USING INSULIN PUMP THERAPY IN POORLY CONTROLLED TYPE 2 DIABETES

Phyllis Wolff-McDonagh, DNP, CPNP, ANP, CDE

Outline

- Clinical Problem
- Study Aims
- Background and Significance
- Research Design
- Results
- Conclusions and Implications

Clinical Problem

- Insulin pumps have been used for people with Type 1 diabetes successfully

- Few people with Type 2 diabetes have been given the opportunity to improve glycemic control with insulin pumps due to Medicare and insurance restrictions

Study Aims

- Effectiveness of insulin pumps (CSII) vs multiple daily injections (MDI)
- Cost analysis of CSII vs MDI
- Build body of evidence
  - Influence Medicare policy regarding eligibility for CSII in subjects with Type 2 diabetes

Background and Significance

- Type 2 diabetes has reached epidemic proportions in the United States

- Leading cause of blindness, kidney failure, cardiovascular disease, and amputations (American Diabetes Association)

- Improved control of blood glucose has been proven to delay or even prevent these complications (Gray, et al, 2002)

Raskin, et al (2003)

- 100 patients with poorly controlled Type 2 diabetes over a 24 week period

- Intensive insulin therapy with either MDI or CSII
  - Both equally effective in improving HbA1C

Neilsen, et al (2005)

- Poorly controlled subjects with Type 2 diabetes despite large doses of insulin and oral agents (n = 4)

- HbA1C levels fell to goal or near goal with CSII treatment

Herman, et al (2005)

- 107 older adult Type 2 with HbA1C>7%

- Randomized to MDI or CSII

- Treatments equally efficacious over 12 months

Wainstein, et al (2005)

- Randomized study of 40 obese Type 2 subjects aged 30 to 70

- MDI vs CSII with a wash out period and crossover

- CSII treatment significantly improved HbA1C relative to MDI

Berthe, et al (2007)

- Type 2 subjects on 2 insulin injections per day intensified to 4 per day or CSII (n = 17)

- CSII improved metabolic control better than MDI

American Diabetes Association (2008)

- Economic impact
  - diabetes care
  - complications

- $174 billion in the US
  - 2007 estimate

Wagner, et al (2001)

- Improved glycemic control vs health care cost

  – Longitudinal study 1992 – 1997

- Improved control saved $685-$950 per subject per year

  – Primary and specialty outpatient care

Gray, et al (2002)

- UKPDS (United Kingdom prospective diabetes study)

- Randomized >5000 subjects into intensive management vs standard management groups

- Preventing complications was more cost effective than treating them

Minshal, et al (2005)

- 10 year projection of economic impact of diabetes care in the US

- Achieving HbA1C goal could save approximately $50 billion over 10 years
  - 4% to 6% of the total annual US healthcare cost

Research Design

- Quantitative, retrospective pilot study at a suburban diabetes and endocrinology private practice

- Convenience sample of adults, ages 40 – 64, who had poorly controlled Type 2 diabetes (HbA1C ≥ 8%) when CSII was implemented (n=15)

- Review of office medical records of subjects meeting above criteria in the previous 7 years
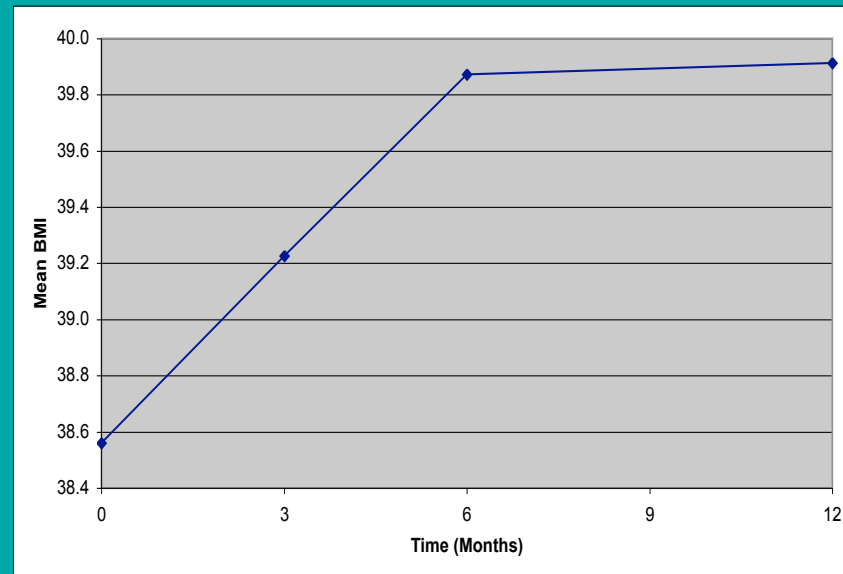
Data Collected at Baseline, 3, 6, and 12 Months

- Weight

- BMI

- Hemoglobin A1C (HbA1C)

- Basal Insulin Use

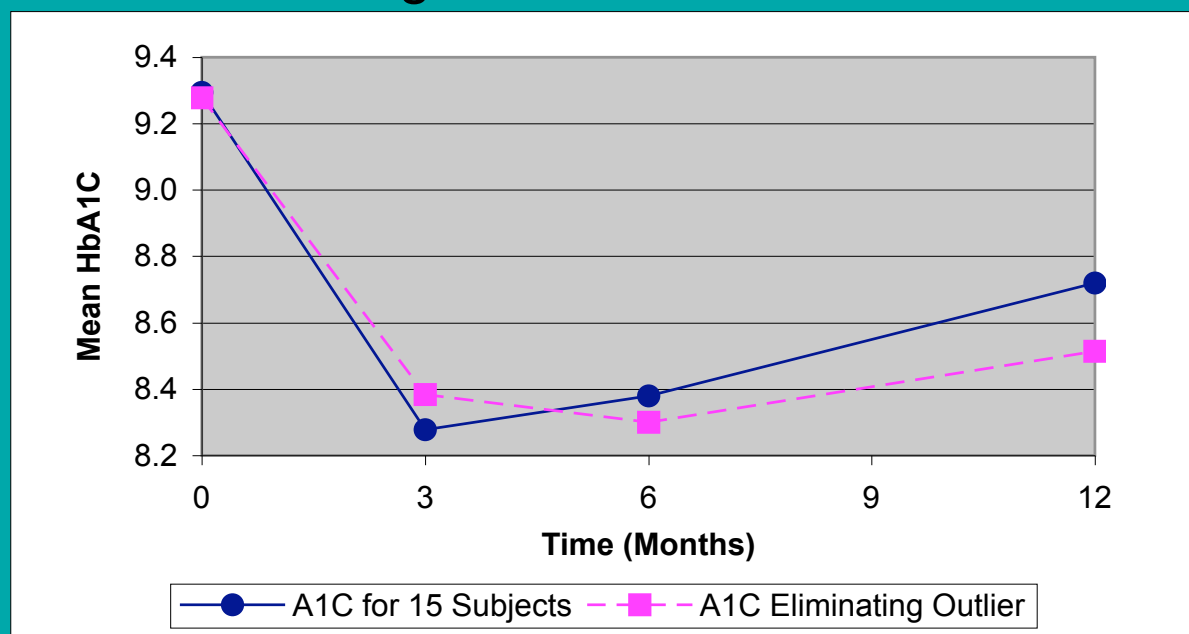- Bolus Insulin Use

- Number of office visits

BMI and Weight Outcomes

- Significant increase in mean BMI from baseline 38.6 to 40.0 (p=.01)

- Significant increase in mean weight from baseline 116.5 kg to 120.8 kg (p=.03)

HbA1C Outcomes

- Significant decrease of 10% at 3 months (p=.002)
- Significant decrease of 9.8% at 6 months (p=.04)
- No significant change at 1 year (p=.13)
- Significant decrease of 8.2% at 1 year
  - after removal of single outlier

Insulin Use Outcomes Bolus

- No significant difference in bolus insulin usage at 3, 6 and 12 months (p=.26,.33,.46 respectively)

- Combined one tailed *t* test: significant increase in usage (p=.04)
  - Likely related to restriction of carbohydrates and fats at CSII start
  - Reverting to past eating habits over time, requiring more bolus insulin to control post-prandial blood sugars

Insulin Use Outcomes Basal

- Significant reduction at 3, 6 and 12 months (p=.01, .01., .02 respectively)
  - Likely due to slow infusion:
    - Reducing insulin resistance
    - Improving absorption
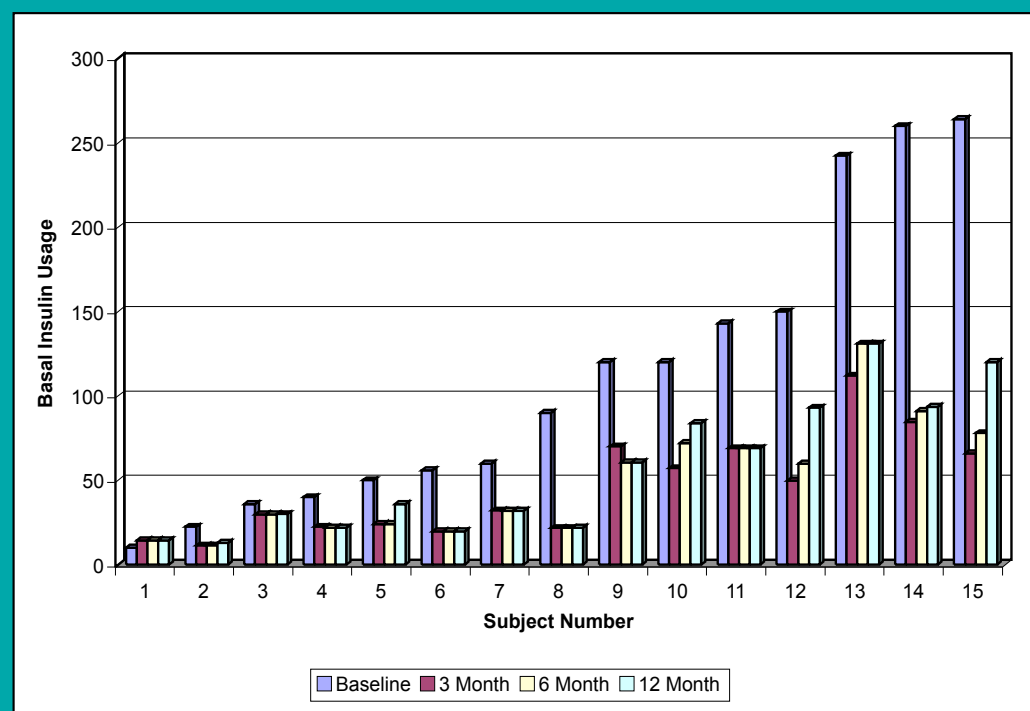
MDI vs CSII
Cost Analysis: Supplies

- MDI: 4 injections/day costs $525/year
  - 4 year cost = $2100
- CSII: pump costs $5250 + annual supplies of $1500
  - 4 year cost = $11,250
  - Pump warranty is 4 years
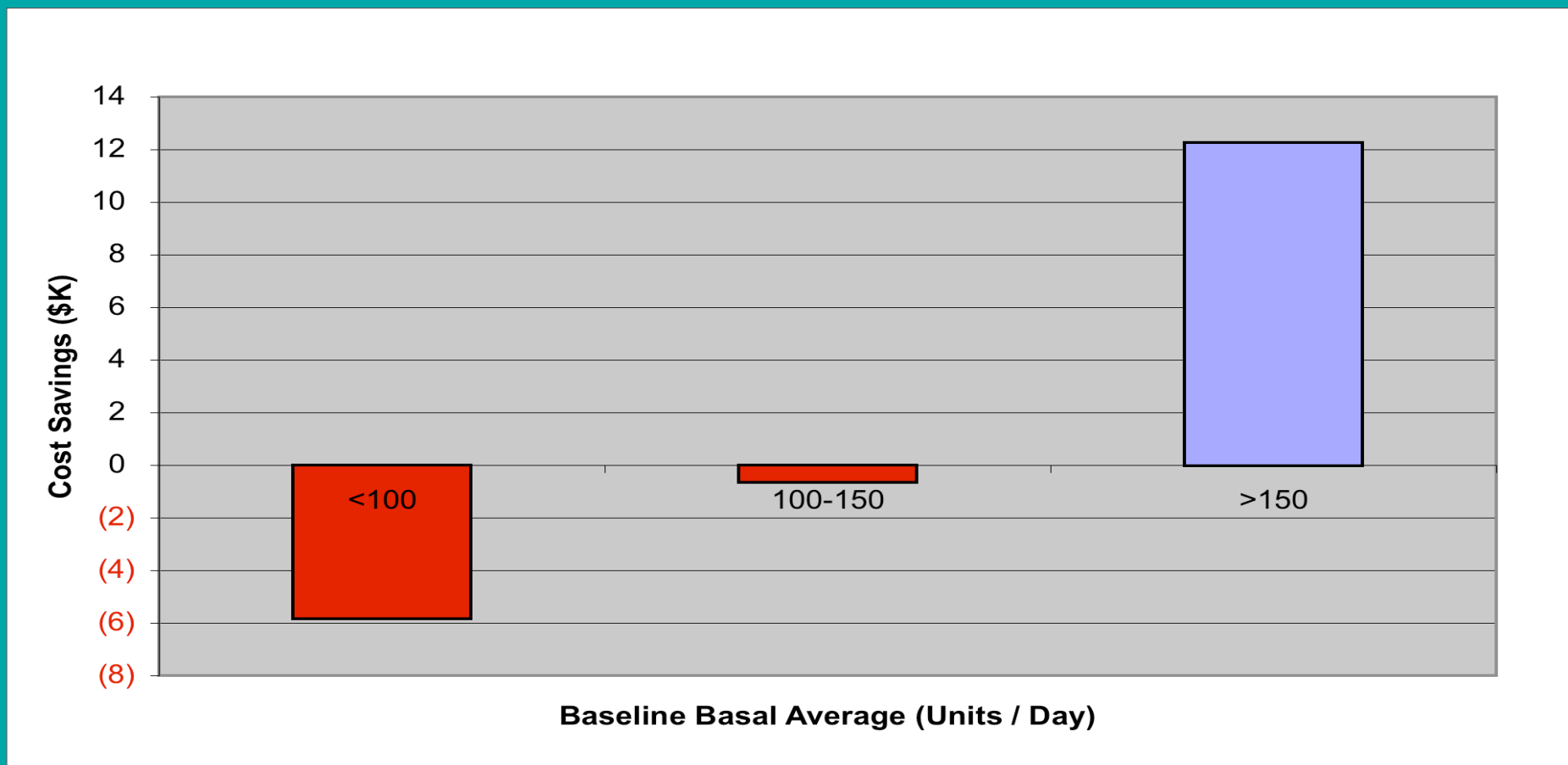
MDI vs CSII
Cost Analysis: Basal Insulin

- Low use: < 100 units/day
  - MDI=$9,172   CSI=$14,994

- Moderate use: 100-150 units/day
  - MDI=$22,380   CSI=$23,002

- Large use: > 150 units/day
  - MDI=$41,100   CSI=$28,826

MDI vs CSII
Cost Analysis: Total Cost Difference

Projected Total Cost Difference (in Thousand Dollars) for MDI vs CSII Over 4 Years

Influencing Medicare Policy Change

- **American Diabetes Association**

  - Legal Advocacy

    - Government Affairs Division
    - Science and Medicine Division

- **Medicare Diabetes Policy Makers**

  - Difficulties with identifying them

Conclusions and Implications

- CSII treatment improves HbA1C for some subjects

- CSII results in cost savings in subjects using large amounts of basal insulin daily

- CSII should be considered for subjects using moderate amounts of basal insulin due to the potential in cost savings from improved glycemic control

- Medicare and private insurers should re-evaluate policies regarding coverage for CSII in type 2 diabetes

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