

Safety and Performance of Stochastic Targeted (STAR) Glycemic Control of Insulin and Nutrition – First Pilot Results



Geoffrey M. Shaw

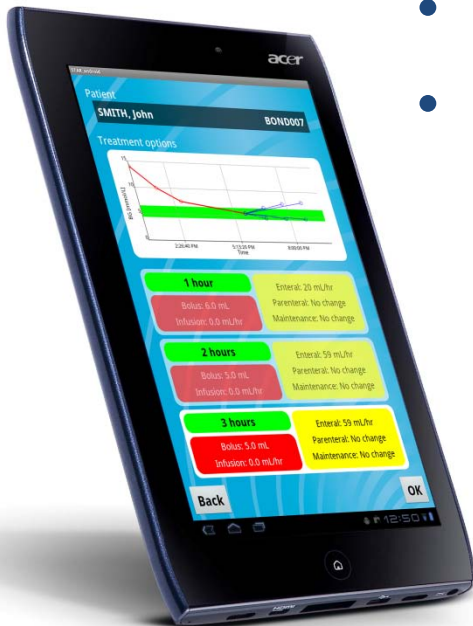
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C. Pretty, S. Penning, T. Desai, JG. Chase*

Introduction

- **Stress-induced hyperglycemia is often experienced in critically ill patients**
- **Tight glycaemic control (TGC) has shown benefits but been difficult to achieve consistently.**
- **STAR: TGC protocol**
 - **Model-based**
 - Forecasts of BG levels are generated by dynamic + stochastic models
 - **Patient variability**
 - Tracks real-time patient response to insulin and adjusts dosages
 - **Maximum 5% risk of blood glucose (BG) < 4.0 mmol/L in Christchurch**
 - Target BG level customisable → flexible
- **Ongoing clinical trial objectives:**
 - **Safety, Efficacy, Clinical workload**

Pilot clinical trial

- 7 patients
- Insulin and enteral nutrition rates modified together for BG control
 - Enteral nutrition can be set to constant rate if required
- 1-, 2- or 3- hours between BG measurements



- Target band: 4.0 – 8.0 mmol/L
- Maximum 5% risk of BG < 4.0 mmol/L & 5% risk of BG > 8.0 mmol/L
 - Results compared to SPRINT (current TGC standard)
 - Tablet computer implementation for bedside computing

Results

	STAR Pilot Trials	SPRINT Clinical Data
Hours of Control (h)	92.0 [29.5 – 113.3]	53.0 [19.0-146.0]
Median BG median [IQR] (mmol/L)	5.9 [5.8 - 6.3]	5.8 [5.3 - 6.4]
%BG in 4.0 - 6.5 mmol/L	61.1 [55.3 - 78.4]	66.7 [51.7 - 78.9]
%BG in 4.0 - 7.0 mmol/L	79.2 [68.6 - 88.8]	77.2 [63.6 - 86.8]
%BG in 4.0 - 8.0 mmol/L	96.2 [89.3 - 100.0]	86.6 [75.0 - 94.3]
%BG < 4.4 mmol/L	4.3 [0.4 - 11.0]	6.9 [1.0 - 16.1]
%BG < 4.0 mmol/L	0.0 [0.0 - 6.0]	1.8 [0.0 - 6.9]
Median insulin rate [IQR] (U/h)	2.5 [0.1 - 5.1]	3.0 [2.0 - 3.0]
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Average Measures / day	14	17

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- **More measurements in target BG bands (SPRINT target 4-6 mmol/L)**
- **More consistent control (spread of median BG between patients tighter)**

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- Reduced low BG measurements → improved safety
- No hypoglycaemia during pilot trials

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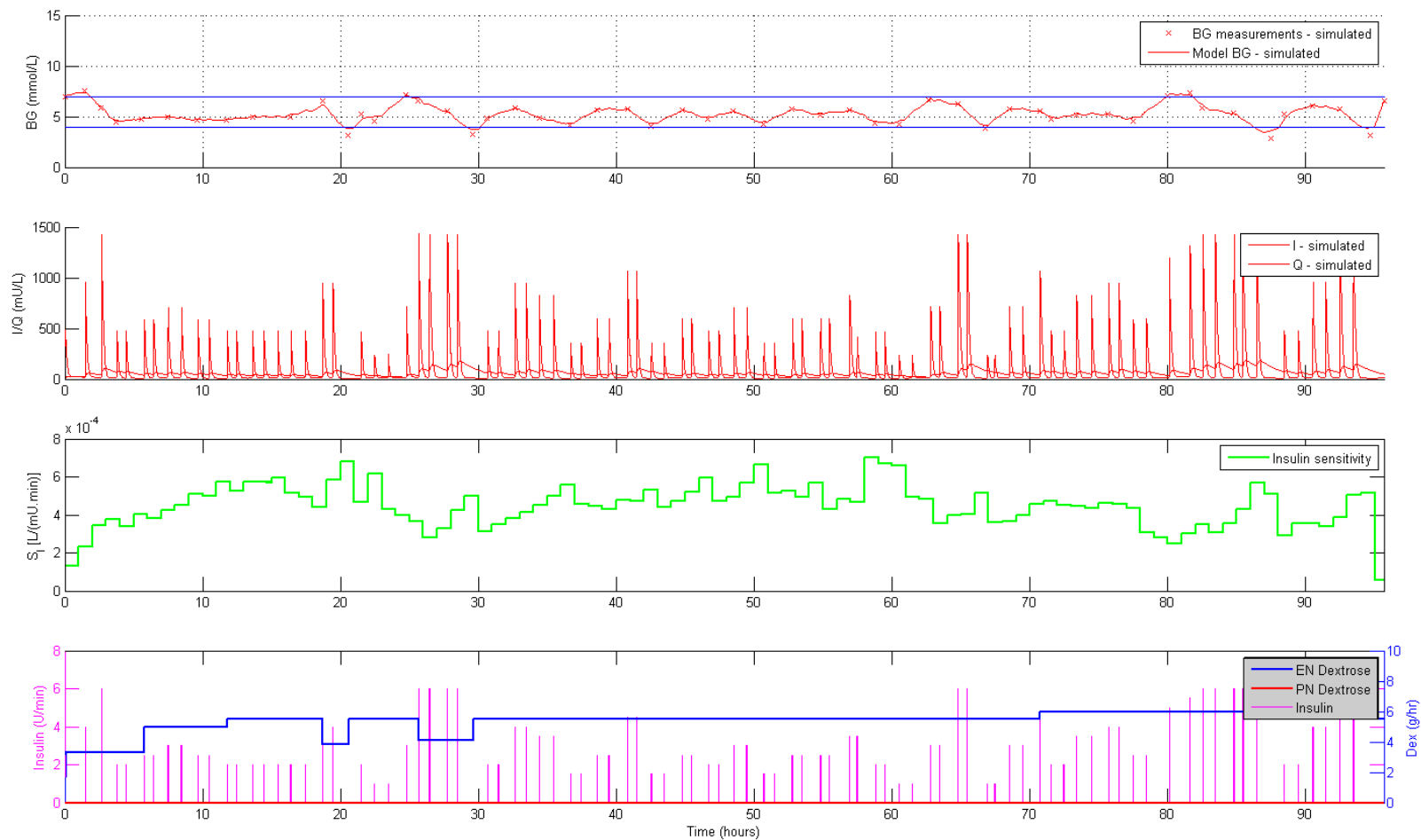
- Much higher enteral nutrition rates used
- More dynamic range of insulin rates used → better matching insulin/nutrition rates to patient response

Results

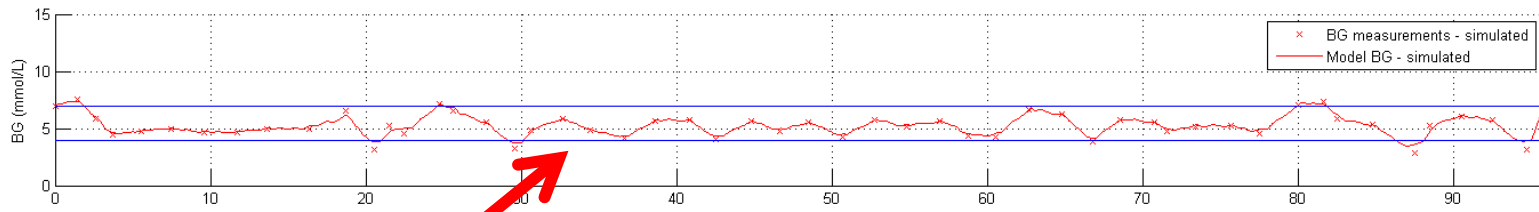
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- Reduced workload → reduced number of BG measurements per day through provision of 3-hourly measurement intervals
- Balance of safety, performance and workload

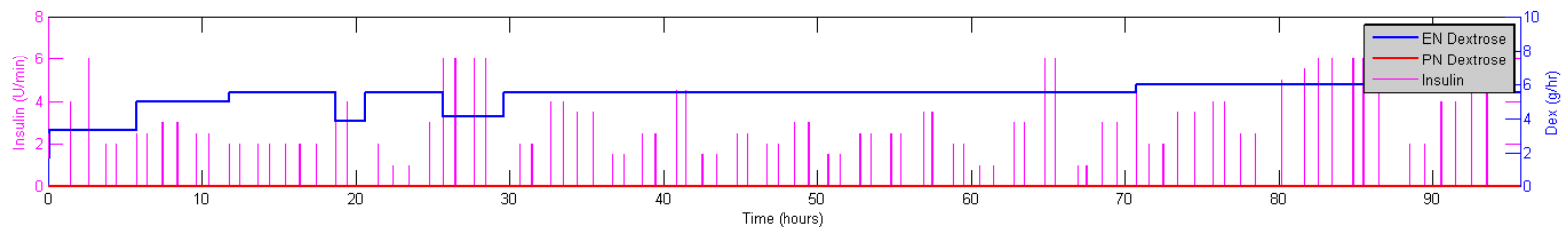
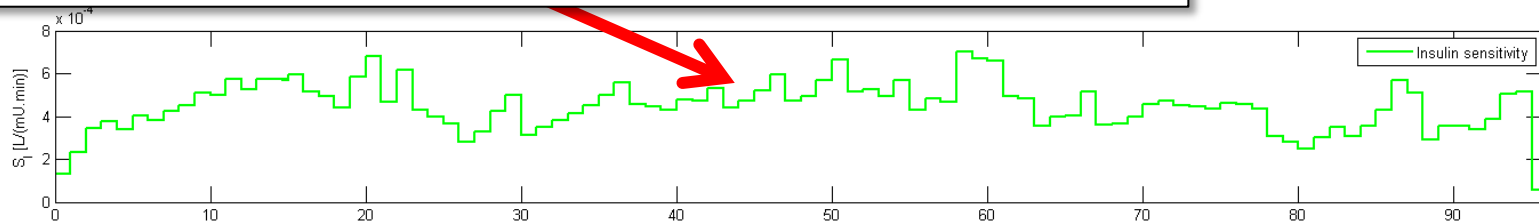
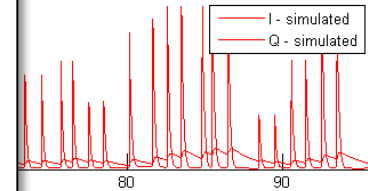
Results: Patient #4



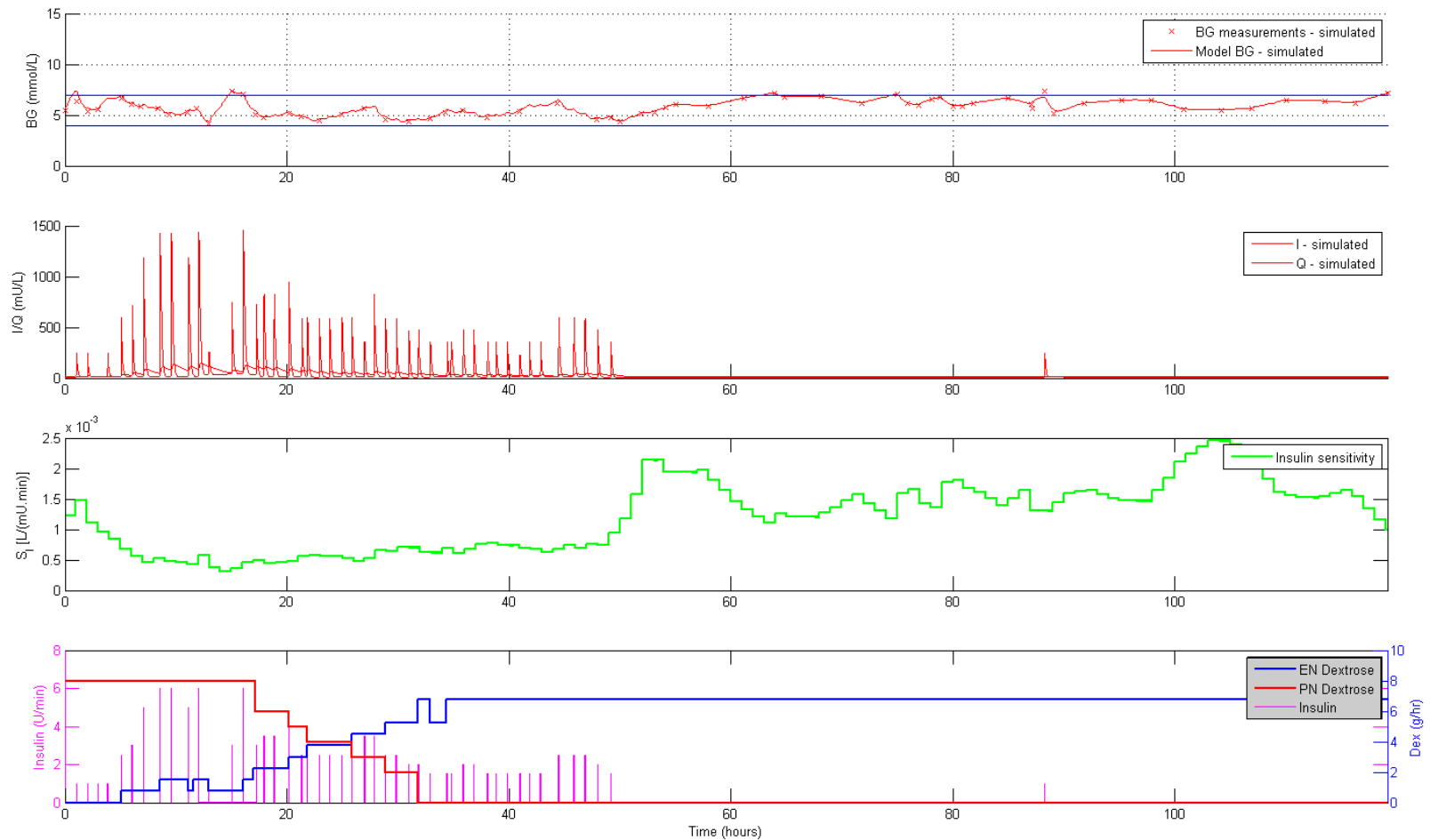
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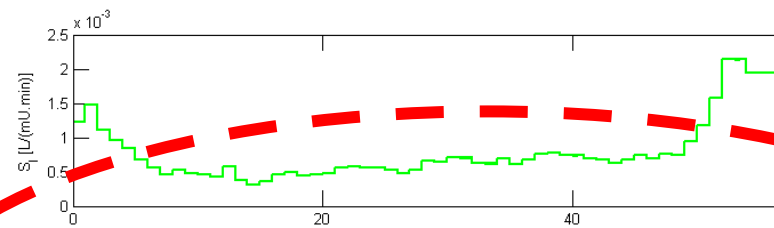
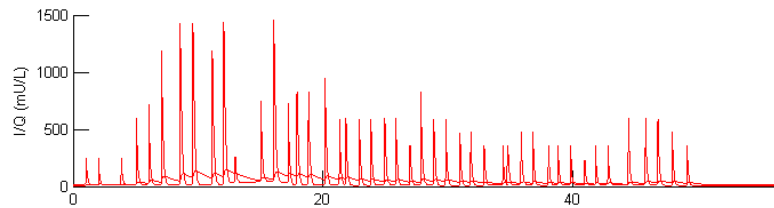
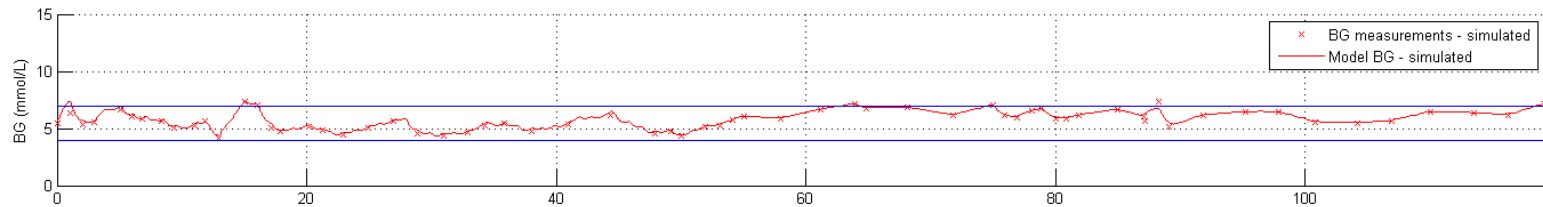
- Dynamic response to insulin
 - green line → insulin sensitivity
- BG remains within target range through insulin/nutrition adjustment



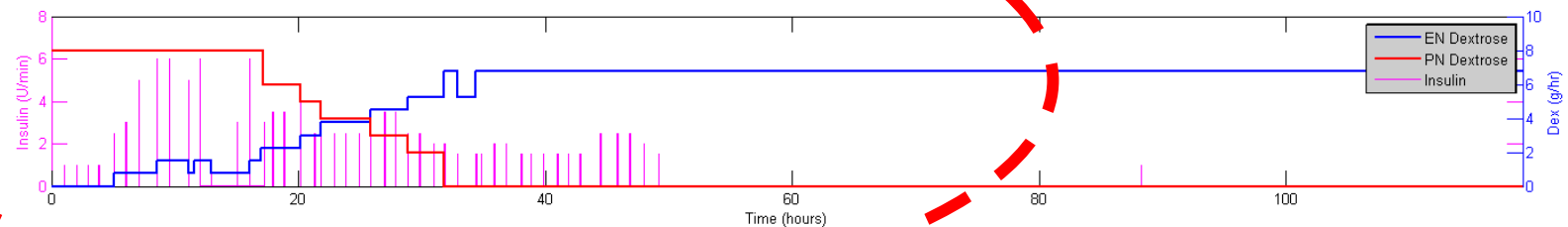
Results: Patient #5



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- Patient response to insulin improved significantly and was able to self-regulate
- STAR automatically doses zero insulin
- Transition from parenteral nutrition (red) to enteral nutrition (blue) also accounted for.



Conclusions

- **STAR provided very consistent, accurate control with minimal variability**
 - Tracking patient response to insulin and matching insulin/nutrition dosage
- **Performance and safety exceeded SPRINT**
 - BG forecasting to mitigate risk of hypo- and hyperglycaemia
- **Workload (#BG measurements) reduced 20% compared to SPRINT**
- **STAR adaptable to other units**
 - Different BG targets
 - Nutrition regimes and targets incorporated into BG control
 - Different patient groups (eg: surgery vs. medical, diabetic, etc.)