

GUGGUL

Evaluation of the safety and efficacy of Guggul in patients with hyperlipidemia:
A randomized, double blind, placebo controlled trial
(Data on file)

INVESTIGATOR

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OBJECTIVES OF THE STUDY

To evaluate the safety and efficacy of Guggul in patients with hyperlipidemia.

STUDY DESIGN

Randomized, double blind, placebo controlled trial.

PRIMARY ENDPOINTS

The predefined primary endpoints include lowering of serum total cholesterol levels and serum triglyceride levels.

SECONDARY ENDPOINTS

The predefined secondary endpoints include reduction of adverse events and overall compliance to treatment.

INCLUSION CRITERIA

- Patients with serum cholesterol levels more than 200 mg/dL or serum triglyceride levels more than 160 mg/dL Patients from the age group of 18-60 years
- Patients of both the sex aged more than 18 years.
- Patients willing to sign informed consent.

EXCLUSION CRITERIA

- Patients with secondary hyperlipidemia, alcoholism, or body weight more than 15% above the ideal weight for their height were excluded from the study.
- Pregnant / Lactating women.
- Unwilling to sign informed consent form.

METHODOLOGY

This study was carried out in 70 patients with hyperlipidemia in the age group of 29 to 64 years. All the patients had serum cholesterol levels of more than 200 mg/dl or more and serum triglyceride 160 mg/dL or more.

Each patient underwent routine hematological and biochemical laboratory investigations. The study planned was randomized, double blind, placebo controlled study for 16 weeks. The written informed consent was obtained from all the patients. Patients were randomized into treatment and placebo group in accordance with random number table. Patients in the treatment group (n=35) were given 2 capsules of Guggul twice daily for 16 weeks. The same dose of placebo was given to the placebo group (n=35) for 16 weeks. The clinical side effects if any were recorded at each visit and discussed with the patient to know the nature, severity and frequency. Repeated laboratory investigations and electrocardiography were done after completion of the study. All patients were evaluated for serum cholesterol and serum triglycerides every two weeks and the observations were recorded in the case report forms.

STATISTICAL ANALYSIS

The results were analyzed statistically using Paired 't' Test. The values were expressed as mean \pm SD or incidence of occurrence. The differences were considered significant at $p < 0.05$.

RESULTS

All the patients completed the study. Results of the patients who took Guggul showed a reduction in the cholesterol from 216.30 ± 7.32 mg/dl to 194.30 ± 5.08 mg/dl. Triglycerides levels were also reduced from 162.0 ± 26.37 mg/dl to 140.7 ± 21.28 mg/dl respectively. The HDL levels increased from 39.00 ± 2.84 mg/dl to 41.26 ± 2.83 mg/dl. Similarly, LDL levels were reduced from 133.10 ± 7.07 mg/dl to 120.20 ± 8.45 mg/dl with Guggul. The VLDL levels were reduced from 41.47 ± 4.33 mg/dl to 39.52 ± 4.16 mg/dl with Guggul. The treatment with Guggul was found to be effective during the trial when compared to the placebo group. The level of significance was found to be $p < 0.05$ when compared to the placebo groups. There were no adverse effects, either observed or reported during the study period.

Table 1

EFFECT OF GUGGUL ON THE LEVEL OF LIPIDS BEFORE AND AFTER TREATMENT

PARAMETERS	BEFORE TREATMENT		AFTER TREATMENT	
	Guggul (n=35)	Placebo (n=35)	Guggul (n=35)	Placebo (n=35)
Total cholesterol (mg/dl)	216.30 ± 7.32	218.20 ± 6.22	$194.30 \pm 5.08^*$	209.12 ± 7.21
Triglycerides (mg/dl)	162.00 ± 26.37	160.20 ± 4.32	$140.70 \pm 21.28^*$	154.15 ± 5.24
HDL (mg/dl)	39.00 ± 2.84	38.24 ± 3.21	41.26 ± 2.83	39.26 ± 2.12
LDL (mg/dl)	133.10 ± 7.07	131.28 ± 8.21	$120.20 \pm 8.45^*$	129.26 ± 3.54
VLDL (mg/dl)	41.47 ± 4.33	40.25 ± 3.28	$39.52 \pm 4.16^*$	40.02 ± 2.89

* $p < 0.05$ as compared to the before treatment values

Adverse effects: no observed adverse effects
Drop outs: 2

DISCUSSION

The risk factors for coronary artery disease have been identified recently in various epidemiological studies. More than half of cases of heart disease are attributable to lipid abnormalities. Development of atherosclerotic disease is a complicated process involving various lipid-containing particles. It has long been recognized that cardiac risk factors tend to cluster in individual patients. The metabolic syndrome (insulin resistance syndrome) is a constellation of abnormalities that is highly predictive of atherosclerosis and is characterized by high triglyceride levels and the presence of small, dense, atherogenic low-density lipoprotein cholesterol particles. Treatment of hyperlipidemia requires a multidisciplinary approach that includes lifestyle modification in addition to medical therapy. Challenge of the physicians is to identify patients who are at high risk and prescribe an appropriate treatment program. By performing risk assessment in every patient, we can help reduce the incidence of heart disease in this country. Guggulsterone, the bioactive constituent of Guggul, has been identified as an antagonist at the nuclear receptor, a key transcriptional regulator for the maintenance of cholesterol.

This study indicates the efficacy of Guggul in bringing about a significant fall in serum cholesterol and triglycerides. It also increases HDL levels at the end of 16 weeks. The exact mechanism of Guggul in decreasing lipids is now known, but, probably it acts by inhibiting the synthesis of cholesterol in liver. 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 The improvement in HDL levels is a significant advantage of Guggul. The hypolipidemic activity of Guggul may be attributed to several mechanisms including inhibition of cholesterol biosynthesis and enhancement in cholesterol degradation and/or excretion. Guggul extracts have been reported to possess antioxidant properties possibly mediating protection against myocardial necrosis.

CONCLUSION

This study indicates efficacy of Guggul on hyperlipidemic patients and reducing the serum cholesterol and triglycerides and significantly increased HDL-cholesterol. There were no adverse effects, either reported or observed in the clinical study during the study period and the compliance to the study drug was good. There were no drop outs or withdrawal from the study and all the 70 patients completed the study. So, it can be concluded that Guggul is effective and safe in the management of hyperlipidemia.