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The Effect of Relaxation on Blood Sugar and Blood Pressure Changes of Women with Gestational Diabetes: a Randomized Control Trial

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Abstract

Objective: Gestational diabetes influences mother's health and is accompanied by severe complications. Relaxation is a complementary method for managing this disease. Hence, the current study aimed to evaluate the effect of relaxation on blood sugar and blood pressure changes of women with gestational diabetes.

Materials and Methods: In present randomized control trial, 58 patients with gestational diabetes who had referred to Hafez hospital, Shiraz, were selected through simple random sampling. Then, they were randomly divided into control and intervention groups. The intervention group received a regular 3-week educational intervention in the form of five 45-minute sessions, including Benson's relaxation training. Both theoretically and practically along with discussion as well as question and answer. Fasting blood sugar, 2-hour postprandial blood sugar, systolic and diastolic blood pressure were measured in both groups before, immediately after and one month after the intervention. Then, the data were analyzed by SPSS statistical software (v. 16) and using Chi-square and independent t-test.

Results: According to the results, the mean of fasting blood sugar was 94.79 and 103 mg/dl in the intervention and control groups, respectively (P<0.001). Besides, the mean of 2-hour postprandial blood sugar was 107 mg/dl in the intervention group and 118 mg/dl in the control group (P<0.001). In addition, the mean of systolic blood pressure was 120 and 127 mg/dl in the intervention and control groups, respectively (P=0.006).

Conclusion: The findings of the current study confirmed the effectiveness of relaxation training in fasting blood sugar, 2-hour postprandial blood sugar and systolic blood pressure.

Keywords: Relaxation, Gestational diabetes, Blood sugar, Blood pressure.

Introduction

iabetes is one of the most important chronic diseases with a high and increasing incidence rate in the world. This disease and its related complications contain the major burden of disease proportion

in the world. Gestational diabetes is a subtype of diabetes (1). Gestational diabetes is one of the most prevalent complications of pregnancy and threats both the mother and fetus (2). Gestational diabetes is defined as any glucose

intolerance or insulin resistance which occurs or is diagnosed during pregnancy (3-4). The gestational diabetes prevalence trend follows type 2 diabetes trend. The gestational diabetes prevalence is reported 1-3% in the United States, 10.9% in Asian countries, 5.2% in Europe and 4.9% in Iran (4-5). Diabetes mellitus has a strong relationship with stress and nervous tensions (6).

Physical and mental stress raises blood sugar level and causes insulin resistance in the body, eventually lead to diabetes (7). One of the best treatment strategies to decrease stress and mental disorders of the women with gestational diabetes is using relaxation in order to improve their physical, psychological, and social functions (8). Moreover, relaxation increases the secretion of endorphins or analgesic hormone, but reduces the secretion of adrenaline hormone (9).

In the present study, relaxation refers to the method introduced by Herbert Benson which is carried out in 4 stages providing a relaxed environment, being in an appropriate physical position, concentration and creation of an inactive state (10).

A previous study entitled "Evaluation of the effect of Benson's relaxation technique on anxiety and cardiac irregularities in the patients with cardiac catheterization" showed that this approach reduced anxiety and cardiac irregularities in these patients (11).

Numerous studies have also been conducted on the effects of relaxation on chronic pains, migraine headaches, cardiovascular diseases, and inflammatory bowel disease (12).

Moreover, the effects of relaxation on improvement of diabetes mellitus have been noted in several studies (13-17), but some other studies have indicated that relaxation had no effects on Fasting Blood Sugar (FBS) control (18-20).

Since the effect of relaxation on diabetes has not been confirmed in all the related studies and diabetes mellitus type 2 rather than gestational diabetes has been investigated in most of them, the current study aims to evaluate the effect of relaxation on blood sugar

and blood pressure changes of women with gestational diabetes.

Materials and Methods

The present controlled clinical trial was performed on 58 pregnant women with gestational diabetes who had referred to Hafez hospital, Shiraz, Iran. The study lasted for 3 months from February to April 2013. Inclusion criteria of the study were having gestational diabetes, being in the pre-diabetic stage, not using insulin injection and psychiatric medications, having no history of previous relaxation, between 18 to 40 years old, gestational age of 24 to 30 weeks. On the other hand, the exclusion criteria of the study were unwillingness to cooperate in any stage of the study, being absent in more than one session of the training classes, not doing relaxation exercises at home for more than 5 days, changing their diet or physical activity during the study and having pregnancy complications during the study.

Based on the previous studies (21-22), considering the type one error of 5%, 80% power, and effect size of 45%, and using the

following formula:
$$n = \frac{2(z_{1-\alpha/2} + z_{1-\beta})^2 \delta^2}{d^2}$$
, a

50-subject sample size (25 in each groups) was determined for the study. Nevertheless, considering the loss rate of 10%, longitudinal nature of the study, and repeated measurements, the sample size was increased to 58 subjects (29 in each groups) using the

following formula:
$$n' = n \times \frac{1}{1-p}$$
.

The samples were not selected at once; they were selected and entered into the study weekly. Every week, 15 to 20 patients were selected through convenience sampling and were divided into two groups A and B using the table of random numbers and permutation blocks. Accordingly, numbers 0-4 and 5-9 were assigned to AB and BA blocks, respectively.

The study started with 69 participants but

during the research 11 patients (8 patients in intervention group and 3 patients in control group) were excluded from the study due to preterm labor and not attending the training classes. Then, the study continued with 58 patients, 29 patients in each group (figure 1). The study data was collected by a general information checklist, including demographic characteristics, history of pregnancy, family history of diabetes, a relaxation chart including questions about the frequency, length, and time of relaxation, and blood pressure, FBS and 2-hour Postprandial Blood Sugar (2hpp) table.

In the intervention group, relaxation training was conducted for 10 weekly, five 45-minute sessions.

The first session of the intervention included training on the nature and mechanism of diabetes, explaining the nature of stress and its effect on body, identifying the stressors in pregnancy, and understanding the concept of relaxation. In second session, different breathing techniques and body positions during relaxation were taught. The third session was about how to relax the muscles in various parts of the body after stress. The fourth session was about relaxation through

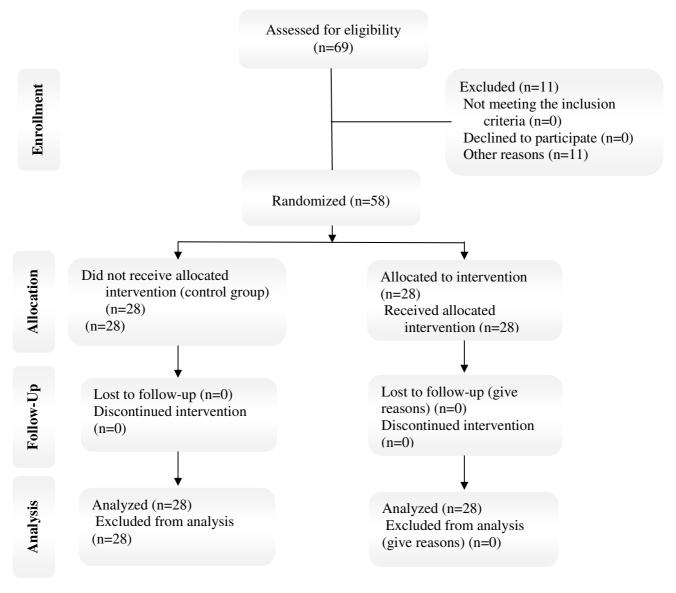


Figure 1. Consort flow diagram of the participants

conditioning. Finally, the fifth session was concerned with training of differential relaxation and relaxation along with the positive mental imagery. From the second session, all the exercises were practically. The training was done similar for all the patients in a relaxed environment with air conditioning and proper lighting. The principles of Herbert Benson were used in this method (24).

The patients were encouraged by the researcher to do relaxation techniques at home for a month. They were also provided with a chart for recording relaxation exercises to evaluate their performance as well as a CD with soft music background about how to do relaxation. They were also contacted through telephone by the researcher three times a week. The control group continued its prior treatment.

FBS, 2hpp, systolic and diastolic blood pressure were measured in both groups before intervention, immediately after the fifth session of relaxation, and one month after the end of intervention.

The blood sugar was measured in a standard laboratory using blood samples. Accordingly, FBS <105 and 2hpp <120 were satisfactory. Besides, blood pressure was measured by a sphygmomanometer. The pregnant women who showed a 30 mmHg increase in systolic blood pressure or a 15 mmHg increase in diastolic blood pressure compared to before required further examination. In general, 140/90 mmHg is considered as normal blood pressure (25). The results were recorded on information sheets. In order to prevent laboratory errors, all the blood samples were analyzed in a similar laboratory.

After data collection, the data were analyzed using the SPSS statistical software (v. 16).

Chi-square and independent t-test were used to compare the variables in the two groups. P<0.05 was considered as statistically significant.

Considering ethical issues: After completing the consent forms, gaining approval of the Ethics Committee of Shiraz University of Medical Sciences (code: 92-6614), and registering the study at IRCT with code of 2013091014612 N1, the samples were entered into the study. The control group also received relaxation training after the end of the intervention. They also received diabetes control methods, including diet and physical activity.

Results

The current study was conducted on 58 women with gestational diabetes who had referred to Hafez hospital in Shiraz city. The results revealed no significant difference groups in demographic between two (P=0.635),characteristics including age gestational age (P=0.576), pre-pregnancy weight (P=.318), number of pregnancies (P=0.734),family history of diabetes (P=0.79), and level of education (P=0.235).

Before the intervention, significant no difference was observed between two groups concerning the mean of FBS (P=0.396). However, a significant difference was found between two groups in this regard immediately and one month after the end of the intervention (P<0.001) (Table 1). Also, the results showed there is no significant difference between two groups regarding the mean of 2hpp before the intervention (P=0.739).Also significant difference was observed in this regard (P<0.001) immediately and one month after the end of the intervention (P<0.001) (Table 2).

Table 1. Comparison of the mean of FBS in two groups before and after the intervention

Groups Stages	Intervention (mg.dl) Mean±SD	Control (mg.dl) Mean±SD	<i>P</i> -value Mean±SD
Before the intervention	100.2±5.15	101±97.2	396.0
Immediately after the intervention	72.96±17.4	101±11.3	< 001.0
1 month after the intervention	79.94±33.3	103±57.2	< 001.0
P-value	< 01.0.0	< 001.0	

Table 2. Comparison of the mean of 2hpp in two groups before and after the intervention

Groups Stages	Intervention (mg.dl) Mean±SD	Control (mg.dl) Mean±SD	<i>P</i> -value
Before the intervention (stage 1)	116±43.4	115±96.4	739.0
Immediately after the intervention (stage 2)	110±39.7	116±45.4	0<001.0
1 month after the intervention (stage 3)	107±92.6	118 ± 87.2	0<001.0
P-value	0<001.0	0<001.0	

Moreover, the study results revealed that there is no significant difference between two groups concerning the mean of systolic blood pressure before (P=0.28) and immediately after the intervention (P=0.666). However, a statistically significant difference was observed in this regard one month after the intervention (P=0.006) (Table 3)

Nevertheless, no significant difference was found between two groups in terms of the mean of diastolic blood pressure before the intervention (P=0.785), immediately after the intervention (P=0.765) and one month after the end of the intervention (P=0.187) (Table 4).

Discussion

Researchers showed that mental stress in people is associated with secretion of cortical, catecholamine's, glucagon and growth hormones (7). These four hormones increase blood sugar and provide a large amount of energy (glucose and lipid) for cells. While stress increases, body reacts to the condition by increasing the secretion of some hormones,

eventually provide a large amount of energy (glucose and lipid) for the cells. In diabetic patients, such a coping response does not work properly and the insulin amount is not enough to enter the excess glucose to cells, therefore, glucose increase in blood (6). Hence, signs of stress are more detectable in the individuals suffering from diabetes (26). A previous study demonstrated an increase in the activity of hypothalamus-pituitary-adrenal axis in the patients with diabetes (27). The first objective of this study was to compare the mean changes of FBS in the intervention and control groups. The results showed that there is a significant difference between two groups regarding the mean changes of FBS. In the same line, one study revealed the effectiveness of relaxation in blood sugar level in the patients with type 1 and 2 diabetes mellitus (13). In another study, the effect of biofeedback on blood sugar showed a significant decrease of FBS in diabetic patients. (14). Another study also measured the effects of relaxation on blood glycosylated hemoglobin (HbA1C) glucose in the patients with diabetes mellitus

Table 3. Comparison of the mean of systolic blood pressure in two groups before and after the intervention

Groups Stages	Intervention (mm.Hg) Mean±SD	Control (mm.Hg) Mean±SD	P-value
Before the intervention	125±78.10	122±07.12	28.0
Immediately after the intervention	122±96.7	123 ± 69.12	666.0
1 month after the intervention	120±40.6	127±61.11	006.0
P-value	0<001.0	0<001.0	

Table 4. Comparison of the mean of diastolic blood pressure in two groups before and after the intervention

the intervention					
Stages	Groups	Intervention (mm.Hg) Mean±SD	Control (mm.Hg) Mean±SD	<i>P</i> -value	
Before the inte	rvention	51.80±03.10	20.81±12.9	785.0	
Immediately at intervention	fter the	86.80±83.4	37.81±89.7	765.0	
1 month after to intervention	the	82.79±49.2	89.81±.95	187.0	
P-value		756.0	865.0		

type 2. The results of this study showed that biofeedback and relaxation had a strong relationship with reduction of HbA1C and amount of glucose (15). Benson has performed various studies on relaxation emphasizing the importance of stress relief. Many studies have also proven the effectiveness of this method concerning its simplicity and easy to use. Benson believed that 4 essential elements of quiet environment, mental preparation strategy, passive attitude, and comfortable position were required in this approach (23).

In addition, one study assessed the effect of Benson's relaxation training on blood sugar control in the patients with diabetes mellitus and disclosed that relaxation had a positive effect on blood sugar control (16).

Furthermore, another study evaluated the effect of combining relaxation and music therapy on biochemical parameters and blood pressure of the patients with diabetes mellitus. The study findings revealed that combining these two methods significantly reduced FBS in the intervention group (17). The results of all the above-mentioned studies are consistent with the present study. The major difference between these studies and the present study is that most of these studies evaluated the effect of relaxation on FBS in diabetes mellitus type 2, while the present study was concerned with the effect of relaxation on FBS in gestational diabetes. Relaxation increases the secretion of endorphin hormone and decreases the secretion adrenalin hormone. Besides, improves blood circulation and decreases anxiety and stress by creating a positive improving attitude and brain function. Relaxation also increases the cellular energy and one's confidence by relieving anxiety. Therefore, it balances the sugar and blood pressure (14). Previous research indicated that relaxation did not affect on blood sugar level, which is contrary to our results (18-19).

The second objective of the present study was to compare the mean changes of 2hpp in the control and the intervention group. The results revealed a significant difference between two groups in this regard. Researchers have demonstrated that monitoring of 2hpp is more valuable than FBS in patients with gestational diabetes, therefore monitoring it, is preferred. On the other hand, Monitoring of 2hpp for glycemic control in gestational diabetic is reliable more than Improvement of glycemic control eventually reduces the infant's hypoglycemic level and macrosomia and the number of cesarean deliveries due to dystocia (25,28). Previous researches have also indicated the effectiveness of stress control in 2hpp (29).

Previous researches have also indicated the effectiveness of stress on 2hpp controlling.

In another study, aerobics exercises along with relaxation decreased 2hpp in patients with diabetes mellitus (30). Moreover, another study investigated the effect of relaxation training on blood sugar changes in insulin independent diabetes. The results showed a considerable reduction in HbA1C and 2hpp in the intervention group (31). The results of these studies are consistent with the current study.

The probable mechanism of the effect of relaxation on 2hpp control is similar to that of FBS. Since cortisol is produced in stressful situations, it seems that relaxation training can be helpful in controlling the blood sugar level through reducing or suppressing cortisol secretion, controlling negative emotions and increasing the adherence to treatment diets at each meal (32,33).

However, in another study, relaxation had no effect on 2hpp of the patients with diabetes type 1 which is not in agreement with our study results. This may be related to the fact that stress has more direct effects on diabetes mellitus type 2. In addition, as mentioned before, some patients with type 1diabetes mellitus show hypoglycemic response, while some others show hyperglycemic response to stress (20).

The third objective of the present study was to compare the mean changes of systolic blood pressure in two groups. The results revealed a significant difference between two groups concerning the mean changes of systolic blood pressure.

One study compared the effects of muscular relaxation along with biofeedback on blood pressure. The results revealed a decrease in systolic blood pressure after relaxation (34).

One other study also examined the effect of relaxation on pregnancy blood pressure and indicated that relaxation caused a significant decrease in systolic and diastolic blood pressure (35). In another study, the effect of biofeedback on the increase of blood pressure was scrutinized in adults. In that study, biofeedback caused a significant reduction in systolic blood pressure (36).

These results are consistent with the present research, indicating a reduction of systolic blood pressure as a result of relaxation. However, a previous study compared the immediate effects of muscular relaxation and mental imagery on pregnant women's mental and cardiovascular function. The results showed that there are no changes in systolic blood pressure in the intervention or the control group (37). In that study, the researchers used a fast method for muscular relaxation in one session. In the current study, on the other hand, the participants received 7 weeks of relaxation including 5 face-to-face sessions. Thus, reduction of systolic blood pressure in the present study can be attributed to collaboration between the researcher and the patients.

The fourth objective of the present study was to compare the mean changes of diastolic blood pressure in two groups. The study findings indicated that there is no significant difference between two groups in terms of the mean changes of diastolic blood pressure.

Similarly, a previous study demonstrated that diastolic blood pressure did not change in control or intervention group (37,38). Relaxation training can have a positive effect on reduction and balance of systolic blood pressure. Therefore it can act as a shield against cardiovascular mortality in the patients with diabetes mellitus. The physiology of behavioral therapy may be different in

hypertensive patients and healthy individuals. Generally, blood cortisol level is reduced as a result of relaxation in the patients with hypertension, while the blood cortisol levels of patients with normal blood pressure does not change after doing relaxation (39). Relaxation or stress relief creates a balance between the posterior hypothalamus (responsible sympathetic stimulation) and the anterior hypothalamus (responsible parasympathetic stimulation) and consequently prevents increase in blood pressure (40). One of the limitations of the present study was that HbA1C was not measured due to shortage of time. In this study, because of the patients' pregnancy and short time of this study, mothers were followed up for less than 8 As a result, our criterion measurement of blood sugar may not be very accurate. Other limitations of the current study small sample size and impaired performance of relaxation due to pregnancy. Also the social and economic status of patients should be considered.

Conclusions

Based on the findings of the current study, it seems that relaxation has been effective in controlling FBS, 2hpp and systolic blood pressure. Since stress management is one of the important elements in metabolic control of diabetes, relaxation training can be effective in first weeks of gestational diabetes. Yet, further studies with larger sample sizes and longer follow-up periods are recommended to be conducted on the issue.

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