

Combined Insulin Pump Therapy with Real-Time Continuous Glucose Monitoring Significantly Improves Glycemic Control Compared to Multiple Daily Injection Therapy in Pump Naïve Patients with Type 1 Diabetes; Single Center Pilot Study Experience

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Abstract

Objectives:

This study assessed the safety and clinical effectiveness of the training protocol for initiating insulin pump therapy with real-time continuous glucose monitoring (MiniMed Paradigm REAL-Time System) in a stepwise approach on pump naïve subjects with type 1 diabetes compared to a control group who remained on multiple daily injection (MDI) therapy.

Methods:

This was a 15-week treat-to-target pilot study of 16 adult subjects ($n = 50\%$ male, age 45.9 ± 16 years) with type 1 diabetes (duration of diabetes 21.9 ± 11 years) on MDI therapy with hemoglobin A1c levels at or above 7.5% at baseline. Subjects were randomized to either the study arm (using a combined insulin pump and real-time continuous glucose monitoring system) or the control arm [which continued on MDI therapy with self-monitored blood glucose (SMBG) only]. All subjects dosed insulin according to results of SMBG by finger stick and uploaded data into the CareLink data management software.

Results:

Significant improvements in glycemic control were observed from baseline in both study groups—study arm: pre-A1c 9.45 ± 0.55 and post-A1c 7.4 ± 0.66 ($p = 0.00037$); control arm: pre-A1c 8.58 ± 1.30 and post-A1c 7.5 ± 1.01 ($p = 0.04$). Both arms had no incidence of severe hypoglycemia.

Conclusion:

In this pilot study, the Paradigm REAL-Time System was initiated safely and effectively in type 1 diabetes patients who were pump naïve using a stepwise educational protocol.

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Abbreviations: (ADA) American Diabetes Association, (CGM) continuous glucose monitoring, (CSII) continuous subcutaneous insulin infusion, (DCCT) Diabetes Control and Complications Trial, (MDI) multiple daily injection, (RT-CGM) real-time continuous interstitial glucose monitoring, (SAE) serious adverse events, (SMBG) self-monitored blood glucose

Keywords: augmented, diabetes, sensor, pump, real time, paradigm

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