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The barberry juice effects on metabolic factors and oxidative stress in patients with type 2 diabetes: A randomized clinical trial



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ABSTRACT

Aim: The aim of this study was to investigate the effect of barberry juice (BJ) on cardiovascular risk factors in patients with type 2 diabetes (T2DM).

Methods: 46 diabetic Patients were randomly allocated to either the BJ group (n = 23) who consumed 200 ml of BJ daily for eight weeks, or the control group (n = 23) with no intervention. At the baseline and the end of 8-week intervention, blood pressure and biochemical markers were measured.

Results: forty-two Patients completed the study. After intervention systolic blood pressure (SBP), diastolic blood pressure (DBP), Fasting Blood Sugar (FBS) Total Cholesterol significantly decreased (P < 0.05for treatment effect) also Triglyceride (TG) decrease significantly in BJ group. Paraoxonase-1(PON1) concentrations significantly increased in Bj group and have a significant difference (P < 0.0001 for treatment effect) compared with control group.

Conclusions: This study revealed that BJ might decrease the risk of cardiovascular diseases in patients with diabetes.

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1. Introduction

Diabetes mellitus (DM) is a major metabolic disease associated with multiple complications such as cardiometabolic risk factors, nephropathy, neuropathy and retinopathy [1]. It is predicted that by the year 2035, more than 590 million people will suffer from type 2 diabetes (T2DM) [2] and during the next decade, the total number of diabetes-related deaths increase by more than 50% [3]

Barberry is a red coloured fruit which grows in Asia and Europe. The shrub of berberry that can grow 1–3 m and the fruits of this plant have a pink colour with 10 mm length [4]. This fruit contains antioxidant ingredient such as berbamine, berberine and berberrubine [5]. Many pharmacological actions in the traditional

medicine of Turkish and Iran have been mentioned for Barberry such as antibacterial, antipyretic, antipruritic and antiarrhythmic [6]. The root of the barberry also have therapeutic properties for example incitement immune system, recovery of appetite and decrease fever [4].

Recent evidences have indicated that one of the Barberry's extract ingredient, berberine which stimulates glucose metabolism via stimulation of glycolysis and reduces insulin resistance [7]. Barberry juice (BJ) is also rich in polyphenols which in turn play an important role in improving of lipid profiles and diabetes complications [8,9].

There are few studies regarding beneficial effect of barberry juice in T2DM, However, effect of BJ on blood sugar in patients with diabetes were controversial and there wasn't a comprehensive study to investigate effect of BJ on metabolic factors. Therefore, this study was performed with the aim of investigating the effects of BJ consumption on metabolic factors and oxidative stress in patients with T2DM.

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2. Materials and methods

2.1. Ethical considerations

This study was confirmed by the ethics committee of National Nutrition and Food Technology Research Institute (NNFTRI) of Shahid Beheshti University of Medical Sciences and written informed consent was obtained from all the patients. This study was registered at ClinicalTrials.gov ID: NCT03299153.

2.2. Study design and participants

The present study was a randomized clinical trial. Forty six T2DM patients (aged 30–70 years, 15men and 27women) with a diagnosis of at least 12 month were recruited from Diabetes Association of Iran-Babul. The inclusion criteria were taking oral hypoglycaemic agents not insulin, not smokers, not suffering from any other chronic diseases and, not using antioxidant supplements and oestrogen or progesterone (if female) and the exclusion criteria were relapse of the disease and hospitalization, change in the type and amount of drug intake and use nutritional supplement a month before the intervention begins.

2.3. Interventions

Patients were random permuted block by gender and randomly divided to one of the two groups including BJ consuming and control group. Random allocation of patients to treatment groups was performed by sequentially numbered containers. Randomization was performed by an assistant and group allocation was blinded for the investigator and participants. The patients in the BJ group were received 200 ml/d PJ for 8 weeks while the control group received no intervention. According to the previous study we use suggested doses of BJ in the diabetic patient [10]. All subjects were asked to maintain their dietary habits, physical activities or medications, during the study period.

2.4. Barberry juice characteristics

The fruits were squeezed. The juice was filtered, pasteurized, concentrated and stored at _18 C. The concentrated BJ was diluted with water in order to obtain a single strength BJ without any conservative. The study product was packed in 1 L tetra packs and was delivered to subjects every two weeks, free of charge. To measure accurately the volume of barberry juice, one Measurement module was given to each patient. The juice were kept at room temperature (<25 C) until opened, as recommended by the manufacturer. Total polyphenols of barberry juice was measured by Folin Ciocalteu reagent, using gallic acid as a standard and had 2403 mg gallic acid equivalent (GAE)/L of BJ [11]. Each 100 ml of BJ was included 45 kcal energy, 8.5 g carbohydrate, 0.52 g protein, 0.06 g fat and 0.8 g fiber.

2.5. Following

The BJ packages for one month have been given to the patients in each visits. The Compliance of patients was evaluated by weekly telephone contacts. Moreover, fixed number of BJ packages were given to each patient and asked them to return the unused packages at the end of the study. According to number of returned packages, their compliance was estimated about 90%. Patients who consumed less than 90% of the packets, excluded from the analysis.

2.6. Anthropometric, dietary, physical activity and biochemical assessment

Each subject's weight was measured by digital scales to the nearest 100 g, while wearing light clothing and no shoes. Height was measured to the nearest 0.5 cm. Body mass index (BMI) was then calculated as weight (kg) divided by square of height (m).

The three-day 24 h food recall questionnaire and public information was completed through interviews for all patients at baseline and after 8 weeks of intervention. The subject's diets were



Fig. 1. Flow chart of the study.

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