The Effect of Bread Enriched With Portulaca Oleracea on Metabolic Control Indices in Patients With Type 2 Diabetes: a Parallel Randomized Clinical Trial

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Research

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Abstract

Background: Diabetes is the most common chronic disease worldwide. Some herbs are used to control diabetes. *Portulaca Oleracea* is a type of plant that has essential fatty acid-rich leaves.

Objectives: This study aimed to evaluate the effect of bread enriched with *Portulaca Oleracea* on metabolic control indices in patients with type 2.

Methods: This parallel randomized controlled clinical trial was conducted on 104 patients with type 2 diabetes. Participants received bulk bread containing 10% *Portulaca* powder for 4 weeks (intervention group), the control group used their normal daily bread. At baseline and end of the study a 12 hours fasting and 2 hours later blood sample were collected to quantify plasma glucose levels and lipid profiles. The effectiveness of the intervention method was compared with the difference between the mean before and after the intervention (change score) in the two groups using t-test.

Results: The results showed that after the intervention, a significant difference was found between Fasting blood sugar, cholesterol and high-density lipoprotein variables in intervention groups, but could not affect serum low-density lipoprotein, triglyceride levels, blood sugar and Glycated hemoglobin(HbA1C) It should be noted that the difference between the means of the two groups before and after the intervention indicates that there is a significant difference between the other groups except HbA1C.

Conclusions: consumption of bread enriched with *portulaca oleracea* did have a significant impact on metabolic indices of diabetes and improvement lipid profile. It is recommended to use bread enriched with *portulaca oleracea* powder, areas where the staple food is bread.

Trial registration in the Iranian clinical trial system with the code IRCT2011030309006010N1.

Background

Diabetes mellitus (DM) is a common and growing problem around the world. According to the report of International Diabetes Federation in 2017, 425 million adults had diabetes [1], and this trend is expected to continue [2]. The prevalence of this disease is also increasing in developing countries, for example, the number of patients with DM in the countries of the MENA (Middle East and North Africa) WHO region in 2019 was reported to be 54.8 million patients. The latest report from Iran in 2016 by the WHO stated that 10.3% had type 2 diabetes [3]. The complications in patients with type 2 diabetes have increased dramatically over the past two decades [4]. The economic burden of DM in Iran is expected to increase dramatically in the coming decades [5]. Therefore, effective prevention programs are needed to reduce the burden of diabetes, and to be cost-effective, there is a need to focus on high-risk individuals [1, 6, 7]. Also, identifying and implementing effective strategies for DM prevention and management should be considered as a health priority.

Medical therapy is one of the priorities for diabetic patients, however it is associated with side effects in some patients [8]. On the one hand, the use of herbal medicines to treat diabetes depends on the cultural background of each country [9]. Therefore, studies on plants with more effective and safer hypoglycemic properties and / or even auxiliary treatment of native plants of an area are among the important studies. The use of chemical medicines has also increased today due to the spread of diabetes, but due to factors such as patients' dissatisfaction with the use of these medicines, side effects of long-term and excessive use, drug intolerance and ineffectiveness over time, and the costs imposed to patients, there is a growing interest in alternative and traditional therapies. For this reason, the use of medicinal herbs, in addition to reducing the cost of treatment, has had satisfactory results in many communities [10]. For example, some of these herbs, such as Fenugreek Seed [11], Flaxseed [12], garlic [13], cinnamon [14] and other medicinal herbs, have been used in previous studies to manage diabetes [15]. One of these plants is *Portulaca Oleracea*. The plant is usually a weed species [16] and has a large amount of omega-3 [17, 18] and has been used in ancient Egypt as a medicinal herb and in the Middle Ages in Arab countries, the Mediterranean and widely used throughout Spain [19]. Several studies have examined phytochemical and pharmacological properties of *Portulaca Oleracea* [20, 21], as well as its other properties, including anticancer [22] and antibacterial properties [23, 24]. The high nutritional and therapeutic value of *Portulaca Oleracea* has led researchers to recommend investing more in this plant [25, 26], in other words, this car plant, which is a weed in horticulture and a challenge for farmers turning to an opportunity for the proper use for health.

Currently, studies have been conducted on the role of this plant in lowering blood sugar and lipid profile of diabetic patients [27–29]. The results of a systematic review and meta-analysis show that in some studies, *portulaca oleracea* may be effective on improving blood lipid and sugar levels [30]. But the challenge is to use nutrients that can be used as a substrate. Since bread can be a good carrier for adding nutrients to meet the needs of consumers, it is considered as a staple food, a good source of nutrition and a cheap diet in half the world [31] that has led researchers to conduct studies on Bread Enrichment with Seeds [32–35] and in the food industry, industry owners claim to design products that lower blood cholesterol and sugar [11, 12]. Also, several studies have been conducted using *portulaca oleracea* seed powder to produce ice cream and cookies [33–35]. None of them, of course, have the same nutritional value as bread, which is staple food in most countries of the world, especially in the Middle East [36]. On the one hand, the use of fiber-rich bread has been more popular among consumers [37, 38]. Given that in Iran, white wheat flour is used for bread, vitamins and minerals are lost during the milling and refining process, and bread made from these ingredients will be much poorer than the original grain. Although several studies have been conducted to enrich flour with *portulaca oleracea* and researchers claim the effects of manufactured products on sugar and fat reduction, the effect of the product on diabetic patients has not been measured and the missed effect using staple food is still felt. On the other hand, the bread used in Iran is mostly flat, which does not have enough fermentation time and has a high glycemic index in terms of nutrition. Therefore, this study was conducted aimed to investigate the effect of bulk bread formulated with *Portulaca Oleracea* on the metabolic control indices of patients with T2D who referred to diabetes clinic in Shahroud Iran.

Materials And Methods

Study design and participants

The Table for allocating individuals to the intervention and control groups was prepared by the statistical consultant using a statistical syntax written in software SPSS. First, all cases of diabetic patients that referred to Shahroud Diabetes Clinic in Northeastern Iran were examined, and then 170 patients with diabetes were called by telephone. Among them, 60 patients were excluded due to lack of the study inclusion criteria. Patient registration with the study inclusion and exclusion criteria was performed by the corresponding author between 2019 and 2020. After explaining the objectives and the method of conducting the study and obtaining informed consent, the patients were assigned to two intervention and control groups by the corresponding author, respectively. Data collection and management was performed by two nurses and a public health student who were masked about the allocation of patients. For increasing participation of subjects, first educational brochures were provided to both groups, including information on the risk factors for diabetes, hyperlipidemia, and how to diagnose, control, and treat the role of diet, especially antioxidants, in reducing the risk. The content of the educational brochures was prepared and reviewed by reviewing the literature according to the opinion of experts.

Declarations

Ethical considerations:

This study has been approved by the Ethics Council in Medical Sciences Research of Shahroud University of Medical Sciences with the code IR.SHMU.REC.1397.200, has been registered in the Iranian clinical trial system with the code IRCT2011309006010N1 and in accordance with the Helsinki Declaration of 1975, as revised in 2008.

Participants

Inclusion and exclusion criteria

The study inclusion criteria included diabetic patients (known as diabetes or fasting blood sugar $\leq 125\text{mg/dl}$, BS $\geq 200\text{mg/dl}$, glycosylated hemoglobin %HbA1c > 6.5 and / or treated with oral hypoglycemic medicines referred to Shahroud diabetes clinic.

Exclusion criteria

The study exclusion criteria included diabetic patients treated with insulin or diabetic patients with: cardiovascular, renal, and hepatic disorders, hypothyroidism and seizures; a history of kidney and bladder stones; treated with estrogen, steroid, beta and thiazide inhibitors; women who decided to become pregnant; pregnant women, women who breast feed, users of E and C supplements, and omega-3s at least six months before sampling, smoking and drug users.

Intervention

The members of the intervention group received bulk bread containing *Portulaca Oleracea* for 4 weeks without considering a special diet, and was followed up by telephone every week. and the control group used ordinary daily bread.

During the study, 4 patients were excluded from the control group for a number of reasons (one patient due to pregnancy, one patient due to arrhythmia, one patient due to hypothyroidism, and one patient due to drug abuse and addiction) and a patient was excluded from the intervention group due to drug abuse during the intervention. Finally, the data of 104 patients (54 patients in the intervention group and 51 patients in the control group) were analyzed (Fig. 1). Regarding the nature of the study, it was not possible to blind participants, but the data collector and analyst were unaware of how patients were allocated to the two groups.

Bread preparation containing *Portulaca Oleracea*

All parts of *Portulaca Oleracea*, which included leaves, stems and seeds, were collected in Shahroud in the summer of 2019, and after preparing the powder, 10% was added to wheat flour. The cooled produced bread was then evaluated by 20 trained evaluators (10 males and 10 females). The sensory properties examined in this study included taste, texture, color, odor, and general acceptance [39]. The bread was then packed in polyethylene bags and distributed to several members of the intervention group on a daily basis at several distribution centers [40] and became necessary recommendations for eating were reminded by phone.

Assessments and outcomes

Primary outcomes.

After obtaining written consent, the subjects completed a questionnaire on demographic information including (age, diabetes years, sex, job, family history diabetic, Married Statues, Family size, Level of education, Oral Contraceptive Pills DM Consumption) and, after 12 hours of fasting, venous blood samples also blood sugar 2 hours later were collected from all the participants and the serums were stored at 70 degrees below zero. Enzymatic assay method and Pars Azmoon Kit were used to perform all tests including fasting blood Sugar (FBS), blood sugar (BS), triglycerides (TG), total cholesterol(Chol), LDL, HDL and glycosylated hemoglobin (HbA1c) was done by analyzer Drew-DSS with the chromatography HPLC method.

Secondary outcomes

Fasting blood sugar, triglyceride, total cholesterol, LDL, and HDL after intervention by enzymatic method and Pars Azmoon reagent, Iran. were performed on all candidates after 12 hours of fasting and 2 hours later blood. and HbA1c was measured by Drew-DS5 analyzer and DS5 Pink Reagent kit. after the intervention.

sample size

The sample size in this study was determined according to the objectives of the study and using Sabzghabae et al.'s study with the default of the first type error less than 0.05, 80% test power. the estimated sample size was $n = 38$ in each group[29]. With regard of missing value and increasing of power of study, finally the number of samples in each group was $n = 55$.

The data were collected using demographic information form as well as experiments. The form of demographic information included age, gender, number of household members, level of education, occupation, marital status, type of medicines used, and the onset of diabetes completed by patients before the intervention in both groups.

Randomization

The present study is a parallel randomized clinical trial. In this interventional study, 104 patients with diabetes referred to Shahroud Diabetes Clinic in Iran. based on the study inclusion and exclusion criteria and after explaining the objectives of the study and obtaining informed consent, were selected. They were randomly assigned to intervention and control group based on permuted block random allocation (block size of 4).

Statistical methods

To analyze the data, we used descriptive statistics (mean, and standard deviation) and the effectiveness of the intervention method was compared with the difference between the mean before and after the intervention (change score) in the two groups using t-test. Using SPSS and Stata software, data analysis was performed at a significant level of 0. 05.

Results

The general information of the subjects is listed in Table 1. The mean age of the participants was 53.56 ± 6.52 years and the ages of participants were between 33 and 63 years. Almost 51% of the subjects were men and 49% were women. The results of statistical analysis showed that the two groups did not have significant differences in terms of demographic information and in other words, the two groups were homogeneous.

Prior to the intervention, no significant difference was observed between the two groups in terms of mean variables of FBS, BS, HbA1C, HDL, LDL, total cholesterol and TG (Table 2).

The results showed that after the intervention, a significant difference was found between FBS, total cholesterol and HDL variables in two groups, but no significant differences were observed in terms of variables BS, HbA1C, LDL and TG between both intervention and control groups (Table 3).

It should be noted that the difference between the means of the two groups before and after the intervention indicates that a significant difference was found between the other variables except HbA1C (Table 4) in both groups, which indicates the effectiveness of the intervention on these parameters.

Discussion

According to the study results, the mean of all metabolic indices of diabetes in patients is higher than the recommended standard values [41]. This finding is consistent with the results of some studies in Iran [42–44] and in other parts of the world [45–47]. Therefore, the proper intervention is of particular importance in improving metabolic indices in these patients.

The results of the present study showed the reducing effect of *Portulaca Oleracea* supplementation on fasting blood sugar and blood sugar. In a study by Al-Sayed et al. (2011) who compared the effect of *Portulaca Oleracea* and metformin on blood sugar levels in diabetic patients, the results showed that *Portulaca Oleracea* seeds had effects on lowering blood sugar and insulin resistance [27] which is consistent with the results of the present study. The results of the present study are also consistent with several experimental animal studies, in which the properties of lowering blood sugar levels in laboratory animals have been reported by *Portulaca Oleracea*-derived polysaccharides [48, 49]. The study results of Esmailzadeh et al on the effect of *portulaca oleracea* seed with yogurt on blood sugar [50], and Wainstie, et al who used a capsule containing *Portulaca Oleracea* seeds for this purpose, were inconsistent with the results of the present study [51]. It seems that the difference in the method of intervention and the duration of the intervention in the above studies may be the probable reason for this inconsistency, so that in the above studies only part of the plant (plant seeds) has been used. While in the present study, the powder from the whole plant has been used. The mechanism of biological yield of *Portulaca Oleracea* is not well known. Several mechanisms have been considered for the beneficial effects of *Portulaca Oleracea* to improve the metabolic indices of diabetes, including affecting membrane depolarization, calcium entry, improving insulin secretion by closing ATP / potassium adenosine triphosphate channels, and increasing glucagon peptide levels [52, 53].

In this study, using bread containing *Portulaca Oleracea* had no significant effect on hemoglobin A1C levels. Since the intervention time in the present study was four weeks, while hemoglobin A1C shows changes in a period of at least three months, it seems that longer time is required for this intervention to be effective on hemoglobin A1C.

In the present study, enriched bread containing *portulaca oleracea* had a significant effect on improving patients' lipid profile, which is similar to the results of experimental animal studies [48]. Also the study results of Sabzghabae et al [29], Esmailzadeh et al [50], and El-Sayed et al [27], and a systematic review by Hadi et al [30], Besong et al. [54] indicated the effectiveness of *Portulaca Oleracea* use on at least one or more parameters of lipid profile of the subjects. Also, according to the study results of Dehghan et al. all the parameters of lipid profile after exercise and use of *Portulaca Oleracea* seeds were improved [55], which is similar to the results of the present study. In their study, Gatreh-Samani et al. with the aim of comparing the use of statin with *Portulaca Oleracea*, showed that the amount of triglycerides in *Portulaca Oleracea* group was significantly higher than in lovastatin group [56]. However, in a study by Waistien et al, the capsule containing *Portulaca Oleracea* seeds had no effect on lipid profile [51]. The reason for this inconsistency can be considered as the effect of the type and time of the intervention. The positive

results of the effect of *Portulaca Oleracea* powder on lipid profile can indicate the presence of omega-3 and antioxidant properties for free radical scavenger cleansing. It can help improve the health and function of the whole human body with high levels of vitamins, antioxidants, minerals, essential fatty acids, omega-3s and bioactive compounds [57, 58]. Since all parts of the plant (including leaves, stems, and seeds) have been used in this study, cholesterol and triglyceride reduction can be attributed to the fiber in *Portulaca Oleracea* or the effect of unsaturated fatty acids on it, the fiber in *Portulaca Oleracea* and pectin by linking to cholesterol in the diet can prevent cholesterol from being absorbed by the gastrointestinal tract, thereby reducing cholesterol [22]. In addition, lipopolitical effect of *Portulaca Oleracea* is due to the presence of omega-3 fatty acids, flavonoids, pectin, and water-soluble fiber in *Portulaca Oleracea*, which may be able to justify the effects of *Portulaca Oleracea*. Also, the presence of flavonoids and polysaccharides can be effective. Since in this study using bread containing *Portulaca Oleracea* had a significant effect on fasting blood sugar, blood sugar and fat profiles of patients with diabetes and dyslipidemia on a daily basis, and given that important evaluation of clinical data on side effects indicates that herbal medicines are generally more tolerable compared to industrial medicines in patients [59].

Conclusion

The results of this study showed that bread enriched with *Portulaca Oleracea* did have a significant impact on fasting blood sugar, blood sugar and improvement lipid profile and for greater stability of metabolic indices. Thus, in addition to medical therapy, it is recommended to use bread enriched with *Portulaca Oleracea* powder.

Study Limitations

The duration of the intervention study can be considered as a limitation of this study, and longer-term use was likely to determine HbA1c levels and show the stability of bread use in individuals.

The most important strengths of the present study are the bulky bread design containing *Portulaca Oleracea* with the best chemical and physical properties and general acceptability in the view of panelists, which does not have a high glycemic index and is in areas where the staple food is bread.

Most of the data generated or analyzed during this study is included in this published article.

Abbreviations

SD: Standard Deviation; FBS: Fasting Blood Sugar; BS: Blood Sugar; HDL-Cholesterol: High-Density Lipoprotein cholesterol; LDL-Cholesterol: Low -Density Lipoprotein .TG, Triglycerides, HbA1c; Glycosylated hemoglobin.

Declarations

Authors' contributions

MD: conceived and design the study, gathering data, perform tests, draft the manuscript and interpret the results, AMN: participated in Manuscript preparation. LN: Thesis supervisor, A K: allocation, Statistical advisor and interpret the results. AB: gathering data, perform Biochemical tests. HE: helped to draft the manuscript and interpret the results. All authors read and approved the final manuscript.

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"The authors confirm that all ongoing and related trials for intervention are registered"

Competing interests

All authors have declared that they don't have any conflict of interest in publishing this research.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This study has been approved by the Ethics Council in Medical Sciences Research of Shahroud University of Medical Sciences with the code IR.SHMU.REC.1397.200 and has been registered in the Iranian clinical trial system with the code IRCT2011030309006010N1.

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Consent for publication

All authors are agreeing with publishing the manuscript.

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Tables

Table 1: General characteristics of the participants in the control and intervention groups

Variables		Intervention	Control	P Value
		Mean $\pm$ SD		
Age		53.50 $\pm$ 6.75	53.60 $\pm$ 6.34	0.91
Duration of DM (years)		2.9 $\pm$ 2.1	3.01 $\pm$ 2.16	0.85
		N (%)	N (%)	
Sex	female	54(100)	51(100)	0.85
	male	26(48.1)	25(50)	
		28(51.9)	25(50)	
Job	officer	15(27.5)	8(10)	0.12
	worker	1(1.9)	4(8)	
	farmer	4(7.4)	5(10)	
	housewife	20(37)	24(48)	
	free	3(5.6)	6(12)	
	unemployed	11(20.4)	3(6)	
Family history(DM)				
	Yes	31(62)	31(57.4)	0.63
	No	19(38)	23(42.6)	
Married Statues				
	single	0(0)	0(0)	0.39
	married	47(87)	47(94)	
	widow	1(1.6)	0(0)	
	divorce	6(11.1)	3(6)	
Family size				
	<2	2(3.7)	1(2)	0.85
	2-5	43(79.6)	36(72)	
	6-9	9(16.7)	13(26)	
Education				
	illiterate	4(7.4)	5(10)	0.80
	Elementary	29(7.4)	27(5.4)	
	Guidance	16(29.6)	13(26)	
	High school	4(7.4)	4(8)	
	Master	1(1.9)	1(2)	
OCPs hypoglycemic				
	Metformin	25(46.3)	19(38)	0.72
	Glibenclamide	2(3.7)	3(6)	
	Both	3(3)	3(5)	
	Other	25(50)	24(44.4)	

OCPs: Oral Contraceptive Pills; DM: Diabetes Mellitus

Table 2: Indices of glucose and lipid profile before the intervention and control groups

Variable	Intervention	Control	P-Value
	Mean $\pm$ (SD)	Mean $\pm$ (SD)	
FBS (mg/dl)	177.48 $\pm$ 48.76	181 $\pm$ 46.13	0.68
BS (mg/dl)	240.94 $\pm$ 58.21	236 $\pm$ 82	0.65
HbA1c %	8.70 $\pm$ 1.44	8.44 $\pm$ 1.69	0.39
Total cholesterol (mg/dl)	197.93 $\pm$ 32.43	202.84 $\pm$ 36.24	0.467
TG (mg/dl)	194.05 $\pm$ 53.45	180.86 $\pm$ 54.47	0.21
HDL (mg/dl)	40.01 $\pm$ 6.8	40.99 $\pm$ 6.91	0.47
LDL (mg/dl)	129.11 $\pm$ 29.04	129.41 $\pm$ 31.79	0.96

SD: Standard Deviation; FBS: Fasting Blood Sugar; BS: Blood Sugar; HDL-Cholesterol: High-Density Lipoprotein cholesterol; LDL-Cholesterol: Low -Density Lipoprotein .TG, Triglycerides, HbA1c; Glycosylated hemoglobin

Table3: Indices of glucose and lipid profile after the intervention and control groups

Variable	Intervention	Control	P-Value
	Mean $\pm$ (SD)	Mean $\pm$ (SD)	
FBS (mg/dl)	157.07 $\pm$ 47.29	179.58 $\pm$ 44.7	0.014
BS (mg/dl)	220.15 $\pm$ 48.09	233.24 $\pm$ 45.07	0.15
HbA1c	8.16 $\pm$ 1.34	8.20 $\pm$ 1.31	0.86
Total cholesterol (mg/dl)	182.07 $\pm$ 31.60	197.8 $\pm$ 32.65	0.014
TG (mg/dl)	177.98 $\pm$ 45.90	187.84 $\pm$ 54.95	0.32
HDL (mg/dl)	47.87 $\pm$ 7.74	41.75 $\pm$ 6.85	<0.001
LDL (mg/dl)	118.22 $\pm$ 29.62	126 $\pm$ 30.47	0.15

SD: Standard Deviation; , FBS: Fasting Blood Sugar; BS: Blood Sugar; HDL-Cholesterol: High-Density Lipoprotein cholesterol; LDL-Cholesterol: Low -Density Lipoprotein .TG, Triglycerides, HbA1c ; Glycosylated hemoglobin

Table4: Compare the differences before and after the variables in the two groups

Variable	Intervention	Control	P-Value
	Mean $\pm$ (SD)	Mean $\pm$ (SD)	
FBS (mg/dl)	20.40 $\pm$ 20.68	1.76 $\pm$ 9.16	<0.001
BS (mg/dl)	20.80 $\pm$ 23.95	3.58 $\pm$ 9.61	<0.001
HbA1c	0.55 $\pm$ 60	0.23 $\pm$ 1	0.69
Total cholesterol (mg/dl)	15.85 $\pm$ 21.1	5.04 $\pm$ 18.81	0.007
TG (mg/dl)	16.07 $\pm$ 29.74	-6.98 $\pm$ 35.04	<0.001
HDL (mg/dl)	-7.85 $\pm$ 4.50	-0.75 $\pm$ 3.16	0.006
LDL (mg/dl)	10.88 $\pm$ 13.35	2.61 $\pm$ 16.38	<0.001

SD: Standard Deviation; , FBS: Fasting Blood Sugar; BS: Blood Sugar; HDL-Cholesterol: High-Density Lipoprotein cholesterol; LDL-Cholesterol: Low -Density Lipoprotein .TG, Triglycerides, HbA1c; Glycosylated hemoglobin

Figures

Figure 1

Flow Diagram

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