CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES
SJIF Impact Factor: 7.187

Avalable online at: http://www.iajps.com *Research Article*

A PILOT STUDY ON THE EFFICACY OF SOOKSHMA ELADI CHOORNAM IN HYPERLIPIDAEMIA

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Article Received: November 2020 **Accepted:**December 2020 **Published:** January 2021

Abstract:

Introduction:*Hyperlipidaemia is an abnormally elevated levels of any or all lipids in the blood. A strong association exists between hyperlipidemia and coronary artery disease (CAD). It also leads to conditions like cerebrovascular stroke, and peripheral vascular diseases. Along with hyperlipidaemia , AIP is also critical marker to evaluate the risk of CAD. Ayurveda enlists numerous drugs which when applied clinically have a very good effect on hridroga. Sookshma eladi choornam which is indicated in hridroga prakrana is selected for the present study to evaluate its effects in hyperlipidaemia and AIP against the controlled drug atorvastatin.*

Objective: *A randomized controlled clinical trial to evaluate the effect of Sookshma eladi choonam[1] in individuals with Hyperlipidaemia.*

Methods: *Ten adults with hyperlipidemia (elevated S cholesterol or Triglycerides or Low density lipoproproteins) or elevated Atherogenic Plasma Index participated in a controlled randomized, open labeled pilot study. Participants were randomly assigned to receive 3 g of Sookshma eladi choornam twice daily (n =5) or Standard drug Atorvastatin (n=5) for 12 wks. The main outcome measures were fasting serum cholesterol,Triglycerides and low-density lipoproteins & AIP. The efficacy outcome was evaluated after 12thwk.*

Results: *Ten participants (n = 5 per group) completed the 12-wk treatment protocol. The control drug was 60% efficacious in controlling the S. cholesterol levels ($p< 0.01$) and the trial drug showed 65% relief ($p< 0.01$). The control drug was 64% efficacious in controlling the TGL levels ($p < 0.01$) and the trial drug showed 72% relief ($p< 0.01$).The control drug was 70% efficacious in controlling the LDL levels ($p< 0.01$) and the trial drug showed 73% relief ($p = 0.01$). The control drug was 89% ($p < 0.01$) efficacious for AIP index and the trial drug showed 93% relief($p < 0.001$).*

Conclusion: *In comparison the trial group has shown much better results when compared to the controlled drug. The overall effect of Sookshma eladi choornam was found to be better in the management of hyperlipidaemia.*

Key words:*Hyperlipidaemia, Atherogenic Plasma Index, Sooskhma eladi choornam, Atorvastatin*

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*Please cite this article in press B. Harinatha Chary et al,**A Pilot Study On The Efficacy Of Sookshma Eladi Choornam In Hyperlipidaemia.,**Indo Am. J. P. Sci, 2021; 08(1).*

INTRODUCTION:

In modern life people are more prone to develop *Santarpana janya vikaras* due to over nutrition and lack of physical exercise. *Medoroga* is one of the diseases of *Santarpanajanya vikaras.* Intake of *sleshmavardhaka aharasevana, madhura rasa anna sevana, divaswapna* and *avyayama* contributes to *Medoroga*. In addition genetic and hereditary factors also play an important role. Hyperlipidaemia can be one of the morbid conditions of *Medoroga* which causes major health hazards. Hyperlipidaemia involves abnormally elevated levels of any or all lipids in the blood.

According to Adult Treatment Panel III (2001)[2] , plasma levels ≥200 mg/dL for TC, ≥150 mg/dL for TG, ≥130 mg/dL for LDL-C, and 40 mg/dL for HDL-C are dyslipidaemicor hyperlipidaemic. It is regarded as a modifiable risk factor for Cardio-vascular diseases due to their influence on athero-sclerosis. A strong association exists between hyperlipidemia and coronary artery disease (CAD). It also leads to conditions like cerebrovascular stroke, and peripheral vascular diseases. The AIP (Atherogenic Index of Plasma) is a critical index which can be used as a stand-alone index for cardiac risk estimation[3]. It is defined as logarithm [log] of the ratio of plasma concentration of Triglycerides to High Density Lipoprotien and is strongly correlated with risk of cardiovascular diseases. The estimated risk of CVD in relation to AIP is according to the values obtained: −0.3 to 0.1 for low risk, 0.1 to 0.24 for medium, and above 0.24 for high risk of CVD[4]. There is a chance of occurrence of atherosclerotic complications with the increased serum lipids levels in the blood. Ayurveda enlists many drugs which are highly efficacious without side effects in treating such conditions. One among such formulations '*Sookshma eladi choornam'* is selected for the present study to evaluate its efficacy in Hyperlipidaemia.

Aims & Objectives:

To study the efficacy of *Sookshma eladi choornam* in the management of Hyperlipidaemia

MATERIALS AND METHODS:

Sources of data:

a . Literary Source: *Ayurvedic*, modern literature and contemporary texts including the journals and internet sources about the disease and drug

b. Pharmaceutical Source : The formulation *Sookshmaeladi choornam*is selected for the present research work purchased from the reputed G.M.P certified pharmacy

c. Clinical Source: Diagnosed patients selected randomly from OPD and IPD of *Kayachikitsa* department, S.V Ayurvedic Hospital, TTD, Tirupati .

Design of the study:

a. No of groups -two groups: Trial & Control

b. No of patients included in the study – five in each group

c. Type of study - Randomizedcontrolled

d. Control drug - Atorvastatin

e. Criteria for the selection of the cases

1. Age group of 30 years to70 years
2. Either gender
3. Obesity (BMI < 50)
4. DM, HTN (Controlled levels)

f. Criteria for exclusion:

1.Genetic causes for hyperlipidaemia
2. Thyroid abnormalities
3. Alcohol intake
4. Liver and renal abnormalities
5. Patients who are on Corticosteroids, Beta-blockers, Oral contraceptives, Diuretics, Cyclosporin, Androgens & Retinoids
6. Any other systemic illness

g. Ingredients, anupana & dose of the trial drug;

i.*Sookshma ela choornam (*Elettaria cardamomum Maton) and *Pippalimoola choornam*(root of Piper longum L) - in equal quantities

ii.Anupana – *Go ghrita* (Cow's ghee)

iii.Dose – 3 grams twice in a day after food

iv.Primary outcome measures: change in plasma lipid levels, AIP (Atherogenic Index of Plasma)

v.Duration of treatment: 3 months

Statistical analysis:

The observed data was subjected to statistical analysis by using Paired t -test in terms of Mean, Standard Deviation (SD), and Standard Error (SE). For intergroup comparison unpaired t-test was used. The results were classified as below basing on the P–value.

1. Insignificant: P> 0.05
2. Significant: P< 0.05
3. Highly Significant: P<0.01, P<0.001, P<0.0001

Observation & Results:

The study had shown that 80% of people belong to the age group of 40 to 60 years. 10% of people belong to 30 to 40 years of age group and 10% of people belong to 60 to 70 years age group (table 1). This study showed that the males (80%) are highly affected with hyperlipidaemia when compared to females (20%) (table 2). The study also showed that

50% of the people belong to *vatakapha prakruti*, 40% of people belong to *vataptta prakruti* and 10% belong to *pitta kapha prakruti* (table 3).

The observations made during the trial period are as follows

Table1. Age wise distribution of patients of hyperlipidaemia

Age group (in years) n=10	No . of patients	Percentage
30 -39	1	10%
40-59	4	40%
50 – 59	4	40%
60-70	1	10%

Table2. Gender wise distribution of patients of hyperlipidaemia

Gender n=10	No . of patients	Percentage
Male	8	80%
Female	2	20%

Table 3. Distribution of Prakruti in patients of hyperlipidaemia

Prakruti n=10	No . of patients	Percentage
Vata Kapha	5	50%
Vata Pitta	4	40%
Pitta Kapha	1	10%

RESULTS:

All the results are calculated by using software GraphPadQuickcals. To calculate the results in each group paired t-test was used. For calculating the inter group comparison unpaired t-test was used.

Table 4.Effect of therapy on Total cholesterol, TGLs, LDL & AIP with Trial drug (paired t test)

S.no	Pareameter	Mean		Mean difference	%of difference	SD		SE	t-value	p-value	Remarks
		BT	AT			BT	AT				
1	Total Cholesterol	440.40	155.60	284.8	65%	79.48	5.18	33.967	8.3847	<0.01	HS
2	TGL	341.00	94.00	247	72%	86.20	14.32	35.903	6.8797	<0.01	HS
3	LDL	340.00	91.20	248.8	73%	89.24	6.14	38.819	6.4092	<0.01	HS
4	AIP	0.66580	0.04980	0.616	93%	0.12040	0.06238	0.045	15.9867	<0.001	HS

Table 5. Effect of therapy on Total cholesterol, TGLs, LDL & AIP with control drug (paired t test)

S.no	Pareameter	Mean		Mean difference	%of difference	SD		SE	t-value	p-value	Remarks
		BT	AT			BT	AT				
1	Total Cholesterol	380.80	151.20	2229.6	60%	131.95	22.93	49.458	4.6424	<0.01	HS
2	TGL	318.60	115.40	203.2	64%	106.26	24.51	50.925	3.9902	<0.01	HS
3	LDL	285.20	86.00	199.2	70%	130.83	18.17	50.543	3.942	<0.01	HS
4	AIP	0.61960	0.06940	0.5502	89%	0.19872	0.09308	0.110	5.0081	<0.01	HS

Table6.Comparison between group A and group B on cholesterol:

Group			Unpaired 't' test			
	n	AT	S.D	t-value	p-value	Remarks
A	5	155.6000	5.1800	0.4185	0.6866	NS
B	5	151.2000	22.9300			

There is no statistically significant difference between the input groups (P =0.6866).

Table 7.Comparison between group A and group B on triglycerides:

Group			Unpaired 't' test			
	n	AT	S.D	t-value	p-value	Remarks
A	5	94.00	14.32	1.6857	0.1303	NS
B	5	115.40	24.51			

There is no statistically significant difference between the input groups (P = 0.1303).

Table 8.Comparison between group A and group B on LDL:

Group			Unpaired 't' test			
	n	AT	S.D	t-value	p-value	Remarks
A	5	91.20	6.14	0.6063	0.5612	NS
B	5	86.00	18.17			

There is no statistically significant difference between the input groups (P = 0.5612).

Table 9. Comparison between group A and group B on AIP:

Group			Unpaired 't' test			
	n	AT	S.D	t-value	p-value	Remarks
A	5	0.04980	0.06238	0.3911	0.7059	NS
B	5	0.06940	0.09308			

There is no statistically significant difference between the input groups (P = 0.7059).

DISCUSSION:

The effect of the trial drug *Sookshma eladi choornam* was highly significant in controlling S. cholesterol, TGL levels, LDL levels and AIP index. The control drug Atorvastatin was also highly significant in controlling S. cholesterol, TGL, LDL levels and AIP index.

The control drug was 60% efficacious in controlling the S. cholesterol levels and the trial drug showed 65% relief. The control drug was 64% efficacious in controlling the TGL levels and the trial drug showed 72% relief.The control drug was 70% efficacious in controlling the LDL levels and the trial drug showed 73% relief. The control drug was 89% efficacious for AIP index and the trial drug showed 93% relief.

Probable mode of action of Trial drug Sookshma eladi choornam:

Sookshma eladi choornam is selected as the trial drug in the present study. It is mentioned in Bhaishaja ratnavali, *Hridroga prakarana.* The ingredients of *Sookshma eladi choornam* are *Sookshma ela, Pippali moola choornam* in the proportion of 1:1. According to the nature of the disease, the drug used for *samana* purpose should have *amahara*, medohara and kapha hara properties. *Sookshma ela*[5] is *katu* and *madhura* in *rasa*, *laghu* and *ruksha* in *guna* with *seeta veerya* and *katu vipaka*. *Pippali moola*[6] is *katu* in rasa, *laghu* and *teekshna* in *guna* with *ushna veerya* and *madhura vipaka*. *Sookshma ela* posesses *deepana, hridya* and *kaphavata hara* properties. *Pippali moola* is *deepana, vata sleshmahara, rechana* and *rasayana* in its actions. Basing on its pharmacodynamic properties the combination of these drugs help in *ama pachana, vatakapha samana* and at the same time also acts as *medohara* and *hridya*. The *medus* involved in *hyperlipidaemia* can be compared to the *abadda medus*[7] which causes *dhamani pratichaya* when vitiated. *Dhamani pratichaya* is the *upalepa* of *dhamanis* with *snigdha guna* of *kapha* and *medus*. This leads to *sroto avarodha* which in turn may lead to *hridrogas.*

The properties of the ingredients of *Sookshma eladi choornam* can act against the pathogenesis of hyperlipidaemia. The *katu rasa, ruksha, ushna* and *teekshna guna* and *ushna veerya* acts as potent *kapha hara* and *medo hara* and thereby reverse the accumulation of *abadda medas* in the *srotas*. Thereby it acts against the pathogenesis of atherosclerosis due to hyperlipidaemia.

Sookshma eladi choornam must be administered along with *goghrita* (*anupana*). When it is taken along with *goghrita* it acts as *yogavahi dravaya*. With its *soumya, slakshna* and *mrudu guna, go ghrita* does not create any gastric irritation. Moreover it is said to be *vatapittakaphapaham* and *rasayanam*[8] .

CONCLUSION:

As per clinical observation and statistics both the trial and control drugs were highly significant in lowering serum cholesterol, TGLs, LDL and AIP index levels. In comparison the trial drug had shown much better results when compared to the controlled drug. The overall effect of *Sookshma eladi choornam* was found to be better in the management of hyperlipidaemia. The trial drug was well tolerated and did not show any complications or adverse reactions during the clinical trial. This study was conducted on a very small sample size and hence, any concrete conclusion may not be drawn from the above results. This research may be a basis for any future researches.

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