



Research Article

## EVALUATION OF ANTIHYPERLIPIDAEMIC AND CARDIOPROTECTIVE ACTION OF A HERBAL FORMULATION

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### ABSTRACT

As per WHO, Cardiovascular Diseases (CVDs) are the leading cause of death globally. CVDs also impart a huge financial burden and remain a hurdle for sustainable development in low and middle income countries. Hence there is an urgent need to identify individuals with high CVD risk and begin appropriate preventive intervention well in advance. In this study, 60 individuals of either sex, within the age group of 30 – 70 years, having hyperlipidaemia along with more than 10% of CVD risk were identified in lipid screening camps with the help of JBS 3 Heart Risk android application tool. A combination of three well known herbs in capsule form containing 500mg extract of *Guggulu* (*Commiphora mukul*), *Pushkarmool* (*Inula racemosa*) and *Arjuna* (*Terminalia arjuna*) in equal proportion was administered in a dose of 1 capsule twice daily after food with warm water for 3 months to treat hyperlipidaemia. Only 55 participants completed the trial. Different parameters of lipid profile, CVD risk score and biological heart age were compared before and after treatment using appropriate statistical method. The intervention resulted in reduction of total cholesterol by 17.49%, LDL by 21.04%, VLDL by 24.55% and Triglycerides by 24.55% whereas HDL increased by 10.48%. As a secondary outcome, the mean CVD risk score was reduced by 6.91% and the mean biological heart age was also reduced by 6.64 years. The trial drug was well tolerated and free from adverse effects. Hence the trial drug can offer a safe and effective solution to individuals with hyperlipidaemia and moderate CVD risk.

### INTRODUCTION

In the last few decades the world has seen a transition in disease burden from communicable diseases to non-communicable diseases. According to WHO, non-communicable diseases (NCD), also known as chronic diseases, are of longer duration and mostly related to life style. As per the Lancet Global Burden of Disease Study (2016) report, NCD contributed to 61.8%, while the communicable diseases contributed to 27.5% to all the deaths.<sup>[1]</sup> Because of their high economic impact, the focus of health care providers and health care policy makers has been shifted to NCD.

Cardiovascular Diseases (CVD) are a growing concern in both men and women being the leading cause of mortality in the world and developing countries like India. <sup>[2]</sup>

Increasing living standard and socioeconomic transformations may look relevant and fascinating but they are taking the toll by promoting obesity, diabetes, dyslipidaemia and increasing CVD risk. The findings of a recent research study jointly conducted by Harvard T.H. Chan School of Public Health & Public Health Foundation of India, published in 2018 were alarming. The cross-sectional study conducted on 797,540 adults revealed many eye opening facts regarding CVD risk across states of India. Both urban lifestyle and household wealth are positively associated with CVD risk. As per the findings of the study, the mean 10-year risk of a CVD event in the population aged 30–74 years was 12.7% (95% CI: 12.7%–12.8%) among females

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and 21.4% (95% CI: 21.3%–21.6%) among males. Mean CVD risk was minimum i.e., 13.2% (95% CI: 12.7%–13.6%) in Jharkhand and highest i.e., 19.5% (95% CI: 19.1%–19.9%) in Kerala. Over all CVD risk tended to be highest in Northern states, North-eastern states, and South India. [3] A typical dyslipidaemia (low HDL, elevated LDL and/or elevated VLDL with or without elevated TG), more particularly an elevated LDL is strongly associated with increased CVD risk. [4] Since it is a modifiable risk factor, Statin therapy has become the standard medical advice for management of dyslipidaemia which in turn can reduce mortality in CVDs. [5] Statins have several adverse effects and limitations.

In the present scenario, the entire world is looking towards safe herbal remedies for life style related diseases. Hence it is the need of the hour to search alternative solutions for statins. There is a list of

drugs used by Ayurveda practitioners as anti-hyperlipidaemic agents. The present study was proactively designed for dual purpose i.e., to evaluate the anti-hyperlipidaemic and cardio-protective efficacy (in terms of CVD risk reduction) of a poly-herbal formulation.

## MATERIALS AND METHODS

The present study was a simple, single arm and open clinical study. It was conducted in the Department of Kayachikitsa, Gopabandhu Ayurveda Mahavidyalaya & Hospital, Puri, Odisha.

Due approval from DRC and IEC was taken prior to beginning of the study. CTRI registration was done with registration number: CTRI/2019/04/018723 and informed consent was also taken from every individual before starting the registration of participants.

**Table 1: Preparation of Trial Drug**

S.No	Sanskrit Name	Latin Name	Quantity in Each Capsule
1	<i>Guggulu</i>	<i>Commiphora mukul</i>	Each Capsule of 500mg contains these ingredients in equal proportions
2	<i>Pushkarmool</i>	<i>Inula racemosa</i>	
3	<i>Arjuna</i>	<i>Terminalia arjuna</i>	

The trial drug was a multi herbal compound in capsule form containing 500mg extract of *Guggulu* (*Commiphora mukul*), *Pushkarmool* (*Inula racemosa*) and *Arjuna* (*Terminalia arjuna*) in equal proportion. It was specially manufactured by Dabur India Limited, which is a well-known Ayurveda company having its own manufacturing unit with OHSAS 1800, ISO 14001 and WHO GMP certification.

### Inclusion & Exclusion Criteria

Individuals of either sex within the age group of 30 – 70 years with hyperlipidaemia and having more than 10% of CVD risk were included. Persons with hypertension, diabetes mellitus and who already had history of any cardiac event or being diagnosed with any type of cardiac problems were excluded from the study.

### Publicity of the Project

Screening camps were organized with the help of Sevayan Foundation, a leading NGO working in health sector in the district of Puri, Odisha. Wide publicity was made for such camps through handouts in newspaper, local TV channels and social media.

### Selection of Participants

Screening of highly vulnerable populations for their individual CVD risk was done by organizing specialized health camps. Populations who usually have a calorie rich diet, high incidence of smoking and sedentary life style were selected for screening. 1068 persons were screened in six screening camps. 81

persons fulfilling the inclusion criteria were segregated out of which only 60 individuals were randomly selected for the study using “Random Name Picker” tool. [6] But only 55 participants completed the trial after 5 dropouts.

### CVD Risk Assessment Tool

CVD risk assessment was done by JBS 3, an android enabled mobile application designed by Joint British Society for Prevention of Cardiovascular Diseases as it was the most accurate tool for prediction of CVD risk in Indian population. [7]

### Routine Examination & Laboratory Investigations

Routine clinical examination was done for every participant on the day of registration. CBC, FBS, PPBS, LFT, RFT and Fasting Lipid Profile was done before starting and after completion of treatment. All the Investigations were done in NABL accredited laboratories. CVD risk score and biological heart age were calculated using JBS 3 application before and after treatment. Analysis of *Prakruti* was carried out with CSIR-IGIB questionnaire.

### Dosage & Duration of the Trial Drug

The trial drug was administered in a dose of 1 capsule twice daily after food with warm water for a period of 90 days (3 months). The follow up was scheduled for every patient on 15<sup>th</sup>, 30<sup>th</sup>, 45<sup>th</sup>, 60<sup>th</sup>, 75<sup>th</sup> day and end of treatment.

### Assessment of the Study Outcomes

The efficacy of the trial drug was assessed based on three objective criteria only like lipid profile, CVD Risk Score and biological heart age. Improvement in lipid profile was the primary outcome and reduction in CVD risk score as well as biological heart age were the two secondary outcome measures for assessment of the study.

### Data Processing & Statistical Analysis

Different data were analysed using MS Excel and graphpad.com (online).<sup>[8]</sup> Paired t-test was applied as the test of significance to compare the before and after treatment values of lipid profile, CVD risk scores and biological heart age. Guidance from qualified statistician was taken as and when required.

### OBSERVATION AND RESULTS

Out of 60, only 55 participants completed the trial after 5 dropouts. The study was dominated by

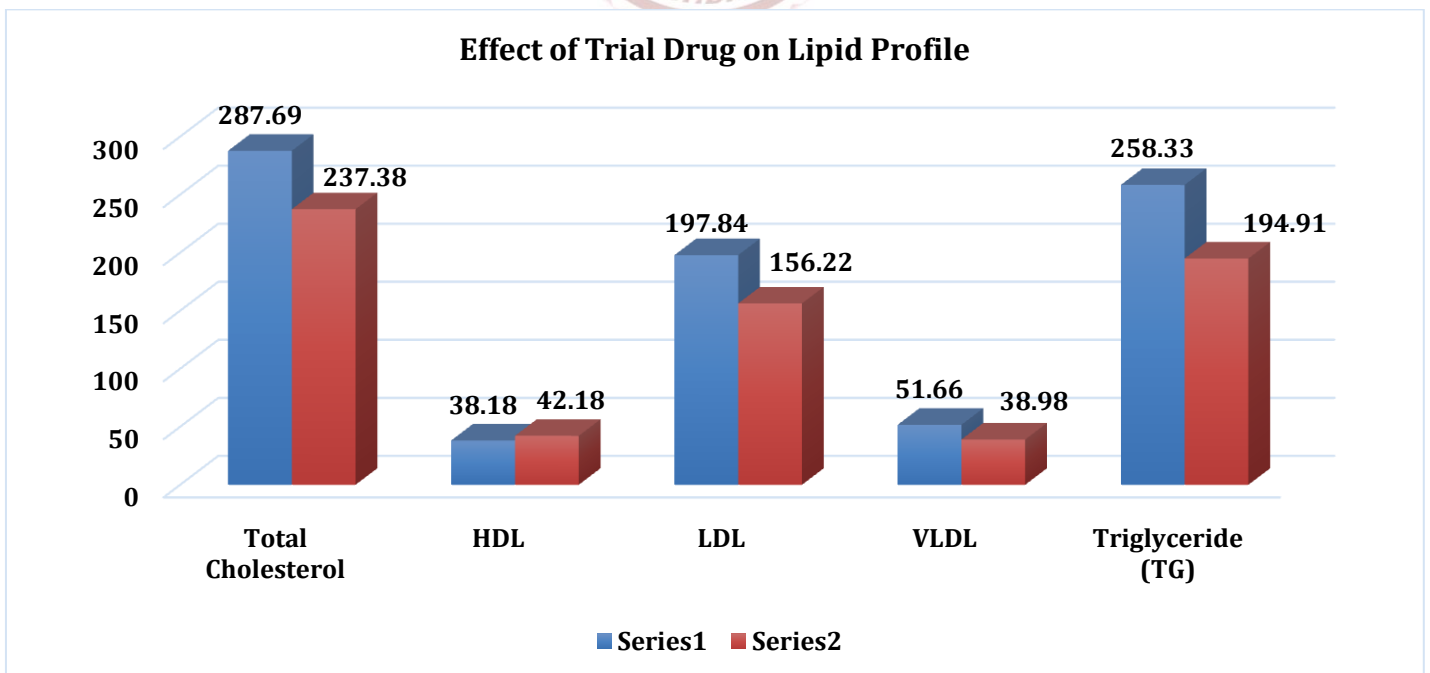
male participants (67%). The most vulnerable age group for CVD was found to be 50–59 years (53%) with higher CVD risk score. Participants with desk job/office job and house wives contributed more than fifty percent (51% to be precise) to the total number. CVD are no more “diseases of the rich and elite class”. In this study it was observed that most participants were from the urban upper or lower middle class. Higher BMI was strongly associated with higher CVD risk. 93% of the participants were either overweight or obese. 55% of the participants were addicted to tobacco in some form or the other like smoking, chewing etc. It was also observed that non-vegetarian food habit has a direct link with hyperlipidaemia and higher CVD risk. 27% of the participants had positive family history of CVD. Analysis of *Prakruti* revealed that 53% of the participants were having *Vata Kaphaj prakruti*.

**Table 2: Effect of Trial Drug on Lipid Profile**

Parameter (mg/dl)	Before treatment		After treatment		n	t - Value	df	p - Value
	Mean	SD	Mean	SD				
Total Cholesterol	287.69	22.17	237.38	22.71	55	14.45	54	< 0.0001
HDL	38.18	3.43	42.18	2.44	55	9.02	54	< 0.0001
LDL	197.84	23.12	156.22	23.21	55	12.87	54	< 0.0001
VLDL	51.66	7.93	38.98	3.47	55	13.49	54	< 0.0001
Triglyceride (TG)	258.33	39.65	194.91	17.39	55	13.50	54	< 0.0001

Note: SD: Standard Deviation, n: frequency, df: degree of freedom, HDL: High-density lipoprotein, LDL: Low-density lipoprotein, VLDL: Very low-density lipoprotein

**Chart - 1**



Note: Series 1: Before treatment Series – 2: After treatment

The trial drug was found effective in all the parameters of lipid profile.

The trial drug significantly reduced the total cholesterol level from 287.69±22.17mg/dl to 237.38±22.71mg/dl (p<0.0001). The mean HDL level was found to be elevated from 38.18±3.43 mg/dl to 42.18±2.44mg/dl. The difference was found to be statistically significant with p-value <0.0001. The LDL got significantly reduced from 197.84±23.12 mg/dl to 156.22±23.21mg/dl after treatment (p<0.0001). The mean VLDL value before treatment was 51.66± 7.93mg/dl which was significantly reduced to 38.98±3.47mg/dl after completion of treatment with p-value <0.0001. The baseline value of serum triglyceride was 258.33±39.65mg/dl. After treatment it was significantly reduced to 194.91±17.39mg/dl (p-value < 0.0001).

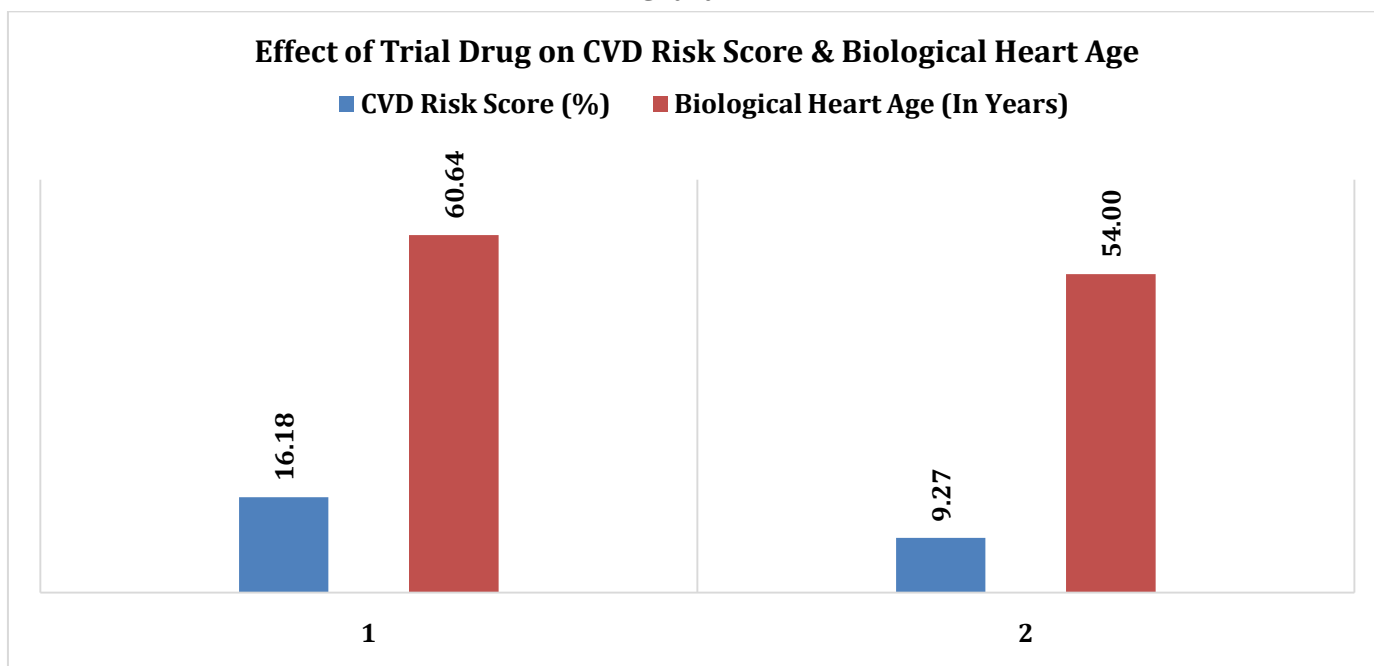
In summary the trial drug reduced serum levels of total cholesterol, LDL, VLDL and triglyceride whereas serum HDL which is considered good cholesterol was found to be elevated. The decrease in bad cholesterol and increase in good cholesterol are both greatly helpful in reducing CVD risk.

**Table 3: Effect of Trial Drug on CVD Risk Score & Biological Heart Age**

Parameter	Before treatment		After treatment		n	t - Value	df	p - Value
	Mean	SD	Mean	SD				
CVD Risk Score (%)	16.18	10.14	9.27	3.71	55	7.52	54	< 0.0001
Biological Heart Age (In Years)	60.64	6.48	54.00	6.06	55	21.35	54	< 0.0001

Note: SD: Standard Deviation, n: Frequency, df: Degree of Freedom, CVD: Cardiovascular Disease

**Chart - 2**



Due to improvement in lipid profile, both CVD risk score and biological heart age were found to be reduced. The baseline mean CVD risk score was 16.18 ±10.14% which was significantly reduced to 9.27± 3.71% after treatment (p-value < 0.0001).

The average chronological age of the participants was 51.45 years. Whereas the average calculated biological heart age at the baseline was 60.64±6.48 years due to several risk factors especially hyperlipidaemia. Due to improvement in lipid profile the mean calculated biological heart age was also reduced to 54.00±6.06 years after treatment. This was found to be extremely significant with p-value <0.0001. The trial drug was well tolerated and did not produce any major adverse effects.

**DISCUSSION**

CVD are usually considered as diseases with male predominance.<sup>[9]</sup> The findings of this study also re-established the fact. Age is an independent risk factor for CVD and persons older than 65 years of age are more prone to develop CVD. <sup>[10]</sup> It was observed in this study that higher the age higher is the CVD risk. 93% of the total participants were in the age group of 40-60 years. There are many age related changes in both heart and vasculature which increases with age. Co-morbidities like diabetes and hypertension are also found very commonly in this age group which adds to increased CVD risk. There are specific occupations which run higher CVD risk. <sup>[11]</sup> Occupations which involve desk jobs or office jobs are likely to be



associated with multiple lifestyle associated risk factors leading to higher CVD risk. The overall demography of the area was dominated by middle class families. This might be a reason behind the finding that the participants belonging to urban middle class were highest in the study. Increase in BMI directly increases the risk of CVD. Findings of the study were also in alignment of this fact. Increase in body weight increases the risk of diabetes, dyslipidaemia, fatty changes in the blood vessels (atherosclerosis), insulin resistance, elevated levels of fibrinogen and acute phase reactants like C- Reactive Protein etc. [12] Each of these are independent risk factors for CVD. Hence obesity strongly and significantly contributes to increased CVD risk. Tobacco users in any form will definitely run a higher CVD risk in comparison to non-users. Chemicals in tobacco increase the viscosity of the blood and induce a hypercoagulable state. This increases the chances of acute thrombosis.[13] The positive association of non-vegetarian food habit and higher CVD risk was observed in the study. It can be scientifically explained on the basis that foods rich in refined sugars, trans fats, refined grains, red meat, processed meat and low in fruits, vegetables, fibre and micronutrients are strongly associated with increased CVD risk.[14] A positive family history of cardiovascular events is certainly and strongly associated with increased CVD risk. The magnitude of risk depends on the degree of relation, number of members having positive family history of CVD and the age at which they got affected. Siblings of persons with a positive family history of cardiac events have about a 40% increased risk to develop CVD in future, whereas offspring of parents with history of CVD at an early age have a 60% to 75% higher risk.[15] *Prakruti* (the Ayurvedic way of classifying body types) has been instrumental in predicting illness as per the principles used in Ayurveda. *Vata Kaphaja prakruti* has been linked to higher CVD risk[16]. It was found that more than 50% of the participants were having *Vata Kaphaj prakruti*. This might be due to hyperlipidaemia, obesity, insulin resistance and presence of inflammatory markers which are commonly encountered in this body type.

The trial drug was moderately effective to improve hyperlipidaemia.

#### **Possible Mechanism of Action of the Trial Drug**

The trial drug was composed of *Guggulu* (*Commiphora mukul*), *Pushkarmool* (*Inula racemosa*) and *Arjuna* (*Terminalia arjuna*). Each of these herbs exhibit anti-hyperlipidaemic and cardioprotective effects on their own merits.

There are multiple proposed mechanisms to explain hypolipidaemic pharmacological effect of

*Guggulu*. Liver plays an important and central role in lipid metabolism. *Guggulu* decreases hepatic steroid production and increases catabolism of low density lipoproteins (LDL). Guggulosterones (E & Z), one of the active components of *Guggulu*, increases LDL clearance.

Guggulosterones are found to work as antagonist of Farnesoid X Receptors (FXR). The Farnesoid X receptor (FXR) is one among the nuclear receptor superfamily and recently emerged as a key player in the control of multiple metabolic pathways including lipid metabolism.[17] FXR inhibition by antagonists like guggulosterone can cause beneficial effects on lipid metabolism, improve liver toxicity in cholestatic conditions and can reduce the proliferation and migration of some cancer cell lines. [18] FXR antagonism by Guggulosterones results in increased cholesterol catabolism and removal from the body through excretion. Guggulosterones also decrease absorption of fat and cholesterol from gastrointestinal tract. [19]

The hypolipidaemic and cardioprotective effect of *Arjuna* has been established in several experimental and clinical studies. *Arjuna* can significantly lower the LDL cholesterol and elevate the HDL cholesterol level.[20] The hypolipidaemic action produced by *Arjuna* is explained on the basis of several mechanisms. It increases hepatic clearance of cholesterol and down-regulates lipogenic enzymes. It also inhibits of HMG-CoA reductase which is a rate limiting enzyme involved in cholesterol synthesis pathway. [21]

Multiple clinical trials have proved that *Pushkarmool* also possess significant hypolipidaemic, antioxidant and cardioprotective properties. [22] It can also improve cardiac ischaemia as found in experimental animals.[23] Lots of textual evidences in support of this plant are available in traditional medicine that it is indicated and effective in disorders of lipid metabolism (*Medoroga*). However, the complete mechanism behind the pharmacological activity of *Pushkarmool* is not clearly understood.

Hence the individual ingredients of the trial drug might have worked in a synergistic way to improve hyperlipidaemia.

#### **Hyperlipidaemia and CVD Risk**

Hyperlipidaemia is a major risk factor in CVD risk calculation. Hence improvement in lipid profile will definitely cause a reduction in CVD risk score as observed in the study.

#### **Biological vs. Chronological Age**

The chronological age is defined as the years a person has actually lived. But the biological age is determined by "how old the cells are". In the present study the mean calculated biological heart age was

found almost 9 years higher than the mean chronological age. This was mainly due to the different associated risk factors including hyperlipidaemia. With improvement in hyperlipidaemia due to intervention with the trial drug, the mean biological heart age was also reduced by 6.64 years.

### Safety and Tolerability of the Trial Drug

All the ingredients of the trial drug were of herbal origin which are time tested for their efficacy and safety. Hence it was well tolerated and did not produce any noticeable adverse effect.

### CONCLUSION

The trial drug was found effective in hyperlipidaemia. It effectively reduced total cholesterol by 17.49%, LDL by 21.04%, VLDL by 24.55% and triglycerides by 24.55% whereas increased the level of HDL by 10.48% which is desirable. Correction in hyperlipidaemia resulted in a reduction of mean CVD risk score by almost 7% and mean biological heart age was also reduced by approximately 7 years (the 7X7 effect). Based on these findings, the trial drug can be an effective and safe treatment option in individuals with hyperlipidaemia along with mild to moderate CVD risk.

### Future Scope

The present study was a single arm clinical trial. Future studies can include standard control treatment for a fair comparison. Further multicentre, parallel RCTs are required to validate the findings with a mechanistic exploration.

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