Evaluation of an IV Insulin Electronic Glucose Management System Using FDA Cleared Feature of EREI (Estimated Residual Extracellular Insulin) to Prevent Severe Hypoglycemia

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Introduction

Intravenous insulin therapy to manage glucose in hospitalized critical care patients is necessary to improve outcomes in wound infection and overall mortality. Insulin titration using paper protocols is frequently associated with hypoglycemia, highly associated with increased mortality (1,2). Prevention of hypoglycemia while maintaining target glucose values is a primary goal of an electronic glucose management system for insulin dosing recommendations (eGMS). Retrospective review of data should intermittently be performed to provide evidence of the success of meeting this goal. A review was performed in early 2017 to provide needed information about the performance of the EndoTool® IV eGMS product cleared by the FDA in 2014 with EREI (estimated residual extracellular insulin), a feature to mitigate future insulin activity and hypoglycemia. EREI is a patented feature in the IV EndoTool application that predicts and adjusts for residual intravenous insulin activity following a dose reduction.

EREI Explained

Every patient who receives IV insulin in a hospital requires a personalized dose based on their individual response to insulin dosing, kidney function, current medical treatment, meals consumed, and stress level among many other variables. As a result, the pancreas must constantly modify the production of insulin. The amount of residual extracellular insulin present in a person's body is an important variable that must be considered in order to achieve correct insulin dosing, maintain glucose control, and avoid hypoglycemia. This is an estimate of excess or extra insulin (excess over the planned dose) in the subject's extracellular space that occurs when a subject's intravenous insulin dose is reduced AND the current glucose level is close to or below the upper glucose target. Similar to the "insulin-on-board" condition associated with subcutaneous insulin administration, EREI refers to residual insulin from intravenous insulin therapy present in a patient's body that has potential for future activity affecting blood glucose levels.

Contingent on a patient's kidney function along with current and historical response to insulin, EndoTool IV predicts and adjusts a patient's subsequent dose to prevent a hypoglycemic event. If a patient has more residual insulin than can be supported by circulating glucose, the software further adapts dosing recommendations, and if desired, recommends a counter-balancing dextrose dose, as directed by the physician.

Based on a patient's kidney function and response to insulin dosing, the software reduces patient's next insulin dose to mitigate potential hypoglycemia

Figure 1 below illustrates the first component of EREI, extra insulin between time of BG and time of insulin pump change, estimated as 3 minutes (3).

FIGURE 1

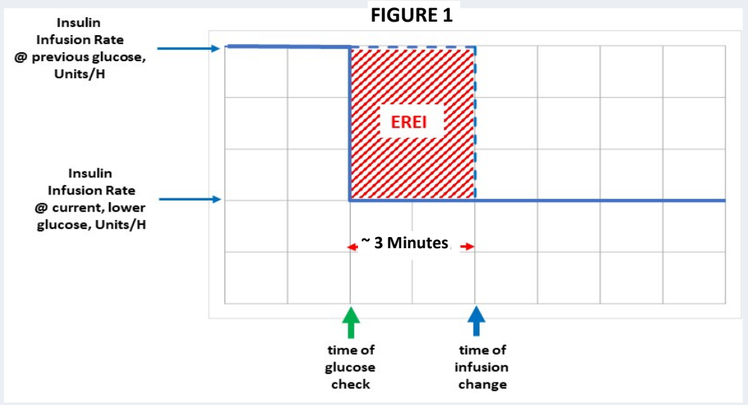


Figure 2 below illustrates the second component of EREI, kidney filtration dependent decay of ECF insulin concentration from old equilibrium concentration to the new, lower concentration.

FIGURE 2
Normal Kidney Function

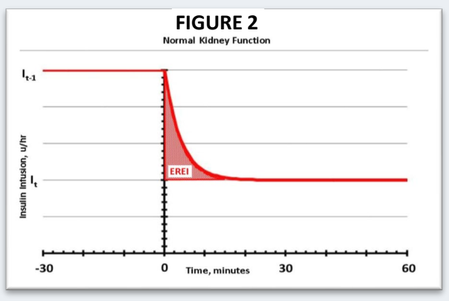


Figure 3 illustrates the second component of EREI with advanced kidney failure and a marked increase in the EREI value related to reduced renal clearance. Figure 4 illustrates the total EREI if the time stamp from the POC device is provided by the EMR.

FIGURE 3
Advanced Kidney Failure

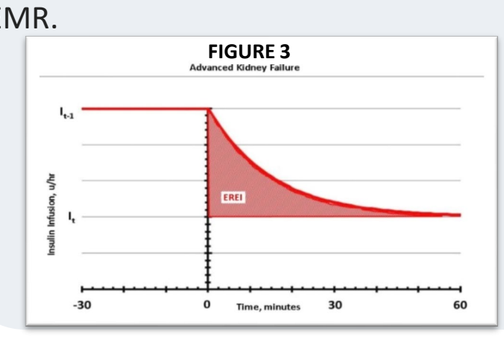
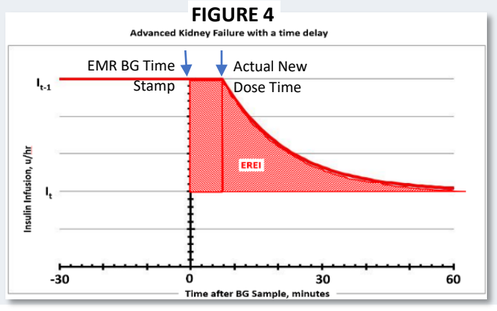


FIGURE 4
Advanced Kidney Failure with a time delay



Method

The data review from 30 community hospitals using the eGMS system EndoTool IV with EREI revealed that patients were able to reach their prescribed glucose target goals within 3.3 hours with a near zero incidence of severe hypoglycemia (0.009% for goal range of 140-180mg/dl and 0.007% for goal range of 135-155 mg/dl). The addition of this EREI feature, with a focused adjustment for future insulin activity, provides additional safety to a patient's intravenous insulin dosing, creating the potential to eliminate severe hypoglycemia, excluding human error, while achieving target glucose levels and eliminating confusing paper protocols for insulin dosing.

Results

The mean starting POC glucose was 267.9 mg/dl. 92% of the runs reached the goal prior to ending the run. The median time to reach the goal was 3.3 hours and the mean POC glucose after first reaching goal was 145.1 mg/dl with a variance of 27%. POC glucose readings less than 40 mg/dl occurred in 0.009% of the readings or once every 577 days of patient therapy. For the patient runs with an upper goal of 135 to 155 mg/dl, the POC glucose readings less than 40 mg/dl occurred in 0.007% of the readings or once every 717 days of patient therapy with similar control performance.

Table 1: Baseline Demographics

Patients	Patient-Runs	Patient Days of Therapy	Point of Care Glucose Readings	Insulin Doses	Mean Starting Glucose
4,764	7,016	7,496	151,751	151,751	267.9 mg/dL

Table 2: Results

Goal Range	% of Runs Reaching Goal	Median Time to Goal	Hypoglycemia <40 mg/dL
140-180 mg/dL	92%	3.3 Hours	0.009%

Table 3: Results

Goal Range	Mean POC Glucose after First Reaching Goal	Median Time to Goal	Hypoglycemia <40 mg/dL
135-155 mg/dL	145.1 mg/dL	3.3 Hours	0.007%

Conclusion

The data review from 30 community hospitals using the eGMS system EndoTool IV with EREI revealed that patients were able to reach their prescribed glucose target goals within 3.3 hours with a near zero incidence of severe hypoglycemia (0.009% for goal range of 140-180mg/dl and 0.007% for goal range of 135-155 mg/dl). The addition of this EREI feature, with a focused adjustment for future insulin activity, provides additional safety to a patient's intravenous insulin dosing, creating the potential to eliminate severe hypoglycemia, excluding human error, while achieving target glucose levels and eliminating confusing paper protocols for insulin dosing.

References

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