Day-and-Night Closed-Loop Control Using the Unified Safety System in Adolescents With Type 1 Diabetes at Camp

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Trang T. Ly,[1,2] Bruce A. Buckingham,[1] Daniel J. DeSalvo,[1] Satya Shanmugham,[1] Marta Satin-Smith,[3,4] Mark D. DeBoer,[5] Mary C. Oliveri,[6] Elaine Schertz,[6] Marc D. Breton,[6] and Daniel R. Cherñavvsky[6]

Adolescence marks a challenging time in diabetes care (1). Automated insulin delivery has the potential to overcome some of the barriers, such as missed meal boluses and nocturnal hypoglycemia. The University of Virginia Unified Safety System (USS) is one of the most tested control-to-range approaches and operates on an Android-based system that uses a Dexcom G4 PLATINUM Share glucose sensor and Roche Accu-Chek pump (2). The objective of this study was to test the efficacy of USS in day-and-night closed-loop control (CLC) in adolescents with type 1 diabetes at camp, where large meals and physical activity challenge glucose control.

In this study, eligible subjects with type 1 diabetes on pump therapy were randomized to either CLC ($n = 17$) or sensor-augmented pump (SAP) ($n = 16$) for 5 days. There was no A1C restriction.

Clinical characteristics of the 33 subjects include mean ± SD (min–max) age of 17.9 ± 5.5 years (10.1–35.0), weight 68 ± 17 kg (37.3–104.3), A1C 8.2 ± 1.5% (6.2–11), and insulin dose 0.9 ± 0.3 units/kg/day (0.4–1.4). The primary outcome of percent time in range, 70–180 mg/dL, was greater with CLC (78.6 vs. 65.4%, CLC vs. SAP, $P = 0.003$) (Table 1). There was a reduction in time spent <70 mg/dL (1.8 vs. 4.2%, CLC vs. SAP, $P = 0.008$) and >180 mg/dL (19.8 vs. 30.7%, CLC vs. SAP, $P = 0.011$). Between 2300 and 0700 h, the percent time between 80 and 150 mg/dL was increased with CLC (73.5 vs. 49.9%, CLC vs. SAP, $P < 0.001$).

Table 1—Glycemic outcomes

	SAP ($n = 16$)	CLC ($n = 17$)	*P*
Overall (0700–0700 h)			
Mean glucose (mg/dL)	156 ± 5	143 ± 3	0.040
Percent time 70–180 mg/dL (%)	65.4 ± 5.3	78.6 ± 2.2	0.003
Percent time 80–150 mg/dL (%)	46.5 ± 3.2	60.0 ± 2.6	0.002
Percent time <70 mg/dL (%)	4.2 ± 0.8	1.8 ± 0.4	0.008
Percent time >180 mg/dL (%)	30.7 ± 3.4	19.8 ± 2.2	0.011
Average number of meter glucose values <70 mg/dL (count)	5.4 ± 0.8	4.0 ± 0.7	0.212
Average daily insulin (units)	56.1 ± 7.4	49.8 ± 4.0	0.214
Average daily insulin relative to that at home (%)	93 ± 3.1	87 ± 4.4	0.292
Night (2300–0700 h)			
Mean glucose (mg/dL)	150 ± 6	128 ± 4	0.003
Percent time 70–180 mg/dL (%)	67.2 ± 4.7	90.3 ± 2.2	<0.001
Percent time 80–150 mg/dL (%)	49.9 ± 4.2	73.5 ± 4.0	<0.001
Percent time <70 mg/dL (%)	4.2 ± 0.9	1.4 ± 0.4	0.007
Percent time >180 mg/dL (%)	28.7 ± 4.5	8.4 ± 2.2	<0.001
Average number of meter glucose values <70 mg/dL (count)	1.6 ± 0.4	0.7 ± 0.2	0.07

Data are mean ± SE.

CLC with USS was effective in increasing time spent in range and reducing both hypoglycemia and hyperglycemia in adolescents with type 1 diabetes compared with SAP therapy alone, achieving an average glucose of 143 mg/dL (estimated A1C of 6.6%) during the 5-day supervised study. Results were confirmed

[1]*Division of Pediatric Endocrinology and Diabetes, Stanford University School of Medicine, Stanford, CA*
[2]*School of Paediatrics and Child Health, The University of Western Australia, Perth, Western Australia*
[3]*Children's Hospital of The King's Daughters, Norfolk, VA*
[4]*Department of Pediatrics, Eastern Virginia Medical School, Norfolk, VA*
[5]*Department of Pediatrics, University of Virginia School of Medicine, Charlottesville, VA*
[6]*Center for Diabetes Technology, University of Virginia, Charlottesville, VA*

Corresponding author: Trang T. Ly, trangly@stanford.edu.

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across the baseline A1C range, with no correlation between A1C and performance in the CLC group. The improvement in glucose control was most impressive at night, with an increase in time spent between 80 and 150 mg/dL from 60% during the day to 74% at night in the CLC group ($P < 0.001$), which did not occur in the SAP group (46 during the day vs. 50% during the night).

When compared with the bihormonal camp studies using insulin and glucagon, the current study achieved a similar mean glucose level of 143 mg/dL versus 137 mg/dL (preadolescents) (3) and 142 mg/dL (adolescents) (4) with bihormonal control. The percentage time <70 mg/dL was lower in the current study with 1.8% vs. 2.9% (preadolescents) and 3.1% (adolescents) with bihormonal control. This is the first outpatient study using an insulin-only system to perform equally as well as bihormonal CLC. This is, however, not a direct comparison as the two studies were not conducted under the same protocol or monitoring procedures and the subjects were not drawn and randomized from the same group; nonetheless, recent publications do indicate similar trends (5).

In conclusion, we have demonstrated that an insulin-only hybrid CLC system can provide safe and effective glycemic control in a challenging camp setting where there is a high level of physical activity in a cohort of adolescents with variable glucose control.

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