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# Early Stage Effectiveness of the Automated Insulin Delivery System—Is Artificial Intelligence Really Effective?

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## ABSTRACT

**Objective:** This study aimed to evaluate the effectiveness of the self-learning capabilities of artificial intelligence (AI) algorithms. The hypothesis was that if the success of closed-loop insulin delivery is mainly attributed to AI algorithms, then the improvement in glycemic control would be more significant just after the "learning" phase.

**Methods:** The Medtrum A8 TouchCare® Nano system was used on 15 patients with type 1 diabetes. Daily continuous glucose monitoring (CGM) data pre-automated insulin delivery (AID) was statistically compared with the post-AID period.

**Results:** Patients (median age 32 (6-54) years, 40% female) had a median HbA1c of 8.4% (5.3-10.7) before initiation of AID and a median GMI of 6.6% (5.8-8.3) after 2 weeks. The shifts in glycemia and glycemic variability between the 5-day period pre-AID vs. the first day and the 3 5-day periods post-AID were significant (pre-AID vs. 1-5-10-15 days; time in range (TIR, %): 55.9 vs. 76.6-81.7-83.8-81.5 ($P = .001$); Q1 (mg/dL): 123 vs. 112-108-106-110 ($P = .009$); Q3 (mg/dL): 204 vs. 176-173-168-169 ($P = .004$); inter-quarter range (IQR, mg/dL): 78 vs. 57.2-56.6-53-55 ($P = .002$)). The biggest shift in TIR was achieved in the first day (10.1%). Comparative analysis of the 5-day intervals post-AID was insignificant by means of the improvement in glycemia ($P > .05$). No significant change in glycemic parameters between 15, 30, and 90 days were noted ($P > .05$).

**Conclusion:** Artificial intelligence-augmented AID becomes effective at the very early stages of initiation. There is a need for further research into glycemic changes in the early days of AID initiation to better define the principles of initiating AID systems.

**Keywords:** Artificial pancreas, glycemic control, automated insulin delivery, type 1 diabetes

## Introduction

The treatment success for type 1 diabetes mellitus (DM) remains a global challenge. A recent study found that the rates of HbA1c of less than 7% varies between 17.4% and 31.5% depending on age groups.[1] However, there has been improvement in treatment success due to the use of diabetes technologies such as continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion therapy (CSII). Closed-loop insulin delivery systems (CLS) mediated with artificial intelligence (AI) have shown superiority in many studies.[2]

Several artificial pancreas systems and insulin pumps use the automated insulin delivery (AID) algorithm to optimize insulin delivery. The AID system relies on mathematical models to predict glucose dynamics, and it may have uncertainties, leading to sub-optimal predictions in certain situations. Heavily depending on accurate CGM data, sensor inaccuracies, or calibration errors can impact the effectiveness of the algorithm. Variability in daily life, such as stress, illness, and exercise, can also challenge the AID system's ability to maintain a stable glucose level.[3,4]

Two important questions about self-learning AID algorithms in CLS insulin delivery remain unanswered. The first question is the extent of the role of AI algorithms in controlling blood glucose levels, and the second question is whether the self-learning features of the algorithms are effective as claimed. There are systematic reviews and protocols for future meta-analyses on the efficacy of AID in patients with type 1 DM.[5,6] However, the literature describing the effect of AID in the initiation period is still lacking. To analyze if the improvement in glycemic control is more significant during the "learning" phase, the data of 15 Type 1 diabetic patients with a brittle course who used CSII with AID was examined in this study.



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## Methods

Between September 2023 and May 2024, 15 type 1 diabetic patients used the Medtrum A8 TouchCare® Nano system equipped with Artificial Pancreas Algorithm (APGO) technology, which includes a hybrid Model Predictive Control-Proportional Integral Derivative Controller (MPC-PID) algorithm powered by an AI self-learning engine.

After informed consent was received from all study group individuals and the study was ethically approved by Acibadem University ATADEK Medical Research Ethical Commission with approval number 2024-17/660 on 31.10.2024, daily glycemic data from Medtrum A8 Nano CGM (n = 9) and S9 CGM (n = 6) were evaluated for periods before and after the initiation of AID. Since the shortest period of CGM data before AID initiation was 5 days in the study group, the 5-day pre-AID data was considered the initial CSII data without AID and was compared with periods after the initiation of AID.

Six patients (40%) transitioned from intensive insulin treatment (IIT) of multiple daily injections to AID, while 9 (60%) were already using CSII without AI assistance. Before switching to AID, CSII was used for at least 3 days (5-13 days) in the IIT group as manufacturers suggested. All patients used predictive low glucose suspend (PLGS) software before AID initiation. This period was longer in the previously CSII-using group (4-11 weeks, n = 9) vs. IIT users (5-13 days, n = 6). The CGM data coverage was at least 90% from at least 5 days before the initiation of AID to the end of the first 2-week period post-initiation for all cases.

Insulin aspart was used in all cases. Carbohydrate counting information was provided manually for 13 patients, while 2 patients utilized the auto-meal algorithm for snacks and main meals. The targeted glycemia level was set at 100, 110, or 120 mg/dL, and the active insulin duration was 2-3 hours depending on individual clinical conditions and risk of hypoglycemia.

"One-day data" was defined as the CGM data from 00:00 to 23:59. The data from the day of switching from CSII to AID (day 0) was excluded from the study due to differences in individual initiation hours, affecting the AID coverage ratio for that day.

The study presents data of the 2-week period divided into 5-day thirds, because the shortest pre-AID data also consisted of 5 days.

Total insulin doses, basal-bolus insulin delivery ratios, and calibration frequency were noted. The margin of error in calibration was calculated as the percentage of sensor data from every calibration point by using a formula of:

$$\text{Margin of error } (\%) \frac{\text{Sensor glucose value - Calibration glucose value}}{\text{Sensor glucose value}} \times 100$$

### HIGHLIGHTS

- Artificial intelligence-augmented AID becomes effective at the very early stages of initiation.
- The most significant change in glycemia and glycemic variability after the initiation of AID was observed on the day after the initiation of AID.
- The success of closed-loop insulin delivery may mainly be attributed to AI algorithms.

### *Statistical Analysis*

Statistical analyses were performed using SPSS version 29 (IBM SPSS Corp.; Armonk, NY, USA). Descriptive variables were presented as median and min-max values. Median values of sensor glucose levels, interquartile range (IQR), Q1, Q3, TAR, TBR, TIR, total hyperglycemia time and total hypoglycemia time variables were compared using the Wilcoxon signed rank test for the assigned periods before and after AID initiation. The 2-week period after AID initiation was divided into 3 periods of 5 days each, and the median values of HbA1c, sensor glucose levels, Q1, Q3, IQR, TAR, TBR, TIR, total hyperglycemia time and total hypoglycemia time variables between these periods were compared using the Friedman test. The overall type 1 error level was at 5%, and the significance level was set at $P < .05$.

## Results

The study group of 15 patients (median age 32 years (6 years, 54 years), 40% female) had a median duration of 11 years (1 year, 32 years) of type 1 DM.

The median HbA1c before using AID was 8.4% (5.3%-10.7%).

The median GMI (estimated HbA1c, %) calculated from 15 days, 30 days and 90 days of CGM data after using AID was 6.6 (5.8-8.3), 6.4 (6.0-7.1), and 6.6 (6.2-7.0) respectively.

Comparing data from the 5 days before AID initiation with the first day after the initiation of AID, the median sensor glucose levels of the study group were reduced from 169 mg/dL (125-315) to 152 mg/dL (124-194) ($P = .003$). Subsequently, the median sensor glucose level was 141 mg/dL (119-167) for the next 15 days after initiation of AID.

### *Comparison of Periods Before and After the Initiation of Automated Insulin Delivery*

The median TIR and the median sensor glucose levels were compared for periods before and after the initiation of AID. Figure 1 shows the box-plot graphic of sensor glucose levels and TIR of the study group in the first 2 weeks, day-by-day. The X-axis represents the days before and after the initiation of AID, with day 0 being the initiation day.

Comparing the 5-day period before the initiation of AID with the total 15-day period after-AID, median TIR (%) significantly improved (55.9 (15.0-98.0) vs. 81.5 (60.0-98.0), $P < .001$). There was a significant reduction in time above range (TAR) (%) (33.5 (0-85.0) vs. 16.1 (2.0-38.0), $P = .002$). Time below range was similar for periods pre and post-AID ($P = .173$) and no cases of severe hypoglycemia were noted for any of the patients. There was a significant decrease in the median IQR (mg/dL) (78 (31-124) vs. 55 (27-86), $P = .004$). The first day of AID and the three 5-day periods after AID initiation were also statistically compared with the 5-day period before AID initiation. The median of sensor glucose levels ($P = .003$), IQR ($P = .002$), TIR ($P = .001$), TAR ($P = .003$), and total hyperglycemia time ($P = .003$) significantly improved, presenting better glycemic regulation with less glycemic variability after AID initiation.

The percentage of increase in the median TIR compared to the pre-AID period for the first day, 1-5 days, 6-10 days, and 11-15 days periods were 10.1%, 12.4%, 15.3%, and 18.3% respectively. The biggest shift in TIR was achieved in the comparison of pre-AID period vs. the first day data (Table 1).

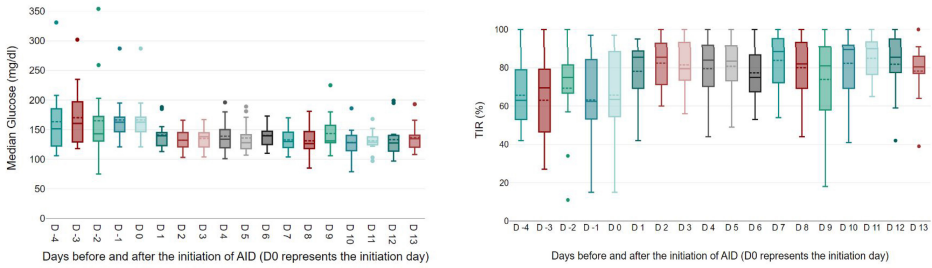


**Figure 1. The shift of sensor glucose levels (mg/dL) and TIR (%) data of 4 days before and the first 2 weeks after the initiation of AID (n = 15). TIR, time in range; AID, automated insulin delivery; D-4 to D-1, days before AID; D0, initiation day of AID; D1-D13, days after AID.**

### *Evaluation of the Early Automated Insulin Delivery Initiation Period*

Since the shortest duration of GCM data from the pre-AID period was 5 days for study participants, this study shares a report on the comparison of 3 sets of days post-AID, each including 5 days.

Analyzing the first 2 weeks post-AID period in thirds of 5 days, there was an increasing trend in the median TIR and a decreasing trend in the median of sensor glucose levels, TAR, and TBR, all statistically insignificant (Table 2).

Each 5-day period post-AID in the first 2 weeks was similar by means of the median of total insulin doses (units/day) (35.2 (18.7-88.9) vs. 34.0 (17.5-83.4) vs. 35.8 (16.2-80.5), $P = .776$), basal/bolus insulin delivery ratios (0.9 (0.4-2.8) vs. 0.7 (0.4-2.4) vs. 0.8 (0.4-2.5), $P = .211$), daily calibration frequency (times/day) (1.0 (1.0-2.0) vs. 1.0 (1.0-3.0) vs. 1.0 (1.0-3.0), $P = .195$) and margin of error in calibration (%) (20.0 (5.0-31.0) vs. 14.4 (7.0-54.0) vs. 15.1 (4.0-30.0), $P = .882$).

### First 3 Months Period after Automated Insulin Delivery Initiation

To evaluate the degree of glycemic regulation throughout the first 3 months after AID initiation, CGM data from patients who had at least 90% AID coverage in the first 90 days were selected (n = 11). There was no significant change in parameters of glycemia, glycemic variability, or insulin use between the 3 periods (Table 1).

## Discussion

In this study, the aim was aimed to understand the role of the APGO AID algorithm in controlling blood glucose levels and to analyze the effectiveness of the algorithm's self-learning features. The study was designed to test the hypothesis that if the success of CLS insulin delivery is primarily linked to the AI algorithm, then there would be a more significant improvement in glycemic control just after the learning phase. To do this, data from the days before and after AID initiation were compared. The results show a significant improvement in glycemic targets after the initiation of AID. The shift in the median of sensor glucose levels and TIR was most noticeable on the day after the initiation of AID. Figure 1 illustrates the median of sensor glucose levels and TIR data daily before and after the initiation of AID.

The improvement in TIR (55.9% vs. 81.5%, $P < .001$) was mainly due to the significant reduction in hyperglycemic episodes represented by the change in the median TAR (33.5% vs. 16.1%, $P = .002$). There was no significant reduction in TBR, possibly due to the use of Predictive Low Glucose Suspend (PLGS) software before AID initiation by all patients. The use of AID resulted in better glycemic variability as evidenced by the significant decrease in IQR (78.0 mg/dL vs. 55.1 mg/dL, $P = .004$). These results indicate an overall improvement in glycemic regulation by reducing hyperglycemia ratios and glycemic variability at the end of the second week after AID initiation.

There was a significant improvement in the median of sensor glucose levels, TIR, TAR, TBR, and IQR when each 5-day period post-AID was compared with the 5-day period before AID initiation. In contrast, these variables showed insignificant improvements when compared within each other. The daily TIR shift of 10.1% that was achieved in the comparison of pre-AID period vs. the first day post-AID was the biggest change in glycemic course. These results confirm that the improvement in glycemic control is most noticeable just after the machine learning phase. This trend suggests that there is a rapid improvement in glycemic regulation at the very early stages of AID initiation, supporting the study's hypothesis that the success of AID is primarily attributed to AI algorithms.

A recent study of real-life observations comparing PLGS and AID periods of the Tandem Control-IQ® system by analyzing 19 354 individuals with type 1 diabetes (DM) also reports that the increase of the initial TIR (58.4%-70.5%, $P < .001$) occurred within the first week after switching from PLGS to AID and was sustained during the 3-month AID use across the entire cohort.[7] The 1.7% change in the initial HbA1c vs. early GMI calculations in our study does not correlate with this study, which describes a lesser reduction in hyperglycemia. But the group with the highest initial GMI (>8.0%), which was similar to the baseline characteristics of our study group, showed an improvement of 23% in TIR, leading to a similar glycemic wellness. The observed differences may also be related to socio-cultural differences and diabetes education levels in the study groups or simply the small sample size of our study group.

Another study aiming to utilize a structured initiation protocol for the MiniMed® 670G hybrid CLS, which uses a PID algorithm, showed continuous significant improvement in sensor glucose levels (193 mg/dL vs. 142 mg/dL, $P = .001$) and TIR (46.9% vs. 75.6%, $P = ?$) comparing periods before CSII and 3 months after AID, in a group of 30 children (age 10.24 ± 2.6 years, diabetes duration 2.8 ± 1.7 years).[8] The rate of increase in TIR was reported to be variable in the follow-up period of this study. The mean TIR of 54% in the 3 days without AID increased to 65.1% in the first 3 days after AID and 66.6% in the 1-14-day period after AID. Time in range ratios in 1-28, 29-56, and 57-84 days were 72.1%, 74.5%, and 75.6% consecutively. Although it was not reported to be statistically analyzed in this study, the 11.1% increase in TIR in the first 3 days seems to be the highest improvement ratio throughout the follow-up period. This study with a different age group and

**Table 1. The 15-day Period Post-Automated Insulin Delivery was Divided into 5-day Thirds to Compare with the Available Data of 5 days Before Automated Insulin Delivery Initiation**

| n = 15 | 5 days Before AID Median (Min-Max) | Day 1 After AID Median (Min-Max) | *P* | Days 1-5 After AID Median (Min-Max) | *P* | Days 6-10 After AID Median (Min-Max) | *P* | Day 11-15 After AID Median (Min-Max) | *P* | Total 15 days After AID Median (Min-Max) | *P* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Sensor glucose levels (mg/dL) | 169 (125.0-315) | 152 (112.218) | **.003*** | 148 (121-168) | **.003*** | 143 (114-175) | **.002*** | 138 (117-184) | **.003*** | 141 (119-167) | **.003*** |
| Q1 (mg/dL) | 123 (99-262) | 113 (92.185) | **.009*** | 112 (97-135) | **.009*** | 108 (91-130) | **.009*** | 106 (87-156) | **.027*** | 110 (96-138) | **.009*** |
| Q3 (mg/dL) | 204 (140-373) | 186 (124.293) | **.004*** | 176 (142-202) | **.004*** | 173 (126-220) | **.003*** | 168 (134-211) | **.002*** | 169 (138-208) | **.005*** |
| IQR (mg/dL) | 78 (31-124) | 62 (20.145) | **.002*** | 57.2 (35-91) | **.002*** | 56,6 (25-96) | **.011*** | 53 (23-92) | **.006*** | 55 (27-86) | **.004*** |
| TAR (%) | 33.5 (2.0-85,0) | 29.09 (2, 80,3) | **.009*** | 20.7 (3.0-40.0) | **.003*** | 16.2 (1.0-44.0) | **.003*** | 13.02 (2.0-51.0) | **.002*** | 16.1 (2.0-38.0) | **.002*** |
| TBR (%) | 1.07 (0-10.0) | 0.95 (0, 7,8) | .931* | 1.03 (0-4.0) | .875* | 1.19 (0-7.0) | .826* | 1.8 (0-8.0) | .245* | 1.73 (0-5.0) | .173* |
| TIR (%) | 55,9 (15.0-98.0) | 69.96 (19.7-99.0) | **.001*** | 76.6 (58.0-97.0) | **.001*** | 81.7 (56.0-99.0) | **.001*** | 83.8 (49.0-99.0) | **.001*** | 81.5 (60.0-98.0) | **<.001*** |
| Total hyperglycemia time (>180 mg/dL) (min/day) | 482.6 (0-886.0) | 414 (0. 1156) | **.009*** | 300.2 (40.0-572.0) | **.003*** | 210.6 (10.0-628.0) | **.003*** | 187.6 (2.0-586.0) | **.003*** | 231.6 (30.0-546.0) | **.003*** |
| Total hypoglycemia time (<70 mg/dL) (min/day) | 12.6 (0-136.0) | 13.6 (0. 112) | .931* | 15.0 (0-60.0) | .875* | 16.0 (0-94.0) | .778* | 25.4 (0-118.0) | .221* | 24.8 (0-78.0) | .173* |

The day of initiation (day 0) was excluded. AID, automated insulin delivery; Q1, first quartile; Q3, third quartile; IQR, interquartile range; TAR, time above range; TBR, time below range; TIR, time in range. *Wilcoxon signed rank test.

**Table 2. Data Compared Between the First 15 Days, 30 Days, and 90 Days after Automated Insulin Delivery Initiation (n = 11)**

| n = 11 | 15 days After AID Median (Min-Max) | 30 days After AID Median (Min-Max) | 90 days After AID Median (Min-Max) | *P* |
|---|---|---|---|---|
| Sensor glucose levels (mg/dL) | 126 (121, 137) | 131 (110, 139) | 126 (119, 135) | .864* |
| Q1 (mg/dL) | 106 (102, 112) | 106 (94, 110) | 104 (95, 126) | .882* |
| Q3 (mg/dL) | 160 (144, 182) | 168 (124, 186) | 156 (135, 173) | .665* |
| IQR (mg/dL) | 43 (32, 72) | 59 (27, 78) | 57 (31, 67) | .243* |
| TAR (%) | 14,6 (1.9, 25.8) | 16,7 (0.2, 27.6) | 13.5 (1.3, 21.7) | .094* |
| TBR (%) | 1.75 ( 0.6, 2.9) | 2.35 (1.1, 4.5) | 2.2 (0.6, 4.1) | .459* |
| TIR (%) | 82.7 (71.6, 97.5) | 84,05 (69.5, 98.6) | 79.4 (76.1, 98.1) | .571* |
| GMI (%) | 6,5 (6.2, 6.9) | 6,4 (6.0, 7.1) | 6.6 (6.2, 7.0) | .760* |
| Total insulin dose (units) | 29.1 (17.45, 46.55) | 29.3 (17.7, 44.40) | 33.9 (17.3, 47.05) | .662* |

AID, automated insulin delivery; IQR, interquartile range; Q1, first quartile; Q3, third quartile; TAR, time above range; TBR, time below range; TIR, time in range; GMI, glucose monitoring index.
*Friedman test.

a different AID system also has clues that the improvement rate of glycemia is higher in the early days of automode initiation.

A different study aiming to characterize the changes seen in the AID initiation period included data for 8 weeks in 25 participants with type 2 diabetes (age: 58 ± 10 years, diabetes duration: 18 ± 8 years).[9] The AID used in this study was the CamAPS FX, which also uses an MPC algorithm. The study reported that, following initial algorithm adaptation, the mean glucose levels were significantly reduced from the first 2 weeks to weeks 5-6 ($P = .039$), and exogenous insulin need increased from the beginning to weeks 3-4. The relatively late decrease in sensor glucose levels and insulin demand of individuals with type 2 diabetes in this study is mostly due to the amelioration of glucotoxicity, resulting in improved beta-cell function and increased endogenous insulin production, as the writers concluded.

This study includes data from a limited number of participants (n = 15) who used CSII for at least 3 days (5-11 days) before initiating AID and lacks sufficient data to compare the effects of shorter and longer periods of CSII with and without AID. The study reports a series of patients who all used a PLGS system prior to AID initiation, so this study can offer limited data on the effect of AID initiation on TBR and hypoglycemic range. Since it is a presentation of real-life observations, AID systems were initiated at random hours of the day and the data from the initiation day was excluded from this study. To assess the earliest response of AID, future clinical trials may standardize the initiation hours.

There is a lack of randomized controlled trials or real-life data on the initiation period of AID in the literature, apart from the information provided by manufacturers.[10] Further research is necessary to assess the optimal concept and timing of an initiation period before AI assistance.

Combining findings from the previous literature and analyzing the data from this study, the AI-augmented AID most probably becomes effective at the very early stages of initiation. A proof for this is the sudden change in glycemia on the first day, if not days. Since no change in total insulin doses or basal/bolus ratios of insulin was noticed between the pre- and post-AID periods, this change in glycemia refers to a well-planned, rational form of insulin delivery paying attention to momentary needs. Integration of AI-augmented AID algorithms helps regulate blood glucose levels regardless of other mechanisms such as increasing insulin doses or ameliorating glucotoxicity. Literature is not sufficient to define the initiation principles of AI-augmented AID systems. Also, studies to clarify the glycemic changes in the early days of initiation are needed. This study suggests that there is a need for further research on these topics.

**Availability of Data and Materials:** The data that support the findings of this study are available on request from the corresponding author.

**Ethics Committee Approval:** This study was approved by the Acibadem University ATADEK Medical Research Ethical Commission University (approval number: 2024-17/660, date: October 31, 2024).

**Informed Consent:** Written informed consent was obtained from the patients who agreed to take part in the study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept – M.T.Y., F.C.; Design – M.T.Y., F.C., E.S.G.; Supervision – M.T.Y., I.A., O.,D.; Resources – H.Y.T., D.G.; Materials – E.S., Ö.T.C.; Data Collection and/or Processing – O.D., I.A., F.C., E.S.G., S.A.; Analysis and/or Interpretation – F.C., O.T.C., E.S.G.; Literature Search – F.C., I.A., E.S.; Writing – F.C., M.T.Y.; Critical Review – M.T.Y., I.A., O.D.

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