EDITORIAL

Standardized Uniform Reporting and Indications for Bariatric and Metabolic Surgery How Can We Reach This Goal?

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The growing obesity epidemic with simultaneous escalation of the type 2 diabetes pandemic¹ followed by the increasing number of bariatric and metabolic surgery² further emphasize the demand and need for evidence-based assessment of

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all effective therapeutic approaches. The status of bariatric surgery as the most ef-

fective treatment in promoting substantial and sustainable weight loss with improvement of obesity-related comorbidities has been thoroughly established at short-term follow-up confirmed also by recently reported longer-term follow-up results.³⁻⁷ The beneficiary effects of bariatric surgery are mainly associated with weight reduction varying between the different procedures, but there is also mounting evidence indicating weight-independent effects of bariatric surgery on glucose homeostasis improvement beyond reduced food intake and body weight.⁸ However, body weight in terms of either weight loss or weight regain after bariatric surgery is a key outcome closely associated with the desired effects of bariatric or metabolic surgery on weight-related comorbidities. Both the increasing obesity health crisis and the associated increased demand for bariatric surgery highlight the importance of using uniform standardized definitions for weight loss and weight regain to provide optimal clinical guidance in the scientific literature, and this important issue has also been addressed by the American Society for Metabolic and Bariatric Surgery guidelines.9

The rising numbers of bariatric procedures currently led by laparoscopic sleeve gastrectomy will likely be followed by increased demand for revisional bariatric procedures for weight regain, which occurs regardless of the procedure performed.^{3,5,6} Different weight regain definitions applied to the same population may significantly alter the proportion of patients categorized as regaining weight.¹⁰ In this week's issue of JAMA, King et al¹¹ address this important outcome definition of weight regain following bariatric surgery by comparing the performance of common weight regain definitions in the Longitudinal Assessment of Bariatric Surgery-2 (LABS-2) study⁴ with a special reference to the performance of these measurements in regard to important clinical outcomes such as concurrent progression of diabetes. For weight loss, there is already some consensus to use the percentage total weight loss for reporting weight loss outcomes, and current standardized reporting guidelines support the use of percentage total weight loss as it is less influenced by the preoperative weight compared with the percentage excess weight loss, which has been traditionally used in previous bariatric surgery literature.⁹ Similar uniform consensus needs to be achieved regarding weight regain after bariatric surgery to assess both the durability of weight loss and to guide surgeons in revisional surgery indications and optimal revisional procedures. In the study by King et al,¹¹ the best performing measurement was weight regain quantified as percentage of maximum weight loss having the strongest associations with most clinical outcomes. Currently this important problem of weight regain is poorly reported and this problem can only be ameliorated by consensus guidelines, which need to review all promising weight regain measurements including thorough assessment of this promising measure of percentage of maximum weight loss.

The mechanisms and benefits of bariatric surgery independent of weight loss have been shown in type 2 diabetes, and similar consistent findings have also been shown for reduced incidence of myocardial infarction and stroke.¹² These macrovascular disease complications of type 2 diabetes are one of the leading causes driving morbidity and mortality for patients with type 2 diabetes. In the other bariatric surgery article by Fisher et al¹³ in this week's issue of JAMA, the authors confirmed these previous results of bariatric surgery being associated with lower risk of major macrovascular outcomes compared with usual medical care in patients with type 2 diabetes and severe obesity in a large retrospective matched cohort study. As stated by the authors, these findings have not yet been confirmed in randomized clinical trials. However, to conduct such a randomized clinical trial with sufficient power to evaluate these rare outcomes would be extremely challenging and expensive,¹⁴ not to mention the evident ethical concern as the mounting evidence clearly shows superior glycemic control and greater macrovascular risk factor reduction after bariatric surgery compared with both intensive lifestyle and medical treatment combined.^{7,12,15,16} The results by Fisher at al¹³ further add to the current debate and discussion of the use of bariatric and metabolic surgery in the treatment for type 2 diabetes-bariatric surgery should also be intended to prevent type 2 diabetes complications as prevention is better than cure.17 Surgical options have not yet been included in the existing diabetes treatment algorithms despite the existing sufficient clinical and mechanistic evidence supporting the inclusion of metabolic surgery among antidiabetes interventions for patients with type 2 diabetes and obesity according to the recent Diabetes Surgery Summit guidelines.¹⁸

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Standardized reporting and consistency in the scientific literature will be the optimal way to the development of consensus statements and guidelines by multidisciplinary groups to be used for optimal clinical decision making and algorithms. Clinical guidelines based on the long-term follow-up are needed for assessment of new bariatric and metabolic surgery indications, results for patients with type 2 diabetes, and also for the accurate identification of weight regain to assist evaluation of long-term surgical results with uniform indications and choice of revisional surgery procedure for weight regain. To reach the goal of standardized reporting in bariatric surgery, all international and national academic bariatric and metabolic surgery societies, as well as scientific journals publishing bariatric surgery studies, need to reach a consensus on reporting bariatric surgery results and then commit to implementation and adherence to these guidelines.

ARTICLE INFORMATION

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REFERENCES

1. Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in obesity among adults in the United States, 2005 to 2014. *JAMA*. 2016;315 (21):2284-2291. doi:10.1001/jama.2016.6458

2. Angrisani L, Santonicola A, Iovino P, et al. IFSO Worldwide survey 2016: primary, endoluminal, and revisional procedures [published online August 18, 2018]. *Obes Surg.* doi:10.1007/s11695-018-3450-2

3. Adams TD, Davidson LE, Litwin SE, et al. Weight and metabolic outcomes 12 years after gastric bypass. *N Engl J Med*. 2017;377(12):1143-1155. doi:10.1056/NEJMoa1700459

4. Courcoulas AP, King WC, Belle SH, et al. Seven-year weight trajectories and health outcomes in the Longitudinal Assessment of Bariatric Surgery (LABS) Study. *JAMA Surg.* 2018; 153(5):427-434. doi:10.1001/jamasurg.2017.5025

5. Peterli R, Wölnerhanssen BK, Peters T, et al. Effect of laparoscopic sleeve gastrectomy vs

laparoscopic Roux-en-Y gastric bypass on weight loss in patients with morbid obesity: the SM-BOSS randomized clinical trial. *JAMA*. 2018;319(3):255-265. doi:10.1001/jama.2017.20897

6. Salminen P, Helmiö M, Ovaska J, et al. Effect of laparoscopic sleeve gastrectomy vs laparoscopic Roux-en-Y gastric bypass on weight loss at 5 years among patients with morbid obesity: the SLEEVEPASS randomized clinical trial. *JAMA*. 2018; 319(3):241-254. doi:10.1001/jama.2017.20313

7. Schauer PR, Bhatt DL, Kirwan JP, et al; STAMPEDE Investigators. Bariatric surgery versus intensive medical therapy for diabetes: 5-year outcomes. *N Engl J Med*. 2017;376(7):641-651. doi:10.1056/NEJMoa1600869

8. Rubino F, Schauer PR, Kaplan LM, Cummings DE. Metabolic surgery to treat type 2 diabetes: clinical outcomes and mechanisms of action. *Annu Rev Med.* 2010;61:393-411. doi:10.1146/annurev.med.051308 .105148

9. Brethauer SA, Kim J, el Chaar M, et al; ASMBS Clinical Issues Committee. Standardized outcomes reporting in metabolic and bariatric surgery. *Surg Obes Relat Dis*. 2015;11(3):489-506. doi:10.1016/j .soard.2015.02.003

10. Lauti M, Lemanu D, Zeng ISL, Su'a B, Hill AG, MacCormick AD. Definition determines weight regain outcomes after sleeve gastrectomy. *Surg Obes Relat Dis*. 2017;13(7):1123-1129. doi:10.1016/j .soard.2017.02.029

11. King WC, Hineman AS, Belle SH, Wahed AS, Courcoulas AP. Comparison of the performance of common measures of weight regain after bariatric surgery for association with clinical outcomes [published online October 16, 2018]. *JAMA*. doi:10 .1001/jama.2018.14433 **12**. Sjöström L, Peltonen M, Jacobson P, et al. Bariatric surgery and long-term cardiovascular events. *JAMA*. 2012;307(1):56-65. doi:10.1001/jama .2011.1914

13. Fisher DP, Johnson E, Haneuse S, et al Association between bariatric surgery and macrovascular disease outcomes in patients with type 2 diabetes and severe obesity [published online October 16, 2018]. JAMA. doi:10.1001/jama .2018.14619

 Courcoulas AP, Yanovski SZ, Bonds D, et al. Long-term outcomes of bariatric surgery: a National Institutes of Health symposium. *JAMA Surg.* 2014; 149(12):1323-1329. doi:10.1001/jamasurg.2014.2440

15. Courcoulas AP, Belle SH, Neiberg RH, et al. Three-year outcomes of bariatric surgery vs lifestyle intervention for type 2 diabetes mellitus treatment: a randomized clinical trial. *JAMA Surg.* 2015;150 (10):931-940. doi:10.1001/jamasurg.2015.1534

16. Cummings DE, Arterburn DE, Westbrook EO, et al. Gastric bypass surgery vs intensive lifestyle and medical intervention for type 2 diabetes: the CROSSROADS randomised controlled trial. *Diabetologia*. 2016;59(5):945-953. doi:10.1007 /s00125-016-3903-x

17. le Roux CW, Schauer PR. Prevention is better than cure: the next frontier for bariatric surgery? *Ann Intern Med.* 2018;169(5):343-344. doi:10.7326 /M18-2114

18. Rubino F, Nathan DM, Eckel RH, et al; Delegates of the 2nd Diabetes Surgery Summit. Metabolic surgery in the treatment algorithm for type 2 diabetes: a joint statement by international diabetes organizations. *Diabetes Care*. 2016;39(6): 861-877. doi:10.2337/dc16-0236