



# Hybrid Closed-Loop Systems and Glycemic Outcomes in Children and Adults With Type 1 Diabetes: Real-World Evidence From a U.S.-Based Multicenter Collaborative

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Increasing evidence demonstrates the benefits of new diabetes technologies, including insulin pumps and continuous glucose monitors (CGM), for glycemic management in people with type 1 diabetes (T1D). In addition to the independent use of these technologies, hybrid closed-loop systems (HCLS), which combine insulin pumps and CGM with a closed-loop algorithm controller to automate insulin delivery, can improve glucose levels (1,2). This study compared glycemic outcomes in users of HCLS with those of users of insulin pumps and CGM without automated insulin delivery and those using multiple daily insulin injections (MDI) with CGM in youth and adults with T1D.

We analyzed electronic medical records data (2019–2021) from the T1D Exchange Quality Improvement Collaborative (T1DX-QIC), a multicenter database for people with T1D (3). A total of 28,019 people, aged  $\geq 6$  years with T1D diagnosis for at least 1 year, were classified into three groups by mode of insulin treatment and CGM use. At their most recent visit, patients who reported using HCLS (either Tandem t:slim X2 pump with Control-IQ or

Medtronic 670G or 770G pump with active automated mode) were classified as HCLS users ( $N = 2,047$ ), those using an insulin pump together with a CGM without automated insulin delivery were classified as Pump+CGM users ( $N = 12,306$ ), and those using MDI for insulin therapy along with a CGM device were classified as MDI+CGM users ( $N = 13,613$ ). DIY loopers (patients having built their own closed-loop systems) were excluded from this analysis. Primary outcome was the most recently recorded HbA<sub>1c</sub> (in percent). Secondary outcomes, available for a subgroup of this population, included time in range (TIR), defined as percentage of time spent between 70 and 180 mg/dL, time below range (TBR) ( $< 70$  mg/dL), and time above range (TAR) ( $> 250$  mg/dL), using an average of the last 14 days. Data collection for this analysis was approved by the Western Institutional Review Board.

In this study, 58% of the HCLS group, 60% of the Pump+CGM group, and 59% of the MDI+CGM group were individuals  $\leq 18$  years of age. Inequities in HCLS use by race/ethnicity and insurance status were observed. Among all non-Hispanic

(NH) Black people with T1D, 3% used HCLS, whereas in the NH White population, 8% used HCLS ( $P < 0.001$ ). Differences in HCLS uptake persisted by race/ethnicity after stratifying by insurance status. Duration of diabetes was longer in the HCLS group than in the Pump+CGM and MDI+CGM groups (mean [SD] 11 [11] vs. 9 [9] and 9 [10] years). In assessment of glycemic outcomes, mean HbA<sub>1c</sub> levels were lower for HCLS users than for the Pump+CGM group (difference in means [95% CI]  $-0.5$  [ $-0.6, -0.5$ ]) and the MDI+CGM group (difference in means [95% CI]  $-0.8$  [ $-0.9, -0.7$ ];  $P < 0.001$ ). HbA<sub>1c</sub> levels were lowest in the HCLS group for both pediatric (aged  $\leq 18$  years) and adult (aged  $> 18$  years) populations (pediatric median HbA<sub>1c</sub> [interquartile range] 7.5 [1.6] vs. 8.0 [2.0] and 8.2 [2.4], respectively; adult median HbA<sub>1c</sub> [interquartile range] 7.0 [1.2] vs. 7.6 [1.8] and 7.7 [2.1], respectively). Linear mixed models, controlling for potential confounding effects of age, sex, race/ethnicity, and insurance status, showed that estimated marginal means (EMM) for HbA<sub>1c</sub> remained lower among HCLS users than for the

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