RESPONSE TO COMMENT ON AMINIAN ET AL.

Cardiovascular Outcomes in Patients With Type 2 Diabetes and Obesity: Comparison of Gastric Bypass, Sleeve Gastrectomy, and Usual Care. Diabetes Care 2021;44:2552–2563

Ali Aminian[1] and Steven E. Nissen[2]

Diabetes Care 2022;45:e101 | https://doi.org/10.2337/dci21-0061

We would like to thank Dr. Violante-Cumpa and colleagues for their interest in our recent publication in *Diabetes Care* (1,2). Our analysis showed that in patients with obesity and type 2 diabetes, compared with usual nonsurgical treatment, Roux-en-Y gastric bypass (RYGB) was significantly associated with 47% lower risk of incident major adverse cardiovascular events (MACE) and 40% lower risk of death, and sleeve gastrectomy was significantly associated with 31% lower risk of MACE and 48% lower risk of death (2).

In the head-to-head comparison between two surgical procedures, we found a dose-dependent response. RYGB was associated with a greater reduction in body weight, glycated hemoglobin, use of medications to treat diabetes and cardiovascular diseases, and risk of six-component MACE compared with sleeve gastrectomy (SG). Specifically, the cumulative incidence of the six-component MACE at 5 years was 13.7% in the RYGB group and 24.7% in the SG group, with an adjusted hazard ratio (HR) of 0.77 (95% CI 0.60–0.98).

In analysis of secondary end points, the HR for nephropathy, coronary artery events, cerebrovascular events, heart failure, and three-component MACE all favored RYGB compared with SG, although the upper 95% CI was <1 only for the nephropathy outcome. For example, the adjusted HR of coronary artery events for RYGB vs. SG was 0.63 (95% CI 0.38–1.05), which did not reach conventional levels of statistical significance (P = 0.08). Notably, the direction of associations for all of these outcomes consistently favored RYGB. Lack of statistical significance on individual components of MACE was most likely related to inadequate statistical power and wide CIs and not due to lack of true effects. More studies with larger sample size, longer follow-up time, and larger number of events are needed to compare the effects of RYGB and SG on individual cardiovascular outcomes.

We would like to further clarify a few other points in response to the submitted letter. First, in our analysis, three-component MACE was one of the secondary outcomes and was not considered a sensitivity analysis. Second, there are different methods to estimate glomerular filtration rate (GFR), and each has advantages and limitations. We consistently used only one method to estimate the GFR at baseline and follow-up for all patients. Therefore, the risk of misclassification related to estimated GFR would be similar among the study groups. Third, in the process of regression adjustment, all analyses were adjusted for over 35 baseline variables, including insulin use. Nonetheless, residual measured or unmeasured confounders could have influenced findings in any observational study (2).

Duality of Interest. A.A. reported receiving research support and speaking honoraria from Medtronic. S.E.N. reported receiving grants from Novartis, Eli Lilly, AbbVie, Silence Therapeutics, AstraZeneca, Esperion Therapeutics, Amgen, and Bristol Myers Squibb. No other potential conflicts of interest relevant to this article were reported.

References

1. Violante-Cumpa JR, Sánchez-Gómez RA, Lavalle-González FJ, Mancillas-Adame LG. Comment on Aminian et al. Cardiovascular outcomes in patients with type 2 diabetes and obesity: comparison of gastric bypass, sleeve gastrectomy, and usual care. Diabetes Care 2021;44:2552–2563 (Letter). Diabetes Care 2022;45:e100. DOI: https://doi.org/10.2337/dc21-2317

2. Aminian A, Wilson R, Zajichek A, et al. Cardiovascular outcomes in patients with type 2 diabetes and obesity: comparison of gastric bypass, sleeve gastrectomy, and usual care. Diabetes Care 2021;44:2552–2563

[1]*Bariatric and Metabolic Institute, Department of General Surgery, Cleveland Clinic, Cleveland, OH*
[2]*Cleveland Clinic Coordinating Center for Clinical Research, Department of Cardiovascular Medicine, Cleveland Clinic, Cleveland, OH*

Corresponding author: Ali Aminian, aminiaa@ccf.org

© 2022 by the American Diabetes Association. Readers may use this article as long as the work is properly cited, the use is educational and not for profit, and the work is not altered. More information is available at https://diabetesjournals.org/journals/pages/license.

Downloaded from http://diabetesjournals.org/care/article-pdf/45/5/e101/678563/dci210061.pdf by guest on 21 January 2022