Advances in Therapy

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Clinical Benefits over Time Associated with Use of V-Go Wearable Insulin Delivery Device in Adult Patients with Diabetes: A Retrospective Analysis

Sutton D, Higdon C, Nikkel C, Hilsinger KA

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Abbreviations

A1C = Glycated hemoglobin

EMR = Electronic medical record

MDI = Multiple daily injections

NIGLM = Non-insulin glucose lowering medications

OV = Office visit

SD = Standard deviation

SE = Standard error

T2DM = Type 2 diabetes mellitus

TDD = Total daily dose

U = Unit(s)

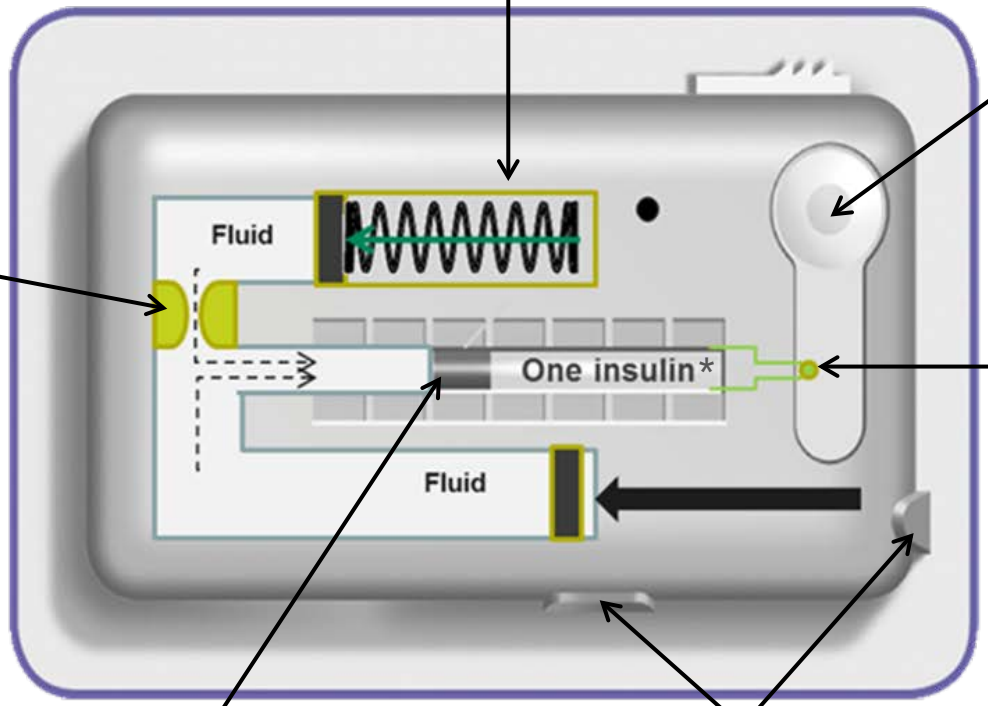
Introduction

- Insulin remains the most potent glucose-lowering agent with the highest potential to achieve glycemic control.[1,2]
- Over 70% of physicians report that patients do not take insulin as prescribed, with the number of injections and the need to inject insulin at a specific time or with meals cited as the two most common difficulties that impact adherence.[3]
- Advances in insulin delivery over time have led to better patient outcomes and improved quality of life and safety.
- V-Go® (Valeritas, Inc., Bridgewater, NJ, USA) is a wearable basal-bolus mechanical insulin delivery device that delivers a continuous basal rate of insulin, as well as on-demand mealtime dosing.
- Long-term clinical and economic variables were evaluated retrospectively in 103 patients with diabetes sub-optimally controlled on previous therapies transitioned to V-Go.

[1]Garber AJ. et al. Endocr Prac. 2017. Feb:23 (2): 2017-238. [2]American Diabetes Association. Standards of medical care in diabetes, 2017. Diabetes Care 2017: 40 (suppl 1): S64-S74. [3]Peyrot M. et al. Diabetes Obes Metab. 2012 Dec: 14 (12): 1081-7.

Introduction

V-Go delivers insulin in a physiologic manner for 24 hours



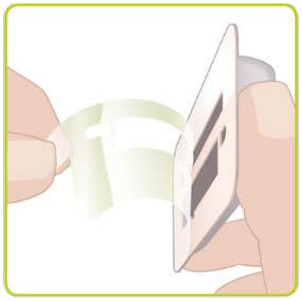
*Fast-acting insulin

Introduction

Fill, Apply and Use of V-Go

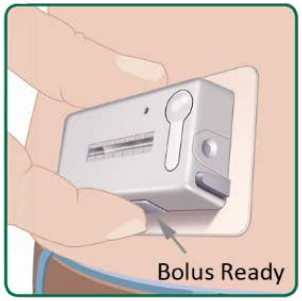
Fill
Patients fill a new V-Go with insulin each day.

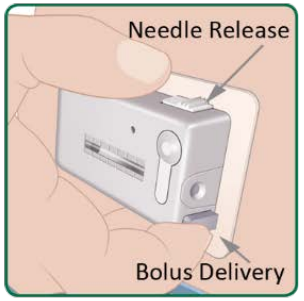
Apply
Patients place V-Go on their skin and press the Start Button to insert the needle and start the preset basal rate.



Use
Patients use the Bolus Ready Button and the Bolus Delivery Button to deliver on-demand insulin at mealtimes.

1 click= 2 units





After 24 hours, activate the needle release button, remove V-Go and replace with a new filled V-Go.

Introduction

Three dosing options are available for V-Go

V-Go option	Preset basal rate	+	On-demand bolus dosing	=	Total available insulin
V-Go 20	20 U/24 hr (0.83 U/hr)	+	Up to 36 U of insulin in 2-U increments for on-demand bolus dosing at meals (1 click = 2 U)	=	56 U
V-Go 30	30 U/24 hr (1.25 U/hr)	+		=	66 U
V-Go 40	40 U/24 hr (1.67 U/hr)	+		=	76 U

Easy to fill, apply, use and remove every 24 hours.
Requires only one insulin type (U-100 fast acting) for filling.
Fully disposable with no batteries, infusion sets, or electronics.

V-Go Instructions for Patient Use. Valeritas, Inc.; 2011.

Introduction

Important risk information for the V-Go

- Insulin requirements:
  - If regular adjustments or modifications to the basal rate of insulin are required in a 24-hour period, or if the amount of insulin used at meals requires adjustments of less than 2-U increments, use of V-Go Disposable Insulin Delivery device may result in hypoglycemia.
- The following conditions may occur during insulin therapy with V-Go:
  - Hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose).
  - Skin irritation from the adhesive pad or infections at the infusion site.
- V-Go should be removed before any MRI testing.

V-Go Instructions for Patient Use. Valeritas, Inc.; 2011.

Methods

- Study was conducted as a retrospective review of the EMR database from a multicenter endocrine practice system in Jacksonville, Florida.
- Patients managed per clinician standard of care.
- A1C measurements, insulin dosing, insulin regimens (e.g. basal, premix, basal-bolus), weight, NIGLM, and patient-reported hypoglycemic events were obtained from the EMR records at baseline and for up to 4 follow-up office visits (OVs) where an A1C measurement was documented.
- The overall population was analyzed for changes in clinical variables as well as further analyses were conducted by subset (all patients prescribed insulin and those specifically prescribed a basal-bolus MDI insulin regimen at baseline).
- Impact to direct pharmacy budget was evaluated for patients prescribed basal-bolus MDI therapy transitioned to V-Go.

Results

	All Patients (*N=103*)	All Insulin Patients[a] (*n* =80)	Basal-Bolus (MDI) Patients[b] (*n* = 58)
Baseline Characteristics			
Age, years	63 ± 11	64 ± 10	64 ± 10
Weight, kg	94.4 ± 22.3	95.8 ± 21.6	98.9 ± 22.3
BMI, kg/m^2	31.98 ± 6.36	32.37 ± 6.24	32.88 ± 6.50
A1C, %	9.80 ± 2.01	9.79 ± 2.18	9.73 ± 2.25
Type of Diabetes			
Type 1	4 (4)	3 (4)	2 (3)
Type 2	99 (96)	77 (96)	56 (97)
Baseline Prescribed Treatment Regimen			
Diet and Exercise Only	1 (1)	-	-
NIGLM Only	22 (21)	-	-
Insulin ± NIGLM	80 (78)	80 (100)	58 (100)
Basal-Bolus	58 (56)	58 (73)	58 (100)
Basal-Only	18 (18)	18 (23)	-
Premixed	3 (3)	3 (4)	-
Prandial Only	1 (1)	1 (1)	-
Insulin TDD, units/day	84 ± 44	84 ± 44	99 ± 40
TDD Range, units/day	0 – 200	10 – 200	32 – 200

Data are *n* (%) or mean ± SD

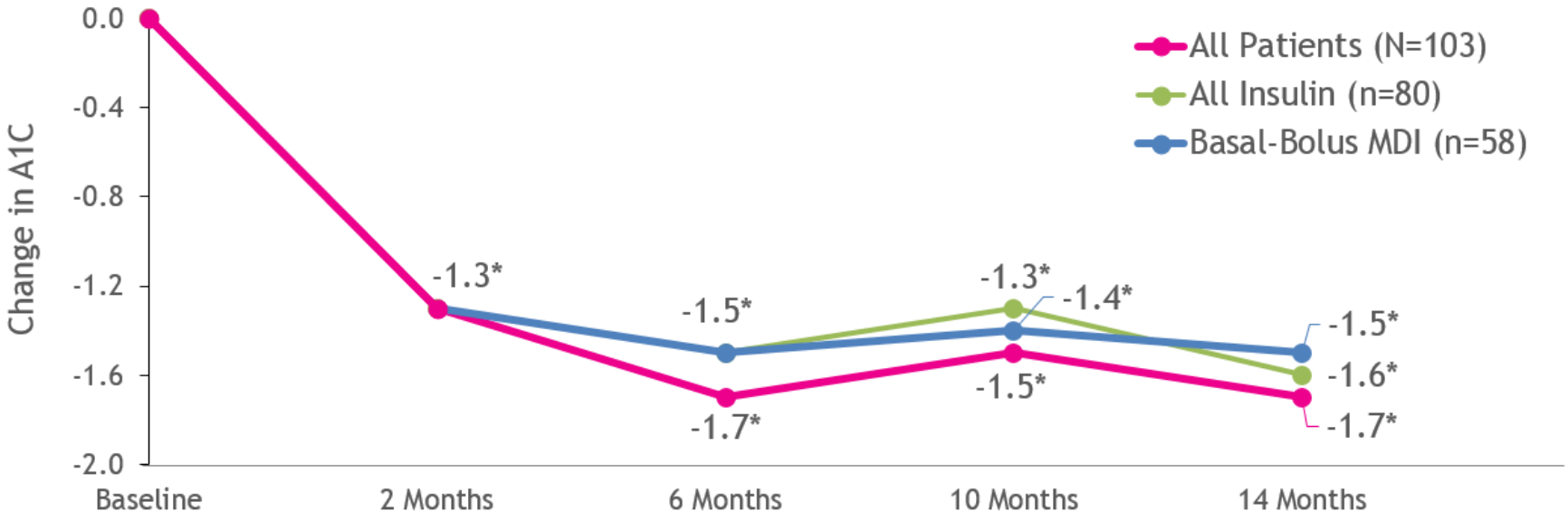
[a] Includes basal-only, premix, prandial and basal-bolus insulin regimens. [b] Includes only patients prescribed basal-bolus regimens.

BMI= Body Mass Index, TDD=Total Daily Dose

Percentages may not add up to 100% due to rounding.

Results

Change in A1C

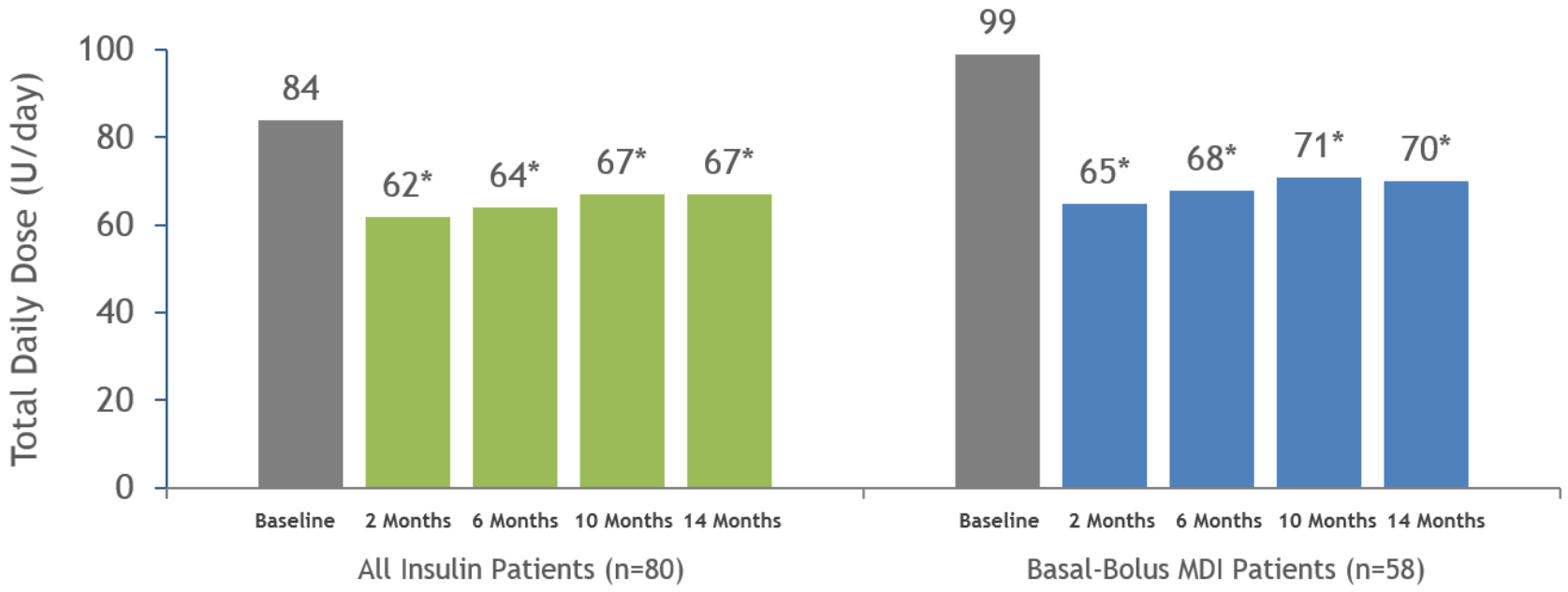


Patients experienced statistically significant decreases in A1C at all follow-up visits compared to baseline after switching to V-Go for insulin delivery.

*P<0.001
Insulin cohort includes patients prescribed: basal-only, basal-bolus, premix or prandial-only at baseline

Results

Insulin Total Daily Dose of Insulin



Patients who used insulin at baseline, as well as the cohort of patients who used a basal-bolus MDI regimen at baseline experienced statistically significant decreases in TDD of insulin at all follow-up visits compared to baseline after switching to V-Go for insulin delivery.

*P<0.05 compared to baseline
Insulin cohort includes patients prescribed: basal-only, basal-bolus, premix or prandial-only at baseline

Results

	All Patients (N=103)		All Insulin Patients[a] (n=80)		Basal-Bolus (MDI) Patients[b] (n=58)	
	Baseline	14 months	Baseline	14 months	Baseline	14 months
Concomitant NIGLM	69 (67)	57 (55)	47 (59)	42 (53)	29 (50)	29 (50)
Metformin	48 (47)	39 (38)	30 (38)	24 (30)	19 (33)	17 (29)
GLP-1 Receptor Agonist	28 (27)	18 (17)	19 (24)	16 (20)	10 (17)	10 (17)
Sulfonylurea	14 (14)	1 (<1%)	5 (6)	1 (1)	2 (3)	1 (2)
DPP-4 Inhibitor	8 (8)	1 (<1%)	4 (5)	1 (1)	0 (0)	1 (2)
TZD	6 (6)	2 (2)	5 (6)	2 (3)	4 (7)	2 (3)
DPP-4 I/Metformin	5 (5)	0 (0)	3 (4)	0 (0)	1 (2)	0 (0)
SGLT-2 Inhibitor	5 (5)	16 (16)	3 (4)	13 (16)	2 (3)	7 (12)
Metformin/Sulfonylurea	2 (2)	0 (0)	1 (1)	0 (0)	1 (2)	0 (0)
Number of NIGLM						
0	34 (33)	45 (44)	33 (41)	37 (46)	29 (50)	28 (48)
1	35 (34)	43 (42)	30 (38)	32 (40)	22 (38)	24 (41)
2	23 (22)	11 (11)	12 (15)	8 (10)	4 (7)	4 (7)
3	9 (9)	4 (4)	4 (5)	3 (4)	3 (5)	2 (3)
4	2 (2)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data are n (%)

[a] Includes basal-only, premix, prandial and basal-bolus insulin regimens. [b] Includes only patients prescribed basal-bolus regimens

DPP= Dipeptidyl Peptidase, GLP-1=Glucagon Like Peptide, NIGLM=Non-insulin Glucose Lowering Medication, SGLT=Sodium Glucose Linked Transporter, TZD=Thiazolidinediones.

Percentages may not add to 100% due to rounding

Results

Diabetes Related Direct Pharmacy Costs in Patients Prescribed Basal-Bolus at Baseline

Costs in US $ Per Patient Per Month	Baseline Basal-Bolus (MDI) N=58		On V-Go (14 Months) N=58	
NIGLM		$176		$187
Prescribed Insulin TDD	99 U	$898	70 U*	$556*
Pen needles/syringes/V-Go	4 pen needles or syringes	$49	1 V-Go*	$332
Total Diabetes Therapeutic Costs		$1122		$1097
Change in A1C from Baseline				-1.5%[a]

[a]Change in A1C reflective of change in glycemic control at study end in this cohort
*TDD includes supplemental insulin prescribed in 6 patients and delivery costs accounts for pen needles/syringes as applicable
Data are means and all costs are normalized based on 30 days and rounded to the nearest dollar, based on WAC=Wholesale Acquisition Cost based on ProspectoRx [database online]. Tampa, FL: Elsevier, Gold Standard, Inc.; 2014. URL: https://prospectorx.com/Home.aspx. Accessed January 1, 2018.

Results

- The percent of patients at high risk (A1C >9.0%) was reduced from 59% at baseline to 26% (p<0.001) at the 14 month visit.
  - In addition, 50% of patients overall achieved an A1C <8% with V-Go at the 14 month visit compared to 17% at baseline (p<0.001).
- There were significant decreases in mean ± SE TDD with V-Go of 21 ± 3.8 units/day after 2 months, 20 ± 3.8 units/day after 6 months, 16 ± 4.0 units/day after 10 months and 17 ± 4.5 units/day after 14 months compared to baseline (p<0.0001). Reductions were more pronounced in patients transitioning to V-Go from basal-bolus MDI regimens.
- By the 14 month visit, the overall study population experienced a mean weight gain of 3.18 kg, p=0.029 from baseline.
  - Patients prescribed a basal-bolus MDI regimen prior to V-Go experienced a change in weight of 0.26 kg, p=0.897.
- The incidence of patient-reported hypoglycemia documented at baseline was similar to the documented incidence at 14 months.

Results

- At 6 months, 88% of patients had documented continued V-Go use, 5% had documented discontinuation and 7% were lost to follow-up.
- At 14 months, 68% of patients had continued V-Go use, 14% had discontinued, and 18% were lost to follow-up.
- Reasons documented for discontinuation were due to insurance coverage/cost (n=6), insufficient insulin volume with V-Go (n=2) and skin irritation, no longer requiring insulin, or patient preference (n=1 each). The reason for V-Go discontinuation was not reported in 3 patients.

Discussion

- Advances in insulin delivery mode can address barriers to insulin use.
- V-Go is an innovative, convenient and flexible insulin delivery option designed to replace MDI and simplify basal-bolus therapy.
- The current study demonstrated that V-Go use was associated with improved A1C that was sustained for over a year in a population of uncontrolled patients in a real-world setting.
- Cost can be a barrier to insulin adoption and adherence. In the cohort of patients using a basal-bolus MDI regimen at baseline, there was a net savings in the direct pharmacy cost of diabetes therapy with use of V-Go.
- In the current study, there was no patient-reported increase in hypoglycemia documented with use of V-Go, and the weight increase in the overall population was within expected range for insulin use.

Conclusion

- Patients with sub-optimally controlled diabetes were safely transitioned to V-Go and achieved significant and sustained A1C improvements with a reduction in TDD of insulin from baseline.
- V-Go is an advancement in insulin delivery that can address multiple barriers to insulin initiation and adherence and ultimately improve patient outcomes.

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- This study was reviewed and approved by Allendale Investigational Review Board prior, and a waiver of informed consent was granted. All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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