Insulin Pump Therapy in children & Adolescents

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Insulin

The most powerful agent we have to control glucose
Banting and Best
The Miracle of Insulin

Patient J.L., December 15, 1922

February 15, 1923
Goals of diabetes care

• Near normal glycemia
• A1c goals for children
• Avoid short-term crisis
• Hypoglycemia
• Hyperglycemia
• DKA
• Minimize long term complications
• Improve quality of life
Ideal Basal/Bolus Insulin Absorption Pattern
Intensive Insulin Therapy Goals

- Maintain normal or near to normal blood glucose
- Avoid short-term crisis
- Prevent and postpone long-term complications
What’s Different about children?

- Marked dawn phenomenon
- Unpredictable activity levels
- Nocturnal hypoglycaemia
- Hormonal changes
- Growth & developmental changes
A1C Goals for Children

young age group < 6 yr = < 8 – 8.5 %
   6 – 11 yr = <7.5%
   12 – 20 yr = <7.0%

How to accomplish ????
DCCT: the price of improved diabetic control – hypoglycaemia

Adapted from: N Engl J Med 1993;329:977–86
Insulin Pump Therapy
• first child of 5 year of age had insulin pump inserted at 2003
EVOLUTION OF INSULIN PUMP THERAPY

• The idea of continuous insulin delivery first emerged in the early 1960s when Dr Arnold Kadish from Los Angeles fashioned a device that would permit such insulin delivery.

• This device was the size of an army backpack making it impractical for everyday use.

• The consensus that insulin replacement should be more physiologic grew during the 70s, first by employing continuous intravenous insulin delivery, and then by the more practical means of continuous subcutaneous insulin infusion (CSII)
• In 1978, Keen and Pickup from Guy's Hospital, London first reported the successful use of portable pumps for CSII
• Followed in 1979 by Tamborlane and Felig of Yale
• These early studies demonstrated that CSII, when used with self-monitoring of blood glucose, could feasibly achieve near normal glycaemic control
• These early insulin pumps - though a vast improvement on the Kadish device - were bulky, being the size of a house brick and weighing up to 400 grams
• Technical issues such as syringe and tubing blockages, over-delivery of insulin and needle dislodgment were widely reported.
• These problems led to clinical complications including, hypoglycemia, diabetic ketoacidosis (DKA) and needle site infection, resulting in only limited acceptance throughout the 1980s by both clinicians and patients.
• Re-Started again late 1990’s, with major advances in the field of medical device technology, which allowed dramatic reductions in the size of the pump, brought enhanced safety & allowed greater ease of use for patients.
• Currently, most pumps are about the size of a hand-held pager and have features such as programmable memory, multiple basal rates, several bolus options, safety lockout features, & remote control.
• 250,000 people in the UK have type 1 diabetes
• UK has variable access and provision of CSII therapy
• Current UK usage of insulin pumps is low (NICE 2008)

![Graph showing estimated insulin pump usage in different countries](image-url)
Current CSII Candidate Selection

- Patient Requirements
  - Motivated to take insulin
  - Educated and reliable parents
  - Willing to monitor and record BG
  - Willing to quantify food intake “Carb counting”
  - Willing to follow-up
Consensus Statement on Pump Use in Peds- Patient Selection

- Recurrent severe hypoglycemia
- Wide fluctuations in bg levels regardless of A1c
- Suboptimal diabetes control
- Micro/macro vascular complications
- Good control but regimen compromises lifestyle
- Infants and neonates
• Adolescents with eating disorders
• Children and adolescents with pronounced dawn phenomenon
• Pregnant adolescents
• Ketosis-prone individuals*
• Competitive athletes
• Children with needle phobia**

Battelino, P.M., Rodriguez, H.D., Kauffman, F. Use of insulin pump therapy in the pediatric age-group: consensus statement from the European Society for Paediatric Endocrinology, the Lawson Wilkins Society and the International Society for Pediatric and Adolescent Diabetes, endorsed by the American Diabetes Association and the European Association for the study of Diabetes Care Diabetes Care 2007;30:, 1653-1662

Pump Therapy Team

1. Endocrinologist
2. 24 – hour technical support company representative
3. Dietician
4. Pump therapy Nurse
5. 24 –Hour hotline contact.
**Basal rate**
- Continuous flow of insulin, took the place of NPH or glargine insulin.

**Meal boluses**
- Insulin needed pre-meal
  - Pre-meal BG
  - Carbohydrates in meal
  - Correction bolus for high BG

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**Graph**
- **X-axis:** Time of day (12 am, 12 pm, 12 am)
- **Y-axis:** Units
- **Basal rate**
- **Meal bolus**
Basal Insulin Flexibility

- Multiple basal rates to match diurnal variations
  - “Most type 1 patients use 3-5 basal rates.”
  - Customized basal rate profiles for different occasions
- Up to 3 basal rate patterns:
  - Weekend vs. Weekday, Ramadan
- Temporary Basal rate feature:
  - Exercise, Illness, etc.

Accessed February 8, 2008.
The Bolus Wizard® Calculator

• Individually customized with:
  – Blood glucose targets
  – Carbohydrate ratios
  – Insulin-sensitivity factors
  – Active Insulin Time

• Simplifies diabetes management
  – Calculates estimated bolus for the patient
  – Tracks active insulin
Benefits of Insulin Pump Therapy

- Improved glycemic control
- Less frequent / severe hypoglycemia
- Enhanced quality of life
- Improved patient satisfaction
- Ease of management
- Reduced glucose toxicity, which may also result in improved β-cell function

Benefits of Insulin Pump Therapy

- Less frequent and/or severe hypoglycemia
- More predictable absorption than with longer acting insulin
- One injection site
- Decreases variable absorption
- Programmable delivery - Fewer injections, convenient
- Improve BG control and A1C
- Flexible eating schedule
- Matching insulin dose precisely to need
- Corrects Dawn phenomenon
- Reduce insulin quickly for exercise
Outcomes of Pump Therapy

Kauffman et al. Diabetes Metabolism and Reviews, 2000
6 months data 130 subjects

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Continuous Subcutaneous Insulin Infusion (CSII) Improves Control

Compared with MDI, insulin pumps are more effective at reducing HbA$_{1C}$

CSII Reduces HbA$_{1c}$

Pump Therapy Reduces Incidents of Severe Hypoglycemia

Severe Hypoglycemic Episodes MDI vs CSII

Decreased Risk of Severe Hypoglycemia

Severe Hypoglycemia in Children by Type of Therapy

Adapted from Jones TW, Davis EA. Hypoglycemia in Children with Type 1 Diabetes: Current Issues and Controversies. Pediatric Diabetes 2003; 4: 143
CGMS shows:
Less Variability With Pump Therapy

Insulin pump

Multiple daily injections
Normalization of Lifestyle

• Liberalization of diet — timing & amount
• Increased control with exercise
• Able to work shifts & through lunch
• Less hassle with travel — time zones
• Weight control
• Less anxiety in trying to keep on schedule
Improved Quality of Life

- Better control makes patients feel better
- No more schedules to follow
- Patients can eat what they want and when they want
- Insulin delivery can be adjusted to daily needs
Improved Health Status with Insulin Pump Therapy

N=886
Self-Reported Data

Association for Insulin Pump Therapy, Diabetes 1991:40:#1807
Continuous Subcutaneous Insulin Infusion (CSII)

N = 165
Average Duration = 3.6 years
Average Discontinuation <1%/yr

Insulin Pump Disadvantages

• Expense
• Requires SBGM at least 4 times a day
• Must be worn 24 hours per day
• Should not be removed for > ~45 min
• Increased risk of DKA
• Must learn to adjust insulin for food & exercise accurately
If A1C Not to Goal

Must look at:

• SMBG frequency and recording

• Diet practiced
  – Do they know what they are eating?
  – Do they bolus for all food and snacks?

• Infusion site areas
  – Are they in areas of lipohypertrophy?

• Other factors:
  – Fear of low BG
  – Overtreatment of low BG
If A1C Not to Goal and No Reason Identified

- Place on a continuous glucose monitoring system (CGMS) to determine the cause
CGM Devices

Medtronic
Real Time

Dexcom

Abbott Navigator
Interstitial fluid glucose (G2) is almost always comparable with blood glucose (G1)
Logbook Diary Limitations: The Traditional Approach

• Problems faced with logbook approach\textsuperscript{1,2}:
  – Noncompliance: inconsistent record-keeping
  – Incorrect transcription of glucose
  – Missing data: “I forgot at home” or “I left it in the car”
  – Adding data: falsification of information
  – Illegibility of diary

FDA Approved Real-Time Continuous Glucose Monitoring System
Summary

• Insulin pump therapy offers improvement in glycemic control with less major hypoglycemia and greater flexibility in lifestyle.

• Insulin pump therapy should be considered in all DM 1 patients and DM 2 patients failing conventional insulin therapy (basal insulin).
Summary

• Good control of blood glucose is important
• Pump therapy has shown in many patients to improve control and life style
• Pump therapy is used by over 250,000 people worldwide
• It is safe, but until CSII is a closed-looped system, pump therapy must only be considered for children who are cared for by a parent or another adult willing and able to learn how to manage all aspects of the pump
Thanks
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