USE OF A DIGITAL HEALTH TOOL TO SUPPORT PEOPLE WITH DIABETES WHO INJECT BOLUS INSULIN IMPROVES THE GLYCEMIA RISK INDEX AND TIME IN TIGHT RANGE

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BACKGROUND

Continuous glucose monitoring (CGM) has emerged as an important tool to help people with diabetes manage food, activity, and insulin dosing and is recommended as the standard of care by the American Diabetes Association for individuals on mealtime insulin [1]. Time in Range (TIR), the measure of time a person spends between 70 mg/dL and 180 mg/dL has become an important metric for clinical practice [2]. We previously reported a significant improvement in TIR from a clinical trial of a digital health tool that provided AI-coaching as well as bolus insulin recommendations to people with diabetes based on their CGM data [3]. In the current analysis, we examined the outcomes and behaviors of the study participants by applying the new CGM metrics of glycemic risk index (GRI) and time in tight range (TITR) [4,5]. TITR is a measure of the time a person with diabetes spends between 70 mg/dL and 140 mg/dL [4]. GRI is a composite measure of hyperglycemia and hypoglycemia [5].

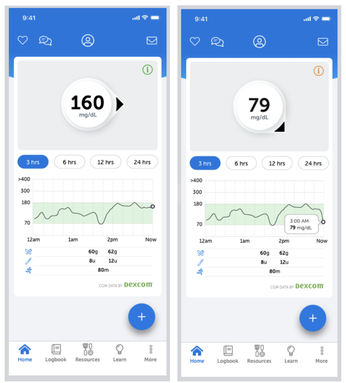
SPECIFIC AIMS/PURPOSE

We sought to correlate the glycemic metrics, TITR and GRI, to level of engagement with the digital health tool.

METHODS

Participants in the clinical study (n=54) were using a CGM device (Dexcom G6, San Diego, CA) prior to enrolling in the trial. At the start of the 30-day study period, the digital health investigational device (BlueStar, Welldoc, Columbia, MD) was configured on the participants' mobile devices. The system securely transmitted the CGM, carbohydrate, insulin and other user data to the cloud where the data was de-identified to create the data set used for this analysis. Of note, data from 5 participants was excluded from the analysis due to missing CGM or insulin calculator data.

Figure 1: Screenshots of the Digital Health Solution



RESULTS

Figure 2: Population Demographics

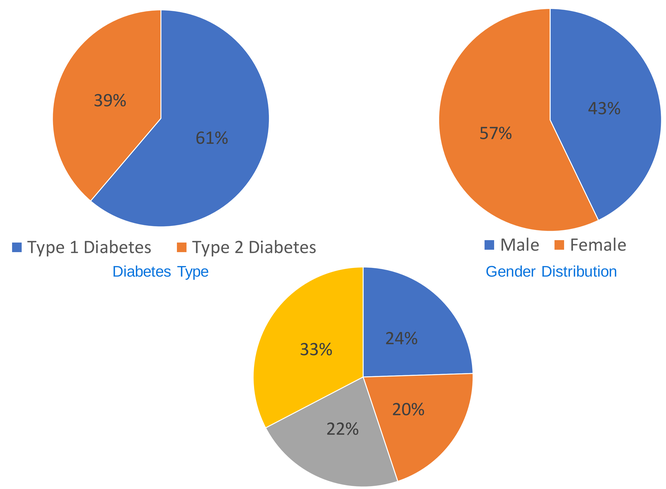


Figure 3: GRI Improvements

	GRI Total			GRI Hyperglycemia Component			GRI hypoglycemia Component		
	Baseline	Intervention	P value	Baseline	Intervention	P value	Baseline	Intervention	P value
T2D (n = 19)	24	17	0.001	14	10	0.003	0.6	0.5	.37
T1D (n = 30)	37	35	.4	21	20	.5	1	1	.54
All (n = 49)	32	28	.01	18	16	.03	.9	.8	.29

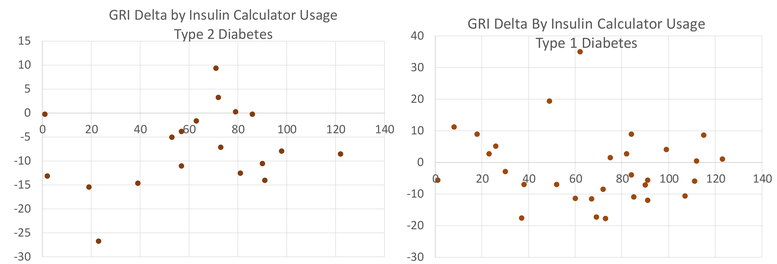
For participants with type 2 diabetes (n=19), the GRI improved from 24 to 17 (p=0.001). The hyperglycemia component of the GRI improved from 14 to 10 (p=.003). The hypoglycemia component was low and did not change significantly.

Figure 4: TIR and TITR Improvements

	TIR			TITR		
	Baseline	Intervention	P value	Baseline	Intervention	P value
T2D (n = 19)	75%	82%	0.001	41%	48%	0.02
T1D (n = 30)	65%	66%	.42	37%	39%	.21
All (n = 49)	69%	72%	.01	39%	43%	.01

TIR improved from 75% to 82% (p=0.001) and TITR improved from 41% to 48% (p=0.02). There were no significant changes in these measures for the participants with type 1 diabetes (n=30).

Figure 5: Glycemic Metrics by Level of Engagement



In examining scatter plots of GRI, TIR, and TITR as a function of insulin calculator uses, a "U"-shaped relationship was identified, suggesting optimal use of the calculator to be about 1.5 to 3 uses per day.

CONCLUSIONS

- Overall, there was a significant improvement in the mean TIR in the study population.
- The current analysis supports that this improvement was driven by those with type 2 diabetes due to a reduction in the hyperglycemia component of GRI and an improvement in TITR.
- These glucose measures had a complex relationship with engagement with the insulin calculator feature on the mobile device, suggesting that both too little use or too frequent use may be suboptimal.
- These findings may help future integration of these novel metrics into AI-driven digital health tools and to optimize feature engagement that drives key outcome measures.
- As CGM use in diabetes continues to rise, so will the criticality of AI and digital health to aggregate & translate CGM real-time data along with other health data into meaningful insights. Continued research in this area will help assess how this data can be utilized and visualized to help individuals better manage their diabetes.

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