Insulin-Only STAR: Liège Clinical Trial Interim Results on Safety and Efficacy

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Background

- Stress-hyperglycaemia is a common complication in the ICU.
- Glycaemic control (GC) has shown improved outcomes but was proven difficult to achieve safely, increasing risks of hypoglycaemia.
- STAR is a model-based GC protocol with proven safety and performance. It uses a unique risk-based dosing approach accounting for both intra- and inter- patient variability.
- STAR determines the best insulin and nutrition treatment option by assessing the likelihood of future metabolic variability based on current identified insulin sensitivity, as depicted in **Figure 1**.

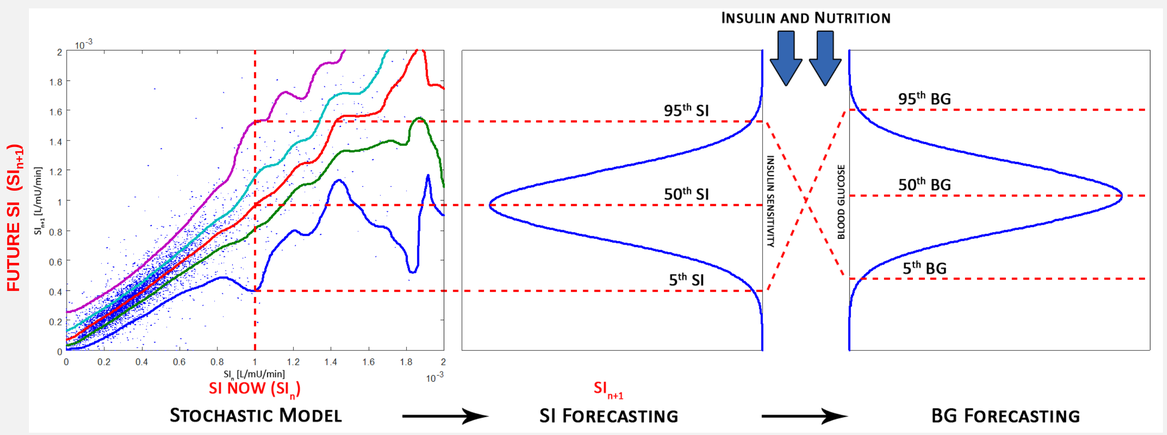

Figure 1 – Future insulin sensitivity (SI) is forecast from current SI. The distribution of future SI is used to predict likely BG outcomes for a given insulin-nutrition treatment intervention.

Objectives

- Most GC design uses insulin-only intervention while STAR uses both insulin and nutrition.
- This study uses an insulin only version of STAR with nutrition set clinically in the University Hospital of Liège, Belgium, to assess safety and efficacy in this use.

Methods

Ethics approval was granted by the University Hospital of Liège Ethics Committee for the STAR-Liège clinical trial. STAR-Liège offers 1-3 hourly blood glucose (BG) measurements options. Insulin is administered through IV catheter continuously and nutrition clinically set.

- **Target band:** 4.4-8.0 mmol/L (80-145 mg/dL)
- **Starting criteria:** 2 BG measurements > 8.0 mmol/L (145 mg/dL)
- **Stopping criteria:** BG stable for 6h at low insulin rates (≤ 2U/h) or 72h after inclusion.
- **Insulin:** Max. 9U/h with maximum increment of 2U/h.

STAR is fully computerised and implemented on a tablet running Android. Nurses are free to choose any possible treatment option (1-3 hourly).

Results from the first **11 patients** are analysed.

Results

- BG traces from clinical data are shown in **Figure 2** and results are shown in **Table 1**.

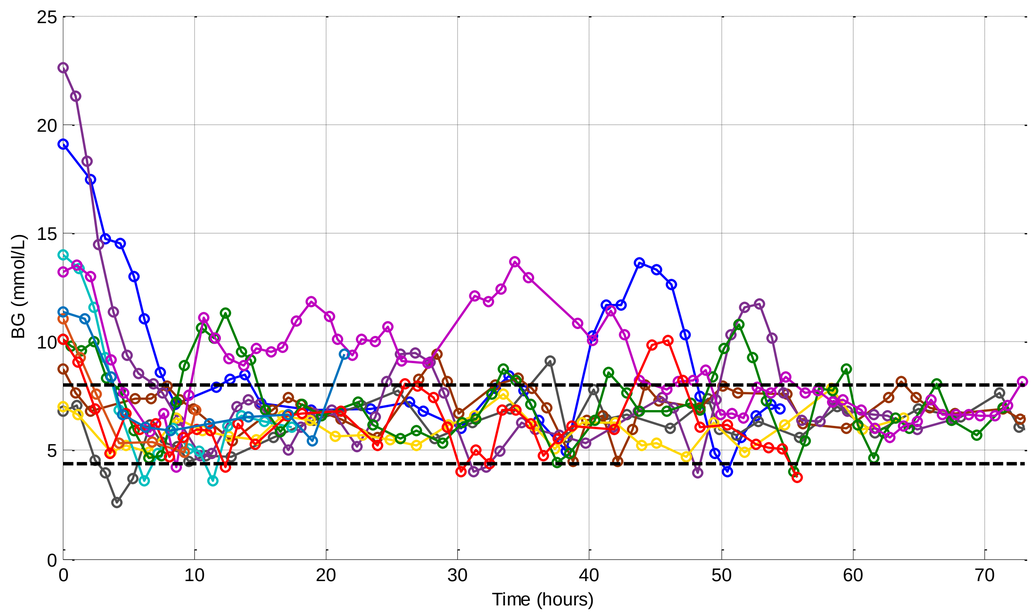

Figure 2 – BG traces over time for the first 11 patients included in the STAR-Liège clinical trial.

Table 1 – Clinical data from 11 STAR-Liège patients. Results are given as median [IQR].

# patients	11
Total hours of control	645
Workload (#measurements/day)	16
Median BG (mmol/L)	6.7 [5.9 7.7]
Insulin rate (U/h)	3.5 [1.5 6.0]
Nutrition (dextrose) rate (g/h)	8.1 [4.9 9.2]
%BG within 4.4-8.0 mmol/L (80-145 mg/dL)	78
%BG > 10.0 mmol/L (180 mg/dL)	10
%BG <4.4 mmol/L (80 mg/dL)	1
%BG <2.2 mmol/L (40 mg/dL)	0
Unchanged intervention (%)	86

- **High performance**: median [IQR] BG of 6.7 [5.9 7.7] mmol/L (122 [106 147] mg/dL) and 78% BG in band.
- **High safety**: only 1% BG < 4.4 mmol/L (80 mg/dL), no incidence of severe hypoglycaemia (BG < 40 mg/dL or 2.2 mmol/L), and 10% of BG > 180mg/dL (10.0 mmol/L).
- **High compliance**: only 14% of intervention changed by clinical staff.

→ **High safety and efficacy for nearly all patients!**

Conclusions

- Insulin-only GC with the STAR-Liège protocol succeeds in providing equally high safety and quality for nearly all patients.
- Failed to reduce BG in 1 consistently highly resistant patient. Reducing nutritional input as per the original STAR design could reduce BG to safer range for this patient.
- These results are encouraging, comparable to previous studies, and support STAR's risk-based dosing approach as a robust solution across different ICU settings and usages.

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