

CLINICAL EVALUATION OF TAB. CHOLESTROLCARE IN PATIENTS OF DYSLIPIDEMIA

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ABSTRACT

Dyslipidemia is globally recognised as serious health related problems and play significant role in the pathophysiology of coronary heart disease (CHD) and atherosclerotic cardiovascular disease. Improper dietary habits and sedentary lifestyle in day to day life play an important role in the diathesis of dyslipidemia. In this regard, *Ayurvedic* texts have vividly described majority of over nutritional disorders and its related problems with a highly evolved manner. In spite of lipid lowering agents, now scholars of biomedical science believes that lifestyle modification impart vital role in its management. At present, specific line of management has not been fully clarified in modern medicine. This study reveals to observe the efficacy and safety of a Polyherbal Ayurvedic formulation Tab. CHOLESTROLCARE manufactured by BACFO Pharmaceuticals (India) Ltd, in patients of dyslipidemia.

A total of 55 dyslipidemic patients of either sex were enrolled during the period January 2012 to July 2012, out of which 8 patients were dropped out from the study. The patients were followed for a period of 3 months with monthly follow ups. The reduction in serum cholesterol (p=0.000), LDL (P=0.000) and TGL (p<0.002) is found statistically significant. Besides, increase trend of serum HDL and reduced trend of VLDL were noted at the end of therapy. There was good compliance to the treatment and no adverse effects were observed during the trial period.

KEYWORDS: Dyslipidemia, Medoroga, Metabolic Syndrome, Obesity

INTRODUCTION

Dyslipidaemia is characterized by increased flux of serum free fatty acids, raised TG, low high density lipoprotein (HDL), increased low density lipoprotein (LDL), and raised apolipoprotein (apo) B levels. It is an independent risk factor for cardiovascular disease¹. Low HDL cholesterol and raised TG levels have been directly related to myocardial infarction/stroke. If serum LDL and TG exceeds beyond the normal range, then it causes abundance of circulating free fatty acids in the blood stream. These free fatty acids occupy the insulin receptors that may lead to insulin resistance and finally leads to hyperglycaemia and other metabolic disturbances^{2,3,4,5}. Beside this LDL ("bad" cholesterol) imparts atherosclerosis in the arteriole. HDL ("good" cholesterol) helps to remove harmful cholesterol from the blood, prevents the fatty build up and formation of plaques⁶.

Obesity and Lipid disorders have been vividly conceived in Ayurveda in the context of *Medoroga* and *Prameha*⁷. The classical Ayurvedic texts have described *Santarpanjanya Vikaras*, which comprise of diseases due to over nutrition and defective tissue metabolism. *Ayurveda* is very much concerned about conservation of health rather than eradication of disease. It presumes that improper dietary habits and deranged functions of different sets of *Agni* may leads to the formation of *Ama* (reactive antigenic factor). When *Meda dhatu* interacts with preformed form of *Ama*, it alters the quality and quality of fatty tissues including cholesterol. The interaction of *Ama* with fatty tissues is known as *Sama Meda dhatu*,

which is the main cause of dyslipidemia. This form of *Ama*, when circulates all over the body may lead to blockage of micro-channels and generate series of inflammatory events in the body that may lead to variety of metabolic disorders^{8,9,10}.

The available modern treatment modalities for dyslipidemia and dyslipidemic disorders includes Lipid lowering drugs, Hypoglycemic drugs etc. No doubt these treatment modalities are effective but in due course of time there requirements gradually increased and it is always associated with various side effects¹¹. In this perspective we have selected 'CHOLESTROLCARE Tablet' to observe its clinical efficacy and safety in patients of dyslipidemia¹².

Aims and Objectives

The present study aims to evaluate the clinical efficacy and safety of the Ayurvedic formulation Tab. CHOLESTROLCARE in cases of Dyslipidemia.

MATERIALS AND METHODS

The trial drug was procured from BACFO Pharmaceuticals (India) Ltd. This study was an open clinical observation of Tab. CHOLESTROLCARE in cases of dyslipidemia. The patients were selected from OPD and IPD of Kayachikitsa, S.S. Hospital, IMS, BHU, Varanasi, for a period of three months.

Inclusion Criteria

- Patients of either sex in the age group of 30 to 60 yrs.
- Fall in the weight range of 50 to 100 kgs.
- Patients with total serum cholesterol in between 200-300 mg/dl, Triglycerides 300- 400 mg/dl, HDL, 30- 40 mg/dl, LDL- 90- 150 mg/dl and VLDL- 100- 130 mg/dl.
- Patients with minimally deranged serum lipids and having raised FBS (>100mg/dl).
- Patients fulfilling the criteria of metabolic syndrome.

Exclusion Criteria

- Patients of either sex in the age group of <30 and >60 yrs.
- In weight range of < 50 kgs and >100 Kgs.
- Patient who did not fulfil the inclusion criteria of lipid profile and FBS
- Suffering from active autoimmune disorders and hypo or hyperthyroidism.
- Having rare form of inborn error dyslipidemia.
- Patients with established renal, hepatic or cardiac failure.

Study Procedure, Dosing Schedule and Duration of Treatment

55 patients were selected for the study and they were properly interrogated, thoroughly examined and investigated. After clinical and laboratory examination patients were registered for the study. Out of 55 patients, 8 patients dropped and rest 47 patients turned up for full fallow up.

All the diagnosed patients were put on CHOLESTROLCARE in the dose of 2 tablets twice daily with luke warm water 30 minutes after meal for a period of three months and fallow up at one month interval. During the course of treatment other *Ayurvedic* and modern medicines were withdrawn and no additional lifestyle interventions were enforced. The patients were treated as above for full trial period.

Composition of CHOLESTROLCARE Tab

Each 500mg tablet contains

Arjuna (Terminalia Arjuna) -350mg

Rasona (Allium sativum) -150mg

It was processed in the extract of Amalaki, Mustak and Amrita^{13,14,15}.

Criteria for Assessment of Therapeutic Response

- Lipid profile
- Blood sugar fasting and postprandial.
- Body Weight range

Overall Assessment

The overall effect of the trial drug was assessed by the significant change in the Lipid profile before and after treatment. The results are presented into four categories as given below.

- Marked improvement
- Moderate improvement
- Mild improvement
- No improvement

Statistical Analysis

Statistical analysis was done according to the intention-to-treat principles. Changes in various parameters from baseline values after the 3rd month were evaluated by paired 't' test. The minimum level of significance was fixed at 95% confidence limit and a 2-sided p value of <0.05 was considered significant.

Observation and Results

In the present study, 55 patients were enrolled, 47 patients turned up for full course of treatment and 8 patients dropped out from the study. The observations made in this study are as follows:

Maximum number of patients i.e. 51.06% was from the age group of 31 to 50 years with 76.59% female and were housewives (57.44%) having no history of addiction (74.47%). Most of them fell under weight range between 75 to 100 Kg (50.91%). 54.54% patients had negative family history of endocrine disorders and most of them (62.27%) had negative history of other associated endocrine disorders. Besides this in this series it was also observed that most of the patients (70.91%) had no treatment history of lipid lowering agents. (Table 1 to 4)

Effect of Trial Treatment on Body Weight

The initial mean \pm SD of body weight was 75.49 \pm 11.33 which is reduced to 75.09 \pm 10.92 after three months of trial treatment. The mean change of body weight after 3 months of therapy was 0.404 (0.5%) which is clinically not significant. Within the group comparison it also was statistically not significant (p=0.06).

Effect of Tab. CHOLESTROLCARE on Laboratory Parameters

On serum total cholesterol, 17.05% patients had marked improvement, 34.04% moderate improvement and 36.17% patients had mild improvement, while in 12.76% patients had no significant improvement at the end of trial

treatment. The mean reduction of serum cholesterol was 19.94 (93.18%) after three months of trial treatment. Within the group comparison it was statistically highly significant (p=0.000).

In case of serum TGL, 10.64% patient had marked improvement, 25.54% patients showed moderate improvement and mild improvement was observed in 31.91% patients. No improvement was observed in 31.91% patients after trial treatment. The mean reduction of serum TGL was 14.43 (83.34%) after three months of therapy. Within the group comparison it was statistically highly significant (p=0.002).

On serum HDL, no patients patient were fell in the category of marked improvement, 12.76% patients had moderate improvement, 48.94% patients showed mild improvement, and 38.91% patients have no improvement after trial treatment. The mean increase of serum HDL was -0.597 (14.13%) after three months of treatment. Within the group comparison it was statistically insignificant (p=0.611).

On serum LDL, 8.51% patients had marked improvement, 24.79% patients had moderate improvement and 51.06% have mild improvement. In 10.64% patients there was no improvement at end of therapy. The mean reduction of serum LDL was 17.53 (14.57%) after three months of treatment. Within the group comparison it was statistically highly significant (p=0.000).

On serum VLDL, 6.39% patients had marked improvement, 12.70% patients had moderate improvement and 29.79% have mild improvement. However, 51.06% patients have no improvement at end of therapy. The mean reduction of serum VLDL was 1.83 (4.04%) after three months of treatment. Within the group comparison it was statistically not significant (p=0.288).Clinically and statistically insignificant changes were observed in the haematological parameters like Hb, TLC and ESR as well as in some of the biochemical parameters like FBS and PPBS. The safety profile of 47 patients in terms of LFT and RFT changes were statistically not significant. (Table no. 5 & 6)

Effect of Tab. CHOLESTROLCARE on Lipid Profile in Body Weight Range Groups

Attempts were made to divided 47 patients into two groups viz - Group 1^{st} patients having body weight between 50 to 75 Kgs and Group 2^{nd} patients having bodyweight between 76 to 100 Kgs. In Group 1^{st} highly significant changes (p=0.000) were observed in serum Total Cholesterol, Triglyceride and LDL. While in the HDL and VLDL the changes were statistically not significant after trial treatment. In group 2^{nd} except HDL the mean reduction was noted in all component of lipid profile but greater reduction was observed in serum LDL, which was statistically highly significant (p=0.000). The mean reduction of serum HDL was negative which goes in favour of group 1^{st} . The greater negativity indicates the response of trial treatment in terms of good cholesterol. (Table no. 7)

Table 1: Incidence of Body Weight (n=55)

Incidence of Body Weight Range	No. of Patients	Percentage
>50 to 75 Kg	27	49.09%
>75 to 100 Kg	28	50.91%
Total	55	100%

Table 2: Incidence of Family History of Endocrine Disease (n=55)

Incidence of F/H of Endocrine Disease	No. of Patients	Percentage of Patients
Positive	25	45.45%
Negative	30	54.54%
Total	55	100%

Incidence of T/H of Other Endocrine Disease	No. of Patients	Percentage of Patients
Positive	18	32.73%
Negative	37	67.27%
Total	55	100%

 Table 3: Incidence of Other Endocrine Disorders in the Patients (n=55)

Table 4: Incidence of Treatment History of Lipid Lowering Agents (n= 55)

Incidence of Treatment with Lipid Lowering Agents	No. of Patients	Percentage of Patients
Yes	16	29.09%
No	39	70.91%
Total	55	100%

Table 5: Change in the Body Weight & Laboratory Parameters before and after Treatment (N=47)

Lah	Mean±SD (n) of Score		Within the Group
Parameters	BT	AT	Comparison Paired "t" Test
Body Weight	75.49 ± 11.335	75.09 ± 10.92	0.404 (0.5%) ±1.439
	(n=47)	(n=47)	t=1.925, p=0.06 NS
Hb in gm%	11.676 ± 1.022	11.797 ± 0.815	-0.121 ± 0.6715
	(n=47)	(n=47)	t= -1.111, p=0.274 NS
Blood TLC	6805.13±1686.94	6612.82 ±1881.51	192.31 ±1559.42
	(n=47)	(n=47)	t=0.770, p=0.446 NS
FBS	101.35 ±24.22	102.37 ±19.57	-1.026 ±11.224
	(n=47)	(n=47)	t=-0.620, p=0.538 NS
PPBS	150.07 ±45.184	149.33 ±40.591	0.744 ±24.903
	(n=47)	(n=47)	t=0.196, p=0.846 NS
Serum T.	213.96 ±57.891	194.02 ±48.594	19.936 (93.18%) ±27.053
Cholesterol	(n=47)	(n=47)	t=5.052, p=0.000 HS
Serum TGL	173.09 ±55.389	158.66 ±39.85	14.426 (83.34%) ±30.022
	(n=47)	(n=47)	t=3.294, p=0.002 S
Serum HDL	42.17 ±9.94	42.77 ±12.32	-0.596 (-14.13%) ±7.983
	(n=47)	(n=47)	t= 0.512, p=0.611 NS
Serum LDL	120.32 ±49.381	102.79 ±45.03	17.532 (14.57%) ±17.637
	(n=47)	(n=47)	t=6.815, p=0.000 HS
Serum VLDL	45.23 ±30.965	43.40 ±24.577	1.830 (4.04%) ±11.664
	(n=47)	(n=47)	t=1.075, p=0.288 NS
Body Weight	75.49 ±11.335	75.09 ±10.92	0.404 (0.5%) ±1.439
	(n=47)	(n=47)	t=1.925, p=0.06 NS

Table 6: Overall Assessment of Improvement in Patients of Dyslipidemia (n=47)

Variable	Patients & % of No Improvement (n=47)	Patients & % of Mild Improvement (n=47)	Patients & % of Moderate Improvement (n=47)	Patients & % of Marked Improvement (n=47)
Sr. T. Cholesterol	6 (12.76%)	17 (36.17%)	16 (34.04%)	8 (17.03%)
Sr.TGL	15 (31.91%)	15 (31.91%)	12 (25.54%)	5 (10.64%)
Sr. HDL	18 (38.30%)	23 (48.94%)	6 (12.76%)	0%
Sr. LDL	5 (10.64%)	24 (51.06%)	14 (29.79%)	4 (8.51%)
Sr. VLDL	24 (51.06%)	14 (29.79%)	6 (12.76%)	3 (6.39%)

Variable	Sr. T. Cholester Terms	Within the Group Comparison Paired	
	BT	AT	"t" Test
Group 1 st	228.13 ± 65.68	203.74 ±58.79	24.39 ±27.35 t= 4.28, p=0.000 HS
Group 2 nd	200.38 ±46.72	184.71 ±35.10	15.67 ±26.69 t=2.88, p>0.005NS
Variable	Sr. TGL (Mean±SD) in Terms of mg/dl		Within the Group Comparison Paired "t" Test
Group 1 st	180.30 ± 47.13	158.96 ±32.52	21.35 ±26.17 t= 3.91, p=0.001HS
Group 2 nd	166.17 ±62.52	158.38 ±46.52	7.79 ±32.46 t=1.18, p>0.005 NS
Variable	Sr. HDL (Mean±SD) in Terms of mg/dl		Within the Group Comparison Paired "t" Test
Group 1 st	40.52 ± 10.58	41.61 ±12.83	-1.09 ±8.90 t= 0.59, p>0.05 NS
Group 2 nd	43.75 ±9.23	43.87 ±11.98	-0.12 ±7.15 t=0.86, p>0.005 NS
Variable	Sr. LDL (Mean±SD) in Terms of mg/dl		Within the Group Comparison Paired "t" Test
Group 1 st	129.35 ± 61.21	113.91 ±55.98	15.43 ±14.43 t= 5.13, p=0.000 HS
Group 2 nd	111.67 ±33.67	92.12 ±28.55	19.54 ±20.35 t=4.703, p=0.000 HS
Variable	Sr. VLDL (Mean±SD) in Terms of mg/dl		Within Group the Comparison Paired "t" Test
Group 1 st	51.57 ± 39.21	48.65 ±32.14	2.91 ±13.31 t= 1.05, p>0.05 NS
Group 2 nd	39.17 ±19.18	38.38 ±12.89	0.79 ±10.02 t=0.39, p>0.05 NS

Table 7: Effect of Tab. CHOLESTROLCARE on Lipid Profile in between Two Weight Range Groups

(*Group 1^{st} was under weight range of 50-75 kgs (n=22) and Group 2^{nd} was under weight range of 76-100 kgs (n=25))

DISCUSSIONS

Dyslipidemia is a term used for deranged and imbalanced lipid level in the body which on long term leads to various metabolic dysfunction like Atherosclerosis, MI, Hyperglycemias, Insulin resistance and other chronic inflammatory conditions in the body. Dyslipidemia, Central obesity, Hyperglycaemia and Hypertension, together constitutes a syndrome known as Metabolic Syndrome (MS)^{16,17}. The treatment modalities for such types of disorders include Lifestyles interventions (including exercise and weight control), Lipid lowering drugs, hypoglycaemic drugs and Antihypertensive drugs. In this regard *Ayurvedic herbal* and herbo-mineral formulations have been claimed to be more effective and safer in comparison to conventional drugs for long term use.

Laboratory profile suggests that Body weight, Hb, ESR, TLC, RFT and LFT level fluctuated within the range. The present study also reveals that the trail drugs have no response in FBS and PPBS. The reduction in serum cholesterol (p=0.000), LDL (P=0.000) and TGL (p<0.002) is found statistically significant. While there is no significant improvement

Clinical Evaluation of TAB. Cholestrolcare in Patients of Dyslipidemia

noted in HDL and VLDL at the end of therapy. The negativity of HDL level at the end of therapy shows increasing trend of HDL after therapy¹⁸. It is quite interesting to note that reduction of body weight in patients of dyslipidemia was clinically and statistically not significant. This indicates that reduction of body weight is not directly related to reduction of serum cholesterol, TG, LDL and VLDL level. In clinical setting most of the time it is also observed that some of the grossly obese patients have normal range of lipid profile in spite of abnormal. This signifies that there are two form of dyslipidemia one is obesity dependent and other obesity independent.

Besides this an attempts is made to find out the effect of trial treatment in patients of two body weight range groups i.e Group 1st and Group 2nd. In Group 1st the trial drug response is good in terms of serum cholesterol, TG, and LDL. While in Group 2nd the significant reduction is observed only in LDL level and rest other lipid variables shows no significant improvement at the end of therapy. HDL is increased more in group 1st i.e weight range of 50 to 75 kgs. This reflects that CHOLESTROLCARE is not only reduces bad cholesterol but it also improves good cholesterol in the body. That is why it reduces the risk of complications in dyslipidemic patients¹⁹.

Besides this, no unwanted effect were observed in case of liver function test and renal functions tests and other haematological parameters before and after trial treatment. It reveals that trail drug is safe as regards the Renal, Liver and Cardiac functions.

Probable Mode of Action of Tab. CHOLESTROLCARE

The primary constituent of CHOLESTROLCARE tablet is *Arjuna* (*Terminalia Arjuna*), which contains *Kashaya rasa* and *Sheeta virya* in potency. It is *Kapha shamaka* due to *Kashaya rasa* hence used in *Medo roga*. Principal constituents of *Arjuna* are B-sitosterol, ellagicacid and Arjunin acid. The bark possesses diuretic and prostaglandin enhancing and coronary risk factor modulating properties. It reduces the level of triglycerides and cholesterol and enhances the synthesis of LDL-apoprotein which inhibits the oxidation of LDL and accelerates the turnover of LDL-Cholesterol in the liver^{20,21,22,23}. The recent studies demonstrate the lipid lowering and antioxidant activities in extract of *A. sativum*, which could help in prevention of cardiovascular diseases, particularly atherosclerosis. Hence, it is useful in dyslipidemia and other lipids disorders^{24,25,26}. *Amalaki (Emblica officinalis)* fruit powder is used to cleanse and nourish the bodily tissues. It is a natural antioxidant with the richest source of Vitamin C. It has *Tridoshahara* effect and considered as a *Rasayana* in *Ayurveda*. It possesses anti-inflammatory, dyslipidemic and atherosclerotic properties^{27,28,29}. *Amrita (Tinospora Cordifolia)* is also considered as *Rasayana* to improve the immune mechanism and protect body against infection³⁰. Recent studies suggest that *Mustaka (Cyperus rotundus)* has hepatoprotective action against carbon tetrachloride induced liver damage^{31,32}. Hence it may also helpful in cases of dyslipidemia too.

CONCLUSIONS

The present study reveals that the trial drug Tab. CHOLESTROLCARE seems to be a good combination of herbal drugs having *Hridya* (cardiotonic), *Medohara* (anti-obesity), *Shothahara* (anti-inflammatory), *Rasayana* (anti-ageing) and *Valya* (immuno enhancing) effects. It possesses all the desired qualities which pacify abnormal *Meda* and vitiated *Ama Dosha*. By virtue of these properties it works as disease modifying agent and is helpful in the management of Dyslipidemia. No adverse effects were observed during the full course of treatment. CHOLESTROLCARE is not only moderately effective and safe medicine in the management of Dyslipidemia but it also improves the state of wellness of the patient.

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