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ORIGINAL ARTICLE

Frequency of Mealtime Insulin Bolus Predicts Glycated Hemoglobin in Youths with Type 1 Diabetes

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Abstract

Background: Within pediatric diabetes management, two electronic measures of adherence exist: frequency of daily blood glucose monitoring (BGM) and the BOLUS score, a measure of frequency of mealtime insulin bolusing. Past research has demonstrated that the BOLUS score is superior to daily BGM in predicting youths' glycated hemoglobin (HbA1c) in a cross-sectional study. We present data comparing the two adherence measures in predicting HbA1c using a prospective, longitudinal design.

Subjects and Methods: Blood glucose meter data and insulin pump records were collected from a clinical database of 175 youths with type 1 diabetes (mean age, 11.7 ± 3.6 years at baseline). Youths' HbA1c levels occurring at the download time and at 3, 6, 9, and 12 months post-downloads were also collected. We calculated youths' mean BGM and BOLUS score using a standardized protocol.

Results: Intraclass correlations (ICCs) revealed significant absolute equivalence between youths' predicted HbA1c values using BOLUS and BGM scores and future actual HbA1c values up to 12 months post-download. However, the ICCs of BOLUS scores with future HbA1c values were consistently higher than those of the BGM scores. Also, the predictions of the BOLUS scores were significantly more accurate ($P \leq 0.002$) than those of the BGM scores based on the root mean squared error of predictions.

Conclusions: In a prospective, longitudinal design, youths' BOLUS scores were superior to youths' daily BGM in predicting future values of HbA1c. Calculating a BOLUS score versus BGM can help researchers and clinicians achieve a better prediction of youths' HbA1c.

Introduction

It is well established in the literature that many youths with type 1 diabetes mellitus struggle in achieving an adequate level of glycemic control, as measured by glycated hemoglobin (HbA1c).[1,2] The achievement and maintenance of an adequate level of glycemic control are important in patients with type 1 diabetes to forestall the development of diabetes-related complications, including retinopathy, neuropathy, and kidney disease.[3–5] Although multiple physiological, disease, and behavioral factors are involved in determining a youth's HbA1c level,[1,6,7] adherence to diabetes self-care is the only factor that is directly modifiable.[7] Within the pediatric diabetes literature, adherence to diabetes self-care has been a focus of both assessment and intervention research. In particular, two electronic measures of self-care adherence have emerged in the literature: frequency of daily blood glucose monitoring (BGM)[8] and mean mealtime insulin bolusing (BOLUS).[9] In a cross-sectional study, both of these electronic measures were found to correlate negatively with youths' HbA1c, suggesting more frequent blood glucose testing and more frequent mealtime insulin bolusing were related to lower HbA1c levels. However, in a direct comparison, youths' BOLUS scores were found to be superior to daily BGM in explaining the variance in youths' HbA1cs when measured concurrently.[10]

What is not known is whether these two objective measures of adherence are equivalent in predicting youths' HbA1c levels when measured prospectively 3, 6, 9, and 12 months removed from the time the adherence measures were obtained. This is the focus of the current study, and we hypothesized that youths' BOLUS scores at baseline would correlate with and predict youths' HbA1c levels when measured at baseline and 3, 6, 9, and 12 months post-baseline, whereas youths' daily BGM score at baseline would not correlate and predict as well with youths' prospective HbA1c

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levels, suggesting youths' BOLUS and daily BGM scores are not equivalent when predicting HbA1c levels.

Subjects and Methods

Data for this study were randomly extracted from a clinical database of 3,453 patient records. We set up the following rules for inclusion in the analyses: (1) the patient cohort needed to be the same for all five time periods, (2) patients could not have any missing sequential values, (3) patients could only have one HbA1c measure within each time period, (4) the inclusion of as many patients as possible dominated the strict rule of having an HbA1c measure exactly every 3 months, and (5) although we allowed patients with more than 3 months between HbA1c measures, the time between patients' HbA1c measures had to be less than 6 months. These rules yielded 175 eligible youths between 2.75 to 17 years old at baseline, with a confirmed diagnosis of type 1 diabetes for at least 1 year and reported daily use of an insulin pump. Institutional approval was obtained before the data search was performed, and all data were de-identified prior to the analyses.

Procedure

For each youth, the data extraction included 14 days of self-monitoring blood glucose data, 14 days of insulin pump use, and HbA1c values measured at the time of the glucometer and pump downloads (baseline) as well as HbA1c values measured 3, 6, 9, and 12 months post-baseline. The same 14-day periods were used to calculate youths' BGM and BOLUS scores. Basic demographic data, such as youths' age at baseline and gender and race/ethnicity, were also recorded. Youths' glucometer and insulin pump records were reviewed and independently coded for BGM and BOLUS by a team of trained, certified diabetes educators. Inter-rater reliabilities for the BGM and BOLUS scores were measured ($n=175$) using intraclass correlations (ICCs).[10,11]

Measures

Daily BGM. Using 14 days of home glucometer data, we calculated a BGM score for each youth. Youths' BGM score was based on the average number of checks performed each day over the 14-day period. Inter-rater reliability for daily BGM was 0.995 ($P=0.000001$), suggesting nearly perfect reliability.

BOLUS score. Using 14 days of insulin pump data, we calculated youths' BOLUS scores based on published procedures.[12] Youths received 1 point each for a mealtime bolus occurring between 0600 to 1000 h, 1100 to 1500 h, and 1600 to 2200 h, for a total possible of 3.0 points per day. Inter-rater reliability was 0.989 ($P=0.00000001$), suggesting a very high rate of reliability.

Analyses

Predicted values. Youths' BGM and BOLUS scores were used in generalized linear models to estimate the HbA1c values at the time of data collection (i.e., baseline). The resulting estimated HbA1c values at baseline (BGM:HbA1C and BOLUS:HbA1C) were defined by the regression relationships Eqs. 1 and 2, which were identified through theory-directed exploratory data analysis.[13] Similar models had been fitted to 100 children in a previous study (included in the 175 analyzed herein).[14] Then, the predicted HbA1c values of BGM:HbA1C and BOLUS:HbA1C were used to predict youths' actual HbA1c values 3, 6, 9, and approximately 12 months in the future using generalized linear models, where $t=3$, 6, 9, and 12 are used to identify the future quarters being modeled:

$$\text{BGM:HbA1C}_1 = 8.89 - 0.198 \times \text{BGM}_1 + e_1 \quad (1)$$

where $n=175$, $F=16.7$ ($P<0.00001$), adjusted $R^2=0.153$, and β coefficient $=-0.332$ ($P<0.0001$).

$$\text{BOLUS:HbA1C}_1 = 11.13 - 1.351 \times \text{BOLUS}_1 + e_1 \quad (2)$$

where $n=175$, $F=41.5$ ($P<.00001$), adjusted $R^2=0.316$, and β coefficient $=-0.535$ ($P<0.00001$). For Eqs. 1 and 2, where ":" is read as "prediction of," BGM:HbA1C$_1$ is the BGM prediction of HbA1c at baseline, and BOLUS:HbA1C$_1$ is the BOLUS prediction of HbA1c at baseline. The β coefficients are standardized regression coefficients denoting that a 1 SD change in the independent variable (BGM or BOLUS) is associated with that change in the dependent variable (HbA1c). Thus, it is shown that the β coefficient of BOLUS is much higher and denotes that a 1 SD increase in BOLUS is associated with a 0.535% decrease in HbA1c$_1$. Also, for bivariate relationships, the β coefficient is equal to a Pearson correlation coefficient.

Root mean square error. The root mean square error (RMSE) is an objective measure of the accuracy of predictions that simultaneously captures bias (i.e., mean error vs. zero) and the variance of the error. As shown in Eq. 4, the RMSE is derived from the mean squared error (MSE):

$$\text{MSE} = \Sigma(\text{Predicted HbA1c} - \text{Actual HbA1c})^2/n \quad (3)$$

As a variance, its square root is a SD-like measure called the root mean squared error:

$$\begin{aligned}\text{RMSE} &= \text{MSE}^{0.5} \\ &= [\Sigma(\text{Predicted HbA1c} - \text{Actual HbA1c})^2/n]^{0.5} \quad (4)\end{aligned}$$

This measure was used to generate prediction intervals for future HbA1c values as illustrated in Table 1. The functional Eqs. 5 and 6 illustrate the procedures of this analysis:

$$\begin{aligned}&\text{BGM used in Eq. 1} > \text{Predicted HbA1c} \\ &\quad > \text{RMSE[BGM:HbA1C} - \text{Actual HbA1c]} \quad (5)\end{aligned}$$

$$\begin{aligned}&\text{BOLUS used in Eq. 2} > \text{Predicted HbA1c} \\ &\quad > \text{RMSE[BOLUS:HbA1C} - \text{Actual HbA1c]} \quad (6)\end{aligned}$$

where $>$ is read as yields.

Statistical tests. Means, SDs, and frequencies were calculated to describe the sample based on demographic, adherence (BGM and BOLUS), and health outcome (HbA1c). Pearson correlations were calculated to examine associations between predicted values of HbA1c based on youths' daily BGM or BOLUS scores at baseline and youths' actual HbA1c values at baseline and approximately 3, 6, 9, and 12 months

Table 1. Pearson Correlation, Intraclass Coefficient, and Root Mean Square Error for Actual and Predicted Glycosylated Hemoglobin Values

Pearson correlations[a]	*BOLUS*	*BGM*	*A1c0*	*A1c3*	*A1c6*	*A1c9*	*A1c12*	*Female*	*Base age*
BOLUS	1	0.589*	−0.564*	−0.578*	−0.571*	−0.562*	−0.541*	0.003	−0.383*
BGM	0.589*	1	−0.391*	−0.519*	−0.504*	−0.512*	−0.397*	−0.030	−0.501*
Female	0.003	−0.030	0.020	−0.001	−0.012	−0.033	0.008	1	0.019
Base age	−0.383*	−0.501*	0.282*	0.343*	0.308*	0.333*	0.300*	0.019	1
ICC[b]									
BOLUS			0.657*	0.667*	0.679*	0.677*	0.657*		
BGM			0.437*	0.527*	0.536*	0.550*	0.463*		
RMSE[c]									
BOLUS[d]				1.58*	1.46*	1.49*	1.56*		
95% CI BOLUS[e]				0–11.5	0–9.8	0–9.5	0–10.3		
BGM[d]				1.69*	1.55*	1.55*	1.68*		
95% CI BGM[e]				0–12.6	0–10.6	0–11.2	0–12.2		

Unless indicated otherwise, $P > 0.05$ for all comparisons.
[a]Correlations including four quarters of glycosylated hemoglobin (HbA1c) values post-baseline.
[b]Intraclass correlation coefficients (ICCs) of predicted HbA1c values of Eqs. 1 and 2 with future HbA1c values.
[c]Root mean squared error of predicted HbA1c values of Eqs. 1 and 2 to actual HbA1c values of quarters 3–12.
[d]Root mean square errors (RMSEs) of mealtime insulin bolusing (BOLUS) are statistically significantly lower than RMSEs of blood glucose monitoring (BGM) ($P < 0.015$).
[e]95% confidence intervals (CIs) of RMSEs of adherence measures.
*$P < 0.01$.
A1c3, A1c6, A1c9, and A1c12, mean HbA1c at 3, 6, 9, and 12 months, respectively, post-baseline; Base age, baseline age of youths.

post-baseline. To determine how equivalent youths' baseline BGM and BOLUS scores were in predicting future HbA1c values, ICCs were calculated. The ICC assesses the accuracy (equivalency) of measurements made by multiple methods when estimating the same quantity; in this case, BGM:HbA1C and BOLUS:HbA1C were used to predict future HbA1c values.[10,11] Thus, the ICCs estimate absolute equivalence of BGM:HbA1C and BOLUS:HbA1C (which were derived by BGM and BOLUS scores) to youths' actual HbA1c values. In addition, the MSE in predictions of actual HbA1c values in Periods 3–12 were calculated. The MSE measures both the consistent error (bias) and dispersion (variance) of errors when making predictions. As is true with the variance, the square root of MSE yields a SD measure, the RMSE, which is measured in HbA1c percentages.

Results

The sample of 175 youths with type 1 diabetes had a mean age of 11.7 ± 3.6 years. There were 87 boys. At baseline, youths' mean daily BGM score was 4.75 ± 3.17, and their mean BOLUS score was 2.18 ± 0.75. Table 2 lists the means and SDs for youths' actual HbA1c values at baseline through 12 months post-baseline. The sample did not differ from the clinic population from which it was drawn with respect to youth age, sex, and HbA1c (sample versus clinic population reported for each; all $P > 0.25$). For this clinic population, over 90% of youths with type 1 diabetes are on an insulin pump.

Table 2. Youths' Mean Glycosylated Hemoglobin from Baseline to 12 Months Post-Baseline

	Mean ± SD
A1c0	8.7 ± 1.9
A1c3	8.9 ± 1.9
A1c6	8.9 ± 1.8
A1c9	9.1 ± 1.7
A1c12	9.2 ± 1.8

A1c0, mean glycosylated hemoglobin (HbA1c) at baseline; A1c3, A1c6, A1c9, and A1c12, mean HbA1c at 3, 6, 9, and 12 months, respectively, post-baseline.

Table 1 illustrates the Pearson correlations, ICCs, and MSE of youths' predicted HbA1c values versus their actual HbA1c values. As shown, consistent with our hypothesis, Pearson correlations reveal strong and significant associations between predicted values of HbA1c based on youths' baseline BOLUS scores (BOLUS:HbA1C) and their future actual values of HbA1c measured 3, 6, 9, and 12 months post-baseline. In contrast, Pearson correlations between predicted values of HbA1c, based on youths' baseline daily BGMs (BGM:HbA1C), and future actual values of HbA1c were all lower, but still significant. If the BOLUS and BGM scores were equally correlated, the likelihood of all five correlations being higher for BOLUS would have $P \leq 0.03$ (i.e., 0.5^5). Although these correlations do not deviate greatly, in all cases the BOLUS prediction was better as shown in Table 1 and retained that superiority using all measures of analysis.

Using ICC, predicted values of HbA1c (BOLUS:HbA1C) correlated strongly and significantly with all of youths' actual HbA1c values, whereas predicted values of HbA1c based on youths' daily BGM (BGM:HbA1C) correlated somewhat less with actual values collected at baseline and up to 12 months post-baseline. This suggested that the derived BOLUS:HbA1C values were superior to BGM:HbA1C values when predicting future HbA1c values up to 12 months in the future (see Table 1). However, as a final and perhaps better approach to determine which adherence measure is a better predictor of future HbA1c, RMSE was used. As illustrated in the last four rows of Table 1, the confidence intervals based on RMSE were tighter for the BOLUS:HbA1C predictions

than for the BGM:HbA1C predictions, and the differences were significant based on *F* tests of the differences between the MSEs of BOLUS versus BGM ($P \leq 0.002$), also suggesting that BOLUS:HbA1C values were superior to BGM:HbA1C values when predicting youths' HbA1c up to 12 months in the future.

Discussion

Within type 1 diabetes management, two valid electronic measures of adherence now exist: BGM[8] and BOLUS.[15] The BOLUS is a measure of missed mealtime insulin boluses and follows a line of research that has shown an association between missed mealtime boluses and poorer glycemic control in youths.[9,16–18] In this study, we investigated how BGM and the BOLUS perform in predicting youths' HbA1c values prospectively up to 12 months post-measurement of adherence. Consistent with our hypothesis, youths' predicted HbA1c values based on their baseline BOLUS scores correlated strongly and significantly with youths' actual HbA1c levels up to 12 months post-baseline, whereas youths' predicted HbA1c values based on their baseline BGM scores did not correlate as well with their actual HbA1c levels. In addition, ICCs and RMSE revealed that youths' baseline BOLUS scores (BOLUS:HbA1C) were superior to the baseline BGM:HbA1C in predicting HbA1c levels up to 12 months post-baseline. The significance of these findings is that we have confirmed, through use of a prospective design, a stronger association between youths' BOLUS:HbA1C and future HbA1c values than between youths' BGM:HbA1C and future HbA1c values. Thus, our analyses further demonstrate that obtaining a BOLUS score from a youth with type 1 diabetes typically will provide a better assessment of current adherence and a better prediction of future HbA1c than obtaining a daily BGM.

Identifying the predictive abilities of relationships among variables is paramount in theory validation.[12] Therefore, as a further measure of validation, our data demonstrate that youths' BOLUS scores may be valid in predicting their HbA1c values up to 12 months post-measurement, but youths' BGM may be less valid in predicting their HbA1c values. To our knowledge, this is the first time youths' BGM have been correlated with HbA1c in a prospective model beyond 6 months. BGM is the most commonly reported electronic measure of adherence in youths with type 1 diabetes[8,13–15,19–24]; thus, it is important to report results that help to clarify its value as an adherence measure. However, in our experience, it is no more time-consuming or difficult to obtain a BOLUS than a BGM score, provided youths are using an insulin pump for diabetes management. Therefore, we would suggest, based on our current findings, that researchers and clinicians will achieve a better prediction of HbA1c based on youths' adherence behaviors if they calculate a BOLUS score instead of BGM and that the BOLUS should replace BGM as an adherence measure in clinical research and routine management. It is also possible that interventions focused on changing youths' mealtime insulin bolusing behaviors may be more successful in changing HbA1c values than interventions focused on increasing BGM, although a randomized controlled trial of each of these intervention foci will be needed to definitively determine their respective effects on HbA1c levels.

A limitation of the current study is its exclusive focus on youths managing diabetes with insulin pumps. This is inherently a limitation of the BOLUS score methodology, which relies on pump downloads to calculate scores.[25] Although insulin pump therapy is becoming more widely adopted by youths with type 1 diabetes,[25] the BOLUS score and our findings would not generalize to youths who do not use a pump. In addition, there is a possible limitation in our use of youths' home glucometer data. It is common for youths to have multiple glucometers. Therefore, it is possible that we did not capture all available blood glucose data, which could have limited our ability to prospectively relate youths' blood glucose data to their HbA1c levels. However, we would assert that this problem also exists for studies that only use BGM to measure adherence. In contrast, youths typically have only one insulin pump and will wear their pump to the clinic. Thus, an adherence measure based on insulin pump data should be more complete. Finally, the data for this study were entirely observational and gathered from a clinical database. Thus, any conclusions related to causation are limited. We can now see youths' baseline BOLUS scores are superior to their baseline BGM scores in predicting HbA1c values prospectively. However, we cannot determine that youths' baseline BOLUS or BGM scores caused youths' HbA1c values. Strengths of the present study are its prospective longitudinal design and our inclusion of quarterly HbA1c data that extend out 12 months for all youths.

In conclusion, our study now provides data examining associations between youths' BOLUS and BGM scores and their HbA1c values prospectively up to 12 months. Although our results show a gradual decline in the strength of the correlations as HbA1c values are further removed in time from youths' adherence scores (a slight decline for BOLUS:HbA1C and much greater for BGM:HbA1C), our results also show that youths' BGM:HbA1C values have a weaker correlation with HbA1c across all time points than youths' BOLUS:HbA1C scores. Additionally, we show that the predictions from the BOLUS model are statistically significantly more accurate than those of the BGM model. Thus, in this study, we provide further evidence that our adherence score based on mealtime insulin bolusing (BOLUS) is a better measure of adherence in type 1 diabetes than daily BGM.

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Author Disclosure Statement

No competing financial interests exist.

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