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EFFECTS OF CURCUMIN ON CARDIOVASCULAR RISK FACTORS IN OBESE AND OVERWEIGHT ADOLESCENT GIRLS: A RANDOMIZED CLINICAL TRIAL.

[1]Dr Syeda Faiqa Batool Bukhari,[2]Dr Deeba Yousaf,[3]Dr Aqsa Baloch.
[1,2,3]MBBS, Rawalpindi Medical University,Rawalpindi.

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Abstract:

Introduction: *The risk of developing cardiovascular risk and obesity for obese teens is higher in adult life. Dietary intake as an active ingredient of turmeric extract of antioxidants particularly curcumin may have noticeable implications for obesity and its essential complications, including cardiovascular risk factors. The goal of this research was therefore, to determine cardiovascular risk factors in overweight and obese adolescents with the effects of curcumin supplementation.*

Methods: *Fifty girls [aged 18 years] got placebo or intervention randomly. The teenagers were required to eat a standardised 95% turmeric extract or a placebo-containing one 500 mg pill daily, and to retain weight or a moderate weight loss diet for 10 weeks. The baseline and the conclusion of the intervention is measured with anthropometric and biochemical indexes.*

Results*: The body's mass index [P=0.019], waist circumference [P=0.007], hip circumference [P=0.028], high density ratios of lipoprotein [P=0.046], and triglyceride/high density ratio of lipoprotein [P = 0.022] have positive results on curcumin supplementation. In univariate covariance study, however after 10 weeks of supplementation there have been no major variations between the intervention and placebo groups [P>0.05].*

Conclusion: *Prescription of curcumin supplements together with the implementation of a light weight loss diet may beneficially influence many overweight and obese women's cardiovascular risk factors. Larger clinical trials are required to validate the findings of the current research, with higher curcumin doses and longer duration.*

Corresponding author:
Dr. Syeda Faiqa Batool Bukhari,
MBBS, Rawalpindi Medical University, Rawalpindi.

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INTRODUCTION:

The epidemic of overweight teenage patients is becoming a grave one in the world today. Overweight teens in adult adults, for example, have raised the incidence of obesity-related comorbidities as ischemic heart disease [1]. It appears that children's obesity [under 18] may be a significant indicator for adult comorbidities, such as hypertension and dyslipidemia. Thus, seeking a realistic alternative is highly important [2]. This is around 5% -13.5% and 3.2% -11.7%, respectively, among Iranian teenagers. It has been reported to be identified as the probable cause of childhood obesity by different lifestyle factors, including length of night sleep, physical exercise and the time spent watching television [3].

One research has shown that certain types of foods, such as spices, may play an important role in reducing obesity and its related complications [4]. In this sense, interest in turmeric extract has been increasingly focused, provided that its active ingredient is curcumin. Several studies have documented the possible impact of curcumin on obesity, inflammation, diabetes and cardiovascular disease and related risk factors [5]. However, the findings of the available research assessing the impact of curcumin on lipid profiles have been contradictory. One meta-analysis found that there was no beneficial effect of curcumin supplementation on lipid fractions [6].

Drawing upon our literature analysis we found no research evaluating any possible cardiovascular risk factors of curcumin supplementation in adolescents. Therefore it is important to choose this target group to assess the potential effects of curcumin.

Objective:

The aim of this analysis is to examine the effects on cardiovascular risk factors such as anthropometric assessment, glycemic indices and lipid profile for overweight and obese women in Pakistan.

METHODS:

Study design and setting

This was a randomized parallel clinical trial conducted at the Pediatric Cardiovascular Research Centre, Lahore University of Medical Sciences, and Lahore, Pakistan. The present clinical trial report followed the CONSORT checklist.

Participants:

This research undertaken over a 10-week period, involved overweight or obese female teenagers. These young ladies, aged 13 to 18, participated in this randomised placebo controlled study at the Pediatric Cardiovascular Research Centre, Lahore, Pakistan from November 2019 to February 2020. This research centre has a clinic for children and teenagers aged 6-18, with overweight and obese children and medical history of 1992. Overweight and obese children are included in this centre from all over the region, general practitioners and some related clinicians, such as endocrinologists. At this clinic, children are advised to increase physical exercise, minimise their empty intake of calories, prefer nutritious diets and enhance their diet [solid fat and added sugar calories] [through measures such as reducing their television time].

237 young people were considered qualified subjects out of 1,176 patient papers that were screened by current researchers [for being overweight or obese]. Of these 237 teenagers who had an opportunity for qualifying, 105 were not eligible, 27 were unable to participate in this research, 17 had chronic illnesses or drank prescription products, 14 had a particular diet in other mass control clinics and 4 had not begun a menstrual cycle yet. A total of 50 girls with overweight or obese post-pubescence were included in the following listing requirements. The percentile body mass ratio of 85-95 years of age was regarded as being overweight and according to the World Health Organisation guidelines, over 95 years of age was regarded as being obese [7].

The selection criteria for participants included: menstrual cycles for more than six months, lack of any history of chronic diseases such as diabetes, hypothyroidism, liver, renal, cardiovascular and polycystically syndrome, absence of use of medicine [medications affecting lipid and carbohydrate metabolism, such as statins, metformin, homogeneity] medicinal products. If participants were not able to proceed with the study, participants would be disqualified if they were improperly adhered to the diet and supplements that were prescribed [usage of below 80% of supplements].

Study conduction:

Random sequence generation and distribution concealment The data generated by the researchers from the files accessible at the paediatric cardiovascular resource facility are the random permuted blocks [dual blocks] of participants based on BMI percentile [85th < BM IBM percentile < 95th and BMI percentile < 95th]. A specialised workers from a cardiovascular research centre for podiatrist who were blinded to the random sequence of allocation allocated curcumin and placebo groups to adolescents using random numbers created by SPSS software.

Blinding procedures:
The Vital Medicinal and Nutritional Supplements Corporation developed and coded the curcumin supplement with its relatively similar placebo [shape, colour or smell and label] to preserve blinding. Subsequently, each research arm obtained supplements A and B randomly. Therefore the delegated intervention was largely oblivious of the interviewer, participants and statistical analysis.

Intervention:
For those with a BMI between 85th and 95th percentiles, weight control is recommended, and for those with a BMI diet of over 95th percentile [maximum of one pound or 454 grammes per month] [7]. Based on safe food recommendations, the prescription diet was planned. In the diets recommended, the distribution of macronutrients was 50% to 60% for carboxylic items, 15% to 20% for protein and 30% for total fat close to the standard Iranian trend [8]. The exact sum of each food category and a sample menu were obtained. These teens were also issued a detailed exchange list. Community workshops for teens and their mothers were conducted before the start of the study [9]. In these workshops, both teens and mothers were shown the correct way of using the sample food menu and trade list [10].

One 500 mg tablet daily, with either 95% normal turmeric extract or placebo, was requested from adolescents for 10 weeks with meals. The participants completed a questionnaire on physical activity and three days dietary record during their study time [Week 5] [one weekend day and two weekdays].

Faster blood samples were obtained at the conclusion of the research period. Furthermore, both participants had to calculate anthropometric indexes and blood pressure. Both participants completed the questionnaire on physical exercise and three-day eating reports. Telephone calls to both teenagers and mothers were made every fortnight to ensure that participants agreed with the use of curcumin supplements.

In addition, at the end of week 10, teenagers were expected to complete and return their supplementary containers. The commitment of the teenagers to their diet was monitored by their dietary histories during the study.

Outcomes:
We also carried out preliminary and final analyses of the findings. Anthropometric and Glycemic tests were mainly the result and the lipid profile was the secondary consequence.

The research began by gathering fasting blood samples and by calculating the adolescents' blood and anthropometric indexes. Both participants were presented with the general statistics, including schooling and jobs of parents, family revenue, a history of smoking, prior health history and use of medicine. In addition, teenagers completed a verified questionnaire on physical exercise and a 3-day eating record [one weekend and two weekdays] [11]. In compliance with the Institute of Medicine guidelines, gross energy consumption for each teenager was determined.[12]

Statistical analysis:
The sample size was determined on the basis of a formula for parallel checking. The error of type 1 [α] was calculated to be 0.05; the error of type2 [β] was 0.1 [i.e. power = 90]; d [a large variance in plasma glucose rapidity levels] was 0.38; [13] S1, a normal change in the control plasma glucose level, was 0.32; and S2 [S2] was the standardised deviation in the test category to the plasma glucose level [14].

On the basis of these results, each arm of the study needed participants. We included 25 young people in each group i.e. in the intervention group and in placebo groups, to allow for potential withdrawals during the research.
Using Q-Q plots and a Shapiro-Wilk test, the existence of normal variables distributions was measured. For variables with an irregular distribution, the logarithmic transferred means were used. Linear regression was used to estimate missing data's estimated values. There were just 5 withdrawals in the present sample [less than 10 percent of the study population]. Furthermore the baseline and endpoint values have been strongly correlated. Linear regression thus has the potential to reliably model missing results. This approach regarded the endpoint values of variables as dependent variables and baseline values as independent variables. The endpoint values of the variables could be predicted by the formula "y [endpoint] = x [baseline] +b [constant value],"

The general features of the participants were compared by means of the independent-sample t test and the chi-square test. In addition, dietary intakes, and physical activity levels and between groups comparisons were checked using an independent-sample t test. For within-group analyses, a paired-sample t test was applied. Univariate analysis of covariance [ANCOVA] was used to compare between-group

differences. Confounding factors were detected by conducting a correlation test between potential confounding factors and the baseline values of the variables.
Variables with r correlation ≥ 0.2 were considered to be confounding factor. In this regard, the potential effects of physical activity level, turmeric powder intake and intakes of some dietary antioxidants such as vitamin C, vitamin E, selenium and beta-carotene were controlled for, in the adjusted model.

All variables were reported as the mean ± standard deviation [SD]. The Statistical Package for the Social Sciences, version 18, was used for the statistical analyses. P-values less than 0.05 were considered to be significant in this study.

RESULTS:

Five youth withdrew from research on personal grounds, educational challenges including adversarial appointments, fear of blood collection, and movement to a different town during the study time. The data of all 50 participants were nevertheless incorporated into the statistical study by estimating the missing values [25 in each group].
The patients had no major side effects. Any teenagers though have mild headaches and nausea, solved by the regular use of curcumin capsules. Sampling, the subject's registration, intervention execution and data processing took nearly seven months.

Based on the available data, the anthropometric measures in the teenage population in curcumin have been substantially decreased. In the intervention group, there has also been a desirable change in the lipid profile.

The findings of the pairing test revealed only substantial weight and body mass loss for participants in the placebo community. The mean and the end values for the factors between the two classes did not discriminate.

DISCUSSION:

The findings of this parallel randomised trial found that curcumin supplementation in overweight and obese female teens over 10 weeks had a decrease in the body mass index, circumference of the hips, circumference of the neck, high-density lipoprotein content and lipoprotein ratio triglyceride/ high-density and an improved impact on insulin levels in joint examination. The weight and body mass index of subjects in the placebo category declined dramatically. While no substantial variations were observed between the intervention and control groups, there were considerable in-group effects. For the first time in a developing world, the effects of the curcumin supplements have been studied among overweight or obese female teenagers.

Previous studies have shown that childhood obesity and central obesity can be strong predictors for the presence of obesity and cardiovascular risk factors later in life [15]. However, body mass index presents some limitations as a marker for obesity. It does not show individuals' fat distribution or their degree of muscularity [16]. It seems that measurements of waist circumference and central obesity are better than body mass index as indicators for cardiovascular risk factors among children and adolescents [17].

In the present analysis, while no substantial differential could be observed between intervention and placebo groups, the body mass index, waist circumference and hip circumference of the intervention group decreased substantially after ten weeks. Curcumin complementation in addition, among the participants in the Curcumin group, there was a tendency towards substantial reductions in relation to the body weight and the waist hip ratio [WHR]. The weight and body mass index of participants in the placebo category was considerably decreased. The reduction in the index of weight and body mass can be related to recommended diets of both categories. However there was a substantial decrease in body size of participants in the curcumin community [i.e. waist circumference and hip circumference]. The findings of several previous research follow those of this study [18].

In this research, after ten weeks of curcumin inclusion, we have reported a substantial rise in insulin levels [19]. However the fast blood sugar level and the insulin tolerance evaluation of the homeostasis model did not substantially change. A previous research did not demonstrate an effect on accelerated insulin and blood glucose in obese children that was helpful from a hypo caloric diet even after reduction of the calories needed for preservation of weight by 30 percent [20]. This large rise in insulin content therefore appears to be mediated by the consumption of curcumin.

Some findings indicate that curcumin supplementation decreases accelerated glucose levels and resistance to insulin in diabetic patients. However further research in non-diabetic patients struggled to show that the impact of curcumin on glycemic indices was important [21]. A considerable rise in insulin levels among participants in the curcumin community has been found in the present study.

Curcumin consumption may increase insulin secretion from pancreatic cells and improve pancreatic function over the course of time [22]. The results from a study on animals suggested that curcumin intake might increase insulin secretion by increasing stimulation of glucagon-like peptide-1 secretion [23]. The results from an in-vitro study also confirmed the insulin-releasing effect and stimulating action of turmeric in cell cultures from the pancreas and muscle tissues of adult mice [24]. However, for more precise interpretation of such results, larger clinical trials with higher doses of curcumin are needed.

As well we know, this was the first time that in relation to cardio metabolic risk factors in post-pubescent or obese female teenagers in a developing world, the outcomes of curcumin supplementation were measured in combination with diet leading to a limited diet. As a basic intervention to monitor the confusing effects of food intake, the patients obtained complementary diets for low weight loss with the precise distribution of macronutrients. In addition, in the mathematical review, the consequences of suspected confuses were taken into account. Otherwise, balanced oversize and obese girls were included in the present report. The findings of this analysis may also be applied to related teenage populations.

However, several limitations might affect the final results. We were unable to determine the serum curcumin levels to validate the conformity of the participants due to financial constraints. There are therefore other potential ways to test the conformity of the recommended supplements. Moreover, we would have had to test serum-free fatty acid levels in order to better explain the results, in particular glycemic indices and insulin tolerance status. Yet because of financial limits we were unable to do so. Though retirement figures were insignificant during the study, the lack of data from these subjects may impact the end-results of this study. However by evaluating linear regression, we were attempting to reduce this effect by calculating the missing values.

CONCLUSION:

Prescription of a curcumin supplement along with a diet which leads to a mild loss of weight can have beneficial effects in overweight and obese women in certain cardiovascular risk factors. To validate the findings of this analysis, larger clinical trials are needed with higher doses of curcumin and longer duration.

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