

Basal–Prandial Insulin Delivery in Type 2 Diabetes Mellitus via the V-Go™: A Novel Continuous Subcutaneous Infusion Device

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Abstract

Background:

The V-Go™ is a once-daily disposable device that allows coverage of basal and prandial insulin requirements over a period of 24 hours. The aim of this proof-of-concept study was to evaluate the clinical functionality, safety, and pharmacodynamics of the V-Go delivering insulin aspart and redistributing a single basal dose of insulin glargine as a constant basal infusion supplemented with prandial insulin in subjects with type 2 diabetes mellitus.

Methods:

In six subjects receiving once-daily subcutaneous (SC) injections of insulin glargine (≥ 15 U/day) with or without concomitant oral antidiabetic drugs, glargine was discontinued following a 3-day baseline phase. The V-Go was then applied to the lower abdomen of the subjects once daily for 7 days (days 1–3 inpatient, days 4–7 outpatient). Each V-Go provided a continuous 24-hour preset basal infusion rate of insulin aspart (0.6 U/h) and up to three daily prandial doses at mealtimes. Capillary blood glucose concentrations were measured at 11 time points per day during the baseline and inpatient phases and at 4 time points per day during the outpatient phase. Additionally, glucose profiles were measured continuously on all days.

Results:

The V-Go was well tolerated and operated as anticipated. The mean \pm SEM prestudy daily dose of SC insulin glargine was 33.3 ± 13.8 U; the mean daily total insulin aspart dose infused with the V-Go was 31.5 ± 7.5 and 32.3 ± 7.8 U for the inpatient and outpatient periods, respectively. Fasting blood glucose values were similar to those observed at baseline throughout the study, with nonsignificant (NS) reductions in readings collected during the outpatient phase before lunch (-35 ± 27 mg/dl) and before dinner (-38 ± 25 mg/dl). The 2-hour postprandial glucose trended lower from 231 to 195 mg/dl (NS) at breakfast, 234 to 166 mg/dl (NS) at lunch, and 222 to 171 mg/dl (NS) at dinner. Bedtime blood glucose decreased (mean change from baseline -52 ± 21 mg/dl; $P = 0.0313$), as did nighttime (3:00 AM) measurements (-20 ± 9 mg/dl; $P = 0.0313$). Overall glycemic control tended to improve, as shown by continuous glucose monitoring changing from 173 to 157 mg/dl ($P = 0.063$, NS) and 156 mg/dl ($P = 0.219$) during inpatient and outpatient periods, respectively. Glycemic variability assessed by the M value similarly tended to decrease from 33 ± 9 to 25 ± 4 (NS) and 21 ± 4 (NS) for inpatient and outpatient periods, respectively.

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Abbreviations: (AEs) adverse events, (CGM) continuous glucose monitoring, (CSII) continuous subcutaneous insulin infusion, (DCCT) Diabetes Control and Complications Trial, (ECG) electrocardiogram, (FBG) fasting blood glucose, (FPG) fasting plasma glucose, (HbA1c) hemoglobin A1c, (NS) nonsignificant, (OADs) oral antidiabetic drugs, (SC) subcutaneous, (T2DM) type 2 diabetes

Keywords: basal–prandial insulin, continuous subcutaneous insulin infusion, glycemic control, h-Patch, type 2 diabetes, V-Go

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Abstract cont.

Conclusions:

These first data suggest that use of the V-Go is an attractive alternative to SC insulin injection therapy because metabolic control appears to be maintained or even improved without increasing daily insulin doses.

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