Journal of Diabetes Science and Technology
Volume 4, Issue 1, January 2010

SYMPOSIUM

Hypoglycemia Alarm Enhancement Using Data Fusion

Victor N. Skladnev, M.Eng.,[1] Stanislav Tarnavskii, Ph.D.,[1] Thomas McGregor, Ph.D., BTech,[1] Nejhdeh Ghevondian, Ph.D.,[1] Steve Gourlay, Ph.D., M.B.B.S., M.B.A.,[1] and Timothy W. Jones, M.D., FRACP[2,3]

Abstract

Background:

The acceptance of closed-loop blood glucose (BG) control using continuous glucose monitoring systems (CGMS) is likely to improve with enhanced performance of their integral hypoglycemia alarms. This article presents an *in silico* analysis (based on clinical data) of a modeled CGMS alarm system with trained thresholds on type 1 diabetes mellitus (T1DM) patients that is augmented by sensor fusion from a prototype hypoglycemia alarm system (HypoMon®). This prototype alarm system is based on largely independent autonomic nervous system (ANS) response features.

Methods:

Alarm performance was modeled using overnight BG profiles recorded previously on 98 T1DM volunteers. These data included the corresponding ANS response features detected by HypoMon (AiMedics Pty. Ltd.) systems. CGMS data and alarms were simulated by applying a probabilistic model to these overnight BG profiles. The probabilistic model developed used a mean response delay of 7.1 minutes, measurement error offsets on each sample of ± standard deviation (SD) = 4.5 mg/dl (0.25 mmol/liter), and vertical shifts (calibration offsets) of ± SD = 19.8 mg/dl (1.1 mmol/liter). Modeling produced 90 to 100 simulated measurements per patient. Alarm systems for all analyses were optimized on a training set of 46 patients and evaluated on the test set of 56 patients. The split between the sets was based on enrollment dates. Optimization was based on detection accuracy but not time to detection for these analyses. The contribution of this form of data fusion to hypoglycemia alarm performance was evaluated by comparing the performance of the trained CGMS and fused data algorithms on the test set under the same evaluation conditions.

continued →

Author Affiliations: [1]AiMedics Pty. Ltd., Eveleigh, New South Wales, Australia; [2]Telethon Institute for Child Health Research, Centre for Child Health Research, The University of Western Australia, Perth, Western Australia, Australia; and [3]Department of Endocrinology and Diabetes, Princess Margaret Hospital, Perth, Western Australia, Australia

Abbreviations: (ANS) autonomic nervous system, (BG) blood glucose, (CGMS) continuous glucose monitoring system, (NPV) negative predictive value, (PMA) premarket approval, (PPV) positive predictive value, (SD) standard deviation, (T1DM) type 1 diabetes mellitus, (YSI) Yellow Springs Instruments

Keywords: continuous glucose monitoring, data fusion, hypoglycemia alarms, HypoMon®

Corresponding Author: Victor Skladnev, AiMedics Pty. Ltd., Suite 113, National Innovation Centre, Australian Technology Park, 4 Cornwallis St., Eveleigh, NSW 2015, Australia; email address skladnev@aimedics.com

Abstract cont.

Results:

The simulated addition of HypoMon data produced an improvement in CGMS hypoglycemia alarm performance of 10% at equal specificity. Sensitivity improved from 87% (CGMS as stand-alone measurement) to 97% for the enhanced alarm system. Specificity was maintained constant at 85%. Positive predictive values on the test set improved from 61 to 66% with negative predictive values improving from 96 to 99%. These enhancements were stable within sensitivity analyses. Sensitivity analyses also suggested larger performance increases at lower CGMS alarm performance levels.

Conclusion:

Autonomic nervous system response features provide complementary information suitable for fusion with CGMS data to enhance nocturnal hypoglycemia alarms.

J Diabetes Sci Technol 2010;4(1):34-40