

# Roux-en-Y Gastric Bypass Versus Sleeve Gastrectomy in Young Adults: a Dutch Registry Study

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#### **ORIGINAL CONTRIBUTIONS**





# Roux-en-Y Gastric Bypass Versus Sleeve Gastrectomy in Young Adults: a Dutch Registry Study

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#### **Abstract**

**Background** The most commonly performed bariatric procedures worldwide are Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG), yet outcomes following these procedures in young adults are limited. Therefore, the objective of this study was to compare weight loss outcomes between RYGB and SG in young adults.

**Methods** This is a nationwide retrospective cohort study of young adults, aged 18–25 years, who underwent RYGB or SG between 2015 and 2019, with data from the Dutch Audit Treatment of Obesity (DATO). The primary outcome was weight loss expressed as percentage total weight loss (%TWL) in a period of 3 years after surgery. Secondary outcomes were the incidence of complications (<30 days) and progression of obesity-related comorbidities.

**Results** In total, 2313 patients were included, 1246 in the RYGB group and 1067 in the SG group. Percentage TWL was significantly higher in the RYGB group compared to the SG group at 1, 2, and 3 years after surgery (respectively 2.4%, 2.9%, and 3.3% higher, p < 0.001). RYGB was associated with an on-average 2.75 higher %TWL compared to SG in females (p < 0.001), although this was not seen in males (p = 0.63, p = 0.514). No differences were found in the incidence of complications, nor the progression of obesity-related comorbidities except for gastroesophageal reflux disease (GERD). There was more improvement or resolution of GERD in the RYGB group (95.2% vs. 56.3%, p < 0.001).

**Conclusion** Similar numbers of RYGB and SG were performed in young adults, whereas RYGB was associated with greater weight loss in the short- and midterm, particularly in females.

**Keywords** Obesity · Bariatric surgery · Young adults · Gastric bypass · Gastric sleeve

#### **Key Points**

- Similar numbers of RYGB and SG are performed in young adults
- Bariatric surgery in young adults appears to be safe.
- RYGB is associated with greater weight loss, particularly in females.
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#### Introduction

The obesity epidemic is a serious and chronic problem. Obesity leads to impaired quality of life, overall health, and life expectancy [1]. The prevalence of severe obesity has increased substantially worldwide; this trend is also seen in youth and young adults [2, 3]. Consequently, an alarming shift in the early onset of obesity-related comorbidities has been noted, illustrating the need for effective treatment options to achieve enduring weight loss and improvement of obesity-related comorbidities early in life [4–7].

In the majority of adults with severe obesity, bariatric surgery has proven to be the most effective and long-lasting treatment [8–11]. The most commonly performed bariatric procedures worldwide are Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) [11]. RYGB has traditionally been the gold standard and remains the most frequently performed bariatric procedure in the Netherlands with 61% of



all procedures in 2019 [12, 13]. However, SG has grown in popularity due to its technical ease and the belief that it leads to fewer complications [14].

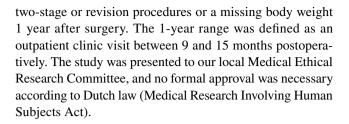
To date, several randomized controlled trials (RCTs) and meta-analyses have been performed in adults comparing RYGB and SG [11, 15, 16]. A recently published meta-analysis demonstrated that patients who underwent RYGB had a significantly greater decrease in body mass index (BMI) when compared to SG at 1 and 3 years after surgery [11]. Nevertheless, most studies in the field of bariatric surgery have only focused on adults and not on young adults [11, 15, 16]. Due to possible variations in metabolism and compliance rates, the results between RYGB and SG for young adults may differ from adults [17–19]. In light of this possibility, a small cohort study retrospectively evaluated weight loss after bariatric surgery in young adults, aged 18-25 years. RYGB and SG were compared in these young adults, and no differences in terms of weight loss were found. However, the number of included young adults was low (n = 103), and based on this retrospective study with an impaired number of included patients, no firm conclusions can be drawn [20]. Therefore, the aim of this nationwide population-based cohort study was to compare RYGB and SG in terms of weight loss in young adults with severe obesity. Secondary objectives were the incidence of complications and progression of obesity-related comorbidities. It was hypothesized that RYGB might lead to greater weight loss and improvement of obesity-related comorbidities, as well as more complications in comparison with SG in young adults.

#### Methods

The methods of this study are in line with the methods of a similar study performed by our research group [21].

### **Study Design**

This is a national population-based cohort study of young adults, aged 18–25 years, who received a RYGB or SG in the Netherlands. Pseudo-anonymized data was derived from the Dutch Audit Treatment of Obesity (DATO). The DATO is a nationwide mandatory quality registry covering all bariatric procedures performed in the Netherlands since January 2015 [12]. Young adults were included if they received primary RYGB or SG between 01 January 2015 and 31 December 2019 and had a preoperative BMI  $\geq$  40 kg/m<sup>2</sup> or a BMI  $\geq$  35 kg/m<sup>2</sup> accompanied by an obesity-related comorbidity. Eligibility for surgery was evaluated by a multidisciplinary team and was according to the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) guidelines [22]. Exclusion criteria were



## **Study Outcomes**

The primary outcome was weight loss expressed as %TWL at 1, 2, and 3 years after surgery. Percentage TWL was calculated as ((preoperative weight – postoperative weight)/preoperative weight)  $\times$  100%. Secondary outcomes were change in BMI and %TWL in a period of 5 years after surgery, successful weight loss, weight regain, the incidence of complications, and progression of obesity-related comorbidities. Change in BMI was calculated as preoperative BMI–postoperative BMI. In addition, successful weight loss was defined as  $\geq$  20% TWL according to the DATO, and weight regain was defined as  $\geq$  20% regain of a patients' lost weight at their last follow-up visit after initial successful weight loss 1 year after surgery [13, 23].

Perioperative and postoperative complications within 30 days were registered. Postoperative complications were defined according to the Clavien-Dindo (CD) classification of surgical complications [24]. Obesity-related comorbidities included T2DM, hypertension, dyslipidemia, gastroesophageal reflux disease (GERD), obstructive sleep apnea syndrome (OSAS), and musculoskeletal pain. The obesity-related comorbidities were assessed at 1 and 2 years after surgery. The latter comorbidity status was compared with the status before surgery and classified as resolved or improved, unchanged or deteriorated, or de novo according to the ASMBS guideline [25]. Previous research based on the DATO described the classification of the comorbidities extensively [26]. The comorbidity status was frequently missing at 3, 4, and 5 years after surgery; therefore, this outcome was only assessed up to 2 years postoperatively.

# **Statistical Analysis**

All statistical analyses were conducted using IBM SPSS statistic software, version 25.0. A two-sided p-value < 0.05 was considered statistically significant. Continuous variables are presented as mean  $\pm$  standard deviation (SD), and categorical variables are presented as absolute number (percentage). Outcomes between RYGB and SG were compared using an independent samples t-test for continuous variables and  $\chi 2$  test for categorical variables. The associations between bariatric procedure (RYGB versus SG) and %TWL at 1, 2, and 3 years after surgery were analyzed using linear mixed model (LMM) analyses. In the LMM, the factor-analytic



covariance matrix and restricted maximum likelihood estimation were used. Within these analyses, an interaction variable for bariatric procedure and gender was added, and corrections were made for known confounders. Known confounders were based on literature (preoperative BMI) and variables that had a confounding effect in the univariate analysis [27].

#### Results

A total of 2341 young adults with a 1-year follow-up weight were registered from 2015 until 2019; 28 (1.2%) were excluded due to a two-stage procedure or revision surgery. Of the 2313 young adults who were included, 1246 received a RYGB (53.9%) and 1067 received a SG (46.1%). Two-year follow-up in the RYGB group was available in 583 (60.0%) of the 971 young adults who had surgery in or before 2018. Three-, 4-, and 5-year follow-up was obtained from 331/751 (44.1%), 185/528 (35.0%), and 78/262 (29.8%) of the young adults, respectively. Two-year follow-up in the SG group was available in 542 (64.9%) of the 835 young adults who had surgery in or before 2018. Three-, 4-, and 5-year follow-up was obtained from 265/575 (46.1%), 113/302 (37.4%), and 33/110 (30.0%) of the young adults, respectively.

The baseline characteristics of the study population were in general similar (Table 1). Notably, young adults who received a RYGB had a lower preoperative BMI compared to young adults who received a SG (44.1 kg/m<sup>2</sup> vs.  $45.3 \text{ kg/m}^2$ , p < 0.001). Besides this, preoperative T2DM,

Table 1 Baseline characteristics of the included young adults

	RYGB, $n = 1246$	SG, $n = 1067$	p-value				
Age (years, $\pm SD$ )	$23.1 \pm 2.0$	22.9 ± 2.1	0.002*				
Gender, no. (%)							
Female	1073 (86.1)	925 (86.7)	0.687				
Preoperative weight (kg, <i>SD</i> )	$127.3 \pm 18.0$	$130.4 \pm 19.4$	<0.001*				
Preoperative BMI (kg/ $m^2 \pm SD$ )	$44.1 \pm 4.7$	$45.3 \pm 5.1$	<0.001*				
Preoperative comorbidities, no. (%)							
T2DM	56 (4.5)	30 (2.8)	0.033*				
Hypertension	67 (5.4)	52 (4.9)	0.585				
Dyslipidemia	88 (7.1)	29 (2.7)	< 0.001*				
GERD	102 (8.2)	71 (6.7)	0.163				
OSAS	60 (4.8)	46 (4.3)	0.563				
Musculoskeletal pain	431 (34.6)	311 (29.1)	0.005*				

Data presented as number (%) or mean (SD). \*p-value is below the threshold of <0.05. RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; BMI, body mass index; T2DM, type 2 diabetes mellitus; GERD, gastroesophageal reflux disease; OSAS, obstructive sleep apnea syndrome

dyslipidemia, and musculoskeletal pain were significantly more represented in the RYGB group.

# **Weight Loss**

Percentage TWL was significantly higher in the RYGB group compared to the SG group at 1, 2, and 3 years after surgery. One year after surgery, TWL was 34.3% in the RYGB group versus 31.9% in the SG group, 35.0% versus 32.1% 2 years after surgery, and 33.1% versus 29.8% 3 years after surgery (all p < 0.001). This trend is preserved 4 and 5 years after surgery, although not significant. Similar patterns were found for change in BMI (Table 2). Next to this, the percentage of young adults who achieved successful weight loss (≥20% TWL) after a RYGB was higher compared to young adults after a SG, respectively 97.2% versus 91.3% 1 year after surgery and 95.7% versus 88.7% 2 years after surgery (all p < 0.001). Weight regain after initial successful weight loss was equally seen in the two groups, 14.7% in the RYGB group and 17.6% in the SG group (p = 0.160) (Table 2). LMM was used to analyze the association between bariatric procedure (RYGB versus SG) and %TWL. LMM analyses were stratified for gender, since gender and bariatric procedure showed a significant interaction effect on %TWL (Table 3). In female young adults, bariatric procedure, after adjustment for confounders, was significantly associated with %TWL at 1, 2, and 3 years after surgery. RYGB had an on-average 2.75 higher %TWL compared to SG (p < 0.001) in females. Interestingly, this association was not found in male young adults  $(\beta = 0.63, p = 0.514).$ 

#### **Complications**

No significant differences were detected between RYGB and SG in perioperative complications, nor in postoperative complications within 30 days (Table 4). Furthermore, no mortality was reported in both groups.

# **Obesity-Related Comorbidities**

Regarding the progression of obesity-related comorbidities, no differences were found between the two groups in terms of T2DM, hypertension, dyslipidemia, OSAS, and musculoskeletal pain (Table 5). However, in the RYGB group, more resolution or improvement of GERD compared to the SG group was found (95.2% vs. 56.3%, p < 0.001). In line with this, the RYGB group had two (0.18%) de novo developments of GERD compared to 14 (1.38%) in the SG group.



**Table 2** Weight loss outcomes comparing RYGB and SG in young adults

	RYGB	,	SG		
	No. <sup>1</sup>	% ± SD	No. <sup>1</sup>	% ± SD	<i>p</i> -value
TWL 1 year	1246/1246	$34.3 \pm 7.3$	1067/1067	$31.9 \pm 8.5$	< 0.001*
TWL 2 years	583/971	$35.0 \pm 8.3$	542/835	$32.1 \pm 10.0$	< 0.001*
TWL 3 years	331/751	$33.1 \pm 9.2$	265/575	$29.8 \pm 11.5$	< 0.001*
TWL 4 years	185/528	$30.9 \pm 10.4$	113/302	$29.9 \pm 12.9$	0.521
TWL 5 years	78/262	$29.5 \pm 11.2$	33/110	$26.5 \pm 15.1$	0.307
	No. <sup>1</sup>	$kg/m^2 \pm SD$	No. <sup>1</sup>	$kg/m^2 \pm SD$	
Change in BMI 1 year	1246/1246	$15.1 \pm 3.6$	1067/1067	$14.4 \pm 4.3$	< 0.001*
Change in BMI 2 years	583/971	$15.4 \pm 4.1$	542/835	$14.6 \pm 5.2$	0.003*
Change in BMI 3 years	331/751	$14.6 \pm 4.6$	265/575	$13.6 \pm 5.8$	0.024*
Change in BMI 4 years	185/528	$13.6 \pm 5.0$	113/302	$13.9 \pm 7.1$	0.676
Change in BMI 5 years	78/262	$13.1 \pm 5.2$	33/110	$12.4 \pm 7.1$	0.589
	No. in analysis	No. (%)	No. in analysis	No. (%)	
Successful weight loss 1 year <sup>2</sup>	1246	1211 (97.2)	1067	974 (91.3)	< 0.001*
Successful weight loss 2 years <sup>3</sup>	583	558 (95.7)	542	481 (88.7)	< 0.001*
Weight regain <sup>4</sup>	673	99 (14.7)	620	109 (17.6)	0.160

Data presented as mean ( $\pm SD$ ). \*p-value is below the threshold of < 0.05. <sup>1</sup>Number of patients in analysis/number of patients who could have had a follow-up visit. <sup>2</sup>Defined as  $\geq$  20% TWL at 1 year after surgery. <sup>3</sup>Defined as  $\geq$  20% TWL at 2 years after surgery. <sup>4</sup>Defined as  $\geq$  20% weight regain of a patients' lost weight at their last follow-up visit, with a minimum of 2 years after surgery, and after initial successful weight loss ( $\geq$  20% TWL) at 1-year follow-up. *RYGB*, Roux-en-Y gastric bypass; *SG*, sleeve gastrectomy; *TWL*, total weight loss; *BMI*, body mass index

Table 3 Stratified for gender linear mixed model analysis of variables associated with %TWL after RYGB or SG at 1–3 years after surgery

	Female			Male		
	Beta coefficient	95% CI	<i>p</i> -value	Beta coefficient	95% CI	p-value
Bariatric procedure (RYGB vs. SG)	2.75	2.07-3.44	< 0.001*	0.63	-1.27-2.53	0.514
Follow-up compared to 1 year after surge	ry					
2 years	0.43	0.10-0.75	0.010*	0.38	-0.52 - 1.28	0.404
3 years	-1.34	-1.86-0.83	< 0.001*	-1.82	-3.17 - 0.47	0.009*
Preoperative BMI (kg/m <sup>2</sup> )	-0.07	-0.14-0.00	0.064	0.16	-0.01-0.34	0.064
Preoperative T2DM (yes vs. no)	-4.44	-6.35 - 2.54	< 0.001*	-2.49	-6.59 - 1.60	0.232
Preoperative hypertension (yes vs. no)	-1.37	-3.04-0.31	0.110	-3.81	-6.85 - 0.78	0.014*
Preoperative OSAS (yes vs. no)	-2.05	-3.85 - 0.26	0.025*	-3.33	-6.55-0.12	0.042*

<sup>\*</sup>p-value is below the threshold of < 0.05. *RYGB*, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; BMI, body mass index; T2DM, type 2 diabetes mellitus; OSAS, obstructive sleep apnea syndrome

# Discussion

Several studies and meta-analyses have been performed comparing RYGB and SG, yet so far the young adults were underrepresented [11, 15, 16, 28]. To our knowledge, this is the first nationwide population-based cohort study comparing weight loss outcomes between RYGB and SG in young adults (18–25 years). We demonstrated that RYGB is associated with an on-average higher %TWL at 1, 2, and 3 years after surgery compared to SG, particularly in females. This study also indicates that in general,

bariatric surgery appeared to be safe in young adults and that RYGB more often resulted in resolution or improvement of GERD.

In terms of short- and midterm weight loss, this study suggests that RYGB should be favored as surgical technique in young adults rather than SG. This is supported by a recent meta-analysis among adults, demonstrating that RYGB led to a significantly greater decrease in BMI compared to SG at 1 and 3 years after surgery (1.25 kg/m<sup>2</sup> and 1.71 kg/m<sup>2</sup>). In a sensitivity analysis, this favorable effect of RYGB was also seen 5 years after surgery [11]. Besides this, a large



Table 4 Perioperative and postoperative complications (<30 days) comparing RYGB and SG in young adults

	RYGB, $n = 1246$	SG, n = 1067	<i>p</i> -value
Perioperative complications, no. (%)			
Perforation	1 (0.1)	0 (0)	NA
Bleeding	4 (0.3)	2 (0.2)	NA
Spleen injury	1 (0.1)	1 (0.1)	NA
Liver injury	1 (0.1)	1 (0.1)	NA
Total	10 (0.8)	7 (0.7)	0.681
Number of readmissions within 30 days, no. (%)	30 (2.4)	18 (1.7)	0.225
Therapeutic intervention for complication within 30 days, no. (%)	10 (0.8)	6 (0.6)	0.487
Clavien-Dindo classification, no. (%)			
CD grade I	7 (0.6)	7 (0.7)	0.771
CD grade II	8 (0.6)	8 (0.7)	0.755
CD grade III	14 (1.1)	9 (0.8)	0.499
CD grade IV	3 (0.2)	0 (0)	NA
Postoperative complication within 30 days, no. (%)			
Major bleeding	10 (0.8)	6 (0.6)	0.487
Anastomotic leakage	0 (0)	2 (0.2)	NA
Intra-abdominal abscess	0 (0)	1 (0.1)	NA
Wound infection	2 (0.2)	2 (0.2)	1.000
Intestinal obstruction	5 (0.4)	0 (0)	NA
Anastomotic stricture	1 (0.1)	1 (0.1)	1.000
Nonsurgical complications	15 (1.2)	18 (1.7)	0.329

Data presented as number (%). \*p-value is below the threshold of <0.05. RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy, NA, not applicable; CD, Clavien-Dindo classification; I is any deviation from the normal postoperative course without intervention, except some drugs such as antiemetics, antipyretics, analgesics, diuretics, and electrolytes; II is a complication requiring pharmacological treatment other than such allowed for grade I; III is a complication requiring intervention under anesthesia; IV is a complication resulting in organ failure

Table 5 Progression of obesity-related comorbidities comparing RYGB and SG in young adults

	RYGB 1–2 years of follow-up		SG 1-2 years of follow-up				
	No. <sup>1</sup>	Resolved or improved <sup>2</sup> no. (%)	Unchanged or deteriorated <sup>2</sup> no. (%)	No. <sup>1</sup>	Resolved or improved <sup>2</sup> no. (%)	Unchanged or deteriorated <sup>2</sup> no. (%)	p-value
T2DM	37/56	31 (83.8)	6 (16.2)	20/30	20 (100.0)	0 (0)	0.081
Hypertension	55/67	47 (85.5)	8 (14.5)	39/52	37 (94.9)	2 (5.1)	0.187
Dyslipidemia	69/88	58 (84.1)	11 (15.9)	19/29	16 (84.2)	3 (15.8)	1.000
GERD	62/102	59 (95.2)	3 (4.8)	32/71	18 (56.3)	14 (43.8)	< 0.001*
OSAS	35/60	28 (80.0)	7 (20.0)	19/46	15 (78.9)	4 (21.1)	1.000
Musculoskeletal pain	306/431	261 (85.3)	45 (14.7)	171/311	146 (85.4)	25 (14.6)	0.980

Data presented as number (%). \*p-value is below the threshold of <0.05. \(^1\)Number of patients from which comorbidity status is known at 1 or 2 years follow-up with a preoperative comorbidity/number of patients with preoperative comorbidity and known status at 1 or 2 years of follow-up. RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; T2DM, type 2 diabetes mellitus; GERD, gastroesophageal reflux disease; OSAS, obstructive sleep apnea syndrome

cohort study of three national quality registries revealed that more adults who underwent RYGB achieved successful weight loss (≥ 20% TWL) 1 year after surgery (95.8% vs. 84.6%) [28]. Similar findings were found in this study, 95.7% of the young adults who received a RYGB achieved

successful weight loss versus 88.7% of the young adults who received a SG. However, it should be noted that in our study, no significant differences were found in weight loss 4 and 5 years after surgery, presumably because there was a large loss to follow-up of approximately 64% and 70% which may

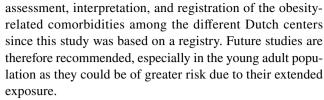


have affected the outcomes. In order to assess the superiority of the RYGB in young adults in the long term, a large comparative study should be designed in which long-term complications, physical well-being, and quality of life will also be included, especially in this population, since young adults with obesity are expected to have a reduced quality of life, lower educational attainment, and are more likely to stay single [29, 30].

One unexpected finding was that RYGB was significantly associated with higher %TWL compared to SG in female young adults, whereas this effect was not seen in male young adults. Previously, this has not been reported in young adults, and the current literature on gender differences in bariatric surgery reveals significant heterogeneity. One study indicated that SG was more effective in men [31]. On the contrary, a large retrospective cohort study of 20,296 patients showed no gender differences in patients who received SG, nor in patients who received RYGB [32]. Gender differences between females and males might be caused by variations in fat metabolism, eating habits, or compliance rates but are in general not well understood [33]. Therefore, continued efforts are needed to gain more insights into gender-specific differences in bariatric surgery.

Regarding the postoperative complications after bariatric surgery in young adults, the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) of North America recently published an overview [34]. In 21,592 young adults, it was shown that the rate of readmissions and reinterventions within 30 days was low (all below < 5%), and that serious complications such as bleedings (0.4%) were rarely documented. Besides this, they reported that young adults who received RYGB had threefold higher rates of reoperation, intervention, and serious complications. The complication rate in this study was also low; perioperative and postoperative complications within 30 days were all below 5%. In contrary to the report of the MBSAQIP, the current study revealed no differences between RYGB and SG in postoperative complications within 30 days. A possible explanation for this could be the lower presence of preoperative comorbidities, or it could be due to the fact that this study did not have enough power to assess these outcome measures.

In the last couple of years, the development of GERD after SG has raised concerns. There is a growing body of evidence that SG could lead to the development of GERD and eventually Barrett's esophagus [35, 36]. This might be due to the increased intragastric pressure, the final shape of the sleeve, or the disruption of the anatomical anti-reflux barrier after SG [36, 37]. So far, there is limited evidence comparing RYGB and SG on the development of GERD. Our study revealed more resolution or improvement of GERD after RYGB. Nevertheless, these results need to be interpreted with caution, as there could be differences in the



This study has certain limitations. The first limitation is the significant loss to follow-up, which might have led to a selection bias of the results, as poorer weight loss outcomes could be a possible reason for loss to follow-up [38]. Another limitation of this study is the fact that the study is based on a registry; this might have caused differences in the interpretation and registration of the data entry in the different Dutch centers. Thirdly, our study only assessed the short-term complications, and mainly due to the extended exposure of this young population, the long-term complications would be of interest for future research. Despite these limitations, we believe that this study gained insights into the weight loss outcomes, complications, and progression of obesity-related comorbidities between RYGB and SG in young adults.

# Conclusion

Population-based data revealed that similar numbers of RYGB and SG were performed in young adults in the Netherlands and appeared to be safe. The short- and midterm RYGB was associated with greater weight loss, particularly in females. Besides this, RYGB resulted in more improvements of GERD compared to SG. Based on these findings, RYGB might be favored in female young adults. However, future research with an extended follow-up is needed to definitively assess the superiority of the RYGB in the long term. This research should ideally also focus on complications (> 30 days), physical well-being, and quality of life, especially in this young population.

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#### **Declarations**

Ethics Approval All procedures performed in these studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

**Informed Consent** Reporting to DATO in the Netherlands is mandatory. Informed consent does not apply according to Dutch law.

Conflict of Interest The authors declare no competing interests.

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