

Research Article

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## Pilot Study of Amukkara Kizhangu Chooranam in the Management of Hyperlipidemia (Athimetham)

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### Abstract

Despite there is awareness about lifestyle and diet there is marked increase life style modification disorders alike Hyperlipidemia. The main aim of the study was to assess the efficacy of poly herbal formulation Amukkara Kizhangu Chooranam in the management of Hyperlipidemia. It was diagnosed by clinical signs, history and was confirmed by increased levels of lipids through haematological investigations. It was an open labeled, single centric, non-comparative prospective, pilot study conducted in 20 patients of hyperlipidemia in National Institute of Siddha. 2 grams of Amukkara Kizhangu Chooranam was given with honey after meals twice a day for 30 days. After the treatment period there were marked decrease in lipid levels and statistical analysis-paired 't' test, showed "P" value for Serum total Cholesterol is 0.001, LDL is 0.14, VLDL is 0.037 and TGL IS 0.002. No significant change in most of the safety laboratory parameters was observed at the end of the study. Hence Amukkara Kizhangu Chooranam can be used in the treatment of Hyperlipidemia.

### Keywords

Amukkara Kizhangu Chooranam, Hyperlipidemia, Haematological, statistical analysis.

### Introduction

Siddha System is one of the ancient systems of medicine in the world. It is mainly based on three vital humours named Vali, Azhal and Iyyam. The inimitable of this system is efficacy of a single drug with various adjuvant evidenced for assortment of diseases. Siddha system not only deals with diseases and also treatment, prevention, cure and also lifestyle.

Athimetham (Hyperlipidemia) is one of the life style modification diseases in our country. Hyperlipidemia which is increased levels of lipids. Hyperlipidemia includes both hypercholestremia and hypertriglyceridimia. Although it does not show any

symptoms it lay concrete for many diseases that cardiovascular diseases and stroke are very common due to atherosclerosis. Hyperlipidemia is one of the major risk factor for coronary heart disease (CHD) a major leading cause of mortality in developed countries, will soon become the pre-eminent health problem worldwide.

Recent epidemiological studies reveals that there is an increase in lipid levels globally. There is wide variation in the prevalence, awareness, and treatment of hyperlipidemia between populations. According to WHO MONICA PROJECT the prevalence of

hypercholesterolemia varied across populations from 3% to 53% in men, and from 4% to 40% in women. Awareness of hypercholesterolemia varied from 1% to 33% in men, and from 0% to 31% in women. In most populations, over 50% of men and women on lipid-lowering drugs.<sup>1</sup>

Raised cholesterol increases the risks of heart disease and stroke. Globally, a third of ischaemic heart disease is attributable to high cholesterol. Overall, raised cholesterol is estimated to cause 2.6 million deaths (4.5% of total) and 29.7 million disability adjusted life years (DALYS), or 2.0% of total DALYS. Raised total cholesterol is a major cause of disease burden in both the developed and developing world as a risk factor for Ischemic heart disease and stroke.<sup>2</sup>

India is a developing country has been showing an increase in the incidence of hyperlipidemia, for the past few decades. In young adult Indian population the prevalence of dyslipidemia was observed to be higher in males than in females. Among participants who had a total Cholesterol (TC) concentration 200mg/dl, 38.7% were males and 23.3% were females. High density lipoprotein cholesterol (HDL-C) was abnormally low in 64.2% males and 33.8% in females. The increase of prevalence of hypercholesterolemia and hypertriglyceridemia was more prominent in 31-40 age group than in 30 age group<sup>3</sup>.

Another epidemiological study in India conducted ICMR-INDIAB reported, 13.9% had hypercholesterolemia, 29.5% had hypertriglyceridemia, 72.3% had low HDL-C, 11.8% had high LDL-C levels and 79% had abnormalities in one of the lipid parameters. Regional disparity exists with the highest rates of hypercholesterolemia observed in Tamilnadu (18.3%), highest rates of hypertriglyceridemia in Chandigarh (38.6%), highest rates of low HDL-C in Jharkhand (76.8%) and highest rates of high LDL-C in Tamilnadu (15.8%). Except for low HDL-C and in the state of Maharashtra, in all other states, urban residents had the highest prevalence of lipid abnormalities compared to rural residents.<sup>4</sup>

It is the right time for the measures to be taken for this disease. Many Siddha medicines have been indicated for increased levels of lipids. Several indigenous plants have been claimed to possess hypolipidemic and hypocholesteremic properties that may be beneficial to reduce the risk of cardiovascular diseases. In Siddha text Amkkura Kizhangu Chooranam is indicated for athimetham.<sup>5</sup>

Athimetham is a one of the kabam related disorder. Amkkura Kizhangu Chooranam has kaippu suvai. It's vibagam is kaarppu. It is mentioned in the Siddha text that kaarpu taste will reduce fat. Many studies have been conducted in this herb. Ethanolic extract of this herb showed hypolipidemic activity in alloxan induced diabetic rats.<sup>6</sup>

Another study showed that dietary herbal supplementation with *Withania somnifera* exhibited a significant reduction in levels of egg yolk total lipids, egg yolk cholesterol and egg yolk triglycerides of birds.<sup>7</sup>

This study is different from previous studies regarding adjuvant and dosage forms and methods.

Hence the researcher has selected "Amukkara kizhangu chooranam" to evaluate its Hypolipidemic activity in the management of Hyperlipidemia (Athimetham).

## Materials and Methods

Collection and authentication of raw drug:

The Amukkara Kizhangu was procured from Raw drug store in Chennai and authenticated by competent authority in Department of Gunapadam.

### Purification of Amukkara Kizhangu:

Amukkara (*Withania somnifera*) was boiled with milk and then dried in the shadow.

### Method of medicine preparation:

Purified Amukkara kizhangu was pulverised by an electric pulverizer into a fine powder and then it was sieved by using a fine silk cloth (vasthra kaayam). The fine Powder was mixed with milk and backed in a backing pan (pittavial method). Then it was dried and ultrafiltered by a cotton cloth and made into fine powder again. The powder was stored in a clean dry airtight glass bottle.

### Study design:

It was an open labeled, single centric, non-comparative, prospective, pilot study. The study protocol and related documents were reviewed and approved by institutional ethics committee at National Institute of Siddha Chennai- 47, India.

Approval number is NIS/IEC/2011/3/13b-24/12/2011. Based on the protocol approved by IEC,NIS the study was conducted on hyperlipidemia patients. The study was conducted in National Institute of Siddha , Ayothidass Pandithar Hospital, Chennai -47. Patients who was reporting at OPD of Ayothidass Pandithar hospital with inclusion criteria were subjected to screening & documented using screening proforma. As per the patients satisfying the inclusion criteria the pilot study was conducted on Hyperlipidemia (Athimetham) patients. Sample size were 20 patients and were selected by simple random method.

**Inclusion criteria:**

Patients of both sexes of age ranging from 20 - 80 years with an average weight of 45-85 kg with family history of hyperlipidemia and who was already diagnosed as Hyperlipidemia but not taking any system of medication were screened by screening proforma. Diagnosis of Hyperlipidemia was confirmed with any one of the increased levels of Serum total cholesterol (220-400mgs/dl), Serum triglycerides. (170-350mgs/dl), Low density lipoprotein(150-300mgs/dl), Very low density lipoprotein. (50-100mgs/dl). As well as the patients who are willing to provide blood for investigations before and after treatment with willingness to attend OPD once in 7 days were included for the trial.

**Exclusion criteria:**

Patients with Renal failure, Liver disorder, Pregnancy , lactation and any other serious illness were excluded. Patients taking any other medications were excluded and persons having known hypersensitivity to ingredients used in study drug were excluded.

**Conduct of the study:**

Hyperlipidemia patients who were satisfied the inclusion and exclusion criteria were admitted to the clinical trial. Patient’s informed consent was obtained. Routine haematological, urine investigations along

with lipid profile were assessed before and after treatment. Trial drug was issued to them once in 7 days. For every visit they were assessed clinically. On baseline visit, 26 patients were enrolled, who met the inclusion and exclusion criteria. All enrolled subjects were assigned in a single group and were treated with ‘Amukkara Kizhangu Chooranam’ a single herbal formulation in a dose of 2grams with honey twice daily orally after meals for 30 days. Recruited patients were advised to carry on their daily activities, diet and exercises that they had been doing before the enrolment and also advised to continue the same till the end of study period.

**Statistical analysis:**

Consultant statistician performed the analysis of the data using statistical software SPSS 10.0. Data describing quantitative measures were expressed as median or mean ± SD or SE or the mean with range. Qualitative variables were presented as counts and percentage. Comparison of variables representing categorical data was performed using Chi-square test. All P values are reported based on two-sided significance test and all the statistical tests are interpreted at 5% level of significance.

**Results and Discussion**

Athimetham patients who were satisfied the inclusion and exclusion criteria were admitted to the clinical trial. Patients informed consent was obtained. Routine haematological, urine investigations along with lipid profile were assessed before and after treatment. Trial drug was issued to them once in 7 days. Each time they were assessed clinically.

Among 20 patients 45% patients were male 55% were female ( Table 1). Among 20 patients 40% patients were in the age group of 30-45.(Table 2).Among 20 patients 60% patients were in the age group of 45-60.(Table 2)

**Table 1: Gender distribution**

S.no	Gender	No of patients	Percentage
1	Male	9	45%
2	Female	11	55%

Table 2: Age wise distribution

S.no	Age	No of patients	Percentage
1	30-45	8	40%
2	45-60	12	60%

After the treatment with Amukkara Kizhangu Chooranam for 30 days among 20 patients 80% showed decrease in serum total cholesterol, 70% showed decrease in TGL, 45% showed decrease in LDL, 40% showed decrease in VLDL. No adverse effects found during the conduct of study. Some patients showed decreased blood glucose level after the treatment but not significantly.

**Bio-statistics:**

Statistical analysis-paired ‘t’ test, showed “P” value for Serum total Cholesterol is 0.001, LDL is 0.14, VLDL is 0.037 and TGL is 0.002. The results were shown in the (Table 3). So the drug Amukkara kizhangu Chooranam is considered to be statistically significant.

Table 3: Lipid profile for 20 patients before and after treatment.

Sl.no	Variable		Mean	Std. Deviation	t. value	p value
1	S.CHO	BT	245.10	50.004	4.156	.001
		AT	208.75	30.375		
2	HDL	BT	39.05	5.726	-1.650	.115
		AT	40.95	5.916		
3	LDL	BT	129.80	28.050	2.722	.014
		AT	112.35	30.432		
4	VLDL	BT	50.90	15.650	2.244	.037
		AT	45.65	16.429		
5	TGL	BT	268.85	60.796	3.624	.002
		AT	224.40	74.826		

BT-Before treatment, AT- After treatment, S.CHO- Serum cholesterol, HDL- High density lipo protein, LDL-low density lipo protein, VLDL- very low density lipo protein, TGL- Triglycerides.

**Conclusion**

Preclinical evaluation substantiated the textual evidence of this trial medicine. The results for amukkara kizhangu chooranam after 1 month trial period is effective in the management of Hyperlipidemia (Athimetham). Further more it can be evaluated in multicentric trials.

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