



ROLE OF GUGGUL BASED THERAPY TO CONTROL DYSLIPIDEMIA AS AN ADJUVANT TO CONVENTIONAL DILZEM AMONG PATIENTS OF STABLE ANGINA ATTENDING A TERTIARY CARE CENTRE OF BIHAR

Pharmacology

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ABSTRACT

Cardiovascular disease (CVD) is the number one cause of death globally. Hypercholesterolemia (hyperlipidemia /hyperlipoproteinemia/or dyslipidemia) is a condition characterized by an elevation of any or all parameters of lipid profile or lipoprotein levels in the blood. **Methodology:** A double blinded randomized trial with pre and post design was conducted by Department of Pharmacology at Government medical college and hospital, Bettiah (GMCH), Bihar. Prior ethical clearance was obtained from the Institutional Ethics Committee. The study duration was December 2020 to May 2021. During this duration, 30 clinically diagnosed cases of stable angina were selected for participation in the study from the medical OPD. **Results:** Majority of the 30 selected patients were in 6th and 7th decades of their life with a mean age of 58.4 years. Almost half of them had positive family history of IHD. There was a male preponderance among the study subjects. Approximately 3/4th of them were non-vegetarian by dietary preferences and had sedentary lifestyle. **Conclusion:** Based on the study findings, the researcher can conclude that guggul based therapy has shown encouraging results in correcting dyslipidemia among patients of stable angina and has cardio-protective action.

KEYWORDS

Guggul Based Therapy, Dyslipidemia, Conventional Dilzem, Stable Angina

INTRODUCTION

Cardiovascular disease (CVD) is the number one cause of death globally [1]. High blood pressure, high LDL cholesterol, and smoking are the key risk factors for CVD and about 49% of Americans have at least one of the three [2]. Hypercholesterolemia (hyperlipidemia/ hyperlipoproteinemia/or dyslipidemia) is a condition characterized by an elevation of any or all parameters of lipid profile or lipoprotein levels in the blood [3]. Hypercholesterolemia generally means high levels of total cholesterol or LDL-C with normal or low levels of HDL-C. The guidelines of National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) suggests LDL-C level < 100 mg/dL, (100–129) mg/dL, (130–159) mg/dL, and >160 as optimal, above optimal, borderline high, and high, respectively. It also suggests that the LDL-C should be the primary target of any cholesterol reducing therapy [4]. As with other types of CVD, genetics, age, and gender are some of the non-modifiable risk factors for hypercholesterolemia. Hypercholesterolemia is one of the most significant contributors to the development of CVD, and if managed properly, is directly responsible for reducing risk of morbidity and mortality associated with CVD [5, 6] (The Lipid Research Clinics Coronary Primary Prevention Trial results I and II). The burden of hypercholesterolemia is also reflected by recurring acute cardiovascular events [7] and higher healthcare costs [8]. Hypercholesterolemia is one of the top 10 costliest medical conditions in 2008 in the US adult population [9].

METHODOLOGY

A double blinded randomized trial with pre and post design was conducted by Department of Pharmacology at Government medical college and hospital, Bettiah (GMCH), Bihar. Prior ethical clearance was obtained from the Institutional Ethics Committee. The study duration was December 2020 to May 2021. During this duration, 30 clinically diagnosed cases of stable angina were selected for participation in the study from the medical OPD. Exclusion criteria were: IHD with Acute Myocardial Infarction, Unstable angina, congenital anomalies, valvular diseases, severe hypertension, hypertrophic cardiomyopathies, congestive heart failure and those who did not give consent to participate.

30 selected patients were divided in 3 groups with 10 patients each. Intervention given in each group:

1. Group A: Tab Dilzem 30 mg TDS for 45 days
 2. Group B: Lasunadi Guggulu Vati 2 grams with lukewarm water TDS for 45 days
 3. Group C: Combined therapy of Tab Dilzem 30 mg and Lasunadi Guggulu Vati 2 grams with lukewarm water TDS for 45 days
- Parameter used to assess the therapeutic response was biochemical evaluation: Biochemical markers used for

assessment were a) Serum cholesterol (S. Ch), b) Serum Triglycerides (S. Tg), c) Serum High Density Lipoproteins (S. HDL), d) Serum Low Density Lipoproteins (S. LDL) and e) Serum Very Low-Density Lipoproteins (S. VLDL)

All the patients were given advice on dietary and lifestyle modification and motivated during the course of the study to adhere to them.

Statistical analysis was done using Statistical Package for Social Sciences ver 20.0 (IBM, Chicago). Paired t-test was done to evaluate effectiveness of the given intervention against various indicators of biochemical parameters. P value < 0.05 was considered statistically significant.

RESULTS

Majority of the 30 selected patients were in 6th and 7th decades of their life with a mean age of 58.4 years. Almost half of them had positive family history of IHD. There was a male preponderance among the study subjects. Approximately 3/4th of them were non-vegetarian by dietary preferences and had sedentary lifestyle. All the three groups were comparable based on these background characteristics. There was significant reduction in all the biochemical parameters of lipid profile in group B and C patients (Table 2 & 3). However, only serum triglycerides showed significant changes in group A patients (Table 1). This showed good dyslipidemia correction and cardio protective action of guggul.

Table 1: Changes of lipid profile in group A patients (N = 10)

Parameter	Mean value before intervention	Mean value after intervention	Mean diff	Standard error	t value	p value
S. Ch	239.6	228.5	11.1	6.6	1.7	> 0.05
S. Tg	179.6	171.5	8.1	2.8	2.1	> 0.05
S. HDL	42.6	44.1	-1.5	1.8	-0.5	> 0.05
S. LDL	159.5	151.5	8.0	5.9	1.5	> 0.05
S. VLDL	34.6	32.9	1.7	0.7	2.1	< 0.05 [*]

Table 2: Changes of lipid profile in group B patients (N = 10)

Parameter	Mean Before intervention	Mean After intervention	Mean diff	Standard error	t value	p value
S. Ch	213.4	178.8	34.6	7.2	3.2	< 0.05 [*]
S. Tg	197.8	159.2	38.6	12.1	4.1	< 0.05 [*]
S. HDL	47.9	52.5	-4.6	1.2	-2.1	< 0.05 [*]
S. LDL	124.7	103.5	21.2	6.9	2.5	< 0.05 [*]
S. VLDL	38.6	30.8	7.8	2.1	3.6	< 0.05 [*]

Table 3: Changes of lipid profile in group C patients (N = 10)

Parameter	Mean Before intervention	Mean After intervention	Mean diff	Standard error	t value	p value
S. Ch	224.8	185.7	39.1	6.7	5.1	< 0.05 [*]
S. Tg	211.5	160.4	51.1	10.1	4.8	< 0.05 [*]
S. HDL	50.5	56.7	-6.2	3.1	-4.6	< 0.05 [*]
S. LDL	132.4	96.8	35.6	7.2	5.1	< 0.05 [*]
S.VLDL	41.5	31.4	10.1	2.1	5.2	< 0.05 [*]

DISCUSSION

The findings of the current study are consistent with the clinical experiences and recommendations of traditional Ayurvedic literature. The two promising herbs for clinical improvements in hypercholesterolemia were found to be garlic and guggul. The study of the current study suggested that guggul based therapy is safe and effective in reducing major cholesterol biomarkers. Among various Ayurvedic herbs, Lashunadi guggul topped the list in its effectiveness, but due to the lack of enough number of studies, the strength of the evidence on this finding is fairly low. Garlic and guggul had the most consistent effects on cholesterol, except garlic did not seem to be as effective in increasing HDL-C as compared to guggul.

Seven randomized controlled trials in eight trial arms enrolling a total of 380 participants compared guggul with a placebo for its effect on various cholesterol levels. It was observed that guggulu reduces TC by 16.78 mg/dL (95% C.I.: 30.96 to 2.61, p value = 0.02) and LDL-C by 18.78 mg/dL (95% C.I.: 34.07 to 3.48, p value = 0.02). These findings on guggul came from the analysis of end results from eight trial arms of seven RCTs involving 380 people (184 in the control group and 197 in the experimental group). One of the studies included in this analysis [10] seems to have had a big influence on the overall effect of this intervention. Likewise, as compared to a placebo, guggulu reduced TG levels by 7.35 mg/dL (95% C.I.: 23.29 to 8.59; p value = 0.37) and raised HDL-C by 2.19 mg/dL (95% C.I. 0.27 to 4.12; p -value = 0.03). This effect size counts for a reduction in TC and LDL-C by nearly 6.5% and 10%, respectively. This finding is of clinical significance, as it is associated with a 38% reduction in the risk of coronary events at age 50 (Law et. al, 1994) [11]. The risk of coronary events is *dependent* on other cardiovascular risk factors such as hypertension and age. In addition, it is also understood that a 10% reduction in LDL-C levels helps minimize the risk of coronary and vascular events [12].

One of the studies included in the analysis of guggul is Verma (1988) [10] shows a bigger effect size. However, this study included patients with a baseline total cholesterol level of 275 mg/dL or more or triglycerides levels of 200 mg/dL. Thus, there is a possibility that guggulis more effective when the baseline cholesterol and triglyceride levels are high. Moreover, they described the process of purification of guggul that if done insufficiently may pose serious side effects. Similar comments on purification were given by Szapary et al. [13], which showed negative effects of guggul, if the product was not purified as per the Ayurvedic protocol.

In summary, guggul is effective in terms of total cholesterol, LDL-C, and HDL-C, and there is strong evidence to this end. Thus, it can be recommended as an adjuvant to cholesterol-lowering pharmacological therapy or as a supplement to a healthier diet and lifestyle for those who have borderline cholesterol levels.

CONCLUSION

Stable angina is a chronic disease which is multifactorial and has multiple etiologies. It is difficult to establish one exact correlate of this condition as well as one mode of defining prognosis. Dyslipidemia is one such known correlate. Based on the study findings, the researcher can conclude that guggul based therapy has shown encouraging results in correcting dyslipidemia among patients of stable angina and has cardio protective action.

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