



## **Single-Center, Open, Non-Controlled Feasibility Study on the Performance of the CS-1 Decision Support System with Incorporated Software-Algorithm eMPC Used for Blood Glucose Control over 72 Hours in Critically Ill Patients at the Intensive Care Unit**

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**Background:** The presence of hyperglycaemia in hospitalized patients indicates an increased risk for mortality and morbidity. Single center trials have demonstrated that tight blood glucose improves prognosis for ICU patients. Despite the availability of several insulin titration protocols tight glycaemic control is difficult to establish in ICU patients. The purpose of this study was to investigate the performance of a newly developed prototype decision support system for the establishment of tight glycaemic control in patients at the medical ICU for a period of 72 hours.

**Methods:** The study was conducted as a single-center, open, non-controlled clinical investigation in ten mechanically ventilated patients at the Medical University Graz (patient recruitment April-June 2007). After admission to the ICU, arterial blood glucose values were monitored and the CS-1 Decision Support System (interacting infusion pumps with integrated algorithm eMPC and user interface) was used to adjust the infusion rate of intravenously administered human soluble insulin to normalize arterial blood glucose. Efficacy and safety were assessed by calculating percentage within the target range (4.4 to 6.1 mM), hyperglycaemic index (HGI) mean glucose and the number of hypoglycaemic episodes ( $< 2.2\text{mM}$ ).

**Results:** For the first time a Decision Support System fully integrated into an infusion pump system was tested clinically. Percentage time of readings within the target range was 47.0% ( $\pm 13.0$ ). Average blood glucose concentration and HGI were 6.08mM ( $\pm 0.73$ ) and 0.54mM ( $\pm 0.52$ ), respectively. No hypoglycaemic episode ( $< 2.2\text{mM}$ ) was detected. Despite technical malfunctions, the performance of this prototype system of the CS-1 Decision Support System device was from a clinical point of view already effective in maintaining tight glycaemic control. Accordingly and with technical improvement required, the CS1

system has the capacity to serve as a reliable tool for routine establishment of glycaemic control for critically ill patients.

The results of this clinical trial provided substantial input for further development of the system and its integration in a system for every-day use in the ICU. The enhanced version of the system (CS-2 system) was successfully tested in another clinical trial at Royal Brompton Hospital.

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