Basal insulin titration by the app

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Many patients with type 2 diabetes (T2D) require insulin therapy to achieve adequate glycemic control, often in adjunct to other glucose-lowering agents. Long-acting basal insulins are the cornerstone of most insulin regimens, but optimal dosing is often not reached due to therapeutic inertia or fear of hypoglycemia.

In The Lancet Regional Health—Europe, Hermanns and colleagues report the results of the My Dose Coach study, an open-label, randomized controlled study in 36 diabetes practices in Germany that compared the change in HbA1c after 12 weeks use of a smartphone application versus standard care for basal insulin titration.[1] Inclusion criteria were T2D with an HbA1c of 7.5–10% (58.5–85.6 mmol/mol), and an indication for once-daily basal insulin therapy, combined with oral glucose-lowering agents or non-insulin injectables, but no prandial insulin. The final study population of 251 participants had a median age of approximately 60 years, a BMI of 31 kg/m^2, an HbA1c of 8.3% and more than 80% of participants were on basal insulin treatment for at least one year. After 12 weeks, the median HbA1c in the control group reduced by 0.6% and by 0.9% in the intervention group, resulting in a model-based adjusted between-group difference of –0.31% (95% CI: 0.01%–0.69%; p = 0.0388) in favour of the intervention group. In the per-protocol analysis, the improvement in HbA1c mounted to a clinically significant between-group difference of –0.46% (–5.0 mmol/mol). In addition, the risk of hypoglycemia was similar between both groups.

Of note, is the relatively large drop in HbA1c noted in both groups, despite longstanding follow-up in specialized centers in a high-income country. This might reflect the heightened awareness of staff and patients as in any clinical trial, but also the initial enthusiasm for the app during the unblinded intervention. On the other hand, the improvement also exemplifies that clinical inertia can be overcome. The current findings, are in line with emerging positive results of an uncontrolled study in Mexico with a previous version of the app,[2] and a recent observational analysis of the real-life use of a similar basal insulin dosing app (Insulia) in France.[3] However, longer-term prospective studies are warranted to evaluate whether the benefit of a smartphone application persist over time.

It is also important to consider that participants in the intervention group were first registered in the online platform and received an individually tailored titration algorithm from the physician (including target range, correction dose, insulin sensitivity, multimorbidity, hypoglycemia risk). Second, the treating physician could monitor and adjust the patient's therapy in the platform, and changes were automatically transferred to the participants with an alert. Third, the users were required – and reminded by the app - to perform at least one fasting blood glucose measurement per day. In contrast, participants in the control group received only a written chart to titrate their basal insulin. The individualized algorithm and the active follow-up in the intervention group are likely to reassure and motivate patients, but they require a non-negligible effort by the diabetes team.

The majority of the intervention group participants rated the functionality and usability of the application good to very good. This was also reflected in a low drop-out rate and the fact that the intervention group used the application consistently (median 87 out of 93 days follow-up). Interestingly, treatment satisfaction, self-efficacy and diabetes empowerment ratings were similar in the between the control and intervention group. Of course, this study has its limitations. As mentioned, the intervention was unblinded and rather short-term. People with a BMI <25 kg/m^2 or the use of prandial insulin were excluded, which warrants caution on the generalizability, especially as these groups might be more prone to hypoglycemia. The next steps could be to confirm the findings in these subgroups, which might however require careful dietary monitoring, e.g. carb counting.

In addition, some aspects have to be addressed before applications can find their way to the general clinical practice. Legal aspects (e.g. Medical Devices Regulation, reference[4]) and approval by the regulatory authorities will have to be cleared. Indeed, the Sanofi–My Dose Coach application received FDA-approval as a Class 2 medical device in 2017 and is available through app stores, but with the disclaimer "not intended to replace the care or advice of your doctor".[5] Agreements with health care providers and insurance companies will have to be found to incorporate the 'remote' titration follow-up in the clinical routine. Attention will have to

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be paid to compatibility (3 candidates had to be excluded from intervention group), and access for all socioeconomic backgrounds.

In conclusion, this randomized, multicenter study suggests that a smartphone application providing patient-specific dose recommendations for titrating basal insulin can improve glycemic control safely. It might be a promising tool to counteract therapeutic inertia and fear of hypoglycemia.

Contributors

RV wrote the commentary, which was then edited and approved by BV. RV was responsible for submitting the article to the journal.

Declaration of interests

RV serves or has served on the speakers bureau for Eli Lilly, Novo Nordisk, Sanofi. RV has participated in advisory boards of Boehringer Ingelheim, Eli Lilly, Sanofi. Financial compensation for these activities has been received by KU Leuven. BV declares no conflict of interest related to the current manuscript.

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