Risk-based Dosing of Insulin and Nutrition Improves Glycaemic Control Outcomes

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AT GLANCE : STAR glycaemic control framework has **a unique risk-based dosing approach** modulating insulin and nutrition.
Nurses are free to choose any possible treatment option (1-3 hourly).
An **insulin only** version is compared to **full version of STAR**.
Clinical results from **21 patients** are analysed.

TAKE HOME MESSAGE : STAR MODEL-BASED CONTROLLER PROVIDES **SAFE AND EFFECTIVE GLYCAEMIC CONTROL FOR ALL ICU PATIENTS**

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**.

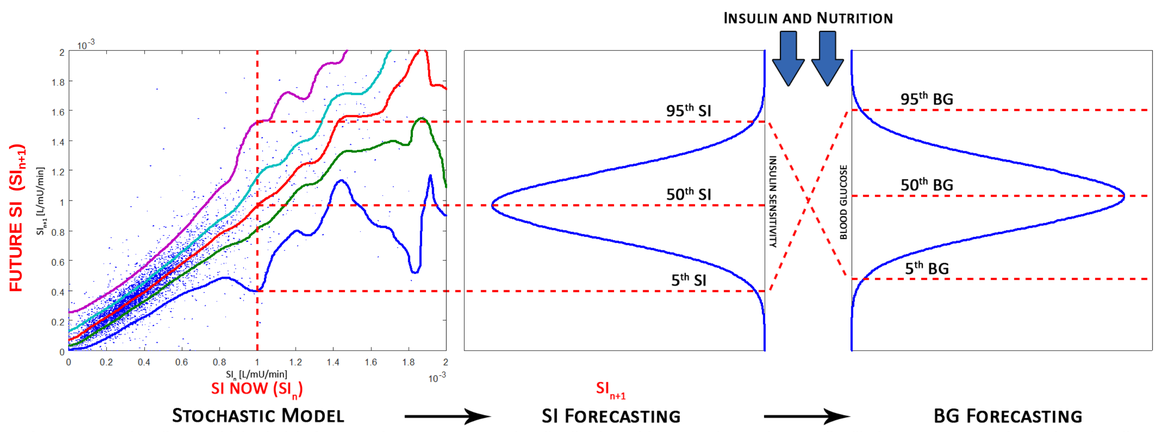

Fig. 1. Future insulin sensitivity (SI) is forecast from current SI. The distribution of future SI is used to predict likely BG outcomes for a given insulin-nutrition treatment intervention.

Objectives

- This study compares safety and efficacy of intermediate clinical results of the STAR-Liège trial in the University Hospital of Liège, Belgium.
- Most GC design uses insulin-only intervention while STAR uses both insulin and nutrition. An insulin only version (STAR-IO) is compared to the full STAR framework.

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. Nutrition is clinically set for STAR-IO.

- **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.
- **Nutrition:** Decrease to a min. of 30% original goal feed.

Results

- Clinical results comparing STAR-IO and STAR are shown in **Table 1**.

Table 1 – Clinical data from 11 STAR-IO and 10 STAR patients. BG is resampled hourly. Results are given as median [IQR].

	STAR-IO	STAR
# patients	11	10
Total hours of control	645	455
Workload (#measurements/day)	16	12
Cohort BG (mmol/L)	6.7 [5.9 7.7]	6.5 [6.1 7.2]
Cohort ΔBG (mmol/L)	0.4 [0.2 0.8]	0.3 [0.1 0.5]
Per-patient median insulin rate (U/h)	3.5 [1.5 6.0]	3.0 [2.0 4.0]
Per-patient median dextrose rate (g/h)	8.1 [4.9 9.2]	7.3 [5.0 8.4]
Per-patient median dextrose rate (%Goal)	90 [60 130]	90 [60 100]
%BG in 4.4-8.0 mmol/L (80-145 mg/dL)	78	89
%BG in 8.0-10.0 mmol/L (145-180 mg/dL)	11	9
%BG > 10.0 mmol/L (180 mg/dL)	10	2
%BG <4.4 mmol/L (80 mg/dL)	1.4	0.7
%BG <2.2 mmol/L (40 mg/dL)	0	0
Unchanged intervention (%)	90	98

- **Both arms are highly effective,** but STAR performed significantly better than STAR-IO (89% vs. 78% BG in target band). Median BG is lower for STAR, and achieved in a less variable manner.
- **Both arms are safe,** with only 1,4% and 0,7% BG < 4,4 mmol/L for STAR-IO and STAR respectively, and no severe hypoglycaemia. STAR achieved significantly lower severe hyperglycaemia (2% BG > 10,0mmol/L) than STAR-IO (10%).
- **High compliance to protocol in each arm,** with less than 10% interventions changed.
- Lower insulin and nutrition were used in STAR. But **per-patient median nutrition rates are similar** in terms of % Goal feed.

→ STAR achieved better GC than STAR-IO, **for lower workload**.

Conclusions

- Modulating nutrition in addition to insulin significantly improves GC outcomes, and reduces workload
- It is possible to provide safe, and effective control for all patients despite lower intermediate glycaemic target ranges
- 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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