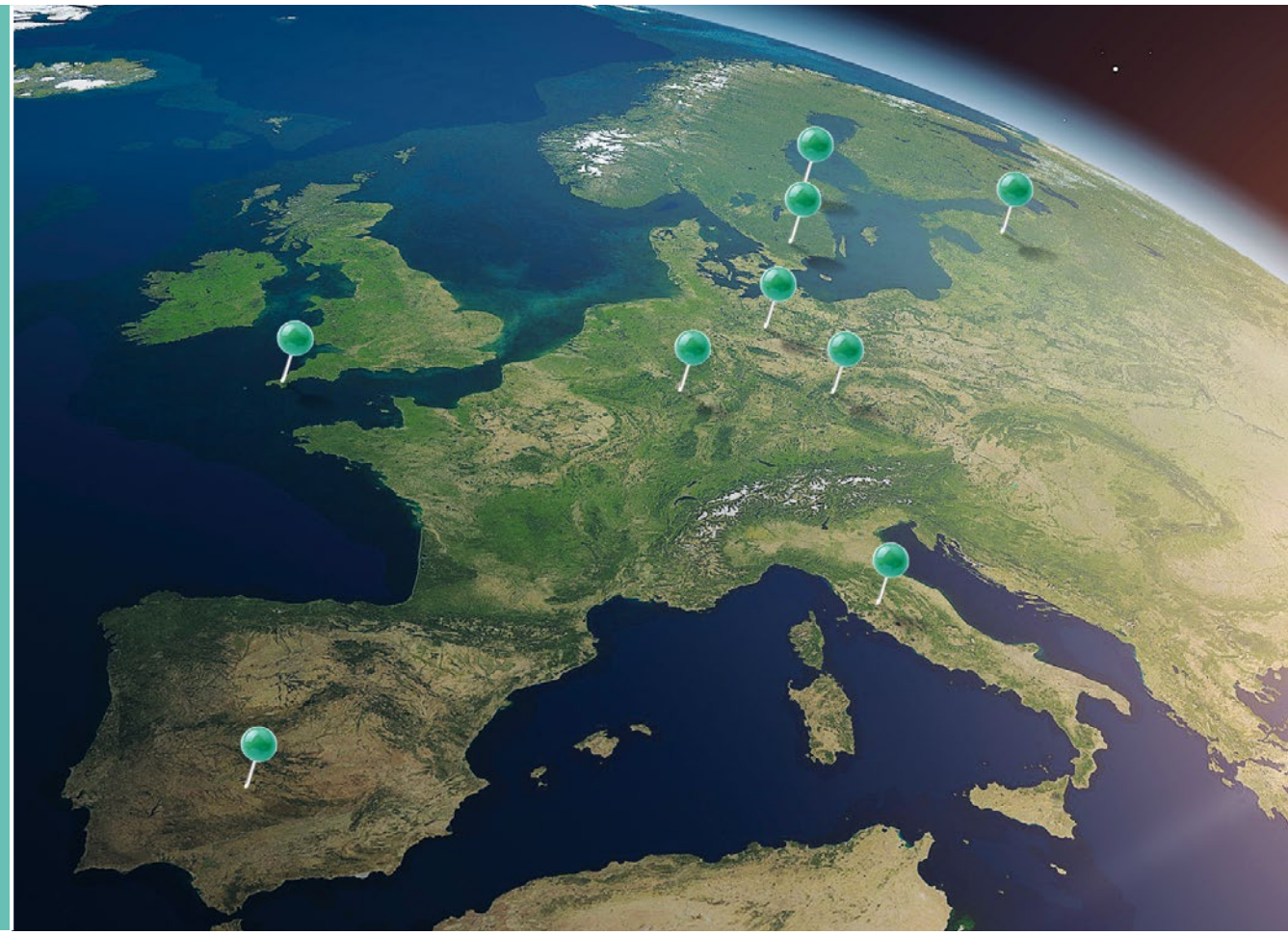
The Non Interventional Study with Space GlucoseControl – Clinically Proven Performance



B. Braun Melsungen AG | Hospital Care | 34209 Melsungen | Germany
Tel. +49 5661 71-0 | www.bbraun.com

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SHARING EXPERTISE

Evaluation of blood glucose control in ICU patients using the Space GlucoseControl system.

A multicentre European study

Karolinska University Hospital, Stockholm; Country Hospital Ryhov, Jönköping
Rigshospitalet, Copenhagen; Vejle Sygehus, Vejle
General University Hospital, Prague; University Hospital Motol, Prague;
University Hospital, Plzen; University Hospital, Hradec Kralove
Azienda Ospedaliera Universitaria Senese, Siena; Azienda Ospedaliera di Legnano, Legnano
Wroclaw Medical University, Wroclaw
Tartu University Hospital, Tartu
Klinikum Augsburg, Augsburg; Universität Leipzig, Leipzig
Capio Hospital Sur, Madrid
Royal Cornwall Hospital, Truro; West Suffolk Hospital, Bury St Edmunds

JAN BLAHA
on behalf of study group

INTRODUCTION

Glycaemia control (GC) remains an important therapeutic goal in critically ill patients, despite the ongoing debate on optimum target ranges. Risk of hypoglycaemia is the most important concern in GC implementation; standardizing GC by a nurse-managed protocol has been found to improve its safety, and also efficiency [1]. Although comparison of existing insulin protocols is difficult due to significant differences in processes and outcome measures, the computerized forms generally achieved better GC with lower hypoglycaemia rates than that achieved with paper based protocols.

The enhanced Model Predictive Control (eMPC) algorithm, which models the behaviour of glucose and insulin in ICU patients with a variable sample, is the effective clinically proven protocol, which has been successfully tested at multiple institutions on medical and surgical patients with different nutritional protocols [2-4]. It has been integrated in the B. Braun Space GlucoseControl system (SGC), which allows direct data communication between pumps and Space Control with the incorporated eMPC algorithm [5].

METHODS

Primary objective of the study was to assess the efficiency of the Space GlucoseControl system for glycaemia control in ICU patients under routine conditions. Secondary objectives were the safety and usability of the SGC system. The primary endpoint was the percentage of time within the target range, secondary outcome measures were the frequency of hypoglycaemic episodes and BG measurement intervals.

Patients were assigned to the target range 4.4-8.3 mmol/l. Blood glucose (BG) was monitored, and insulin was given as a continuous infusion according to the suggestions of SGC system. The system does not automatically change the rate of insulin on its own, the medical staff always had the final decision if he/she wants to accept the suggested insulin rate or not. Nutritional management (enteral, parenteral or both) was carried out at the discretion of the each centre.

STUDY POPULATION

17 centres from 9 European countries included in the period June 2011 - July 2013 overall 508 patients with complete study documentation.

Patients Characteristics at Entry (N=508) Data are presented as mean ± SD, or number (%)	
Female / Male [n]	198 (39.0) / 310 (61.0)
Age [years]	65.6±12.9
Height [m] / Weight [kg] / BMI [kg/m²]	1.70±0.1 / 85.1±20.5 / 29.0±6.5
APACHE II [points]	21.1±7.4
Blood glucose [mmol/l]	10.6±5.6
History of Diabetes	
Total / Type 1 / Type 2 / Other	280 (55.1) / 33 (6.5) / 244 (48.0) / 3 (0.6)

ADMISSION DIAGNOSIS Data are presented as number (%)	
Heart insufficiency, myocardial infarction	166 (32.7)
Respiratory insufficiency	104 (20.5)
Sepsis, septic shock	63 (12.4)
Gastrointestinal disease, bleeding	38 (7.5)
Diabetes, diabetic ketoacidosis	21 (4.1)
Acute pancreatitis	21 (4.1)
Cerebral hematoma, bleeding, infarction	19 (3.7)
Infections; meningitis/ encephalitis	14 (2.8)
Other	62 (12.2)

BLOOD GLUCOSE MEASUREMENT

Blood samples for glucose measurement were obtained by means of arterial (61%) and central venous catheters (27%) or as capillary samples (12%). BG levels were measured with the use of point-of-care (58%) or blood gas (42%) analyzers. Central laboratory analyzer was use in one patient only.

During the whole study period a total of 29575 recommendations because of BG sampling were rendered by SGC system. Mean proposed next measurement time was 2.0 ± 0.5 hours of which 0.15% was shorter than 30 min, 46.6% in the range 30-90 min, 22.7% in the range 91-150 min, 12.3% in the range 151-210 min and 18.4% was longer than 210 min.

RESULTS

All study patients were assigned to wider glucose control target range 4.4 - 8.3 mmol/l. 300 (59%) patients started with BG level higher than 8.3 mmol/l, while 204 (40.2%) had BG level within target range at the start of insulin therapy. In 4 patients Space GlucoseControl system was initialized when BG level was below 4.4 mmol/l. In 7 (2.3%) patients target BG was not achieved during the study period.

Blood Glucose Control Characteristics Data are presented as mean ± SD, or number (%)	
Total study time [days]	4.9 ± 5.4
BG level at entry [mmol/l]	10.6 ± 5.6
Time to reach target range [hours]	7.4 ± 13.1
Mean BG level [mmol/l]	7.1 ± 1.8
Hypoglycaemia <2.2 mmol/l [no. of patients/no. of episodes]	4 (0.8) /4 (0.01)
Risk of hypoglycaemia (2.2-4.3 mmol/l) [% of time]	1.2 ± 3.0
Target range [% of time]	77.5 ± 20.9
Hyperglycaemia >8.3 mmol/l [% of time]	21.2 ± 20.8
Mean insulin infusion rate [U/h]	4.1 ± 3.2
After reaching Target range	
Mean BG level [mmol/l]	6.9 ± 0.7
Target range [% of time]	84.4 ± 14.5

NUTRITION

Nutritional management was carried out at the discretion of the each participating center and treating clinicians. A total of 61 (12.0%) patients received enteral bolus, 287 (56.2%) patients received enteral infusion, 77 (15.2%) patients received parenteral bolus and 340 (66.9%) patients received parenteral infusion.

Nutrition (carbohydrates) Data are presented as mean ± SD, or number (%)		
Enteral Nutrition	N	
Enteral bolus [g]	61	44.4 ± 87.3
Enteral infusion [g/kg/day]	287	1.4 ± 2.8
Time of enteral infusion [% of total study time]	287	73.2 ± 26.1
Parenteral Nutrition		
Parenteral bolus [g]	77	9.8 ± 19.3
Parenteral infusion [g/kg/day]	340	1.2 ± 2.7
Time of parenteral infusion [% of total study time]	340	75.6 ± 28.4

Technical parameters of the SGC system performance

The eMPC uses a model of the glucoregulatory system to predict a value of incoming glucose measurement, taking into account individual insulin sensitivity and nutrition. If the entered value significantly differs from the predicted, SGC is evaluating it as not plausible and displays on-screen warning to prevent incorect BG entry as result of human/laboratory error.

Blood Glucose Not Plausible Warnings				
Blood glucose sampling	Number of BG too Low		Number of BG too High	
29575	591	2%	585	2%

Conclusion

The Space GlucoseControl system with integrated eMPC algorithm has demonstrated its high efficiency and safety in critically ill medical and surgical patients when used under routine conditions and under different nutritional protocols. It remains to be elucidated, which cohort of the patients (type of surgery, type of nutrition, long-stayers, etc) would benefit the most from application of SGC.

REFERENCES
1. Jacobi J et al.: Crit Care Med 2012; 40(12):3251-76
2. Cordingley JJ et al.: Intensive Care Med 2009; 35(1):123-8
3. Blaha J et al.: Diabetes care 2009; 32(5):757-61
4. Kopecky P et al.: Biomed Res Int 2013; 2013:186439
5. Amrein K et al.: Diabetes Technol Ther 2012; 14(8):690-5

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