

A numerical scale to assess the outcomes of metabolic/bariatric surgery (NOMS)

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Abstract

Introduction: Absent today is a simple numerical system of outcomes assessment that recognizes that bariatric surgery is metabolic surgery and incorporates weight loss, hypertension control, and type 2 diabetes control.

Aim: To introduce a simple, new Numerical Scale to Assess the Outcomes of Metabolic Surgery (NOMS).

Material and methods: For the stratification of weight outcomes, we used the percentage excess weight loss (%EWL); for hypertension, the systolic blood pressure (SBP) and diastolic blood pressure (DBP) combined with medication usage; and for type 2 diabetes, the hemoglobin A_{1c} (HbA_{1c}) value combined with medication usage.

Results: Utilizing the guidelines of the American Diabetes Association, the Working Group of the European Society of Hypertension, the European Society of Cardiology, and the American College of Cardiology/American Heart Association, we propose for %EWL: W1 ≥ 50, W2 > 25 and < 50, and W3 ≤ 25; for hypertension H1 SBP/DBP < 140/90 mm Hg on no medication, H2 SBP/DBP ≥ 140/90 mm Hg with improvement of SBP or possible reduction of antihypertensive medication, and H3 no change or SBP higher than before surgery; for diabetes mellitus D1 HbA_{1c} ≤ 7% and no medication, D2 HbA_{1c} > 7% with a decrease of the HbA_{1c} level or possible reduction of medication, D3 no change in HbA_{1c} or HbA_{1c} higher than before surgery. Designations of H0 and D0 are given if hypertension or diabetes was not present before surgery. Patient examples for numerical scores are provided.

Conclusions: The introduction of our numerical scale (NOMS) can be of benefit in metabolic/bariatric outcomes assessment; communications among metabolic/bariatric surgery centers, physicians, and patients; and for more precise reporting in the evidence-based literature.

Key words: numerical system, outcomes assessment, metabolic surgery, bariatric surgery, diabetes, comorbidities.

Introduction

The prevalence of obesity and related diseases caused by obesity or associated with it poses a huge challenge for modern medicine. The numbers of obese people in western civilizations continues to increase. There is no single state in the USA with less than 30% of the population affected by obesity [1]. Out of several therapeutic options

developed in the 20th century, only surgery offers long-lasting and effective treatment for obesity [2]. Surgical procedures continue to be in evolution. Not only have the surgical procedures changed, but patients' expectations of possible outcomes have changed as well.

One of the major changes in the perception of aims and outcomes of bariatric surgery has been the realization that bariatric surgery is metabolic

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surgery. Today, emphasis is placed not only on the number of lost kilograms (kg) or the reduction in the body mass index (BMI) as a result of surgery but also the impact of various surgical procedures on certain metabolic diseases [3]. Modern research also questions the classification of bariatric procedures based on the physiologic mechanisms of restriction, malabsorption or both. Metabolic surgery links all possible mechanisms of excess weight reduction such as regulation of the orexigenic and anti-orexigenic axes, the homeostasis of incretins and anti-incretins with foregut and hindgut theory, inflammatory background of obesity, and the impact of electrophysiological imbalances on weight gain and reduction [4–10]. Reporting of this extensive research on surgical outcomes requires simple and uniform means of communication between surgeons, other physicians, allied health specialists, and their patients.

Reviewing available literature, we noticed the absence of a simple and uniform classification of the results of surgical treatment of obesity. Bariatric surgeons use multiple tools to assess outcomes such as % excess weight loss (%EWL), the SF-36 questionnaire, the Sickness Impact Profile, the Quality of Well-Being Scale, and the Bariatric Analysis and Reporting Outcome System (BAROS), as well as some new concepts such as percent baseline weight loss (%WL) or BMI units lost (Δ BMI) [11–18]. All these tools lack balance between the assessment of weight loss and the assessment of the impact of bariatric surgery on other aspects of obesity. %EWL is a simple measure that provides information on weight change only. On the other hand, the BAROS scale allows for a very broad assessment of multiple factors associated with obesity such as %EWL, comorbidities, postoperative complications, reoperations, and finally the quality of life assessment in five domains: self-esteem, physical activity, social activity, work, and sexual activity [16]. The multitude of assessed factors makes the BAROS scale a very powerful instrument. It is, however, cumbersome to use on a daily basis in a busy bariatric center. Due to its complexity, its use in communications among medical practitioners is also difficult.

Aim

Based on the above considerations, we would like to introduce a simple, new Numerical Scale to

Assess the Outcomes of Metabolic Surgery (NOMS), not to replace BAROS but to supplement it.

Material and methods

We reviewed the American Diabetes Association Standards of Medical Care in Diabetes, 2014; the Guidelines of the Working Group of the European Society of Hypertension (ESH), 2013; the Guidelines of the European Society of Cardiology (ESC), 2013; and the Guidelines of the American College of Cardiology/American Heart Association (AHA), 2013 [19–23]. These guidelines were combined with a stratification of bariatric weight outcome, expressed as the %EWL as follows: %EWL > 50 – very good, %EWL 50–25 – average/satisfactory, %EWL < 25 – unsatisfactory/failure.

A numerical scale assessing the outcomes of metabolic/bariatric surgery should be simple, easy to obtain, and, therefore, based on a minimal number of gradable outcomes, comparable to the TNM classification of tumors developed by the Union for International Cancer Control [24]. For our numerical classification, we chose to use three cardinal outcomes of metabolic/bariatric surgery, each having a precise numerical metric for evaluation:

- weight change: symbol W; determined by %EWL;
- arterial hypertension control: symbol H; determined by arterial blood pressure (BP);
- diabetes mellitus control: symbol D; determined by hemoglobin A_{1c} levels (HbA_{1c}).

An extension of this numerical scale to other outcomes, e.g., obstructive sleep apnea control, can be added to this basic nomenclature as desired.

Results

The bases for the numerical scale for the assessment of metabolic/bariatric surgery with the three parameters of weight change, arterial hypertension control, and type 2 diabetes mellitus control are presented in Table I.

Examples:

- Patient A: %EWL > 50%, hypertension slightly improved (BP 160/90 mm Hg), HbA_{1c} > 7%, still requires antidiabetic and antihypertensive medication – W1H2D3.
- Patient B: %EWL < 25%, blood pressure returned to normal (BP < 140/90 mm Hg), HbA_{1c} < 6%, does not require any diabetic or hypertensive medication – W3H1D1.

Table I. A numerical scale to assess the outcomes of metabolic/bariatric surgery (NOMS)

| Parameter | Outcome value | Additional comments |
|-------------------|--|---|
| Weight change | | |
| W1 | % EWL \geq 50 | |
| W2 | 50 > % EWL > 25 | |
| W3 | % EWL \leq 25 | |
| Hypertension | | |
| H0 | No hypertension before surgery | |
| H1 | SBP/DBP < 140/90 mm Hg | No medication |
| H2 | SBP/DBP \geq 140/90 mm Hg | Improvement of SBP or possible reduction of antihypertensive medication |
| H3 | No change or SBP higher than before surgery | |
| Diabetes mellitus | | |
| D0 | No DMT2 before surgery | |
| D1 | HbA _{1c} \leq 7% | No medication |
| D2 | HbA _{1c} > 7% | Decrease of the HbA _{1c} level or possible reduction of medication |
| D3 | No change in HbA _{1c} or HbA _{1c} higher than before surgery | |

– Patient C: %EWL = 40%, no previous diabetes or hypertension, normal BP and HbA_{1c} values – W2H0D0.

Discussion

The main objective of bariatric surgery is certainly weight reduction, most universally expressed by %EWL. With the emphasis on metabolic/bariatric surgery, or even pure metabolic surgery without significant weight loss, the main objectives of therapy become control or resolution of hypertension and type 2 diabetes [2, 25, 26]. The American Diabetes Association (ADA) Standards of Medical Care in diabetes, 2014, set three major goals that would lead to significant improvement of diabetes, arterial hypertension, and obesity [19]. These goals are for HbA_{1c} to be less than 7%; systolic BP < 140 mm Hg, diastolic BP < 80 mm Hg; and LDL-cholesterol < 100 mg/dl. The Guidelines of the Working Group of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC), 2013, define high normal values of blood pressure at systolic BP \leq 139 mm Hg and diastolic BP \leq 89 mm Hg [20, 21]. The American Heart Association, in its latest recommendations from 2013, sets several different BP goal levels de-

pending on ethnicity, age, and comorbidities [22, 23]. To establish the guidelines for our numerical classification, we decided to incorporate the BP recommendations for adults younger than 60 years of age, as they reflect the majority of patients submitted to metabolic/bariatric surgery today and are consistent with the recommendations of the ESH and ESC.

The proposed numerical scoring system can be easily determined and incorporated in each patient's records from the time of the first postoperative visit. Comparisons to subsequent visits, and long-term follow-up, allows for the monitoring of satisfactory or non-satisfactory changes in the three primary outcomes of metabolic/bariatric surgery over time. The proposed numerical determination should be of benefit to the staff and to the patients of any given metabolic/bariatric surgery center or practice, as well as to enhanced communications among different metabolic/bariatric surgery centers and physicians representing various specialties. Furthermore, use of the proposed numerical scale can facilitate studies comparing different metabolic/bariatric procedures, centers, and regions. By its adaptation, this scale can allow for more precise reporting in the evidence-based literature.

Conclusions

The introduction of our numerical scale meets two needs of metabolic/bariatric surgery: a simple manner in which to express postoperative outcomes and a tool that acknowledges and assesses the immutable marriage of bariatric and metabolic surgery.

Conflict of interest

Doctors Maciej Michalik, Maciej Bobowicz, and Henry Buchwald declare that they have no conflict of interest or financial ties to disclose.

Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors.

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