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A novel telemedicine protocol improved outcomes for high-risk patients with type 1 diabetes: A 3-month quality improvement project during the COVID-19 pandemic

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ABSTRACT

Our endocrinology practice needed to protect its highest-risk patients with type 1 diabetes (T1D) during the COVID-19 pandemic. To do so, we needed to identify these patients and develop a protocol to keep them out of the hospital (to limit risk of infection and conserve medical resources), and do so without in-person visits. So we used our peer-reviewed software, Diabetes Reporting, to identify 87 patients whose glucose management indicator (GMI) scores were over 9%. The GMI is a method for estimating the laboratory A1C using the patient's actual blood glucose measurements over the past 90 days. A GMI (or A1C) over 9% indicates a heightened risk of diabetic ketoacidosis (DKA) and, possibly, a slightly higher risk of severe hypoglycemia (SH), the two most common acute complications leading patients with T1D to be hospitalized. We contacted these 87 at-risk patients and enrolled them in a quality improvement project. This project consisted of additional online meetings with their doctors as well as weekly reports generated by Diabetes Reporting for three months, between March 28, 2020 and June 28, 2020. We hypothesized that this heightened communication would reduce the incidence of DKA and SH among the participants by reducing their GMI. As a comparison group, we used data from the T1D Exchange, which showed that, among patients with an A1C over 9%, 6.7% were hospitalized for DKA and 7% experienced SH leading to loss of consciousness in a three-month period. This led us to predict 6 incidences of DKA and 6 incidences of SH among our 87 participants during the three-month period. Instead, we saw 2 incidences of DKA and 1 incidence of SH. Moreover, the mean GMI of our participants dropped from 9.91% to 9.25%, a clinically-significant 0.66% improvement, which supports the conclusion that our protocol helped avoid acute complications among a cohort of at-risk patients with T1D by improving glycemic control during a time when we were limited to largely online care. This telemedicine protocol merits further research for its potential to improve and lower costs of care for patients with T1D, particularly for those at higher risk for acute complications.

1. Introduction

On March 11, 2020, the World Health Organization declared COVID-19 to be a pandemic. Our clinic's endocrinology practice, which cares for over 2000 patients with type 1 diabetes (T1D)[1] using in-person visits, had to change. Our first priority was keeping our high-risk T1D patients out of the hospital, both to conserve limited resources and to prevent them from contracting COVID-19.

Diabetic ketoacidosis (DKA) and severe hypoglycemia (SH) are the most common reasons for patients with T1D to be hospitalized [1]. Patients with a laboratory assay A1C (A1C) over 9% are significantly more likely to be hospitalized for diabetic ketoacidosis[2] and may even be

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[1] Abbreviations used in this paper include "T1D" (type 1 diabetes), "GMI" (glucose management indicator), "DKA" (diabetic ketoacidosis), and "SH" (severe hypoglycemia).

[2] *See* Ref. [2], Table 1 (Among the 3087 patients in the T1D Exchange with an A1c $\geq$ 9%, 207 had been hospitalized for DKA in the 3 months prior to a survey, or 6.7%; of the 7440 patients with A1cs under 9%, only 80 had been hospitalized for DKA in the prior 3 months, or 1%, making the cohort with an A1c over 9% approximately 7 times more likely to be hospitalized for DKA within a given time period than the cohort with better control).

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slightly more likely to experience severe hypoglycemia.[3] [2]. The A1C has traditionally been the most widely-accepted measure of blood sugar management in diabetes [3]. The Glucose Management Indicator, or GMI, is a mathematically-calculated estimate of the A1C based on the patient's average glucose values over the prior 3 months, which is much easier to determine than administering a laboratory test and yet is highly correlated with traditional A1C.[4] To quickly identify our patients whose current GMI was over 9%, we used our software, Diabetes Reporting [4], which calculates each patient's GMI every day. We identified and enrolled 87 at-risk patients in a three-month quality improvement project to attempt to, at minimum, keep them out of the hospital and, hopefully, to improve their blood sugar management as well.

We hypothesized that increasing communication (using weekly automated reports generated by our software, Diabetes Reporting, and online meetings) with our high-risk patients would decrease their GMI and thereby decrease hospitalizations. As a comparison group, we chose participants in the T1D Exchange registry with an A1C over 9%. The T1D Exchange registry included a broad, diverse sample of patients with T1D in the U.S., and reported on incidences of SH and DKA among those patients in the 3-month period prior to their survey [2].

2. Methods

We contacted 87 patients with T1D whose GMI over 9% indicated their diabetes was out of control and enrolled them in our quality improvement project. They were identified based on their current GMI[5] that we calculated using Diabetes Reporting. The project started on March 28, 2020 and ended on June 28, 2020.

During the project, the participants received weekly reports generated by our software, Diabetes Reporting [4]. These reports provide easy-to-digest information about the patient's blood sugar and insulin dosing over the prior week. This information includes their low blood glucose index (LBGI), high blood glucose index (HBGI), average glucose value, coefficient of variation, GMI, hourly average glucose values and associated basal insulin levels. The reports also include a figure that breaks down the patient's hourly risk of highs (HBGI) and lows (LBGI) over the prior week so they can identify the best time periods to focus on (see Fig. 1 below).

The reports also include recommendations based on the patients' measurements to teach patients to change their own insulin dosages, which we have found to be associated with much better glycemic control. If the patient changes their basal insulin, in the next report we show them how that change impacted their average blood sugar and LBGI for that period. The reports are reviewed by a care provider each week, which allows additional attention for patients whose glucose values are out of control.

Our intervention also included online visits (during the project, our clinic was practically closed to in-person appointments). The participants had an initial online visit with a senior endocrinologist. During this visit, the endocrinologist told the patient about the short-term and long-term risks of elevated GMI, and the risk of exposure to COVID-19 and the current hospital burden that made it particularly important to avoid unnecessary hospital visits. During the first month of the project, the patients were invited to attend four weekly, one-hour online conferences on various topics, including nutrition, psychological support, tech support, and a group session for a care provider to make recommendations for individual patient reports. The participants were then invited to attend at least two more online conferences during the final two months of the project.

After the three-month period was over, we compared our participants' outcomes to patient data from out-of-control patients (A1C of 9% or higher) in the T1D Exchange. Specifically, our two primary outcomes of interest were number of hospitalizations for diabetic ketoacidosis, and incidences of severe hypoglycemia causing a loss of consciousness or seizure (these were the definitions used in the T1D Exchange survey), and our secondary outcome was change in GMI.

3. Results

Table 1 compares our three outcomes of interest with data from the T1D Exchange. Among our participants, we saw markedly fewer incidences of DKA and SH than the comparison group. There were no three-month changes in A1C reported in the T1D Exchange, but we would assume none occurred given there was no change in treatment during the period in the survey.

We also analyzed the effect of meeting attendance on patients' GMI improvement. We asked participants to attend one one-on-one visit with a senior endocrinologist and six online televisits (typically consisting of around 10 patients), and tracked attendance during the 3-month intervention. Overall, there was only a modest correlation (r^2 of approximately .07) between the number of meetings attended and improvement in GMI among the 70 patients from whom we had sufficient data to estimate GMI at the conclusion of the study. But looking at the various cohorts of patients at different tiers of attendance is suggestive (see Table 2 below).

If you look at the 24 patients who attended 3 or more visits or meetings during the intervention, you can see an average improvement of just about 1 in GMI, and none of these patients had their GMI increase during the period. On the other hand, among the 46 patients who attended 2 or fewer meetings or visits, while they still showed a modest improvement of GMI overall (mean of -0.47), their improvements were much more modest, and 14 of these patients actually saw an increase in GMI over the intervention period. It's difficult to say whether the number of meetings attended indicated patient engagement, which was itself the driving factor behind better outcomes, or whether the meetings themselves contributed to the improvement. But we believe that some real-time personal component was likely a meaningful part of our intervention and should be included in similar programs in the future.

4. Discussion

The pandemic has permanently changed the way we practice medicine. Instead of an adjunct to care, telemedicine became our primary way to provide care to patients with T1D. These changes have persisted even now (October 2020), when we are again seeing patients in person.

We have been working on Diabetes Reporting, our software for T1D patients, since 2016. During the pandemic it has proved crucial to continuity of care in our practice. Our goal for the software has always been to improve on the 3–4 visits per year typical of T1D care. The weekly reports provide 52 contacts with the doctor per year, educate patients on how to safely change insulin between visits (and provide feedback on those changes), and allow care providers to customize the reports and efficiently review patients' diabetes management on a weekly basis.

So when the pandemic started, we already had approximately 1000 patients using our software, and we used it to assist our rapid switch to remote medicine. We were also able to identify and quickly enroll our 87 at-risk participants, which would not have been possible if we didn't

[3] *See* Ref. [2], Table 1 (Among the 3087 patients in the T1D Exchange with an A1c $\geq$ 9%, there were 217 incidences of SH within the prior 3 months, or about 7%. Compare this with the 441 incidences of SH reported by the 7440 patients with A1cs below 9%, or about 6%).

[4] Our formula is GMI = (Mean Glucose for Prior 90 days in mmol/l + 2.59)/1.59, which is taken from Ref. [3]. The authors found this formula to be highly-correlated with laboratory A1C ($r^2 = 0.84$). We have confirmed a high correlation ($r^2 = 0.68$) using our own data.

[5] To ensure that their GMI was an accurate depiction of their glycemic control (and thus highly correlated with A1C), we further limited enrolled patients to those with a GMI based on at least 50 days worth of data from their continuous glucose monitor.

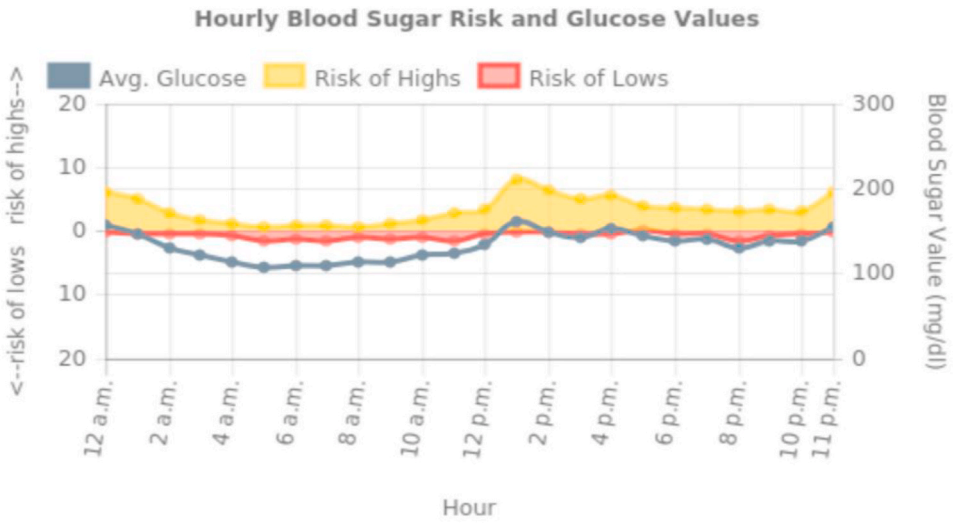

Fig. 1. Hourly risk chart from patient report.

Table 1
Results of quality improvement project.

	Our Quality Improvement Project	T1D Exchange [2]
Number of Patients with T1D and A1C/GMI[a] ≥ 9%	87	3087
Hospitalization for DKA in Prior 3 Months	2 (2.2%)	207 (6.7%)
Severe Hypoglycemia[b] in Prior 3 Months	1 (1.1%)[c]	217 (7%)
Change in Mean GMI[d]	-.66% (9.91%–9.25%)	NA

[a] The T1D exchange [2] used A1C and we used GMI as a proxy for A1C, which (as described above) correlates highly with laboratory A1C. If anything, the GMI may *underestimate* the laboratory A1C, meaning our patients may have had worse blood sugar control than the over 9% cohort in the T1D exchange, making our results more compelling. *See* Ref. [5], (finding that lab values of A1C were significantly higher than the estimates provided by the GMI ($p < .0001$), and that difference increased with higher A1C values).

[b] Defined in both groups as seizure or loss of consciousness due to low blood sugar.

[c] This patient's hypoglycemia may have been unusual, however, as it was diagnosed as alcohol-induced hypoglycemia.

[d] Out of 87 participating patients, 70 ended the 3-month period of our project with a calculated GMI based on data from at least 50 days (this was our initial data sufficiency criterion for inclusion, too). We excluded the other 17 patients from our GMI change results because their change in GMI may have been due to lack of data rather than actual change in blood glucose. By contrast, the 70 patients who were included uploaded data during, at minimum, 50 of the 92 days in our improvement project. If we had included all participants, the average change would actually be higher (−0.72% instead of −0.66%).

Table 2
Relationship between number of meetings attended and GMI improvement.

# of Meetings/Visits Attended	Average Starting GMI	Average GMI Change
5-8 (n = 9)	9.91	-.92
3-4 (n = 15)	10.17	-1.05
1-2 (n = 36)	9.81	-.57
0 (n = 10)	9.83	-.13

have software that calculated up-to-date GMIs each day (at best, we would have had to rely on the patients' latest A1C, which is often months out-of-date).

Our initial hypothesis was largely confirmed, which was that increasing communication with our cohort of at-risk patients with T1D over a three-month period would reduce their predicted acute complications that result in hospitalization (DKA and SH). We used data from the T1D Exchange as a comparison group to estimate how many such complications we would expect.

The demographics of the T1D Exchange participants are roughly analogous to our patient population, with 52% of the participants in the T1D exchange reporting a household income over $75,000, placing them above the overall median income in the U.S [2]. (supplementary table S1). Our patient population from suburban Chicago is similarly above-average in household income, which tends to correlate with better blood sugar management [6]. Yet a potential confound is our patients may have been drawn from even higher socioeconomic groups, be less racially diverse, and more likely to use CGM, insulin pumps and software than the T1D Exchange patients. Still, whatever differences exist in the demographics and use of technology between the groups should be largely ameliorated by their shared A1Cs (or, in our case, GMIs) over 9%. Given that out-of-control blood sugar is the greatest risk factor for acute complications (especially DKA [7]), we would expect our participants to be roughly equally at-risk for SH and DKA as those in the T1D Exchange but for our intervention.

Assuming that the frequencies of DKA and SH in the T1D Exchange at-risk cohort apply to our participants, we would have expected 6 incidences of hospitalization based on DKA and 6 severe lows characterized by loss of consciousness. Instead, we observed 2 incidences of DKA and 1 of SH. We therefore avoided 4 incidences of predicted DKA and 5 incidences of predicted SH.

One measure of the size of this effect is the costs avoided by keeping these patients out of the hospital. (The cost of potential COVID-19 exposure, of course, is difficult to quantify but needs to be added in as well.) In 2014, the average hospital stay for DKA was 3.24 days, and was billed at $26,566 [8]. In a 2016 paper, the average cost per hospital visit for severe hypoglycemia was $1387 [9]. Given the increase in medical costs over the last 6 years, using these figures to estimate the costs avoided in our project is conservative. Based on these amounts, we can estimate the cost savings of our 3-month intervention: $106,264 (4 avoided DKA hospitalizations) and $2080 (1.5 avoided SH hospitalizations, assuming that only 30% of the episodes resulted in hospitalization [12]) for a total estimated savings of $108,344 over 3 months for only 87 patients. If these results could be replicated for larger groups over longer periods, the savings could be substantial.

Our secondary outcome – improved GMI – was also encouraging. Beyond lowering the risk of acute complications, we know from the Diabetes Control and Complications Trial that lowering A1C improves patient outcomes 30 years later (patients with lower A1Cs had markedly

fewer microvascular complications such as retinopathy, neuropathy, and nephropathy) [10]. And any change in A1C of over 0.5% is thought to be clinically-significant [11]. Given that we saw an overall improvement of mean GMI by 0.66% in three months, we believe the potential clinical implications of our protocol for efficiently treating at-risk patients with T1D are significant.

5. Conclusions

Sometimes necessity is the mother of invention. The pandemic hamstrung our ability to care for patients with T1D in the usual way while keeping them safe from COVID-19. It took away our ability to see many patients in person. And it made a patient trip to the hospital more costly than ever. So we were forced to rely almost exclusively on our telemedicine software (Diabetes Reporting) coupled with increased online meetings to create a protocol to safeguard our most at-risk patients with T1D safe. While there were only 87 participants monitored over 3 months in our project, it appears to have worked, avoiding 4 predicted hospitalizations for DKA and 5 incidences of SH. We also lowered these patients' average GMI by 0.66%, a clinically-significant amount, which reduces their risk for both acute and long-term complications. These changes not only improved care, but saved a lot of money (over $100,000 in estimated hospital billings) for a minimal provider time commitment in reviewing reports and hosting online meetings. We believe further research is warranted on using this protocol to help at-risk patients with T1D.

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Declaration of competing interest

● The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The authors have ownership interests in Diabetes Reporting, the software they developed and used as part of the intervention in this quality improvement project.

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