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Brief Report

Managing gestational diabetes mellitus using a smartphone application with artificial intelligence (SineDie) during the COVID-19 pandemic: Much more than just telemedicine

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ABSTRACT

We describe our experience in the remote management of women with gestational diabetes mellitus during the COVID-19 pandemic. We used a mobile phone application with artificial intelligence that automatically classifies and analyses the data (ketonuria, diet transgressions, and blood glucose values), making adjustment recommendations regarding the diet or insulin treatment.

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Gestational diabetes mellitus (GDM) is a frequent disease and if the glucose control is inadequate, it increases the risk of perinatal complications. Its management involves frequent hospital visits to check self-monitoring data (glycemia levels,
Table 1 – Summary of Sinedie app data received from GDM women.

| Start date | Id | Number of days using the app | Total BG uploaded (BG/day) | Glucose levels<sup>b</sup> FBG / 1hBG | App therapy change proposals |
|------------|----|-----------------------------|---------------------------|--------------------------------------|-------------------------------|
|            |    |                             |                           | First 3 days                           | Last 3 days                   |
| 31/03      | 1  | 43.3                        | 168 (3.9)                 | 84 / 115                              | 87 / 103                      |
| 06/04      | 2  | 3.5                         | 23 (6.5)                  | 103 / 125                             | –                             |
| 08/04      | 3  | 36.6                        | 147 (4.0)                 | 82 / 119                              | 73 / 104                      |
| 08/04      | 4  | 36.6                        | 146 (4.0)                 | 94 / 123                              | 96 / 120                      |
| 08/04      | 5  | 12.0                        | 52 (4.3)                  | 85 / 130                              | 92 / 134                      |
| 08/04      | 6  | 37.1                        | 164 (4.4)                 | 84 / 129                              | 84 / 112                      |
| 08/04      | 7  | 36.0                        | 144 (4.0)                 | 89 / 132                              | 91 / 131                      |
| 08/04      | 8  | 37.0                        | 151 (4.1)                 | 93 / 136                              | 96 / 141                      |
| 08/04      | 9  | 22.2                        | 89 (4.0)                  | 83 / 126                              | 92 / 120                      |
| 10/04      | 10 | 29.0                        | 115 (4.0)                 | 87 / 132                              | 93 / 118                      |
| 22/04      | 11 | 22.6                        | 91 (4.0)                  | 85 / 127                              | 93 / 126                      |
| 28/04      | 12 | 16.5                        | 36 (2.2)                  | 83 / 115                              | 78 / 117                      |
| 28/04      | 13 | 16.5                        | 71 (4.3)                  | 97 / 124                              | 95 / 138                      |
| 29/04      | 14 | 15.4                        | 71 (4.6)                  | 92 / 128                              | 89 / 122                      |
| 29/04      | 15 | 4.6                         | 17 (3.7)                  | 96 / 122                              | –                             |
| 29/04      | 16 | 15.5                        | 55 (3.6)                  | 86 / 123                              | 89 / 120                      |
| 06/05      | 17 | 8.6                         | 36 (4.2)                  | 71 / 128                              | 71 / 111                      |
| 06/05      | 18 | 8.6                         | 37 (4.3)                  | 91 / 122                              | –                             |
| 12/05      | 19 | 2.5                         | 12 (4.7)                  | 82 / 96                               | –                             |
| 12/05      | 20 | 2.1                         | 10 (4.8)                  | 64 / 104                              | –                             |

BG, blood glucose measurement; FBG, fasting blood glucose; 1hBG, 1-h postprandial blood glucose

<sup>a</sup> From 31 March to 14 May 2020

<sup>b</sup> Mean glucose levels (mg/dL) during the first 3 full days vs. last 3 full days. If there is not enough data, the field is blank.
fasting ketonuria, adherence to the diet). Throughout the follow-up clinicians decide whether any treatment adjustment is necessary.

Telemedicine is commonly defined as health services provided by healthcare professionals using remote communication technologies and it includes a wide selection of modalities. In the field of GDM, telemedicine can reduce the need for hospital outpatient visits, allowing remote patient monitoring and requiring face-to-face visits only if insulin treatment is initiated [1]. A recent meta-analysis of 32 randomized controlled trials (5108 patients) showed that compared to standard care, the use of telemedicine could improve glycemic levels of women with GDM more effectively and reduce the risk of pregnancy complications [2].

Some limitations of telemedicine include usability, real-time feedback, a more significant workload (as it generates a greater amount of data), and decision-making capabilities (both for patients and clinicians). Decision support tools integrated into telemedicine systems can help clinicians with the analysis of the information generated. In 2016 we developed a web-based telemedicine platform (SineDie) that operated as a clinical decision support system designed to manage GDM treatment. SineDie automatically prescribed diet therapy modifications, identified the need for insulin treatment and proposed insulin dose changes to doctors. We performed a randomized clinical trial that showed an 88.6% reduction of the face-to-face visits and a 27.4% reduction of the time devoted by clinicians to patients’ evaluation. The system detected all situations that required therapy adjustment, generating safe recommendations [3]. However, when using the web-based system some patients experienced downloading problems with the glucose meter, patients had to be trained very well before using it and they needed access to the computer for data registration. Lately, we have developed the mobile version (only available on Android smartphones) to make the tool more user-friendly and easy to use, and we are about to start the clinical study.

The current COVID-19 pandemic has brought telemedicine in the spotlight [4,5]. In such an exceptional situation, we started using the SineDie app for the remote evaluation of all GDM patients visited in our Endocrinology department (after they signed an informed consent form). Women with GDM using the SineDie app follow the same self-monitoring and reduce the risk of pregnancy complications [2].

From 31 March to 14 May 2020, 20 pregnant women with GDM started using the Sinedie app. They were followed during a median of 16.5 days (8.6–36.2; Q25-Q75). Mean ± SD number of daily glucose measurements were 4.2 ± 0.8 and data transfer frequency was 0.9 ± 0.2 upload/24 h (342 uploads in 7 weeks). Mean ± SD fasting blood glucose and 1-hour postprandial blood glucose were 89 ± 12 mg/dL and 122 ± 23 mg/dL (breakfast), 123 ± 21 mg/dL (lunch), and 122 ± 22 mg/dL (dinner). Table 1 includes mean of fasting blood glucose and 1-hour postprandial the first three days using the app and the last three days, for patients followed for more than 8 days. During the follow-up, the system generated diet adjustments in 20% of the patients, 12 patients initiated insulin treatment and 41.7% of them required therapy adjustment afterwards (Table 1). 45.2% of insulin proposals generated by the system were accepted, 29.0% postponed and 25.8% rejected. Before publication, we reviewed maternal and neonatal outcomes: 18 women gave birth at a median of 39 weeks of gestation (38–40; Q25-Q75). Two women had planned caesarean section delivery, one for breech presentation and the other due to intrauterine growth restriction (IUGR). Four women had c-section delivery after failure of labor induction. None had preeclampsia. None of the newborns were large for gestational age (median percentile weight was 42 [32.5–58; Q25-Q75]). Newborns did not present hypoglycemia however, six of them had jaundice and three of them were admitted to neonatal intensive care unit due to preterm birth (IUGR in a twin pregnancy and a premature rupture of membranes).

Currently, we might have to wait a long time before the routine outpatient clinic follow-up is restored. We must adapt to the new situation and leverage the potential of telemedicine resources. The use of telemedicine in the usual care entails a paradigm shift and its use could reduce the impact of a pandemic to healthcare. SineDie app may be an excellent tool to prevent unnecessary hospital visits while keeping the best quality healthcare and reducing clinicians’ workload for GDM management.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
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Author Contributions

L.A. made clinical visits where GDM patients were taught about Sinedie app and wrote the manuscript. M.R. contributed to the development of the Sinedie app and critically revised the manuscript. I.C. made critical revisions. G.G-S, P.M./C0 and M.E.H contributed to the development of the Sinedie app, analyzed the data and revised the document. M.R. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

REFERENCES

[1] Pérez-Ferre N, Galindo M, Dolores Fernández M, Velasco V, Runkle I, José de la Cruz M, et al. The Outcomes of Gestational Diabetes Mellitus after a Telecare Approach Are Not Inferior to Traditional Outpatient Clinic Visits. Int J Endocrinol 2010;2010. https://doi.org/10.1155/2010/386941.

[2] Xie W, Dai P, Qin Y, Wu M, Yang B, Yu X. Effectiveness of telemedicine for pregnant women with gestational diabetes mellitus: an updated meta-analysis of 32 randomized controlled trials with trial sequential analysis. BMC Pregnancy Childbirth 2020;20:198. https://doi.org/10.1186/s12884-020-02892-1.

[3] Caballero-Ruiz E, García-Sáez G, Rigla M, Villaplana M, Pons B, Hernando ME. A web-based clinical decision support system for gestational diabetes: Automatic diet prescription and detection of insulin needs. Int J Med Inform 2017;102:35–49. https://doi.org/10.1016/j.ijmedinf.2017.02.014.

[4] Hollander Judd E, Carr Brendan G. Virtually Perfect? Telemedicine for Covid-19. N Engl J Med 2020;382:1679–81. https://doi.org/10.1056/NEJMmp2003539.

[5] Garg SK, Rodbard D, Hirsch IB, Forlenza GP. Managing New-Onset Type 1 Diabetes During the COVID-19 Pandemic: Challenges and Opportunities. Diabetes Technol Ther 2020;22:1–9. https://doi.org/10.1089/dia.2020.0161.