DiabetesTherapy

OPEN ACCESS

PEER-REVIEWED SLIDE DECK

Use of V-Go® Insulin Delivery Device in Patients with Sub-optimally Controlled Diabetes Mellitus: A Retrospective Analysis from a Large Specialized Diabetes System

Lajara R, Fetchick DA, Morris TL, Nikkel C. Diabetes Ther. 2015.

This slide deck represents the opinions of the authors. Valeritas, Inc., Bridgewater, NJ, USA provided funding for investigational review board review and publication. Medical writing assistance for this study was provided by Maria Paluselli. For a full list of acknowledgments and disclosures for all authors of this article, please see the full text online.

Abbreviations

ADA = American Diabetes Association

CI = Confidence interval

EMR = Electronic medical record

FPG = Fasting plasma glucose

HbA1c = Glycated hemoglobin

LADA = Latent autoimmune diabetes in adults

LSM = Least squares mean

MDI = Multiple daily injections

MRI = Magnetic resonance imaging

SD = Standard deviation

TDD = Total daily dose

U = Unit(s)

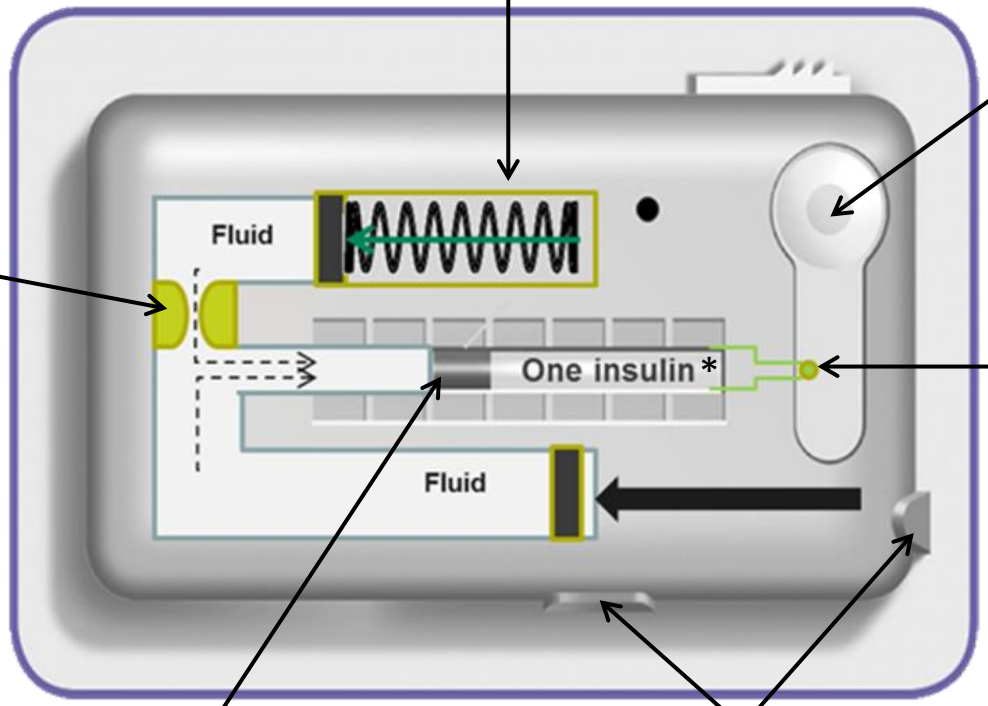
Introduction

- Tight glycemic control and timely treatment can improve outcomes in patients with diabetes, yet many remain sub-optimally controlled.
- Basal insulin therapy is sufficient for many patients; however, despite optimization of basal insulin evidence suggests less than 40% of patients with type 2 diabetes achieve glycemic targets.[1]
- V-Go® (Valeritas, Inc., Bridgewater, NJ, USA) is a disposable, wearable insulin delivery device that delivers a continuous basal rate of insulin, as well as on-demand mealtime dosing.
- Clinical effects were assessed retrospectively in 204 patients with diabetes sub-optimally controlled on previous therapies switched to insulin delivery by V-Go Disposable Insulin Delivery device.

[1]Gallwitz B, Bretzel RG. Diabetes Care. 2013;36(Suppl 2):S180-9.

Introduction

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



*Fast-acting insulin

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 for Diabetes America, a specialized diabetes system.
- Patients managed per clinician standard of care.
- Clinical data extracted included HbA1c values, fasting plasma glucose levels, prescribed and patient reported insulin use, body weight, concomitant anti-hyperglycemic medications, and patient-reported hypoglycemic events.
- The overall population was analyzed for changes in clinical variables as well as further analyses were conducted by subset (type 1 or type 2 and insulin or non-insulin use at baseline).
- Changes in anti-hyperglycemic concomitant medications were evaluated to determine impact on efficacy findings.

Results

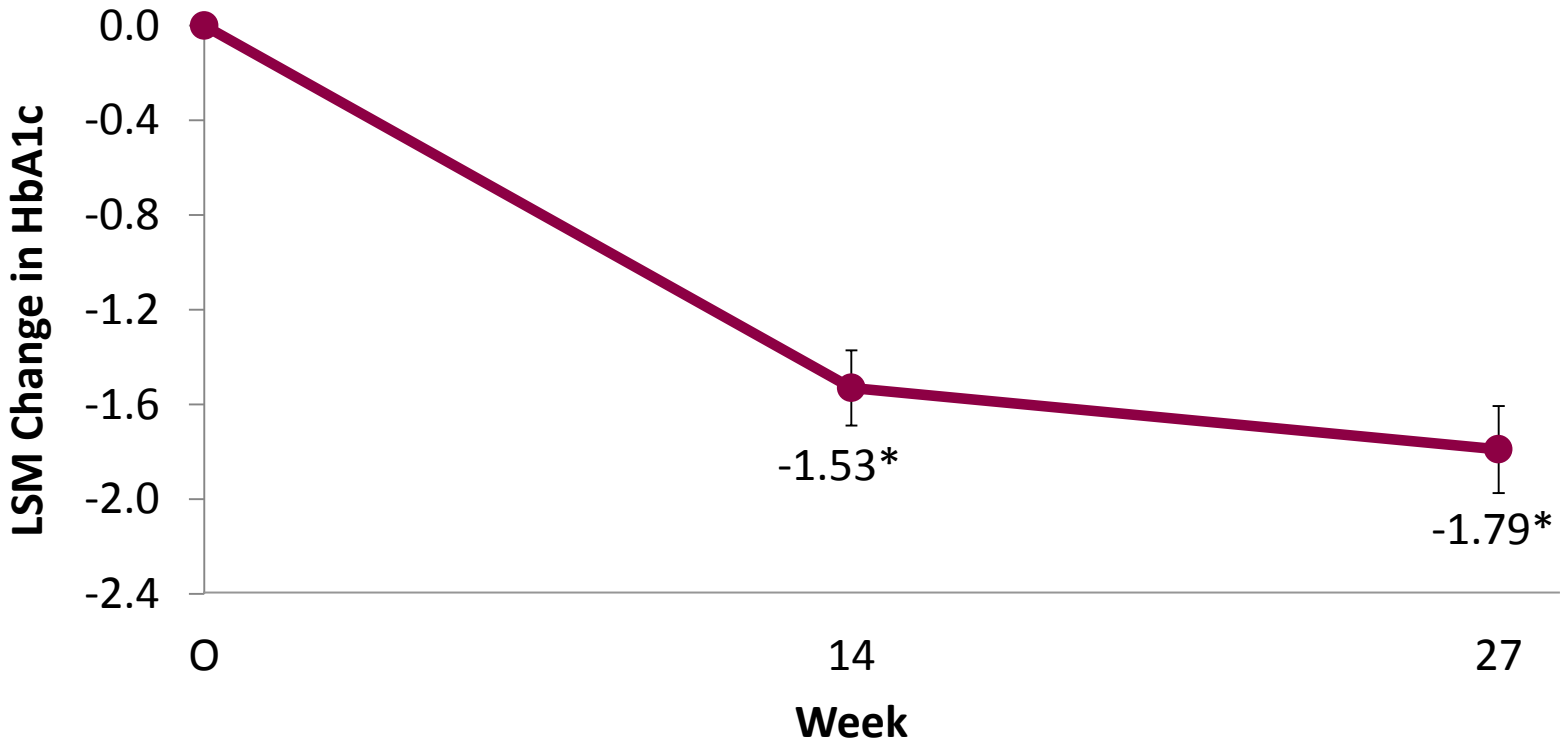
Study population

	All patients (*n* = 204)	Type 2 cohort (*n* = 175)	Type 1/LADA cohort (*n* = 29)	Insulin cohort (*n* = 180)	Naïve cohort (*n* = 24)
Age, years	53 ± 13	55 ± 12	43 ± 13	54 ± 12	47 ± 13
Duration of diabetes, years	13.7 ± 8.4	13.2 ± 7.5	17.0 ± 12.4	14.5 ± 8.3	8.0 ± 6.7
Weight, kg	96.6 ± 21.1	98.0 ± 20.5	88.6 ± 23.2	97.1 ± 21.2	93.3 ± 20.1
HbA1c, %					
Mean ± SD	9.63 ± 1.59	9.65 ± 1.62	9.48 ± 1.44	9.41 ± 1.46	11.28 ± 1.63
≥7% to <9.0%, *n* (%)	80 (39)	68 (39)	12 (41)	78 (43)	2 (8)
≥9.0 to < 10.5%, *n* (%)	62 (30)	52 (30)	10 (34)	56 (31)	6 (25)
≥10.5 < 14.0%, *n* (%)	62 (30)	55 (31)	7 (24)	46 (26)	16 (67)
Basal insulin dose, U/day					
Lower limit prescribed	-	56 ± 31	41 ± 16	54 ± 30	-
Upper limit prescribed	-	60 ± 31	49 ± 22	58 ± 30	-
Prescribed range	-	12–220	18–100	12–220	-
Insulin TDD, U/day					
Lower limit prescribed	-	86 ± 50	86 ± 35	86 ± 48	-
Upper limit prescribed	-	98 ± 55	104 ± 41	99 ± 53	-
Prescribed range	-	16–310	31–180	16–310	-

Data are *n* (%) or mean ± SD

Results

Effect of insulin delivery by V-Go: All patients (*n* = 204)

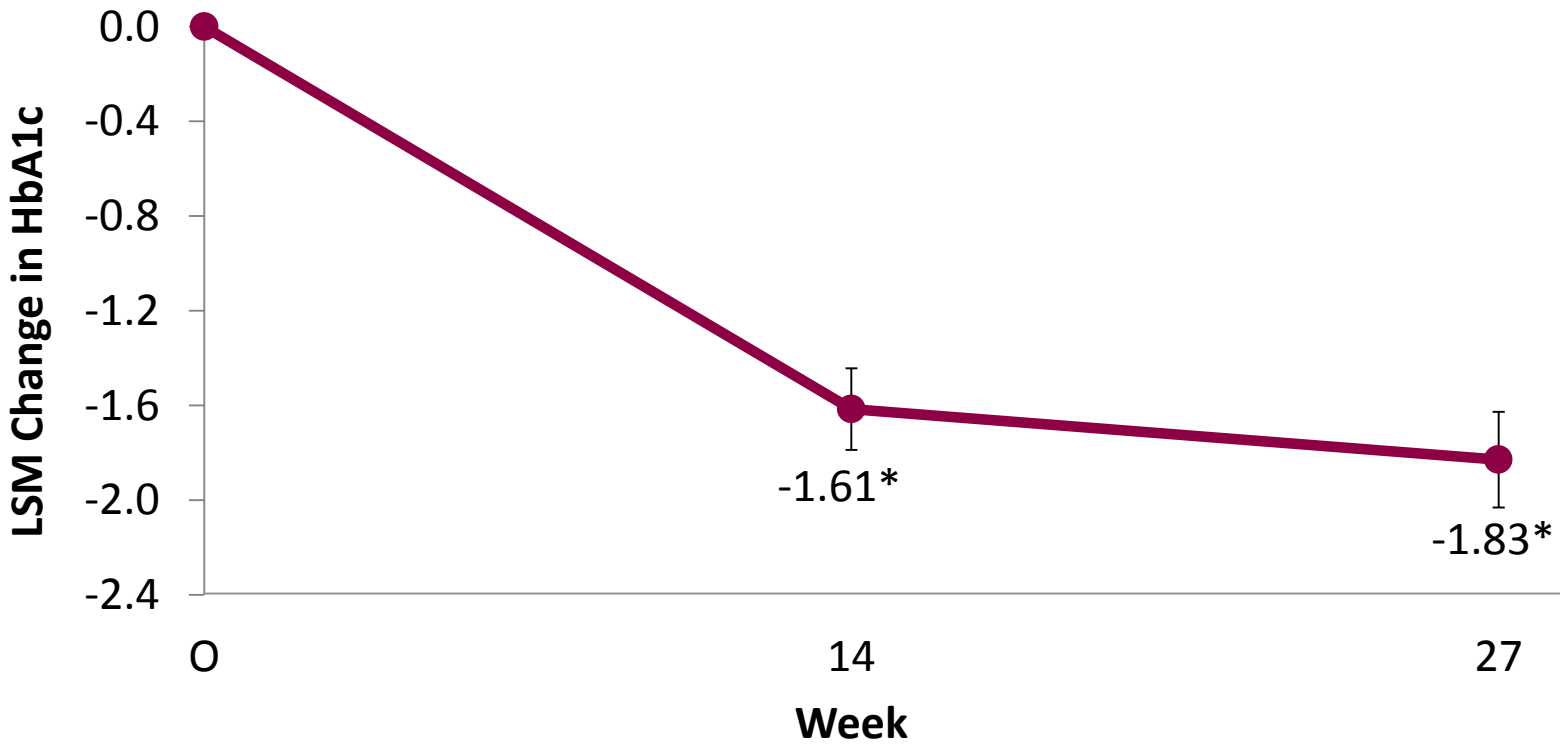


Change in HbA1c reported as LSM with corresponding 95% confidence intervals derived from a repeated measures mixed model for first recorded HbA1c on V-Go (14 week mean) and second recorded HbA1c on V-Go (27 week mean) from baseline (week 0). Time points represent the mean time elapsed between V-Go initiation and follow-up HbA1c results for the total population.

*$P < 0.001$ compared to baseline.

Results

Effect of insulin delivery by V-Go: Type 2 cohort (*n* = 175)

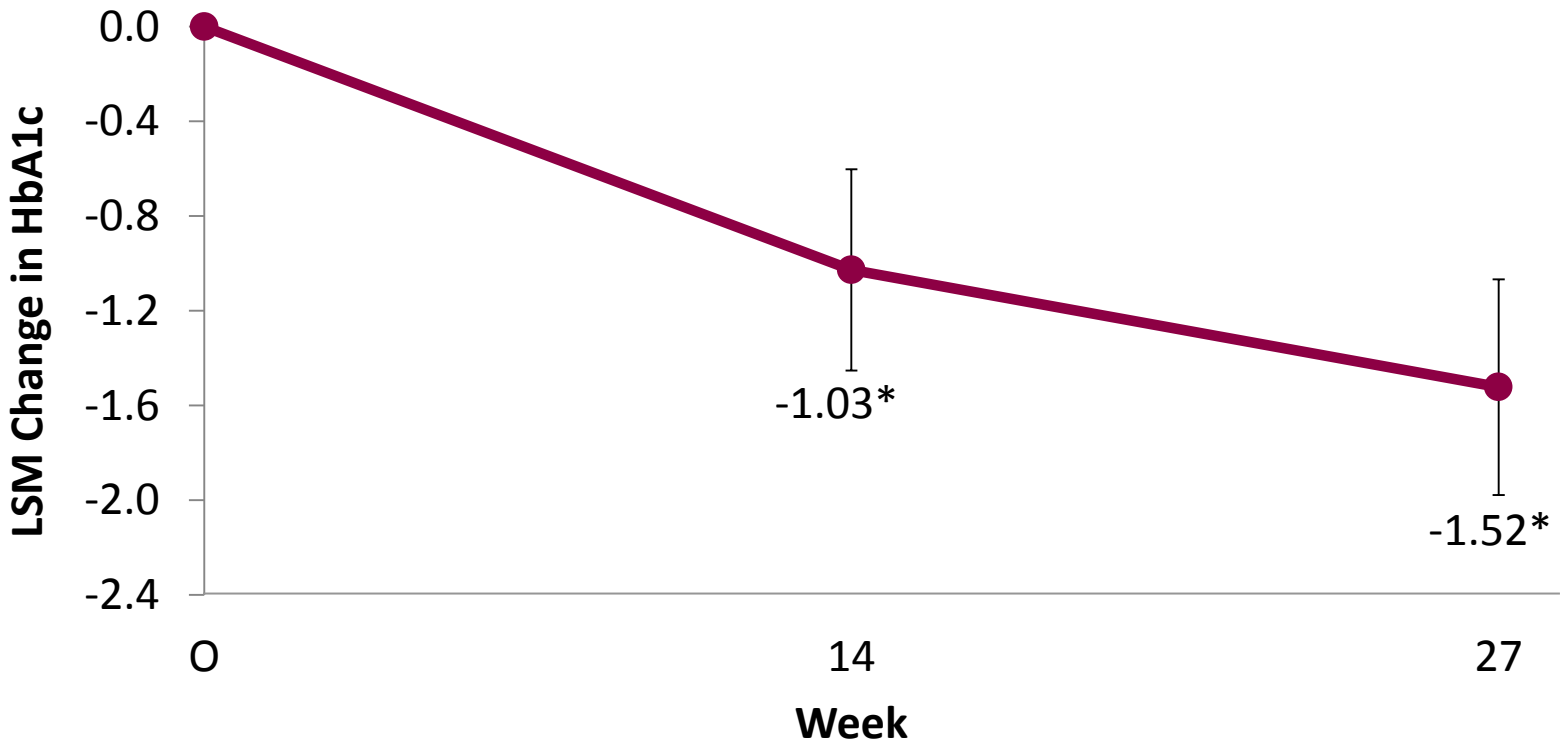


Change in HbA1c reported as LSM with corresponding 95% confidence intervals derived from a repeated measures mixed model for first recorded HbA1c on V-Go (14 week mean) and second recorded HbA1c on V-Go (27 week mean) from baseline (week 0). Time points represent the mean time elapsed between V-Go initiation and follow-up HbA1c results for the total population.

*$P < 0.001$ compared to baseline.

Results

Effect of insulin delivery by V-Go: Type 1/LADA cohort (*n* = 29)

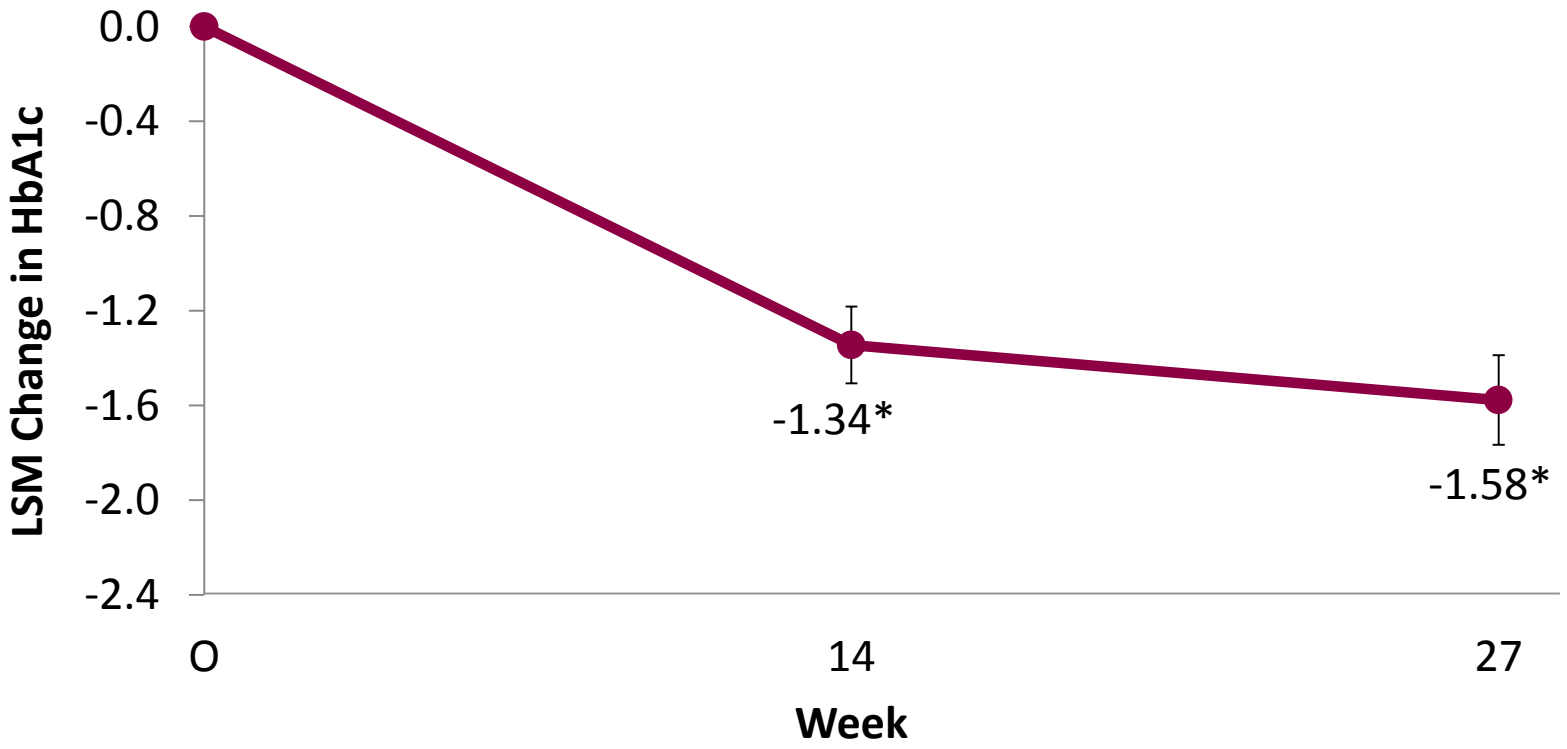


Change in HbA1c reported as LSM with corresponding 95% confidence intervals derived from a repeated measures mixed model for first recorded HbA1c on V-Go (14 week mean) and second recorded HbA1c on V-Go (27 week mean) from baseline (week 0). Time points represent the mean time elapsed between V-Go initiation and follow-up HbA1c results for the total population.

*$P < 0.001$ compared to baseline.

Results

Effect of insulin delivery by V-Go: On insulin at baseline (*n* = 180)

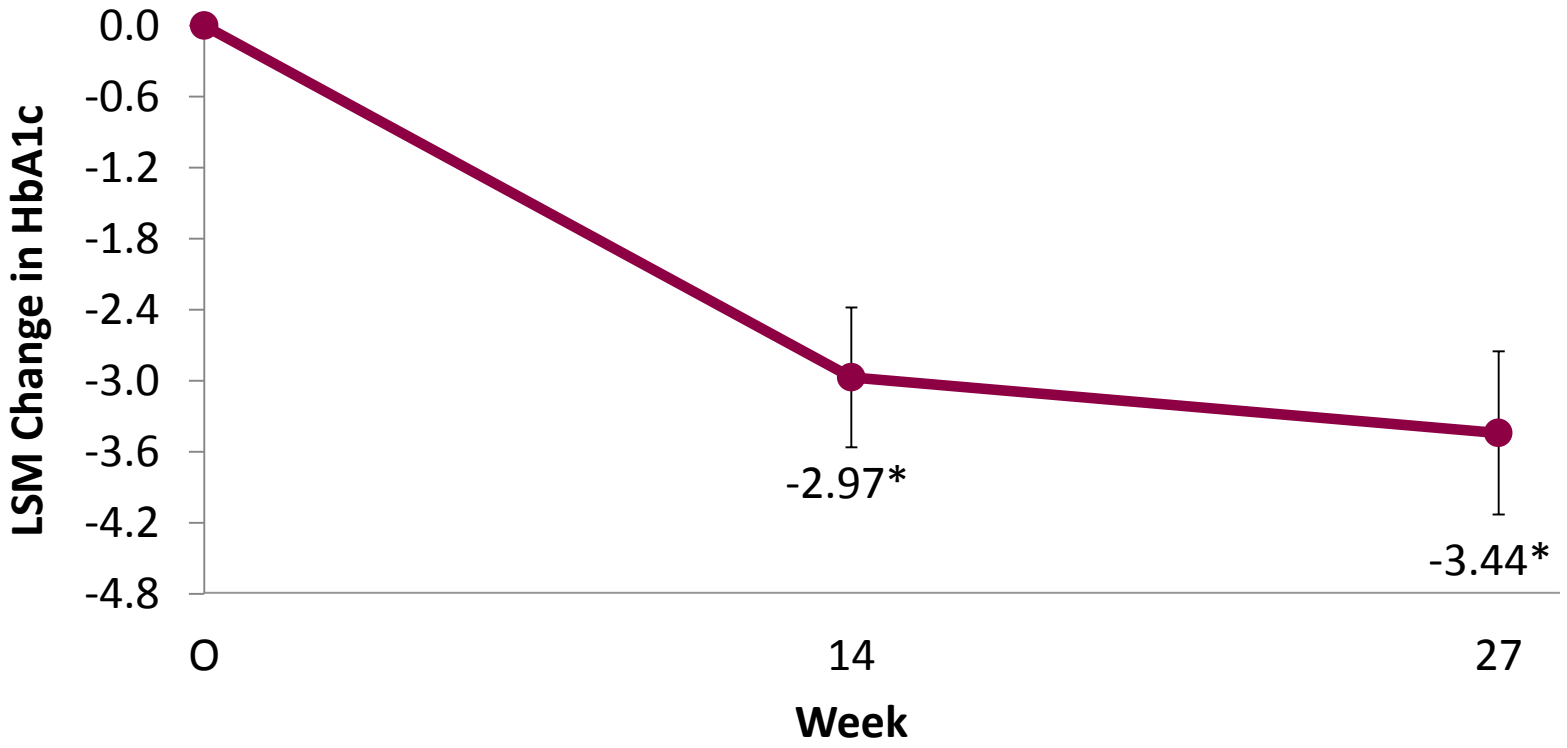


Change in HbA1c reported as LSM with corresponding 95% confidence intervals derived from a repeated measures mixed model for first recorded HbA1c on V-Go (14 week mean) and second recorded HbA1c on V-Go (27 week mean) from baseline (week 0). Time points represent the mean time elapsed between V-Go initiation and follow-up HbA1c results for the total population.

*$P < 0.001$ compared to baseline.

Results

Effect of insulin delivery by V-Go: Insulin naïve at baseline (*n* = 24)

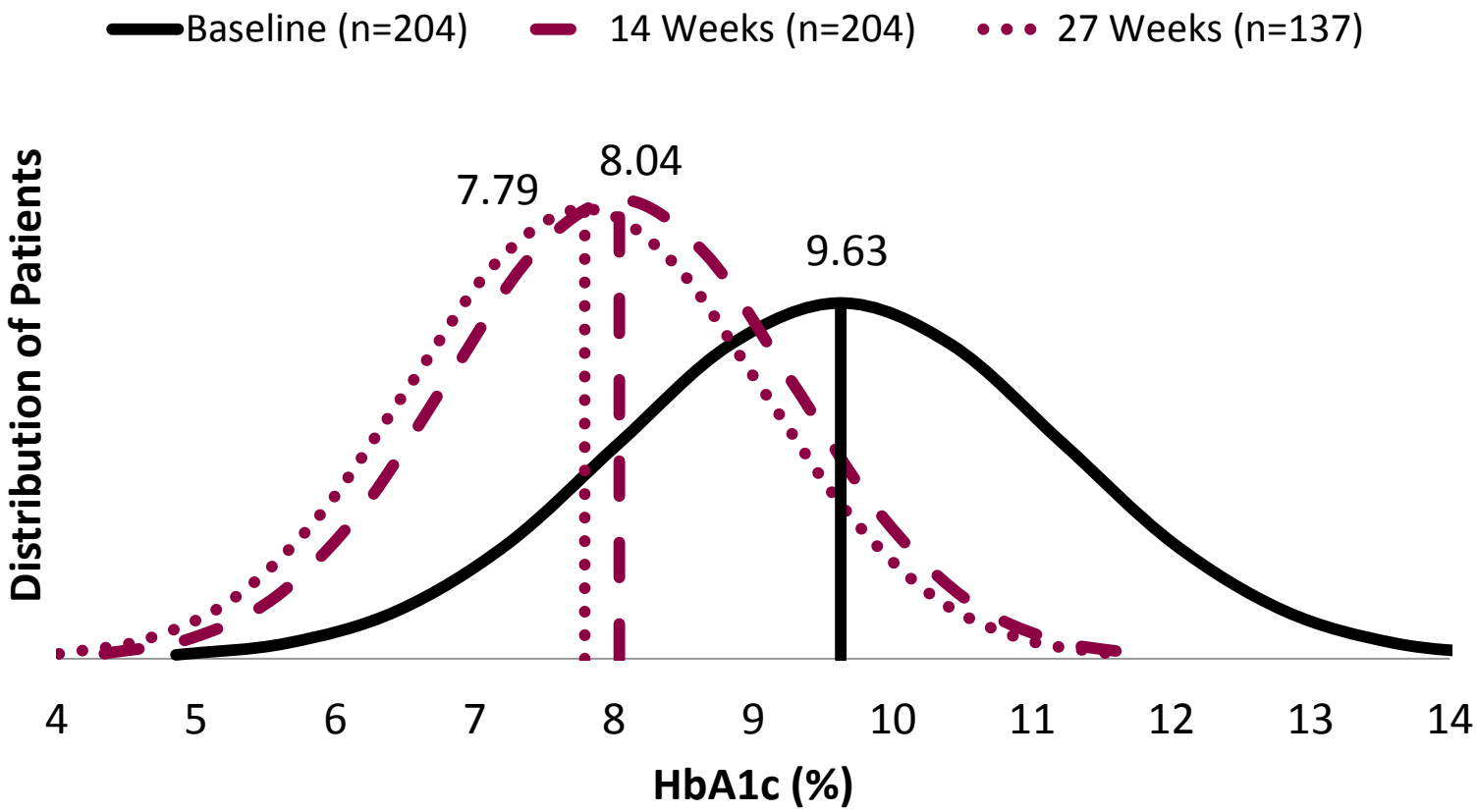


Change in HbA1c reported as LSM with corresponding 95% confidence intervals derived from a repeated measures mixed model for first recorded HbA1c on V-Go (14 week mean) and second recorded HbA1c on V-Go (27 week mean) from baseline (week 0). Time points represent the mean time elapsed between V-Go initiation and follow-up HbA1c results for the total population.

*$P < 0.001$ compared to baseline.

Results

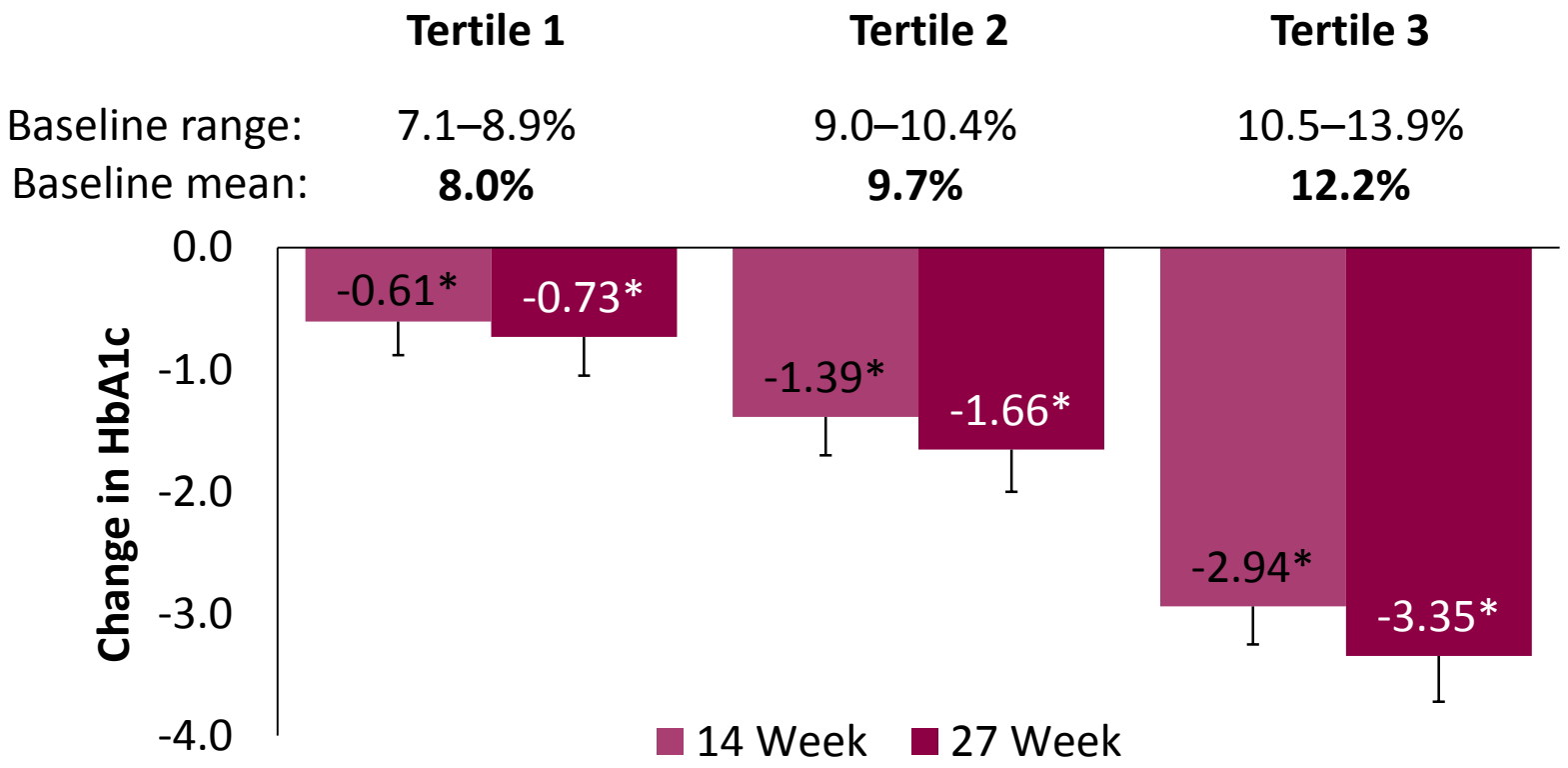
Change in HbA1c distribution on V-Go



HbA1c data are arithmetic means at baseline (week 0) compared to first recorded HbA1c on V-Go (14 week mean) and second recorded HbA1c on V-Go (27 week mean). Curves represent the HbA1c distribution of patients for each time point based on available data.

Results

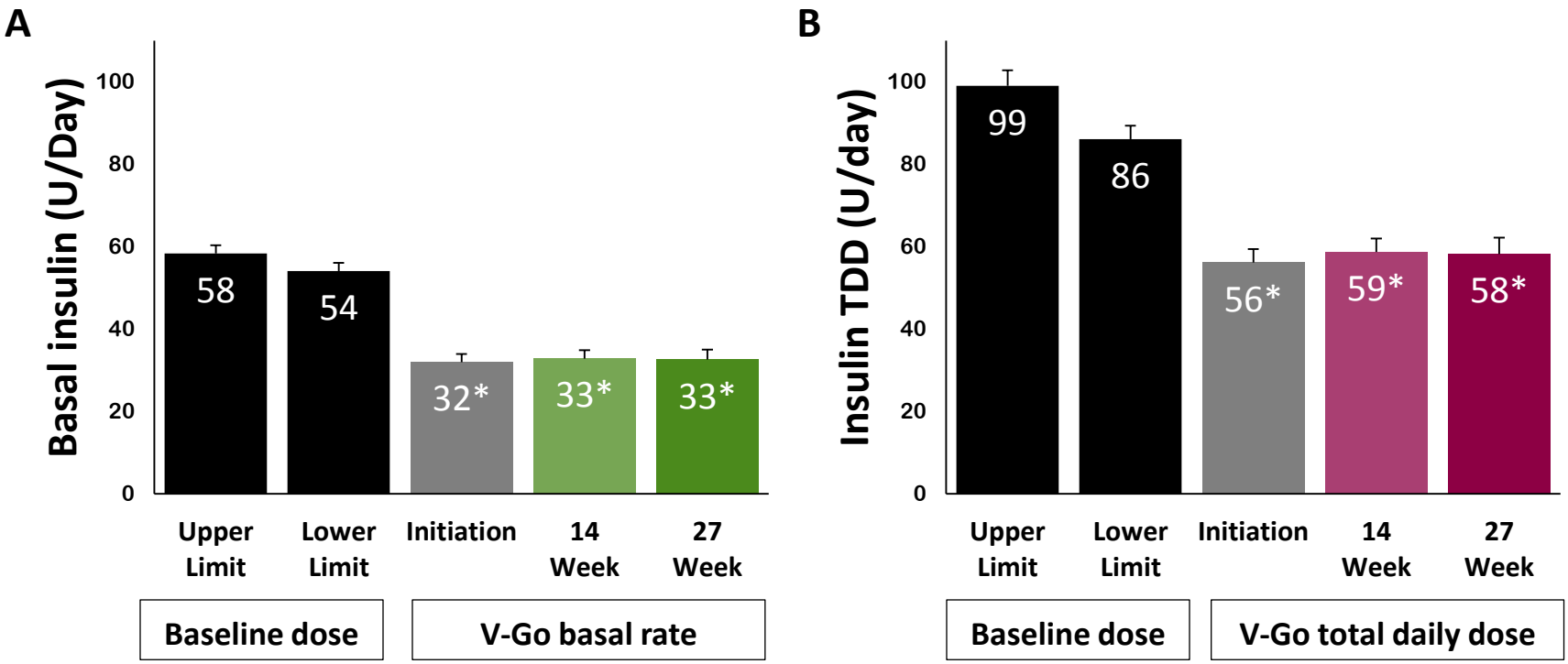
Efficacy response by baseline HbA1c tertile on V-Go



Tertile 1 (n = 80), tertile 2 (n = 62), and tertile 3 (n = 62). Data are LSM change in HbA1c with corresponding 95% confidence intervals derived from a repeated measures mixed model for both first recorded HbA1c on V-Go (14 week mean) and second recorded HbA1c on V-Go (27 week mean) respectively from baseline by tertile. Time points represent the mean time elapsed between V-Go initiation and follow-up HbA1c results for the total population. *P < 0.001 compared to baseline.

Results

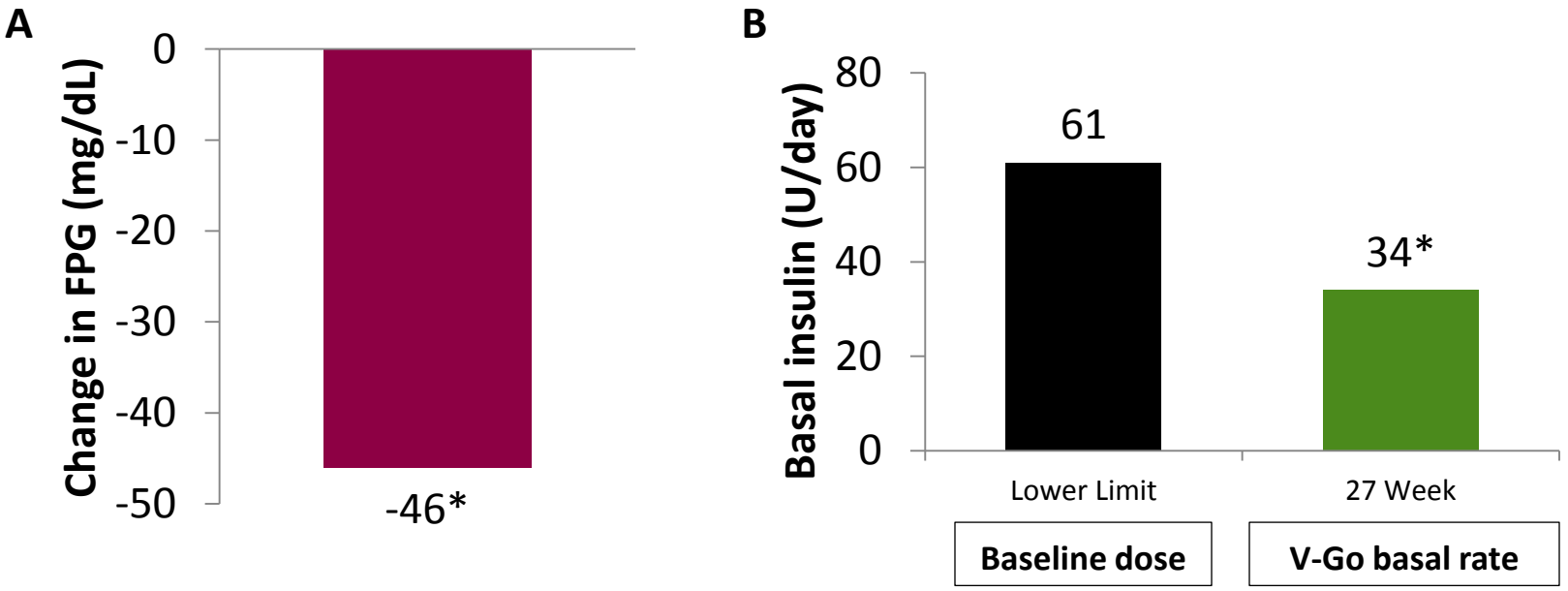
Insulin dosage at baseline and on V-Go



(A) Basal insulin dose/rate; (B) Insulin TDD. Data reflects insulin cohort (*n* = 180). Insulin data are LSM with corresponding 95% confidence intervals derived from a repeated measures mixed model for baseline upper and lower limit prescribed dose range compared to V-Go initiation dose, dose at first recorded HbA1c on V-Go (14 week mean) and dose at second recorded HbA1c on V-Go (27 week mean). Lower limit represents the primary dose excluding titration and correction, and the upper limit allows additional units to optimize insulin therapy (titration, correction, sliding scale) as prescribed. *$P < 0.001$ compared to baseline lower limit prescribed dose.

Results

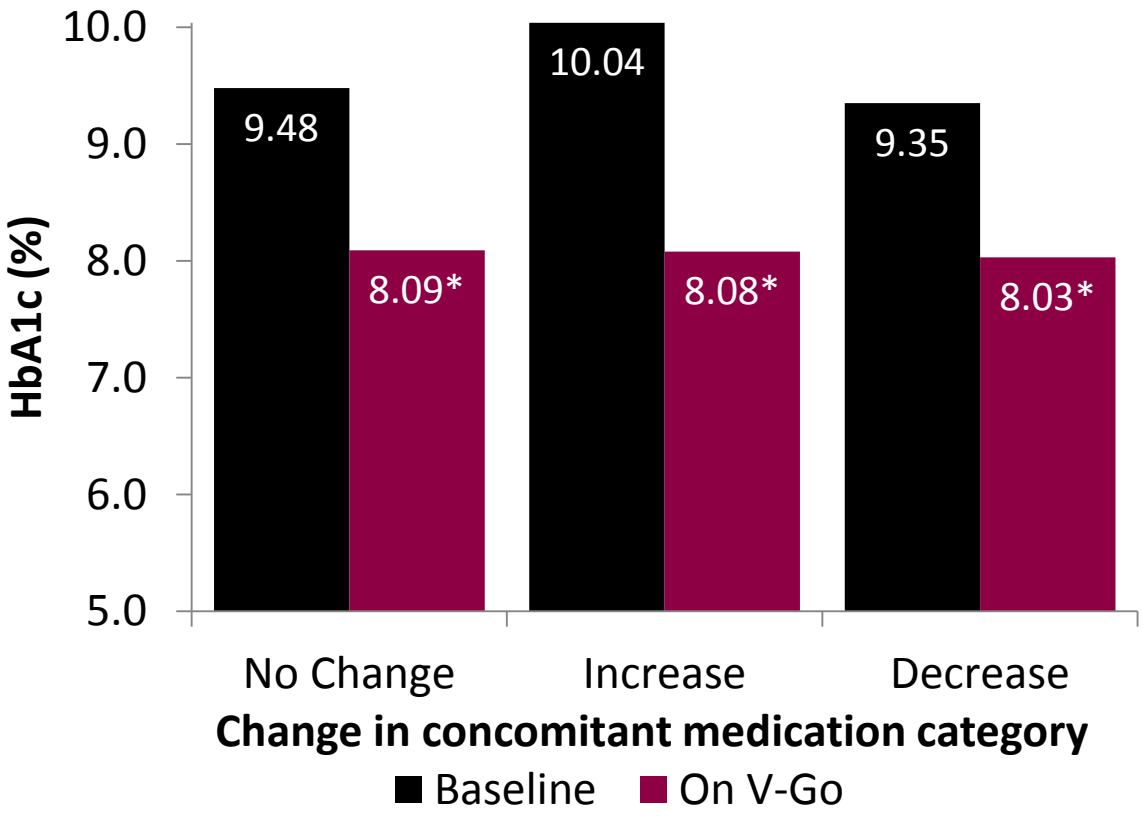
- Based on the significant reduction in basal insulin a follow-up analysis was conducted to evaluate if the reduction in basal insulin dose impacted fasting plasma glucose.



(A) Change in FPG from a baseline of 182 mg/dL. (B) Basal insulin dose from prescribed lower limit at baseline and on V-Go. Data reflects a subset of patients with repeating FPG measures available in the EMR (n = 67). FPG and basal insulin data are expressed as means from a paired t-test analysis at 27 weeks. *P < 0.001 compared to baseline.

Results

Change in HbA1c on V-Go based on changes to concomitant medications



- Impact of concurrent changes to anti-hyperglycemic medications upon initiation of V-Go were evaluated.
- Patients were categorized as having no change (*n* = 110), an increase (*n* = 43), or a decrease (*n* = 39) in concomitant medication.
- Patients in the increase category weighed significantly more and required significantly more insulin at baseline compared to other categories.
- All patients had a similar decrease in HbA1c regardless of changes to anti-hyperglycemic concomitant medications.

Data are LSM with corresponding 95% confidence intervals derived from a repeated measures mixed model based on 14 week results. Only those changes in concomitant anti-hyperglycemic medication(s) providing sufficient time for clinical effect were categorized as an increase or decrease. *$P < 0.001$ compared to baseline. There was no significant difference in HbA1c between categories at baseline or on V-Go.

Results

- Among all subjects there was a significant change in weight from baseline with insulin delivery by V-Go ($P < 0.001$).
  - LSM weight was 96.6, 97.9, and 98.1 kg at baseline and at 14 weeks and 27 weeks after switching to V-Go, respectively.
- Hypoglycemia captured from charts was similar during V-Go use compared to baseline with rates of 19%, 20%, and 22% at baseline, 14 weeks, and 27 weeks, respectively.
- Of the 204 subjects included in the study 32 discontinued use of V-Go prior to the second HbA1c follow-up for reasons including:
  - Skin irritation (9), cost/insurance coverage (7), transitioned to an insulin pump (5), weight gain (2), undetermined reason (2), and did not prefer V-Go, pain, gastrointestinal effect, hyperglycemia, hypoglycemia, and lack of adherence to skin (1 each).

Conclusions

- V-Go is an appropriate therapy for a broad range of patients; statistically significant reductions in HbA1c were seen with V-Go use in all subsets of patients including type 2, type 1/LADA, naïve to insulin, and patients administering insulin prior to V-Go.
- Reports of hypoglycemia were similar prior to and after switching to V-Go.
- Patients administering insulin at baseline experienced substantial decreases in HbA1c while requiring a lower total daily dose of insulin.
- V-Go offers an efficient and efficacious method of insulin delivery that can enhance patient compliance and optimize glycemic control.

Acknowledgments

No funding or study product was provided to the study site, study participants, or study investigators. Valeritas, Inc., Bridgewater, NJ, USA provided funding for investigational review board review. The article processing charges for this publication were funded by Valeritas, Inc. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval to the version to be published. The authors would like to thank Donna Doherty, MS, RD, LD, CDE for assistance in data collection and study conduct, and Jessica Sanders and Ariel Webb from the University of Central Oklahoma for support with statistical analyses. The authors received writing/editorial support for manuscript preparation from Maria Paluselli, founder of Panaceum Clinical, LLC, funded by Valeritas, Inc.

Disclosures

Rosemarie Lajara has received speaker or consulting honorariums from Valeritas, Novo Nordisk, Astra Zeneca, Boehringer Ingelheim and Takeda. Dianne A. Fetchick and Tracy L. Morris declare they have no conflicts of interest. Carla Nikkel is currently employed and a shareholder of Valeritas, Inc. Findings from a portion of the dataset used in preparing this manuscript were presented at the Academy of Managed Care Pharmacy, American Association of Clinical Endocrinologists, American Diabetes Association, and the American Association of Diabetes Educators scientific sessions earlier this year (see the electronic supplementary material for full details).

Compliance with ethics guidelines

This study was reviewed and approved by Allendale investigational review board, and a waiver of informed consent was approved. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964, as revised in 2013.

Copyright