

IMPROVED GLYCEMIC CONTROL AND REDUCED GLUCOSE EXCURSIONS WITH THE V-GO® INSULIN DELIVERY DEVICE IN THE LONG-TERM CARE SETTING

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ORIGINAL ABSTRACT

Objective: Poorly controlled diabetes mellitus (DM) and fluctuations in blood glucose (BG) present a significant challenge for patients and their healthcare team in the long-term care (LTC) setting. The objective of this study was to assess impact of utilizing V-Go, a disposable insulin delivery device, to deliver and simplify insulin therapy.

Methods: A healthcare team collaborative retrospective chart review of de-identified data evaluated the effect of utilizing V-Go in four LTC patients with DM on insulin therapy. Patients were switched from insulin injections to the V-Go device. Daily BG readings were obtained by nursing staff at up to 4 daily time points for 31 days pre-V-Go and 31 days post-V-Go initiation. Efficacy variables included proportion of BG Time in Range (100-200mg/dl), change in mean daily BG, change in injection sites and impact on insulin administration costs.

Results: Statistically significant mean BG reduction (SD) was observed: 198 mg/dl (10.5) pre-V-Go to 176mg/dl (34.9) during V-Go therapy (p=0.009). BG Time in Range during V-Go therapy increased to 56.2% from 46.1% pre-V-Go. Glucose excursions >200mg/dl were reduced 32% and there were no reports of hypoglycemic events below 50mg/dl. The number of unique daily injection sites decreased from pre-V-Go average of 5.25 to 1 application of V-Go. Calculated nursing/labor time and cost savings were 26.3 mins/day/patient and \$20,948/year/four patients. Calculated mean A1C reduction was 8.53% to 7.76%. Total daily insulin dose was reduced by 9% from 78.6 U/day to 71.3 U/day.

Conclusion: Use of V-Go in the LTC setting in patients requiring insulin therapy demonstrated favorable changes in glycemic control, improved time in range, fewer injection sites and decreased nursing/labor costs. In addition, the patients achieved a calculated average A1C Quality measure of <8%. Larger controlled studies are needed to fully evaluate the use of V-Go in this patient population.

V-GO DISPOSABLE INSULIN DELIVERY DEVICE

V-Go provides the convenience of basal-bolus therapy in one injection that may improve adherence.

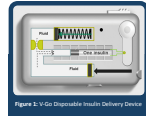


Figure 1 - V-Go Disposable Insulin Delivery Device

METHODS

- A healthcare team collaborative retrospective chart review of de-identified data evaluated the effect of utilizing V-Go in four LTC patients with DM on insulin therapy and another patient was added to the review for a total of five patients.
- Patients that were switched from SOC insulin injections to the V-Go device.
- Daily BG readings were obtained by nursing staff at up to 4 daily time points for 31 days pre-V-Go and 31 days post-V-Go initiation.
- Efficacy and cost variables included proportion of BG Time in Range (100-200mg/dl), change in mean daily BG, number of injection sites and impact on insulin administration time and costs.

HEALTH ANALYSIS

- Evaluate the % change of diabetes quality metrics including: mean daily BG, BG at up to 4 times per day, Time in Range (100mg/dl - 200mg/dl), variability as measured by SD, and change in glucose fluctuations (>200mg/dl) for LTC patients on V-Go therapy.
- Evaluate the change in insulin administration time and cost
- Evaluate the decrease in number of injections/sites per day

RESULTS

Patient Demographics and Collection of Blood Glucose Data

- The baseline demographics for the five NH patients (1 male and 4 female) at one LTC facility included an average age of 78 years (68-87) with a duration of insulin-dependent diabetes >1 year (Table 1).
- Other metabolic complications and comorbid conditions were hypertension (100%), Dyslipidemia, Depression and Coronary Artery Disease (60%), Congestive Heart Failure (40%) and Peripheral Vascular Disease (20%). The mean baseline average daily BG was 204.0 mg/dl and calculated baseline A1C was 8.7%.
- In total 1119 BG measurements were collected with 510 and 609 blood glucose measurements recorded and analyzed pre V-Go and during V-Go, respectively (Table 2).

Statistically significant improvements in glucose control were observed from the pre V-Go to during V-Go time period:

- Mean Daily BG (SD) decreased from 204.0 mg/dl (87.7) to 163.5 mg/dl (65.8) (p<0.001), as well as at the time periods of 12pm (p=0.044), 4pm (p<0.001) and 9pm (p<0.001) (Figure 1).
- The Time in Range that is defined as between 100-200 mg/dl increased to 59.8% during V-Go therapy from 42.2% pre V-Go. An Odds Ratio Analysis for V-Go as compared to Pre V-Go SOC showed an odds ratio of 1.94, 95% CI 1.153-2.46 with p-value <0.001 (Table 3).
- Glucose excursions >200 mg/dl were reduced with an Odds Ratio of 0.36 comparing V-Go therapy to pre V-Go SOC with 95% CI 0.28-0.46 with p-value <0.001. In addition, there were no reports of hypoglycemic events <50 mg/dl.
- Calculated mean A1C reduction from 8.7% to 7.3% was observed.
- The number of unique injection sites decreased from pre V-Go average of 5.25 to an average of 1 during V-Go therapy.
- Calculated nursing/labor time and cost savings were 26.3 minutes/day/patient or \$26,185/year/5 patients based on time and motion survey analysis.

Table 1 - Patient Demographics

Baseline Characteristics	n	%
N	5	(68 - 87)
Age (years)	78	(68 - 87)
Male/Female	1/4	
Duration of Diabetes		
> 1 year	5	
Baseline Mean BG (mg/dl)	204	
Baseline Calculated A1C (%)	8.7	
Complications, n, %		
Hypertension	5	100%
Dyslipidemia	3	60%
Depression	3	60%
Coronary Artery Disease	3	60%
Congestive Heart Failure	2	40%
Peripheral Vascular Disease	1	20%

Table 2 - Mean Variable Analysis, Standard Deviation and Significance

Variable	n	Mean	SD	p-value @ 50%	Min	Max
Pre V-Go Baseline	511	204.0	87.7		44	343
During V-Go Baseline	554	163.5	65.8	0.001	62	241
Pre V-Go 12pm	100	213.9	86.7		36	305
During V-Go 12pm	101	189.4	75.6	0.044	60	238
Pre V-Go 4pm	100	224.4	88.8		60	400
During V-Go 4pm	100	165.7	57.8	<0.001	41	248
Pre V-Go 9pm	100	244.6	90.5		11	400
During V-Go 9pm	100	185.0	67.7	<0.001	79	314
Total Pre V-Go	510	204.0	87.7		36	400
Total During V-Go	609	163.5	65.8	<0.001	41	314

Table 3 - Odds Ratio Analysis for Time in Range and Hyper-Glycemic Fluctuations

Treatment	Parameter Achieved (mg/dl)	Odds Ratio	95% CI Odds Ratio	p-value
V-Go compared to Pre-V-Go	100-200	1.94	1.153-2.46	<0.001
V-Go compared to Pre-V-Go	>200	0.36	0.28-0.46	<0.001

Figure 1 - Mean Daily Blood Glucose Measurements (mg/dl)

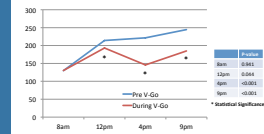


Figure 2 - Percent Time in Range

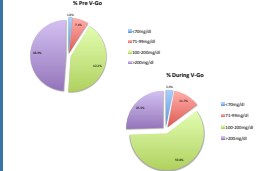
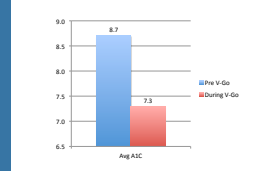


Figure 3 - Calculated A1C Levels, Pre-V-Go and During V-Go Treatment



SUMMARY AND CONCLUSIONS

A retrospective chart review of 5 patients that were placed on V-Go was completed to assess the impact from 31-days before to 31-days after transition. In total, 1,119 blood glucose measurements were analyzed over this time period.

Utilizing the V-Go disposable insulin delivery device to optimize insulin therapy resulted in favorable impact to a number of key diabetes metrics, including:

- Statistically significant reductions were observed in mean daily BG (mg/dl) and mean BG measurements at 12pm, 4pm and 9pm of -40.5, -20.5, -75.7, and -59.6, respectively.
- For above BG measurement time periods, Standard Deviation was reduced to 65.8, 75.6, 57.3, and 58.2 reflecting decreased variability.
- Time in Range (100-200mg/dl) increased to 59.8% from 42.2% with no hypoglycemic events recorded < 50mg/dl during the V-Go therapy period.

Cost savings with the change in insulin administration with V-Go, due primarily to decreased nursing and labor administration time of 26.3 per patient/day and a decrease in insulin injection sites from 5.25 to 1, resulted in a projected annual savings of over \$26,000 for these five patients.

Optimizing insulin therapy for older patients in the NH/LTC setting was simple, efficacious and also resulted in substantial cost savings.

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BACKGROUND

According to HHS, people who reach the age of 65 have a 40% chance of entering a nursing home and 10% of the people who enter nursing homes will stay there at least five years, with the average stay being two-and-a-half years. (1) There are over 15,700 nursing homes in the country servicing more than 1.4 million residents. (2,3)

Evidence supports that patients with poor glycemic control and glucose fluctuations (hyper- and hypo-glycemic events) are:

- More likely to have diabetic and cardiovascular complications, falls, and higher healthcare costs. (4,5)
- At increased risk for cognitive impairment, vascular dementia, Alzheimer's dementia and hospitalization. (6)
- Present a significant challenge for the healthcare staff that cares for them.
- Improvements in insulin administration and timing could improve glycemic control helping to reduce patient morbidity and, possibly, mortality.

More than 25% of the US population and nursing home residents aged >= 65 years have diabetes. (7,8) Projections by the CDC suggest that the prevalence will double in the next 20 years due, at least in part, to the aging population.

V-Go® Disposable Insulin Delivery Device (Figure 1) is approved for the continuous delivery of insulin in adult patients requiring insulin and is designed to provide patients a simple method to deliver basal-bolus insulin therapy using one insulin type (U-100 fast acting). V-Go delivers a continuous preset basal rate of insulin over 24 hours and provides on-demand bolus dosing at mealtimes, which may help improve glycemic control.