

A Computer Program, Directed by Clinicians for Outpatients, which Re-adjusts Subcutaneous Multiple Daily Injections (MDI) of Insulin, Achieves an Improvement of 2.6 A1c% Points

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PURPOSE

This study examines the performance of a computerized algorithm for adjusting subcutaneous MDI insulin regimens for outpatients.

GLUCOMMANDER SUBQ ALGORITHM

This algorithm determines the meal bolus for a meal by applying an adjustment to the previous day's same-time meal bolus based upon the subsequent BG response.

Basal doses are adjusted in a similar manner based upon the lower of pre-breakfast BG or any immediately preceding night-time lower BG tested earlier on the same day.

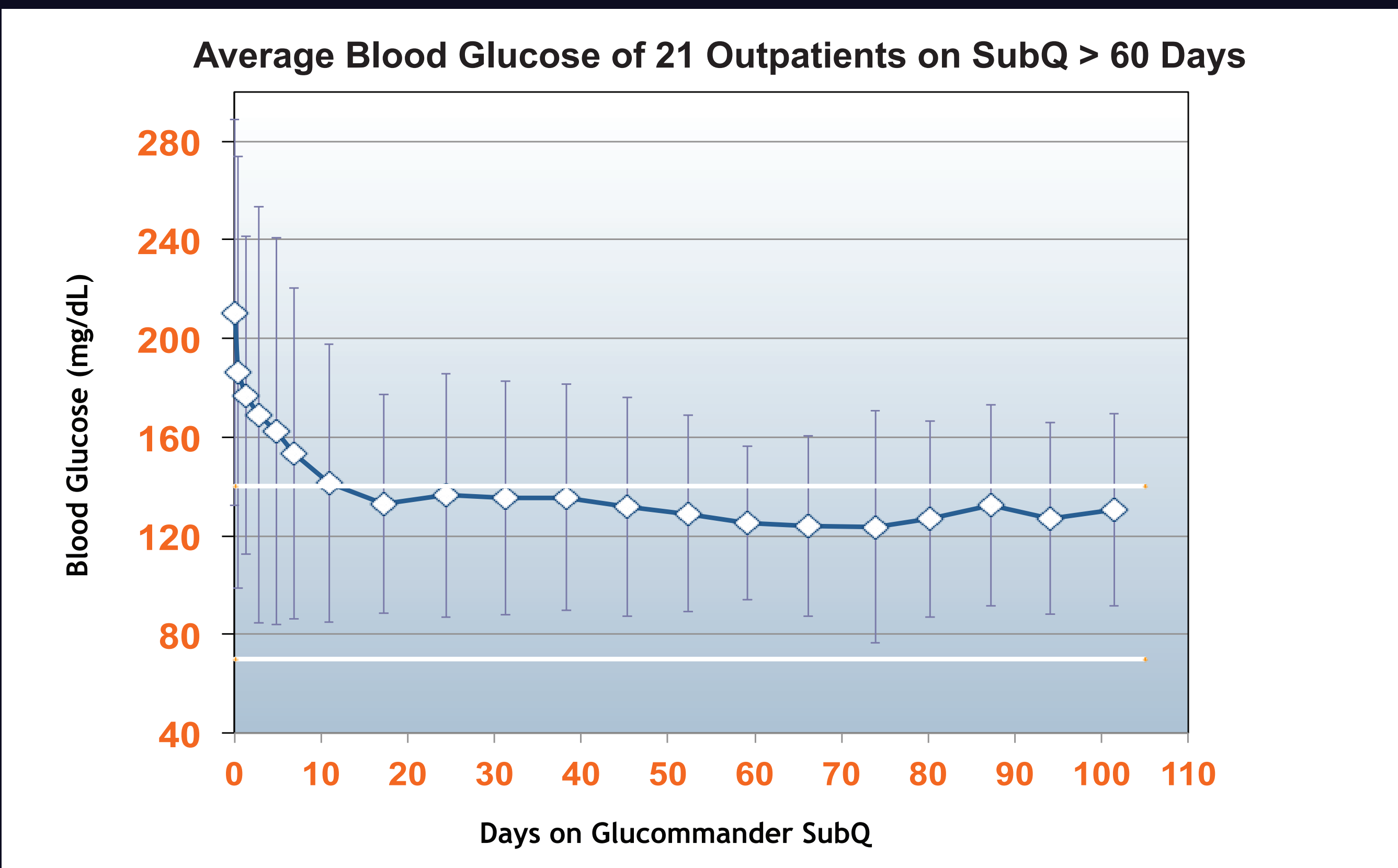
DATA COMMUNICATIONS METHODS

Data Collection:

The patients reported their BGs by text-messaging, email, telephone or the Telcare™ real-time cell-based meter system.

Dosing Instructions:

Adjusted dosing information was relayed to the patient.



STATISTICAL METHODS

Glycemic Control:

All the subjects were started on the Glucomander SubQ algorithm at the beginning of the study. The statistics followed a paired before-and-after design.

- **Method 1:** For patients treated for > 60 days - Each patient's pre-study A1c was compared to his/her post-study A1c.
- **Method 2:** For all patients - The mean of the last 12 BGs of each patient was converted to an A1c value using the ADA-approved correlation. This value was compared to the pre-study A1c.

Hypoglycemia:

- The BG readings below threshold were counted for thresholds of 40, 50, and 60 mg/dL.
- The patients with at least one BG < threshold were counted for 40, 50, and 60 mg/dL.

RESULTS for GLYCEMIC CONTROL

METHOD 1

Patients treated for > 60 days

Patients	Pre-study A1c	----	Post-study A1c	Significance
21	10.1%	----	7.5%	P<0.0004

METHOD 2

All patients. Mean BG after treatment converted to A1c

Patients	Pre-study A1c	Post-study Mean BG	Estimated Post-study A1c*	Significance
30	10.2%	134	6.3%	P<0.00001

* Per ADA-endorsed linear correlation

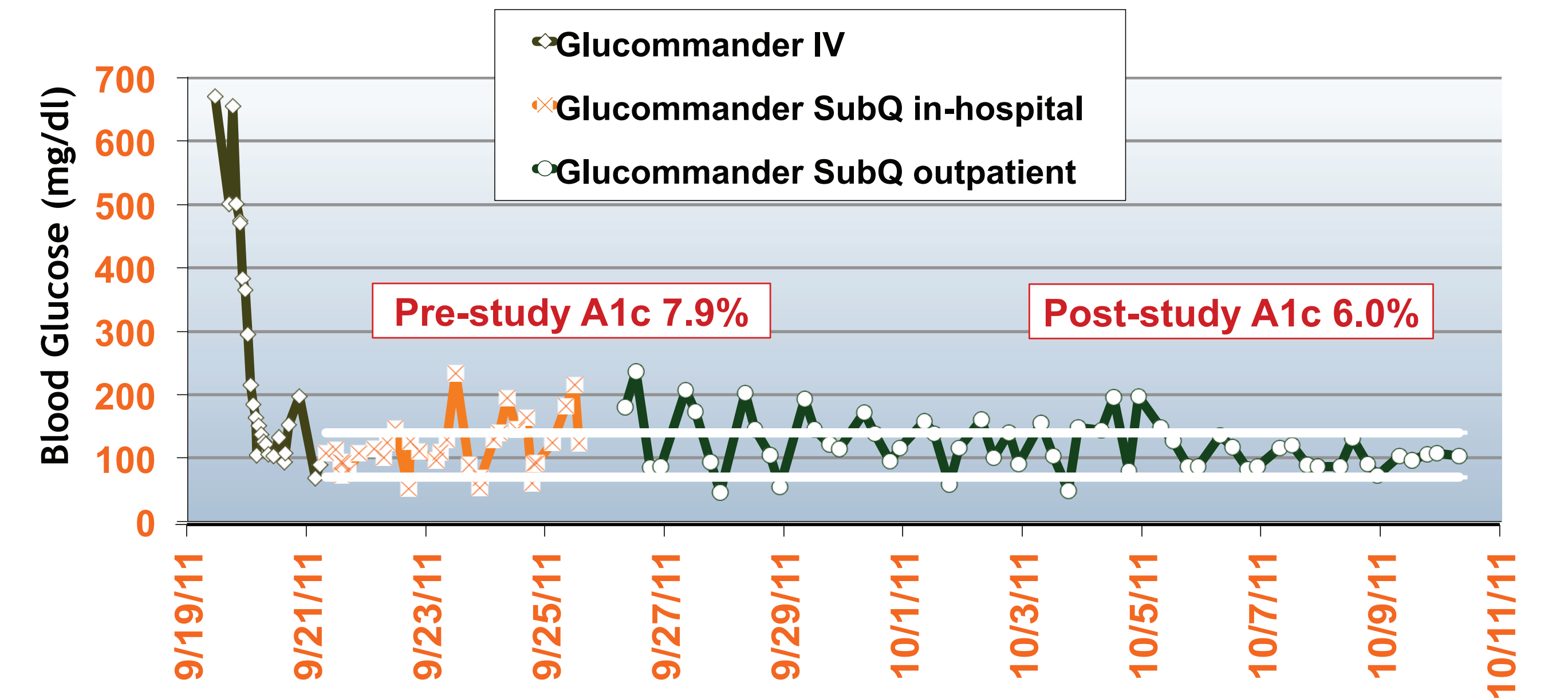
RESULTS for HYPOGLYCEMIA

Patients treated for > 60 days

		Hypoglycemia Threshold		
		<40	<50	<60
# BGs: 5,811	% BGs < threshold →	0.0%	0.4%	1.0%
# Patients: 30	% Patients with at least one BG < threshold →	0.0%	17%	38%

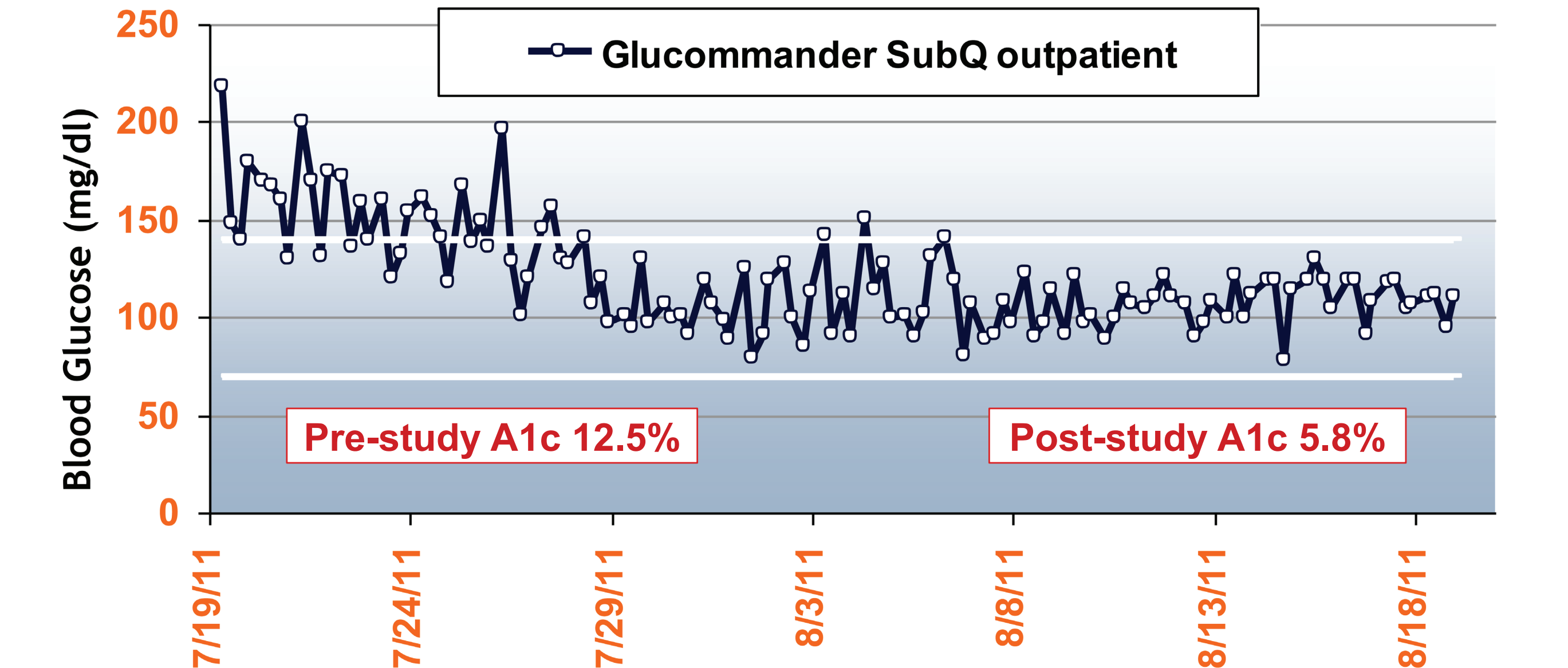
Case Study:

Female, age 69. Urinary tract infection.



Case Study:

Male, Age 46; DM2
Oral therapy failed before Glucomander SubQ



CONCLUSION

This algorithm (Glucomander SubQ) showed itself to be a valuable tool for adjusting subcutaneous MDI regimens. The algorithm is incorporated into a web-based platform for continuous, ongoing dosing guidance. [*IHDM 2012, Cambridge, MA*]

ABSTRACT

Objective: This study examines the performance of a computerized algorithm for adjusting subcutaneous basal-bolus MDI insulin regimens for outpatients.

Method: This algorithm determines the meal bolus for the current meal by applying an adjustment to the previous day's similar-time meal bolus based on its BG response. Basal dosing is adjusted in the same manner based upon the lower of either the pre-breakfast BG tested earlier on the same day or any immediately preceding night time lower BG if available. Dosing data was collected by the patient's reporting of insulin dosing and BG data daily.

Result: In a total of 30 patients, there were 21 patients, treated for 120 days, who had paired before-and after A1cs. Mean A1c before was 10.0% and mean A1c after was 7.5%; P<0.00004. Of a total of 5,446 BG tests, the percent less than threshold: 1.0% <60, 0.3% <50 and zero <40 mg/dL.

Alternate Analysis: All 30 patients were treated for an average of 93 days and had a starting A1c averaging 7.8%. The mean of the last 12 BGs of all patients was 135, which correlates to an estimated final A1c of 6.3% yielding P<0.00001.