Continuous Glucose Monitoring and insulin pump—a primary care perspective

Manisha Bhide, MD.
Mara Schwartz, RN, BSN, CDE.
Questionnaire

Q.1 Do you ask your patients with Diabetes to bring glucometer or blood glucose log to clinic? 10%, 50% 75%, >90 % of the times.
Q.2 Do you review the log with them? 10%, 50% 75%, >90 % of the times.
Q.3 Are you aware about the guidelines regarding self blood glucose monitoring?
Q.4 Are you aware of continuous glucose monitoring?
Q.5 If you are a lone physician in rural Colorado, do you think you will be able to manage an insulin pump?
Barbara Davis Center for Diabetes
## Diabetes prevalence

<table>
<thead>
<tr>
<th>Incidence of diabetes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>in US population</td>
<td>25.8 million, 8.3 % of population</td>
</tr>
<tr>
<td>Incidence in &gt;65 year</td>
<td>26.9 %</td>
</tr>
<tr>
<td>New diagnosis in &gt;20yr</td>
<td>1.9 million</td>
</tr>
<tr>
<td>Incidence of pre-diabetes</td>
<td>79 million</td>
</tr>
</tbody>
</table>

Ref: Data from the 2011 National Diabetes Fact Sheet (released Jan. 26, 2011)
Complications of diabetes

- Eighth leading cause of death in 2011.
- Cardiovascular mortality and morbidity - heart attack, stroke.
- Kidney failure – Diabetes is a leading cause
- Diabetic eye complications, blindness.
- Neuropathy
- Loss of limb - amputation
Diabetes management is team work
Self monitoring of blood glucose (SMBG)

ADA recommends SMBG for patient with-
- Type 1 Diabetes
- Diabetes Control and Complications Trial (DCCT) T1D exchange data, PRISMA- self monitoring improves outcomes.
- Type 2 diabetes on insulin
- Type 2 diabetes on oral hypoglycemic agents.

Type 2 Diabetes patients who are diet controlled or on other oral medications SMBG improves A1c by 0.25 % at 6 months, but after that benefits may be too small for the cost.


Case

55 year professor Dr. Hardy has type 1 diabetes. He is working hard to meet the deadlines to write grants. He has been having recurrent morning seizures due to hypoglycemia and has intermittent blood sugar of 400 mg/dl when he has dinner with family. Can you help?
What do PCPs think about CGM

Responses of Various Primary Care Physicians Who Work in Colorado and Utah when asked About Continuous Glucose Monitoring (CGM)

“I have no clue.”

“I have patients with T1D in my practice. They may be able to use it. I have no clue how to get it.”

“I don’t think it’s evidence-based.”

“I would like to use it for patients with T2D on sulfonylureas who are having low blood sugars.”

“I have never seen it.”

“It sounds cool.”

“I think patients should pay for it, at least partly, since it is too much to ask insurance, they would never pay for it.”

“It is not a technology that I think will stick around, with the bulk of stuff to carry around it’s likely to become redundant. It’s just for research stuff.”

“It would be good to use in non-compliant patients for a short time, but would be just too much data to handle in the long run.”

“I don’t know how much value it adds in adults, but I can think of it in children with T1D.”

“I don’t have the documentation to prove it’s accurate and I don’t know about the cost.”

Continuous glucose monitoring (CGM)

Indications for CGM- per ADA

- Type 1 Diabetes.
- Insulin requiring Type 2 Diabetes.
- Gestational Diabetes.
- Re-establish glucose control after acute episodes of hypoglycemia, DKA or coma.
- Switch from insulin injection to insulin pump.
- Manage large glycemic fluctuations.
- Hypoglycemia unawareness, nocturnal hypoglycemia.
Mean A1c by CGM use in Type 1 diabetes

HbA$_{1c}$ Change in T2D From Baseline

(RT-CGM vs. SMBG)

Parts of CGM

CGM has been available since 2006.

Basic parts of CGM-
- sensor under skin
- Transmitter
- Monitor
- Computer is needed to download the CGM data
CGMs Available in US

Dexcom Platinum G4

Minimed with Enlite
CGMs in markets

- Abbott's free style navigator (not available in US)
- Dexcom G4 Platinum (stand only CGM)
- Medtronic Guardian REAL-Time System - CGM only
- Medtronic 530G with Enlite (Pump and CGM integrated)
CGM download

Pattern Insights Summary

<table>
<thead>
<tr>
<th>Nighttime Lows (0 Found)</th>
<th>No significant patterns detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daytime Lows (9 Found)</td>
<td>No significant patterns detected</td>
</tr>
<tr>
<td>Nighttime Highs (1 Found)</td>
<td>Most significant pattern of highs found between 2:30 AM and 3:30 AM</td>
</tr>
<tr>
<td>Daytime Highs (0 Found)</td>
<td>No significant patterns detected</td>
</tr>
</tbody>
</table>

Statistics

- Average Glucose: 149 mg/dL
- Sensor Usage: 14 of 14 Days
- Calibrations / day: 2.6
- Standard Deviation: ± 68 mg/dL

- 25% High
- 67% Target
- 8% Low

Target Range: 70 - 120 mg/dL
Nighttime: 10:00 PM - 6:00 AM

Interpretation

Note: See above graph for other patterns as well as review any individualized considerations.
CGM download
Benefits of CGM

- Provides multiple readings - day and night approx. 300 readings /day.
- Helps in fine tuning metabolic control.
- Recommended in T1 D and insulin requiring T2 D (JDRF algorithm for T1D).
- Acts as a motivator.
- Decreased glucose variability.
- Decreased nocturnal hypoglycemia.
- Hypoglycemia unawareness.
- Can use intermittently to get benefit for T2D

Challenges of CGM use

- Lack of technical knowhow
- Lack of simple algorithms for T2D
- Interstitial readings and inherent lag.
- Data overwhelming
- **Alarm Fatigue**
- Cost benefit studies lacking
- Extra burden to carry
- Requires calibration
- Overreacting and insulin stacking

Challenges to CGM in primary care

- Trained diabetes care team member needed to download CGM.
- CGM download needs to be accessible in EMR.
- Provider needs to have the technical expertise to interpret the data.
- Lack of diabetes educators in primary care clinics to educate patients regarding CGM use.
- Lack of resources- getting insurance approval
  - As of 7/2013 Humana, Cigna and Anthem BCBS cover CGM for any diabetic (Type 1 and 2) on Insulin.
Coding for CGM

CPT code 95250- ambulatory CGM for min 72 hour, sensor placement, calibration, patient training, print out
This is the technical component.
CPT 95251 interpretation of CGM and report
This is not restricted to physicians.
Codes can be used only once/month
CGM is not covered by CMS
Medicare/Medicaid. Commercial insurance plans are covering CGM.

Ref: Coding guidelines for CGM AACE position statement 2010
Future of CGM in primary care

- Team approach in PCMH
- Group visits
- CMS has a code for CGM
- Improve knowledge by revised curriculum in medical schools and medicine residency.
- Govt. intervention to make CGM affordable.
23 year old male JD with type 1 diabetes wants to climb Mt. McKinley. His blood glucose varies from fasting of 40 mg/dl to 400 mg/dl, depending on his hikes. He has been using insulin injections but wants something better for his dream hike. Can you help?
Insulin pump

- Also called Continuous subcutaneous Insulin infusion therapy (CSII)
- In 1970- size of backpack, now size of cellphone.
- Improved accuracy- can deliver insulin at accuracy of 0.025 units.
- Individualize glucose target.
Indications for insulin pump

- Recurrent severe hypoglycemia.
- Wide fluctuations in glucose levels, regardless of A1c.
- Suboptimal Diabetes control.
- Recurrent DKA.
- Pregnant, children, athletes.
Insulin pump

Any US physician can prescribe 25-41 % of Type 1 Diabetic pts are on pumps. 
ADA Recommends min 3 times/day BG check with CSII(continuous subcutaneous insulin therapy) 
CMS covers CSII in T1D and T2D in eligible patients.

Ref: AACE statement
Ref:The American Diabetes Association (ADA) Standards of Medical Care 2011
Insulin pump

Components-
- **Reservoir** - rapid acting insulin only
  - Requires change in reservoir and infusion every 2-3 days
  - Delivers insulin every few min round the clock
- **Cannula** in interstitial tissue.
- Programmed by hand held control
- Battery powered, worn on waste band/clipped
Current Insulin Pumps Available

Animas Ping

Tandem T-Slim

Omni Pod

Minimed with Enlite

Accu-Chek Combo
Basal Insulin or Basal Rate: A continuous 24 hour delivery of insulin that matches background insulin need. When the basal rate is correctly set, the blood sugar does not rise or fall during periods in which the pumper is not eating. Basal rates are given in Units/hour. Replaces long acting insulin.

Meal Bolus: A spurt of insulin given at meal time. The amount given is usually calculated based on your insulin to carb ratio.

Correction Bolus: A spurt of insulin given to bring a high blood sugar back into range. It can be given with the meal bolus or between meals.

Insulin sensitivity is amount of glucose lowering by 1 unit of insulin.

Carb. Ratio- grams of carbs covered by 1 unit of insulin.
Advantages of insulin pump

- The ability of infuse precise amount of insulin at a basal rate and post-prandial rate closely mimics normally functioning pancreas.

- Typically insulin in pump is 50% basal and 50% bolus
- Bolus calculators
- Pumps provide bolus over extended time period, this type of delivery is not possible with injections hence useful for diabetic gastro paresis.

- Insulin reservoir- Can program based on dawn phenomenon, stress, exercise
INITIATING PUMP THERAPY

• Patient must be on MDI for at least 6 M
• Willing and can afford to do SMBG at least 4 times a day
• Consider initiating CGM/CHM for 7-10 days to see glycemic patterns
• A1c between 6-8%
INITIATING PUMP THERAPY

- Consider Saline Pump for 2-3 weeks
- EDUCATION, EDUCATION........
- Pre-pump visit (Psycho-social also?) going through all pumps (Pros and Cons)
- Post-Pump 2-4 weeks and 2 month follow-up
- Insulin dose expectation (decline first and gradually increase over time)
INITIATING PUMP THERAPY

- Pump Class in two parts:
  - Button Pushing and other features
  - Concept of Basal/Bolus Rx
  - Review of DKA and Hypoglycemia
  - Sick day management
  - Exercise/Alcohol etc
  - Pre-Pregnancy start for at least 2-3 M
Insulin pump download
Insulin pump download

11 Hypoglycemic Episodes, by preceding Event Type - Threshold: 50 mg/dL

Most Common Event Types preceding Hypoglycemia:
- Nocturnal Hypoglycemia (11 PM - 5 AM): 67%
- Bolus Wizard Food Bolus: 25%
- Hypoglycemia Preceding Hypoglycemia: 24%

Event Type Descriptions:
- Nocturnal Hypoglycemia (11 PM - 5 AM): Consider assessing overnight basal rates and counseling your patient on evening boluses.
- Bolus Wizard Food Bolus: Consider assessing the Bolus Wizard settings, counseling your patient on accurate carbohydrate counting, and the timing of insulin delivery with respect to carbohydrate intake.
- Hypoglycemia Preceding Hypoglycemia: Consider counseling your patient on the management of hypoglycemia.

10 Hyperglycemic Episodes, by preceding Event Type - Threshold: ≥180 mg/dL

Most Common Event Types preceding Hyperglycemia:
- Rising Sensor Rate of Change Without Bolus: 60%
- Bolus Wizard Food Bolus: 17%

Event Type Descriptions:
- Rising Sensor Rate of Change Without Bolus: Consider counseling your patient on bolus use with meals and correcting rapid glucose excursions.
- Bolus with Rising Sensor Rate of Change: Consider counseling your patient to modify bolus amounts when sensor glucose values are rising (safety harrow is present).
- Bolus Wizard Food Bolus: Consider assessing the Bolus Wizard settings, counseling your patient on accurate carbohydrate counting, and the timing of insulin delivery with respect to carbohydrate intake.

Other Observations:
No overall issues observed.
Safety features of pumps

- Bolus dose needs to be confirmed.
- Pump alarms to alert for occlusion of cannula.
CSII Is Associated with Improved Patient Satisfaction Compared to MDI

93% of patients using CSII preferred the pump to their previous injectable insulin regimen

Needs of patients on insulin pump

1. Access to customer support. Help line phone number is located on the back of the pump.
2. Interruption in pump use can cause hyperglycemia and potential DKA.
3. Should have Lantus insulin available in case of pump failure.
Insulin pump in hospitalized pt

- Most patients are safest being on pump unless incapacitated\(^1\).
- Patients on insulin pump are candidates for Diabetes self management.
- Hospital policies and expertise are needed for in-patient pump use.
- Nursing documentation needed for basal and bolus insulin use\(^2\).

Ref-
2. ADA 2011 statement.
3. AACE and ADA consensus statement on in-patient Diabetes control. Moghissi E S et al. Diabetes Care June 2009 vol. 32 no. 6 1119-1131
Disadvantages of pump use

- Infusing insulin at the same site can cause lipo- dystrophy, tissue irritation and interfere with insulin absorption. Site rotation is imp.
- Cost
- “attached to a machine”
- Alarm will sound only if cannula is completely occluded, but will not sound if kinked or if insulin in flowing freely but cannula is dislodged.
Insulin pump for Type 2 Diabetes

Insulin pump has not been shown superior to multiple daily insulin injections for T2D\(^1\).

CSII did improve glycemic control in patients with T2D who had failed multiple daily injections\(^2\).

Ref-

1. **Insulin pump use in type 2 diabetes.**
   Bode BW.

   Use of insulin pump therapy in patients with type 2 diabetes after failure of multiple daily injections.
   Leinung MC, Thompson S, Luo M, Leykina L, Nardacci E.
T2 Diabetes Insulin pump use Literature Review Summary

- 2 large RCTs comparing CSII vs MDI - no difference in A1C.
- 3 smaller RCTs comparing CSII vs MDI - improvement in A1C.
- Longitudinal Data with Labrousse-Lhermine et al. (n=59) Sustained A1c reduction (baseline = 9.45%, 1 year = 7.8%, 2 year = 8.0% and 3 year 8.3%).
- (n= 21) Intra-subject variability was 41% lower with CSII versus MDI (P = .012) Parkner et al.

Parkner et al Insulin and glucose profiles During CSII and long acting insulin. Diabetic Medicine 25, 585-591
Literature review

- 33 RCT compared CSII with MDI (n=19), rt-CGM with SMBG (n=10), or sensor-augmented insulin pump use with MDI and SMBG (n=4).
- Insulin pump and MDI have similar effects on glycemic control.
- Adult type 1 Diabetes- CSII has a favorable effect on glycemic control.
- rt-CGM is superior to SMBG.
- Sensor-augmented insulin pumps are superior to MDI and SMBG without increasing the risk for hypoglycemia.

Future of insulin pump

- Closed loop system.
- Sensor augmented pump - suspends insulin delivery in response to hypoglycemia\(^1\).

Closed-loop system - glucose sensor feeds information to the pump to automatically suspend insulin delivery for 2 h. Threshold suspend feature reduces hypoglycemia without change in A1. A large RCT-type 1 diabetes showed significant reduction in nocturnal hypoglycemia.

An early version of the closed-loop system (Veo\(^\circledR\); Medtronic, Northridge, CA) has been available in Europe for the past 4 years and is under review by the U.S. FDA.

Ref- Trang T.Ly et al Jama sept2013. Sensor augmented pumps
Mean AUC of Nocturnal Hypoglycemia events was 38% lower in the Threshold Suspend Group.

Similar A1c values at the End of the Study

Similar or Better Benefits in Children and Young Adults

Bergenstal, Klonoff, Garg et al: NEJM 2013
Picture of pt JD- T1D with insulin pump hiking to top of Mt. McKinley, Alaska

University motto- all things possible!
Through careful planning, training, strict diabetes control, perseverance, and God’s merciful protection I was able to climb North America’s tallest peak, despite my condition.

As a Type 1 Diabetic, I am capable of anything any “normal” human being is able to achieve.

Don’t settle for less, seek out your passions and dreams!
Thank you

Global Prevalence of Diabetes-
Estimates for the year 2000 and
projections for 2030, SARAH WILD,
MB BCHIR, DIABETES CARE, VOLUME
27, NUMBER 5, MAY 2004