Accurate Glycemic Control with STAR

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Background: Accurate glycemic control (AGC) has proven difficult without excessive hypoglycemia risk. Stochastic TARgeted (STAR) glycemic control forecasts changes in insulin sensitivity to calculate a range of glycemic outcomes for an insulin intervention, creating a risk framework to increase safety and performance.

Objective: Create a new protocol with improved safety from hypoglycemia and reduced clinical burden using virtual trials, prior to clinical pilot trials.

Method: Clinically validated virtual trials were run on 371 virtual patients (39,841 hours) from the SPRINT AGC cohort. Model forecasts target control to a clinically specified glycemic range (80mg/dL to 145mg/dL). Robustness to measurement error limit insulin increases to +2U/hour (max 6U/hour bolus and 3U/hr infusion) and nutrition changes to ±30% (between 30-100% of ACCP goal) per intervention. Measurement intervals of 2-3 hours were used when predicted 5^{th} and/or 95^{th} percentile BG were within target range. Performance was compared to clinical SPRINT and measured as time within glycemic bands, and safety assessed by patients with severe (BG < 40mg/dL) and moderate (BG < 72mg/dL) hypoglycemia.

Results: Severe hypoglycemia was reduced from 14 patients (clinical SPRINT data) to 5 with a simultaneous 23% workload reduction from 26,646 BG measurements to 20,591. Moderate hypoglycemia was reduced from 2.89% to 1.33%. Whole-cohort %BG in 80-145mg/dL was 90.6% (86.0% for SPRINT) and enteral nutrition was increased overall by 21% in median amount. Limiting measurement intervals to 2-hourly (as in SPRINT) reduced severe hypoglycemia to 2 patients, reduced moderate hypoglycemia to 0.99% and increased %BG in 80-145mg/dL to 91.5%.

Conclusions: Safe, accurate glycemic control that also reduces clinical effort is achieved using stochastic forecasting of potential patient variation. Initial pilot clinical trials are successful and ongoing.