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Effect of synbiotic supplementation on weight, body mass index and blood sugar in type II diabetic patients

Akram Kooshki[1], Tahereh Tofighian[2], Roya Akbarzadeh[3]

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1. Department of Nutrition and Biochemistry, Faculty Member of Medicale, Sabzevar University of Medical Sciences, Sabzevar, Iran
2. Department of Nursing and Midwifery, Faculty Member of Nursing and Midwifery, Sabzevar University of Medical Sciences, Sabzevar, Iran
3. **Correspondence to:** Department of Operating Room & Anesthesia, Faculty Member of Paramedics, Sabzevar University of Medical Sciences, Sabzevar. Iran
Email: Roakbarzadeh53@gmail.com

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Abstract

Obesity disrupts glucose homeostasis by metabolic disorders. Probiotics are nutritional and medicinal potential to control obesity and its related disorders. This study was aimed to investigate effects of synbiotic supplementation on weight, Body Mass Index (BMI) and blood sugar in type II diabetic patients. This clinical double-blind trial study was done on 43 (15 males and 28 females) type II diabetic patients who reffered to diabetes clinic in Sabzevar. The patients in the study were randomly divided into two groups Synbiotic and the control. The synbiotic group received 1 tablet synbiotic and placebo group received 1placebo for 8 weeks. At the beginning and end of the study, all of patients' weight and height and fasting plasma glucose levels were measured according to standard protocols. Before and after study, 24-hour dietry recall was taken and food intake and calorie consumption were calculated throughout day. Mean age and duration of disease was 54.88 ± 11.10 and 7.33 ± 5.4 years. Synbiotic supplementation leads to weight loss. BMI and blood sugar in intervention groups patients in comparison of control group. The results showed that Synbiotic supplementation reduced weight, BMI and blood glucose in type II diabetic patients and its intake can be usefull for diabetics.

Keywords: Diabetes Mellitus, Obesity, Probiotic, Synbiotic

Introduction

Type II diabetes is metabolic disorder that is characterized by high levels of glucose, insulin resistance and relative insulin deficiency in the body and is one of the most prevalent diseases in the world [1]. In Iran is estimated at approximately 8% of adults are infected by this disease [2]. Studies have shown that obesity is one of the most important factors in the appearance of insulin resistance and type II diabetes [3,4]. Unbalanced food dietary intake and low physical activity in recent decades has been led to an epidemic in the community [5]. In a prospective study on the 9 million people around the world in the last three decades has shown that the average of Body Mass Index (BMI) in each decade was increased about 0.4-0.5 kg/m2 and the overall average of BMI was increased about 1.4 kg/m2 in men and 1.9 kg/m2 in women [6]. The World Health Organization (WHO) has declared that more than 1.4 billion adults are overweight and

at least 200 million men and 300 million women, are obese [7].

Obesity is distinguished as chronic subclinical inflammation that affects insulin metabolic activity sensitive tissues, particularly liver, muscle, fat tissue and disrupts glucose homeostasis by metabolic disorders homeostasis in the body [8]. It also observed that pro-inflammatory cytokines such as Tumor Necrosis Factor-Alpha (TNF-Alpha) in the adipose tissue of obese people is increased and by inflammation increasing insulin resistance and type II diabetes occurs as result of obesity [9].

Currently, various methods have been provided for weight loss and obesity treatment that one of them is the use of probiotics. Probiotics are living organisms that are included most positive gram bacteria, yeasts and molds which can easily pass through the digestive tract to live and multiply in the intestines. These particular groups of bacteria (lactobacillus and bifidus) are able to produce and secrete range of useful materials and active substances in the intestine. The probiotics make pseudo cytokines that called which includes short chain fatty acids, amino acids, active peptides, polyamines, carbohydrates, vitamins (K,B), anti-oxidants, growth factors and substance called phytosterols that are strongly anti-cancer [10]. Prebiotics are non-absorbent products that by growth set to host gut microbs have beneficial effects for human [11].

Most probiotics are used to regulate growth of probiotic that contains inulin Fructo-oligosaccharide, various types of Galacto-oligosaccharides and resistant starches. Prebiotics act as substrate for the production of metabolites of active metabolism, particularly Short Chain Fatty Acids (SCFA) that include the acetate, Butyrate and Propionate [12,13]. Several studies have shown that prebiotics are usefull in reducing accumulation of ectopic fat, especially fat tissue analysis, reducing fat white fat tissue, reduction in systemic inflammation and insulin resistance in obese patients [14,15].

Today, combination of probiotics and prebiotics are used in Symbiotic supplements. Some researchers have reported that probiotics causes weight gain in children with diarrhea but could not understand its reason [16,17] and some other researchers have been reported anti-obesity effects of probiotics for regulating lipid metabolism and glucose [18,19].

Preliminary studies have shown that in patients with diabetes, low levels of inflammatory factors and biomarkers of oxidative stress is associated with better glycemic control. Recently, some studies have shown that Symbiotic foods may help control profiles metabolic and inflammatory factors[20] Patients with type II diabetes and systemic inflammation are likely to increase metabolic effects of these factors that can lead to complications such as retinopathy progression, neuropathy and nephropathy [21,22]. Such effect have been observed in animal models or non-diabetic patients. Recent studies have shown the effect of probiotics in controlling weight gain in adults [23].

Many attempts have been made to reduce the complications of diabetes due to the beneficial effects of probiotic and Synbiotic on metabolic factors in animal models and patients without diabetes and since obesity is the most important causes diabetes and its complications. However, few studies have investigated effects of Synbiotic supplements on diabetes complications. Previous studies were conducted on the effects of Synbiotic in healthy adults [24] and in patients with lesions [25], so this study was conducted to investigate the effect of Synbiotic supplement on weight, BMI and blood sugar in type II diabetic patients.

Method

This clinic double-blind trial study was done on 43 type II diabetic patients who referred to diabetes clinics in Sabzevar, the east north of Iran. Selection of samples was considered based on sample size formula in small groups 20 patients in each group. Due to likelihood of loss, 3 participants were added to each group and a final sample size was 23 participants in each group and total sample size was 46 patients [26]. In this study, patients had been entered with type II diabetes who have fasting blood glucose greater than 126 mg/dl of blood sugar two hours more than 200 mg/dl had in the age range 35-70 years and it lasts at least two years of diabetes.

Pregnant women, patients with chronic renal and hepatic function in patients with coronary artery disease, acute or chronic lung disease, short bowel syndrome, allergies, insulin consumers and dietary supplements were excluded. Patients participating in the study were divided random into the intervention group who received Synbiotic supplement and the control group who get placebo supplements or placebo for 8 weeks.

The intervention group 1 received Synbiotic supplement containing 1.5×107 Bacillus coagulants and 100 mg Fructo-oligosaccharides of nature only company and 1 placebo was given to control group daily. To run double-blind study, at baseline set of cans containing supplements or placebo were coded by anyone other than the researchers as A and B to achieve complete lack of information received by each group. To the subjects recommended do not change physical activity, diet and medication intake.

At baseline and end of the study, all patients weight and height were measured according to standard protocols. Thus, the weight of fasting, without shoes and clothes was measured by using precision digital scale Seca 100 grams and height with tape measure and with accuracy of 1cm. BMI was calculated by dividing weight in kilograms by the square of height in meters. Befor and after study, 5 ml blood was taken in fasting plasma glucose level of patients and the method based on glucose oxidase/peroxidase were measured by using commercial kits Pars test. At the beginning and end of the study the patients were asked to note food consumption in the last 24 hours (food frequency questionnaire was filled by the interviewer with questions of samples which is standard questionnaire) that for precision recall 24 hours was considered for two days a week. By this method, food intake and calorie consumption were calculated per day. During the study all patients were asked not change their diet in terms of quantity and diversity.

Data was analyzed by descriptive statistical tests, Kolmogorove-Smirnov (to assess the normal distribution of variables) and independent and paired t test to compare variables between groups and within groups with SPSS-16 that p-value was considered less than 0.05.

This study was registered in the Iranian Registry of clinical trials with the registry code of IRCT 2014110519816N1. Moreover the study was approved by the Ethics Committee of Sabzevar University of Medical Sciences, Iran (code: 122.1696).

Results

Among 46 patients during study, 3 patients were excluded due to lack of desire to continue research and 43 patients (15 males and 28 females) completed the study. The mean age and duration of illness was 54.88±11.1 and 7.33±5.4 years respectively. The weight mean and BMI are presented in Table 1. In the beginning of the study two groups were not significantly different to each other with respect to age, sex, physical activity, age and anthropometric measurements, blood glucose and lipid lowering medication type and dosage, duration of diabetes. As you can seen weight and BMI in the intervention group has a significant decrease at the end of the study compared to the beginning of the study than the control group (p=0.01).

Table 1 *The average weight and BMI* of patients in the two groups*

Index \ Group	Intervention group	Control group	p-value between groups
Weight in beginning study(kg)	71.25±10.17	71.07±9.94	p>0.05
Weight in end of study(kg)	67.37±9.74	70.66±9.90	p=0.01
Weight alteration	-2.88	-0.41	p=0.01
BMI in beginning study(kg/m^2)	27.97±4.24	27.88±3.22	p>0.05
BMI in end of study(kg/m^2)	27.26±4.24	27.71±3.23	p=0.01
BMI alteration	-0.71	-0.17	

*Body Mass Index

The mean of fasting blood sugar levels is shown in Table 2. At the end of the study, blood sugar changes showed statistical significant difference in intervention group in comparison of control (p=0.01).

According to survey data and food intake of patients, there was no significant difference in terms of energy, carbohydrate, protein and fat between the beginning and end of the study in both intervention and control group.

Table 2 *The average fasting blood sugar patients in the two groups*

Group / FBS(mg/dl)	Intervention group	Control group	p-value between groups
Beginning study	188.56±69.93	186.80±52.94	
End of study	167.5±53.58	183.06±56.70	p=0.01
p-value inter groups	0.003	0.214	

Discussion

This study shows that Synbiotic supplementation for 8 weeks in patients with type II diabetes can lead to significant reduction in weight and BMI. The results were relatively consistent the result of Jung study [27]. In his study, Lactobacillus Gasseri BNR 17 supplementation was measured for 12 weeks in obese or overweight, weight loss, waist and hip circumferences. Jung [27] stated that anti-obesity effects of Lactobacillus can be set due to lipid metabolism and sugar, conjugated linoleic acid production (CLA), to reduce the size and number of adipocytes small adipocytes in white fat tissue and the regulation of body lecithin [27]. Carvelho [28] also suggests that probiotics produce short-chain fatty acids (SCFA) control food intake and weight through induced mechanisms Glucagon-Like Peptide 1 (GLP-1) and Peptide YY (PYY) in intestinal cells [28]. In another study by Safavi and colleagues [23] conducted syudy on the 70-man 18-6-year-old with BMI equal to or higher than 85 percentile in 2012 and was found that the consumption of Synbiotic supplement for 8 weeks significantly higher decreased BMI, waist circumference and the ratio of waist hip ratio [23].On the other hand, some researchers believe opposition of Jung's theory and believed that probiotics and intestinal microflora have important role in the development of obesity, inflammation-related obesity and insulin resistance which wasn't confirmed by the results of our study [29].

The meta-analysis of Million on 17 clinical trials in humans 51 studies on animals and 14 studies on laboratory models showed that Lactobacillus species have different effects on body weight and BMI. He stated that Lactobacillus fermentum (LB. fermentum) and Lactobacillus Ingluie (LB. ingluviei) cause weight gain in animals. L. Gasser (LB.gasseri) causes the weight loss in obese humans and animals [30]. Marik [31] also believes that gastrointestinal tract microflora changes in obese patients and treatment with probiotics decrease metabolic effects of caused by gut microflora changes in obese and diabetic and probiotics are as nutritional and medicinal substances to control obesity and its disorders particularly diabetes [31].

Also the results of this showed that Synbiotic supplementation caused significant reduction of sugar at the end of the study in comparison of control group. Few conducted studies on the effects of probiotics on the sugar in patients with type II diabetes were inconsistent. Jang In his study found no effect of supplementation on blood sugar and insulin lactobacillus Gasser which was inconsistent with the results of this study [27]. O'Hara [32] in his study reported that probiotics, delays glucose intolerance in mice fed by high-fructose diet and are usefull in the treatment of insulin resistance [32]. Alokai's [33] study also didn't report the effect of probiotics on blood glucose in diabetic patients [33]. Also in Esteve's [34] study there is no report about reduction of fasting blood glucose not with standing improving insulin sensitivity by prebiotics [34]. Repugnance of these results with above studies about effect on blood sugar

in type II diabetic patients could be due the type of supplement, species of Lactobacillus and its bacteria in it.

Conclusion

The results of this study showed that prebiotics and probiotics supplementation (Synbiotics) consumption for 8 weeks have beneficial effects on weight loss, Body Mass Index and fasting plasma glucose in patients with type II diabetes and the use of them is desirable in the diet of diabetic patients due to reduced complications of obesity in these patients.

According to survey data, Synbiotic supplementation was not effective on body mass index. It is seem that longer intake of Pre and Probiotics supplementation will be greater benefits. Further may have studies using higher doses of pre and probiotics (Synbiotics) or longer in patients with diabetes may be more effective. These finding could warrant future studies to determine the mechanism of the effects of Synbiotics on weight and BMI in type 2 diabetic patients.

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Contribution

Study design: AK,
Data collection and analysis: AK, TT,
Manuscript preparation: RA, AK

Conflict of Interest

"The authors declear that they have no competing interest."

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