Advances in Diabetes Care Technologies

1979

2015
Glucose Monitoring and Outcomes

• Several studies suggest a relationship between more frequent monitoring and improved glucose control

• Increased frequency of monitoring reduces hypoglycemia in patients with Type 1 and 2 DM

• There are ongoing trials on the effect of SMBG on provider and patient outcomes in non-insulin patients with Type 2 DM

SMBG: Self-Monitoring of Blood Glucose

Diabetes Care June 2003 vol. 26 no. 6 1759-1763
AACE Consensus Conference of Glucose Monitoring, 2014
British Journal of Biomedical Sciences 2012; 69 (2)
Accuracy of Glucometers

• FDA guidance (non-binding):
  +/- 15% for OTC self-monitoring devices
  +/- 10% for clinical use meters

Acceptable to measure only as low as 50mg/dl for self-monitoring devices

• 2013 ISO Standards:
  95% of blood glucose results
    below 100 mg/dl need to be within 15 mg/dl of reference
    above 100 mg/dl need to be within 15% of reference

At least 30% of glucometers do not meet ISO 2013 standards!

FDA draft guidance issued January 2014
AACE Consensus Conference of Glucose Monitoring, 2014
When finger-stick testing is more reliable than HbA1c measurement

- Several anemias due to low Hb values (sickle cell, hemolytic,..)
- CKD on erythropoietin-analogue therapies
- Pregnancy
- Splenectomy
- Some ethnic groups

A1c Measurements and Mean Blood sugar levels

Glucometers for the Blind

Glucometers that have:

- Speech output
- Capillary traction
- No need for test strip coding
Mobile Phone based testing

• Some systems allow checking glucose and managing data generated directly from a phone

• Other systems pair the glucose meter with a mobile phone for a data sync
Glucose monitoring apps

Several apps for both Android and iOS are available to facilitate data tracking, trending and communication with providers.

BG Monitor  BlueLoop  OnTrack Diabetes

-Some studies suggest positive results using mobile phone based interventions for DM control
- Apps specific for the needs of minorities with diabetes are needed

Diabetes Technol Ther. 2011 May;13(5):563-9
Are there needle-free glucometers?

Glucowatch Biographer:
  Released in 2002
  Needed 3 hour ‘warm-up period
  Skin irritation
  Discontinued by manufacturer

In development:
  - Temporary sensor ‘tatoo’
    Tested in 7 patients at UCSD
  - ‘Smart’ Contact Lens Project
What is CGM?

- Consists of a sensor inserted through the skin that measures interstitial glucose levels every 5 minutes
  - About 9 minute lag behind blood glucose values, which can differ by up to 20%
- Useful for identifying blood glucose trends
- Is NOT a replacement for SMBG
  - Still requires 2-4 blood sugar checks daily
  - Should not use the values for calculating insulin dosing
Types of CGM

• Professional
  – Blinded, retrospective
  – Reviewed in clinic typically by MD, although often can also be reviewed by CDE

• Personal
  – Monitor shows real time (RT) glucose levels with trends
Available Continuous Glucose Sensors

Available outside of US
CGM data

Overall 24 hour blood sugar patterns over days are displayed:

• look for overlap patterns at same time of day
• Look for hypoglycemia- frequency, time of day
• Check timing of insulin injections, meal choice effect
• Check for effect of increased physical activity
Who can benefit from CGM?

• Patients with type 1 diabetes
  – With A1C < 7.0% to maintain control with lower risk of hypoglycemia
  – With A1C above goal, if they can use it on a daily basis
  – Severe hypoglycemia unawareness

• Intermittent, retrospective CGM useful in certain situations for both Type 1 and Type 2 diabetes
  – Concern for nocturnal hypoglycemia
  – Dawn phenomena
  – Post-prandial hyperglycemia
Continuous Glucose Monitor Use in Clinical Practice- Real World Experience

• Retrospective review of university based clinical practice patient base
• Review of 30 months of clinical encounters
• Severe hypoglycemia defined as needing assistance to treat
• Continuous CGM use versus intermittent (defined as <2/3 of time)
• All on pump therapy

Reduction in Hypoglycemia

Table 2. Results of CGM use.

<table>
<thead>
<tr>
<th></th>
<th>Continuous Users</th>
<th>Internett Users</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c baseline</td>
<td>7.5%</td>
<td>7.7%</td>
<td>7.6%</td>
</tr>
<tr>
<td>HbA1c on CGM</td>
<td>7.2%</td>
<td>7.3%</td>
<td>7.2%</td>
</tr>
<tr>
<td>P value</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
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<tr>
<td>Rate of Severe Hypoglycemia</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>(per 100 pt. years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>baseline</td>
<td>66.4</td>
<td>44.8</td>
<td>58.9</td>
</tr>
<tr>
<td>on CGM</td>
<td>22.3</td>
<td>29.0</td>
<td>23.6</td>
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<tr>
<td>odds ratio</td>
<td>0.34</td>
<td>0.65</td>
<td>0.40</td>
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<tr>
<td>CI</td>
<td>0.19-0.59</td>
<td>0.24-1.78</td>
<td>0.24-0.65</td>
</tr>
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</table>
Benefits of CGM?

• A1C lowering with less hypoglycemia
  – 0.5% for adults with type 1 DM
• Hypoglycemia warning for individuals with hypoglycemia unawareness
Professional CGM in T2DM

- Adults with type 2 diabetes NOT on prandial insulin had A1c decrease (mean – 1.16% over a year) with RTCGM used intermittently for 12 weeks.
- CGM tracings can prompt changes in lifestyle or adherence to medications more so than SMBG

Vigersky R A et al. Dia Care 2012;35:32-38
Drawbacks to CGM

- Can be overwhelming for some patients
- Alarms can be annoying, discontinued
- Cost; not covered by Medicaid or Medicare
- Comfort
- Accuracy
- Frustration - analog (fast) insulin is slow!
CGM Billing Protocols

Professional CGM

1. Pre-CGM Evaluation
   E/M 99212 - 99215

2. CGM Startup and Instruction
   CPT 95250

3. CGM Removal and Download
   No Billing

4. CGM Data Interpretation
   CPT 95251

5. Post-CGM Evaluation
   E/M 99212 - 99215

Billing Notes:
- Use modifier **-25** with an E/M code when billing 95250 or 95251 on the same day.
- E/M can only be billed separately on the same day when a significant and separately identifiable service took place above and beyond the services associated with CGM.
- CGM data interpretation (95251) can be billed on an ongoing basis, but should not be billed more than once per month, per patient.

Personal CGM

1. Pre-CGM Evaluation
   E/M 99212 - 99215

2. CGM Startup and Training*
   CPT 95250

3. CGM Data Interpretation
   CPT 95251

4. Post-CGM Evaluation
   E/M 99212 - 99215

* For Personal CGM, the -25 modifier should be used at the initial hookup and training. Check with the payer on coding for personal CGM, since reporting requirements may vary.

Medicare Rates for Common Procedures

- CGM Interpretation: $43
- CGM Startup: $159

* 2015 Medicare national average fee schedule amount for office procedures. Note: Medicare rates only apply to Professional CGM. Personal CGM is less covered by Medicare and does not meet Medicare Benefit Category requirements. Source: Medicare Physician Fee Schedule, December 2014.

Accessed 1/11/16
http://professional.medtronicdiabetes.com/coding-and-reimbursement
What about Pumps?

• Roughly 20% - 30% of patients with T1DM and fewer than 1% of insulin-treated patients with T2DM use an insulin pump
• In 2007, the US FDA estimated that the number of patients with T1DM using CSII was ~375,000
• By 2050, up to one-third of US residents may have T2DM; many of these individuals will be insulin-requiring
• Therefore, more clinicians must develop a comprehensive understanding of these devices

U.S. FDA. General Hospital and Personal Use Medical Devices Panel. 2010

T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus
FDA: U.S. Food and Drug Administration
CSII: continuous subcutaneous insulin infusion
Pharmacokinetics of CSII vs MDI

• Uses only immediate acting insulin
  – More predictable absorption

• Uses one injection site
  – Reduces variations in absorption

• Eliminates most of the subcutaneous insulin depot

• Closest match with physiologic needs

* Lauritzen: Diabetologia 1983; 24:326-9
## Insulin Pumps on the Market

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<tbody>
<tr>
<td>Roche Health Solutions</td>
<td>Asante Solutions</td>
<td>Medtronic MiniMed</td>
<td>Medtronic MiniMed</td>
<td>Insulet Corporation</td>
<td>Animas</td>
<td>Tandem Diabetes Care</td>
<td>Valeritas, Inc.</td>
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</tbody>
</table>
Advantages of Pump Therapy

• Improved blood glucose control
  – Improved AIC’s
  – Decreased hypoglycemia and hyperglycemia
  – Delay in incidence and progression of complications

• Precise dosage delivery

• Improved control for pre-conception and pregnancy

• Management of dawn phenomenon

• Increased flexibility in lifestyle

• Improved control during exercise

• Improved gastroparesis management
Type 1 Diabetes

• A 2010 Cochrane review compared the use of CSII vs. MDI insulin regimens (23 randomized studies involving 976 patients with T1DM)
  – A significant difference was documented in HbA$_{1c}$ response, favoring CSII
  – CSII users demonstrated greater improvements in quality of life measures
  – Severe hypoglycemia appeared to be reduced in CSII users


CSII: continuous subcutaneous insulin infusion
MDI: multiple daily injection
T1DM: type 1 diabetes mellitus
Insulin Pumps Reduce Incidence of DR Vs MDI In Pts. With Similar A1Cs

Followed incidence of DR in 1604 adolescents with T1DM ages 12-20 x 20 years
Incidence of DR declined by 38 % as more patients were transitioned to MDI and CSII vs twice daily injections
A1Cs were identical in all cohorts suggesting that reduction in GV influenced progression towards DR

Downie, et al Diabetes Care 2011;34:2368-73
CSII in Type 2 Diabetes


331 pts with A1c 8-12%

<table>
<thead>
<tr>
<th>Treatment</th>
<th>6 month A1c</th>
<th>6 month A1c &lt; 8%</th>
<th>TDD*</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSII</td>
<td>-1.1%</td>
<td>55%</td>
<td>91 units</td>
</tr>
<tr>
<td>MDI</td>
<td>-0.4%</td>
<td>38%</td>
<td>122 units</td>
</tr>
</tbody>
</table>

* p<0.0001

3.31 units vs 1.12 units

TDD: Total Daily Dose

A1c: Glycated Hemoglobin
Indications and Contraindications for CSII

Indications:
• Failure to achieve targeted A1c with MDI
• Hypoglycemia unawareness
• Athletes and patients who incorporate exercise into daily routines
• Persistent fasting hyperglycemia ("Dawn phenomena")
• Pregnancy
• Frequent travel
• Shift workers
• Poorly adherent DKA prone adolescent patients
• Insulin resistant patients
• Females in whom glycemic control is lost during menstruation

Contraindications:
• Uncontrolled psychiatric disorders (until corrected or stabilized)
• History of lack of adherence to prescribed treatment regimen (pumps do NOT cure diabetes)
  – However, some insulin is better than no insulin. Some non-adherent patients may do better on a pump than MDI
• Lack of financial ability to pay for pump and supplies

Unger, J. Diabetes Management in Primary Care. 2nd Ed. Lippincott. 2012.
Sensor Linked to Pump

- Glucose trends visible on pump or PDA
- Pump suspend feature available on one system
- Integration of insulin delivery and real-time glucose trends
Pump + CGM patterns

- Adds information regarding blood sugar trends between checks, after boluses and overnight