## Does sleeve gastrectomy stand for its popularity?

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The sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB) are the most performed bariatric operations worldwide.<sup>1</sup> However, there is still debate on which procedure delivers safe and better long-term weight loss (WL) and comorbidity control as only a few level 1 studies compared both techniques.<sup>2,3</sup>

In this Issue of *The Lancet Regional Health—Europe*, Hart et al.<sup>4</sup> compared the long-term WL effects after SG and RYGB in a randomised controlled trial (RCT).

The SleeveBypass study was designed as an equivalence study conducted in two Dutch bariatric hospitals, including 628 patients. The primary outcome was weight loss reported by percentage excess body mass index loss (EBMIL) at 5 years, and the predefined clinically relevant equivalence delta was  $\pm 13\%$ , while the secondary outcomes were control of type 2 diabetes (T2D), hypertension, obstructive sleep apnoea (OSA), gastroesophageal reflux disease (GERD), and healthrelated quality of life (HRQOL).

In all measures of weight loss, RYGB was significantly better than SG. Total body weight loss (TBWL) after RYGB at 5 years was 26.5% and 22.5% after SG (p < 0.001). The minimum TBWL after RYGB was the maximum TBWL after SG (24.3%), while the highest weight reached after RYGB was the lowest after SG at 5 years. At 1 year of follow-up, SG and RYGB produced similar WL; however, at 5 years, weight-regain (WR) was statistically significant after SG.

This clinical trial has some limitations that need to be highlighted and may affect its interpretation. First, a delta of ±13% EBMIL was used. A well-selected margin is vital for the quality of the entire study. A margin that is too wide may obscure relevant differences between the treatments. Unfortunately, there is no consensus on defining the margin, and this process is often poorly reported.<sup>5</sup> Secondly, choosing EBMIL and not total body weight loss (TBWL) made the primary endpoint dependent on baseline BMI. Previous RCTs that have compared RYGB with SG and used weight loss as the primary outcome have shown better WL outcomes after RYGB (Table 1).

The SleeveBypass study was not powered to detect differences in secondary outcomes. There is a trend for better control of OSA and hypertension and a statistical significance of dyslipidaemia resolution favouring

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RYGB. However, in this study, no solid conclusion can be drawn related to the effects of either technique.

SG and RYGB had similar rates of major complications. Minor ones were more frequent after RYGB and up to 30 days after surgery. Reoperations rate was similar (12.5% after SG and 10.1% after RYGB). However, most reoperations after RYGB were due to internal hernias and were incidental findings in planned laparoscopies. It was unclear if all mesenteric defects were closed during the index operations and that step sharply decreases the incidence of internal hernias after RYGB.<sup>8</sup>

Like other RCTs, both interventions improved HRQOL. The Sleevepass study<sup>9</sup> showed that HRQOL decreases to baseline levels at 7 years, regardless of the procedure. However, disease-specific QOL (DSQOL) was still better at 7 years and related to the magnitude of WL, which was greater after RYGB. Moreover, people with GERD experience health-related quality of life decrements compared with the general population.<sup>10</sup> That was not accounted for in the SleeveBypass study, and the appropriate questionnaires were not used. Thus, that may mislead the interpretation of QOL in this trial, either not considering GERD or DSQOL.

In conclusion, RYGB had better WL, similar rate of major complications, and a trend for better comorbidities control despite more minor complications. WR and GERD leading to the conversion of SG to RYGB and the lack of precise measures of QOL are significant concerns. Obesity is a chronic illness; thus, safe and durable treatments and superiority trials are still needed to help decide the best surgical option. The SleeveBypass did

Study	FU	Endpoint	Weight loss		р	Type 2 diabetes control		р
			RYGB	SG		RYGB	SG	
Wölnerhanssen, <sup>2</sup> 2021 <sup>a,b</sup>	5 years	WL	62.7% EBMIL 27.8% TWL	55.5% EBMIL 23.9% TBWL	<0.001 <0.001	32%	24%	0.65
lgnat <sup>3</sup> i, 2017 <sup>a</sup>	5 years	WL	74.8% EWL	65.1% EWL	0.017	19%	16%	0.77
Schauer, <sup>6</sup> 2017 <sup>c</sup>	5 years	T2D control	23% TWL	19% TBWL	0.01	29%	23%	0.48
Svanevik, <sup>7</sup> 2023	3 years	T2D control	25.3% TWL	17.2% TBWL	<0.0001	30%	16%	0.0018

WL = weight loss; T2D = type 2 diabetes; EBMIL = excess body mass index loss; EWL = excess weight loss; TBWL = total body weight loss; SG = sleeve gastrectomy; RYGB = Roux-en-Y gastric bypass. <sup>a</sup>Not powered to detect differences in T2D control. <sup>b</sup>Combination of data from 2 randomised controlled trials (Sleevepass and SMBOSS). <sup>c</sup>Not powered to detect differences between techniques, but showed a trend favouring RYGB.

Table 1: Summary of randomized controlled trials that compared the sleeve gastrectomy and Roux-en-Y gastric bypass regarding weight loss and type 2 diabetes control.

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not answer the question but showed that RYGB may still be the preferred option, with better and more durable WL.

## Contributors

RVC and TBZP conceived the idea and contributed equally in writing the Comment.

## Declaration of interests

RVC received research grants paid to the Institution from Johnson&-Johnson Medical, Brazil, and Medtronic, Brazil. Payment or honoraria for lectures from Johnson&Johnson Medical Brazil, Medtronic, Novo Nordisk, and participates in Scientific Advisory Board for Baritek; Morphic Medical, and Medtronic.

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## References

- Welbourn R, Hollyman M, Kinsman R, et al. Bariatric-metabolic surgery utilisation in patients with and without diabetes: data from the IFSO global registry 2015–2018. *Obes Surg.* 2021;31:2391–2400.
  Wölnerhanssen BK, Peterli R, Hurme S, et al. Laparoscopic Roux-
- 2 Wölnerhanssen BK, Peterli R, Hurme S, et al. Laparoscopic Rouxen-Y gastric bypass versus laparoscopic sleeve gastrectomy: 5-year outcomes of merged data from two randomized clinical trials (SLEEVEPASS and SM-BOSS). Br J Surg. 2021;108:49–57.

- 3 Ignat M, Vix M, Imad I, et al. Randomized trial of Roux-en-Y gastric bypass versus sleeve gastrectomy in achieving excess weight loss. *Br J Surg.* 2017;104:248–256.
- 4 Biter LÜ, Hart JWH, Noordman Bo J, et al. Long-term effect of sleeve gastrectomy vs. Roux-en-Y Gastric Bypass in people living with severe obesity: a phase III multicentre randomised controlled trial (SleeveBypass). *Lancet Reg Health Eur.* 2024. https://doi.org/ 10.1016/j.lanepe.2024.100836.
- 5 Althunian TA, De Boer A, Klungel OH, Insani WN, Groenwold RHH. Methods of defining the non-inferiority margin in randomized, double-blind controlled trials: a systematic review. *Trials.* 2017;18:107.
- 6 Schauer PR, Bhatt DL, Kirwan JP, et al. Bariatric surgery versus intensive medical therapy for diabetes — 5-year outcomes. N Engl J Med. 2017;376:641–651.
- 7 Svanevik M, Lorentzen J, Borgeraas H, et al. Patient-reported outcomes, weight loss, and remission of type 2 diabetes 3 years after gastric bypass and sleeve gastrectomy (Oseberg); a single-centre, randomised controlled trial. *Lancet Diabetes Endocrinol*. 2023;11:555–566.
- 8 Stenberg E, Ottosson J, Magnuson A, et al. Long-term safety and efficacy of closure of mesenteric defects in laparoscopic gastric bypass surgery: a randomized clinical trial. JAMA Surg. 2023;158:709.
- 9 Nielsen HJ, Nedrebø BG, Fosså A, et al. Seven-year trajectories of body weight, quality of life and comorbidities following Roux-en-Y gastric bypass and sleeve gastrectomy. Int J Obes. 2022;46:739–749.
- 10 Yeung KTD, Penney N, Ashrafian L, Darzi A, Ashrafian H. Does sleeve gastrectomy expose the distal esophagus to severe reflux?: A systematic review and meta-analysis. Ann Surg. 2020;271:257–265.