



CODEN [USA]: IAJPBB

ISSN: 2349-7750

**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**<http://doi.org/10.5281/zenodo.1120321>Available online at: <http://www.iajps.com>**Research Article****INVESTIGATING THE EFFECT OF BARBERRY JUICE
CONSUMPTION ON GLYCATED HEMOGLOBIN IN
PATIENTS WITH TYPE II DIABETES**Ali Mansouri¹, Mohammad SadeghSargolzai^{2*}, Hosniyeh Mir³, Najmeh Keshavarz³¹Master of Nursing, Instructor, Faculty Member of Nursing Midwifery Faculty, Zabol University of Medical Sciences, Zabol, Iran²Bachelor of Science in Nursing, Student Research Committee, Faculty of Nursing and Midwifery, Zabol University of Medical Sciences, Zabol, Iran³Graduate Student of Nursing, Student Research Committee, Faculty of Nursing and Midwifery, Zabol University of Medical Sciences, Zabol, Iran**Abstract:**

Introduction & Objective: Diabetes mellitus is one of the most severe metabolic disorders associated with increased blood glucose, metabolic disorders of carbohydrates, lipids, proteins, and partial or absolute insulin deficiency. One of the important criteria for diagnosis and control of diabetes is the evaluation of fasting blood glucose and glycosylated hemoglobin levels in these patients. On the other hand, the use of medicinal plants in the treatment of diabetes has a special clinical significance. The purpose of this study was to investigate the effect of barberry juice on glycosylated hemoglobin in patients with type II diabetes.

Materials and Methods: This study was a clinical trial with control group in which 60 subjects who had inclusion criteria of this study were entered into the study by objective sampling method and randomly divided into two groups of test and control. Initially, the level of glycosylated hemoglobin was measured. The test group was then treated with barberry juice for 8 weeks, after which the level of glycosylated hemoglobin was measured. Data were analyzed by independent t-test and paired t-test in SPSS software version 22.

Results: The results showed that in the test group, the measured biochemical index was significantly lower than the control group. This means that there was no significant difference between the two variables before the intervention. But after the intervention, this difference was significant ($P < 0.05$).

Discussion and Conclusion: The findings of this study indicate that barberry juice consumption can decrease the level of glycosylated hemoglobin in type II diabetic patients. However, further research is recommended to confirm the results.

Keywords : Diabetes, Barberry, glycosylated hemoglobin

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Please cite this article in press as Mohammad SadeghSargolzai et al., *Investigating the Effect of Barberry Juice Consumption on Glycated Hemoglobin In Patients With Type II Diabetes*, Indo Am. J. P. Sci, 2017; 4(12).

INTRODUCTION:

Diabetes Mellitus is one of the most severe metabolic disorders associated with increased blood glucose, metabolic disorders of carbohydrates, lipids, proteins, and insufficient or partial insulin deficiency (1). Type II diabetes is about 90-95% of cases of diabetes. According to the World Health Organization, the number of people affected by this disease is expected to increase from 171 million in 2000 to 366 million in 2030. This organization also predicts that the number of people with diabetes in Iran will reach from 210,302 (5.7 percent) in 2000 to 5215,000 (6.8 percent) in 2025 (2). In addition to acute metabolic complications (diabetic ketoacidosis and hyperosmolar coma) is accompanied with severe long-term complications such as ocular complications (retinopathy), kidney complications (nephropathy), neuropathic complications, cardiovascular complications (hypertension and atherosclerosis) and the diabetic foot (3).

Unlike type I diabetes, type II diabetes has a slower process and begins with the problem of insulin resistance (4). Obesity complicates the control of type 2 diabetes by increasing insulin resistance and increasing blood glucose concentrations. Insulin resistance due to impaired message transmission of insulin in target tissues is also the common cause of type II diabetes (5). One of the criteria for diagnosis and control of diabetes is the measurement of glycated hemoglobin in blood (6). The binding of sugar to hemoglobin leads to the formation of a stable glycated hemoglobin, and has been shown to be a clinical demonstration of diabetes control. The glycated hemoglobin, as a major contributor to predicting long-term complications of diabetes mellitus, should also partly reflect the short-term control of the disease (7). Although diabetes is a multi-factorial disorder, it is known that diet has a major role in exacerbating or preventing the disease (8). Considering the side effects of medications, especially in the long term, as well as contraindications in some patients, finding more effective dietary formulations in the treatment of diabetes and reducing its complications has been considered (8-9).

Over the past years, there has been a lot of effort to find other therapies that can reduce the complications of diabetes. Today, the use of some fruits and vegetables and all kinds of foods is highly regarded (10). Some herbs such as saffron extract (11), blueberries (3), and dill (12) have been studied as diabetic glucose lowering drugs in diabetic patients. In this regard, one of the most effective medicinal plants used to control diabetes is barberry (13).

Barberry is a plant that grows in the form of barbed shrubs at a height of 1.5 to 3 meters and has fractured branches and the parts used for its application include skin, root, stem, leaf and fruit. The most important alkaloid of barberry extract is berberine that its most important properties include reducing blood sugar and fat and an antioxidant (14). Studies have shown that barberry juice is rich in antioxidant compounds, the most important of which are palmatine, oxacetine, malic acid and bromine (15, 16 and 17).

Due to limited studies on the effects of barberry juice especially in humans, as well as the abundance of barberry fruit in Iran and its availability, the present study was conducted to investigate the effect of barberry juice on glycated hemoglobin levels in diabetic patients type II.

MATERIALS AND METHODS:

This study is a clinical trial with control group. The statistical population of this study was all patients with type II diabetes, including 60 patients aged 18-65 years old, who referred to the Diabetes Clinic of Imam Khomeini Hospital in Zabol city and had medical history and records and monthly or once every three months, they were evaluated regarding health and improved the course of the disease. Patients to participate in the study should meet the following conditions: having type II diabetes, they should have been diagnosed with a disease for at least six months, no smoking and alcohol use, no pregnancy and lactation, no use of herbal and oxidants supplements during the past 3 months and the absence of chronic and acute renal, liver, infectious and cardiovascular diseases. After explaining how to do the study, written consent was obtained from the subjects. For these people, there was a possibility to leave at each stage of the study. Participants in this study were enrolled with purposeful sampling method and then patients were introduced to the laboratory to measure glycated hemoglobin. At the beginning of the study, demographic information questionnaire including gender, age, type of drug, duration of diabetes and diet were completed for all participants. In the next step, the patients were randomly divided into two groups of 30 subjects, the test and control. The used barberry juice was provided from Margon Barberry Flower Company.

Barberry juice was produced in such a way that barberry fruit was first dewatered and then the extract was entered into the reservoirs and pasteurized and packaged after adding citric acid (0.5%) and sugar (5%). Individuals in the intervention group received barberry juice 200 cc daily for two consecutive days

in the morning and evening, each time 100 cc, for 8 weeks. They were asked to mark the consumption of barberry juice at the same time in a special record sheet that was given to them. There was no intervention on the control group.

At the end of the 8-week period, HbA1c was re-measured. The follow up of patients in this study was carried out once every 20 days by phone and home visits for the delivery of barberry juice. If patients had conditions such as unstable diet, changes in the dosage of blood glucose lowering drugs and discontinuation or irregular consumption of barberry juice were excluded from the study. The patients were asked about possible side effects of barberry juice. Barberry juice tolerance was good in patients and no complications were reported.

To measure HbA1c the WHO calorimetric method using the Sismex K800 was used. The data were analyzed by SPSS v.22 software. To examine the coherence of the two groups before the intervention, the Kolmogorov-Smirnov test was performed and the data distribution was normal ($\text{sig} = 0.8$). Descriptive statistics were used to describe the frequency data and for data comparison, independent t-test, paired t-test and Pearson correlation coefficient were used.

The significance level for all tests was considered to be 0.05.

FINDINGS:

This study was performed on 60 patients with type II diabetes who referred to diabetes clinic of Imam Khomeini Hospital in Zabol. At first, patients were randomly divided into two groups: barberry juice (test group) and control group (no intervention). The treatment group consisted of 30 participants whose mean age was 48.2 ± 4.3 years and the age range of the group was 46-68 years. In this group, 18 subjects (52%) were women and 12 subjects (48%) were men and 30 subjects with mean age of 48.2 ± 4.3 years and age range of 38-69 years were included in the control group of which 19 subjects (57%) were women and 11 subjects (47%) were men.

The mean serum levels of glycosylated hemoglobin in two groups of barberry and control at the beginning and the end of the study are presented in Table 1. The results showed that the biochemical parameters measured in the test group were significantly lower than the control group. This means that there was no significant difference between the two variables before the intervention. But after the intervention, this difference was significant ($P < 0.05$).

Table 1: Comparison of main study variables

Variable		Start of study		End of study	
		Mean \pm standard deviation	P-value	Mean \pm standard deviation	P-value
HbA1c	Test	11.02 \pm 1.45	0.43	8.70 \pm 0.92	0.001
	Control	11.06 \pm 2.01		11.06 \pm 2.04	

DISCUSSION AND CONCLUSION:

The aim of this study was to investigate the effect of barberry juice on glycosylated hemoglobin levels in patients with type II diabetes mellitus. The findings of this study showed that consumption of 8 weeks of barberry juice in patients with type II diabetes significantly reduced the level of HbA1c in the test group compared to the control group.

The most prominent clinical symptom of type II diabetes is the increase in blood glucose, which leads to glycation of various proteins of body (19). Protein glycation also has an effect on metabolic control and pathogenesis of diabetes complications. In fact, this process plays an important role in the development of microscopic or macroscopic damage of vessels (20). Although many authors have reported the dangers of this disease, diabetes can be controlled by maintaining blood glucose levels (21-22). Today, chemical drugs are used to reduce blood glucose, which is associated with adverse side effects (19).

Barberry has a variety of flavonoids and alkaloids responsible for the antioxidant effects of this plant. These compounds reduce serum glucose and lipoproteins. Their antioxidant properties also remove free radicals (23). Barberry has 2 percent saponin, which in previous studies moderate antioxidant effects and a decrease in blood sugar levels by saponin were found. Compounds containing saponin have a lowering effect on blood glucose and lipids (24).

The results of this study showed that FBS in barberry juice consumption group had a significant decrease compared to the beginning of the study. The results of this study were consistent with the results of the Mehraban's study that evaluated the hypoglycemic effects of barberry rootstock in patients with type II diabetes (25). A study by Tahmasebi in 2014 illustrates the effect of daily consumption of barberry

root extract on fasting blood glucose, fructose amine and fasting insulin (26).

Also, in a study carried out by Golfaraz et al. (2008), the anti-diabetic effect of ethanol extract of barberry root in comparison with pure berberine was studied in healthy and diabetic with similar doses of alloxan rats. Oral administration of Barberry and berberine extract to healthy and diabetic rats caused a significant decrease in blood glucose during 73 days of treatment (27).

HbA1c is an indicator for monitoring the blood glucose control in diabetic patients over the past two to three months (28). In the present study, the level of glycated hemoglobin in the intervention group showed a significant decrease compared to the control group. In the study of Hajinejad and colleagues in 2015, which investigated the effect of the hydro-alcoholic extract of wild barberry root on serum glucose, glycated hemoglobin and aldehyde in diabetic rats, it was found that serum glucose, HbA1c and MDA serum levels of diabetic rats without treatment were significantly higher than rat in the test group (29).

Considering the significant decrease in fasting blood glucose and glycated hemoglobin level in the test group, it is recommended to use barberry juice to diabetic patients and thereby reduce the complications of this disease.

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