

GUGGUL

An open label, prospective non-comparative clinical trial to evaluate the effects of Guggul in patients with hypercholesterolemia. (Data on file)

INVESTIGATOR

Dr. Kamdev Dash MD PhD (Ay)

Prof. & Head, Gopabandhu Ayurved

Mahavidyalaya, Puri - 2

OBJECTIVES OF THE STUDY

To evaluate the effects of Guggul in patients with hypercholesterolemia.

STUDY DESIGN

Open, prospective, non comparative clinical trial.

PRIMARY ENDPOINTS

The predefined primary end-points were reduction in the serum cholesterol levels.

SECONDARY ENDPOINTS

The pre-defined secondary end-points were reduced incidence of adverse events and overall compliance to study drug under investigation.

INCLUSION CRITERIA

- PHypercholesterolemic cases of both the sexes aged more than 18 years with serum cholesterol exceeded 260 mg/100 ml after 16 hours of fasting and those who were obese with BMI>30 Kg/m2Patients of both sex aged between 18 to 69 years
- Willing to sign informed consent form

EXCLUSION CRITERIA

- Patients having evidence of diabetes mellitus
- Pregnant or lactating women
- Undergoing other therapies for high cholesterol or anti-coagulant therapy
- Unwilling to sign the informed consent

METHODOLOGY

A total of 60 patients having serum cholesterol exceeded 260 mg/100 ml after 16 hours of fasting and those who were obese with BMI 30 Kg/m2 were included in the trial. All subjects were more than 18 years of age. Patients who had history of diabetes or those undergoing other therapies for high cholesterol were excluded from the study.

The overnight fasting blood sample was taken and the serum total cholesterol (TC) and high density lipoprotein cholesterol (HDL-C) were measured. After careful clinical and laboratory examination, Guggul was introduced to all the patients at a dosage of 2 capsules twice daily for 12 weeks. All the patients were advised a prescribed regimen of diet and exercise during the entire course of the study. At the end of 12 weeks, all the investigations were repeated. Those cases who could not follow the prescribed regimen of diet and therapy were excluded from the series.

STATISTICAL ANALYSIS

Statistical analysis were performed by Paired 't' Test. values were expressed as Mean \pm SD or incidence of occurrence. The differences were considered significant at $p < 0.05$.

RESULTS

A total of 60 subjects more than 18 years of age and weight 68.12 ± 8.32 with mean BMI $> 30 \text{ Kg/m}^2$ were enrolled in the study (Table 1). The ratio of male to female was 34:26. A significant elevated level of total cholesterol was noticed in the present series, the ratio of TC/HDL-C being found increased. After 12 weeks of therapy, a reverse trend was observed. TC showed a decreasing trend and the ratio also decreased to a significant extent (Table 2). Thus it was evident that Guggul has a capacity to modify the increased TC/HDL-C ratio.

Table 1

DEMOGRAPHIC DATA OF SUBJECTS ON ENTRY (n=60)

PARAMETERS	ASHWAGANDHA CAPLETS (n=55)
Age in years (mean \pm SD)	22.27 \pm 08.08
Weight in Kg (mean \pm SD)	64.12 \pm 12.32
SEX	
Sex ratio/ M:F	34:26
BMI	$>30 \text{ Kg/m}^2$

Table 2

EFFECT OF GUGGUL THERAPY ON TOTAL CHOLESTEROL AND HDL CHOLESTEROL (mean \pm SD)

TIME PERIOD	TOTAL CHOLESTEROL (MG/DL)	HDL CHOLESTEROL (mg/dl)	TC/HDL-C (risk factor)
Initial	280.09 \pm 46.68	49.05 \pm 11.72	6.19 \pm 2.30
After 12 weeks of therapy	220.02 \pm 40.24*	54.02 \pm 11.82*	4.03 \pm 1.42*

p < 0.05* with respect to baseline values

Adverse effects
None of the patients showed any adverse effects.

DISCUSSION

An inverse association between the incidence of CHD and HDL-C concentrations has been observed. In multiple epidemiologic studies, different ethnic groups have shown decreased HDL and elevated low density lipoprotein (LDL) levels as a potent risk factor of CHD. Several factors are now known to alter the levels of HDL-C. Age, sex, body-mass index, exercise and alcohol intake are associated with HDL-C levels. Diet and drugs also alter the levels of HDL-C in clinical as well as in experimental studies.

In the Ayurvedic system of medicine, several drugs have been mentioned as cardioprotective. Scientific evaluation of such drugs is, however, limited. In recent years global attention has been directed towards the clinical evaluation of indigenous drugs in the prevention and management of CHD. Guggul is a herbomineral compound generally advocated for maintaining normal cholesterol levels and normal lipid levels. Guggul provides oleo gum resin commonly known as "gum guggul" or "Indian myrrh". It is very effective in lowering blood cholesterol levels and helps in maintaining LDL and HDL levels in blood in normal limits widely used for reducing fat levels from body and as anti obesity agent. In the present study, it was found that daily use of Guggul for 12 weeks had brought about a significant decrease in serum cholesterol levels and enhanced HDL level in patients with no observed side effects. These excellent results may be due to the synergistic activities of the ingredients present in Guggul capsules.

CONCLUSION

Guggul showed statistically significant fall in cholesterol levels, it is a effective formulation for regulating hypercholesterolemia and effective in enhancing HDL levels in patients with hypercholesterolemia. HDL-C is one of the most important risk factors for the development of CHD. High HDL-C prevents atherosclerosis and reduces the risk of CHD. From this present it was evident that the TC/HDL-C ratio dropped significantly after 12 weeks of Guggul therapy. It indicates that this drug has a cardioprotective property. The continuous oral administration of Guggul may prevent the development of CHD.