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

R. E. Brown1 | T. Vienneau2 | R. Aronson1

1LMC Diabetes and Endocrinology, Toronto, ON, Canada
2Insulet 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 HbA1c at 3- to 6-month follow-up.

Results: Propensity-score matching resulted in a final analytical cohort of 286 individuals (143/cohort). HbA1c 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]. HbA1c change was seen only in persons with baseline HbA1c ≥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 HbA1c 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 HbA1c change was seen only in people with baseline HbA1c ≥ 75 mmol/mol (9.0%). (Clinical trials registration: NCT04226378).
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, HbA1c levels in individuals with type 1 diabetes in the USA have not improved since 2010. In the USA, only 21% of adults with type 1 diabetes are meeting the target mean HbA1c levels, similar to a recent report in an adult Canadian type 1 diabetes population.

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). Better glycaemic control and lower risk of nocturnal hypoglycaemia have been reported in both children and adults with type 1 diabetes using CSII. Retrospective analyses of medical records have also reported lower HbA1c values in adults with type 1 diabetes using CSII compared to those using MDI, or a reduction in HbA1c in adults who switched from MDI to CSII.

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 HbA1c 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. A large uncontrolled retrospective analysis similarly found an HbA1c reduction in paediatric, adolescent and adult Omnipod therapy initiators in the USA, 3 months after switching from either MDI or traditional CSII. 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.

MATERIALS AND METHODS

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 >42000 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.

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 HbA1c 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 HbA1c, 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.
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 HbA1c 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 HbA1c in the matched Omnipod and MDI cohorts is presented in Table 2. There was a statistically significant reduction in HbA1c 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 HbA1c during the follow-up period: mean –3 mmol/mol (95% CI –6, –1); P = 0.01 [–0.3% (95% CI –0.5, –0.1)].
Among individuals with baseline HbA₁c ≥75 mmol/mol (≥ 9.0%), there was a larger, statistically significant reduction in HbA₁c 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 HbA₁c <75 mmol/mol (<9.0%), there was no statistically significant change in HbA₁c 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 Hba₁c 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 Hba₁c.

Within the predefined age subgroups, the reduction in Hba₁c 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 Hba₁c 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 Hba₁c <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 Hba₁c <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 2

|                        | Omnipod                        | MDI               |
|------------------------|--------------------------------|-------------------|
|                        | 3-6-month change | Between-treatment change |
| **Hba₁c, mmol/mol**    | n = Baseline | 3-6-month change | n = Baseline | 3-6-month change | P  |
| Baseline Hba₁c ≥75 mmol/mol (≥9.0%) |                    |                   |
| Hba₁c, %               | 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 Hba₁c <75 mmol/mol (<9.0%) |                    |                   |
| Hba₁c, mmol/mol        | 60 ± 8 | 1 ± 7 | 58 ± 10 | 1 ± 9 | –1 (–2, 1) | 0.59 |
| Hba₁c, %               | 115 7.6 ± 0.8 | 0.1 ± 0.6 | 100 7.5 ± 0.9 | 0.1 ± 0.8 | –0.1 (–0.2, 0.1) | 0.95 |

**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.
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 Hba1c during a 3- to 6-month follow-up period. The change in Hba1c 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 Hba1c and especially among those with Hba1c >75 mmol/mol (> 9.0%).8,9,12 In the present cohort, the Hba1c reduction post-Omnipod treatment initiation was similarly seen in uncontrolled individuals [baseline Hba1c ≥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 Hba1c level in a smaller group of individuals with 12-, 24- and 36-month data trends 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 Hba1c 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 Hba1c 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.

| 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.
who maintained MDI therapy. A treatment difference in HbA1c change was seen only in people with baseline HbA1c ≥75 mmol/mol (≥9.0%).

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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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