A Method for Evaluating Insulin Pump Controller Performance

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1) Introduction

In the search for a safe and effective artificial pancreas for the treatment of type1 diabetes several insulin pump controllers have been introduced and evaluated[1].

A means of transforming and evaluating blood glucose data has been proposed by Kovatchev et al.[2] as the low blood glucose risk (LBGI) and high blood glucose risk (HBGI) indices, as well as 3 risk groups[3] (0.0-2.5, 2.5-5.0, >5.0) to delineate effectiveness. This is shown graphically for one controller and 10 *in silico* subjects on the top graph.

We then define the Centroid Distance (CD) as the distance from the origin to the centroid of multiple subjects (LBGI, HBGI) coordinates, and propose it be used as a primary metric for evaluating the overall safety and effectiveness of insulin pump controllers.

2) Objective

To develop an objective means of evaluating the safety and effectiveness of insulin pump controllers

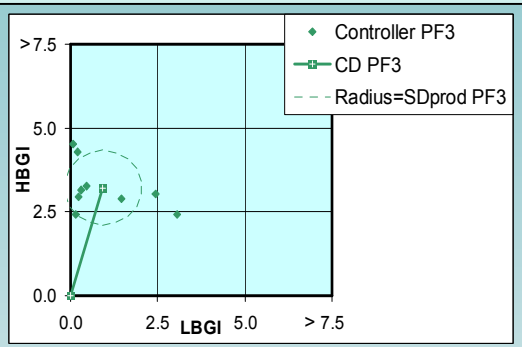
3) Primary Metric

The response of multiple subjects to a particular controller can be combined geometrically into a single value by finding the distance from the origin to the centroid of the (LBGI, HBGI) coordinates. This is termed the Centroid Distance (CD), and is shown in the top and middle graphs as a line radiating from the origin. A smaller CD is superior. It is calculated by this formula:

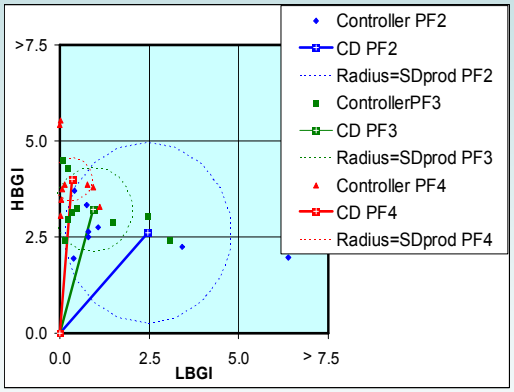
$$CD = \left[\left(\sum_{i=1}^{k} \frac{LBGI_i}{k} \right)^2 + \left(\sum_{i=1}^{k} \frac{HBGI_i}{k} \right)^2 \right]^{1/2}$$

Using this method a shorter CD indicates a superior controller, much like a superior BG meter would have more data points fall in region A on the **Clarke Error Grid**.

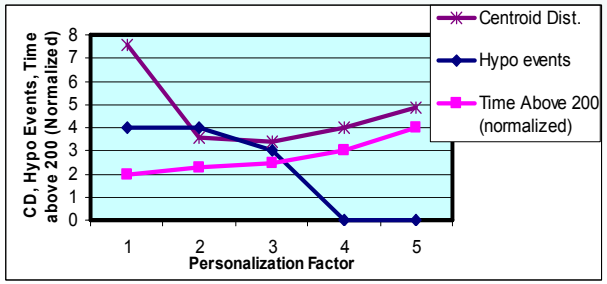
(LBGI, HBGI) Graph, 1 Controller



(LBGI, HBGI) Graph, 3 Controllers



CD, Hypo & Hyperglycemic Events



4) Secondary Metric

A measure of the variability of dispersion of the (LBGI, HBGI) data for a particular controller can be taken as the product of the sample standard deviations of LBGI and HBGI across subjects. This is found from the standard formula for the product of two standard deviations[3], $SD_{LBGI*HBGI}$, or simply SD:

$$SD_{LBGI\text{-}HBGI} = \frac{\overline{LBGI} \cdot \overline{HBGI}}{\sqrt{K}} \left[\frac{SD_{LBGI}^{\,2}}{\left(\overline{LBGI}\right)^2} + \frac{SD_{HBGI}^{\,2}}{\left(\overline{HBGI}\right)^2} + 2 \cdot \frac{COV_{LBGI\text{-}HBGI}}{\overline{LBGI} \cdot \overline{HBGI}} \right]^{1/2}$$

It is recommended that SD be used as a secondary metric of controller performance because of the tendency of LBGI values to have less variability than HBGI values.

5) Results & Conclusion

CD was found for 10 adults using *in silico* simulation, developed at the University of Virginia[5], using a fuzzy logic controller with 5 personalization factors (PF1-5). The PFs modify the aggres-siveness of treatment, with a higher PF administering more insulin for a given condition. The number of hypoglycemic events and hyperglycemic periods (Time > 200 mg/dl) was plotted as a function of PF on the lower graph. The minimum CD corresponded to the crossing of the number of hypoglycemic, and hyperglycemic events. This can be taken as an appropriate compromise of safety and effectiveness for a controller. The use of CD will be evaluated further during planned *in silico* & human studies of an insulin pump controller.

References

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