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Clinical Efficacy of a Polyherbal Instant Formulation (Arogh) in the Management of Hyperlipidaemia

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Abstract: Hyperlipidemia is one among the risk factors affecting normal health. Though various hypocholesteremic agents are available, they are having their own limitations. Arogh is a scientifically validated polyherbal Instant Formulation indicated for hypercholesteremia, stress, cardiac ailments and Obesity. This study is focused as a randomized clinical study in treating hyperlipidaemia. Arogh was found to effectively reducing total cholesterol, triglycerides and LDLc levels and increased TC/HDLc ratio HDLc levels. This helps preventing atherosclerosis and reduces the risk of CHD.

Key words: Arogh, polyherbal, hyperlipidemia, cholesterol

INTRODUCTION

Cholesterol and atherosclerosis are interlinked[1] and later established that hyperlipidaemia as an independent risk factor for coronary artery disease. But now hyperlipidaemia is being proved an as independent risk factor for ischemic stroke[2]. Additional evidences from the prospective studies[2] have shown the relationship between plasma cholesterol levels and risk of stroke. Reduction in the plasma cholesterol[3] is accompanied by significant decrease in the incidence of coronary artery disease and stroke.

Data from individual randomised trials and meta-analyses of randomised trials consistently show a reduction in risk for both fatal and nonfatal coronary heart disease following primary and secondary prevention[4-6]. Recent study indicated that 10% reduction in serum cholesterol level resulted in highly significant reductions mortality from coronary heart disease[7,8]. These datas from randomised trials are consistent with observational data where treatment lasts for 5 years or more. A 10% reduction in cholesterol levels were associated with 25% reduction in coronary events among persons treated for more than 5 years. These findings from meta-analyses are also supported by recent reports from the Scandinavian study[7] and the West of Scotland Coronary Prevention Study[8].

Herbs have been used since ancient times for reducing elevated lipids. Arogh, a mixture of polyherbal formulation, is an approved treatment for elevated cholesterol in India and has been a mainstay in preventing atherosclerosis. With the above leads we planned a clinical study with Arogh.

MATERIALS AND METHODS

Thirty five patients were evaluated for general health and lipid profile through a medical history and a thorough physical examination. Patients with secondary hyperlipidaemia, alcoholism, or body weight more than 15% above the ideal for their height were excluded from the study. Baseline cholesterol and triglycerides of estimation were carried out. The patients showing serum total cholesterol levels more than 200 mg dL^{-1} or serum triglyceride levels more than 200 mg dL^{-1} were included in the study.

After screening twenty patients qualified for the study, their ages ranged from 25 to 57 years, with a mean age of 41. There were 12 male and 8 female patients. Each patient underwent routine hematological and biochemical laboratory investigations. Patients were asked not to eat any food, except water, for 12 to 14 h before taking blood samples. Routine urine analysis and electrocardiography was also carried out. The study planned was randomized clinical study for 8 weeks. Written and informed consent was obtained from all patients. Patients took 3 gm of the powder with 120 mL of hot water before food, three times daily. The patients had to visit every 2 weeks for 8 weeks. Patients were instructed to take a diet low in cholesterol and saturated fats.

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Table 1: Level of lipids before and after treatment

Parameters	Before treatment	After treatment
Total cholesterol (mg dL^{-1})	216.25±6.58	191.30±8.77*
Triglycerides (mg dL^{-1})	215.00±26.40	185.65±20.78*
HDL (mg dL^{-1})	39.45±2.64	40.50±2.78
LDL (mg dL^{-1})	134.30± 6.85	114.45±7.50*
VLDL (mg dL^{-1})	40.34±3.95	37.60±3.98*

*$p<0.001$ as compared to the before treatment value

Clinical side effects, if any were recorded at each visit and discussed with the patient to know the nature, severity and frequency. Patients were instructed to follow the same diets and to maintain weight, physical activity levels. To evaluate diet compliance, patients made written records of the quantity and type of food consumed in 4 consecutive days, including a weekend, between visits. Patients reported their usual physical activity at every visit. Repeated laboratory investigations and electrocardiography were done after completion of the study.

Concomitant medications were monitored throughout the study. Sixteen patients took no other drugs, two took vitamins, or mineral supplements, two took NSAID's, two took antacids and three took antibiotics. The results were analyzed using students paired 't' test.

RESULTS

Out of thirty five patients selected for the study, twenty patients were scrutinized and selected for this randomized clinical trial. They followed fairly uniform dietary patterns during the trial and their compliance was assured by routine interviews and review dietary pattern during every visit. Routine follow-up resulted in a good overall dietary compliance and accounted for the attainment, in many patients of normal cholesterol levels in both the drug treatment. Results of those patients taking Arogh showed a reduction of cholesterol from 216.25 to 191.30 mg dL^{-1}. Triglycerides levels were also reduced from 215 to 185.65 mg dL^{-1}. HDL was found to be increased.

Similarly, LDL reduced from 134.30 to 114.45 mg dL^{-1}. VLDL levels reduced from 40.34 to 37.60 mg dL^{-1} Table 1. Arogh reduced cholesterol, triglycerides, LDL and VLDL levels and increase HDL cholesterol levels.

DISCUSSION

High serum cholesterol is regarded by many as the main cause of coronary arherosclerosis[1]. Several cholesterol lowering interventions have reduced Coronary Heart Disease (CHD) events in primary and secondary prevention clinical trials[9,10]. Even expert panels in Europe and the USA have therefore recommended dietary changes and if necessary, addition of drugs to reduce high cholesterol concentrations especially Low-Density-Lipoprotein (LDL) cholesterol[11,12] especially in patients with CHD. No statistically or clinically significant changes were seen in weight, blood pressure, serum blood glucose levels, uric acid levels, or findings of other routine biochemical tests.

Many guidelines have been recommended for reducing levels of total cholesterol, triglycerides and low-density lipoproteins to decrease risk for coronary heart disease. Most cardiologists agree that adherence to these guidelines would reduce rates of morbidity and mortality from heart disease. There is little doubt that elevated cholesterol levels increases the risk for coronary heart disease. Observational research indicates that a linear relation exists: A 20% increase in risk for coronary heart disease is associated with a 10% increase in serum cholesterol levels. This dose-response effect occurs at any cholesterol level and is apparent in both men and women.

Arogh however, have shown that it is safe and effective in treatment of hypercholesteremia[13]. In a study Arogh reduced total cholesterol, triglycerides and LDLc levels in patients with essential hypertension[14] and Angina[15]. In another study, Arogh increased the TC/HDLc ratio and increased HDLc levels thereby indicating that Arogh prevents atherosclerosis[16] and reduces the risk of CHD[17].

Our findings show Arogh to have the unique ability to lower serum low density cholesterol levels with lowering of serum triglyceride levels without causing any side effects and the biochemical tests showed that all the parameters were within normal limits before and after treatment.

CONCLUSION

According to our results, Arogh produce significant reduction of cholesterol and triglycerides and alternative in treating hypercholesteremia.

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