



DIABETES IS PRIMARY

TIMELY NEWS AND NOTES FOR PRIMARY CARE PROVIDERS

from the American Diabetes Association

By Max Bingham, PhD

FROM THE JOURNALS.....

Study Evaluates Eating Patterns for Type 2 Diabetes Remission and Weight Reduction

Weight reduction is seen as a key approach to managing type 2 diabetes and (whisper it) possible remission, but there is continual debate over which dietary approach is best.

According to a recent umbrella review by Churuangasuk et al. (*Diabetologia*, doi.org/hfkv), very-low-energy diets and formula meal replacements are likely the most effective approaches for weight reduction in diabetes. Notably, the researchers found that a focus on one macronutrient or dietary style did not offer any advantage over any other. This means the evidence does not favor low-carbohydrate meal plans over higher-carbohydrate ones or, for that matter, high-protein, Mediterranean-style, low-fat, high-monounsaturated-fat, vegetarian, or low-glycemic-index plans. Evidence supporting the currently popular intermediate fasting approach is also limited.

In a separate systematic review, the authors also looked for evidence supporting the use of diet for remission of type 2 diabetes, finding that programs with a total diet replacement induction phase were the most effective, particularly when used as early as possible after diagnosis.

In what emerges as a mixed picture of experimental designs, different controls, varying risks and benefits, certainty over evidence, and risks of bias, the authors managed to at least land on energy restriction as a key target for both weight loss and diabetes remission.

“Practitioners can . . . be confident that a variety of diet types can all achieve the intended weight losses, and potentially remission of type 2 diabetes, if their patients are able to adhere to the program sufficiently,” they write. “We cannot conclude that any individual with type 2 diabetes, in any context, will do equally well with any diet advice, or that a skilled practitioner may not have greater success advising one diet type. The skills and empathy

of practitioners may overcome any diet-specific effects on weight loss by providing consistent evidence-based support.”

These reviews will inform an effort to update the dietary recommendations of the European Association for the Study of Diabetes.

Nearly One in 20 Individuals With Type 2 Diabetes Achieve Remission in Scotland

Just under one in 20 individuals with type 2 diabetes in routine care achieved remission in Scotland in 2019, according to a study by Captieux et al. (*PLOS Medicine*, doi.org/gnn2wn).

Individuals who achieved remission tended to be older, had a lower initial A1C, and had lost weight. However, the strongest factors associated with remission were previous bariatric surgery and never having used glucose-lowering pharmacological therapy. Based on the findings, the authors suggest that such characteristics can be used to identify and support individuals with the best chances of achieving remission.

“There is a sizeable proportion of people who achieve remission of type 2 diabetes outside of research trials and without bariatric surgery,” the authors write, suggesting that individuals who have not yet started glucose-lowering prescription drugs might be the best group with whom to initiate discussions around remission and weight management. However, they note, “It is important to recognize that remission of diabetes may not be permanent.”

In a statement (bit.ly/3IYkhQw), lead author Mireille Captieux said it is important to understand how many individuals are in remission and their characteristics, as this knowledge creates a baseline for further studies and might help clinicians identify individuals with the best chances of achieving remission. “We have been able to show for the first time that 1 in 20 people in Scotland with type 2 diabetes achieve remission. This is higher than expected and indicates a need for updated guidelines to support clinicians in recognizing and supporting individuals.”

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Weight Loss of Up to 20% After Bariatric Surgery Linked to Type 2 Diabetes Remission

Weight loss after bariatric surgery can lead to initial remission of type 2 diabetes, with report after report suggesting that many individuals see such benefits. Yet, quite how much weight loss is needed to achieve this result has been a moot point among physicians and patients alike. However, a study by Barthold et al. (*Diabetes Care*, doi.org/hfk3) suggests that post-surgery weight losses >20% have little extra effect on remission rates.

The study is notable, as it uses retrospective real-world data on weight loss after surgery. With data from just under 6,000 people with diabetes, it should help to reassure physicians and patients with lingering concerns about the potential benefits of bariatric surgery.

“Our findings can be used to help providers and patients discuss realistic expectations for weight loss following bariatric surgery and how this will affect their type 2 diabetes remission,” the authors write. They also point to data suggesting that patients using insulin or having a very high initial weight will also see a benefit from surgery if total weight loss is at least 20%.

The study looked at outcomes over ~6 years after surgery, finding that ~70% achieved remission after about 1 year. Using weight loss of 0–5% as a reference, the authors found that individuals were two to three times more likely to remit with every extra 5% of weight loss up to 20%. However, with >20% weight loss, chances of remission remained about the same.

“This information should be used by providers in combination with other recent studies about nonsurgical treatments for [type 2 diabetes] and obesity, in a shared decision-making approach to treatment such that each patient receives the treatment that will most likely benefit them,” the authors conclude.



TREATMENTS + THERAPIES

Diabetes Tech: Use It Now to Potentially Save on Care Costs Later

General thinking on continuous glucose monitoring (CGM) is that it can be game-changing in people treated with intensive insulin therapy and sometimes in other circumstances such as in patients using basal-only insulin or even when used intermittently to better understand glycemic patterns in individuals on noninsulin therapies.

Now, at least one digital technology and health care company is trying to build a case for using CGM in people at risk for, but not yet diagnosed with, diabetes as a means of cutting later health care costs for payers, employers, and patients. It is a bold pitch: “Using technology now could save money (and potentially yield better health outcomes) in the long run.”

This story begins with a company called Steady Health that specialized in helping patients with type 1 diabetes understand the steady stream of data coming from their CGM systems. The company’s focus eventually stretched to include people with type 2 diabetes, but that was as far as it went.

However, in June 2020, Steady Health was bought by Carbon Health (<https://bwnews.pr/3tjBxcG>), a California-based provider of primary care services throughout much of the United States. In December 2021, Carbon Health made a bold move to put CGM sensors on the arms of its patients who were at risk of diabetes but had not yet been diagnosed (bwnews.pr/3GpDyZg).

So far, the program is only available to the company’s patients in California who are deemed to be at risk of diabetes by one of its physicians. Individuals meeting those requirements can receive a 2-week prescription for CGM and a “metabolic health assessment” involving different eating and activity patterns. After wearing the sensor, individuals review their glucose trends with a provider and map out a plan to reduce their diabetes risk.

The notable point about this is that many insurers only reimburse for CGM use for people with diabetes managed with intensive insulin therapy. Carbon Health is making the service available to eligible patients at no cost other than usual fee for primary care clinic visits (bit.ly/3se2bTG).

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MARKETPLACE.....

Omnipod 5 Automated Insulin Delivery System Receives FDA Clearance

Insulet Corporation recently announced (bit.ly/34cqo4X) that the U.S. Food and Drug Administration (FDA) has cleared its Omnipod 5 Automated Insulin Delivery System for use by individuals ≥ 6 years of age with type 1 diabetes. It is the third hybrid closed-loop insulin delivery system to be cleared in the United States and, notably, the first that has no tubing component. The system integrates an Omnipod patch pump with a Dexcom G6 continuous glucose monitoring system and either a smartphone app controller or separate controller device. The system can automatically adjust basal insulin in response to CGM data, while users will still administer bolus doses manually.

JDRF, which has been leading the effort to develop a fully automated, closed loop artificial pancreas system said in a statement (bit.ly/3Hs6i51), “Authorization of the Insulet Omnipod 5 is a huge win for the type 1 diabetes community. As the first tubeless hybrid closed loop system to receive FDA clearance, this is a critical step forward in making day-to-day life better for people living with the disease.”

Second Biosimilar of Insulin Glargine Gets FDA Nod

The FDA has approved (bit.ly/3ATH1hR) a second biosimilar product that references Sanofi’s insulin glargine. Called Rezvoglar (insulin glargine-aglr), it is a long-acting human insulin analog that is indicated to improve glycemic control in adults and children with type 1 diabetes and adults with type 2 diabetes. Although the approval was based on data demonstrating no clinically meaningful difference between the biosimilar and its reference insulin, patients will still need a separate prescription for Rezvoglar because the products are not considered interchangeable. Eli Lilly, the manufacturer of Rezvoglar had not announced pricing for the new biosimilar insulin at the time of writing.

The approval of Rezvoglar follows the July 2021 approval of Seemglee, another insulin glargine biosimilar product. In that case, the biosimilar was designated interchangeable, meaning that pharmacists could switch a prescription for insulin glargine to the Seemglee product without the approval of a prescribing physician. Express Scripts, a pharmacy benefits manager, recently announced (prn.to/34nole1) that it will substitute Seemglee for Lantus in its largest formulary.

More biosimilar insulin glargine products may be forthcoming. Lannett has announced (bit.ly/3ul6ijG) its submission of a new drug application for its insulin glargine biosimilar candidate. A pivotal trial of the product was scheduled to begin in March 2022, with a potential launch of the product by early 2024.

Treatments + Therapies, *continued from p. 134*

Blood Pressure Reduction Linked to Reduced Diabetes Risk

Blood pressure lowering can reduce the risk of new-onset type 2 diabetes, according to a meta-analysis by Nazarzadeh et al. (*The Lancet*, doi.org/gnqnm). The effect varies, however, based on the class of antihypertensive drug used to lower blood pressure.

Specifically, the authors found an 11% overall reduction in risk for every 5-mmHg lowering of systolic blood pressure. For ACE inhibitors and angiotensin receptor blockers (ARBs), the relative risk (RR) of new-onset diabetes was 0.84, whereas β -blockers and thiazide diuretics increased risk, with RRs of 1.48 and 1.20, respectively. There was no overall effect from calcium channel blockers (RR 1.02).

These findings come from a meta-analysis of individual participant data in a series of randomized placebo-controlled or head-to-head trials of the five classes of antihypertensive drugs conducted between 1973 to 2008. Collectively, the studies included just under 146,000 individuals, of whom 9,883 developed new-onset type 2 diabetes.

In a complementary analysis, the authors used a Mendelian randomization approach to replicate the effects of each drug class. In this case, they found a 12% reduction in risk for each 5-mmHg reduction in systolic blood pressure, reduced risks with ACE inhibitors and ARBs, a null effect with calcium channel blockers, and an increased risk with β -blockers. The analysis of thiazide diuretics did not reach statistical power for replication.

“The differing effects of some drug classes . . . support decision making for drug choice according to an individual’s risk profile,” the authors write. “In particular, [ACE] inhibitors and [ARBs] should become the drugs of choice when clinical risk of diabetes is of concern, whereas β -blockers and thiazide diuretics should be avoided where possible.”



ADA NEWS

American Diabetes Association Provides New Guidance on Diabetes Screening, Therapies, Technology, and More

The American Diabetes Association's (ADA's) *Standards of Medical Care in Diabetes—2022*, recently published online and as a supplement to *Diabetes Care*, provides the latest in comprehensive, evidence-based recommendations for the diagnosis and treatment of people with type 1, type 2, or gestational diabetes; strategies for preventing or delaying type 2 diabetes; and therapeutic approaches that can reduce complications, mitigate cardiovascular and renal risk, and improve health outcomes.

Highlights From the 2022 Standards of Care

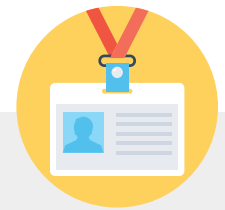
Some notable updates and additions this year include:

- Guidance on first-line therapy based on comorbidities
- Screening for prediabetes and diabetes beginning at age 35 for all people
- Changes to gestational diabetes recommendations regarding when to test and in whom testing should be done
- Updated recommendations on diabetes technology selection based on individual and caregiver considerations, ongoing education on the use of devices, continued access to devices across payers, support for students using devices in school settings, use of telehealth visits, and early initiation of technology

- A new recommendation about adequate carbohydrate intake before oral glucose tolerance testing as a screen for diabetes

The ADA also publishes an abridged version of the Standards of Care specifically for primary care providers yearly online and in *Clinical Diabetes* and offers a convenient app and pocket chart for health care providers. A webcast on the latest ADA guidelines, with continuing education credit, can be accessed through the Association's continuing education portal (bit.ly/3gezuk6).





CONFERENCE SPOTLIGHT

IDF Atlas: One in 10 Adults Worldwide Has Diabetes

The 10th edition of the International Diabetes Federation's (IDF's) *IDF Diabetes Atlas* was published in December 2021 (bit.ly/3L6vxMA), with highlights presented at two sessions of the IDF Virtual Congress 2021 (bit.ly/3Hm95Ne).

Updates include new estimates of global diabetes incidence and prevalence, mortality, and diabetes-related health care costs. There are also new sections focused on adult-onset type 1 diabetes, childhood-onset type 2 diabetes, and coronavirus disease 2019 and diabetes.

Each new edition of this authoritative work paints a sobering picture, and this edition presented a particularly grim reality: 537 million adults aged 20–79 years (about one in 10) are living with diabetes worldwide, and three in four adults with diabetes

live in low- and middle-income countries. Furthermore, diabetes caused 6.7 million deaths in 2021 and was responsible for \$966 billion USD in global health care expenditures in 2021.

One of the most striking datasets depicts the rates of adults living with diabetes in various regions around the globe. In the Middle East and North Africa, one in six adults had diabetes in 2021, and this proportion was one in seven in North America and the Caribbean; one in eight in the Western Pacific; one in 11 in Europe, South and Central America, and Southeast Asia; and one in 22 in Africa.

These sobering statistics remind us that diabetes, when viewed from a global perspective, is still a pandemic of enormous proportions. A full report on the 2021 Atlas is available on Medscape ([wb.md/3uoPSGS](https://www.medscape.com/webpage/wb.md/3uoPSGS)).

To learn more about ADA's continuing education opportunities, including Diabetes Is Primary events in your community, please visit professional.diabetes.org/ce.