Managing Diabetes in Pregnancy Using Cell Phone/Internet Technology

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IN BRIEF For pregnant women with diabetes, using cell phone/Internet technology to track and report self-monitoring of blood glucose results improves compliance and satisfaction compared to using the more traditional methods of log books, telephone calls, and voicemail messages.

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The prevalence of hyperglycemia during pregnancy and subsequent type 2 diabetes is increasing along with that of obesity (1,2). Self-monitoring of blood glucose (SMBG) improves glycemic control (3,4). Treatment of hyperglycemia during pregnancy improves outcomes for both mothers and infants (5–7). Effectively performing and reviewing SMBG is time-consuming for patients and care providers. Twenty-two percent of women with gestational diabetes mellitus (GDM) falsify or invent glucose values (8).

Internet technology–based interventions improve health care utilization, self-efficacy, and glycemic control in nonpregnant populations (9–12). The use of Internet technology particularly featuring cell phone connectivity eliminates the potential inaccuracy of patient reporting of results. Such technologies may also improve patient satisfaction by increasing ease of use and decreasing the time needed to report results. Little is known about the potential benefits of employing this technology for the treatment of pregnant women with diabetes.

Monitoring via cell phone–Internet technology (CIT) involves collecting and sending daily readings from a patient's glucose meter, scale, or blood pressure monitor directly to a cell phone using a wireless device (e.g., Bluetooth). Information may be viewed by patients and health care providers via a secured Web site with electronic communication back and forth. The U.S. Food and Drug Administration (FDA)-approved Confidant CIT system (Confidant, Inc., Durham, NC) has been used in pilot studies of nonpregnant people with diabetes and congestive heart failure. Improvements in A1C and disease awareness were found (13,14).

Design and Methods

We performed a prospective, randomized, crossover study comparing a conventional voicemail system (control) with a CIT system for management of hyperglycemia during pregnancy. The primary outcome was compliance with SMBG reporting, measured as the percentage of expected SMBG results that were actually reported. The secondary outcome was patient satisfaction.

Women were enrolled in the study between 4 February 2009 and 11 March 2010. All subjects were participants in the Kapi'olani Medical Center for Women and Children (KMCWC) diabetes in pregnancy program, "A Sweeter Choice." Inclusion criteria were women ≥18 years of age with GDM or type 2 diabetes who were referred to the program before 30

weeks, 1 day of gestation. Exclusion criteria were age <18 years; gestations of 30 weeks, 1 day, or longer; type 1 diabetes; and inability to speak English. GDM was diagnosed with the parameters previously described by Carpenter and Coustan and supported by the American College of Obstetricians and Gynecologists (15). Diagnoses of type 2 diabetes were based on history provided by the women or referring physicians.

Institutional review board approval was obtained before the start of the study. All participants provided informed consent. The security officer at KMCWC approved the use of the cell phone and secured Web site. The study was registered with ClinicalTrials.gov (NCT01907516).

A grant from the Hawaii Medical Service Association (HMSA) provided funding for the study. The cost of the CIT system was estimated at ~$300 per user. The Confidant CIT system was supplied by Ho'okele Personal Health Planners, LLC. No employees of Confidant, Ho'okele Personal Health Planners, or the HMSA were involved in data collection, analysis, or writing of this report. Physicians and staff were trained to access data on the Web site. A technical support person was available onsite during the first week of the study and subsequently by request to providers and participants.

Participants were randomized to CIT or the control system at entry into the diabetes program, during a consultation with a maternal fetal medicine (MFM) physician. The women performed their assigned monitoring system for 3 weeks. They then switched to the other monitoring system for the next 3 weeks. Participants completed a satisfaction survey after the second 3-week interval. The survey was written by the investigators and adapted from a survey used in a previous pilot study of the CIT system (14). Supplementary Table 1 contains the full survey.

A sample size calculation was conducted to determine the number of participants required to discern a statistically significant change in the primary outcome of mean SMBG compliance rate. According to current standards of care, four tests per day (fasting and 2 hours postprandially) were recommended for each participant. Over 6 weeks, this would equal 168 readings per participant or 84 per 3-week interval. Before the study, a random sampling over a 3-week interval from our diabetes program database indicated a baseline compliance rate of 78%. A sample size of 97 participants was required to ascertain a statistically significant change of 5% in the compliance rate from 78 to 83% (80% power, $\alpha = 0.05$).

Randomization was carried out with a random number generator. Assignments were placed in opaque sealed envelopes and labeled with numbers 1–100. Participants opened their envelope after signing the informed consent form. Study staff members were not blinded to randomization.

After randomization and before starting the first 3-week interval on a monitoring system, all women attended a 3-hour diabetes education class taught by certified diabetes educators. Women who required medication (insulin or glyburide) were provided personalized instruction regarding correct usage. All women received equivalent education, training, and consultation regarding a carbohydrate-controlled diet, exercise, SMBG, and reporting SMBG results.

All women received the same glucose meters (OneTouch; LifeScan, Inc., Milpitas, Calif.) and testing supplies. They were instructed to perform SMBG four times per day (fasting and 2 hours postprandially) and record values using the reporting method to which they were assigned. The glucose meters held 150 values in memory, which was the equivalent of four-times-daily testing for 5 weeks. The women were told they could call the nurses during business hours or page the physician on call 24 hours per day, 7 days per week.

Women using the control method were advised to record blood glucose values in a log book and report their handwritten glucose results to the program nurse each week by dictating the values on the voicemail system. Nurses listened to the voicemail messages and recorded the values on paper. MFM physicians reviewed the paper records weekly to make recommendations. Nurses then communicated the recommendations to the women by telephone.

Women using the CIT method were advised to upload their blood glucose results at least weekly, although they could upload at every test, every day, or at their convenience within that timeframe. The system uploaded every value in the meter each time an upload occurred. Uploading began by turning on the cell phone and glucose meter. The wireless device was plugged in to the glucose meter and turned on. The phone was placed within 3 feet of the wireless device. Participants pressed a menu button and then selected the "collect" option on the phone menu to start the application. A confirmation of data receipt was displayed on the phone. Supplementary Figure 1 shows the components of the CIT glucose meter system. Each week, MFM physicians reviewed the blood glucose values on the Web site. The nurses communicated the recommendations to patients by telephone.

Women randomized first to the CIT method received additional training regarding use of the system at the initial education class. Women randomized to CIT second were provided training at a separate visit after their 3 weeks on the control method. They were provided with the same mobile phone (AT&T, Dallas, Tex.), the CIT application, and a connector (Bluetooth converter). Those using the CIT method could review their progress on the Web site or in graphs created on the phone. They also

received automatic encouraging text messages. Sample text messages were:

- "You didn't submit readings for the second week in a row. Try to submit your readings every week."
- "Did you notice your overall glucose average rose over the past week?"
- "Thanks for submitting your readings. Keep up the good work!"

CIT technical support was available by telephone 12 hours/day. During the first week, technical problems with the CIT prolonged the uploading process. This was corrected in 1 day, after which women were able to upload within 1–2 minutes.

At the end of the 6-week comparison period, the women were given the option to continue their method of choice until their delivery. For women who did not wish to continue using the CIT for the remainder of their pregnancy, cell phone service was terminated with the option to be reactivated at the women's expense. For women who did want to continue with the CIT, the service was provided free of charge until delivery, although data from this period were not used in the analysis. All women who entered the study were given free parking for study-related visits and the cell phone to keep.

Data analysis included demographics, blood glucose compliance, glucose values, and satisfaction scores. Continuous variables were analyzed with Student's *t* tests. Categorical variables were analyzed with the χ^2 test.

Results

One hundred women were randomized, 50 for CIT during the first 3 weeks and 50 for the control method first. Twenty-six women did not complete the study; analysis included data from the remaining 74 participants. Forty of the 74 women (54.7%) were randomized to the CIT method first and 34 (45.3%) to the control method first. Of those who did not complete the study, 11 did not wish to continue study visits, 6 never switched methods, 3 discontinued their participation in the diabetes program, 4 had preterm delivery before completing the study, 1 had a spontaneous abortion, and 1 developed diabetic ketoacidosis. (The latter participant did not have type 1 or type 2 diabetes. The self-limited event was attributed to a toxic exposure, and her hyperglycemia completely resolved after delivery, as evidenced by a normal 2-hour result on a postpartum 75-g glucose tolerance test.)

TABLE 1. Compliance With SMBG Reporting Using CIT and Voicemail Methods

	CIT (%) (*n* = 40)	Voicemail (%) (*n* = 34)	*P*
Total (fasting and 2-hour postprandial)	89.3	87.6	0.049
Fasting	92.9	91.0	0.048
2-hour postprandial	88.1	86.4	0.048

The mean age of participants was 33.2 ± 5.37 years, 28 (38.7%) were primiparous, and 45 (61.3%) were multiparous. Mean gestational age at randomization was 23.8 ± 6.0 weeks. Mean gestational age at delivery was 38.6 ± 1.2 weeks. Mean birth weight was 3,467 ± 515.0 g. Thirty-four women (46%) described themselves as mixed ethnicity, 17 (24%) as Filipino, 12 (17%) as Japanese, 4 (6%) as Hawaiian, 4 (6%) as Caucasian, and 1 (1.3%) as Chinese.

Sixty-two percent of the women had GDM treated with diet only. Thirty-four percent had GDM treated with glyburide. Eighteen percent had GDM treated with insulin. Twenty percent had type 2 diabetes, all of whom were treated with insulin. Percentages did not total 100% because some glyburide subjects were switched to insulin when clinically indicated.

A total of 51.4% graduated from college; 24.3% completed some college; 20.3% completed 12th grade, graduated high school, or earned a general education diploma; and 4.1% had less than a 12th-grade education. A total of 74.3% percent never participated in a diabetes program during pregnancy, 20.2% participated in our diabetes program during pregnancy two or more times, 4.1% participated in another diabetes during pregnancy program, and 1.4% participated in our diabetes program once before. A total of 90.5% reported that they always use cell phones in daily life, 6.8% said they often use cell phones in daily life, and 2.7% reported that they rarely use of a cell phone. No participants reported never using a cell phone. A total of 85.1% reported that they always use a computer, 9.5% said that they often use a computer, and 5.4% reported rarely using a computer. No participants reported never using a computer.

Compliance with SMBG reporting was higher during use of the CIT method for total, fasting, and 2-hour postprandial glucose values (Table 1). The effect of method order was evaluated. The highest compliance rate (91.7%) was found with the CIT method in women who used CIT first, which was significantly higher than the CIT method compliance rate of women who used the voicemail method first ($P = 0.048$). The compliance rate with the voicemail method was the same (87.6%) regardless of which method women used first (P = NS).

The mean 2-hour postprandial SMBG value was 108.3 mg/dL when the CIT method was used first and 112.7 mg/dL when the control method was used first ($P = 0.023$). The mean fasting blood glucose value was 89.5 mg/dL when CIT was used

first and 92.5 mg/dL when voicemail was used first ($P = 0.049$).

With regard to the secondary outcome of satisfaction, 68.9% of women preferred ("liked best") the CIT method compared to 24.3% who said they preferred ("liked best") the voicemail method ($P < 0.001$); 6.8% had no preference for reporting methods. More than half (59.5%) of the women found the automatic text messages to be "always helpful," whereas 24.3% found them "often helpful," 10.8% found them "rarely helpful," and 5.4% found them "never helpful." Figure 1 shows the results of other specific satisfaction-related questions.

Discussion

The use of CIT for self-management of hyperglycemia during pregnancy increased glucose reporting compliance by a small but statistically significant amount compared to the use of the traditional control method (voicemail). Satisfaction scores for the CIT system were significantly higher than for the voicemail method with regard to preference, ease of use, time management, motivation, self-efficacy, personalization, and recommendations to friends and family. The majority of women found the automatic text messages always or often helpful, supporting the premise that patients welcome electronic feedback tailored to their needs.

The similarity in compliance rates can be explained in our unit by the standard protocol of weekly phone calls from nurses to remind women to upload or report their results. If CIT systems become commonplace and automatic text messages are appropriately composed, the need for reminder calls and time spent on the phone could decrease. Moreover, a CIT system can directly interface with an electronic medical record and increases flexibility for women who already have cell phones.

Compliance was higher for both methods of SMBG reporting when the CIT system was used first, indicating that incorporating CIT may stimulate more interest in diabetes self-management. Two-hour postprandial blood glucose values were also lower when CIT was used first, although there was no statistical difference in fasting blood glucose values between women who did or did not use CIT first. Women may have been more compliant with their diet and medication regimens because they could not report factitious numbers while using the CIT system.

Strengths of this study include its randomized crossover design, through which each woman could compare the methods; the provision of free cell phones; available technical support; a well-established diabetes management program; and an FDA-approved CIT system. Weaknesses include selection bias toward English-speaking, better-educated, and technologically experienced women; a 25% dropout rate; a high rate of glucose reporting compliance in the control (voicemail) system; and technical problems when the CIT system first started that were quickly resolved. Although we found statistical significance for SMBG compliance favoring the CIT system, only 74 of 100 subjects enrolled went on to complete the study, which did not meet the sample size calculation of 97. This may have introduced a type 1 error (i.e., those who dropped out may have had better compliance with or preferred the control system). Alternatively, if the necessary power had been reached, we may have seen a larger difference or stronger P value. We purposely excluded women with type 1 diabetes because the standard frequency for SMBG for these women is more than four times per day.

The women in our study were well educated and experienced with technology. There may be concern that underserved populations may not benefit from technologically advanced health care systems using CIT. We postulate that some women may have been hesitant to enroll because of the lengthy consent form, multiple study visits, and fear of being a research subject. Women with less education and computer experience may be more amenable to this type of program if it is not associated with a research study, does not require multiple visits, and is described as part of usual diabetes care. Approximately 85% of U.S. households use a cell phone. Poor, minority, and underserved populations use cell phones the most and more often discontinue landline service in favor of cell phone service (16,17).

SMBG compliance was high (87.6%) among participants when using the voicemail method. This is a result of time expenditure of the diabetes program nursing staff. Staff time was not measured. Exact time measurements were not feasible with the workflow at the time. In our unit, two nurses each spend ~5 hours of their 8-hour workday on the phone listening to and hand recording glucose values left on voicemails, returning calls to relay management recommendations, and tracking down those who do not call in their glucose values as recommended. CIT obviously eliminates the time spent retrieving voicemail information and recording glucose values. This leaves more time for interpretation of SMBG results, diabetes management, and patient education. It should be noted that the CIT method does not preclude the need for some individualized contact with nurses.

Other studies regarding the use of technology for GDM management do not appear to have incorporated direct uploading capability, as we did. Homko et al. (18,19) performed two randomized studies comparing Internet and weekly office visits for SMBG review. Women ($n = 63$) were asked to go to a Web site and type in information regarding their blood glucose level and insulin doses. Computers were provided to the participants; however, compliance in the 2007 study (18) was limited by modem Internet service, and women transmitted only one-third of the

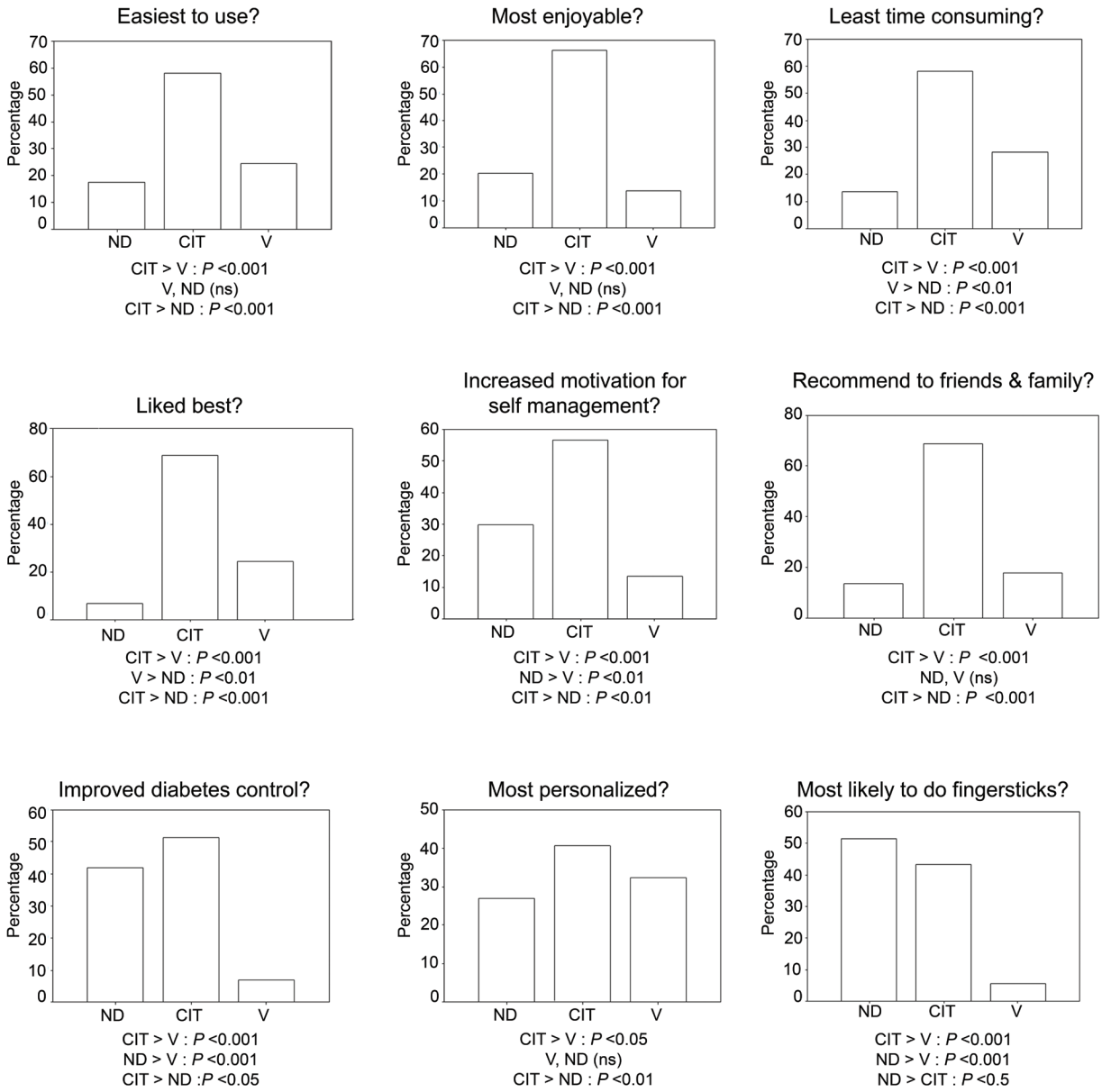

FIGURE 1. Satisfaction survey results of pregnant women using a CIT or voicemail SMBG reporting system in a diabetes management program. ND, no difference; V, voicemail method.

data expected. Compared to review of handwritten log books at weekly prenatal visits, patient and provider satisfaction were higher with the Internet method, but glycemic control was equivalent. In the 2012 study (19) (n = 80), although modems were no longer used, computers were not provided to all participants, and some reported their data by phone. Results indicated increased system utilization and contact with providers but no change in pregnancy outcomes. Both studies used automated reminders and allowed two-way electronic communications.

Time and efficacy of patient care were the primary outcomes of another study (20), in which 38 women were randomized to modem or telephone reporting of SMBG results. There were no significant differences in telephone consultation time or clinic visit time between the two groups. With use of the modem, staff reported better data accuracy and more time to interact with patients in ways other than recording data.

Using the search terms "cellular phone," "cell phone," "Internet," "diabetes," "pregnancy," and "gestational diabetes" alone and in combination, we could not locate another study of hyperglycemia during pregnancy using CIT in which compliance was the primary outcome and women did not have to perform an extra step of entering data by hand or logging in to the Internet. The cell

phone system has the advantage of working if home Internet access is unavailable or undesired. Our population is predominately mixed Hawaiian, Filipino, and Japanese. This population has more pregnancy complications after GDM compared with other ethnicities (21). CIT with cell phones has the potential to make self-management of diabetes easier for such vulnerable populations.

The International Association of Diabetes and Pregnancy Study Group recommendation to lower the diagnostic threshold for GDM (22) will increase the number of pregnant women diagnosed with GDM and type 2 diabetes. The prevalence of GDM is expected to increase to an estimated 20%, and practice patterns will need to change to accommodate this (23). CIT appears to be feasible as part of the solution from the perspective of pregnant patients. Future directions for investigation should include cost-benefit analyses, staff time expenditure analyses, and larger studies to determine whether CIT improves glycemic control or pregnancy outcomes.

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Prior Presentation

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Duality of Interest

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

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