Glycemic Variability And Indices Of Glycemic Control Among Pregnant Women With Type 1 Diabetes Based On Use Of Constant Glucose Share Technology

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GLYCEMIC VARIABILITY AND INDICES OF GLYCEMIC CONTROL AMONG PREGNANT WOMEN WITH TYPE 1 DIABETES BASED ON USE OF CONTINUOUS MONITORING SHARE TECHNOLOGY

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Chronic Disease Epidemiology Department
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Abstract

Pregnant women with type 1 diabetes (T1D) experience increased glycemic variability as a result of changing insulin sensitivity and resistance throughout gestation. Therefore, strategies that help pregnant women with T1D manage their glycemic control are of great interest. We examined whether remote monitoring of Continuous Glucose Monitor (CGM) data by friends and family affects glycemic variability during pregnancy compared to CGM use alone in a pilot non-randomized trial (n = 28). During preconception or the first trimester, women with T1D were placed in one of two groups based on device compatibility: (1) CGM Alone (n = 13): women without iPhone, iPad or iPod Touch; or (2) CGM Share (n = 15): women with iPhone, iPad, or iPod Touch and followers with devices compatible for data viewing. Linear mixed models and t-tests we used to compare indices of glycemic control and glycemic variability over time between groups and during each trimester. Mean sensor glucose was lower in the CGM Share group than the CGM Alone group (p = 0.003). Estimated hemoglobin A1c from CGM data decreased in both groups as pregnancy progressed and was significantly lower over time in women using CGM Share compared to CGM Alone (p = 0.028). Glucose management index was also lower among women in the CGM Share group (p = 0.041, Table 2). Average number of excursions above 200 mg/dL was higher in the CGM Alone group (p = 0.021). In this small pilot study, use of CGM with remote monitoring was associated with a lower risk of hyperglycemia, lower standard deviation, and lower area under the curve. However, other measures of glycemic variability including mean amplitude of glucose excursions, and coefficient of variation, were similar between groups. A larger, randomized study is warranted to confirm if CGM Share use helps pregnant women with T1D achieve tighter glucose control across multiple clinical measures.
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Introduction

Pregnancies complicated by type 1 diabetes (T1D) are associated with a high rate of maternal and neonatal complications, with an estimated 50% of newborns experiencing complications associated with maternal hyperglycemia. While significant advances have been made regarding treatment options to improve glycemic control in pregnancies among women with T1D, there have been minimal improvements in neonatal morbidity over the past several decades.

Tightly regulating blood glucose levels and decreasing hemoglobin A1c (HbA1c) to the normal or near-normal range, without inducing significant hypoglycemia, before and throughout gestation is associated with a reduced risk of adverse health outcomes. HbA1c has long been considered the gold standard measure of glycemic control. Yet, a growing body of evidence lead to a consensus statement by multiple leading scientific organizations suggesting that HbA1c should be supplemented by data from continuous glucose monitoring (CGM). The consensus statement includes a pregnancy-specific time in range (63-140 mg/dL). An emerging body of evidence suggests that measures of CGM-derived glycemic control (like time in range) and of glycemic variability (GV), may provide a more comprehensive understanding of glycemic control.
fluctuations within and between days compared to the HbA1c alone. Several studies have also suggested that GV may be a predictor independent of HbA1c of micro- and macrovascular complications in patients with T1D. Though these data were derived from non-pregnant populations, the associations between GV and complications may be particularly true during pregnancy, as evidenced by the CONCEPTT trials. The CONCEPTT trial was a large, international multi-center study wherein women with T1D either in preconception or in pregnancy were randomized to CGM therapy or self-monitoring of blood glucose levels for the remainder of their pregnancies. The use of CGM was associated with significant reductions in rates of multiple adverse neonatal outcomes (large-for-gestational age infants, neonatal hypoglycemia requiring intravenous dextrose, neonatal intensive care unit stays >24 hours), but only a modest reduction in HbA1c (6.53% control group vs. 6.35% CGM group, p=0.021 for difference between groups of the mean difference of HbA1c over pregnancy). The significant and clinically meaningful reduced rates of adverse neonatal outcomes despite similar HbA1c levels between groups may be due to factors beyond HbA1c, specifically improved glucose control (time in range) and reductions in GV measures (e.g. standard deviation (SD), mean amplitude of glucose excursions (MAGE), and rate of change) which were significantly different between the arms.
A limited number of trials have assessed whether diabetes technology interventions minimize glycemic fluctuations and/or reduce adverse outcomes for pregnant women and their neonates. Among diabetes technology studied in pregnancy, data on remote monitoring has been particularly scarce. Remote monitoring is technology in which followers of patients can view glucose trends and receive glucose alerts, with providers and/or patient supporters (e.g. family members) being followers. In the several studies assessing the role of remote monitoring of pregnant women by providers, there have been conflicting results with some showing lowered mean blood glucose and J-indices\textsuperscript{10} and others showing no significant differences in HbA1c\textsuperscript{11,12}. However, none of these studies have assessed the impact of remote monitoring by family/friends, as opposed to providers, on glycemic control in pregnant women.

To understand more about if Share Technology could be beneficial in pregnancies complicated by T1D, we conducted a pilot intervention study among pregnant women with T1D comparing CGM use by itself (CGM Alone) to CGM use with remote monitoring by family and friends (CGM Share). Previously, we reported on the effect of CGM Share on HbA1c, median sensor glucose levels, maternal and neonatal outcomes, and fear of hypoglycemia\textsuperscript{13} Presently, we evaluate the effect of CGM with and without remote monitoring on other indices of glycemic control and GV.
Materials and Methods:

Study Design and Stratification

This single-center, open-label, non-randomized, investigator-initiated pilot study prospectively enrolled two cohorts of patients: (1) women with T1D who were within the first trimester of gestation or who were seen for preconception care, and (2) followers (family and friends) of pregnant women with T1D within the first trimester. We previously reported the full study design and methods14, but briefly, pregnant women enrolled in the study were prospectively stratified to one of two groups based on device compatibility and willingness to wear a CGM: (1) CGM use with Share (CGM Share): women with iPhone, iPad, or and followers with devices compatible for data viewing or (2) CGM use alone (CGM alone): women without iPhone, iPad, or iPod Touch. At the time of study enrollment, CGM Share was not available on Android devices.

Study Procedures

Participants were given the Dexcom G4 system for the duration of their pregnancy, or the Dexcom G5 sensors if they were using this system prior to study enrollment. Pregnant participants were trained on the use of the Dexcom G4/G5 Platinum CGM system with Share™ (CGM Share) or without Share (CGM Alone) depending on their group assignments. Share is a Bluetooth low energy secure wireless communication system. Share allows remote viewing of sensor glucose levels, trends, and data between the person with diabetes wearing the CGM and her designated family members/friends, and provides alerts (alarms) for prespecified low and high CGM values.
Pregnant women came to the Barbara Davis Center Pregnancy & Women’s Health Clinic at least once a month for routine peri-partum care and study visits. Participants were seen for a final post-partum study visit between 4 weeks and 3 months after delivery. Glucose meters, insulin pumps, and CGMs were downloaded throughout the study, and point-of-care HbA1c levels were collected at each study visit. As acetaminophen use may affect CGM device performance\textsuperscript{15}, women were instructed to document each use both as an event marker in the CGM system and on paper.

\textit{Statistical Analysis}

Participant data were excluded from analysis in the case of miscarriages without re-enrollment in the study from a subsequent pregnancy, participant drop-outs, and investigator withdrawal of participants. CGM data within 12 hours of acetaminophen use were also excluded. Demographic and clinical characteristics of the groups were compared using Wilcoxon Mann-Whiney U-test for continuous variables or Fisher exact tests for categorical variables. Linear mixed models were used to compare indices of GV and glycemic control over time. Trimester of pregnancy was treated as a categorical variable to assess nonlinear trajectories over time. For each GV measure and indices of glycemic control, the interaction between group and time was evaluated to assess whether trajectories varied by group. Non-significant interactions were removed. The mean values of each indices of GV and control across trimesters were compared using t-tests. Multiple regression analysis was conducted to assess the predictive ability of baseline characteristics on mean measures of GV during the second trimester that were found be statistically significantly different between CGM Share and CGM Alone. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of
Colorado Denver. All statistical analyses were conducted using SAS Version 9.4 and statistical significance was set at $p = 0.05$.

**Results:**

Forty women were prospectively enrolled during preconception ($n=15$) and the first trimester of gestation ($n=25$). Eight women in the preconception group became pregnant within the study period (53%). Two women had miscarriages and became pregnant again during the study period in the preconception group, thus they were re-enrolled. There were 5 miscarriages, 1 woman dropped out, and 1 woman was withdrawn, leaving a total of 28 out of 35 pregnancies for analyses. There were 13 women assigned to CGM Alone and 15 assigned to CGM Share.

There were no significant differences in median age, diabetes duration, body mass index, basal insulin, and bolus insulin between pregnant women in the CGM Alone group and CGM Share group at the preconception baseline (Table 1). Significantly more women in the CGM Alone group reported a history of past cigarette use (67% CGM alone, 20% CGM Share, $p = 0.034$). There were borderline significant differences in method of insulin delivery, with more women in the CGM Alone group using multiple daily injection (MDI) therapy at baseline (54% CGM Alone, 13% CGM Share, $p = 0.055$) when compared to women in the CGM Share group. Additionally, women in the CGM Alone group had non-significant, but clinically meaningful, higher median baseline HbA1c (8.1% CGM Alone, 7.1% CGM Share, $p = 0.112$) when compared to women using CGM Share (Table 1).

During follow-up, mean sensor glucose was significantly lower in CGM Share users than CGM Alone users in each trimester ($p = 0.033$) (Table 2). Estimated HbA1c from CGM data decreased in both groups as pregnancy progressed and was significantly lower over time in
women using CGM Share compared to CGM Alone (p = 0.028). Glucose management index (GMI) was also lower among women in the CGM Alone group (p = 0.041). Time spent under 63 mg/dL and over 140 mg/dL were similar between the two groups. Average number of excursions over 200 mg/dL was significantly lower in CGM Share users (p=0.021). Although statistically insignificant, there was a trend in which those in the CGM share group, spent more time in the pregnancy-specific time in range of 63 to 140 mg/dL (0.060).

Those in the CGM Alone group had a significantly higher High Blood Glucose Index (HBGI) and mean area under the curve (AUC) than those in the CGM Share group in each trimester (p = 0.012 and p = 0.261, respectively) (Table 3). Those in the CGM Alone group also had a lower standard deviation compared to those in the CGM Share group (p = 0.046). Other measures of GV including the coefficient of variation, mean amplitude of glycemic excursions (MAGE), and low blood glucose index (LBGI) were similar between the two groups.

Finally, we also evaluated baseline characteristics as potential predictors of mean HBGI, AUC, and SD during the second trimester, but there were no statistically significant associations in our multivariate regression model (data not shown).

**Discussion:**

In this pilot study of 28 pregnancies complicated by T1D, we found that use of CGM with remote monitoring was associated with a lower risk of hyperglycemia (HBGI), lower standard deviation, and lower area under the curve (AUC). However, other measures of GV (MAGE and coefficient of variation) were similar between groups. As previously reported, while HbA1c decreased in both groups throughout the pregnancy, HbA1c over time was significantly lower among women using CGM Share compared to CGM Alone compared to preconception HbA1c.
levels. Mean sensor glucose was also lower among women in CGM Share compared to CGM alone.

The effect of remote monitoring by friends and family on GV and other glycemic control parameters in pregnant women has not previously been assessed, to our knowledge. However, there are studies using interventions with remote monitoring by providers and studies with family or friends as followers conducted in non-pregnant diabetic populations. One study assessed the effect of remote monitoring by providers compared to standard of care weekly clinical examinations. Providers reviewed data collected and uploaded by pregnant patients with T1D every day and communicated modifications by phone to participants. Among those in the intervention group, there was a significant improvement in GV (J-index) when compared to those in the control group. Another study assessed the effect of real-time CGM monitoring by parents and daytime caregivers in school-aged children, but did not assess the effect on GV. They found that all parents and caregivers reported improved psychosocial measures such as decreased overall worry/stress. Remote monitoring by providers has also been studied in a diabetes camp setting, with one study reporting a significant reduction in prolonged nocturnal hypoglycemia, such that campers without remote monitoring had a median duration of hypoglycemic events <70 mg/dL of 35 minutes compared to those with remote monitoring having a median duration of 30 minutes (p = 0.078).

In our study of pregnant women with T1D followed by a non-provider population, we found a significant reduction in HBGI, AUC, and SD. We also found numerical reductions in other indices of GV such as MAGE and LBGI, favoring CGM Share, though they did not meet statistical significance. A larger randomized trial could more definitely assess if indices of
glycemic control and GV would differ with an intervention utilizing remote monitoring by friends and/or family.

This finding of reduced HBGI, AUC, and standard deviation in this high-risk population should be interpreted with caution, as this was a pilot study, but nonetheless, may have clinical implications. First, the Hyperglycemia and Adverse Outcomes Study (HAPO) measured glucose values before, 1 hour, and 2 hours after a glucose load (oral glucose tolerance tests) in pregnant women and analyzed the data based on septiles of glucose control. They found that increases in all these values were independently associated with birth weight >90th percentile, cesarean delivery, and neonatal hypoglycemia. These findings were based on a single oral glucose tolerance test performed between 24 and 32 weeks gestation. The CONCEPTT study found that in pregnant women with T1D randomized to CGM or self-monitoring of blood glucose throughout gestation, the mean HbA1c levels were similar between groups (and similar to the mean HbA1C levels in our cohort as well). Yet, CGM time in range and time spent >140 mg/dL were significantly lower in the CGM group. These differences may be enough to reduce rates of adverse neonatal outcomes. This provides additional evidence that in pregnancy, glycemic excursions are clinically meaningful and impactful. Second, outside of pregnancy reduced glycemic fluctuations are associated with a higher quality of life. If such a relationship also exists in pregnancy, this is particularly important as pregnancies complicated by T1D are associated with lower psychological well-being and quality of life.

Our study has several strengths. To our knowledge, this was the first study that has analyzed the role of remote monitoring by family and friends of pregnant women on GV and other glycemic parameters. All participants used CGM devices manufactured by the same company and the adherence to CGM use was high. However, our study has some limitations that should be
noted. First, our power to detect differences across all measures of GV and glycemic control may have been limited due to this being a small pilot study. Additionally, this was a non-randomized trial. At the time of study enrollment, CGM Share was not available on Android devices and the option of providing all study participants with CGM Share compatible devices was cost prohibitive. This may have introduced confounding in that the CGM Share arm may have underlying differences for which we have not accounted and which may be associated with a difference in socioeconomic status. There were underlying differences between the two groups, most notably the method of insulin delivery at baseline and maternal cigarette use.

**Conclusions:**

In this non-randomized pilot study, remote monitoring of sensor glucose trends and real-time alerts by family/friends (CGM Share) was associated with a lower risk of hyperglycemia in pregnancies complicated by T1D. Remote monitoring by a non-provider population may have therapeutic potential to assist pregnant women to optimize glucose control during gestation. Larger randomized trials are needed to see whether there is a reduction in other GV indices and if the findings of this pilot can be replicated.
References


14. Polsky, S. et al. Continuous glucose monitor use with and without remote monitoring in


Table 1. Characteristics at First Pregnancy Visit by CGM Share Status

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CGM Alone (n =13)</th>
<th>CGM Share (n =15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) ab</td>
<td>24.4 (21.2, 30.3)</td>
<td>28.9 (26.7, 31.0)</td>
</tr>
<tr>
<td>Diabetes durations (years) a</td>
<td>13.2 (7.0, 19.0)</td>
<td>18.0 (10.0, 21.0)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>25.8 (24.6, 28.5)</td>
<td>24.7 (24.2, 31.4)</td>
</tr>
<tr>
<td>Past cigarette use, n (%) b</td>
<td>8 (67)</td>
<td>3 (20)</td>
</tr>
<tr>
<td>Method of insulin delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple daily injections) bc</td>
<td>7 (54)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Insulin pump therapy</td>
<td>6 (46)</td>
<td>9 (69)</td>
</tr>
<tr>
<td>Basal insulin (units) a</td>
<td>32.5 (20.0, 54.0)</td>
<td>23.1 (18.6, 30.0)</td>
</tr>
<tr>
<td>Bolus insulin a</td>
<td>24.1 (15.5, 31.9)</td>
<td>19.7 (14.3, 28.3)</td>
</tr>
<tr>
<td>Preconception HbA1c (%) a</td>
<td>8.1 (7.2, 9.0)</td>
<td>7.1 (6.3, 8.4)</td>
</tr>
</tbody>
</table>

Abbreviations: CGM, continuous glucose monitor

a Median (25th percentile, 75th percentile)
b P-value < 0.05 at baseline
c Three women on CGM Alone and two on CGM Share changed MDI to insulin pump therapy during the pregnancy (p = 0.07)
<table>
<thead>
<tr>
<th>Trimester</th>
<th>Glycemic Control Index</th>
<th>CGM Alone</th>
<th>CGM Share</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean glucose (mg/dL) *</td>
<td>131 (120.9, 148.1)</td>
<td>128 (115.1, 136.4)</td>
</tr>
<tr>
<td></td>
<td>Estimated HbA1c (%)</td>
<td>6.2 (5.9, 6.8)</td>
<td>6.1 (5.6, 6.4)</td>
</tr>
<tr>
<td></td>
<td>GMI</td>
<td>6.5 (4.5, 8.9)</td>
<td>6.4 (6.1, 6.6)</td>
</tr>
<tr>
<td>1</td>
<td>Time spent below 63 mg/dL (%)</td>
<td>7.3 (4.5, 8.9)</td>
<td>7.1 (3.4, 8.2)</td>
</tr>
<tr>
<td></td>
<td>Time spent 63-140 mg/dL (%)</td>
<td>52.9 (46.6, 74.1)</td>
<td>60.0 (54.6, 69.0)</td>
</tr>
<tr>
<td></td>
<td>Time spent above 140 mg/dL (%)</td>
<td>35.6 (21.7, 49.0)</td>
<td>34.0 (24.3, 41.0)</td>
</tr>
<tr>
<td></td>
<td>Average excursions &gt; 140 mg/dL</td>
<td>2.8 (2.3, 3.1)</td>
<td>2.7 (2.4, 3.2)</td>
</tr>
<tr>
<td></td>
<td>Average excursions &gt; 200 mg/dL *</td>
<td>1.30 (0.8, 1.9)</td>
<td>1.03 (0.3, 1.5)</td>
</tr>
<tr>
<td>2</td>
<td>Mean glucose (mg/dL) e</td>
<td>140 (123.9, 154.8)</td>
<td>131 (111.3, 140.8)</td>
</tr>
<tr>
<td></td>
<td>Estimated HbA1c (%)</td>
<td>6.5 (5.9, 7.0)</td>
<td>6.0 (5.5, 7.1)</td>
</tr>
<tr>
<td></td>
<td>GMI</td>
<td>6.7 (6.30, 7.00)</td>
<td>6.40 (6.00, 6.70)</td>
</tr>
<tr>
<td>3</td>
<td>Time spent below 63 mg/dL (%)</td>
<td>4.84 (3.62, 7.35)</td>
<td>5.20 (3.91, 8.12)</td>
</tr>
<tr>
<td></td>
<td>Time spent 63-140 mg/dL (%)</td>
<td>50.7 (44.1, 58.1)</td>
<td>56.8 (48.8, 69.1)</td>
</tr>
<tr>
<td></td>
<td>Time spent above 140 mg/dL (%)</td>
<td>38.2 (21.7, 49.0)</td>
<td>35.1 (24.3, 41.0)</td>
</tr>
<tr>
<td></td>
<td>Average excursions &gt; 140 mg/dL</td>
<td>46.1 (30.4,51.1)</td>
<td>37.2 (21.9,43.1)</td>
</tr>
<tr>
<td></td>
<td>Average excursions &gt; 200 mg/dL *</td>
<td>12.9 (5.9, 21.0)</td>
<td>9.1 (2.4,15.5)</td>
</tr>
</tbody>
</table>

Abbreviations: GMI, glucose management index.
* P-value < 0.05 for group difference.
Descriptive statistics are median (25th percentile, 75th percentile)
Table 3: Indices of Glycemic Variability by CGM Share Status among Pregnant Women with T1D

<table>
<thead>
<tr>
<th>Trimester</th>
<th>Glycemic Variability Index</th>
<th>CGM Alone</th>
<th>CGM Share</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coefficient of Variation</td>
<td>0.39 (0.33, 0.44)</td>
<td>0.38 (0.36, 0.39)</td>
</tr>
<tr>
<td>1</td>
<td>MAGE mg/dL (%)</td>
<td>100.4 (63.8, 112.6)</td>
<td>75.1 (73.2, 86.7)</td>
</tr>
<tr>
<td></td>
<td>LBGI (%)</td>
<td>4.9 (4.5, 6.4)</td>
<td>4.9 (3.9, 5.4)</td>
</tr>
<tr>
<td>2</td>
<td>HBGI (%) *</td>
<td>7.2 (3.1, 8.4)</td>
<td>5.3 (3.9, 5.8)</td>
</tr>
<tr>
<td></td>
<td>Average AUC per day *</td>
<td>1.9 e 10 (1.7 e 10, 2.2 e 10)</td>
<td>1.8 e 10 (1.7 e 10, 1.9 e 10)</td>
</tr>
<tr>
<td></td>
<td>Standard deviation *</td>
<td>55.7 (36.1, 60.7)</td>
<td>45.9 (41.3, 49.2)</td>
</tr>
<tr>
<td></td>
<td>Coefficient of Variation</td>
<td>0.39 (0.35, 0.44)</td>
<td>0.35 (0.35, 0.38)</td>
</tr>
<tr>
<td>2</td>
<td>MAGE mg/dL (%)</td>
<td>91.1 (76.3, 103.3)</td>
<td>81.7 (67.2, 92.1)</td>
</tr>
<tr>
<td></td>
<td>LBGI (%)</td>
<td>4.9 (4.1, 5.7)</td>
<td>4.8 (4.3, 4.9)</td>
</tr>
<tr>
<td>3</td>
<td>HBGI (%) *</td>
<td>6.8 (5.6, 9.9)</td>
<td>4.8 (3.3, 6.9)</td>
</tr>
<tr>
<td></td>
<td>Average AUC per day *</td>
<td>2.0 e 10 (1.8 e 10, 2.2 e 10)</td>
<td>1.8 e 10 (1.6 e 10, 2.0 e 10)</td>
</tr>
<tr>
<td></td>
<td>Standard deviation *</td>
<td>53.0 (47.6, 64.5)</td>
<td>46.5 (39.0, 61.7)</td>
</tr>
<tr>
<td></td>
<td>Coefficient of Variation</td>
<td>0.37 (0.35, 0.41)</td>
<td>0.33 (0.31, 0.38)</td>
</tr>
<tr>
<td>3</td>
<td>MAGE mg/dL (%)</td>
<td>92.1 (76.3, 108.9)</td>
<td>75.6 (63.6, 81.1)</td>
</tr>
<tr>
<td></td>
<td>LBGI (%)</td>
<td>4.3 (3.7, 6.3)</td>
<td>4.1 (3.8, 5.3)</td>
</tr>
<tr>
<td></td>
<td>HBGI (%) *</td>
<td>6.3 (5.2, 9.0)</td>
<td>4.4 (3.1, 5.8)</td>
</tr>
<tr>
<td></td>
<td>Average AUC per day *</td>
<td>2.0 e 10 (1.9 e 10, 2.2 e 10)</td>
<td>1.8 e 10 (1.6 e 10, 2.0 e 10)</td>
</tr>
<tr>
<td></td>
<td>Standard deviation *</td>
<td>50.1 (45.0, 65.1)</td>
<td>41.9 (38.1, 49.8)</td>
</tr>
</tbody>
</table>

Abbreviations: MAGE, mean amplitude of glycemic excursion, LBGI, low blood glucose index, HBGI, high blood glucose index, AUC, area under the curve.

*P-value < 0.05 for group difference

Descriptive statistics are median (25th percentile, 75th percentile)