MOTIV4CONTROL

Managing Optimization and Titration of Insulin delivery with V-Go 4 improved glycemic control

Evaluation of a Weekly Physician-Driven Insulin Titration Algorithm for a Wearable Insulin Delivery Device

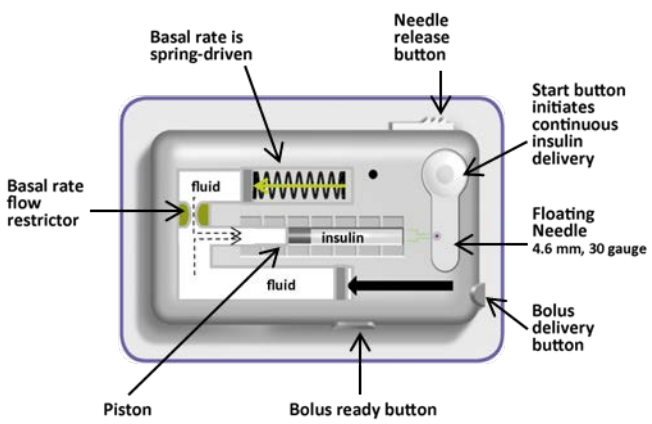
Sandip Mehta, DO[1] , Mara Vecchio, BS, RN[2] , Carla Nikkel, BS, RD, LD, CDE, CDTC[3]

BACKGROUND AND METHODS

- To support development of dosing guidance, this retrospective proof-of-concept study evaluated the use of a weekly physician-driven insulin titration algorithm in adult patients diagnosed with Type 2 diabetes prescribed V-Go in-order to formulate the design of a prospective patient-driven insulin titration study.
- Improvement in glycemic control with V-Go is well documented yet no data exists evaluating efficacy and safety outcomes when a specific dosing algorithm is applied for titration.
- Primary endpoints were achievement of an A1C target <7.5% and to evaluate the incidence of hypoglycemia based on self-monitored blood glucose (SMBG) logs.
- Adjustments to insulin were captured for all weekly visits between V-Go initiation and the first follow-up A1C post-initiation.

V-Go® WEARABLE INSULIN DELIVERY DEVICE

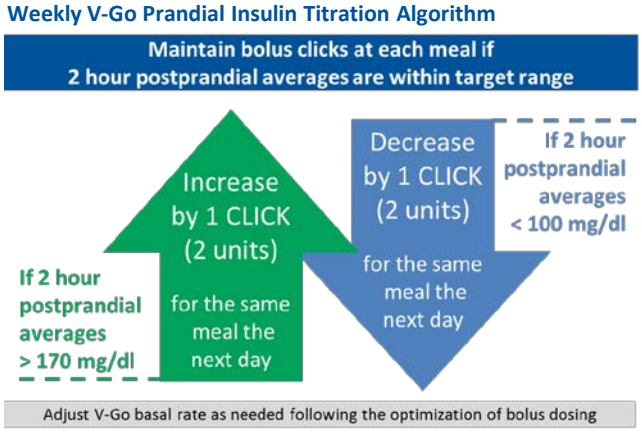
- Filled with U-100 fast acting insulin and delivers a continuous preset basal rate of insulin over 24 hours and provides on-demand bolus dosing at mealtimes with the click of a button.
- V-Go is available in basal rates of 20, 30 or 40 units/24 hours and can administer up to an additional 36 units of insulin for mealtime bolus dosing in 2-unit increments.



INSULIN TITRATION APPROACH

- Daily four-point (fasting and 2 hour postprandial breakfast, lunch and dinner) SMBG were used for weekly titration decisions.
- Basal rates were adjusted if needed following the optimization of bolus dosing for all meals.

Weekly V-Go Prandial Insulin Titration Algorithm



RESULTS

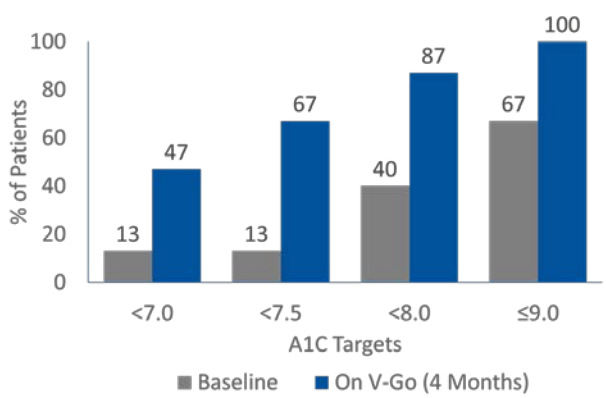
Baseline Characteristics (N=15)

Age, (years)	60 ± 9
Weight, (lbs)	256 ± 73
Range, (lbs)	154 to 389
BMI, (kg/m^2)	39 ± 10
A1C, (%) Range, (%)	8.7 ± 1.4 6.7 to 10.8
Insulin TDD, (Units/day)* Range, (Units/day)	144 ± 81 45 to 292

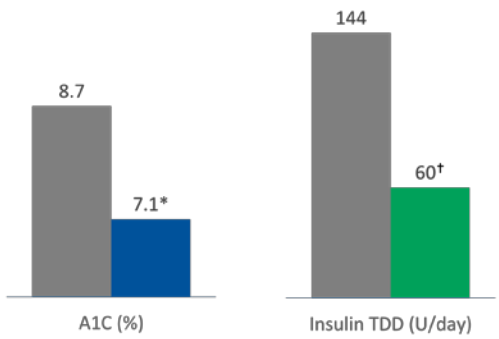
*Represents 12 patients on insulin
Data are mean ± SD

- Of the 24 patients screened, fifteen patients met eligibility requirements and were evaluated after 4 months of V-Go use.
- After one week, bolus up-titration occurred in 73% of patients (18 to 33 bolus U/day) and active bolus titration continued for two additional weeks. Basal rates increased in five patients and decreased in one patient during the first month.
- A1C target achieved in 67% of patients and a mean significant A1C reduction of 1.6%; p<0.001, was observed with a significant decrease in the mean total daily dose (TDD) of insulin.
- Hypoglycemia incidence decreased from 23% at baseline to 7% of patients by month four.
- No change in weight from baseline was observed.

Percent of Patients Achieving A1C Targets



A1C and TDD from Baseline to 4 Months on V-Go



* p<0.001, †p=0.002

CONCLUSION

- With appropriate titration and management, insulin therapy is the most effective option to treat hyperglycemia.
- The adoption of this simple physician-driven dosing titration approach proved safe and efficacious.
- Applying these findings to a patient-driven approach needs further investigation.

[1]Texas Star Adult Medicine, Bedford, TX , [2]Texas Health Research & Education Institute, Dallas, TX,
[3]Valeritas, Inc., Bridgewater, NJ

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