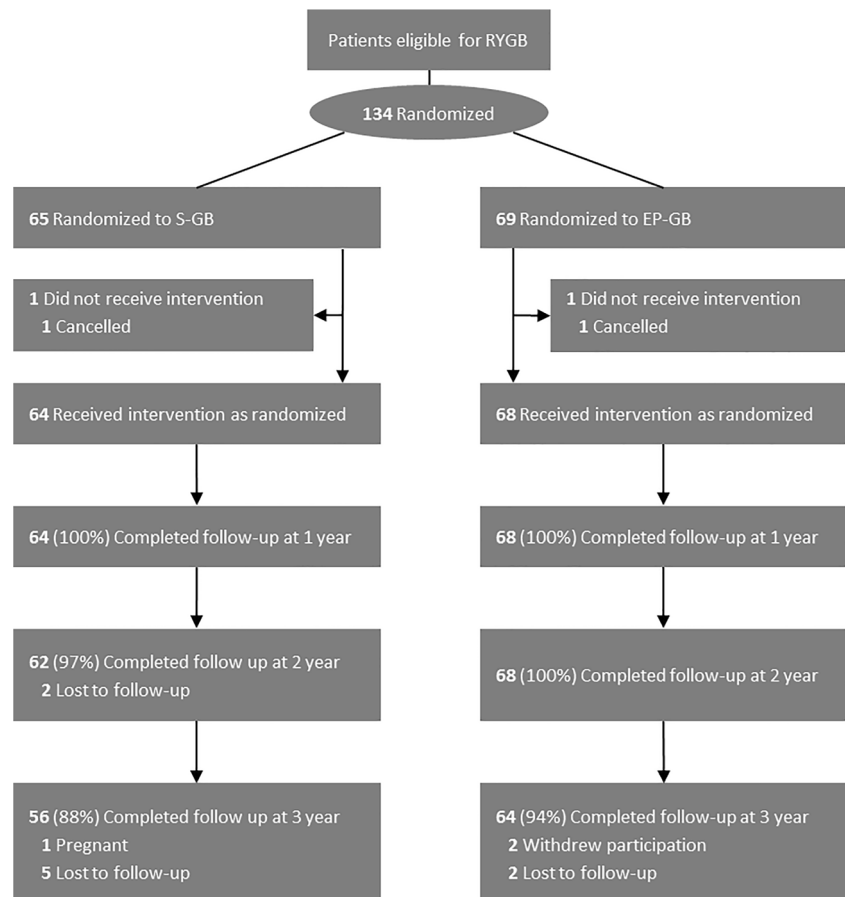


Table 2 Weight loss parameters

		S-GB	EP-GB	<i>p</i> value
Weight, kg	12 months	88 ± 15	87 ± 16	0.687
	24 months	89 ± 17	86 ± 16	0.308
	36 months	92 ± 17	86 ± 17	0.061
BMI, kg/m ²	12 months	30 ± 4	30 ± 5	0.731
	24 months	30 ± 5	30 ± 5	0.344
	36 months	32 ± 5	30 ± 5	<i>0.035</i>
%EWL	12 months	74 ± 20	75 ± 20	0.696
	24 months	73 ± 24	77 ± 23	0.331
	36 months	65 ± 23	76 ± 25	<i>0.023</i>
%TBWL	12 months	31 ± 7	31 ± 8	0.728
	24 months	30 ± 10	32 ± 10	0.327
	36 months	27 ± 9	31 ± 11	<i>0.023</i>

Italic values indicate statistical significant outcomes

S-GB standard pouch Roux-en-Y gastric bypass, *EP-GB* extended pouch Roux-en-Y gastric bypass, *EWL* excess weight loss, *TBWL* total body weight loss

Table 3 Remission of obesity related comorbidities

		S-GB	EP-GB	<i>p</i> value
Type 2 diabetes (%)		31 (48)	23 (34)	0.111
24 months	Remission	19 (61)	16 (70)	0.612
	Improved	11 (36)	7 (30)	
	Unchanged	–	–	
	Unknown	1 (3)	–	
36 months	Remission	22 (71)	13 (57)	0.325
	Improved	8 (26)	7 (30)	
	Unchanged	–	–	
	Unknown	1 (3)	3 (13)	
Hypertension (%)		25 (39)	28 (41)	0.860
24 months	Remission	6 (24)	15 (54)	<i>0.043</i>
	No remission	19 (76)	12 (43)	
	Unknown	–	1 (4)	
36 months	Remission	9 (36)	17 (61)	<i>0.043</i>
	No remission	16 (64)	9 (32)	
	Unknown	–	2 (7)	
Dyslipidemia (%)		17 (27)	20 (29)	0.847
24 months	Remission	10 (59)	10 (50)	0.743
	No remission	7 (41)	10 (50)	
36 months	Remission	10 (59)	6 (30)	0.097
	No remission	7 (41)	11 (55)	
	Unknown	–	3 (15)	

Italic values indicate statistical significant outcomes

S-GB standard pouch Roux-en-Y gastric bypass, *EP-GB* extended pouch Roux-en-Y gastric bypass

Dyslipidemia

At baseline, 37 (28%) patients used lipid-lowering medication. In the S-GB group, remission was achieved in ten (59%) patients after 24 and 36 months. In the EP-GB group, the remission rate dropped from 50% after 24 months to 30% after 36 months. The differences between the groups were not significant.

Complications

All short- and long-term complications are listed in Table 4. A total number of 11 (8%) patients suffered a short-term complication. Three patients in the S-GB group underwent a reoperation within 30 days. In two patients, the enteroenterostomy was revised because of persistent dysphagia due to a stenosis at the anastomosis. One patient underwent relaparoscopy because of complaints of dysphagia due to adhesions already observed during the primary procedure.

A long-term complication occurred in 25 (19%) patients. In total, 21 reoperations were performed, most (11) of which were cholecystectomies because of symptomatic gallstones. In the S-GB group, one patient underwent surgery due to a perforation at the gastroenterostomy caused by a stomach ulcer in the third year of follow-up. No significant differences in short- and long-term complications between the groups were found.

Table 4 Short- and long-term complications

	S-GB	EP-GB	<i>p</i> value
Short term (< 30 days)			
Total number of patients (%)	6 (9)	5 (7)	0.759
Reoperation	3	0	
Revision enteroenterostomy	2	0	
Adhesion	1	0	
Conservative-treated bleeding	2	3	
Readmission	1	2	
Mortality	0	0	
Long term (> 30 days)			
Total number of patients (%)	11 (17)	14 (21)	0.662
Reoperation	8	13	
Cholecystectomy	4	7	
Internal herniation	1	2	
Perforation gastroenterostomy	1	0	
Stenosis gastroenterostomy	0	1	
Diagnostic laparoscopy	2	3	
Incisional hernia (no surgery)	0	1	
Gastric ulcer	2	1	
Readmission	3	2	
Mortality	0	0	

S-GB standard pouch Roux-en-Y gastric bypass, *EP-GB* extended pouch Roux-en-Y gastric bypass

Nutritional Status

The number of patients with a deficiency preoperative or during follow-up are listed in Table 5. The number of patients that used specialized multivitamins as prescribed decreased from 79% after 1 year to 68% after 3 years of follow-up. Twelve months after surgery, significantly more patients in the S-GB group developed a vitamin B₁₂ deficiency, and after 2 years, more ferritin deficiencies were found in the EP-GB group.

Quality of Life

Gastroesophageal Reflux

The GERD-HRQL scores after 24 and 36 months in both groups were between 1.00 and 2.00 and did not significantly differ. After 36 months, 22% in the EP-GB group was (still) using a proton pump inhibitor (PPI) compared to 21% in the S-GB group ($p = 1.000$).

BAROS

Two years after surgery, 81% of the patients had a result of good or better with a mean score of 4.5 in the S-GB and 4.8 in the EP-GB group ($p = 0.435$). Comparable results were found after 3 years of follow-up.

RAND-36

Significant improvement in almost all domains was seen after 24 and 36 months in all patients compared to the preoperative values. Only in the role functioning/emotional domain a non-significant decrease of the score was seen after 36 months. There were no significant differences found between the groups.

Discussion

The growing number of patients with severe obesity is alarming, and many patients and healthcare providers are looking for the most effective bariatric procedure with the least morbidity. But then, the question remains which procedure will result in the best long-term outcomes for a specific patient. Although promising new procedures are introduced, the sleeve gastrectomy and the RYGB are still the two most performed procedures.

The majority of operated patients are satisfied and reach a TBWL > 25% or an EWL > 50%. These levels are often used to define success; however, additional weight loss above these thresholds is associated with the increase of remission of comorbidities and a better quality of life [18]. To improve results of the gastric bypass, the diameter of the gastroenterostomy, limb lengths, and pouch size could be gripping points.

The EP-GB was designed based on the sleeve gastrectomy and the one anastomosis gastric bypass (OAGB) when it was introduced. These procedures share a relative long and narrow gastric reservoir that differs from gastric bypass design. It could well be that this pouch design plays an important role in the excellent weight loss results seen after these procedures. When added to the gastric bypass design, it could potentially improve outcomes.

In the present study, the effect of an extended pouch gastric bypass in the first 3 years after surgery was analyzed. After adjustment for age, sex, preoperative BMI, and preoperative T2DM, no differences in TBWL and EWL were found during the first 2 years of follow-up, but after 3 years a difference in TBWL of 3.7% ($p = 0.043$) in favor of the EP-GB was seen. This difference was mainly caused by the fact that no weight regain in the second and third year of follow-up was observed in the EP-GB group. In contrast, in the S-GB group, TBWL dropped from a maximum of 31% after 12 months to 27% after 36 months due to regain of approximately 3 kg. This is an interesting finding at 3 years. As weight regain is observed in most metabolic surgery patients especially in year two to five

Table 5 Nutritional and vitamin deficiencies

	S-GB				EP-GB			
	Baseline (%)	12 months (%)	24 months (%)	36 months (%)	Baseline (%)	12 months (%)	24 months (%)	36 months (%)
Anemia	3	5	7	10	6	10	17	20
Folic acid	0	2	2	2	0	0	3	2
Vitamin B ₁₂	33	<i>16</i>	15	12	19	5	6	16
Ferritin	9	5	9	12	6	6	23	26
Vitamin D	63	5	9	8	76	3	8	16

Italic values indicate that scores between the S-GB group and the EP-GB group are significantly different at this time point

S-GB standard pouch Roux-en-Y gastric bypass, EP-GB extended pouch Roux-en-Y gastric bypass

post-surgery, it would be interesting to see if this effect is even more pronounced in upcoming years.

Weight regain after bariatric surgery is seen in a subset of patients, and several factors such as lifestyle, metabolic imbalance, and technical aspects following bariatric surgery are thought to contribute to this phenomenon [19]. When taken into account Poiseuilles' Law, which states that flow rate is dependent on pipe length, and other physiological variables are ignored, patients with long pouches should have a longer pouch emptying time compared to patients with short pouches. Theoretically, a slower passage through the pouch, as a result of extending the pouch, could induce a more gradual and longer period of gut hormone secretion resulting in a more pronounced metabolic effect of the RYGB. This concept is supported by Deden et al. who found a slow gastric pouch passage of food in good responders after RYGB and a fast passage in bad responders [14].

Alternatively, the results in the EP-GB group could be explained by the fact that, according to Laplace's law, a longer and smaller pouch has less tendency to dilate compared to a short and wide pouch [6]. Since dilatation of the pouch is often suggested to contribute to weight regain in the long term, preventing it could improve results after RYGB. It is unclear whether both laws are applicable in the clinical setting. Also, other poorly understood variables such as peristalsis, the diameter of the gastroenterostomy, and vagal nerve stimulation are likely to play a significant role. In future research for the optimal design of the RYGB, all these variables should be taken into account.

When weight loss increases, the resolution of comorbidities improves. The remission rate of HT was significantly higher in the EP-GB group after 24 and 36 months; however, this study fails to demonstrate a difference in remission of T2DM and DL. The most likely explanation is the lack of statistical power for these secondary outcomes. As mentioned before, despite randomization, more patients in the S-GB group were diagnosed with multiple comorbidities needing multidrug regimens. In those cases, remission is harder to achieve.

In contrast to the results of this study, other authors did not found a correlation between pouch size and weight loss. However, they did conclude that a smaller pouch reduces the risk of reflux symptoms and marginal ulcers [12]. In this study, in total, three (2%) patients had a gastric ulcer, which is low compared to literature [20]. Moreover, results of this study do not confirm the claim that smaller pouches reduce the occurrence of ulcers since more patients in the S-GB group (2) were diagnosed with a stomach ulcer compared to the EP-GB group (1). In fact, in the S-GB group, one patient needed revisional surgery due to a perforation caused by a stomach ulcer. Additionally, after 36 months, approximately 20% of patients in both groups still used a PPI. When compared to preoperative data, the number of users in the EP-GB group decreased and in the S-GB increased. Finally, GERD-HRQL

scores of both groups did not significantly differ. Unfortunately, preoperative GERD-HRQL scores were not assessed. The number of patients with an ulcer in this study could be underestimated because not all patients with this complication experience symptoms or were referred to the hospital for a gastroscopy to confirm the diagnosis.

Extending the gastric pouch is a safe method to prevent weight regain after RYGB which is illustrated by comparable complication rates. A mean complication rate of 21% in the EP-GB group appears high compared to the literature. However, cholecystectomies were also scored as a complication. When this common phenomenon after bariatric surgery is not taken into account, complication rates drop to 10%, which is more in line with expectations.

More patients in the S-GB group suffered a vitamin B12 deficiency after 12 months, despite a comparable number of patients using multivitamins as prescribed preoperatively in both groups. Better vitamin B12 digestion and absorption could be the result of the longer pouch with slower gastric emptying. More patients in the EP-GB group developed a ferritin deficiency 24 months after surgery. At this specific time point, more patients with an extended pouch were using a PPI compared with the patients of the S-GB group, which reduces the absorption of iron. This could be an important reason for the higher deficiency rate observed.

From a surgical perspective, the EP-GB procedure has advantages compared to the S-GB procedure. When pulling up the alimentary limb to create the gastroenterostomy, less traction is needed on the small intestine and the mesentery to reach the level of the pouch. Theoretically, less traction on the alimentary limb could also result in less (unexplained) postoperative pain. Unfortunately, postoperative pain was not assessed in a standardized manner. Secondly, an EP-GB makes revisional surgery of the pouch less difficult to perform, especially when there is an indication for shortening the pouch. A financial disadvantage of the EP-GB includes the fact that a longer pouch is more expensive to create since an additional stapler is needed.

Weight loss after bariatric surgery is associated with an improvement in QoL [21]. In line with literature, improvement in all physical domains of the RAND-36 was observed, with no significant difference between the two surgical groups. The minor difference in weight loss we observed could have played a role.

Together with three other RCTs performed in our center, this study looks into possible gripping points for improvement of the RYGB design. We acknowledge that the number of patients included in this study has its limitations. Secondly, the follow-up period of 3 years to observe weight regain is questionable. It also remains a matter of debate if a difference of 3.7% TBWL, which equals approximately 6 kg, in favor of the EP-GB is of clinical relevance. However, to our knowledge, this is the first RCT describing the effect of EP-

GB. Together with other improvements such as optimizing limb lengths and placement of a non-adjustable ring around the pouch, it could result in even more pronounced and perhaps lifelong sustainable weight loss after RYGB.

Conclusion

Extending the gastric pouch is a promising modification of RYGB design that seems to be a safe and effective technique which improves mid-term weight loss, potentially driven by a lower occurrence of weight regain.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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