

Atlanta Diabetes Associates

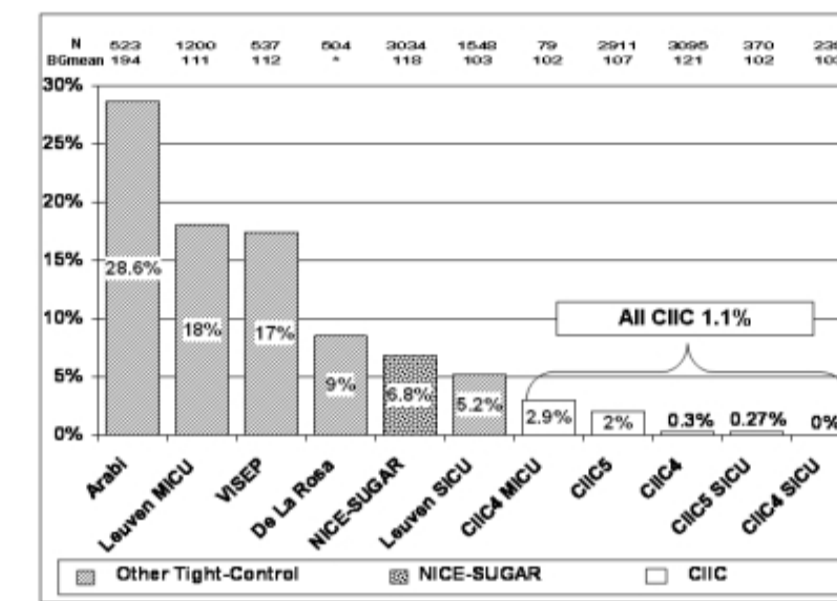
A Computerized Intravenous Insulin Controller (CIIC) Shows Significantly Less Hypoglycemia Than NICE-SUGAR and Eight Paper Protocols for Intensive Control--0.3% vs. 12.6%

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ABSTRACT

The optimal target BG range for critically ill patients is controversial. Normoglycemia has been publicized as ideal but many studies have failed to achieve this goal without severe hypoglycemia. NICE-SUGAR observed significantly higher mortality in the intensively managed group. Considering that the reason for this may be increased hypoglycemia, the guidelines of ADA/AACE have been revised. Multiple recent studies of intensive insulin management in ICUs have reported severe hypoglycemia ranging from 5.2% to 28.6%. In our combined non-CIIC data, the average rate of severe hypoglycemia is 10.6%. CIIC is a computerized system for advising on insulin dosing to control BG to any desired target with very limited hypoglycemia. When BG does drop insulin is phased out while enteral or parenteral nutrition continues. In a further move to prevent hypoglycemia the carbohydrate intake is augmented with a titrated D50 correcting glucose level to mid-target range. CIIC has been used in over 100 hospitals and is currently available to any investigators proposing a randomized control trial. The data available to the inventors of the device was {6693 runs in 18 hospitals, showing BG's <40 mg/dl in 1.1% of runs}. This compared favorably (p <0.0001), to both NICE-SUGAR, and to all the paper protocols. The data from the inventors' current version, CIIC4, shows that severe hypoglycemia is virtually eliminated, i.e. 0.3% of 3095 runs without any BG <40 mg/dl. This is compared in the figure to other large studies.



CIIC4: Version used since 1992.
CIIC4 SICU: CV Surgery study by authors.
CIIC5: A commercial version of CIIC. Data from 12 hospitals.

CIIC4 MICU: Multicenter RCT, Medical ICU's.
CIIC5 SICU

ALL-GLUCOMMANDER™ Group, VERSIONS and SOURCES of data:

- Version 4: It collected data from 1992 to 1998 from 1 hospital. N=3095.
- Surg ICU (Version 4): CV Surgery study by authors, 2006, N=238, 1 hospital.
- Med ICU (Version 4): A randomized study. Collected in 2008 from 4 hospitals, N=79.
- G+™: A commercial version of Glucommander™. MICU data, 3 hospitals, N=1019
- Lecompte P et al: From Georgia Hospital Association. A paper protocol using a tabular algorithm based on Glucommander™. SICU data, N=651

STATISTICAL COMPARISON of ALL-GLUCOMMANDER™ to OTHER GROUPS

(The combined All-Glucommander™ data: 5082 patients in 10 hospitals)

COMPARISON to NICE-SUGAR:

- % patients with at least one BG < 40 mg/dl :
NICE-SUGAR- 6.8%. All Glucommander™-0.3%.
(P < 0.0001, Chi-Squared test).

COMPARISON to TIGHT-CONTROL PAPER-PROTOCOLS:

- Four tight-control paper protocols (* Di La Rosa used non-parametric methods) were combined and compared to All Glucommander™:
- % patients with at least one BG < 40 mg/dl:
Paper Protocols-12.6%. All Glucommander™-0.3%.
(P < 0.0001, Chi-Squared test).

STANDARD DEVIATION and ACCURACY

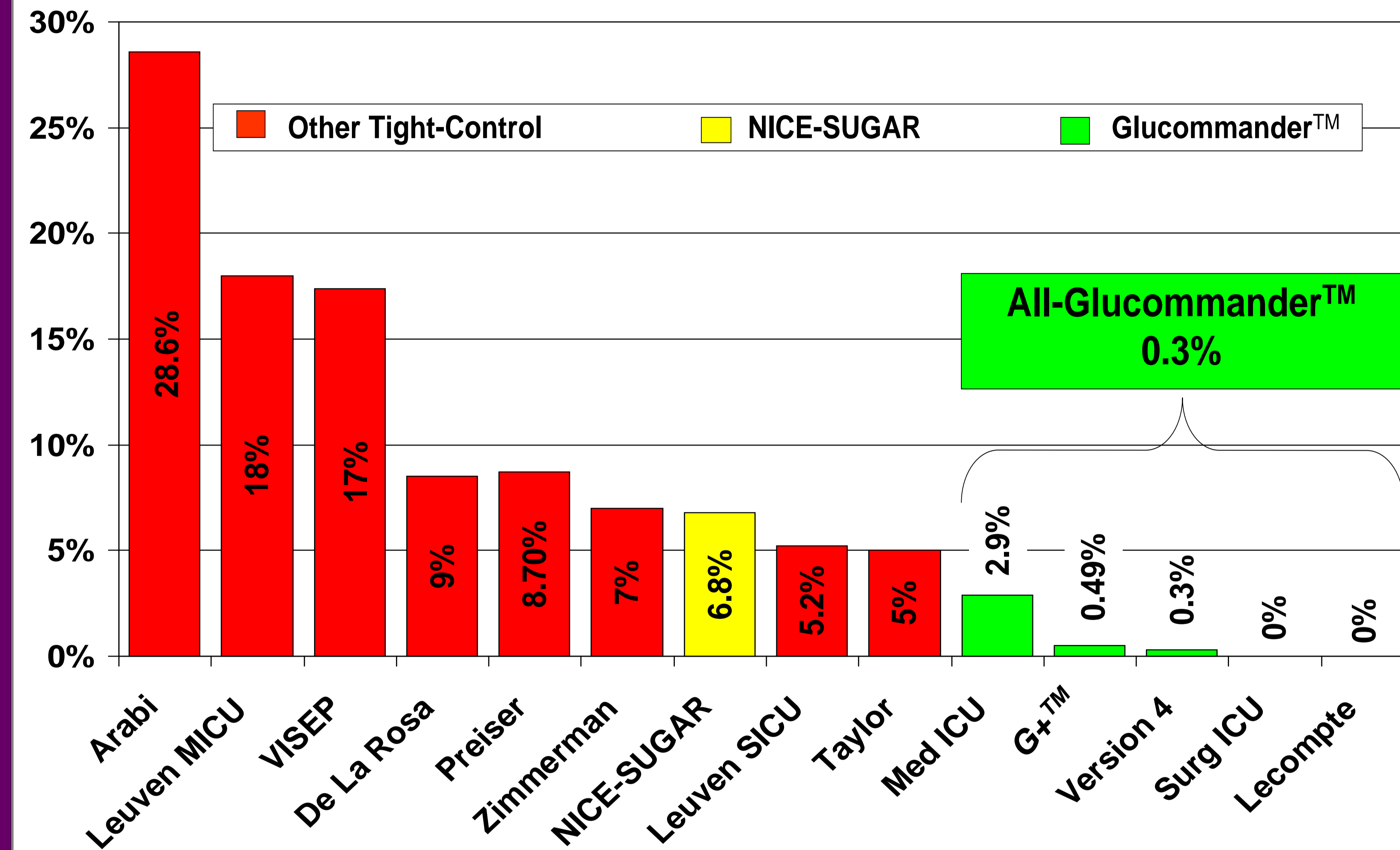
Glucommander™ StDev = 25 mg/dl

The small Standard Deviation of Glucommander™ allows the Target Range to be placed with a fine degree of precision.

- Target Range can be set closer to the normoglycemic range without risk of hypoglycemia

% of PATIENTS with AT LEAST ONE BG < 40 mg/dL

N	523	1200	537	504	536	168	3034	1548	119	79	1019	3095	238	651
BGmean	194	111	112	*	117		118	103	132	102	104	121	103	105
StDev	76	29	18	*	36		25	19		26	18	30	19	18



BACKGROUND

- The optimal target range for blood glucose in critically ill patients is not known.
- Tight glycemic control has been supported by numerous randomized and observational studies.
- However, recent studies have reported excessive rates of severe hypoglycemia. The initial response from the ADA and AACE is to compromise by accepting levels that were previously associated with increased complications.
- There is no need to compromise if a computerized system is available with the precision to achieve a normal target range with a low rate of hypoglycemia.

GLUCOMMANDER™

Glucommander™ is a computer-controlled algorithm for managing IV insulin, which is able to achieve any desired target range with very limited hypoglycemia. Its features are:

- Alarms for prompting BG measurement at varying intervals, programmed to avoid hypoglycemia.
- The ability to calculate insulin adjustments to prevent excursions outside the target range.
- The ability to react to a decreasing BG by phasing-out insulin and calling for D50.

CONCLUSIONS of COMPARISON STUDY

It is possible with the Glucommander™ to implement tight glycemic control in all institutions and to achieve the ideal 110-140 range cited by ADA / AACE. We propose that more hospital settings should implement this effective, safe, and more normoglycemic algorithm, in an accurate, computer-controlled system.

CONTACTS

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