Clinical Evaluation of
Safoof-e-Darchini
(*Cinnamomum zeylanicum* Blum.) in
Primary Hyperlipidaemia

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A single blind standard controlled study was designed to evaluate the efficacy of *Safoof-e-Darchini* in the management of Primary Hyperlipidaemia. The study was conducted at ZVM College Pune. Before starting study ethical clearance was obtained from Ethical Committee. Sixty diagnosed patients were selected on the basis of inclusion criterion. Patients were randomly divided into two groups 'A' and 'B' comprising 30 patients in each group. In group 'A' test drug was given in a dose of 3 gram twice a day whereas in group 'B' standard drug Atorvastatin 20 mg was given once a day for the period of 60 days. Assessment of efficacy was done on the basis of objective parameters. In this study both test and control group exhibited significant hypolipidaemic activity (P<0.001).

Keywords: Antihyperlipidaemic activity, Primary Hyperlipidaemia, *Safoof-e-Darchini.*

Introduction

Hyperlipidaemia is a highly atherogenic lipid metabolic disorder characterized by abnormally elevated levels of circulating total cholesterol and/or triglycerides in the blood. When there is elevation in both of cholesterol and triglycerides, it is known as combined hyperlipidaemia (CHL).

It is also known as Hyperlipoproteinemia or Dyslipidemia. It results either from increase in synthesis or decrease in degradation of lipoproteins, which transport cholesterol and triglycerides. The predisposing factors of hyperlipidaemia are obesity, a high-fat diet, lack of exercise, family history of hyperlipidaemia, smoking, alcohol and use of drugs containing hormones. Hyperlipidaemia plays major role in the etiopathogenesis of atherosclerosis which is responsible for several vascular complications like Ischaemic Heart diseases (IHD), Cerebro-vascular accidents (CVA) and increased blood pressure[1-8].

In Unani system of medicine, there is no such description of hyperlipidaemia found, but Hippocrates[10], Rofas[11-12], Galen[10], Razes[13] and Avicenna[14] described that the obesity (*Saman-e-mufrat*) develops as a result of excessive phlegm (*Khilt-e-Balgham*). Abu Sahal Maseehi had given the concept of *dosoomat-e-khoon* (oily substance of blood)[9]. Their observation of etiological factors, presentation, complications, patho-physiology is in close resemblance to the presentation of hyperlipidaemia. The ancient scholars also concluded that obesity is a predisposing factor of paralysis, stroke, narrowing of blood vessels, hemorrhage and sudden death etc.[10, 12-14].

Now it is expected that hyperlipidaemia will become the world's leading cause of all deaths till 2020 (33% of all mortality)[15], but the data of World Health Organization showing that IHD had already become the prime cause of death in 2004 and CVA stands second, with mortality about 39.6% and 27.9% of all deaths respectively (total 67.5% of all deaths, approximately 13.14 million)[16-17]. Therefore, scientists are focusing themselves to develop some preventive intervention with the aim to reduce the complications of such life threatening condition.

The corner stone of cholesterol reduction is lifestyle modification, dietary interventions and pharmacological interventions[1-8]. But most of the lipid lowering drugs known to cause intolerable adverse effect, not only this, there is also a possibility of hypolipoproteinemia[18-19]. Furthermore, some of these drugs are beyond the buying capacity of low socio-economical status peoples and are even contraindicated in some combination. Hence, there is a need to a search a drug which is effective, safe, cost effective and should be freely available.

In the Unani system of medicine, there is a description of a number of effective drugs and formulations for the management of obesity such as *Bisfaij* (*polypodium vulgare* Linn.), *Zaranbad* (*Zingiber zerumbet*), *Rasaut* (*Berberis arista*), *Muquil* (*Commiphora mukul*), *Magaz-e-Tukhm-e-Neem* (*Azadirachata indica*) and *Safoof-e-Darchini* etc.[13].

Selection of test drug *Safoof-e-Darchini* (*Cinnamomum zeylanicum* Blum.) is supported by classical Unani and Scientific literatures. Classical literature claims that it possesses *Mullattif, Muffateh,*

Mohallil-e-Mawad-e-Barida, Munzij-e-Ufoonat-e-Akhalat, Mujaffif-e-Ratubaat-e-Dimag, Mufareh wa Muqavi-e-qalb-wa-dimag, Dafa-e-Khafqan, Dafa-e-Ratubat Lajija and *Mufatteh Sudda-e-Jigaproperties*[20-21]. Hippocrates observed that it normalizes the viscosity of all humours and useful in paralysis and facial palsy also[22]. In some experimental and clinical studies, it has shown hypolipidaemic property in the patients of DM I and II[23-41]. *Darchini* also possess lipolytic, antihypertensive and anti-oxidant properties[42-44]. Therefore, the selection of the test drug seems to be rational. *Safoof-e-Darchini* probably acts either by reducing absorption or increasing utilization of cholesterol in body by metabolism[13]. Further, these drugs have been reported to possess triglycerides reducing properties in experimental trials.

Materials and Methods

The present study entitled "Clinical Evaluation of *Safoof-e-Darchini* (*Cinnamomum zeylanicum* Blum.) in Primary Hyperlipidaemia" has been carried out in the P.G. Department of Moalajat, ZVM College, Pune, after approval of ethical committee, during the period of March 2008 to September 2010. After detail history and examination patient were subjected for laboratory investigations. The Patients fulfilling inclusion criterion were selected for the study. Total 60 patients of either gender between the age group of 40-80 years were randomly allotted for the study in to two groups Group "A" and Group "B". Group "A" received test drug *Safoof-e-Darchini* 03 gm twice a day while group "B" received standard drug Atorvastatin 20 mg one tablet at bed time for the period of 2 months. The assessment of subjective and objective parameters was carried out on 0, 30th, and 60th days. After completion of the study, the data was subjected to statistical analysis. The statistical analysis of data was done with the help of computer designed software "GraphPad InStat. Test of significance was calculated by using paired and unpaired "t" test.

Inclusion Criteria

1. Both male and female patients belonging between 40-80 years of age group
2. Patients with Primary hyperlipidaemia (Serum Cholesterol> 200 mg/dl, Triglycerides>160 mg/dl, LDL>130 mg/dl, VLDL> 30 mg/dl)
3. Those Patients whose SGOT, SGPT Alkaline Phosphate, Serum Creatinine, Serum Amylase, Blood Urea, Blood Sugar (F), and TSH were found within normal limits
4. Patients not taking any antihyperlipidaemic drug

Exclusion Criteria

1. Secondary Hyperlipidaemia.
2. Any systemic diseases like Diabetes mellitus, Coronary heart disease, Chronic renal disease, Malignancies, Tuberculosis.
3. Mentally retarded patient.
4. Pregnant women and children

Withdrawal Criteria

1. Any serious adverse effect.
2. If the patient is not taking medicine as per the schedule explained to him/her and the lost of follow up.

Study Design: Open label randomized Standard-controlled Clinical study.

Sample Size: Sixty patients (30 patients in each group allotted randomly by Lottery method).

Subjective Parameters

1. Palpitation
2. Dyspnoea on Exertion
3. Chest pain/Heaviness
4. Joints pain
5. Xanthalesma

Objective Parameters

1. Serum Cholesterol
2. Serum Triglyceride
3. HDL Cholesterol
4. LDL Cholesterol
5. Body Weight
6. WHR

Standard drug: *Safoof-e-Darchini.*

Method of Preparation

Test drug was purchased from authentic sources from Pune Market. The crude drugs were identified by chief Pharmacist of College,

on the basis of colour, smell, taste and weight. After proper identification, the drugs were cleaned from impurities and grinded well. After sieving process *Safoof (*powder) was formed.

Observation and Results

In this, study out of sixty patients of Hyperlipidaemia, 24 patients were 40-50 years of age, 16 patients were 51-60 years of age, 17 patients were 61-70 years of age, 02 patients were 71-80 years of age and 01 patient was >81 years of age group. The highest prevalence was found in 4th decade. The percentage of male patients is 58.3% which was slightly higher than female patients i.e. 41.6%. All the demographic data of patients in both test and control groups are shown in Table 1.

TABLE 1
Demographic Data of Patients in
Test and Placebo group n=60

	N	Fp%		N	Fp%
Age group			*Mizaj*		
40-50	24	40.0%	*Balghami*	49	81.67%
51-60	16	26.6%	*Damvi*	11	18.33%
61-70	17	28.3%	*Safravi*	0	0%
71-80	02	3.3%	*Saudavi*	0	0%
>80	01	1.6%			
Smoker			**Alcohol intake**		
Positive	41	68.33%	Alcoholic	28	46.67%
Negative	19	31.67%	Non alcoholic	32	53.33%
Anxiety			**Dietary habit**		
Positive	49	81.67%	Vegetarian	13	21.67%
Negative	11	18.33%	Mixed diet	47	78.33%
BMI					
Normal (18.5-25)	01	1.67%			
Overweight (25-30)	29	48.33%			
Obese Class I (30-35)	18	30.0%			
Obese Class II (35-40)	09	15.0%			
Obese Class III (>40)	03	5.0%			

The effect of test drug on objective parameters i.e., Lipid profile (Serum Cholesterol, Serum Triglyceride, HDL, LDL, VLDL), Body Weight and WHR are as follows:

Effect on Serum Cholesterol

In test group mean serum cholesterol level was 221.27±12.5 mg/dl before treatment and at the end of study it was 177.73±12.9 mg/dl, showing mean reduction was 43.54±0.4 mg/dl and which was found to be significant (P<0.001) (Table 2).

In standard group mean serum cholesterol level was 310.57±46.2 mg/dl before treatment and at the end of study it was 201.1±23.1 mg/dl, showing mean reduction was 109.47±23.1 mg/dl and which was found to be significant (P<0.001) (Table 2).

Effect on Serum Triglyceride

In test group mean serum triglyceride level was 189.43±38.75 mg/dl before treatment and at the end of study it was 114.73±10.52 mg/dl, showing mean reduction was 74.70±28.23 mg/dl and which was found to be significant (P<0.001) (Table 2).

In standard group mean serum triglyceride level was 281.43±77.33 mg/dl before treatment and at the end of study it was 148.53±19.25 mg/dl, showing mean reduction was 132.90±58.08 mg/dl and which was found to be significant (P<0.001) (Table 2).

Effect on High Density Lipoprotein

In test group mean High Density Lipoprotein (HDL) level was 49.8±9.25 mg/dl before treatment and at the end of study it was 51.5±5.99 mg/dl, showing mean reduction was 1.7±3.26 mg/dl and which was found to be significant (P>0.10) (Table 2).

In standard group mean High Density Lipoprotein (HDL) level was 51.5±8.21 mg/dl before treatment and at the end of study it was 56.6±3.11 mg/dl, showing mean reduction was 5.10±5.10 mg/dl and which was found to be significant (P>0.10) (Table 2).

Effect on Low Density Lipoprotein

In test group mean Low Density Lipoprotein (LDL) level was 133.58±17.04 mg/dl before treatment and at the end of study it was 102.8±12.85 mg/dl, showing mean reduction was 30.78±4.46 mg/dl and which was found to be significant (P<0.001) (Table 2).

TABLE 2
**Various Changes of Objective Parameters in
Test and Placebo Group n=60**

S.No.	Parameter	Group-A			Group-B		
		Before treatment (Base line)	After 60 days	P-Value	Before treatment (Base line)	After 60 days	P-Value
1.	Serum Cholesterol	221.27±12.5	177.73±12.9	<0.001	310.57±46.2	201.1±23.1	<0.001
2.	Triglyceride	189.43±38.75	114.73±10.52	<0.001	281.43±77.33	148.53±19.25	<0.001
3.	HDL	49.8±9.25	51.5±5.99	>0.10	51.5±8.21	56.6±3.11	<0.001
4.	LDL	133.58±17.04	102.8±12.85	<0.001	202.78±47.2	116.26±22.61	<0.001
5.	Body weight	90.173±4.75	83.4±4.44	<0.001	85.56±6.64	81.57±6.25	<0.0199
6.	WHR	1.031±0.044	0.94±0.044	<0.001	1.0434±0.033	1.007±0.034	<0.001

In standard group mean Low Density Lipoprotein (LDL) level was 202.78±47.2 mg/dl before treatment and at the end of study it was 116.26±22.61 mg/dl, showing mean reduction was 86.52±24.59 mg/dl and which was found to be significant (P<0.001) (Table 2).

Effect on Body Weight

In test group mean Body weight level was 90.173±4.75 kg before treatment and at the end of study it was 83.4±4.44 kg, showing mean reduction was 6.77±0.31 kg and which was found to be significant (P<0.001) (Table 2).

In standard group mean Body weight level was 85.56±6.64 kg before treatment and at the end of study it was 81.57±6.25 kg, showing mean reduction was 3.99±0.39 kg and which was found to be significant (P<0.0199) (Table 2).

Effect on Waist Hip Ratio

In test group mean Waist Hip Ratio (WHR) level was 1.031±0.044 before treatment and at the end of study it was 0.94±0.044, showing mean reduction was 0.09±0.00 and which was found to be significant (P<0.001) (Table 2).

In standard group mean Waist Hip Ratio (WHR) level was 1.0434±0.033 before treatment and at the end of study it was 1.007±0.034 showing mean reduction was 0.036±0.001 and which was found to be significant (P<0.001) (Table 2).

Discussion

Hyperlipidaemia is considered as a major risk factor for genesis of atherosclerosis. It is a major public health problem throughout the world which is responsible for several dreadful complications such as MI, Angina pectoris and hypertension etc. Presently, hypolipidaemic drugs are being used for the prevention of atherosclerosis. But the currently available treatments have many adverse effects and relatively expensive. Therefore, search of safe and cost effective drug is quite necessary. In order to meet growing need of Hypolipidaemic drug, the efficacy of *Safoof-e-Darchini* was evaluated on scientific parameters. Administration of *Safoof-e-Darchini* exhibited significant Hypolipidaemic effect without demonstrating any side effects in the patients of primary hyperlipidaemia. These effects might be due to pharmacological properties of test drug. As *Darchini* possess diverse pharmacological action such as anti obesity, lipolytic, antioxidant and diuretic properties. These results are also in

accordance with the findings of who reported that administration of extract of *Darchini* exhibited hypolipidaemic effect in patients of Type-1 Diabetes Mellitus in experimental studies.[44] Numerous other studies also validate the findings of this study. Moreover, dietary restriction and increased physical activities may also reduce the body weight and thereby produce significant Hypolipidaemic effects in the patients of Hyperlipidaemia. Hence the test drug can be safely used for the management of Hyperlipidaemia.

Conclusion

The result of present clinical trial demonstrates that test drug *Safoof-e-Darchini* is effective for the management of Hyperlipidaemia by reducing serum cholesterol, serum triglyceride, LDL, VLDL and increasing HDL level without producing any adverse effect. Therefore, it can be concluded that the test drugs possess significant hypolipidaemic effect and can be safely used for the remedy of hyperlipidaemia. Although, the test formulation is found effective in preliminary study but a long term study on larger number of patients is recommended to explore the hidden potential of test formulation.

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