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DOI: 10.1056/NEJMe2502491

Automated Insulin Pump in Type 2 Diabetes

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Approximately 1 in 10 persons in the United States have type 2 diabetes, and such numbers are increasing among children, teens, and young adults.[1] Adults with diabetes have struggled to lower their glucose and glycated hemoglobin levels, with only 50% reaching the recommended goal of less than 7% for the latter.[2]

Type 1 diabetes is always managed by insulin administration, whereas insulin therapy for type 2 varies. According to the Centers for Disease Control and Prevention, insulin is prescribed within a year after diagnosis in 12.3% of patients with type 2 diabetes,[3] in addition to other treatment options, such as glucagon-like peptide-1 receptor agonists and sodium–glucose cotransporter 2 inhibitors. Technologic advances during the past few decades have improved care and outcomes in patients with type 1 diabetes, but their use in patients with type 2 disease is just catching up. Broader acceptance and use of continuous glucose monitoring (CGM) devices now exists, especially among primary care practitioners.[4,5]

Improvements in pump technology have included the automated suspension of insulin delivery to help prevent hypoglycemia, improved ease of daily management to help with the burden of diabetes, and the achievement of glycemic control to prevent complications — all advances that have focused on the type 1 population. However, in this issue of the *Journal*, Kudva and colleagues[6] describe a clinical trial involving a population that many practitioners traditionally would not have considered to be candidates for automated insulin delivery (AID). In this trial, investigators at 21 centers recruited 319 insulin-treated patients with type 2 diabetes, ranging in age from 19 to 87 years. The patients were randomly assigned in a 2:1 ratio to receive AID or to continue their pretrial insulin-delivery method.

The patients in the AID group were assigned to use the t:slim X2 insulin pump with Control-IQ, a device that had been found to significantly improve levels of mean glucose and glycated hemoglobin in patients with type 1 diabetes.[7] In the current cohort with type 2 diabetes, the mean glycated hemoglobin level in the AID group dropped by 0.9 percentage points (from 8.2% at baseline to 7.3% at 13 weeks), with an even greater decrease among the patients who had a baseline glycated hemoglobin level of 9.0% or greater (from 10.3% to 7.9%).

The investigators also analyzed the mean percentage of time that patients spent in the target glucose range of 70 to 180 mg per deciliter, a measure obtained from CGM systems that complemented the measures of glycated hemoglobin. In studies involving patients with type 1 diabetes who used AID, glucose levels stayed within the targeted time-in-range.[7] It is encouraging that the desired increase in the percentage of time in the target range was also observed in the current trial among patients in the AID group, who were also able to decrease their total insulin dose by 8 units per day, although their mean weight increased by 2.4 kg.

The current trial showed a relatively low risk of adverse events with the AID system. One severe hypoglycemia event, which was deemed to be

unrelated to device functionality, occurred in the AID group. The investigators noted that infusion-set failures were mainly responsible for other device-related adverse events. Given that only 4% of the patients had used an infusion pump before the trial, the safety profile seems to be reassuring.

These promising findings suggest that there may be a future shift in treating patients with type 2 diabetes who are currently receiving insulin. The use of CGM in these patients has increased with wider availability, inclusion in professional society guidelines, and the possibility of health insurance coverage, so some practitioners may be considering an AID system as the next step in treatment. Of course, widespread use of such systems will need to be evaluated by already-challenged medical systems. In addition, AID systems require an insulin pump, CGM, and a software application run by a mobile device.[8] Given these requirements, some patients may not be able to bear the cost burden for this system. Furthermore, some insurers currently mandate 3-month follow-ups for supplies, even for patients with well-controlled disease, which may burden already-strained specialty clinics.

Finally, diabetes education in the United States is currently in crisis, with a lack of services and resources to ensure that patients learn self-management skills.[9] This gap will be further challenged with the wider use of AID systems and their higher demand for training. Other barriers may include necessary training to ensure that the technology is used properly, as well as possible recalls for software applications that could pose a serious risk to users.[10]

In the face of these obstacles, the current trial has shown the efficacy and safety of an advanced technology, as compared with CGM alone, in patients with type 2 diabetes. These findings may prompt clinicians to consider the use of AID systems in this population as part of our ongoing review of the gaps within diabetes care.

Disclosure forms provided by the author are available with the full text of this editorial at NEJM.org.

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DOI: 10.1056/NEJMe2504046