



Research Article

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A COMPARATIVE STUDY TO ASSESS THE EFFECT OF HARITAKI CHOORNAM WITH MADHU AND LIFESTYLE MODIFICATIONS ON SERUM TOTAL CHOLESTEROL LEVEL

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ABSTRACT

The prevalence of dyslipidemia is very high in India (79%), which requires urgent intervention strategies to prevent and manage this critical cardiovascular risk factor. This study aimed to explore the efficacy of Haritaki choornam with madhu and lifestyle modification on serum total cholesterol levels. Elevated serum total cholesterol can be returned to normal by kaphamedohara, deepana, rookshana and lekhana drugs. Haritaki (*Terminalia chebula* Retz.) and madhu (honey) have all the mentioned properties. A pre and post-interventional study was conducted in 60 subjects of both sexes, satisfying inclusion and exclusion criteria. Thirty subjects were randomly allocated to the Intervention group (Group 1) and comparison group (Group 2). The study group received 3 gm. of Haritaki choornam with 6 gm. of madhu as anupama after food in the morning and evening, along with lifestyle modifications for 45 days, while the comparison group kept on lifestyle modifications only for 45 days. On statistical analysis, the reduction in serum total cholesterol in the study group taking Haritaki choornam with madhu and lifestyle modifications is more than in the comparison group who were kept on lifestyle modifications alone. The results were analysed statistically using paired t-tests and independent t-tests within the group and between groups, respectively. The serum total cholesterol was statistically significant with a p-value of $p < 0.05$ in between-group comparison. The study concluded that Haritaki choornam with madhu and lifestyle modifications is more effective than lifestyle modifications alone in serum total cholesterol.

Keywords: Dyslipidemia, Haritaki choornam, madhu, lifestyle modification, *Terminalia chebula*

INTRODUCTION

The impact of chronic disease on people is serious when measured in terms of loss of life, disablement, poverty, and economic loss to the country¹. Dyslipidemia is a disorder of lipoprotein metabolism, including lipoprotein overproduction or deficiency. The report of the ICMR survey 2014 concluded that over 79% of the general Indian adult population covered in the survey has an abnormality of at least one of the lipid parameters, which calls for urgent intervention strategies to prevent and manage this important cardiovascular risk factor². Many researches show that herbals have the potential to avoid problems of lifestyle. So, treating early borderline hyperlipidemia is one of the key factors in primary-level prevention for reducing the prevalence of coronary heart disease (CHD).

In Ayurveda, there is no exact term for dyslipidemia, but it can be correlated with Medodushti, a condition caused by derangement of Agni. Thus, the lipid profile can be returned to normal by correcting Agni and ensuring proper dhatuparinama. Here, kaphamedohara, deepana, pachana, rookshana, lekhana, guru and apatarpana drugs are helpful. Haritaki and madhu (honey) is a combination explained by Acharya Charaka in Santarpaniyamadyayam³. Many animal studies found that treatment with Haritaki produced a significant decrease in the serum level of lipids in atherogenic diet-induced hyperlipidemia in rats⁴. Honey has antioxidant, anti-inflammatory, and antimicrobial activities. Growing evidence and scientific data support the use of honey in patients with diabetes, hypertension, dyslipidemia, obesity, and CVD⁵.

Since the condition needs regular management, the selected option must be economical, readily available, safe to administer and can be practised for a long duration. Hence, those among the nithyasevaniya dravyas are preferable. Haritaki and madhu were prescribed a wholesome diet (nithya sevaniya dravya) with Medohara property (hypolipidemic action)³. Based on these points, this study has planned the beneficial drug Haritaki choornam and madhu as a particular Ayurvedic regimen. Lifestyle modifications also play an essential role in dyslipidemia based on the National Cholesterol Education Program Adult Treatment Plan III (NCEP APT III) review, which stated that diet and exercise can benefit lipid profile⁶.

MATERIALS AND METHODS

Haritaki (*Terminalia chebula*) was washed perfectly in running water to remove foreign material and dried correctly. Then, it was finely powdered and packed airtight in appropriate amounts. Agmark-certified honey was distributed to the subjects. The study was conducted at the Government Ayurveda Panchakarma Hospital, Poojappura, Thiruvananthapuram, Kerala, India.

Procedure

270 gm of Haritaki choornam and 540 ml of honey were required for each subject for 45 days. Haritaki choornam were packed in 45 packets, each separately containing 6 gm. After taking a detailed case history, the subject was given 15 packets of Haritaki choornam and 180 ml of honey for 15 days. The mode of administration of medicine was instructed to each subject, and the prescription was enclosed with the packets. On the 16th day, the

next set of 15 packets and honey was dispensed. The last 15 packets of medicine and honey were distributed on the 31st day. Subjects were advised to take 3 gm of the Haritaki choornam twice daily after food (as per API norms) with madhu (honey) of double quantity (6 gm)⁷ along with lifestyle modifications in the form of a diet chart and exercise of 30 minutes brisk walking daily morning.

Lifestyle modification alone was advised to the comparison group. This includes dietary modifications and exercise of 30 minutes of brisk walking daily in the morning. Both groups were analysed before and after the study period (0th and 46th day). On ethical considerations, the comparison group was also given the medicines after the completion of the study.

Sampling

Study Population: Subjects of either sex aged 35 - 65 years, having serum total cholesterol levels between 200 mg/dl- 239 mg/dl.

Sampling procedure: The study's sample size was 30 in each group by simple random sampling method. From the accessible population that satisfies the inclusion and exclusion criteria, 60 subjects were selected and randomly assigned to 2 groups: Intervention group (Group I) and Comparison group (Group II).

Data Collection

Data were collected from each group using a case performa. Laboratory investigation of blood was done before and after administration of the drug. Blood samples were collected early in the morning by venipuncture from an antecubital vein after at least 12 hours of fasting. The laboratory conducted a blood biochemistry analysis in the Ayurveda Panchakarma Hospital, Poojapura. The fasting blood samples measured TC by the direct enzymatic method.

Statistical Analysis

Mean, standard deviation, paired difference and coefficient of variation are calculated for study variables to analyse the data. The Student t-test or Independent t-test was used to compare the treatment effect between the two groups. Paired t-test was used to evaluate the effect of treatment within the groups separately before and after the study.

Ethical Consideration

Written informed consent from the subject was obtained before the study. The conditions of informed consent were entirely carried out, and the subject's autonomy was respected. Institutional Ethical Committee clearance (Ref.no. AVC IEC 411/2019) was also taken before the study.

Table 1: Effect of treatment on total cholesterol within group comparison

		N	Total cholesterol (mg/dl)		Paired Differences		95% CI of the Difference		Paired t-test	
			Mean	SD	Mean	SD	Lower	Upper	T	P
Group I	BT	30	226.1	12.6	20.6	17.7	14.0	27.2	6.4	<0.001
	AT	30	205.5	20.7						
Group II	BT	30	226.3	11.7	9.5	7.9	6.6	12.5	6.6	<0.001
	AT	30	216.7	15.2						

After treatment, groups 1 and 2 showed a statistically significant reduction in total cholesterol at P <0.001.

Table 2: comparison between the effects of treatment on TC of two groups

Total cholesterol	Group I		Group II		T	P
	Mean	SD	Mean	SD		
BT	226.13	12.588	226.27	11.691	4.7	0.966
AT	205.5	20.703	216.73	15.184	2.72	0.020

The effect was statistically significant when comparing groups by student t-test at P value <0.05.

BT: Before Treatment, AT: After Treatment, T: T-value, P: P value, SD: Standard Deviation

RESULTS AND DISCUSSION

Effect of treatment on Serum total cholesterol

As per Table 1, the mean difference in total cholesterol levels in the intervention and comparison groups, before and after the treatment, was 20.6 mg/dl and 9.54 mg/dl, respectively. It is observed that there is a considerable reduction in the total cholesterol level of subjects in the intervention group (Group I) than the comparison group (Group II). A paired t-test was used to analyse the within-group effect in the intervention and comparison groups separately before and after the intervention. After the treatment, both groups showed a statistically significant mean reduction in total cholesterol (p <0.001) statistically.

Independent sample t-test (unpaired t-test) was used to compare the treatment effect in the Intervention and comparison groups. Group I showed a higher mean reduction in total cholesterol than the comparison group in comparison between the two groups. By student t-test, the difference was statistically significant (p<0.05).

Probable Mode of Action

An ideal drug breaks the pathogenesis of the disease without producing any side effects. So, drugs used in the study have Vatakapha shamaka, deepana, pachana, laghurukshaguna, srotosodhana and medohara properties. Trial drugs, i.e., Haritaki and madhu, had the said property.

Haritaki possess laghu, rukshaguna, Kashaya pradhana lavana varjitha pancharasa, ushna virya, doshanulomana, deepana, pachana, srotovibhandahara, pramehahara property. By ushna veerya, Haritaki can do the function of srotosodhana, Kaphakledamedohara, and Agnideepana. By the doshanulomana property, Haritaki will excrete lipids from the body as bile. In the present study, Haritaki choornam is taken after the meal. Acharya Bahvaprakash opined that in all kinds of annajadosha and Vata Pitta Kaphodhbharogas, Haritaki is taken after the meal because of its deepana property⁸. Oushada kala of Vyanavayu is after food. The study used madhu as anupana, which potentiated the drug's action. Because of kashaya rasa, guru, and rukshaguna, it acts as tridoshashamaka and medoghna. The gastric emptying property of Haritaki might be the reason for decreased

absorption⁹. An animal study on the antidyslipidemic activity of Haritaki choornam and madhu showed a highly significant reduction in TC¹⁰. The chemical constituents like chebulinic acid, saponins, phytosterols and corilagin in Haritaki may be responsible for the hypolipidemic effect^{11,12}. As an anti-hypercholesterolemia agent, honey undergoes several studies in animals and humans with varying results. Adnan *et al.*¹³ also stated that honey from acacia trees lowers LDL, TC and triglyceride levels in rats. Bogdanov *et al.*¹⁴ said that honey can increase Lactobacillus in the small intestine and colon, which may reduce blood cholesterol levels by inhibiting the reabsorption of bile acids into the liver.

Acharya Vagbhata has quoted that vyayama brings lightness in the body, which enhances digestive capacity and reduces extra Kapha and meda. Several epidemiological studies have reported a robust and direct association between physical inactivity and metabolic and cardiovascular diseases. C-reactive protein, biomarkers of inflammation, which are associated with chronic diseases, are reduced in active individual¹⁵. Diet chart prepared under the principle of apatarpanaahara described in classics. In dyslipidemia, excessive consumption of madhura snigdhaahara increases Kapha dosha and Medo dhatu. Therefore, Kaphahara ahara can reduce the Medhodhatu. Therefore, tikta, katu, kashaya rasa predominant ahara is recommended for the condition due to its Kaphahara property. Tiktha rasa is deepana, pachana, lekhana and shoshana. So, it can be used in Medoroga chikitsa and maintain the dhatu at the optimum level. Due to ushna veerya, katu rasa depletes sneha, and kleda, thereby decreasing Medo dhatu, removing obstruction (sangam pathology) of the srotas and correcting the tissue metabolism in optimum.

CONCLUSION

The present research study has proposed to evaluate the effect of Haritaki choornam with madhu and lifestyle modifications in dyslipidemia. In the present study, the intervention group who received Haritaki choornam with madhu and lifestyle modifications showed a significant reduction in serum total cholesterol than the comparison group who kept with lifestyle modifications alone. The result also suggests that Haritaki has helped improve the physiological digestive process, relieves constipation, and is an excellent lipid-lowering agent. Hence, Haritaki could be advised for dyslipidemia as a daily dietary intervention to prevent cardiovascular risks since no adverse effects were observed during or after the study period. The study concluded that Haritaki choornam with madhu and lifestyle modifications are more effective than lifestyle modifications alone in dyslipidemia.

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