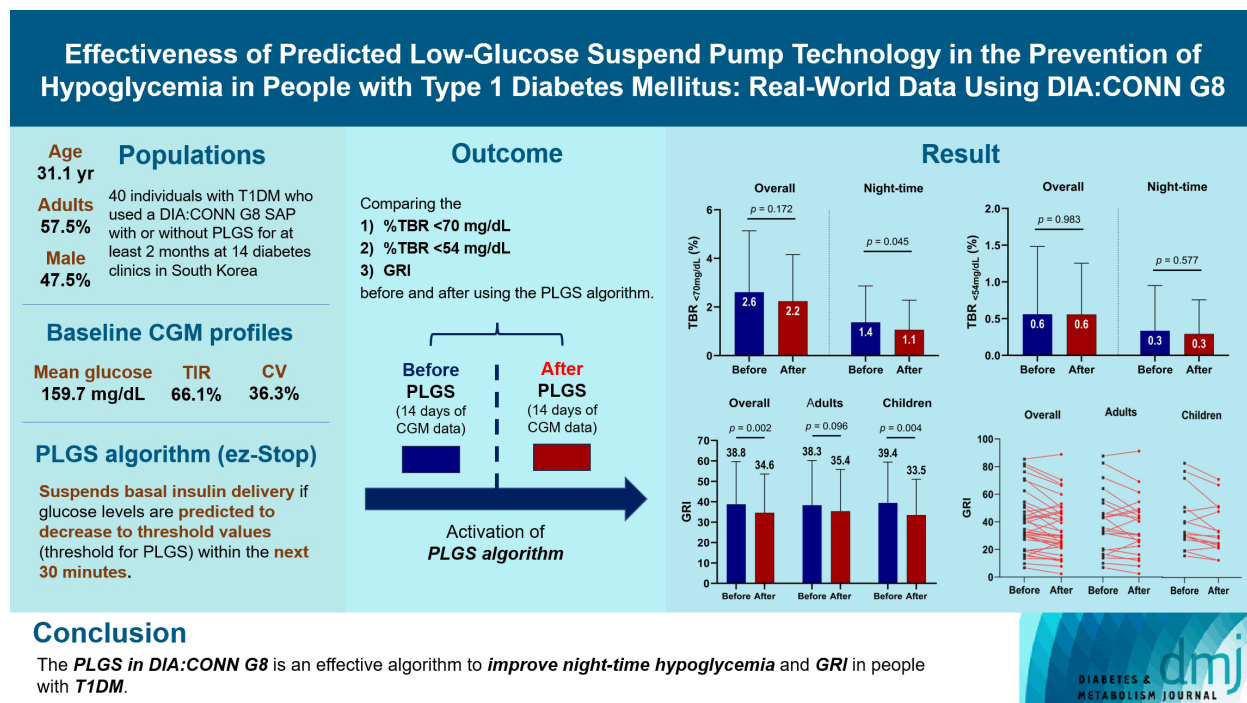


Effectiveness of Predicted Low-Glucose Suspend Pump Technology in the Prevention of Hypoglycemia in People with Type 1 Diabetes Mellitus: Real-World Data Using DIA:CONN G8

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Highlights

- We evaluated the effectiveness of the PLGS algorithm in DIA:CONN G8 (ez-Stop) for T1DM.
- CGM metrics were compared before and after using the ez-Stop.
- ez-Stop significantly reduced the overnight %TBR <70 mg/dL.
- The algorithm also improved the glycemia risk index.
- PLGS in DIA:CONN G8 effectively prevents hypoglycemia in T1DM.

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Effectiveness of Predicted Low-Glucose Suspend Pump Technology in the Prevention of Hypoglycemia in People with Type 1 Diabetes Mellitus: Real-World Data Using DIA:CONN G8

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We evaluated the effectiveness of the predictive low-glucose suspend (PLGS) algorithm in the DIA:CONN G8. Forty people with type 1 diabetes mellitus (T1DM) who used a DIA:CONN G8 for at least 2 months with prior experience using pumps without and with PLGS were retrospectively analyzed. The objective was to assess the changes in time spent in hypoglycemia (percent of time below range [%TBR]) before and after using PLGS. The mean age, sensor glucose levels, glucose threshold for suspension, and suspension time were 31.1 ± 22.8 years, 159.7 ± 23.2 mg/dL, 81.1 ± 9.1 mg/dL, and 111.9 ± 79.8 min/day, respectively. Overnight %TBR < 70 mg/dL was significantly reduced after using the algorithm (differences = 0.3%, from $1.4\% \pm 1.5\%$ to $1.1\% \pm 1.2\%$, $P = 0.045$). The glycemia risk index (GRI) improved significantly by 4.2 (from 38.8 ± 20.9 to 34.6 ± 19.0 , $P = 0.002$). Using the PLGS did not result in a change in the hyperglycemia metric (all $P > 0.05$). Our findings support the PLGS in DIA:CONN G8 as an effective algorithm to improve night-time hypoglycemia and GRI in people with T1DM.

Keywords: Blood glucose; Continuous glucose monitoring; Diabetes mellitus, type 1; Hypoglycemia; Insulin infusion systems

INTRODUCTION

The incidence of hypoglycemia, which affects diabetes complications, including cardiovascular diseases and death [1,2], is high in people with type 1 diabetes mellitus (T1DM). More than half of people with T1DM experience severe hypoglycemia during the night [3,4].

Predictive low-glucose suspend (PLGS) is a technology which can reduce hypoglycemia by suspending basal insulin before reaching below a pre-set glucose threshold level [5-8]. Smartphone app-based automated insulin delivery (AID) has

also proven to be effective in improving glycemic status while providing convenience [9-12]. Users can check their glucose levels and control administration of meal insulin using an app on a smartphone, without having to take out the pump, making daily bolusing behavior easier [12].

The DIA:CONN G8 (G2E, Seoul, Korea) insulin pump was the first smartphone (Android app)-based sensor-augmented pump (SAP) to use the PLGS algorithm available in South Korea. However, there is no real-world evidence. We therefore aimed to assess the efficacy of it in preventing hypoglycemia in people with T1DM in real-world practice.

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METHODS

Study design and population

This study was designed to evaluate the difference in the risk of hypoglycemia before using an SAP without and after using the PLGS algorithm. The study population consisted of individuals with T1DM who used a DIA:CONN G8 SAP with or without PLGS for at least 2 months at 14 diabetes clinics in South Korea from July 2022 to August 2023. Participants whose sensor wear time <70% were excluded. Forty people were eligible in the final study.

The Institutional Review Board of the Samsung Medical Center approved this study protocol (No. 2023-10-074) and the need for informed consent requirement was waived because participant information was de-identified. The methods followed the protocols of the Declaration of Helsinki guidelines, including any relevant details.

Data collection

The PLGS algorithm was added in September 2022 to DIA:CONN G8 SAP. Fourteen days of data were collected from the SAP before and after activation of the PLGS algorithm, respectively. Either Dexcom G6 or FreeStyle Libre 1 with third-party transmitters (Miao Miao or Bubble Mini) was used concomitantly with the DIA:CONN G8.

PLGS algorithm of DIA:CONN G8 (ez-Stop)

The DIA:CONN G8 suspends basal insulin delivery if glucose levels are predicted to decrease to threshold values (threshold for PLGS) within the next 30 minutes. It also suspends insulin delivery if the sensor glucose level drops by more than 10 mg/dL from the threshold for PLGS (threshold for low-glucose suspend [LGS]). Basal insulin delivery resumes automatically when glucose levels exceed the threshold for LGS and concomitantly if the glucose is about to rise. If the pump and DIA:CONN app are disconnected for ≥ 30 minutes, insulin delivery resumes automatically. No maximal or minimum suspension time exists. The users can change the threshold glucose level from 60 to 100 mg/dL. The app on the smartphone communicates with both a continuous glucose monitor (CGM) and the DIA:CONN G8 pump through Bluetooth connectivity. All data in the app are sent to the cloud server where the PLGS algorithm is located. The algorithm sends commands to the pump via a Bluetooth-connected app. The app automatically uploads the data to a DIA:CONN Care web application.

Statistical analysis

The primary outcome was to distinguish the percent of time below range (%TBR) <54 mg/dL and %TBR <70 mg/dL before and after using the PLGS algorithm. We used paired *t*-tests and confirmed with Wilcoxon signed-rank tests. The glycemia risk index (GRI) is a method of assessing glycemic quality using CGM data. It evaluates four CGM metrics, including TBR <54 mg/dL, TBR 54 to 69 mg/dL, time above range (TAR) 181 to 250 mg/dL, and TAR >250 mg/dL simultaneously and converts them into a single score ranging from 0 (best, no risk) to 100 (worst, maximum risk). GRI places greater emphasis on extreme hypoglycemia and hyperglycemia and the equation is as follows:

$$\text{GRI} = (3 \times \text{hypoglycemia component}) + (1.6 \times \text{hyperglycemia component}) [13]$$

$$\text{Hypoglycemia component (\%)} = \text{TBR} < 54 \text{ mg/dL} + (0.8 \times \text{TBR } 54 \text{ to } 69 \text{ mg/dL})$$

$$\text{Hyperglycemia component (\%)} = \text{TAR} > 250 \text{ mg/dL} + (0.5 \times \text{TAR } 181 \text{ to } 250 \text{ mg/dL})$$

Significance in the analyses was established using two-tailed tests, and a $P < 0.05$ was considered significant. All statistical analyses were carried out in SPSS version 29.0 (IBM Co., Armonk, NY, USA).

RESULTS

Baseline characteristics

The mean age was 31.1 ± 22.8 years, 57.5% ($n=23$) were adults, and 47.5% ($n=19$) were male (Supplementary Table 1). The mean sensor glucose level and glucose threshold level was 159.7 ± 23.2 and 81.1 ± 9.1 mg/dL, respectively.

Time spent in hypoglycemia

Fig. 1 depicts the changes in hypoglycemic metrics and GRI before and after activating the PLGS algorithm. Overall %TBR <70 mg/dL tended to decrease from $2.6\% \pm 2.5\%$ when a SAP was used without PLGS to $2.2\% \pm 1.9\%$ when PLGS was applied, although the difference was not statistically significant. Overnight (10:00 PM to 6:00 AM) %TBR <70 mg/dL was reduced significantly, making differences of 0.3% (5 minutes/overnight) before and after using the PLGS algorithm ($1.4\% \pm 1.5\%$ vs. $1.1\% \pm 1.2\%$, $P=0.045$). The overall and overnight %TBR <54 mg/dL did not differ. When analyzed according to

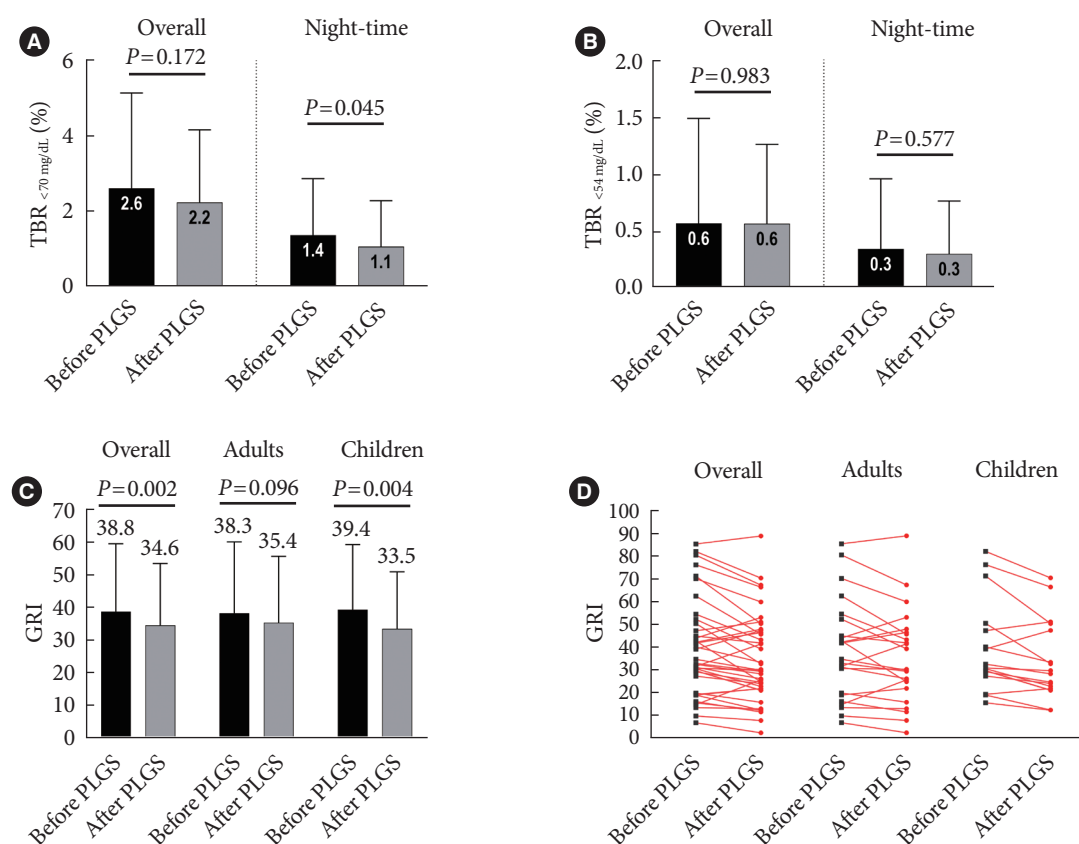


Fig. 1. Hypoglycemia metrics and glycemia risk index (GRI) before and after using the predictive low-glucose suspend (PLGS) algorithm: (A) percentage of time below range (%TBR) <70 mg/dL, (B) %TBR <54 mg/dL, (C, D) GRI. Values are statistically significant when analyzed with the paired *t*-test and Wilcoxon signed-rank test.

the age groups, overnight %TBR <70 mg/dL tended to reduce from $1.4\% \pm 1.45\%$ to $0.9\% \pm 1.0\%$ in adults, but it was not statistically significant ($P=0.073$). In children, the overnight %TBR <70 mg/dL did not improve (from $1.4\% \pm 1.6\%$ to $1.2\% \pm 1.4\%$, $P=0.399$).

GRI

We found the GRI improved significantly by 4.2 (95% confidence interval, -6.7 to -1.7 ; from 38.8 ± 20.9 to 34.6 ± 19.0 ; $P=0.002$) after PLGS activation (Fig. 1). There were no significant changes in the hypoglycemia metrics of TBR <70 mg/dL and TBR <54 mg/dL based on age subgroup. We reevaluated the GRI changes which enforce the hypoglycemia risk according to age groups to ensure the effectiveness of PLGS across age groups. In children, GRI improved significantly, from 39.4 ± 20.0 to 33.5 ± 17.5 ($P=0.004$). The GRI also tended to improve in adults, from 38.3 ± 21.9 to 35.4 ± 20.5 ($P=0.096$).

Other glycemic metrics

The overnight %TBR <70 mg/dL improved, without worsening any hyperglycemic metrics (Table 1). Although the observed differences in total daily insulin doses were not statistically significant, they tended to increase when PLGS was activated due to increases in bolus insulin doses (33.1 ± 19.0 units to 37.0 ± 24.3 units, $P=0.058$). Mean numbers of PLGS alerts were 4.1 ± 2.5 per day and suspension time was 111.9 ± 79.8 minutes per day. Despite the set-up algorithm, PLGS did not act for a median of 8.0 minutes (interquartile range, 4.0 to 19.3).

DISCUSSION

We demonstrated for the first time that the use of the PLGS algorithm with the DIA:CONN G8 reduced 5 minutes overnight %TBR <70 mg/dL in people with T1DM. In addition, glycemic quality as assessed by GRI improved while using the PLGS algorithm.

Table 1. Comparing glycemic parameters before and after using the PLGS algorithm

Variable	SAP (before suspension)	PLGS (after suspension)	Differences (95% CI)	P value
Overall				
TBR (< 54 mg/dL), %	0.6±0.9	0.6±0.7	0.0 (−0.2 to 0.2)	0.983
TBR (< 70 mg/dL), %	2.6±2.5	2.2±1.9	−0.4 (−0.9 to 0.2)	0.172
Night-time				
TBR (< 54 mg/dL), %	0.3±0.6	0.3±0.5	0.0 (−0.2 to 0.1)	0.577
TBR (< 70 mg/dL), %	1.4±1.5	1.1±1.2	−0.3 (−0.6 to 0.0)	0.045 ^a
GRI	38.8±20.9	34.6±19.0	−4.2 (−6.7 to −1.7)	0.002 ^a
Sensor wear time, %	91.3±11.0	93.1±10.3		0.424
Sensor mean glucose, mg/dL	159.7±23.2	160.1±24.1		0.785
TIR (70–180 mg/dL), %	66.1±15.5	66.6±15.0		0.550
TAR (> 180 mg/dL), %	31.3±15.0	31.2±15.0		0.862
TAR (> 250 mg/dL), %	10.1±9.7	9.9±9.5		0.831
CV, %	36.3±6.6	35.8±6.4		0.329
Total daily insulin dose, units	49.8±26.1	54.2±30.6		0.079
Basal insulin dose, units	16.8±8.9	17.1±9.0		0.664
Bolus insulin dose, units	33.1±19.0	37.0±24.3		0.058
PLGS dysconnectivity time during hypoglycemia, min/day		8.0 (4.0–19.3)		
PLGS alerts/day, <i>n</i>		4.1±2.5		
PLGS time, min/day		111.9±79.8		

Values are presented as mean ± standard deviation or median (interquartile range). Night-time is defined as 10:00 PM to 6:00 AM.

PLGS, predictive low-glucose suspend; SAP, sensor-augmented pump; CI, confidence interval; TBR, time below range; GRI, glycemia risk index; TIR, time in range; TAR, time above range; CV, coefficient of variation.

^aValues are statistically significant when analyzed with the paired *t*-test and Wilcoxon signed-rank test.

These results are in line with other studies [7,8,14,15]. A randomized controlled trial (RCT) that evaluated the efficacy of MiniMed 640G (Medtronic, Northridge, CA, USA) with SmartGuard in adults with T1DM also showed the %TBR reduction by 3.8% (from 8.0% to 4.2%) [7]. In a real-world study comparing the MiniMed 640G with SmartGuard and Tandem T:slim X2 with the Basal-IQ, showed 2.5% and 3.0% reductions in %TBR <70 mg/dL, respectively, showing similar results as previously reported [8].

However, our study showed smaller reduction in preventing hypoglycemia compared with other PLGS studies. Several potential reasons can explain why the real effect have diminished. First, the baseline %TBR <70 mg/dL was 2.6%, which was extremely low compared to other studies (5% to 8%) [7,15]. Only 20% of individuals had a %TBR <70 mg/dL, failing to meet the target of 4%. Although the %TBR reduction size was relatively

small, the outcome was even lower than those of other studies. We found significant improvement in GRI for all day, which was analyzed to compensate for the weakness of a lower proportion of hypoglycemia.

Second, daily bolus doses tended to increase while the PLGS algorithm was activated. We assumed that the PLGS use reduced the fear of hypoglycemia. Users might have intensified the insulin treatment to reach the mean glucose target. Some users may have mistaken the glucose rise after insulin suspension as an insulin dose deficiency. As this was a real-world study, structured education was not provided in all diabetes clinics, but we anticipate an even greater effect with it.

The ez-Stop has several advantages differ from other mechanisms. It has no maximal suspension time in contrast to the SmartGuard, which has a 2-hour maximal suspension time. In a study by Choudhary et al. [16] suspension time by Smart-

Guard was 56.4 min/day, much lower than 111.9 min/day produced in our study, despite comparable mean sensor glucose values (162.1 mg/dL vs. 160.1 mg/dL). These have led to different outcomes (%TBR $\leq$ 50 mg/dL: 25.3 min/day vs. %TBR $<$ 54 mg/dL: 8.6 min/day). Second, the DIA:CONN G8 is a smartphone-based system. Various studies have proven the benefits of it on glycemic outcomes [9-12].

However, the algorithm located in the smartphone (Tidepool Loop app [11], CamAPS Fx app [10], and Diabeloop DBLG1 system [17]) may have connectivity issues. In RCTs demonstrating the efficacy of smartphone-based AID, hyperglycemia were larger or similar in AID group than the SAP users [9,10]. Connectivity failure appears to have contributed to these events. Indeed, we found that PLGS was disconnected for 8 min/day. Thus, education should be provided to avoid problems with connectivity issues when using the DIA:CONN G8.

Our study is limited by a short duration, and our data may not accurately represent the effectiveness of PLGS over longer time periods. The sample size was small that a larger study population may provide additional insight into the effectiveness of PLGS. The retrospective nature of our study also poses limits to interpretation and generalizability. Finally, the low %TBR in this population obscures the potential benefits of the PLGS algorithm.

In conclusion, our findings support the ez-Stop algorithm to reduce night-time hypoglycemia and improve overall GRI while maintaining overall glycemic control in people with T1DM.

SUPPLEMENTARY MATERIALS

Supplementary materials related to this article can be found online at <https://doi.org/10.4093/dmj.2024.0039>.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

AUTHOR CONTRIBUTIONS

Conception or design: J.H.Y., J.H.K.

Acquisition, analysis, or interpretation of data: all authors.

Drafting the work or revising: J.H.Y.

Final approval of the manuscript: all authors.

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Supplementary Table 1. Baseline characteristics of study participants with experience with an SAP before and after using the PLGS algorithm

Characteristic	Study participants (n=40)
Age, yr	31.1±22.8
≥18	23 (57.5)
6≥ and <18	17 (42.5)
Sex	
Male	19 (47.5)
Female	21 (52.5)
Weight, kg	54.2±17.8
Body mass index, kg/m ²	21.6±4.2
Total daily insulin dose, units	48.9±25.8
Total daily basal insulin dose, units	16.6±8.9
Total daily bolus insulin dose, units	32.3±18.7
Mean threshold setting for hypoglycemia, mg/dL	81.1±9.1
Threshold setting for hypoglycemia, mg/dL	
≥60 and <70	3 (7.5)
≥70 and <80	5 (12.5)
≥80 and <90	23 (57.5)
≥90	9 (22.5)

Values are presented as mean±standard deviation or number (%).
SAP, sensor-augmented pump; PLGS, predictive low-glucose suspend.