

Nocturnal Blood Glucose Control by Fuzzy Logic (FL) Dosing Algorithm

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Objective

To compare the nocturnal glucose control of the Dose Safety closed loop fuzzy logic (FL) dosing algorithm with the subjects own care at home.

Introduction

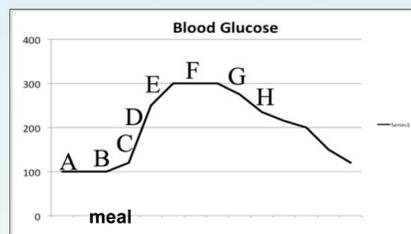
Most current approaches to closed-loop systems, such as proportional-integral-derivative (PID) control and model predictive control (MPC) dosing algorithms rely on mathematical differential equations describing the dynamics of the human glucoregulatory system. The Fuzzy Logic Dosing Module (FLDM) instead uses FL technology, which does not require differential equations of the glucoregulatory system. The FLDM instead relies on the codified expertise of diabetes clinicians.

The physicians' clinical expertise is codified in terms of 'dosing rules,' where each rule addresses a different glucose circumstance. Each circumstance, or state, is specified by three, and only three terms: glucose level, glucose slope or rate, and glucose acceleration, which is the rate of change of the slope. This is important because the FLDM automatically compensates for meals and exercise without the need for patient intervention. Also, blood glucose is the best primary input because it is measured accurately and in a timely manner compared to other physiological measurements that must be estimated.

Unlike current PID and MPC dosing algorithms, which depend on and augment the users scheduled basal insulin doses, the FLDM provides total insulin required by the patient. Between meals and overnight the FLDM provides the equivalent of basal insulin through 'dosing rules' determined mini-boluses (via q5min boluses). Non-reliance on the user basal schedule is a benefit because these schedules are often wrong and need to be adjusted for illness, stress and exercise.

The FLDM within the Dose Safety Controller (DSC) determines dosing based on absolute glucose value, rate and acceleration. Instead of using an arbitrary duration of suspension our FLDM allows the resumption of dosing when the blood glucose level, rate and acceleration indicate that it is safe to do so. For example if the rise is slow dosing is reduced and if the rise is more rapid dosing is increased. These dosing capabilities are embedded into the overall design of the FLDM.

Example BG trajectory



Dosing Rules Matrix template (covers all possible BG trajectories)

BGL Rate (mg/dL/min): Very Negative, Negative, Zero, Positive, Very Pos.	VN: <-2.50			N: -1.25			Z: 0.0			P: 1.25			VP: >2.5		
BGL Accel: (mg/dL/min/min) Negative, Zero Positive	N:<0	Z:>0	P:>0	N:<0	Z:>0	P:>0	N:<0	Z:>0	P:>0	N:<0	Z:>0	P:>0	N:<0	Z:>0	P:>0
BGL Trajectory	↘	↘	↘	↘	↘	↘	↘	↘	↘	↘	↘	↘	↘	↘	↘
VH: >250 mg/DL				G											
VH: 180-250 mg/DL					H										
H: 120-180 mg/DL															
N: 80-120 mg/DL							A						B		C
L: <80 mg/DL															

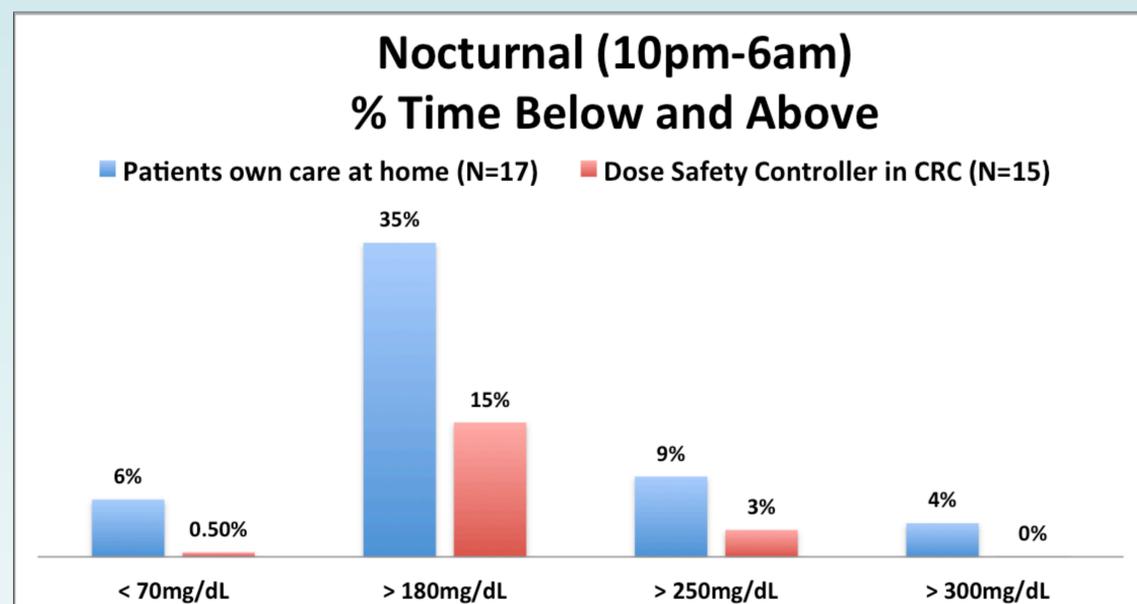
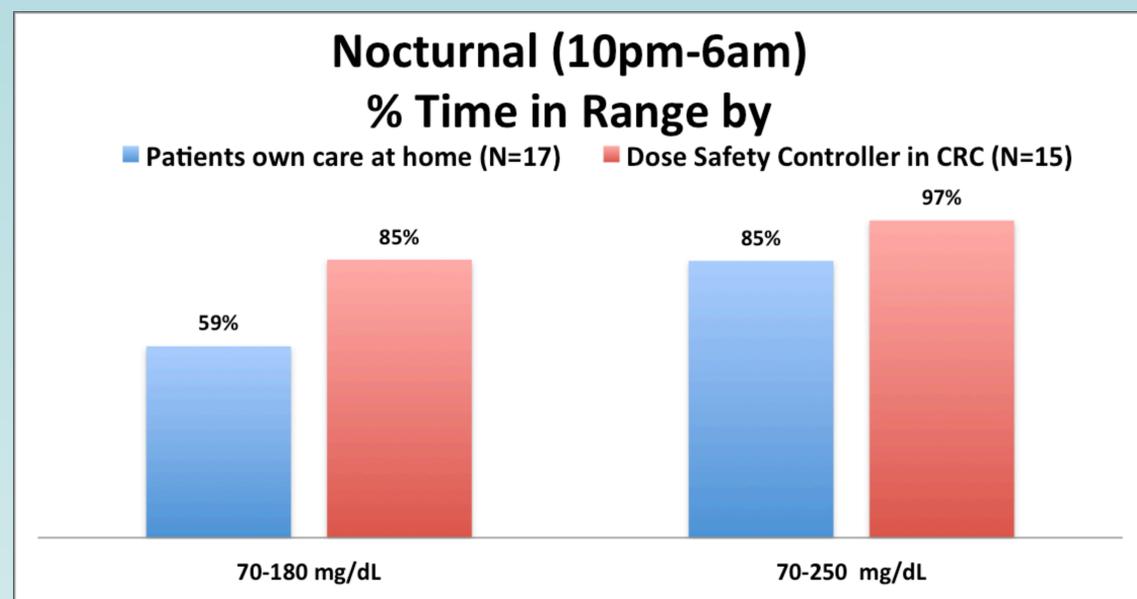
Methods

We reviewed data from several of our JDRF and NIH funded studies and compared overnight (10 pm to 6 am) results to patients at home results under their own care. Both at home and CRC blood glucose data were collected via a Dexcom G4 CGMS.

We collected data for 48 hours prior to CRC admission and this was compared to the same time period in the CRC. A total of 17 subjects had data that met criteria of preadmission data and completion of the overnight segment of the study. All statistics were calculated from Dexcom G4 CGMS data.

Results

The % time < 70mg/dL at home was 6.4% versus <1.0% for the FLDM; the % time in the range of 70-180 mg/dL was 58.5% at home versus 85% for the FLDM; and the average glucose value was 157mg/dL at home versus 145 mg/dL for the FLDM. The FLDM produced no blood glucose values less than 60 mg/dL and no treatment was required to avoid hypoglycemia.



Conclusion

The Dose Safety FL dosing algorithm produced superior overnight control when compared to the participants' own care.

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