

Real Life Analysis of Simplified Carbohydrate Announcement in Patients With Type 1 Diabetes Using a Patch Pump With Automated Insulin Delivery

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Keywords

Type 1 diabetes, Omnipod 5, automated insulin delivery system, closed-loop system, carbohydrate announcement

Introduction

Most people with type 1 diabetes are not meeting recommended clinical targets, placing them at an increased risk for serious adverse health outcomes.¹ Automated insulin delivery (AID) systems have consistently demonstrated their effectiveness.² Automated insulin delivery users are still required to perform accurate carbohydrate (CHO) counting to optimize their results. The purpose of this study was to investigate, for patients equipped with the Omnipod 5 AID System (OP5), the impact of different meal declaration methods on glycemic control.

This real-world study was a retrospective, longitudinal, monocentric observational design. Informed consent was obtained before data collection. A total of 147 participants (70% females, mean age 37 years) were included in

the analysis, consisting of 46 subjects in the FIX group with simplified meal announcements and 101 in the FLEX group with precise CHO evaluation, initiating OP5 therapy between July 2024 and June 2025. Baseline demographic and clinical data are summarized in Supplemental Tables S2 and S3. Subjects from both groups had similar age ($P = .71$), duration of diabetes ($P = .92$), gender and body mass index (BMI). On the contrary, subjects from the FLEX group had higher time in range (TIR = 70-180 mg/dL) at baseline (50.3% [47.9, 52.7] vs 42.8% [38.7, 47.1], $P < .01$). Time in range levels after 6 months were correlated with age ($P < .01$), daily CHO entries ($P < .001$), number of insulin bolus ($P < .05$) and baseline TIR ($P < .01$), but not with duration of diabetes or BMI (Tables S4 and S5). Glycemic outcomes over 6 months of AID revealed major differences between groups, as shown in Figure 1. With a 5% risk, by adjusting

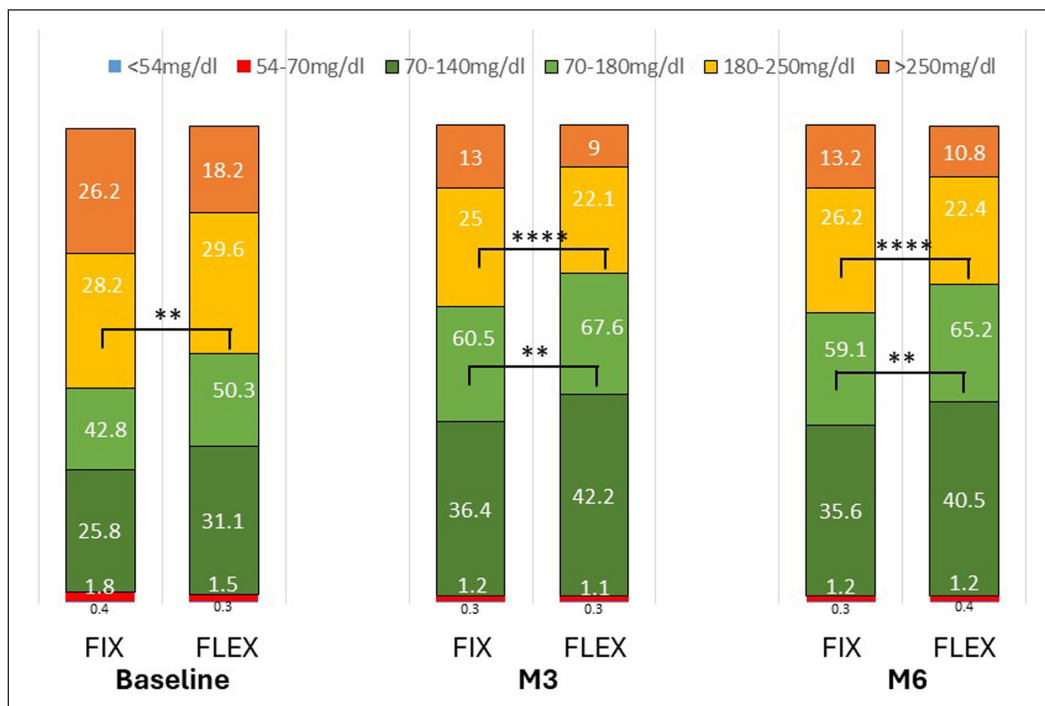


Figure 1. Mean percent of time in tight range (dark green, 70-140 mg/dL), time in range (green, 70-180 mg/dL), time above range (orange, 180-250 mg/dL and dark orange, >250 mg/dL) and time below range (red, 54-70 mg/dL and blue <54 mg/dL) at baseline, at 3 and 6 months after Omnipod 5 initiation for subjects with simplified carbohydrate announcements (FIX, $n = 46$) or precise carbohydrate counting (FLEX, $n = 101$).

P values after the Mann-Whitney test, $** < .01$; $*** < .0001$.

for age, duration of disease, gender and baseline TIR, there is a statistically significant relationship between TIR levels and FIX or FLEX strategies (-3.44 [-6.68 ; -0.198] at 6 months; $P < .05$). After 6 months, the number of CHO-associated boluses/day was reduced in the FIX group ($P < .05$).

Simple meal announcements could serve as an alternative approach to managing prandial insulin needs, potentially alleviating some of the burdens associated with CHO counting. Although the OP5 algorithm is capable of dynamically adapting insulin delivery, it does not fully compensate for underestimation or approximation of CHO intake. The OP5 system includes a bolus insulin delivery feature that responds slowly and conservatively.³ Recent studies have shown that simplified meal announcement strategies can be effectively used with the MiniMed 780G system, demonstrating its effectiveness during a randomized study.⁴ A recent meta-analysis⁵ reported that the simplified meal announcement strategy with AID achieved high TIR but was accompanied by significantly greater time below range (TBR), increased time above range (TAR) and higher basal insulin delivery. In contrast with this literature, we showed that simplified meal announcements with OP5 are safe, with no significant increase in hypoglycemic episodes.

Taken together, these findings support the concept that simplified CHO announcement at the initiation of OP5 may represent a pragmatic and effective option for selected individuals (eg, those with limited technological proficiency or difficulties with numerical calculations), while confirming that precise CHO counting remains the optimal strategy for maximizing the glycemic benefits of this specific AID system.

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Abbreviations

AID, automated insulin delivery; CHO, carbohydrate; CGM, continuous glucose monitoring; GRI, glycemia risk index; OP5, Omnipod 5; TIR, time in range; TITR, time in tight range.

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Author Contributions

NB and CT wrote the first draft of the manuscript. FA, SL-P and SV-F contributed to the discussion and reviewed and edited the manuscript. All authors approved the final version of the manuscript. CT is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Declaration of Conflicting Interests

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Supplemental Material

Supplemental material for this article is available online.

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