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Research paper

Effect of crocin extracted from saffron on pro-oxidant-anti-oxidant balance in subjects with metabolic syndrome: A randomized, placebo-controlled clinical trial



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ABSTRACT

Introduction: Oxidative stress is associated with metabolic syndrome and cardiovascular disease. Crocin, is a natural carotenoid that has anti-oxidant properties. The aim of this study was to investigate the effect of a crocin preparation extracted from saffron on a measure of serum pro-oxidant/anti-oxidant status in subjects with metabolic syndrome.

Methods: This randomized placebo-controlled clinical trial (RCT) was carried out on 60 volunteers with metabolic syndrome. The latter was defined using the International Diabetes Federation (IDF) criteria. Participants were randomly allocated to one of two groups of 30 subjects as the intervention and control groups. The intervention group received crocin tablets for 8 weeks at a dose of 15 mg twice a day; the control group were given a placebo over the same period. Blood samples were taken before and after the intervention period. Pro-oxidant-anti-oxidant balance (PAB) assay was used to evaluate the change in serum pro-oxidant, anti-oxidant balance.

Results: Mean serum PAB fell by 11.7% in the intervention group (p: 0.006), whilst there was no significant change in serum PAB in the control group (p > 0.05). The change in mean serum PAB was statistically significant between the groups (p = 0.014). No statistically significant differences were observed in fasting blood glucose (FBG) and blood lipid profile (including cholesterol, triglycerides, LDL and HDL) between the two groups before and after the intervention (p > 0.05).

Conclusion: This study demonstrates that crocin, a derivative of saffron, at a dose of 30 mg/d can significantly reduce serum PAB in individuals with metabolic syndrome.

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1. Introduction

Metabolic syndrome is associated with an increased risk of cardiovascular disease and diabetes mellitus, which is now the leading cause of death and morbidity in most countries globally. Metabolic syndrome is a term that describes a clustering of cardiovascular risk factors that is also associated with an increased risk of diabetes mellitus. These defining features of metabolic syndrome include high waist circumference, impaired glucose tolerance and insulin resistance, a dyslipidaemia with raised serum triglycerides and low serum HDL-cholesterol, and a high blood

Abbreviations: PAB, pro-oxidant-anti-oxidant balance; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; FBS, fasting blood glucose.

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pressure. Metabolic syndrome is associated with a 2-fold increased risk of cardiovascular disease and a 5-fold risk of diabetes mellitus. Metabolic syndrome is also associated with a two-fold increase in mortality from cardiovascular disease, and a 1.5-fold increase in mortality from other causes [1]. The prevalence of metabolic syndrome is increasing globally. The prevalence of metabolic syndrome in Iran is high, being estimated at about 33.7%. This prevalence increases with age, and is more prevalent in women than men (42% vs. 24%) [2], and is higher than for many other global populations [3]. The prevalence of metabolic syndrome among Iranian young adults, especially obese adolescents is also very high [4]. The management of metabolic syndrome is essentially through lifestyle modification, and drug therapy, or bariatric surgery if associated with severe obesity [5].

Oxidative stress is an imbalance between oxidants and antioxidants in favor of the production of pro-oxidants, and is generally

the treatment

associated with excess production of reactive oxygen radical species (ROS). Metabolic syndrome is reported to be associated with increased oxidative stress; and central obesity (excess fat in the abdomen) that is often a component of metabolic syndrome is associated with both oxidative stress and insulin resistance [6]. It is thought that oxidative stress plays a role in the pathogenesis and development of cardiovascular disease and its complications [7], and is also considered to be an independent risk factor for hypertension [8]. Serum PAB, is a measure of the balance between pro-oxidant activity and anti-oxidant defense, and has been proposed as a potential risk marker for cardiovascular disease [9,10]. The reduction of pro-oxidant stress may be an important therapeutic target in the treatment of patients with metabolic syndrome to avoid the associated risk of cardiovascular disease [11].

Herbal medicines may be combined with conventional drugs for the treatment of many conditions [12]. Saffron (*Crocus sativus*

Information about the study provided to the volunteers in the both oral and written forms, all subjects signed a consent form. Measuring waist circumference, weight, height and BMI were conducted IF abdominal obesity: waist circumference> 80 cm in females and >94 cm in males or BMI > 30kg/m2 Measurements of blood pressure and fasting serum glucose and lipid profile (including total cholesterol, TG, HDL and LDL cholesterols). The final diagnosis of metabolic syndrome according to the IDF criteria as follows: TG > 150 mg/dl or treatment for this abnormality. Central obesity 2 risk factors of HDL < 40 mg/dl in males and <50 mg/dl in females, or (WC>94 cm in males treatment for this abnormality. and >80 cm in females) Raised blood pressure (systolic PB ≥130 or diastolic BP≥85) or the treatment for this abnormality. FBG ≥ 100 mg/dl or the treatment for this abnormality and previously diagnosed type 2 diabetes Questionnaires about socio-demographic, clinical history and dietary information were filled. All subjects received dietary advice according to the American Heart Association (AHA) suggestions. Subjects randomized to the drug or control groups Follow-up meetings every two-week: Subjects were asked about adverse effect of the drug and taking the tablets.

Fig. 1. The process of study.

Anthropometric measurements, serum PAB assay, fasting BG and lipid profile were measured at the beginning and end of week 8 of

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