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A nationwide 12-month observatory of automated insulin delivery shows improved glucose control, sustained adoption, and reduced acute severe events

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Abstract

Aims: A nationwide observational study was conducted to assess the 12-month effectiveness of AID systems in the routine care of people with Type 1 diabetes (PwT1D).

Methods: All PwT1D, adults, and children, who initiated AID between January 1, 2022, and December 31, 2022, were included across 79 centres. Clinical data, continuous glucose monitoring (CGM) parameters, acute severe events in the last year, and HbA1c levels were collected at AID initiation, and after 3, 6, and 12 months of AID treatment. Median values [interquartile range, IQR] and % PwT1D with acute severe events were reported. The primary outcome was the change in time in range (TIR; 3.9–10 mmol/L) after 1 year with AID.

Results: A total of 2741 PwT1D were included: 44.4% male, age 38 years [29], BMI 24.5 kg/m² [6.7], diabetes duration 19 years [20]. AID systems were MiniMed 780G in 49.7%, Tandem Control-IQ in 49.3%, others in 1%. After 12 months, TIR increased from 58.0 [21] to 70.1% [14] while HbA1c levels decreased from 7.6 [1.2] to 7.0% [0.8]. Percent PwT1D experiencing severe hypoglycaemia (SH) decreased from 4.1 to 0.9%, and ketoacidosis from 1.2 to 0.6%. All improvements were observed after

For affiliations refer to page 9

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3 months, sustained through 12 months, and statistically significant ($p < 0.05$). Only 2.8% of PwT1D discontinued AID.

Conclusions: Twelve months of AID use in routine care improved glucose control in PwT1D, among whom there was less experienced SH and a minor discontinuation.

KEYWORDS

automated insulin delivery, HbA1c, ketoacidosis, severe hypoglycaemia, time in range, type 1 diabetes

1 | INTRODUCTION

Type 1 diabetes is an autoimmune disease characterized by the loss of insulin-producing β -cells in the pancreas, resulting in hyperglycaemia. In 2022, 8.75 million people were living with type 1 diabetes globally, and 530 000 new cases at all ages, with 201 000 of these <20 years of age.¹ Lifelong intensive insulin therapy is the most effective way to achieve glycaemic targets and prevent complications.² It is recommended to maintain a glycated haemoglobin (HbA1c) level below 7.0%,³ which corresponds to a time in range (TIR; 70–180 mg/dL [3.9–10.0 mmol/L]) exceeding 65%–75%, as determined by continuous glucose monitoring (CGM).^{3,4} Conventional treatments using multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII) often fall short of achieving optimal glycaemic targets.^{5,6} As a result, people living with type 1 diabetes (PwT1D) remain exposed to the risk of micro- and macrovascular complications. By now, automated insulin delivery (AID) systems have become widely available and are transforming the management of type 1 diabetes. Several systems, including the MiniMed 780G and Tandem Control-IQ, are now accessible to patients. Randomized controlled trials (RCTs) evaluating these devices have demonstrated significant improvements in glucose control, particularly overnight and between meals, compared to non-automated insulin pump therapy.^{7–10} On average, these systems have been associated with a \sim 10% increase in TIR, a halving of time spent below range (TBR) <3.0 mmol/L or <3.9 mmol/L, and a \sim 0.3% reduction in HbA1c.^{11–13} AID is therefore an effective and well-accepted therapeutic approach in controlled study settings. However, these data were generated from trials that enrolled carefully selected populations, excluding patients with erratic follow-up or a history of severe hypoglycaemia (SH). Consequently, the study populations did not reflect the broader PwT1D community. Hence, there is a need to evaluate the long-term effectiveness, safety, and adoption of AID in routine clinical practice, particularly in a large, unselected population outside the constraints of controlled trials. Some observational, or real-world, studies have been conducted.^{14,15} A recent meta-analysis confirmed the efficacy and safety of AID systems in these settings.¹⁶ However, critical information on patient characteristics, early discontinuation and its causes, and clinical outcomes such as diabetic ketoacidosis (DKA) or SH are often lacking. Moreover, the organizational impact of AID on healthcare delivery, including the role of the medical team during initiation and follow-up, has not been adequately assessed. The reported observatory

(Observatoire de la Boucle Fermée en France, OB2F), a nationwide publicly funded survey, was launched to assess the real-world effectiveness, safety, and persistence of AID in both adult and paediatric PwT1D, as well as to evaluate the involvement of healthcare teams during initiation and over a 1-year follow-up period.

2 | MATERIALS AND METHODS

2.1 | Study design and population

OB2F is a large nationwide retrospective survey conducted across 79 centres. In France, AID systems have been fully and largely reimbursed since 2021 for patients with type 1 diabetes whose optimal glucose control is not reached, with access granted based on a shared decision between the diabetologist and the patient. The primary objective of this study was to evaluate in usual practice the 12-month evolution of glucose control in PwT1D who initiated an AID system during the year 2022 as part of their diabetes management. Eligible participants were adults or children PwT1D who started AID between 1 January 2022, and 31 December 2022. Those who declined to include their data in this observatory were excluded. The recruitment of centres was carried out through the newsletter of the French-speaking Diabetes Society (SFD). Study participants were then recruited from the pool of eligible PwT1D who initiated AID during the year 2022 at participating study centres. OB2F was conducted in line with the principles of the Declaration of Helsinki, those of good clinical practice, and with local legislation in France. The study was approved by the ethics committee “Paris Nord” (Institutional Review Board—IRB 00006477—of HUPNVS, Université Paris Cité, AP-HP, N° CER-2022-138) on July 22, 2022.

The following data were retrospectively collected by the participating centres at initiation of AID (M0), and after 3 (M3), 6 (M6) and 12 months (M12). At M0, demographic and clinical characteristics, including age, sex, body mass index (BMI), HbA1c level, diabetes duration, history of diabetic complications (retinopathy, nephropathy, neuropathy), prior cardiovascular events, previous insulin therapy (MDI or CSII), history of severe SH or DKA in the past 12 months.

In addition, centres reported any support provided by a healthcare service provider (HSP) before or during AID initiation, the setting of AID initiation, categorized as either outpatient (ambulatory consultation or day hospital stay) or inpatient (hospital stay including at least

one overnight), and the use of remote monitoring tools for post-initiation follow-up. In France, HSP are professionals or organizations that deliver medical and supportive care as an alternative or a complement to hospital-based services, ensuring continuity and safety of care for individuals with chronic disease.

CGM-derived metrics—percentage of time below target range (TBR, <3.9 mmol/L), time in target range (TIR, 3.9–10 mmol/L), time above target range (TAR, >10.0 mmol/L), glucose management indicator (GMI), and % CV—were extracted from 15-day Ambulatory Glucose Profile (AGP) reports generated by platforms such as MyDiabby, CareLink, and Glooko XT and transcribed into the electronic case report form (eCRF).

At M3, M6, and M12, follow-up assessments included HbA1c level, the percentage of time spent with the AID system activated, history of SH or DKA over the preceding 3, 6, or 12 months, and the same CGM-derived metrics as at initiation. Additionally, AID continuation status was recorded, along with the reason for discontinuation if applicable. DKA and severe hypoglycaemia (SH) events were retrospectively extracted from medical records completed by physicians at each consultation, and adjudicated by an independent study monitoring committee, based on clinical information obtained from structured telephone interviews conducted with each centre at baseline and at 12 months.

2.2 | Endpoints and statistical hypotheses

The primary endpoint was the change in the percentage of Time in Range (%TIR) over 1 year (measured at M0, M3, M6, and M12). The primary hypothesis tested was that %TIR increased significantly after initiation of an Automated Insulin Delivery (AID) system, using a linear mixed-effects model with a pre-specified contrast (−3, +1, +1, +1), representing a superiority framework comparing follow-up values to baseline. This approach allowed us to avoid imputing missing data, as the model accounts for multiple observations per participant and inherently handles missing data at certain time points.

Secondary endpoints were divided into hierarchical and exploratory analyses. Hierarchical endpoints were CGM-derived metrics including %TAR (Time Above Range), %TBR (Time Below Range), GMI (Glucose Management Indicator), coefficient of variation (%CV), and HbA1c levels. These were also assessed using linear mixed-effects models under superiority testing assumptions.

Exploratory endpoints included the proportion of participants achieving target thresholds (e.g., %TIR > 70%, %TAR <4%, HbA1c <7% [i.e., <53 mmol/mol]), incidence of severe hypoglycaemia (SH) or diabetic ketoacidosis (DKA), percentage of time with the AID system active, causes of AID discontinuation, and details of patient education and follow-up before, during, and after AID initiation. Generalized linear mixed models were used for binary outcomes.

All generalized linear mixed models were adjusted for age, sex, baseline HbA1c, and included the centre and subject ID as random effects. For specific pairwise comparisons between time points, superiority testing was used for early changes (M0 vs. M3),

while non-inferiority testing was applied to evaluate whether outcomes at M6 and M12 remained comparable to those at M3. Non-inferiority margins were predefined based on clinical relevance and literature standards: 0.4% for HbA1c and GMI, 5.0% for %TIR and %CV, 3.0% for %TAR, % of patients with TIR >70.0%, or TBR <4.0%, and 1.0% for %TBR. A non-inferiority margin of 5% was predefined for the percentage of time with active AID. All analyses were conducted at a two-sided alpha level of 0.05 on an intention-to-treat basis, regardless of therapy adherence or AID usage rates.

Data preprocessing, data cleaning, and all statistical analyses are described in greater detail in the Statistical Analysis Plan (version 3.0_02.13.25), which was finalized before conducting the analyses and is provided in the supplemental materials.

The datasets generated during and/or analyzed in the current study are available from the corresponding author upon reasonable request.

3 | RESULTS

3.1 | Characteristics of study population at AID initiation

The registry includes 2741 PwT1D who initiated AID therapy, either MiniMed 780G (Medtronic Diabetes, Northridge, CA) in 49.0% of cases or Tandem Control-IQ (Tandem Inc., San Diego, CA) in 50.0% of cases or others in 1.0% of cases between 1 January and 31 December 2022, across 79 centres. Baseline characteristics of patients initiating MiniMed 780G or Tandem Control-IQ differed significantly, and the results of these descriptive analyses are presented in Table S1. Among these 79 centres, 56 are adult care centres and 23 are pediatric centres. They include 38 university hospitals (CHU), 30 general hospitals (CHG), and four private practices. These centres are distributed across the entire French territory, as shown in the map in Figure S1. This cohort comprises two children under 6 years of age, 307 children aged 6–13 years, 450 adolescents and young adults (14–24 years), 1771 adults (25–64 years), and 211 elderly individuals over 65 years old. The population consists of a slight majority of women (55.6%), with a median diabetes duration of 19 years (10–30). At the time of AID initiation, HbA1c level was 7.6% (7.0–8.2), and TIR was 58.0% (48–69). Only 14.0% of the total population achieved both a TIR >70% and a TBR <4% according to consensual objectives for not-frail individuals (Battelino et al., Diabetes Care) at baseline, with this percentage increasing with age (7.8% in those under 14 years old, 26.0% in those over 65). Additionally, 4% reported having experienced at least one SH event in the year prior to inclusion, while 1.2% had a history of DKA in the same period. The population had relatively low rates of microangiopathic (25% retinopathy, 9% nephropathy) and macroangiopathic complications (4% coronary artery disease, 1% stroke). The full clinical and CGM baseline characteristics of the total population and the different age groups are presented in Table 1.

TABLE 1 Baseline characteristics of the study population and age-stratified subgroups.

	Overall population	Age <14 years old	Age 14–24 years old	Age 25–64 years old	Age ≥65 years old
Number of people	2741	309	450	1771	211
Age, years	38 [23–52]	10 [8–12]	18 [16–22]	44 [35–52]	70 [67–74]
Number of female (%)	1524 (55.6%)	147 (47.6%)	243 (54.0%)	1038 (58.6%)	96 (45.5%)
Diabetes duration, years	19 [10–30]	6 [3–7]	10 [6–14]	24 [16–32]	37 [24–47]
Number with retinopathy (%)	675 (25.0%)	0 (0.0%)	4 (0.9%)	587 (33.1%)	84 (39.8%)
Number with nephropathy (%)	234 (9.0%)	0 (0.0%)	2 (0.4%)	192 (10.8%)	40 (19.0%)
Number with neuropathy (%)	235 (9.0%)	0 (0.0%)	1 (0.2%)	181 (10.2%)	53 (25.1%)
Number with coronary heart disease (%)	100 (4.0%)	0 (0.0%)	0 (0.0%)	60 (3.4%)	40 (19.0%)
Number with stroke (%)	29 (1.0%)	0 (0.0%)	0 (0.0%)	19 (1.1%)	10 (4.7%)
Number with peripheral artery disease (%)	67 (2.0%)	0 (0.0%)	0 (0.0%)	47 (2.7%)	20 (0.1%)
BMI, kg/m ²	24.5 [21.6–28.3]	17.5 [16.1–19]	22.7 [20.5–25.5]	25.7 [22.9–29.4]	26 [23.8–29.5]
Daily insulin dose, UI/kg/d	0.61 [0.30]	0.75 [0.63–0.89]	0.82 [0.65–0.98]	0.56 [0.45–0.7]	0.49 [0.39–0.65]
Daily insulin dose, UI/d	41 [29.6–55.0]	23 [17.0–30.4]	52 [41–65]	41.7 [31.2–54.6]	36.6 [28.1–50.6]
HbA1c, %	7.6 [7.0–8.2]	7.5 [7.0–8.0]	7.6 [7.0–8.2]	7.6 [7.0–8.2]	7.5 [7.1–8.0]
HbA1c, mmol/mol	60 [53.64]	58 [53–64]	60 [53–64]	60 [53–64]	58 [53–64]
Number with HbA1c <7% (%)	718 (26.2)	87 (28.3)	123 (27.3)	456 (25.7)	52 (24.6)
Number with at least one SH for the last 12 months (%)	112 (4.1%)	5 (1.3%)	20 (4.4%)	79 (4.5%)	8 (0.4%)
Number with at least one DKA for the last 12 months (%)	34 (1.2%)	4 (1.3%)	9 (2.0%)	21 (1.2%)	0 (0.0%)
Number with available CGM data (%)	1989 (73)	257 (83)	354 (79)	1227 (69)	150 (71)
Time in range (TIR, 3.9–10 mmol/L), %	58 [48–69]	55 [46–63]	54 [44.5–65.1]	60 [50–70]	66 [54–73]
Time below range (TBR, <3.9 mmol/L), %	2.0 [1.0–4.0]	2.3 [1–4.6]	2.2 [1.0–4.3]	2.0 [1.0–4.0]	1.0 [0.7–3.0]
Time above range (TAR, >10 mmol/L), %	39 [27–49]	42 [32–51]	42 [30–52]	37 [26–48]	32 [23–44]
Glucose management index, %	7.5 [7.0–8.0]	7.7 [7.2–8.2]	7.7 [7.0–8.3]	7.4 [7.0–7.9]	7.2 [6.9–7.7]
Coefficient of variation, %	37.5 [33.6–41.5]	40.3 [37–43]	39.4 [35.0–43.4]	36.8 [32.9–40.5]	34.3 [30.7–37.6]
Number with TIR >70% (%)	429 (22)	33 (13)	50 (14)	292 (24)	54 (36)
Number with TBR <4% (%)	1382 (72)	166 (68)	237 (69)	861 (70)	118 (79)
Number with TIR >70% and TAR <4% (%)	265 (14)	19 (8)	34 (10)	173 (14)	39 (26)
AID Systems, n (%)					
Tandem control IQ	1362 (50)	185 (60)	269 (60)	835 (47)	73 (35)
MiniMed 780G	1352 (49)	124 (40)	179 (40)	913 (52)	136 (65)
Others	26 (1)	0 (0)	2 (0.5)	23 (1)	1 (0.5)

Note: Continuous variables are presented as median [Q1–Q3], and categorical variables as number (percentage).

Abbreviations: BMI, body mass index, CGM, continuous glucose monitoring; DKA, diabetic ketoacidosis; SH, severe hypoglycaemia.

3.2 | Modalities of AID initiation

Initiation of AID therapy most commonly occurred in an outpatient setting (76%), which included both ambulatory consultations and day hospital stays without overnight hospitalization. In centres where AID initiation is performed on an outpatient basis, the care team includes a diabetologist in 98.4% of cases, a nurse (specialized in advanced practice, therapeutic education, or diabetes care) in 100% of cases, and a dietitian

in 91.8% of cases. Only 23% of initiation teams include a psychologist, predominantly in paediatric settings (45.5% vs. 10.3% in adult care).

The remaining 24.0% of patients initiated AID during an inpatient stay, involving hospitalization with at least one overnight stay, with a mean length of stay of 4.3 ± 1.5 days. In centres where patients are hospitalized for AID initiation, the care team systematically includes a diabetologist, a nurse, and a dietitian (100% of cases), and includes a psychologist in 45.5% of cases.

TABLE 2 Evolution of glucose control and percentages of people experiencing severe hypoglycaemia or ketoacidosis before and after AID initiation.

	M0	M3	M6	M12	p\$	p‡	IC¥	CI‡
Number	2741	2461	2235	2215	NA	NA	NA	NA
HbA1c, %	7.6 [7.0–8.22]	7.0 [6.6–7.4]	7.0 [6.6–7.4]	7.0 [6.7–7.5]	<0.0001	<0.0001	[–0.01; 0.02]	[0.08; 0.12]
Number of people with HbA1c <7% (%)	718 (26)	813 (55)	859 (53)	855 (51)	<0.0001	<0.0001	[–0.17; 0.04]	[–0.35; –0.16]
Number of people experiencing at least one SH for the last 12 months (%)	112 (4.1)	–	–	19 (0.9)	<0.0001	NA	NA	NA
Number of people experiencing at least one DKA for the last 12 months (%)	34 (1.2)	–	–	13 (0.6)	<0.0001	NA	NA	NA
Number of people with available CGM data (%)	1989 (73)	2242 (91)	1995 (89)	1923 (87)	NA	NA	NA	NA
TIR, %	58 [48–69]	72 [65–78]	71 [63–77]	70 [63–77]	<0.0001	<0.0001	[–1.60; –1.16]	[–2.20; –1.75]
TBR, %	2.0 [1.0–4.0]	1.9 [1.0–3.0]	1.6 [0.9–3.0]	1.5 [0.9–3.0]	<0.0001	<0.0001	[–0.3; –0.1]	[–0.3; –0.2]
TAR, %	39 [27–49]	25 [19–35]	27 [20–35]	27 [21–35]	<0.0001	<0.0001	[1.40; 1.83]	[1.90; 2.40]
GMI, %	7.5 [7.0–8.0]	6.9 [6.7–7.3]	7.0 [6.7–7.4]	7.0 [6.7–7.4]	<0.0001	<0.0001	[0.06; 0.08]	[0.09; 0.11]
CV, %	37.5 [33.6–41.5]	35.2 [31.3–37.7]	35 [32–39]	35 [31–38]	<0.0001	<0.0001	[–0.11; 0.10]	[–0.02; 0.20]
Number of people with TIR above 70% (%)	429 (22)	1307 (58)	1035 (52)	963 (50)	<0.0001	<0.0001	[–0.50; –0.33]	[–0.61; –0.44]
Number of people with TBR below 4% (%)	1382 (72)	1838 (82)	1648 (83)	1593 (83)	<0.0001	<0.0001	[0.04; 0.35]	[0.12; 0.43]
Number of people with TIR above 70% and TBR below 4% (%)	265 (13)	1065 (48)	846 (42)	776 (40)	<0.0001	<0.0001	[–0.36; –0.20]	[–0.50; –0.35]

Note: Continuous variables are presented as median [Q1–Q3], and categorical variables as number (percentage). Non-inferiority margins were: 0.4% for HbA1c and GMI, 5.0% for %TIR and %CV, 3.0% for %TAR, % of patients with TIR >70.0%, or TBR <4.0%, and 1.0% for %TBR. p\$: M0 vs. Follow up; p‡: Superiority analysis M3 vs. M0; IC¥: Non inferiority analysis M3 vs. M6; CI‡: Non inferiority analysis M3 vs. M12.

Abbreviations: AID, automated insulin delivery; CI, confident interval, CGM, continuous glucose monitoring; CV, coefficient of variation of glycaemia; DKA, diabetic ketoacidosis; GMI, glycaemic monitoring index; NA, not applicable; SH, severe hypoglycaemia; TAR, time above range; TBR, time below range; TIR, time in range.

These patterns varied by age. Among children under 14 years, 90% started AID in an outpatient setting, compared to 70% of patients over 65. Conversely, inpatient initiation was more frequent among older adults, observed in 29% of patients aged 25–64 and ≥65, while only 6% of those under 14 and 15% of those aged 14–24 initiated AID in this way (Table S2).

After AID initiation, 70% of patients benefited from telemedicine follow-up by the diabetes care centre, with slightly higher proportions among those under 14 years (73%) and those aged 65 and older (72%) (Table S2).

3.3 | Healthcare service provider support before and during AID initiation

Before AID initiation, 28% of patients had no contact with a HSP. Among those who did, most received support at home (56%),

particularly in younger age groups (66% of children under 14). 13% received HSP support exclusively in hospital, and a small fraction (2%) received both home- and hospital-based support. Older adults were more likely to begin AID without prior HSP involvement, with 36% of patients aged ≥65 reporting no previous support, compared to 23% in the 14–24 age group (Table S2).

During AID initiation, 56% of patients received some form of HSP support. Home-based support was provided to 16% of participants, more commonly in young adults (28% in the 14–24 group). Hospital-based HSP support was more frequent (39%), and only 1% received combined support at home and in hospital. The proportion of patients without HSP support during initiation was similar across age groups, around 44% (Table 2).

When examining the continuity of support, some patients received HSP support only before AID initiation ($n = 582$, 21.2%), while others benefited from support only during the initiation phase

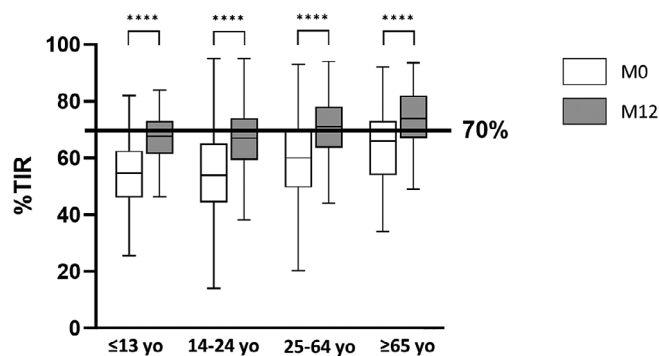


FIGURE 1 One-year evolution of %time in target range (3.9–10 mmol/l) as primary study outcome according to age categories.

($n = 154$, 5.6%). However, the majority received support at both time points ($n = 1384$, 50.5%). Six hundred twenty-one patients (22.7%) did not receive any direct educational or clinical support from HSPs. In these cases, HSP involvement was limited to logistical aspects, such as shipping materials, without providing educational or counselling services.

We compared the two groups, with and without HSP support at initiation, and found no significant TIR differences (Mann-Whitney test) at baseline (mean 57.6 ± 15.1 vs. 58.0 , ± 14.7 ; $p > 0.05$), at 3 months (mean 71.2 ± 10.4 vs. 71.3 ± 10.8 ; $p > 0.05$), and at 12 months (mean 69.2 ± 11.2 vs. 69.0 ± 12.0 ; $p > 0.05$).

We also compared the occurrence of severe hypoglycaemia between patients with and without HSP support. At baseline, the proportion of patients who had experienced at least one severe hypoglycaemic event in the previous 12 months was higher among those with HSP support (4.76% vs. 2.87%; Fisher's exact test, $p = 0.047$). However, this difference was no longer observed at 12 months (0.71% vs. 0.59%; not significant). This finding supports the hypothesis that HSP involvement during AID initiation may partly contribute to the reduction of severe hypoglycaemia events over time.

3.4 | Primary and secondary outcomes

Regarding the primary outcome, the analysis showed a significant increase in TIR after initiation of AID therapy, rising from 58.0% at baseline to 72.2%, 71.0%, and 70.1% at M3, M6 and M12, respectively ($p < 0.0001$ between baseline and follow-up, after adjustment for age, sex, baseline HbA1c level, and inclusion centre). The evolution of CGM parameters was similar in all age categories (Figure 1 and Tables S3–S6).

The hierarchical analysis of the secondary outcomes demonstrated significant improvements following the initiation of AID therapy. The percentage of TAR decreased from 38.7% at baseline to 25.0%, 27.0%, and 27.4% at M3, M6, and M12, respectively ($p < 0.001$ between baseline and follow-up, after adjustment for age, sex, baseline HbA1c, and inclusion center). The GMI improved from 7.5% at baseline to 6.9%, 7.0%, and 7.0% at M3, M6, and M12,

respectively ($p < 0.0001$ after adjustment for age, sex, baseline HbA1c level, and inclusion center). Similarly, HbA1c decreased significantly from 7.6% at baseline to 7.0% at M3, M6, and M12 ($p < 0.0001$ after adjustment for age, sex, baseline HbA1c level, and inclusion center). The percentage of TBR showed a significant reduction from 2.0% at baseline to 1.9%, 1.6%, and 1.5% at M3, M6, and M12 ($p < 0.0001$ after adjustment). Lastly, the %CV decreased from 37.5% at baseline to 35.2%, 35.0%, and 35.2% at M3, M6, and M12, respectively ($p < 0.0001$ after adjustment).

The median percentage of time with active AID was 96.7% [92.0–99.0] at M3, decreasing slightly to 96.0% [91.0–98.9] at M6 and 95.1% [90.6–98.0] at M12. In all cases, non-inferiority was demonstrated, with a 95% confidence interval of [−0.54; 0.24] for M3–M6 and [−1.7; −0.8] for M3–M12, remaining within the predefined 5% margin.

The exploratory analysis of consensual glycaemic target achievements showed significant improvements following AID initiation. The percentage of people achieving a %TIR > 70 increased from 22.0% at baseline to 58.0%, 52.0%, and 50.0% at M3, M6, and M12, respectively, with a significant difference between baseline and follow-up ($p < 0.0001$ after adjustment). Similarly, the percentage of people with a TBR $< 4\%$ improved from 72% at baseline to 82.0%, 82.6%, and 82.8% at M3, M6, and M12, respectively ($p < 0.0001$ after adjustment). Finally, the proportion of patients achieving both TIR $> 70\%$ and TBR $< 4\%$ increased from 13.3% at baseline to 47.5%, 42.0%, and 40.0% at M3, M6, and M12, respectively, with a significant improvement compared to baseline ($p < 0.0001$ after adjustment). Regarding severe acute events over the 12-month period, there was a significant reduction in the percentage of participants experiencing SH, decreasing from 4.1% at baseline to 0.86% at M12 ($p < 0.0001$ after adjustment). Similarly, the percentage of those experiencing DKA decreased from 1.2% at baseline to 0.6% at M12 ($p < 0.0001$ after adjustment).

The non-inferiority analysis results indicate that the implementation of AID at M0 maintains consistent glycaemic control over time. Key metrics such as HbA1c levels, Time in Range (TIR), Time Above Range (TAR), Time Below Range (TBR), Glucose Management Indicator (GMI), and Coefficient of Variation (CV) all remain within their predefined non-inferiority margins when comparing M3 with M6 or M12 Table 2.

Definitive AID discontinuation occurred in 43 cases, representing 1.6% of the total. No discontinuation was observed in the population under 14 years of age. The timing of these interruptions varied, with eight cases (0.3%) at the 3-month mark, 22 cases (0.8%) at 6 months, and 13 cases (0.5%) at the M12 point. Decisions to stop treatment were predominantly made by the patients themselves, accounting for 72.1% of the cases, while medical teams were responsible for 6.9% of the decisions, and joint decisions by both parties accounted for 21.0%. The primary cause cited for treatment stop was the burden of treatment, which applied to 58.0% of the cases. Other significant causes included technical issues (12.0%), insufficient AID effectiveness (14.0%), and acute events (7.0%). Less common reasons included inconsistent medication taking and external causes, each contributing to 4.5% of the cases Table S7.

TABLE 3 Characteristics of people who achieved or not combined glucose targets (TIR >70% and TBR <4%) after 12 months of AID use.

	Not on target at M12	On target at M12	p value
<i>n</i>	1147	776	
Age, years	32 [16–48]	43 [27–56]	<0.0001
<14	181 (16%)	64 (8%)	<0.0001
14–24	271 (24%)	111 (14%)	
25–64	618 (54%)	508 (65%)	
≥65	77 (7%)	93 (12%)	
Sex			
Female	621 (54%)	437 (56%)	ns
Male	526 (46%)	339 (44%)	
BMI, kg/m ²	23.9 [20.2–27.3]	25.0 [22.0–29.3]	<0.001
Diabetes duration, years	16 [7–26]	22 [11–34]	<0.0001
Insulin treatment mode before AID initiation			
Pump	335 (29%)	243 (31%)	ns
Pump with hypoglycaemia minimizer	792 (69%)	523 (67%)	
MDI	20 (2%)	9 (1%)	
Insulin doses at initiation, IU/kg/d	0.65 [0.51–0.83]	0.59 [0.46–0.77]	<0.0001
Retinopathy, Yes	246 (22%)	209 (27%)	0.01
Nephropathy, Yes	89 (7.7%)	71 (9.2%)	ns
Neuropathy, Yes	97 (8.5%)	76 (9.8%)	ns
History of ischemic cardiopathy, Yes	33 (2.9%)	34 (4.4%)	ns
History of stroke, Yes	7 (0.6%)	10 (1.3%)	ns
History of peripheral arteriopathy, Yes	24 (2.1%)	20 (2.6%)	ns
HbA1c at initiation, %	7.6 [7.1–8.3]	7.3 [6.9–7.9]	<0.0001
%HbA1c <7% at initiation	257 (22.4%)	271 (34.9%)	<0.0001
At least 1 SH/year before initiation	50 (4.4%)	28 (3.6%)	ns
At least 1 ketoacidosis/year before initiation	18 (1.6%)	6 (0.8%)	ns
TIR at initiation, %	54 [45–64]	63.5 [55.0–72.6]	<0.0001
TBR at initiation, %	2.1 [1.0–4.3]	2 [1.0–3.7]	0.01
TAR at initiation, %	42.8 [31.2–52.9]	32.3 [24.0–42.0]	<0.0001
TIR >70% at initiation	128 (13.8%)	188 (32.2%)	<0.0001
TBR <4% at initiation	619 (68.6%)	426 (76.5%)	0.01
	65 (7.2%)		<0.0001

(Continues)

TABLE 3 (Continued)

	Not on target at M12	On target at M12	p value
TIR >70 + TBR <4 at initiation		133 (23.9%)	
HSP support before AID initiation			
None	323 (28%)	245 (32%)	ns
At home	675 (59%)	429 (55%)	
At hospital	115 (10%)	85 (11%)	
Both home and hospital	31 (3%)	16 (2%)	
Initiation in			
Outpatient visit	35 (3%)	20 (3%)	ns
Daytime in-clinic	856 (75%)	564 (73%)	
Multiple-day in-clinic	254 (22%)	192 (25%)	
HSP support during AID initiation			
None	507 (44.0%)	355 (45.7%)	0.0001
At home	218 (19.0%)	90 (11.6%)	
In hospital	409 (36.0%)	324 (41.8%)	
Both at home and in hospital	12 (1%)	7 (0.9%)	
Medical telemonitoring	802 (70.1%)	560 (72.2%)	ns

Note: Continuous variables are presented as median [Q1–Q3], and categorical variables as number (percentage). Comparisons of continuous variables were performed using the Mann–Whitney–Wilcoxon test, while categorical variables were compared using the Chi-squared test. Abbreviation: SH, severe hypoglycaemia.

3.5 | Subgroup analyses of study outcomes

The evolution of glucose control under AID demonstrates improvements across all age groups in key glycaemic metrics, including HbA1c, TIR, TAR, GMI, and CV. Additionally, the percentage of patients achieving HbA1c <7%, TIR >70%, TAR <4%, and both TIR >70% and TAR <4% increased across all groups. However, only the 14–24 and 25–64 age groups showed a significant reduction in SH incidence over the past 12 months. Similarly, no subgroup exhibited a significant reduction in DKA rates, and TBR only decreased significantly in the 14–24 and 25–64 groups (Tables S3–S6).

At M12, patients who achieved the consensual targets (TIR >70% and TBR <4%) were older (median age: 43 vs. 32 years), had a higher BMI (median: 25.0 vs. 23.9 kg/m²), and had a longer diabetes duration (22 vs. 16 years). They also required less insulin per kilogram per day (0.58 vs. 0.65 UI/kg/d) while achieving better metabolic outcomes. Indeed, their baseline glycaemic control was superior, both in terms of HbA1c (7.3 vs. 7.6%) and CGM metrics (%TIR 63.5 vs. 54.0). There were no differences between achievers and non-achievers regarding the mode of initiation or the use of remote monitoring after initiation. Table 3.

4 | DISCUSSION

This nationwide observatory of AID confirms the effectiveness of AID previously reported in clinical trials and device-specific real-world data after a 1-year follow-up in routine clinical conditions. Glucose control assessed on TIR as primary outcome improved significantly, and improvements were confirmed on secondary outcomes, including HbA1c level, TAR, and TBR reductions. Moreover, the number of severe acute events declined.

Several meta-analyses have shown that in randomized controlled trials (RCTs), AID systems have favourable effects on TIR, TBR, and TAR, improve HbA1c, and are associated with very few adverse events.^{7,8,17–19} Real-world evidence is essential to confirm the effectiveness of AID in routine care outside of clinical trial conditions. One meta-analysis found that AID systems are more effective than conventional insulin therapy for PwT1D in real-life conditions, including both children and adults.²⁰ However, the majority of included studies were retrospective and relied on data downloaded from platforms. They also often failed to analyse AID discontinuations or severe acute events such as DKA and SH.

Our study, which includes a large and diverse sample across ages, sexes, geographic areas, and types of centres (university hospitals, general hospitals, and private practices), likely reflects the general population of PwT1D in France using AID, though not necessarily those with other types of diabetes or less well-controlled baseline metabolic parameters. Furthermore, only the AID systems available in 2022 (Control-IQ and MiniMed 780G) were evaluated, and these findings should be confirmed with other AID devices.

In our observatory, AID was well adopted by the participants, as only 1.6% of them had discontinued AID after 1 year. The main reasons for discontinuation were most often related to perceived treatment burden and technical challenges in AID management. This highlights both the need for thorough presentation of the therapy to people before initiation and the useful support of technical education before and at initiation. This observatory included patients who initiated AID in 2022, prior to the availability of patch-pump AID systems in France. Possibly, adoption of AID could have been even greater with catheter-free systems, as recently demonstrated in a survey of adults and parents of children with T1D.²¹ Good user adherence to AID is also encouraged by the health care system in France, which allows patients to avoid having to bear the cost of treatment.

The OB2F observatory also shows a clinically meaningful reduction in the occurrence of SH and DKA under routine care. This decline in acute complications was not observed in two recent reports. The T1D Exchange Registry reported SH events in 16% of AID users, that is, much higher than what we observed.²² The Diabetes Prospective Follow-up (DPV) showed a higher incidence of DKA among AID users, especially for those with an HbA1c level >8.5% at AID initiation.²³ Of note, populations of PwT1D in these studies were comparable to ours in terms of age and glucose control status at AID initiation. The specific support to PwT1D and healthcare professionals for AID initiation in France may contribute to our observations. The support to healthcare professionals includes a national recommendation guideline

which was published in 2021 and updated in 2025 to help centres implement and monitor AID therapy.^{24,25} Besides, the HSP covered by the National Health Insurance system to facilitate technical education of candidates for AID may also contribute to adoption of AID and the lower occurrence of severe acute events. However, reporting bias cannot be excluded, as acute metabolic events were retrospectively retrieved from medical records.

Nevertheless, only half of the participants achieved the combined consensual glucose targets (TIR >70% and TBR <4%). Those who failed to reach this optimal goal were younger, had a shorter diabetes duration, and had higher glucose levels at AID initiation. Besides the need for individualized intensified support for these people, improvements in AID technology are expected, including reduced user involvement in device management, such as meal and exercise announcements.²⁶ Importantly, even though some participants did not meet the consensus glycaemic targets, they still greatly benefited from AID use, as the substantial improvement observed in their TIR is likely to have a meaningful positive impact on their overall health and long-term outcomes.

Several limitations should be acknowledged. We cannot fully rule out that the reported data by the participating centres were not exhaustive. CGM metrics were obtained through a variety of systems, with different error characteristics as a limitation. In addition, specific device settings and details regarding individual patient use patterns were not available, which may influence outcomes and limit the interpretability of comparative results. Nevertheless, the observed improvements of glucose control in a large, diverse population, recruited in various diabetes care structures over the whole country, which were sustained over 1 year, are compelling about the effectiveness of AID in the management of type 1 diabetes in routine care.

5 | CONCLUSION

In conclusion, this large, nationwide observatory of patients treated with AID systems found good effectiveness on glucose control and acceptance of the technology after 1 year of routine clinical follow-up. These results need to be confirmed after longer-term follow-up.

AUTHOR CONTRIBUTIONS

Jean-Pierre Riveline, Eric Renard, Jean-François Gautier conceived and designed this study. Jean-Pierre Riveline and Jean-Baptiste Julla had full access to all the study data and were responsible for the integrity of the data and the accuracy of the data analyses. They curated the data, performed the data analysis and created the figures and tables. Jean-Baptiste Julla, Eric Renard, Marc Breton, Jean-François Gautier and Jean-Pierre Riveline analysed the results. All authors participated in the collection or interpretation of the data. All authors critically revised the manuscript for important intellectual content and gave final approval for publication. Jean-Pierre Riveline is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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CONFLICT OF INTEREST STATEMENT

Jean-Pierre Riveline is an advisory panel member for Sanofi, MSD, Eli Lilly, Novo Nordisk, Abbott, Alphadiab, Air Liquide, Insulet, Dexcom and Medtronic and has received research funding from and provided research support to Eli Lilly, Abbott, Air Liquide, Sanofi, Novo Nordisk, Insulet, Dexcom and Medtronic. Jean-Baptiste Julla has received consulting fees from Sanofi and lecture fees from Eli Lilly, Novo Nordisk, and Sanofi. Elisabeth Bonnemaïson declares consultant/speaker fees from Abbott, Air Liquide SI, Astra-Zeneca, Dexcom Inc., Insulet Inc., Medtronic, Sanofi-Aventis. Michael Joubert declares consultant and/or speaker fees and/or research support from Abbott, Amgen, Astrazeneca, Boehringer- Ingelheim, Dexcom, Glooko, Insulet, Lifescan, Lilly, Medtronic, Novonordisk, Roche Diabetes, Sanofi, Tandem, Ypsomed. Sandrine Lablanche is an advisory panel member for Sanofi, Abbott, Insulet, Dexcom, Roche and Medtronic. Agnès Sola-Gazagnes declares consultant and/or speaker fees and/or research support from Abbott, Dexcom, Lilly, Medtronic, Novonordisk, Roche Diabetes, Sanofi. Didier Gouet declares consultant and/or speaker fees for Sanofi, Eli Lilly, Novo Nordisk, Abbott, NHC, Insulet, Dexcom and Astra Zeneca. Pauline Schaepeplynck declares consultant and/or speaker fees from Abbott, Dexcom, Lilly, Medtronic, Novonordisk, Sanofi. Chloé Amouyal is an advisory panel member for Sanofi, Dexcom, Boehringer Ingelheim and received lecture fees from Eli Lilly, Abbott and Sanofi. Fabienne Dalla-Vale declares consultant/speaker fees from Air Liquide SI, Dexcom Inc., Insulet Inc., Medtronic, Sanofi-Aventis. Anne Spiteri declares consultant and/or speaker fees for Medtronic. Sophie Borot declares speaker fees for Dexcom, Eli-Lilly and Insulet Inc. Guy Fagherazzi has provided advisory/speaking services for and/or has received research grants and/or speaker honoraria from Sanofi, MSD, MSDAvenir, Eli Lilly, Roche Diabetes Care, AstraZeneca, Danone Research, Diabeloop, Bristol Myers Squibb, L'Oréal R&D, Abbvie Pharmaceutical, Pfizer, and Vitalaire. Jean-François Gautier reports lecture fees from AstraZeneca, Bayer, Bristol-Myers Squibb, Eli Lilly, Gilead, Novo Nordisk, Pfizer, and Sanofi. He received consulting fees from AstraZeneca, Pfizer and Sanofi and non-financial support from AstraZeneca, Novo Nordisk and Sanofi. Eric Renard declares consultant/speaker fees from A. Menarini Diagnostics, Abbott, Air Liquide SI, Astra-Zeneca, Becton-Dickinson, Boehringer-Ingelheim, Cellnovo, Dexcom Inc., Eli-Lilly, Hillo, Insulet Inc., Johnson & Johnson (Animas, LifeScan), Medtronic, Medirio, Novo-Nordisk, Roche, and Sanofi-Aventis and research support by Abbott, Dexcom Inc., Insulet Inc., Roche, and Tandem Diabetes Care.

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DATA AVAILABILITY STATEMENT

Data Availability Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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