

Clinical Evaluation of a Noninvasive Alarm System for Nocturnal Hypoglycemia

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Abstract

Background:

The aim of this study was to evaluate the performance of a prototype noninvasive alarm system (HypoMon[®]) for the detection of nocturnal hypoglycemia. A prospective cohort study evaluated an alarm system that included a sensor belt, a radio frequency transmitter for chest belt signals, and a receiver. The receiver incorporated integrated “real-time” algorithms designed to recognize hypoglycemia “signatures” in the physiological parameters monitored by the sensor belt.

Methods:

Fifty-two children and young adults with type 1 diabetes mellitus (T1DM) participated in this blinded, prospective, in-clinic, overnight study. Participants had a mean age of 16 years (standard deviation 2.1, range 12–20 years) and were asked to follow their normal meal and insulin routines for the day of the study. Participants had physiological parameters monitored overnight by a single HypoMon system. Their BG levels were also monitored overnight at regular intervals via an intravenous cannula and read on two independent Yellow Springs Instruments analyzers. Hypoglycemia was not induced by any manipulations of diabetes management, rather the subjects were monitored overnight for “natural” occurrences of hypoglycemia. Performance analyses included comparing HypoMon system alarm times with allowed time windows associated with each hypoglycemic event.

Results:

The primary recognition algorithm in the prototype alarm system performed at a level consistent with expectations based on prior user surveys. The HypoMon system correctly recognized 8 out of the 11 naturally occurring overnight hypoglycemic events and falsely alarmed on 13 out of the remaining 41 normal nights [sensitivity 73% (8/11), specificity 68% (28/41), positive predictive value 38%, negative predictive value 90%].

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Abbreviations: (ANS) autonomic nervous system, (BG) blood glucose, (CI) confidence intervals, (ISO) International Organization for Standardization, (NPV) negative predictive value, (PMH) Princess Margaret Hospital for Children, (PPV) positive predictive value, (T1DM) type 1 diabetes mellitus, (YSI) Yellow Springs Instruments

Keywords: alarms, clinical evaluation, nocturnal hypoglycemia

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Abstract cont.

Conclusion:

The prototype HypoMon shows potential as an adjunct method for noninvasive overnight monitoring for hypoglycemia events in young people with T1DM.

J Diabetes Sci Technol 2010;4(1):67-74