A digital health solution with a CGM-informed insulin calculator reduces diabetes distress in individuals with type 1 and type 2 diabetes

Mansur Shomali, MD, CM[1], Abhimanyu Kumbara, MS[1], Anand Iyer, PhD[1], Jean Park, MD[2], Grazia Aleppo, MD[3]
[1]Welldoc, Columbia, Maryland,USA,[2]MedStar Health Research Institute, Baltimore, MD,USA, [3]Northwestern University, Chicago, IL, USA

ABSTRACT

People with diabetes, treated with insulin, are challenged with self-managing their insulin dosage and glucose levels in line with their nutrition, activity and sleep. This burden can often lead to distress.[1] We developed a digital health solution with an in-app calculator that automatically recommends insulin doses using continuous glucose monitoring (CGM), to help ease this burden. In a 30-day study, we found significant reductions in measures of diabetes distress as compared to baseline.

BACKGROUND

Welldoc's digital health solution provides AI-driven personalized digital coaching and support for diabetes. We enhanced the in-app calculator within the solution to automatically recommend insulin doses based on CGM data, in order to assist the user with insulin dosing, while also supporting overall health.

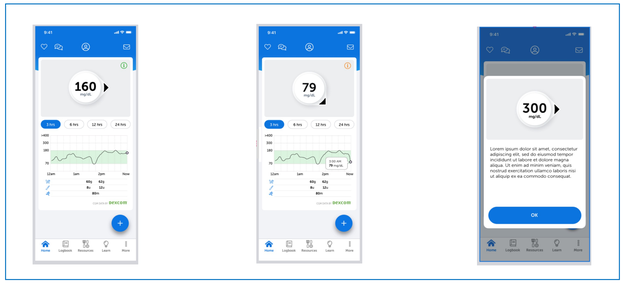
There is some evidence from blood glucose monitoring data that insulin bolus calculators (IBC) may improve glycemic control and treatment satisfaction.[2] Since the product enhancement created a new investigational device that required a safety study, we also sought to study the impact of the device on diabetes distress.

METHODS

We recruited individuals with type 1 and type 2 diabetes who were prescribed meal-time insulin and were using a CGM. Study participants downloaded the app on their personal mobile device and used it for 30 days. The 17-point diabetes distress survey (DDS17)[3,4] was administered at the first study visit as well as the final study visit 30 days later. The study was conducted at two sites in Chicago (n=28 surveys) and Baltimore (n=26 surveys).

Since study participants were not recruited based on diabetes distress levels, we examined the change in diabetes distress of the entire cohort and also in a cohort excluding participants who had little or no diabetes distress at baseline. We also examined DDS17 sub-scores, which included emotional burden, physician distress, regimen distress, and interpersonal distress. The paired t-test (2-tails) was used to assess for significance. The data collection is from an empirical study and is complete.

Figure 1: Screenshots of the IBC Mobile Application*



*The insulin bolus calculator (IBC) is an investigational device not yet cleared by the U.S. Food and Drug Administration

Figure 2: The 17-point Diabetes Distress Survey

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
3. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
4. Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
6. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
7. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
8. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6
9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
10. Feeling that diabetes controls my life.	1	2	3	4	5	6
11. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

Moderate distress 2.0 – 2.9

High distress >=3.0

Regimen distress sub-score

Interpersonal distress sub-score

Physician distress sub-score

Emotional burden sub-score

SUMMARY of FINDINGS

Figure 3: Demographic Information

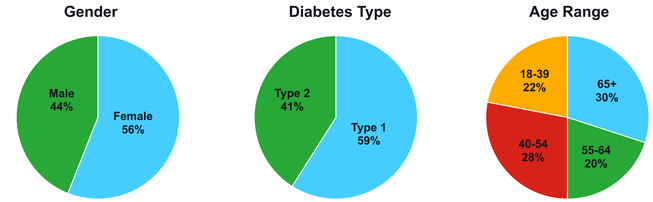


Table 1: Change in DDS17 During the Study

Group	N	Baseline DDS	End-of-Study DDS	P value
All participants	54	1.72	1.68	0.106
Distressed group*	25	2.15	2.04	0.038
DDS17 sub-scores: Regimen distress	21	2.50	2.29	0.047
Interpersonal distress	14	2.67	2.05	0.004
Physician distress	15	1.78	1.70	0.54
Emotional burden	23	2.84	2.64	0.16

*Defined as the group of participants with baseline DDS17 score greater than the median DDS17 score

IMPLICATIONS

A digital health solution that assists people with diabetes self-management and insulin dosing may reduce diabetes distress, particularly around their treatment regimen and interpersonal relationships. Future research may help reveal the mechanisms for this reduction in diabetes distress. Digital health tools can then be optimized to enhance engagement and clinical outcomes.

REFERENCES

[1]Kalra S, Jena BN, Yeravdekar R. Emotional and Psychological Needs of People with Diabetes. Indian J Endocrinol Metab. 2018 Sep-Oct;22(5):696-704.

[2]Schmidt S, Nørgaard K. Bolus calculators. J Diabetes Sci Technol. 2014 Sep;8(5):1035-41.

[3]Polonsky WH, Fisher L, Earles J, Dudl RJ, Lees J, Mullan J, Jackson RA. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. Diabetes Care. 2005 Mar;28(3):626-31.

[4]Fisher L, Hessler DM, Polonsky WH, Mullan J. When is diabetes distress clinically meaningful?: establishing cut points for the Diabetes Distress Scale. Diabetes Care. 2012 Feb;35(2):259-64.

May 25-28, 2023, Washington, D.C.