

A 16-Week Open-Label, Multicenter Pilot Study Assessing Insulin Pump Therapy in Patients with Type 2 Diabetes Suboptimally Controlled with Multiple Daily Injections

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Abstract

Background:

We assessed the efficacy, safety, and patient-reported outcomes (PROs) of insulin pump therapy in patients with type 2 diabetes mellitus (T2DM) who were suboptimally controlled with a multiple daily injection (MDI) regimen.

Methods:

In this subanalysis of a 16-week multicenter study, 21 insulin-pump-naïve patients [age 57 ± 13 years, hemoglobin A1c (A1C) $8.4 \pm 1.0\%$, body weight 98 ± 20 kg, total daily insulin dose 99 ± 65 U, mean \pm standard deviation] treated at baseline with MDI therapy with or without oral antidiabetic agents discontinued all diabetes medications except metformin and initiated insulin pump therapy. Insulin was titrated to achieve the best possible glycemic control with the simplest possible dosing regimen. Outcome measures included A1C, fasting and postprandial glucose, body weight, incidence of hypoglycemia, and PROs.

Results:

Glycemic control improved significantly after 16 weeks: A1C $7.3 \pm 1.0\%$ ($-1.1 \pm 1.2\%$, $p < .001$), fasting glucose 133 ± 33 mg/dl (-32 ± 74 mg/dl, $p < .005$), and postprandial glucose 153 ± 35 mg/dl (-38 ± 46 mg/dl, $p < .001$). At week 16, the mean daily basal, bolus, and total insulin doses were 66 ± 36 , 56 ± 40 , and 122 ± 72 U (1.2 U/kg), respectively, and 90% of patients were treated with two or fewer daily basal rates. Body weight increased by 2.8 ± 2.6 kg ($p < .001$). Mild hypoglycemia was experienced by 81% of patients at least once during the course of the study with no episodes of severe hypoglycemia. There were significant improvements in PRO measures.

Conclusions:

Insulin pump therapy using a relatively simple dosing regimen safely improved glucose control and PROs in patients with T2DM who were unable to achieve glycemic targets with MDI therapy. Controlled trials are needed to further assess the clinical benefits and cost-effectiveness of insulin pumps in this patient population.

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Abbreviations: (A1C) hemoglobin A1c, (DSC-R) Diabetes Symptom Checklist-Revised, (EQ-5D) EuroQoL-5 Dimensions, (GAD) glutamic-acid decarboxylase, (HR-QoL) health-related quality of life, (IDSRQ) Insulin Delivery System Rating Questionnaire, (ITT) intent to treat, (LOCF) last observation carried forward, (MDI) multiple daily injection, (PRO) patient-reported outcome, (SD) standard deviation, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus

Keywords: insulin pump, multiple daily injections, type 2 diabetes

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