

# Comparison of a computer-based intravenous insulin program with a standard paper protocol in terms of safety and efficacy in management of DKA patients in community hospitals: A pilot study

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## BACKGROUND

Vidant Medical Center has successfully used an electronic glucose management system (eGMS) known as EndoTool® (now marketed by Monarch Medical Technologies) for intravenous insulin dosing since December 2008.

The technology was introduced to 6 of the 7 Vidant Health community hospitals in November 2015. At the time of its initiation, a new mode of therapy was introduced for insulin management in Diabetic Ketoacidosis (DKA).

Introduction of the eGMS at the community hospitals provided an opportunity to evaluate the safety and effectiveness of this technology compared to the previous standard of care, a standardized nurse-driven protocol.

## METHODS

Patients admitted with DKA to 6 community hospitals in Eastern North Carolina between 12/2014 and 4/2016 were identified retrospectively.

40 and 42 consecutive patients treated with standard paper protocol (PP) and with software program (SP) were included in the paper arm and software arm respectively.

Pertinent clinical and demographic variables were collected by chart review and analyzed to compare the outcomes.

Time to resolution of DKA was calculated as time required to get calculated Anion Gap (AG) less than or equal to 12. Total time on IV insulin was calculated as the difference between initiation and discontinuation of IV insulin. Hypoglycemia was counted as a FSBS  $\leq 70$ .

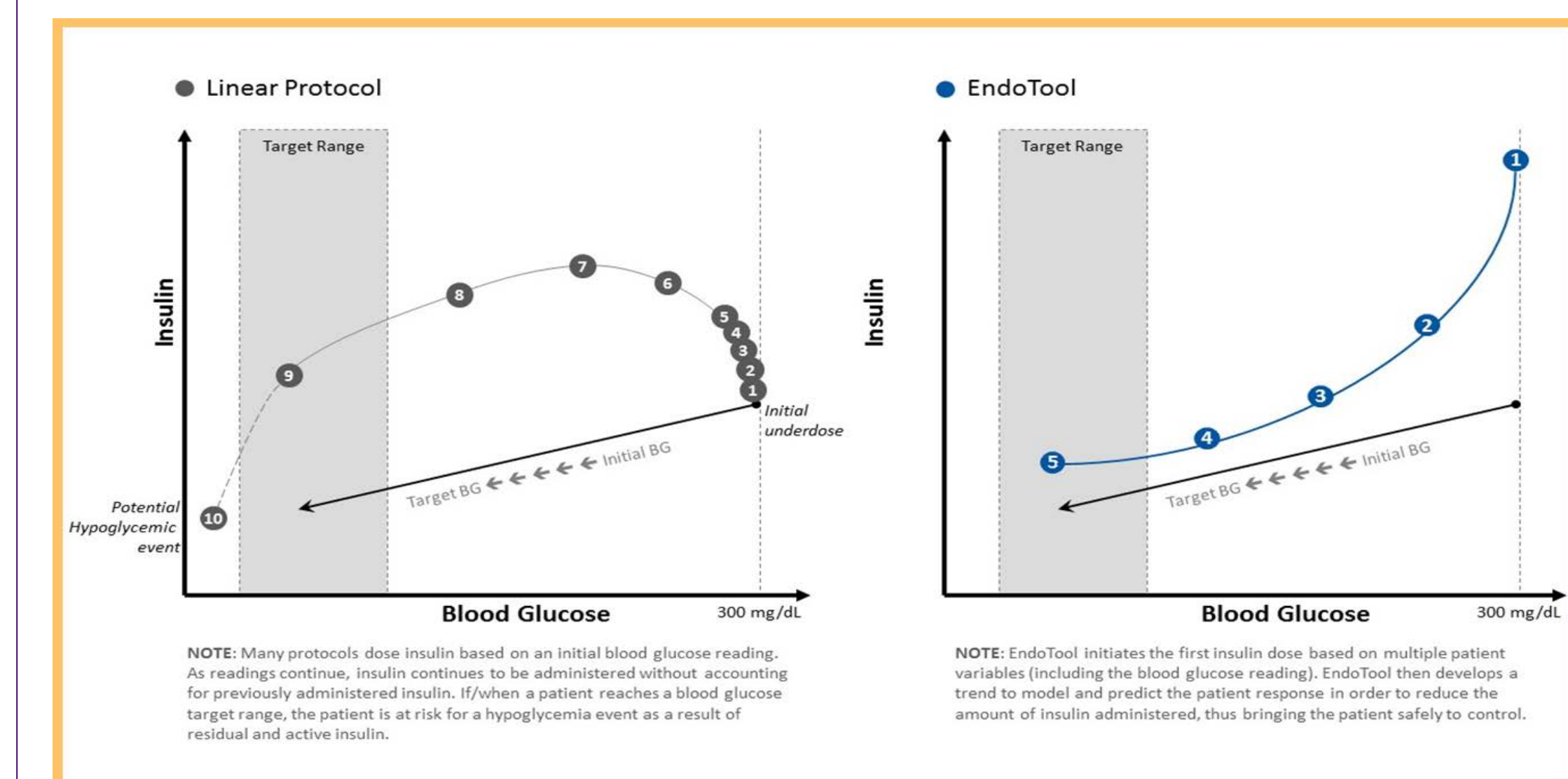
T test was done to compare the means of the variables between two groups. SPSS (v.17.0) was used to analyze the data.

### Paper Protocol (PP)

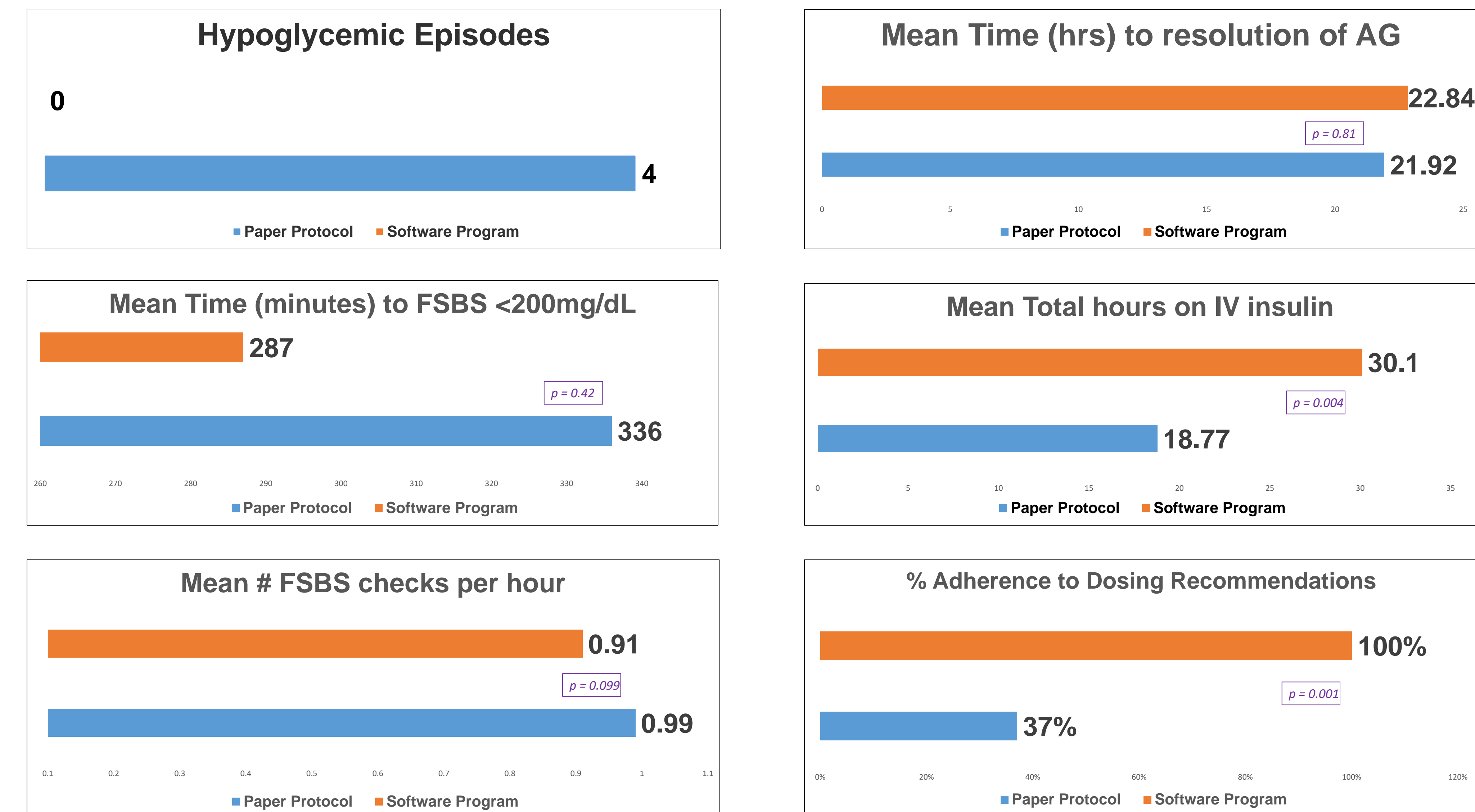
- Paper algorithm followed by nursing staff
- Initial insulin infusion rate determined by provider
- Dose titration requires nurse input of current fingerstick blood sugar (FSBS) and change in FSBS from previous entry, and nurse calculation of dose
- Assumes linear relationship of insulin to FSBS

### Software Program (SP)

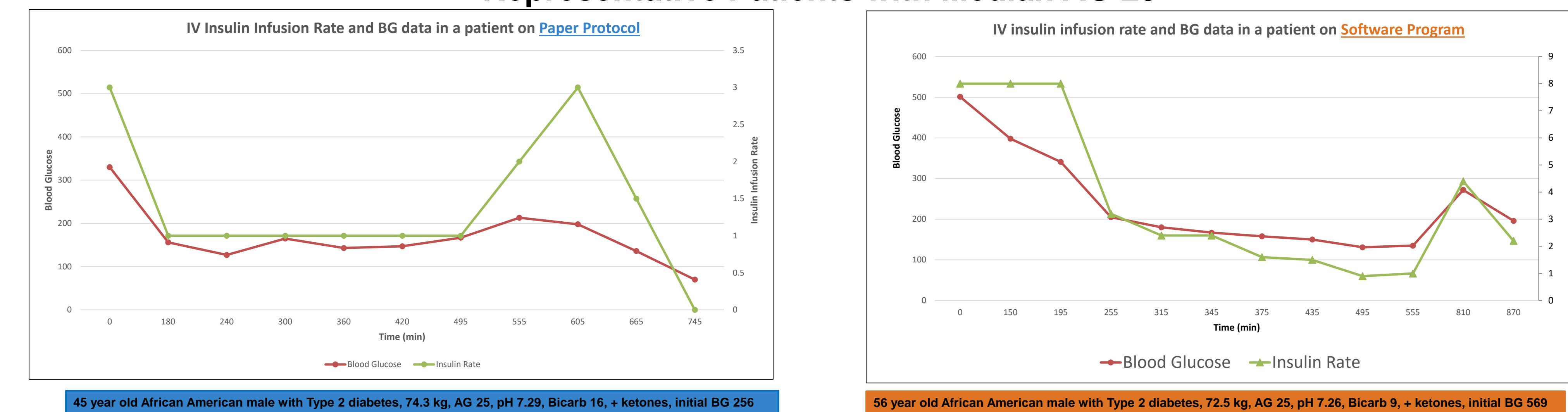
- Software system that Integrates with hospital information systems
- Uses mathematical modeling and feedback controls
- Develops patient-specific physiologic insulin dosing curves based on patient's weight, age, diabetes type, and GFR
- Model predictive control algorithms make automatic nonlinear adjustments to dose recommendations to minimize and prevent hypoglycemia and hyperglycemia



## RESULTS



## Case Examples Representative Patients with Median AG 25



## DKA Mode of Therapy

When the DKA mode of therapy with EndoTool® is ordered, an intermediate FSBS goal is set (150-200 mg/dL), which slows down the rate of decline of the blood glucose. An alert is embedded in the software to ask the nurse if dextrose is begun when FSBS is  $<200$ mg/dL, and VMC order set reflects the best practice of adding D5½NS (rate entered by MD) at this point. Once blood sugars reach the goal of 150-200mg/dL for 2 hours, another alert asks the nurse if the anion gap is less than 12; when the anion gap is confirmed to be less than 12, the software converts the goal of therapy to 140-180mg/dL.



### Complementary Order Set Components

- Initiate EndoTool® software by entering necessary patient information into the patient's EndoTool® Computer profile; Enter Type of Diabetes (1, 2, Unknown, None)
- Follow EndoTool® software instructions
- If Total Parenteral Nutrition (TPN) or Tube Feeds (TF) on hold for any reason run D10W at same rate until TPN or TF resumed
- If patient is eating, check FSBS 30 min after start of meal and follow EndoTool® instructions
- Notify prescriber if EndoTool® program runs at 15 units/hr or greater for 2 consecutive hours
- Monitor lab results for Anion Gap (Ordered every 4 hours)
- Notify prescriber immediately when blood glucose decreases below 200mg/dL
- D5½NS (enter rate). Stop all other IV fluids and start when FSBS is less than 200mg/dL.

## DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

Variable	Paper Protocol (PP)	Software Program (SP)	p value
Age (mean, years)	38.8	40.2	0.68
Gender (Female)	45%	52%	0.50
% of Type 1 DM	70%	62%	0.44
BMI	27.14	25.72	0.31
Race	AA 57% Caucasian 38% Other 5%	AA 45% Caucasian 55%	
<b>Initial Labs</b>			
Serum glucose	582 mg/dL	536 mg/dL	0.35
pH	7.22	7.26	0.40
Anion gap	25	25	0.95
Serum Bicarbonate	13.73 mEq/L	13.59 mEq/L	0.91
HbA1c	11.0 %	11.3 %	0.56

## DISCUSSION

- Literature has shown both safety and efficacy of computer-based insulin infusion protocols among hospitalized patients for hyperglycemia in various settings (i.e. post surgery, MICU, ER) but to the best of our knowledge, there is no published literature on safety and efficacy of computer-based insulin infusion programs in adult hospitalized DKA patients.
- The difference in incidence of hypoglycemia between the two groups indicates that an eGMS is a safer approach for managing insulin infusions for DKA patients.
- The time to resolution of DKA was not different between the two approaches indicating a similar efficacy in terms of IV insulin infusion.
- Secondary comparisons indicated similar results on Mean Time to FSBS  $<200$ mg/dl and Mean # FSBS checks per hour. Longer duration of IV insulin on the Software Program may indicate greater ease of nursing use with the Software Program.
- The Software Program simplifies insulin dosing, removing need for nurse calculation and improving adherence to dosing recommendations.
- Our study also illustrates the implementation of an eGMS for insulin dosing in community hospitals. Orders that complement the software instructions were grouped in an order set.
- In the composite management of DKA, hyperglycemia is one of several metabolic components that requires active management. Irrespective of method used, other supportive measures (i.e. aggressive IV hydration, potassium, initiation of dextrose containing fluid when required, etc) are equally important. To achieve optimal outcomes, providers can use IV insulin dosing systems as a tool for glucose management as part of their DKA management plan.

## REFERENCES

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## CONCLUSIONS

Initiation of eGMS in community hospitals can be accomplished safely and effectively. A computer-based insulin-dosing software program for treatment of patients with DKA appears to be safer and no less efficacious than a standard paper protocol. Larger prospective and multicenter studies are needed to validate these findings.