TRADITIONAL AND INTEGRATIVE MEDICINE

Trad Integr Med, Volume 6, Issue 3, Summer 2021

Original Research

The Effect of Oxymel Syrup on Some Cardiovascular Risk Factors in Overweight and Obese People: A Randomized Controlled Trial Study

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Received: 23 Mar 2021 **Revised:** 18 May 2021 **Accepted:** 12 Jun 2021

Abstract

High blood pressure, diabetes, hyperlipidemia and obesity are risk factors for cardiovascular diseases. With regard to the significant role of a healthy diet in the prevention and even treatment of diseases together with the high cost and side effects of drugs, finding foods effective in the treatment of metabolic disorders has been widely considered. This study aimed to evaluate the effect of oxymel – an Iranian traditional syrup with vinegar base – on cardiovascular risk indicators in obese and overweight people. Candidates were selected based on a set of inclusion criteria and were divided into two groups of control and test. The control group received 250 cc of water, while the test group received 250 cc water containing 30 cc of the oxymel for 30 days. Anthropometric and biochemical indicators were measured at the beginning and end of the study. The results showed that there were no significant changes in the body mass index, waist circumference, hip circumference, waist to hip ratio, HDL, LDL, triglycerides, systolic and diastolic blood pressure, and blood glucose level. However, weight (P = 0.053) and cholesterol (P = 0.083) decreased relatively significantly in the test group compared to the control group. This study shows that consumption of oxymel has positive cardiovascular effects such as lowering the blood cholesterol level and can contribute to weight loss; however, studies with a larger sample size are recommended.

Keywords: Persian medicine; Overweight; Cardiovascular risk indicators; Oxymel syrup

Citation: Mahdavi-Roshan M, Salari A, Emaminejad S, Parvinroo S, Ashouri A, Alizadeh I. **The Effect of Oxymel Syrup on Some Cardiovascular Risk Factors in Overweight and Obese People: A Randomized Controlled Trial Study.** Trad Integr Med 2021; 6(3): 204-215.

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Introduction

The World Health Organization identifies obesity as an epidemic. Over one billion people in the world are overweight, of which 300 million are obese. This trend reflects the changing lifestyles and behavioral patterns of societies. High blood pressure, diabetes, hyperlipidemia, and obesity are risk factors for cardiovascular disease. According to studies, prevention of atherosclerosis and hypertension as its key risk factor is possible by modifying diet, exercise, and not smoking. As a healthy diet performs an important role in the prevention and even treatment of diseases, and due to the high cost and side effects of drugs, finding effective food compounds in the treatment of metabolic disorders has been received a lot of attention. Several studies have been conducted on the effect of different foods on health [1]. One of the foods whose health effects have been studied is vinegar. The results of several studies have indicated the positive effects of vinegar on lipid profile and weight loss [2-5].

Oxymel syrup is one of the products of Persian medicine with a vinegar base that has been considered by Iranian physicians in maintaining health and treating diseases [6]. Oxymel is a combination of honey or sugar with vinegar. In the textbooks and resources of Persian medicine, oxymel is mentioned as a vinegar syrup, which means that this product is a kind of liquid medicinal form of vinegar that is used as a basic component in the process of making a syrup. By adding other constituents such as different parts of medicinal herbs, numerous formulas of oxymel are obtained with various therapeutic effects [6-7]. Iranian physicians view oxymel as a compound for preserving health. Describing oxymel, IbnSina says "It is the best drink of all temperaments and ages to maintain health. It opens narrow ducts and does not allow thick chyme to be trapped in the ducts. Aghilikhorasani considers drinking oxymel as one of the measures to maintain health in the spring [5]. Razes considers preventing the closure of blood vessels in the body as one of the most important factors in maintaining health. One of the benefits of oxymel is that it opens the vessels without creating heat [8].

Oxymel is one of the foods consumed by Iranians and has a special place in Persian medicine. Few scientific studies have been done on oxymel [1,9-10] and there are no definite results on the therapeutic properties of this food compound. Based on the commendations of Persian medicine on the consumption of oxymel to maintain health, the present study aimed to examine the effect of consumption of oxymel syrup on some cardiovascular risk indicators such as blood pressure, blood lipids, body mass index, waist size, hip size, waist ratio around the hips, blood sugar among overweight and obese healthy people in the north of Iran.

Methods

Study design

We conducted a randomized controlled trial study with the aim of examining the effect of consuming the oxymel syrup on some cardiovascular risk indicators such as blood pressure, blood lipids, body mass index, waist size, hip

size, waist ratio around the hips, and blood sugar among overweight and obese healthy people in the north of Iran. The patients were recruited from the Cardiovascular Research Center and the Cardiovascular Outpatient Clinic of Heshmat Heart Hospital in Rasht, Iran.

Study setting

The patients were recruited from the Cardiovascular Research Center and the Cardiovascular Outpatient Clinic of Heshmat Heart Hospital in Rasht, Iran from February 2019 to March 2020.

The sample size was estimated based on a moderate effect size for the total cholesterol level. According to Derakhshani-Rishahri et al, with the standard deviations of the total cholesterol level as 34.8 and 26.0 mg/dl and assuming a mean difference of 17 mg/dl as a moderate effect size, considering an alpha level of 0.05 and power of 80%, the minimum required sample size was determined as 50 participants in each group; however, to compensate for a 10% attrition rate, a total of 111 participants were randomized in the study (Figure 1).

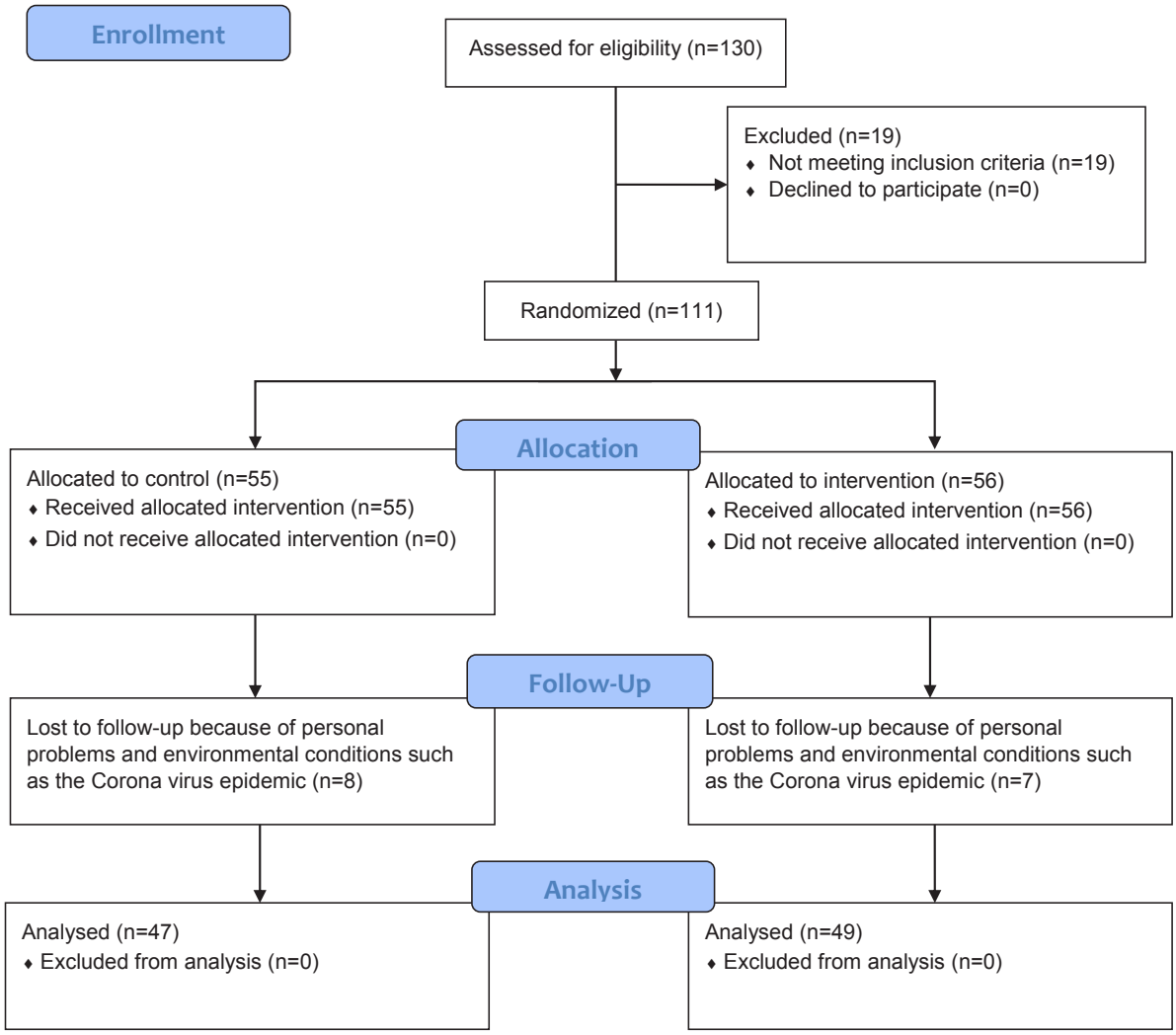

Figure1. Flow diagram of participants in the study

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Inclusion criteria

The inclusion criteria were: having a body mass index of 25 kg per square meter and above, age from 20 to 50 years, no history of allergies to oxymel or vinegar, no gastrointestinal problems, no lung diseases especially cough, no use of drugs lowering blood sugar, blood lipids, blood pressure or drugs that affect appetite, not using a special diet, not taking oxymel and vinegar regularly, not using narcotics and alcohol, not being pregnant and not breastfeeding.

Exclusion criteria

The exclusion criteria were: unwillingness to participate in the study and also any problems or dissatisfaction during the study, pregnancy diagnosis during the study, diagnosis of a specific disease, and initiation of medication during the study.

Interventions and comparisons

In this clinical trial study, 130 individuals volunteered to participate in the study (figure 1). Of this number, 19 were excluded because of not meeting the inclusion criteria. During the study, 15 people withdrew from the study due to personal problems and environmental conditions such as the Corona epidemic. Finally, the study was performed with 96 patients who were randomly divided into two groups of control (47 people) and intervention (49 people). Randomization sequences were generated based on quadruple random permutation blocks using web-based software (http://www.randomization.com). Only the project manager knew the random sequence which remained hidden from the persons participating in the study and the evaluator checked the inclusion of the participants into the study until the intervention started.

The sampling was done based on the inclusion criteria and among the individuals who had volunteered during a call for participation in the study at the Cardiovascular Research Center and the Cardiovascular Outpatient Clinic of Heshmat Heart Hospital. The participants were identified based on the inclusion criteria by a nutritionist and the necessary information was collected by the researcher. The purpose of the study was explained to the participants and they were asked to read and sign the informed consent form.

The control group received only dietary recommendations for weight control and the intervention group, in addition to dietary recommendations for weight control, received 30 cc of oxymel per day, which was reduced to 250 cc after being mixed with water, as an evening meal. The duration of the intervention was 30 days. All subjects in the two groups were given the same dietary recommendations to control the possible effects of nutritional suppressors, and the participants in both groups were asked to continue their diet during the study period. They were also urged not to change their levels of physical activity during the study and were asked to inform the researcher of any decisions to receive a special diet or medication. The 24-hour dietary intake recall questionnaire was used and the average daily intake of calories and macronutrients was calculated using Nutrition VI software.

Calculation of grape vinegar acidity and preparation of oxymel syrup

Grape vinegar was titrated with a semi-normal sodium hydroxide in the presence of phenolphthalein as a reagent. Then vinegar with the acidity of 5% was obtained. To prepare the oxymel, grape vinegar, sugar, and water in proportions of 1, 2, 4 were heated on a low heat for 1 hour [5]. After preparing the oxymel, 30 cc of oxymel was added to water in 250 cc bottles and was given to the intervention group weekly. For the control group, 250 cc water bottles (without oxymel) were prepared.

Ethical considerations

This study was a randomized clinical trial. It was registered in the Iranian Registry of Clinical Trials (https://www.irct.ir/) as IRCT20171203037724N2. Full date of first registration in IRCT is 2019-02-12.

This study received approval from the Ethics committee of Guilan University of Medical Sciences, Rasht, Iran (Ethics code: IR.GUMS.REC.1397.318). Written informed consent was obtained from all patients before participation in the study.

Data collection

Data collection on such variables as age, sex, occupation, education, place of residence was done in the form of interviews with the participants. Anthropometric indices including weight and body mass index (to measure the height and weight of the subjects, a lever scale with an accuracy of 0.1 kg connected to a calibrated gauge with an accuracy of 0.1 cm) were used. Height and weight were measured with the participants being barefooted and wearing light clothes; the body mass index was calculated based on the standard formula. Waist circumference was measured at the narrowest point and close to the last rib at the level of the umbilicus and the end of natural exhalation and the hip circumference was measured at the point of the largest hip diameter using an inelastic tape measure with an accuracy of 0.1 cm. Waist-hip ratio and other cardiovascular indices including systolic blood pressure, diastolic blood pressure (resting and sitting blood pressure were measured twice at the left arm with a mercury sphygmomanometer; the measures were then averaged and the final blood pressure was calculated) were calculated under the supervision of a nutritionist. Serum parameters including fasting blood sugar, total cholesterol, high-density lipoprotein cholesterol, and triglyceride were measured enzymatically using an auto analyzer, low-density lipoprotein cholesterol with Friedewald formula in the same center at the beginning and end of the study. The person performing the laboratory tests and measurement evaluation did not know what group the people were in. Monitoring and controlling the consumption and reminding the participants of the consumption of oxymel were done through text messages and phone calls twice a week.

Statistical analyses

The data are described as mean and standard deviation. To compare the baseline measurements, independent student t-test and chi-square test were used for quantitative and qualitative char-

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acteristics, respectively. Analysis of covariance (ANCOVA) was used to compare the post intervention outcomes of the two groups (i.e. effect of the intervention), after adjusting to the baseline values recorded at the beginning of the study. Also, adjusted means to the baseline values and related 95% confidence intervals of the outcomes measured post intervention were reported. Partial eta squared values of .01 to .06 were considered as small, .06 to .14 as medium and more than .14 as large effect, respectively. Partial eta squared values lower than .01 indicated a negligible effect. The modified intention-to-treat method was used for analyzing the missing data. All analyses were performed by SPSS software version 21.0 (IBM Corp., Armonk, NY).

Table 1. Demographic, anthropometric and clinical characteristics of participants at baseline

Factor	Total (n=96)	group		P*
		Intervention (n=49)	Control (n=47)	
Sex, no. (%)				0.717**
Male	33 (34)	16 (48)	17 (52)	
Female	63 (66)	33 (52)	30 (48)	
Age (years)	35.25 (7.53)	35.29 (7.27)	35.21 (7.87)	0.962
Height (m)	167.48 (10.28)	167.06 (11.5)	167.91 (8.93)	0.686
Weight (kg)	83.93 (14.62)	82.97 (14.78)	84.93 (14.54)	0.514
BMI (kg/m2)	29.91 (4.51)	29.78 (4.92)	30.03 (4.09)	0.786
BMI category, no. (%)				0.429**
Overweight	59 (61)	32 (54)	27 (46)	
Obese	37 (39)	17 (46)	20 (54)	
WC (cm)	95.73 (10.99)	96.22 (11.16)	95.21 (10.90)	0.654
HC (cm)	110.97 (8.98)	110.59 (8.67)	111.37 (9.38)	0.673
Waist to hip ratio	0.86 (0.08)	0.87 (0.07)	0.85 (0.08)	0.404
SBP (mmHg)	11.67 (1.27)	11.67 (1.13)	11.66 (1.42)	0.958
DBP (mmHg)	7.6 (0.53)	7.65 (0.48)	7.55 (0.58)	0.363
FBS (mg/dl)	91.04 (10.70)	91.92 (9.77)	90.13 (11.63)	0.415
TG (mg/dl)	143.33 (64.1)	140.16 (52.71)	146.64 (74.60)	0.623
TC (mg/dl)	175.39 (28.77)	176.39 (26.47)	174.34 (31.24)	0.729
HDL C (mg/dl)	46.17 (11.15)	46.9 (12.07)	45.4 (10.17)	0.515

LDL C (mg/dl)	95.23 (26.33)	98.69 (26)	91.63 (26.45)	0.191
Energy (kcal)	1715.08 (588.5)	1644.62 (555.1)	1788.54 (618.8)	0.233
Protein (g)	74.86 (30.30)	71.23 (27.93)	78.65 (32.45)	0.233
Fat (g)	56.25 (30.17)	51.65 (25.21)	61.05 (34.22)	0.128
Carbohydrate (g)	222.26 (81.28)	219.42 (83.67)	225.22 (79.51)	0.729

The values are mean (SD) unless otherwise indicated. SD indicated standard deviation; BMI, body mass index; WC, waist circumference; HC, hip circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBS, fasting blood sugar; TG, triglyceride; TC, total cholesterol; HDL, high density lipoprotein; LDL, low density lipoprotein.
*P-value was reported from independent t test.
**P-value was obtained from chi square test.

Results

In total, 96 overweight or obese individuals with a mean ± standard deviation (SD) of 35.25 ± 7.50 years old (range: 20 to 50 years) were included in the study. Sixty-six percent of the participants were female and 34% were male. In total, the mean±SD duration of the intervention was 38±7 days (38±8 and 39±7 days for the intervention and control group, respectively). Sixty-one percent of the participants were overweight and 39% were obese. In total, 34 (35%) of the participants were employees, 28 (29%) were housewives, 28 (29%) were self-employed, one (1%) were doctor and 5 (6%) were students (Table 1). None of the anthropometric indices and clinical characteristics measured at beginning of the study differed between two the groups significantly (P> 0.05 for all, Table 1). Additionally, the energy and nutrients of the 24-hour feeding at the beginning and the end of the study received by the participants in the two groups did not differ significantly (table 1 and 2).

After the intervention, the results of the analysis of the covariance showed that controlling for the baseline values measured at the beginning of the study, all the recorded characteristics of body mass index, waist and hip circumference, waist to hip ratio and also systolic and diastolic blood pressure, fasting blood sugar, triglyceride, HDL and LDL remained unchanged or had a slight and insignificant decrease in the intervention group compared to the control group (table 2). In other words, the intervention did not have a significant effect on any of these characteristics. Nevertheless, the results illustrated that participants weight and cholesterol level decreased marginally significantly in the intervention group compared to the control group (P = 0.053 and P = 0.083, respectively). Details are shown in Table 2. Although, it should be noted that the effect sizes of the intervention (regarding to the values of eta squared) on both weight and blood cholesterol characteristics were small (with Eta squared 0.04 and 0.03, respectively) (Table 2).

Discussion

The results of the present study showed that after a 30-day intervention, serum weight, and cholesterol index in the intervention group had a significant

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Table 2. Anthropometric and clinical characteristics of participants at baseline and post intervention

Factor	Intervention group (n=49), mean (SD)			Control group (n=47), mean (SD)			F**	P***
	baseline	post	Adj. mean (95% CI)*	baseline	post	Adj. mean (95% CI)*		
Weight (kg)	82.97 (14.78)	82.02 (14.28)	82.97 (82.41-83.53)	84.93 (14.54)	84.76 (14.98)	83.77 (83.19-84.34)	3.85	0.053
BMI (kg/m2)	29.78 (4.92)	29.49 (4.94)	29.61 (29.4-29.81)	30.03 (4.09)	29.92 (4.11)	29.8 (29.59-30)	1.63	0.205
WC (cm)	96.22 (11.16)	95.55 (10.64)	95.1 (92.67-97.53)	95.21 (10.90)	95.33 (15.49)	95.8 (93.32-98.29)	0.16	0.687
HC (cm)	110.59 (8.67)	109.68 (9.34)	110.03 (108.69-111.37)	111.37 (9.38)	110.28 (9.5)	109.92 (108.55-111.28)	0.01	0.907
Waist to hip ratio	0.87 (0.07)	0.87 (0.07)	0.86 (0.84-0.89)	0.85 (0.08)	0.86 (0.12)	0.87 (0.85-0.89)	0.035	0.852
SBP (mmHg)	11.67 (1.13)	11.33 (1.07)	11.32 (11.01-11.63)	11.66 (1.42)	11.57 (1.26)	11.58 (11.26-11.89)	1.28	0.260
DBP (mmHg)	7.65 (0.48)	7.49 (0.51)	7.48 (7.34-7.63)	7.55 (0.58)	7.47 (0.50)	7.47 (7.33-7.62)	0.01	0.924
FBS (mg/dl)	91.92 (9.77)	89.98 (8.19)	89.49 (87.42-91.55)	90.13 (11.63)	90.98 (10.54)	91.49 (89.38-93.6)	1.81	0.182
TG (mg/dl)	140.16 (52.71)	135 (54.93)	138.31 (120.36-156.26)	146.64 (74.60)	155.28 (119)	151.83 (133.5-170.16)	1.09	0.298

TC (mg/dl)	176.39 (26.47)	163.78 (33.56)	163.38 (153.4-173.36)	174.34 (31.24)	175.55 (39.86)	175.96 (165.77-186.16)	3.06	0.083
HDL C (mg/dl)	46.9 (12.07)	42.78 (7.91)	42.43 (40.56-44.3)	45.4 (10.17)	42.68 (8.9)	43.04 (41.13-44.95)	0.21	0.651
LDL C (mg/dl)	98.69 (26)	96.91 (22.88)	95.36 (86.56-104.15)	91.63 (26.45)	102.84 (40.77)	104.45 (95.47-113.44)	2.05	0.156
Energy (kcal)	1644.62 (555.1)	1830.53 (608.59)	1852.01 (1695-2009.02)	1788.54 (618.8)	1760.27 (541.89)	1737.88 (1577.54-1898.22)	1.012	0.317
Protein (g)	71.23 (27.93)	74.72 (29.12)	75.4 (66.75-84.04)	78.65 (32.45)	74.78 (32.26)	74.08 (65.26-82.91)	0.044	0.834
Fat (g)	51.65 (25.21)	62.25 (24.81)	62.95 (55.78-70.13)	61.05 (34.22)	57.00 (26.04)	56.26 (48.93-63.58)	1.661	0.201
Carbohydrate (g)	219.42 (83.67)	236.55 (99.67)	237.23 (211.78-262.68)	225.22 (79.51)	236.81 (81.76)	236.1 (210.11-262.08)	0.004	0.951

The values are mean (SD) unless otherwise indicated. SD indicated standard deviation; CI, confidence interval; BMI, body mass index; WC, waist circumference; HC, hip circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBS, fasting blood sugar; TG, triglyceride; TC, total cholesterol; HDL, high density lipoprotein; LDL, low density lipoprotein.
*Post intervention mean, adjusted to the baseline measures and related 95% confidence interval was reported.
**All degrees of freedom of F statistics were 1 and 93.
***P-value was reported from analysis of covariance.

decrease compared to the control group. Other anthropometric indices as well as blood pressure, triglycerides, HDL and LDL, and blood sugar decreased partially and insignificantly. Some indicators remained unchanged.

According to the literature, few studies have been performed on the effects of prescribing oxymel on blood pressure, lipid profile, fasting blood sugar, weight, and body size.

In a study by Abolghasemi et al. (2020), overweight patients were randomly divided into 3 groups. Group A received 0.75 g of Zataria multiflora in 10 ml of oxymel, group B received 1.5 g of Z.multifera in 10 ml of oxymel, and group C, which was the control group, received only 10 ml of oxymel. All three groups received the

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doses twice a day for 12 weeks. After 12 weeks, the Z. multifera group had a significant reduction in waist size but no significant reduction in the BMI. Group A showed a significant decrease in hip circumference and groups B and C showed a decrease in insulin resistance but no decrease in FBS. The results of the study showed that consumption of Z.multiflora and oxymel decreases insulin resistance and reduces waist and hip size in overweight patients [11]. Nimrouzi et al. (2020) investigated the anti-inflammatory, antioxidant, and anti-hyperlipidemic effects of different doses of oxymel and a combination of thyme and oxymel on obesity caused by a high-fat diet and fructose (HFFD) in male rats for 24 weeks. The results showed that oxymel or a combination of oxymel and thyme can reduce HFFD-induced obesity by improving fat metabolism and the function of weight-regulating hormones, and having a positive effect on oxidative stress and inflammation [12]. Derakhshani-Rishahri et al. (2014) conducted a study on serum lipid and glucose profiles in healthy individuals, reporting that daily consumption of two spoons of oxymel (21.66 g) in 250 cc of water for 4 weeks as an evening meal reduces total cholesterol and increases insulin levels. It, however, did not have any effect on LDL triglyceride and fasting blood sugar [10]. Ehsani et al. (2016) conducted a study on 57 patients with class A and B liver cirrhosis in 2 groups: group A who received a light diet and a lifestyle based on traditional medicine) and group B who received dietary recommendations and routine lifestyle for 3 months. The findings suggested that the recommendations of Persian medicine, which emphasized the consumption of oxymel (a tablespoon per day in a cup of water), on losing weight can be useful for cirrhotic patients [9].

Zand et al. (2016) evaluated the effect of apple vinegar and honey on blood lipids in patients admitted with hypertension in the internal wards of Arak hospitals. The results showed that consuming a glass of 200 cc water, one spoon of honey, and a tablespoon of vinegar twice a day for 4 weeks reduces cholesterol, triglycerides, and LDL significantly and increases HDL significantly [13].

As vinegar is one of the main components of oxymel, some of the positive effects of oxymel can be attributed to the vinegar. According to studies, vinegar has positive effects on lipid profile, blood pressure, and anthropometric factors. In a study by Vajaykumar et al. (2015) on rats with hyperlipidemia, it was found that consuming 1 ml of apple cider vinegar per day for 14 days reduces total cholesterol, triglyceride, the LDL, and VLDL levels and the HDL level increases significantly [14].

In a randomized double-blind clinical study on obese individuals over 12 weeks in three control groups (low-dose apple cider vinegar (15 cc) and high-dose apple cider vinegar (30 cc) and the control group), Kondo et al. (2009) showed that the weight, body mass index, visceral fat, waist circumference, and serum triglyceride levels of the vinegar group was significantly lower than the control group [15].Jafarian et al. (2007) conducted a study on 25 patients with hyperlipidemia in three groups: Group A received 10 cc of apple cider vinegar, group B received 10 cc

of verjuice, and group C received 20 mg of lovastatin tablets. After 4 weeks, it was observed that apple cider vinegar and verjuice both had a significant effect on the treatment of hyperlipidemia and apple cider vinegar was as effective as lovastatin [16]. The difference between the results of this study with other studies can be due to differences in sample size, duration of the study, and the doses of vinegar used in the preparation of oxymel. Moreover, the different preparation methods and ingredients of oxymel can be effective in this regard. Since the participants in the study were healthy people, different results may be observed by increasing the dose of oxymel or increasing the duration of the intervention. Additionally, the consumption of oxymel did not show any side effects, this food can be used by people with high blood pressure or patients with high blood fats to evaluate the possible effects of the food on these groups of people.

The aim of this study was to investigate the effect of oxymel syrup and therefore patients were asked not to change their diet. Due to the lack of significant changes in the nutritional status of individuals during the study, which was the purpose of us, the effects observed in this study were only due to oxymel syrup and dietary intakes did not affect the results of the study.

Conclusion

In general, the present study showed that the consumption of 30 g of oxymel, which was added to 250 cc of water, for 30 days by overweight and obese people had a significant effect on the serum cholesterol and weight, but did not affect other anthropometric and biochemical indicators.

Study Limitations

One of the limitations of this study was the small sample size and duration of the intervention. The next limitation could be the fact that just one dose of oxymel was studied.

Availability of data and materials

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that there are no conflicts of interest in relation to this study.

Funding

This work was supported by the Guilan University of Medical Sciences [grant numbers 97081205]

Acknowledgements

The authors would like to appreciate Guilan University of Medical Sciences for supporting this work.

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