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The effect of okra powder on blood glucose levels in women with gestational diabetes mellitus: A non-blinded randomized controlled trial

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Abstract

Background: Gestational Diabetes Mellitus (GDM) is one of the common medical complications during pregnancy, and a diet is the first line of treatment for it.

Objectives: This study determined the effect of okra powder on the blood glucose levels of women with GDM who were on diet.

Methods: This non-blinded randomized controlled trial was conducted on 60 women with GDM who were randomly allocated into two groups. The usual diet for gestational diabetes was taught to both groups. The intervention group also consumed 6 grams of okra skin and seed powder orally in a divided dosage twice daily for 4 weeks. Before, two and four weeks after the start of the study, fasting and 2-hour postprandial glucose (PPG) was measured. The data were analyzed by t-test, Mann-Whitney U test, Chi-square, and Friedman test.

Results: The mean baseline fasting blood sugar (FBS) did not differ significantly between the women in the intervention and control groups (P=0.954). However, mean FBS was significantly lower in the intervention group at two weeks and four weeks after the baseline (P<0.001). The mean baseline 2-hour PPG did not significantly differ between women in the intervention and control groups (P=0.955). However, the mean 2-hour PPG was significantly lower in the intervention group at two weeks and four weeks after the baseline (P<0.001).

Conclusion: The okra powder was effective in reducing FBS and 2-hour PPG in women with GDM who were on diet therapy.

Keywords: Gestational Diabetes Mellitus, Diet therapy, Abelmoschus.

Introduction

Gestational Diabetes Mellitus (GDM) is a carbohydrate intolerance of varying degrees that first occurs or is diagnosed during pregnancy. It is diagnosed by at least one abnormal Oral Glucose Tolerance Test (OGTT) and typically begins in mid-pregnancy and continues until the end of pregnancy.[1] Asian women are at greater risk for GDM.[2] In a systematic review in Iran, the lowest and the highest prevalence was reported in Ardebil (1.3%) and Karaj cities (18.6%), respectively.[3]

Due to changes in pregnancy hormones, insulin resistance peaks in the third trimester of pregnancy. Then, the mother's pancreas releases more insulin to compensate for insulin resistance.[4] GDM occurs when the compensatory mechanism is impaired and insulin is insufficient for glucose metabolism.[5,6]

GDM is associated with short- and long-term maternal and fetal complications.[7] Maternal complications include preeclampsia, polyhydramnios, need for induction of labor and cesarean section, spontaneous abortion, and preterm labor, whereas macrosomia, intrauterine growth retardation, shoulder dystocia, bone fractures, nervous paralysis, hypoglycemia, respiratory distress syndrome, hyperbilirubinemia, and fetal death are among the fetal consequences of GDM.[1,8] Studies show that optimal control of maternal blood glucose levels can reduce the

incidence of complications.[9]

Currently, diet is the first-line treatment for GDM.[5] Pregnant women with a fasting blood sugar (FBS) <95 and a 2-hour postprandial glucose (PPG) <120 mg/dl are treated with diet.[1] Adherence to diet and physical activity in the early stages of GDM helps 70-85% of women achieve good glycemic control, but 15-30% of them require insulin.[10,11] Women with GDM who have not received timely treatment or who have failed to control their blood sugar with diet are placed on insulin or oral glucose-lowering agents such as metformin. Metformin can be used in women with GDM whose FBS is <110 mg/dL. However, the United States Food and Drug Administration has not approved the use of oral glucose-lowering drugs during pregnancy.[1] Acceptance of insulin injections is also difficult for most patients.[12] Insulin and oral chemicals have many side effects[13] and dietary strategies are also difficult for patients to follow.[11] Therefore, researchers are looking for ways to help control blood sugar in women with GDM. [14]

Okra (*Abelmuschus esculentus*) is a plant of the *Malvaceae* family.[15] Okra has an antispasmodic effect and is recommended during pregnancy because it contains vitamin B, which is involved in fetal growth, and folate, which is involved in fetal brain development and prevention of neural tube defects.[16] Okra also contains the flavonoids quercetin and catechin, which due to their antioxidant properties prevent cell destruction and therefore may be able to repair damaged beta cells and increase insulin secretion.[17] The high concentration of fiber and mucilage in okra can also help reduce blood sugar by inhibiting glucose uptake from the intestinal tract. Quercetin in this plant also prevents glucose absorption by inhibiting alpha-glucosidase in the intestine.[18-20] A study investigating the therapeutic effect of okra extract in rats with streptozotocin-induced GDM showed that okra extract inhibited insulin resistance, improved blood glucose levels, and promoted fetal growth.[21] Another study also reported that okra skin and seeds had hypoglycemic and hypolipidemic effects in diabetic rats.[22] A study also reported that okra powder could improve the glycemic markers and lipid profiles in patients with type 2 diabetes. [23] However, no studies were found on the effect of okra on blood glucose levels in women with GDM.

Objectives

This study aimed to examine the effect of okra powder on blood glucose levels in women with GDM who were on diet therapy.

Methods

Study design and participants

This non-blinded randomized controlled trial was conducted from October 2018 to April 2019 in 60 women with impaired Oral Glucose Tolerance Test (OGTT) referred to the health centers of Mashhad, Iran.

Inclusion criteria were consent to participate in the study, literacy, age from 18 to 35 years, gestational age between 24 and 28 weeks, FBS≥92 mg/dl, blood glucose 1 hour after consumption of 75 g glucose ≥180 mg/dl, or blood glucose 2 hours after receiving 75 g glucose ≥153 mg/dl in 24 to 30 weeks gestational screening, FBS <95 mg/dl, and 2-hour PPG <120 mg/dl[1] in a test to validate dietary control/treatment of GDM, and no allergy to okra or *Malvaceae* family herbal products. Women were also included if had no known medical diseases and midwifery problems (i.e. history of infertility, polycystic ovary syndrome, history of preterm labor, premature contractions in the current pregnancy, history of 2 or more stillbirths, gestational hypertension, abnormal bleeding, placenta previa, polyhydramnios and oligohydramnios on sonography), and no speech and hearing problems that hinder communication with the researcher. Women were excluded in cases of hospitalization, pregnancy complications, pregnancy termination, taking any other hypoglycemic medications, failure to use okra powder correctly and regularly (do not take 6 intermittent doses of okra powder during the study or 3 consecutive doses), and refusal to continue the study.

We calculated the sample size based on the results of a pilot study of 10 women with GDM and using the formula for comparing two means. In the pilot study, the mean 2-hour PPG was 115.2±5.8 and decreased to 108.2±6.0 after two weeks. Then, considering S1 = 5.8, S2 = 6, $\mu 1 = 115.2$, $\mu 2 = 108.2$, $\alpha = 0.05$, and $\beta = 0.2$, the required sample size for each group was determined to be 12 women. However, because of the likely dropouts and to increase the power of the study, we enrolled 30 women in each group.

A two-stage sampling was performed. First, two health centers out of the five main centers in the city were randomly selected. Two sub-centers were then selected from the centers covered by each of these two main centers (4 centers in total). Using a table of random numbers, of the 4 selected sub-centers, two were assigned to the control group and the other two centers were assigned to the intervention group. Then, among eligible women who were already registered at each center, convenient sampling was conducted to recruit the required number of women in the study groups.

Every morning, the researcher visited the health centers to find women who were in the 24th to 30th weeks of pregnancy, whose OGTT was impaired, who came in for routine checkups, and who were eligible for the study. The researcher informed eligible women of the study objectives, and if they agreed to take part, their FBS and 2-hour PPG were checked to confirm dietary control/treatment of GDM.

Preparation of okra powder

The identity of okra plant was confirmed by the herbarium of the Institute of Plant Sciences of the Ferdowsi University of Mashhad with code E 1047-FUMH and standardized based on phenolic and gallic acid compounds. Each gram of okra powder contained 3.6 mg of phenolic composition equivalent to gallic acid. The dose used was determined by a specialist in traditional medicine at the Ferdowsi University of Mashhad based on the study of Tian et al. who studied the effect of okra extract on rats with streptozotocin-induced GDM.[21] Then, three grams of okra powder were poured into 6*8 sachets, labeled "natural", and the manufacturing and expiration dates were recorded on them.

Measurement instruments and intervention

At the beginning of the study, the researcher trained all participants through lectures and an educational booklet on routine diet in GDM and on monitoring daily FBS and 2-hour PPG with a glucometer. Each participant was also provided with a glucometer to measure FBS and 2-hour PPG for a period of 4 weeks.

The intervention group received 56 sachets containing 3 grams of okra powder to be consumed twice daily over a four-week period (i.e. at breakfast and lunch, one sachet per meal). They were also trained to keep a 6-hour interval between meals. Each woman in the intervention group was called to the health center at the end of the second and fourth weeks, her forms and checklists were reviewed, okra sachets were counted, and if she had not taken okra more than six times intermittently or three times consecutively during the study, she was excluded from the study.

Intravenous FBS and 2-hour PPG tests were performed for all participants at the beginning of the study, and at the second and fourth weeks after the start of the study. Participants with a FBS >95 mg/dl, or a 2-hour glucose >120mg/dl, were also excluded from the study because they required insulin.

The data collection instruments include a demographic questionnaire; a nutrition, diet, and physical activity performance form (NDPPF), and a blood glucose monitoring form. In addition, a glucometer (Brand: EasyGluco) was used to check the FBS and the 2-hour PPG. The intervention group was also given an "okra powder consumption checklist" to be completed daily during the study. The demographic questionnaire and NDPPF were first completed by the researcher through face-to-face interviews with the participants, and then the researcher trained the participants on how to fill it daily.

The NDPPF was adopted from the study conducted by Hosseinzade et al.[24] It was designed to accurately assess dietary compliance by examining the share of food groups taught to the patient in the first 3 days of the study. The researcher examined the daily FBS and the 2-hour PPG in the first 3 days of the study, and if the participants had good control over their blood glucose with the diet and did not need insulin, they were advised to continue the same regimen and complete the NDPPF daily until the end of the study. Participants were asked to fill out the forms at home and deliver them to the researcher at their subsequent referrals.

During the study, the researcher was in regular contact with the participants to be informed of any problems or complications. In cases of sudden hypoglycemia, participants were referred to a gynecologist and excluded if necessary. The control group was also taught on the usual diet for GDM and instructed to complete the NDPPF and check and record their blood sugar with a glucometer during the study.

Statistical analysis

The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to ensure normal distribution of the data. Descriptive statistics were calculated. Chi-square and Fisher's exact tests were used to compare the two groups in terms of nominal and categorical variables. The independent samples t-test and Mann-Whitney U test were used respectively to compare the normally distributed and non-normal quantitative variables between the two groups. The Friedman test was used for intra-group testing and comparison of the three stages before, two weeks later, and four weeks after the start of the study. All statistical analyses were performed with SPSS (version 16.0, SPSS Inc, Chicago, IL, USA). A "P-value" less than 0.05 was considered significant.

Ethical considerations

This study was approved by the Ethics Committee of Mashhad University of Medical Sciences (IR.MUMS.NURSE.REC.1397.038) and registered in the Iranian Registry of Clinical Trials with the registration number: IRCT20181009041296N1. The researcher described the objectives and procedures of the study to all participants. Then, written informed consent was signed by the participants. All of them were also informed that they could withdraw from the study at any time.

Results

We screened 100 women to select 66 eligible ones for the study. Of the 66 eligible women, two from the intervention group and four from the control group lost to follow-up. Finally, data from 30 women in each group were analyzed [Figure-1].

No significant difference was found between the two groups in baseline characteristics, except for their education levels [Table 1].

Table 1. Baseline characteristics of the participants of the study groups

Variable	Intervention group	Control group	P value
Age (year)	29.0±3.9	28.0±4.6	0.336[a]
Pregnancy age (year)	28.3±1.1	28.3±1.0	0.987[a]
Education level			
Elementary school	5 (16.7)	2 (6.7)	0.029[a]
Mid or high school	23 (76.6)	20 (66.6)	
Academic	2 (6.7)	8 (26.7)	
Body mass index (kg/m^2)	27.3±4.2	26.2±4.0	0.319[a]
Abortion history			
Yes	6 (20)	4 (13.3)	0.488[c]
No	24 (80)	26 (86.7)	
History of gestational diabetes			
Yes	4 (13.3)	3 (10)	0.99[d]
No	26 (86.7)	27 (90)	
History of diabetes in first-degree relatives			
Yes	9 (30)	12 (40)	0.417[c]
No	21 (70)	18 (60)	
Type of pregnancy			
Wanted	22 (73.3)	25 (83.3)	0.347[c]
Unwanted	8 (26.7)	5 (16.7)	
The duration of daily work			
Light daily cleaning tasks (min per day)	27.3±5.4	27.7±5.0	0.707[b]
Heavy daily cleaning tasks (min per day)	47.0±11.9	45.5±11.8	0.645[b]
Daily slow walking (h)			
<0.5 h	18 (60)	18 (60)	0.917[b]
0.5 to 1 h	12 (40)	11 (36.7)	
1 to 2 h	0	1 (3.3)	
Weekly slow walking (h)			
0.5 to 1 h	1 (3.3)	2 (6.7)	0.528[b]
1 to 2 h	8 (26.7)	3 (10)	
2 to 3 h	9 (30)	12 (40)	
> 3 h	12 (40)	13 (43.3)	
Glucose tolerance test results in 24-30 weeks of gestation			
FBS (mg/dl)	90.4±8.0	91.8±7.6	0.463[b]
1-hour blood-glucose	177.0±21.4	166.4±25.7	0.110[b]
2-hour blood-glucose	140.3±24.6	134.6±18.1	0.312[a]

Data presented as Mean ±SD or n (%), [a] Independent t-test, [b] Mann-Whitney, [c] Chi Square, [d] Fisher's exact test

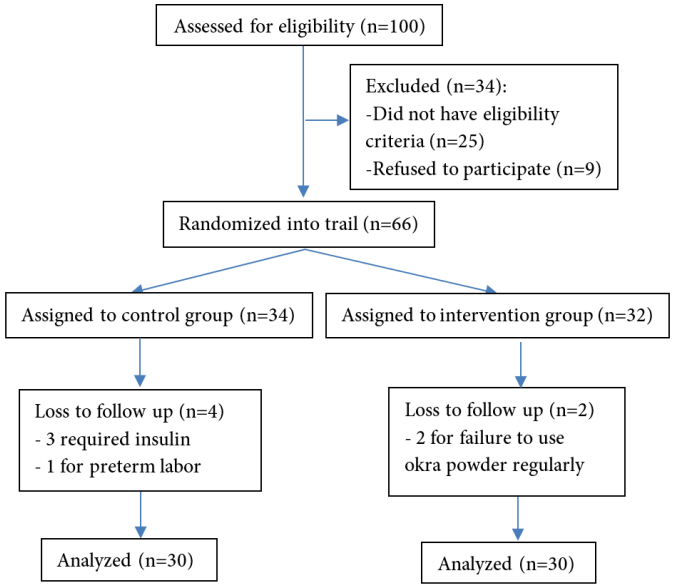

Figure 1. Flow diagram of the study

The mean consumption shares of food groups did not differ significantly between the intervention and control groups during the study [Table 2]. The mean baseline FBS did not differ significantly between the women in the intervention and control groups (P=0.954). However, mean FBS was significantly lower in the intervention group at two weeks and four weeks after the baseline (P<0.001) [Table 3]. The mean baseline 2-hour PPG did not significantly differ between women in the intervention and control groups (P=0.955). However, the mean 2-hour PPG was significantly lower in the intervention group at two weeks and four weeks after the baseline (P<0.001) [Table 4]. It should be noted that of the 34 subjects initially assigned to control group, 3 (9.1%) developed hyperglycemia and required insulin, which were excluded from the study, whereas no case of hyperglycemia was observed in the intervention group.

Table 2. Mean consumption share of different food groups per day for 4 weeks in women with gestational diabetes

Food groups (share)	**Intervention group**	**Control group**	**P value** [a]
Bread and cereals	9.1±0.4	9.0±0.4	0.755
Meat	2.8±0.2	2.8±0.2	0.641
Milk and dairy	2.8±0.1	2.8±0.2	0.322
Fruit	2.0±0.2	2.0±0.2	0.592
Vegetable	2.4±0.2	2.3±0.2	0.515
Average adherence of consuming materials (share)	6.3±0.0	6.3±0.0	0.616

[a] Independent t-test

Table 3. Mean of fasting blood glucose in the intervention and control groups at subsequent measurements

Fasting-blood-glucose mg/dl	**Intervention group**	**Control group**	**P value**
At baseline	90.0±2.3	90.0±2.2	0.954 [a]
After 2 weeks	84.1±2.6	92.0±2.4	<0.001 [b]
After 4 weeks	79.9±2.2	91.9±2.3	<0.001 [b]
The difference between two week later and baseline	-5.9±1.8	2.0±3.1	<0.001 [a]
The difference between four week later and baseline	-10.1±2.1	1.9±3.5	<0.001 [b]
P value	<0.001 [c]	0.001 [c]	

[a] t-test, [b] Mann-Whitney, [c] Friedman test

Table 4. Mean of 2-hour postprandial blood glucose in the intervention and control groups at subsequent measurements

2-hour postprandial blood glucose (mg/dl)	**Intervention group**	**Control group**	**P value**
At baseline	109.8±4.7	109.7±4.5	0.955 [a]
After 2 weeks	100.9±3.9	113.1±4.7	<0.001 [b]
After 4 weeks	95.3±3.5	113.3±5.3	<0.001 [b]
The difference between two week later and baseline	-8.8±3.1	3.4±5.8	<0.001 [a]
The difference between four week later and baseline	-14.5±3.8	3.6±6.1	<0.001 [a]
P value	<0.001 [c]	0.0789 [c]	

[a] t-test, [b] Mann-Whitney test, [c] Friedman Test

Discussion

The mean FBS and 2-hour PPG decreased significantly two weeks and four weeks after the beginning of the study in the okra powder group compared to the control group. Our results are in agreement with an earlier study in 27 pregnant rats, where oral administration of 200

mg/kg/day could reduce FBS and fasting insulin levels in the experimental group by inhibiting insulin resistance.[21] In another study, the hypoglycemic effect of okra seed and skin powders was investigated in 42 male rats with streptozotocin-induced diabetes mellitus. Administration of 100 and 200 mg/kg of okra skin and seed powders for 4 weeks significantly reduced blood glucose levels. The decrease was also greater in the rats that received 200 mg/kg than in those that received 100 mg/kg of okra skin powder.[22] We also used the powder of both parts of okra (i.e. seed and skin), and our results were consistent with the latter study. In another study, Moradi et al., investigated the effects of okra powder on lipid profiles and glycemic indices in patients with type 2 diabetes. The findings showed that an 8-week consumption of okra powder could significantly decrease FBS and lipid profiles.[23]

The herb okra can effectively lower blood glucose levels through several mechanisms. The flavonoids quercetin and catechin of the okra plant have antioxidant properties that prevent the cells from being destroyed by oxidative factors and thus are able to repair damaged beta cells and increase insulin secretion from these cells.[17,25] Quercetin may also increase insulin sensitivity by activating intracellular mediators, inhibiting hepatic glucose production, and stimulating glucose uptake in skeletal muscles and liver. Therefore, it may be an acceptable therapeutic agent for the symptoms of diabetes. High levels of fiber and mucilage in okra can also decrease blood glucose by inhibiting the rate of glucose uptake in the intestinal tract.

One of the limitations of the present study was that individuals might respond differently to drugs. In addition, precise control of the diet of the pregnant women was impossible and the diet was partially controlled by the checklist. Due to the nature of the study, we were also unable to blind the study. Conducting similar studies with blinded designs is recommended.

Conclusions

This study showed that okra powder was effective in reducing FBS and 2-hour PPG and in keeping them in the normal range in women with GDM who were on diet therapy. Therefore, okra powder can be safely used along with a nutritional diet to maintain the blood sugar in the normal range in women with GDM.

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Competing interests

The authors declare that they have no competing interests.

Abbreviations

Gestational Diabetes Mellitus: GDM;
Fasting blood sugar: FBS;
Oral Glucose Tolerance Test: OGTT;
Postprandial glucose: PPG;
Nutrition, diet, and physical activity performance form: NDPPF.

Authors' contributions

All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Role of the funding source

None.

Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. This study was approved by the Ethics Committee of Mashhad University of Medical Sciences (IR.MUMS.NURSE.REC.1397.038). The study is also registered in the Iranian Registry of Clinical Trials with the registration number: IRCT20181009041296N1.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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