Glycemic Management in a Modern Age: The Use of an Electronic Glycemic Management System

November 1, 2019
Introduction

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Agenda

• Discuss challenges to inpatient glycemic optimization
• Review what an electronic glucose management system (eGMS) is and the benefits of use
• Assess what to look for in an eGMS
• Describe how EndoTool is a unique and effective solution compared to standard practices
Challenges to Inpatient Glycemic Management
Poor Glycemic Management is a Problem

Infection
- Patients with higher glucose levels have higher rates of infection

Patient Safety
- Hypoglycemia is the top source of inpatient adverse drug events (ADEs)

Cost of Care
- Roughly $98 billion is spent on inpatient diabetes annually, and each year approximately 1.5 million individuals are newly diagnosed

Length of Stay
- An increase in blood glucose levels is associated with a longer length of stay

Society of Hospital of Medicine, 2016. Lecture presented at New York State Partnership for Patients.
Level of Glycemia Impacts Length of Stay

**Brody School of Medicine, East Carolina University:** 1574 CABG patients

- Each 50 mg/dL increase in perioperative BG level*
  - Added 0.76 days to LOS
  - Increased hospital cost by $2824

**Portland Diabetic Project: 5510 CABG patients, 1987-2005**

- Each 50 mg/dL increase in 3-BG** level added 1 day to LOS
  - Treatment-induced LOS savings: 1.8 days/patient
    - Actual non-OR charge for 1 CABG LOS day = $1150
    - Savings from use of intensive insulin protocol, 1.8 x 1150 = $2081

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* Perioperative BG = average of day of and day after surgery.
** 3-BG: 3-day average perioperative blood glucose.
Both studies: Levels measured up to >250 mg/dL; lowest level measured <150 mg/dL, no threshold effect

Inpatient Glucose Management is Complicated

- Insulin is a “high alert” medication that is frequently associated with medication errors
- Lack of standardization
- Fewer inpatient diabetes specialists
- Nurses are over-burdened
- Adherence to protocols is low

Glucose Abnormalities in the Hospital Are Common!

<table>
<thead>
<tr>
<th></th>
<th>Critically Ill</th>
<th>Noncritically ill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperglycemia (BG&gt;180 mg/dL)</td>
<td>32.2% patient-days</td>
<td>32.0% patient-days</td>
</tr>
<tr>
<td>Hypoglycemia (BG&lt;70 mg/dL)</td>
<td>6.3% patient-days</td>
<td>5.7% patient-days</td>
</tr>
</tbody>
</table>

Paper Protocols are Challenging

Paper protocols are complex, time-consuming, and prone to medication error.
New Anticipated Quality Measures for Glucose Control

• Two new electronic clinical quality measures are under CMS review:
  
  ◦ **Severe Hyperglycemia**
    – The percentage of hospital days in severe hyperglycemia, defined as an elevated blood glucose greater than 300 mg/dL or not measured that day and not preceded by two consecutive days where glucose levels were all measured and less than 200 mg/dL.
  
  ◦ **Severe Hypoglycemia**
    – The rate of severe hypoglycemic events (<40 mg/dL) within 24 hours of administration of antihyperglycemic medication and no subsequent glucose value greater than 80 mg/dL within five minutes of the low glucose event.

• Once implemented, collected data may be used in quality reporting programs.
“The complexity of inpatient glycemic management necessitates a system approach that facilitates safe practices and reduces the risk for errors”.

-AACE and ADA Consensus Statement on Inpatient Glycemic Control.
EndoTool Glucose Management System

- Proprietary technology that uses complex algorithms to model, predict and adapt dosing to each patient’s physiology and individual response
- Precise insulin dose recommendation for intravenous and subcutaneous delivery
- FDA Class II medical device with more than 15+ years of experience and more than 300 facilities under contract
What is an eGMS?

Electronic glucose management systems (eGMS) use algorithms to guide insulin delivery, based on blood glucose readings and other patient information.

**Electronic Glucose Management Systems Commonly Used in the ICU**

<table>
<thead>
<tr>
<th>EGMS</th>
<th>Glucommander</th>
<th>Glucostabilizer</th>
<th>GlucoCare</th>
<th>EndoTool</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algorithm</td>
<td>Variable multiplier</td>
<td>Multiplier or ISF</td>
<td>Δ infusion rate</td>
<td>Multifactorial Model</td>
</tr>
<tr>
<td>Reported time to target (hrs)</td>
<td>4.8 [56]</td>
<td>6.9 [60]</td>
<td>4.3 [63]</td>
<td>2.3 [54]</td>
</tr>
<tr>
<td>Reported hypoglycemic rates</td>
<td>3.9% (&lt;40 mg/dL), 42.9% (&lt;60 mg/dL) [56] 12.9% (&lt;70 mg/dL) [57]</td>
<td>0.4% (&lt;50 mg/dL) [60]</td>
<td>0.3% (&lt;40 mg/dL), 17.6% (&lt;70 mg/dL) [63]</td>
<td>0.05% [52], 0.03% [54] (&lt;40 mg/dL), 0.46% (&lt;70 mg/dL) [54]</td>
</tr>
</tbody>
</table>

Salinas P, Mendez CE. Glucose Management Technologies for the Critically Ill
A 7-Year, Retrospective Study at a 900-bed AMC

AMC Case Study

Vidant Medical Center, a 900-bed Tertiary Care Teaching Hospital

Retrospective data analysis of 492,078 BG readings between 2009 and 2015

• Blood glucose levels were brought to target more rapidly
  ◦ 1.5 to 2.3 hours (4.5 to 4.8 hours for cardiovascular patients)
• Minimal hypoglycemia was observed
  ◦ 0.03% for glucose values <40 mg/dL; 0.93% for <70 mg/dL
  ◦ Significant reductions over time in hypoglycemia frequency (<70 mg/dL), from 1.04% in 2009 to 0.46% in 2015
• Infections decreased
  ◦ HAC-8 rates were reduced from 0.083 per 1,000 patients in 2008 to 0.032 per 1,000 patients in 2011

Original Article

USE OF A COMPUTER-GUIDED GLUCOSE MANAGEMENT SYSTEM TO IMPROVE GLYCEMIC CONTROL AND ADDRESS NATIONAL QUALITY MEASURES: A 7-YEAR, RETROSPECTIVE OBSERVATIONAL STUDY AT A TERTIARY CARE TEACHING HOSPITAL

Robert J. Izmirly, MD, FACP†; Sonja Barlow, PharmD, CDE;†
Carrie Rothermel, MA, MPH; Ahmed J. Drake, MD, FACP†

ABSTRACT

Objective: Hyperglycemia, hypoglycemia, and glucose variability are associated with mortality and morbidity. The use of computer-guided glucose management systems has been shown to significantly improve blood glucose (BG) control. This retrospective observational study examined the impact (January 2009-December 2015) of the TracePoint eCBM system and integrated insulin on Vidant Medical Center, a 900-bed tertiary teaching hospital.

Methods: Patients exposed to eCBM had indications for IV insulin infusion, including uncontrolled diabetes, severe hyperglycemia, and/or postoperative BG levels >155 mg/l. The study evaluated time required to achieve target BG levels (<60 mg/dL; <90 mg/dL; <180 mg/dL) for each diabetes indication, hypoglycemia incidence (<70 mg/dL; <40 mg/dL), and reductions over time in glucose variability (CV%) and hypoglycemia frequency (<70 mg/dL). The impact of eCBM on hospital acquired condition rates (HACs) was evaluated.

Results: Data were available for all treated patients (60,308 BG readings from 11,800 patients). Total BG levels were brought to target within 1.5 to 2.3 hours (4.5 to 4.8 hours for cardiovascular patients). Minimal hypoglycemia was observed (CV% values <70 mg/dL; <60 mg/dL; <40 mg/dL). Significant reductions occurred over time in hypoglycemia frequency (<70 mg/dL) from 1.04% in 2009 to 0.46% in 2015 (P <0.001). The CV% per patient was 20.5 ± 12.9%, and 6% of patients experienced glucose excursions defined as BG values >180 mg/dL once control was achieved. HAC-8 rates were reduced from 0.083 per 1,000 patients (2008) to 0.032 per 1,000 patients (2011).

Conclusions: The use of eCBM resulted in improved, effective control of important BG levels, including significantly reduced hypoglycemic events. (Endocrine Pract. 2015;21:338-344)

INTRODUCTION

A disproportionate number of hospitalized patients experience hypoglycemia (1,2) and these episodes are associated with increased morbidity and mortality (3). Despite advances in perioperative care and perioperative emergency care, the problem remains unacceptably high. Eighty percent of the increase in mortality among surgical patients was attributed to hypoglycemia, most of which was multidrug-induced (1). This work is supported by the Diabetes Patient Safety Initiative, a collaborative effort of the American Diabetes Association and the Joint Commission, to improve patient safety in the hospital setting. (3-5) Hypoglycemia is defined as glucose levels <60 mg/dL, and hypoglycemia on insulin is associated with a higher rate of in-hospital mortality and hospital length of stay (6). A high rate of hypoglycemia has been documented in this population of patients. (7) A 7% to 8% reduction in hypoglycemia (8) and a 12-day decrease in hospital length of stay have been demonstrated. (9) A hypoglycemia alarm system can be used to identify hypoglycemic episodes. (10) A 7% reduction in hypoglycemia and a 12-day decrease in hospital length of stay have been demonstrated. (11)
Use of an eGMS in Cardiac Surgery ICU

Cardiac ICU Case Study

Virginia-based Academic Medical Center
14-bed Cardiac Surgery ICU
Retrospective data analysis of 2,169 patients between 2013 and 2016

- Organization moved to EndoTool IV from Paper Protocol because they were unable to meet SCIP and STS outcomes measures consistently
- All patients on insulin infusion:
  - Post op cardiac surgery patients (initiated in OR or pre-operatively) x 48 hours minimum post op.
  - All thoracic, vascular, ECMO (non-surgical) and Esophagectomy patients with 2 consecutive BG > 180 mg/dL.
- Data analysis showed:
  - More patient achieving target glucose levels
  - Faster time to goal
  - Increased prevention of hyperglycemia
  - Significantly reduced hypoglycemia
Case Study: EndoTool IV Safer than Paper Protocol in Cardiac Surgery ICU
Case Study: EndoTool IV Safer than Paper Protocol in Cardiac Surgery ICU
Use of an eGMS for Managing Glucose in Challenging Patient Cases

DKA Patient Case Study

Six Community Hospitals in Eastern Carolina

Retrospective data analysis of all admitted patients with DKA between 2014 and 2016
- December 1, 2014-March 30, 2015
  40 patients on paper protocol
- December 1, 2015-March 30, 2016
  42 patients on software program

• Flagship hospital moved to EndoTool IV for safer and more patient-specific glycemic management
• After success in the hospital, the technology introduced in 6 of the 7 community hospitals a part of the system
• A retrospective analysis found that 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

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Hypoglycemic Episodes

<table>
<thead>
<tr>
<th>Paper Protocol</th>
<th>Software Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4</td>
</tr>
</tbody>
</table>

% Adherence to Dosing Recommendations

<table>
<thead>
<tr>
<th>Paper Protocol</th>
<th>Software Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>37%</td>
</tr>
</tbody>
</table>

Case Examples

Representative Patients with Median AG 25

45 year old African American male with Type 2 diabetes, 74.3 kg, AG 25, pH 7.29, Bicarb 16, + ketones, initial BG 256

56 year old African American male with Type 2 diabetes, 72.5 kg, AG 25, pH 7.26, Bicarb 9, + ketones, initial BG 969
Summary of Research on Computer Protocols vs Linear Paper Protocols


- Decreased severe hypoglycemia
- Significantly decreased standard deviation of glucose in medical, cardiac trauma and neuroscience ICU
- No difference in mortality or length of stay


- Computer decision support systems can help reduce the risk of insulin infusion rate calculation errors and standardize insulin therapy.


- The management of computerized glucose management system EndoTool is both safe and effective at lowering BG in DKA and HHS patients. The mean rate of glucose reduction was 87 mg/dL/hr and a reduction of at least 50 mg/dL was achieved in 84% of patients.
Summary of Research on Computer Protocols vs Linear Paper Protocols


- Nurses perceived EndoTool to be superior to the Burn DSS protocol for:
  1. adequacy of training
  2. comfort in the system
  3. ease of use and
  4. trust in the recommendation (P<.001)

Crockett S. E. et al. (2012). Risk of Postoperative Hypoglycemia in Cardiovascular Surgical Patients Receiving Computer-Based Versus Paper-Based Insulin Therapy. Endocrine Practice Vol 18 No. 4

- Computerized glucose management system can successfully attain goal glucose levels with significant reduction in hypoglycemia compared to paper protocol.
What to Look for in an eGMS
1. Individualized Insulin Dosing

EndoTool adjusts to each patient’s unique physiology and individual response with **11 patient-specific factors**:

- Blood glucose level
- Diabetes mellitus diagnosis
- Age
- Sex
- Height
- Weight
- sCr
- eGFR
- Carbohydrate intake
- Steroid presence
- Estimated residual extracellular insulin (EREI)
Estimated Residual Extracellular Insulin (EREI)

- EREI is a patented feature of the IV application that predicts and adjusts for residual insulin.
  - 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.
  - EREI is also similar in concept to Insulin On Board for subcutaneous insulin

- Based on a patient’s kidney function and response to insulin dosing, the software adjusts a patient’s next insulin dose to prevent subsequent hypoglycemia.
EndoTool® IV Hypoglycemia Outcomes
Before and After EREI

Before & After EREI – 900 Bed Facility

% of Total Reading

- <70 BG Readings
  - 1.05%
  - 0.3%
  - 71% Improvement

- <60 BG Readings
  - 0.36%
  - 0.135%
  - 63% Improvement

- <50 BG Readings
  - 0.11%
  - 0.04%
  - 64% Improvement

- <40 BG Readings
  - 0.04%
  - 0.025%
  - 38% Improvement

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**EndoTool IV**

The table below demonstrates how **EndoTool IV** determines the *safest* dose for each patient based on the individual response to insulin. Compared to other systems that treat based on weight, last glucose reading, and a FIXED multiplier, **EndoTool IV** offers a more personalized approach.

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<tr>
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</thead>
<tbody>
<tr>
<td>300 mg/dL</td>
<td>5</td>
<td>4.5</td>
<td>5</td>
<td>6.5</td>
</tr>
<tr>
<td>300 mg/dL</td>
<td>5</td>
<td>4.5</td>
<td>6.5</td>
<td>3.4</td>
</tr>
<tr>
<td>300 mg/dL</td>
<td>5</td>
<td>4.5</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>300 mg/dL</td>
<td>5</td>
<td>4.5</td>
<td>5</td>
<td>18</td>
</tr>
</tbody>
</table>

**Other Systems**

Treat based weight, last glucose reading, and a FIXED multiplier.
EndoTool’s Non-Linear Dosing Curve

- Dose recommendations based on the trend over the last 4 data points and the current to uniquely treat patient’s glucose response
- More than 70 decision point calculations focused on safety and control
2. The Safest Patient Outcomes

- 98.4% Patients Achieve Control
- 54% Hospital Acquired Infection Reduction
- 95% Hypoglycemia Reduction
- <3hrs Avg Time to Control
- 46% Finger Stick Reduction
- 0.009% < 40 mg/dL Blood Glucose Readings (statically zero severe hypoglycemia)

*EndoTool IV Outcomes; Data on file
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Personalized Control for the SAFEST Dosing

Goal Range: 100 - 140

Example 1
1:00pm: BG of 300mg/dL
2:00pm: BG of 285 mg/dL (Inadequate Response)
Up-regulation prior to next dosing calculation

Example 2:
1:00pm: BG of 300mg/dL
2:00pm: BG of 175 mg/dL (Excessive Response)
Down-regulation prior to next dosing calculation
3. Real-Time Analytics to Measure Performance

• EndoTool Analytics
  ◦ 14 predefined patient, unit, facility and provider-level reports
  ◦ Ability to easily export data and share in PDF or CSV files

• Self- Service Analytics
  ◦ Pre-built data warehouse that can be used to:
    – Generate standard monthly reports
    – Support ad-hoc reporting
    – Extract EndoTool data and combine in own local Enterprise data warehouse
4. Comprehensive EMR Integration

- Integrates with all major EMR Systems via HL7
- Keeps users in a single record
- Simplifies order sets
- Removes double confirmation in EMR
- Reduces clicks and duplicate input
4. Robust Support

**DISCOVERY**
- Readiness assessment
- Clinical parameters
- Technical system design

**PLANNING**
- Customized project plan based on hospital practices and process

**EDUCATION**
- On-site super user training
- Customized e-learning and quizzes
- Resident training book

**PARTNERS**
- Dedicated project team consisting of project manager, clinical specialist, and technical consultant

**GO-LIVE**
- On-site for super-user and technical training
- Clinical Specialist present for go-live

**SUPPORT**
- 24/7/365 remote support
- Ongoing optimization and reviews
Thank you!

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