EVALUATING COST OF THERAPY AND CLINICAL EFFICACY WITH V-GO® IN PATIENTS WITH SUB-OPTIMALLY CONTROLLED DIABETES FROM AN ENDOCRINE SPECIALTY SYSTEM

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Background and Introduction

Managing diabetes can produce significant expenditures and the steady rise in the cost of insulin presents a financial dilemma for many patients and payers. The affordability of insulin can affect adherence which can impact rates of diabetes–related health complications. These events may affect overall health care costs due to needed medical intervention including emergency room visits, hospitalization, and other therapy considerations. Addressing patients' concerns for an affordable and efficacious insulin regimen is necessary as the number of people with diabetes increases and subsequently those that will need insulin therapy.

V-Go® has previously demonstrated to be safe for use with short- or fast-acting insulin, and has been shown to allow patients to achieve blood sugar control with a continuous preset basal rate of insulin and on-demand mealtime bolus dosing. The V-Go Disposable Insulin Delivery system was first cleared for use by the FDA in December 2010.

The purpose of this retrospective study was to evaluate the impact on glycemic control and other variables for patients with diabetes who were transitioned to the V-Go® Disposable Insulin Delivery Device (V-Go) and managed at a large multi-centered endocrine practice in Jacksonville, Florida.

Objective

A retrospective analysis evaluated costs and efficacy for patients with sub-optimally controlled diabetes being switched to the V-Go Disposable Insulin Delivery Device (V-Go) to simplify insulin delivery.

Methods

An electronic medical records database from a large endocrine system was queried. Data was collected starting for patients initiating August 1, 2012 and completed March 1, 2016. The data collected for this analysis was conducted by the primary investigator or designee acting under the authority of Northeast Florida Endocrine and Diabetes Associates in the United States of America. De-identified data collected will be analyzed for statistical reporting in conjunction with Mercer University College of Pharmacy.

Inclusion Criteria

- Diagnosed with Diabetes (Type 1 Diabetes, Type 2 Diabetes, or LADA)
- Age > 21 years
- HbA1c >7
- Initially using any insulin therapy, oral antihyperglycemic medications and/or naive to diabetes treatment
- Initiated V-Go therapy
- Baseline HbA1c value captured within 120 days of V-Go initiation
- Minimum of one subsequent HbA1c lab value on V-Go therapy within 12 months of initiation
- Patient follow up care provided with subsequent HbA1c value collected post V-Go initiation

Exclusion Criteria

- Treatment with U-500 regular insulin preceding V-Go therapy or during V-Go use
- Insulin delivery via traditional insulin pumps immediately preceding V-Go initiation
- Patients that are pregnant, lactating or intending to become pregnant
- Insulin dosing undeterminable at baseline or after initiation of V-Go therapy due to insufficient chart information
- Current diagnosis of cancer with chemotherapy treatment.
- Diagnosis of HIV with protease inhibitor therapy or other infectious or immune related diseases with treatments that increase insulin resistance

Statistics

Mercer University College of Pharmacy analyzed and verified the findings. In general, descriptive statistics (mean, median, range) will be used to report HbA1c values and other continuous variables from the patient cohort as a whole and each individual cohort.

- Two tailed paired t-test (parametric) was used for reporting change in HbA1c
- Wilcoxon matched pairs signed rank test (nonparametric) was used for reporting change in insulin and change in weight
- Two way ANOVA was used for comparison between groups

Descriptive analysis will be used to compare percentages between groups and over time for reported hypoglycemia and other variables. Data involving insulin dosing and other measures with V-Go will use Last Observation Carried Forward (LOCF) for imputing missing data beyond the initiation visit.

The efficacy variable was the reduction in A1C for patients on insulin at baseline switched to V-Go longitudinally at office visit (OV) follow-up times. Cost evaluation was calculated using wholesale acquisition cost (WAC) pricing for insulin, delivery devices, and concomitant antidiabetic medications (CAM).

Results

Efficacy and Safety Assessment:

Sixty patients were identified who had transitioned to V-Go therapy from previous insulin therapies. At baseline patients had a mean A1C of 9.6±2.08%, body weight of 95± 20.35kg, and total daily insulin dose (TDD) of 82 u/day (0.86u/kg). Additionally, 58% (N=35) were on CAMs and 77% (N=46) were on multiple daily insulin injections (MDI). At the 1st office visit (OV1) with a mean duration of 61±36 days, switching to V-Go resulted in a mean A1C reduction of -1.2±1.6% (p<0.0001) and a 50% reduction of patients with an A1C≥ 9.0%. Despite the robust improvement in A1C the overall incidence of reported hypoglycemia was similar to baseline and there was a mean increase of 2.1± 19.43 kg in weight observed.

Cost of Therapy Analysis:

Baseline cost of $950 per patient per month (PPPM) was reduced to $866 PPPM in part due to a 22% (-19 u/day,-.21u/kg) reduction of TDD. Additional realized savings were attributed to having a reduced percentage (50%) of patients on CAM, 58 to 50%.

Table 1: Demographics (Continuous Variables)

	Mean	SD
Age	63.95	10.14
Baseline A1C	9.64	2.08
Baseline weight	207.72	46.70
Insulin dose at baseline	82.20	40.87
Baseline BMI	32.25	6.45

Table 2: Demographics (Categorical Data)

		N	%
Baseline CHF	N	57	95
	Y	3	5
Baseline HTN	N	21	35
	Y	39	65
Baseline Neuropathy	N	43	72
	Y	17	28
Baseline Renal Disease	N	57	95
	Y	3	5
Baseline Retinopathy	N	57	95
	Y	3	5
Gender	F	26	43
	M	34	57
Hispanic	N	57	95
	Y	1	2
	Unknown	2	3
Race	Asian	1	2
	Black	11	18
	Caucasian	46	77
	Native American	1	2
	Unknown	1	2
Smoker	Former	20	33
	N	28	47
	Unknown	3	5
	Y	9	15
Baseline Patients on Insulin	N	0	0
	Y	60	100
Baseline Basal Insulin Regimen	Basal	12	20
	MDI	46	77
	Pre-Mix	2	3

Table 3: Results after using V-Go therapy: A1C, Total Daily Insulin Dose, and Cost of Therapy Compared to Baseline

	Mean	SD
Number of days on V-GO	61.27	36.23
Change in A1C:		
Baseline A1C	9.64	2.08
V-Go OV A1C	8.41	1.57
Change in Total Daily Insulin Dose (U/Day)		
Insulin dose at baseline	82.20	40.87
Insulin dose after V-Go	63.70	32.92
Change in Cost of Diabetes Therapy Per Patient Per Month (PPPM)		
Cost of therapy at baseline	$950.07	499.68
Cost of therapy at first visit	$866.37	317.43

OV = Office Visit results after initiating V-Go

Percentage with concomitant medications at baseline 35/60 (58%); Percentage with concomitant medications after V-Go 30/60 (50%)

Table 4: Analysis of Cost Effectiveness With V-Go

	Mean Reduction	SD	95% CI	P-value
Cost Improvement After Switching to V-Go	$83.70	380	-14.46-322.1	
A1C Improvement After Switching to V-Go	1.12	1.6	0.8138-1.9585	<.0001
Reduction in Insulin Dose After Switching to V-Go	18.5 U/Day	38.2	8.63-32.39	0.0004

Percentage with concomitant medications at baseline 35/60 (58%); Percentage with concomitant medications after V-Go 30/60 (50%)

Figure 1. Change in A1C and Total Daily Insulin Dose at First Office Visit for V-Go Therapy vs. Baseline (P < 0.001)

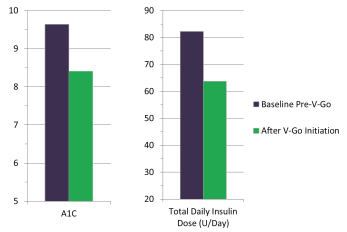
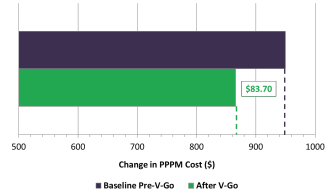


Figure 2. Change in Cost of Diabetes Therapy after V-Go Initiation vs. Baseline (Per Patient Per Month, PPPM)



Summary and Conclusions

Patients with sub-optimally controlled diabetes switched to V-Go achieved significant A1C improvements with a reduction in total daily insulin dose, concomitant anti-diabetes medications, and improved cost impact for payers which may improve affordability for patients. This real world assessment validates similar findings of previous observations with V-Go.

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