High Risk Population Using Mobile Logging Application Shows Significant Reduction in LBGI

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mySugr

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BACKGROUND

Using mHealth tools for diabetes self-management has been shown to have a beneficial impact on the quality of metabolic control. Based on a meta analysis the impact on glycaemic control of digital tracking and remote coaching has been shown to be around -0.38% points [95% CI -0.40 to -0.37]) in an adult population[1]. However, relevant and sufficient real-world data convincingly demonstrating the usefulness of mHealth tools in clinical care or less controlled settings is lacking, as many mHealth projects never go beyond the pilot stage.

mySugr Logbook (a registered class I medical device application) was developed to make logging of metabolic control data appealing and useful in day-to-day life. The app is one of the market leading diabetes management solutions with over 1 million users (May 2017). In a retrospective analysis the logging function has shown significant results in well controlled populations as well as in populations with high eA1c at baseline, reducing estimated HbA1c (eA1c) by 0.3%-points (from 7.3% to 7.0%)[2] and 1.3%-points (from 9.0% to 7.7%)[3] respectively among real world users over an observational period of 6 months. The data presented here will be utilized to generate future research hypotheses to further test the clinical utility of mySugr in a prospective manner and to improve mySugr's diabetes management features.

OBJECTIVE

In this analysis of real-world data we looked into the impact of logging, using mySugr Logbook, on the occurrence and severity of severe hypoglycaemic events; measured using Low Blood Glucose Index (LBGI).[5,6]

METHOD

Data from 4,000 engaged (logging ≥5 days/week for ≥6 months) T1D users from the active mySugr user-base was anonymized and exported for analysis. 1837 users with complete and consistent datasets were analysed. From this group the highest quartile regarding LBGI at t_0 (day 1-3) was selected, n = 457; aged 35.51±15.58 years, 50.3% male. Changes in BG-results (mean, standard deviation (SD), Coefficient of Variability (CV), High Blood Glucose Index (HBGI) and LBGI) at baseline (t_1) and at month 4-6 (t_2) were analysed. Baseline was selected as t_1 (day 4-7), to mitigate for regression to the mean in the sample, as it was selected based on extreme LBGI-values at t_0. Furthermore we reviewed if the effect of logging on LBGI was different between users from 4 nations and if if gender had any impact on LBGI, hypothesizing that these two factors may affect baseline data and potentially also could affect the outcomes. The analysis was performed in R.

RESULTS

At t_2 a reduction in LBGI of 17.39%, from 1.07 to 0.88 ($P < 0.001$), had occurred accompanied by a significant yet small increase in mean BG, from 141.27 to 147.82 mg/dl ($P < 0.001$), which equates to 0.23% increase in eA1c[4]. Changes in SD, CV and HBGI were not significant ($P > 0.001$).

Demographics | **Results**

				LBGI		HBGI		BGM[mg/dL]	
Segment	N	Female [%]	Age [years]	t_0	t_2	t_0	t_2	t_0	t_2
DE	122	41.8	37.2±13.5	1.30	0.9	1.8	2.1	136.7±63.4	147.3±61.3
FR	30	56.7	37.7±13.4	1.53	0.9	1.9	2.3	135.3±63.3	149.7±59.8
GB	32	53.1	43±13.6	1.50	0.9	1.9	2.1	135.6±67.3	146.6±60.7
US	114	57.9	36.6±17.2	1.31	0.8	2.1	2.7	140.1±70	156.7±65

Table 1. Segmented by nationality of the participant a difference in baseline results as well as outcome results can be noted. At this level of detail, the statistical significance is diminished in many of the groups. t_0: the first 3 days of usage, t_2: month 4-6 of usage.

The results shown in Table 1 indicate that there is no difference in the impact of logging on LBGI and HBGI between nationalities. A common trend of decrease in standard deviation is indicated in all groups, accompanying the rise in mean blood glucose levels.

Demographics | **Results**

			LBGI		HBGI		BGM[mg/dL]	
Segment	N	Age [years]	t_0	t_2	t_0	t_2	t_0	t_2
Male	225	33.6±15.5	1.4	0.8	1.9	2.4	136.5±65.3	150.8±62.7
Female	232	37.6±15.4	1.4	0.9	1.8	2.1	136.5±65.2	146.1±60.7

Table 2. The included population segmented by gender, indicates no difference in impact between the two groups ($p > 0.001$), but the results indicate a sharper increase in BG among the male participants. t0: the first 3 days of usage, t2: month 4-6 of usage.

The results shown in Table 2 indicate an insignificant difference in impact between genders.

Change in relative group size, t_2 against t_0

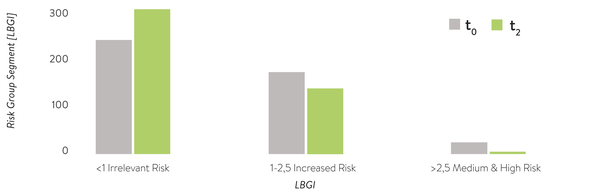
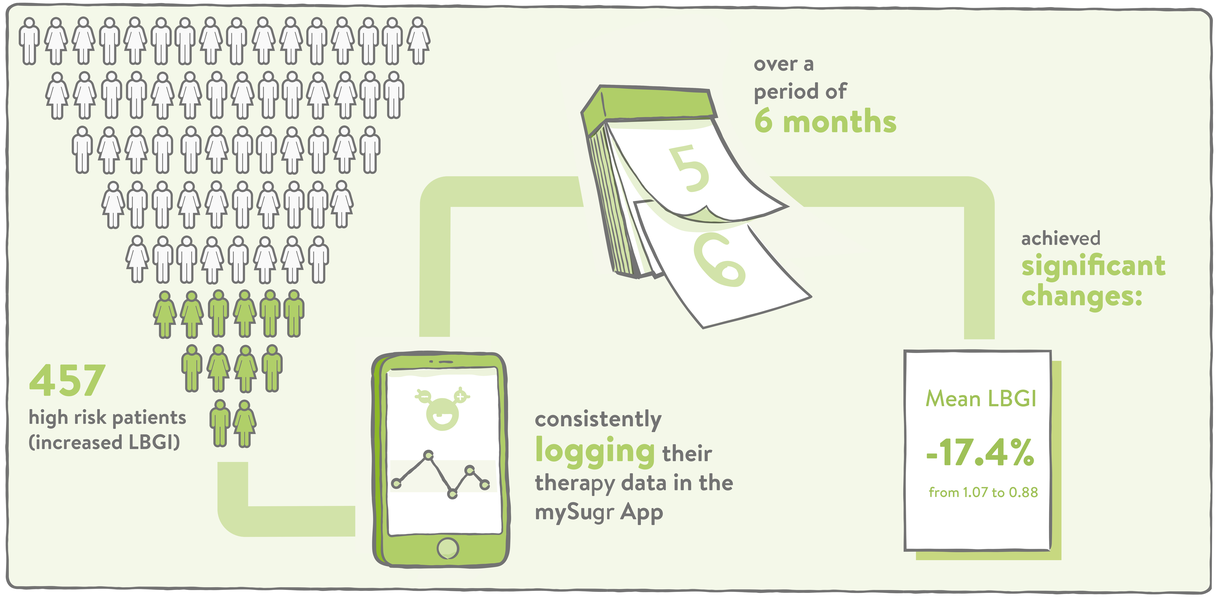


Figure 1. Shift in size of population groups segmented by risk levels of severe hypoglycemia as expressed in LBGI-risk-level, between t_0 and t_2 results.[5]

The within population shift between LBGI-based risk levels was also investigated. The respective analysis, shown in Figure 1, shows a consistent shift of patients from LBGI-categories indicating increased risk levels to lower ones at t_2.



DISCUSSION AND CONCLUSIONS

The significant reduction in LBGI, expressing the risk of severe hypoglycaemic events, demonstrates that logging with the mySugr Logbook may have positively impacted the patient population. The LBGI in the investigated population was already at an acceptable level upon inclusion, indicating a rather well controlled user base in general. While a larger change in HBGI was expected the insignificant change between t_0 and t_2 is encouraging, indicating a positive and balanced change in the user's therapy. The increase in mean blood glucose is considerable, but based on the rather small change in HBGI, and the significant change in LBGI, leads us to conclude that the low mean blood glucose at baseline may have been a result of the frequency and severity of hypoglycemic events. Further, the observed effects are consistent across the investigated population and independent of nationality or gender, which seems to indicate a successful cultural adaptation of the mySugr application.

While this study is providing valuable insights into real world data, its limitation is that it is retrospective and observational; however, these study observations and conclusions will inform the design of future prospective observational and interventional studies.

In general, mHealth tools have been identified as tools that can positively change and impact the standard and quality of diabetes care. The results of this study further strengthens our hypothesis that the mySugr technologies platform can have a positive impact on the quality of diabetes care in the T1D population. These findings should be confirmed in a prospective, controlled clinical trial. We further hypothesize that the now launched additions of mySugr Bolus, and the Certified Diabetes Educator-led mySugr Coaching as well as integration with a growing number of CGM, BGM and insulin pumps can result in significant health care and health economics benefits across a broader range of users.

References

1. Forisch M, Grohmann-Izay B. Use of Digital Tracking Devices in the Management of Diabetes Mellitus: A Systemic Review and Meta-analysis [abstract]. Diabetes. 2015; 64 (suppl 1).
2. Hompesch M, Hergesheimer L, Kalcher K, Boubela R, Debong F. Retrospective analysis of Impact on SMBG and Glycemic Control of Mobile Health (mHealth)-Application for Diabetes Management. JDST. 2017;11(2):346-437 (A31). doi:10.1177/1932296817696371.
3. Hompesch M, Kalcher K, Debong F, Morrow L. 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. 2017;64(suppl 1):2337. doi:10.2337/dc08-0878.4.
4. Kahn R, Fonseca V. Translating the A1C assay. Diabetes Care. 2008;31(8):1704-1707. doi:10.2337/dc08-0878.
5. Kovatchev BP, Straume M, Cox DJ, Farhy LS. Risk Analysis of Blood Glucose Data: A Quantitative Approach to Optimizing the Control of Insulin Dependent Diabetes. Comput Math Methods Med. 2000;3(1):1-10. doi:10.1080/10273660008833060.
6. Kovatchev BP, Cox DJ, Gonder-Frederick LA, Clarke W. Symmetrization of the Blood Glucose Measurement Scale and Its Applications. Diabetes Care. 1997;20(11):1655-1658. doi:10.2337/diacare.20.11.1655.