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Canadian Real-World Outcomes of Omnipod Initiation in People with Type 1 Diabetes (COPPER study): Evidence from the LMC Diabetes Registry

R. E. Brown[1] | **T. Vienneau**[2] | **R. Aronson**[1]

[1]LMC Diabetes and Endocrinology, Toronto, ON, Canada

[2]Insulet Canada Corporation, Oakville, ON, Canada

Correspondence
R. Aronson, LMC Diabetes and Endocrinology, Toronto, ON, Canada.
Email: Ronnie.aronson@lmc.ca

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Abstract

Aims: To investigate real-world clinical outcomes in adults with type 1 diabetes who initiated the Omnipod Insulin Management System (Insulet Corp., Acton, MA, USA) compared to a matched cohort who maintained multiple daily injection therapy.

Methods: This retrospective observational study used data from the Canadian LMC Diabetes Registry. Adults with type 1 diabetes who switched from multiple daily injections to the Omnipod system as usual standard of care between January 2011 and April 2019 were matched to a cohort of adults with type 1 diabetes who maintained multiple daily injection therapy, using propensity-score matching. The primary outcome was change in HbA_{1c} at 3- to 6-month follow-up.

Results: Propensity-score matching resulted in a final analytical cohort of 286 individuals (143/cohort). HbA_{1c} in the Omnipod cohort was reduced by a mean ± SD of –3 ± 10 mmol/mol (–0.2 ± 1.0%; $P = 0.005$) with no change in the MDI cohort [0 ± 10 mmol/mol (0.0 ± 1.0%); $P = 0.74$]. HbA_{1c} change was seen only in persons with baseline HbA_{1c} ≥75 mmol/mol (≥9.0%) [Omnipod cohort: –15 ± 12 mmol/mol (–1.4 ± 1.1%); $P < 0.001$] with a between-treatment difference [mean (95% CI)] of –12 (–18, –6) mmol/mol [–1.1 (–1.6, –0.5) %, $P < 0.001$]. The median total daily dose of insulin was lower following Omnipod initiation (baseline 0.63 U/kg vs follow-up 0.53 U/kg; $P < 0.001$), with no change in the MDI cohort (baseline 0.68 U/kg vs follow-up 0.67 U/kg; $P = 0.23$).

Conclusions: Adults with type 1 diabetes who initiated use of the Omnipod system in a real-world clinical setting had lower HbA_{1c} and total daily dose of insulin at 3- to 6-month follow-up compared to a matched cohort of adults who maintained multiple daily injection therapy. A treatment difference in HbA_{1c} change was seen only in people with baseline HbA_{1c} ≥ 75 mmol/mol (9.0%). (Clinical trials registration: NCT04226378).

1 | INTRODUCTION

Poor glycaemic control is associated with increased risk of diabetes complications in people with type 1 diabetes. Despite advancements in insulin therapies and technologies, HbA_{1c} levels in individuals with type 1 diabetes in the USA have not improved since 2010.[1] In the USA, only 21% of adults with type 1 diabetes are meeting the target mean HbA_{1c} levels, similar to a recent report in an adult Canadian type 1 diabetes population.[2]

Managing intensive insulin therapy with continuous subcutaneous insulin infusion (CSII) or pump therapy has been associated with improved glycaemic control and quality of life with less severe hypoglycaemia than is associated with multiple daily injections (MDI).[3] Better glycaemic control and lower risk of nocturnal hypoglycaemia have been reported in both children and adults with type 1 diabetes using CSII.[4] Retrospective analyses of medical records have also reported lower HbA_{1c} values in adults with type 1 diabetes using CSII compared to those using MDI,[5] or a reduction in HbA_{1c} in adults who switched from MDI to CSII.[6]

Traditional insulin pumps deliver insulin via a catheter between the pump and cannula. By contrast, the Omnipod® Insulin Management System (Insulet Corp., Acton, MA, USA) is a 'tubeless' pump that consists of a handheld controller and a disposable pod that delivers insulin. A retrospective analysis of the German/Austrian DPV Registry reported that paediatric populations with type 1 diabetes had significantly improved HbA_{1c} levels 1 year after switching from MDI to Omnipod treatment compared with those who maintained MDI therapy, with diminishing of the benefit by 2 and 3 years of follow-up.[7] A large uncontrolled retrospective analysis similarly found an HbA_{1c} reduction in paediatric, adolescent and adult Omnipod therapy initiators in the USA, 3 months after switching from either MDI or traditional CSII.[8] However, to date, the Omnipod system has not been compared to MDI therapy in adults with type 1 diabetes in a 'real-world' setting.

The aim of the present study was to perform a retrospective, propensity-matched analysis of the Canadian LMC Diabetes Registry to determine differences in clinical outcomes in adults with type 1 diabetes who initiated the Omnipod system compared to a matched cohort of MDI users.

What's new?

- Insulin pump systems have shown improved glycaemic control in clinical trials. These findings have been confirmed in paediatric populations in the real world, with control cohorts using multiple daily injection (MDI) therapy.
- This study is the first to report the outcomes of pump initiation among adults, in a 'real-world' environment, compared to a matched cohort of MDI therapy users, and the first to do so among tubeless pump users.
- Our findings confirm previous observations of improved glucose control in short-term outcomes (3-6 months), especially for individuals with poor baseline glycaemic control.
- Finally, our unique non-physician approach to collection of hypoglycaemia frequency further confirms previous randomized controlled trial findings of no increase in frequency of clinical hypoglycaemia events.

2 | MATERIALS AND METHODS

2.1 | Study design and data source

This study was an industry-funded (Insulet Canada), retrospective, observational study using demographic and clinical data from the Canadian LMC Diabetes Registry. The LMC Diabetes Registry includes >42 000 active participants with diabetes (4200 with type 1 diabetes) under the care of >50 endocrinologists, sharing one electronic medical record system, in a publicly funded healthcare system. A detailed description of this registry has been published.[9,10]

Adults with type 1 diabetes duration of ≥12 months were eligible for inclusion if they had used MDI therapy and switched to Omnipod therapy, as part of standard care, between 1 January 2011 and 30 April 2019, and had measured HbA_{1c} during the baseline period and follow-up periods (Omnipod cohort). Individuals were eligible for the matched cohort if they were adults with type 1 diabetes duration of ≥12 months, were an LMC patient for ≥6 months between 1 January 2011 and 30 April 2019, and had continued MDI therapy during the follow-up period (MDI cohort).

The Omnipod system start date was the index date for the Omnipod cohort and, for the matched cohort, the first visit date of the most recent year of care was set as the index date. For baseline HbA_{1c}, weight, insulin dose and hypoglycaemia, the last available values up to 6 months (+ 6 weeks) prior to the index date were recorded. Outcome values were recorded at the last available follow-up visit at 3 to 6 months (+ 6 weeks) after the baseline date. Beginning in 2016, hypoglycaemia data were collected at each visit using a structured interview, by trained non-physician staff. Any hypoglycaemia was recorded as weekly frequency (over the preceding month) and severe hypoglycaemia was recorded as annual frequency (over the preceding year). If individuals had started using the Omnipod prior to their care at LMC, their index date, as well as their

prior HbA_{1c}, weight and insulin dose, were retrieved from their prior healthcare records.

2.2 | Study outcomes

The primary outcome was change in HbA_{1c} between baseline and follow-up (3-6 months) between the matched Omnipod and MDI cohorts. Secondary endpoints included change in weight, change in total daily dose (TDD) of insulin, incidence of self-reported hypoglycaemia, and proportion of individuals with HbA_{1c} <53 mmol/mol (<7.0%) and <64 mmol/mol (<8.0%) at follow-up. Exploratory endpoints included change in HbA_{1c} at 12 and 24 months. Change in HbA_{1c} was also evaluated in predefined subgroups: individuals with baseline HbA_{1c} <75 mmol/mol (<9.0%) and ≥75 mmol/mol (≥9.0%), and according to age category (18-25 years, 26-49 years and ≥50 years).

2.3 | Statistical analyses

The population used for the primary, secondary and exploratory endpoints was an on-treatment analysis population. Baseline demographics and clinical characteristics were summarized. Continuous variables were reported using means and SD values or medians and interquartile ranges. Discrete variables were reported using counts (n) and percentages. All data were inspected for outliers and potential data entry errors. Dependent variables were examined for normality.

Adults initiating Omnipod therapy were matched 1:1 to adults using MDI by means of propensity-score matching. The propensity score was estimated with a logistic regression model, with Omnipod therapy as the outcome variable and the following variables included as covariates: age; gender; ethnicity; education level; duration of type 1 diabetes (years); HbA_{1c}; body weight; macrovascular conditions; microvascular conditions; and year of index date. The matching algorithm was created using %GMATCH macro[11] in SAS software, which is provided by the Division of Biostatistics at the Mayo Clinic. The two treatment cohorts were randomly sorted prior to matching. Individuals were matched using a greedy nearest-neighbour process without replacement. The matching started with the individuals who could be matched best. A control was selected for a particular case if it had the smallest absolute difference between the control and case in the propensity score, with a maximum caliper width equal to 0.2 of the SD of the logit of the propensity score. In the case of ties, the first match encountered was used. The baseline characteristics of the Omnipod cohort and matched MDI cohort are presented by the standardized difference. Since weight was part of the propensity-score calculation, 16 people who were missing a weight value at baseline were not included in the propensity-score calculation.

Differences between cohorts in change in HbA_{1c}, weight and weekly incidence of hypoglycaemia were evaluated with linear regression models, adjusting for baseline value. Change in TDD of insulin was assessed using a Wilcoxon signed-rank test. The proportion of participants with HbA_{1c} <53 mmol/mol (<7.0%) and <64 mmol/mol (<8.0%) at follow-up between cohorts was assessed with a chi-squared test. Change in HbA_{1c} between the Omnipod and MDI cohorts according to baseline HbA_{1c} <75 mmol/mol (<9.0%) and ≥75 mmol/mol (≥9.0%), and according to age category, was evaluated with a linear regression model, adjusting for baseline HbA_{1c}.

Missing data were not replaced. P values <0.05 were taken to indicate statistical significance, and all tests were two-sided. Changes within each cohort are presented as mean ± SD and between cohort differences are presented as mean (95% CI). All statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA).

2.4 | Ethics

An independent ethics committee (Advarra IRB, Columbia, MD, USA) approved the protocol and patients provided consent for their medical data to be used for research purposes (NCT04226378).

3 | RESULTS

Between January 2011 and April 2019, 417 individuals initiated an Omnipod pump. Individuals were excluded if they switched from another insulin pump to Omnipod ($n = 163$), if they had used Omnipod therapy for <6 months and/or if they used insulin injections simultaneously with Omnipod therapy ($n = 7$), if the Omnipod treatment start date was not known ($n = 22$), if they did not have an available HbA_{1c} value within the baseline observation period ($n = 27$), and if they did not have an HbA_{1c} value within the follow-up observation period ($n = 19$). The remaining Omnipod cohort consisted of 179 participants, of whom 156 started using the Omnipod while they were an LMC patient, and 23 started using it prior to joining an LMC practice. Between January 2011 and April 2019, there were 3253 participants with type 1 diabetes using MDI. After exclusions for being followed at LMC for <6 months ($n = 1075$), type 1 diabetes of <12 months' duration ($n = 44$), unavailable HbA_{1c} within the baseline observation period ($n = 160$), and unavailable HbA_{1c} within the follow-up observation period ($n = 492$), the final MDI cohort comprised 1482 participants.

TABLE 1 Participant characteristics of unmatched and matched Omnipod and multiple daily injection cohorts

	Unmatched			Matched		
	Omnipod	**MDI**	**d**	**Omnipod**	**MDI**	**d**
N	179	1482		143	143	
Age, years	40 ± 13	47 ± 16	0.505	40 ± 13	41 ± 14	0.061
Men, *n* (%)	93 (52)	844 (57)	0.100	77 (54)	77 (54)	0.000
Duration of type 1 diabetes, years	15.4 ± 12.1	21.7 ± 15.3	0.458	16.4 ± 12.8	16.4 ± 13.9	0.001
Ethnicity, *n* (%)						
White	131 (73)	985 (67)	0.147	103 (72)	105 (73)	0.031
East or South Asian	17 (9.5)	145 (9.8)	0.010	16 (11)	14 (9.8)	0.046
Other*	16 (8.9)	155 (11)	0.051	13 (9.1)	13 (9.1)	0.000
Declined	15 (8.4)	197 (13)	0.159	11 (7.7)	11 (7.7)	0.000
Education, *n* (%)						
High school	39 (22)	346 (23)	0.037	33 (23)	35 (25)	0.033
College or university	103 (58)	785 (53)	0.092	79 (55)	74 (51)	0.070
Declined	37 (21)	351 (24)	0.073	31 (21)	34 (23)	0.050
Index year, *n* (%)						
2011	2 (1.1)	0 (0.0)	0.150	0 (0.0)	0 (0.0)	0.000
2012	13 (7.3)	6 (0.4)	0.363	6 (4.2)	6 (4.2)	0.000
2013	18 (10)	13 (0.9)	0.412	14 (9.8)	12 (8.4)	0.049
2014	17 (9.5)	15 (1.0)	0.387	11 (7.7)	10 (6.9)	0.027
2015	19 (11)	19 (1.3)	0.402	13 (9.1)	16 (11)	0.070
2016	17 (9.5)	16 (1.1)	0.383	13 (9.1)	11 (7.7)	0.050
2017	41 (23)	52 (3.5)	0.598	36 (25)	35 (25)	0.016
2018	45 (25)	111 (7.5)	0.492	44 (31)	47 (33)	0.045
2019	7 (3.9)	1250 (84)	2.762	6 (4.2)	6 (4.2)	0.000
Macrovascular condition†, *n* (%)	12 (6.7)	103 (7.0)	0.010	9 (6.3)	10 (7.0)	0.028
Microvascular disease‡, *n* (%)	38 (21)	606 (41)	0.407	36 (25)	36 (25)	0.000
HbA_{1c}, mmol/mol	64 ± 14	66 ± 16	0.117	65 ± 13	66 ± 15	
HbA_{1c}, %	8.0 ± 1.2	8.2 ± 1.5	0.117	8.1 ± 1.2	8.2 ± 1.4	0.035
Weight§, kg	76.8 ± 16.5	79.4 ± 18.4	0.145	76.9 ± 16.5	76.2 ± 17.2	0.038

Note: Data are presented as mean ± SD, unless otherwise indicated.

Abbreviations: d, standardized mean difference; MDI, multiple daily injections.

d < 0.1 indicates a variable is balanced between cohorts. *Black, Arab, First Nations, Hispanic or Latino. †History of coronary artery disease, cerebral vascular disease or peripheral vascular disease. ‡History of retinopathy, neuropathy or nephropathy. §Pre-matching, baseline weight was available for 163 Omnipod participants and 1453 MDI participants.

Baseline characteristics of the unmatched and matched Omnipod and MDI cohorts are presented in Table 1. Prior to matching, the Omnipod cohort tended to be younger, have a shorter duration of type 1 diabetes, a lower body weight, were more likely to be of white ethnicity, and had a lower prevalence of microvascular disease compared to the MDI cohort. After matching, there were 143 individuals in each cohort, who were well matched on their baseline characteristics. The mean (± SD) of the propensity score for the Omnipod cohort was 0.434 ± 0.168 (range 0.003-0.763) and for the MDI cohort 0.425 ± 0.161 (range 0.003-0.715). Their mean age was approximately 41 years, mean duration of type 1 diabetes was 16 years, and mean HbA_{1c} was 65 mmol/mol (8.1%). Their mean duration of care at LMC was 3.6 ± 3.2 years and did not differ between cohorts.

Change in HbA_{1c} in the matched Omnipod and MDI cohorts is presented in Table 2. There was a statistically significant reduction in HbA_{1c} in the Omnipod cohort between baseline and follow-up of –3 ± 10 mmol/mol (–0.2 ± 0.9%; $P = 0.005$), and no statistically significant change in the MDI cohort [0 ± 11 mmol/mol (0.0 ± 1.0%); $P = 0.74$]. Compared to the MDI cohort, the Omnipod cohort had a statistically significantly greater reduction in HbA_{1c} during the follow-up period: mean –3 mmol/mol (95% CI –6, –1); $P = 0.01$ [–0.3% (95% CI –0.5, –0.1)].

TABLE 2 Baseline and 3- to 6-month change in HbA_{1c}, weight and self-reported hypoglycaemia in the matched cohorts ($n = 286$)

	Omnipod			MDI				
	n	Baseline	3-6-month change	*n*	Baseline	3-6-month change	Between-treatment change	*P*
HbA_{1c}, mmol/mol		65 ± 13	–3 ± 10		66 ± 16	0 ± 10	–3 (–6, –1)	
HbA_{1c}, %	143	8.1 ± 1.2	–0.2 ± 0.9	143	8.2 ± 1.4	0.0 ± 1.0	–0.3 (–0.5, –0.1)	0.01
Weight, kg	132	77.1 ± 16.9	0.5 ± 3.8	108	76.3 ± 17.5	0.4 ± 3.6	0.1 (–0.8, 1.1)	0.75
Weekly incidence of any hypoglycaemia	90	1.1 ± 1.6	0.1 ± 1.9	73	1.1 ± 1.4	0.5 ± 1.9	–0.4 (–0.8, 0.1)	0.15
Baseline HbA_{1c} ≥75 mmol/mol (≥9.0%)								
HbA_{1c}, %	28	10.1 ± 1.0	–1.4 ± 1.1	43	9.8 ± 1.0	–0.2 ± 1.3	–1.1 (–1.6, –0.5)	<0.001
HbA_{1c}, mmol/mol		86 ± 10	–15 ± 12		84 ± 11	–2 ± 14	–12 (–18, –6)	
Baseline HbA_{1c} <75 mmol/mol (<9.0%)								
HbA_{1c}, mmol/mol		60 ± 8	1 ± 7		58 ± 10	1 ± 9	–1 (–2, 1)	
HbA_{1c}, %	115	7.6 ± 0.8	0.1 ± 0.6	100	7.5 ± 0.9	0.1 ± 0.8	–0.1 (–0.2, 0.1)	0.59

Note: Data for baseline and change within each cohort are presented as mean ± SD. Between-treatment effects are presented as mean (95% CI). Models were adjusted for baseline value.

Abbreviation: MDI, multiple daily injections.

Among individuals with baseline HbA_{1c} ≥75 mmol/mol (≥ 9.0%), there was a larger, statistically significant reduction in HbA_{1c} in the Omnipod cohort of –15 ± 12 mmol/mol (–1.4 ± 1.1%; $P < 0.001$), with no statistically significant change in the MDI cohort [–2 ± 14 mmol/mol [–0.2 ± 1.3%]; $P = 0.32$). The between-treatment difference of –12 mmol/mol [(95% CI –18, –6) –1.1% (95% CI –1.6, –0.5)] was statistically significant ($P < 0.001$). In those with a baseline HbA_{1c} <75 mmol/mol (<9.0%), there was no statistically significant change in HbA_{1c} in either the Omnipod ($P = 0.36$) or the MDI cohort ($P = 0.12$).

Longer-term follow-up was also investigated as an exploratory outcome in individuals with available data at longer follow-up times. At 12 months post-Omnipod therapy initiation, the follow-up HbA_{1c} was 64 ± 14 mmol/mol [8.0 ± 1.2%, change: 1 ± 10 mmol/mol (–0.1 ± 0.9%), $n = 112$; $P = 0.29$]. Among the smaller cohorts who had 24-month data [$n = 80$, change: 0 ± 11 mmol/mol (0.0 ± 1.0%); $P = 0.98$], or 36-month data [$n = 42$, change: 0 ± 11 mmol/mol (0.0 ± 1.0%); $P = 0.85$] available, there was no change from the baseline HbA_{1c}.

Within the predefined age subgroups, the reduction in HbA_{1c} in the Omnipod cohort was numerically greater but not statistically significant compared to the MDI cohort in the 18-25 years age subgroup, with a between-treatment difference of –8 mmol/mol [(95% CI –16, 0) –0.7% (95% CI –1.5, 0); $P = 0.06$], and in the 26-49 years age subgroup, with a between-treatment difference of –2 mmol/mol [(95% CI –6, 1) –0.2% (95% CI –0.5, 0.1); $P = 0.11$]. In the ≥50 years age subgroup, the change in HbA_{1c} between the Omnipod and MDI cohorts was –1 mmol/mol [(95% CI –4, 2) –0.1% (95% CI –0.4, 0.2); $P = 0.58$].

There was no statistically significant change in weight in either the Omnipod or MDI cohorts (Table 2). The proportion of adults with HbA_{1c} <53 mmol/mol (<7.0%) at follow-up did not differ between the Omnipod (19%) and MDI cohorts (22%; $P = 0.47$). Similarly, the proportion of adults with HbA_{1c} <64 mmol/mol (<8.0%) at follow-up did not differ between the Omnipod (56%) and MDI cohorts (49%; $P = 0.24$).

In the Omnipod cohort with available data for self-reported hypoglycaemia ($n = 90$), mean self-reported weekly incidence of hypoglycaemia was similar at baseline (1.1 ± 1.6 events) and at follow-up (1.2 ± 1.6 events; $P = 0.79$). In the MDI cohort who had available data for hypoglycaemia ($n = 73$), mean self-reported weekly incidence of hypoglycaemia was statistically significantly higher at follow-up (1.5 ± 1.7 events) compared to baseline (1.1 ± 1.4 events; $P = 0.04$). The difference between treatment cohorts was not different [–0.4 (95% CI –0.8, 0.1) events; $P = 0.15$]. In the Omnipod cohort, the proportion of participants who reported ≥1 weekly incidence of any hypoglycaemia at baseline (41%) and follow-up (46%) did not differ ($P = 0.49$). In the MDI cohort, a higher proportion of participants reported ≥1 weekly episode of any hypoglycaemia at follow-up vs baseline (59% vs 41%; $P = 0.02$). At follow-up, the proportion reporting any hypoglycaemia was not statistically significantly different between cohorts ($P = 0.08$). Severe hypoglycaemia was reported by three individuals in the Omnipod cohort and by six in the MDI cohort.

The median TDDs of insulin are presented in Table 3. There were 106 and 102 individuals in the Omnipod cohort who had available basal and bolus insulin dose information for absolute and relative insulin doses, respectively.

TABLE 3 Median total daily dose of insulin in the matched cohorts

	n	Baseline	Follow-up	Change	*P*
Omnipod cohort					
TDD, U	106	47.8 (27.0)	39.5 (19.9)	–8.4 (13.2)	<0.001
TDD, U/kg	102	0.63 (0.30)	0.53 (0.17)	–0.12 (0.21)	<0.001
MDI cohort					
TDD, U	94	50.0 (35.0)	50.0 (38.0)	0.0 (6.00)	0.45
TDD, U/kg	82	0.68 (0.39)	0.67 (0.42)	0.01 (0.13)	0.23

Note: Data are presented as median (interquartile range).

Abbreviation: MDI, multiple daily injections; TDD, total daily dose.

The median TDD in units (U) and in U/kg was statistically significantly lower following Omnipod initiation vs baseline [–8.4 U ($P < 0.001$); –0.12 U/kg ($P < 0.001$)]. In the MDI cohort, 94 and 82 participants had available basal and bolus insulin dose information for absolute and relative insulin doses, respectively. There was no change in median TDD of insulin in the MDI cohort [0.0 U ($P = 0.45$); 0.01 U/kg ($P = 0.23$)].

4 | DISCUSSION

The present COPPER study was a retrospective observational analysis that investigated real-world clinical outcomes in adults with type 1 diabetes who switched from MDI to Omnipod therapy, and compared these clinical outcomes to a matched cohort of MDI users. Adults who initiated use of an Omnipod system had a statistically significant reduction in HbA_{1c} during a 3- to 6-month follow-up period. The change in HbA_{1c} was also greater than that seen in matched adults who had continued MDI therapy. In subgroup analyses, this glycaemic improvement was seen only in individuals with poorer baseline glycaemic control [HbA1c ≥75 mmol/mol (≥9.0%)].

Prior reports have found greater glycaemic benefit associated with CSII compared with MDI among individuals with higher HbA_{1c}[9] and especially among those with HbA_{1c} >75 mmol/mol (> 9.0%).[7-9,12] In the present cohort, the HbA_{1c} reduction post-Omnipod treatment initiation was similarly seen in uncontrolled individuals [baseline HbA_{1c} ≥75 mmol/mol (≥ 9.0%)] who showed a decrease of 1.4%. It may be particularly beneficial to offer pump therapy to adults with type 1 diabetes with poor glycaemic control. We note that, despite the statistically significant glycaemic improvement in the overall Omnipod cohort at 3-6 months, the HbA_{1c} level in a smaller group of individuals with 12-, 24- and 36-month data trended back up to baseline values at these later time points.

The influence of CSII on weight is conflicting, with some trials reporting no significant weight differences in participants using CSII vs those using MDI,[3] and a recent retrospective analysis reporting a small weight gain 1 year after switching from MDI to CSII in adults whose baseline HbA_{1c} was >75 mmol/mol (>9.0%).[6] In the present study, there was no significant change in weight between baseline and follow-up in the Omnipod cohort, and no between-treatment differences in weight change.

The change in weekly hypoglycaemia was not statistically significantly different between cohorts, consistent with a meta-analysis that reported no difference in hypoglycaemia between CSII and MDI users.[4] Although one study found a significant reduction in weekly incidence of self-reported hypoglycaemia, their cohort had started with a higher baseline rate of weekly hypoglycaemia (2.6 events/week) than our cohort (1.1 events/week).

Total daily dose of insulin was statistically significantly lower at follow-up in the Omnipod cohort, while the TDD remained unchanged in the MDI cohort, consistent with an earlier report.[8] A lower TDD of insulin has also been reported in a cross-sectional analysis of insulin pump users vs MDI users in a Canadian population of older adults with type 1 diabetes.[12]

A strength of the present study is that it is the first to report the outcomes of tubeless pump initiation in a real-world environment, reflected against a matched cohort of individuals who continued MDI use. However, the observational design limits the inclusion of some key outcomes (quality of life and hospital-based events such as diabetic ketoacidosis), the assessment of some populations (children and those switching from a tubed to tubeless pump), and conclusions about causality. The setting of a specialist practice with advanced resources, in a publicly funded healthcare system, possibly limits generalizability. In addition, individuals who were using non-insulin glucose-lowering therapy were not excluded (although such use was extremely rare). Although we report TDD in both groups, TDD was determined by quarterly patient self-report in participants using MDI.

In conclusion, this retrospective study demonstrated that adults with type 1 diabetes who switched from MDI to Omnipod therapy in real-world clinical practice experienced an improvement in HbA_{1c} at 3- to 6-month follow-up, with no increase in weight, and had a significant reduction in TDD of insulin, compared to a matched cohort of adults

who maintained MDI therapy. A treatment difference in HbA_{1c} change was seen only in people with baseline HbA_{1c} ≥75 mmol/mol (≥9.0%).

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COMPETING INTERESTS

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ORCID

R. E. Brown https://orcid.org/0000-0001-8897-3138
R. Aronson https://orcid.org/0000-0002-8976-2321

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