

Research Article

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Extended Comparison Study among lab-Tested HbA1C, ADA's eGA HbA1C Conversion Model, and eclaireMD HbA1C Prediction Model based on lower Bound and Higher Bound of Measured Glucoses Using GH-Method: Math-Physical Medicine (No. 341)

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ABSTRACT

This paper describes the author's extended study regarding American Diabetes Association (ADA) recently recommended estimated average glucose (eAG) equation. He conducts a rational range analysis with lower bound and higher bound of different HbA1C values for type 2 diabetes (T2D) conditions by using glucoses collected via finger-piercing test strip method (Finger) and continuous glucose monitoring sensor (CGM Sensor). This study also includes his developed eclaireMD mathematical model of predicted HbA1C and A1C value calculated using the ADA's eAG A1C conversion equation.

This article covers Phase 3, from 5/5/2018 - 10/8/2020, of the same eAG research started in Phase 1 for paper No. 100, from 5/5/2018 - 7/7/2019, and Phase 2 for paper No. 155, from 5/5/2018 - 12/21/2019. Therefore, the Method section in Phase 3 is the same as in Phase 2; however, the results in this report are based on a much broader time-range of glucose data.

The results are as follows:**(A) Glucose comparison**

Phase 2 (5/5/2018-12/21/2019):

Average Finger glucose: 115 mg/dL

Average Sensor glucose: 131 mg/dL

Phase 3 (5/5/2018-10/8/2020):

Average Finger glucose: 113 mg/dL

Average Sensor glucose: 127 mg/dL

(B) HbA1C comparison

Phase 2 (5/5/2018-12/21/2019):

Lab-tested A1C: 6.7000% (100%)

EclaireMD A1C: 6.6908% (100%)

eAG (finger) A1C: 5.6364% (84%)

eAG (sensor) A1C: 6.1299% (91%)

Phase 3 (5/5/2018-10/8/2020):

Lab-tested A1C: 6.6250% (100%)

EclaireMD A1C: 6.5892% (100%)

eAG (finger) A1C: 5.5779% (84%)

eAG (sensor) A1C: 6.0428% (91%)

These three sets of converted HbA1C values from two different sources of glucose datasets (74,424 total data size) plus lab-tested

A1C data show that the eclaireMD A1C has the highest accuracy (100%), followed by the sensor A1C (91%), while finger A1C has the lowest accuracy (84%).

This conclusion proves the applicability and effectiveness of using the GH-Method: Math-physical medicine (MPM) method due to the high accuracy of the eclaireMD predicted HbA1C model (near 100%). The author recognized the lower accuracy associated with the Finger glucose data from his previous research work; however, he is surprised to see the existence of a 9% accuracy deviation between the sensor eAG A1C and lab-tested A1C. He has collected a sufficient amount of glucose data (~80 glucoses each day) to serve as the foundation of his numerical analysis; therefore, the possible sources of the 9% discrepancy can be found in three places: the environment and operating procedures of A1C lab-tests, the reliability of CGM Sensor device, and the data integrity from the collected dataset and validity of the ADA's eGA A1C conversion equation. Perhaps, the ADA should separate its collected dataset into two distinguished sub-groups for type 1 diabetes and type 2 diabetes.

Introduction

This paper describes the author's extended study regarding American Diabetes Association (ADA) recently recommended *estimated average glucose* (eAG) equation. He conducts a rational range analysis with lower bound and higher bound of different HbA1C values for type 2 diabetes (T2D) conditions by using glucoses collected via finger-piercing test strip method (Finger) and continuous glucose monitoring sensor (CGM Sensor). This study also includes his developed eclaireMD mathematical model of predicted HbA1C and A1C value calculated using the ADA's eAG A1C conversion equation.

This article covers Phase 3, from 5/5/2018 - 10/8/2020, of the same eAG research started in Phase 1 for paper No. 100, from 5/5/2018 - 7/7/2019, and Phase 2 for paper No. 155, from 5/5/2018 - 12/21/2019. Therefore, the Method section in Phase 3 is the same as in Phase 2; however, the results in this report are based on a much broader time-range of glucose data.

Methods

The ADA is recommending the use of a new term known as the *estimated average glucose* (eAG) for diabetes management (see the following excerpt from ADA literature).

“Healthcare providers can now report A1C results of patients by using the same units (mg/dl or mmol/l) that patients routinely see in their blood glucose measurements. Although the A1C test is an important tool, it can't replace the daily self-monitoring of blood glucose (SMBG). A1C tests don't measure a person's day-to-day control. People with diabetes can't adjust their insulin on the basis of their A1C tests. That's why blood glucose checks and log results are so important to stay in good control. From 1994, the goal for most people with diabetes has been less than 7% of HbA1C value. ADAG Study was conducted by ADA, EASD, and IDF with 507 recruited people, including 268 patients with type 1 diabetes (53%), 159 with type 2 diabetes (31%), and 80 people without diabetes (16%) from 10 international centers.”

The author conducted four glucose measurements per day by using the Finger method over the past 9-years over 3,201 days, from 1/1/2012 - 10/8/2019, with 12,804 measured finger glucose data. Furthermore, by applying a Sensor on his upper arm and measuring ~80 times per day on average, he has collected additional 70,880 measured sensor glucose data over 886 days from 5/5/2018 to 10/8/2029. However, in this study, in order to have a fair comparison, he decided to use the same time frame of 884 days from 5/5/2018 to 10/8/2020 with a total of 74,424 glucose data from finger and sensor methods. It should be noted that the author is a severe T2D patient, who had no medication intervention during the selected time period.

Based on this daily glucose measurement of 84 glucoses per day for 884 days, his big data of 74,424 collected glucose data served as a useful dataset to conduct analysis using the ADA's eAG A1C conversion equation. He has observed that his average daily sensor glucose is ~10% higher than the average daily finger glucose. These two sets of self-monitoring blood glucose (SMBG) data include fasting plasma glucose (FPG), and postprandial plasma glucose (PPG). However, his Sensor data also consist of the glucoses measured throughout the day, for example during sleep, between meals, and pre-bed.

His findings can provide some additional insights of glucose conditions to worldwide diabetes patients. Therefore, he conducted this extended big data analysis in order to compare various HbA1C results via four different methods, Finger data, Sensor data, ADA calculated data, and his mathematical prediction data.

The following ADA's equation for the conversion between eAG and A1C is used in this calculation. However, the term of eAG is replaced by the *measured average Finger glucose* and *measured average Sensor glucose* in two separate calculations, i.e. lower-bound and high-bound analyses.

$$eAG (mg/dL) = (A1C \times 28.7) - 46.7$$

or

$$A1C (\%) = (eAG + 46.7) \div 28.7$$

His HbA1C conversion calculation would yield two separate HbA1C values, representing a range of probable HbA1C values. Therefore, he could continuously research and develop a more appropriate and accurate mathematical model to calculate the HbA1C.

In 2016, he applied big data analytics, artificial intelligence (AI) techniques, auto-correction capability, and “safety margin” concept to develop a mathematical HbA1C prediction model to simulate the HbA1C value from his collected daily finger glucose data. He named it the *EclairMD A1C Model*.

His Lab-tested data were collected at the same medical laboratory on a quarterly basis for the past 8 years.

Results

Figures 1 and 2 show the time-series of daily glucose charts, finger and sensor collected, in the forms of a straightforward daily data curve and 90-days moving average curve form for Phases 2 and 3.

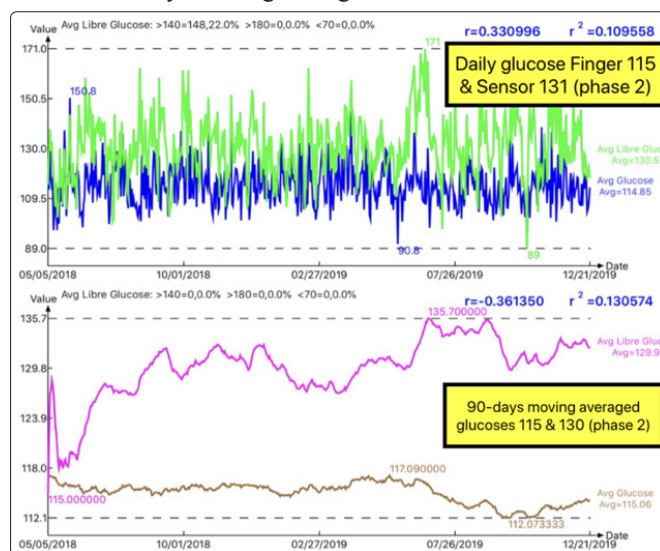


Figure 1: Phase 2: Daily glucose and 90-days moving averaged daily glucose (both finger and sensor)

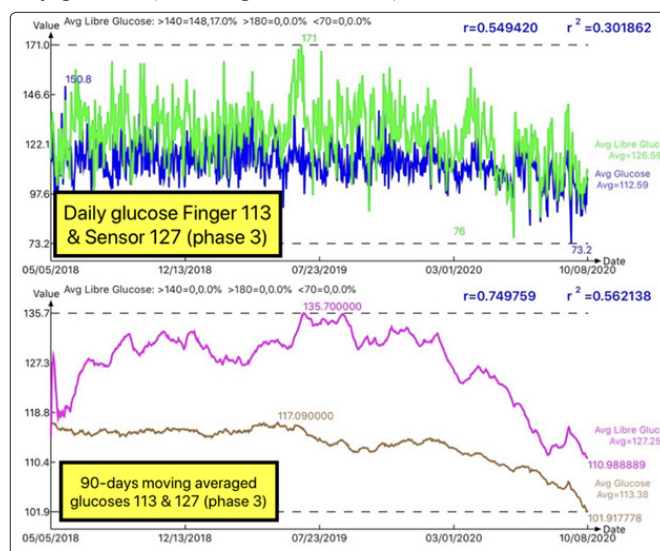


Figure 2: Phase 3: Daily glucose and 90-days moving averaged daily glucose (both finger and sensor)

The results are as follows:

Phase 2 (5/5/2018-12/21/2019)

Average Finger glucose: 115 mg/dL
Average Sensor glucose: 131 mg/dL

Phase 3 (5/5/2018-10/8/2020)

Average Finger glucose: 113 mg/dL
Average Sensor glucose: 127 mg/dL

His average glucoses are lower in Phase 3 resulting from the peaceful COVID-19 quarantined lifestyle during 1/19/2020 - 10/8/2020.

He then applied the ADA's eGA A1C conversion equation shown below to calculate the converted HbA1C values from replacing the eAG term by measured average finger glucose and measured average sensor glucose, respectively:

$$A1C (\%) = (eAG + 46.7) \div 28.7$$

Figures 3 and 4 illustrate the comparison between the Lab-tested A1C and eclaireMD A1C, and eAG A1C using the average finger glucose and average sensor glucose, for Phases 2 and 3.



Figure 3: Phase 2: Lab-tested A1C, eclaireMD A1C, Finger eAG A1C, Sensor eAG A1C

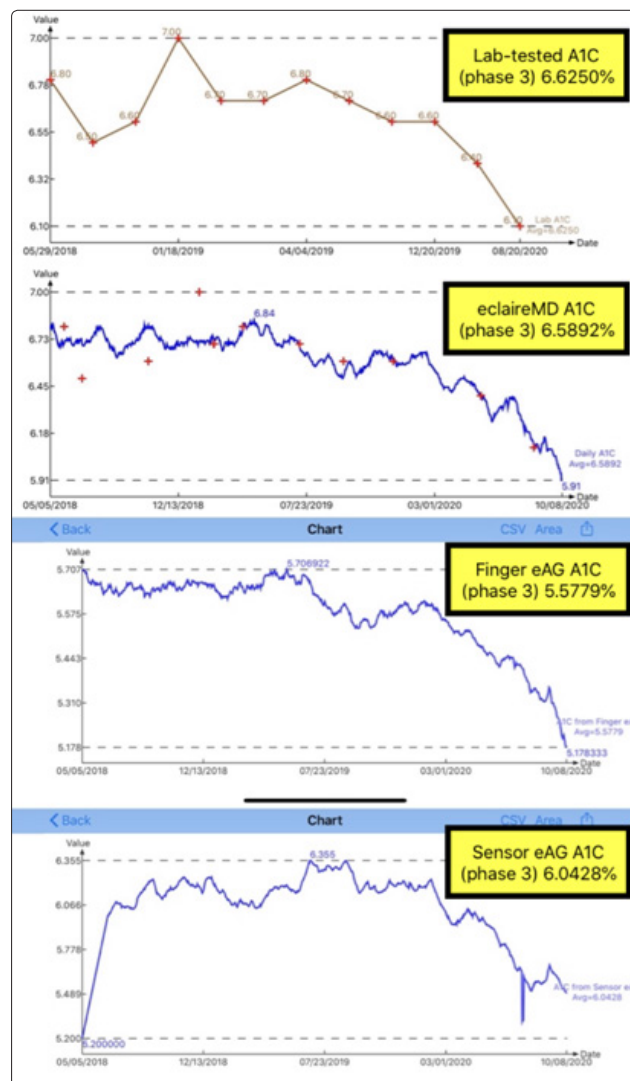


Figure 4: Phase 3: Lab-tested A1C, eclaireMD A1C, Finger eAG A1C, Sensor eAG A1C

The results are as follows:

Phase 2 (5/5/2018-12/21/2019)

Lab-tested A1C: 6.7000% (100%)
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The small data deviations between Phase 2 and Phase 3 are insignificant and minimal. This finding reveals that, after collecting 10 extra months of additional glucose data, the major characteristics of glucoses and their variations remain the same. However, by paying closer attention to the sharp declination of 2020 glucose data, it is obvious that living in a longer peaceful and non-traveling lifestyle, while still maintaining the same stringent diet and exercise routines, would offer a significant contribution to the HbA1C reduction.

From Figures 3 and 4, the average EclairMD A1C is approximately the same as the average lab-tested A1C (99.5% - 99.9%). If readers are interested to learn more about his A1C predictions of 8 equal-length periods during the past 40 months, they can view article No. 329 in Reference 4.

His Sensor eAG based A1C is 9% below the lab-tested A1C, while his finger eAG based A1C is 16% below the lab-tested A1C. This finding further proves that finger glucoses cannot portray a complete picture of a patient's glucose conditions due to its limited data amount. That is why the ADA developed the eAG standard and conversion equation based on the CGM Sensor collected glucoses. However, the finding of a 9% HbA1C deviation between Sensor eAG A1C and lab-tested A1C indicates that he may need to investigate further into the procedures and environments of the lab tests and ADA's eAG defined equation.

Conclusion

These three sets of converted HbA1C values from two different sources of glucose datasets (74,424 total data size) plus lab-tested A1C data show that the eclaireMD A1C has the highest accuracy (100%), followed by the sensor A1C (91%), while finger A1C has the lowest accuracy (84%).

This conclusion proves the applicability and effectiveness of using the GH-Method: Math-physical medicine (MPM) method due to the high accuracy of the eclaireMD predicted HbA1C model (almost 100%). The author recognized the lower accuracy associated with the Finger glucose data from his previous research work; however, he is surprised to see the existence of a 9% accuracy deviation between the sensor eAG A1C and lab-tested A1C. He has collected a sufficient amount of glucose data (~80 glucoses each day) to serve as the foundation of his numerical analysis; therefore, the possible sources of the 9% discrepancy can be found in three places: the environment and operating procedures of A1C lab-tests, the reliability of CGM Sensor device, and the data integrity from the collected dataset and validity of the ADA's eGA A1C conversion equation. Perhaps, the ADA should separate its collected dataset into two distinguished sub-groups for type 1 diabetes and type 2 diabetes [1-4].

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