OBSERVATIONS

OmniPod Insulin Management System

Patient perceptions, preference, and glycemic control

This 30-day study, supported by a grant from Insulet, assessed the comfort, function, and use of the OmniPod system (Pod) compared with the use of a conventional insulin pump among subjects with type 1 diabetes.

The OmniPod system features the Pod, a lightweight, watertight, self-enclosed insulin pump with automated cannula insertion. The Pod delivers insulin according to preprogrammed instructions transmitted wirelessly from the personal diabetes manager, a hand-held device that programs the pump with customized insulin instructions, monitors the operation of the pump, performs suggested bolus calculations, and contains an integrated blood glucose meter.

Twenty subjects with type 1 diabetes used the OmniPod system (Insulet, Bedford, MA) to manage their diabetes (15 female and 5 male subjects; mean age 43 years [range 27–68]; mean diabetes duration 20.8 years [4–53]). The following was the inclusion criteria: use of continuous subcutaneous insulin infusion therapy for at least 6 months, an HbA_{1c} (A1C) ≤8.5% (mean 7.1% [range of initial A1C 5.5–8.1]), measures glucose at least four times each day, and no more than one severe hypoglycemic or ketoacidosis episode within the past year and none within the past 3 months. The following were the exclusion criteria: clinical diagnosis of hypoglycemic unawareness, known dermal hypersensitivity to products that contain Beiersdorf Hypafix medical adhesive, pregnancy, and taking prescription medications that could complicate the management of glycemic control (i.e., steroids, diuretics, β-blockers).

Subjects recorded daily activities, insulin dosages, glucose results, and observations and were required to check glucose values using the personal diabetes manager's integrated Freestyle blood glucose meter (Abbott, Alameda, CA). Clinic visits were scheduled on days 3, 14, and 30 to reinforce the study protocol procedures and to evaluate patient status. Subjects completed an exit questionnaire. Each question required the subject to answer on a scale from 1 to 5, where 1 = most favorable, 5 = least favorable, and 3 = neutral response. The following are the results comparing the Pod with their current pump: convenience of using the OmniPod system = (means ± SD) 1.85 ± 0.93, satisfaction with wearing the OmniPod system = 1.7 ± 0.98, pain associated with automated cannula insertion = 2.0 ± 0.65, satisfaction with current insulin pump = 1.9 ± 0.45, wearing while sleeping = 1.15 ± 0.49, wearing while showering = 1.10 ± 0.45, and time involved in the OmniPod change process = 2.05 ± 0.89.

Ninety percent of subjects (18 of 20) preferred using the OmniPod's automated cannula insertion system versus inserting with their current infusion sets. All 20 subjects completed the 30-day study. A1C values at the end were significantly lower (mean 6.8% [range 5.4–7.6]; *P* value <0.002).

The results suggest that the OmniPod system was well received among existing pump therapy type 1 diabetic patients. Most subjects preferred the OmniPod system to their conventional insulin pump. Preliminary A1C results, in addition to feedback supplied by patients, indicate that there may be additional benefits related to using the OmniPod system that need to be studied further.

HOWARD ZISSER, MD
LOIS JOVANOVIC, MD

From the Sansum Diabetes Research Institute, Santa Barbara, California.

Address correspondence to Lois Jovanovic, MD, Sansum Diabetes Research Institute, 2219 Bath St., Santa Barbara, CA 93105. E-mail: ljovanovic@sansum.org.

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Use of U-500 Regular Insulin in Type 2 Diabetes

In a recent report in *Diabetes Care*, experience using U-500 regular insulin (U-500) in syndromic forms of insulin resistance was described (1). Due to its higher concentration, U-500 has pharmacokinetics that are believed to be similar to U-100 NPH insulin peaking later and lasting longer than U-100 regular insulin. These authors suggest that U-500 may be used in type 2 diabetic patients with severe insulin resistance who fail usual treatment (1). We report our experience using U-500 insulin in type 2 diabetic patients with poor glycemic control despite >200 units of insulin/day.

We studied 15 patients (7 men and 8 women, mean age 59.8 years, mean weight 126.6 kg) using a mean daily dose of insulin U-100 of 219 units and mean HbA_{1c} (A1C) of 9.8%. After initiation of U-500, the A1C decreased to 7.9% at 3 months and to 7.6% at 1 year. The patients required a mean of 285 units of U-500 at 3 months and 335 units at 1 year (this corresponds to the 57 and 67 markings on a U-100 syringe, respectively). Their weight increased by 3.2% at 3 months and by 1.6% at 12 months. At baseline, hypoglycemia rarely occurred (one to two episodes per month). The frequency of hypoglycemia did not change at 3 and 12 months after the initiation of U-500, and none of these episodes were severe. With the exception of insulin U-500, no other changes were made in the antidiabetes medications.

Reports on the use of U-500 in type 2 diabetic patients have been limited to several case reports and case series (2–4). The largest series examined 20 poorly controlled diabetic patients with severe insulin resistance, and a 1% reduction in A1C was observed after 6 months of administration of U-500 (4). In our series, reduction in A1C was more pronounced.

Our experience adds to the evidence from others that U-500 can be used effectively in a subset of type 2 diabetic patients with poor glycemic control despite >200 units of insulin daily (1–4). An ~2% reduction in A1C, small weight gain, and no increase in hypoglycemia were observed. This improvement in glycemic control could be related to delivery of higher doses of insulin, better absorption, and/or differences in duration of action. Large, prospective studies are needed to confirm these findings. Pharmacodynamic and pharmacokinetic studies of U-500 would be helpful to better understand optimal U-500 dosing regimens in this difficult-to-control subgroup of patients.

WAFIC S. WAFA, MD
MUKHTAR I. KHAN, MD, FACE

From the Division of Endocrinology, Diabetes and Metabolism, Department of Internal Medicine, State University of New York Upstate Medical University, Joslin Diabetes Center, Syracuse, New York.

Address correspondence and reprint requests to Mukhtar I. Khan, MD, FACE, Joslin Diabetes Center, 90 Presidential Plaza, Syracuse, NY 13202. E-mail: khanm@upstate.edu.

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