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Original article

The effects of Melissa officinalis supplementation on depression, anxiety, stress, and sleep disorder in patients with chronic stable angina☆

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SUMMARY

Background: Despite advances in the treatment of cardiovascular diseases in recent decades, patients experience high levels of depression, anxiety, stress, and insomnia. Since the calming effect of Melissa officinalis (MO) has been known, this study aimed to determine the effects of MO supplementation on depression, anxiety, stress, and sleep disturbances in patients with chronic stable angina (CSA).

Methods: In this double-blind placebo-controlled clinical trial, 80 patients with CSA were divided randomly into two groups (taking 3 g MO supplement or placebo daily for 8 weeks). The shortened 21-item version of the depression, anxiety and stress scale (DASS-21) test and Pittsburgh sleep quality index were done before and after the intervention.

Results: At the end of the study, the intervention group receiving MO capsules had a significant reduction in scores of depression, anxiety, stress, and total sleep disturbance, compared with the placebo group ($P < 0.05$).

Conclusions: The results showed that 8-week supplementation with 3 g MO can decrease depression, anxiety, stress, and sleep disorder in patients with CSA.

1. Introduction

Coronary heart disease (CHD) is a major cause of mortality caused by non-communicable diseases in the world, including Iran [1]. This disease is responsible for 3–38% annual mortality in Iran [2]. CSA is a type of myocardial ischaemia. About half of the CHD patients have symptoms of myocardial perfusion (ischaemic heart disease). Its prevalence increases with age in both sexes; it is reported in 0.1–1% of women aged 45–54 years in Europe that reaches 10–15% between the ages of 65–74 years. Also, in men aged 45–54 years, it is 2–5% that reaches 10–20% in ages 65–74 years [1].

CHD not only affects a patient's physical health, but also social relationships, lifestyle, family environment, employment and income levels [3]. The prevalence of depression is 10–60% in patients with heart failure [4], Which is two-to three-fold more than the general population [5]. Also, among cardiovascular patients, those who suffer from depression are two-to three-fold more exposed to cardiac events (both lethal and non-lethal) compared to other patients [6]. Prevalence of anxiety in patients with heart failure has been reported at 11–45% [4]. It is known that anxiety after myocardial infarction leads to negative consequences and, independent of depression, it is associated with recurrent cardiac events within six months [7]. Stress can cause cardiovascular ischaemia in patients. Finally, adverse consequences follow. So that

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it predicts mortality and re-hospitalization after one year of myocardial infarction occurrence [8].

The prevalence of sleep disorders is 31–51% in CHD patients which is higher than normal subjects [9].

Melissa officinalis (lemon balm) belongs to Lamiaceae family. According to recent studies, it improves depression [10] anxiety [11] and stress [12] in rats. In humans, it reduces anxiety [13,14], and stress [15,16] as well as sleep disorders [17,18]. Since no study has focused on the use of MO for CHD patients, this study aimed to investigate the effect of MO capsules on depression, stress, anxiety, and sleep disorders of patients with CSA.

2. Materials and methods

2.1. Plant material

The aerial parts of MO were collected in August 2016 from Botanical Garden of Tabriz University, and identified by a botanist of the Department of Botany, Tabriz University. A voucher specimen (KF1429-1) of the plant was deposited in the Herbarium Centre, Faculty of Pharmacy, Tabriz University of Medical Sciences. MO was dried in shade at room temperature for 12 days.

2.2. Participants

This randomized double-blind controlled clinical trial study involved 80 patients with CSA in 2016 (April to August 2016) conducted in Golestan Hospital, Ahwaz, Iran.

The inclusion criteria were male and female patients with CSA, 40–75 years of age, and body mass index (BMI) between 18.5 and 40. Subjects were excluded if they had history of hypertension, diabetes mellitus, arrhythmia, renal, hepatic, gastrointestinal, endocrinological or haematological disease, musculoskeletal disease or arthritis rheumatoid, depression, mental disorders, being vegan, drug abuse, smoking, alcoholism, supplement use in the last 2 months and allergic to MO.

Sample size was calculated based on type one (α) and type two errors (β) as 0.05 and 0.10 (power = 90%), respectively according to the previous study [19] considering 8.6 and 9.9 as standard deviations (SD) and 7.2 as the difference in mean or effect size (d) of serum HDL level, the main outcome. Therefore, a sample size of 35 subjects in each group was calculated. Finally regarding with some probable dropouts, 40 subjects in each group were recruited.

2.3. Intervention

Patients were randomly divided into two groups of the intervention group (n = 40), receiving 3 capsules (3 g) per day of MO, and the control group (n = 40), receiving 3 capsules (3 g) per day of placebo for 8 weeks. The capsules containing MO were prepared by an automatic filler filling with 1 g MO powder. The Placebo capsules were similarly filled with 1 g corn starch. The dose determination was based on previous studies [20].

2.4. Data collection

Body weight was measured with minimal clothing using a digital scale (Seca, Hamburg, Germany) to the nearest 0.1 kg. Height was measured to the nearest 0.1 cm using a tape measure (Seca, Hamburg, Germany). Body mass index (BMI) was calculated as weight in kg divided by height in metres squared. Waist circumference (WC) was measured using an inelastic tape measure (Seca, Germany) at the midpoint between the costal margin and the iliac crest.

Dietary record for three days (two normal days and one holiday) was completed. Then, it was analysed using Nutritionist IV software (First Databank, San Bruno, CA, USA) adjusted for Iranian foods.

Level of physical activity was assessed using the International Physical Activity Questionnaire (IPAQ), based on MET-min/week [21].

DASS-21 was used to assess depression, anxiety and stress [22]. It is a standard questionnaire with approved reliability and validity in Iran [23]. Also we examined its reliability through a pilot study on 20 patients that resulted in a Cronbach's α coefficient of 87%.

To study sleep disorders, the Pittsburgh sleep quality index was completed. It is a standard questionnaire with confirmed validity and reliability in Iran [18]. In the present study the reliability of this instrument was examined on 20 patients that resulted in a Cronbach's α coefficient of 81%.

2.5. Ethical considerations

The international instructions of the Declaration of Helsinki on research on humans were met and a completed consent was obtained from all subjects. The trial was approved by the Ethical Committee of Ahwaz Medical University of Medical Sciences and International Registry of Clinical Trials (www.irct.ir) with the code: IRCT2016052928152N1.

2.6. Statistical analysis

Normal distribution of all variables was tested by the Kolmogorov–Smirnov test. Demographic variables were analysed using a Chi-square, Mann–Whitney U test or independent sample t-test. Comparisons within groups were done by paired-sample t-test. Independent t-test was performed to detect differences between the two groups independently. Analysis of covariance (ANCOVA) was applied to identify differences between the two groups at the end of the study, adjusting for baseline value and dietary MUFA intake. $P < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS Version 20 (SPSS Inc., Chicago, Illinois, USA) (see Fig. 1) .

3. Results

A total of 73 patients completed the trial. There were no significant differences in gender, race, age, BMI, WC, marital and education status, job, economic status, disease duration, physical activity and using medications ($P > 0.05$ for all) between two groups (Table 1). No significant differences were seen in dietary intakes of total energy, carbohydrates, proteins, fat, PUFA, SFA, cholesterol, Beta-carotene, vitamins C and E except for MUFA between two groups at the end of intervention (Table 2).

Between groups analysis showed that the mean scores of depression, anxiety, and stress were significantly ($P < 0.001$) lower in the intervention group (6.46 ± 5.42, 4.85 ± 3.37, 8.91 ± 7.95 respectively) compared with the control group (6.71 ± 6.32, 5.89 ± 3.39, 9.38 ± 7.54 respectively) post intervention. For total sleep disorder score, there was significant ($P = 0.033$) decrease in the intervention group compared with control group (4.23 ± 2.78 vs. 4.24 ± 3.35) post intervention. Among seven areas of sleep disorder, the mean scores of sleep quality, sleep duration, and sleep efficiency were significantly ($P < 0.05$) lower in the intervention group (0.970 ± 0.529, 0.910 ± 0.526, 0.550 ± 0.552 respectively) compared with the control group (1.24 ± 0.629, 1.11 ± 0.737, 1.23 ± 0.43 respectively) post intervention (Table 3).

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