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Effect of oral intervention of 'Spice mixture' on lipid profile and body composition of obese females

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Abstract

Obesity increases dramatically and is related to a variety of complications, such as type 2 diabetes, hypertension, stroke, and hyperlipidemia etc. The aim is to evaluate the use of spice mixture as a dietary intervention for 4 months to reduce excess weight and improve the lipid profile on overweight /obese individuals. Spice mixture contains Cumin (Cuminum cyminum), Garlic (Allium sativum), Curry Leaves (Murraya koenigii), Cinnamon (Cinnamomun zeylanicum) and Pepper (Piper nigram). Lipid profile, Hb %, SGPT and Serum Creatinine (SC) were considered as biomarkers. Blood samples were analyzed at the National Diabetic Centre, Rajagiriya and Asiri Hospitals Ltd. A significant weight reduction (p < 0.01) with the improvement of lipid profile was observed after the intervention. The total cholesterol, triglycerides, LDL and VLDL were reduced significant (p < 0.01) and increased after the intervention. SGPT and SC showed a change towards a normal level. The study concluded that the intervention of the spice mixture reduces the excess weight and also improves the lipid profile, increases the Hb % and not affect the liver or renal function of the study participants.

Key words: Obesity, lipid profile, Spice mixture, Intervention.

1. INTRODUCTION

Obesity has become one of the biggest health problems in the world. The Sri Lankan population is also gradually affected by the epidemic and the prevalence of obesity is estimated to be 20.3 % in men and 36.5 % in women in four provinces in Sri Lanka. The highest prevalence being in the more urbanized Western Province, Colombo and was estimated to be 32.2 % among adults [1]. Further a recent research study revealed that the countries of the South Asia are significantly affected by the obesity epidemic including Sri Lanka [2]. Consequences of the epidemic of obesity are the increasing incidence of non-communicable diseases such as type 2 diabetes, hypertension, cardiovascular disease, stroke, depression and hyper-lipidaemia [3].

High dietary fat intakes have been linked with atherogenic dyslipidaemia [4] and increased body weight with play a significant role in the pathogenesis of obesity [5]. In addition, excess carbohydrate consumption, results in the conversion of carbohydrate (glucose) to palmitic and oleic acid; these fatty acids are assimilated into triglycerides for storage [6].

Since from ancient period natural food additives or spices have been used for flavor, colour or preserve the food. The general purpose of most of the spices is to enhance the taste and smell of food. In contrast Unani system of medicine mentioned that the spices apart from having food-flavoring properties it possess various therapeutic properties, also.

Avicenna wrote in his book "Canon of Medicine' as a statement that "*the stomach is the house of disease and the diet is the head of healing*. Therefore, the effective treatment of a disease, Unani medicine says to start correct from the stomach. According to the Unani concept most spices belong to the 'hot' temperament, they enhance the process of food digestion and improve the 'digestive fire'. Avicenna mentioned in his book that one of the causes for obesity is weak digestion [7]. To achieve a proper digestion and assisting the weight reduction process, to overweight /obese participants, the spice mixture had been included as intervention in this study.

The present study aimed to evaluate the use of spice mixture as a dietary intervention for 4 months to reduce excess weight and improve the lipid profile on overweight /obese individuals. Authors hypothesized that the use of spice mixture would aid to reduce weight and improve dyslipidemia.

2.MATERIALS AND METHODS

2.1 Study Participants

The study was conducted at the Ayurveda Teaching Hospital, Borella, Sri Lanka. This research was a longitudinal study conducted from July 2012 to December 2014 and the subjects studied constituted a convenience sample of 247 representing different socio-economic districts who were attending the outpatient's department (OPD) and with the exclusion criteria each 100 participants were placed to two groups. 209 participants were completed the intervention and eligible for the analysis.

2.2 Criteria for selection of patients

- i. Inclusion criteria
 - From 18 to 60 years females only
 - Overweight (BMI between 25 30 Kg/m²)
 - Obese $(BMI > 30 \text{ Kg/m}^2)$
- ii. Exclusion criteria
 - Participants who currently taking a weight loss medication
 - Gastrointestinal disorders
 - Psychiatric illness under the care of a psychiatrist
 - Cushing's syndrome
 - Hypothalamic etiology of obesity
 - Uncontrolled or untreated thyroid disease
 - History of an eating disorder such as bulimia
 - Surgery done in the past 3 months or surgery planned to do
 - Pregnant or disabled females
 - People who were on a special diet for medical reasons

2.3 Study Design

The research was approved by the Ethics Review Committee (ERC12/02), Institute of Indigenous Medicine, University of Colombo, Sri Lanka. All voluntary participants were read and signed informed consent about the purpose of the study. Each survey respondent was approached with a possibility of voluntary withdrawal at any time. Each patient was attributed a personal number, from 1 to 200.

Anthropometric measurements and clinical biomarkers were taken. Biomarkers considered in this study were lipid profile, Hb %, SGPT (Serum glutamate-pyruvate transaminase) and Serum Creatinine. Lipid profile comprises of the total cholesterol (TC), triglycerides (TG), high density lipoprotein (HDL), low density lipoprotein (LDL) and very low density lipoprotein (VLDL).

To follow the changes in levels of biomarkers, blood sample (5 mL) of each patient fasted overnight (12 - 14 hours) was drawn twice (at the entrance and at the completion of the program) by a trained laboratory technician. Analysis of blood sample was performed at National Ayurvedic Teaching Hospital, Borella, National Diabetic Centre, Rajagiriya and Asiri Hospitals Ltd.

2.4 The Diet intervention

The powdered 'spice' mixture contained, *Allium sativum, Cuminum cyminum, Piper nigram, Cinnamomun zeylanicum* and *Murraya koenigii*. According to the dosage for each individual the intervention last for 4 months.

2.5 Variables of Biomarkers

Biomarker variables such as Lipid profile, and Haemoglobin percentage (Hb %) were taken from all the participants whereas SGPT and Serum creatinine were taken from randomly selected participants due to limitation of funds.

The cut off values of these variables were categorized according to the report of National Cholesterol Education Program [8]. Based on the above values of the variable of total cholesterol was given as < 200 mg / dL (Desirable), 200-239 mg / dL (Borderline high) and > 240 mg / dL (High). The cut off values of the variable TG was categorized as < 150 mg / dL (Normal), 150-199 mg / dL (Borderline high), 200 – 449 mg / dL (High) and > 500 mg / dL (Very high). The values of the variable of LDL

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cholesterol was categorized as < 100 mg / dL (Optimal), 100-129 mg / dL (Near optimal), 130-159 mg / dL (Borderline high), 160-189 mg / dL (High) and >190 mg / dL (Very high)'. The values of the variable of HDL cholesterol was categorized as < 40 mg / (Low) and > 60 mg / dL (High).

Cut-off points for the haemoglobin percentage variable were defined according the points proposed by WHO [9]. The cut off points on hemoglobin percentage to the non-pregnant women was as follows: $\geq 12 \text{ mg} / \text{dL}$ (Non anaemia), 11.9 - 11 mg / dL (Mild anaemia), 10.9 - 8 mg / dL (Moderate anaemia) and below 8 mg / dL (Severe anaemia).

Cut-off points of the variable SGPT levels for non – obese adults are defined as follows: 0- 45 Units /L (Normal) and > 45 Units / L (Abnormal). The reference ranges of the normal levels of variable serum creatinine for adult females are 0.4 - 1.1 mg/dL [10].

2.6 Statistics

Mean comparison of weight reduction before and after intervention was considered. The 'paired sample t test' was done at the 0.05 significant levels to analyze the effectiveness of the intervention in the clinical trial. As variables, the BMI and selected biomarkers both before and after therapeutic intervention were compared, separately. To investigate whether the 'spice' mixture affect liver or renal function during the intervention, SGPT and Serum creatinine of the participants were analyzed before and after the therapeutic intervention.

3 RESULTS AND DISCUSSION

3.1 General view of the effectiveness of the intervention

The effectiveness of the intervention was analysed using pearson correlation and the results indicates that there is a moderate positive correlation between 'BMI before the intervention' and 'change in weight reduction' (r = 0.411, N = 129, p < 0.05).

Table 1 represents the results of 'paired sample *t* test' before and after the intervention, in the BMI and the selected biomarkers in all population. The effectiveness of the intervention on the whole population was shown by this. Before the intervention the mean BMI was 32.92 Kg/m^2 . The analysis done using the data after the intervention shows that the reduction has occurred by 2.7 Kg/m^2 (BMI after the intervention was 30.23 Kg/m^2). The association between the BMIs of the participants before and after the intervention was highly significant (t=29.20, df =128, p < 0.01).

	M	an			Completion			
	Iviean				Correlation			
Variables	Before	After	Ν	Mean change		t	df	Sig
BMI	32.92	30.23	129	2.69	0.976	29.20	128	0.000**
	(SD=4.5)	(SD=4.1)		(SD=1.0)				
Total	210.76	193.62	128	17.15	0.661	5.53	127	0.000**
Cholesterol	(SD=44.61)	(SD=39.91)		(SD=35.08)				
Triglycerides	118.94	110.53	128	8.41	0.499	2.02	127	0.046*
	(SD=52.57)	(SD38.38)		(SD=47.15)				
HDL	49.77	47.07	127	2.69	0.184	2.06	126	0.042*
	(SD=13.24)	(SD=9.46)		(SD=14.79)				
LDL	138.35	122.59	127	15.75	0.584	5.04	126	0.000**
	(SD=41.44)	(SD=34.74)		(SD=35.25)				
VLDL	24.23	22.29	128	1.93	0.471	2.22	127	0.028*
	(SD=10.60)	(SD=8.15)		(SD=9.87)				
Haemoglobin	12.11	12.70	127	-0.59	0.635	-6.18	126	0.000**
	(SD=1.30)	(SD=1.22)		(SD=1.07)				

Table 1 Changes in BMI and Biomarkers of total population before and after the intervention

** p < 0.01 level, * p < 0.05 level

According to the results obtained from the study group the mean 'total cholesterol' of the population before and after the intervention was 210.76 ± 44.61 and 193.62 ± 39.91 respectively. The difference between the 'total cholesterol' before and after the intervention was highly significant (t=5.53, df =127, p < 0.01).

Before the intervention, mean "triglyceride" level was 118.94 ± 52.57 . After the intervention, it was noticed that the reduction of "triglyceride" was by 8.41 ± 47.15 for the whole set up. Hence, the correlation between triglycerides before and after the intervention was positive and significant (t=2.02, df=127, p< 0.05). The mean values of "LDL" before and after the intervention

were 138.35 ± 41.44 and 122.59 ± 34.74 , respectively. The average "LDL" reduction or mean change was by 15.75 ± 35.25 after the intervention. The association between the "LDL"s before and after the intervention was highly significant (t=5.04, df=126, p< 0.01). The analysis showed that the "VLDL" values before and after the intervention were 24.23 ± 10.60 and 22.29 ± 8.15 , respectively. The mean reduction of "VLDL" after the intervention was by 1.93 ± 9.87 and the association was significant before and after the intervention (t=2.22, df = 127, p < 0.05). The "HDL" levels of the population before and after the intervention was 49.77 ± 13.24 and 47.07 ± 9.46 , respectively. The mean "haemoglobin" before and after the intervention was 12.11 ± 1.3 and 12.7 ± 1.22 , respectively.

3.1 Evaluation of total cholesterol levels of the study participants before and after the intervention

Percentage differences of total cholesterol before and after the intervention are shown in the Figure 1. The cut off values are categorized for the analysis as follows: < 200 - Desirable, 200 - 239 - Borderline high and <math>> 240 - High [8].





The figure 1 clearly denotes that prior to the intervention, the percentages of 'High' and 'Borderline high' cholesterol were 17.8 % and 38.8 %, respectively. After the intervention these amounts reduced to 7 % and 22.7 %. Although before the intervention only 43.4 % of the participants were in the normal total cholesterol range, it increased to 70.3 % after the intervention. This change was significant (p < 0.05) statistically.

3.3. Evaluation of triglyceride levels of the study participants before and after the intervention

Percentage differences of triglycerides before and after the intervention are shown in the Figure 2. The cut off values for triglycerides levels in the study group were categorized for analysis as follows: < 150 mg/dl (Normal), 150 - 199 mg/dl (Borderline high) and 200 - 449 mg/dl (High) [8].



Figure 2 Evaluation of triglyceride levels of the study participants before and after the intervention

Out of this population, 6.2 % belonged to the 'High triglyceride' category before the intervention was reduced to 2.2 % after the intervention. Also the 'normal' triglyceride level has gone up from 83.7 % to 88.3 % after the intervention. These differences were significant at p < 0.05.

3.4 Evaluation of LDL levels of the study participants before and after the intervention

Percentage differences of LDLs before and after the intervention are shown in the Figure 3. The cut off values are categorized for analysis as follows: < 100 mg/dl (Optimal), 100 - 129 mg/dl (Near Optimal), 130 - 159 mg/dl (Borderline), 160 - 189 mg/dl (High) and > 190 mg/dl (Very high) [8].



Figure 3. Evaluation of LDL levels of the study participants before and after the intervention

Figure 3 shows that the percentage of participants who belong to the 'Optimal' and 'Near optimal' levels of LDLs increased from 17.1 % to 27.6 % and from 28.7 % to 39.4 % after the intervention, respectively. Further, the figure shows that the percentage of 'Borderline' and 'High' levels of LDLs were reduced from 31 %, 15.5 % to 15.5 %, 3.9 % after intervention, respectively. The 'Very high' level of LDLs had gone down from 7.8 % to 3.9 % after the intervention. The change of LDL before and after intervention was statistically significant at p < 0.01.

A research study by a lipologist revealed that if a post-menopausal female went on a low carb paleo diet for a span of a few months she may develop high total cholesterol (TC) and LDLs. Further in this study it was said that the low carbohydrate diet exhibits tremendous improvements in insulin sensitivity including loss of weight, decrement in waist size, improved TG and HDL-C, and decreased inflammatory markers but on the other hand it may cause an increment in TC and LDL-C [11].

3.5 Evaluation of HDL levels of the study participants before and after the intervention

Percentage differences of HDLs before and after the intervention are shown in the Figure 4. The cut off values are categorized for the analysis as follows: < 40 mg / dL (low), 40 and above (Desirable). Our study shows that 19.4 % of the participants had 'low HDL' before the intervention and it went up to 23.4 % after the intervention [8].



Figure 4. Evaluation of HDL levels of the study participants before and after the intervention

3.5 Evaluation of Haemoglobin % of the study participants before and after the intervention

Differences of Hb % before and after the intervention are shown in the Figure 5. The cut off values are categorized for the analysis as follows: < 8 mg/dl (Severe anaemia), 8 - 10.9 mg / dL(Moderate anaemia), 11 - 11.9 mg / dL (Mild anaemia) and > 12 mg / dL (Non anaemia) [9].



Figure 5. Evaluation of Hb % of the study participants before and after the intervention

The above chart depicts the reduction in the percentage of the participants who belong to the 'mild' and 'moderate' anemia by 15.3 % and 13.2 %, respectively and its increment 'normal haemoglobin' by 28.5 %.

3.3.18 Evaluation of serum creatinine of the study participants before and after the intervention

Percentage difference of serum creatine (SC) before and after the intervention is shown in the Figure 6. The cut off values are categorized for analysis as follows: 0.4 - 1.1 mg / dL (Normal) and > 1.1 mg / dL (Abnormal) [10]. Out of the participants 72.1 % and 27.9 % belonged to 'normal SC' and 'abnormal SC', respectively. However, it was also observed that after the intervention the 'normal SC' increased to 74.4 % and the 'abnormal SC' reduced by 2.3 %. The changes in the levels of serum creatinine before and after intervention were statistically significant at p < 0.01.



Figure 6. Evaluation of serum creatinine of the study participants before and after the intervention

3.3.19 Evaluation of SGPT of the study participants before and after the intervention Percentage difference of SGPT before and after the intervention is shown in the Figure 7.

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Figure 7. Evaluation of SGPT of the study participants beforeand after the intervention

The cut off values are categorized for analysis as follows: 0 - 45 mg/dL (Normal) and > 45 mg / dL (Abnormal). This study revealed that out of the participants 64.3 % came under the 'normal SGPT' category and after the intervention it was increased to 88.7 %. The changes in the levels of SGPT before and after intervention were statistically significant at p < 0.01.

The effectiveness of biomarkers was evaluated by performing a Paired sample t test analysis on the biomarkers both before and after the intervention. Considering the whole population the effectiveness of those biomarkers was significant at the level p < 0.05.

A study said that all the components of the dyslipidaemia, including high total cholesterol, TG, small and dense LDL particles and decreased HDL levels, have been shown to be atherogenic and considered as CVD risk factors. Further it mentioned that weight loss and exercise, normalization of body weight also can improve the dyslipidaemia and thus reduce CVD risk [12]. The results of the present study also agree with the above results. In our study, all the pre-intervention dyslipidaemic levels reduced significantly (P < 0.05) and most turned towards the normal level after the intervention.

Being overweight or obese increases the risk of having high cholesterol. People with a high body mass index (BMI) tend to have lower levels of "good" HDL and higher levels of "bad" LDL cholesterol and triglycerides than people of normal weight. One study found that for every kilogram of body weight lost by a person, the HDL increases by 0.35 mg / dL [13]. In this study even though the change in HDL level was significant (p<0.05), the mean values of HDL before and after the intervention in the population were 49.77 ± 13.24 and 47.07 ± 9.46 , respectively. However, the mean values LDL before and after the intervention were 138.35 ± 41.44 and 122.59 ± 34.74 , respectively and the association was significant too. National Heart, Lung, and Blood Institute revealed the risk factors for coronary artery diseases. According to them, healthy levels of both LDL and HDL cholesterol will prevent plaque from building up in the arteries. In addition to that, they said that the cholesterol level is affected by many factors. For example, after menopause, women's LDL cholesterol levels tend to rise, and their HDL cholesterol levels tend to fall. Other factors such as age, gender, diet, and physical activity also affect the cholesterol levels [14], [15]. In the present study, it was observed that above 50 % of participants had abnormally high TC and abnormally high LDLs. Further, 90.9 % of the population were physically inactive (sedentary) and also 42.6 % of the participants belong to the "pre old age".

A study suggests that the weight loss decreases the plasma concentrations of VLDL, cholesterol and triglycerides [16]. Our study also concurs with findings of Chan *et al* due to the fact that in our study the percentage of participants who have a 'High triglyceride' level, has dropped from 6.2 % to 2.2 % after the intervention. Also the 'normal' triglyceride level has gone up from 83.7 % to 88.3 % after the intervention. The statistical analysis indicated that this change was significant (p < 0.05). Further, the percentage of participants who have a 'desirable (normal)' level, of cholesterol has increased from 43.4 % to 70.3 % after the intervention and this change is also significant at the level p < 0.05.

Anaemia, the major clinical manifestation of iron deficiency, is the most common nutritional problem throughout the world and is recognized as a serious public health problem in Sri Lanka too. Further, it was reported that in a study that 45 % of its non-pregnant participants and 39 % of its pregnant participants were anaemic [17]. In another study, 39 % of the participants in Iranian women aged from 15 to 49 years had iron deficiency and it was observed that iron deficiency anaemia was more prevalent in the overweight participants than the participants of normal weight or at risk for overweight [18]. In our study it was observed that the normal haemoglobin level of overweight/obese study population was 55 % before the intervention. However after the intervention, it rose to 83.5 %. Further it was analyzed using the paired sample *t* test that the change was significant at the level p < 0.05.

Poor nutrition habits and lack of nutritional awareness are main reasons in the etiology of chronic diseases including CVD and obesity [19], [20]. Present study too agrees with the above mentioned research because totally 84.4 % of study population consumed green leaves less than three occasions per week and considering the choice of rice, 64.4 % of total population selected polished rice like "samba" and "keerisamba". Further more frequent choice of dessert of our study population was ice cream (66.7 %).

Previous studies revealed that liver disease of metabolic origin (non-alcoholic fatty liver disorder) is associated with obesity and the elevated level of SGPT and SGOT [21], [22]. Generally, SGPT tests are used to assess liver functions and any type of liver cell injury can reasonably increases ALT levels but the elevation does not correlate with the extent of liver cell damage [23]. However these enzymatic variations are useful to diagnose the disease [24]. Out of the total population of the present study, 64.3 % had the normal SGPT level prior to the intervention and this value increased by 24.4 % after the intervention. Statistical analysis of these results indicates that the change in the SGPT before and after the intervention was significant (p < 0.05). Therefore, it is obvious that the intervention of "spice" mixure' not affects the liver or damage to the liver cells. On the contrary it improves the liver function.

Excess weight is a major risk factor and it affects the kidneys in various way while paving the way to renal diseases. In the long term excess weight, increases systemic arterial pressure, create hemodynamic burden on the kidneys which leads to glomerular injury and ultimately the renal function is impaired [25]. Measurement of serum creatinine has been accepted as one of the best possible tests to evaluate kidney function [26]. A study revealed that weight loss improves the glomerular hemodynamic abnormalities (a disease associated with severe obesity) without overt renal disease [27]. The result of the present study is comparable to that of Avry *et al*, 2003. We observed that the percentage of the participants who had a normal SC level increased from 72.1 % to 74.4 % after the intervention. This indicates that the renal function improves with the weight loss and that the "spice" mixture' had no negative effects on the kidney function.

4. CONCLUSION

A significant weight reduction and improvement was observed in the entire lipid profile after the weight reduction intervention. The total cholesterol, triglycerides, LDL and VLDL were reduced significantly after the weight reduction intervention. The level of HDL was significant and within the normal range. The change in the level of haemoglobin was significant and it was also discovered that the haemoglobin level has increased after the intervention. SGPT and Serum Creatinine showed a significant change towards a normal level and it indicates that there is no adverse effect to the liver or kidney by the 'spice' mixture which was given to the participants during the weight reduction intervention.

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