Continuous Glucose Monitoring: Using CGM to Guide Insulin Therapy Virtual Trials Results

Laurent Mombaerts, Felicity Thomas, Matthew Signal, Thomas Desaive and J. Geoffrey Chase

INTRODUCTION

Continuous glucose monitoring (CGM) devices can estimate blood glucose levels with a 1-5min sampling period. However, the relation between tissue and blood glucose is dynamic and the sensor signal can degrade over time. In addition, CGM readings contains high frequency noise. However, CGM has the potential to improve performance of glycaemia control and reduce nurse workload. A simple model was designed and tested to see the effect of inherent CGM error on the insulin therapy protocol, STAR (Stochastic TARgeted).

Modelling Continuous Glucose Monitoring Output

CGM Patients

Data from 9 patients admitted to the Christchurch Hospital ICU that were enrolled in an observational pilot study of CGM was used to generate the CGM error model

TABLE I. SUMMARY OF CGM STUDY PATIENT CHARACTERISTICS. DATA ARE SHOW AS MEDIAN [INTERQUARTILE RANGE] WHERE APPROPRIATE

Number Patients	9
Age (years)	57 [38-64]
Gender (M/F)	5/4
APACHE II score	22 [17 – 28]
Hospital mortality (L/D)	(5/4)
Duration of CGM (days)	3.6 [2.5 – 5.7]

Error Model

$$CGM = BG_{real} + noise + drift$$

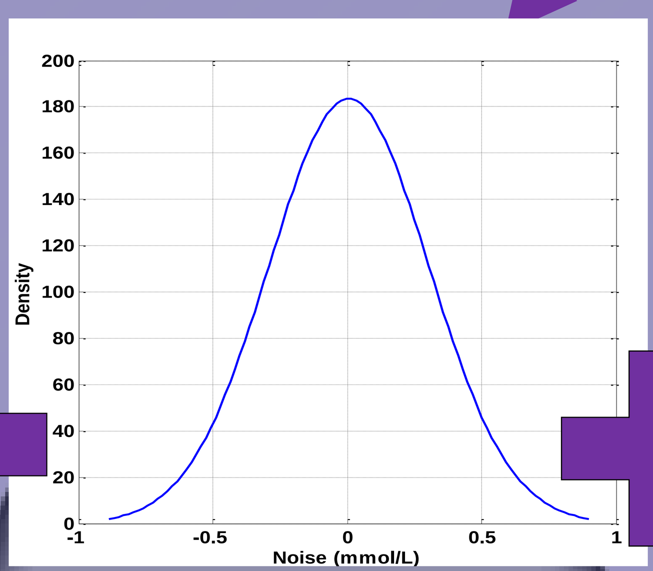

FIGURE I. 1/4 GOLDBERG NOISE DISTRIBUTION USED TO MODEL THE HIGH FREQUENCY NOISE SEEN IN CGM SIGNALS

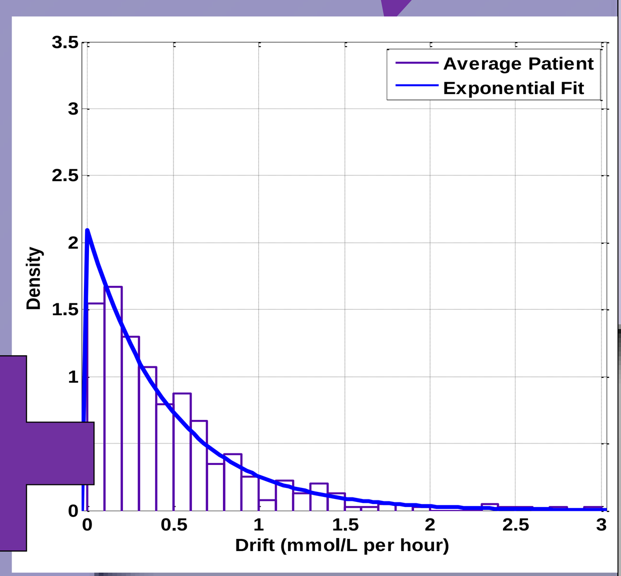

FIGURE II. DISTRIBUTION OF ABSOLUTE DRIFT FOR THE ENTIRE COHORT

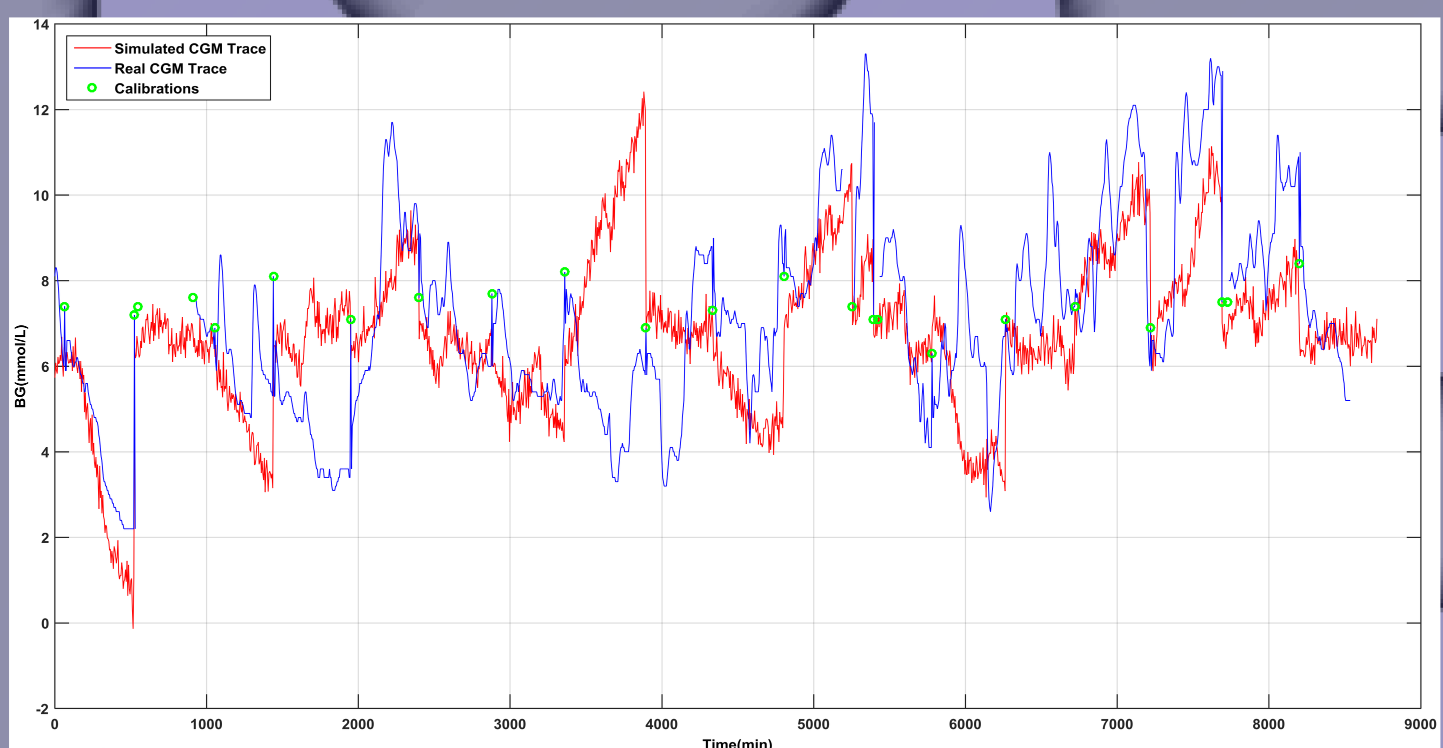

FIGURE III. COMPARING CGM TRACES SIMULATED USING THE CGM ERROR MODEL AND BG CALIBRATION MEASUREMENTS TO THE REAL CGM TRACE FROM OBSERVATIONAL TRIALS.

Using CGM to guide insulin Therapy – Insilco

Virtual Patients

Virtual trials were performed using retrospective data from 183 patients treated by accurate glycaemic control protocols at Christchurch Hospital ICU between 2011 and 2013.

TABLE II. COHORT DEMOGRAPHICS OF THE PATIENTS USED FOR VIRTUAL TRIALS. DATA ARE SHOW AS MEDIAN [INTERQUARTILE RANGE] WHERE APPROPRIATE

N	183
Age (years)	65 [54-72]
Gender (M/F)	123/60
APACHE II score	21 [15 – 25]
Hospital mortality (L/D)	131/52

Results

TABLE III. RESULTS OF VIRTUAL TRIAL SIMULATIONS AS WELL AS CLINICAL DATA. DATA ARE PRESENTED AS MEDIAN [INTERQUARTILE RANGE] WHERE APPROPRIATE.

Whole cohort statistics	STAR MC	STAR CGM MC	Clinical
N	183	183	183
BG meas/day/patient	**13.5 [12-16]**	**7.00 [5.9-8.6]**	**13.0**
BG (mmol/L)	6.99 [6.0-8.2]	7.06 [6.0-8.3]	6.80 [5.9- 8.0]
% time in 4.4-8.0 mmol/L	**81.0**	**72.2 [72-73]**	**81.3**
% time < 4.4 mmol/L	1.59	4.7 [4.6-4.9]	1.69
% time < 2.2 mmol/L	0.03	0.320 [0.28 - 0.37]	0.01

- reduced workload by ~50%.
- low level of hypoglycaemia - under the clinically acceptable value of 5% below <4.0mmol/L
- Shows great promised for the future of CGM and their use in clinic, newer generation of sensors being specifically designed for the ICU environment promising less error and drift

CONCLUSION

The STAR CGM protocol gave good performance and reduced workload by ~50%, reducing the number of measurements per day per patient from 13 to 7. The number of hypoglycaemic events increased compared to the current STAR from 0.03% <2.2mmol/L to 0.32%. However, in comparison to other published protocols it is still a very low level of hypoglycaemia and less than clinically acceptable value of 5% <4.0mmol/L. More importantly this study shows great promise for the future of CGM and their use in clinic. With the a newer generation of sensors, specifically designed for the ICU, promising less noise and drift suggesting that a reduced nurse workload without compromising safety or performance is with in reach.

Canterbury District Health Board
Te Poari Hauora ō Waitaha

UC BIOMEDICAL ENGINEERING

UC UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND