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Perspective

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Standardizing outcomes in metabolic bariatric surgery - more than meets the eye, less than counts the scale

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Abstract

The era of precision medicine necessitates standardization in reporting outcomes, in order to provide a common ground of communication among specialists and yield objective measurements at the same time. Although metabolic bariatric surgery spearheads innovation and standardization with regard to technique, this is not the case when measuring outcomes, particularly regarding weight recurrence. The multitude of definitions of weight regain and insufficient weight loss stems not only from a lack of consensus but also from the inherent deficiencies of weight- and BMI-based formulas to incorporate a global and comprehensive assessment for obesity. In this Perspective, we investigate current knowledge as well as potential amendments that will ameliorate our ability to assess weight recurrence and improve the services that we offer to people living with obesity.

Keywords: BMI, weight recurrence, artificial intelligence, precision medicine, multidisciplinary management

Almost a decade ago, Brethauer *et al.* published a seminal, highly cited paper on the standardization of outcome reporting following metabolic bariatric surgery (MBS)[1]. The year of publication might seem remote, but the debate revolving around this subject is anything but obsolete. Among the examined parameters, presumably, the hardest one to calculate and report reliably is weight loss. It is a paradox that our main objective as professionals is to help people lose weight, yet the ideal metric for quantifying the effectiveness of our job remains elusive.

A major controversy lies within the utilization of body mass index (BMI) as a surrogate for defining obesity. Obesity itself has been recognized as a chronic relapsing progressive disease[2], and in this respect, BMI is a suboptimal measure of this process. BMI has several flaws as a metric, even though it can be readily available in clinical routine. First, it cannot discriminate between adipose tissue and lean body mass. Second, it does not take into consideration the diversity of adiposity across different ethnic groups, sexes, and age groups. This happens because BMI is largely based upon data collected from previous generations of non-Hispanic white populations. This way, BMI might serve far beyond its objective as a determinant of obesity to nurture social discrimination and promote the obesity stigma. Most importantly, BMI does not account for the different phenotypes of obesity. One of the attributes of obesity is the diversity of metabolic (i.e., metabolically healthy obesity, sarcopenic obesity, *etc.*), genetic, and functional (i.e., abnormal satiety *vs.* abnormal satiation[3], emotional and hedonic eating, decreased metabolic rate) phenotypes, as well as phenotypes related to adiposity (i.e., brown, white, and beige adipose tissue, in addition to cases of lipodystrophy and lipedema)[4,5]. For all these reasons, an organization as highly esteemed as the American Medical Association (AMA) has recently advocated utilizing BMI in conjunction with at least one more metric to diagnose and classify obesity on an individual basis, including relative body shape and composition[6].

A derivative of the suboptimal role of BMI as a measurement of obesity is the diversity that prevails in the definition of weight recurrence (WR) following MBS. The subject of WR itself is currently one of the hottest topics within the bariatric community. The term WR encompasses weight regain and insufficient weight loss (IWL), while at the same time, it reflects the chronic and evolving nature of obesity as a disease, as well as different behaviors in different obesity phenotypes to some extent. Regardless of its pivotal role in the continuum of disease progress and management, no single definition of WR has been unanimously acceptable to date. Back in 2016, Nedelcu *et al.* made the first attempt to record the most acceptable conditions of weight regain among bariatric surgeons[7]. These definitions entailed the comparison of the current measurement, be it weight or BMI, to the nadir, or the percentile increase of total or excess weight to nadir. Largely based on Nedelcu's definitions, another group of researchers found a deviation regarding the prevalence of weight regain, depending on the different definitions adopted, ranging from 16% (when weight regain to a BMI of 5 Kg/m^2 from nadir was used as the definition) to 87% (when any weight regain was implemented for the same purpose)[8]. Most importantly, these metrics feature variable sensitivity and specificity in detecting actual WR[9]. More recently, the American Society for Metabolic and Bariatric Surgery (ASMBS) performed an in-depth review of the existing definitions of WR[10]. This research retrieved 29 different definitions of WR/weight regain, 1 regarding primary and secondary non-responders, and 3 regarding IWL. Another study compared the performance of multiple measures of weight regain in a cohort of more than 1,400 individuals who had undergone Roux-en-Y gastric bypass (RYGB) and found that the percentage of maximum weight loss had the best correlation with most clinical outcomes, thus could serve as a reliable standardized measurement of weight regain[11]. Furthermore, an elaborate algorithm for meticulously defining and promptly detecting WR post-MBS was developed by another group of researchers[12]. The drawback of this approach is that it necessitates a very close follow-up, which might not be feasible in real-time conditions. Eventually, the Dutch Audit for Treatment of Obesity (DATO) developed the concept of classification for post-bariatric weight regain, which is based on data retrieved from > 18,000 patients, is expressed as percentage total weight loss (%TWL) with standard deviations, and is incorporated in an algorithmic approach to classifying patients who experience WR[9]. All these approaches demonstrate not only the lack of a universal definition for WR but, most importantly, the difficulty in achieving so, owing to the complexity of obesity and its pathophysiologic sequelae.

The realization of the fact that obesity and weight loss are more complex than their respective measures leads to the next concept. Weight and BMI goals are very important, because they are specific, measurable, and trackable, serving as useful tools for people living with obesity to adhere to any weight loss scheme. However, they tell half the story about obesity. They are based on population measurements, thus obscuring and challenging the modern concept of individualized or precision medicine. Other important factors, such as environmental influences, behavioral and eating habits, genetic predisposition and epigenetic modifications, transcriptomics and metabolomics, the gut microbiome, and even variations of body habitus during the same individual's lifetime (pre- *vs.* post-menopausal, young *vs.* middle-aged, on or off medications, different lifestyles according to occupation, variations in sleep patterns, stressful and challenging situations, *etc.*), should also be taken into account when determining the appropriate therapeutic modality for treating obesity[13]. One can easily understand that each of these parameters increases the level of complexity and hinders the development of a meaningful yet easy-to-use tool for defining and managing obesity in daily clinical practice.

Adhering to one or more metrics also bears the risk of undermining the essential goal of intercepting obesity, which extends beyond weight reduction and is mostly about restoring health and well-being. As mandated by Prof. Arya Sharma more than a decade ago, the consequences of obesity and, at the same time, the barriers to its effective management can be summarized by four "Ms", that is mechanical (musculoskeletal pain, obstructive sleep apnea, intertrigo, *etc.*); metabolic (type 2 diabetes mellitus, dyslipidemia, arterial hypertension, metabolic-associated fatty liver disease, several types of cancer, *etc.*); mental (knowledge, expectations, self-image, mood and personality disorders, *etc.*); and monetary (education, employment, low income, insurance capability, healthcare costs, *etc.*). These factors should be taken into consideration, not only because of their inherent connection to obesity, but most importantly because they might deprive people living with obesity from accessing high-quality and effective treatments for their disease. Based on these parameters, the same investigators have developed the Edmonton Obesity Classification System (EOSS), which, in combination with BMI, might serve as an improved functional and prognostic tool for the management of patients living with obesity[14].

All the previous statements acquire a whole new level of significance in view of the advent of new anti-obesity medications (NAOMs), including GLP-1 receptor agonists, dual GIP/GLP-1 receptor agonists, agonists, triple GIP/GLP-1/glucagon receptor agonists, *etc.* Given that new agents and combinations with increasing effectiveness are discovered virtually on a daily basis, it is the responsibility of the scientific community to meticulously investigate and determine the eligibility criteria for prescribing NAOMs, particularly in conjunction with MBS and endoscopic bariatric therapy (EBT). More specifically, one of the following possibilities is applicable to people living with obesity: monotherapy with NAOMSs; NAOMs given before MBS, in a "neo-adjuvant" or pre-emptive fashion; NAOMs given routinely after MBS ("adjuvant" pharmacotherapy); or NAOMs given only in cases of WR following MBS ("salvage" or rescue therapy). A traditional trial-and-error approach would be non-realistic, time-consuming, counter-productive, and ineffective in terms of cost. Here is where out-of-the-box thinking might come in handy. This takes us to a new frontier in quantifying, classifying, and eventually demystifying the soft spots of obesity, which incorporates artificial intelligence (AI) with its various applications and subcategories[15-17]. With the help of AI algorithms, the clinician can analyze extensive datasets (the so-called "big data"), including patient medical history, genetic factors through whole genome sequencing and genome-wide association studies (GWAS), and lifestyle, and consequently construct accurate predictive models that will help select the appropriate treatment plan for each individual patient. Similar platforms have already been developed and validated to predict, for example, the remission of T2DM after RYGB[18], the development of GERD following sleeve gastrectomy[19], or 5-year weight trajectories after MBS (SOPHIA study)[20]. Likewise, an algorithm could utilize appropriate background information of an individual presenting to the outpatient bariatric clinic to determine the most effective and sustainable treatment strategy. In such a context, the role of pre-determined metrics and definitions such as BMI and WR are obviously weakened and substituted by the relentless power of big data.

Are artificial intelligence and automation the answer to objectifying obesity? Quite the contrary. Artificial intelligence, with its various clinical applications, is just one of many tools and by no means should it be considered a panacea, because clinical judgment will (and should) never be undermined when it comes to treating people. AI can definitely assist in the decision-making process, but even this should take place in a constitutional context. This vector can be provided in the form of a multidisciplinary approach, on the model of multidisciplinary team (MDT) for decision-making in oncologic boards. Let us take the surgical management of colorectal liver metastases as an example[21]. Patient selection is determined by three vectors: patient factors, tumor factors, and anatomic factors. Patient factors entail associated medical problems and patient performance status, which are universal for cancer and obesity. Tumor factors can be substituted by obesity factors and include genetic setup and measurements like BMI, adiposity, *etc.* Finally, anatomic factors that should be taken into account include the presence of gastroesophageal reflux disease (GERD), Barrett's esophagus, the surgical history of previous MBS, *etc.* All these factors, i.e., beyond simply the changes that have occurred regarding BMI, should be deemed before proceeding to revisional bariatric surgery (or any other relevant intervention). This process necessitates brainstorming and insight by several experts, whereas AI may facilitate the integration of a multitude of data that are hard to process on an individual basis.

All the aforementioned facts signify that we are at the dawn of a fascinating era in bariatrics and the management of obesity, in general. Traditional linear models will (and should) be surpassed by multilevel approaches. In this context, the question is not how to reach a consensus regarding the ideal measurement of weight recurrence, but how to effectively address obesity as a recurring disease with all the available tools on an individualized basis.

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