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Effect of Reflexo Therapy of Sole on Gestational Diabetes Mellitus: A Randomized Controlled Trial

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Abstract

Background and aim: Gestational diabetes mellitus (GDM) represents a critical disorder affecting many women and their fetuses. The aim of this study was to detect the effects of reflexo therapy of sole on GDM.

Materials and Methods: Thirty-six pregnant women, maternally-aged between 20-35 years old and body mass index not exceeding 30 kg/m^2. They were randomly assigned to one of two groups; Group A received the reflexo therapy of sole combined with the standard antenatal care and group B that received the standard antenatal care only. The treatment protocol was applied for three sessions a week for four consecutive weeks. The main outcome measures were assessed pre- and post-intervention and included first, the 75 g oral glucose tolerance test in two occasions; fasting plasma glucose and 2-h post-prandial glucose. Second, the Hemoglobin A1C test.

Results: Post-treatment analysis revealed significant differences between both groups in oral glucose tolerance test and HbA1c (p= < *0.05*) in favor of group A as compared to group B.

Conclusions: Reflexo therapy of sole combined with the standard antenatal care is more effective than the standard antenatal care alone in reducing fasting plasma glucose, 2-h post-prandial glucose, and HbA1c for women with GDM.

Keywords: Gestational diabetes mellitus, Sole reflexo therapy, oral glucose tolerance test, HbA1c.

Introduction

Gestational diabetes mellitus (GDM) is regarded as a risk factor for prenatal problems affecting the mother and her fetus which needs proper assessment and treatment procedures **[1].** When pregnancy first appears or is suspected, it has varying degrees of glucose intolerance **[2].** It affects 14% of births globally, and the population investigated, ethnicity, and diagnostic criteria are constantly changing **[3].**

Although the exact cause of GDM is still unknown, some theories were postulated. It was hypothesized that human placental lactogen functions similarly to growth hormone, causing lipolysis and raising circulating fatty acid levels that inhibit the action of insulin and causes insulin resistance in pregnant women. These factors seem to be critical in the pathophysiology mechanism of GDM **[4].**

Maternal and fetal consequences from glucose intolerance include many symptoms and disorders including anxiety, birth trauma, macrosomia, and neonatal hypoglycemia **[5].** The likelihood of recurrence in subsequent pregnancies is significant for women with GDM which stresses the need for proper follow-up for these women **[6].** Additionally, as kids become older, their risk of developing type 2 DM increases **[7].**

The management of GDM is a critical health issue that has a negative impact on society and healthcare facilities. For many women, non-pharmacologic strategies including diet and exercise are sufficient to achieve

acceptable glycemic control. It is imperative that all women with GDM risk factors undergo testing during the first trimester to exclude the presence of pre-existing diabetes **[8].**

The most important intervention for all females with GDM is lifestyle guidance, which includes proper and continuous dietary changes to help get rid of the consequences of this disorder. It was discovered that 7–20% of women fail to achieve sufficient glycemic control with diet and exercise alone. To manage their GDM, these women will need to take insulin or oral hypoglycemic medications. These drugs include glibenclamide and metformin that cross the placenta with no urgent precautions for the fetus have been demonstrated as of yet [**9].** However, it was found that certain oral hypoglycemic drugs can have side effects including diarrhea and abdominal pain **[10].**

Reflexology is known as regional therapy and reflex massage therapy. The idea behind it is that each part of the hands and feet represents a different part of the body, such as the heart, liver, spleen, lungs, kidneys, and other internal organs. By stimulating different parts of the hands and feet, massage can improve blood circulation, energy, nutrition, or nerves, which can lead to therapeutic effects like reducing mental stress, detoxifying the body, promoting weight loss, delaying aging, and improving internal health **[11].**

Up to now, the exact mode of action of reflexology on the human body is unknown, however some theories have been postulated to explain for this mechanism. Some of these theories include the pain gate concept, neural impulse theory, improved lymphatic nerve and blood flow, and ultimately, the toxins increased excretion from the whole body **[12].**

It was found that reflexo therapy of sole is useful in lowering glycemic levels in DM patients. In addition to regulating blood sugar, reflexology protects organs that may be impacted by chronic diabetes **[13].**

The effects of solo reflexo therapy on GDM in terms of glycemic control and insulin need were not directly observed by any prior investigation, according to a review of the available published publications. In order to investigate these implications for women with GDM, this study will be carried out. Women's health has increased demand for safer and well-developed physical therapy therapeutic methods. Both women and therapists will benefit from the conclusion of this study, which will help them save time and effort and get the best outcomes in the shortest amount of time.

Patients and Methods

Participants

This study was conducted on 36 woman (eighteen in each group) who met the inclusion criteria aged between 20-35 years old and BMI not exceeding 30 kg/m^2.

Inclusion and exclusion criteria:

Women were included in this study if they fulfilled the following criteria. They had GDM having values of fasting plasma glucose level more than 126 mg/dL and a 2-hour postprandial value more than 140 mg/dL. Their age ranged from 20 to 35 years old while the gestational age ranged from 24 and 36 weeks; less than 30 kg/m^2 body mass index (BMI); the fetus was a singleton survive; and the women didn't have any risks during pregnancy. Women who were smoking, using of oral sedatives, poor obstetric conditions or illnesses that could affect participation, and high-risk pregnancies were excluded from participating in this study.

Design

A randomized controlled trial was to determine the impact of reflexo therapy of sole on GDM at the Department of Gynecology and Obstetrics, Kafrelsheikh University Hospital between February 2024 and December 2024. All women were assigned at random using a simple random procedure by selecting one of two wrapped cards that represented the two treatment groups in order to prevent selection bias. These groups included group A that received the reflexo therapy of sole combined with the standard antenatal care and group B that received the standard antenatal care only.

Sample size calculation

Based on the previous study by El-Shamy et al. **[14]** and using the G-power software tool (version 3.1.9.4), it was calculated that a sample size of 30 women would achieve a power of 80% with assuming a type I error (p= 0.05) to detect an effect size of (1.06) in the outcome measure of interest. There were about 36 women recruited, 18 in each group, and a 20% dropout rate was anticipated.

Interventions

The treatment protocol was applied for three sessions a week for four consecutive weeks. All participants received sufficient information regarding the study's objectives, methods, possible risks, and advantages prior to any study-related procedures. Each participant provided written informed consent attesting to participate voluntary and comprehension of the study's conditions. The Declaration of Helsinki and regional ethical standards for research were followed during this procedure.

Reflexo therapy of sole was applied in Group A only. Before starting reflexology work on each session, the posture and angle of each foot, the two feet on the couch, the feet differences, each toe and the relations with other toes, color differences, patches, flecks, and spots of color, textural differences, dips, swellings, irregularities, infections, and skin variations were all assessed on the skin of the feet. Since they can make it difficult to properly examine the feet or to hold them in order to administer the treatment, no creams, lotions, or powders were utilized **[15].** In order to loosen it up, the foot was then rubbed all over for approximately 30 seconds, starting at the toes and working down towards the heel, gently but firmly **[16].** Then, using the thumb for that and the forefinger for gripping, apply a controlled, firm, and equal pressure without causing pain or tickling. The fundamental thumb walking method for feet was gently pressing into the tissue while walking by alternating between bending and straightening the thumb **[17].**

Using the foot chart as a guide, the reflexology steps were performed, concentrating on the pancreatic region and visualizing the body map. Following the initial treatment, the therapist should ask the woman about her state at the next meeting, noting any reactions, side effects, worries, or advancements or declines in her overall health. This made it possible for the therapist to modify the treatment as needed and serve as the foundation for continued care **[15].**

Each reflexo point took two to three minutes to apply, for a total of fifteen minutes for the right foot and fifteen minutes for the left.

The standard antenatal care was applied in both groups. Every participant received an informational brochure with recommendations for a healthy diabetic diet that was divided into three mealtimes and three snacks and included 40% carbohydrates, protein percentage of 20%, while the fat content reached 40%. The subject's ideal pre-pregnancy weight of the body was used to compute this. Weekly weight increase was tracked. Every participant was told to walk about 30 to 45 minutes, three days a week. They were also told to walk to monitor their own heart rates and make sure they didn't exceed 140 beats per minute **[18].**

If any of the two accompanying values were consistently elevated during nutrition therapy, insulin treatment was initiated. Insulin therapy was individualized for every patient according to the physician decision and prescription. Short-acting insulin was administered prior to meals and intermediate-acting insulin for those women, for whom insulin is advised **[14].**

Outcome measures

1. The Oral Glucose Tolerance Test:

All participants underwent a 75-g OGTT at inclusion and at the end of intervention. Fasting and 2-h glucose levels were measured in serum by the routine methods used by a certified laboratory at the Department of Clinical Chemistry, Kafrelsheikh University. According to WHO guidelines, the fasting plasma glucose level of 126 mg/dL or a 2-hour postprandial value of 140 mg/dL were considered indicators of GDM **[19].** The measurement of the 75-g OGTT was performed before and after twelve weeks.

2. The Hemoglobin A1C Test:

The HbA1c was measured using a sample of blood from a finger stick or from the patients arm. The certified laboratory at Department of Clinical Chemistry, Kafrelsheikh University used it. The percentage of glycosylated HbA1c in human whole blood, which is used to diagnose DM, indicates the average plasma glucose concentration over a prolonged period of time **[19].** It was found that the HbA1c levels in GDM women were 37 ± 5 mmol/mol (5.5 ± 0.5%) **[20].** The measurement of the HbA1c was performed before and after twelve weeks.

Data analysis

The SPSS version 26 (IBM Corp, Armonk, NY) was utilized in conjunction with more comprehensive statistical analyses to support these initial assessments. We initially determined if the data distribution for each variable was normal during the statistical analysis phase of the study using the Shapiro-Wilk test, a standard procedure to assess the appropriateness of parametric testing. After the normality of the data was confirmed, paired t-tests were used to compare groups to find changes before and after the intervention. To evaluate the varied impacts of the therapies, however, unpaired t-tests were employed for between-group comparisons. For all analyses, the threshold for statistical significance was set at $(p < 0.05)$.

Results

All the 36 participants were presented for the final data analysis with no recorded harms or dropouts (Figure 1).

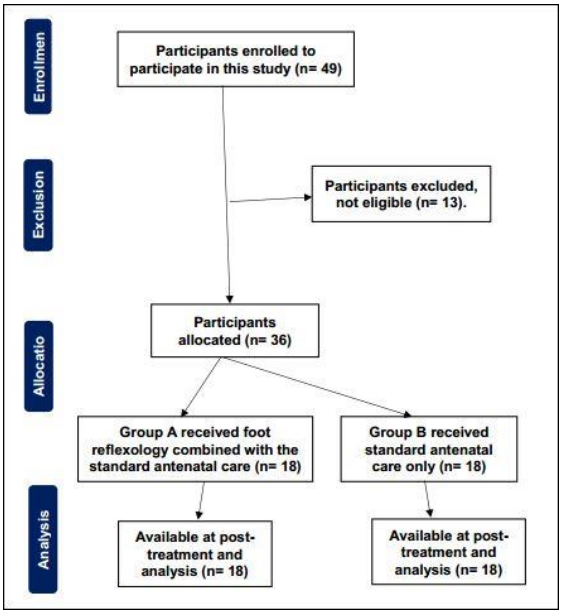

Figure 1: The study flow chart.

General Characteristics

First, comparing the mean values of maternal age, weight, height, and BMI using unpaired t-test revealed that there were no significant differences between both groups in maternal age (p= 0.75), weight (p= 0.28), height (p= 0.36), and BMI (p= 0.88), (Table 1).

Table 1: Comparison of demographic data between both groups.

Items	Mean ± SD		*p-value*	Sig.
	Group A	Group B		
Maternal Age (year)	28.11 ± 2.74	28.39 ± 2.43	0.75	NS

Weight (kg)	78.17 ± 4.68	79.89 ± 4.35	0.28	NS
Height (cm)	168.06 ± 5.67	169.83 ± 5.74	0.36	NS
Body mass index (kg/m^2)	27.28 ± 2.08	27.39 ± 2.25	0.88	NS

SD= Standard deviation, T-value= T-statistic, *p-value*= Probability, Sig.= Significance, NS= Non-significant.

Within and Between-Groups Comparison:

First, within groups comparison using paired t-test revealed that there were significant difference in both groups A ($p = < 0.05$). Second, between groups comparison using unpaired t-test for pre-treatment mean values revealed that there were no significant differences *($p = > 0.05$),* and for post-treatment mean values revealed that there were significant differences between both groups in favor of group A in all the outcome meausres ($p = < 0.05$) (Table 2).

Table 2: Within- and between-group comparisons in both groups.

Items	Mean ± SD		*p-value*
	Group A	Group B	
Oral glucose tolerance test			
Fasting plasma glucose			
Pre-treatment	129.56 ± 2.26	129.89 ± 2.39	0.67
Post-treatment	116.44 ± 3.31	119.67 ± 4.01	0.01
P-Value	0.0001*	0.0001*	
Two-hour post-prandial glucose			
Pre-treatment	145.67 ± 2.45	145.39 ± 2.12	0.72
Post-treatment	125.39 ± 2.68	128.06 ± 2.56	0.004*
p-value	0.0001*	0.0001*	
Hemoglobin A1C			
Pre-treatment	46.83 ± 2.64	45.61 ± 2.85	0.19
Post-treatment	37.33 ± 1.91	40.89 ± 2.19	0.0001*
p-value	0.0001*	0.0001*	

SD = standard deviation, *p-value* = probability, *= Statistically significant.

Discussion

The results of this study showed that; first, there was a significant within group effect in terms of reduction in the 75-g OGTT ($p = < 0.05$) and the HbA1c ($p = < 0.05$) in both groups. Second, there were significant differences between both groups in post-treatment mean values of all the outcome measures in favor of group A.

The current work results are in line with other trials that demonstrated reflexo therapy of sole, when combined with other treatment approaches, had impacts on concentrations of HbA1c levels which means controlling of glycemic levels. Reflexo therapy of sole involves hand movements in form of pressing, rubbing, rolling, squeezing, and stimulating the muscles of the feet, calves, knees, and foldable joints of both legs. In order

to restore equilibrium to the critical systems of the human body including the respiratory, circulatory, endocrine, and lymphatic systems, reflexology can be applied via using a stick of wooden type to help well-stimulate the feet by massaging the typical points for the zones reflecting the systems or structures in the human body. In order to balance insulin secretion and enable insulin to function more effectively on controlling the glycemic levels by importing sugar into the cells, the pancreas and livers synthesize glucose, which is related to the control mechanism of HbA1c and can flow smoothly **[21, 22].**

Additionally, the findings of this study are also in line with Sakdanuparp, **[23],** who examined how the reflexo therapy of sole affected type 2 diabetic patients' blood glucose levels and numbness and discovered that the HbA1c level dropped and diabetes was controlled. Furthermore, research on patients with type 2 DM showed that reflexo therapy of the sole improved their foot impairment, making it a realistic treatment that merits funding **[24].**

Moreover, the current study results agree with Devi and Venkatesan, **[25]** who found that the reflexo therapy of sole is effective and it can be used in the hospitals among patients with DM, to reduced peripheral neuropathic pain.

The results of the current study may be explained by Stephenson, **[26]** who stated that the foundation of reflexology is the idea that the body is reflected in the hands and feet. The individual central and distant organs throughout the human body are represented by those reflex points. Reflexology is considered a treatment method that improves comfort and restores the body's balance without the need for any pharmacological factors. It works by applying pressure to responsive points on the foot and occasionally the palm that correlate to each body section. Reflexologists believe that applying pressure to these certain reflex sites on the palm and sole during illness will improve the blood flow throughout the whole body, break up the crystals of calcium and uric acid that are trapped in the endings of nerve fibres, and open the blocked pathways of nerves. During birth, the pituitary gland, hypothalamus, solar plexus, and uterine stimulation all help to ease and relive tension, pain, and anxiety symptoms. Reflexology can treat a range of physiological disorders during pregnancy, including headaches, constipation, edema, nausea, vomiting, pain during labor, aiding lactation, and controlling diabetes **[27]**.

As for targeting the pancreas zone to control DM, Tiran, **[16]** stated that the pancreas zone, which is primarily found on the left foot, is situated on the plantar surface of both feet, above the stomach zone and beneath the diaphragm. Although it is a small area, it is easily overstimulated if the transverse colon's reflex zone is being vigorously worked over. This is especially important for women with GDM, who might benefit from reflexo therapy of the sole and achieve positive clinical results.

It should be emphasized that reflexo therapy of sole is mostly recommended and used for symptoms and certain organic disorders by complementary, functional, and alternative therapies. It is important to use caution despite the abundance of possible physiological pathways. Even though the current study's findings indicated some effects on GDM, reflexo therapy for soles is still being researched, and its biological mechanisms are still unknown.

Finally, this study made a step toward obtaining an evidence of this treatment strategy for this population. Future research on the effects of reflexo therapy of sole on GDM should concentrate on objective assessments and consistent treatment protocols.

Study limitations

The present study has certain limitations; it did not examine the follow-up or long-term consequences, but it does provide a straightforward approach to obtaining the optimal management guidelines for GDM. Patients' dedication was also impacted, and if they did not finish the entire program, some of them were replaced.

Conclusion

Reflexo therapy of sole combined with the standard antenatal care is more effective than the standard antenatal care alone in reducing fasting plasma glucose, 2-h post-prandial glucose, and HbA1c for women with

GDM.

Funding

None.

Ethics approval

The Scientific Research Ethics Committee of Kafrelsheikh University carefully examined and approved the study protocol (Reference: KFSIRB200-470).

Trial registration

The current trial was registered on ClinicalTrials.gov, Protocol Registration and Results System (Identifier: NCT06976164).

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