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Nutritively Sweetened Beverage Consumption and Obesity:

The Need for Solid Evidence on a Fluid Issue

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The prevalence of obesity has increased substantially in the past several decades, and clinicians, policy makers, and others seek tools to abate this epidemic. One tantalizingly simple solution is to identify a single class of foods for which the elimination or radical reduction would meaningfully decrease the energy intake/expenditure ratio and obesity prevalence. Nutritively sweetened beverages (NSBs) (eg, sugar-sweetened beverages, soft drinks) seem to have become a leading contender, and the surrounding dialogue has become contentious, evoking scientific, clinical, and sociopolitical questions.

The key question is whether reducing NSB consumption will help prevent the onset, reduce the prevalence, or contribute to the management of obesity. The controversy hinges on the strength of the current evidence. Clearly there are other important issues, such as potential NSB effects on overall diet quality, dental and bone health, glucose tolerance, hydration, quality of life, the economy, and the environment. In this Commentary, we address only the obesity question.

Plausibility That Reducing NSB Consumption Will Reduce Obesity

Some epidemiological studies support an association between NSB consumption and obesity,¹ some animal studies have shown that ad libitum NSB consumption increases body weight,² and some short-term food intake studies suggest that NSB consumption may be poorly compensated (compensation here refers to the adjustment of subsequent energy intake or expenditure downward or upward in response to NSB ingestion; hence, its influence on overall energy balance).³ However, other epidemiological,⁴ animal,⁵ and short-term behavioral studies⁶ do not show such results. The stage for evidence that can provide clearer answers has been set.

For some questions, such as whether smoking causes lung cancer, it is impractical or unethical to randomize study participants to receive or not receive the putatively influential agent and observe its effects. In such situations, consideration of the totality of evidence is

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recommended to draw reasonable conclusions despite uncertainty. However, when researchers can ethically and practically randomly assign participants to an exposure and observe the effects on the outcome of interest, sources of evidence other than randomized controlled trials (RCTs) remain reasonable tools for hypothesis generation but fall short of providing the dispositive evidence that is practically attainable. This view has been expressed since 1931, when Gossett (writing as “Student,” of the Student *t* test) chided investigators of a non-randomized trial of the effects of milk consumption on child body weight for poor study design and offered suggestions that remain useful today.⁷

Current Evidence Involving NSB Consumption

If RCTs of the health effects of NSBs are to be the basis for drawing more definitive conclusions, their distinguishing features warrant clarification. There are efficacy RCTs in which consumption is controlled and effectiveness RCTs in which the feasibility of moderating NSB consumption is as much an outcome measure as changes of weight or adiposity. In the present context, published efficacy studies have focused on effects of mandatory consumption, often in excess of the customary levels of study participants. Such trials are interesting but not probative because increased NSB consumption is not suggested as a public health or clinical approach to weight management.

Nearly all RCTs of NSB consumption reduction are effectiveness trials, as they provide information on the effects of programs aimed at decreasing NSB consumption on weight or adiposity without strict control over consumption levels. Peer-reviewed journal publications include 4 studies (5 reports)⁸⁻¹² with durations of 16 to 52 weeks (1 having a 3-year follow-up) and sample sizes ranging from 103 to more than 1000. Considering only the studies' primary analyses of their total sample of participants (as opposed to specific subsets of the study participants) reveals that none has shown a statistically significant effect of reducing NSB consumption on mean body weight, body mass index, or adiposity. Only 1 study reported a significant effect on the probability of being overweight,⁹ and this effect was not maintained at follow-up.¹⁰

Given current evidence, little can be concluded with confidence beyond the fact that requiring individuals to drink large amounts of NSBs causes greater weight gain than not doing so. Randomized controlled trials of NSB consumption reduction have been applied effectiveness studies rather than rigorously controlled efficacy studies. Only the latter ensures fidelity of the intervention. Even the study by Ebbeling et al,⁸ arguably the most rigorous, relied on the voluntary behavior of free-living participants and, in trying to promote adherence, introduced additional factors (eg, extra counseling to those in the treatment group) that most likely confounded the study. Hence, the current evidence cannot establish whether these studies reporting null effects have shown no consistently detectable effect of actually reducing NSB consumption on weight or an insufficiently large effect of attempting to reduce NSB consumption on actual NSB consumption.

Potential for Bias in the Research Record

In nutrition research, strong economic interests exist, and concerns about biases have been raised. A frequent implication is that food and beverage industry scientists or industry-funded scientists act in a fashion that leads to downwardly biased estimates of the causal adverse health effects of their products. Vartanian et al¹³ reported that among observational studies of the association between NSB consumption and obesity, the estimated magnitude of an adverse association was statistically significantly larger among studies not funded by industry than among studies funded by industry, a concerning finding that merits further investigation. Conceivably, there could be opposite and competing publication biases such that industry researchers may be disinclined to publish significant results supporting a strong

association between NSB consumption and obesity, and nonindustry scientists may be disinclined to publish results with non–statistically significant associations—a conjecture worthy of testing.

Furthermore, funders with a vested interest in the outcome of a study may weigh the probabilities of various outcomes before selecting an investigator and study design to fund. Competent, ethical investigators who approach questions from different perspectives and with varying methods (eg, short- vs longer-term trials, different study populations) may differentially attract industry funding, hence yielding valid outcomes, but may be more inclined to support one conclusion than another. Researchers of scientifically meritorious work that happens to support a funder's interests may also be more inclined to seek funding from the sponsor than those generating contrary findings. Collectively, these observations and hypotheses suggest at least 2 competing sets of factors at play—one that may lead industry-funded studies to show weaker associations of NSBs with obesity and another that leads non–industry-funded studies to provide upwardly biased estimates of this association as a result of publication bias.

Bias also may have entered discourse via secondary representations of results in the news media, or other subsequent peer-reviewed publications. For example, the report by Ebbeling et al⁸ describing an NSB reduction RCT stated that “change in body mass index (BMI) was the primary end point. . . . The net difference, $0.14 \pm 0.21 \text{ kg/m}^2$, was not significant overall.” The authors then reported a subgroup finding: “Among the subjects in the upper baseline-BMI tertile, BMI change differed significantly between the intervention . . . and control . . . groups.”⁸ Contrast this modest finding in a sample subset and the circumspect presentation in the original article with the presentation of the findings in some news reports. For instance, a *New York Times* article stated that “the teenagers who had been the most overweight had significant reductions in their body mass indexes at the end of the 25 weeks”¹⁴ and made no mention that the primary analysis in the total sample showed no significant effect. Likewise, a BBC news report indicated that “researchers found that the heavier the teenager had been initially, the stronger the effect on body weight,” again failing to mention the nonsignificant result overall.¹⁵ Similarly, some articles in the peer-reviewed literature^{10,11} described the study by Ebbeling et al as showing that NSB reduction reduces weight, obesity, or adiposity without explicitly stating that the results were not significant in the primary analysis of the total sample. Such statements have the potential to mislead readers who rely on secondary sources.

A third way the literature may have been distorted is by authors of review articles including some studies inappropriately and not including others that should be reviewed. For example, some past reviews¹³ have included a study of short-term (24-hour) weight changes that used weight as an index of hydration status and was never intended nor is adequate to assess the effects of habitual NSB consumption on adiposity. Thus, multiple factors, by no means limited to those with industry funding, seem to be leading to distortion of the research record on this controversial topic.

Appropriate Standards of Evidence

When considering appropriate standards of evidence, an important issue is “Appropriate for what?” Two goals beyond scientific conclusion making can be distinguished: prudent advising and public policy action. Reasonable evidentiary standards may differ dramatically for these different objectives. Prudent advising refers to parents, health care professionals, government agencies, consumers, and others advising that a particular action seems wise without necessarily being certain about the effects of such actions. The evidentiary threshold for prudent advising is generally taken to be fairly low, conceptually akin to the “more likely

than not” civil litigation standard as opposed to the “beyond a reasonable doubt” of criminal trials. Thus, for example, parents may advise children to moderate NSB consumption to help minimize excess weight in the belief that it is a reasonable idea even though present data are not dispositive. The evidence warranting public policy action will depend on legal, economic, moral, cultural, and other inputs outside the scientific (empirical) domain. While scientists may contribute evidence to such deliberations, they alone cannot set the standard of evidence. This standard may vary with the issue based on perceived costs, benefits, and risks, but the standard for the empirical contribution from the scientific community should be set as high as research capabilities allow.

In conclusion, on the issue of NSB consumption and obesity, scientists should undertake rigorous efficacy RCTs that will enable confident ascertainment of the benefit of NSB reduction on body weight and mechanistic studies to explain the basis of findings. The latter should differentiate effects attributable to sweetener, sweetness, palatability, and vehicle to identify avenues for a suitable response, should a significant association be documented. While the evidence establishing a causal association between NSB consumption and obesity is imperfect, it is weaker yet for current recommendations assuming some sweeteners are more problematic than others or that substitution of one type of beverage is preferable over another. To move forward in a productive way, it is important to recognize that NSB research has been an area in which the published research record, including reviews, and news reports following primary studies have apparently been extensively influenced by extrascientific factors (biases). Authors, reviewers, and editors as well as news reporters need to find better ways to minimize biases and maintain the commitment to reporting objective science and maintaining the common goal of improving health.

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