Pilot Trials of STAR Target to Range Glycemic Control

S Penning[1]; AJ Le Compte[2]; P Massion[3]; KT Moorhead[1]; J-C Preiser[4]; GM Shaw[5]; T Desaive[1]; JG Chase[2];

1: Univ of Liege, Belgium
2: Univ of Canterbury, Christchurch, NZ
3: CHU de Liege, Liege, Belgium
4: Erasmus Hospital, Brussels, Belgium
5: Christchurch Hospital, Christchurch, NZ

Introduction: Tight glycemic control (TGC) has shown benefits in cardiac surgery ICU patients. STAR (Stochastic TARgeted) is a flexible, model-based TGC protocol accounting for patient variability with a stochastically derived maximum 5% risk of blood glucose (BG) below 90 mg/dL.

Objectives: To assess the safety, efficacy and clinical workload of the STAR TGC controller in pilot trials.

Method: Each trial was 24 hours with BG measured 2-3 hourly. Nine patients were recruited; one was stopped by the clinician after 7 hours after a diagnosis of pancreatic disease. Insulin interventions every 2-3 hours are selected to maximize the overlap of potential (5-95th percentile) range of glycemic outcomes with the 100-140mg/dL band = Target to Range.

Interventions are calculated using clinically validated computer models of human metabolism and its variability in critical illness. Carbohydrate intake (all sources) was monitored, but not changed from clinical settings. Insulin infusion rates were limited (6U/hour maximum), with limited increases based on current infusion rate (0.5-2.0U/hour). All measurements were taken with a mix of bedside glucometers and blood gas analyzer as chosen by the attending nurse and availability. Approval was granted by the Ethics Committee of the Medical Faculty of the University of Liege (Liege, Belgium).

For context, BG results are compared to 24-hour pre-trial and 24-hour post-trial BG results of the same nine patients (control results).

Results: A total of 91 measurements over 194 hours were taken (every 2.1 hours (11/day) on average; range: 10.5-11 measurements/day). Initial BG median [IQR] was 155.0 mg/dL [126.5-165.0]. Median [IQR] cohort BG was 134.0 [117.2-150.8]mg/dL. The percentage of BG measurements within 100-140 mg/dL was 54.9%, where 40.7% were ≥ 140 mg/dL and 4.4% (4 measurements) had BG<100 mg/dL. There were no hypoglycemic events (BG<40 mg/dL) and the minimum recorded BG was 70 mg/dL.

Median [IQR] per-patient results were: Median BG, 137.0 [120.3-142.4] mg/dL; Median Carbohydrate Administered, 0.0 [0.0-4.7] g/hour; Median Insulin Administered, 1.4 [0.2-2.6] U/hour. The median [IQR] time to BG<140 mg/dL was 1.8 [0.0-2.6] hours (7.5% of trial length on average) and 6.6 [1.9–9.0] hours to BG<125 mg/dL. Longer trials would have increased time in glycemic bands and overall performance.

For comparison, the control BG was 144.0 [118.5-167.0]mg/dL, and per-patient median BG was 144.0 [142.0-156.1]mg/dL, with no hypoglycemia.

Conclusion: STAR with Target to Range effectively controlled all patients with reduced effort. STAR effectively managed intra- and inter- patient variability with no hypoglycemia, and provided tight safe control. Clinical workload was acceptable (10-11 measurements per day) and are expected to drop slightly as patients become more stable. The use of glucometers did not appear to impact the quality of TGC.