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## Intensive Glycemic Control in Type 2 Diabetes Mellitus—A Balancing Act of Latent Benefit and Avoidable Harm:

### A Teachable Moment

**Rene Rodriguez-Gutierrez, MD,**

Knowledge and Evaluation Research Unit, Division of Endocrinology, Diabetes, Metabolism and Nutrition, Department of Medicine, Mayo Clinic, Rochester, Minnesota

Endocrinology Division, Department of Internal Medicine, University Hospital “Dr Jose E. Gonzalez,” Monterrey, Mexico

**Kasia J. Lipska, MD,** and

Section of Endocrinology, Department of Internal Medicine, Yale School of Medicine, New Haven, Connecticut

**Rozalina G. McCoy, MD, MSc**

Division of Primary Care Internal Medicine, Department of Medicine, Mayo Clinic, Rochester, Minnesota

Department of Health Sciences Research, Mayo Clinic, Rochester, Minnesota

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### Story From the Front Lines

A 55-year-old construction worker diagnosed as having type 2 diabetes mellitus 5 years ago, with current glycosylated hemoglobin (HbA<sub>1c</sub>) level of 7.4% of total hemoglobin, was referred to the diabetes clinic to optimize glycemic control. He was obese and had hypertension, dyslipidemia, and obstructive sleep apnea, but no known cardiovascular disease. He was prescribed metformin, 1000 mg twice daily; sitagliptin, 100 mg daily; glimepiride, 4 mg daily; and NPH insulin, 20 U at bedtime. (To convert HbA<sub>1c</sub> to a proportion of total hemoglobin, multiply by 0.01.)

The patient and his primary care physician (PCP) sought specialty guidance on achieving an HbA<sub>1c</sub> level lower than 6.5% to 7.0% owing to concern about developing chronic diabetes mellitus complications. However, recurrent episodes of mild hypoglycemia and 1 episode of severe hypoglycemia also made the patient afraid of “lows.” These hypoglycemic episodes

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**Corresponding Author:** Rozalina G. McCoy, MD, MSc, Division of Primary Care Internal Medicine, Department of Medicine, Mayo Clinic, 200 First St SW, Rochester, MN 55905, (mccoy.rozalina@mayo.edu).

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started 6 months ago, when his HbA<sub>1c</sub> level was 7.8% and insulin was started. His primary care team considered the patient to be noncompliant and his care challenging.

During his visit to the diabetes clinic, the diabetologist engaged the patient in conversation about the risks, benefits, and goals of diabetes mellitus therapy. The patient acknowledged feeling overwhelmed by his chronic conditions, treatment burden, and fears of hyperglycemia and hypoglycemia alongside personal and financial pressures. They decided together to stop insulin, temporarily have a target HbA<sub>1c</sub> level of 7.0% to 8.0%, and continue remaining medications unchanged. After 6 months, while the patient's HbA<sub>1c</sub> level rose to 7.7%, he was no longer experiencing hypoglycemia, reported less disease- and treatment-related anxiety, and returned to his PCP for ongoing care. In addition, he reported greater capacity to engage in his care (eg, lifestyle changes, medication adherence) and gradually improve his glycemic control.

### Teachable Moment

Current guidelines recommend targeting HbA<sub>1c</sub> levels lower than 6.5% or 7.0% when treating adults with type 2 diabetes mellitus, unless patients have recurrent severe hypoglycemia, high-comorbidity burden, or limited life expectancy. These recommendations stem on the reduction in microvascular and macrovascular events among patients with markedly uncontrolled type 1 or recently diagnosed type 2 diabetes mellitus randomized to intensive glycemic control in early randomized clinical trials (RCTs).<sup>1</sup> Driven by these findings, patients, clinicians, and policy-makers have focused on reaching this HbA<sub>1c</sub> target.

More recent RCTs and meta-analyses, however, have shown no difference of intensive glycemic control when compared with a conventional approach (an HbA<sub>1c</sub> level of approximately 8.0%), on many important microvascular (end-stage renal disease, renal death, blindness, clinical neuropathy) or macrovascular outcomes (all-cause and cardiovascular mortality, amputations or stroke).<sup>1,2</sup> In contrast, landmark trials found a 2- to 3-fold increase in the risk of hypoglycemia with intensive treatment.<sup>1,2</sup> Hypoglycemia is associated with adverse health outcomes, including cardiovascular events, cognitive impairment, fractures, death, and decreased quality of life.<sup>3,4</sup> As a result, many clinical practice guidelines now advocate an individualized approach that balances benefits of glycemic control and harms of hypoglycemia.

Treatment decisions about optimal glycemic control are complex for several reasons. The benefit of intensive glycemic control on clinical outcomes remains uncertain.<sup>1,2</sup> Potential benefits also need to be weighed against the risk of harms, including hypoglycemia. Patients may place different values on achieving the benefits and avoiding the harms of treatment. Finally, the nature of the treatment plan, which includes lifestyle changes and medications, requires full-participation by the patient. Patients' contexts and capacities to carry out the treatment plan vary considerably.<sup>5</sup> Therefore, it is imperative to involve patients in the decision-making process.

Shared decision-making is a patient-centered approach in which patients and clinicians engage in a dialogue to identify an optimal and practical course of action while considering

the patient's context. In shared decision-making, both patients and clinicians are considered "experts"; clinicians are knowledgeable about the disease and the evidence, while patients are experts on how they experience the disease, their goals, and expectations of medical care.<sup>5</sup> In the case of the patient described herein, the process of shared decision-making involved a conversation about tradeoffs. While the patient wanted to reduce the risk for chronic complications, he was also overwhelmed by the burden of treatment, hypoglycemia, polypharmacy, and multimorbidity. Various options were discussed, including continuing insulin, trying a different type of insulin, or stopping glimepiride or insulin. In addition, the marginal benefits of achieving an HbA<sub>1c</sub> level of 7.0% to 8.0% vs less than 7% were discussed. Given what it would take him to get to his HbA<sub>1c</sub> level to below 7.0% at that time, the patient did not think the effort and risk were worth it.

Patient-centered care and SDM require a comprehensive and transparent discussion of known risks, benefits, costs, and burden of the available and clinically reasonable treatment options. This requires acknowledgment of treatment uncertainties, including the strength and consistency of currently available evidence in support or against a particular treatment approach. Patient-centered care also mandates occasional deviation from standards of care and glycemic targets recommended by publically reported performance metrics, if these metrics are not congruent with patient wishes, preferences, and context. Ultimately, patient-centered care requires that clinicians be evaluated based on metrics aligned with each patient's clinical and personal context, not a "one-size-fits-all" metric that leaves patients out of the discussion.

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