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Effects of Royal Jelly Supplementation on Body Weight and Dietary Intake in Type 2 Diabetic Females

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ABSTRACT

Background: The objective of the current study was to assess the effects of royal jelly supplementation on body weight, total daily energy and macronutrients intakes in type2 diabetic females.

Methods: In this randomized clinical trial, fifty female volunteers with type2 diabetes were assigned into the supplemented (n=25) and placebo (n=25) groups, given a daily dose of 1000 mg royal jelly soft gel or placebo, for 8 weeks, respectively. Before and after the intervention, body weight and height of subjects were measured and body mass index was calculated. Dietary intake of patients was assessed using 24-hour food recall questionnaire for three non consecutive days (including 1 weekend day) and analyzed with Nutritionist IV software. The normally distributed data were compared using paired and independent *t*-tests, where appropriate.

Results: Royal jelly supplementation significantly ($P<0.01$) decreased the mean body weight (72.45±4.42 vs. 71.00±6.44 kg) while it increased insignificantly in placebo group (73.02±6.44 vs 73.52±6.80 kg). Royal jelly supplementation resulted in significant decrease of mean daily total energy ($P<0.01$) and carbohydrate ($P<0.01$) intakes, while in placebo group the mean daily total energy and fat intakes were increased significantly ($P<0.05$).

Conclusion: Supplementation with royal jelly may be beneficial in weight management of diabetic patients.

Keywords: Type 2 diabetes, Royal jelly, Weight management

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Introduction

"Type 2 diabetes mellitus is increasingly common, primarily because of increases in the prevalence of a sedentary lifestyle and obesity" [1]. The World Health Organization estimated that the number of people with diabetes in age range of 45-64 yr old would be more that 140 million in developing countries and more than 30 million in developed countries by 2030 [2]. Therefore, the global burden of diabetes on health and economy will continue to rise [3].

It is well known that diet and lifestyle play an important role in the glycemic control and consequently, in development of

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type 2 diabetes [4]. Obesity is a major risk factor contributing in development of diabetes. Several studies indicated that about 80–90% of patients with type 2 diabetes are overweight or obese. Excessive energy intake and obesity leads to insulin resistance and pancreatic beta-cell dysfunction [5]. Hence, energy restriction and weight loss plays an important role in preventing type 2 diabetes progress in overweight or obese patients. In addition, a 5 to 10% weight loss can significantly reduce diabetes-related complications by improving glycemic control, lipid profiles and blood pressure [6].

Nowadays, besides life style modification, most researches focus on using of complementary medicine for weight management in patients with type 2 diabetes [7].

Royal jelly is a viscous and milky substance secreted by the hypopharyngeal and mandibular glands of worker honeybees (*Apis mellifera*) and is an essential food for both the queen and her larvae [8]. Royal jelly comprises 60–70% water, 10–12% carbohydrates, 12–15% proteins, 3–7% lipids. 10-Hydroxy-2-decenoic acid (10H2DA) is a characteristic fatty acid of royal jelly which found only in royal jelly in nature [9]. Based on unique composition of royal jelly, recently in vivo and in vitro studies focused on its health promoting characteristics such as hypotensive [10], anti-hypercholesterolemic [11], anti-inflammatory [12], anti-tumor [13], antioxidant [14] and weight management effects [15].

Royal jelly exerts beneficial effects on energy metabolism and pancreatic lipase activity [15-18]. In addition, in human study royal jelly supplementation had positive effects on body composition [19]. Taking into account, the important role of weight management in overweight or obese diabetic patients and to the best of our knowledge there is no human study about the effect of royal jelly on body weight and dietary intakes in type 2 diabetic females, therefore, we investigated the effects of royal jelly supplementation on body weight, total daily energy and macronutrients intakes in diabetic females.

Materials and Methods

This was a double-blind randomized controlled clinical trial. Fifty overweight diabetic females were recruited from the outpatient Endocrine Clinic of Sina Hospital in Tabriz City from December 2010 to March 2011 with written consent. Study inclusion criteria were patients who had been diagnosed with type 2 diabetes within the previous 1 year, aged 30-65 years, BMI 25-30, taken glucose-lowering medications for type 2 diabetes but without insulin injection. Exclusion criteria included consuming trace element and antioxidants supplements in the previous 6 months, pregnancy and lactation, having acute renal disease, endocrine dysfunction and allergy.

The study protocol was approved by the Ethics Committee of Tabriz University of Medical Sciences and was registered in the Iranian Registry of Clinical Trials website (IRCT201011131197N5).

A computer-generated random sequence was kept in a remote secure location and administered by an independent third party who was not involved with the clinical conduct of study until all study data were collected and verified. Patients and those involved in enrolling participants, administering interventions and assessing outcomes were blind to group assignments. The patients randomly were assigned into the supplemented group (n=25), receiving royal jelly soft gel (each soft gel include 1000 mg lyophilized royal jelly providing 1 gram fresh royal jelly) once a day after breakfast or a control group (n=25) receiving one placebo soft gel for 8 weeks. The participants were asked to keep their usual dietary intake, physical activity and medication during the study period unchanged. Patients were monitored weakly for any side-effects of royal jelly supplementation. A total of 5 patients did not complete the study for reasons that included: 3 patients due to poor compliance with study protocols, 1 patient due to gastrointestinal disturbances, and 1 patient due to personal reasons.

Anthropometric measurements

Before and after 8 weeks, the weight of the subjects with barefoot and light clothing was recorded to the nearest 0.1 kg with a Seca scale. Height was measured using a mounted tape, with the subject's arm hanging freely by their sides, and recorded to the nearest 0.5 cm. Body mass index (BMI) was calculated as the weight in kg divided by the square of the height in meters.

Dietary intake assessment

Dietary intake of patients was assessed using a 24-hour recall food questionnaire for three days (2 weekdays and 1 weekend day). Food models and photos of common Iranian dishes of various portions, as well as household cups and measures, were used to define amounts regarding type and amount of food and beverages consumed during previous days. All of the 24-hours food recalls were analyzed with Nutritionist IV software program and mean intakes of energy, macronutrient were calculated.

Statistical analysis

Descriptive parameters were obtained for all study variables of each study group. The normality of variables was tested by the Kolmogorov–Smirnov test. Paired *t*-test and independent *t*-test were used to compare the differences within a group or between groups, respectively. A *P*-value less than 0.05 were considered statistically significant.

Results

As shown in Table 1, at the beginning of the study, the two groups were similar based upon the mean age, weight, BMI (body mass index) and diabetes duration.

Table 1: Baseline characteristics of patients

	Royal jelly group (n=23)	**Placebo group (n=22)**	****P***
Age (yr)	51.71±6.3	51.45±9.6	0.91
Weight (kg)	72.45±4.42	73.07±6.44	0.71
*BMI (kg/m2)	28.98±1.10	28.70±1.60	0.64
Known duration of diabetes (years)	5.2±3.1	5.1±2.8	0.87

Results are expressed as mean ± standard deviation

*BMI, body mass index

** Independent *t*-test value

The results of mean body weight, BMI, the mean daily total energy and macronutrients intakes are depicted in Table 2. Royal jelly supplementation significantly decreased the mean body weight while it increased insignificantly in placebo group.

Table 2: Comparison of Mean±SD body weight, BMI daily total energy and macronutrients intakes before and after intervention in both groups

Variables	**Royal jelly supplemented group (n=23)**			**Placebo group (n=22)**		
	Before	**After**	***P***	**Before**	**After**	****P***
weight (kg)	72.45±4.42	71.00±6.44	0.001	73.02±6.44	6.80±73.52	0.72
BMI (kg/m²)	28.98±1.10	28.40±1.06	0.001	28.70±1.60	28.80±1.36	0.63
Energy(kcal/day)	2006±55.23	1806.1±20.77	<0.001	2032±36.68	59.30±2225.30	0.02
Carbohydrate(g/day)	280.77±14.39	227.83±6.31	0. 01	277.33±9.69	305.98±14.69	0.11
Protein(g/day)	75.37±3.27	68.38±2.82	0.07	85.55±7.53	81.25±3.72	0.63
Fat(g/day)	65.14±4.50	70.16±1.80	0.23	66.16±3.28	77.16±4.64	0.05

**P*: in comparison with before intervention; paired *t*-test

Royal jelly supplementation resulted in significant decrease of the mean daily total energy ($P<0.001$) and carbohydrate ($P<0.01$) intakes, while in placebo group the mean daily total energy and fat intakes were increased significantly ($P\leq0.05$).The mean protein intake were decreased insignificantly in both groups.

Discussion

Based on our literature review, this is the first report about the effects of royal jelly supplementation on body weight and dietary intake in diabetic patients. In contrast to placebo group, royal jelly supplementation significantly decreased the mean body weight.

Different doses (500 mg or 1 or 2 g) of royal jelly supplementation in male swimmers, 5 days a week for 4 weeks did not decrease body weight, BMI and body fat mass [20]. But royal jelly supplementation in young football players led to significant increase of body weight and muscle component, and significant decrease of fat component after 8 weeks [19]. We could not compare our findings with the results of previous studies because their studies had been carried out in sportsmen and they emphasized on body composition, however observed positive effects of royal jelly supplementation on weight managements in studies in vivo and in viter may be due to increasing oxygen metabolism, respiration and oxidative phosphorylation [17] , furthermore 10H2DA of royal jelly activated TRPA1 (Transient receptor potential ankyrin 1) and TRPV1 (vanilloid1) which inducing thermogenesis and energy expenditure [16] and inhibiting pancreatic lipase activity consequently decreasing fat absorption from intestine [15] .

The observed body weight reduction in supplemented group can be justified by aforementioned mechanisms, since in the present study the mean daily total energy intake decreased significantly in supplemented group ($P< 0/05$), weight reduction may be due to decrease in mean daily total energy intake, however, other mechanisms such as appetite suppression may be involved in weight control in the supplemented group.

In conclusion, our findings revealed that royal jelly supplementation led to significant mean daily total energy intake and body weight reduction. Although, based on the results of the present study, supplementation with royal jelly may be beneficial in weight management for diabetic patients; further studies are needed to achieve precise results.

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