



## Real-world outcomes of Omnipod DASH system use in people with type 1 diabetes: Evidence from the Association of British Clinical Diabetologists (ABCD) study

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### ABSTRACT

**Aims:** To evaluate real-world outcomes in people with Type 1 Diabetes (PwT1D) initiated on Omnipod DASH® Insulin Management System.

**Methods:** Anonymized clinical data were submitted to a secure web-based tool within the National Health Service network. Hemoglobin A1c (HbA1c), sensor-derived glucometrics, total daily dose of insulin (TDD), and patient-reported outcome changes between baseline and follow-up were assessed. Individuals were classified to “new-to-pump” (switched from multiple daily injections) and “established-on-pump” (switched from a tethered insulin pump) groups.

**Results:** 276 individuals from 11 centers [66.7 % female; 92 % White British; median age 41 years (IQR 20–50); diabetes duration 20 years (IQR 11–31); 49.3 % within “new-to-pump” group] were included. Baseline HbA1c was  $8.0 \pm 1.3$  % ( $64 \pm 14$  mmol/mol). At follow-up [3 years (IQR 1.5–3.2)], HbA1c reduced by 0.3 % [(3 mmol/mol);  $p = 0.002$ ] across the total population, 0.4 % [(5 mmol/mol);  $p = 0.001$ ] in those “new-to-pump” and remained unchanged in those “established-on-pump”. TDD decreased in the “new-to-pump” cohort (baseline:  $44.9 \pm 21.0$  units vs follow-up:  $38.1 \pm 15.4$  units,  $p = 0.002$ ). Of those asked, 141/143 (98.6 %) stated Omnipod DASH had a positive impact on quality of life.

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**Conclusions:** Omnipod DASH was associated with improvements in HbA1c in PwT1D “new-to-pump” and maintained previous HbA1c levels in those “established-on-pump”. User satisfaction in all groups and TDD reduction in those “new-to-pump” were reported.

## 1. Introduction

Type 1 diabetes (T1D) is associated with an increased risk of cardiovascular disease including myocardial infarction and heart failure as well as premature death [1,2]. Improving glycemic levels have been shown to significantly reduce long-term vascular complications and mortality in people with T1D (PwT1D) [3,4]. As a result, the National Institute for Health and Care Excellence (NICE) guideline on the management of adults with T1D recommends a target hemoglobin A1c (HbA1c) level of 6.5 % (48 mmol/mol) or lower to minimize the risk of complications [5]. However, according to recently published data from the National Diabetes Audit (NDA) in England and Wales, only 10.6 % of PwT1D achieved the NICE HbA1c target of 6.5 % (48 mmol/mol) or lower, while 20.7 % and 33.7 % achieved the HbA1c treatment target of 7 % (53 mmol/mol) or lower and 7.5 % (58 mmol/mol) or lower, respectively. Over a third of PwT1D had an HbA1c  $\geq$  8.5 % (69 mmol/mol) [6]. Similarly, outcomes from the T1D Exchange registry showed that only a minority of PwT1D in the United States (U.S.) achieved the American Diabetes Association (ADA) goals for HbA1c [7]. These data indicate that introducing therapies to improve glycemia and mitigate the excess risk of complications is imperative.

The use of continuous subcutaneous insulin infusion (CSII) has been shown to improve HbA1c without an increase in hypoglycemia rates, reduce diabetes distress and improve quality of life in PwT1D [8–12]. Despite the clinical evidence suggesting the benefits of this therapy, the overall adoption of CSII in the United Kingdom (U.K.) has been low. Specifically, the recent NDA reported that CSII is used by 11.5 % of adults with T1D in England and 16.7 % in Wales [6]. Some potential barriers to the uptake of CSII include the constant presence of a catheter/tubing, interface requiring direct control of a tethered device and size of such devices. This has potential for interference with activities and stigma which can make PwT1D reluctant to transition or continue CSII [13].

Using tubeless insulin pumps may enable PwT1D to overcome some of the barriers to the uptake of CSII. Also, controlling insulin delivery without the need to interact with the pump could support more discreet pump use [14]. In this regard, it was important that the accuracy of tubeless pumps is assessed. Early studies questioned the accuracy of the Omnipod (patch) pump compared to tethered insulin pumps, however, there was criticism of the methodologies utilized to make these assessments [15–17]. Luijck et al assessed clinical outcomes in 20 individuals with Type 1 diabetes treated with patch pump compared to traditional catheter pumps in a short-term study and identified no between-pump differences in peak glucose concentrations or mean plasma insulin levels [18]. This was further supported by a retrospective study from the U.K., which showed no significant differences in HbA1c improvement when comparing different pump types under routine clinical care, including a comparison of patch pumps and traditional catheter pumps [19].

The Omnipod DASH® Insulin Management System is the most widely used tubeless insulin pump for the management of T1D. To date, there are a limited number of studies exploring the efficacy of Omnipod DASH, while the number of people using tubeless insulin pumps is increasing [20]. This highlights the need to better understand the long-term outcomes of this tubeless pump therapy in clinical practice. Therefore, the aim of this study was to evaluate real-world clinical outcomes, including efficacy, safety, utility, and acceptability of Omnipod DASH in individuals with T1D.

## 2. Materials and methods

### 2.1. Patient recruitment and data collection

Data for this real-world observational study were obtained from the Association of British Clinical Diabetologists (ABCD) Omnipod audit tool ([http://www.diabetologists-abcd.org.uk/Omnipod/Omnipod\\_Audit.htm](http://www.diabetologists-abcd.org.uk/Omnipod/Omnipod_Audit.htm)). The audit was launched in 2021 with the aim of capturing real-world clinical outcomes from people attending adult or pediatric diabetes services with a diagnosis of T1D and managed with Omnipod DASH. Anonymized clinical outcome data were collected at baseline and follow-up during routine clinical care, and clinical systems and electronic health records were reviewed and submitted via a secure online tool. Data collection was performed between November 2021 and June 2023. Based on previous insulin therapy before starting pod therapy, the total population was divided into 2 groups; “new to pump” group for individuals previously treated with multiple daily injections (MDI) insulin regimen, and “established on pump” group for those previously established on a tethered insulin pump which was changed onto pod therapy. Pod therapy was initiated between May 2011 and March 2023. Individuals initially started on Omnipod Eros were transitioned to Omnipod DASH and all patients were using Omnipod DASH at follow-up.

### 2.2. Outcome measures

The primary outcome was change in laboratory-derived HbA1c between baseline and follow-up. Secondary outcomes included continuous glucose monitoring (CGM) metrics time in range (TIR) (3.9–10 mmol/L or 70–180 mg/dL), time below range (TBR) (<3.9 mmol/L or < 70 mg/dL), time above range (TAR) (>10 mmol/L or > 180 mg/dL), glucose management indicator (GMI) (estimated HbA1c), percentage coefficient of variation, two-item diabetes distress screening instrument (DDS2) (question 1 “feeling overwhelmed by the demands of living with diabetes”, question 2 “feeling that I am often failing with my diabetes regimen”) [21], Gold score to assess hypoglycemia awareness [22], event rates (hospital admissions, paramedic callouts, severe hypoglycemia requiring third party assistance), and user opinion of Omnipod DASH (question 1 “what impact would you rate Omnipod DASH has had on your quality of life” and question 2 “would you recommend Omnipod DASH to other people with diabetes”; a 7-point Likert scale was used: 1 = strongly negative impact, 7 = strongly positive impact [for question 1]; 1 = would not recommend at all, 7 = would highly recommend [for question 2]). Demographic data included weight, body mass index (BMI), gender, and index of multiple deprivation decile (a measure of relative deprivation at a small local area level in the U.K; 1 = most deprived, 10 = least deprived). Data on funding resources and criteria under which pod therapy was funded were captured. Data on previous attendance at structured education sessions related to diabetes and method of glucose monitoring at baseline were reported. Sensor glucometrics were reported over 14 days as per the international consensus guidelines and in keeping with routine clinical practice [23]. Events of interest were reported by the clinical teams via the online tool. Follow-up frequency was determined by the responsible clinical team based on clinical need. Data were captured between baseline and follow-up (defined as the date of the latest available records submitted to the online tool).

### 2.3. Ethical approval

The ABCD national audit program, which includes the ABCD Omnipod audit, has Caldicott Guardian Approval. The program collects anonymized and routinely available clinical data, and additional investigations besides standard care are not required. Hence, this study did not require specific approval by a research ethics committee.

### 2.4. Statistical methods

Continuous variables were presented as mean  $\pm$  standard deviation (SD) or median and interquartile range (IQR) and assessed using paired *t*-test, two-sample (independent samples) *t*-test or Wilcoxon signed rank test depending on normality of distribution (determined by Shapiro-Wilk test and Kolmogorov-Smirnov test). Categorical variables were expressed as numbers and percentages. To address loss to follow-up, the analysis of each outcome of interest included only individuals who had available data at both baseline and follow-up. A two-sided *p*-value  $<$  0.05 was considered statistically significant. Statistical analysis was performed on SPSS v26.0 (IBM, Chicago, IL).

## 3. Results

Baseline data were available for 358 individuals (including 20 children aged between 6 and 17 years) across 11 centers in the U.K., with follow-up data reported for 290 (82.4%), of whom 95.2% (276 of 290) continued to use Omnipod DASH at follow-up (total population). The number of patients recruited in the study and sample size of those with follow-up are shown in Fig. 1. The median follow-up was 3 years (IQR 1.5–3.2). Stratified by previous insulin therapy, the total population was divided into 2 groups; “new to pump” group (136/276, 49.3%) and “established on pump” group (140/276, 50.7%). 271 out of 276 (98.2%) had their pump funded via NHS under the following criteria: HbA1c above target (106/271, 39.1%); problematic hypoglycaemia (97/271, 35.8%); paediatric use (16/271, 5.9%); pregnancy or planning pregnancy (5/271, 1.8%); and other causes including Dawn phenomenon, diabetes-related distress, and fear of needles (36/271, 13.3%). [Supplementary Material 1](#) contains the flow diagram for this analysis.

### 3.1. Baseline characteristics

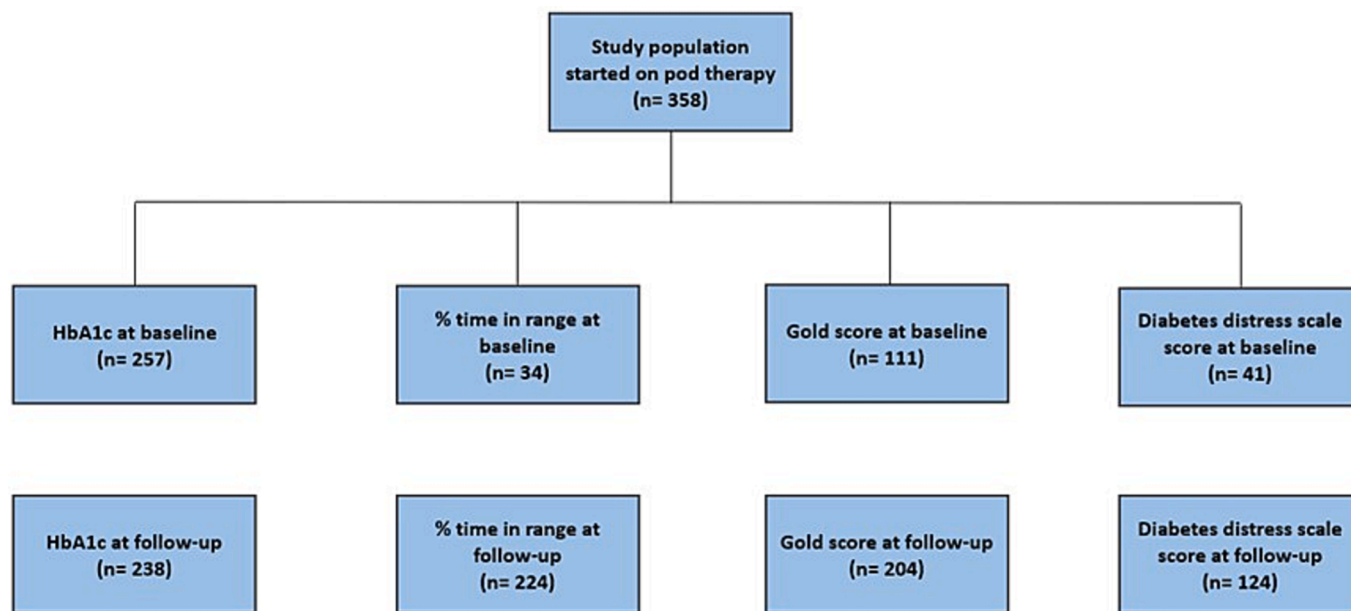
For the 276 individuals with baseline and follow-up data, the median age was 41 years (IQR 20–50); 66.7% ( $n = 184$ ) were female; mean ( $\pm$ SD) weight was 74.2 ( $\pm$ 19.2) kg; median diabetes duration was 20 years (IQR 11–31); and 92% ( $n = 254$ ) were White British with a median index of multiple deprivation decile of 8 (IQR 5–9). The baseline characteristics of the study population are summarized in [Table 1](#).

### 3.2. HbA1c and sensor-based outcomes

HbA1c reduced from a mean  $\pm$  SD of 8.0  $\pm$  1.3% (64  $\pm$  14 mmol/mol) at baseline to 7.7  $\pm$  1.2% (61  $\pm$  13 mmol/mol) at follow-up, a mean reduction of 0.3% (3 mmol/mol) [95% CI -0.1, -0.4;  $p = 0.002$ ,  $n = 171$ ], over a median follow-up of 3 years (IQR 1.5–3.2). Stratified by previous insulin therapy, patients in the “new to pump” group experienced a significant reduction in HbA1c of 0.4% (5 mmol/mol) (95% CI -0.2, -0.6;  $p = 0.001$ ,  $n = 81$ ). There was no significant change in HbA1c for the “established on pump” users, who experienced a mean reduction in HbA1c of 0.1% (1 mmol/mol) (95% CI 0.1, -0.3;  $p = 0.2$ ,  $n = 90$ ). The changes in HbA1c across all groups are summarized in [Table 2](#) and [Fig. 2A](#).

The percentage of people within total population, with both baseline and follow-up HbA1c data available ( $n = 171$ ), who achieved the NICE treatment target of 6.5% (48 mmol/mol) or lower was 11.1% (19/171) at baseline and 14.6% (25/171) at follow-up ( $p = 0.36$ ). Once stratified by previous insulin therapy, an HbA1c  $\leq$  6.5% (48 mmol/mol) was achieved by 12.3% (10/81) at baseline and 14.8% (12/81) at follow-up within the “new to pump” group ( $p = 0.67$ ), and by 10.0% (9/90) at baseline and 14.4% (13/90) at follow-up within the “established on pump” group ( $p = 0.39$ ).

Stratified by baseline HbA1c, individuals of the total population with baseline HbA1c  $<$  7% (53 mmol/mol) ( $n = 32$ ) maintained similar level of glycemic control between baseline (6.3  $\pm$  0.7%) and follow-up (6.5  $\pm$  0.7%) ( $p = 0.2$ ). People with baseline HbA1c between 7% (53 mmol/mol) and 8% (64 mmol/mol) ( $n = 64$ ) experienced no change in HbA1c between baseline and follow-up (7.5  $\pm$  0.3% vs 7.6  $\pm$  0.8%,  $p = 0.6$ ). Patients with baseline HbA1c higher than 8% (64 mmol/mol) and lower



**Fig. 1.** Study schematic demonstrating data for HbA1c, % time in range, Gold score and Diabetes distress scale score in the ABCD real-world study of Omnipod DASH. Study outline shows the number of patients recruited in the study and sample size of those with follow-up data for HbA1c, % time in range, Gold score, and Diabetes distress scale score.

**Table 1**  
Baseline characteristics.

| Characteristics                                                          | Population started on pod therapy (n = 338) | Total population † (n = 276) | New to pump † (n = 136) | Established on pump † (n = 140) |
|--------------------------------------------------------------------------|---------------------------------------------|------------------------------|-------------------------|---------------------------------|
| Age, years, median (IQR)                                                 | 41 (30–50)                                  | 41 (20–50)                   | 40 (19–50)              | 43 (26–55)                      |
| Diabetes duration, years, median (IQR)                                   | 21 (12–31)                                  | 20 (11–31)                   | 20 (11–31)              | 21 (13–31)                      |
| Weight, Kg, mean ± SD                                                    | 77 ± 17                                     | 74 ± 19                      | 74 ± 19                 | 75 ± 21                         |
| BMI, Kg/m <sup>2</sup> , mean ± SD                                       | 27 ± 7                                      | 25 ± 8                       | 25 ± 7                  | 24 ± 8                          |
| Index of multiple deprivation decile*, median (IQR)                      | 8 (5–9)                                     | 8 (5–9)                      | 8 (5–9)                 | 7 (5–9)                         |
| Sex, number (percentage)                                                 |                                             |                              |                         |                                 |
| Female                                                                   | 224 (66.3)                                  | 184 (66.7)                   | 86 (63.2)               | 98 (70.0)                       |
| Male                                                                     | 114 (33.7)                                  | 92 (33.3)                    | 50 (36.8)               | 42 (30.0)                       |
| Ethnicity, number (percentage)                                           |                                             |                              |                         |                                 |
| White, British                                                           | 306 (90.5)                                  | 254 (92.0)                   | 126 (92.6)              | 128 (91.4)                      |
| Other                                                                    | 13 (3.9)                                    | 11 (4.0)                     | 7 (5.1)                 | 4 (2.9)                         |
| Asian                                                                    | 10 (3.0)                                    | 6 (2.2)                      | 1 (0.7)                 | 5 (3.6)                         |
| White, Other                                                             | 7 (2.1)                                     | 4 (1.4)                      | 1 (0.7)                 | 3 (2.1)                         |
| Black                                                                    | 2 (0.5)                                     | 1 (0.4)                      | 1 (0.7)                 | 0                               |
| Method of glucose monitoring, number (percentage)                        |                                             |                              |                         |                                 |
| isCGM                                                                    | 187 (55.3)                                  | 141 (51.1)                   | 67 (49.3)               | 74 (52.9)                       |
| SMBG                                                                     | 71 (21.0)                                   | 70 (25.4)                    | 31 (22.8)               | 39 (27.9)                       |
| rtCGM                                                                    | 24 (7.1)                                    | 11 (4.0)                     | 4 (3.0)                 | 7 (5.0)                         |
| No data                                                                  | 56 (16.6)                                   | 54 (19.5)                    | 34 (24.9)               | 20 (14.2)                       |
| Previous attendance at structured education session, number (percentage) |                                             |                              |                         |                                 |
| Yes                                                                      | 252 (74.6)                                  | 200 (72.5)                   | 101 (74.3)              | 99 (70.7)                       |
| No                                                                       | 23 (6.8)                                    | 23 (8.3)                     | 9 (6.6)                 | 14 (10.0)                       |
| Uncertain or no data                                                     | 63 (18.6)                                   | 53 (19.2)                    | 26 (19.1)               | 27 (19.3)                       |

isCGM: Intermittently scanned continuous glucose monitoring (also known as flash glucose monitoring); IQR: Interquartile range; rtCGM: Real-time continuous glucose monitoring; SD: Standard deviation; SMBG: Self-monitoring of blood glucose.

The population started on pod therapy included all adults with type 1 diabetes who were initiated on pod therapy at baseline.

† The total population, new to pump and established on pump groups included individuals with type 1 diabetes who were initiated on pod therapy at baseline, had available data and continued to use Omnipod DASH at follow-up.

\* Indices of multiple deprivation (IMD) are a measure of relative deprivation at a small local area level (LSOAs) in the United Kingdom based on seven domains of deprivation. The deciles are calculated by ranking all LSOAs (IMD for England, Scotland and Wales are calculated separately) from most deprived to least deprived and dividing them into 10 equal groups (1 = most deprived, 10 = least deprived).

than 9 % (75 mmol/mol) (n = 47) had a mean reduction of 0.6 % in HbA1c, from 8.5 ± 0.3 % at baseline to 7.9 ± 0.8 % at follow-up (p < 0.001). Individuals with baseline HbA1c ≥ 9 % (75 mmol/mol) (n = 28) experienced a mean reduction of 0.8 %, from 10.0 ± 1.2 % at baseline to 9.2 ± 1.6 % at follow-up (p = 0.002) (Fig. 2B).

Once the total population with paired baseline and follow-up HbA1c data available (n = 171) was stratified by baseline method of glucose monitoring, there was a reduction in HbA1c by 0.2 % (2 mmol/mol) (95 % CI -0.02, -0.3; p = 0.03, n = 115) in CGM group (intermittently scanned CGM [isCGM] or real-time CGM [rtCGM]), and by 0.4 % (5 mmol/mol) (95 % CI -0.2, -0.7; p = 0.03, n = 52) in the self-monitoring of blood glucose (SMBG) cohort at follow-up (Table 2). The difference in HbA1c reduction between CGM and SMBG groups was not statistically significant (p = 0.4). 94.3 % (n = 66) of individuals within total population using SMBG at baseline were using CGM (isCGM or rtCGM) at follow-up (missing data: 1.4 %), while all individuals within total population using CGM at baseline continued to use CGM at

**Table 2**  
Changes in HbA1c between baseline and follow-up after Omnipod DASH initiation, across all groups\* and stratified by baseline method of glucose monitoring.

| HbA1c, mean ± SD                                                     | n   | Baseline  | Follow-up | Change (95 % CI)   | p       |
|----------------------------------------------------------------------|-----|-----------|-----------|--------------------|---------|
| Total population                                                     |     |           |           |                    |         |
| DCCT %                                                               | 171 | 8.0 ± 1.3 | 7.7 ± 1.2 | -0.3 (-0.1, -0.4)  | 0.002   |
| mmol/mol                                                             | 171 | 64 ± 14   | 61 ± 13   | -3 (-2, -4)        | < 0.001 |
| New to pump                                                          |     |           |           |                    |         |
| DCCT %                                                               | 81  | 8.1 ± 1.5 | 7.7 ± 1.3 | -0.4 (-0.2, -0.6)  | 0.001   |
| mmol/mol                                                             | 81  | 66 ± 16   | 61 ± 14   | -5 (-3, -7)        | < 0.001 |
| Established on pump                                                  |     |           |           |                    |         |
| DCCT %                                                               | 90  | 7.8 ± 1.0 | 7.7 ± 1.1 | -0.1 (0.1, -0.3)   | 0.2     |
| mmol/mol                                                             | 90  | 62 ± 12   | 61 ± 12   | -1 (1, -3)         | 0.2     |
| Baseline method of glucose monitoring (total population) isCGM/rtCGM |     |           |           |                    |         |
| DCCT %                                                               | 115 | 7.8 ± 1.5 | 7.6 ± 1.3 | -0.2 (-0.02, -0.3) | 0.03    |
| mmol/mol                                                             | 115 | 62 ± 15   | 60 ± 15   | -2 (-0.1, -4)      | 0.04    |
| SMBG                                                                 |     |           |           |                    |         |
| DCCT %                                                               | 52  | 8.4 ± 1.0 | 8.0 ± 0.9 | -0.4 (-0.2, -0.7)  | 0.03    |
| mmol/mol                                                             | 52  | 69 ± 10   | 64 ± 10   | -5 (-2, -8)        | 0.03    |
| No data                                                              |     |           |           |                    |         |
| DCCT %                                                               | 4   | 8.5 ± 0.7 | 7.6 ± 0.9 | -0.9 (0.5, -2.2)   | 0.13    |
| mmol/mol                                                             | 4   | 69 ± 7    | 60 ± 10   | -9 (5, -23)        | 0.13    |

isCGM: Intermittently scanned continuous glucose monitoring (also known as flash glucose monitoring); rtCGM: Real-time continuous glucose monitoring; SMBG: Self-monitoring of blood glucose.

\*Only individuals with both baseline and follow-up HbA1c data available were included in the analysis.

Missing data: 38.0 % (105/276) in total population, 40.4 % (55/136) in new to pump group, and 35.7 % (50/140) in established on pump group.

HbA1c levels increased during follow-up in 28.4 % (n = 23) of individuals new to pump and 46.7 % (n = 42) of individuals established on pump.

follow-up (missing data: 3.3 %).

TIR increased by 8.4 % from baseline to follow-up (51.2 ± 20.1 % vs 59.6 ± 18.7 %; p = 0.03, n = 25), while no other significant changes in CGM-derived glucose metrics were observed in the total population with available paired sensor-based outcomes. In the “new to pump” group, TIR increased by 10.7 % (48.7 ± 21.2 % vs 59.4 ± 19.7 %; p = 0.04, n = 14), while there were no significant changes in TAR, TBR, GMI, and percentage coefficient of variation. Similarly, all CGM-derived glucose metrics remained unchanged in the “established on pump” group (p > 0.05). Fig. 3 depicts a stacked bar chart demonstrating TIR at baseline and follow-up for total population.

### 3.3. Weight and total daily dose of insulin

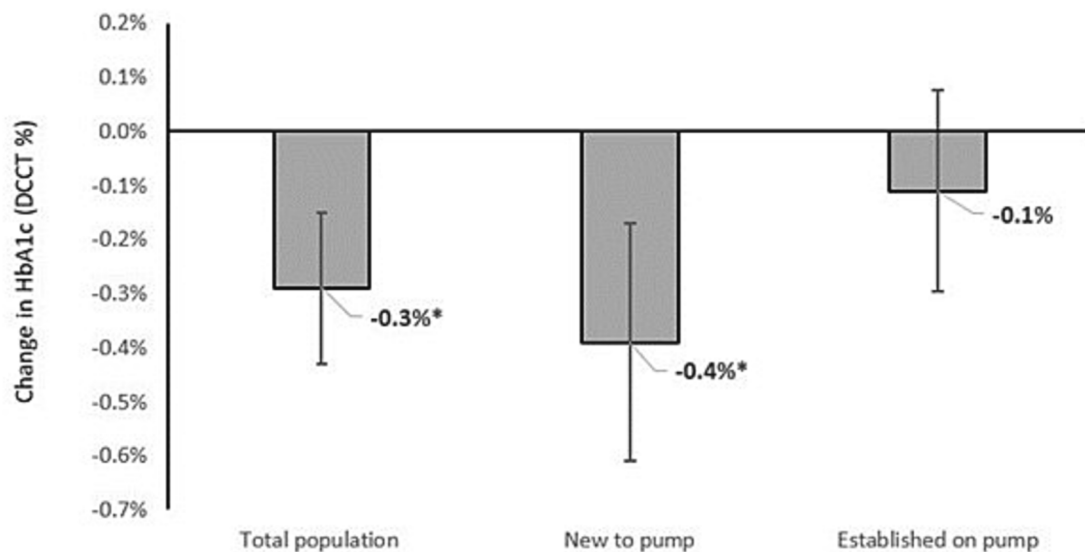
Weight of the total population remained unchanged between baseline and follow-up (73.9 ± 21.2 kg vs 73.5 ± 18.9 kg; p = 0.5). Similar results were observed in the “new to pump” group (73.5 ± 20.3 kg vs 73.1 ± 19.1 kg; p = 0.5) and the “established on pump” group (74.6 ± 22.5 kg vs 74.1 ± 18.8 kg; p = 0.7).

Total daily dose (TDD) of insulin reduced from a mean ± SD of 43 ± 19 units at baseline to 37 ± 15 units at follow-up in the total population, a mean reduction of 6 units (95 % CI -2, -9; p < 0.001). Stratified by previous insulin therapy, the TDD of insulin significantly decreased by 6.8 units (44.9 ± 21.0 units at baseline vs 38.1 ± 15.4 units at follow-up; p = 0.002) in those previously treated with MDI and non-significantly by 4.5 units (39.3 ± 14.6 units at baseline vs 34.8 ± 15.1 units at follow-up; p = 0.07) in the “established on pump” cohort.

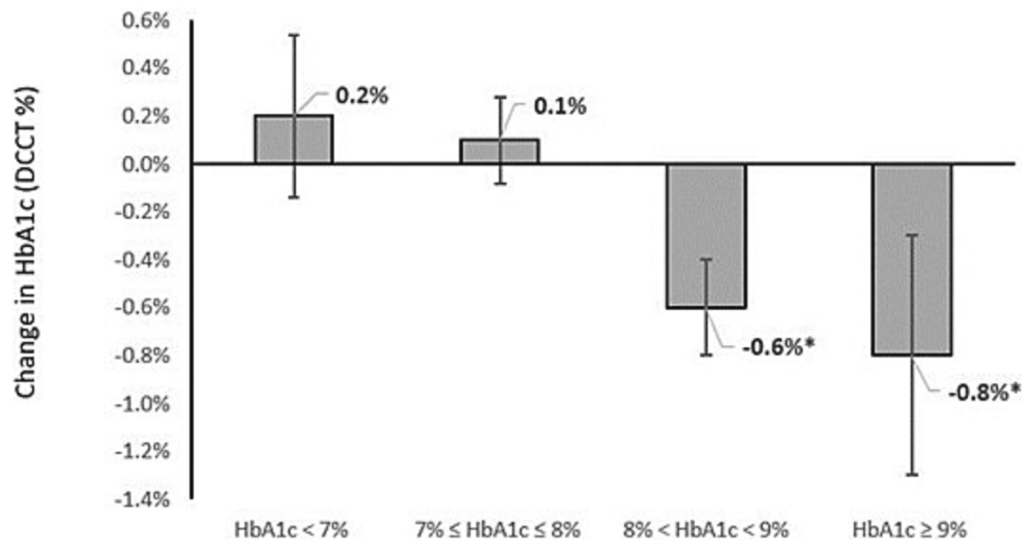
### 3.4. Gold score, diabetes distress and user satisfaction

There was a non-significant reduction in Gold score (-0.3; 95 % CI

A



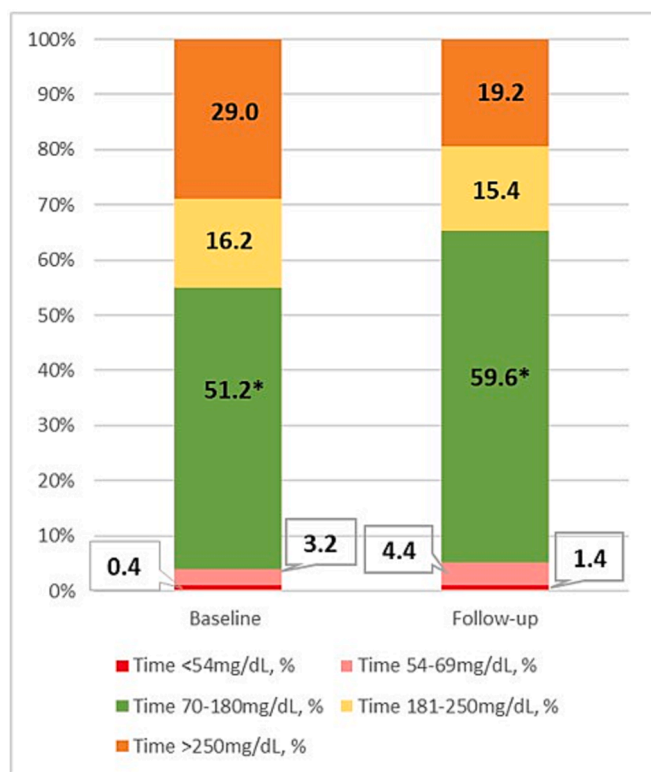
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**Fig. 2.** Change in HbA1c (DCCT %) at 3 years post Omnipod DASH initiation, stratified by previous insulin therapy (2A) and baseline HbA1c (2B). \* $p < 0.05$ . (2A): The change in HbA1c was significant for the total population ( $n = 171$ ;  $p = 0.002$ ) and the “new to pump” group ( $n = 81$ ;  $p = 0.001$ ) and non-significant for the “established on pump” group ( $n = 90$ ;  $p = 0.2$ ). The error bars indicate 95 % CIs. (2B): The change in HbA1c was significant for the cohort “8% < baseline HbA1c < 9 %” ( $n = 47$ ;  $p < 0.001$ ) and the cohort “baseline HbA1c  $\geq$  9 %” ( $n = 28$ ;  $p = 0.002$ ) and non-significant for the cohort “baseline HbA1c < 7 %” ( $n = 32$ ;  $p = 0.2$ ) and the cohort “7%  $\leq$  baseline HbA1c  $\leq$  8 %” ( $n = 64$ ;  $p = 0.6$ ). The error bars indicate 95 % CIs.

0.1,  $-0.6$ ;  $p = 0.1$ ,  $n = 76$ ) and diabetes distress score (DDS) ( $-1.1$ ; 95 % CI 0.1,  $-2.3$ ;  $p = 0.08$ ,  $n = 23$ ) in the total population. Looking at each question of DDS separately, the score of the second question significantly reduced from a mean  $\pm$  SD of  $2.8 \pm 1.4$  at baseline to  $2.1 \pm 1.5$  at follow-up, a mean reduction of 0.7 points (95 % CI  $-0.1$ ,  $-1.4$ ;  $p < 0.02$ ). Similarly, no changes in Gold score or DDS were observed in the “new to pump” cohort. In those established on an insulin pump, the Gold score decreased by 0.5 points (95 % CI  $-0.08$ ,  $-0.8$ ;  $p = 0.02$ ), while DDS did not change.

Of those asked to rate on a 7-point Likert scale, 141 out of 143 (98.6 %) stated that Omnipod DASH had a positive impact on their quality of life (QoL) and would recommend the system to other people with diabetes (average score of 6 in Likert scale for both questions). Similar results were observed in both the “new to pump” and “established on pump” groups (98.9 % and 98.1 %, respectively; average score of 6 in Likert scale in both groups).



**Fig. 3.** Stacked bar chart demonstrating time in range at baseline and follow up for population with complete sensor data only ( $n = 25$ ; 9% of total cohort). \* $p < 0.05$ .

### 3.5. Acute and adverse events

The number of hospital admissions related to hypoglycemia and hyperglycemia/diabetic ketoacidosis (DKA) and paramedic callouts (not resulting in admission) was low. Compared to hospital admissions before initiation of Omnipod DASH ( $n = 18$ ; hyperglycemia/DKA: 14 events, hypoglycemia: 4 events; missing data: 33.7%), a total of 9 admissions (hyperglycemia/DKA: 6 events; hypoglycemia: 3 events; missing data: 14.9%) were reported at follow-up ( $p > 0.05$ ).

A total of 14 users (3.9%) discontinued Omnipod DASH (missing data: 19%) (Supplement 1). Reasons for discontinuation were change to a different insulin pump to transition to hybrid closed-loop (50%;  $n = 7$ ), infusion site failure (21.4%;  $n = 3$ ), skin site reactions (14.3%;  $n = 2$ ) and patient choice with no reasons provided (7.1%;  $n = 1$ ).

## 4. Discussion

This multicenter observational study showed that transitioning to Omnipod DASH system in a real-world clinical setting is associated with significant improvement in HbA1c in PwT1D, driven by a clinically meaningful decrease in HbA1c in individuals new to insulin pump therapy. PwT1D switching to Omnipod DASH from other insulin pumps maintained comparable glycemia between baseline and follow-up. The benefits of this tubeless insulin pump on glycemia were achieved without an increase in body weight and accompanied with a reduction in daily insulin requirements and a positive impact on QoL. Hospital admissions related to hypoglycemia, hyperglycemia or DKA were small in number and only a small proportion of PwT1D discontinued Omnipod DASH mainly due to transition to hybrid closed-loop systems.

Pod therapy has been associated with improved glycemic control across all age groups over 3–12 months and in youth (<20 years old) over a longer period of time [20,24–27]. Nevertheless, long-term outcomes of the use of Omnipod DASH in real-world adult populations are

limited. Our study, with a median follow-up of 3 years, enhances our understanding and knowledge regarding the long-term efficacy, safety and feasibility of this tubeless insulin pump in PwT1D.

The reduction in HbA1c of 0.3% (3 mmol/mol) in the total population in this analysis is consistent with the results of a retrospective study from Mehta et al that showed a 0.3% drop in HbA1c in 156 adults with T1D who used Omnipod for 1 year [20]. Retrospective observational studies with a shorter follow-up period have also reported similar findings. Specifically, Layne et al showed a mean decrease in HbA1c of 0.6% at 3 months after Omnipod treatment initiation [24]. Outcomes from the COPPER study, which used data from the Canadian LMC Diabetes Registry, showed a statistically significant mean reduction in HbA1c of 0.2% in the tubeless pump cohort between baseline and follow-up (3–6 months) [28]. In contrast to our study, a retrospective analysis of a German/Austrian registry showed an initial improvement in HbA1c in the first year of tubeless insulin pump, which was followed by a moderate increase in years 2 and 3. The majority of this study population were 15 years old or younger and the authors suggested that the increased HbA1c beyond the first year could be explained by factors associated with puberty [29].

Once stratified by previous insulin therapy, our data showed that users switching from MDI to Omnipod DASH experienced a significant reduction in HbA1c of 0.4% (5 mmol/mol), which is in line with reports from other studies using pod therapy [19,20,24]. Also, our results were similar to the outcomes reported in studies using other insulin pumps. An observational retrospective analysis from the U.K. showed that the use of tubed insulin pumps was associated with a decrease in HbA1c of 0.7%, which was sustained for 5 years [30]. Similar long-term improvement in glycemia after CSII therapy was described in another cohort from the UK, who experienced a reduction in HbA1c of 0.6% that was sustained at 6 years of follow-up [31]. A systematic review and meta-analysis showed that compared to MDI, HbA1c was reduced by 0.4% in adults who used CSII [9]. Hence, our results suggest that Omnipod DASH provides benefits which are similar to other insulin pumps.

For those transitioning to Omnipod DASH from tethered CSII, HbA1c remained unchanged between baseline and follow-up. Similar results were reported in the study of Mehta et al which demonstrated no significant change in HbA1c for prior CSII users, who experienced a mean non-significant reduction in HbA1c of 0.1% (comparable with our study) [20]. A previous observational retrospective study, comparing the glycemic outcomes of individuals with T1D transitioning to different types of insulin pump, demonstrated no significant difference in the change in HbA1c when comparing different types of insulin pump, including Omnipod. This suggests that patients already treated with a tubed CSII prior to initiating a tubeless insulin pump are not expected to have a significant change in glycemia, as they already experience the beneficial effects of insulin pump therapy at baseline [19]. Hence, these data indicate that the choice of an insulin pump should be influenced by and tailored to people's requirements and needs rather than the desired degree of HbA1c reduction. In contrast, a different study showed a significant decrease in HbA1c of 0.5% in patients previously treated with CSII who were transitioned to tubeless pump. However, it should be acknowledged that the follow-up period of this study was 3 months and outcomes over a longer period were not described [24].

Individuals new to pump therapy experienced reductions in HbA1c which were similar to the changes observed in studies before isCGM was present. A meta-analysis of CSII compared with MDI in PwT1D measuring capillary blood glucose showed that the mean difference in HbA1c between MDI and CSII was 0.6% [8]. In our study, there was a similar reduction in HbA1c in the new to pump group who mainly used isCGM as a method of baseline glucose monitoring [isCGM: 63% ( $n = 51$ ); rtCGM: 4.9% ( $n = 4$ ); SMBG: 28.4% ( $n = 23$ ); no data: 3.7% ( $n = 3$ )]. So, we confirm additional benefits of CSII over MDI even in those on isCGM.

Our study indicated that individuals with higher HbA1c levels at baseline achieved the greatest reduction in HbA1c after initiating

Omnipod DASH. Similar results were observed in two retrospective studies which showed that regardless of previous insulin therapy people with suboptimal HbA1c control could experience the greatest benefit in HbA1c reduction after starting a tubeless insulin pump [24,27]. This suggests that HbA1c levels significantly above target may be an important consideration for PwT1D to initiate CSII, such as Omnipod DASH. The NICE technology appraisal guidance on hybrid closed loop (HCL) systems in T1D [32] has been recently updated and now PwT1D with elevated HbA1c or disabling hypoglycaemia, and PwT1D who are pregnant or planning a pregnancy, will have access to Omnipod 5 HCL system whose real-world clinical outcomes are awaited with high interest in the future.

The results of the present study also demonstrated a statistically significant increase in TIR from  $51.2 \pm 20.1$  % at baseline to  $59.6 \pm 18.7$  % at follow-up, with no corresponding increase in TBR in total population. However, it should be recognised that the number of available paired sets of sensor-based data was small due to missing data at baseline. To the best of our knowledge, there are no other studies reporting changes in CGM-derived glucose metrics between baseline and follow-up in individuals using Omnipod DASH.

TDD of insulin was significantly reduced at follow-up in the total population and those previously treated with MDI. Similar results have been described in another study suggesting that tubeless insulin pump therapy can lower daily insulin requirements [24]. Weight was stable for individuals transitioning from both MDI and CSII and these results are consistent with recent observational studies from the U.S. and Canada [20,28].

Another interesting finding of our study was the patient-reported outcomes including patient satisfaction. Although the reduction of Gold score and DDS in the total population did not reach statistical significance, PwT1D in our cohort stated that Omnipod DASH had a positive impact on QoL and would recommend this therapy to other people with diabetes. These findings are in line with the results of a survey of Omnipod users, which suggested that individuals using this insulin therapy experienced important QoL benefits, with more obvious positive outcomes in those who trusted the device and had improved glycemic outcomes [10]. However, the findings observed in our study should be interpreted with caution given that the patient satisfaction-related questions were answered by 143 of 276 individuals (48 % of missing data).

Additionally, Omnipod DASH did not increase the number of admissions related to hypoglycemia, hyperglycemia or DKA. Our analysis supports the findings of a previous real-world study, which demonstrated that the frequency of DKA and severe hypoglycemia decreased after 3 years of tubeless insulin pump use compared with prior treatment [29]. Similar results were observed in a cohort of youth with T1D using CSII suggesting that insulin pump use was associated with a lower prevalence of DKA-related admissions, compared to MDI therapy [33].

The main strength of this study includes the multisite, real-world setting which enabled the collection of data from PwT1D using Omnipod DASH in routine clinical practice across multiple diabetes centers in the U.K. The real-world nature of our analysis provides observations which are more representative of the U.K. practice and generalizable to a broad unselected population of individuals with T1D, without restrictive inclusion and exclusion criteria commonly used in randomized controlled trials (e.g. exclusion of high-risk groups). Another key strength is the long-term follow-up period of 3 years, which allowed for evaluation of the durability of clinical outcomes observed beyond the initial treatment period. To the best of our knowledge, only a small number of studies evaluating the effects of tubeless insulin pump have a long-term follow-up similar to our analysis.

The study should be interpreted within the context of its limitations. The inherent limitation of its retrospective design along with lack of control group can introduce the risk for selection bias. Other limitations include the possibility of unmeasured confounders contributing to the changes observed (e.g. transition from SMBG to CGM which occurred in

the recent few years in the UK, especially after the publication of the updated 2022 NICE guideline [5], and could have accounted for glycaemic improvements as described in the literature [34], transition from Omnipod Eros to Omnipod DASH), lack of information of other events (e.g. attendance at CGM initiation sessions) and underreporting of adverse events. Also, we acknowledge that there are missing data (e.g. 38 % of total population, 40.4 % of new to pump group and 35.7 % of the established on pump group did not have HbA1c data available at both baseline and follow-up), loss of follow up in 19 % (n = 68) of people with baseline data available including lack of information about Omnipod DASH continuation or discontinuation during follow-up, and lack of information about follow-up frequency of the patients. The study population was predominantly of White British ethnicity and lived in less deprived areas, limiting the generalizability of its findings to other racial and ethnic populations or individuals from deprived regions. Also, there was a small number of paired CGM-metrics data, paired Gold score data and paired DDS data, which may have affected our ability to assess significant changes in this cohort.

In conclusion, our analysis demonstrated that Omnipod DASH was associated with a 0.3 % reduction in HbA1c, increase in TIR, reduced insulin requirements and positive impact on quality of life in PwT1D in the real-world. Stratified by previous insulin therapy, Omnipod DASH was associated with a clinically meaningful decrease in HbA1c and improved TIR in individuals previously treated with MDI. PwT1D switching from other CSII systems to Omnipod DASH maintained previous HbA1c levels and TIR. These benefits were accompanied by user satisfaction in all groups. However, given the limitations previously described, these findings should be interpreted with caution. Nevertheless, our findings add to the body of evidence on the long-term effects of Omnipod DASH system on glycaemic, safety and patient-reported outcomes, and support wider access of tubeless insulin pumps in people living with T1D.

### Ethics approval

The ABCD national audit program, which includes the ABCD Omnipod audit, has Caldicott Guardian Approval. The program collects anonymized and routinely available clinical data, and additional investigations besides standard care are not required. Hence, this study did not require specific approval by a research ethics committee.

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### Declaration of interest

ALL has received support to attend conferences from Eli Lilly and Novo Nordisk and research support from ABCD. NH has no competing financial interests to disclose. TSJC has received speaker fees and/or support to attend conferences from Eli Lilly, Novo Nordisk, Sanofi, Abbott Diabetes Care, Dexcom and Insulet. LL has received personal fees from Abbott Diabetes Care, Dexcom, Insulet, Medtronic, Novo Nordisk and Sanofi Diabetes Care. PH has received personal fees from Medtronic and Eli Lilly. SH has received personal fees for non-promotional educational activities from Abbott, Dexcom and Sanofi. MH has no competing financial interests to disclose. AA has no competing financial interests to disclose. EG has no competing financial interests to disclose. FWG has received personal fees from Abbott, Eli Lilly, Insulet and Novo Nordisk. AL has received personal fees from Abbott, Dexcom, Eli Lilly, Insulet, Medtronic, Novo Nordisk, Roche and Sanofi and research support from Abbott and Novo Nordisk. KB has no competing financial interests to disclose. EC has no competing financial interests to disclose. GC has no competing financial interests to disclose. DMW has received personal fees from AstraZeneca. PC has received personal fees from

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### CRedit authorship contribution statement

**Alexandros L. Liarakos:** Writing – original draft, Visualization, Formal analysis. **Nebras Hasan:** Data curation. **Thomas S.J. Crabtree:** Writing – review & editing, Formal analysis, Data curation, Conceptualization. **Lalantha Leelarathna:** Writing – review & editing, Conceptualization. **Peter Hammond:** Writing – review & editing, Conceptualization. **Sufyan Hussain:** Writing – review & editing, Conceptualization. **Masud Haq:** Data curation. **Aisha Aslam:** Data curation. **Ernedda Gatdula:** Data curation. **Fraser W Gibb:** Writing – review & editing, Conceptualization. **Alistair Lumb:** Writing – review & editing. **Kirsty Bull:** Data curation. **Eswari Chinnasamy:** Data curation. **Giorgio Carrieri:** Data curation. **David M. Williams:** Data curation. **Pratik Choudhary:** Writing – review & editing, Conceptualization. **Robert E.J. Ryder:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Emma G. Wilmot:** Writing – review & editing, Supervision, Methodology, Data curation, Conceptualization.

### Declaration of competing interest

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

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### Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2024.111597>.

### References

- [1] Larsson SC, Wallin A, Håkansson N, Stackelberg O, Bäck M, Wolk A. Type 1 and type 2 diabetes mellitus and incidence of seven cardiovascular diseases. *Int J Cardiol* 2018;262:66–70.
- [2] Lind M, Svensson AM, Kosiborod M, Gudbjörnsdóttir S, Pivodic A, Wedel H, et al. Glycemic control and excess mortality in type 1 diabetes. *N Engl J Med* 2014;371(21):1972–82.
- [3] Nathan DM, Cleary PA, Backlund JY, Genuth SM, Lachin JM, Orchard TJ, et al. Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. *N Engl J Med* 2005;353(25):2643–53.
- [4] Orchard TJ, Nathan DM, Zinman B, Cleary P, Brillonn D, Backlund JY, et al. Association between 7 years of intensive treatment of type 1 diabetes and long-term mortality. *JAMA* 2015;313(1):45–53.
- [5] National Institute for Health and Care Excellence (NICE) Guideline on Type 1 Diabetes in adults: diagnosis and management. Available at: <https://www.nice.org.uk/guidance/ng17> [accessed 5 January 2024].
- [6] National Diabetes Audit 2021-2022, Type 1 Diabetes - Overview. Available at: <https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit-type-1-diabetes/nda-type-1-2021-22-overview> [accessed 5 January 2024].
- [7] Foster NC, Beck RW, Miller KM, Clements MA, Rickels MR, DiMeglio LA, et al. State of type 1 diabetes management and outcomes from the T1D exchange in 2016–2018. *Diabetes Technol Ther* 2019;21(2):66–72.
- [8] Pickup JC, Sutton AJ. Severe hypoglycaemia and glycaemic control in Type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. *Diabet Med* 2008;25(7):765–74.
- [9] Benkhadra K, Alahdab F, Tamhane SU, McCoy RG, Prokop LJ, Murad MH. Continuous subcutaneous insulin infusion versus multiple daily injections in individuals with type 1 diabetes: a systematic review and meta-analysis. *Endocrine* 2017;55(1):77–84.
- [10] Polonsky WH, Hessler D, Layne JE, Zisser H. Impact of the Omnipod. *Diabetes Technol Ther* 2016;18(10):664–70.
- [11] Speight J, Choudhary P, Wilmot EG, Hendrieckx C, Forde H, Cheung WY, et al. Impact of glycaemic technologies on quality of life and related outcomes in adults with type 1 diabetes: A narrative review. *Diabet Med* 2023;40(1):e14944.
- [12] Jeyam A, Gibb FW, McKnight JA, Kennon B, O'Reilly JE, Caparrotta TM, et al. Marked improvements in glycaemic outcomes following insulin pump therapy initiation in people with type 1 diabetes: a nationwide observational study in Scotland. *Diabetologia* 2021;64(6):1320–31.
- [13] Seereiner S, Neeser K, Weber C, Schreiber K, Habacher W, Rakovac I, et al. Attitudes towards insulin pump therapy among adolescents and young people. *Diabetes Technol Ther* 2010;12(1):89–94.
- [14] Zisser HC. The OmniPod Insulin Management System: the latest innovation in insulin pump therapy. *Diabetes Ther* 2010;1(1):10–24.
- [15] Jahn LG, Capurro JJ, Levy BL. Comparative dose accuracy of durable and patch insulin infusion pumps. *J Diabetes Sci Technol* 2013;7(4):1011–20.
- [16] Borot S, Franc S, Cristante J, Penformis A, Benhamou PY, Guerci B, et al. Accuracy of a new patch pump based on a microelectromechanical system (MEMS) compared to other commercially available insulin pumps: results of the first in vitro and in vivo studies. *J Diabetes Sci Technol* 2014;8(6):1133–41.
- [17] Zisser H. Insulin pump (dose-to-dose) accuracy: what does it mean and when is it important? *J Diabetes Sci Technol* 2014;8(6):1142–4.
- [18] Luijff YM, Arnolds S, Avogaro A, Benesch C, Bruttomesso D, Farret A, et al. Patch pump versus conventional pump: postprandial glycaemic excursions and the influence of wear time. *Diabetes Technol Ther* 2013;15(7):575–9.
- [19] Leelarathna L, Roberts SA, Hindle A, Markakis K, Alam T, Chapman A, et al. Comparison of different insulin pump makes under routine care conditions in adults with Type 1 diabetes. *Diabet Med* 2017;34(10):1372–9.
- [20] Mehta SN, Tinsley LJ, Kruger D, Bode B, Layne JE, Huyett LM, et al. Improved glycaemic control following transition to tubeless insulin pump therapy in adults with type 1 diabetes. *Clin Diabetes* 2021;39(1):72–9.
- [21] Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. *Ann Fam Med* 2008;6(3):246–52.
- [22] Gold AE, MacLeod KM, Frier BM. Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia. *Diabetes Care* 1994;17(7):697–703.
- [23] Battelino T, Danne T, Bergenstal RM, Amiel SA, Beck R, Biester T, et al. Clinical targets for continuous glucose monitoring data interpretation: Recommendations from the international consensus on time in range. *Diabetes Care* 2019;42(8):1593–603.
- [24] Layne JE, Parkin CG, Zisser H. Efficacy of the Omnipod insulin management system on glycaemic control in patients with type 1 diabetes previously treated with multiple daily injections or continuous subcutaneous insulin infusion. *J Diabetes Sci Technol* 2016;10(5):1130–5.
- [25] Beck RW, Riddlesworth TD, Ruedy KJ, Kollman C, Ahmann AJ, Bergenstal RM, et al. Effect of initiating use of an insulin pump in adults with type 1 diabetes using multiple daily insulin injections and continuous glucose monitoring (DIAMOND): a multicentre, randomised controlled trial. *Lancet Diabetes Endocrinol* 2017;5(9):700–8.
- [26] Danne T, Schwandt A, Biester T, Heidtmann B, Rami-Merhar B, Haberland H, et al. Long-term study of tubeless insulin pump therapy compared to multiple daily injections in youth with type 1 diabetes: Data from the German/Austrian DPV registry. *Pediatr Diabetes* 2018;19(5):979–84.
- [27] Aleppo G, DeSalvo DJ, Lauand F, Huyett LM, Chang A, Vienneau T, et al. Improvements in glycaemic outcomes in 4738 children, adolescents, and adults with type 1 diabetes initiating a tubeless insulin management system. *Diabetes Ther* 2023;14(3):593–610.
- [28] Brown RE, Vienneau T, Aronson R. Canadian real-world outcomes of Omnipod initiation in people with type 1 diabetes (COPPER study): Evidence from the LMC diabetes registry. *Diabet Med* 2021;38(6):e14420.



- [29] Biester T, Schwandt A, Heidtmann B, Rami-Merhar B, Haak T, Festa A, et al. Declining frequency of acute complications associated with tubeless insulin pump use: Data from 2,911 patients in the German/Austrian Diabetes Patienten Verlaufsdokumentation registry. *Diabetes Technol Ther* 2021;23(8):527–36.
- [30] Beato-Vibora P, Yeoh E, Rogers H, Hopkins D, Amiel SA, Choudhary P. Sustained benefit of continuous subcutaneous insulin infusion on glycaemic control and hypoglycaemia in adults with Type 1 diabetes. *Diabet Med* 2015;32(11):1453–9.
- [31] Anyanwagu U, Olaoye H, Jennings P, Ashton-Cleary S, Sugunendran S, Hughes D, et al. Continuous subcutaneous insulin infusion (CSII) therapy at Derby Teaching Hospitals: sustained benefits in glucose control. *Diabet Med* 2017;34(8):1154–7.
- [32] National Institute for Health and Care Excellence (NICE) technology appraisal guidance (TA943) on hybrid closed loop systems for managing blood glucose levels in type 1 diabetes. Available at: <https://www.nice.org.uk/guidance/ta943> [accessed 13 February 2024].
- [33] Everett EM, Copeland TP, Moin T, Wisk LE. Insulin pump-related inpatient admissions in a national sample of youth with type 1 diabetes. *J Clin Endocrinol Metab* 2022;107(6):e2381–7.
- [34] Thomas MG, Avari P, Godslan IF, Lett AM, Reddy M, Oliver N. Optimizing type 1 diabetes after multiple daily injections and capillary blood monitoring: Pump or sensor first? A meta-analysis using pooled differences in outcome measures. *Diabetes Obes Metab* 2021 Nov;23(11):2521–8.