CONTINUOUS BLOOD GLUCOSE MONITORING (CGM) SYSTEM BASED ON INTRAVENOUS MICRODIALYSIS AND GLUCOSE SENSING

H. Greiner¹, R. Schaller-Ammann², A. Huber¹, M. O’Connell³, J. Krejci⁴, G. Porro⁵, S. Korsatko¹, J. Gurban¹, S. Deller¹, M. Brunner¹, A. Berghofer¹, J. Priedl⁶, E. Zijlstra⁶, T. Heise⁶, T.R. Pieber¹,², L. Schaupp¹

¹Division of Endocrinology and Metabolism, Medical University of Graz, Austria
²JOANNEUM RESEARCH Forschungsgesellschaft mbH, Graz, Austria
³Probe Scientific Ltd, Coventry, United Kingdom
⁴BVT Technologies a.s., Brno, Czech Republic
⁵dataMED S.r.L, Rodano, Italy
⁶Profil Institut für Stoffwechselforschung GmbH, Neuss, Germany

hannah.greiner@aon.at

Abstract: A new CGM system that combines an intravenous microdialysis probe with a glucose sensor can be used for continuous blood glucose monitoring. The aim of this 24 hour clinical trial was to investigate the overall measurement performance of the CGM system regarding both glucose sampling (microdialysis) and glucose sensing.

Keywords: intravenous microdialysis, glucose sensor, continuous blood glucose monitoring system

Introduction

According to the International Diabetes Federation about 366 million people are currently suffering from diabetes mellitus worldwide. By 2030 this number will have increased by another 50% [1] causing additional direct health care costs of 10,000$ per person and year in the USA [2]. General health and quality of life of diabetes patients can be improved by insulin substitution therapy. Before new types of insulin are released to the market they are tested in clinical clamp trials regarding their time-action-profiles [3]. Our continuous blood glucose monitoring system is the basis for an automated clamp device to standardize clamp procedures.

Methods

27 intravenous microdialysis probes (PME011, Probe Scientific, UK) were investigated in healthy and type 1 diabetic subjects (27 ± 4 years, BMI 24 ± 2.3 kg/m²). Each subject was clamped to 4 different blood glucose levels (90/180/130/90 mg/dl) for 6 hours each. The dialysate was sampled and analysed offline for glucose and ion content to calculate blood glucose concentrations from the relative recovery using the “Ionic Reference Technique” [4]. In 5 subjects the microdialysis probe was also connected to an online electrochemical glucose sensor (AC1.GOD, BVT Technologies, CZ).

Results

A relative glucose recovery > 5% was associated with a good correlation coefficient (r > 0.8) between blood glucose and dialysate glucose (Fig. 1). The mean correlation coefficient was f_{dialysate-sensor} = 0.94 ± 0.02, f_{blood-dialysate} = 0.91 ± 0.13 and f_{blood-sensor} = 0.83 ± 0.20 (Fig. 2). The overall system error (blood-sensor) was 13.38 ± 7.94% and the MARD (mean absolute relative difference) was 17.34 ± 7.25% for data 1-point-calibrated and IRT corrected.

Discussion

We were able to show that intravenous microdialysis in combination with glucose sensing has the potential to be an attractive alternative for frequent manual blood sampling as currently used in hospitals and clinical trials. It avoids considerable blood loss as blood samples are only required for calibration purposes.

Figure 1: Relation between correlation coefficient (blood-dialysate or blood-sensor) and mean glucose recovery for all subjects.
Figure 2 A-E: Glucose profiles of the continuous blood glucose monitoring systems (n = 5). Red curves indicate the blood glucose concentrations. Blue curves indicate the filtered and shifted sensor currents. Green curves indicate the dialysate glucose concentrations. Black triangles on the x-axis indicate calibration points.

Acknowledgement
This project was supported by the European Commission, Project EU-CLAMP (FP7-SME-2010-01; project number 26007).

Bibliography