COMMENTARY

Apps and the Woman With Gestational Diabetes Mellitus

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Diabetes Care 2021;44:313–315 | https://doi.org/10.2337/dci20-0068

Gestational diabetes mellitus (GDM) affects 1–45% of pregnancies depending on the population and diagnostic criteria selected (1). A meta-analysis with 12 randomized controlled trials (RCTs) showed that GDM management improves pregnancy outcomes (2). GDM management involves counseling, dietary modification, physical activity, glucose monitoring, and, where glycemic thresholds are exceeded, supplemental pharmacological therapies. Implementation varies, with possible consequences for the pregnancy outcomes. For example, the Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) and Maternal–Fetal Medicine Units Network (MFMUN) RCTs, the two largest GDM treatment trials, differed in their insulin use (20% vs. 8%, respectively) and outcomes (3,4). Within the MFNUM RCT, the median glucose achieved was 10–12 mg/dL (0.6 mmol/L) higher in the insulin-treated than the non–insulin-treated group, particularly after dinner, when 50% of the self–blood glucose monitoring results were over the target glucose (median glucose was 120 mg/dL [6.7 mmol/L]). The more self–blood glucose monitoring results occur above target, the greater the chance of an adverse pregnancy outcome. In one study, adverse outcomes occurred in 25% vs. 60% of births among those with none vs. >30% above-target results, respectively (5). There are multiple barriers to GDM management for women with GDM (6). Besides a range of socioeconomic, service, and access barriers, women may experience misunderstanding or confusion over the advice provided, as well as a range of emotional and psychological challenges. Meanwhile, the increasing number of women with GDM (7) has created greater pressure on health care providers to streamline their services with different models of care, often sharing management with non–diabetes service staff (8).

New technologies such as telemedicine, SMS messaging, websites, e-mail, and smartphone applications ("apps") have been introduced in a range of settings to help address access and educational and behavioral support needs (9), and GDM management is no exception. Telemedicine technologies can be effective in GDM management (10). However, smartphone-based apps alone have not been clearly shown to improve glycemia or pregnancy outcomes in women with GDM. Studies have tested the clinical use (11–16) and cost-effectiveness (12) of GDM apps. All (12,13,15) have been underpowered (including 120–238 women) to detect improvement in pregnancy outcomes. Better compliance with blood glucose monitoring (13,14), significantly lower blood glucose (11,13,14), and a lower rate of insulin need (13) have been shown in some studies. However, others (12,15) have shown no improvement in glycemic control in the antenatal period (12) or postpartum (15) nor any difference in breastfeeding practice (15). Some studies have reported fewer hypo- and hyperglycemia episodes (13,14), fewer outpatient visits (14), and achievement of recommended gestational weight gain (11,14) in those who received the app-based intervention (Fig. 1). A GDM app was highly desired among women (12,13), and no adverse events were reported (12,15). The use of an app enabled more frequent reviews of blood glucose values, timely dose adjustments, and lifestyle advice by clinicians (12,13). Applications can be embedded with an emergency alarm system to notify clinicians of abnormal values that require immediate management (11,12). One trial (12) that assessed the economic impact of mobile apps showed no significant savings in direct costs compared with standard care, although the study lacked a comprehensive cost analysis.

The article by Yew et al. (17) in this issue of *Diabetes Care* reports on an RCT (n = 170 in each arm, GDM diagnosed between 12 and 30 weeks) to evaluate the effects of a smartphone app–based lifestyle coaching program designed for and used by women with GDM. The primary outcome was the proportion of women with excess gestational weight gain (EGWG) as defined by the 2009 Institute of Medicine guidelines (18), an

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See accompanying article, p. 456.

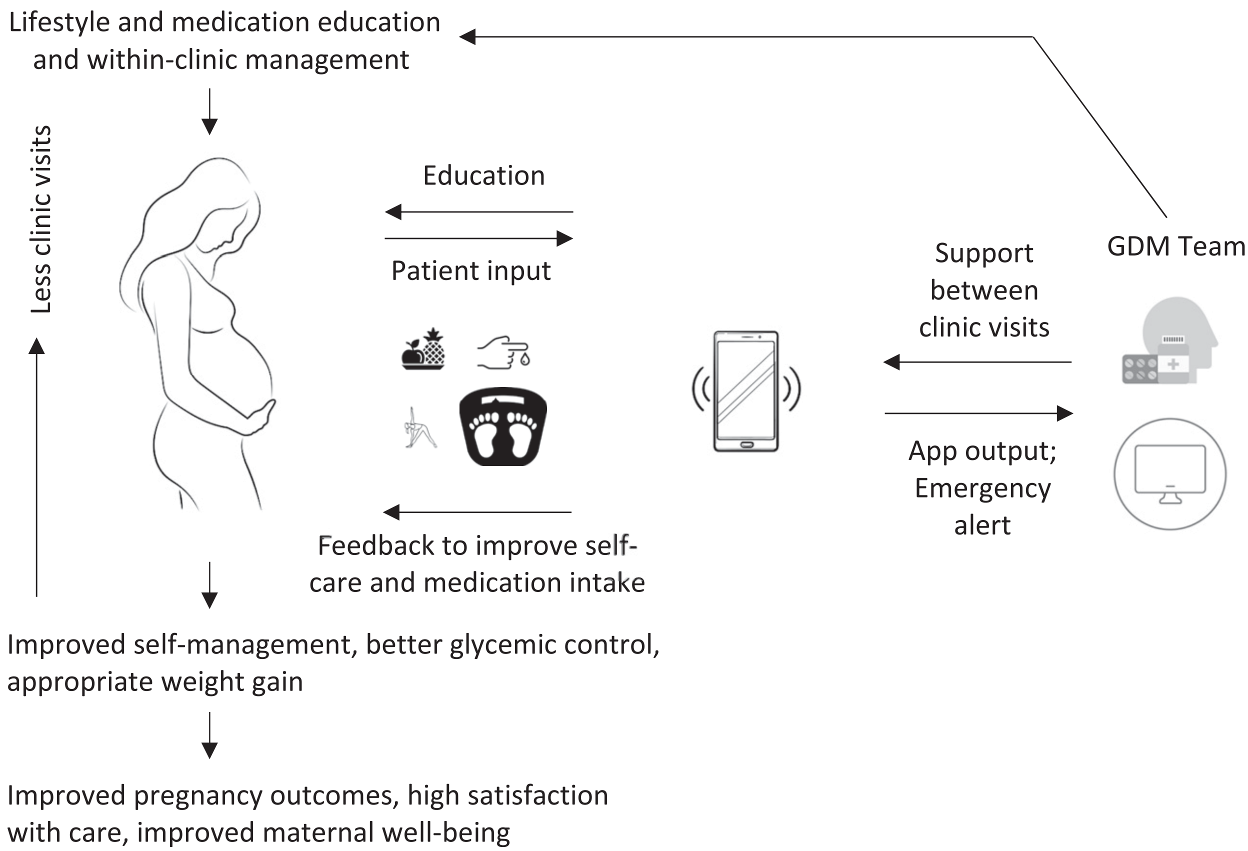

Figure 1—Implications of using smartphone-based apps for GDM management.

independent predictor of adverse pregnancy outcomes (19). Secondary outcomes included glycemic control and maternal, delivery, and neonatal outcomes. The app covered 12 topics: 4 informational, 6 on lifestyle, 1 on glucose monitoring, and 1 on stress management. A Bluetooth weighing scale and a blood glucose meter were provided that could communicate results to the app (control women used a paper diary). The app included a manual chat function requiring a health care team response within 24 h. There were no differences in the primary outcome; indeed, EGWG was nonsignificantly greater in the intervention than the control group (20.8% vs. 14.6%, $P = 0.152$). There were also no differences in secondary outcomes besides a 0.15 mmol/L lower mean glucose with fewer glucose results above target (5% preprandial and 30% 2-h postprandial). Insulin treatment was nonsignificantly less in the intervention group (10.1% vs. 16.4%, $P = 0.106$). A post hoc composite of birth trauma, neonatal hypoglycemia, hyperbilirubinemia, respiratory distress, neonatal intensive care unit admission, and perinatal death occurred in 38.1% of the intervention group and 53.7% of the control group (odds ratio 0.53 [95% CI 0.34–0.84]).

The study has a number of strengths including sufficient power to detect a 15% difference in EGWG, use of concealed electronic randomization stratified by ethnicity (44% Chinese) and BMI (47.7% overweight or obese), and low drop-out rates. The app had more advanced functionality than those used previously and was better tailored to the needs of women with GDM.

The study has a number of weaknesses, particularly insufficient power to show potentially important effect sizes of 5%. The post hoc creation of a composite outcome is open to query; for example, why not include preterm delivery or Apgar score <7 at 1 min? The mechanisms by which the slightly better glycemia and improved post hoc composite occurred are unclear. Only 49.4% of the intervention women accessed the educational lessons and only 68% logged their weight at least once every week. While the intention-to-treat results are reported, no per-protocol comparisons are shown (e.g., those who regularly accessed some aspect of the app). It would be useful to see if per-protocol analyses attenuated or strengthened the findings. The use of the "chat" functionality was not reported and, along with the lack of blinding, this may have resulted in the women receiving more attention from health staff. It is important to assess total costs from an intervention and not only those relating to face-to-face clinical encounters.

This is the largest of the RCTs using a smartphone app and confirms that smartphone apps as part of a package can improve glycemia but possibly not EGWG. The post hoc nature of the composite was unfortunate, and future studies should include an a priori composite, be better powered (5% difference), include health economic analyses, and undertake per-protocol analyses. However, it is more important to build upon this functionality and continue to develop (and test) better theory-based messages and technology, including smartphone apps, that are even more tailored to the individual, e.g., using machine learning approaches. It would be interesting to test whether the app improves postpartum healthy lifestyle behaviors, including breastfeeding uptake, and postpartum oral glucose tolerance test attendance (6). Of particular value would be to test the inclusion of the app in approaches to reduce the demands upon health services, including reducing the frequency of clinic visits, particularly where staffing is limited. Incorporating such an app in different models of care could improve triaging and reduce the number of women requiring step-up to more specialist care (8). At a time when the numbers of women with GDM are high and increasing, any tool that can both increase satisfaction and reduce demand could be of substantial benefit to both health services and the women.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

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