



## Original research

# Long-term efficacy of sensor-augmented pump therapy (Minimed 640G system) combined with a telemedicine follow-up in patients with type 1 diabetes: A real life study

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## ABSTRACT

**Objective:** Evaluate the efficacy of a new modality of insulin therapy associating both the sensor-augmented pump therapy with predictive low-glucose management (SAP-PLGM) and a telemedicine follow-up in patients with Type 1 diabetes (T1D) in a real-life setting.

**Methods:** T1D adults under Minimed 640G system with a telemedicine follow-up for glucose management were included in a retrospective study. The primary endpoint was HbA1c while continuous glucose monitoring parameters (CGM) and treatment compliance were the secondary endpoints. These parameters were analyzed according to the therapeutic indication, HbA1c  $\geq 8\%$  (Group A) or severe hypoglycemic events (Group B) and in patients switched to SAP-PLGM therapy.

**Results:** 62 patients were analyzed with a  $28 \pm 12$  months of follow-up. In Group A, HbA1c decreased from  $8.3 \pm 0.4\%$  to  $7.7 \pm 0.7\%$  ( $p < 0.05$ ) and to  $7.9 \pm 0.3\%$  ( $p < 0.05$ ) after 2 and 3 years, respectively. In patients switched to SAP-PLGM therapy, HbA1c decreased from  $7.7 \pm 0.7\%$  to  $7.2 \pm 0.8\%$  ( $p < 0.05$ ) at 2 years. After 6 months, the time-below-range ( $<70$  mg/dL) decreased from  $2.1\%$  [0.6–4] to  $1.1\%$  [0.3–2.6] ( $p < 0.05$ ). Severe hypoglycemic events decreased from 1.62 to 0.5 events/patient/year in Group B ( $p < 0.05$ ). At 3 years, treatment compliance was  $92\%$  [70–97] in the total population.

**Conclusions:** Long-term real-life treatment with the SAP-PLGM therapy combined with telemedicine was associated with improved glycemic control in T1D, along with high treatment compliance.

## Introduction

Type 1 diabetes (T1D) is becoming increasingly common worldwide [1]. New cases are rising by 3 to 4 % per year, with earlier diagnosis especially in children under 5 years of age [2]. The Diabetes Control and Complications Trial demonstrated that an intensive treatment approach

is associated with fewer chronic vascular complications of diabetes [3,4], thereby improving patients' quality of life and reducing the risk of mortality associated with the disease.

The main challenge in the management of T1D is therefore to optimize glycemic control without increasing the risk of hypoglycemia, especially in case of significant glycemic variability. Less than one-third

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of T1D patients display optimal glycemic control despite the many advances made in diabetes treatment over recent years [5,6]. The management of hypoglycemia, especially when severe, remains a major public health problem. Recurrent hypoglycemic events have been shown to increase the risk of severe hypoglycemia and contribute to the development of hypoglycemia unawareness, which is observed in approximately one-fifth of T1D patients [7].

The introduction of real-time sensor-augmented pump (SAP) is considered a major step toward the development of closed-loop insulin delivery or artificial pancreas [8,9]. As from 2015, the Minimed 640G system (Medtronic) has integrating smart features, including active insulin tracking, bolus progress bar, and predictive battery life, and it automatically suspends basal insulin delivery based on the prediction of low glucose levels using the SmartGuard algorithm [8]. Recently, the therapeutic arsenal has expanded, with the emergence of closed loops integrating algorithms for the preventive management of hypoglycemic and hyperglycemic excursions. However, these are not widely available for all T1D patients due to their high costs and reimbursement difficulties, particularly in France.

Previous randomized controlled or retrospective trials have assessed the widely available automated basal insulin delivery systems with predictive low-glucose management (PLGM) function and have demonstrated that approximately 75–83 % of hypoglycemia can be avoided without deterioration of glycemic control in T1D [3,7,10–13]. However, very few real-life studies conducted in the last decade have evaluated the clinical efficacy of such devices in terms of therapeutic compliance, HbA1c, continuous glucose monitoring (CGM) parameters and severe hypoglycemic events in T1D. Indeed, high therapeutic compliance (>75 %) is key to the success of those high-end SAPs.

Moreover, recently and during the COVID-19 pandemic, numerous studies have documented the added value of telemedicine, in diabetes care to improve both metabolic control and caregivers' and patients' satisfaction [14–15]. Telemedicine creates a strong link between patients and caregivers and was recently shown to improve medication adherence and clinical outcomes [16]. The combination of telemedicine with high-end SAPs incorporating PLGM may provide solid foundations for both high therapeutic compliance and improved metabolic balance.

We therefore conducted an extended real-life study to evaluate the efficacy of a new modality of insulin therapy associating both the sensor-augmented pump therapy with predictive low-glucose management (SAP-PLGM) and a telemedicine follow-up in patients with Type 1 diabetes (T1D).

## Patients and Methods

### Participants

We carried out a longitudinal, retrospective, single-center observational study between May 2015 and March 2020 in the Diabetology, Endocrinology and Nutrition Department of the University Hospitals of Strasbourg, France. Adult patients aged 18 years or older with T1D managed by SAP with PLGM (Minimed 640G system, Medtronic) were included in the study. For the participants, the time of study participation was between 6 months and 3 years. Pregnant patients and those with missing data or insufficient sensor use (<50 %) were excluded from the study. The study was approved by local ethics committee and each patient has provided signed written informed consent.

### 640G sensor-augmented insulin pump

The Minimed 640G system is an automated basal insulin delivery system integrating three main features: an Enlite glucose sensor that measures interstitial glucose and sends data to an external insulin infusion pump via a transmitter. Additionally, the SmartGuard algorithm suspends automated delivery of basal insulin when sensor glucose levels reach a value of 20 mg/dL above the set low limit threshold within

approximately 30 min (stop before hypoglycemia) and when sensor glucose readings are at or below a set threshold (stop at hypoglycemia). Two initial sensor calibrations are required to start the system. Then, a calibration is necessary at least every 12 h to optimize the glucose sensor reliability. The Carelink platform allows patients to store and share relevant insulin pump, CGM, and glucose meter data with their physician. This technology enables telemedicine, especially remote monitoring in clinical practice, which may contribute to improving the efficiency of diabetes care.

### Telemedicine management

The patients were followed under usual practice conditions. For all patients telemedicine monitoring was synchronous with the sensor-augmented pump therapy with predictive low-glucose management (SAP-PLGM). Adjustments of 640G therapy by changing basal rates and/or meal boluses were performed by their diabetologist during routine medical visits, twice a year during face to face consultation. In the meantime, patients were telemonitored every 2 months by analysis of continuous glucose monitoring via the Carelink platform, leading to a change in therapy if necessary. Patients benefited from a teleconsultation by videoconference or by phone with a telemedicine nurse. The modalities of the teleconsultation were the following: administrative registration of patient in a secure site, transfer of biological or CGM data, summary of the consultation in the patient file, date of the next consultation. Insulin doses were adapted to obtain a daily PLGS duration, between 120 and 180 min/day allowing to reach the optimal balance between occurrence of hypoglycemia and occurrence of hyperglycemia. In addition, patients were also given a protocol for adjusting prandial insulin doses according to blood glucose values during each medical visit. Carelink data collected were anonymized, uploaded, and analyzed.

### Study design

Among the patients included in the study, some patients were already treated with 640G pump with PLGM. The patients who were under insulin pump with CGM were switched to 640G pump with PLGM. Any patient was treated with multiple daily insulin injections. Patients under insulin pump without SAP-PLGM function (522, 722 Minimed Paradigm, Omnipod, Roche Accu chek spirit combo, animas vibe insulin pumps) before switching to Minimed 640G treatment were analyzed. These patients performed CGM using the Freestyle sensor, or DexCom G4 sensor. Patients starting treatment with the 640G system received, as recommended, initial training in the use of the pump, including technical procedures, alarm and hypoglycemia management, and use of the bolus assistant. The present lower limit value when the PLGM feature was introduced was 70 mg/dL. Patients were divided into 2 groups according to the indication for treatment with the 640G system: HbA1c  $\geq$  8 % or severe hypoglycemia: Group A was composed of patients with HbA1c  $\geq$  8 % without severe hypoglycemia, Group B consisted of patients with at least one severe hypoglycemia in the year before treatment with the 640G system whatever was the HbA1c value.

### Metabolic outcomes

Metabolic parameters were collected for patients in both group: HbA1c measured by high-performance liquid chromatography (HPLC) was the primary endpoint. The secondary endpoints were the parameters of CGM (time-in-range [TIR], *i.e.*, time spent in the glucose target range of 70–180 mg/dL [3.9–10 mmol/L]; time-below-range [TBR], *i.e.*, time spent below blood glucose levels of 70 mg/dL [3.9 mmol/L]; time-above-range [TAR], *i.e.*, time spent above blood glucose levels of 180 mg/dL [10 mmol/L]), coefficient of variability and the percentage of sensor wear. Severe hypoglycemia was defined as the occurrence of hypoglycemia requiring external assistance with hospitalization or the

injection of glucagon by a third party. Data were collected at the beginning of the study, then at 6 months, 1 year, 2 years, and 3 years of Minimed 640G system use.

### Statistical analysis

The characteristics of the total population and HbA1c were expressed as mean  $\pm$  standard deviation (SD). CGM data were expressed as median [25th–75th percentile]. Comparisons of CGM data, HbA1c, and Enlite sensor adherence between the different groups were performed using the Student's test. The threshold for statistical significance (*p*-value) was set at 5%. All statistical analyses were performed with the XLSTAT software.

## Results

### Characteristics of the population

In total, 62 T1D patients, aged  $46.6 \pm 14.8$  years, with a diabetes duration of  $27.8 \pm 13.8$  years and a body mass index of  $26.6 \pm 5$  kg/m<sup>2</sup> were included in the study. The mean follow-up of total population was  $28 \pm 12$  months. Compared to Group A (*n* = 21), patients in Group B (*n* = 41) were older and had longer disease duration and more frequent vascular complications. Thirty-three patients (age:  $49.8 \pm 14.3$  years, diabetes duration:  $28.3 \pm 14.4$  years, BMI:  $27.6 \pm 5.4$  kg/m<sup>2</sup>) were switched to SAP-PLGM therapy. Detailed patient characteristics are summarized in Table 1.

### HbA1c evolution

In the total population, HbA1c decreased significantly from  $7.7 \pm 0.8$  % to  $7.3 \pm 0.7$  % (*p* < 0.05) and to  $7.4 \pm 0.8$  % (*p* < 0.05) after 6 months and 2 years, respectively, and then rose to  $7.6 \pm 0.5$  % at 3 years of follow-up (*p*, ns). After 2 and 3 years of follow-up, HbA1c in Group A decreased significantly from  $8.3 \pm 0.4$  % to  $7.7 \pm 0.7$  % (*p* < 0.01) and to  $7.9 \pm 0.3$  % (*p* < 0.05), respectively. In patients switched to SAP-PLGM therapy HbA1c decreased from  $7.7 \pm 0.7$  % to  $7.2 \pm 0.8$  % (*p* < 0.05) and to  $7.5 \pm 0.5$  % (*p*, ns), respectively after 2 and 3 years of follow-up. HbA1c in Group B was not significantly different on the

**Table 1**

Baseline characteristics of the total population and of each group. Group A: patients with HbA1c  $\geq 8$  %; Group B: patients who had at least one severe hypoglycemia in the year before treatment with the 640G system. BMI: body mass index, PLGM: predictive low-glucose management. Microangiopathy was defined as the occurrence of at least one of the following criteria: diabetic retinopathy, chronic renal failure with glomerular filtration rate  $\leq 60$  mL/min, positive microalbuminuria or proteinuria, or diabetic neuropathy (positive monofilament test or electroneuromyography) and macro angiopathy as the occurrence of at least one of the following criteria: cardiovascular event (acute myocardial infarction, ischemic cardiac disease, stroke, or peripheral vascular disease), foot ulcer, lower extremity endovascular or surgical revascularization, or lower limb amputation. Data are presented as mean  $\pm$  standard deviation (SD) or as number of cases (percentage). Comparison between Group A and B (\* *p* < 0.05, \*\**p* < 0.01, \*\*\* *p* < 0.001).

Patients	Total population	Group A	Group B
<i>n</i>	62	21	41
Men/women ( <i>n</i> )	35/27	8/13	27/14
Age (years)	$46.6 \pm 14.8$	$41 \pm 15.7$	$49.5 \pm 13.7^*$
BMI (kg/m <sup>2</sup> )	$26.6 \pm 5$	$26.2 \pm 6.1$	$26.8 \pm 4.5$
HbA1c (%)	$7.7 \pm 0.7$	$8.3 \pm 0.4$	$7.4 \pm 0.7^{***}$
Diabetes duration (years)	$27.8 \pm 13.4$	$23.0 \pm 12.6$	$30.3 \pm 13.4^*$
Micro-macro angiopathy (%)	38 (61.3)	10 (47.6)	28 (68.3)***
Treatment:			
<i>n</i> (%)640G pump with PLGM	29 (47)	10 (47.6)	19 (46.3)**
Insulin pump without PLGM	33 (53)	11 (52.4)	22 (53.7)**
Treatment duration (months)	$28 \pm 12$	$26 \pm 11$	$29 \pm 12.8$

follow-up period (Fig. 1).

### CGM parameters

Patients of Group B had a decrease in TBR from 2.2 % [0.8–4.1] to 1.1 % [0.2–3.4] (*p* < 0.05) at 6 months and to 0.4 % [0–1.6] (*p* = 0.37) at 3 years. A non-significant increase in TAR was observed from 29.6 % [24.3–38.3] to 34 % [26–41.6] after 6 months of follow-up, while TIR remained stable.

After 2 years of follow-up, in Group A, TIR decreased from 62.5 % [50.9–64] to 51.6 % [43.7–56.9] and TAR increased from 36.6 % [31.5–48.8] to 47.8 % [41.7–56.1] without modification in TBR. These changes were not statistically significant.

In patients switched to SAP-PLGM therapy, TBR decreased from 2.1 % [0.6–4] to 1.1 % [0.3–2.6] (*p* < 0.05) at 6 months and to 0.5 % [0–1.2] (*p* = 0.046) after 3 years of treatment. TIR remained stable at around 64 % in these patients. (Tables 2 and 3).

Glycemic variability, expressed by the coefficient of variation (CV), decreased from 33.3 % to 30.8 % at the end of the study in Group B, while CV remained stable from 33.5 % to 33.4 % in Group A. In patients switched to SAP-PLGM therapy, CV decreased from 34 % to 32.6 % after 2 years of follow-up.

### Hyperglycemic and severe hypoglycemic events

No episodes of ketosis was reported during the study period. In Group B, only 2 of 41 patients continued to experience severe hypoglycemia under PLGM. A reduction in severe hypoglycemia events from 1.62 to 0.05 events/patient/year were observed after 3 years of follow-up (*p* < 0.05).

### Treatment compliance.

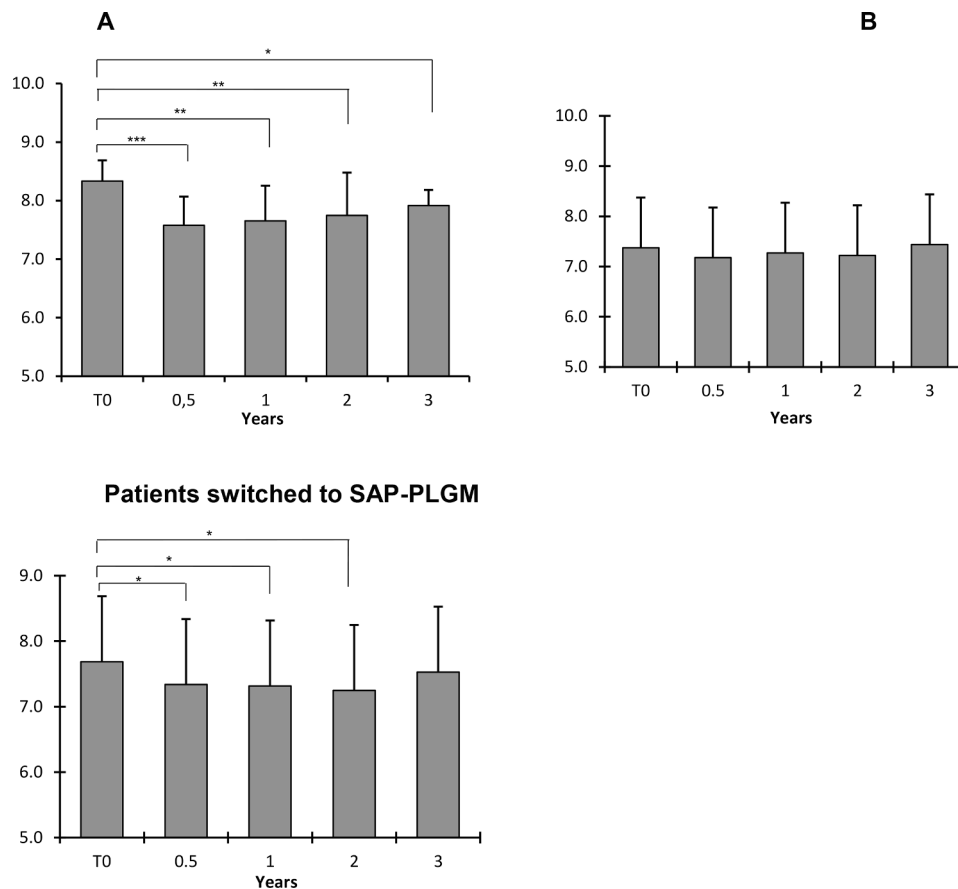
10 patients with insufficient sensor use (<50 %) were excluded from the study. In the population, sensor compliance was 93 % [84–96] at baseline and 92 % [70–96] at 3 years of follow-up. After 3 years, sensor compliance decreased from 91 % [81–94] to 70 % [62–80] in Group A while it increased from 93 % [85–97] to 95 % [88–97] in Group B. In patients switched to SAP-PLGM, therapy sensor compliance increased from 82 % [84–96] to 93 % [75–97] after 3 years of follow-up. These changes were not significant (Tables 2 and 3).

## Discussion

In this 3-year longitudinal study, PLGM with the 640G Minimed system improved metabolic control of T1D patients, as evidenced by the reduction in HbA1c and hypoglycemic events including severe hypoglycemia, along with a good therapeutic compliance.

Adherence to treatment is mandatory to achieve good therapeutic efficacy. Although treatment observance was very good in the total population of our study, amounting to 91 %, patients with severe hypoglycemic events before PLGM use exhibited a sensor compliance that reached 95 %. In accordance with the recommendations, a sensor wear above 75 % of time was associated with an improved glycemic control<sup>17</sup>. In addition, this very good treatment compliance can be explained also by the telemedicine follow-up realized every 2 months allowing a better adaptation of insulin doses and a personalized contact. The exclusion of patients with sensor wear < 50 % of the time after the first 3 months can explain also the very good observance of the treatment.

We observed a significant improvement in HbA1c in the total population, particularly in patients with HbA1c  $\geq 8$  % during the 3 years of follow-up, with no increase in hypoglycemic events. In the literature, a variable impact of the 640G system on HbA1c has been reported. A similar improvement in HbA1c from 7.5 % to 7 % (*p* < 0.02) was observed in the real-life study by Tubili et al., [3] conducted in 71 T1D adults over a 5-year follow-up period. However, the time spent in



**Fig. 1.** Evolution of HbA1c during the 3 years of follow-up in the different groups. A: patients with HbA1c  $\geq 8\%$ ; B: patients who had at least one severe hypoglycemia in the year before treatment with the 640G system; patients who switched to the 640G system at the beginning of the study. Data are presented as mean  $\pm$  SD. \*\*\*  $p < 0.001$ , \*\*  $p < 0.01$ , \*  $p < 0.05$ .

**Table 2**

Evolution of continuous glucose measurement according to the indication of SAP therapy with PLGM during the 3 years of follow-up. Group A: patients with HbA1c  $\geq 8\%$ ; Group B: patients who had at least one severe hypoglycemia in the year before treatment with the 640G system. (TIR) time-in-range; (TBR) time-below-range; (TAR) time-above-range; (PLGM) predictive low-glucose management. Data are presented as median (25th–75th percentile). \*  $p < 0.05$  (6 months versus T<sub>0</sub>).

Follow-up (years)	Group A					Group B				
	0	0.5	1	2	3	0	0.5	1	2	3
n	21	20	16	12	4	41	38	34	29	8
Sensor use (%)	91 (81–94)	85 (74–92)	79 (70–90)	83 (76–90)	70 (62–80)	93 (85–97)	93 (85–97)	92 (85–97)	93 (88–95)	95 (88–97)
TAR: >180 mg/dL	36.6 (31.5–48.8)	45.5 (35.1–51.2)	39.7 (30.2–47.3)	47.8 (41.7–56.1)	60.3 (48–70)	29.6 (24.3–38.3)	34 (26–41.6)	34.9 (28.9–42.8)	32.3 (26.2–40.5)	25.5 (20.3–42.5)
TIR: 70–180 mg/dL	62.5 (50.9–64)	54 (45.9–62)	59.1 (52.3–68.8)	51.6 (43.7–56.9)	38.4 (30–49.6)	64.2 (60–74)	63.3 (56.8–72.1)	63.2 (56.4–68.7)	66.3 (58.6–70.3)	70.7 (57.5–78.5)
TBR: <70 mg/dL	1.1 (0.4–2.7)	1.1 (0.3–2.4)	0.7 (0.2–1.8)	0.8 (0.4–2)	0.9 (0.1–1.9)	2.2 (0.8–4.1)	1.1 <sup>(*)</sup> (0.2–3.4)	1.5 (0.3–2.6)	1 (0.2–2.5)	0.4 (0–1.6)

hypoglycemia was not analyzed and there was no significant reduction in severe hypoglycemia that could demonstrate therapeutic safety when improving HbA1c in real life. In the study by Gomez et al., [18] there was no change in HbA1c under 640G pump therapy with PLGM over 3 months of follow-up. Instead, Tsumeni et al. [13] observed a significant increase in HbA1c from  $7.6 \pm 1.0\%$  to  $7.8 \pm 1.1\%$  ( $p = 0.01$ ), with a decrease in hypoglycemia, after 3 months of follow-up. This short-term degradation of HbA1c was explained by the presence of hyperglycemic excursions observed after the interruption of insulin delivery for preventing hypoglycemia.

The improvement in HbA1c observed in our study could be

accounted for by the safety offered by the 640G device in terms of prevention of hypoglycemia, allowing insulin therapy to be intensified while reducing the risk of hypoglycemia. It is also important to set up the device properly, especially with regard to the duration of stops before hypoglycemia and the total insulin dose to obtain maximum efficiency of the system. However, as the patients benefited simultaneously from the 640G device and monitoring by telemedicine, it is very likely that the observed metabolic benefit integrates the effect of the device and the telemonitoring.

As reported in a few prospective randomized studies, the use of PLGM in T1D significantly reduced hypoglycemic events, including

**Table 3**

Evolution of continuous glucose measurement in patients who switched to the 640G system at the beginning of the study. (TIR) time-in-range; (TBR) time-below-range; (TAR) time-above-range; (SAP): Sensor-augmented pump, (PLGM) predictive low-glucose management. Data are presented as median (25th–75th percentile). \*  $p < 0.05$  (6 months versus baseline).

Follow-up (years)	Patients switched to SAP-PLGM				
	0	0.5	1	2	3
n	33	33	29	26	8
Sensor use (%)	82 (84–96)	87 (79–94)	88 (81–94)	93 (80–95)	93 (75–97)
TAR: >180 mg/dL	32 (24.5–42)	34.2 (26.8–41.7)	35.4 (28.3–43.7)	32.6 (29.3–44.3)	31.8 (24.4–49)
TIR: 70–180 mg/dL	64 (56.7–72.5)	63.4 (58.1–70.4)	62.5 (56.1–69)	64.7 (53.6–68)	64 (51.1–74.6)
TBR: <70 mg/dL	2.1 (0.6–4)	1.1 <sup>(*)</sup> (0.3–2.6)	1.5 (0.2–3)	0.9 (0.2–2.4)	0.5 (0–1.2)

severe hypoglycemia [7,19,20]. We found a downward trend in TBR over the 3 years of follow-up in all groups, with a statistically significant decrease in patients who switched to the 640G system at baseline and in those with severe hypoglycemia before PLGM use. Only 2/41 patients continued to have severe hypoglycemia at the end of follow-up. In agreement with these results, in the study by Choudhary et al., [11] the participants using PLGM had a TBR of 1.8 %, while those using only a low glucose suspension function had a TBR of 2.1 %. In the retrospective study by Zhong et al., [12] patients who switched from a Minimed Paradigm Veo pump with the suspend-on-low glucose function to the Minimed 640G with PLGM had a median change from 0.4 to 0.33 severe hypoglycemia/day ( $p < 0.001$ ) after 1 year.

In our study, the lack of statistical significance regarding the decrease in TBR after 2 and 3 years could be explained by the insufficient size of the study population. Because some of the patients had previously been treated with a pump with suspend-on-low feature, it would have been very useful to have a larger number of patients in order to observe a statistically significant reduction in TBR over the long term.

Regarding the evolution of TAR, we did not observe any significant improvement during treatment with the 640G system in our patients. TAR decreased after 3 years in patients with severe hypoglycemia, while it remained stable in patients who switched to the 640G system at the beginning of the study. Few previous prospective studies [7,12,19,21] have shown a significant increase in daytime TAR (>180 mg/dL) in different groups, with a simultaneous decrease in hypoglycemic events < 70 mg/dL and < 55 mg/dL in T1D adults after 6 months of treatment. Similarly, in their 12-month retrospective study, Tsunemi et al. [13] observed a significant increase in TAR > 180 mg/dL along with a significant reduction in TBR < 50 mg/dL and a non-significant decrease in TBR < 70 mg/dL after 3 months of follow-up. According to the authors, this increase in TAR was related to hyperglycemia observed after the predictive suspension of insulin delivery by the pump and to the inappropriate consumption of carbohydrate substances by some patients in order to correct hypoglycemia.

Regarding TIR in our patients, it should be noted that we did not find any increase as described by Battelino et al., [17] considering the significant decrease in HbA1c. The lack of significant improvement in TIR and TAR could be related to the fact that each 15-day period CGM data were only collected every 6 months during the follow-up. Therefore it did not reflect the HbA1c value, which represented the average blood glucose level of the 3 months preceding collection date. In addition, it is difficult to directly influence the time spent in hyperglycemia with the PLGM function. In addition, the population was heterogeneous with half of patients already under 640G pump with PLGM while the others were switched to this treatment. However, correct configuration of the insulin pump, with an increase of the daily insulin dose, would indirectly limit the TAR. Furthermore, it is essential to properly understand the system's functionality and to let the system operate in order to limit the time spent in hyperglycemia. This implies a good therapeutic education on the use of the system before its implementation. Interestingly, no significant increase in TBR was observed in patients already treated for at least 6 months with the 640G system before study initiation, which would imply a glycemic control from baseline.

Our study has some limitations. Aside from biases related to the retrospective design of the study, its main limitation was the small number of patients included for 2 to 3 years of follow-up, which did not allow for statistical significance to be reached. Another limitation is the exclusion of patients with insufficient sensor use (<50 %). However, we applied the French guidelines of glucose sensor real life use which propose to continue the use of sensors only if they are worn >75 % of the time [22]. A major limitation of this study is the absence of control group, do not permitting to differentiate the metabolic impact of the 640G device itself from monitoring by telemedicine. Finally, the last limitation is the monocentric design of the study. However, due to the personalized follow-up of patients, we demonstrated the interest to combine the SAP-PLGM therapy with telemedicine to improve treatment compliance on a long-term period.

In conclusion, PLGM with the 640G insulin pump combined with a telemedicine follow-up improved glycemic control in unbalanced T1D patients and reduced severe hypoglycemia in patients with brittle diabetes over the long term in a real-life setting. The very good treatment compliance promotes enhanced therapeutic efficiency.

#### Ethical approval

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and/or with the Helsinki Declaration of 1964 and later versions. This study was approved by the ethics committee (Reference: CE-2021-55).

Informed consent was obtained from all patients for being included in the study.

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#### Authors' contributions:

All authors listed above provided substantial contributions to the study conception or design; data acquisition, analysis, or interpretation; drafting of the research work or critical revision of it for important intellectual content; final approval of the version to be published; or agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work were appropriately investigated and resolved.

#### Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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