



## **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 24 Hours in Postoperative Cardiac Surgery Patients in the Intensive Care Unit**

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**Background:** Tight blood glucose (BG) control reduces morbidity and mortality in critically ill patients but is difficult to achieve safely with current insulin administration algorithms. A software enhanced model predictive control algorithm (eMPC) that provides advice on insulin infusion rate and time to next glucose measurement has been shown to be safe and effective over 72 hours in critically ill patients. This study investigated the effectiveness over up to 24 hours of a decision support system (CLINICIP CS-1) that included the eMPC algorithm integrated into a device that included infusion pumps for enteral and parenteral feeding and insulin (B Braun Space system). The system provides automatic data transfer concerning carbohydrate and insulin administration from the infusion pumps to the algorithm and is controlled via a graphical user interface that includes a display of glucose concentration history and reminder alarms.

**Methods:** The study was an open, single center study in 10 patients admitted to the Adult Intensive Care Unit following cardiac surgery, for at least 20 and up to 24 hours (patient recruitment May-July 2007). The study was conducted in the Adult Intensive Care Unit (ICU) of the Royal Brompton Hospital, a University specialist cardiothoracic hospital. The study was approved by the Brompton, Harefield and NHLI (National Heart & Lung Institute) Ethics Committee prior to commencement. The trial was conducted in accordance with the Declaration of Helsinki and ISO 14155. 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:** In summary it was not possible to comment on the efficacy of the CS-1 system as a whole because of the substantial problems in internal system communications. However a number of useful issues relating to system handling, infusion pumps and the user interface became clearer during the study. Suggestions for improvements have been made. The system should be retested once the communication problems have been resolved and potential improvements implemented.

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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