A Novel Methodology to Evaluate Continuous Glucose Monitoring Accuracy
and Clinical Representation of Glucose Exposure and Variability

1. Abstract

SMBG combined with Ambulatory Glucose Profile (AGP) analysis was used to determine whether time lag and difference between glucose in blood and interstitial fluid (ISF) could be ameliorated. For 8 days subjects with type 1 diabetes used Guardian RT® (RT) for CGM and OneTouch Ultra® (OT) for SMBG. On the study. YSI vs. OT showed overlapping paths, -0.5±1.9 min lag, and 4.8% mean relative absolute difference (RAD); YSI vs. RT produced variable lag, 21.9±4.7 min (range 17-32 min) and 19.3% RAD (exaggerated during glucose instability). Clarke Error Grid (CGM vs. YSI) showed 61% clinically accurate (A), 36% benign (B) CGM (averaging 2300±300) into a modal day and depicting the data as 5 algorithmically smoothed curves the effect of time lag on insulin administration (Figure 1).

6. Findings

PART C: CGM Employing AGP Analysis

Example of the AGP for one subject using the DEX for 8 days.

The AGP analysis in a) overlaid graphically upon downloading sensor data.

PART B: Laboratory Comparison Using GRT and DEX Simultaneously

In terms of accuracy (time lag, value difference, rate of change and glucose exposure) the devices vary between each other and the YSI reference.

In terms of reliability, both devices lost measurements due to calibration, sensor failure and user error.

In terms of possible clinical errors (Clarke Analysis), while both devices had over 90% values within "clinically accurate" or "benign" zones, GRT had 7% of values in the "failure to treat" zone. When AGP analysis was applied, we found that despite device limitations the use of the Guardian RT and the Similarity AGP for overall assessment of glycemic control is promising. During periods of spontaneous use, the clinical difference between devices were propagated through application of AGP analysis; otherwise, we do not believe that these devices, in their current form, are useful for routine clinical decision-making due to their variability in concurrent accuracy and reliability.