Glycemic Control Protocol Comparison using Virtual Trials

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**Background:** Several accurate glycemic control (AGC) protocols for critical care patients exist but making comparisons is very hard.

**Objective:** This study uses clinically validated virtual patient methods to compare safety and performance for several published AGC protocols.

**Method:** Clinically validated virtual trials were run on 371 patients (39,481 hours, 26,646 measurements) created from the SPRINT AGC cohort. For protocols that do not modulate feed rates enteral nutrition was held at 100% of ACCP goal (25kcal/kg/day) when the patients were clinically fed, and parenteral nutrition rates were matched to clinical data. Performance was defined as %BG within glycemic bands and BG measurement frequency. Safety was defined as the incidence of severe (number patients with BG<40mg/dL) and moderate (%BG<72mg/dL) hypoglycemia. Clinical data from SPRINT is also compared.

**Results:** Clinical SPRINT performance data matched re-simulated SPRINT with 86% vs. 86% BG in 80-145mg/dL, 2.00% vs. 2.07% BG above 180mg/dL and 7.83% vs. 7.29% BG below 72mg/dL, with 14 measurements (over 8 patients) of BG<40mg/dL. Yale results were 83.5%, 3.20%, 5.18%, with 6 severe hypoglycemic patients, using 37,961 measurements (23.0/day). Glucontrol had 75.2%, 3.70%, 9.45%, 52 cases and 26,199 measurements (15.8/day). Braithwaite had 84.2%, 3.00%, 4.22%, 19 cases and 24,396 measurements (14.8/day). The STAR (Stochastic TARgeted) model-based method had 90.6%, 1.67%, 1.33%, 5 cases and 20,591 measurements (12.3/day).

**Conclusions:** Virtual trials provided an effective comparison across protocols with different target bands/values and different clinical cohorts. The model-based STAR protocol provided the best management of patient variability yielding the best performance and safety.