



# Real-Life Management and Effectiveness of Insulin Pump with or Without Continuous Glucose Monitoring in Adults with Type 1 Diabetes

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## ABSTRACT

**Introduction:** To describe and compare the routine use of continuous subcutaneous insulin infusion (CSII) in type 1 diabetes (T1D) patients with and without continuous glucose monitoring (CGM) in routine clinical practice and its relationship with glycemic outcomes.

**Methods:** Retrospective observational case-control study collecting routine use of CSII and CGM in T1D patients between January 2016 and December 2016. Patients with T1D using sensor augmented pump (SAP) were matched by sex and disease duration in a 1:3 ratio with those treated only with CSII. Patients used a Paradigm Veo or 640G Medtronic-Minimed<sup>®</sup> insulin pump with

or without a glucose sensor (Enlite, Medtronic-Minimed<sup>®</sup>) for at least 12 months.

**Results:** A total of 160 subjects with T1D were included, 40 using SAP and 120 on CSII (age  $47 \pm 12$  years, 88 women, diabetes duration  $29 \pm 9.0$  years,  $10 \pm 4.7$  years on CSII, HbA<sub>1c</sub>  $7.6 \pm 0.8\%$ ). Those in SAP therapy used the sensor 63% of time, performed less self-monitored blood glucose (SMBG)/day ( $3.3 \pm 1.9$  vs.  $4.5 \pm 2.0$ ;  $p < 0.01$ ), more bolus/day ( $6.2 \pm 3.6$  vs.  $4.8 \pm 1.6$ ;  $p < 0.05$ ), more basal insulin segment/day ( $6.5 \pm 2.1$  vs.  $5.9 \pm 1.5$ ;  $p < 0.05$ ), and more suspension time of the pump ( $97 \pm 93$  vs.  $9.6 \pm 20$  min/day;  $p < 0.0001$ ). Regarding metabolic control, SAP therapy patients had lower HbA<sub>1c</sub> ( $7.4 \pm 0.7$  vs.  $7.7 \pm 0.9\%$ ;  $p = 0.068$ ), lower average SMBG value ( $151 \pm 32$  vs.  $163 \pm 30$  mg/dL;  $p < 0.05$ ), a lower percentage of SMBG values greater than 180 mg/dL ( $30 \pm 19$  vs.  $37 \pm 16\%$ ;  $p < 0.05$ ) with no differences in SMBG values less than 70 mg/dL ( $12 \pm 8.0$  vs.  $9.8 \pm 9.8\%$ ;  $p = 0.33$ ) compared with patients on CSII. There were no differences in bolus wizard targets or in insulin/carbohydrate ratios per day.

**Conclusion:** In a real-world setting, SAP therapy is associated with more self-adjustments of insulin therapy when compared to CSII alone. This could result in an improvement in glucose control.

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## INTRODUCTION

Continuous subcutaneous insulin infusion (CSII) safely improves metabolic control and quality of life in patients with type 1 diabetes (T1D) in the short [1, 2] and long term [3]. Real-time continuous glucose monitoring (RT-CGM) as a standalone device or in combination with CSII (SAP, sensor augmented pump) leads to improvements in HbA<sub>1c</sub> with reduced risk of hypoglycemic events, as shown in randomized controlled trials (RCTs) [4–7]. Theoretically, the additional benefits in terms of metabolic control achieved with both therapies in combination would represent a reduction in diabetes-related complications as was previously reported in some studies using CSII alone [8]. Despite all of this, in a recent publication [9], only 30% of adults with T1D achieved an HbA<sub>1c</sub> < 7%, the goal proposed by the recent guidelines for T1D, and still spent significant parts of the day in hypoglycemia as was reported in a study including both T1D and type 2 diabetes [10].

Most of the studies that evaluate CSII, CGM, and SAP therapies are RCTs including a selected population, for short- or mid-term periods of time and under very specific conditions; therefore, they do not reflect the routine use of these therapies [4–7, 11]. In this context, real-life studies are deemed necessary to complement information obtained from RCTs in order to add data on effectiveness and safety of CSII and CGM in the real-world setting.

Up to now, few real-world studies with SAP have been conducted with controversial results [12–15]. Nowadays, insulin pumps that automatically suspend insulin infusion when glucose is or is predicted to be low are able to reduce hypoglycemic events as well as time in hyperglycemia [16, 17]. This information has been evaluated using data from the glucose sensor values; however, studies evaluating detailed information regarding routine use are lacking.

To analyze the blood glucose control according to CGM use, information downloaded from large databases (such as the CareLink<sup>®</sup> platform) has been used [12, 16–18]. As a result of the anonymity of the data, this kind of study does not let one establish relationships with

demographic and patient-related factors that might influence the use of therapy and its results, and it may be biased if the information is obtained only from those who upload data into the system.

Given all the above, the aim of the present study was to describe and compare the use of CSII in patients with and without CGM in routine clinical practice and its relationship with glycemic outcomes.

## METHODS

We performed a retrospective observational case-control study that involved reviewing the electronic medical records and databases of individuals with T1D followed at the Diabetes Unit, Endocrinology and Nutrition Department at Hospital Clínic of Barcelona. In the current analysis, patients with T1D using SAP therapy were matched in a 1:3 ratio with those treated only with CSII by sex and duration of the disease. We used anonymized CareLink-Pro<sup>®</sup> (Medtronic-Minimed, Northridge, CA, USA) data collected between January 2016 and December 2016 as part of routine visit of patients with T1D using CSII under specific indications of the Catalan National Health Service authorities.

The specific indications for starting CSII therapy under the funding of the Catalan National Health Service were (1) less than optimal glycemic control [intensive insulin therapy with multiple daily injections unable to maintain HbA<sub>1c</sub> < 58 mmol/mol (7.5%) without disabling hypoglycemia]; (2) recurrent severe and disabling hypoglycemic episodes; (3) extreme difficulties in nocturnal glycemic control; (4) preconception and pregnancy planning; (5) rapid disease progression and early microvascular complications; (6) insulin allergy or severe lipoatrophy; and (7) variable work activity schedules.

The addition of CGM to CSII was indicated for suboptimal metabolic control, repeated and disabling hypoglycemia, and hypoglycemia unawareness despite the use of CSII or patient willingness. At the start of SAP therapy, all patients attended a structured educational

program that included special training in the usage of CGM information, interpretation of the tendencies, and technical issues regarding CGM. In all the cases, CGM was not reimbursed by National Health Care authorities.

All the patients had been previously using either a Veo or 640G Medtronic-Minimed insulin pump linked to a glucometer (Contour Next Link<sup>®</sup>/2.4<sup>®</sup>, Ascensia Diabetes Care, Parsippany, NJ, USA) for at least 12 months. Those with CGM were using a glucose sensor (Enlite<sup>®</sup>, Medtronic-Minimed, Northridge, CA, USA) for at least 1 year.

Data from 14 consecutive days were collected from uploads from each patient, including number of self-monitored blood glucose (SMBG) tests, the value of SMBG, number of boluses administered per day, carbohydrate intake per day, insulin units per day as well as some CSII settings: number of segments of basal pattern, number of basal patterns, carbohydrate/insulin ratio, and blood glucose (BG) target for the bolus wizard (BW) configuration. The HbA<sub>1c</sub> (Tosoh G8 Automated HPLC Analyzer, Tosoh Bioscience Inc., South San Francisco, CA, EE. UU-DCCT aligned, normal range 4–6%) was obtained from medical records (the mean HbA<sub>1c</sub> of the last three determinations in the previous 12 months). Demographic characteristics and clinical data were recorded from computerized clinical records.

All procedures carried out were in line with the ethical standards of the Ethical Committee of Hospital Clínic of Barcelona and with the Declaration of Helsinki of 1964, as revised in 2013. All patients provided written informed consent and the study was approved by the Ethical Committee of Hospital Clínic of Barcelona.

The results are presented as mean  $\pm$  SD or percentages. Comparisons between continuous variables were performed using an unpaired Student's *t* test. Comparisons between categorical variables were performed using a Chi-square test. A *p* value less than 0.05 was considered statistically significant. Data analysis was carried out with SPSS software, version 20.0 (IBM SPSS Statistics, Armonk, NY).

## RESULTS

A total of 160 patients were included, 40 using SAP and 120 CSII therapies. Table 1 shows clinical characteristics of the patients. No differences in demographic characteristics between the two groups were observed. The main indication to start CSII was suboptimal metabolic control ( $n = 90$ ; 56%) and it was also the same indication for those remaining only on CSII (63%). Regarding SAP users, the main indication to start CSII was repeated disabling hypoglycemia (43%). In the whole cohort, the mean HbA<sub>1c</sub> was  $7.6 \pm 0.8\%$ . Based on the downloaded data, total daily use of insulin was  $42 \pm 16$  UI/day, 52% as bolus and 48% as basal insulin without differences between both groups.

Routine use of CSII in the two different groups of patients is compared in Table 2. Those patients allocated to the SAP group had used CGM for on average  $28 \pm 30$  months and used the sensor 64% of the time ( $9.0 \pm 3.6$  over 14 days). Regarding the use of CSII and management of glycemia, participants using SAP performed less SMBG per day ( $3.3 \pm 1.9$  vs.  $4.5 \pm 2.0$ ;  $p < 0.01$ ) and more boluses per day ( $6.2 \pm 3.6$  vs.  $4.8 \pm 1.6$ ;  $p < 0.05$ ) without differences in the percentage of use of BW. Moreover, participants using SAP therapy had more basal insulin segments per day ( $6.5 \pm 2.1$  vs.  $5.9 \pm 1.5$ ;  $p < 0.05$ ). The time of CSII suspension was  $9.6 \pm 20$  min/day in the CSII group and  $97 \pm 93$  min/day in the SAP group;  $p < 0.0001$ . In the SAP group, 25 (63%) were using 640G, 91% of those had predictive low glucose suspend (PLGS) activated, and 15 were using Paradigm Veo with the low glucose suspend (LGS) feature. In the 640G group, the total suspension of the pump was  $141 \pm 81$  min/day,  $13 \pm 24$  min/day in LGS and  $115 \pm 84$  min/day in PLGS. In the Veo users the total suspension of the pump was  $31 \pm 33$  min/day, of which  $22 \pm 18$  min/day was in LGS. There were differences neither in BW glucose targets nor in insulin/carbohydrate ratios per day ( $3.5 \pm 1.4$  units/exchanges in the total cohort).

Concerning glucose control, those patients using SAP therapy had a lower average SMBG value ( $151 \pm 32$  vs.  $163 \pm 30$  mg/dL;  $p < 0.05$ ),

**Table 1** Clinical characteristics of the patients

	Total ( <i>n</i> = 160)	SAP ( <i>n</i> = 40)	CSII ( <i>n</i> = 120)	<i>p</i>
Gender, women ( <i>n</i> %)	88 (55%)	22 (55%)	66 (55%)	1.0
Age (years)	47 ± 12	46 ± 10	47 ± 13	0.52
Diabetes duration (years)	29 ± 9.0	29 ± 9.4	29 ± 9.4	0.97
Using CSII (years)	10 ± 4.7	10 ± 5.0	10 ± 4.6	0.92
HbA <sub>1c</sub> (%)	7.6 ± 0.8	7.4 ± 0.7	7.7 ± 0.9	0.068
HbA <sub>1c</sub> by categories				
≤ 7.0%	36 (23%)	11 (28%)	25 (21%)	0.34
> 7.0 to < 7.5%	38 (24%)	12 (31%)	26 (22%)	
≥ 7.5 to < 8.0%	41 (26%)	7 (18%)	34 (28%)	
≥ 8.0%	44 (28%)	9 (21%)	35 (29%)	
Main indication for CSII ( <i>n</i> %)				
SMC	90 (56%)	15 (38%)	75 (63%)	< 0.05
Hypo	44 (28%)	17 (43%)	27 (23%)	
Both	22 (14%)	7 (18%)	15 (13%)	
Pregestational control	1 (0.6%)	1 (2.5%)	0 (0%)	

Values expressed as mean ± SD or percentage

CSII continuous subcutaneous insulin infusion, SAP sensor augmented pump, CGM continuous glucose monitoring, SMC suboptimal metabolic control, Hypo repeated disabling hypoglycemia

**Table 2** Routine use of CSII in patients on SAP or CSII alone

	SAP ( <i>N</i> = 40)	CSII ( <i>N</i> = 120)	<i>p</i> value
SMBG per day	3.3 ± 1.9	4.5 ± 2.0	< 0.01
Total bolus per day	6.2 ± 3.6	4.8 ± 1.6	< 0.05
Manual bolus per day	1.4 ± 2.1	0.8 ± 1.5	< 0.05
BW over total (%)	74 ± 33	82 ± 27	0.19
BW corrected by the patient (%)	16 ± 14	20 ± 22	0.18
Basal segments per day	6.5 ± 2.1	5.9 ± 1.5	< 0.05
Number of basal patterns	1.2 ± 0.4	1.6 ± 0.5	0.06
BW high glucose target at daytime (mg/dL)	120 ± 12	121 ± 12	0.72
BW low glucose target at daytime (mg/dL)	95 ± 11	96 ± 11	0.92
BW high glucose target at night (mg/dL)	128 ± 13	130 ± 14	0.45
BW low glucose target at night (mg/dL)	104 ± 13	104 ± 16	0.98

Values expressed as mean ± SD or percentage

SAP sensor augmented pump, CSII continuous subcutaneous insulin infusion, BW bolus wizard

a lower percentage of values greater than 180 mg/dL ( $30 \pm 19$  vs.  $37 \pm 16\%$ ;  $p < 0.05$ ) without differences in the percentage of SMBG values less than 70 mg/dL ( $12 \pm 8.0$  vs.  $9.8 \pm 9.7\%$ ; N.S.) in comparison with CSII alone users. There was also a trend towards a lower HbA<sub>1c</sub> ( $7.4 \pm 0.7$  vs.  $7.7 \pm 0.9$ ;  $p = 0.068$ ) in patients using SAP therapy.

## DISCUSSION

Our results from a real-world case–control study show that there are significant differences in the use of CSII when it forms part of SAP therapy. Our data indicates that routine use of SAP is associated with more active self-adjustments of insulin therapy. In addition to this, the use of SAP was associated with an increase in the proportion of glucose values within target in terms of short-term SMBG data and a trend towards a better HbA<sub>1c</sub>. The trend to an improvement of HbA<sub>1c</sub> could have more relevant with higher use of the sensor.

SAP therapy has been demonstrated to improve HbA<sub>1c</sub> levels in randomized clinical trials without increasing hypoglycemia when the sensor usage is high [4, 19–21]. However, less information is available about the efficacy in the routine use of this therapy. The INTERPRET study, a 12-month multinational real-world study on SAP, did not observe any improvement in HbA<sub>1c</sub> in the total cohort. However, as the investigators pointed out, the sensor usage was low (around 30% of the time) [12]. Yet, the same study showed that patients who had a better HbA<sub>1c</sub> outcome used the sensor more frequently. Another study that evaluated sensor use in routine clinical care showed similar results; patients with a high sensor usage had significantly lower mean blood glucose, blood glucose standard deviation, and had 50% fewer hypoglycemic episodes [18]. More recently, the RESCUE trial [22], which was performed in T1D individuals who started CGM in a reimbursement program, showed better glycemic control (lowering HbA<sub>1c</sub> by 0.3% at 12 months after initiating CGM) and fear of hypoglycemia with a decrease in admissions for acute diabetic complications and work

absenteeism added to an improvement in quality of life. In this study, the average use of CGM was  $88 \pm 8.2\%$  over a 12-month period, due to the request of more than 70% of sensor usage for continuing in the reimbursement program. From our point of view, the high sensor usage in our patients (64% of the time) could be the most important factor that allows the improvement in glycemic outcomes (mean blood glucose, percentage of SMBG > 180 mg/dL without increasing the percentage of measurements < 70 mg/dL). These results are in consonance with a previous study by our group with similar frequency of sensor usage (61%) [23].

Gómez et al.'s observational study including 111 T1D patients starting SAP with LGS because of repeated hypoglycemia found that HbA<sub>1c</sub> decreased by 1.7% at the end of follow-up (47 months) with an improvement in hypoglycemia awareness and in the incidence of severe hypoglycemic episodes [24].

Our participants did more frequent insulin bolus administration, introduced more basal segments per day in pump settings, and insulin infusion was more frequently suspended. This reflects that CGM information helps patients to be more active in performing self-adjustments in CSII therapy. The relationship between better glycemic control and more active use of CSII in patients under SAP therapy was shown in previous studies including a higher use of the BW feature [25]. The association between the use of BW and HbA<sub>1c</sub> outcome in insulin pump users has been studied with controversial results [26–28].

There was a tendency to a better HbA<sub>1c</sub> in patients using SAP therapy in our study closely similar to the previously mentioned studies, around 0.3% [22]. From our point of view, it is a remarkable result if we consider that it was achieved in a majority of patients in whom CSII failed to solve the indication to start such therapy. This trend to better HbA<sub>1c</sub> could have been higher with more use of the sensor. Besides, the number of finger-stick blood glucose tests performed by patients using SAP was lower than in patients only on CSII (one SMBG measurement less per day). This may reflect that use of sensor information without regular use of



confirmatory SMBG value may be effective and safe, as was recently shown in the randomized REPLACE-BG study [29].

Our study has some limitations. It is a retrospective observational case–control real-world condition study and because of this nature only an association between the data obtained with different therapies, and not causation, can be inferred from the results. This is in contrast to an experimental study, such as a clinical trial, that uses random allocation to control for confounding at baseline. However, as we mentioned before, both types of study could be considered as complementary in clinical investigation. Cases and controls, matched only for gender and disease duration, were sampled from an existing database of clinical records and CSII/SAP downloads on a group of patients from a diabetes unit with a high expertise in the management of both therapies. Thus, our findings could not be considered representative of other centers and populations. Data regarding CSII/SAP use and glycemic control was obtained from a period of 14 consecutive days and this could be considered far from being fully representative. However, this is the recommended approach to generate a report that enables for an optimal analysis and decision-making in clinical practice [30]. Finally, we did not distinguish between different SAP devices, and data from participants using LGS and PLGS features were analyzed together.

## CONCLUSION

In a real-world setting SAP therapy is associated with more active self-adjustments of insulin therapy when compared to CSII alone. This could result in an improvement in glucose control.

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**Compliance with Ethics Guidelines.** All procedures carried out were in line with the ethical standards of the Ethical Committee of Hospital Clínic of Barcelona and with the Declaration of Helsinki of 1964, as revised in 2013. All patients provided written informed consent and the study was approved by the Ethical Committee of Hospital Clínic of Barcelona.

**Data Availability.** The datasets during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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