Pumps and Sensors

- The Bionic Patient -

My Other Pancreas

Is Battery Operated

Subcutaneous Continuous Insulin Infusion (CSII)

Computerized Basal/Bolus Insulin Delivery

Where We Stand

• 20-30% of pts with T1DM and 1-2% of insulin-treated patients with T2DM use an insulin pump
• 2016: ~500,000 pts using CSII in the U.S.
• 2017/2018: 40,000 670G pumps shipped
• From 2009-2016 CGM users have increased 35%
• 2050: Up to 1/3 of US residents may have T2DM; many will be insulin-requiring

• Clinicians must develop a comprehensive understanding of these devices
Technological Features of CSII

**Insulin Delivery** (not all options available on all pumps)
- Small bolus increments: 0.05-0.10 units
- Extended boluses for delayed digestion or grazing
- Multiple insulin-to-carbohydrate ratios, sensitivity factors, BG targets
- Bolus calculators (based on BG level and carbohydrate quantity)
- Low basal rates: 0.025-0.05 units/h
- Multiple basal rates
- Temporary basal rates and suspension mode
- Automated delivery based on CGM data

**Safety Features** (not all options available on all pumps)
- Alarms for occlusion and low insulin reservoir
- Active insulin to prevent insulin stacking
- Keypad lock
- Waterproof or watertight
- Auto-suspends insulin delivery when a CGM value reaches or falls below a pre-set threshold.

**Miscellaneous** (not all options available on all pumps)
- Electronic logbook software (insulin doses, BG levels, carbohydrates)
- Integrated food databases with customization
- Reminder alarms for BG checks, bolus doses
- Wireless communication with remote glucose meter
- Integration with continuous glucose monitoring technology
Dana Armstrong, RD, CDE

Pumps DO NOT . . .
• Take over care of patient’s diabetes
• Make diabetes perfect
• Lessen the work of diabetes (it’s just different)

Patient Selection for CSII

~ Ideal Candidates ~
~ Patient Selection ~

Ideal CSII Candidate
• Pt with T1DM or intensively managed insulin-dependent T2DM
• Currently performing ≥4 insulin injections and ≥4 SMBG measurements daily
• Willing and intellectually able to undergo the rigors of insulin pump therapy initiation and maintenance
• Willing to maintain frequent contact with their health care team

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CSII Candidates of Concern

• Unable/unwilling to perform MDI injections, frequent SMBG and to carb count
• Lack of motivation to achieve tighter glucose control
• Hx of serious psychological or psychiatric condition(s) (e.g., psychosis, severe anxiety, or depression)

CSII Candidates of Concern

• Substantial reservations about pump usage interfering with lifestyle
• Unrealistic expectations of pump therapy (e.g., belief that it eliminates the need to be responsible for diabetes management)

Patient Selection Criteria

• Self-motivated
• Acceptance of diabetes
• Ability to problem solve
• Financial resources
Finances
• More expensive than multiple daily injections
• Initial expense
  • Pump: ~$7,000
  • Start-up: $1,500 - $10,000
• Ongoing expense
  • Supplies: $3,600/year
  • Financial assistance???

Medicare Requirements
On CSII BEFORE Enrollment
• Has documented SMBG ≥4 times per day during the month before enrollment
• Fasting C-peptide ≤110% lower limit of normal or ≤200% lower limit of normal if CrCl ≤50 ml/min with concurrent FPG ≤225 mg/dL; OR beta-cell autoantibody positive (+ICA or GAD antibodies)

Medicare Requirements
Qualifications if CSII AFTER Enrollment
• Has completed a comprehensive DM ed program
• On MDI with self-adjustments for at least 6 months
• Documented SMBG ≥4x/d during the previous 2 mo
• Meets ≥1 of the following criteria:
  • HbA1c >7.0%
  • Hx recurrent hypoglycemia
  • Fluctuating BGs before meals
  • Dawn phenomenon
Programming the Pump

~ Basal Rates ~
~ Bolus Rates ~
~ Active Insulin/Insulin on Board ~

Normal Insulin Production


Insulin Regimen with an Insulin Pump (CSII)

Examples of different meal bolus profiles with an insulin pump

- Standard
- Dual
- Multiple
- Short Extended
- Long Extended
Initial Calculations for CSII

TDD: total daily dose

**METHOD 1**
Pre-pump TDD

Pre-Pump TDD x 0.75

STARTING Pump TDD
Average method 1 & 2

**METHOD 2**
Patient Weight

Wt (kg) x 0.50

**BASAL RATE**
Pump TDD x 0.5 / 24

- Start with 1 basal rate, adjust according to glucose trends over 2-3 days
- Adjust to maintain stability in fasting state (between meals & sleep)
- Add additional basals according to diurnal variation (dawn phenomenon)

**CARB RATIO**
450 / Pump TDD

- Adjust based on low-fat meals with known carbohydrate content
- Acceptable 2-h post-prandial rise is ~60mg/dL above pre-prandial BG
- Adjust carb ratio in 10%-20% increments based on post-prandial BG

**CORRECTION RATIO**
1700 / Pump TDD

- Sensitivity Factor is correct if BG is within 30 mg/dL of target range within 2 hours after correction
- Make adjustments in 10%-20% increments if 2-hr post-correction BGs are consistently above or below target

Hypoglycemia patients – start at lower value of method 1 & 2
Hyperglycemic, elevated A1C or pregnant – start at higher value of method 1 & 2

Initial Calculations for CSII

- Active Insulin (IOB)
  - Generally set from 3-4 hours (shorter in 670G)
- Auto Mode of 670G
  - Carb ratio and IOB **ONLY VALUES** set by provider
  - Carb ratio calculation closer to 300/TDD
- **IMPORTANT** to assess the manual mode settings for patients using the 670G auto mode

Ideal CSM Candidate

- Anyone with T1D
- Anyone with T2D on intensive insulin management
- Everyone else with A1C >goal
- Medicare limits CGM to devices with dosing approval only (currently) and to people with DM who test 4 times per day and use intensive insulin management

CGMS DOES . . .

- Less BG variability – more time in range
- Less apprehension at work, at school, while sleeping, or driving
- Give great data a majority of the time
- Glucose value every 5 minutes
- Eliminate SMBG (for some systems) most of the time

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CGMS DOES NOT . . .

• Completely eliminate the need for SMBG (for some systems)
• ‘Take over’ all diabetes control (getting closer)
• Give 100% data all of the time

Sensor Glucose ≠ Blood Glucose

• **Sensor** measures glucose in the **interstitial fluid**
• **BG meter** measures glucose in the **blood**

Sensor Glucose ≠ Blood Glucose
CGM Systems

- Offer alarms for glucose highs and lows
- Ability to download data and track trends over time and share data
- Offers ability to easily observe how any given food, exercise or insulin dose affects control over the course of a few hours
- Allows immediate feedback - pts able to modify behaviors to gain better control

CGM Systems

- Supplements A1C
- Identify post-prandial glucose excursions
- Identify undetected nocturnal hypo
- Visual patient teaching tool
- Stop insulin delivery when BG < set value (integrated systems only)
- Allow patient to improve dosing (based on arrows)

CGM Systems

- Directional arrows available
- Key aid to control
- Blood glucose levels in a state of flux
- Info regarding direction of glucose
- Predictive alarms based on rate of change
- **Allows for adjustments in insulin dosing**

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<table>
<thead>
<tr>
<th>Glucose not rising or falling &gt;1mg/dL/minute</th>
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<tbody>
<tr>
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* Varies based on system  **Not available on all systems

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**Dexcom G5 & G6 / Abbott Freestyle Libre Dosing Off CGM Values**

- Use Caution:
  - First 24 hours
  - Last 24 hours
  - Higher-carb meals
  - Stressful situations
  - Lows and rebound highs

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Pump & CGM Combo

- Medtronic and Tandem have combination pump/CGM systems
- The sensor is a separate site on the skin from the pump
  - The sensor’s glucose information is visible on the pump screen
- Life-changing future pump technology relies heavily on CGM technology

670G Hybrid Insulin Pump

- Suspend before low – stops insulin 30 minutes before set low limit and restarts when level recovers
- Auto Mode
  - Adjusts basal insulin based on BG to keep glucose at 120 mg/dL
  - Adjusts correction based on learned history

Costs

- Systems
  - $360 to $1,400 for the hardware
  - $3000 when initially introduced
- Sensors
  - Costs vary from $100-300 per month ($3.60-10/day) for continuous use
  - Does not include the cost of the test strips needed for calibration and BG confirmations (if needed)

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Use of CGM
- Improvements in DM management
  - Decreased variability
  - Decreased hypoglycemia
  - Decreased A1C
- Improvements in lifestyle
- Reinforces education
- Increased understanding of self-management choices

Alarm Fatigue
- Patient will say to you:
  “These alarms are going off ALL THE TIME!”
  “I hate this sensor!”
- Issues:
  1) Too many alarms turned on
  2) MOST likely due to . . .
     - Insulin/activity/food behaviors
     - Actions, delivery, rates and/or ratios are what need to be changed

Future Systems and Sensors

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