

# Can Severe Hypoglycemia be Eliminated? Introducing Estimated Residual Extracellular Insulin™ (EREI)

W Patrick Burgess PhD MD<sup>1</sup>, Laura Santana RN<sup>1</sup>, Laurel Fuqua, RN MSN<sup>1</sup>  
<sup>1</sup>Monarch Medical Technologies, LLC, Charlotte, North Carolina

## PURPOSE

Prevention of hypoglycemia is a goal of electronic glucose management systems (eGMS). Estimated Residual Extracellular Insulin (EREI) was introduced as an insulin infusion adjustment to account for future intravenous (IV) insulin activity within an eGMS algorithm. Designed to reduce hypoglycemia, performance of the EREI adjustments is reported in this retrospective analysis.

## METHODS

Retrospective data from 84 community hospitals is stratified into two cohorts related to the date of the introduction of EREI adjustments in the eGMS. The primary analysis is a comparison of incidence of hypoglycemia without EREI vs. with EREI for subjects with an upper goal of 135 to 155 mg/dL. Secondary analyses include time to control and mean blood glucose (BG) after first reaching the upper goal. No data were excluded even for late determinations or low readings without a software recommended insulin dose.

A second analysis of three hospitals with a high percentage of on time glucose checks, EREI supplemental carbohydrate (CHO) options set and no severe hypoglycemia demonstrates the full potential of this methodology.

## RESULTS

The EREI dose adjustment in the eGMS for IV insulin therapy reduced all measures of incidence of hypoglycemia.

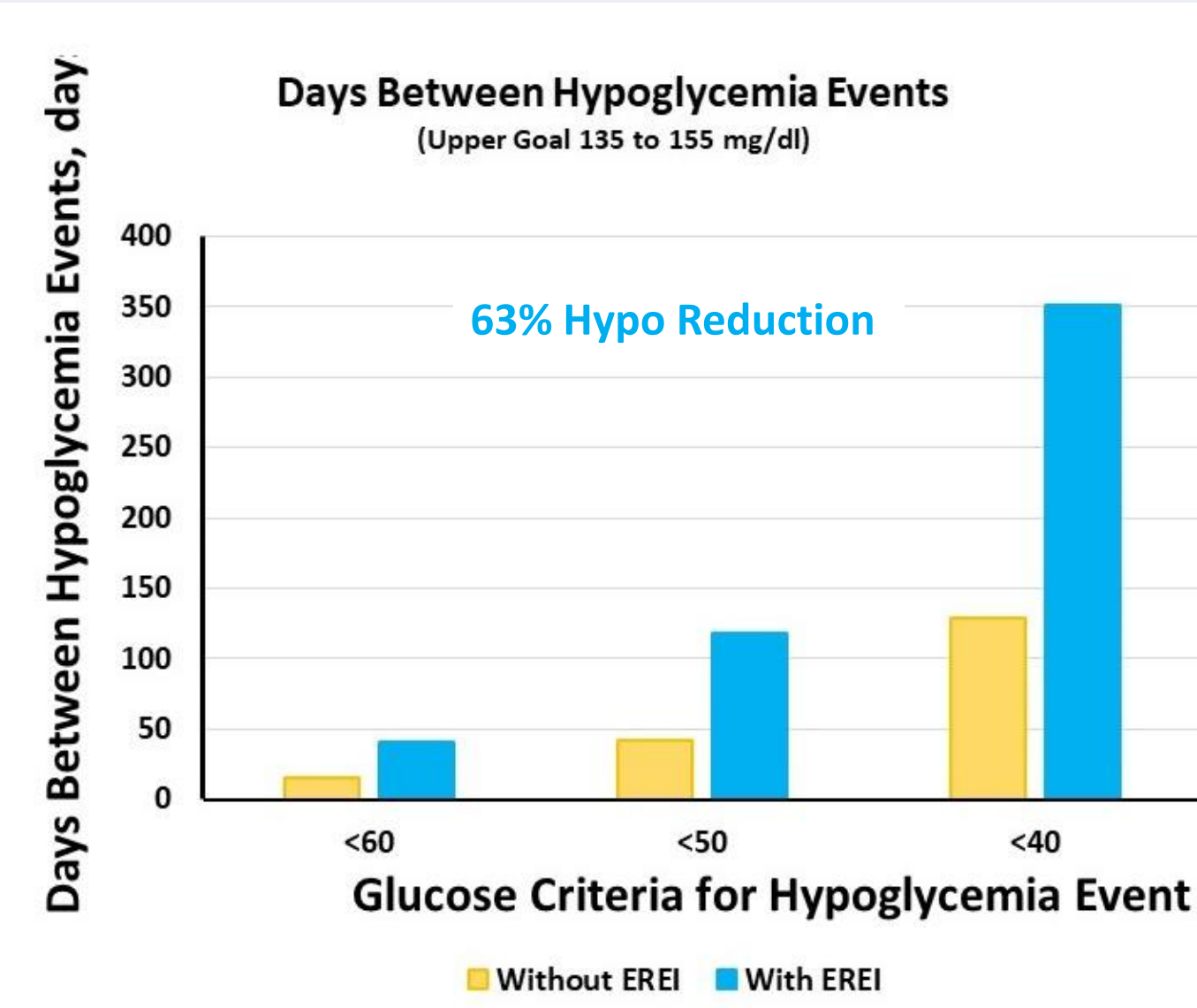
- BG readings <40 mg/dL using eGMS without EREI revealed one hypoglycemic event every 129 patient-days of therapy compared to one event every **351** patient-days with the EREI adjustment.
- Three hospitals who utilized a supplemental carbohydrate feature in addition to EREI experienced no hypoglycemic event of <40 mg/dL in **4,114** patient-days (~13 patient-years) of IV insulin use.

With the introduction of EREI, the primary analysis revealed:

- the time to control increased from 2.7 to 3.6 hours
- mean glucose after first to goal increased from 128 to 136 mg/dL

## RESULTS

### Analysis of EREI Impact at 84 Hospitals



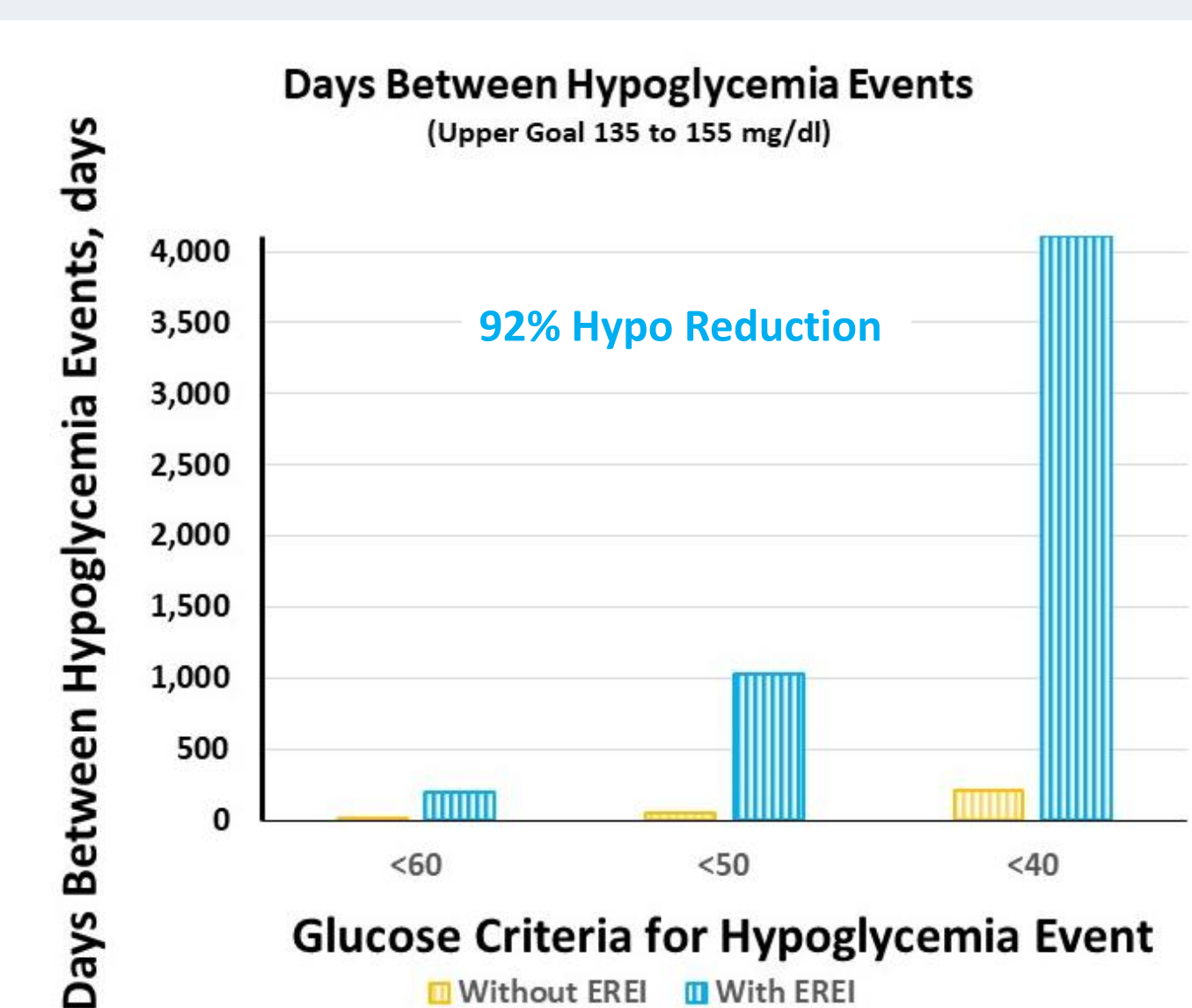
#### Patient Demographics Upper Goal 135-155mg/dl

	Without EREI	With EREI
Number of patients	109,087	50,458
Patients-Days of IV Insulin Therapy	135,349	55,064
Readings, #	2,557,892	1,064,239
Mean Initial Glucose, mg/dL	209	205

#### Patient Results Upper Goal 135-155mg/dl

	Time to Control, hours	Mean Glucose after First Reaching Range, mg/dL	Days Between Glucose <60 Events	Days Between Glucose <50 Events	Days Between Glucose <40 Events
Without-EREI	2.7	128	15 d	42 d	129 d
With-EREI	3.6	136	41 d	118 d	<b>351 d</b>

### Analysis of EREI Impact at 3 Hospitals with Timely BGs and EREI Supplemental Carbohydrate Option



#### Patient Demographics Upper Goal 135-155mg/dl

	Without EREI	With EREI
Number of patients	9,233	2,516
Patients-Days of IV Insulin Therapy	10,399	3,120
Readings, #	207,250	69,008
Mean Initial Glucose, mg/dL	173	175

#### Patient Results Upper Goal 135-155mg/dl

	Time to Control, hours	Mean Glucose after First Reaching Range, mg/dL	Days Between Glucose <60 Events	Days Between Glucose <50 Events	Days Between Glucose <40 Events
Without-EREI	1.9	126	18 d	55 d	215 d
With-EREI	3.2	136	206 d	1,028 d	<b>&gt; 4,114 d</b>

## DISCUSSION

- Adjusting for a very small future insulin activity (average= 7% of the mean insulin dose) applied strategically has a very significant effect on the occurrence of hypoglycemia with a minimal effect on time to control or mean glucose statistics after reaching that goal.
- The complexity and number of variables utilized in the EREI calculation make it an undesirable and an error prone activity for any clinician to perform.
- These calculations in EREI can not only reduce the dose but also lead to an earlier glucose determination.
- Associated mathematical calculations to estimate the appropriate supplemental CHO dose is also undesirable unless made by a computer.

With EREI, severe hypoglycemia is nearly eliminated with supplemental carbohydrates and timely glucose determinations as scheduled.

## CONCLUSIONS

EREI integrated into eGMS significantly improves IV insulin dosing resulting in significantly reduced incidences of hypoglycemia without significantly effecting glycemic control performance. Analysis revealed severe hypoglycemia (< 40 mg/dL) occurred almost a third as often in EREI adjustment cohort or about once a year of patient IV insulin therapy.

At sites using supplemental CHO dosing and EREI with timely glucose determinations, severe hypoglycemia was seen in roughly every 13 years of therapeutic IV insulin treatment.

## DISCLOSURES

At time of study, all authors were employed<sup>(1)</sup>. W. Patrick Burgess invented the eGMS utilized in retrospective study. Data analyzed was obtained by contractual agreement and did not contain patient identification information.