mHealth Enabled Remote Monitoring Improves Diabetes Outcomes

Vikram Singh, Reid Offringa, Ph.D., Tanushree Bose, Ph.D., Michael Greenfield, M.D., Jerome Fischer, M.D. | Diabetes & Glandular Disease Clinic, 5107 Medical Dr, San Antonio, TX 78229

Introduction

The concept of remote monitoring in diabetes management is increasingly discussed by Accountable Care Organizations (ACOs), capitated health systems, and payers as a tool for improving quality of patient care while lowering costs. mHealth solutions that leverage data from patients' existing diabetes devices can facilitate broader diabetes population management and remote monitoring; however, little substantive research has been conducted to understand the value of mHealth-driven clinical interactions on patient outcomes in diabetes. We report here on the results of a pilot using Glooko, an mHealth and diabetes population management platform, for use in remote management of an adult, Type 2 diabetes population experiencing glycemic control issues.

Methodology

RECRUITMENT

Fifty-three adult subjects with Type 2 diabetes were recruited from the Diabetes & Glandular Disease (DGD) Clinic in San Antonio, Texas. Participants owned Glooko compatible smartphones and SMBG meters, and met at least one of two inclusion criteria: 1) an A1c greater than or equal to 8.5% and/or 2) insulin naive.

Subjects consented to participate in a 2 week run-in period followed by 10 weeks of intervention. Participants in both control and intervention groups were given Glooko, trained on Glooko's app and web based functionality, while they continued to receive their treatment as usual (TAU). DGD clinical staff had remote access to subject data via Glooko's Population Tracker, including subjects' most recent blood glucose readings and food, medication/insulin, and activity data logged by the subject in the Glooko mobile app.

CONTROL GROUP (N=26):

- Continued to receive TAU
- Self-managed diabetes via Glooko
- Did not receive additional clinical interaction, unless part of TAU

INTERVENTION GROUP (N=27):

- Continued to receive TAU
- Self-managed diabetes via Glooko
- Clinical Interactions between nurse practitioner and subject every 2-weeks
  - NPs Reviewed subject data via Glooko Population Tracker.
  - Following data review, advised on insulin, medication, exercise, dietary, and/or additional behavioral changes.

ANALYSIS

Linear mixed modeling was used to analyze average blood glucose (BG) and glycemic variability over time across the intervention and control groups. All BG values were log transformed in order to normalize the data and random effects were used to account for individual variation within subjects. All analyses were conducted in R, using the glmmPQL function within the MASS package.

Results

Thirty-six patients (Control: 14; Intervention: 22) adhered to the 12-week study protocol (2-week run-in & 10-week intervention) and were included in the final analysis. Adherence criteria was met for both control and intervention if subjects synced blood glucose readings spanning the full 12-week study duration. Because dropout occurred disproportionately more in the control group, we opted not to impute for missing values to avoid inflating our results in favor of the intervention group.

Nurse practitioners diverged from study protocol and conducted clinical interactions with intervention group on an as-needed basis (i.e. based on need and patient risk-profile determined by recent data and analytics in Glooko Population Tracker). As a result, intervention group subjects received a range of clinical interactions during study (between 1-12). We therefore chose to segment the intervention group, based on the number of clinical interactions they received. All analyses controlled for original membership in the intended intervention group, however this variable did not significantly contribute to the model.

All participants exhibited a significant mean BG decrease of 16.16 mg/dL (p=0.026). Importantly, subjects who received ≥ 3 clinical interactions exhibited a mean reduction of 33.7 mg/dL (p=0.035), which was significantly more than the control group. See table 1 for more information and figure 1 for a visual illustration of this effect.

Graphs

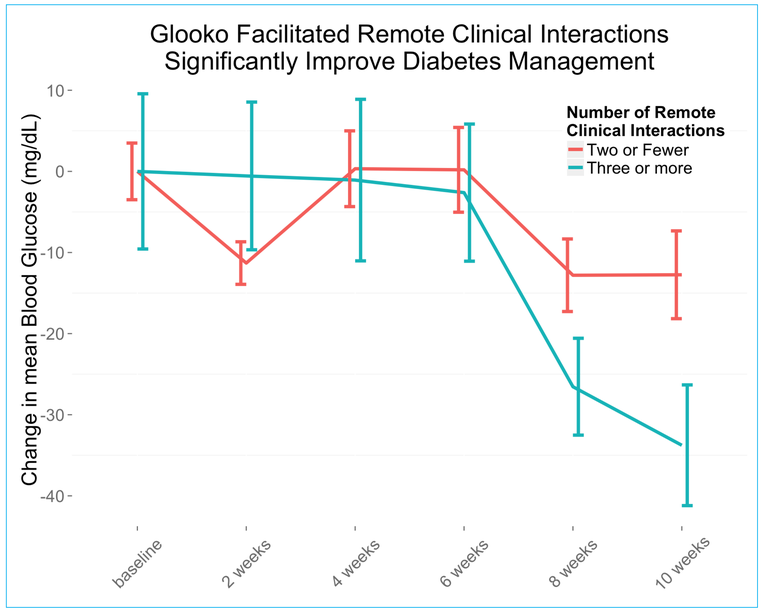

Figure 1: Mean BG Improvement over time. Note that the Control Group and subjects who received 1 or 2 clinical interactions have been combined with the control group for simplicity, as they do not significantly differ.

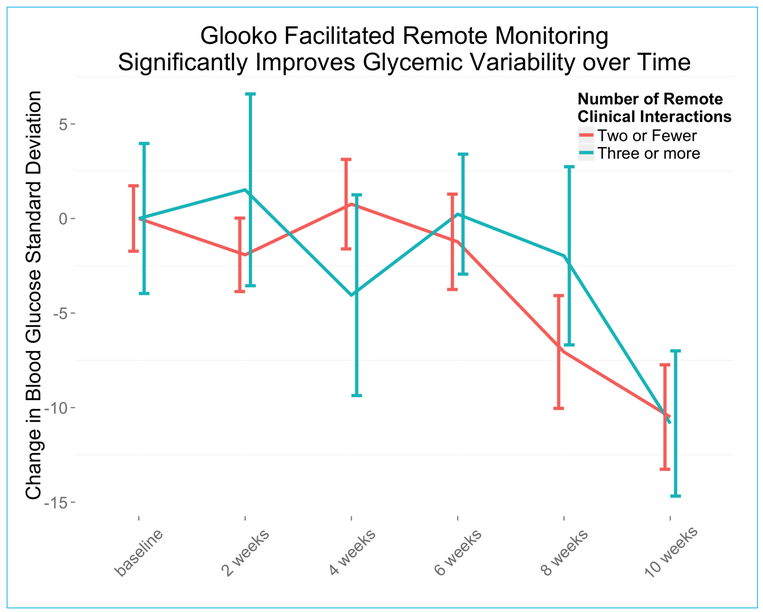

Figure 2: Reduction in standard deviation over time. Note that the Control Group and subjects who received 1 or 2 clinical interactions have been combined with the control group for simplicity, as they do not significantly differ.

Results Continued

	mean (SE) BG Δ in mg/dL	t score	p-value	n
All Participants	-16.16 (9.1)	-2.237	0.026*	36
Control	- 6.09 (19.9)	-2.538	0.013*	14
Intervention w/ 1 to 2 CI	-19.0 (10.2)	-1.210	0.227^	15
Intervention w/ ≥ 3 CI	-33.7 (14.9)	-2.126	0.035^	7

Table 1: Mean decrease in blood glucose scores, from baseline to end of the study period. CI = Clinical Interventions. P-values marked as * are in reference to a change over time, while ^ indicates a comparison to the Control group.

Similarly, we conducted an identical analysis to quantify changes in glycemic variability (measured using standard deviation in BG levels) during the trial. Regardless of treatment group, variability significantly decreased by a mean of 10.561 (SE = 4.7), after ten weeks compared to baseline, t= -2.611, p=0.010. However, no other effects were significant and there was no difference between treatment groups. See table 2 for more information and figure 2 for a visual illustration of this effect.

	mean (SE) BG stdev Δ in mg/dL	t score	p-value	n
All Participants	-10.50 (4.7)	-2.611	0.010*	36
Control	-11.26 (8.7)	-2.675	0.009*	14
Intervention w/ 1 to 2 CI	-9.71 (7.6)	0.205	0.838^	15
Intervention w/ ≥ 3 CI	-10.83 (7.7)	1.358	0.176^	7

Table 2: Mean decrease in blood glucose variance, from baseline to end of the study period. CI = Clinical Interventions. P-values marked as * are in reference to a change over time, while ^ indicates a comparison to the Control group.

Discussion

These results indicate that both Glooko facilitated self-management and Glooko facilitated patient remote monitoring by nurse practitioners led to a significant decrease in mean BG levels and glycemic variability over a 10-week period. Importantly, three or more remote nursing interventions exhibited significant improvement over Glooko facilitated self-management, combined with TAU.

The current pilot diverged from the intended protocol by allowing nurses to conduct remote clinical interactions on an as-needed basis (i.e. based on need and patient risk-profile), instead of adhering to the regimented schedule. However, this type of monitoring reflects a responsive, data-driven work flow, for which the Glooko system was built.

In addition, Glooko allowed nurse practitioners to utilize subject-specific risk identifiers and intelligent analytics based on remotely collected data. This created an environment where at-risk patients could be selectively contacted based on need or risk profile. Although the results of our current pilot are preliminary, based on our initial findings we hypothesize that remote monitoring patients with diabetes could dramatically improve patient outcomes and lower costs. In particular, Accountable Care Organization (ACOs) and other similar health systems or payers could consider implementing remote monitoring systems as an efficient way of improving diabetes outcomes.

Clinical interactions included insulin and medication dose adjustments (data gathered via post-pilot survey). Leveraging its ability to sync data from meters, insulin pumps, and continuous glucose monitors (CGMs), Glooko intends to build insulin-specific titration algorithms to further increase the effectiveness of clinical decision support and remote clinical interactions facilitated by Glooko.

LIMITATIONS

The current pilot presented a number of challenges, including a large attrition rate and a low sample size. Although we had enough power to discover significant effects, these results should be viewed as preliminary and further study is needed to confirm the above findings.