Pilot Study

Peripartum Management of Gestational Diabetes Using a Digital Health Care Service: A Pilot, Randomized Controlled Study

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ABSTRACT

Purpose: The prevalence of gestational diabetes mellitus (GDM) is increasing, and multifaceted interventions are effective in the management of GDM. This study aimed to develop and evaluate a model for the management of GDM with the use of mobile health care.

Methods: This was a prospective, randomized controlled pilot study. A total of 21 patients who were diagnosed with GDM during 24−28 weeks of gestation were randomly divided into a conventional management (CM) group (n = 10) and a mobile management (MM) group (n = 11). The CM group received conventional GDM management and could freely use the mobile health care application. The MM group received mobile health care services, including tailored mobile coaching. After delivery, obstetric outcomes were collected, and 75-g oral glucose tolerance test was performed at 5−12 weeks postpartum.

Findings: Baseline characteristics, including glycosylated hemoglobin (HbA_{1c}), were not significantly different between the 2 groups. No statistically significant differences were found in rates between the 2 groups for (1) neonate large for gestational age and (2) cesarean section at the time of delivery. No significant difference was found in HbA_{1c} between the 2 groups after delivery. However, postpartum homeostatic model assessment insulin resistance, body mass index, weight, and percentage of body fat were significantly lower in the MM group.

Implications: The MM group had no significant difference in glycemic index compared with the CM group. However, the MM group had effective weight control and improved insulin resistance after delivery. This study indicated that mobile health care services could be an efficient GDM management tool. ClinicalTrials.gov identifier: NCT03838380. (*Clin Ther*. 2019;41:2426−2434)

Key words: weight, gestational diabetes, insulin resistance, mobile health care.

INTRODUCTION

Gestational diabetes mellitus (GDM) is one of the most common medical complications of pregnancy. It is defined as GDM that is first diagnosed in the second or third trimester of pregnancy and that is not clearly overt diabetes before gestation.[1,2] The prevalence of GDM is increasing because of the increasing prevalence of obesity and women bearing children at older reproductive ages. It is well known that GDM is associated with several maternal and neonatal

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complications. Women with GDM are at higher risk of undergoing cesarean section and developing preeclampsia.[3,4] Moreover, offspring of women with GDM experience higher rates of neonatal hypoglycemia, hyperbilirubinemia, macrosomia, shoulder dystocia, and birth trauma.[5] However, the risk of preeclampsia, macrosomia, and shoulder dystocia can be reduced with adequate glycemic control during pregnancy.[6,7] Adequate glycemic control could be achieved with tailored counseling about nutrition, exercise, and medical treatment if needed. Currently, women with GDM measure their blood glucose at least 4 times a day, record the results along with details about their diet, and bring the information to the outpatient clinic for counseling. Recently, in the era of the mobile phone revolution, attempts have been made to improve care in all fields of medicine through mobile phone technology and especially in patients with diabetes.[8–10] If mobile health care applications for the management of GDM are applied, timely management may be expected. However, only a few studies about GDM management with mobile phone technology have been published. The purpose of the present study was to develop and evaluate a model for management of GDM with the use of mobile health care.

METHODS

This was a single-center, randomized controlled trial. Patients were recruited from February 2017 to June 2017, and the final delivery occurred August 2017. Singleton pregnant women diagnosed with GDM at 24–28 weeks of gestation were included. GDM was diagnosed with a 2-step approach. Women whose glucose concentrations were >140 mg/dL with a 50-g oral glucose tolerance test (OGTT) underwent a 75- or 100-g diagnostic OGTT. GDM was diagnosed in women who had >1 abnormal value on the 75-g, 2-hour OGTT (fasting, ≥92 mg/dL; 1 hour, ≥180 mg/dL; 2 hours, ≥153 mg/dL) and who had >2 abnormal values with 100-g, 3-hour OGTT (fasting, ≥95 mg/dL; 1 hour, ≥180 mg/dL; 2 hours, ≥155 mg/dL; 3 hours, ≥140 mg/dL). Patients after 30 weeks of gestation and patients with pregestational diabetes were excluded from participating in the study. Patients who were unable to understand Korean, were unfamiliar with mobile phones, who did not have access to a mobile phone, or who were already receiving services from another mobile health care agency were also excluded. Participants were randomly assigned to the conventional management (CM) group or the mobile management (MM) group at a ratio of 1:1. Randomization was performed with a computer-generated sequence. All participants were educated face-to-face about GDM and diet and were asked to answer a questionnaire to measure their baseline self-care behaviors and self-efficacy at the moment of enrollment. The questionnaire included 57 items and was organized into 5 domains as follows: dietary habits, self-care behaviors, self-efficacy for glycemic control, perception of GDM, and perceived social support. The answers to each item were rated on a Likert scale from 1 to 5, ranging from strongly disagree to strongly agree. For all domains, high scores indicate a high level of self-care ability or self-efficacy.

Participants allocated to the CM group received standard antenatal care from obstetricians and endocrinologists. Standard antenatal care consisted of biweekly visits up to 36 weeks of gestation, followed by weekly visits until delivery. Blood pressure, urinalysis (for proteinuria), and blood glucose concentration were evaluated, and fetal surveillance with sonogram or a nonstress test were performed at each visit. Patients were asked to record their blood glucose concentration 4 times daily and were also asked to record their intake at each meal. Women allocated to the MM group received standard antenatal care and tailored mobile health care services. The tailored mobile health care services were provided by a health care provider team by the mobile phone application specifically designed for the study; each team included an endocrinologist, nurses, and nutritionists. Participants in the MM group were given monitoring system devices, including a glucometer with Bluetooth connectivity and an accelerometer to detect physical activity level. The mobile phone application (Huraypositive Inc, Seoul, Korea) specifically designed for this study was installed at enrollment for the MM group to collect clinical data and messages from the patients. The data entered in the mobile application were automatically transmitted by wireless network to the server. The health care providers scanned and

analyzed the transmitted records and sent messages to participants twice a week. Similar application for type 2 diabetes was developed by the same company, and the efficacy was reported in our previous study.[8] Participants received regular messages once a week by mobile application about recommendation for adequate diet and exercise during the study period. The application consisted of 4 sections: clinical data, nutrition and diet, medication, and messaging system and information. The MM group was trained on the application and monitoring devices after random assignment. Patients allocated to the MM group recorded their blood glucose concentration and diet by the mobile phone application, and health care providers regularly scanned clinical data. Patients were allowed to communicate with health care providers through the application. Providers regularly checked the patients' data and messages from patients and sent return messages with tailored medical and nutritional guidance. Patients in the CM group were allowed to access the application and review the information section if desired; however, they did not receive the tailored coaching given to the MM group.

All participants were asked to adhere to regular prenatal visits. At the first, baseline visit the following anthropometric measurements and blood samples were collected from all patients: maternal weight, height, body mass index (BMI; calculated as kg/m^2), percentage of body fat, and complete blood count, glycosylated hemoglobin (HbA_{1c}), glycated albumin, C-peptide, insulin, and a 75-g OGTT. Percentage of body fat was automatically estimated by bioelectrical impedance analysis device. Because insulin resistance (IR) and β-cell dysfunction is related to type 2 diabetes, IR and β-cell function were estimated by using the homeostasis model assessment (HOMA) to screen for high-risk patients of type 2 diabetes. HOMA-IR is calculated as [fasting insulin (μU/mL)] × [fasting glucose (mmol/L)]/22.5 and HOMA-β was defined as (20 × fasting insulin)/(fasting glucose − 3.5).[11,12] Fetal biometry assessment by ultrasonography and a nonstress test were performed at each antenatal visit. Blood samples were collected at delivery. After delivery, all patients were asked to respond to the same questionnaire administered at the time of enrollment and to undergo a postpartum 75-g OGTT at 4−12 weeks after delivery.

This study was approved by the ethics committee of the hospital, and informed consent was obtained from each patient.

The analysis of outcomes was performed according to the intention-to-treat principle. All statistical analysis was performed with SPSS Statistics software Version 24.0 (IBM, Armonk, N Y). Variables were assessed for normality. The researchers used the *t* test or Mann−Whitney *U* test to compare numerical variables, and values are shown as mean (SD) in normally distributed variables and median (interquartile range) in abnormally distributed variables. The $\chi^2$and Fisher exact tests were used to compare categorical variables.

RESULTS

A total of 21 patients were enrolled in the study, 19 patients completed the study, and 2 patients were lost to follow-up (1 in each group). Ten patients were allocated to the CM group and 11 patients to the MM group. The clinical characteristics of both groups are shown in Table I. No significant difference was found between the 2 groups. Maternal age and fasting glucose at enrollment and the rate of family history of diabetes mellitus were higher in the MM group; however, it was not statistically significant.

The obstetrical outcomes are shown in Table II; no significant difference was found between the 2 groups, including gestational age at delivery, birth weight, rate of cesarean section, and rate of large newborn for gestational age. All participants had full-term deliveries and none of the neonates required admission to the neonatal intensive care unit.

Metabolic outcome after delivery measured at 4−12 weeks postpartum is shown in Table III. Median maternal BMI (23.72 [18.99−29.37] versus 20.22 [17.23−20.99]; $P = 0.021$) and weight (62.58 [47.88−79.46] kg versus 54.31 [43.17−57.80] kg; $P = 0.037$) at postpartum were significantly lower in the MM group. Percentage of body fat (38.12% [4.94%] versus 29.20% [5.20%]; $P = 0.005$) and HOMA-IR (1.97 [1.02−4.61] versus 1.46 [0.88−1.71]; $P = 0.011$) were also significantly lower in the MM group compared with the CM group. The levels of fasting glucose, fasting C-peptide, and fasting insulin were also lower in the MM group; however, they were not statistically significant.

Table I. Baseline characteristics.*

Variables†	Total (N = 21)	Conventional Management Group (N = 10)	Mobile Management Group (N = 11)
Age, years	33.43 (4.19)	31.70 (4.92)	35.0 (2.76)
Nulliparity	47.60 (10/21)	80.0 (8/10)	63.60 (7/11)
Gestational age at randomization, weeks	27.33 (1.73)	27.39 (1.61)	27.29 (1.92)
BMI at randomization, kg/m^2	25.45 (4.01)	26.28 (3.51)	24.69 (4.45)
Height, cm	161.45 (4.61)	162.54 (5.14)	161.30 (4.32)
Weight at randomization, kg	66.36 (11.02)	68.70 (10.61)	64.24 (11.45)
BMI before delivery, kg/m^2	25.93 (4.06)	27.61 (4.06)	24.44 (3.66)
Percentage of body fat, %	36.03 (6.83)	38.41 (5.32)	33.89 (7.59)
Systolic BP, mm Hg	108.85 (9.72)	107.33 (7.73)	110.09 (11.32)
Diastolic BP, mm Hg	66.55 (7.66)	67.33 (7.37)	65.91 (8.19)
Fasting glucose, mg/dL	92.03 (16.61)	86.66 (12.15)	97.40 (19.26)
Fasting C-peptide, ng/mL	1.98 (0.69)	1.91 (0.62)	2.04 (0.78)
Fasting insulin, μIU/mL	10.23 (5.97)	10.03 (5.78)	10.40 (6.41)
Glycosylated hemoglobin, %	35.24 (5.10)	33.70 (4.30)	36.64 (5.55)
Glycated albumin, %	13.58 (1.71)	13.20 (2.01)	13.92 (1.41)
HOMA-IR‡	1.91 (0.39–6.12)	2.37 (0.68–5.04)	1.44 (0.39–6.12)
HOMA-β1	2.25 (1.15)	2.38 (1.16)	2.15 (1.19)
Hemoglobin, g/dL	11.42 (0.81)	11.60 (0.75)	11.26 (0.86)
Family history of diabetes	42.9 (9/21)	30.0 (3/10)	54.50 (6/11)
Past alcohol drinker	42.9 (9/21)	50.0 (5/10)	36.40 (4/11)
Regular exercise	61.9 (13/21)	60.0 (6/10)	63.60 (7/11)

BMI = body mass index; BP = blood pressure; HOMA-IR = homeostasis model assessment insulin resistance; HOMA-β1 = homeostasis model assessment β-cell dysfunction.

* Data are expressed as mean (SD) or % (n/N) unless otherwise specified.

† *P* values for all variables were not significant.

‡ Variables that do not have a normal distribution were compared with Mann–Whitney *U* test and presented as median (interquartile range).

We also analyzed the level of physical activity during the study period. No difference was found in the physical activity level between the 2 groups (CM group versus MM group, 16.1 [0–34.3] min/d versus 12.9 [0–30.0] min/d; $P = 0.72$).

Among 21 patients, 15 patients underwent a 75-g OGTT at 4–12 weeks after delivery. Four patients (CM group, n = 2 of 8; MM group, n = 2 of 7) were diagnosed with diabetes, and 10 patients exhibited impaired fasting glycemia and/or impaired GT. Only 4 patients of 15 had normal GT.

A total of 18 patients responded to the questionnaire administered after delivery, and dietary habits and self-efficacy scores indicated improvement on study completion (Table IV).

DISCUSSION

In the present study, patients with GDM who were allocated to the group assigned the use of a mobile phone application for the management of GDM had lower BMI, weight, percentage of body fat, and IR after delivery compared with a CM group. No significant difference in glycemic control during pregnancy and perinatal outcome between the MM and CM groups.

Management through telemedicine seems to be effective in improving glycemic control in the nonpregnant patient with diabetes.[13–15] A meta-analysis reported significant decline in HbA_{1c} values in patients managed through telemedicine compared with a control group (mean difference, –0.44%

Table II. Obstetric outcome.*

Variables†	Total (N = 21)	Conventional Management Group (N = 10)	Mobile Management Group (N = 11)
GA at delivery, weeks	39.08 (0.94)	39.44 (0.70)	38.74 (1.03)
Birth weight, kg	3.25 (0.45)	3.21 (0.37)	3.28 (0.53)
Small for GA‡	26.30 (5/19)	22.20 (2/9)	30.0 (3/10)
Large for GA‡	10.50 (2/19)	0 (0/9)	20.0 (2/10)
Cesarean section‡	52.60 (10/19)	44.40 (4/9)	60.0 (6/10)

GA = gestational age.
* Data are expressed as mean (SD) or % (n/N).
† *P* values for all variables were not significant.
‡ Denominators represent the numbers of patients with available medical records.

[–4.8 mmol/mol]; 95% CI, –0.61% to –0.26% [–6.7 to –2.8 mmol/mol]; $P < 0.001$).[14] Patients with GDM are especially expected to benefit from telemedicine because they are of reproductive age and familiar with using mobile phone technology. Tailored medical and nutritional coaching through mobile phone applications may lead to improvement in glycemic control and therefore pregnancy outcomes. It is well known that for GDM pregnancies, perinatal outcome is closely related to each patient's glycemic control.[5,7,16] The present study found no significant difference in glycemic control between the MM group and the CM group. Consequently, there was no difference in perinatal outcome between the 2 groups. The rate of large for gestational age and small for gestational age neonate and cesarean section is higher in the MM group compared with the CM group; there was no significant difference between the 2 groups. Although without statistical significance, older age in the MM group is a possible risk factor for small for gestational age or cesarean section. Considering that this is a pilot study with small sample size, there is a limitation to interpret the perinatal outcome, and a study with larger sample size is necessary to overcome this limitation.

Early intervention for the management of GDM through a mobile feedback system from the time of diagnosis might be helpful in improving glycemic control. A recent study reported the effectiveness of initial active engagement in glycemic control with telemonitoring in patients with type 2 diabetes.[17] In addition, reciprocal interaction between patients and health care providers increased compliance levels by resolving patients' concerns and reducing unnecessary visits. A few randomized controlled trials were conducted to assess the effect of telemedicine intervention on GDM management.[18–20] Recently, a randomized controlled trial found that a daily mobile phone-based feedback system was effective in the management of GDM compared with standard care.[19] Miremberg et al[19] found that the mobile phone intervention group had a higher level of compliance, lower mean blood glucose (105.1 [8.6] mg/dL versus 112.6 [7.4] mg/dL; $P < 0.001$), and a lower rate of requiring insulin treatment (13.3% versus 30.0%; $P = 0.004$). However, perinatal outcomes did not differ between both groups. A meta-analysis found a slight but statistically significant improvement in HbA_{1c} in patients with GDM managed through telemedicine compared with a standard care group (5.22% [0.7%] versus 5.37% [0.61%], mean difference, –0.14% [95% CI, –0.25% to –0.04%]).[20] However, researchers concluded that there is insufficient evidence that telemedicine intervention is superior to standard care in the management of patients of GDM, because the 7 studies included in the meta-analysis were all small (underpowered) and assessed different technologies.

In the present study, although glycemic control was not improved with the use of mobile management, postpartum BMI, weight, percentage of body fat, and HOMA-IR were lower in the MM group. No significant difference was found in baseline maternal

Table III. Measurement variables at 4–12 weeks postpartum.*

Variables	Conventional Management Group (n = 10)	Mobile Management Group (n = 11)	*P*
BMI at randomization, kg/m^2	26.28 (3.51)	24.69 (4.45)	NS
BMI before delivery, kg/m^2	27.61 (4.06)	24.44 (3.66)	NS
BMI at postpartum,† kg/m^2	23.72 (18.99–29.37)	20.22 (17.23–20.99)	0.021‡
Weight at randomization, kg	68.70 (10.61)	64.24 (11.45)	NS
Weight before delivery, kg	73.90 (12.45)	63.38 (8.09)	NS
Weight gain during study period, kg	3.65 (1.71)	1.98 (2.05)	NS
Weight at postpartum,† kg	62.58 (47.88–79.46)	54.31 (43.17–57.80)	0.037‡
Percentage of body fat at randomization	38.41 (5.32)	33.89 (7.59)	NS
Percentage of body fat at postpartum	38.12 (4.94)	29.20 (5.20)	0.005§
Systolic BP, mm Hg	121.63 (2.83)	120.86 (3.62)	NS
Diastolic BP, mm Hg	79.88 (4.02)	78.71 (8.06)	NS
Fasting glucose, mg/dL	103.63 (10.03)	101.43 (13.59)	NS
Fasting C-peptide, ng/mL	2.08 (0.75)	1.56 (0.34)	NS
Fasting insulin, μIU/mL	8.73 (4.01)	5.33 (1.57)	NS
Glycosylated hemoglobin, %	36.75 (3.24)	35.57 (4.69)	NS
Glycated albumin, %	12.86 (1.39)	13.76 (0.95)	NS
HOMA-IR†	1.97 (1.02–4.61)	1.46 (0.88–1.71)	0.011‡
HOMA- β1	1.74 (0.77)	1.11 (0.40)	NS
Hemoglobin, g/dL	13.23 (0.36)	12.87 (0.91)	NS
NGT‖	25.0 (2/8)	28.62 (2/7)	NS
IFG‖	50.0 (4/8)	28.60 (2/7)	NS
IGT‖	12.50 (1/8)	57.10 (4/7)	NS
Mixed‖	0 (0/8)	14.30 (1/7)	NS
Diabetes‖	25.0 (2/8)	28.60 (2/7)	NS

BMI = body mass index; BP = blood pressure; HOMA- IR = homeostasis model assessment insulin resistance; HOMA-β1 = homeostasis model assessment β-cell dysfunction; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; Mixed = coexistence of IFG/IGT; NGT = normal glucose tolerance; NS = not significant.

* Data are expressed as mean (SD) or % (n/N).

† Variables that do not have a normal distribution were compared with Mann–Whitney *U* test and presented as median (interquartile range).

‡ Determined by Mann–Whitney *U* test.

§ Determined by *t* test.

‖ Denominators represent the numbers of patients with available medical records.

weight and BMI at random assignment between the CM and MM groups. The level of physical activity during the study period indicated no difference between both groups. Collectively, we suggest that frequent education through mobile application might influence the effective weight reduction after delivery in the MM group. Patients in the MM group received messages about the importance of weight reduction at the postpartum period to prevent type 2 diabetes or cardiovascular disease later in life. Especially, recommendations for diet and exercise during the postpartum period was offered through messages around 37 weeks of gestation to the MM group, and no message was offered to the CM group. We collected the number of messages sent to patients and found that 3.7 messages per week were sent on average. Among 3.7 messages, 1.2 messages were about the dietary recommendation. In addition, lower

Table IV. Response of questionnaire.*

Variable	Baseline	Final	P†
Dietary habit	3.14 (0.37)	3.46 (0.33)	0.001
Self-efficacy score	18.65 (5.00)	20.97 (4.30)	0.012
Perception of gestational diabetes	2.98 (0.48)	3.00 (0.63)	NS
Perceived social support	3.58 (0.63)	3.71 .49	NS

NS = not significant.
* Data are expressed as mean (SD).
† Determined by paired sample *t* test.

maternal weight and BMI of the MM group in the postpartum period may have resulted from lower weight gain from random assignment to delivery in the MM group (1.98 [2.05] kg versus 3.65 [1.71] kg; $P = 0.083$) compared with the CM group. It is well known that women with prior GDM have up to 70% risk of type 2 diabetes in 20 years. Family history of type 2 diabetes, maternal obesity, and excessive weight gain during pregnancy seem to confer the greatest risk.[21–24] Along with excessive weight gain during pregnancy, postpartum weight retention is also a risk factor for long-term maternal obesity. According to one study, weight reduction at the postpartum period is correlated with change in cardiometabolic risk factors in women with recent GDM.[25] This study emphasized the importance of postpartum weight control in women with prior GDM to reduce the risk factors for long-term cardiometabolic complications. Considering the effective weight reduction at the postpartum period in our study, management of GDM based on a mobile feedback system might be an adequate model for long-term health care in the near future.

Patients allocated to the MM group were offered messages from health care providers and also sent back questions to the health care providers. Average of 0.8 question was sent back in a week. Mobile phone-based, reciprocal communication between patients and the multidisciplinary team might affect the improvement in dietary habit and self-efficacy score shown in the results of the administered questionnaires.

The strength of the present study is that it was a randomized, controlled trial to compare glycemic control, compliance, and perinatal outcome between a mobile phone intervention group and a standard care group in patients with GDM. Because postpartum weight retention is a risk factor for obesity and is associated with adverse health problems, including type 2 diabetes and hypertension,[24,25] improvement in BMI and body fat levels postpartum in the MM group indicates that mobile phone-based management of GDM may play an important role in the long-term improvement of glucose intolerance.

However, this study could be underpowered because of the small sample size. Obstetric and neonatal data for analysis were insufficient, because many patients delivered at a local hospital.

CONCLUSIONS

The present study found that mobile phone-based technology can be used in the management of GDM and is a potentially useful tool for weight control in the postpartum period. Future study will focus on the effect of mobile phone-based platforms on pregnancy and neonatal outcomes with a larger sample size and more advanced platform.

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C.Y. Park conceived and designed the study. K.P. Min provided technical support for the study and collected data. J.H. Sung and D.Y. Lee organized and analyzed data. J.H. Sung and C.Y. Park wrote the manuscript. C.Y. Park provided supervision and revised the manuscript. All authors read and approved the final manuscript.

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DISCLOSURES

The authors have indicated that they have no conflicts of interest regarding the content of this article.

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