Outcomes of Curcumin Addition to Statin Therapy in Dyslipidemia Patients at High Risk: A Placebo-Controlled Trial

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Abstract

Background: Dyslipidemia is one of the world's most prevalent & fatal diseases. Curcumin is an herbal remedy that may help improve dyslipidemia patterns. Some studies investigated the role of curcumin as a potential adjunct therapy in the management of dyslipidemia; the outcomes of such studies were conflicting. **Objectives:** This study assessed the consequences of curcumin supplementation with statin therapy on dyslipidemia patients at high risk attending Family Medicine Center. **Methods:** This study was conducted as a double-blind randomized placebo-controlled trial. A total of 118 patients with high-risk dyslipidemia profiles were randomly assigned to two groups; an intervention group that received 1 g curcumin capsule once daily and a control group that received a placebo capsule of 1 g starch powder once daily. Statin drug (atorvastatin 40 mg) was prescribed to all participants. The outcomes were assessed at baseline, 6 weeks, and 12 weeks. **Results:** When compared to the placebo group, the curcumin group showed a significant reduction in both LDL-C and total cholesterol. The Mixed ANOVA analysis results showed that the time component of the study had a larger effect size for all participants than the interaction between time and group of intervention. **Conclusion:** Based on this study's findings, curcumin reduced LDL-C and total cholesterol in a significant manner when added to high-intensity statin drugs in dyslipidemia patients at high risk. More research is warranted to determine curcumin's exact effect in patients with lipid profiles at low and moderate risk.

Keywords: Herbal, Hyperlipidemia, primary care, results.

Introduction

Atypical serum lipid levels, such as elevated Total Cholesterol (TC), elevated Low-Density Lipoprotein - Cholesterol (LDL-C), elevated Triglycerides (TGs), and decreased High-Density Lipoprotein - Cholesterol (HDL-C), are indicative of dyslipidemia, one of the prevalent metabolic disorders. [(1)]. It poses a significant risk for coronary heart disease, the world's biggest cause of mortality. According to WHO

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estimates, dyslipidemia is linked to over 4 million annual deaths and more than half of all events of ischemic heart disease worldwide. [2] It is well recognized that several variables contribute to the development of dyslipidemia, including advanced age, hypothyroidism, obesity, sedentary lifestyles, alcohol and tobacco use, type 2 diabetes, and environmental contaminants. [3] Stroke and cardiovascular disease account for 33.1% of all fatalities globally each year. [4, 5].

Elevated LDL-C, low HDL-C, excess lipoprotein, hypertriglyceridemia, atherogenic dyslipidemia, and mixed lipid diseases are the core types of dyslipidemia. Mixed dyslipidemia is seen in most coronary heart disease patients. [6]

These days, cardiovascular illnesses are seen as a serious health risk in developing countries, particularly those in the Eastern Mediterranean region with increasing morbidity and death. The total prevalence of cardiovascular disease in EGYPT in 2017 was found to be approximately 5.4% [7] and accounted for 46.2% of all deaths in the country. [8]

Apart from healthy lifestyle changes, statins constitute the mainstay of lipid-lowering medication therapy. Bile acid sequestrants, PCSK9 inhibitors, and ezetimibe are medications that decrease LDL. [9] Statins are commonly prescribed even though they have the potential to have major side effects such as hepatotoxicity and myopathies. [10] Curcumin is a polyphenolic molecule, it is extracted from the rhizome of Curcuma longa Linn, it possesses several pharmacological effects, such as anti-inflammatory, and antioxidant capabilities. [11]

Multiple studies have documented the protective properties of curcumin against a wide range of chronic illnesses. [12] Studies have shown that curcumin has a cardioprotective effect and can minimize oxidative stress because it lowers cholesterol. [13] Curcumin has more profound effects than regular household turmeric and demonstrated some efficacy in treating hypercholesterolemia. [14]

In an Egyptian study to evaluate the effects of curcumin on total cholesterol, LDL-C, HDL-C, and triglycerides in acute coronary syndrome patients, the administration of a low dose of curcumin showed a trend of reduction in total cholesterol and LDL-C. [15]

In a study carried out on normal, diabetic, and hyper-lipidemic rats sustained on high-fat and cholesterol-enriched diets, the results demonstrated that giving curcumin supplements considerably reduced serum levels of triacylglycerols, LDL-C, and total

cholesterol while significantly increasing HDL-C, nitric oxide, adiponectin, and Endothelin-1. [16]

This study was conducted to investigate the effects of adding curcumin on the lipid profile of patients recommended for statin treatment and following in a family practice center in Ismailia, Egypt.

Aim of the study

To examine the effects of adding curcumin to statin drug on the lipid profile of patients with high 10-year predicted cardiovascular risk.

Subjects and Methods

Subjects:

An estimated sample size of 108 participants was calculated. By accounting for the non-response, and dropout rate at 10% based on previous studies [18], the required sample size was 118 participants. The sampling frame was the total number of registered patients in the Abo-Khalifa family practice center, who were coded with dyslipidemia.

Randomization was done using computerized random tables to assign subjects of the study satisfying inclusion and exclusion criteria to intervention and control groups, each group comprised 59 subjects. Both the investigator and the subjects of the study were blind to the arms of interventions. Allocation was unconcealed and was carried out by an independent colleague using the closed envelope method. The inclusion and exclusion criteria were the following:

Inclusion criteria: Men and women aged 40 to 75 years without a previous diagnosis of Atherosclerotic Cardiovascular Disease (ASCVD) including hypertensive and diabetic with LDL-C 70 to 189 mg/dl and predicted 10-year ASCVD risk of ≥7.5%.

The Pooled Cohort Risk Assessment Equation that was derived from prospective cohorts of volunteers from studies conducted in the 1990s was used in the American College of Cardiology/ American Heart Association (ACC/AHA) 2013 guidelines for assessing an individual's absolute ASCVD risk.

It was designed to predict the 10-year risk of the first ASCVD event and includes sex, age, race, total cholesterol level, HDL-C level, systolic blood pressure, history of treatment for hypertension, diagnosis of diabetes mellitus, and history of smoking (calculated by mobile app- ASCVD Risk Estimator Plus).

Exclusion criteria: Patients with clinical ASCVD, history of familial hypercholesterolemia, diabetic patients with HbA1c ≥ 10, patients with mental disorders, patients with decompensated liver disease,

patients with chronic kidney diseases (eGFR< 30 ml/min), patients with known malignancies.

Methods

The intervention group received 1 g of curcumin capsule once daily, and the control group received a placebo capsule (1 g capsule of starch powder, identical in shape and size to the curcumin capsule) once daily. Both study groups similarly received statin drug (atorvastatin 40 mg), medical nutritional advice as recommended by the National Cholesterol Education Program of USA, and exercise advice of brisk 30-minute -walk for 5 days a week, according to 2018 ACC/AHA Blood Cholesterol Guidelines. (19)

A validated Arabic questionnaire for assessing the socio-economic status (SES) in Egypt (20) was completed by all study subjects. It contains 7 domains with a total score of 84. SES was classified into very low, low, middle, and high status depending on the quartiles of the score calculated.

A general clinical examination was carried out for height, weight, body mass index (BMI), and resting standardized blood pressure measurement. (21) Lipid profiles were measured by Cobas 6000 chemistry autoanalyzer, Roche diagnostics. Lipid profile typically included total cholesterol, HDL- C, LDL-C, and TGs. Total serum cholesterol and HDL-C were estimated by using the enzymatic colorimetric method, while LDL was calculated according to the Friedewald formula. (23) Study subjects were re-examined at 6, and 12 weeks.

Outcome Measures

lipid profile including serum total cholesterol, LDL-C, HDL-C, and TGs measured at baseline,6 weeks, and 12 weeks.

Statistical Analysis

SPSS (Statistical Package of Social Science) Version 24 for Windows was used to analyze the data. For qualitative variables, data was presented as frequencies and percentages, and for quantitative variables, means and standard deviations were used for descriptive statistics.

Shapiro-Wilk test was employed to evaluate the normality of variables distribution. Independent sample t-test was used to compare the means of quantitative variables, while for qualitative variables, Fisher's exact test or Chi-square was employed. The dependent sample t-test was used to compare pre-and post-intervention data within groups.

The p-value was statistically significant at < 0.05. The mixed ANOVA test was used to compare the means of outcome measures of the two groups across time and to examine

the interaction of time and group of intervention. Simple linear regression analysis was used to select significant predictors to be included in the multiple linear regression model for the prediction of the main dependent outcomes of interest.

Ethical considerations

The study's protocol was formally authorized by the Suez Canal University Faculty of Medicine's Research Ethics Committee. All participants provided signed informed consent, and their confidentiality was assured. After the study was over, the results were given to each participant.

Results

The baseline characteristics of the study subjects were comparable, with a mean age of 50.88 ± 4.88 years in the control group and 51.83 ± 5.31 years in the intervention group. Preparatory school education was the most prevalent, followed by secondary school education (51.7%, and 34.7%). No statistically significant differences were found between the two groups in marital status, occupation (P = 0.155), and income level (P = 0.249) (Table 1).

A total of 62.7% of the participants were classified as low SES, 34.7% as moderate SES, and 2.5 percent as high SES. There was no statistically significant difference between intervention and control groups regarding SES (p=0.198) (Table 2).

The laboratory data of the two study groups revealed noteworthy distinctions at various time points for different variables. Total Cholesterol (T- Cholesterol) levels were comparable at the baseline in intervention, and control group (242.78 mg Vs 237.02 mg), at 12 weeks of follow-up there was a highly statistically significant difference between the two groups (147.25 mg Vs 166.63 mg) respectively (p < 0.001).

For HDL-C levels, a marginally significant difference was observed at 12 weeks between the two groups (58.83 mg Vs 53.75 mg) for the intervention and control groups (p = 0.053).

Triglyceride levels (TG) were markedly decreased in the two study groups (242.83 mg Vs 223.22 mg at baseline, and 142.07 mg, Vs 160.69 mg at 12 weeks) for the intervention, and control groups, respectively, but no statistically significant difference was shown (p = 0.147).

LDL-C levels followed a similar pattern to total cholesterol, at the baseline the levels were (151.64 mg, and 147.4mg), while at 12 weeks of follow-up, they were (60.01 mg, and 80.74mg) for the intervention and control groups, respectively (p < 0.001) (Table 3).

The results of linear regression analysis for predicting improvement in total cholesterol level at the 12-week follow-up showed that BMI and the intervention were highly significant predictors in the simple linear regression analysis (p = 0.008, and < 0.001), respectively, and in the multiple linear regression analysis, the standardized regression coefficients (Beta) for BMI, and the intervention were (– 0.215 and 0.295), respectively, indicating that 21.5%, and 29.5% of the change in total cholesterol explained by decrease in BMI, and because of the active intervention (Table 4).

The same predictors, BMI, and the intervention were highly significant for LDL-C (p = 0.019, and < 0.001), with the standardized regression coefficients (Beta) in multiple linear regression analysis (-0.187, and 0.287), indicating that 18.7% and 28.7% of the change in LDL-C explained by a decrease in BMI, and due to the effect of active intervention, respectively (Table 5).

The Mixed ANOVA test was applied to investigate the interaction between the group of intervention and time on the means of the outcome measures at several time points and too. Partial Eta Squared, which expresses the effect size of a given predictor variable after accounting for (partializing) the variance explained by other predictor variables, is the primary statistic used in this ANOVA model. Partial Eta Squared has a value between 0 and 1, with values closer to 1 indicating that a particular model variable may account for a larger percentage of the variation.

The time factor was highly statistically significant for all outcome measures including total cholesterol, TGs, and LDL-C HDL-C (p< 0.001), with variables effect size (partial eta squared of 0.713, 0.708, 0.663, and 0.258) respectively.

The interaction between time and the group of intervention was also highly statistically significant for total cholesterol, TGs, and LDL-C (p = 0.002, 0.007, and 0.005), with smaller effect size (partial eta squared of 0.053, 0.047, 0.046) respectively, but was not significant for HDL-C (p =0.260), with partial eta squared of (0.011) (Table 6).

These findings indicate the relatively more effect of time on favorable changes in the outcomes of the study, compared with the combined effect of time and intervention.

DISCUSSION

Several clinical studies have been conducted in humans to investigate the outcomes of curcumin in dyslipidemia patients with inconsistent findings.

Curcumin, or turmeric root extract, at a daily dose of 1890 mg significantly changed

the lipid profiles of patients with metabolic syndrome, according to a double-blind, placebo-controlled study with an increase in HDL-C (6.18%) and a decrease in T-Cholesterol (9.8%) and LDL-C (11.64%).[24]

Although it contradicted other reports [15,18], this was consistent with other reports of curcumin's ability to decrease cholesterol in both humans and animals. In a double-blind placebo-controlled trial the effects of curcumin supplementation on the serum lipid profile in 36 elderly subjects with Alzheimer's disease were examined at doses of 4 g/day or 1 g/day or placebo, for 6 months.

The results showed non-significant alterations in serum T- cholesterol, HDL-C, and LDL-C concentrations. [18] These findings might be attributed to the smaller number of subjects which might have affected the effect size. In another study, curcumin supplementation of even small doses (10mg twice daily for 28 days) lowered serum LDL-C and increased HDL-C levels in patients with evidence of atherosclerosis. [25]

The male participants in a study who consumed curcumin for 12 weeks demonstrated a lipid-lowering effect on cholesterol levels, in particular, T-Cholesterol and LDL-C, T-Cholesterol/ HDL ratio decrease was associated with a reduction of T-Cholesterol rather than an increase of HDL-C, whereas in the female subgroup, the reduction of the T-Cholesterol/ HDL ratio was associated with an increase in HDL-C[26], which is consistent with the findings of the current study, where HDL-C levels showed a marginally significant difference at 12 weeks between the two groups (58.83 mg Vs 53.75 mg) for the intervention and control groups ($p = 0.053$), a result that may indicate a potential favorable influence of curcumin on HDL levels.

In the last study among patients with established CVD, men were more likely to be prescribed a statin for lipid-lowering compared with women. Healthcare providers tend to underestimate the magnitude of cardiovascular risk in female patients. [27]

Although the available evidence from reports suggests an overall anti-lipid effect of curcumin, the results across different trials have been inconsistent.

The discrepancy in the anti-lipid effect of curcumin extract consumption in human studies might be due to different lengths of follow-up periods (ranging from 7 days to 6 months), different dosages used (ranging from 20 to 6000mg/day), and different background co-morbidities of the participants. [15, 18, 24, 28]

The effect of curcumin on T-cholesterol ranged from a reduction of 0.2%, 5%, and 17%, using a dosage of 45 mg, 500 mg, and 4 g, and the effect of curcumin on LDL-C ranged from a reduction of 3.4 to 38%, using a dosage of 20 mg and 4 g. Higher doses of 6000 mg did not reveal any additional anti-lipid effect. [24] Using higher doses of curcumin from 4000 to 6000 mg did not demonstrate significant adverse effects in clinical trials. [18]

Limitations of the study

Despite being planned as a randomized placebo-controlled trial, the main disadvantage of this work was that all subjects were already on high-intensity statin medication, and the curcumin active intervention was an add-on. As a result, it was impossible to determine the exact effect of curcumin as it was inseparably linked to the well-established and well-evidenced statin outcomes, particularly for patients with high cardiovascular risk. It's also important to mention that the allocation of interventions was not concealed.

Conclusion

The results of this study show that adding curcumin with high-intensity statin medicine decreased LDL-C and total cholesterol in a statistically meaningful way compared with placebo and could be used as adjunctive treatment in dyslipidemia patients at high cardiovascular risk. Further studies employing other methodologies and recruiting patients with lipid profiles of low and moderate cardiovascular risk are necessary to examine the absolute outcome of curcumin.

Declarations

Conflict of interest: there is no conflict of interest to declare.

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Table (1): Socio-demographic characteristics of intervention and control groups

Variables	Interventional group (n=59)	Control group (n=59)	Total group (n=118)	p-value
Age (years), mean ± SD	50.88 ± 4.88	51.83 ± 5.31	51.09± 5.0	0.314[a]
Gender, n (%)				
Male	29 (49.2)	27 (45.8)	56(47.5)	0.854[b]
Female	30 (50.8)	32 (54.2)	62(52.5)	
Marital status, n (%)				
Married	56(94.9)	51(86.4)	107(90.7)	0.155[b]
Widowed	3(5.1)	5(8.5)	8(6.8)	
Divorced	0(0)	3(5.1)	3(2.5)	
Occupation, n (%)				
Non/Housewife	18(30.5)	29(49.2)	47 (39.8)	0.115[b]
Trades/ business	25(42.4)	19(32.2)	44 (37.3)	
Employer	16(27.1)	11(18.6)	27(22.9)	
Educational level, n (%)				
Illiterate	0(0)	0(0)	0 (0)	0.06[b]
Reading/writing	0 (0)	0 (0)	0 (0)	
Primary school	10(16.9)	6(10.2)	16 (13.6)	
Preparatory school	24(40.7)	37(62.7)	61 (51.7)	
Secondary school	25(42.4)	16(27.1)	41(34.7)	
University	0 (0)	0 (0)	0 (0)	
Postgraduate	0(0)	0(0)	0(0)	
Income level, n (%)				
Not Enough	5(8.5)	4(6.8)	9(7.6)	0.249[b]
Barely Enough	32(54.2)	24(40.7)	56(47.5)	
Enough	22(37.3)	31(52.5)	53(44.9)	

a: based on independent t-test, b: based on chi-square test.

Table (2): Comparison of socioeconomic status of the study groups (n=118)

Variables	Interventional group (n=59)	Control group (n=59)	Total group (n=118)	p-value
Socioeconomic level, n (%)				
Low	35 (59.3)	39 (66.1)	74(62.7)	0.198
Middle	21 (35.6)	20 (33.9)	41(34.7)	
High	3 (5.1)	0 (0)	3(2.5)	

The P-value was based on the chi-square test.

Table (3): Comparison of laboratory data of the intervention group (Group 1) and control group (Group 2) at different weeks of follow-up (n=118)

Variable /Time Measure	Mean ± SD (Group 1)	Mean ± SD (Group 2)	p Value
T. Cholesterol (mg)			
- At baseline	242.78 ± 43.48	237.02 ± 43.32	0.472
- After 6 Weeks	186.03 ± 34.13	193.44 ± 35.91	0.253
- After 12 Weeks	147.25 ± 18.96	166.63 ± 34.06	<0.001*
HDL (mg)			
- At baseline	46.17 ± 17.78	44.97 ± 7.97	0.636
- After 6 Weeks	51.69 ± 14.73	48.69 ± 16.58	0.301
- After 12 Weeks	58.83 ± 16.93	53.75 ± 10.55	0.053
TG (mg)			
- At baseline	224.83 ± 83.58	223.22 ± 57.22	0.903
- After 6 Weeks	176.88 ± 81.41	189.44 ± 58.99	0.339
- After 12 Weeks	142.07 ± 79.80	160.69 ± 56.80	0.147
LDL (mg)			
- At Baseline	151.64 ± 45.40	147.41 ± 39.69	0.590
- After 6 Weeks	98.96 ± 40.14	106.86 ± 34.74	0.256
- After 12 Weeks	60.01 ± 23.98	80.74 ± 30.86	<0.001*

The P-value was based on an independent t-test, *: statistically significant.

Table (4): Linear regression analysis for prediction of change in total cholesterol at 12-week follow-up

Variable	B	Beta	SE	p-value	95% CI	
					Lower Bound	Upper Bound
Univariate analysis						
Age	1.123	0.144	0.719	0.121	-0.301	2.547
Sex	2.298	0.029	7.382	0.756	-12.323	16.920
BMI	-14.599	-0.245	5.373	0.008*	-25.240	-3.958
HBA1c	-0.520	-0.019	2.487	0.835	-5.446	4.406
Hypertension	7.434	0.090	7.632	0.332	-7.681	22.550
Intervention	25.14	0.316	6.997	<0.001*	11.278	38.994
Multivariate analysis						
Intervention	23.399	0.295	6.883	<0.001*	9.766	37.032
BMI	-12.808	-0.215	5.171	0.015*	-23.050	-2.567

B: regression coefficient, Beta: standardized regression coefficient, *: statistically significant.

Table (5): Linear regression analysis for prediction of change in LDL-C at 12-week follow-up

Variable	B	Beta	SE	p-value	95% CI	
					Lower Bound	Upper Bound
Univariate analysis						
Age	0.980	0.122	0.742	0.189	-0.489	2.448
Sex	-1.205	-0.015	7.595	0.874	-16.247	13.838
BMI	-13.268	-0.216	5.564	0.019*	-24.288	-2.247
HBA1c	0.227	0.008	2.558	0.930	-4.841	5.294
Hypertension	7.091	0.084	7.854	0.368	-8.464	22.647
Intervention	24.969	0.306	7.223	<0.001*	10.664	39.275
Multivariate analysis						
Intervention	23.413	0.287	7.152	0.001*	9.247	37.580
BMI	-11.476	-0.187	5.373	0.035*	-22.118	-0.834

B: regression coefficient, Beta: standardized regression coefficient, *: statistically significant.

Table (6): Mixed ANOVA results of outcome measures across time among the study participants.

Variable / Effect	df1, df2	F Value	p-value	Partial Eta Squared
T-cholesterol				
- Time Effect	1.856	287.821	<0.001*	0.713
- Time * Group Interaction	1.856	6.516	0.002*	0.053
HDL- C				
- Time Effect	1.214	40.372	<0.001*	0.258
- Time * Group Interaction	1.214	1.317	0.260	0.011
TGs				
- Time Effect	1.587	281.354	<0.001*	0.708
- Time * Group Interaction	1.587	5.721	0.007*	0.047
LDL-C				
- Time Effect	1.867	228.573	<0.001*	0.663
- Time * Group Interaction	1.867	5.629	0.005*	0.046

*: statistically significant.

الملخص العربي

نتائج الكركمين بالإضافة إلى علاج الأستاتين في مرضى اضطراب شحوم الدم عالية الخطورة: تجربة خاضعة للتحكم الوهمي

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الخلفية: يعد اضطراب شحوم الدم أحد أكثر الأمراض انتشارًا وفتكا في العالم. والكركمين هو علاج عشبي قد يساعد في تحسين أنماط اضطراب شحوم الدم. وقد بحثت بعض الدراسات في دور الكركمين كعلاج مساعد محتمل في علاج اضطراب شحوم الدم. وكانت نتائج مثل هذه الدراسات متضاربة. **الهدف من الدراسة:** أجريت هذه الدراسة لتقييم نتائج مكملات الكركمين مع ادويه الدهون المعروفة بالأستاتين على مرضى اضطراب شحوم الدم الذين يراجعون مركز لطب الأسرة في الإسماعيلية، مصر. **المنهجية:** أجريت هذه الدراسة كتجربة عشوائية مزدوجة التعمية محكومة بدواء وهمي. تم توزيع ما مجموعه ١١٨ مريضا يعانون من ارتفاع نسبة الدهون في الدم بشكل عشوائي إلى مجموعتين؛ مجموعة التدخل التي تلقت ١ جرام كبسولة الكركمين مرة واحدة يوميا والمجموعة الضابطة التي تلقت كبسولة وهمية من ١ جرام مسحوق النشا مرة واحدة يوميا، بالإضافة إلى عقار أتورفاستاتين ٤٠ ملغ الذي تم وصفه لجميع المشاركين. تم تقييم النتائج عند الاسابيع ٠ و٦ و١٢. **النتائج:** تم تخفيض نسبه الكوليسترول منخفض الكثافة والكوليسترول الكلي بشكل كبير في مجموعة الكركمين مقارنة بالمجموعة المقارنة. كان لعامل الوقت حجم تأثير أكبر من التفاعل بين مجموعة التدخل والوقت لجميع المشاركين باستخدام تحليل انوفا المختلط. **الاستنتاج:** أظهرت نتائج هذه الدراسة أن إضافة الكركمين إلى أدوية الأستاتين عالية القوة إلى انخفاض نسبه الكوليسترول منخفض الكثافة والكوليسترول الكلي بطريقة ذات دلالة إحصائية. هناك ما يبرر إجراء المزيد من الدراسات لفحص النتيجة المطلقة للكركمين فقط في المرضى الذين يعانون من مستويات دهنية منخفضة ومتوسطة الخطورة.

الكلمات المفتاحية: اضطراب شحوم الدم، الأعشاب، الرعاية الأولية، النتائج.