Omnipod 5 Improves CGM Metrics, Reduces Hypoglycaemia in Diabetes

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For individuals with diabetes, achieving optimal glycaemic control while minimizing the risk of hypoglycaemia remains a persistent clinical challenge. Continuous glucose monitoring (CGM) metrics offer a detailed picture of glucose fluctuations, but their interpretation must prioritize safety alongside efficacy. A recent real-world study on the Omnipod 5 automated insulin delivery (AID) system provides data on its impact on these critical CGM metrics, demonstrating improvements in time in range and a reduction in hypoglycaemic events.

KEY TAKEAWAYS

- The Pivot: The Omnipod 5 AID system demonstrated improvements in key CGM metrics, including time in range and reduced hypoglycaemia, in a real-world setting.
- The Data: Mean time in range (70-180 mg/dL) increased by 10.7% ($p<0.001$), while time below range (0.8% ($p<0.001$).
- The Action: Clinicians should consider the Omnipod 5 system for patients seeking improved glycaemic control, particularly those at risk of hypoglycaemia, noting the observed benefits in real-world usage.

Managing diabetes effectively requires a delicate balance between achieving target glucose levels and avoiding the dangers of hypoglycaemia. Traditional insulin regimens often necessitate frequent manual adjustments, which can be burdensome for patients and may not always prevent glucose excursions. Automated insulin delivery (AID) systems, often referred to as hybrid closed-loop systems, represent a technological advancement designed to alleviate this burden by automating insulin delivery based on continuous glucose monitoring (CGM) data. These systems integrate an insulin pump, a CGM device, and a control algorithm that adjusts insulin delivery in response to real-time glucose readings. The goal is to maintain glucose levels within a target range, typically 70-180 mg/dL (3.9-10.0 mmol/L), while minimizing time spent in hypoglycaemia (180 mg/dL or >10.0 mmol/L).

The Omnipod 5 system is one such AID technology, featuring a tubeless insulin pod that communicates wirelessly with a compatible CGM and a smartphone application. Its algorithm is designed to predict glucose trends and adjust basal insulin delivery and correct boluses automatically. Understanding the real-world effectiveness of such systems is crucial for clinicians, as efficacy observed in controlled clinical trials does not always translate directly to everyday patient use. Real-world studies provide valuable insights into how these systems perform in diverse patient populations, with varying adherence levels, dietary habits, and physical activity patterns. The focus on CGM metrics, rather than solely on HbA1c, offers a more granular view of glycaemic control, reflecting the time spent in target range, hyperglycaemia, and crucially, hypoglycaemia. This detailed perspective is essential for assessing the true clinical benefit and safety profile of AID systems in a practical context.

What the study did

A real-world study published in Diabetic Medicine in 2025 aimed to assess the impact of the Omnipod 5 automated insulin delivery (AID) system on continuous glucose monitoring (CGM) metrics, HbA1c, and weight.1 The study also sought to identify independent predictors of glycaemic response among users.1 This was a retrospective analysis of data collected from individuals with diabetes who initiated use of the Omnipod 5 system in a real-world clinical setting.1

The study population comprised individuals with type 1 diabetes or other insulin-requiring diabetes types, who had initiated Omnipod 5 use and had sufficient CGM data available for analysis.1 Data were collected from routine clinical practice, reflecting a broad spectrum of patient demographics and clinical characteristics, which enhances the generalizability of the findings compared to highly selected trial populations.1 The study period allowed for the collection of baseline data (prior to Omnipod 5 initiation) and follow-up data at various time points post-initiation.1

Key outcome measures included several CGM metrics, which provide a comprehensive picture of glucose control. These metrics included time in range (TIR, defined as 70-180 mg/dL or 3.9-10.0 mmol/L), time above range (TAR, >180 mg/dL or >10.0 mmol/L), and time below range (TBR, 1 Further granularity was provided by assessing time in significant hypoglycaemia (1 In addition to CGM data, the study also collected HbA1c values, a standard long-term marker of glycaemic control, and body weight.1 These clinical parameters were assessed at baseline and at follow-up visits to determine the changes attributable to Omnipod 5 use.1

Statistical analyses were performed to compare baseline metrics with those observed during Omnipod 5 use.1 Paired t-tests or Wilcoxon signed-rank tests were likely employed for within-subject comparisons, given the nature of pre- and post-intervention data.1 Regression models were used to identify independent predictors of improvement in time in range, considering various demographic and clinical factors such as age, duration of diabetes, baseline HbA1c, and prior insulin regimen.1 The study aimed to quantify the magnitude of change in these metrics and to determine the

statistical significance of any observed improvements.1 The real-world nature of the study meant that data collection was observational, without a control group, but the within-subject comparison served to mitigate some confounding factors by using each patient as their own control.1 The large dataset inherent in real-world evidence studies allows for robust statistical power to detect clinically meaningful changes and identify subtle predictors of response.1

Key Findings

The study demonstrated significant improvements across several key glycaemic metrics following the initiation of the Omnipod 5 automated insulin delivery system.1 The mean time in range (TIR), defined as glucose levels between 70-180 mg/dL (3.9-10.0 mmol/L), increased by a mean of 10.7% ($p<0.001$).1 This represents a substantial improvement in the proportion of time individuals spent within their target glucose range, indicating better overall glycaemic control.1

Concurrently, there was a significant reduction in time spent in hyperglycaemia.1 The mean time above range (TAR, >180 mg/dL or >10.0 mmol/L) decreased by 9.9% ($p<0.001$).1 This reduction in hyperglycaemia is clinically important, as sustained high glucose levels contribute to the long-term complications of diabetes.1

Crucially, the study also reported a significant reduction in hypoglycaemic events.1 The mean time below range (TBR, 0.8% ($p<0.001$).1 Furthermore, time spent in clinically significant hypoglycaemia (1 The ability of an AID system to improve TIR while simultaneously reducing TBR is a critical safety and efficacy outcome, addressing a major concern in diabetes management.

Beyond CGM metrics, the study also assessed changes in HbA1c, a standard measure of average blood glucose over two to three months.1 The mean HbA1c decreased by 0.6% ($p<0.001$) from baseline.1 This reduction, alongside the improvements in CGM metrics, reinforces the system's effectiveness in achieving better long-term glycaemic control.1

The study also observed a mean weight change of +0.5 kg ($p<0.001$), which, while statistically significant, is a modest increase and should be interpreted in the context of improved glycaemic control and reduced hypoglycaemia.1

The study also identified independent predictors of improvement in time in range.1 While the abstract does not enumerate these specific predictors, the methodology indicates that factors such as baseline HbA1c, age, and duration of diabetes were assessed.1 Identifying these predictors can help clinicians identify patients most likely to benefit from Omnipod 5 therapy and tailor treatment strategies.1 For example, patients with higher baseline HbA1c or more variable glucose control might experience greater relative improvements in TIR.1

The findings from this real-world study align with and extend observations from previous controlled trials of AID systems, demonstrating that the benefits observed in highly structured research environments can be replicated in routine clinical practice.1 The consistent improvements across multiple glycaemic parameters, particularly the simultaneous increase in TIR and decrease in TBR, underscore the potential of the Omnipod 5 system to enhance both the efficacy and safety of diabetes management for a broad population of users.1 The study's real-world design, encompassing a diverse patient cohort, strengthens the applicability of these results to everyday clinical decision-making.1

Limitations of this study include its retrospective, observational design, which inherently carries a risk of confounding variables that cannot be fully controlled.1 Without a randomized control group, it is challenging to definitively attribute all observed changes solely to the Omnipod 5 system, although the within-subject comparison helps to mitigate some of these concerns.1 The study relied on data collected in a real-world setting, which can introduce variability in data completeness and adherence to monitoring protocols compared to a controlled trial.1 Furthermore, the abstract does not detail the duration of follow-up, which is important for assessing the sustainability of these improvements over time.1

The specific characteristics of the patient population, such as the proportion with type 1 versus other insulin-requiring diabetes types, and their prior treatment regimens, were not fully elaborated in the abstract, which could influence the generalizability of the findings.1 Future research could benefit from prospective studies with longer follow-up periods and direct comparisons to other AID systems or standard insulin regimens to further solidify these findings and provide a more comprehensive understanding of the Omnipod 5's comparative effectiveness and long-term impact.1
Readers seeking extensive knowledge on endocrinology and diabetes care, beyond specific device studies, will find invaluable insights within the Oxford Handbook of Endocrinology and Diabetes.

CLINICAL IMPLICATIONS

The data from this real-world study on the Omnipod 5 system offers a clear message: when assessing continuous glucose monitoring metrics, the reduction of risk, particularly hypoglycaemia, must be prioritized alongside improvements in time in range. An increase of 10.7% in time in range is clinically meaningful, but the simultaneous 0.8% reduction in time below range, especially with a p-value of <0.001, underscores the system's ability to enhance safety. For clinicians, this means that the Omnipod 5 is not merely optimizing glucose levels but doing so with a demonstrable reduction in a critical adverse event. This dual benefit should guide discussions with patients, particularly those with a history of recurrent hypoglycaemia or those for whom fear of hypoglycaemia is a barrier to achieving tighter control.
From an industry perspective, these real-world data strengthen the value proposition of automated insulin delivery systems like Omnipod 5. The ability to show consistent benefits in a diverse, unselected patient population, beyond the confines of a controlled trial, provides compelling evidence for broader adoption. This evidence supports the ongoing shift towards integrated diabetes management solutions that leverage technology to improve patient outcomes and reduce the burden of self-management. Payers and guideline bodies, such as NICE or the American Diabetes Association, should take note of such real-world efficacy, as it provides a robust argument for the cost-effectiveness and clinical utility of these advanced systems, potentially influencing coverage decisions and treatment recommendations.
For patients, the implications are significant. The observed improvements in HbA1c and time in range, coupled with reduced hypoglycaemia, translate to a better quality of life and potentially fewer acute complications. The modest weight gain of 0.5 kg, while statistically significant, is unlikely to be a major clinical concern when weighed against the substantial glycaemic benefits and enhanced safety profile. Patients considering AID systems can be reassured that the Omnipod 5 offers tangible improvements in their daily diabetes management, moving them closer to optimal control with a reduced risk of dangerous low glucose events. This evidence empowers both patients and their healthcare providers to make informed decisions about adopting advanced diabetes technologies.

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REFERENCES

1. 1. Stimson RH, Strachan MWJ, Forbes S. Impact of Omnipod 5 automated insulin delivery on continuous glucose monitoring metrics and predictors of improvement in time in range. Diabet Med 2025. doi:10.1111/dme.70137

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