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The GH-Method

Applying TBR/TIR/TAR or TxR Formulas Defined by the American Diabetes Association Along with the Concept and a Tool of Glucose Density (GD%) from Distributional Data Analysis to Investigate Four Annual Continuous Glucose Monitoring Sensor Collected Glucose Data of a Type 2 Diabetes Patient Based on GH-Method: Math-Physical Medicine (No. 511)

Gerald C. Hsu*

eclaireMD Foundation, USA

Abstract

The author has read an article recently, "Glucodensities: a new representation of glucose profiles using distributional data analysis", dated August 19, 2020. Incidentally, he also made two further improvements on his glucose data analysis with his collected big data of sensor glucose via a continuous glucose monitoring (CGM) sensor device. First, HbA1C is the mean value or average value of the past 90 to 120 days (in some cases 115 days) of the red blood cell's carried glucose. Although using the HbA1C of patients as the golden standard in evaluating their diabetes condition is presently a common practice, using the mean value alone cannot tell medical doctors detailed diabetes information. Therefore, the author investigated the glucose fluctuation (GF) (glucose excursion or glycemic variability) and then transforms the GF values from a wave's time-space into an energy's frequency-space via Fourier Transform operations. Using this approach, he can then guesstimate the degree of damage on internal organs caused by the energies associated with GF. Although the GF research is one step deeper compared to the study of mean value of glucose, such as HbA1C, it is still not deep enough to provide additional detailed and useful information hidden inside of the glucose waves. Second, he realized that the average values or mean values of glucose defined by the American Diabetes Association (ADA), such as the HbA1C or time below range (TBR), time in range (TIR), time above range (TAR) can only offer partial overviews of diabetes condition due to the limitation of mean or average of data. However, these types of biomarkers are still missing some hidden internal turmoil, e.g., glucose vibrations or its severe stimulations due to all kinds of external and/or internal stimulators. Therefore, by applying his knowledge on distributional data analysis, he defined another term known as glucose density (GD) in order to explore additional, deeper, and different information hidden in collected glucose data and their waveforms. GD is defined as the occurrence frequency at a specific glucose value, for example 2.1% occurrence rate at 110 mg/dL glucose value among all of collected sensor glucose over a selected time period. In this way, he can then calculate and examine each glucose value's occurrence rate within a glucose range that is suitable to a specific patient. If this glucose examination method would be accepted by the medical community, it could be an extremely beneficial tool for doctors to quickly study the conditions of their diabetes patients. Furthermore, the author programmed this algorithm into an iPhone app software. Through the combination of his published papers and medical books along with a widely distributed app for patient's use in the future, he believes that worldwide type 2 diabetes (T2D) patients can benefit from his research work. As a part of his follow-on research tasks, he plans to further examine his GD% resulted from certain food/diet nutritional types and exercise intensity levels. Hopefully, in this way, his research papers would not be limited within the scope of a "descriptive style using 26 alphabets" but instead as a "quantitative style using 10 digits". Numbers do not lie as long as we don't use fake, unorganized, and/or uncleaned data. Statistics is a tricky tool to use because it has the obvious characteristics of garbage in and garbage out (GIGO). It is also important to know that by using statistics with different selected time-windows for certain studies will result into varying conclusions. This part of the introduction assists the author to organize and summarize his thoughts and forces him to express his abstract

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*Corresponding author: Gerald C. Hsu, eclaireMD Foundation, USA

ideas and theoretical concepts by writing them down on a piece of paper, which has helped him before. Actually, there is nothing fancy or unique about the above-mentioned two analysis methodologies. However, he would like to re-iterate what he has learned in the past and apply the mathematical tools to interpret certain interesting biophysical phenomena or solving some biomedical challenges. In this article, he compares the two final results from using both time in/above/below range (TxR) and GD% for 4 annual time periods. In summary, the author has selected to perform his research work using TxR formulas and the GD tool with his collected CGM sensor glucose data over 4 pseudo-annual periods of 2018, 2019, 2020, and 2021. Moreover, he chose a consistent glucose range covering 40 mg/dL to 285 mg/dL with a total of 246 glucose points on the x-axis of GD diagram and the GD% amplitude on the y-axis (between 0% and 3.5%). Initially, he performed his TxR analysis for each annual period. Actually, his Y2018 and Y2021 are pseudo-annual periods with 5/8/2018-12/31/2018 for Y2018 and 1/1/2021-9/8/2021 for Y2021. It should be noted that, his T2D conditions have greatly improved in recent years due to his stringent lifestyle management, he designated his TIR as the range between 70 mg/dL and 140 mg/dL and his TAR as above 140 mg/dL. Through the use of his CGM sensor glucose within the 4 pseudo-annual periods and developed app software program on the iPhone, he can generate these 4 sets of GD data and GD curves, then combine them into one diagram with the same scales of both x-axis and y-axis. He also segmented his GD% curves into 3 range of TBR, TIR, and TAR to observe their GD moving patterns individually, especially for the TIR case. With a closer examination of the above-mentioned diagrams of TxR and GD%, the author has the 3 key following observations: (1) His two calculated TxR results, by using the ADA formulas and GD% data and curves, have shown extremely high consistency between the two results. The average results of these two methods have indicated that his TIR (normal conditions) covers the range of 69%-87%, his TAR (hyperglycemia) covers the range of 11%-31%, while his TBR (hypoglycemia) covers the range of 0.2%-1.8%. In other words, he is free of risk from insulin shock, and his normal conditions have occupied the majority of his dataset. (2) Using tools of data pattern analysis and data trend analysis with the observations from the summation of GD% and average glucose values within each glucose range (TxR), in terms of his overall diabetic conditions, Y2021 is the best year, Y2020 is second, Y2018 is third, and Y2019 is the worst year. (3) A detailed examination on TIR GD% chart can reveal two more additional facts. The first fact is that Y2018 and Y2019 have highly comparable waveforms to each other which have 4 major GD spikes at the glucose levels around 99, 109, 119, and 129. Second, Y2020 and Y2021 also have highly similar waveforms in the shape of "rolling hills" with their plateaus around 100 mg/dL. These observations provide proof that his T2D control was better in 2020-2021 than 2018-2019. These types of discoveries cannot be achieved through any mean value, such as HbA1C or ADA TxR.

Keywords: Glucose density; Type 2 diabetes; Glucose fluctuation; Sensor glucose; Hyperglycemia; Hypoglycemia

Abbreviations: CGM: continuous glucose monitoring; HbA1C: hemoglobin A1C; GF: glucose fluctuation; ADA: American Diabetes Association; TBR: time below range; TIR: time in range; TAR: time above range; GD: glucose density; T2D: type 2 diabetes; TxR: time in/above/below range; MPM: math-physical medicine; FPG: fasting plasma glucose; PPG: postprandial plasma glucose

1. INTRODUCTION

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Incidentally, he also made two further improvements on his glucose data analysis with his collected big data of sensor glucose via a continuous glucose monitoring (CGM) sensor device.

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This part of the introduction assists the author to organize and summarize his thoughts and forces him to express his abstract ideas and theoretical concepts by writing them down on a piece of paper, which has helped him before. Actually, there is nothing fancy or unique about the above-mentioned two analysis methodologies. However, he would like to re-iterate what he has learned in the past and apply the mathematical tools to interpret certain interesting biophysical phenomena or solving some biomedical challenges.

In this article, he compares the two final results from using both time in/above/below range (TxR) and GD% for 4 annual time periods.

2. METHODS

2.1 MPM background

To learn more about his developed GH-Method: Math-Physical Medicine (MPM) methodology, readers can read the following three papers selected from his ~500 published medical papers.

The first paper, No. 386 describes his MPM methodology in a general conceptual format. The second paper, No. 387 outlines the history of his personalized diabetes research, various application tools, and the differences between the biochemical medicine (BCM) approach vs. the MPM approach. The third paper, No. 397 depicts a general flow diagram containing ~10 key MPM research methods and different tools.

In particular, his paper No. 453 illustrates his GH-Method: MPM in great details, "Using Topology Concept of Mathematics and Finite Element Method of Engineering to Develop a Mathematical Model of Metabolism in Medicine in Order to Control Various Chronic Diseases and their Complications via Overall Health Conditions Improvement".

2.2 The author's case of diabetes and complications

The author has been a severe T2D patient since 1996. He weighed 220 lbs. (100 kg, BMI 32.5) at that time. By 2010, he still weighed 198 lbs. (BMI 29.2) with average daily glucose of 250 mg/dL (HbA1C of 10%). During that year, his triglycerides reached to 1161 (diabetic retinopathy or DR) and the albumin-creatinine ratio (ACR) at 116 (chronic kidney disease or CKD). He also suffered from five cardiac episodes within a decade. In 2010, three independent physicians warned him regarding his need for kidney dialysis treatment and future high risk of dying from severe diabetic complications. Other than the cerebrovascular disease (stroke), he has suffered most of the known diabetic complications, including both macro-vascular and micro-vascular complications.

In 2010, he decided to launch his self-study on endocrinology, diabetes, and food nutrition in order to save his own life. During 2015 and 2016, he developed four prediction models related to diabetes condition: weight, postprandial plasma glucose (PPG), fasting plasma glucose (FPG), and A1C. As a result, from using his developed mathematical metabolism index (MI) model in 2014 and the four prediction tools, by end of 2016, his weight was reduced from 220 lbs. (100 kg, BMI 32.5) to 176 lbs. (89 kg, BMI 26.0), waistline from 44 inches (112 cm, nonalcoholic fatty liver disease/NAFLD) to 33 inches (84 cm), average finger glucose reading from 250 mg/dL to 120 mg/dL, and the lab-tested A1C from 10% to ~6.5%. One of his major accomplishments is that he no longer takes any diabetes medication since 12/8/2015.

In 2017, he has achieved excellent results on all fronts, especially his glucose control. However, during the pre-COVID period of 2018 and 2019, he traveled to approximately 50+ international cities to attend 65+ medical conferences and made ~120 oral presentations. This hectic schedule inflicted damage to his diabetes control, through dining out frequently, post-meal exercise disruption, jet lag, and along with the overall metabolism impact due to his irregular life patterns through a busy travel schedule; therefore, his glucose control and overall metabolism state were somewhat affected during this two-year heavier traveling period.

During 2020 with a COVID-19 quarantined lifestyle, not only has he published ~400 medical papers in 100+ journals, but he has also reached his best health conditions for the past 26 years. By the beginning of 2021, his weight was further reduced to 165 lbs. (BMI 24.4) along with a 6.1% A1C value (daily average glucose at 105 mg/dL), without having any medication interventions or insulin injections. These good results are due to his non-traveling, low-stress, and regular daily life routines. His knowledge of chronic diseases, practical lifestyle management experiences and developed various high-tech tools contributed to his excellent health status since 1/19/2020, which is the start date of being self-quarantined.

On 5/5/2018, he applied a CGM sensor device on his upper arm and checks his glucose measurements every 5 minutes for a total of ~288 times each day. He has maintained the same measurement pattern to the present day. In his research work, he uses the CGM

sensor glucose at a time-interval of 15 minutes (96 data per day). By the way, the difference of average sensor glucose between 5-minute intervals and 15-minute intervals is only 0.4% (average glucose of 114.81 mg/dL for 5-minutes and average glucose of 114.35 mg/dL for 15-minutes with a correlation of 93% between these two sensor glucose curves) during the period from 2/19/20-8/13/21.

Therefore, over the past 11 years, he could study and analyze the collected 2+ million data regarding his health status, medical conditions, and lifestyle details. He applies his knowledge, models, and tools from mathematics, physics, engineering, and computer science to conduct his medical research work. His medical research work is based on the aim of achieving high precision with quantitative proof in the medical findings.

The following timetable provides a rough sketch of the emphasis of his medical research during each stage:

2000-2013: Self-study diabetes and food nutrition, developing a data collection and analysis software.

2014: Develop a mathematical model of metabolism using engineering modeling and advanced mathematics.

2015: Weight and FPG prediction models using neuroscience.

2016: PPG and HbA1C prediction models using optical physics, artificial intelligence (AI), and neuroscience.

2017: Complications due to macro-vascular research such as cardiovascular disease (CVD), coronary heart disease (CHD), and stroke using pattern analysis and segmentation analysis.

2018: Complications due to micro-vascular research such as chronic kidney disease (CKD), bladder, foot, and eye issues such as diabetic retinopathy (DR).

2019: CGM big data analysis, using wave theory, energy theory, frequency domain analysis, quantum mechanics, and AI.

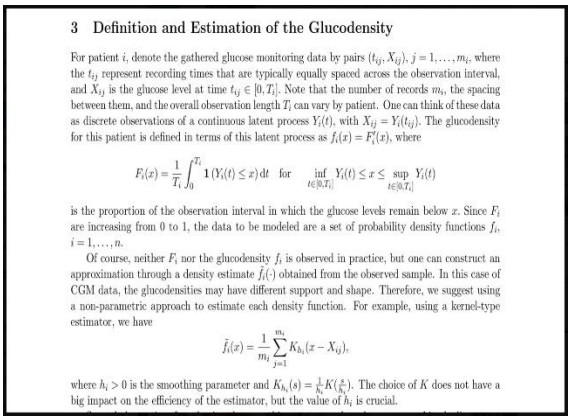
2020: Cancer, dementia, longevity, geriatrics, DR, hypothyroidism, diabetic foot, diabetic fungal infection, linkage between metabolism and immunity, and learning about certain infectious diseases such as COVID-19.

2021: Applications of linear elastic glucose theory (LEGT) and perturbation theory from quantum mechanics on medical research subjects, such as chronic diseases and their complications, cancer, and dementia. Using metabolism and immunity as the base, he expands his research into cancers, semantic, and COVID-19.

To date, he has collected more than two million data regarding his medical conditions and lifestyle details. In addition, he has written 498 medical papers and published 400+ articles in 100+ various medical journals, including 6 special editions with selected 20-25 papers for each edition. Moreover, he has given ~120 presentations at ~65 international medical conferences. He has continuously dedicated his time and effort on medical research work and shared his findings and learnings with other patients worldwide.

2.3 Glucose density (GD%)

The author took the following photo directly from the beginning part of section 3 in the "Glucodensities" paper[1] because he is not quite familiar with how to write English articles with LATAX math symbols using Page application on iPad.



3 Definition and Estimation of the Glucodensity

For patient i, denote the gathered glucose monitoring data by pairs (t_{ij}, X_{ij}), $j = 1, \ldots, m_i$, where the t_{ij} represent recording times that are typically equally spaced across the observation interval, and X_{ij} is the glucose level at time $t_{ij} \in [0, T_i]$. Note that the number of records m_i, the spacing between them, and the overall observation length T_i can vary by patient. One can think of these data as discrete observations of a continuous latent process $Y_i(t)$, with $X_{ij} = Y_i(t_{ij})$. The glucodensity for this patient is defined in terms of this latent process as $f_i(x) = F_i'(x)$, where

$$F_i(x) = \frac{1}{T_i}\int_0^{T_i} \mathbf{1}\left(Y_i(t) \le x\right) dt \quad \text{for} \quad \inf_{t\in[0,T_i]} Y_i(t) \le x \le \sup_{t\in[0,T_i]} Y_i(t)$$

is the proportion of the observation interval in which the glucose levels remain below x. Since F_i are increasing from 0 to 1, the data to be modeled are a set of probability density functions f_i, $i = 1, \ldots, n$.

Of course, neither F_i nor the glucodensity f_i is observed in practice, but one can construct an approximation through a density estimate $\hat{f}_i(\cdot)$ obtained from the observed sample. In this case of CGM data, the glucodensities may have different support and shape. Therefore, we suggest using a non-parametric approach to estimate each density function. For example, using a kernel-type estimator, we have

$$\hat{f}_i(x) = \frac{1}{m_i}\sum_{j=1}^{m_i} K_{h_i}(x - X_{ij}),$$

where $h_i > 0$ is the smoothing parameter and $K_{h_i}(s) = \frac{1}{h_i}K\left(\frac{s}{h_i}\right)$. The choice of K does not have a big impact on the efficiency of the estimator, but the value of h_i is crucial.

For the case of one patient of himself (i = 1), he can then ignore the index i and only use j = 1,…..T, where T is the overall observation length of glucose, or in this case, the total T is 246 (from 40 mg/dL to 285 mg/dL).

His gathered CGM glucose data by pairs (tj, Xj), j=1,…,T, where the Xj = Y(tj) = CGM glucose and the tj represents recording time (every 15 minutes for 96 times each day). Therefore, he can simplify the above equation in the photo further into a simplified equation for one patient only. The GD for himself can be defined in terms of a continuous format as follows:

$$GD(x) = \left(\int_{1}^{T} Y(t)\,dt \right) / T$$

with $x1 < Y(t) < x2$

where x1 and x2 are boundaries of his selected glucose range.

The GD for himself can also be defined in terms of a discrete format as follows:

$$GD(x) = \left(\sum_{j=1}^{T} Y(tj) \right) / T$$

with $x1 < Y(t) < x2$

where x1 and x2 are boundaries of his selected glucose range.

He then developed his software program using the above-described algorithm. He has turned it into one of his app software subroutines on the iPhone device in order to calculate the GD values and draw the associated GD curves.

3. Results

Figure 1 shows his raw data stored on the iPhone app. It demonstrates the results of ADA TxR results and average glucose within each TxR range for each pseudo-annual period, i.e., Y2018, Y2019, Y2020, and Y2021.

Figure 2 depicts the combined four GD% curves and his calculation data table related to the 4 pseudo-annual periods. The top diagram displays the combined GD waveforms and the bottom diagram reveals his calculated data table.

Figure 3 illustrates 3 separated diagrams of TBR <70 mg/dL, TIR 70-140 mg/dL, and TAR >140 mg/dL. It is clear that his TBR values are low, below 0.3%, his TIR values occupy the majority of the dataset, and his TAR values have a moderate volume of data size due to the selection of TAR definition of above 140 mg/dL instead of the ADA recommended 180 mg/dL. Should he use 180 mg/dL as the dividing line between TIR and TAR, his TIR would be higher than 95% while the TAR would be below 5% (see his paper No. 508).

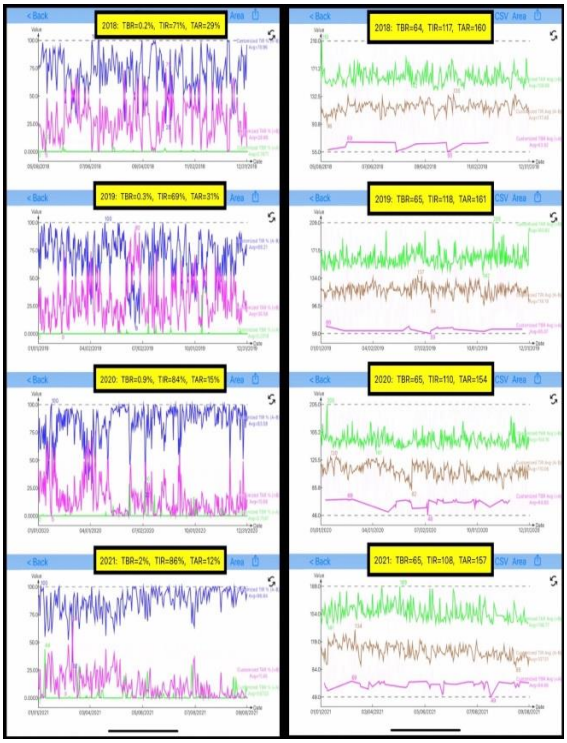
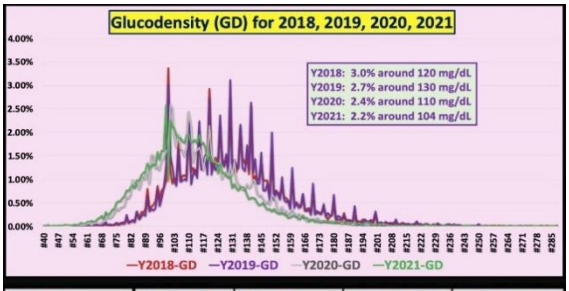


Figure 1: Raw data and curves of Y2018, Y2019, Y2020, and Y2021.



GD-TxR	Y2018-GD	Y2019-GD	Y2020-GD	Y2021-GD
Sum TBR	0.2%	0.3%	0.9%	2.0%
Sum TIR	70.5%	69.1%	84.1%	86.4%
Sum TAR	29.4%	30.6%	15.0%	11.5%
Total	100%	100%	100%	100%
APP-TxR %	**Y2018-GD**	**Y2019-GD**	**Y2020-GD**	**Y2021-GD**
TBR	0.1%	0.2%	0.8%	1.7%
TIR	71.0%	69.2%	83.6%	86.8%
TAR	28.9%	30.6%	15.7%	11.5%
Total	100%	100%	100%	100%
AVG-TxR %	**Y2018-GD**	**Y2019-GD**	**Y2020-GD**	**Y2021-GD**
TBR	0.2%	0.3%	0.8%	1.8%
TIR	71%	69%	84%	87%
TAR	29%	31%	15%	11%
TxR mg/dL	**Y2018-GD**	**Y2019-GD**	**Y2020-GD**	**Y2021-GD**
TBR	64	65	65	65
TIR	117	118	110	108
TAR	160	161	154	157

Figure 2: The combined 4 GD% curves and calculation data table.

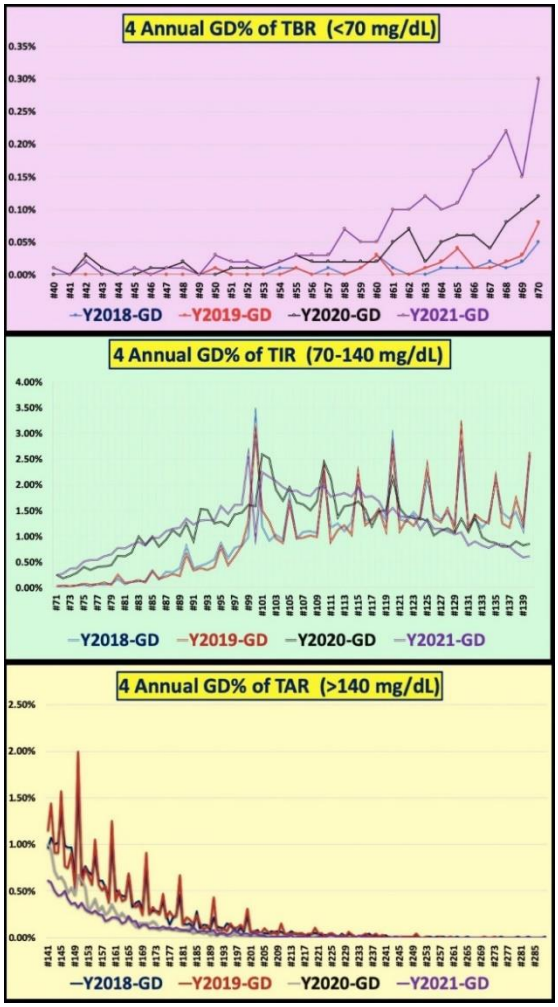


Figure 3: GD% of TBR, TIR, and TAR.

Figure 4 signifies his TxR% and GD% and average glucose mg/dL value within each range of the 4 pseudo-annual periods. The following table lists his data in the format of TBR%, TIR%, TAR%.

Y2018: 0.2%, 71%, 29%
Y2019: 0.3%, 69%, 31%
Y2020: 0.8%, 84%, 15%
Y2021: 1.8%, 87%, 11%

Another table lists his average glucose values (mg/dL) in the format of TBR, TIR, and TAR.

Y2018: 64, 117, 160
Y2019: 65, 118, 161
Y2020: 65, 110, 154
Y2021: 65, 108, 157

It is evident that his TxR% and GD% and average glucose values with range have shown that the order of his health conditions are arranged from best year to worst year: Y2021, Y2020, Y2018, and Y2019. The busy travel schedule of attending medical conferences in Y2019 made his condition worse than Y2018. This GD diagram can reveal the types of buried secrets contained in many lifestyles' abnormalities. During the on-going COVID-19 quarantine lifestyle, his health performance in Y2021 is slightly better than Y2020 due to his continuously accumulated knowledge in 2021 from his medical research work on both neuroscience and intermittent fasting.

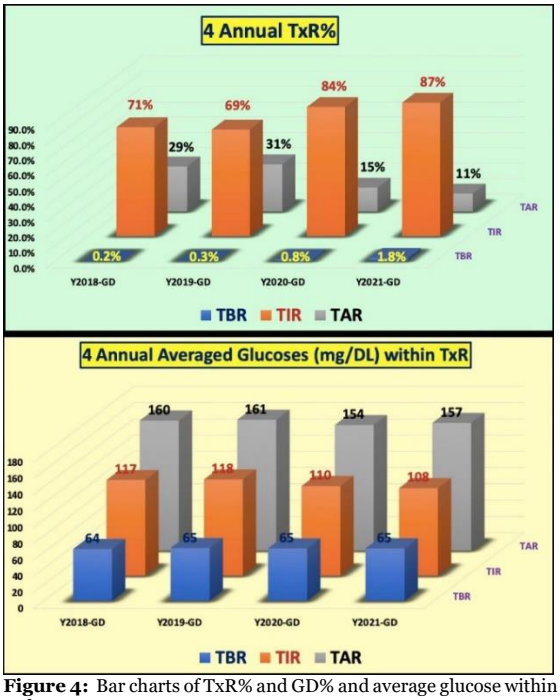


Figure 4: Bar charts of TxR% and GD% and average glucose within 3 glucose range.

4. Conclusion

In summary, the author has selected to perform his research work using TxR formulas and the GD tool with his collected CGM sensor glucose data over 4 pseudo-annual periods of 2018, 2019, 2020, and 2021. Moreover, he chose a consistent glucose range covering 40 mg/dL to 285 mg/dL with a total of 246 glucose points on the x-axis of GD diagram and the GD% amplitude on the y-axis (between 0% and 3.5%).

Initially, he performed his TxR analysis for each annual period. Actually, his Y2018 and Y2021 are pseudo-annual periods with 5/8/2018-12/31/2018 for Y2018 and 1/1/2021-9/8/2021 for Y2021. It should be noted that, his T2D conditions have greatly improved in recent years due to his stringent lifestyle management, he designated his TIR as the range between 70 mg/dL and 140 mg/dL and his TAR as above 140 mg/dL.

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5. REFERENCES

For editing purposes, majority of the references in this paper, which are self-references, have been removed for this article. Only references from other authors' published sources remain. The bibliography of the author's original self-references can be viewed at www.eclairemd.com.

1) Matabuena M, Petersen A, Vidal JC, et al. Glucodensities: A new representation of glucose profiles using distributional data analysis. Stat Methods Med Res. 30(6);1445–1464:2021.

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