The Use of a Novel CGM-Informed Insulin Bolus Calculator Mobile Application by People with Type 1 and Type 2 Diabetes Improves Time in Range (Poster 928-P)

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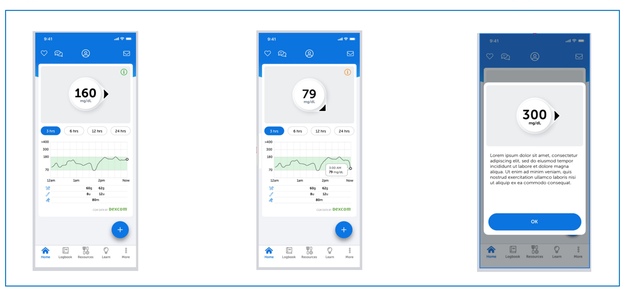
BACKGROUND AND AIMS

- People with diabetes treated with basal-bolus insulin regimens face challenges adjusting bolus doses.
- There is some evidence from blood glucose monitoring (BGM) data that insulin bolus calculators may improve glycemic control and treatment satisfaction.[1]
- Continuous glucose monitoring (CGM) systems can assist users with bolus dose optimization using trend arrows. Expert panels have published recommendations on how individuals with diabetes can use the trend arrows to more precisely calculate bolus insulin doses.[2,3]
- In every day clinical practices, the rules that are described by the expert panels for using trend arrows safely and effectively are complicated for clinicians to teach and may be challenging for patients to follow. [2,3]
- The purpose of this study was to demonstrate the safety and efficacy of a novel, CGM-informed insulin bolus calculator (IBC*, Welldoc, Inc., Columbia, Maryland, U.S.A.) that applies trend arrow adjustments to the bolus insulin dose recommendation; the trend arrow adjustment factors in exercise and recent hypoglycemia.
- The IBC was imbedded into Welldoc's BlueStar® mobile application.
- This investigational software also provided real-time coaching on CGM data to assist users in improving their time in range (TIR).

METHODS

- Fifty-four participants with T1 and T2 diabetes using CGM (Dexcom, San Diego, California, U.S.A.) were enrolled at two sites in a 30-day prospective study where they were asked to use the investigational mobile application to monitor their CGM data and calculate their insulin doses using the IBC.
- CGM metrics during the prospective 30-day study period were compared to those from 30 days of baseline data.
- Three populations were defined:
  - The intention-to-treat (ITT) group consisted of all enrolled subjects
  - The complete cases (CC) group had >=90% sensor wear time
  - The per-protocol (PP) group used the IBC at least 30 times during the study period

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

RESULTS

Figure 2: Demographic Information

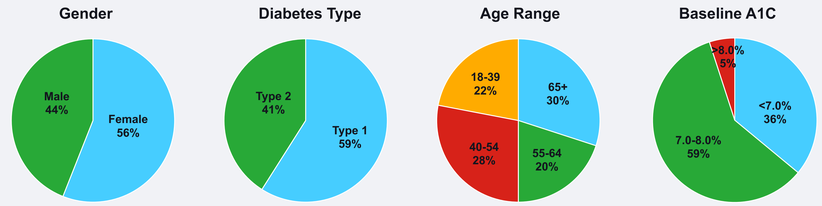


Table 1: Percentage of Time in Range (70-180 mg/dL)

Analysis Population	Baseline %	Post-Baseline (IBC) %	Difference (IBC - Baseline) %	Non-Inferiority P-value**	Superiority P-value***
Primary Effectiveness Endpoint					
Per-Protocol (PP)					
n	39	39	39		
Mean (SE)	69.2 (2.2)	73.0 (2.2)	3.8 (1.5)	< 0.0001	0.017
95% CI for Mean	(64.8, 73.6)	(68.6, 77.4)	(0.7, 6.9)		
Sensitivity Analyses					
Complete Cases (CC)					
n	49	49	49		
Mean (SE)	69.1 (1.8)	73.0 (1.8)	3.9 (1.3)	< 0.0001	0.005
95% CI for Mean	(65.4, 72.8)	(69.4, 76.7)	(1.3, 6.6)		
Intention-to-Treat (ITT)					
n	52	54	54		
Mean (SE)	68.4 (1.9)	71.8 (1.9)	3.4 (1.3)	< 0.0001	0.013
95% CI for Mean	(64.6, 72.3)	(68.0, 75.6)	(0.7, 6.0)		

**P-value is from a one-sided test, testing for non-inferiority of the IBC app to baseline using a non-inferiority margin (NIM) of 6.2%; ***P-value is from a two-sided test, testing for superiority of the IBC app to baseline

Table 2: Subgroup Analyses for Percentage of Time in Range

Subgroup	Baseline Mean (SE) %	Post-Baseline (IBC) Mean (SE) %	Difference (IBC - Baseline) Mean (SE) %	95% CI of Mean Difference %
Type of Diabetes				
Type 1 (n = 32)	64.40 (2.27)	65.20 (2.80)	1.28 (1.79)	(-2.37, 4.93)
Type 2 (n = 22)	74.73 (1.93)	81.39 (1.64)	6.53 (1.69)	(3.00, 10.06)
Number of IBC Uses				
< 30 times (n = 13)	65.51 (3.59)	66.41 (4.73)	2.25 (2.87)	(-4.08, 8.57)
30-60 times (n = 10)	68.16 (3.44)	74.13 (4.88)	5.97 (3.33)	(-1.56, 13.51)
> 60 times (n = 31)	69.93 (2.34)	73.30 (2.60)	3.00 (1.64)	(-0.35, 6.36)

Table 3: Secondary Endpoints

Parameter	Intention-to-Treat (ITT) Baseline %	Intention-to-Treat (ITT) Post-Baseline (IBC) %	Complete Cases (CC) Baseline %	Complete Cases (CC) Post-Baseline (IBC) %	Per-Protocol (PP) Baseline %	Per-Protocol (PP) Post-Baseline (IBC) %
Percentage of Time with High Glucose (> 180 mg/dL)						
n	52	54	49	49	39	39
Mean (SD)	30.33 (12.28)	27.22 (15.15)	29.78 (11.69)	25.94 (13.67)	29.67 (12.12)	25.94 (14.46)
Median	28.14	24.37	27.66	24.19	28.63	23.62
SE	1.70	2.06	1.67	1.95	1.94	2.32
Min, Max	8.3, 59.9	6.1, 73.1	8.3, 50.5	6.1, 69.5	8.3, 50.5	6.1, 69.5
Percentage of Time with Low Glucose (< 70 mg/dL)						
n	52	54	49	49	39	39
Mean (SD)	1.10 (1.05)	0.98 (0.91)	1.13 (1.07)	1.02 (0.89)	1.15 (1.10)	1.09 (0.94)
Median	0.83	0.73	0.84	0.77	0.83	0.78
SE	0.15	0.12	0.15	0.13	0.18	0.15
Min, Max	0.0, 4.5	0.0, 4.1	0.0, 4.5	0.0, 4.1	0.0, 4.5	0.0, 4.1
Glucose %CV*						
n	52	54	49	49	39	39
Mean (SD)	31.77 (6.36)	30.24 (6.54)	32.01 (6.23)	30.33 (6.45)	32.21 (6.58)	30.70 (6.95)
Median	31.03	29.58	31.35	29.79	31.35	29.79
SE	0.88	0.89	0.89	0.92	1.05	1.11
Min, Max	17.9, 48.0	17.9, 44.0	17.9, 48.0	17.9, 44.0	17.9, 48.0	17.9, 44.0
Glucose Standard Deviation						
n	52	54	49	49	39	39
Mean (SD)	49.27 (11.24)	46.06 (11.94)	49.47 (11.35)	45.84 (12.06)	49.84 (11.93)	46.54 (13.09)
Median	48.59	43.84	48.79	43.79	48.81	42.57
SE	1.56	1.62	1.62	1.72	1.91	2.10
Min, Max	29.4, 77.1	28.8, 70.5	29.4, 77.1	28.8, 70.5	29.4, 77.1	28.8, 70.5

*%CV was calculated on the log-transformed data

CONCLUSIONS

- Use of a novel CGM-informed insulin bolus calculator with trend arrow dose adjustment by individuals with type 1 and type 2 diabetes was associated with significant improvement in TIR (approximately 4%) without increasing hypoglycemia.
- IBC use was also associated with improvements in measures of glucose variability.
- The improvement in TIR was greater in individuals with type 2 diabetes (6.5%) and in those who used the IBC between 30 and 60 times per month (6%).
- The combination of digital health tools with CGM appears to confer additional benefits over the use of CGM by itself.
- Further research may fuel the development of advanced, AI-based digital health tools that help support people living with diabetes.

REFERENCES

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