**Comparing the effects of face-to-face training and booklet-based education on maternal outcomes in gestational diabetes: a randomized controlled clinical trial**

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**ABSTRACT**

**Background & Aim:** Gestational diabetes is a medical condition that can lead to adverse outcomes of pregnancy. In this regard, the best way to reduce symptoms can be patient education. Hence, the aim of this study was to determine the effects of face-to-face training and booklet-based education on the maternal outcomes of diabetes in pregnancy.

**Methods & Materials:** A total of 126 patients with gestational diabetes were randomly enrolled in this controlled clinical trial. The patients were randomly allocated into three groups and were followed up to 1 week after birth. The 42 samples in the first intervention group, received face-to-face training by the researcher. The 42 samples. The second intervention group received a researcher made educational booklet and the 42 samples. This group as a control received routine hospital care and education. Then, the participants were contacted by the researcher, and a record sheet was completed by them. In this study, Fisher’s exact test, chi-square, ANOVA and Kruskal–Wallis were used to analyze the data.

**Results:** Among the studied outcomes, the number of maternal readmission, changing of the treatment from diet control to insulin therapy, increasing doses of insulin, showed significant differences in the groups, but among other outcomes, there were no statistically significant differences in the groups.

**Conclusion:** Training by different methods is effective in patients with gestational diabetes and can increase the health of mothers and children. It also leads to lower costs of hospital stay.

**Introduction**

Pregnancy is a physiological and normal process which women can experience it. However, it maybe changes to a critical period, especially when medical conditions threatens maternal health. Underlying problems, diseases and disorders caused during the pregnancy as well as external factors can endanger the health of mother and fetus or both. Some problems during pregnancy can lead to unpleasant consequences. Pregnancy outcomes are also strongly influenced by maternal health and her physical-mental condition, in a way that, issues like maternal medical or surgical problems affect the outcomes of pregnancy (1). One of the most common medical conditions is gestational diabetes. Around the world, there has been a progressive increase in the prevalence of diabetes in recent decades which is
considered as one of the major health problems (2). The World Health Organization, according to the statistics and the growing trend of diabetes worldwide, has announced diabetes as a latent epidemic and has called all the countries in the world to confront the epidemic (1) since the year 1993. In the United States of America, gestational diabetes occurs in 135,000 women per year (3) and by the year 2030 the number of people with diabetes is likely to reach double its current level and this “epidemic diabetes” also includes pregnant women (4). The prevalence of gestational diabetes at the world is 5-10% and is reported in different parts of Iran. Probably a different race or ethnicity accounts for differences in the prevalence of gestational diabetes. The prevalence of gestational diabetes has been reported from 1.3% to 8.9% in Iran (5). Gestational diabetes is a common and noteworthy medical condition that deserves attention in the field of carbohydrate intolerance which affects the pregnancy phenomenon and can lead to adverse consequences during pregnancy or cause risky delivery and adversely affect mother and fetus (6, 7). Maternal adverse effects include; increased incidence of hypertension and preeclampsia, increased rates of cesarean delivery, cardiovascular side effects associated with dyslipidemia, abdominal obesity, hydranmious, pyelonephritis and prolonged hospital stay (2, 6-9). Fetal complications related to gestational diabetes are including macrosomia, fetal growth restriction, unexplained fetal death, neonatal hypoglycemia, hyperbilirubinemia, cardiac hypertrophy, hypocalcemia, polycythemia, and obesity (2, 6, 8).

In this regard, education can be the best way to reduce complications and improve the quality of life for people with diabetes, which does not cost a lot and is applicable to all patients (1). Thus, with effective training methods for patients or clients, health improvement at hospital and home is accelerated (10). Learning about care for the patients and their family should be included in the care plan and the patients should receive tips and instructions on how to take care of themselves, at the time of admission and before discharge (3). It seems, treatment of gestational diabetes along with the midwifery supports, reduces the risk of perinatal complications (9). Improving midwifery cares, as well as diagnosis and better treatment of gestational diabetes reduces maternal complications (6, 11).

There are different methods for patient education such as face-to-face training that can improve the relationship between people and health care providers. The method can more applicable for people who have low levels of literacy and education or having learning problems or disabilities. However, face-to-face training may be not good enough for patients who have a lack of time. Thus, lack of time and rapid discharge of patients is a main obstacle for patient efficient education. In addition, negative effects of the hospital environment, such as lack of quiet and solitude environment and social isolation, can interfere in the inpatient-centered decision making about health and their involvement in the learning process. Hence, pamphlet or booklet can be used to reduce the negative effects of training in hospital (12). Using the educational booklet is also widely used in education and it can be used as a guide for patients and health-care professionals. One of the advantages of educational booklet is that it can be used in any situation and circumstances (13), but we should cost estimate for preparing it.

However, each type of education has some advantages and limitations, educational method should be select based on the patient condition. Hence, women with gestational diabetes are not excepted. Therefore, the aim of this study was to determine the effects of face to face training and booklet-based education on the maternal and fetal - neonatal outcomes of diabetes in pregnancy.

**Methods**

This study was a randomized controlled clinical trial that compared two types of educational methods including face-to-face training and educational booklet on maternal and neonatal-fetal outcomes. Pregnant women with gestational diabetes were enrolled to the study who had a gestational age of 28-36 weeks and were admitted at one of three selected hospitals affiliated with Tehran University of Medical Sciences due to high blood sugar or diabetes diagnosis in 2012-2013. Other inclusion criteria were gestational, being literate, and lack of any known physical or mental disease that make trainings impossible. Women who received diabetes training before entering the study were excluded. The absence in one of the training sessions and reluctance to continue participation in the study were
considered as the other exclusion criteria.

After obtaining approval from the Ethics Committee and the necessary permits from the Research Council of Tehran University of Medical Sciences, and coordinating with officials of the hospitals through available sampling, hospitalized patients with gestational diabetes, eligible for the study, were selected. Written informed consent was obtained from the participants, and then, they were allocated in three groups (two interventions and one control groups). Because we could not find similar study, with assuming $P_0 = 0.05$ (ratio of readmission of patients after discharge) and expected loss to follow up to $P_1 = 0.1$ after training and select $\alpha = 0.05$ and $\beta = 0.05$, sample size was calculated as 126 subjects which 42 samples were allocated in each (according to the following formula).

$$n = \left( \frac{z_{\alpha/2} + z_{\beta/2}}{p - q} \right)^2 \frac{P_0(1-P_0) + P_1(1-P_1)}{2}$$

$$P = \frac{P_0 + P_1}{2}$$

$$p = 0.5 + 0.1 = 0.3 \Rightarrow q = 1 - p = 1 - 0.3 = 0.7$$

$$n = \left( \frac{2(1.96 + 1.64)^2 \times 0.3 \times 0.7}{(0.5 - 0.1)^2} \right) = 34$$

Three hospitals were selected, then to allocate the participants in each group, randomized block method was used. In all three hospitals, three groups (14 samples in each group) of samples were selected to receive the intervention at hospitals. The first intervention group received face-to-face training and the second intervention group took educational booklet. In this study, control group received routine hospital care and education. Allocation of samples in each group took place after previous samples were discharged from the group to prevent the exchange of information by the participants (Figure 1).

Data were collected through interviews, completing the questionnaires and recording patient’s medical profile. Questionnaire was containing demographic data, obstetrics history, medical data about gestational diabetes and data sheet up to a week post-delivery. Studied outcomes were included; pregnancy outcomes associated with the mother, including; mother’s hospital admission or not admission due to maternal diabetes during pregnancy until the delivery, method of delivery, changing of treatment method from diet control to insulin therapy and increase in insulin intake. Cases of stillbirths were also reported. Validity and reliability of questionnaire were confirmed by expert panel as well as content of education.

In the intervention group, two training sessions were held on 2 consecutive days and each session took about 40 minutes. Training items mentioned in the first session of the training were included; a definition of gestational diabetes, causes, side effects, individuals at risk, and control and treatment of gestational diabetes such as glycemic control. Training items that were taught in the second session were included; nutrition, physical activity and exercise, insulin injection, and following-up after the pregnancy. In the other intervention group, all the items taught by face-to-face training method were distributed in the form of an educational booklet, to be studied by the patients. In the control group, the patients received routine hospital care and intervention. Thus, in all three hospitals, mothers received comprehensive guidance on how to feed themselves by a diettian. Up to a week after the birth, the mothers were contacted by researcher via phone to answer the questions, the mothers’ medical records were also used, and then, the record sheet was completed by the researcher. According to the exclusion criteria, no sample was removed. Blinding was not possible, according to the study. Data were analyzed using SPSS software (version 16; SPSS Inc., Chicago, IL, USA).

Results

The mean age of the participants in the first intervention group was $30.930 \pm 5.663$ years, and in the second intervention group was $30.740 \pm 5.575$ years, and in the control group was $30.140 \pm 5.515$ years. Gestational age at the time of diagnosis of gestational diabetes in the control group was about 25-30 weeks in most subjects, in the intervention Groups 1 and 2, it was 30-35 and 30-35 weeks, respectively, in most subjects. One case of stillbirth was reported in the control group.
The results of ANOVA, chi-square and Fisher’s exact test showed that the three groups in terms of demographic variables, midwifery, and laboratory were not significantly different at baseline (Table 1).

None of the experimented subjects had readmission after the intervention in the face-to-face training intervention group, but 10 patients in the control group and 4 patients in the educational booklet intervention group, did not have readmission after the intervention. Fisher’s exact test showed a significant difference between the three groups after the intervention (P = 0.032). It means that, the face-to-face training intervention group and training booklet intervention, had no need to change the type of treatment from diet to insulin therapy.

In the control group, half of the experimented subjects had increased their insulin dose until the delivery. In the face-to-face training intervention group and educational booklet intervention group, the majority of experimented subjects did not increase their insulin dose. Chi-square test showed a significant difference among the three groups after the intervention (P = 0.019).
Table 1. Characteristics of subjects according to demographic, obstetric and laboratory criteria

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control group</th>
<th>Intervention Group 1 (face-to-face training)</th>
<th>Intervention Group 2 (training booklet)</th>
<th>Test result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age of mothers</td>
<td>30.14</td>
<td>30.93</td>
<td>30.744</td>
<td>P = 0.798</td>
</tr>
<tr>
<td>Mean mother’s BMI before pregnancy</td>
<td>28.12</td>
<td>26.31</td>
<td>26.93</td>
<td>P = 0.342</td>
</tr>
<tr>
<td>The mean mother’s BMI at the time of sampling</td>
<td>32.4</td>
<td>30.64</td>
<td>31.33</td>
<td>P = 0.383</td>
</tr>
<tr>
<td>Education level of mother</td>
<td>High school</td>
<td>High school 57.1%</td>
<td>High school 52.40%</td>
<td>P = 0.709</td>
</tr>
<tr>
<td>Economic status</td>
<td>Average 64.20%</td>
<td>Average 76.20%</td>
<td>Average 64.30%</td>
<td>P = 0.466</td>
</tr>
<tr>
<td>Abortion</td>
<td>No 81%</td>
<td>Not 73.80%</td>
<td>Not 71.40%</td>
<td>P = 0.611</td>
</tr>
<tr>
<td>History of stillbirth</td>
<td>Not 90.5</td>
<td>Not 95.2</td>
<td>Not 90.20%</td>
<td>P = 0.505</td>
</tr>
<tr>
<td>Exercise during pregnancy</td>
<td>No 76.20%</td>
<td>No 61.90%</td>
<td>No 69%</td>
<td>P = 0.367</td>
</tr>
<tr>
<td>Type of treatment</td>
<td>Diet 54.80%</td>
<td>Diet 61.90%</td>
<td>Diet 61.90%</td>
<td>P = 0.7443</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Not 88.1%</td>
<td>Not 78.60%</td>
<td>Not 85.70%</td>
<td>P = 0.462</td>
</tr>
<tr>
<td>The mean birth weight of the previous infant</td>
<td>3090.22</td>
<td>3259.41</td>
<td>3147.08</td>
<td>P = 0.830</td>
</tr>
<tr>
<td>History of gestational diabetes in a previous</td>
<td>Not 72.9</td>
<td>Not 88.9</td>
<td>Not 84.6</td>
<td>P = 0.775</td>
</tr>
<tr>
<td>Previous birth time ,if she had gestational</td>
<td>Premature</td>
<td>Premature delivery 50%</td>
<td>Premature delivery 50%</td>
<td>P = 0.758</td>
</tr>
<tr>
<td>diabetes</td>
<td>delivery 80%</td>
<td></td>
<td>At the date of birth 50%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>At the date of birth 50%</td>
<td></td>
</tr>
</tbody>
</table>

Variance analysis test results revealed that there was no significant difference between the three groups in terms of gestational age at delivery based on the date of the 1st day of the last menstrual period, gestational age at delivery based on the first ultrasound (first trimester).

Discussion

Maternal age range, in the face-to-face intervention group, was 20-50 years, in the educational booklet intervention group was 20-42 years and in the control group was 19-45 years. Range of body mass index of mothers before pregnancy, in face-to-face intervention group, was 17-41, in the educational booklet intervention group was 20-46 and in the control group was 15-53, and in the third trimester were; 21-45, 23-53, and 22-58 in the face-to-face teaching intervention group the educational booklet intervention group, and the control group respectively.

The main objective of this study was to evaluate the effect of various teaching methods on maternal outcomes in women suffering from gestational diabetes. Findings showed that training, regardless of method, reduced the number of mothers’ readmission until the delivery, and led to reduction in the rate of changing treatment from diet to insulin therapy.

One of the common maternal complications in patients with gestational diabetes is prolonged hospitalization (6).

Table 2. Distribution of readmission after the intervention in the three studied groups

<table>
<thead>
<tr>
<th>Readmission after intervention</th>
<th>Control</th>
<th>Intervention 1 (face to face learning)</th>
<th>Intervention 2 (training booklet)</th>
<th>The result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>Did not have</td>
<td>32 (76.2)</td>
<td>41 (100)</td>
<td>38 (90.5)</td>
<td>Fisher’s exact test</td>
</tr>
<tr>
<td>Had</td>
<td>10 (23.8)</td>
<td>0 (0)</td>
<td>4 (9.5)</td>
<td>P = 0.002</td>
</tr>
<tr>
<td>Total</td>
<td>42 (100)</td>
<td>41 (100)*</td>
<td>42 (100)</td>
<td></td>
</tr>
</tbody>
</table>

P < 0.050 is significant. *One of the experimented subjects in the control group 1 (face-to-face training) did not respond to phone calls
A study showed that the prevalence of the disease in Iran is from 1.3% to 8.9% (3) and causes many complications for the mother and the infant. Therefore, implementation of educational programs for pregnant women, screening the risky groups and attention to cited complications of diabetes in pregnancy, seems to be essential (14, 15). Suzuki et al. (16) showed that, in the 1st and 2nd days of hospitalization, it is important to focus on the health education for diabetics. Studies show that this is the best time to start training. Therefore, in this study, the trainings began, when the patient was hospitalized. However, other studies have shown that training on the readmission due to other diseases has had less impact. For example, in a study of Shirani (17), which was conducted on patients with coronary artery disease, education at the time of discharge did not significantly influence the readmission. However, in a study by Ranjbar et al. (18) on schizophrenia patients training at discharge had reduced the readmission within 3 months after the discharge.

Bener et al. (19) study showed that, cesarean delivery, preterm birth (12.6%, P = 0.030), and macrosomia (10.3%, P = 0.010), were significantly more in diabetic pregnant women. Furthermore, Fardi Azar et al. (20) study showed that, among common maternal complications, incidence of cesarean delivery was high (88.3%), and among the maternal complications in diabetes mellitus and gestational diabetes, incidence of preterm delivery was 18%. Forced cesarean delivery between the three groups in this study had a high incidence, but premature birth did not have a high prevalence and a greater number of samples who had given birth at 36-38 weeks of their pregnancy.

It seems that other factors affect the above variables. Therefore, just education does not affect the method of delivery and birth time. The incidence of complications in such women is high, due to associated outcomes with gestational diabetes. However, it seems that, studies with larger number of samples and also with follow-up for a longer time than this study, may produce some results in relation to the above variables, and the researchers suggest, more research should be conducted in this way.

One of the limitations of this study was that, as the researcher did not match the knowledge of mothers before the study, and it was possible for the participants to obtain information from other resources a part from the researchers’ intervention. To compensate for this issue, the researchers attempted to conduct the study in three groups.

Education, particularly in patients with gestational diabetes, increases mothers’ awareness about accuracy and time-monitoring of blood glucose. It also increases their understanding of the disease control, and hence, increases the health of mothers and children at risk groups, and may also lead to reduced hospital costs. Comparing the effects of training methods for gestational diabetes during pregnancy is recommended. Findings from the future such studies can be termini the best education and training strategies for patients during pregnancy, and improve maternal and child health outcomes.

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Conflict of interest

The authors declare no conflict of interest.

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