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ORIGINAL RESEARCH

The Effect of Cinnamon Supplementation on Hemoglobin A1c in Patients with Type 1 Diabetes Mellitus

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Abstract: **Introduction:** Type 1 diabetes mellitus (T1DM), one of the most common endocrine disorders in children, is an autoimmune disease that manifests itself as an increase in blood sugar as a result of impaired insulin production due to the destruction of the islets of Langerhans in the pancreas. To treat this disease, along with the use of insulin and numerous drug protocols, the use of herbal medicinal supplements has always been considered. However, due to the lack of studies related to these supplements, there is not enough evidence for their therapeutic use.

Methods: We investigated the therapeutic effectiveness of a cinnamon medicinal supplement with a dose of 50 mg every 8 hours per day, on glucose hemostasis in patients with T1DM. Thirty patients with T1DM were enrolled. They are subjected to sampling and examination of blood sugar indicators, including fasting blood sugar and hemoglobin A1c, as well as indicators of insulin consumption (total daily dose of insulin) and insulin resistance, including the ratio of insulin to carbohydrates on days 0, 90 and 180 of the start of treatment with cinnamon.

Results: The level of hemoglobin A1c in this group had a significant decrease. Also, there was no significant increase in the amount of insulin consumption in the drug supplement-consuming groups in contrast to the control group during six months.

Conclusions: The use of cinnamon supplements along with treatment protocols has a significant effect in reducing hemoglobin A1c during six months of treatment in these patients. These results can be useful in promoting the use of therapeutic supplements in the treatment of patients with diabetes.

Keywords: Diabetes Mellitus, Type 1; Hemoglobin A1c; HbA1C; Cinnamon

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1. Introduction

Type 1 diabetes mellitus (T1DM) is a chronic autoimmune disease characterized by elevated levels of blood glucose (hyperglycemia). The underlying cause of the disease is insulin deficiency, which occurs as a result of the destruction of β-cells of the pancreatic Langerhans islets (1, 2). DM is one of the most common endocrine metabolic disorders affecting children and adolescents worldwide (3). Although the age of onset of symptoms is usually in childhood or youth, sometimes symptoms may develop much later (2). According to the International Diabetes Federation, approximately 542,000 children aged 0–14 years have T1DM, with 86,000 new cases diagnosed worldwide each year, and the overall annual increase in T1DM incidence is estimated to be approximately 3–4% (4). The incidence of T1DM in children and adolescents under 15 years of age varies greatly by geographical region. The highest prevalence rates were reported in Finland (57.4/100,000/year) and Canada (21.7/100,000/year), and the lowest in China (0.6/100,000/year) and Venezuela (0.1/100,000/year) (5). A recent study stated that the life expectancy of people with T1DM is approximately 12 years less than the general population (6).

Since the underlying mechanism and risk factors associated with T1DM are not fully understood, the treatment and pre-

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vention strategies developed to date have been unsuccessful, and most patients are dependent on lifelong insulin therapy (6). Various types of traditional, complementary or alternative therapies have been increasingly used for various chronic diseases including DM in developing and developed countries (7). Herbal medicines are the major part of these treatments. However, there is insufficient evidence-based studies on their efficacy and safety (7). A number of herbs and spices have a long history of traditional use in the treatment of high blood sugar levels (8). Among the herbs used for DM, cinnamon is one of the most popular herbs studied. Various studies have shown the beneficial effects of cinnamon, including anti-inflammatory, antibacterial and antioxidant properties (9). Several studies have been conducted to confirm the effect of cinnamon on reducing blood glucose in patients with DM (10). Cinnamon increases the sensitivity of peripheral insulin receptors. Many laboratory studies have shown that cinnamon increases the entry of glucose into cells by increasing the phosphorylation of the insulin receptor and the transport of glucose transporter-4 (GLUT4) to the plasma membrane (9). However, its exact antidiabetic mechanism is not yet known. Khan et al. (11), and Crawford et al. (12) showed that cinnamon has an anti-diabetic effect, but Blevins et al. (13) disagreed about the effect of cinnamon. Furthermore, in another study patients consumed 3 grams of cinnamon daily for four months, which had no significant effect on HbA1C levels, and no significant difference was observed between the two groups or within the group (14). Therefore, Cinnamon is considered as an important anti-diabetic supplement, and various studies related to its administration have brought conflicting results. The purpose of this double-blind randomized clinical trial is to analyze the effect of cinnamon supplementation on hemoglobin A1c, sugar control, and the amount of insulin needed to control sugar in patients with T1DM.

2. Methods

2.1. patient selection

In this trial, the study population were patients with T1DM admitted to the pediatric endocrine clinic at Mofid's Children Hospital, during 15 months. The sample size was calculated based on a clinical algorithm with a 0.05 error. Patients older than 18 years, patients with pregnancy and breastfeeding, hemoglobinopathy, and acute infection were excluded from the study. Finally, thirty patients were enrolled to the study. The ethical code, was IR.SBMU.MSP.REC.1400.572.

2.2. Experimental Procedure and Data Collection

The participants received the cinnamon supplement. A tablet of cinnamon contained 50 mg of the product. The phase of receiving the drug by the patients was three times in a day in the form of 90 days, and the patient received supplements for 180 days in total. (This part is not clear, please explain so it could be edited.) Patients were instructed to choose a time of day that was most convenient and to consistently take the supplement at that time. After fully explaining the objectives and steps of conducting the study and ensuring that there was no history of allergy to the supplement, informed consent was obtained from the parent or legal guardian and from the patient.

Patient characteristics including age, sex, weight, height, body mass index (BMI), stage of puberty and history of nutrition and physical activity, duration of DM diagnosis, number of sugar drops in a week, type of insulin used and total amount of insulin received daily and number of daily insulin injection times were recorded. Venous blood samples were taken to measure HbA1c, and FBS at the beginning of the study. Participants were given the researcher's contact information in case they had any questions or concerns. Patients were also asked to record their total daily insulin dose and other required information during the study. The research team did not recommend any changes in other aspects of medical care, diet, or exercise.

A member of the research team called each participant every 2 weeks during the study to assess adherence to the study protocol, collect data on subjects' current insulin dose, and determine potential side effects. Specific adverse events extracted included episodes of hypoglycemia, recent illnesses, or other changes in health status that were monitored frequently. Patients visited the clinic 90 days after the start of the study, and at that time, the daily insulin consumption was collected and the drugs needed for the next 90 days were given. Adherence to the study was also evaluated using the number of used and remaining tablets. HbA1c level and other mentioned tests and data were measured at 90 days and 180 days after receiving the drugs. The final visit to the clinic was on the 180th day after the start of the study.

2.3. Data Analysis

The data obtained from the information forms were analyzed using SPSS statistical software (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp). After data collection, the data was examined for the presence of information defects and the data with more than 30% defects were removed. Afterwards, the statistical analysis was performed after the pre-processing steps. The normality of the distribution of the variables was measured using the Shapiro-Wilk test. For continuous variables, mean ± standard deviation (SD) and median, interquartile range (IQR) and for categorical variables percentage were used for description. Statistical analyzes included chi-square, paired t-test and independent t-test, repeated measure ANOVA, and

Table 1: Demographic characteristics of patients in three time periods

Characteristics	Baseline	3-month	6-month	p-value
Weight (kg)	44.7±13.4	45.0±13.1	45.2±12.8	0.557
Height (m)	1.50±0.16	1.51±0.15	1.51±0.15	0.112
BMI (kg/m^2)	29.34±7.03	29.37±6.85	29.45±6.67	0.081

All characteristics are described by mean ± standard deviation, **BMI:** body mass index.

Table 2: Sugar laboratory factors of patients in three time periods

Factors	Baseline	3-month	6-month	p-value
FBS (mg/dl)	141.5; 110.7	144.0; 76.3	121.5; 46.0	0.067
HbA1c (mmol/mol)	8.2; 2.4	8.3; 1.8	7.9; 1.8	0.001
Lantus Insulin	28.0; 19.2	28.0; 18.5	28.0; 18.5	0.756
Insulin to Carbohydrate Ratio	1.7; 1.1	1.6; 0.8	1.5; 0.8	0.368

All characteAll factors are described by median and IQR, **FBS:** fasting blood sugar, **HbA1c:** hemoglobin A1c.

Pearson's correlation coefficient. The level of significance in these tests was considered as P<0.05.

3. Results

This study was conducted on 30 patients under 18 years of age with T1DM who referred to Mofid Hospital clinic in 2021 for routine care. The purpose of this study was to determine and compare the effect of cinnamon supplementation on hemoglobin A1c and blood sugar control in patients with T1DM. Sex distribution in children with T1DM was 55.6% for girls and 44.4% for boys. Consequently, the ratio of girls to boys was estimated to be 1.25 to 1. The mean±SD age of children with T1DM at the beginning of the study was 12.4 ± 2.5 years. Also, the mean±SD duration of the disease was 3±1.8 years. Based on the results obtained in the present study, the number of girls was slightly higher than boys . In the following, the changes in the height and weight characteristics of the patients receiving cinnamon were investigated at baseline, three months after the start of treatment, and six months after the start of treatment.

Based on the results in the above table, the use of Cinnamon supplements in the period of three months and six months from the start of treatment did not cause a significant difference in the weight and height of the patients (P>0.05). Also, BMI in this group did not show a significant increase (P>0.05). Moreover, the following table demonstrates the changes in patient's laboratory indices and drug related factors.

Based on the abovementioned results in the table, the change in fasting blood sugar (FBS) level during the three-month and six-month treatment period in patients receiving cinnamon was not significant (P>0.05). However, the amount of hemoglobin A1c in this group decreased significantly during six months (P<0.05). This finding can confirm the effectiveness of the treatment protocol for these patients. In addition, the total amount of received insulin and the insulin to carbohydrate ratio (ICR) in this group did not show a significant increase (P>0.05). As a result, it can be concluded that the use of medicinal supplements along with the treatment protocol of patients is effective in partially treating these patients and there is not increasing need for insulin.

4. Discussion

The present study was conducted to investigate the therapeutic effect of cinnamon on patients with T1DM in order to reduce the blood sugar level of these patients. During this study, 30 patients under 18 years of age with T1DM were enrolled and sugar indicators including fasting blood sugar of patients and hemoglobin A1c as a long-term indicator of blood sugar monitoring in these people were measured to investigate the therapeutic effect of cinnamon tablets. Cinnamon 50mg tablet was used as a product containing cinnamon. The results of the hemoglobin A1c comparison showed that there was a significant difference in the reduction of this index during six months of supplement use in the pharmaceutical supplement user group. However, the fasting blood sugar index in this group did not show a significant decrease during six months. The obtained result indicates the effectiveness of using the mentioned therapeutic supplement in reducing blood sugar level in patients with T1DM. However, the lack of reduction in fasting blood sugar in patients consuming cinnamon can be related to various reasons, such as the short duration of the study and the long effect of cinnamon, the lower effectiveness of this supplement due to the low dose administration, or the small number of the study population. More detailed studies are needed to investigate each of these causes to justify the obtained results.

Several studies have emphasized the therapeutic effectiveness of products containing cinnamon in controlling patients with DM and metabolic syndrome (15). These studies

have shown that the products obtained from cinnamon act through several mechanisms including the augmentation of insulin sensitivity and its secretion, regulating the activity of enzymes involved in glucose metabolism, regulating glucose metabolism in the liver, fat tissue and muscles, reducing oxidative stress and inflammatory processes, and accelerating the improvement of complications caused by DM to control and treat diabetes mellitus, especially T2DM (16). In addition to these studies, it has been shown that this substance is effective in the treatment of cardiovascular complications caused by DM through various mechanisms, including endothelium protection, regulating the immune response, reducing the blood level of lipids, reducing the growth of vascular smooth muscles, and reducing thrombosis and platelet activity. It also plays a role in reducing vascularization (16).

Although most studies show the therapeutic effect of this substance on T2DM (17), recent studies have shown that cinnamon and its products are also effective in the treatment and control of T1DM as well (18, 19).

Furthermore, this study tried to evaluate the possible mechanisms of the effect of these medicinal supplements in the process of controlling T1DM and reducing the amount of insulin consumption by examining the changes of other factors affecting DM. Based on the obtained results, it was found that the insulin to carbohydrate ratio (ICR), which is an indicator of the amount of insulin received, did not increase significantly in cinnamon consumers during six months. This shows the effectiveness of the mentioned medicinal supplement in controlling the amount of insulin received. Another noteworthy point was the lack of increase in BMI, which in turn confirms the therapeutic effectiveness of these supplements.

The current study faces several limitations. First, the number of the statistical population was small, which were selected based on the rate of visits of patients with T1DM to the clinic and the rate of acceptance of the use of medicinal supplements. Future studies with a higher statistical population can be important in confirming or rejecting the results obtained in the present study. In addition, in this study we only investigated on one group of patients receiving cinnamon. To investigate the independent effect of cinnamon on the improvement of T1DM and especially the mechanism of its effect through the reduction of insulin resistance, more studies are needed with control groups receiving cinnamon and placebo separately.

5. Conclusion

The present study investigated the effect of cinnamon supplementation on the control and treatment of T1DM in children with this disease. During this study, the therapeutic effect was investigated during 6 months of its prescription at the same time as receiving the normal treatment protocol of the patients. The results indicated that cinnamon supplement played a significant role in reducing the blood sugar level and the amount of insulin intake in diabetic patients. Also, examining the control indicators of drug intake, such as ICR, determined that there is no need to increase the insulin dose in these patients due to the use of this supplement. The results of this study and other similar studies emphasize the therapeutic benefits of medicinal supplements and the role of these supplements in increasing the effectiveness of treatment protocols. Furthermore, these results can be used to confirm the use of these supplements in the treatment of patients with chronic diseases, including DM and metabolic syndrome.

6. Appendix

6.1. Acknowledgment

None.

6.2. Conflict of interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

6.3. Funding support

None.

6.4. Author's contributions

All the authors had the same contribution.

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