Clinically-Relevant Improvement in Quality of Blood Glucose Control in Well-Controlled Users of mySugr's Mobile Diabetes Management Tool

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BACKGROUND

The mySugr App is the most widespread mobile health application in the diabetes industry, reaching 1.4M patients in 61 countries. The positive impact of the application among users has previously been reported, indicating reduction of risk scores and improvement of BG control in a number of user groups with Type 1 Diabetes.[1-3] The mySugr Bundle introduces unlimited test strip delivery and Certified Diabetes Educator-led coaching. In this retrospective study, we explored real world changes in blood glucose (BG) in a US population of mySugr Bundle users.

Figure 1. *The mySugr Bundle consists of the mySugr app, unlimited and usage-based resupply of teststrips and CDE-led glucose-centric coaching via in-app messaging interface.*

METHODS

We analyzed changes in BG control (mean BG, BG Standard Deviation (BG STD), tests in range (TIR), estimated A1c (eA1c)[4] and frequency of BG testing in a random sample of users. Participants monitored BG ≥3 times/day during the observation period. Data from the first two weeks of use (t_0), two months before (t_1) and two months after (t_2) initiation of Bundle usage were aggregated and statistically compared using two-sided t-tests. A subgroup analysis was also performed, splitting the group by the median estimated A1c at baseline (t_0). Further subgroup analysis was not possible due to low population in the study.

RESULTS

Study participants were 52 users; 55.8% with type 1 diabetes, 36.5% with type 2 diabetes, 5.8% with LADA and 3 with unreported diabetes type. Of these, 77.1% used insulin, 19.4% used insulin pumps and 22.9% used non-insulin therapies. Baseline BG was 154.3±55.5mg/dl, TIR 64.48%. Significant ($p<0.05$) improvements were observed in mean BG (-16 mg/dl), TIR (+8.5%), readings above target (-8.85%) and eA1c (-0.43%) between t_0 and t_2. Significant improvement was also observed in monitoring frequency (+17.51%) at t_2. An indicated clinically relevant change in eA1c (defined as ≥0.3% according to EMA guidelines[5]) was achieved by 30.77% of the population.

Value	t_0	t_1	t_2	$p(t_0 \rightarrow t_2)$	$p(t_1 \rightarrow t_2)$
Mean BG (mg/dl)	154,3	140,4	138,2	**0,011**	0,378
BG STD (mg/dl)	55,5	52,1	50,3	0,071	0,235
eA1c (%)	6,7	6,3	6,3	**0,011**	0,378
Tests in range (%)	64,48	73,51	73,03	**0,021**	0,677
Test frequency (tests/day)	5,79	5,31	6,24	0,239	**< 0,001**

Table 1. *The changes experienced by the population were significant in terms of BG control, test frequency as well as tests in range, when comparing following periods with baseline t_0.*

We found the median estimated A1c at baseline to be 6.7%. Splitting the group by this value yielded two groups with 26 users each. For the group with an eA1c equal to or above the median, significant ($p < 0.001$) improvements of -39.53 mg/dl were observed in mean BG between t_0 and t_2. Also, significant ($p = 0.002$) improvements of -14.06 mg/dl were observed in BG STD from t_0 to t_2 and -5.70 mg/dl from t_1 to t_2 ($p = 0.007$). For the group with an eA1c below the median, no significant changes were observed.

Value	t_0	t_1	t_2	$p(t_0 \rightarrow t_2)$	$p(t_1 \rightarrow t_2)$
Mean BG (mg/dl)	186,2	153,1	146,7	**< 0,001**	0,076
eA1c (%)	7,7	6.9	6.6	**< 0,001**	0,076
BG STD (mg/dl)	71,2	62,8	57,1	**0,002**	**0,007**

Table 2. *Results for the subgroup (n=26) of people with an estimated A1c equal to or higher than median eA1c after registration (6.694%). Results for the other subgroup (estimated A1c smaller than median) are not shown as there was no significant changes in this subgroup.*

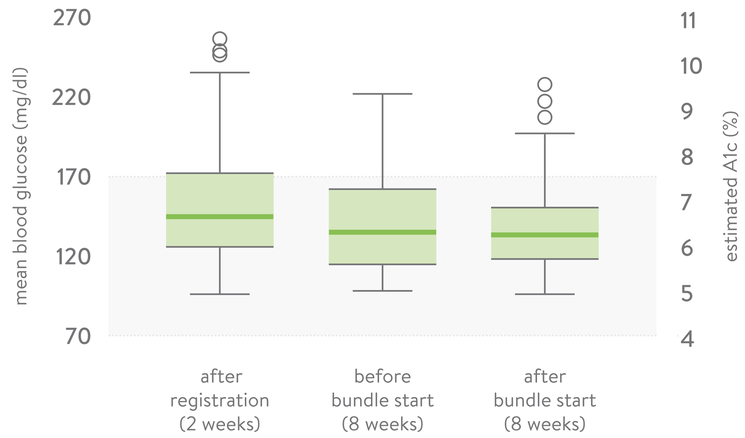

Figure 2. *The change of mean blood glucose and variability within the population at registration, before and after initiation of mySugr Bundle. Significant reduction of mean BG occurs compared to baseline ($p < 0.05$).*

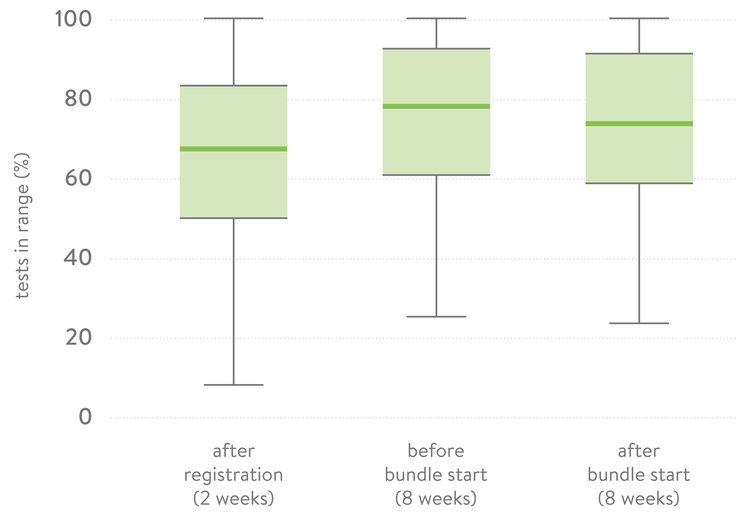

Figure 3. *The tests in range during the time periods observed indicates a significant increase, by 13.3% ($p < 0.05$).*

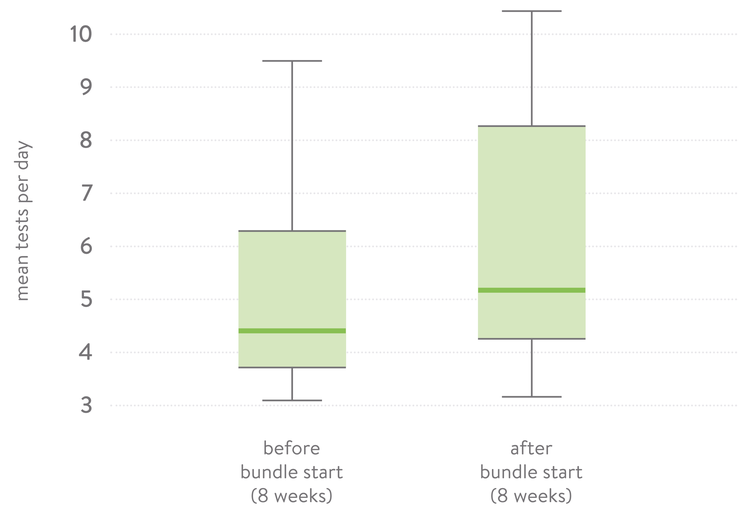

Figure 4. *The change in test frequency observed after initiation of mySugr Bundle. A significant increase in mean daily test frequency of 0.9 tests per day was observed ($p < 0.05$).*

CONCLUSION

This retrospective study suggests that use of the mySugr app to log BG can trigger positive changes of glucose control, 8 weeks (t_0 – t_1); the impact of logging BG is further enhanced in individuals who are less well-controlled. Positive trend data on parameters of BG variability and mean BG are further indicating that the educator-led coaching after Bundle start (week 8) might positively impact the sustainability of favourable changes and in fact, might lead to additional longer-term improvements in glucose control. These findings support further prospective studies in the field.

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1 M. Hompesch, K. Kalcher, and F. Debong, "High Risk Population Using Mobile Logging Application Shows Significant Reduction in LBGI [Abstract]", Diabetes, vol. 66, no. suppl 1, p. 952–P, 2017. **2** M. Hompesch, K. Kalcher, F. Debong, and L. Morrow, "Significant Improvement of Blood Glucose Control in a High Risk Population of Type 1 Diabetes Using a Mobile Health App – A Retrospective Observational Study", DTT, vol. 64, no. suppl 1, p. 2337, 2017. **3** M. Hompesch, L. Hergesheimer, K. Kalcher, R. Boubela, and F. Debong, "Retrospective analysis of Impact on SMBG and Glycemic Control of Mobile Health (mHealth)-Application for Diabetes Management," JDST, vol. 11, no. 2, p. 346–437 (A31), 2017. **4** Kahn R, Fonseca V. Translating the A1C assay. Diabetes Care. 2008;31(8):1704-1707. doi:10.2337/dc08-0878. **5** European Medicines Agency, Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus, CPMP/EWP/1., May. European Medicines Agency, 2012.