In Silico Monte Carlo Virtual Trials of a Model-Based Adaptive T1DM Control Protocol

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1 The Background...

- The hormone insulin controls blood glucose levels. Diabetes results from defective insulin secretion and/or action, causing wildly fluctuating glucose levels.
- Low levels (hypoglycaemia) and high levels (hyperglycaemia) increase the risk of complications and death.
- Diabetes is an epidemic in developed countries. In 2002, the disease cost US$132 billion, and affected 7% of the population (US figures). In NZ, that cost is NZ$400 million, set to rise to NZ$1 billion by 2020.
- Complications and associated healthcare costs can be reduced by up to 76% with good control. But, ~45% of people with diabetes are deemed 'poorly controlled'.
- This Research: Examines an adaptive protocol using Monte Carlo analysis for robustness, performance and safety.

2 The Protocol

- Basal: Titration based on published methods (Fritsch & Riddel et al).
- Prandial: 2 measurements / meal at t=0 and t=90 mins for correction.
- Correction Bolus: Only on those meals requiring it (fit S(t) + carb count).
- Use up to 3 meals and 2 snacks (Measure: 10 total, goal is 4 or less).
- Goal: The system must rely on minimal glucose measurements and minimal technology for the 85% or more who don’t use pumps.

3 What we did...

- Monte Carlo virtual patient (simulation) study using 40 AIDA cohort patients as a basis.
- Average HbA1c = 8% matching US.
- Account for variability and error in model parameters (physiology, dosing, carb counting, etc) with published data or larger.
- Each patient simulated 1 week x 8300 variations → 1.4M different patient hours.
- HbA1c estimated with published formula.

4 The Results...

- Our findings...
  - 6 measmt/day satisfy ADA guidelines for 100% of patients.
  - Using conventional control (CC), just ~49-52% meet guidelines.
  - Hypoglycaemia reduced by ~8x.
  - Time below 54mg/dL ~0.
  - Barely different for 4/day.

- Conclusions: This control approach doubled the number of patients safely meeting clinical guidelines. It uses common low cost treatment methods.

References