Continuous Glucose Monitoring: A New Tool for Optimizing Diabetes Management

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Traditional Self Blood Glucose Monitoring

- Average of 136 mg/dL
- Standard Deviation of 62%
- 84% within target range

Where we are now...

View with Continuous Glucose Monitoring (CGM)

- Average of 152 mg/dL
- Standard Deviation of 62%
- 62% within target range

Glycemic Characteristics in Continuously Monitored Patients with Diabetes

- N=101 (60 type 1, 41 type 2)
- 287 hrs of CGM masked, 9 BG checks per day

- <70 mg/dl: 8% of the time (1.9 hrs/d)
- 70-180 mg/dl: 63% of the time
- 90-130 mg/dl: ~28% of the time
- >180 mg/dl: 29% of the time (7 hrs/d)

Duration of hypoglycemia (hrs/day): Type 1 - 2.3 hrs, Type 2 - 1.0 hr
Potential Benefits of CGM

- Reduce glycemic variability
- Improve HbA1C
  - Without increasing risk of hypoglycemia
- Reduce incidence of serious hypo- and hyperglycemic events
- Identify unrecognized hypoglycemia

What studies support the use of CGM?


CGM* Detects Unrecognized Hypoglycemia

Percentage of patients with type 1 and type 2 diabetes with asymptomatic hypoglycemia detected by CGM

Use of CGM* to Reduce Hypoglycemia

Number of hypoglycemic episodes per day in masked vs unmasked CGM in Type 1 patients

*CGMS®

N=70

N=137

P= .0001
Effect of CGM* on A1C

Change in A1C in type 1 children and adults with A1Cs >8.1%

N=162

<table>
<thead>
<tr>
<th>Baseline</th>
<th>1 Month</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.5</td>
<td>9.0</td>
<td>9.5</td>
</tr>
<tr>
<td>9.0</td>
<td>9.5</td>
<td>10.0</td>
</tr>
</tbody>
</table>

P = 0.006 P = 0.003

Control group
Biweekly group
Continuous group

Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes

Study: Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes
– The Juvenile Diabetes Research Foundation

Purpose: To evaluate the efficacy and safety of CGM in adults and children with type 1 diabetes

Study Design

ENROLLMENT
165 CGM 157 Control
50:50 randomization

Randomization

Real Time CGM
Self Blood Glucose Monitoring

JDRF CGM Study

• Continuous vs non-continuous use
• Ability to lower A1C without severe hypoglycemia

A1C Change

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>CGM</th>
<th>SMBG</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>25+ years</td>
<td>-0.53%</td>
<td>0.02%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>15-24 years</td>
<td>-0.18%</td>
<td>-0.21%</td>
<td>0.52</td>
</tr>
<tr>
<td>8-14 years</td>
<td>-0.37%</td>
<td>-0.22%</td>
<td>0.29</td>
</tr>
</tbody>
</table>


Diabetes Care 29:2730-32 2006

Guardian RT
A1C Improvement by Sensor Utilization

<table>
<thead>
<tr>
<th>CGM Use</th>
<th>4.0 days/week</th>
<th>2.0-4.0 days/week</th>
<th>≥6.0 days/week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 225</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Age 15-24</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Age 8-14</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Change in A1c (%)

A1C drop in all age groups, but dependent on CGM utilization

Glycemic Variability

Patient A: A1C = 8.0%

Patient B: A1C = 8.0%

24-hr CGM Profile with Similar A1Cs

Use of CGM* to Identify and Reduce Glycemic Variability

Glucose range (mg/dL)

N=91
p<0.001

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* DexCom S7S

Mazze RM, Strock E, et al. Late-breaking abstract, American Diabetes Association Scientific Sessions, 2006. Adapted with permission, International Diabetes Center

JDRF CGM Study Group, NE Jnl Med 359:1494-76, 2008

Blood Glucose (mg/dl)

Glycemic Variability

Approx Change in A1c (%age points)

Change in A1c (%)

A1C drop in all age groups, but dependent on CGM utilization

Use of CGM* to Identify and Reduce Glycemic Variability

Glucose range (mg/dL)

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Nocturnal Glycemic Variability

Nocturnal Glycemic Ranges

- Time Spent (hours/night)
- Glucose value (mg/dL)
- Control
- Display

p<0.001

Evolution of CGM Systems

- Retrospective/Intermittent
  - Provider makes decisions based on glucose patterns retrospectively
  - No real-time assessment of glycemia by patient (glucose trends, alarms)
  - Identification of hypoglycemia unawareness

- Prospective/Continuous – “Real-time”
  - Allows patient to respond to glucose changes
  - Immediate identification and treatment of hypohyperglycemic events following confirmatory blood glucose check
  - Used in clinical arena

CGM Systems

Glucose Testing Timeline

1941 1980s 2000+

Interstitial Fluid (ISF) Glucose Measurements
Continuous Glucose Monitoring

- FreeStyle Navigator® Continuous Glucose Monitoring System
- DexCom™ Seven ® Continuous Glucose Monitoring System, and DexCom™ Seven ® Plus Continuous Glucose Monitoring System
- MiniMed Paradigm® REAL-Time System Insulin Pump and Continuous Glucose Monitoring System and Guardian® REAL Time Continuous Glucose Monitoring System

Characteristics of Prospective, Real-time CGM Systems

- Provides Continuous Glucose Readings
- Measures Interstitial Fluid Glucose
- Calibrated with Blood Glucose
- Alarms to Warn of Hypo- and Hyperglycemia
- Trend Arrows indicate Glucose Rate and Direction

Getting Started with CGM

- Potential Candidates for CGM
  - Patients with type 1 or type 2 diabetes who are not reaching treatment goals despite adequate SMBG
    - A1C/ glycemic variability
  - Intentional hyperglycemia due to fear of hypoglycemia
  - Frequent hypoglycemia or hypoglycemia unawareness
  - Gastroparesis
### Considerations for Patient Selection

- Ability to interpret and respond to the data appropriately
- Motivated to take diabetes meds and perform SMBG as indicated

### Getting Started with CGM Technology

- User expectations
  - What are users’ expectations of CGM system?
  - Goals in using CGM
  - Scope and limitations of CGM
  - How will he/she use the information in decision making?
  - User readiness to utilize CGM information
  - Is additional help needed for success in user’s daily life?

### Managing Expectations

- Continuous glucose monitors are monitoring devices
  - CGM systems are not a cure for diabetes
  - CGM systems do not replace the need for fingersticks

- To improve diabetes control, users of CGM devices must:
  - wear the CGM device
  - look at the display frequently
  - work with HCP to make decisions based on the data after confirmatory blood glucose tests

### Education Considerations

- Diabetes basics review
  - Insulin action and duration
  - Role of food choices
  - Safe self-management practices
  - i.e., checking blood glucose before driving

- CGM education
  - Sensor basics
  - Interstitial fluid (ISF) glucose and lag
  - Data interpretation
Capillary vs. Interstitial Fluid (ISF) Glucose

- CGM systems measure ISF glucose and are calibrated to plasma glucose
- ISF and capillary glucose levels similar when glucose levels stable
- Glucose diffusion between capillary and ISF accounts for a lag of ~14 minutes on average during periods of rapid glucose change

Setting Glucose Alarms

- Find a balance between useful glucose information and excessive alarms
  - Prevent “alarm burnout”
- Consider setting alarms “widely” during training period
  - Low alarms lower and high alarms higher
- Caution patients not to rely entirely on glucose alarms to manage their diabetes

Setting Low Glucose Alarms

- Setting at lower glucose level will minimize excessive alarms, but not capture all hypoglycemic events
  - Users at low risk of hypo events
- Setting at higher glucose level will result in more false alarms, but will capture more hypo events
  - Hypoglycemic unawareness

Setting High Glucose Alarms

- Setting at higher glucose level will minimize excessive alarms, but not capture all hyper events
- Setting at lower glucose level will capture more hyper events, but will also increase the risk of false alarms
  - Can be used to alert user of missed meal bolus
**Utilizing the Data**

- Assess overall glycemic goals
- Address safety: severe hypoglycemia/hypoglycemia unawareness and hyperglycemic events
  - Identify glycemic trends and patterns

**Utilizing Real-time Data on the Receiver**

- **Where you are…**
  - Adjustment of therapy in response to current glucose readings and high and low glucose alarms
- **Where you’re going…**
  - Prediction of hypo- and hyperglycemic events by trends and rates of change (trend arrows and graphs, projected alarms)
- **What preceded the event**
  - Feedback about glucose response to food, exercise, illness, medication (line graph)

**Utilizing Real-time Data on the Receiver**

- Scenario: Patient is getting ready to go to a restaurant for lunch and has the following information on his CGM receiver
- What would his likely response be?

**Learnings from the Line Graph – Insulin Timing**

<table>
<thead>
<tr>
<th></th>
<th>Yesterday</th>
<th>Today</th>
</tr>
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<tbody>
<tr>
<td>Insulin bolus</td>
<td>7:30 AM</td>
<td>7:00 AM</td>
</tr>
<tr>
<td>Breakfast:</td>
<td>7:30 AM</td>
<td>7:30 AM</td>
</tr>
</tbody>
</table>

Graphs showing glucose levels and insulin bolus times.
Learnings from the Line Graph – Effect of Food

Yesterday

Today

Bagel Breakfast

Oatmeal breakfast

Learnings from the Line Graph – Effect of Exercise

Bike ride – 20 minutes

Retrospective Data

• Review overall glycemic control
• Evaluate repeated glycemic patterns and day-to-day differences
• Optimize care by analyzing statistics, pie charts, and other retrospective data, as individualized for clinician and user

Navigating the Future with CGM

• Increase our knowledge
• Augment current therapies
• Develop new treatment options
• Enhance quality of life