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Standardized outcomes reporting in metabolic and bariatric surgery

Stacy A. Brethauer, MD[a,*], Julie Kim, MD[b], Maher el Chaar, MD[c], Pavlos Papasavas, MD[d], Dan Eisenberg, MD[e], Ann Rogers, MD[f], Naveen Ballem, MD[g], Mark Kligman, MD[h], Shanu Kothari, MD[i] for the ASMBS Clinical Issues Committee

[a]*Bariatric and Metabolic Center, Digestive Disease Institute, Cleveland Clinic, Cleveland, Ohio*
[b]*Department of Surgery, Tufts University, Boston, Massachusetts*
[c]*Department of Surgery, St. Luke's Hospital, Allentown, Pennsylvania*
[d]*Department of Surgery, Hartford Hospital, Hartford, Connecticut*
[e]*Department of Surgery, Stanford University and Palo Alto VA Health Care Center, Palo Alto, California*
[f]*Department of Surgery, Penn State University, Hershey, Pennsylvania*
[g]*Center for Advanced Surgical Weight Loss, Montclair, New Jersey*
[h]*Department of Surgery, University of Maryland Medical Center, Baltimore, Maryland*
[i]*Department of Surgery, Gundersen Health System, La Crosse, Wisconsin*

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Executive summary of American Society for Metabolic and Bariatric Surgery (ASMBS) outcome reporting standards

The purpose of this document is to provide guidance to authors and editors who write, review, and publish manuscripts focusing on bariatric and metabolic surgery. In addition to providing consistency within the field of bariatric and metabolic surgery, standardized outcome reporting will provide a uniform method of communicating our findings throughout the medical literature.

1. Follow-up

% Follow-up. When appropriate for the study design, the percentage of patients comprising the original study group who complete each follow-up period reported for the study should be reported (i.e., report the numerator and denominator available for follow-up at each time point reported).

For prospective studies, % follow-up should represent the percentage of patients from the original study group(s) who remained in the study until the study endpoint(s) are reached or for the final reported follow-up interval. The reasons for patient attrition from the study should be reported when possible. For retrospective studies, the total number of patients in the database(s) who meet the inclusion criteria should be reported in addition to the percentage available for data analysis for the study endpoints.

Duration of follow-up. *Short-term* follow-up is defined as <3 years after intervention. *Medium-term* follow is defined as >3 and <5 years after intervention. *Long-term* follow-up is defined as >5 years after intervention.

2. Diabetes

Definitions of glycemic outcomes after bariatric surgery

Outcome	Definition
Remission (complete)	Normal measures of glucose metabolism (HbA_{1c} $<6\%$, FBG <100 mg/dL) in the absence antidiabetic medications
Remission (partial)	Subdiabetic hyperglycemia (HbA_{1c} 6%–6.4%, FBG 100–125 mg/dL)

*Correspondence: Stacy A. Brethauer, MD Bariatric and Metabolic Center, Digestive Disease Institute, Cleveland Clinic, 9500 Euclid Ave., M61, Cleveland, OH 44195.
E-mail: brethas@ccf.org

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	in the absence antidiabetic medications
Improvement	Statistically significant reduction in HbA_{1c} and FBG not meeting criteria for remission or decrease in antidiabetic medications requirement (by discontinuing insulin or one oral agent, or ½ reduction in dose)
Unchanged	The absence of remission or improvement as described earlier
Recurrence	FBG or HbA_{1c} in the diabetic range ($\geq$126 mg/dL and $\geq$6.5%, respectively) *or* need for antidiabetic medication after any period of complete or partial remission

HbA_{1c} = glycosylated hemoglobin; FBG = fasting blood glucose.

3. Hypertension

Stage of hypertension before and after bariatric surgery at the defined follow-up intervals are as follows:

Prehypertension (120–140/80–89 systolic/diastolic)
Stage 1 hypertension (140–159/90–99)
Stage 2 hypertension (>160/>100)

Antihypertensive medication use should be reported (clearly define indication for medication as treatment of hypertension). Reporting medication type or class and duration of therapy is also recommended with the understanding that this may not be feasible in retrospective studies.

Improvement:	Defined as a decrease in dosage or number of antihypertensive medication or decrease in systolic or diastolic blood pressure (BP) on the same medication (better control).
Partial remission:	Defined as prehypertension values (120–140/80–89) when off medication.
Complete remission:	Defined as being normotensive (BP <120/80) off antihypertensive medication.
	If medication such as beta-blockade is used for another indication (atrial fibrillation), this needs to be clearly described but cannot be included as complete remission because of the dual therapeutic effect of some medications.

4. Dyslipidemia

It is recommended that reporting practice for dyslipidemia after bariatric surgery follow the *Adult Treatment Panel III Guidelines, 2001,* of the National Heart, Lung and Blood Institute. These values reflect fasting blood samples:

LDL cholesterol	<100 mg/dL = optimal (or <40 mg/dL if another risk factor is present)
	100–129 mg/dL = near optimal
	130–159 mg/dL = borderline high
	160–189 mg/dL = high
	>190 mg/dL = very high
HDL cholesterol	<40 mg/dL = low
	>60 mg/dL = high
Total cholesterol	<200 mg/dL = desirable
	200–239 mg/dL = borderline high
	>240 mg/dL = high
Triglycerides	<150 mg/dL = normal
	150–199 mg/dL = borderline high
	200–499 mg/dL = high
	>500 mg/dL = very high

LDL = low-density lipoprotein; HDL = high-density lipoprotein.

Cardiovascular risk may then be calculated as the total cholesterol/HDL ratio:

½ average risk = 3.27
average risk = 4.44
2× average risk = 7.05
3× average risk = 11.04

Indication for cholesterol and lipid-lowering medication use should be clearly stated.

Improvement:	Decrease in number or dose of lipid-lowering agents with equivalent control of dyslipidemia *or* improved control of lipids on equivalent medication.
	Authors must specify which components of the lipid profile are being studied and report them as individual outcomes when possible.
	Cardiovascular risk based on total cholesterol (TC)/HDL or other risk scoring systems can be used to provide a more global assessment of lipid changes after surgery.
Remission:	Normal lipid panel (or specific component being studied) off medication.

5. Obstructive sleep apnea (OSA)

Recognizing that not all patients will undergo repeat testing, a "subjective" category is included here in addition to the "objective" findings. Reporting complete remission or objective improvement is preferred over subjective improvement.

Complete remission:	In those patients with preoperative polysomnography (PSG) with diagnosis of OSA, complete remission would be defined as AHI/RDI of <5 off CPAP/BI-PAP on repeat objective testing with PSG.
Improvement Objective:	Requires some form of measurable improvement:
	Reduced pressure settings on CPAP/BI-PAP as recommended by a sleep medicine provider.
	Decreased severity of disease on repeat objective testing with PSG (e.g., going from severe to mild).
	Improved repeat score on screening tool compared with preoperative.