



Mono-Centric, Open, Non-Controlled Study To Investigate The Feasibility Of Blood Glucose Control With The Software-Algorithm eMPC (Enhanced Model Predictive Control) In ICU Patients

B. Braun Melsungen AG, Hospital Care, Clinical Development

Background: Hyperglycemia is common in critically ill patients and associated with an adverse outcome. Large randomized controlled trials have demonstrated that tight glycaemic control (TGC) reduces morbidity and mortality in this population. Based on this emerging evidence intensive insulin therapy is currently finding its way into the critical care practice. Numerous insulin infusion protocols, which are based on frequent bedside glucose monitoring, have been implemented. Recent reviews comparing different types of protocols describe widely ranging practice and difficulties in achieving TGC despite extensive efforts of the intensive care unit (ICU) staff. A fully automated algorithm may help to overcome some of these limitations by excluding intuitive interventions and integrating relevant clinical data in the decision-making process. The primary objective of the current study is to investigate the performance (efficacy) of a control algorithm for glycaemic control in ICU patients for the whole length of ICU stay.

Methods: The study was a single-center, open, non-controlled clinical investigation in twenty mechanically ventilated patients at the Medical University Graz. A computer algorithm (eMPC) running on a laptop computer was used as decision support system to normalize the arterial blood glucose level. The eMPC suggests an infusion rate of intravenously administered human insulin based on arterial blood glucose values and on administered parenteral and enteral nutrition. 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 (< 2.2mM).

Results: 20 patients (age 69 ± 11 , BMI 27.4 ± 4.5 , APACHE II 25.5 ± 5.2 , 16 male, 6 diabetic) were included for a period of 7.8 ± 4.1 days. Mean arterial blood glucose was 105.7 ± 8.9 mg/dl. Three single hypoglycaemic episodes occurred during the trial, corresponding to a rate of 0.018 per treatment day. No malfunctions of the eMPC algorithm were observed.

blood glucose (BG) range	< 40 mg/dl	40 - 60 mg/dl	60 - 80 mg/dl	80 - 110 mg/dl (target range)	110 - 150 mg/dl	>150 mg/dl
time in BG range, (%), mean \pm SD	0.02 \pm 0.08	0.79 \pm 0.66	11.39 \pm 3.50	58.12 \pm 10.05	23.09 \pm 7.00	6.59 \pm 7.15

[Percentage of time within glucose ranges]

From a clinical point of view, performance of the eMPC algorithm was excellent. The eMPC algorithm is a safe and reliable method to control blood glucose in critically ill patients in the medical ICU.

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Status: Finalized as planned

Sponsor: B. Braun Melsungen AG

Publication: Amrein *et al.* Hospital Glucose Control: Safe and Reliable Glycemic Control Using Enhanced Model Predictive Control (eMPC) Algorithm In Medical ICU Patients. *Diabetes Technology and Therapeutics. In press.*

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<http://www.clinicaltrials.gov/ct2/show/NCT00735163?term=NCT00735163&rank=1>