Investor Supplemental Presentation

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Forward Looking Statements

This presentation shall not be deemed an offer to sell securities nor a solicitation of an offer to purchase securities. Any sale by the company shall be made pursuant to a definitive purchase agreement. Unless otherwise stated in this presentation, references to "Valeritas," "we," "us," "our" or "our company" refer to Valeritas Holdings, Inc. and its subsidiaries.

This presentation contains estimates, projections and forward-looking statements. Our estimates, projections and forward-looking statements are based on our management's current assumptions and expectations of future events and trends, which affect or may affect our business, strategy, operations or financial performance, including but not limited to our revenue, gross margin and cash-flow break-even projections. Although we believe that these estimates, projections and forward-looking statements are based upon reasonable assumptions and expectations, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Many important factors may adversely and materially affect our results as indicated in forward-looking statements. All statements other than statements of historical fact are forward-looking statements. The words "believe," "may," "might," "could, "would," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar words are intended to identify estimates, projections and forward-looking statements. Estimates, projections and forward-looking statements speak only as of the date they are made, and, except to the extent required by law, we undertake no obligation to update or review any estimate, projection or forward-looking statement because of new information, future events or other factors.
Our estimates, projections and forward-looking statements may be influenced by one or more of the following factors:

- our history of operating losses and uncertainty regarding our ability to achieve profitability;
- our reliance on V-Go® Wearable Insulin Delivery device, or V-Go, to generate all of our revenue;
- our inability to retain a high percentage of our patient customer base or our significant wholesale customers;
- the failure of V-Go to achieve and maintain market acceptance;
- our inability to operate in a highly competitive industry and to compete successfully against competitors with greater resources;
- competitive products and other technological breakthroughs that may render V-Go obsolete or less desirable;
- our inability to maintain or expand our sales and marketing infrastructure;
- any inaccuracies in our assumptions about the insulin-dependent diabetes market;
- manufacturing risks, including risks related to manufacturing in Southern China, damage to facilities or equipment and failure to efficiently increase production to meet demand;
- our dependence on limited source suppliers and our inability to obtain components for our product;
- our failure to secure or retain adequate coverage or reimbursement for V-Go by third-party payers;
- our inability to enhance and broaden our product offering, including through the successful commercialization of the pre-fill V-Go;
- our inability to protect our intellectual property and proprietary technology;
- our failure to comply with the applicable governmental regulations to which our product and operations are subject;
- our ability to operate as a going concern; and
- our liquidity.

Investor Supplemental Presentation

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Diabetes Background

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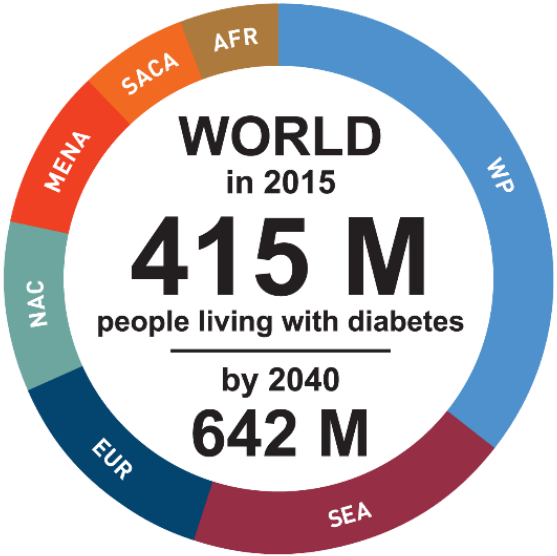
Diabetes is a Global Epidemic & Healthcare Burden



Globally, diabetes is projected to increase 35% by 2040

	Global	USA
2015	415 million	29 million
2040	642 million	35 million

It is estimated that 12% of global health expenditure is spent on diabetes

	Global	USA
2015	$673 billion*	$320 billion*
2040	$802 billion*	$349 billion*

* Based on USD

AFR=Africa, EUR= Europe, MENA= Middle East and North Africa, NAC= North America and Caribbean, SACA=South and Central America, SEA= South East Asia, WP= Western Pacific

Adapted from International Diabetes Foundation, IDF Diabetes Atlas, Seventh Edition, 2015

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Primary Classifications of Diabetes

	Type 1 Diabetes	Type 2 Diabetes
Age of onset	Often diagnosed in children and young adults	Usually diagnosed in adults
Characteristics	Insulin producing cells are destroyed by the body's own immune system which results in insulin dependence	Blood glucose levels rise due to 1) Lack of insulin production due to beta cell dysfunction 2) Insufficient insulin action (resistant cells)
Medication(s)	Insulin essential	Oral(s), and/or non-insulin injectables and/or insulin
Onset of symptoms	Acute	Gradual (may be asymptomatic)
% of Diabetes	~5%	90 to 95%

Adapted from "Type 1 and Type 2 Diabetes." *JDRF*. JDRF, n.d. Web. 25 May 2017. <https://jdrf.org.uk/about-type-1-diabetes/understanding/what-is-the-difference-between-type-1-and-type-2-diabetes/>.

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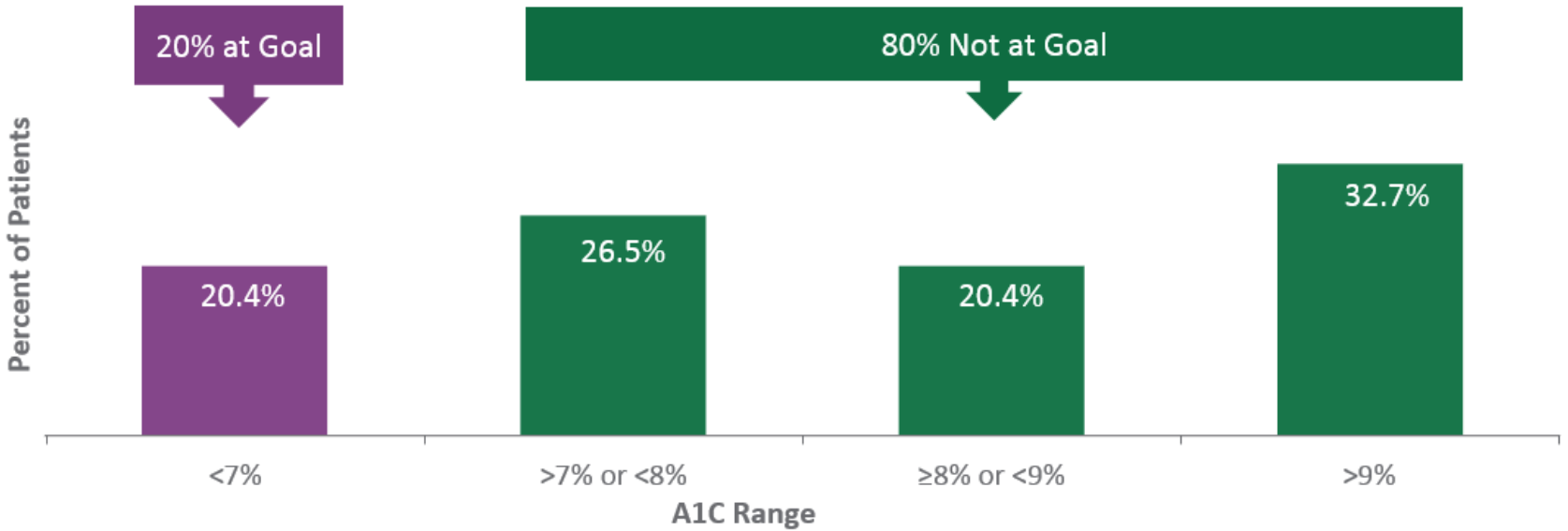
Most Patients On Insulin Therapy are Not at Goal

2011 HealthCore database analysis of 27,897 adult patients with diabetes on insulin*



>95% of Patients in Study were Diagnosed with Type 2 Diabetes

* Insulin: Basal, Basal plus one, Premixed or Multiple Daily Injections.

Grabner et al. *ClinicoEconomics and Outcomes Research.* 2013:5 471–479 and Chen Y et al, Poster presented at the 2012 ACCP Annual Meeting, October 21 – 24, 2012, Hollywood, Florida, USA .

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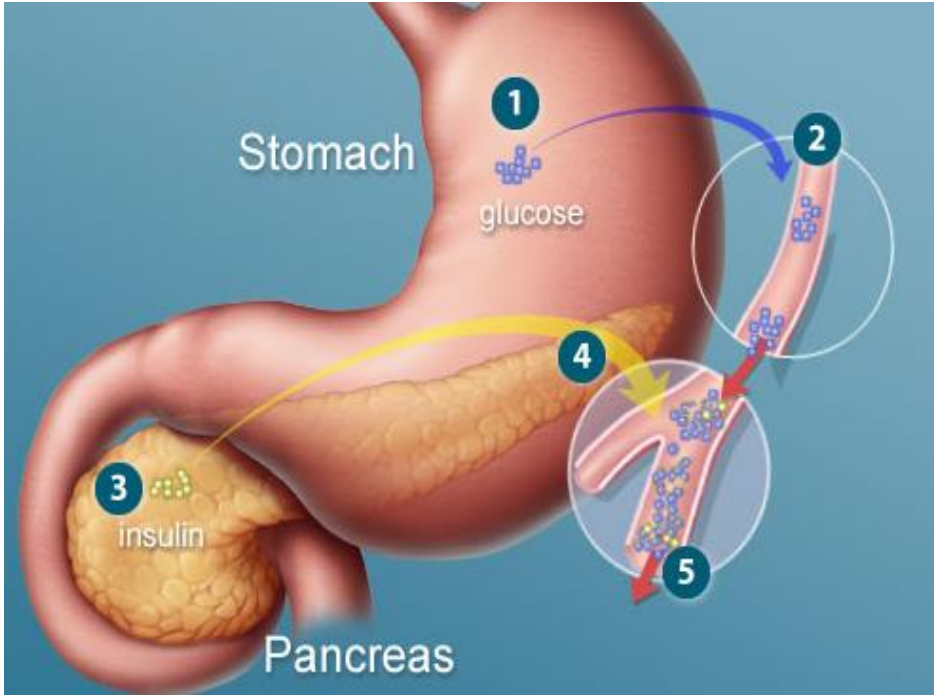
Pathophysiology of Diabetes

1. Digestion converts food into glucose
2. Glucose enters the bloodstream
3. The pancreas makes little (T2DM) or no insulin (T1DM)
4. Little or no insulin enters the bloodstream
5. Glucose builds up in the bloodstream



Adapted from "Diabetes Pictures: Type 2 Diabetes Symptoms, Diagnosis, and Treatments." *WebMD*. Ed. Michael Dansinger. WebMD, 2 Feb. 2016. Web. 25 May 2017. <http://www.webmd.com/diabetes/ss/slideshow-type-2-diabetes-overview>.

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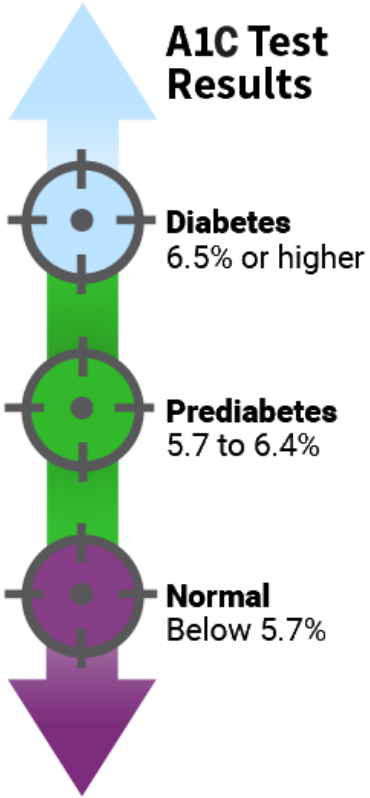
A1c as a Measurement of Glycemic Control

- An **A1c test** is a blood test used to diagnose diabetes and assess how well someone is managing their diabetes.
    - The value is reflected as a percentage and reflects average blood glucose over the past 2 to 3 months and has strong predictive value for complications.



"Hemoglobin A1c (HbA1c) Test for Diabetes." *WebMD*. Ed. Michael Dansinger. WebMD, 26 Oct. 2016. Web. 25 May 2017. <http://www.webmd.com/diabetes/guide/glycated-hemoglobin-test-hba1c>.

Assessment of Glycemic Control in Diabetes

A1c	Considerations	2015 Report Card[2]	
		Commercial PPO	Medicare PPO
< 7%	*A reasonable A1c goal for many non-pregnant adults*[1]	67% Did not Achieve	Not applicable*
< 8%	*Appropriate for some patients including those with long-standing diabetes in whom the goal is difficult to achieve despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin.*[1]	53% Did not Achieve	36% Did not Achieve
> 9%	*Designated as poor A1c control and places patients at high risk for complications and comorbidities. Decreasing this risk is an established priority.*[3]	44% Poorly Controlled	27% Poorly Controlled

*Less stringent goals <8% are reserved for this patient population

1. ADA Standards of Care 2017. **2.** "Report Cards." *Diabetes Care*. NCQA, 2016. Web. 25 May 2017. <http://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality/2016-table-of-contents/diabetes-care>. Reported achievement from 2015. **3.** Stratton IM et al. *BMJ.* 2000;321:405-412.

Strong Need and Opportunity for V-Go®

A1c	Considerations	2015 Report Card[2]	
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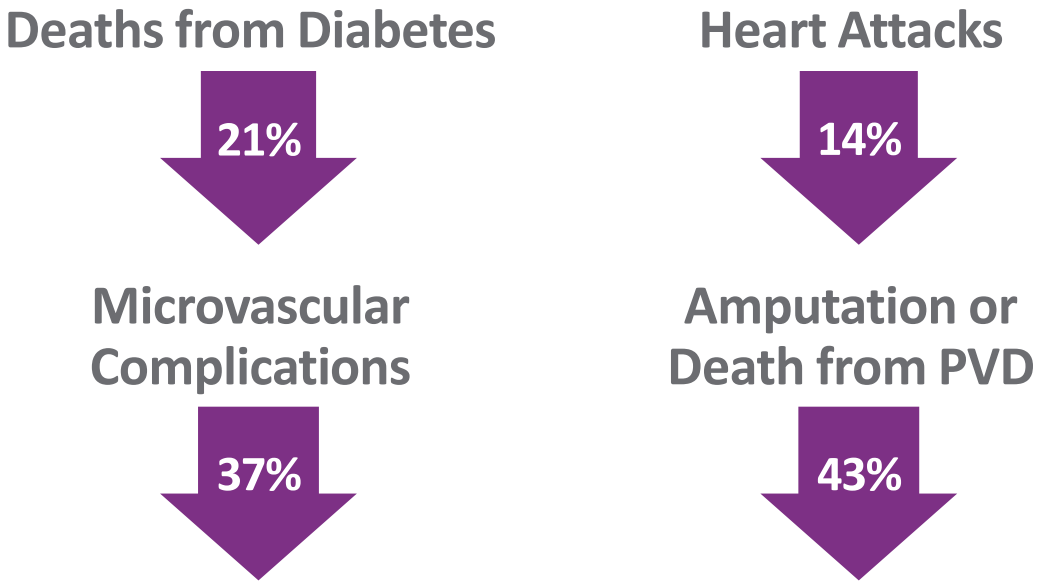
1. ADA Standards of Care 2017. **2.** "Report Cards." *Diabetes Care*. NCQA, 2016. Web. 25 May 2017. <http://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality/2016-table-of-contents/diabetes-care>. Reported achievement from 2015. **3.** Stratton IM et al. *BMJ*. 2000;321:405-412.

Better Glycemic Control Improves and Extends Lives

Significant Adverse Health Effects Influenced by Poor Glycemic

Each 1% reduction in mean A1c reduces risk for



PVD= Peripheral Vascular Disease

Stratton IM et al. *BMJ.* 2000;321:405-412.

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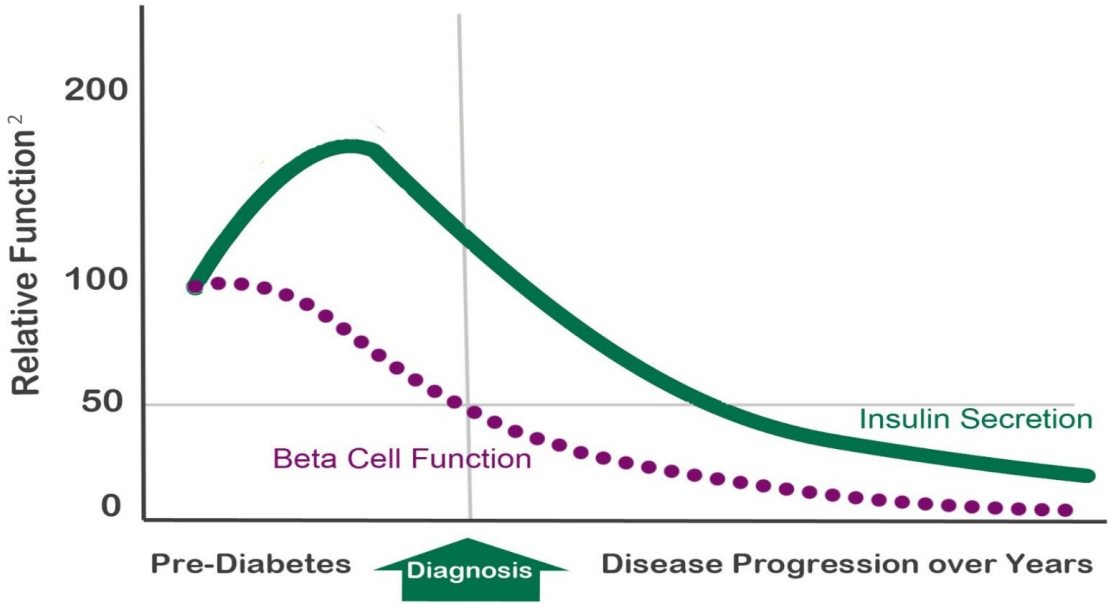
Most Patients will Eventually Require Insulin Therapy

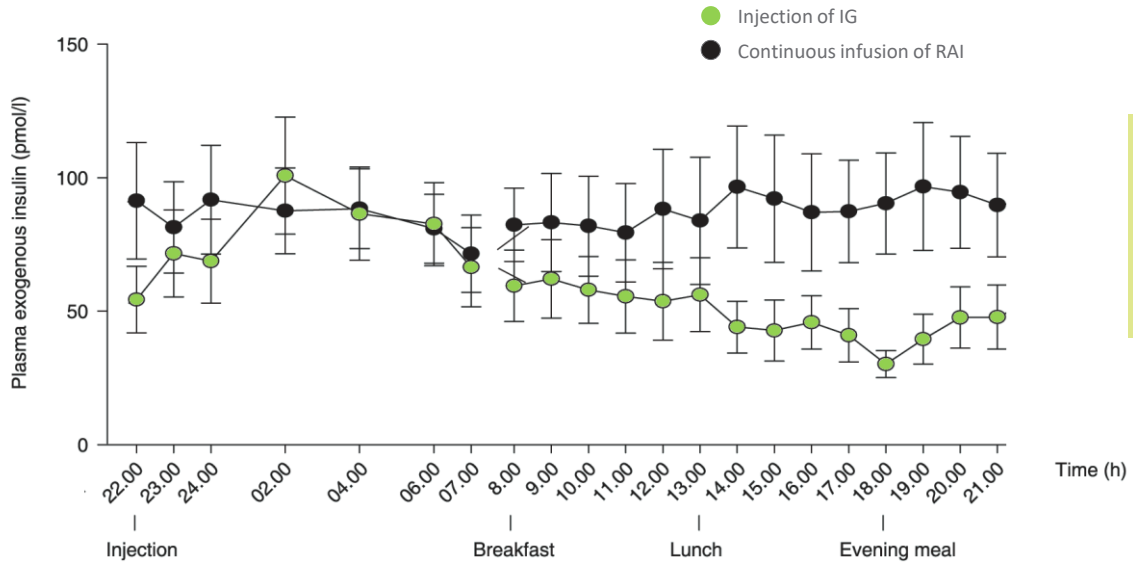
The UKPDS found that more than half of newly diagnosed people with type 2 diabetes will require insulin initiation within 6 years of starting other antidiabetic therapies.[1]



1. Wright A et al. *Diabetes Care* 2002; 25: 330–336. **2.** Graphic conceptually adapted from Holman RR. *Diabetes Res Clin Pract*. 998;40(suppl):S21-S25.

Continuous Delivery of a Basal Rate of Improves Insulin Profiles

Cross over study in 21 patients with T2DM comparing equal doses (mean 26 U) of continuous basal subQ infusion (CSII) of rapid-acting insulin (RAI) to once daily subQ of insulin glargine (IG)



CSII with RAI resulted in flatter insulin profile with a lower variability and improved glucose profiles compared with IG injection

AUC for plasma exogenous insulin was 72% higher with CSII with RAI vs IG injection (p=0.003)

AUC= area under the curve, subQ.= subcutaneous, T2DM=type 2 diabetes

Adapted from Parkner T et al. *Diabet Med*. 2008 May;25(5):585-91

V-Go® Clinical Summary

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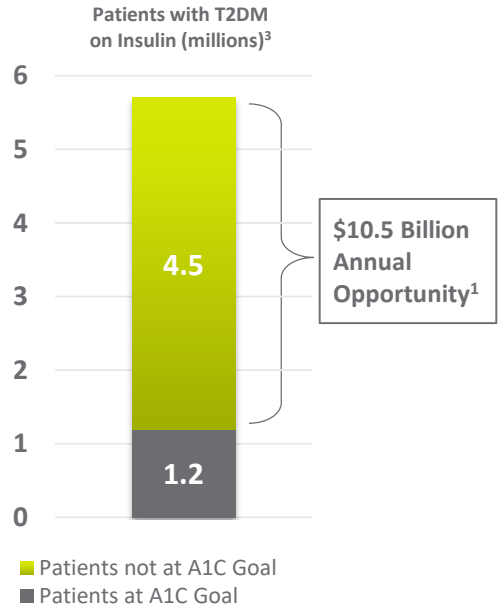
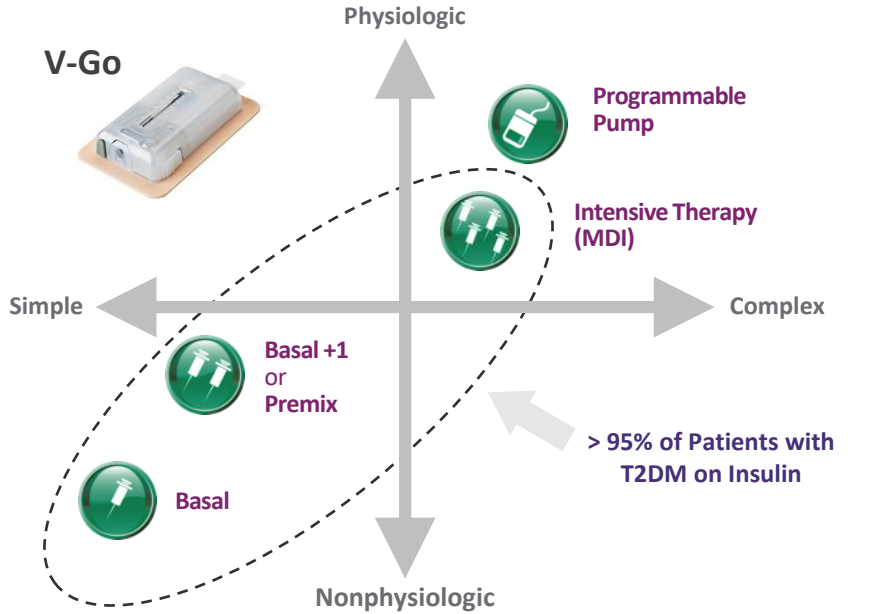
Addresses Key Unmet Needs for Patients with T2DM on Insulin

The 4.5 Million Patients V-Go® Can Benefit and Represent a $16.5 Billion Market[1,3]





~82% of Patients with T2DM on a basal insulin-based regimen required the addition of mealtime insulin.[2]

MDI=Multiple daily injections T2DM= Type 2 diabetes mellitus

1. Based on V-Go® net price $6.5 x 360 days x 12 months x 4.5M Patients with Type 2 Diabetes on Insulin not at goal.
2. Holman RR et al. N Engl J Med. 2009;361(18):1736-1747
3. Number of patients with T2DM on insulin are approximate and based on 2014 US Roper Diabetes Patient Market Study provided by GfK Customer Research LLC and achievement of A1C goal based on Grabner et al. ClinicoEconomics and Outcomes Research. 2013:5 471–479.

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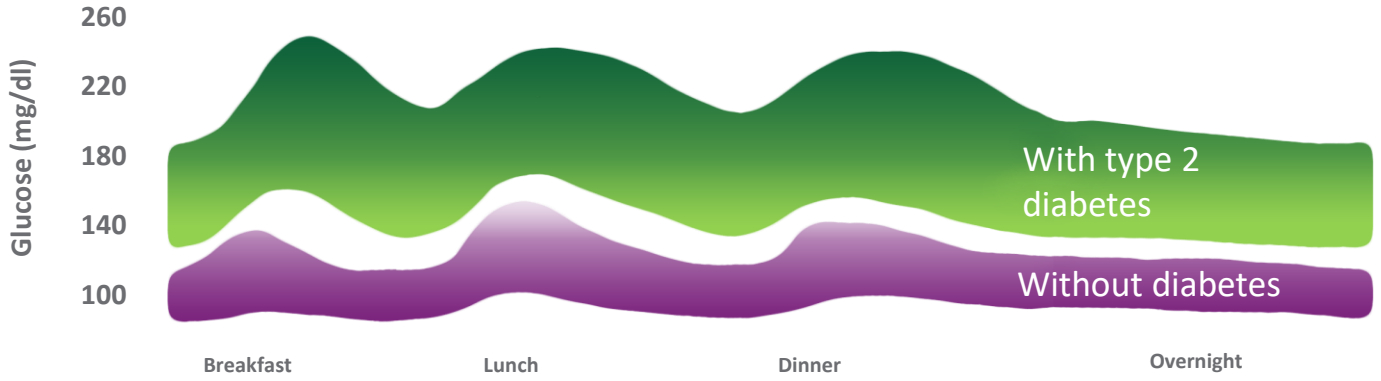
Basal & Mealtime Insulin Needed to Achieve or Maintain Glycemic Control



Mean 24- hour CGM sensor glucose profiles[1]

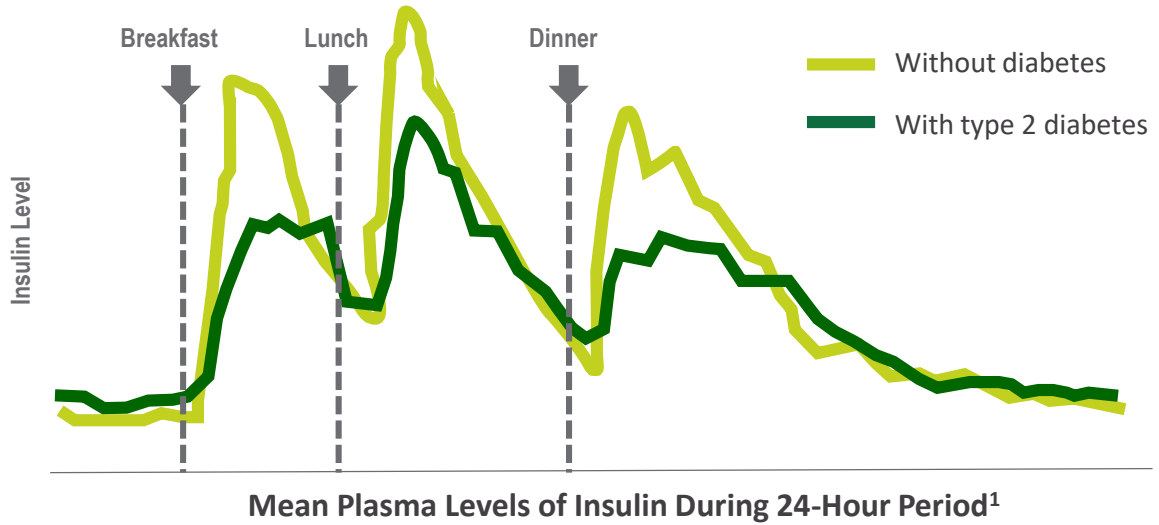
N=53 without diabetes and N=56 with T2DM

Basal insulin has a flat insulin profiles and is not designed to cover glucose excursions from meals[2]

Continued upward titration of basal insulin glargine to doses > 0.5, > 0.7 and even > 1.0 U/kg does not appear to result in further improvements in glycemic control[3]

1. Wang et al. *Clinical Endocrinology* 2012 Jun;76(6):810-5. **2**. Pearson, et al. *The Diabetes Educator* 32.1 (2006): 19S-28S. **3.** Reid et al. *Int J of Clinical Practice* 2016 2016;70(1):56-65.

Goal of Insulin Therapy: Mimic Physiologic Insulin Secretion



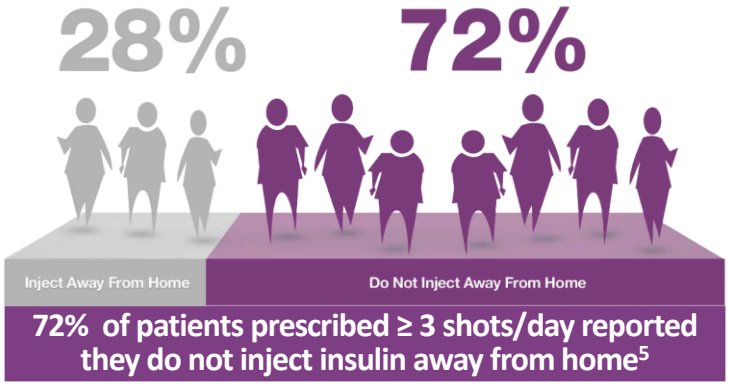
~82% of Patients with Type 2 Diabetes Initiated on Basal-Only Insulin Regimens Required the Addition of Mealtime Insulin[2]

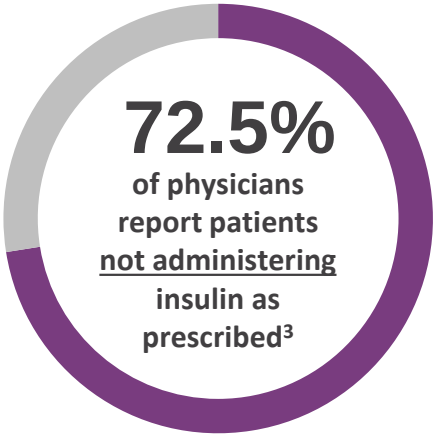
1. Polonsky KS, et al. *N Engl J Med*. 1988;318(19):1231-1239. **2.** Holman RR et al. *N Engl J Med*. 2009 Oct 29;361(18):1736-47.

Non-adherence to Insulin is Associated with Poor Glycemic Control[1]

Common barriers contributing to non-adherence[2]

- Impact to daily living
- Injection embarrassment & pain
- Number of injections





1. Donnelly L et al. *Q J Medicine* 2007:100;345-350. **2.** Peyrot M et al. *Diabetes Care* 2010:33;240-245. **3**. Peyrot M et al. *Diabet Med*. 2012:May;29(5): 682-689. **4**. Yavuz D et al. *Patient Preference and Adherence.* 2015:9; 225-231. **5**. Data from U.S. Roper Diabetes Patient Market study provided by GfK Custom Research LLC and distributed only with express written permission of GfK Custom Research LLC. This study is an annual survey of over 2,000 diabetes patients (n=2,104 in 2011; 692 who use insulin) via telephone and internet.

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V-Go® Addresses Physicians' Greatest Concerns

Challenges Patients with T2DM Face on MDI

Greatest Challenges that my T2DM Patients on MDI Face	Highest Rated Benefits of V-Go
• Having to inject multiple times/day	• Reduces multiple daily injections
• Remembering to take insulin	• No need to carry insulin and needles
• Needing to test blood glucose	• Only need to use one type of insulin
• Having to inject outside their home	• Allows discreet mealtime dosing
• Hypoglycemia	• Easy to remember to take meal time insulin
• Required to carry pens/syringes	• Easy to learn how to use

MDI – Multiple Daily Injections of insulin, T2DM- Type 2 Diabetes Mellitus

Based on market research conducted in October, 2016, n=102, Doctors ranked their Top 5 Challenges and separately the Greatest Benefits from V-Go

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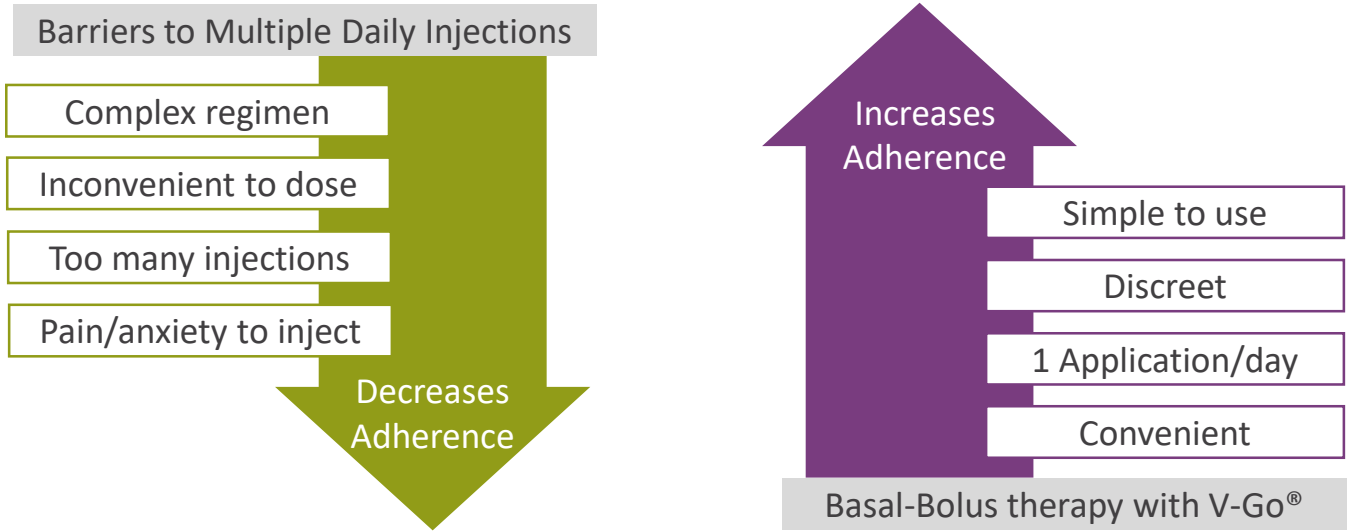
Insulin works……..if the Patient Takes it as Prescribed

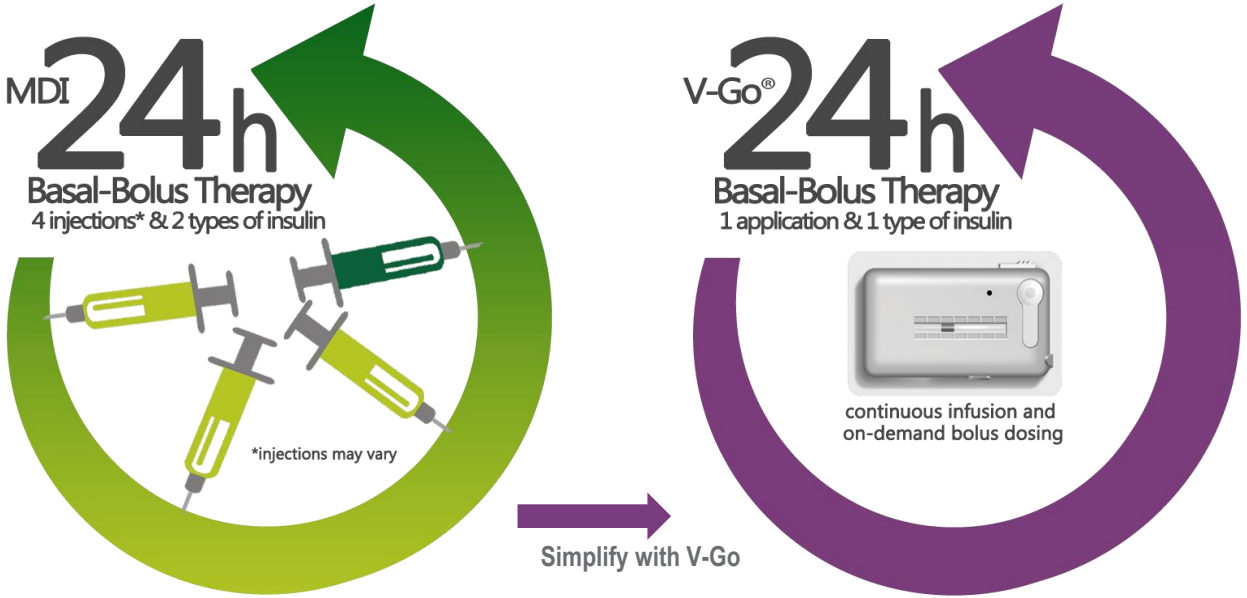
When taken, insulin is the most potent agent available to treat hyperglycemia[1]



Adherence Impacts Efficacy[2]

1. Nathan DM, et al. *Diabetes Care* 32: 193-203, 2009. **2.** Garcıa-Perez L, et al. *Diabetes Therapy*. 2013;4:175–94.

Simplify Basal-Bolus Insulin Therapy with V-Go®



Basal-Bolus therapy with MDI requires a long or intermediate acting insulin plus a short or rapid acting insulin and typically 4 injections/day.
Basal-Bolus therapy with V-Go requires only a rapid acting insulin and 1 application/day

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Strong Clinical Evidence

Demonstrated Statistically Significant Improvements in A1c[1-11]

Improved Diabetes Management Performance Measures[4,7,9,10,11]

Lowered Total Daily Dose of Insulin (Prescribed / Administered)[1-11]

Demonstrated Cost Savings Compared to Baseline or Other Insulin Regimens[4,6-8,11]

14 Published Clinical Papers

>1,500 V-Go® Patients Studied

60 Presentations at National Conferences

1. Rosenfeld CR, et al. *Endocr Pract*. 2012; 18 (5):660-667. **2.** Grunberger, G, et al. Poster presented at 73rd Scientific Sessions of the ADA; 2013 June 21-25; Chicago, IL. 985-P. **3.** Omer, A. et al. Poster presented at 73rd Scientific Sessions of the ADA; 2013 June 21-25; Chicago, IL. 980-P. **4.** Lajara, R, et al. *Drugs-Real World Outcomes* 2016 Jun 2;3(2):191-199. **5.** Lajara R, et al. *Diabetes Ther*. 2015;6 (4):531-545. **6.** Lajara R et al. *Endocr Pract*. 2016 June; 22 (6): 726-725. **7.** Sutton D, et al. *Advances in Therapy*. 35(5), 631-643 2018. **8**. Cziraky M, et al. *JHEOR* 2019;6(2):70-83. **9**. Wu P, et al. Poster presented at AACE 27th Annual Scientific Meeting, May 2018. **10**. Hundal R, et al. Poster presented at the Academy of Managed Care Pharmacy, April 2018. **11.** Everitt B, et al. *Research in Social and Administrative Pharmacy*, https://doi.org/10.1016/j.sapharm.2018.09.016

Robust Clinical Data

Demonstrated Ability of V-Go® to Deliver Clinically Relevant Reductions in A1c with Less Insulin

Baseline Insulin Dose U/day: V-GoAL-71, SIMPLE-62, VALIDATE 1-99, EVIDENT-67, IMPROVE-84, Jones-76, KAISER-72, UMASS-119, MOTIV-144 and ENABLE-76

†Change in A1c based on mean V-Go Duration rounded to the nearest month. Protocol for V-GoAL study specified end of study A1c as 3 months (+30 days) from baseline. Duration for JONES study varied by patient with up to 1 year of V-Go use.

‡Insulin change reported based on comparison to prescribed upper limit at baseline

1. Cziraky M, et al. *JHEOR* 2019;6(2):70-83. **2**. Grunberger G, et al. Poster presented at 73rd Scientific Sessions of the ADA, June 2013. **3**. Lajara R, et al. *Diabetes Therapy*. 2015;6(4):531-545. **4**. Everitt B, et al. *Research in Social and Administrative Pharmacy*, https://doi.org/10.1016/j.sapharm.2018.09.016. **5**. Sutton D, et al. *Advances in Therapy*. 35(5), 631-643 2018. **6**. Sink J, et al Poster Presented at Diabetes Technology Meeting, Nov. 2014. **7**. Wu P, et al. Poster presented at AACE 27th Annual Scientific Meeting, May 2018. **8**. Omer A, et al. Poster presented at ADA 73rd Scientific Sessions, June 2013. **9**. Mehta S, et al. *Annals of Diabetes, Metabolic Disorders & Control.* 2018; 1(2):120. **10**. Hundal R, et al. Poster presented at the Academy of Managed Care Pharmacy, April 2018. **11**. Valeritas has additional smaller studies not disclosed in this summary.

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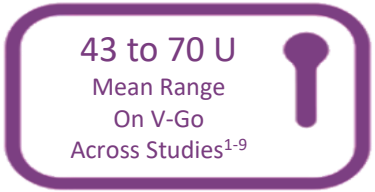
Regardless of Insulin Starting Point, V-Go® has Resulted in Clinical Benefit

Patients Switched to V-Go Significantly Lowered their A1c with ~55 U/day

> 80% of Patients in U.S. with T2DM on insulin are Prescribed ≤ 150 U/day of Insulin[10]

Total Daily Insulin Doses Prescribed Before V-Go (U/Day) Across Multiple Studies									
Study	UPP[6]	SIMPLE[1]	EVIDENT[3]	Jones[5]	IMPROVE[4]	VALIDATE 1[2]	UMASS[7]	VALIDATE 1[9]	MOTIV[8]
Max dose	**86**	**NR**	**200**	**NR**	**200**	**310**	**300**	**280**	**292**
Mean dose	**49**	**62**	**69**	**76**	**84**	**99**	**119**	**143**	**144**
Min dose	**25**	**NR**	**10**	**NR**	**10**	**16**	**34**	**100**	**45**

V-Go has consistently shown improvements in A1c using less insulin



NR= Not reported, T2DM= Type 2 Diabetes Mellitus

1. Grunberger G, et al. Poster presented at ADA, June 2013. **2**. Lajara R, et al. *Diabetes Therapy*. 2015. **3**. Everitt B, et al. *Research in Social and Administrative Pharmacy*, https://doi.org/10.1016/j.sapharm.2018.09.016. **4**. Sutton D, et al. *Advances in Therapy*. 35(5), 631-643 2018.. **5**. Sink J, et al Poster Presented at Diabetes Technology Meeting, Nov. 2014. **6**. Rosenfeld CR, et al. *Endocr Pract*. 2012. **7**. Omer A, et al. Poster presented at: ADA, June 2013. **8**. Mehta S, et al. *Annals of Diabetes, Metabolic Disorders & Control.* 2018; 1(2):120. **9.** Lajara R, et al. Poster presented at Diabetes Technology Meeting, November 2015. **10.** Eby EL et al. Clin Ther. 2015 Oct 1;37(10):2297-2308.

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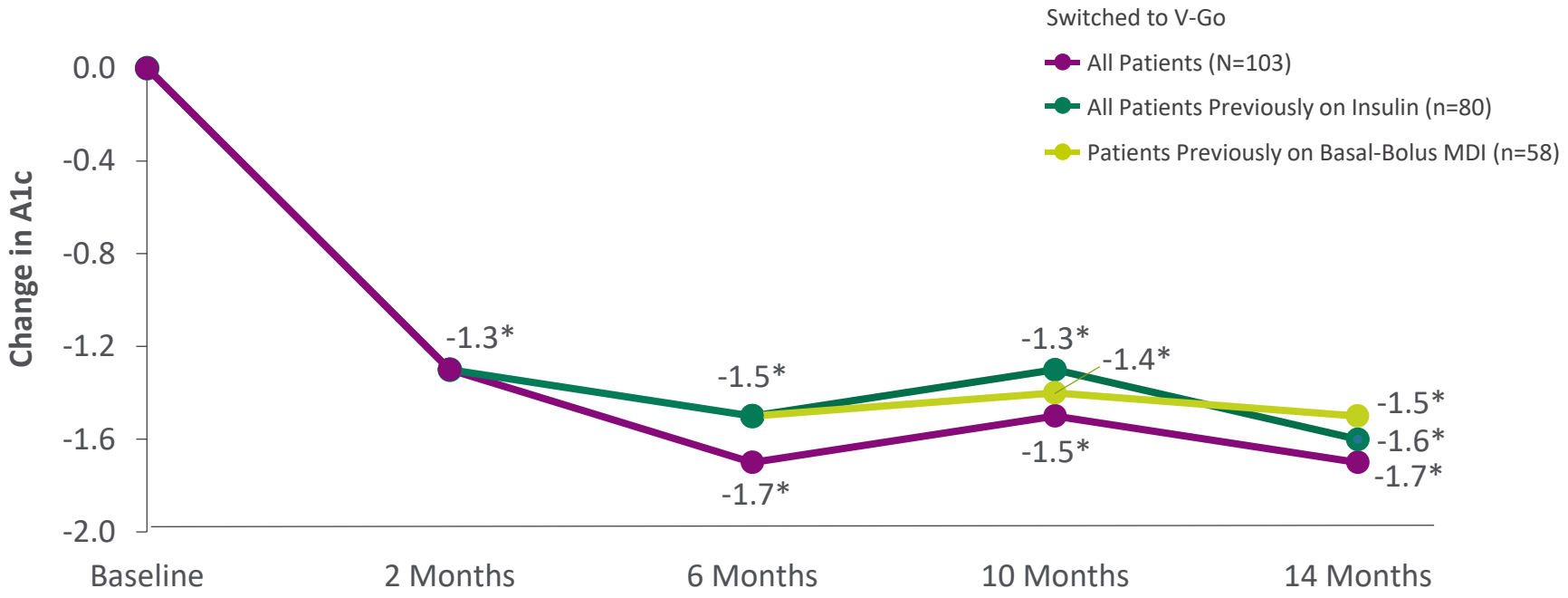
V-Go® Demonstrated Reduction in Glucose at 14 Months



*P<0.001
Baseline A1c= All: 9.80%, All Insulin: 9.79%, MDI: 9.73%
Insulin cohort includes patients prescribed: basal-only, basal-bolus, premix or prandial-only at baseline
MDI=Multiple Daily Injections

Sutton, D. et al. *Advances in Therapy*. May 2018

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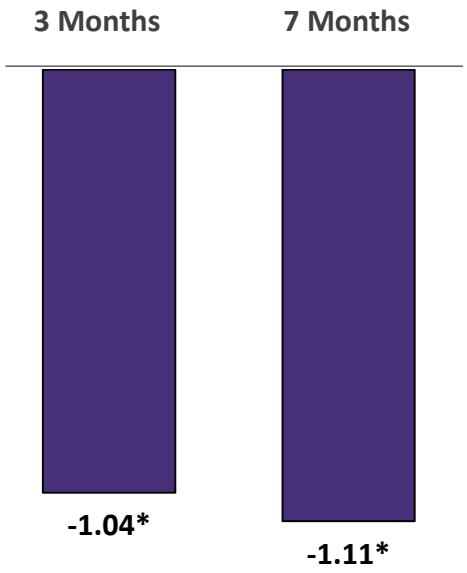
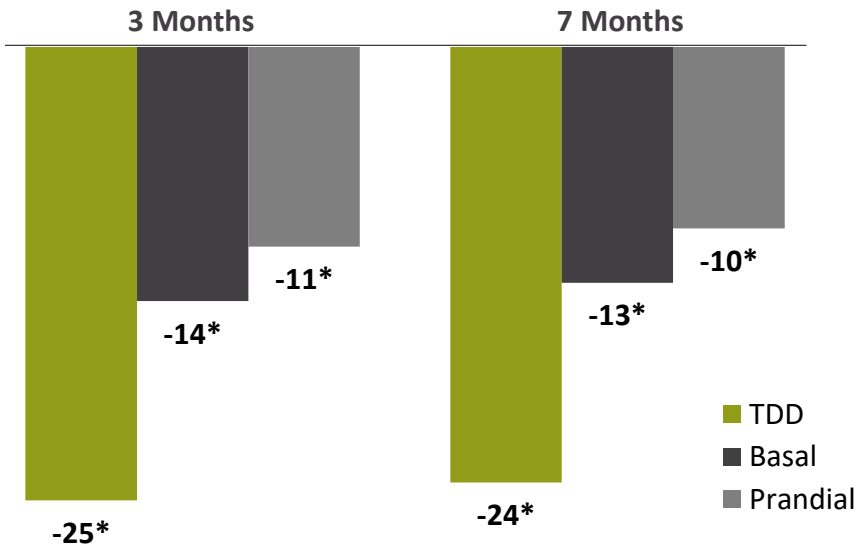
V-Go® Offers Efficient Delivery for Improved Glycemic Control

V-Go Demonstrated Significant Reductions in A1c and Insulin For Patients with Type 2 Diabetes Compared to Pen Therapy

Mean Change in A1c On V-Go



Mean Change in Insulin (units/day) On V-Go



N=148 , Mean Baseline A1c 9.1%, insulin basal, prandial and total U/Day were 47, 35 and 82, respectively
*p<0.0001 compared to baseline
TDD= Total daily dose of insulin, Change in insulin is rounded to the nearest whole number
Hundal R, et al. Poster presented at the Advanced Technologies & Treatments for Diabetes, February 2019.

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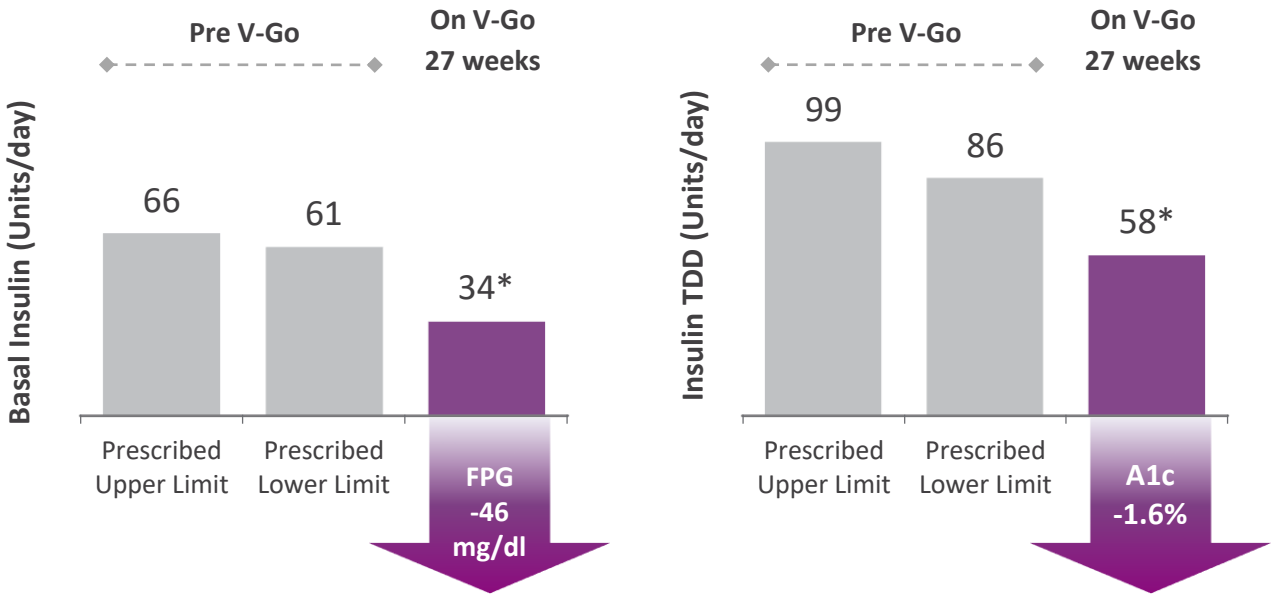
V-Go® Improves Glycemic Control and Reduces Prescribed Insulin



Significant reduction in fasting glucose even with nearly ½ the basal insulin dose

Fasting Plasma Glucose (FPG) reductions based on patients with baseline FPG measurements and corresponding basal insulin dosage (n=67). A1c reductions based on patients on insulin at baseline (n=180) compared to V-Go insulin total daily dose. 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.

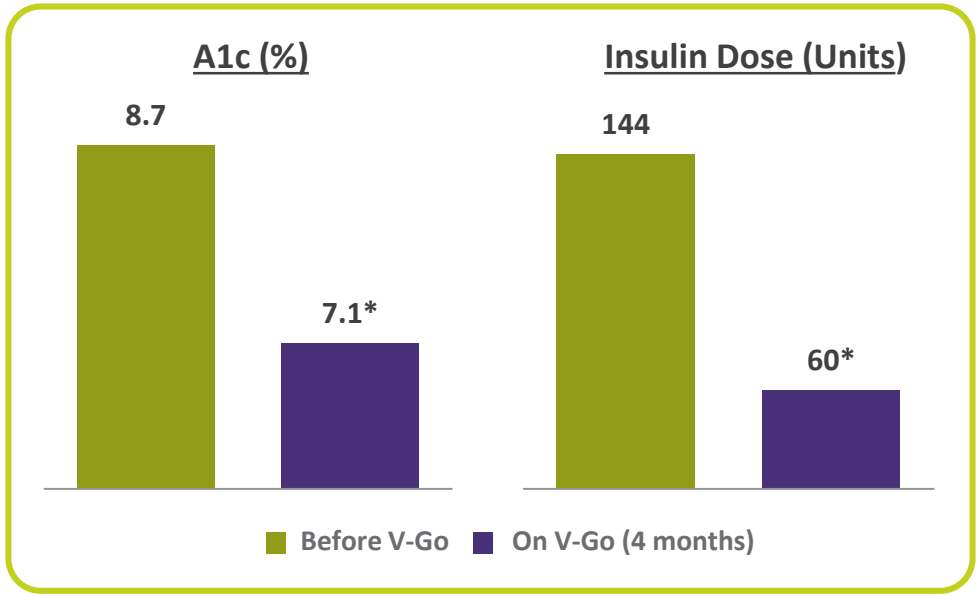
Lajara R, et al. *Diabetes Therapy*. 2015.

VALIDATE 1 Study

valeritas

Simple Titration Approach Significantly Lowered A1c

Use of a weekly physician-driven mealtime dosing titration approach with patients with Type 2 Diabetes uncontrolled on prior regimens



A1c Goal Achievement

	Before V-Go®	On V-Go
< 7%	13%	47%
< 8%	40%	87%
≤ 9%	67%	100%

Hypoglycemia (very low blood glucose) was reported in 23% of patients at baseline and 7% of patients at 4 months.

Source: Texas Health Resources. MOTIV (Managing Optimization and Titration of Insulin Delivery with V-Go) Retrospective Study
TDD=Total daily dose of insulin *Significant compared to baseline N=15
Mehta S, et al. Mehta S, et al. *Annals of Diabetes, Metabolic Disorders & Control.* 2018; 1(2):120.

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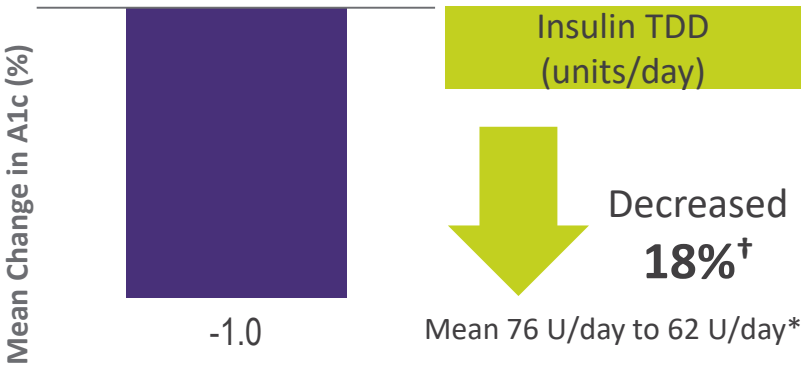
Clinical Benefit Realized with V-Go®

Switching Patients from Prior Insulin Injections to V-Go Resulted in Improved A1c and Less Insulin Regardless of Baseline Insulin Regimen or Dose

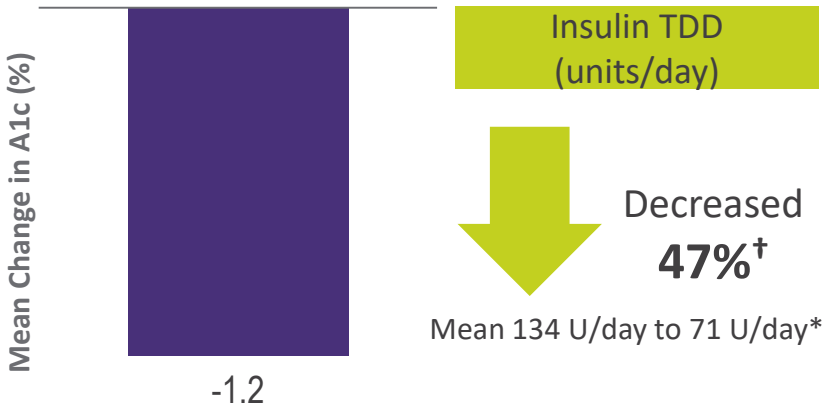
All Patients Switched to V-Go[1]



Reduced the percent of patients AT HIGH RISK (A1c >9%) by nearly half[1]

Patients with High Dose MDI Switched to V-Go[2]

(MDI Patients Prescribed between 90- 300 U/day)



*P<0.0001 compared to baseline

†After 7 months of V-Go use. Duration rounded to month

All patients N=283 from regimens of basal-only, basal-bolus, premix and other combinations. Baseline A1c: 9.2% and 46% of patients defined at high risk which was reduced to 24% by end of observation.

High Dose MDI patients N=63 from basal-bolus regimens with prescribed doses between 90 and 300 U/day. Baseline A1c: 9.3%.

MDI= Multiple Daily Injections, TDD=Total Daily Dose of Insulin.

1. Hundal R, et al. Poster presented at the Academy of Managed Care Pharmacy, April 2018. 2. Hundal, R, et al. Poster Presented at the American Diabetic Association Scientific Sessions, June 2018.

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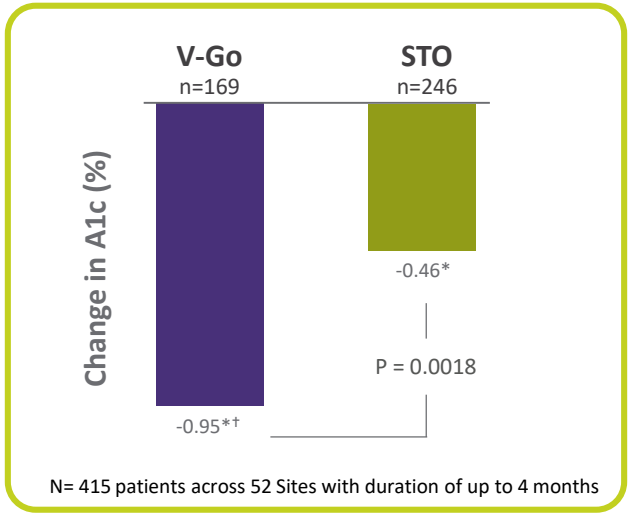
V-Go®: Improved A1c Control with Less Insulin

A prospective study of 415 patients showed V-Go superiority vs. Standard Treatment Optimization (STO)[1]

Greater Improvement in A1c[2]



N= 415 patients across 52 Sites with duration of up to 4 months

Less Insulin Used & More Cost Effective

29%
Less Insulin
with V-Go
vs STO
at 4 months
(54 vs 72 u/day)
P<0.001

V-Go $24.48 vs STO $39.95 per patient per day for each 1% drop in A1c[3]

1 Study conducted by HealthCore, Inc., an outcomes research subsidiary of Anthem, Inc.
STO included patents currently using insulin therapy with a total daily dose of 30 U to 120 u/day and treated using standard of care by their physician, without forced or mandated protocols or titration regimens
*Significant compared to baseline. †Significant between groups. Statistical significance between groups was maintained when adjusted for imbalance in baseline A1c (data on file).
Baseline A1C (%): V-Go 9.88 and STO 9.34 Baseline total daily insulin dose (u/day): V-Go 71 and STO 72
2 As measured by A1c levels
3 Cost includes the WAC cost for all diabetes treatments and medications and based on per patient/day (PPPD) at study end.
The cost is calculated as the sum of published price of insulin, device and concomitant medications.
Abbott, S, et al. Presented as an oral presentation at the 77th ADA Scientific Sessions, San Diego, CA 2017

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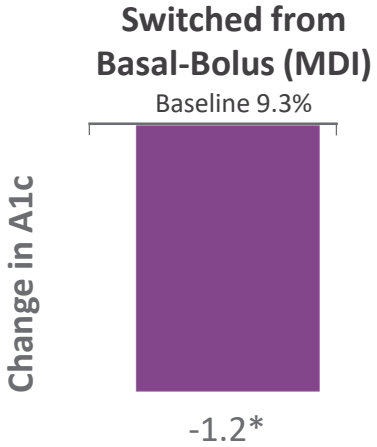
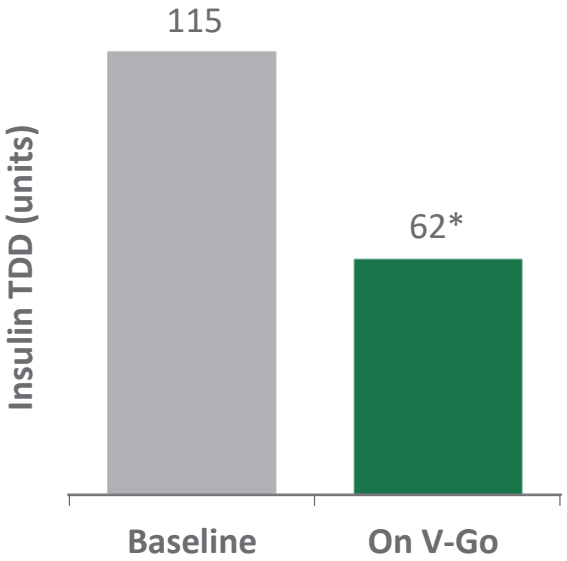
V-Go® Demonstrated Clinical Benefits in Patients with T2DM

Switched from Basal-Bolus (MDI)





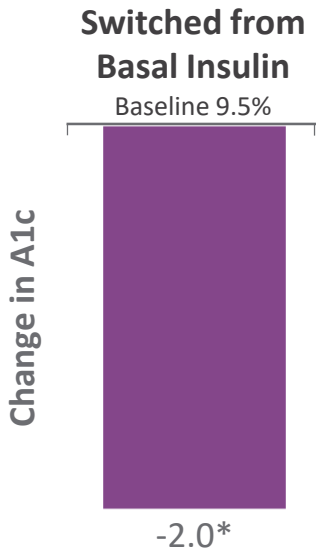
VALIDATE 1 Study

n=70 (all patients with two follow-up A1c values for a mean duration of 7 months)
*p<0.0001 compared to baseline
MDI=Multiple Daily Injections, TDD= Total Daily Dose of Insulin, T2DM= Type 2 Diabetes Mellitus

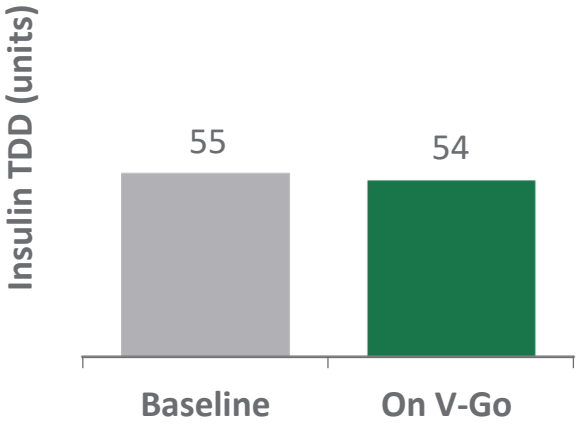
Lajara R, et al. *Practical Diabetology*. 2016.

V-Go® Demonstrated Clinical Benefits in Patients with T2DM

Switched from Basal-Only Regimen



Significant reduction in A1c by reducing the basal dose and adding meal time insulin with simple clicks of V-Go



n=47 (all patients with two follow-up A1c values for a mean duration of 7 months)
*p<0.0001 compared to baseline
TDD= Total Daily Dose of Insulin, T2DM= Type 2 Diabetes Mellitus

Lajara R, et al. *Practical Diabetology*. 2016.

VALIDATE 1 Study

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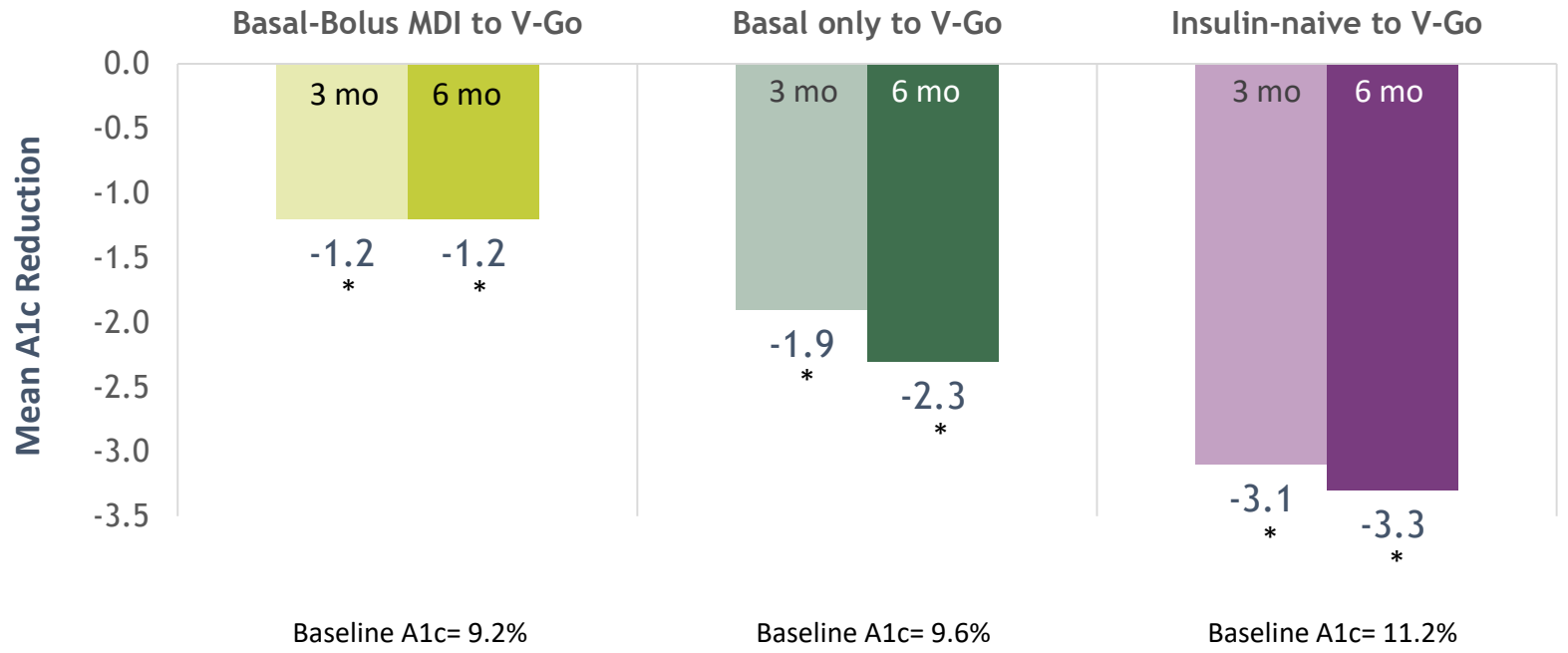
V-Go® Benefits a Wide Range of Patients

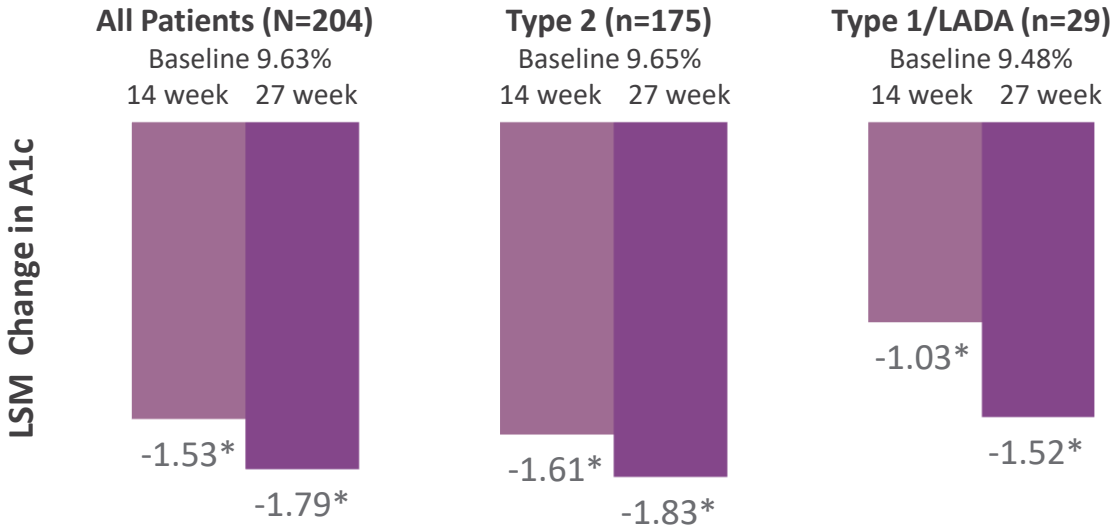


Baseline N= 86, 45, 22, respectively
Data are means
**P*<0.0001 vs baseline

VALIDATE 1 Study

Lajara R, Nikkel C. Poster presented at: AACE 24th Annual Scientific and Clinical Congress; May 2015; Nashville, TN.

V-Go® Demonstrates Clinical Benefits Across All Types of Diabetes



Mean Insulin TDD†	Baseline: 99 U V-Go: 58 U*	Baseline: 98 U V-Go: 59 U*	Baseline: 104 U V-Go: 51 U*

Patients naive to insulin reduced A1c by 3.4%

VALIDATE 1 Study

*p<0.001 compared to baseline
†Total daily dose (TDD) based on upper limit of prescribed insulin

Lajara R, et al. *Diabetes Therapy*. 2015 and data on file

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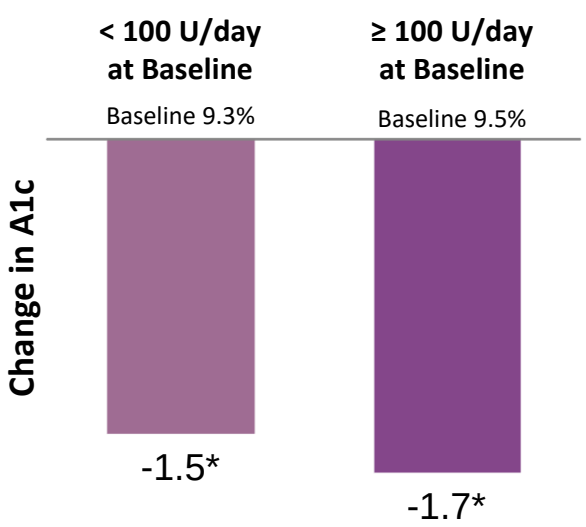
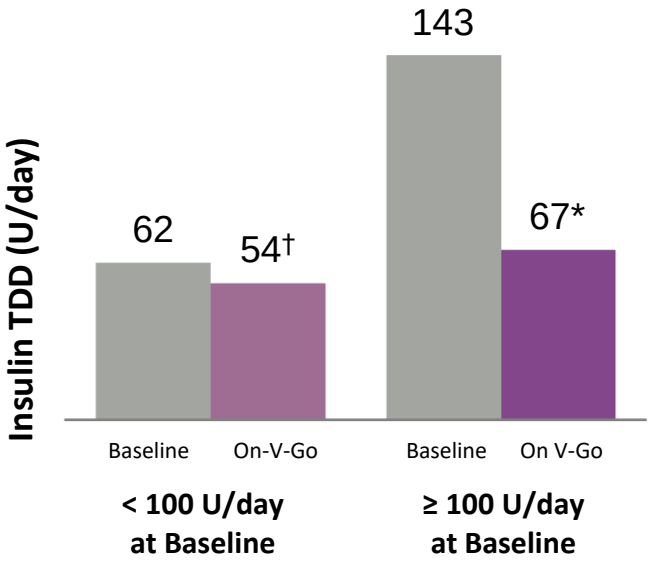
V-Go® Improved A1c Control Regardless of Baseline Insulin Dose

After 6 months of using V-Go for Insulin Delivery





VALIDATE 1 Study

N= 66 patients < 100 U/day at baseline and 38 patients ≥ 100 U/day at baseline
*p<0.0001 compared to baseline at 6 months, †P<0.05 compared to baseline at 6 months

Lajara R, et al. *J Diabetes Sci Technol*. 2016 Mar;10(2), data on file

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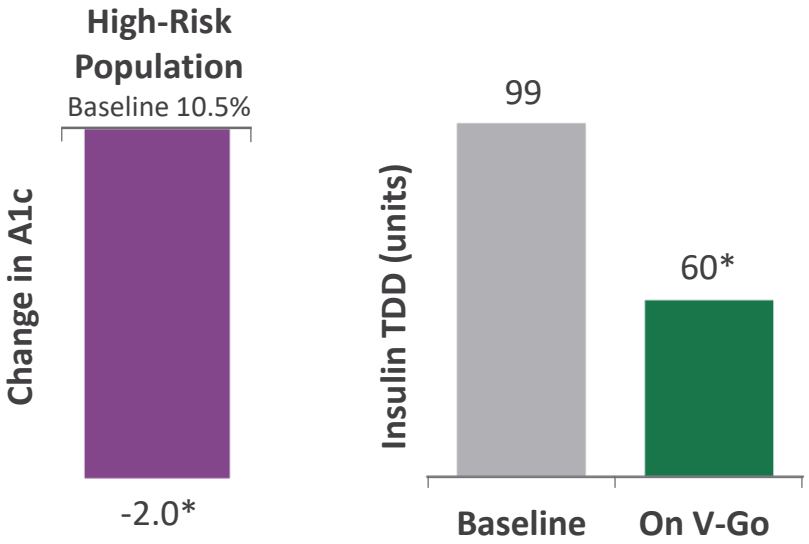
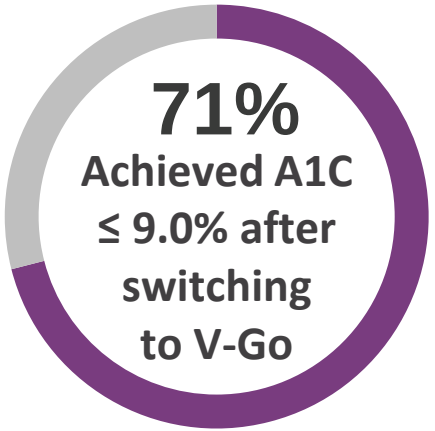
Patients at High Risk (A1c > 9%) Benefit from V-Go® Use

V-Go Resulted in Clinical and Economic Benefits



Quality Measures



Direct Pharmacy Savings to Plan†

$119/mo/patient

N=97 All patients were previously on basal (37%) or basal-bolus (63%) insulin injections
*p<0.001 at 3 months compared to baseline

†Savings are based on WAC pricing and calculated from subtracting total diabetes-related mean costs on V-Go from the baseline diabetes-related mean costs before V-Go for each group. Savings represented in US dollars and rounding was applied. Based on WAC=Wholesale Acquisition Cost.

Lajara R et al. *Drugs- Real World Outcomes*. 2016.

VALIDATE 1 Study

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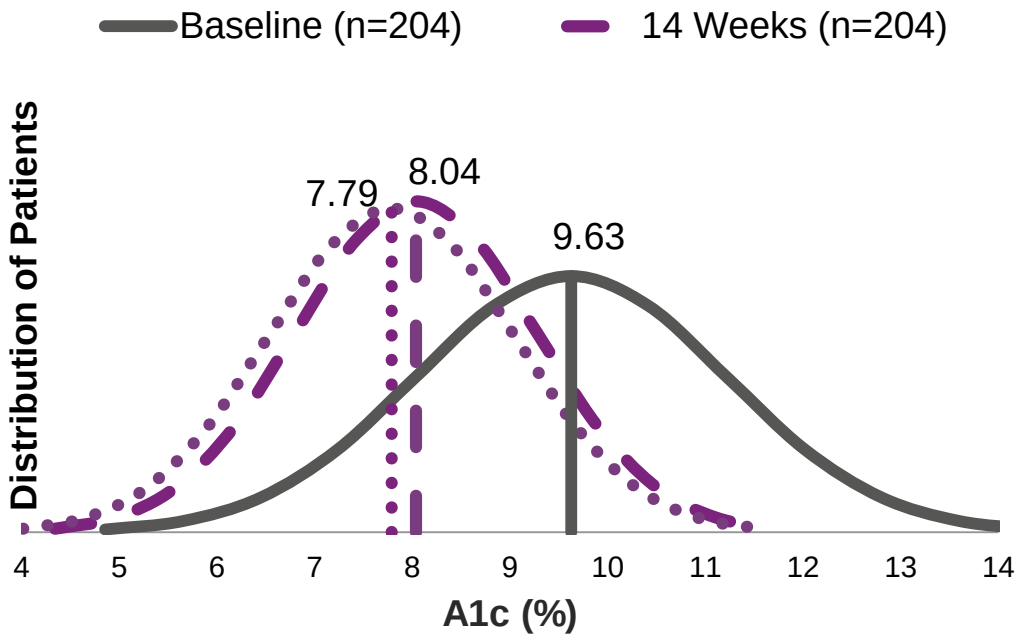
V-Go® Improved Glycemic Control with Less Insulin



A1c Lowering with a

41% Decrease† in Insulin with V-Go

(99 to 58 U/day at 27 weeks)

A1c data are arithmetic means at baseline (week 0) compared to first (14 week mean) and second (27 week mean) recorded A1c values on V-Go.
Curves represent the A1c distribution of patients for each time point based on available data.
By 27 weeks, 32 patients had discontinued V-Go and 35 patients had not returned for a 2nd follow-up appointment.
†Insulin decrease at 27 weeks on V-Go compared to upper limit of baseline prescribed dose ($p<0.001$)

VALIDATE 1 Study

Lajara R, et al. *Diabetes Therapy*. 2015.

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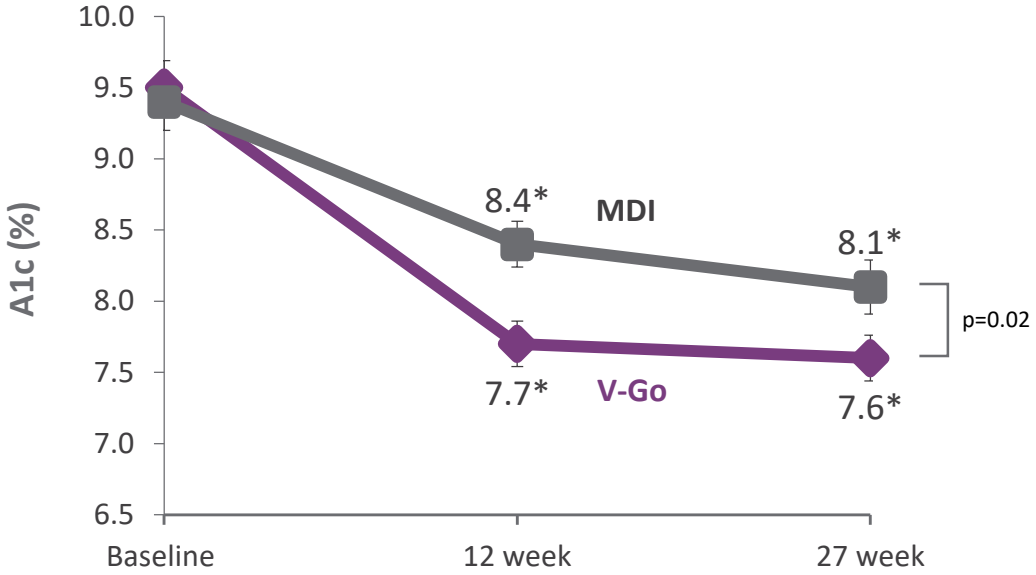
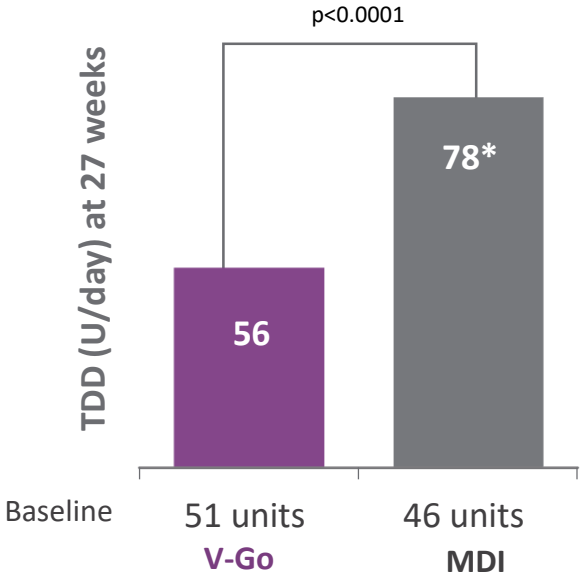
V-Go® Demonstrated Significantly Greater Improvements In Glycemic Control vs Multiple Daily Injections (MDI)

Better Control with Less Insulin vs MDI





VALIDATE 2 Study

V-Go: N=56 BL A1c- 9.5% BL TDD - 51 U/day, Starting V-Go TDD- 52 U/day, 12 week TDD- 56 U/day, 27 week TDD- 56 U/day
MDI: N=60 BL A1c- 9.4, BL TDD- 46 U/day, Starting MDI TDD- 64 U/day, 12 week TDD- 75 U/day, 27 week TDD- 78 U/day
Data are mean (SE)

Lajara R, Davidson JA, et al. *Endocr Pract*. 2016 June; 22 (6): 726-725.

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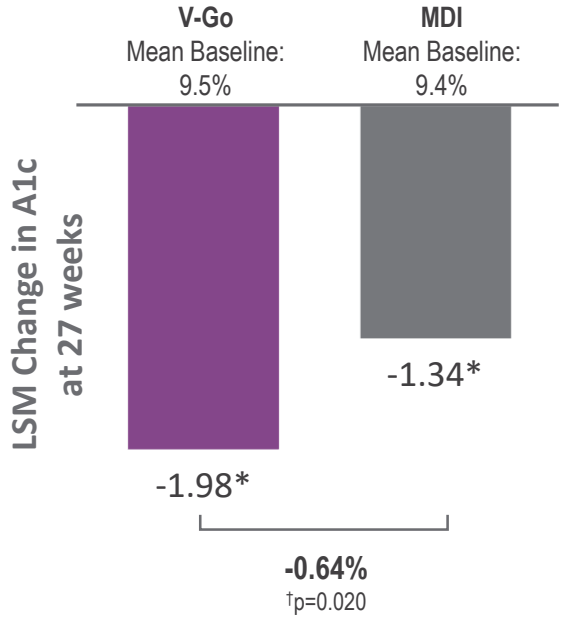
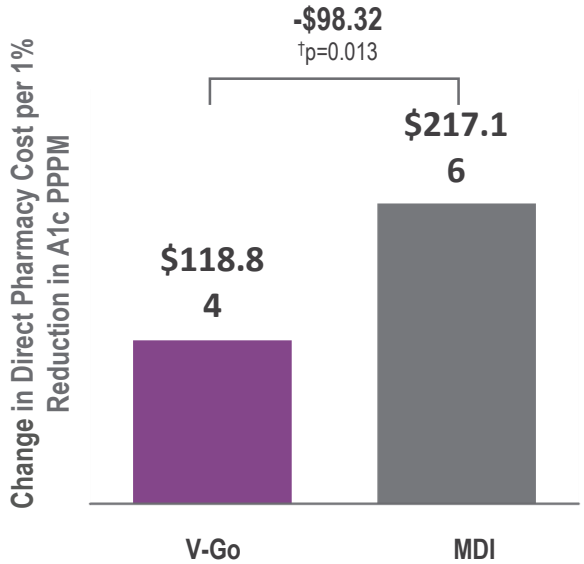
V-Go® is More Cost-Effective for Basal-Bolus Therapy Compared to Multiple Daily Injections (MDI)





*p<0.001 compared to baseline

†p-value calculated using a mixed model to determine least squares mean change from baseline between group difference

VALIDATE 2 Study

Insulin costs include both the insulin and associated delivery method. The costs of insulin were normalized by calculating a 30 day insulin requirement based on the total prescribed daily insulin dose for each insulin and multiplying the monthly dose in units by the unit cost. Only branded antihyperglycemic agents were included in total therapy costs. All pricing based on published wholesale acquisition costs in 2015 U.S. dollars as of 9/1/2015.

Lajara R, Davidson JA, et al. *Endocr Pract*. 2016 June; 22 (6): 726-725.

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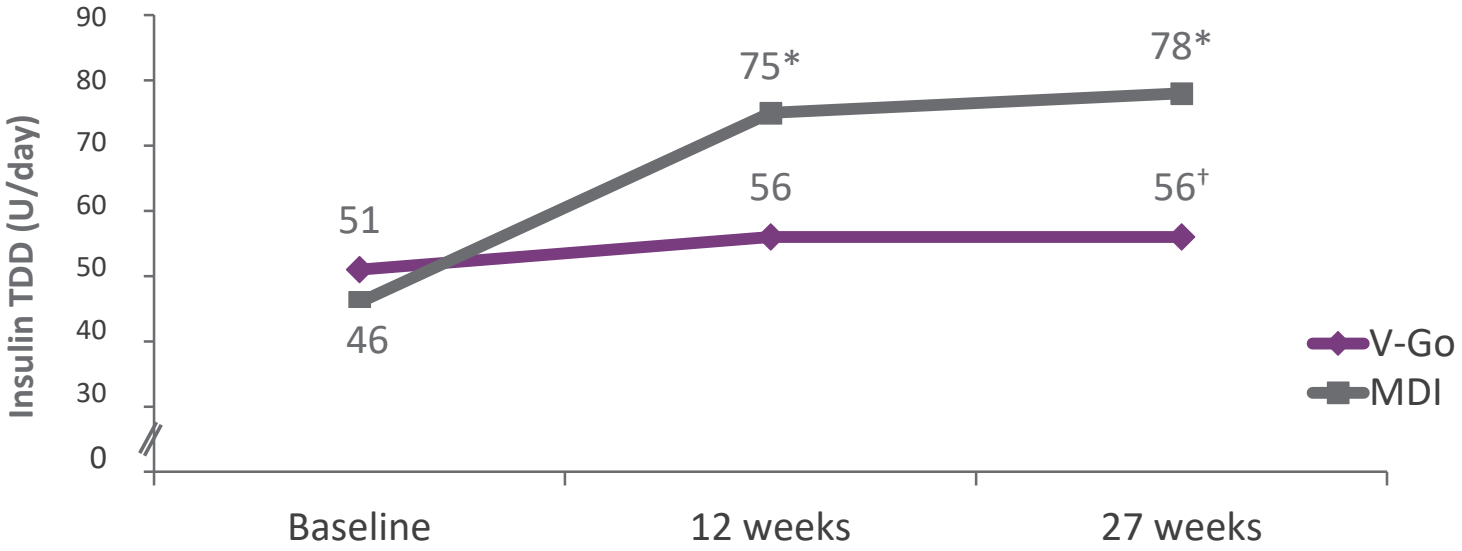
Patients Intensified to Basal-Bolus from Basal Insulin Required Less Insulin with V-Go® vs MDI



N=116
MDI=Multiple Daily Injections
*p<0.001 vs baseline.
†p<0.0001 vs MDI at 27 weeks

VALIDATE 2 Study

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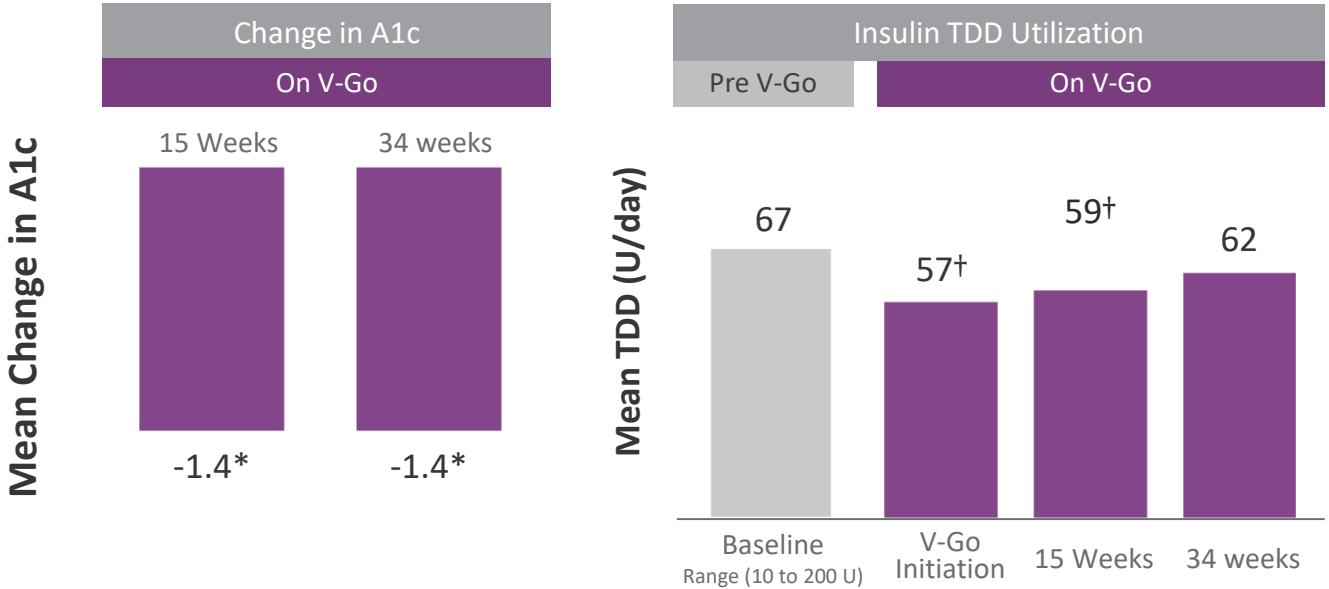
Lajara R, Davidson JA, et al. *Endocr Pract*. 2016 June; 22 (6): 726-725.

V-Go® Demonstrated Improvements in A1c and Reductions in Insulin



Pre V-Go Insulin Regimens included from 1 to 5 injections/day

*p<0.0001 compared to baseline †p=0.006 compared to baseline
N=103 at 15 weeks with a baseline A1c of 9.6% and N=84 at 34 weeks with a baseline A1c of 9.7%.

Harrison C, et al. Poster presented at the AACE 26rd Annual Scientific and Clinical Congress. May 2017; Austin, TX

EVIDENT Study

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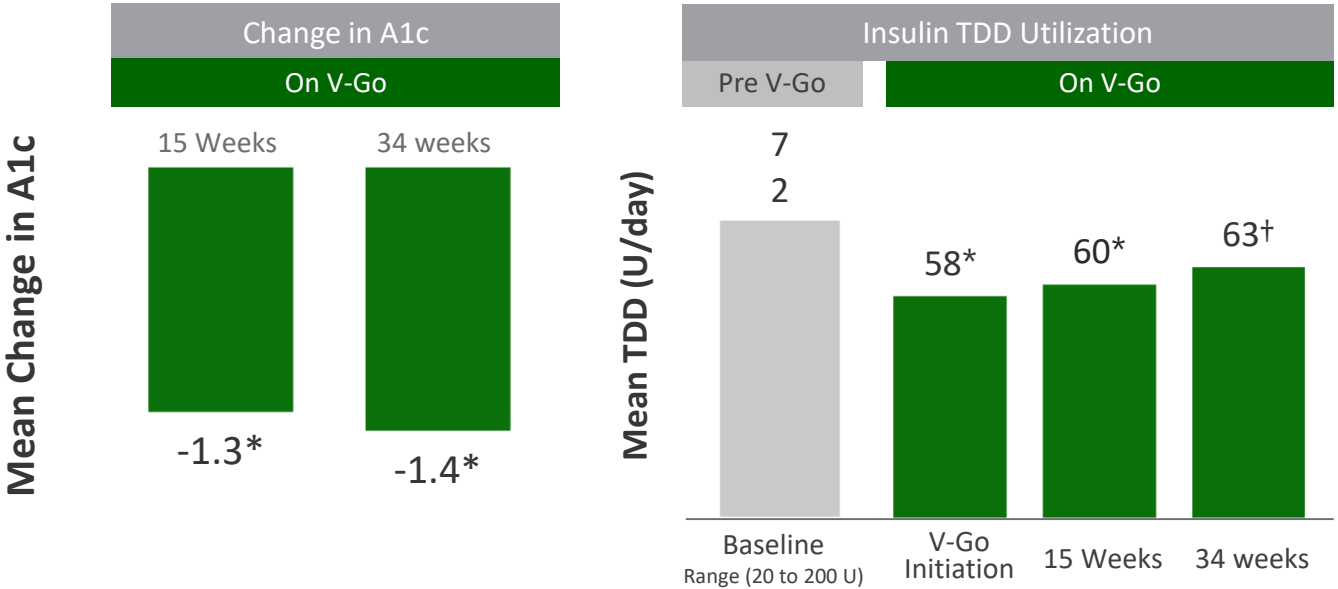
Switching to V-Go® Demonstrated Significant Clinical Benefits

In Patients on ≥ 2 Insulin Injections/Day



Pre V-Go Insulin Regimens included 2 or more injections/day

*p<0.0001 compared to baseline †p=0.007 compared to baseline
N=88 at 15 weeks with a baseline A1c of 9.6% and N=71 at 34 weeks with a baseline A1c of 9.6%.

Harrison C, et al. Poster presented at the AACE 26rd Annual Scientific and Clinical Congress. May 2017; Austin, TX

EVIDENT Study

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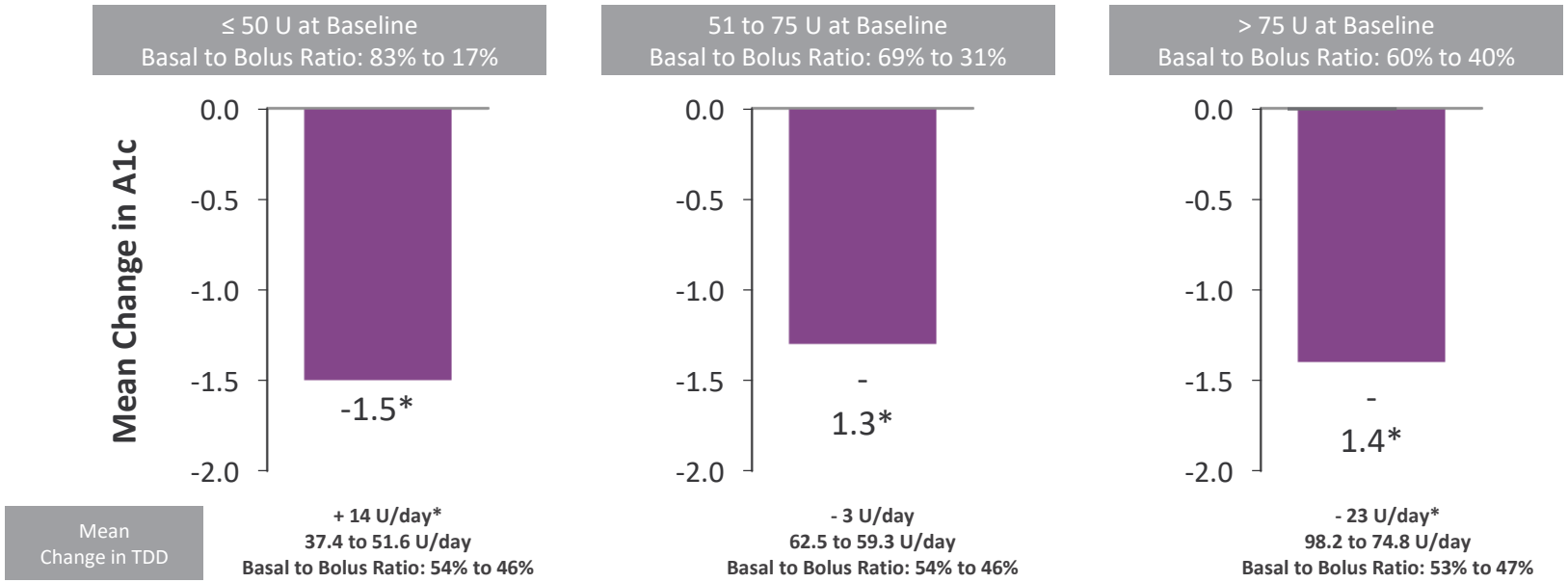
V-Go® Improved A1c Control Regardless of Baseline Insulin Dose



EVIDENT Study

*p<0.0001 compared to baseline
N= 84 (29, 24, 31 respectively after a mean of 34 weeks on V-Go with baseline A1cs of 9.7, 9.3 and 9.9% respectively).

Harrison C, et al. Poster presented at the AACE 26rd Annual Scientific and Clinical Congress. May 2017; Austin, TX

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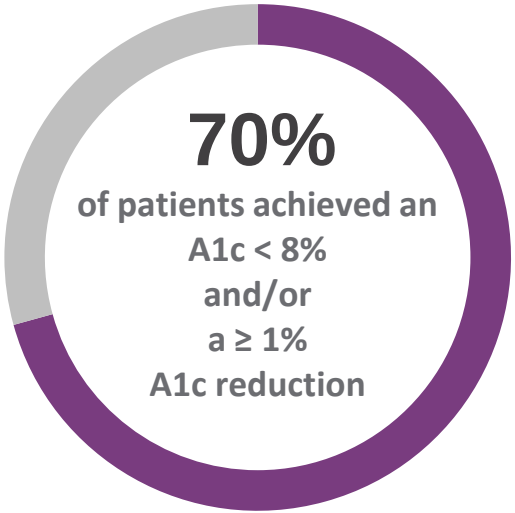
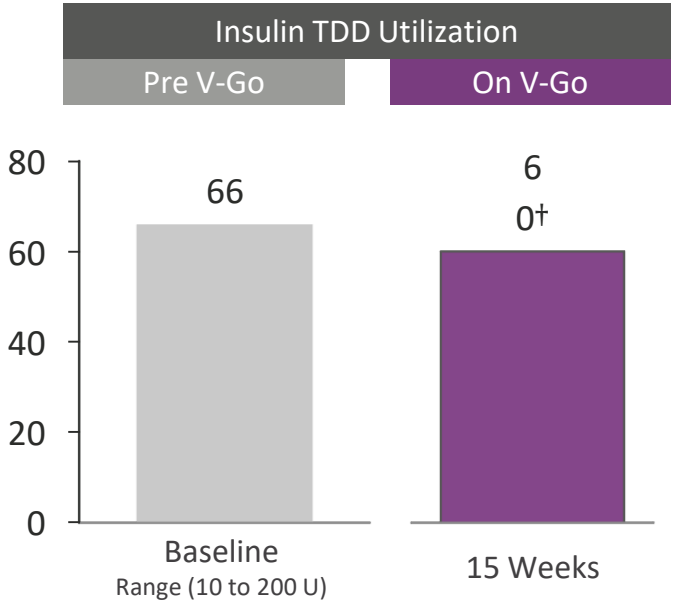
Glycemic Targets Achieved in the Majority of Patients with V-Go® using Less Insulin

A sub analysis to evaluate the % of patients with uncontrolled type 2 diabetes (A1c > 8%) who achieved an A1c < 8% and/or a reduction in A1c of ≥ 1% after being switched from conventional insulin delivery (syringe or pen device) to V-Go® wearable insulin delivery.



After a mean of 15 weeks of V-Go use

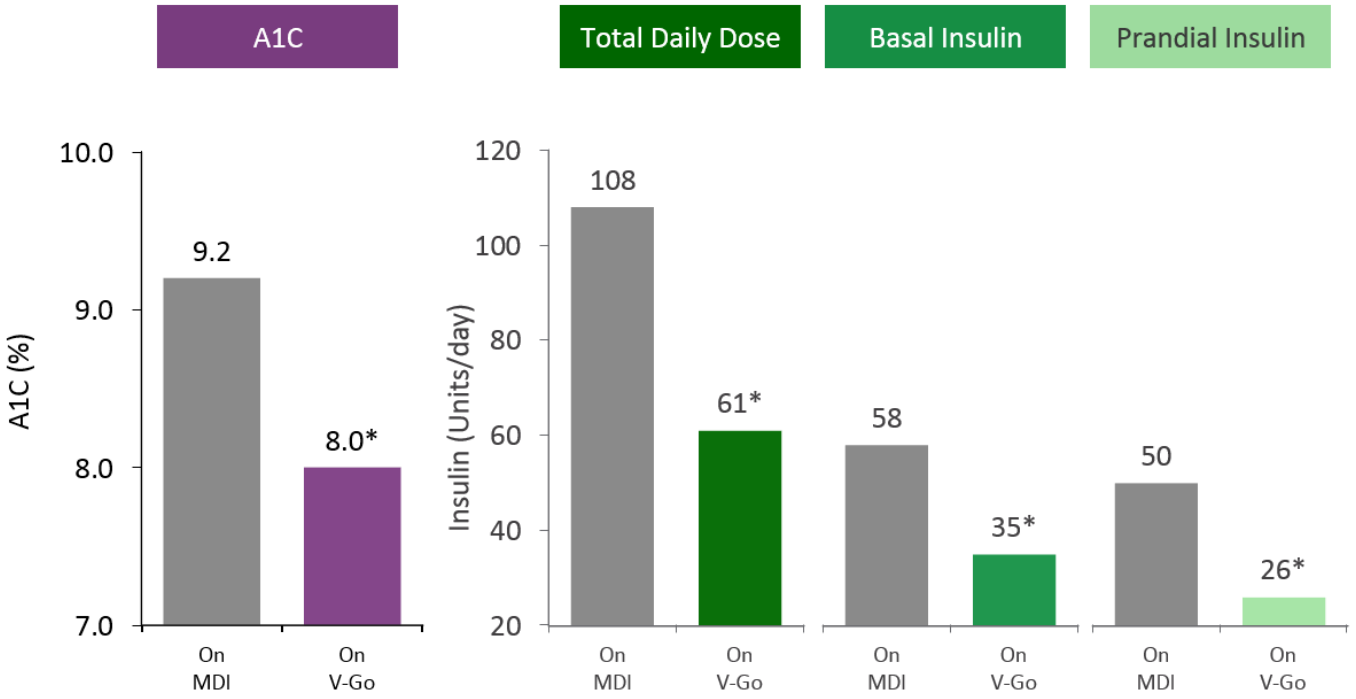


EVIDENT Study

N=89, baseline A1c 9.9%
†p=0.04 compared to baseline

Harrison C, et al. Poster presented at the AACE 26rd Annual Scientific and Clinical Congress. May 2017; Austin, TX

V-Go® Offers Clinical Benefits when Switching from MDI



N=86
MDI=Multiple Daily Injections
*p<0.0001 compared to baseline regimen of MDI
Mean duration on V-Go: 29 weeks

Lajara R, et al. Poster presented at the 22nd Annual ISPOR Meeting, May 2017; Boston, MA

VALIDATE 1 Study

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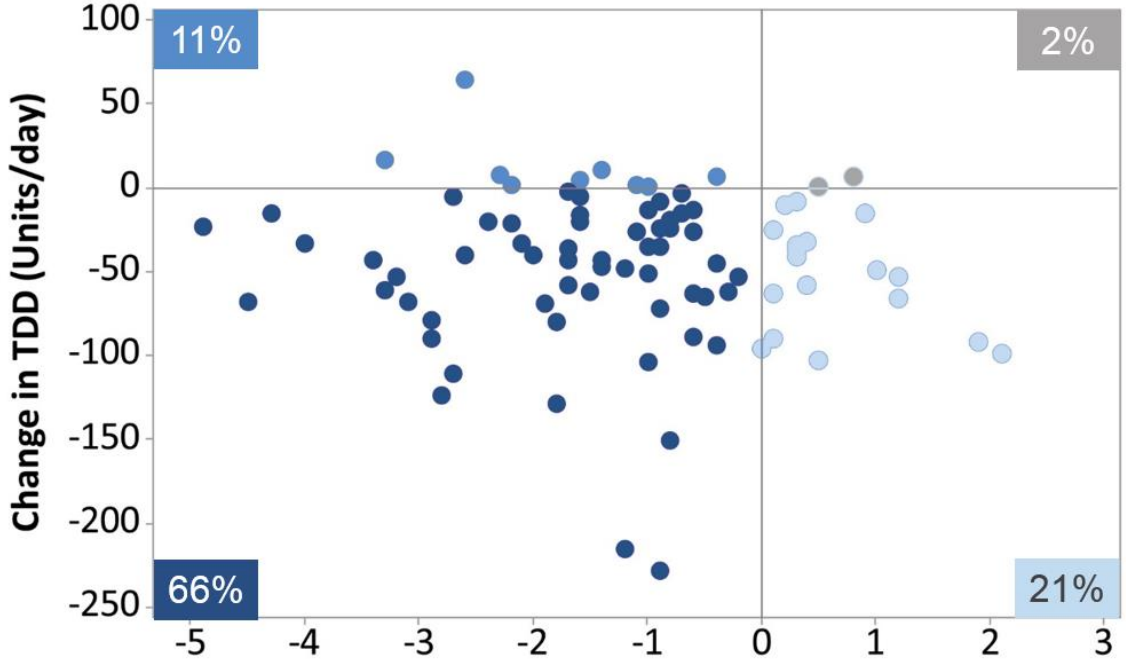
In 66% of Patients Both A1c Improved and Insulin was Reduced when Switched from MDI to V-Go®

Relationship between Change in A1c and Change in TDD on V-Go



N=86 patients, each dot represents a patient

VALIDATE 1 Study

Lajara R, et al. Poster presented at the 22nd Annual ISPOR Meeting, May 2017; Boston, MA

Switching Patients from MDI to V-Go® Resulted in a Direct Pharmacy Cost Savings to the Plan

Direct Pharmacy Costs Per Patient Per Month (PPPM)	On MDI N=86	On V-Go N=86
Prescribed insulin costs PPPM	$888.00	$471.00
Pen needles/syringes/V-Go costs PPPM	$37.00	$308.00†
Total insulin therapy costs PPPM	$925.00	$779.00
Savings* with V-Go (per patient/month) **Savings* with V-Go (per patient/quarter)** **Projected Savings with V-Go (per patient/year)**		**$146.00*** **$438.00*** **$1,752.00**

*p=0.001
MDI=Multiple Daily Injections, PPPM=Per Patient Per Month
Data are means and rounded to the dollar.
Average monthly costs are normalized to 30 days and based on calculated costs for basal and/or prandial units/day based on average market leaders unit pricing. MDI pen needles and/or syringes (4 per day) based on market leader average unit pricing.
Concomitant antihyperglycemic non-insulin agents not included.
†Average cost inclusive of V-Go and pen needles for patients administering supplemental insulin

Lajara R, et al. Poster presented at the 22nd Annual ISPOR Meeting, May 2017; Boston, MA

VALIDATE 1 Study

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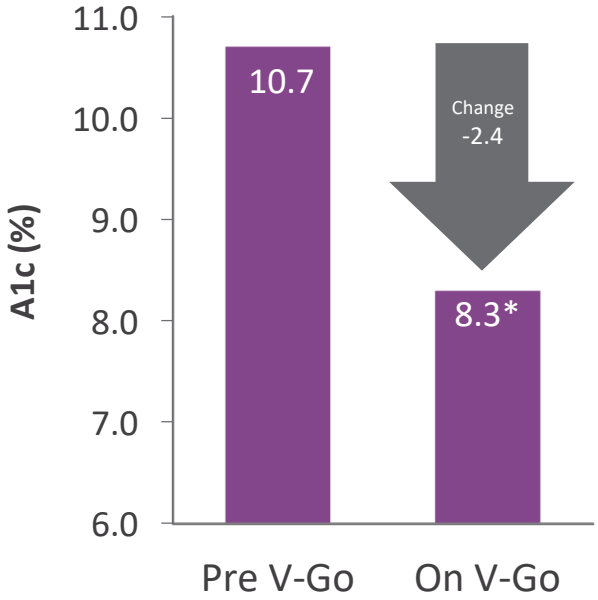
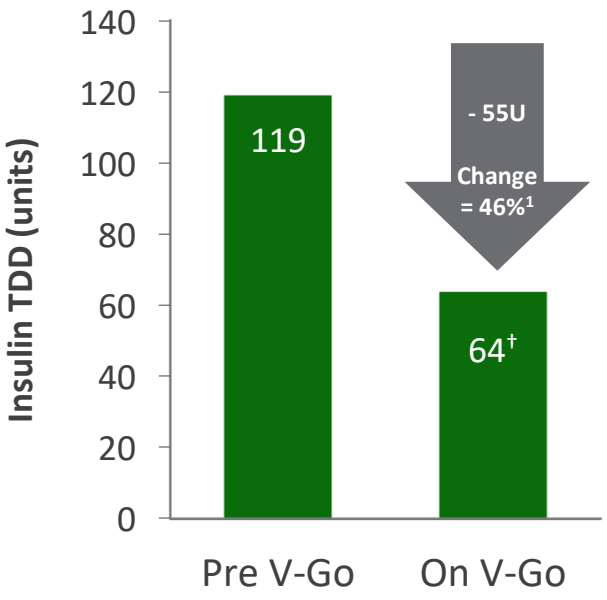
V-Go® Significantly Reduced A1c with Less Insulin

Key Benefit to Both Patients and Payors





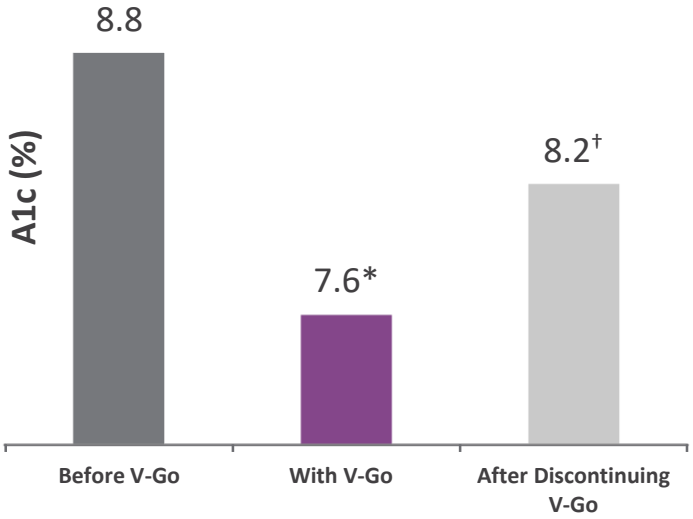
N=14 Average Duration = 88 days
†p=0.01, *p=0.001
[1]Based on Insulin TDD absolute units

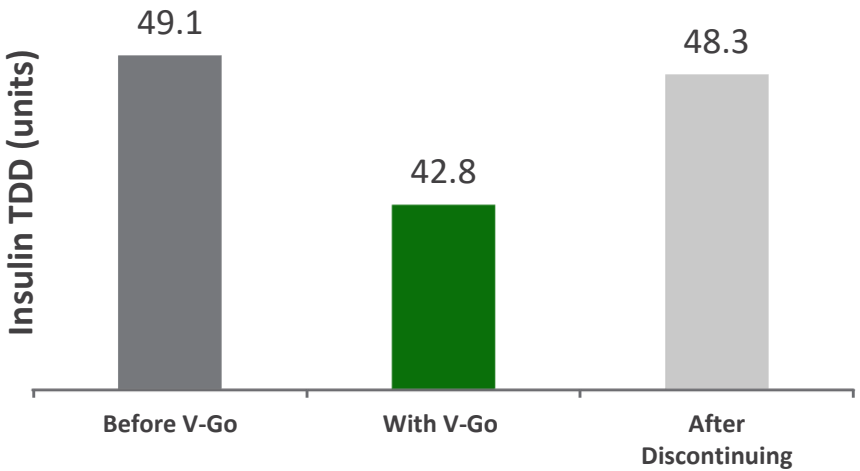
UMASS Study

Omer, A. et al. Poster presented at 73rd Scientific Sessions of the ADA; 2013 June 21-25; Chicago, IL. 980-P. UMASS Study .

Glycemic Control Improved with V-Go® using Less Insulin and Deteriorated after V-Go was Discontinued

A retrospective clinical chart review was conducted in a subset of patients to assess the change in A1c and insulin dosing with V-Go and after discontinuation of V-Go. This chart review occurred after the completion of a prospective study designed to gather patient and HCP feedback in patients prescribed insulin initiated on V-Go.





N=23

A1c- *p=0.002 vs "Before V-Go", †p=0.011 vs "With V-Go"

This V-Go study was conducted prior to FDA filing, therefore following the study, all patients had to resume insulin delivery via pens/syringes.

Patients prescribed an insulin therapy providing fasting and mealtime coverage: Before V-Go- 57%, With V-Go- 100%, After V-Go-74%

Insulin- No statistical analysis available.

Rosenfeld CR, et al. *Endocr Pract*. 2012.

User Preference Program

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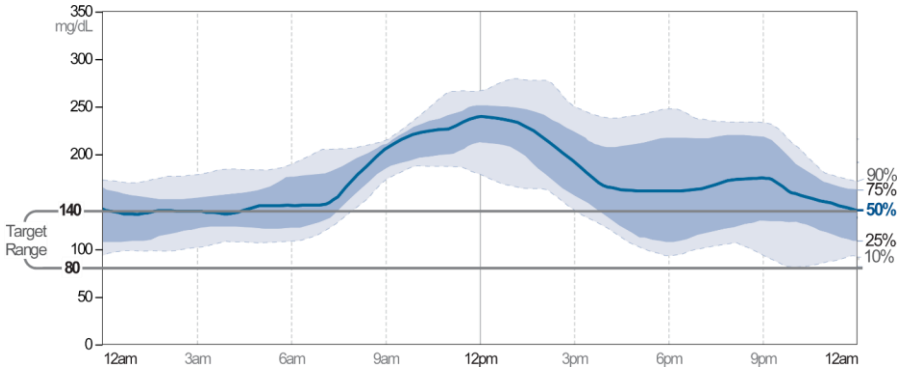
V-Go®: Insulin Delivery Matters

Better Glucose Profile, Similar Insulin Dose- *Optimizing Insulin Delivery Matters*

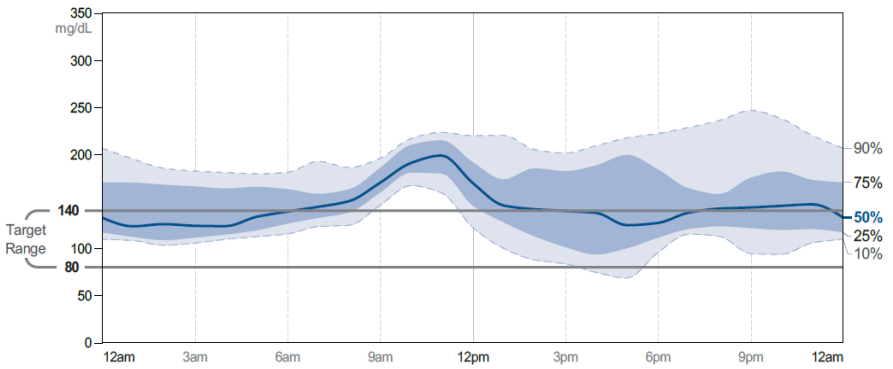
Basal-Bolus MDI TDD at baseline:
Degludec 30 U/day + Lispro 15 U/day = 45 U TDD

Estimated A1c	**7.6%**
Time in Range, %	**27**



V-Go Regimen:
V-Go 20 basal rate + 26 bolus U/day = 46 U TDD

Estimated A1c	**6.9%**
Time in Range, %	**44**



MDI= Multiple Daily Injections; TDD= Total Daily Dose

Parikh S, et al. AACE 27th Annual Scientific and Clinical Congress; May 2018; Boston, MA.

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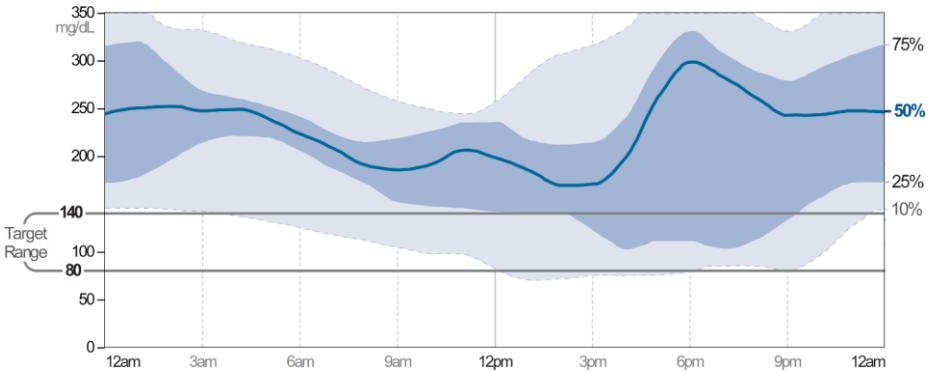
V-Go®: The Right Amount of Insulin at the Right Time

Better Glucose Profile, Less Insulin- *The Right Amount of Insulin at the Right Time*

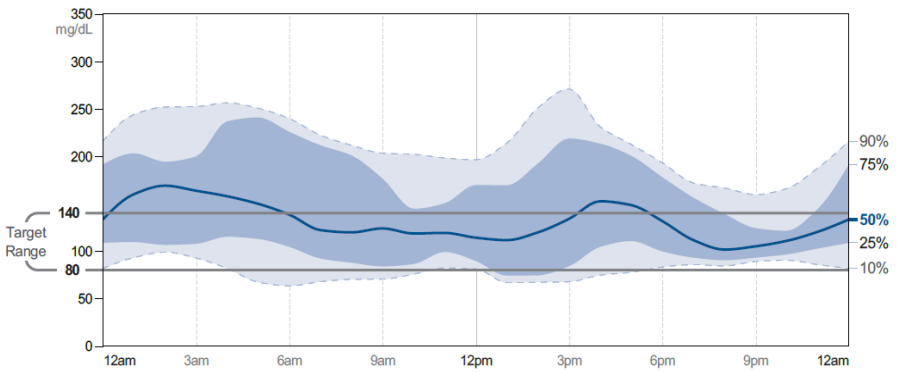
Basal-Bolus MDI TDD at baseline:
Glargine (U-300) 50 U/day + Lispro 45 U/day = 95 U TDD

Estimated A1c	**9.2%**
Time in Range, %	**16**



V-Go Regimen:
V-Go 20 basal rate + 20 bolus U/day = 40 U TDD

Estimated A1c	**6.5%**
Time in Range, %	**46**



MDI= Multiple Daily Injections; TDD= Total Daily Dose

Parikh S, et al. AACE 27th Annual Scientific and Clinical Congress; May 2018; Boston, MA.

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Study Design & Quality Measures

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Real World Evidence Demonstrates Real Results

Valeritas has focused on providing data that demonstrates clinical and economic benefits in a real-world setting

- Based on standard clinical practice
- Inclusive of a wide range of patients (good control to poor control)
- No forced insulin titration algorithms
- No mandated office visits or regular phone contact
- Patients pay for product and office visits copays

Randomized Controlled Trials vs Real World Evidence

Randomized Controlled Trials

- Prospective in design
- Required for FDA submissions of pharmaceuticals, not devices
- Tests a pre-conceived hypothesis that may or may not be based on previous scientific observations
- Strict criteria for subjects studied; “sterile environment”
- Controls for concomitant diseases and medications; not “real-world”
- Tests for impact of a single treatment modality

Real World Evidence

- Prospective or retrospective in design
- Real-world; few controls other than standards for comparison for scientific credibility
- Rich database already exists via clinical observations and assessment notes and can accessed
- Can compare several different treatment modalities in the same treatment environment
- Generates hypotheses for future prospective efficacy and safety studies

1 Gearing, R. E., Mian, I. A., Barber, J., & Ickowicz, A. (2006). A Methodology for Conducting Retrospective Chart Review Research in Child and Adolescent Psychiatry. *Journal of the Canadian Academy of Child and Adolescent Psychiatry*, *15*(3), 126–134.

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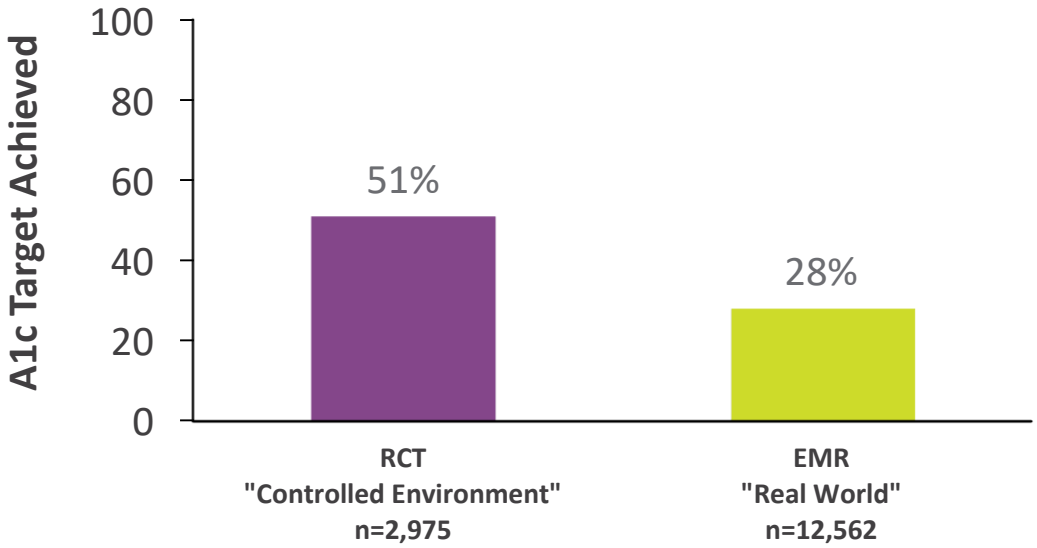
Disparity May Exist between Randomized Controlled Trials (RCTs) and Real World Clinical Practice

- RCTs follow restrictive/controlled methodologies and patients are carefully screened based on precise clinical criteria.
- Findings may not be generalizable to everyday clinical practice.



Study in patients prescribed basal insulin to evaluate achievement of A1C target (<7.0%) after 6 months across 11 pooled RCTs and 1 electronic medical record (EMR) database representing “real world” clinical practice

Blonde L et al. Diabetes 2014;63(Supp 1):A235

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A Changing Healthcare Landscape

Quality Measures and Performance Standards

- Health plans and physicians are being called on to close gaps in care and improve overall quality
  - “Quality of Diabetes Care” is measured across all performance standards
- The Centers for Medicare and Medicaid (CMS) use quality measures and performance to
  - Allocate shared savings for ACO’s
  - Assign *Star Ratings* highlighting the quality of medical/health care services provided by a plan which can influence rebates/bonuses to plans and allow for comparisons between plans by beneficiaries.
- Commercial plans also use quality measures for accreditation and have financial incentives for improving performance based on scores

V-Go® Product Overview

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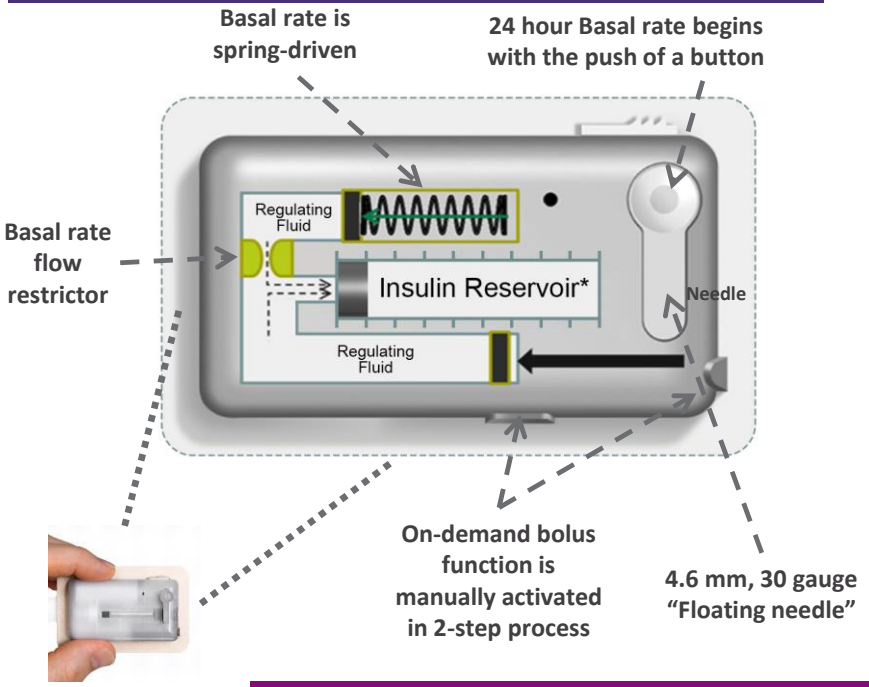
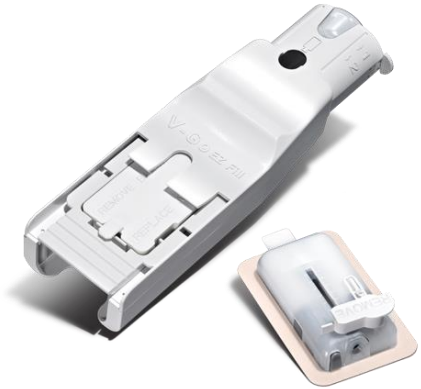
V-Go®: Easy to Use & High Quality Commercial Scale Manufacturing

V-Go Device Overview



V-Go® EZ FILL



- **Simple filling does not require calculations, measuring or needles**
- **Reduces accidental needle sticks**

Robust IP with > 80 patents issued and > 40 pending

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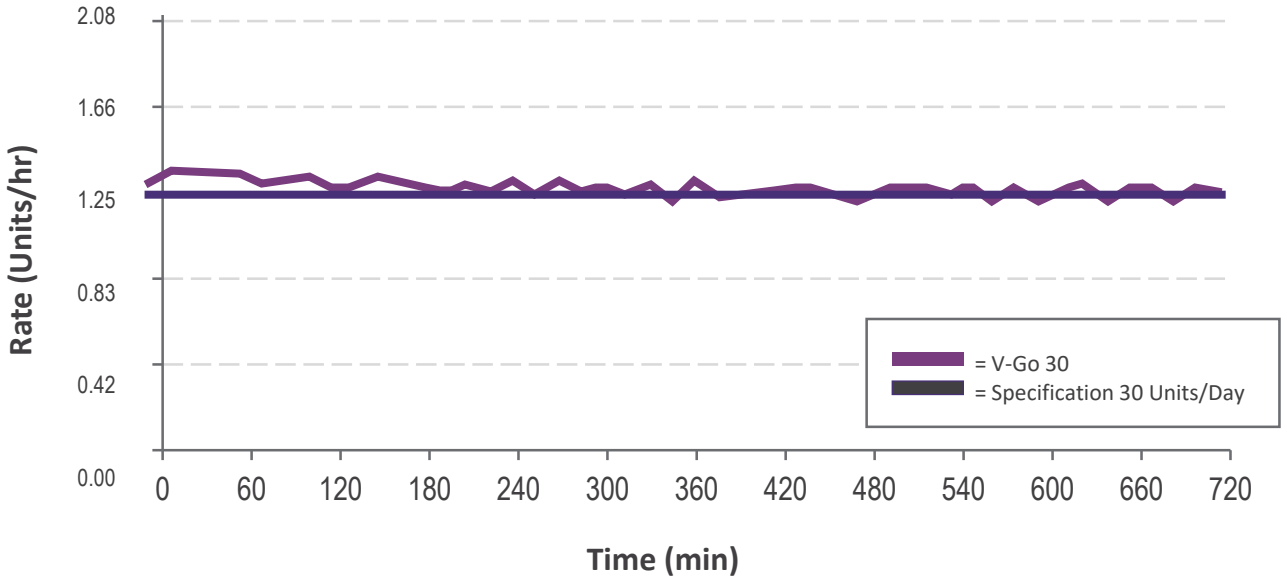
Continuous and Consistent Basal Rate

Flow Rate Study of V-Go® 30 Units/Day*



*Proportional results achieved with 20 Units/Day and 40 Units/Day.
Basal and Bolus Accuracy is ±10%.

V-Go® Instructions for Patient Use. Valeritas, Inc. 2018.

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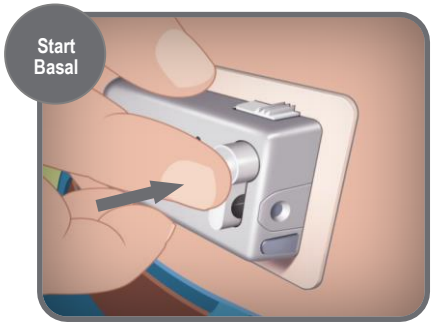
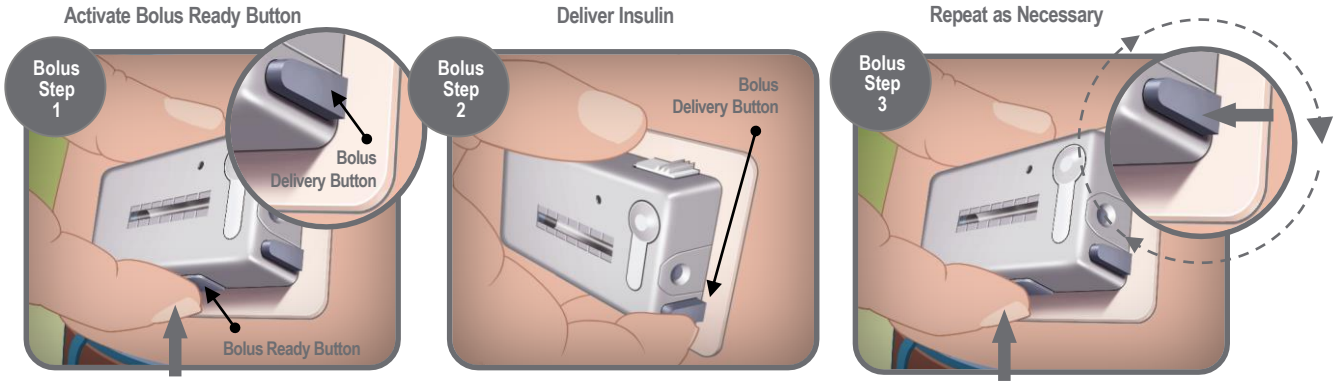
V-Go® Combines Simplicity and Physiologic Insulin in Patient-Friendly and Easy-to-Use Wearable Device



Press button to insert needle and start basal rate of insulin delivered at a constant rate

Deliver on-demand insulin for mealtime coverage in 2 units/click



Robust IP with 77 patents issued and 53 pending

61

Training Patients on V-Go®

Fill, Wear & Go…

You, Your Staff, or a Valeritas Representative can easily train the patient

FILL

WEAR

GO

For a more detailed review, see the multimedia resources at www.go-vgo.com/hcp/patient-support/starting-patients

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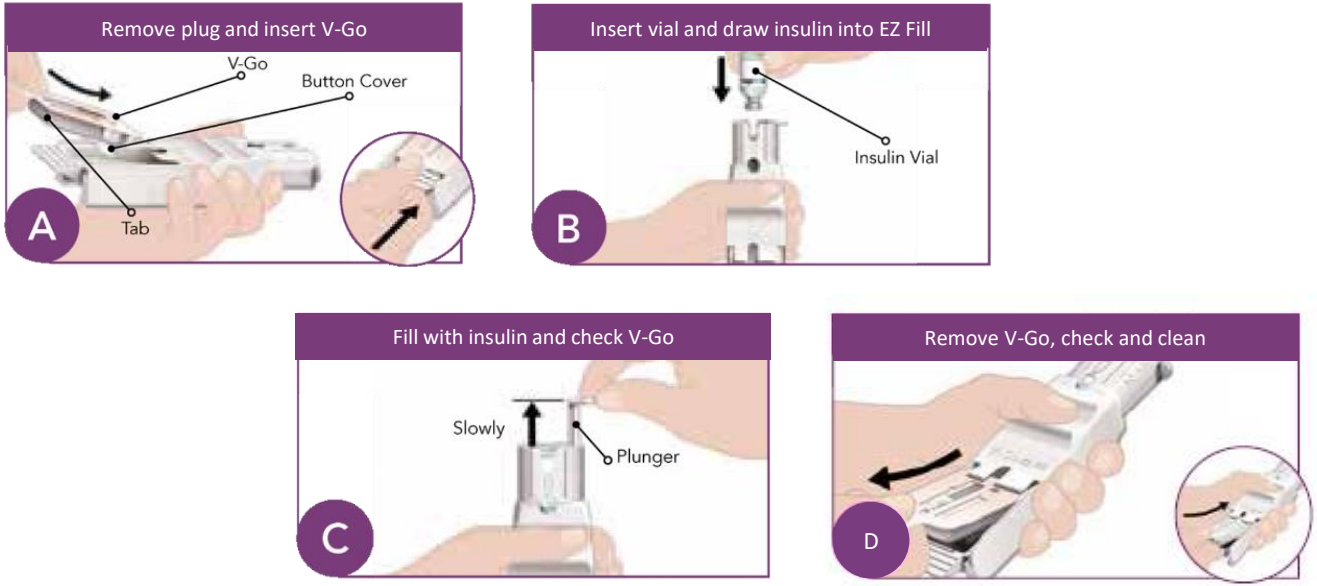
V-Go® Filling Process

Requires no syringes, measuring or calculating…..



V-Go is filled with a single type of insulin, a U-100 fast-acting insulin (also referred to as a rapid acting insulin). Humalog® (insulin lispro, rDNA origin) and NovoLog® (insulin aspart, rDNA origin) have been tested by Valeritas and found to be safe for use in V-Go.

V-Go® Instructions for Patient Use. Valeritas, Inc. 2018.

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Patient Satisfaction

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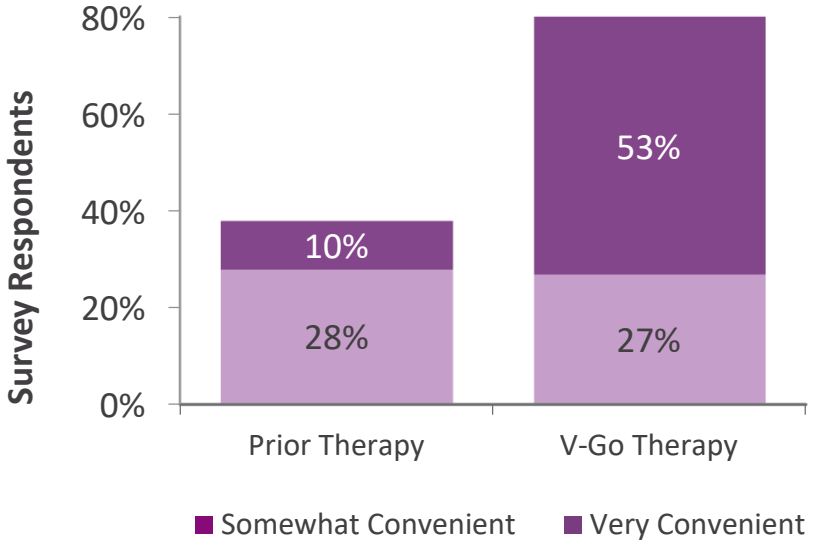
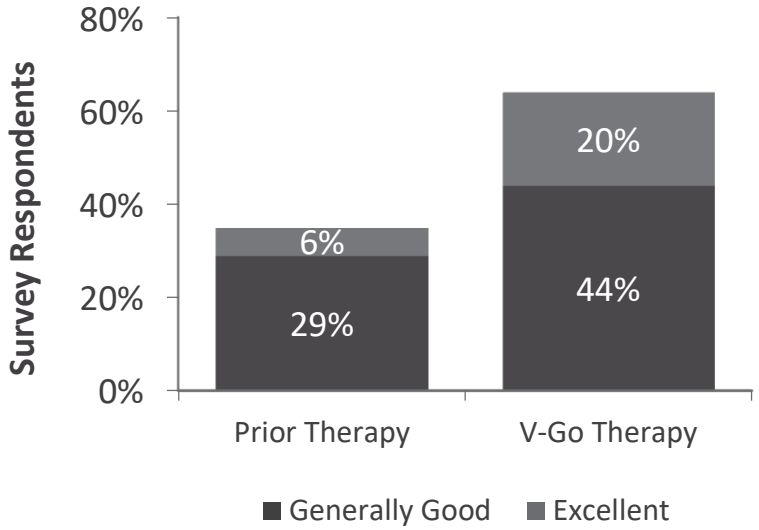
Patients Rated the Convenience of V-Go® and Their Quality of Life as Improved vs. Previous Therapies

Convenience



Quality of Life

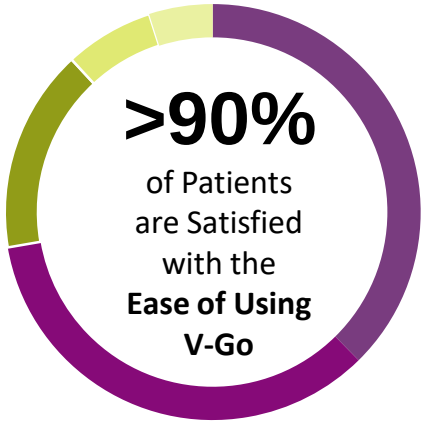


How do you feel physically & mentally on a typical day?

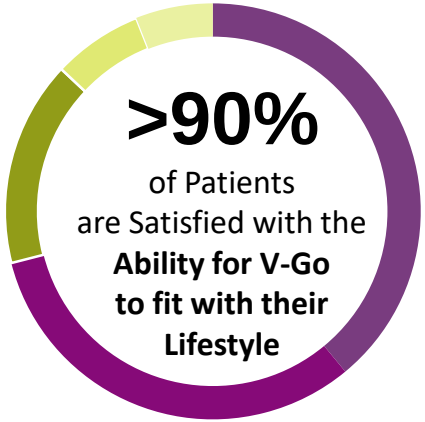
Data on File Opportunistic Copay Card, V-Go Patient Mkt Research (Jul-Dec2014)
Note: Patients were surveyed prior to starting V-Go and again ~30 days after being on V-Go.

V-Go® Patient Feedback is Very Strong

An online survey of V-Go users conducted by dLife showed



- Extremely Satisfied = 38%
- Very Satisfied= 35%
- Satisfied= 16%
- Somewhat Satisfied= 7%



- Extremely Satisfied = 39%
- Very Satisfied= 32%
- Satisfied= 16%
- Somewhat Satisfied= 7%

N=720 patients prescribed V-Go

dLife Survey 1Q 2016, commissioned by Valeritas, Inc. as part of the V-Go Life Online Educational Program

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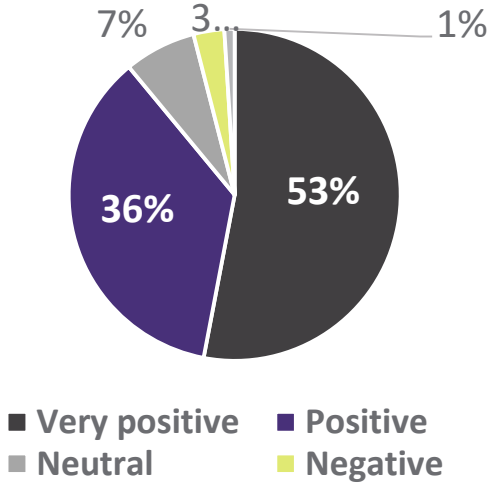
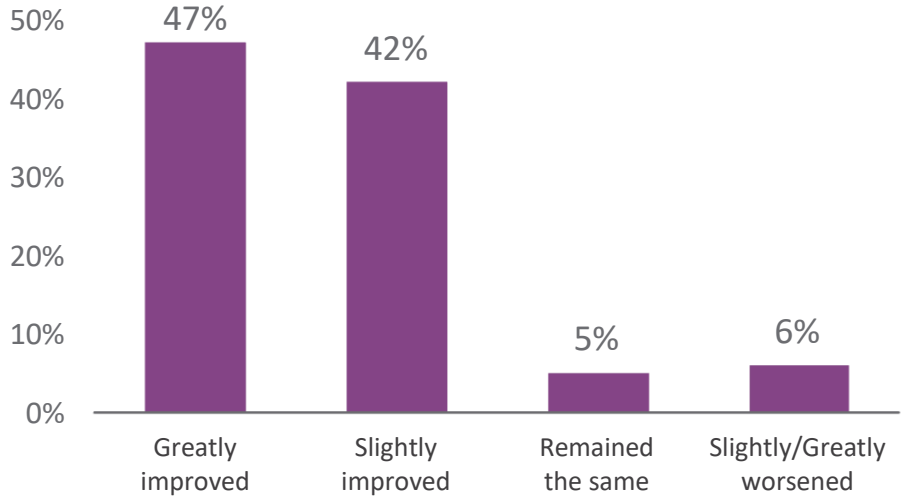
Patients on V-Go® See Improved Control, Have a Positive Experience and Achieve High Compliance

~ 90% of V-Go Users have a Very positive/Positive Impression of V-Go*



~ 90% of Patients on V-Go Reported Improvements in Their A1C Since Starting* V-Go



95% of V-Go Users Report Using V-Go 7 Days a Week *

*2017 Valeritas V-Go User Research, N=100, Internet based survey.
Q2. Base: Users of V-Go, What is your overall impression of the V-Go?, Q3. Which of the following best describes your blood glucose/A1c level since starting V-Go? Please select one. Q10/11/12. How many days, per week, do you use/wear your V-Go?

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V-Go SIM

(Simple Insulin Management)

VGO sim
simple insulin management

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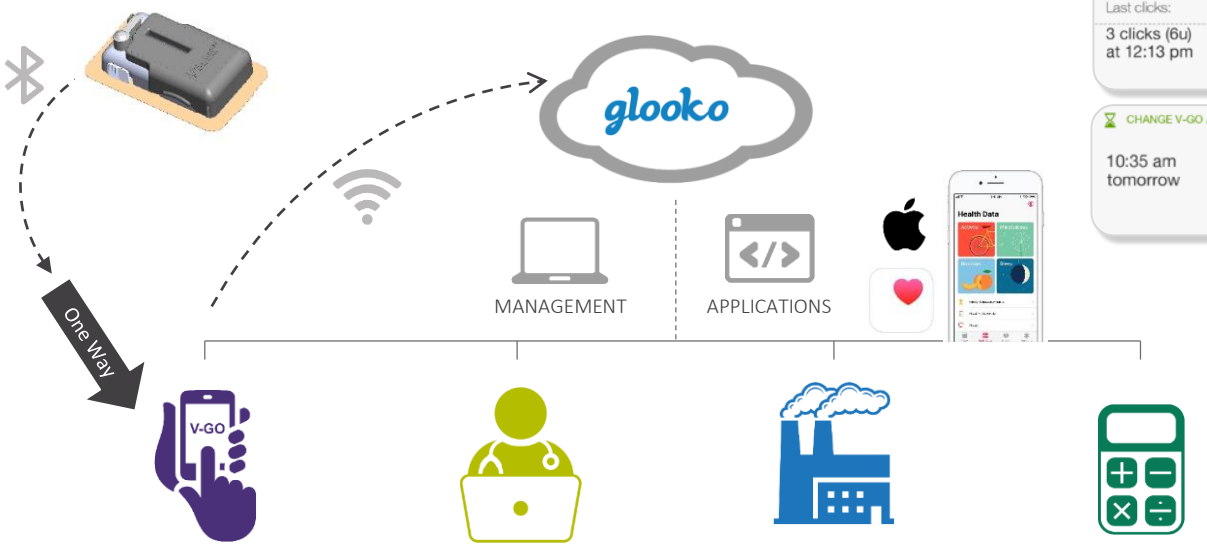
V-Go® with V-Go SIM™ Technology

Simple Insulin Management™



PATIENT

V-Go SIM sends data one-way to a smart device. SIM App provides data on V-Go insulin dosing. SIM App can transfer data to the cloud, other apps, and allows the user to message their information by email. The V-Go SIM App can also transfer data to Apple Health.

PHYSICIAN

V-Go SIM will enable simple and timely access to data that can be used to improve medical practice, clinical decision making and deliver individualized care. Partnerships will allow the integration of glucose and insulin dosing information.

INDUSTRY

Adherence, utilization and other health data can improve success and effectiveness of therapies. The data can inform clinical trial development and business decision making.

PAYERS

Evidence of treatment effectiveness, adherence and other data can bolster payer relationships