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A systematic literature review and meta-analysis of real-world evidence on commercially available automated insulin delivery systems in people with type 1 diabetes

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Abstract

Aims: Automated insulin delivery (AID) is part of the standard of care for type 1 diabetes (T1D), but real-world evidence (RWE) comparing AID systems remains limited. A systematic review and meta-analysis was conducted for outcomes across commercially available AID systems in real-world settings.

Materials and Methods: PubMed and Embase were searched to March 2025 for RWE studies of commercial AID systems in ambulatory people with T1D. Eligible studies had $n \geq 250$ with ≥10 days of continuous glucose monitoring data. Main outcomes were time in range (TIR) and glycated haemoglobin (HbA1c). Random-effects meta-analyses with AID system as moderator were performed, including scenario analyses by age and optimal device settings.

Results: Thirty-six records covering 34 studies with 635 463 users were included. Studies evaluated MiniMed™ 780G ($n = 16$), Control-IQ™ ($n = 9$), MiniMed™ 670G ($n = 6$), and other systems (≤3 studies each). Meta-analysis demonstrated frequently statistically significant between-system differences in TIR, ranging from 60.1% (95% confidence interval [CI] 54.0 to 65.9) for Omnipod® 5 to 73.9% (95% CI 72.3 to 75.5)

for MiniMed 780G. For HbA1c, estimates ranged from 6.5% (95% CI 5.4 to 7.7) for Loop to 7.0% (95% CI 6.7 to 7.4) for MiniMed 780G, although differences were not significant. Significant residual heterogeneity was observed. Age was an important effect modifier, with younger users experiencing less favourable outcomes. Optimal device settings improved glycaemic outcomes.

Conclusions: RWE demonstrated differences in glycaemic outcomes, including TIR, between commercially available AID systems. User age influenced outcomes for all systems. Results must be interpreted cautiously given challenges and potential biases with RWE.

KEYWORDS

advanced hybrid closed loop, automated insulin delivery, glycaemic outcomes, meta-analysis, systematic literature review

1 | INTRODUCTION

Automated insulin delivery (AID) systems combine insulin pumps, continuous glucose monitoring (CGM), and algorithms that adjust insulin delivery automatically dependent on glucose levels.[1–3] Currently, the most advanced implementations of AID are hybrid closed-loop (HCL) systems, which include a closed loop between CGM monitor and insulin pump but require user input on carbohydrate intake.[1]

The management of type 1 diabetes (T1D) has been transformed by AID, as part of a general improvement in T1D care attributed to advances in technology.[4–6] In both paediatric and adult populations, AID is safe, efficacious, and effective in improving glycaemic outcomes,[7–25] including in older users[26,27] and in severe illness such as after failure of beta cell replacement (when AID is an alternative to re-transplantation).[28] In addition, AID has been found to be associated with positive effects beyond glycaemic control, both on users with T1D and caregivers. These include increased well-being and quality of life (QoL),[29–31] reduced disease burden and fear of hypoglycaemia,[29,30] and, in adults and caregivers, reduced diabetes distress.[32,33] Consequently, AID systems are now considered standard of care for insulin delivery in T1D.[34,35]

It is worth noting that glycaemic control in the context of AID use has been established using metrics that complement the established focus on HbA1c, by introducing metrics only available from CGM.[36] Time in range (TIR), defined as the percentage of sensor glucose readings and time at 70–180 mg/dL (3.9–10.0 mmol/L), has emerged as a key glycaemic target, with international consensus recommending TIR to be ≥70%.[37,38] Related metrics include time above range (TAR; >180 mg/dL [10.0 mmol/L]), often reported separately as TAR180 (181–250 mg/dL [10.1–13.9 mmol/L]) and TAR250 (>250 mg/dL [13.9 mmol/L]), and time below range (TBR; <70 mg/dL [3.9 mmol/L]), often reported separately as TBR54 (<54 mg/dL [3.0 mmol/L]) and TBR70 (54–69 mg/dL [3.0–3.8 mmol/L]). More recently, time in tight range (TITR), defined as the percentage of readings and time at 70–140 mg/dL (3.9–7.8 mmol/L), has been proposed as another important metric, particularly for near-normal glucose levels or stricter glycaemic control.[39,40] These metrics are now widely used in research and clinical practice,[8,12,22,41] with user age an important factor in setting glycaemic targets and for AID effectiveness.[37,42–44]

Despite the wealth of evidence available on AID use for T1D, quantitative synthesis and meta-analysis of glycaemic outcomes have so far largely focused on evidence generated in randomized clinical trials.[8,11,17,20,22,24,45] Reviews of real-world evidence (RWE) exist but often either lack quantitative synthesis of outcomes[18,19,21,23] or, where a meta-analysis has been performed, were not focused on glycaemic outcomes.[30] A quantitative synthesis of RWE on AID, noted as being of increasing importance to inform clinical and user decision-making as well as to differentiate between AID system,[18] was therefore identified as a gap in the currently available literature. The present review was designed to fill this gap by providing a comprehensive, quantitative synthesis of glycaemic outcomes reported in large-scale RWE studies on commercially available AID systems in people with T1D.

2 | MATERIALS AND METHODS

This systematic review (SR) and meta-analysis was based on a protocol pre-registered with PROSPERO (CRD420251019526) and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses.[46,47]

2.1 | Literature search

PubMed including MEDLINE and Embase was searched, using their respective web search interfaces, from inception to March 14, 2025. Neither additional sources nor citations were searched.

Search strategies were developed from published strategies and study design filters but not peer-reviewed (for adaptation of published search filters/strategies and full search strategies, see Tables S1 and S2 and the study protocol on PROSPERO).[48,49] Briefly, search

strategies were structured around a population component (patients living with T1D), an intervention component (AID systems, including specification of the component parts of an AID system and brand names for commercially available AID systems; "AID" and "HCL" were used interchangeably in this article), and a study design component (capturing observational studies and containing terms designed to capture RWE). Searches were limited to articles published in English. The Embase search was restricted to exclude studies available from MEDLINE to avoid duplicate hits and to exclude conference abstracts, which were considered unlikely to provide sufficient information.

Results from literature searches were uploaded to Sourcerer (Covalence Research, Harpenden, United Kingdom), which was used for record deduplication and title-abstract screening. Full-text review was performed using Zotero (Corporation for Digital Scholarship, Vienna, VA, USA).

2.2 | Study selection and eligibility criteria

Records were screened and reviewed by two reviewers (J.P., J. S-P.) independently, with conflicts resolved through consensus against prespecified eligibility criteria. Studies were eligible for inclusion if: (a) conducted in free-living, ambulatory people with T1D; (b) using a commercially available AID or CGM system with ≥10 days of CGM data available for whom; (c) data on glycaemic outcomes or hypoglycaemic events were available from; (d) a real-world study with ≥250 participants using an AID system.

Regarding population criteria, studies were excluded if conducted in highly specific groups with T1D, such as participants selected for baseline HbA1c values or in specific settings/circumstances, such as pregnancy, fasting during Ramadan, or treated in hospital.[19] Studies including participants with T1D and type 2 diabetes (T2D) were eligible only if outcomes were available separately for users with T1D. If a study reported only "users" and there was no clear indication that the population had T2D, the study was assumed to have been conducted in T1D, given the predominant use of AID systems in T1D in contemporary clinical practice.

Eligible AID systems were CamAPS® FX (CamDiab, London, UK), Control-IQ™ (Tandem Diabetes Care, San Diego, CA, USA), Diabeloop Generation 1 (DBLG1; Diabeloop, Grenoble, France), iLet® Bionic Pancreas (Beta Bionics, Irvine, CA, USA), Loop (Tidepool Project, Palo Alto, CA, USA), MiniMed™ 670G, 770G, or 780G (Medtronic, Minneapolis, MN, USA), and Omnipod® 5 (Insulet, Boston, MA, USA). Studies investigating only overnight AID use or not reporting results separately by AID system, or not reporting which AID system was used, were excluded. No restriction was imposed regarding data collection modes. While most AID systems offer automatic data upload to central platforms and data management systems, other data collection modes were permissible, including for glycaemic metrics but also, for example, for HbA1c, which requires in-person visits for measurement.

The main outcomes were TIR and HbA1c. Additional glycaemic outcomes relevant for eligibility were TITR, TAR, TBR, mean glucose and its standard deviation (SD), coefficient of variation (CV), and glucose management indicator (GMI).[37,50] In addition, the percentage of users achieving glycaemic targets such as TIR >70% or HbA1c <7% was an eligible outcome. Hypoglycaemic events of any definition were also eligible.

Only real-world studies were eligible, including comparative studies and studies investigating AID use longitudinally, in a pre-post design, or reporting outcomes as a snapshot in time without baseline data. Studies conducted in a clinical setting and with a pre-defined study protocol extending beyond standard of care, such as randomized clinical trials, were excluded, as were studies without a full-text publication available in English and those not reporting extractable numerical data on at least one outcome. Only studies with ≥250 participants were considered, to ensure that results could be considered to be based on reliable evidence and to reduce the risk of reporting bias from smaller studies and generalizable to the overall population of people with T1D.

2.3 | Data collection

Data (see Section 2 in the Supporting Information for the list of prespecified data items) were extracted from full-text papers and supplementary materials by a single reviewer using a standardized extraction form in Google Sheets (Google, Mountain View, CA, USA). No other data sources were used, and study authors were not contacted for information.

Data were independently checked by a second reviewer by cross-referencing extracted values with the report. In addition, data were checked programmatically, for example, to ensure that uncertainty ranges included central estimates, for example, that confidence intervals (CIs) included means, and that extracted values fell within physiologically plausible ranges for HbA1c and glucose. Note that, for the purposes of data aggregation, time in automated modes, which were variably labelled across studies, for example, as "time in automation" or "time in auto mode", were grouped as a single outcome.

For outcomes, central estimates (e.g., means) and, where available, estimates of uncertainty (e.g., SD) were extracted for overall cohorts/groups and for groups defined by baseline age and the use of optimal device settings. Data for all measures and time points were extracted, with estimates from the shortest follow-up used in the base case analysis. Outcome data were supplemented with information on sample size and age ranges. In addition, study meta-data such as the first author, year of publication, and journal were extracted, as was baseline information, where available, on age, sex, ethnicity/race, diabetes duration, and prior treatment.

2.4 | Risk of bias

The risk of bias (RoB) was assessed separately for glycaemic outcomes obtained from CGM, which were based on automatic data upload, and for outcomes measured at healthcare points of contact, such as

HbA1c, or via questionnaire and patient report, such as hypoglycaemic events. The ROBINS-I tool (version 2) was used for RoB evaluation, independently by two reviewers, with conflicts resolved by consensus.

2.5 | Statistical analysis

For each outcome, as a first step, unweighted and sample size-weighted means of means were calculated across studies (Figure 1). Subsequently, random-effects models with AID system as a moderator variable were estimated for each outcome for which ≥2 estimates were available. Specifically, random effects assumed that different user groups contributing data to the analysis could be nested within studies, for example, when groups using different AID systems in head-to-head studies were included.[51,52] Models were fitted using restricted maximum likelihood (REML), on the logit scale for continuous proportions (such as TIR) and on the identity scale for other outcomes (such as SG). Profile likelihood plots were used to investigate REML estimates and parameter identifiability.[53]

Test statistics and CIs for fixed AID system effects were computed using t-tests, for an alpha level of 0.05 (unless specified differently, "significant" in this paper refers to statistical significance at an alpha level of 0.05). Omnibus tests were performed to assess if there were significant differences between model coefficients, with MiniMed™ 780G chosen as the intercept as it was the AID system with the most data available.[52] Residual heterogeneity was assessed with the Q_E test.[52,54]

Standard errors and CIs reported with a mean value were directly converted to SDs.[55] If no SD, standard error, or CI was available, SDs were derived using the prognostic method developed by Ma et al., which predicts missing SDs as the average of available SDs.[55,56] If no SD could be calculated, the corresponding mean estimate was tabulated and included in pooled means, but not in meta-analysis. Medians were converted to means using the Box-Cox method, which does not assume the underlying data to be normally distributed.[8,57] For the study by Forlenza et al.,[58] only a median with no measure of uncertainty was available for the entire cohort, but means and SDs were available for subgroups covering the entire cohort, so these were used instead.

The development and analysis of evidence networks, which was planned to be conducted if feasible, could not ultimately be performed. Analyses and plotting were done using R v.4.5.0.[52,59–61]

2.6 | Sensitivity and scenario analyses

Sensitivity analyses (not pre-specified) were conducted with means derived from medians using quantile estimation[57] and the method for unknown, non-normal distributions,[62] respectively. Additional sensitivity analyses were performed by selecting estimates with the longest follow-up from longitudinal studies and by using small sample-adjusted, cluster-robust tests.[52,63,64]

Pre-specified scenario analyses were performed by overall RoB and age group, by stratifying by these variables when calculating pooled means and by adding them as another moderator variable

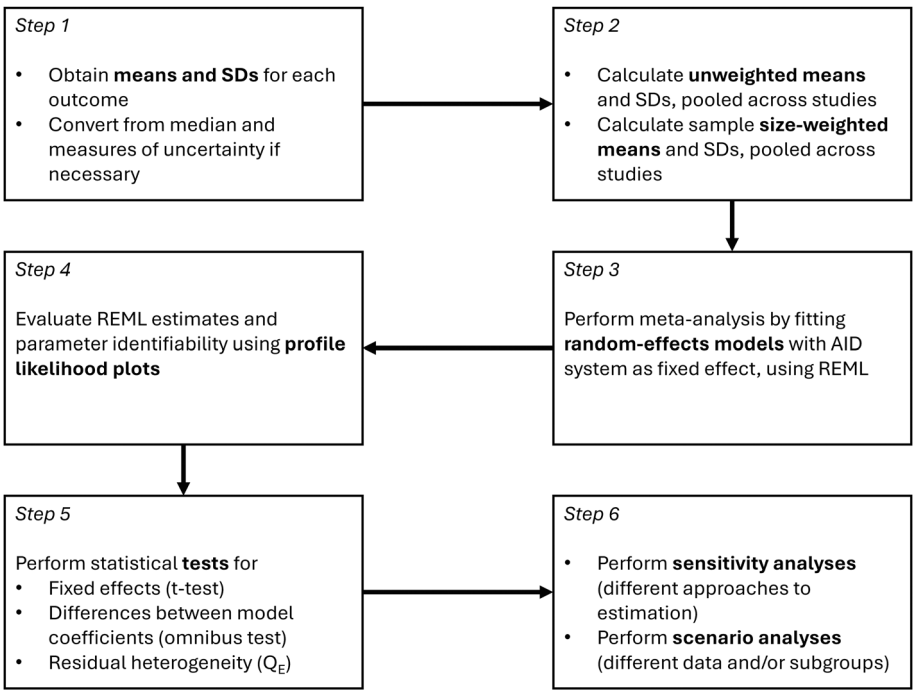

FIGURE 1 Analytic workflow for each outcome. AID, automated insulin delivery; REML, restricted maximum likelihood; SD, standard deviation.

besides AID system in meta-analyses. While an age-based scenario analysis was prespecified, the exact age ranges to be used were not, as it was anticipated that studies would employ different definitions, for example, for paediatric groups. Instead, age groups were informed by age inclusion criteria specified in each study, defining the youngest age group as ≤15, ≤18, and ≤21 years and the oldest age group as >55 and >65 years, respectively, leading to six analyses conducted for age groups. Note that the available data on age allowed only relatively coarse grouping. Groups with no age inclusion criteria specified were excluded from these analyses.

An additional, non-prespecified scenario analysis was conducted for using "optimal" device settings, which were grouped across different manufacturer terminology as using the manufacturer-recommended settings (consistent use of a 100 mg/dL glucose target and active insulin time of 2 h for the MiniMed 780G; 110 mg/dL for Omnipod 5) to achieve the best outcomes in the absence of specific concerns such as user propensity towards hypoglycaemia. For this analysis, data from the cohorts using optimal settings reported across studies were used. The analysis was not prespecified as it was not initially anticipated that sufficient data would be available from the literature but, when data were ultimately found to be sufficient, was conducted to assess outcomes with stringent use recommended for tight glycaemic control. Another non-prespecified scenario analysis was run by incorporating baseline TIR, where reported, as a predictor in meta-analysis. For meta-analyses, scenario analyses were implemented by adding the variable of interest as a moderator in addition to the AID system.

One pre-specified scenario analysis, by type of data upload, could not be conducted as there was no variation in the data.

2.7 | Ethics

The present analysis uses previously collected data from published studies. It does not contain any studies with human participants or animals performed by any of the authors.

3 | RESULTS

3.1 | Study selection and overview

The literature searches retrieved 846 hits, of which 63 were removed as duplicates (Figure 2). Forty-five articles underwent full-text review, with 36 records covering 34 studies ultimately included (see Table 1, and Table S3 for studies excluded during full-text review).[27,40,43,58,65–96] The studies reported on 635 463 users, mostly from European/Middle Eastern/African countries ($n = 17$ studies) and the US ($n = 12$). Sixteen studies reported on the MiniMed™ 780G, nine on Control-IQ™, six on the MiniMed™ 670G, with ≤3 studies for other devices but ≥1 study for each commercial AID system. Seven studies reported data on two systems, with four reporting on different MiniMed™ devices[75,80,84,85] and three comparing systems from different manufacturers.[82,93,95] The mean (SD) reported follow-up time was 8.2 (5.8) months, whereas the

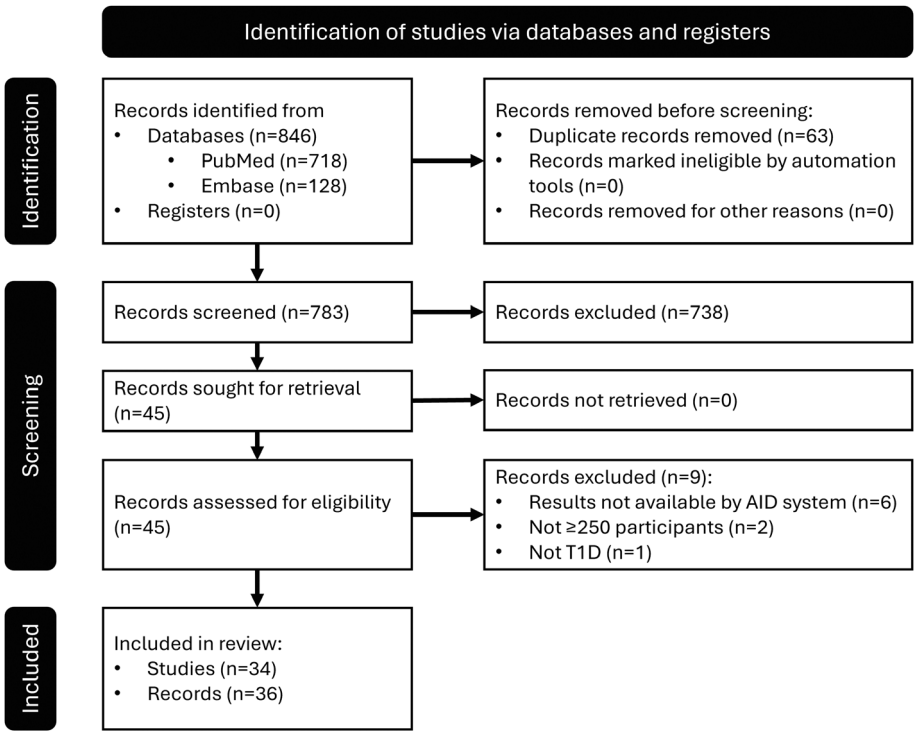

FIGURE 2 PRISMA flow diagram. AID, automated insulin delivery; PRISMA, preferred reporting items for systematic reviews and meta-analyses; T1D, type 1 diabetes. A record is a published unit for a piece of research (a study). Multiple records may exist for a study, for example, a published article investigating effectiveness outcomes and another article investigating safety outcomes.

TABLE 1 Studies included in analyses.

Study	Country/region	Cohort(s) in analysis	Cohort size, *n*	Age, years	Women, %	Diabetes duration, years	BMI, kg/m^2	HbA1c, %
CamAPS FX								
Alwan et al. 2023[65]	AUS, AUT, CZE, DNK, FIN, DEU, IRL, ITA, LUX, NDL, POL, ESP, SWE, CHE, GBR	Post-AID	1805	30.2 (19.3)	—	—	—	—
Royston et al. 2025[94]	—	All users	7464	32.0 (19.0)	—	—	—	—
Control-IQ								
Breton and Kovatchev 2021[71]	USA	All users	7813	—	—	21.8 (20.6)	—	—
De Meulemeester et al. 2025[79]	BEL	All users	473	38.5 (13.1)	57.3	20.0 (12.6)	25.8 (4.3)	7.4 (1.0)
Gera et al. 2025[82]	USA	Pre- and post-AID	214	Median: 14.3 (IQR: 12.1 to 16.3)	46.7	Median: 5.5 (IQR: 2.9 to 9.3)	—	—
Graham et al. 2024[83]	USA	All users	3157	Median: 29.0 (IQR: 16.0 to 45.0)	55.7	—	Median: 25.7 (IQR: 21.9 to 30.2)	Median: 7.7 (IQR: 6.9 to 8.7)
Kovatchev et al. 2022[86]	USA	All users	19 354	Median: 39.0 (IQR: 19.0 to 58.0)	55.4	—	—	—
Messer and Breton 2023[92]	USA	All users	20 764	Median: 39.0 (IQR: 19.0 to 59.0)	55.0	—	—	—
Pinsker et al. 2021[70]	USA	All users	1435	45.5 (16.6)	51.3	25.4 (15.4)	—	—
Piona et al. 2024[93]	ITA	All users	284	12.8 (3.2)	49.3	5.9 (3.6)	20.7 (3.7)	—
Santova et al. 2023[95]	CZE	All users	211	12.5 (4.4)	—	6.0 (3.5)	—	—
DBLG1								
Benhamou et al. 2023[68]	DEU	Post-AID	3706	45.1 (14.5)	41.0	—	—	—
Lebbad et al. 2024[87]	Europe	All users	9036	45.6 (14.3)	—	—	—	—
Loop								
Lum et al. 2021[89]	USA	All users	558	23.0 (16.0)	57.0	Median: 8.0 (IQR: 4.0 to 20.0)	26.0 (5.0)	—
MiniMed 670/770G								
Halim et al. 2024[85]	AUS	All users	5676	—	—	—	—	—
MiniMed 670G								
Arunachalum et al. 2023[67]	USA	All users	123 555	—	—	—	—	—
Berget et al. 2021[69]	USA	Youth|Young adults|Adults|Older adults	75|40|121|33	—	—	—	—	—
Da Silva et al. 2021[77]	Europe	Post-AID	14 899	—	—	—	—	—
Stone et al. 2018[96]	—	All users using Automode	3141	—	—	—	—	—

TABLE 1 (Continued)

Study	Country/region	Cohort(s) in analysis	Cohort size, *n*	Age, years	Women, %	Diabetes duration, years	BMI, kg/m^2	HbA1c, %
MiniMed 780G								
Arrieta et al. 2022[66]	EMEA	Post-AID	12 870	–	–	–	–	–
Castañeda et al. 2022[43]	–	All users	12 870	–	–	–	–	–
Castañeda et al. 2024[40,73]	EMEA	Users aged ≤15 years|Users aged >15 years	14 459|41 692	–	53.0|57.0	–	–	–
Choudhary et al. 2024[74]	EMEA	Post-AID	101 629	–	–	–	–	–
Cordero et al. 2023[76]	EMEA	Users aged ≤15 years|Users aged >56 years	10 204|26 099	–	–	–	–	–
Da Silva et al. 2022[78]	EMEA	Post-AID	4120	–	–	–	–	–
Dekker et al. 2024[80]	NDL	All users	481	19.9 (11.9)	53.6	–	22.9 (5.4)	7.6 (1.2)
Grassi et al. 2023[84]	LATAM	All users	1025	–	–	–	–	–
Halim et al. 2024[85]	AUS	All users	3566	–	–	–	–	–
Lepore et al. 2024[88]	ITA	All users	296	42.8 (16.5)	58.1	22.5 (12.8)	24.9 (4.7)	–
Matejko et al. 2024[90]	BEL, CZE, POL, DNK, FIN, GBR, GRC, HUN, ISL, IRL, ITA, LUX, NDL, PRT, ROM, SVK, SLO, SWE, CHE, TUR	Users in Poland|Users in European region outside Poland	1304|55 659	–	–	–	–	–
Passanisi et al. 2024[72]	ITA	All users	368	–	–	–	–	–
Piona et al. 2024[93]	ITA	All users	329	12.5 (2.8)	48.0	5.4 (3.6)	21.3 (3.9)	–
Santova et al. 2023[95]	CZE	All users	217	13.8 (3.9)	–	8.3 (3.7)	–	–
Smaniotto et al. 2025[27]	EMEA	Users aged 16–55 years|Users aged ≥56 years	35 366|7415	–	–	–	–	–
Thrasher et al. 2024[75]	USA	All users	7499	–	–	–	–	–
Omnipod 5								
Forlenza et al. 2024[58]	USA	All users	69 902	32.2 (19.5)	56.0	–	–	–
Gera et al. 2025[82]	USA	Pre- and post-AID	214	Median: 12.4 (IQR: 8.6 to 15.5)	56.5	Median: 1.6 (IQR: 0.7 to 4.3)	–	–
Meighan et al. 2024[91]	USA	CDCES-trained users|Self-starters	126|171	Median: 11.8 (IQR: 8.9 to 15.3)|Median: 12.7 (IQR: 9.7 to 15.5)	41.3|47.4	Median: 2.5 (IQR: 1.3 to 5.5)|Median: 5.0 (IQR: 2.6 to 7.9)	–	–

Note: Values are mean (SD) unless specified differently. Values are reported for each cohort included in the analysis, with different cohorts reported in the same study separated by "|". Note that some papers, for example, Berget et al.,[69] reported baseline data (only) for groups/cohorts that were not considered in the present analyses. These baseline data are not included here as they could not inform the present analysis. Studies reporting on more than one AID system are listed with the corresponding cohort for the respective device.

Abbreviations: AID, automated insulin delivery; AUS, Australia; AUT, Austria; BEL, Belgium; BMI, body mass index; CDCES, Certified Diabetes Care and Education Specialist®; CHE, Switzerland; CZE, Czech Republic; DBLG, Diabeloop Generation 1; DEU, Germany; DNK, Denmark; EMEA, Europe, Middle East, and Africa; ESP, Spain; FIN, Finland; FRA, France; GBR, United Kingdom; GRC, Greece; HbA1c, glycated haemoglobin; HUN, Hungary; IQR, interquartile range; IRL, Ireland; ISL, Iceland; ITA, Italy; LATAM, Latin America; LUX, Luxembourg; NDL, Netherlands; POL, Poland; PRT, Portugal; ROM, Romania; SD, standard deviation; SLO, Slovenia; SVK, Slovakia; SWE, Sweden; TUR, Türkiye; USA, United States.

mean (SD) reported follow-up time weighted by sample size was 7.2 (2.8) months.

3.2 | Main analyses

3.2.1 | Pooled means

Time in range and glucose outcomes

Pooling mean values across studies indicated that unweighted mean (SD) TIR ranged from 60.0% (5.4) for Omnipod® 5 to 73.8% (2.8) for MiniMed™ 780G (Table 2 and Figure S1). Sample size-weighted means for TIR ranged from 63.2% (5.5) to 73.2% (1.5) for the same AID systems (Table 2 and Figure 3). There was between-system variation for other time-in-range outcomes (Table 2), including TBR54 (weighted means from 0.3% for Control-IQ, Omnipod 5, and DBLG 1 to 0.6% for MiniMed 670G; Figures S2 and S3) and TBR70 (weighted means from 1.2% for Control-IQ to 2.6% for CamAPS FX; Figures S4 and S5), as well as TAR180 (weighted means from 23.7% [2.6] for MiniMed 780G to 35.4% [5.7] for Omnipod 5; Figures S6 and S7) and TAR250 (weighted means from 5.8% [0.8] for MiniMed 780G to 17.2% [0.8] for Omnipod 5; Figures S8 and S9). Estimates for TITR were available for only three devices, with weighted means ranging from 45.1% (1.6) for Control-IQ to 49.1% (1.0) for MiniMed 780G (Figures S10 and S11).

Among glycaemic outcomes, HbA1c, one of the main outcomes, was available for only three devices (Table 2). Mean values ranged from 6.5% for Loop (based on a single estimate) to 7.1% (0.3 for unweighted, 0.2 for weighted means) for MiniMed 780G (Figure 4, Figure S12). More data were available for SG, for which weighted means ranged from 147 mg/dL for Loop (based on a single estimate) to 175.9 mg/dL (2.3) for Omnipod 5 (Figures S13 and S14), and for SD, for which weighted means ranged from 47.1 mg/dL (1.2) for Control-IQ to 55.8 for CamAPS FX (based on a single estimate; Figures S15 and S16). For CV, weighted means ranged from 29.9 (0.7) for Control-IQ to 39.1 (0.6) for Omnipod 5 (Figures S17 and S18). There was limited variability between AID systems in GMI (Figures S19 and S20) and GRI (Figures S21 and S22), with GRI data available only for Control-IQ and MiniMed 780G.

3.2.2 | Glycaemic targets, hypoglycaemia, and time in automation

With respect to data on glycaemic targets, MiniMed 780G was the only system for which data were reported consistently and with multiple estimates available (Table S4). A between-system comparison was possible for users reaching TIR >70%, for which MiniMed 780G showed the highest percentage when compared to Loop and MiniMed 670G, although few estimates were available for the latter two systems. For users reaching TBR54 < 1%, estimates based on <1000 users indicated slightly higher percentages for Control-IQ and Omnipod 5, relative to the pooled estimate across 161,900 users for MiniMed 780G (weighted mean 89.1% [2.2]). For TBR70 < 4%, mean achievement ranged from 68% with Loop to 94.2% (1.9) for Omnipod 5.

Severe hypoglycaemic events (SHE) data were available from one estimate each for CamAPS FX and Loop, and two estimates for Control-IQ, with per-person-year estimates of 0.0–0.1.

Weighted estimates for time in automation/closed loop ranged from 63.5% for MiniMed 670/770G, based on a single estimate, to 93.6% (0.9) for Control-IQ (Figures S23 and S24).

3.2.3 | Meta-analyses

Meta-analysis could be performed for 15 outcomes. For TIR, meta-analysis indicated the numerically highest mean (95% CI) for MiniMed 780G (73.9% [72.3 to 75.5], $p < 0.0001$), followed by Loop (73.0% [63.1 to 81.1], $p = 0.795$) (Table 3 and Figure 5). MiniMed 670G and Omnipod 5 were associated with significantly lower TIR than MiniMed 780G. While accounting for AID system already explained a significant amount of TIR, TAR180, and TAR250 variation between studies (as seen from omnibus tests), significant residual heterogeneity remained even after adjusting for system. Specifically, MiniMed 670G (for TAR180) and Omnipod 5 (for TAR180 and TAR250) were associated with higher TAR than MiniMed 780G (Table 3 and Figure S25). For TITR, the highest estimate, based on a single study, was for Loop (51.0% [45.8 to 56.2]), which was not significantly different from MiniMed 780G (50.1% [48.9 to 51.4]), which in turn was significantly higher than for Control-IQ (44.6% [40.7 to 48.7]). No significant differences between systems were identified for TBR54, but DBLG 1 was associated with significantly lower TBR70 relative to MiniMed 780G. Profile likelihood plots for time-in-range outcomes indicated no issues with estimation and parameter identifiability (Figures S27–S34).

For HbA1c, both Loop (6.5% [5.4 to 7.7]) and Control-IQ (6.8% [6.0 to 7.6]) were associated with numerically lower estimates than MiniMed 780 (7.0% [6.7 to 7.4]), but the difference was not significant (Table 3 and Figure 5). As with TIR, there was significant residual heterogeneity after adjusting for AID system, with adjustment unable to account for the HbA1c variation observed. For the remaining glycaemic outcomes, significant residual heterogeneity but no significant difference between systems was observed, except for GMI and SG, which were significantly higher for Omnipod 5 and, for SG, MiniMed 670/770G, than for MiniMed 780G (Table 3 and Figure S26). For MiniMed 670/770G, time in automation was also significantly lower than for MiniMed 780G, while time in automation with Control-IQ was significantly higher. Profile likelihood plots for glycaemic outcomes and time in automation (Figures S35–S41), except for between-cluster variance for SG (Figure S36) and SD (Figure S37) as well as within-cluster variance for GRI (Figure S40), again indicated no issues with estimation and parameter identifiability.

TABLE 2 Pooled unweighted and sample size-weighted means for time-in-range and glucose outcomes.

AID system	Nr. of user groups contributing data	Total participants	Mean (SD)	
			Unweighted	Weighted
TIR (%)				
CamAPS FX	2	9269	72.8 (0.3)	72.9 (0.2)
Control-IQ	9	53 654	71.0 (4.4)	70.8 (1.7)
DBLG1	2	12 743	69.9 (2.6)	69.1 (1.7)
Loop	1	558	73.0	73.0
MiniMed 670/770G	1	5523	67.3	67.3
MiniMed 670G	7	141 864	69.3 (4.9)	70.6 (0.7)
MiniMed 780G	20	337 364	73.8 (2.8)	73.2 (1.5)
Omnipod 5	6	70 233	60.0 (5.4)	63.2 (5.5)
HbA1c (%)				
Control-IQ	3	1013	6.8 (0.1)	6.8 (0.1)
Loop	1	558	6.5	6.5
MiniMed 780G	4	1350	7.1 (0.3)	7.1 (0.2)
CV (%)				
CamAPS FX	1	1805	36.2	36.2
Control-IQ	5	42 355	31.8 (2.1)	29.9 (0.7)
DBLG1	1	3707	31.2	31.2
Loop	1	558	36.1	36.1
MiniMed 670/770G	1	5523	34.5	34.5
MiniMed 670G	1	123 555	36.1	36.1
MiniMed 780G	12	123 235	31.6 (8.7)	33.1 (5.5)
Omnipod 5	2	297	39.0 (0.9)	39.1 (0.6)
GMI (%)				
CamAPS FX	1	1805	6.9	6.9
Control-IQ	3	20 156	7.0 (0.1)	7.0 (0.0)
DBLG1	1	3707	7.0	7.0
MiniMed 670/770G	1	5523	7.2	7.2
MiniMed 670G	2	138 454	7.0 (0.0)	7.0 (0.0)
MiniMed 780G	18	336 666	6.9 (0.1)	6.9 (0.1)
Omnipod 5	3	69 722	7.5 (0.4)	7.4 (0.2)
GRI				
Control-IQ	2	684	32.6 (2.0)	32.1 (1.3)
MiniMed 780G	3	822	29.4 (1.6)	29.1 (1.3)
SD (mg/dL)				
CamAPS FX	1	1805	55.8	55.8
Control-IQ	3	20 156	50.5 (3.6)	47.1 (1.2)
DBLG1	1	3707	50.7	50.7
Loop	1	558	52.6	52.6
MiniMed 670/770G	1	5523	55.7	55.7
MiniMed 780G	6	61 394	52.5 (3.5)	52.1 (2.7)
SG (mg/dL)				
CamAPS FX	2	9269	151.1 (0.1)	151.0 (0.1)
Control-IQ	7	53 229	154.4 (5.8)	156.4 (2.7)
DBLG1	1	3707	157.0	157.0
Loop	1	558	147.0	147.0

(Continues)

TABLE 2 (Continued)

AID system	Nr. of user groups contributing data	Total participants	Mean (SD)	
			Unweighted	Weighted
MiniMed 670/770G	1	5523	160.6	160.6
MiniMed 670G	6	126 965	158.9 (8.0)	155.9 (0.7)
MiniMed 780G	17	332 546	149.6 (4.9)	150.7 (2.2)
Omnipod 5	2	297	176.2 (3.2)	175.9 (2.3)
TAR140 (%)				
Control-IQ	1	473	51.6	51.6
MiniMed 780G	1	7499	42.9	42.9
TAR140–180 (%)				
Control-IQ	1	473	25.7	25.7
MiniMed 780G	1	7499	25.6	25.6
TAR180 (%)				
CamAPS FX	2	9269	24.9 (0.2)	24.9 (0.1)
Control-IQ	7	45 627	25.7 (3.4)	27.7 (1.6)
DBLG1	1	3707	20.7	20.7
Loop	1	558	24.0	24.0
MiniMed 670/770G	1	5523	30.6	30.6
MiniMed 670G	7	141 864	28.7 (5.0)	27.3 (0.7)
MiniMed 780G	20	337 364	23.6 (3.1)	23.7 (2.6)
Omnipod 5	5	70 019	38.9 (5.7)	35.4 (5.7)
TAR180–250 (%)				
Control-IQ	5	28 180	18.7 (1.1)	19.7 (0.5)
MiniMed 670/770G	1	5523	22.2	22.2
MiniMed 670G	3	141 595	19.9 (0.8)	20.7 (0.4)
MiniMed 780G	20	337 364	18.4 (1.6)	18.9 (0.8)
TAR250 (%)				
CamAPS FX	2	9269	6.2 (0.7)	5.9 (0.4)
Control-IQ	8	53 440	6.9 (1.9)	7.7 (0.9)
DBLG1	1	3707	6.2	6.2
Loop	1	558	5.7	5.7
MiniMed 670/770G	1	5523	8.4	8.4
MiniMed 670G	3	141 595	6.0 (0.7)	6.6 (0.3)
MiniMed 780G	20	337 364	5.5 (1.4)	5.8 (0.8)
Omnipod 5	2	297	17.3 (1.2)	17.2 (0.8)
TBR54 (%)				
CamAPS FX	2	9269	0.5 (0.0)	0.5 (0.0)
Control-IQ	7	45 627	0.5 (0.3)	0.3 (0.1)
DBLG1	1	3707	0.3	0.3
Loop	1	558	0.8	0.8
MiniMed 670/770G	1	5523	0.5	0.5
MiniMed 670G	3	141 595	0.5 (0.2)	0.6 (0.0)
MiniMed 780G	20	337 364	0.5 (0.1)	0.4 (0.1)
Omnipod 5	5	70 019	0.4 (0.2)	0.3 (0.0)
TBR54–70 (%)				
Control-IQ	5	28 180	1.8 (0.7)	1.3 (0.2)
MiniMed 670/770G	1	5523	1.5	1.5

TABLE 2 (Continued)

AID system	Nr. of user groups contributing data	Total participants	Mean (SD)	
			Unweighted	Weighted
MiniMed 670G	3	141 595	1.7 (0.1)	1.6 (0.1)
MiniMed 780G	20	337 364	1.8 (0.4)	1.7 (0.2)
Omnipod 5	3	69 722	1.0 (0.2)	1.1 (0.2)
TBR70 (%)				
CamAPS FX	2	9269	2.6 (0.1)	2.6 (0.0)
Control-IQ	7	45 627	2.1 (0.9)	1.5 (0.2)
DBLG1	2	12 743	1.1 (0.2)	1.2 (0.1)
Loop	1	558	3.1	3.1
MiniMed 670/770G	1	5523	2.0	2.0
MiniMed 670G	7	141 864	2.3 (0.4)	2.2 (0.1)
MiniMed 780G	20	337 364	2.3 (0.5)	2.1 (0.3)
Omnipod 5	5	70 019	1.8 (0.7)	1.4 (0.2)
TITR (%)				
Control-IQ	2	802	44.8 (2.3)	45.1 (1.6)
Loop	1	558	51.0	51.0
MiniMed 780G	8	107 564	50.2 (1.3)	49.1 (1.0)

Note: AID systems are ordered alphabetically for each outcome. If a device is not reported for an outcome, no usable data were identified for this outcome–device combination. Data are means and standard deviations of reported and derived means.
Abbreviations: AID, automated insulin delivery; CV, coefficient of variation; GMI, glucose management indicator; GRI, glycaemic risk index; HbA1c, glycated haemoglobin; SD, standard deviation; SG, sensor glucose; TAR140, time above 140 mg/dL; TAR140-180, time in 140–180 mg/dL range; TAR180, time above 180 mg/dL; TAR180-250, time in 180–250 mg/dL range; TAR250, time above 250 mg/dL; TBR54, time below 54 mg/dL; TBR54-70, time in 54–70 mg/dL range; TBR70, time below 70 mg/dL; TIR, time in range; TITR, time in tight range.

3.2.4 | Sensitivity analyses

Pooled means

Using different methods to derive means from medians had minimal impact on pooled means (Tables S5 and S6). Estimates for Control-IQ, Loop, and Omnipod 5, many of which were reported as medians, were consequently affected more than for the remaining systems, but changes were small and did not meaningfully influence conclusions regarding relative system performance. Similarly, using outcomes reported at the longest, rather than the earliest, follow-up time point in longitudinal studies led to minimal numeric changes across devices and outcomes (Table S7).

Meta-analyses

Meta-analyses based on data with means derived from medians using quantile estimation and MLN generally confirmed numerical and significance findings from the main analyses (Tables S8 and S9 and Figures S42–S71), as did the sensitivity analyses based on selecting outcomes from the longest follow-up (Table S10 and Figures S72–S86). An exception was GRI, for which Control-IQ estimates were significantly higher than those for MiniMed 780. When using MLN, the numerically higher SG value for Control-IQ was also no longer significantly different from MiniMed 780G.

With robust estimation, most CIs narrowed, particularly for devices with a more limited evidence base (Table S11 and Figures S87–S101). Relative to the main analysis, TIR was significantly lower for DBLG 1 and MiniMed 670/770G versus MiniMed 780G. Loop was now associated with significantly lower HbA1c than MiniMed 780G. There was no consistent pattern in changes of statistical significance versus the main analysis across outcomes.

3.2.5 | Scenario analyses

Pooled means

Investigating groups using optimal device settings limited the analysis to Omnipod 5 and MiniMed 780G, with most results for the former system based on single estimates (Table S12). Pooled unweighted and weighted means indicated higher TIR for MiniMed 780G versus OmniPod 5 (weighted means: 79.6% [1.0] vs. 67.7%, respectively). Notably, when using optimal settings, TAR estimates were higher (weighted mean TAR180: 30.6% vs. 18.3% [1.1]) and TBR estimates lower (weighted mean TBR70: 1.6% vs. 2.3% [0.4]) for Omnipod 5 versus MiniMed 780G.

Analyses around age groups reduced the number of estimates and participants across AID systems. Age-related differences were generally modest, but across systems, younger and, albeit to a lesser extent, older users exhibited less favourable outcomes relative to users in middle age and overall estimates (Tables S13–S18). This pattern was particularly pronounced for MiniMed 780G, for which

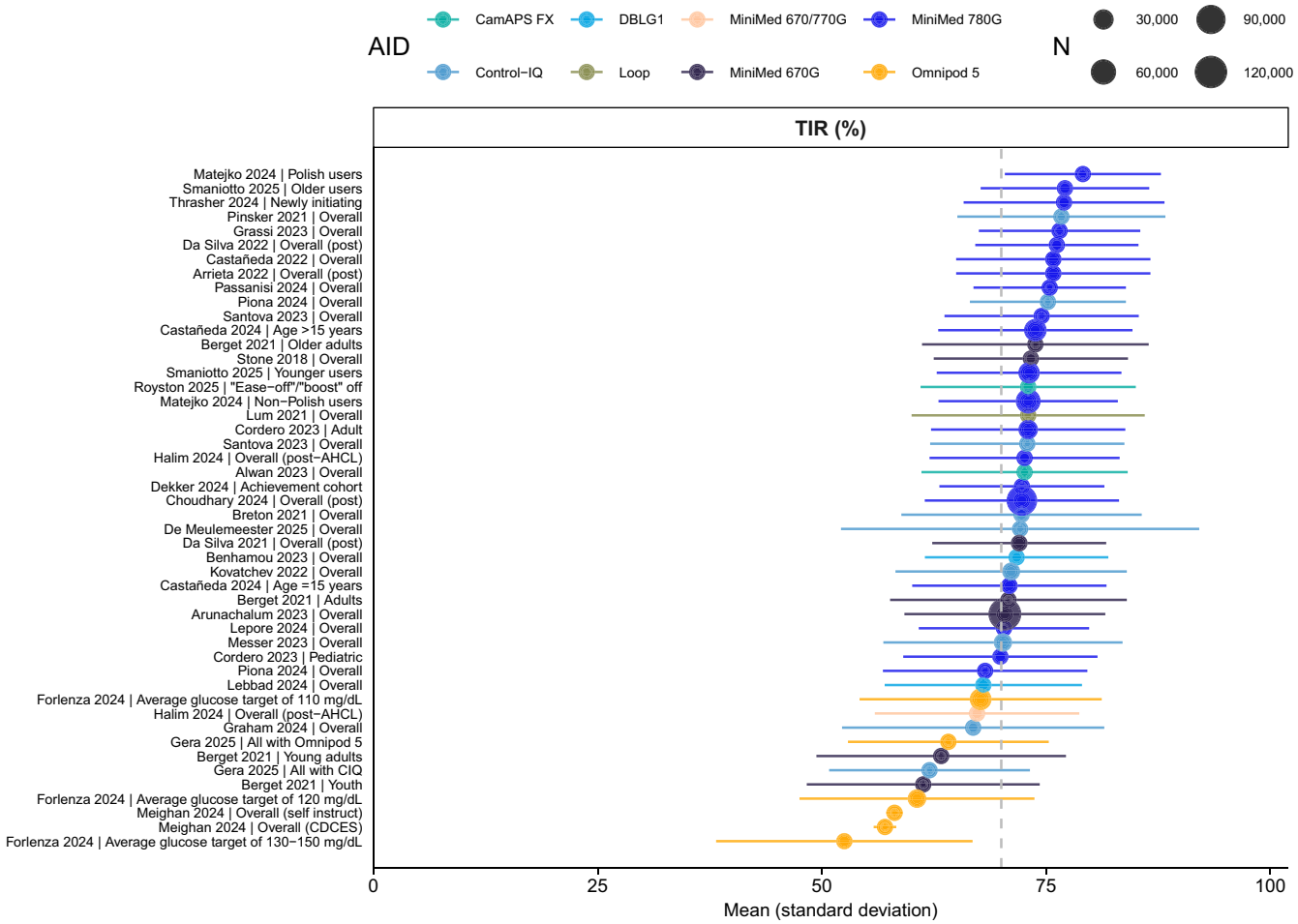

FIGURE 3 Sample size-weighted TIR estimates. AHCL, advanced hybrid closed loop; AID, automated insulin delivery; CDCES, Certified Diabetes Care and Education Specialist®; CIQ, Control-IQ; DBLG 1, Diabeloop Generation 1; TIR, time in range (70–180 mg/dL [3.9–10.0 mmol/L]). The dashed line indicates the consensus target of TIR >70%.[37,38] Circles indicate means, and bars indicate standard deviations. Note that Meighan et al. reported exceptionally narrow uncertainty intervals for TIR.[91]

glycaemic outcomes, including TIR, were consistently less favourable in younger users relative to the overall cohort and middle-aged users. For Control-IQ, glycaemic variability was consistently higher in younger users, but results regarding TAR, TBR, and SG showed more variable change across age groups relative to overall estimates (of note, MiniMed 780G and Control-IQ were the only systems with sufficient data available to allow meaningful age-related scenario analyses). As RoB varied little across studies and outcomes (Figure S177), scenario analyses were limited to exploring HbA1c and SHE, for which no meaningful differences in pooled means versus the main analysis were observed (Table S19).

Meta-analyses

Meta-analyses of groups using optimal device settings were also limited to a comparison of Omnipod 5 with MiniMed 780G and feasible only for GMI and several time-in-range outcomes, with significant residual heterogeneity in all analyses (Table S20 and Figures S102–S107). Significant differences were estimated for TIR, which was higher for MiniMed 780G (79.9% [79.0 to 80.8]) than for Omnipod 5 (67.7% [61.8 to 73.1]), and for GMI and TAR180, where lower values were estimated for MiniMed 780G. Time in automation and TBR estimates were non-significantly higher for MiniMed 780G.

Scenario analyses demonstrated age to be a major effect modifier, with heterogeneity significantly reduced if age was accounted for (Table S20–S25 and Figures S108–S176). Younger users, across age group definitions and AID systems, experienced more hypoglycaemia and glucose variability relative to overall and older user groups, while time in automation was significantly higher for older versus younger and overall user groups. System-specific estimates after age adjustment showed limited changes relative to the main analysis for MiniMed 780G and Omnipod 5. More pronounced changes in numeric estimates and statistical significance were observed for Control-IQ, for which several outcomes, including TIR and TAR250, remained numerically less favourable than for MiniMed 780G but with the difference were no longer significant. Notably, TITR remained lower with Control-IQ versus MiniMed 780G in age group scenario analyses. Scenario analyses considering RoB were limited to HbA1c (Table S27 and Figure S178), for which no significant change versus the main analysis

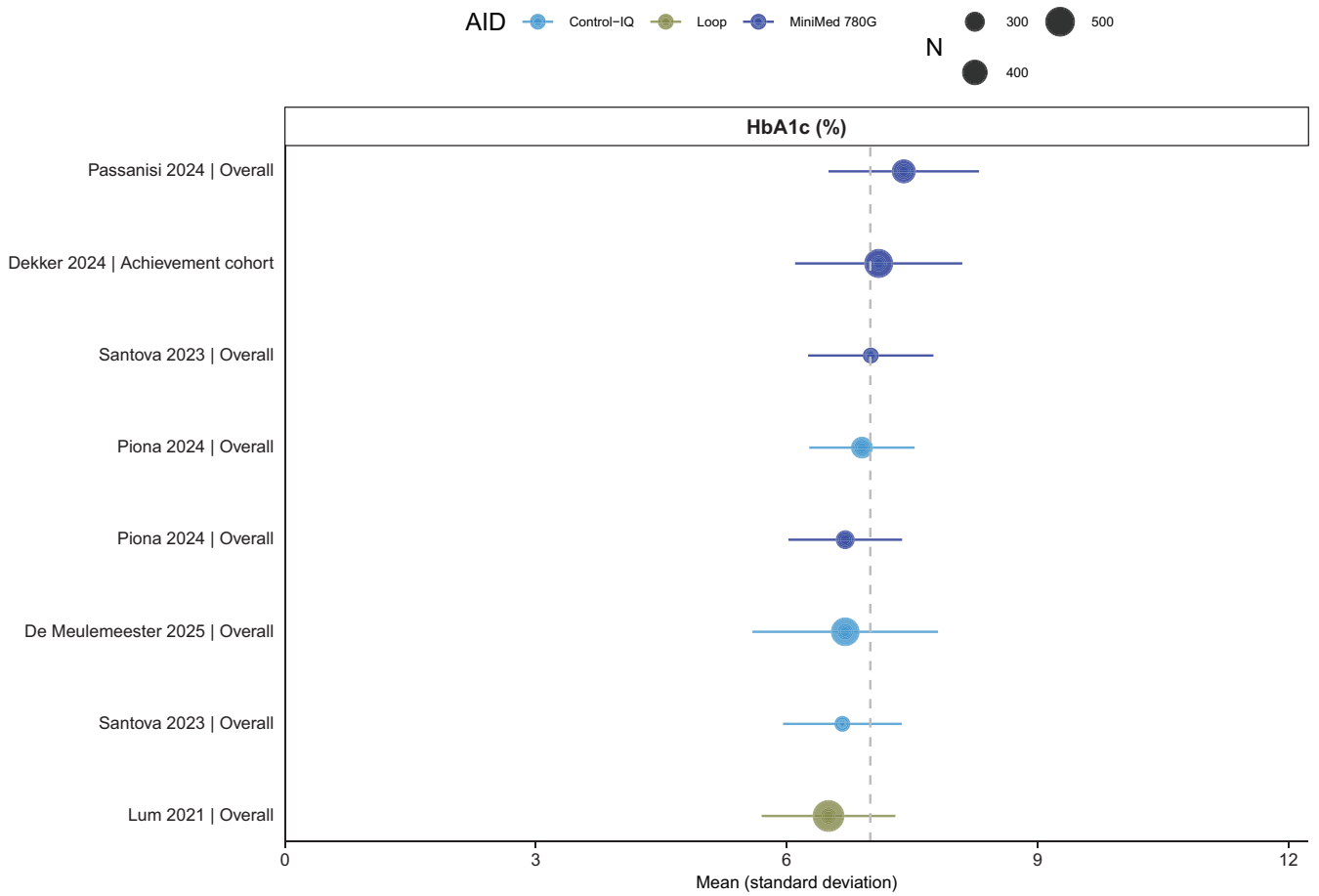

FIGURE 4 Sample size–weighted HbA1c estimates. AID, automated insulin delivery; HbA1c, glycated haemoglobin. The dashed line indicates an HbA1c target of <7%.[38] Circles indicate means, and bars indicate standard deviations.

and no significant effect of serious versus moderate RoB were identified. When adjusting for baseline TIR, which was feasible for only 11 studies, the numerically highest TIR was observed for MiniMed 780G, followed by Control-IQ, but differences between systems were no longer statistically significant (Table S28 and Figures S179–S188). Statistically significant differences favouring MiniMed 780G were observed for SG, TAR180–250, TAR250, and TBR54–250, while Omnipod 5 was associated with numerically and statistically significantly higher TAR250 than other devices. No statistically significant differences between the remaining devices and for other outcomes were observed. For most outcomes, including TIR, statistically significant residual heterogeneity remained after adjusting for baseline TIR.

4 | DISCUSSION

The present review provides an overview and synthesis of a range of glycaemic outcomes associated with real-world use of commercially available AID systems. Large studies reflective of real-world AID use by populations with T1D were eligible, with considerable differences in data availability and user cohort size between the different systems. Means pooled across studies for and meta-analyses demonstrated notable differences in glycaemic control achieved by different systems. MiniMed 780G demonstrated the highest TIR at 72.9%, with meta-analysis indicating higher TIR compared with other systems. CamAPS FX also showed high pooled TIR (72.9%), although fewer estimates were available, followed by Control-IQ, which had the highest time in automation and Loop. Omnipod 5 users had the lowest pooled TIR at 63.2%. MiniMed 780G additionally exhibited the most favourable TAR metrics, whereas Omnipod 5 showed the highest values in these domains. Control-IQ, Omnipod 5, and DBLG1 were associated with the lowest rates of hypoglycaemia (TBR54 and TBR70). Low SHE rates were estimated for all systems with available data. The limited HbA1c data suggested no significant between-system differences. Sensitivity analyses confirmed the main analysis. Scenario analyses based on optimal settings limited the comparison to MiniMed 780G and Omnipod 5, with significantly higher GMI and TAR180 but significantly lower TIR for Omnipod 5. Analyses incorporating age suggested that this was an important predictor, with younger patients consistently reporting higher hypoglycaemia and glycaemic variability relative to overall estimates and older users. Adjusting for baseline TIR, albeit only feasible for relatively few studies, reduced differences between systems, including TIR, although residual heterogeneity remained.

TABLE 3 Meta-analytic results for the main analysis.

	Mean (95% CI) coefficient		
c	Model	Converted	*p*-value
TIR (QE: 9285.9 [$p = 0.000$]; QM: 6.317 [$p = 0.000$]; between|within cluster variance: 0.000|0.028; estimates: 45)			
MiniMed 780G	1.043 (0.966 to 1.120)	73.9% (72.4 to 75.4)	0.000
CamAPS FX	−0.058 (−0.314 to 0.198)	72.8% (65.7 to 78.9)	0.643
Control−IQ	−0.138 (−0.275 to 0.000)	71.2% (66.6 to 75.4)	0.050
DBLG1	−0.201 (−0.457 to 0.055)	69.9% (62.4 to 76.4)	0.118
Loop	−0.048 (−0.406 to 0.309)	73.0% (63.6 to 80.7)	0.783
MiniMed 670/770G	−0.321 (−0.669 to 0.027)	67.3% (57.4 to 75.9)	0.069
MiniMed 670G	−0.216 (−0.374 to −0.058)	69.6% (64.4 to 74.3)	0.010
Omnipod 5	−0.648 (−0.859 to −0.437)	59.7% (52.7 to 66.4)	0.000
HbA1c (QE: 150.4 [$p = 0.000$]; QM: 2.864 [$p = 0.201$]; between|within cluster variance: 0.000|0.001; estimates: 8)			
MiniMed 780G	−2.579 (−2.637 to −2.521)	7.1% (6.7 to 7.4)	0.000
Control−IQ	−0.046 (−0.117 to 0.026)	6.8% (6.0 to 7.6)	0.163
Loop	−0.087 (−0.216 to 0.042)	6.5% (5.5 to 7.7)	0.121
CV (QE: 27299.1 [$p = 0.000$]; QM: 0.149 [$p = 0.991$]; between|within cluster variance: 0.407|0.006; estimates: 24)			
MiniMed 780G	−0.861 (−1.247 to −0.475)	29.7% (22.3 to 38.3)	0.000
CamAPS FX	0.294 (−1.173 to 1.762)	36.2% (8.2 to 78.4)	0.668
Control−IQ	−0.043 (−0.276 to 0.191)	28.8% (17.9 to 42.9)	0.702
DBLG1	0.070 (−1.398 to 1.538)	31.2% (6.6 to 74.3)	0.918
Loop	0.291 (−1.177 to 1.759)	36.1% (8.1 to 78.3)	0.671
MiniMed 670/770G	0.012 (−0.228 to 0.252)	30.0% (18.6 to 44.5)	0.916
MiniMed 670G	0.290 (−1.178 to 1.757)	36.1% (8.1 to 78.3)	0.672
Omnipod 5	0.414 (−1.048 to 1.877)	39.0% (9.2 to 80.2)	0.546
GMI (QE: 13260.6 [$p = 0.000$]; QM: 2.032 [$p = 0.136$]; between|within cluster variance: 0.000|0.000; estimates: 26)			
MiniMed 780G	−2.607 (−2.616 to −2.597)	6.9% (6.8 to 6.9)	0.000
CamAPS FX	0.005 (−0.037 to 0.046)	6.9% (6.6 to 7.2)	0.814
Control−IQ	0.012 (−0.013 to 0.037)	6.9% (6.7 to 7.2)	0.325
DBLG1	0.027 (−0.015 to 0.068)	7.0% (6.7 to 7.4)	0.187
MiniMed 670/770G	0.050 (0.010 to 0.090)	7.2% (6.9 to 7.5)	0.016
MiniMed 670G	0.020 (−0.010 to 0.050)	7.0% (6.7 to 7.3)	0.171
GRI (QE: 15.6 [$p = 0.001$]; QM: 7.192 [$p = 0.075$]; between|within cluster variance: 2.100|0.000; estimates: 5)			
MiniMed 780G	29.327 (25.494 to 33.159)	29.3 (25.5 to 33.2)	0.001
Control−IQ	2.984 (−0.557 to 6.525)	32.3 (24.9 to 39.7)	0.075
SD (QE: 3918.5 [$p = 0.000$]; QM: 0.621 [$p = 0.696$]; between|within cluster variance: 0.000|12.063; estimates: 13)			
MiniMed 780G	52.501 (48.540 to 56.462)	52.5 mg/dL (48.5 to 56.5)	0.000
CamAPS FX	3.299 (−7.158 to 13.756)	55.8 mg/dL (41.4 to 70.2)	0.431
Control−IQ	−2.080 (−7.960 to 3.800)	50.4 mg/dL (40.6 to 60.3)	0.431
DBLG1	−1.801 (−12.236 to 8.634)	50.7 mg/dL (36.3 to 65.1)	0.657
Loop	0.820 (−9.711 to 11.351)	53.3 mg/dL (38.8 to 67.8)	0.839
MiniMed 670/770G	3.199 (−5.687 to 12.085)	55.7 mg/dL (42.9 to 68.5)	0.423
SG (QE: 9170.6 [$p = 0.000$]; QM: 7.898 [$p = 0.000$]; between|within cluster variance: 0.000|27.865; estimates: 37)			
MiniMed 780G	149.551 (146.860 to 152.241)	149.6 mg/dL (146.9 to 152.2)	0.000
CamAPS FX	1.549 (−6.732 to 9.829)	151.1 mg/dL (140.1 to 162.1)	0.700
Control−IQ	4.885 (0.012 to 9.759)	154.4 mg/dL (146.9 to 162.0)	0.049
DBLG1	7.449 (−3.937 to 18.836)	157.0 mg/dL (142.9 to 171.1)	0.187
Loop	−2.551 (−14.103 to 9.002)	147.0 mg/dL (132.8 to 161.2)	0.649

TABLE 3 (Continued)

	Mean (95% CI) coefficient		
c	Model	Converted	*p*-value
MiniMed 670/770G	11.049 (−0.074 to 22.172)	160.6 mg/dL (146.8 to 174.4)	0.051
MiniMed 670G	8.932 (3.329 to 14.535)	158.5 mg/dL (150.2 to 166.8)	0.003
Omnipod 5	26.719 (18.446 to 34.993)	176.3 mg/dL (165.3 to 187.2)	0.000
TAR180 (QE: 19251.5 [$p = 0.000$]; QM: 5.436 [$p = 0.001$]; between|within cluster variance: 0.006|0.025; estimates: 41)			
MiniMed 780G	−1.179 (−1.262 to −1.095)	23.5% (22.1 to 25.1)	0.000
CamAPS FX	0.072 (−0.197 to 0.341)	24.9% (18.9 to 32.0)	0.585
Control−IQ	0.107 (−0.049 to 0.263)	25.5% (21.2 to 30.3)	0.172
DBLG1	−0.164 (−0.535 to 0.207)	20.7% (14.2 to 29.1)	0.368
Loop	0.026 (−0.351 to 0.403)	24.0% (16.6 to 33.4)	0.888
MiniMed 670/770G	0.340 (−0.015 to 0.694)	30.2% (21.8 to 40.1)	0.060
MiniMed 670G	0.231 (0.051 to 0.410)	27.9% (23.0 to 33.5)	0.014
Omnipod 5	0.760 (0.469 to 1.050)	39.7% (31.1 to 48.9)	0.000
TAR180–250 (QE: 4931.9 [$p = 0.000$]; QM: 2.629 [$p = 0.082$]; between|within cluster variance: 0.000|0.009; estimates: 29)			
MiniMed 780G	−1.492 (−1.538 to −1.446)	18.4% (17.7 to 19.1)	0.000
Control−IQ	0.023 (−0.080 to 0.125)	18.7% (16.5 to 21.1)	0.655
MiniMed 670/770G	0.238 (0.032 to 0.444)	22.2% (18.2 to 26.8)	0.025
MiniMed 670G	0.101 (−0.026 to 0.228)	19.9% (17.3 to 22.8)	0.111
TAR250 (QE: 9660.3 [$p = 0.000$]; QM: 7.485 [$p = 0.000$]; between|within cluster variance: 0.000|0.064; estimates: 38)			
MiniMed 780G	−2.878 (−2.997 to −2.760)	5.3% (4.8 to 6.0)	0.000
CamAPS FX	0.161 (−0.229 to 0.551)	6.2% (3.8 to 9.9)	0.401
Control−IQ	0.253 (0.034 to 0.472)	6.8% (4.9 to 9.2)	0.025
DBLG1	0.159 (−0.379 to 0.698)	6.2% (3.3 to 11.3)	0.546
Loop	0.096 (−0.445 to 0.637)	5.8% (3.1 to 10.7)	0.717
MiniMed 670/770G	0.489 (−0.041 to 1.019)	8.4% (4.6 to 14.9)	0.069
MiniMed 670G	0.123 (−0.202 to 0.448)	6.0% (3.9 to 9.0)	0.441
Omnipod 5	1.315 (0.925 to 1.704)	17.3% (11.2 to 25.8)	0.000
TBR54 (QE: 7528.6 [$p = 0.000$]; QM: 0.869 [$p = 0.546$]; between|within cluster variance: 0.036|0.082; estimates: 37)			
MiniMed 780G	−5.381 (−5.549 to −5.213)	0.5% (0.4 to 0.5)	0.000
CamAPS FX	0.093 (−0.439 to 0.624)	0.5% (0.3 to 1.0)	0.721
Control−IQ	−0.082 (−0.385 to 0.221)	0.4% (0.3 to 0.7)	0.584
DBLG1	−0.598 (−1.332 to 0.136)	0.3% (0.1 to 0.6)	0.105
Loop	0.512 (−0.238 to 1.262)	0.8% (0.3 to 1.9)	0.170
MiniMed 670/770G	0.129 (−0.549 to 0.807)	0.5% (0.2 to 1.2)	0.700
MiniMed 670G	0.035 (−0.410 to 0.480)	0.5% (0.3 to 0.9)	0.870
Omnipod 5	0.122 (−0.478 to 0.723)	0.5% (0.2 to 1.1)	0.676
TBR54–70 (QE: 8583.6 [$p = 0.000$]; QM: 0.134 [$p = 0.939$]; between|within cluster variance: 0.021|0.036; estimates: 29)			
MiniMed 780G	−4.017 (−4.136 to −3.898)	1.8% (1.6 to 2.0)	0.000
Control−IQ	−0.032 (−0.269 to 0.205)	1.7% (1.2 to 2.4)	0.785
MiniMed 670/770G	−0.107 (−0.572 to 0.358)	1.6% (0.9 to 2.8)	0.639
MiniMed 670G	−0.060 (−0.373 to 0.253)	1.7% (1.1 to 2.5)	0.692
TBR70 (QE: 10986.6 [p = 0.000]; QM: 2.718 [$p = 0.032$]; between|within cluster variance: 0.028|0.038; estimates: 43)			
MiniMed 780G	−3.798 (−3.924 to −3.671)	2.2% (1.9 to 2.5)	0.000
CamAPS FX	0.169 (−0.227 to 0.565)	2.6% (1.6 to 4.3)	0.387
Control−IQ	−0.123 (−0.344 to 0.098)	1.9% (1.4 to 2.7)	0.265
DBLG1	−0.680 (−1.076 to −0.284)	1.1% (0.7 to 1.9)	0.002

(Continues)

TABLE 3 (Continued)

c	Mean (95% CI) coefficient		
	Model	Converted	*p*-value
Loop	0.400 (−0.149 to 0.948)	3.2% (1.7 to 6.2)	0.145
MiniMed 670/770G	−0.033 (−0.513 to 0.447)	2.1% (1.2 to 3.8)	0.889
MiniMed 670G	0.055 (−0.235 to 0.344)	2.3% (1.5 to 3.5)	0.701
Omnipod 5	−0.166 (−0.531 to 0.198)	1.9% (1.1 to 3.0)	0.356
Time in automation/closed loop (QE: 5438.0 [$p = 0.000$]; QM: 14.309 [$p = 0.000$]; between|within cluster variance: 0.027|0.050; estimates: 29)			
MiniMed 780G	2.395 (2.235 to 2.554)	91.6% (90.3 to 92.8)	0.000
CamAPS FX	0.271 (−0.346 to 0.888)	93.5% (86.9 to 96.9)	0.365
Control−IQ	0.295 (−0.001 to 0.590)	93.6% (90.3 to 95.9)	0.050
MiniMed 670/770G	−1.687 (−2.238 to −1.137)	67.0% (49.9 to 80.5)	0.000
MiniMed 670G	−0.762 (−1.141 to −0.383)	83.6% (74.9 to 89.8)	0.001
Omnipod 5	−0.352 (−0.749 to 0.045)	88.5% (81.6 to 93.1)	0.079
TITR (QE: 774.1 [$p = 0.000$]; QM: 10.737 [$p = 0.016$]; between|within cluster variance: 0.000|0.003; estimates: 11)			
MiniMed 780G	0.005 (−0.045 to 0.055)	50.1% (48.9 to 51.4)	0.815
Control−IQ	−0.220 (−0.332 to −0.108)	44.6% (40.7 to 48.7)	0.002
Loop	0.026 (−0.133 to 0.185)	50.8% (45.5 to 56.0)	0.696

Note: MiniMed 780G is specified as the reference category as it had the largest number of estimates available for most outcomes (its p-value refers to being different from zero). The Q_E test is for residual heterogeneity; the Q_M test is an omnibus test of moderators.
Abbreviations: AID, automated insulin delivery; CI, confidence interval; df, degrees of freedom; GMI, glucose management indicator; GRI, glycaemic risk index; HbA1c, haemoglobin A1c; SD, standard deviation; SG, sensor glucose; TAR180, time above range 180 mg/dL; TAR180-250, time above range 180–250 mg/dL; TAR250, time above range >250 mg/dL; TBR54, time below range < 54 mg/dL; TBR54-70, time below range 54–70 mg/dL; TBR70, time below range <70 mg/dL; TIR, time in range; var., variance.

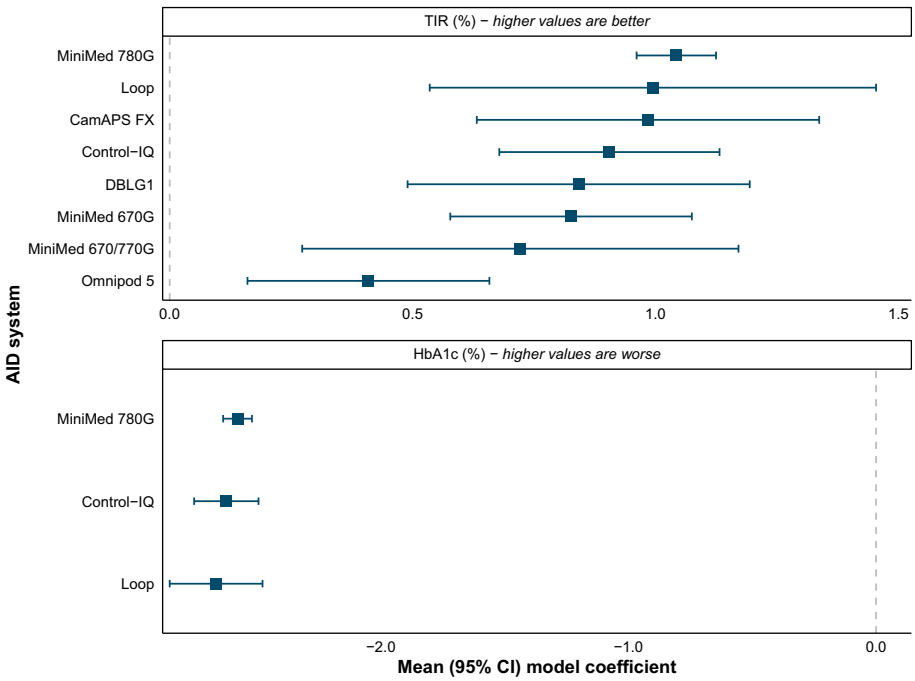

FIGURE 5 Forest plot for main meta-analyses for TIR and HbA1c. AID, automated insulin delivery; CI, confidence interval; DBLG 1, Diabeloop Generation 1; HbA1c, glycated haemoglobin; TIR, time in range. Model coefficients are from random-effects meta-analysis (see Table 3 for numeric and converted values). Depending on the metric, higher (for TIR) and lower (for HbA1c) coefficients suggest better outcomes. The dashed line at 0 is for orientation.

These findings demonstrate that different AID systems yield varying glycaemic outcomes in real-world settings. Given that high HbA1c and low TIR (or high TAR) are well-established risk factors for long-term diabetes-related complications,[12,97–101] achieving and maintaining optimal glycaemic control is of critical importance. These results demonstrate that glycaemic outcomes should play a central role in guiding the choice of AID system, alongside factors such as usability, device form factor, and individual preferences.

The various AID algorithms follow distinct design principles.[102] For some algorithms, specific settings, such as glucose targets or active insulin time, have been shown to enhance glycaemic control. Several real-world studies included in this analysis have reported stratified results based on so-called "optimal settings".[27,40,43,66,73–75,80,81,84,85,90] Scenario analyses confirmed that weighted means for TIR were higher by approximately 6–7% points in users employing such settings, primarily driven by a reduction in TAR. Specifically, TIR for MiniMed 780G with optimal settings was 79.6% (1.0), relative to 73.2% (1.5) in the overall cohort, and was 67.7% with optimal settings for Omnipod 5, relative to 63.2% (5.5) in the overall cohort. However, results for Omnipod 5® should be interpreted with caution, as they were derived from a single study. Optimizing settings may offer substantial benefits to certain users, especially considering the long-term diabetes-related complications.

These results were aligned with findings from RCTs on the generally good performance of AID systems regarding glycaemic outcomes in populations with T1D, with effectiveness varying between systems and age groups.[8,17,22,25,45] Results also confirmed earlier narrative findings for RWE, including differences in available evidence[21] and in real-world effectiveness between AID systems[18] as well as the importance of using optimal device settings.[103] In turn, the present results were confirmed by recent real-world studies not eligible for inclusion or published after the search cut-off date. These included several head-to-head comparisons between MiniMed 780G and Control-IQ, which were the systems with the best performance overall in the present analyses, with studies investigating the interaction of user characteristics with comparative system performance and for specific settings such as after high-carbohydrate meals.[104,105] Notably, in an observational study from Denmark covering 139 persons with T1D, higher TIR and TITR values with MiniMed 780G relative to Control-IQ were observed even after adjustment for users' baseline characteristics.[106] Findings such as these, and those of the present analysis in which adjustment for age reduced differences between systems, suggest that further research is required to corroborate relative system performance across user groups, although particular challenges with younger relative to older users have been firmly established.[107]

Given the established benefits in terms of glycaemic control, AID has become part of standard T1D care in many settings.[2] Published guidance recommends AID for insulin delivery in paediatric and adult populations with T1D,[34,42,108] particularly in people not achieving individual treatment targets on intensified insulin therapy using CGM or suffering from frequent or severe hypoglycaemia.[35,109] Notably, for children and adolescents, a lower HbA1c target (≤6.5%) is recommended if AID is available, compared with ≤7.0% when advanced diabetes technologies are unavailable.[42]

Despite these recommendations and the wealth of evidence supporting AID, the technology is currently used only by a minority of people with T1D. In 2023, 1 million people globally were estimated to be using AID, compared with an estimated 8.1 million people globally with T1D (in 2023).[110,111] Commonly cited barriers to the uptake of AID are high costs and limited reimbursement,[110,112–114] which disproportionately affect people with T1D who are socially disadvantaged, as recently shown for the uptake of insulin pumps and CGM in Canada.[115] Recent recommendations to remove access barriers therefore include offering an AID system to each person with T1D as soon as possible after a diagnosis, with the specific device selected based on individual needs, preferences, and circumstances.[116] An additional barrier to uptake, noted by young people with T1D and their caregivers, is device usability and technical problems.[117] While technical problems may be partially addressed through ongoing technological developments, for example, novel sensors,[107,117] a learning curve for device use exists for both users and, at least in the case of open-source systems, for healthcare providers.[118,119] Acknowledging this learning curve and increasing users' and healthcare professionals' familiarity with AID systems would likely contribute to improving access to and use of AID in T1D.[110,116,120,121]

The present review is associated with both strengths and limitations. Strengths included the fact that the review was limited to relatively large-scale studies to maximize the robustness and generalizability of the findings. Other strengths were the large number of outcomes assessed, as well as extensive sensitivity and scenario analyses. Limitations included a frequent lack of baseline data, which precluded comprehensive assessments of the comparability of study populations at baseline and of factors such as glycaemic control at the initiation of AID system use (a key contributor to the glycaemic outcomes achieved during treatment with AID), nor could the duration of system use be adjusted for. The analysis adjusting for baseline TIR was similarly limited by a relatively small number of studies providing data for most outcomes, with most studies with large sample sizes, based on multinational databases, removed from the analysis as they provided no baseline TIR. As could be noted from scenario analyses using relatively coarse age grouping, differences in user characteristics likely accounted for a substantial share of between-study heterogeneity, so the inability to adjust for user characteristics plausibly left some residual confounding unaddressed, although the robustness of results across the feasible sensitivity and scenario analyses suggests that comparative system performance might have been relatively unaffected. Another limitation is that not all AID systems are compatible with every CGM sensor. CGM sensors vary in their glucose sensing designs, and regulatory documentation as well as scientific studies have highlighted that different CGMs may exhibit varying biases across different glucose ranges. Additionally, sensor accuracy was not accounted for explicitly in the present analysis due to a lack of reported data. It is known that glucose readings can vary considerably within and across CGM systems and across glycaemic ranges, to the extent that therapeutic decision-making may be affected in some

cases.[122–124] It remains unclear if, or to what extent, these differences impacted the results of the present analysis. Notably, future analyses might benefit from more standardized CGM measurement and consequently reduced intersystem differences in accuracy, with standardized study procedures and comparator measurements advocated for assessing CGM performance.[123] Further limitations included the availability of only a few head-to-head studies and the limited evidence base for some AID systems, which, within the framework of a complete case analysis, restricted some analyses to just a handful of available estimates, suggesting that several AID systems cannot currently be judged meaningfully regarding their real-world performance for important glycaemic metrics. The exclusive focus on RWE data may be considered a further limitation, for example, combining AID systems users from different country and healthcare system settings, which could potentially be considered to introduce some bias as AID systems have differential availability across jurisdictions. Relative to RCTs, which are considered the gold standard study design, RWE studies tend to be less methodologically robust, more heterogeneous in terms of reported outcomes and their definitions, and at a higher RoB. These shortcomings are acknowledged, and findings from the present review should therefore be treated with caution. However, RWE complements RCT data by providing valuable insights into outcomes that can be achieved within routine practice. Populations within RWE studies are generally more heterogeneous compared with RCTs[125] and may include people who are challenging to manage, for example, those with multiple comorbidities, who may not be eligible for RCTs. As a further limitation, the analysis was limited to commercially available AID systems and did not capture data on "do-it-yourself" systems. Data on discontinuation or switching between different systems were also not included, which may have excluded difficult-to-treat or underserved user groups; one recent study showed that common reasons for switching include pregnancy, not achieving glycaemic targets, and technical issues.[126]

5 | CONCLUSIONS

This systematic review and meta-analysis of large-scale RWE studies demonstrated that commercially available AID systems are generally associated with good glycaemic outcomes in routine clinical practice for populations with T1D. Despite variable data availability and user characteristics, findings were generally consistent with previous results, highlighting differences in system performance and underscoring the importance of individualized AID selection and optimal device settings.

AUTHOR CONTRIBUTIONS

Johannes Pöhlmann: Methodology (equal); software (lead); formal analysis (lead); investigation (lead); data curation (lead); writing—original draft (lead); visualization (lead). **Jayne Smith-Palmer**: Conceptualization (equal); investigation (equal); data curation (equal); writing—reviewing and editing (equal); project administration (equal). **Erik H. Serné**: Writing—reviewing and editing (equal). **Anna-Kaisa Tuomaala**: Writing—reviewing and editing (equal). **Johan Jendle**: Writing—reviewing and editing (equal). **Pratik Choudhary**: Writing—reviewing and editing (equal). **Emanuele Bosi**: Writing—reviewing and editing (equal). **Viswanathan Mohan**: Writing—reviewing and editing (equal). **Tim van den Heuvel**: Conceptualization (equal); writing—reviewing and editing (equal); supervision (lead); project administration (lead). **Ohad Cohen**: Conceptualization (equal); writing—reviewing and editing (equal); supervision (lead); project administration (lead). **Richard F. Pollock**: Conceptualization (equal); methodology (equal); investigation (equal); data curation (equal); validation (equal); writing—reviewing and editing (equal); project administration (equal); supervision (lead).

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CONFLICT OF INTEREST STATEMENT

J.P. and J.S-P. are current employees of, and R.F.P. is a director at Covalence Research Ltd., which has received consulting fees from Medtronic related to the analyses presented in this article and its preparation. A.K.T. reports lecture honoraria from Medtronic, Nordic Infucare, Novo Nordisk, Ypsomed, and Sanofi; advisory board membership for Sanofi and Medtronic; and ERP grants from Medtronic and Dexcom. J.J. reports remuneration for participation in advisory boards or invited lectures from Abbott, Medtronic, Eli Lilly, Novo Nordisk, Ypsomed, and Tandem; and research support to his institution from Novo Nordisk and Medtronic. E.B. reports remuneration for participation in advisory boards or acting as a speaker from Abbott, Medtronic, Roche, and Sanofi. P.C. reports consulting fees from Abbott, Dexcom, Eli Lilly, Insulet, Medtronic, and Sanofi; honoraria and payments for lectures, presentations, speaker bureaus, manuscript writing, and educational events from Eli Lilly, Glooko, Insulet, Medtronic, Novo Nordisk, and Sanofi. T.v.d.H. and O.C. are employees at Medtronic. E.H.S. and V.M. have nothing to disclose.

PEER REVIEW

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