



## Clinical Research

# Safety and efficacy evaluation of Ayurvedic treatment (*Arjuna* powder and *Arogyavardhini Vati*) in dyslipidemia patients: A pilot prospective cohort clinical study

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### Abstract

Cardiovascular disease has multifaceted in which dyslipidemia, inflammation, and immunity play an important role. *Arjuna* powder and *Arogyavardhini Vati* used for centuries has potential for combating these factors. Therefore, the objective of this study was to evaluate the safety and efficacy of Ayurvedic treatment (*Arjuna* powder and *Arogyavardhini Vati*) for dyslipidemia patients. Total of 108 patients were screened at CGHS Ayurvedic Hospital, New Delhi. Ninety-six patients satisfied inclusion criteria, and signed informed consent and detailed medical history was recorded. *Arjuna* powder (5 g, BD) for 3 weeks and then *Arogyavardhini Vati* (500 mg, BD) for 4 weeks were prescribed to the patients. The primary efficacy endpoint was reduction in serum total cholesterol, LDL, triglycerides, and increased HDL levels. Secondary endpoints included reduction in serum C-Reactive Protein (CRP) and blood glucose levels. Safety assessments included hepatic function (aminotransferase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), bilirubin, and  $\beta^2$  microglobulin), renal function (urea and creatinine and NGAL) tests, and urine mercury level. The study was completed by 87 patients. The male and female patients were 65.5% (57/87) and 34.5% (30/87), respectively. There was a significant reduction in total cholesterol, LDL, triglycerides, CRP, and blood glucose. However, raised HDL level was also observed. Safety assessment results showed no significant change in serum ALT, AST, ALP and bilirubin, urea, creatinine  $\beta^2$  microglobulin, and NGAL levels at the end of study as compared to the baseline levels. In conclusion, the results of the present prospective cohort study showed that Ayurvedic treatment (*Arjuna* powder and *Arogyavardhini Vati*) is safe and effective for dyslipidemia.

**Key words:** *Arjuna*, *Arogyavardhini Vati*, dyslipidemia, efficacy, safety

## Introduction

The epidemic of cardiovascular diseases (CVDs) is the most prevalent cause of death and disability in both developed as well as developing countries. Rapid urbanization and its accompanying adverse lifestyle changes (i.e., unhealthy diet, physical inactivity, and drug and alcohol addiction) are likely to be the risk factors of CVDs.<sup>[1]</sup> According to National Commission on Macroeconomics and Health (NCMH), a Government of India undertaking, there would be around

62 million patients with coronary artery disease (CAD) by 2015 in India and of these, 23 million would be patients younger than 40 years of age.<sup>[2]</sup> CAD is due to atherosclerosis of large and medium sized arteries and dyslipidemia has been found to be one of the most important contributing factor (NCEP, ATP III).<sup>[3]</sup> During the past three decades, dyslipidemia as a risk factor for CVD has increased markedly in India. Several risk factors of CVD, namely hypertension, obesity, impaired glucose tolerance, increased triglycerides, low HDL cholesterol etc., have also become common in India.<sup>[4]</sup>

Dyslipidemia is a disorder characterized by alterations in the levels and composition of plasma lipids. According to Adult Treatment Panel III (2001), plasma levels  $\geq 200$  mg/dL for TC,  $\geq 130$  mg/dL for LDL-C,  $< 40$  mg/dL for HDL-C, and  $\geq 150$  mg/dL for TG are dyslipidemic. Dyslipidemia may result from inborn defects of lipoprotein production or metabolism;

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but in most cases, it is secondary to an unhealthy lifestyle (e.g., excessive cigarette smoking or alcohol consumption), other health disorders (e.g., obesity, diabetes, infection, and obstructive liver disease), or medication (e.g.,  $\beta$  blockers, steroids).

Currently available hypolipidemic drugs have been associated with a number of side effects. Statins are generally well tolerated by most individuals. However, a significant increase in hepatic alanine aminotransferase (ALT) and aspartate transaminase (AST) levels has been observed in 1% of the patients.<sup>[5]</sup> Although statin therapy is contraindicated in liver disease, there is no evidence of aggravation of liver function in subjects with fatty liver, chronic hepatitis C, or primary biliary cirrhosis.<sup>[6-8]</sup> Patients on treatment with crystalline niacin or extended-release niacin showed significant elevation in ALT and risk of hepatotoxicity is much greater with slow-release niacin.<sup>[9]</sup> A general recommendation is to measure ALT levels at the baseline and between 1 and 3 months after initiating statin or niacin therapy. Increases in plasma creatinine of 15–20% are common in fibrate-treated patients and more significant increases can occur in patients with underlying renal disease.<sup>[10, 11]</sup>

C-reactive protein (CRP), an acute phase protein, has been clinically used as a sensitive marker for systemic inflammation.<sup>[12]</sup> High-sensitivity CRP (hs-CRP) has been used for prediction of first myocardial infarction along with blood lipid measures.<sup>[13]</sup> Investigators have begun to develop therapies to lower hs-CRP concentrations and reduce the potential risk factor for cardiovascular diseases.<sup>[14-16]</sup>

The pursuit of finding the new safe and effective drug for dyslipidemia is going to be a continuous process. Herbs have been used as food and for medicinal purpose for centuries. Research interest has focused on various herbs that possess hypolipidemic effect that may be helpful adjunct in reducing the risks of CVD. *Arogyavardhini Vati* is a polyherbal formulation mentioned in Ayurvedic formulary.<sup>[17]</sup> It has been used for centuries with claimed efficacy and safety in treatment of jaundice, liver disorders, and various skin disorders. It consists of *Terminalia chebula* (*Haritaki*), *Terminalia bellerica* (*Bibhitaka*), *Emblica officinalis* (*Amalaki*), *Asphaltum* (*Silajatu-Suddha*), *Commiphora wightii* (*Guggulu Shuddha*), *Ricinus communis* (*Eranda*), *Picrorrhiza kurroa* (*Katuka*), leaf juice of *Azadirachta indica* (*Nimba*) and metals including *Shuddha Rasa* (purified mercury), *Shuddha Gandhaka* (purified sulfur), *Lauha Bhasma* (iron compound in ash form), *Abhraka Bhasma* (mica in ash form), and *Tamra Bhasma* (copper compounds in ash form). A randomized controlled trial of *Terminalia arjuna* in patients with coronary heart disease showed significant decrease in total cholesterol and LDL cholesterol and also significant decrease in lipid peroxide.<sup>[18]</sup> Safety of *Arogyavardhini Vati* on liver, kidney, and brain has been evaluated in earlier studies.<sup>[19]</sup> Hence, considering the antioxidant, anti-inflammatory, and hypolipidemic property, this study was designed to study the effect of *Arogyavardhini Vati* and *Arjuna* powder in dyslipidemic patients.

## Materials and Methods

### Patients population and study design

Between September 2009 and April 2011, 108 patients were

screened for dyslipidemia and a poor history of lipid control. Ninety-six patients meeting inclusion/exclusion criteria were enrolled in the prospective clinical study. Eighty-seven (57 males and 30 females) patients diagnosed with hyperlipidemia, aged between 33 and 59 years, were the study sample. Patients with consistent high lipid levels by previous medical test records were selected for the study.

### Inclusion and exclusion criteria

Inclusion criteria were (a) plasma levels  $\geq 200$  mg/dL for TC,  $\geq 130$  mg/dL for LDL-C,  $< 40$  mg/dL for HDL-C, and  $\geq 150$  mg/dL (according to Adult Treatment Panel III, 2001) and (b) serum CRP  $> 5$  mg/dL. Exclusion criteria were (a) medical history of unstable angina, (b) myocardial infarction, (c) heart failure or stroke within 3 months of the study, (d) uncontrolled hypertension (diastolic blood pressure  $> 100$  mmHg), (e) uncontrolled diabetes mellitus, (f) ALT and AST  $> 2 \times$  upper limit of normal (40 mg/dL), (g) impaired renal function (creatinine  $\geq 2.0$  mg/dL), (h) pregnancy/lactation, and (i) patients on any ayurvedic drugs during the last 15 days. The study was closed for participation in April 2011.

### Ethical consideration

The study was conducted according to the declaration of Helsinki guidelines and after getting approval from Institute Human Ethics Committee, All India Institute of Medical Sciences, New Delhi (vide the approval number Ref. No. T-16/01.05.2009). This study has been registered with Clinical Trial Registry of India, Indian Council of Medical Research, New Delhi, India (Vide the approval number REFCTRI-2009 000699).

### Medication

Patients satisfying the inclusion criteria were sequentially enrolled and assigned a patient code number by the investigator. All participants had an initial screening visit where medical history was reviewed by an ayurvedic physician prior to enrollment. The study was conducted for 7 weeks. All patients received *Arjuna* powder (5 g, twice a day) for the first 3 weeks followed by *Arogyavardhini Vati* (500 mg, twice a day) for 4 weeks. The last week of the study was utilized to follow up on patient data. *Arjuna* powder (Dabur India Ltd, India, Lot No. CG/AR/001-09) and *Arogyavardhini Vati* (Maharishi Ayurveda Products Pvt. Ltd, India, Batch no. AVV 013) were supplied in pre-labeled containers by GMP certified company of a single batch for the whole clinical trial. The study participants were not blinded to the study treatment during the entire week period. However, final data were reviewed independently blinded to the investigators.

### Measurements and assessment

Five milliliters of blood were collected by a phlebotomist into plane tubes from all patients on the day of enrollment and at the end of the study. Samples were centrifuged at 3000 rpm, and serum was stored at  $-80^{\circ}\text{C}$  for biochemical analysis. Fresh, clear, unhemolyzed serum was collected as the specimen with the patient fasting for 12 h prior to specimen collection. Serum total cholesterol, triglyceride, LDL, HDL, LFT and KFT were analyzed by a semiauto analyzer (Mini Techno, USA).

Lipid lowering effect of *Arogyavardhini Vati* was measured by comparing the lipid profile levels tested on initiation of the

study (day 1) to the end of the study. Efficacy was measured by percent reduction in lipid profile levels as compared to baseline. Safety assessments included hepatic function (ALT, AST, alkaline phosphatase (ALP), and bilirubin) and renal functions (urea and creatinine) tests. An early sensitive marker of liver ( $\beta^2$  microglobulin) and kidney (NGAL: neutrophil gelatinase-associated lipocalin) were assessed to evaluate the effect of the *Arogyavardhini Vati* exposure. LFT and KFT levels were correlated with the urine mercury level.

### Outcomes and sample size determination

The primary end-point of the study was percentage change from baseline in directly measured levels of total cholesterol, LDL, HDL, and triglycerides at the end of treatment. This was calculated as [(at the end of treatment lipid levels–baseline lipid levels) /baseline LDL-C level $\times$  100] for each participant. Secondary endpoints included percentage changes in levels serum CRP, blood glucose at the end of treatment, as well as safety laboratory tests (renal function, hepatic function). On the basis of the published literature, we anticipated reductions of at least 10% of total cholesterol, LDL, HDL and triglycerides at the end of treatment. Considering a higher dropout rate (20%) and lack of sufficient data from published hypolipidemics drug trials using ayurvedic medicines, we estimated that a sample size of 90 would provide at least 80% power to detect differences from baseline values, using a two-tailed  $\alpha$  value of 0.05 and an estimated within-group SD of 10%.

### Statistical analysis

Data are expressed as mean with standard deviation (SD). The  $\chi^2$ -test was applied for patients showing improvement/cure after therapy. Laboratory measurements were compared with baseline using an analysis of covariance. For all statistical tests, the significance level is taken as  $P < 0.05$  (SPSS, version 16).

## Results and Discussion

In this study, 108 patients were screened over a 20 months period and 96 were deemed eligible based on inclusion criteria. Eighty-seven of the 101 patients completed all study-related visits (13.9% dropout rate). The most frequent reason for exclusion from the per protocol group was concomitant disease (10 of 12) or the study indication requiring therapy with inadmissible medication (2 of 12). The reason for dropout was concomitant use of allopathic medications (8 of 14), noncompliance to medication (3 of 14), and unknown reasons (3 of 14). The study was completed by 65.5% (57/87) male and 34.5% (30/87) female patients. The age (mean  $\pm$  SD) were  $48.3 \pm 6.9$  years, with the low standard deviation indicating the small age range of patients, which was between 33 and 59 years. The median age was 49 years and thus similar to the mean age.

The serum levels of total cholesterol, LDL, HDL, triglycerides and CRP were determined at the start and at the end of treatment. There was a significant reduction in total cholesterol, LDL, and triglycerides, whereas there was a significant elevation in the HDL level [Table 1]. The fall in CRP levels was quite significant at around 13.6% [Table 1]. Statistical analysis by ANOVA of the results confirmed the significance of the above observation with the reduction in total cholesterol, LDL and triglycerides ( $P < 0.01$ ), and HDL elevation ( $P < 0.05$ ). The

percentage decrease in the levels of serum total cholesterol, LDL, and TG were 9.8%, 8.8%, and 9.9%, respectively, and increased HDL was 8.1% [Figure 1]. There was a significant fall in blood glucose showing better glucose metabolism [Table 1].

The results showed that treatment with *Arjuna* powder (5 g, twice a day) for 3 weeks followed by *Arogyavardhini Vati* (500 mg, twice a day) for next 4 weeks brought about significant reduction in the level of risk factors of CVD arising from dyslipidemia and inflammation. Taking into consideration that there are unavailability of therapeutic options for inflammation in atherosclerosis as a specific target, the results of *Arjuna* powder and *Arogyavardhini Vati* should be considered significant.

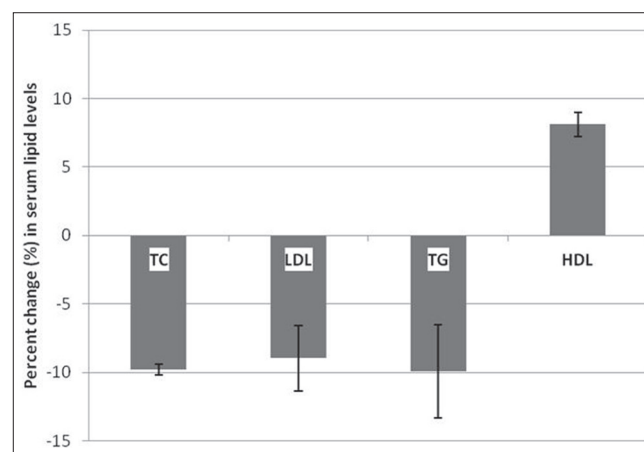
Safety of these ayurvedic formulations is an added feature. Results showed that there were no significant changes in serum ALT, AST, ALP and bilirubin, urea, and creatinine at the end of study as compared to baseline levels [Table 2]. An early sensitive marker of liver ( $\beta^2$  microglobulin) and kidney (NGAL: neutrophil gelatinase associated lipocalin) showed non significant changes. The results of this study showed that *Arjuna* powder and *Arogyavardhini Vati* are safe drugs.

CVD is a multifactorial disease. Immunity plays an important role in atherosclerosis which is a third component after inflammation and dyslipidemia.<sup>[20]</sup> Considering these factors, *Terminalia arjuna* can potentially modulate all the three components of the disease. There are plethoras of clinical and experimental animal studies, which showed the role of

**Table 1: Lipid profile, CRP, and blood glucose values of dyslipidemia patients (mean $\pm$ SD)**

Parameters	Baseline	Post-treatment
Total cholesterol (mg/dL)	236.4 $\pm$ 15.1	213.2 $\pm$ 14.7***
LDL-cholesterol (mg/dL)	162.9 $\pm$ 12.8	148.3 $\pm$ 10.4***
Triglycerides (mg/dL)	219.9 $\pm$ 26.9	198.1 $\pm$ 21.5***
HDL-cholesterol (mg/dL)	39.9 $\pm$ 4.1	43.14 $\pm$ 3.2***
C-reactive protein (mg/L)	5.9 $\pm$ 0.9	5.1 $\pm$ 0.8***
Blood glucose (mg/dL)	106.3 $\pm$ 15.3	91.8 $\pm$ 11.6***

Data are expressed as mean $\pm$ SD; \*\*\* $P < 0.001$  as compared to baseline levels



**Figure 1: Percentage change from the baseline in serum lipid parameters at the end of treatment. HDL-C: High-density lipoprotein cholesterol; LDL-C: Low-density lipoprotein cholesterol; TC: Total cholesterol, TG: Triglyceride**

**Table 2: Safety evaluation of liver and kidney of dyslipidemia patients on treatment with *Arjuna* powder and *Arogyavardhini Vati***

Biochemical parameters	Visit 1 (Day 0)	Visit 2 (Day 21)	Visit 3 (day 35)	Visit 4 (Day 49)
ALT (IU/L)	28.5±4.6	25.8±3.5	28.1±3.3	30.2±3.4
AST (IU/L)	28.8±4.1	27.6±3.9	28.9±4.0	30.3±4.3
ALP (IU/L)	142.6±17.9	141.1±17.7	143.4±16.5	144.6±17.8
Bilirubin (mg/dL)	0.80±0.18	0.84±0.17	0.86±0.18	0.88±0.16
Urea (mg/dL)	28.5±5.3	28.9±5.2	29.3±5.3	29.8±5.2
Creatinine (mg/dL)	0.83±.10	0.83±0.09	0.85±0.11	0.89±0.14
B2MG (mg/dL)	1.08±0.4			1.11±0.3
NGAL (ng/mL)	36.4±9.2			36.2±7.1

Data are expressed as mean±SD

*Terminalia arjuna* in CVD.<sup>[21-23]</sup> It has anti-inflammatory as well as immunomodulatory activity which could be the reason for improving the efficacy of *Arogyavardhini Vati* in this study. There are several components of *Arogyavardhini Vati*, which are known to have hypolipidemic effects, i.e., *Picrorrhiza kurroa*, *Terminalia chebula*, *Terminalia bellerica*, *Embllica officinalis*, and *Guggulu*.<sup>[24-29]</sup>

The mechanisms by which *Arogyavardhini Vati* exerted the beneficial effects in dyslipidemia are presently not clear. *Picrorrhiza kurroa*, a major component *Arogyavardhini Vati*, has choleric effects.<sup>[30]</sup> *Amla*, which is another component of ayurvedic drug, has HMG CoA reductase inhibitory activity.<sup>[31]</sup> Ellagitannins and the ellagic acid obtained on hydrolysis of these tannins (by lipases and/or esterases) are inhibitors of squalene epoxidase, a rate-limiting enzyme of cholesterol biosynthesis.<sup>[32]</sup> These inhibitory activities may explain the beneficial effects of *Arogyavardhini Vati* on lipid parameters. Inflammation is known to reduce HDL levels, and *Arogyavardhini Vati* has anti-inflammatory activity. Hence, this could be the reason for raised HDL levels.<sup>[33]</sup> In this study, the serum CRP level, which is a marker of systemic infection, was significantly reduced at the end of the treatment as reported in the literature.<sup>[12]</sup> Therefore, it is likely that a reduction in serum lipid levels observed in this study by *Arogyavardhini Vati* may be mediated through above mechanisms.

## Conclusion

Considering the above action, it is suggested that *Arjuna* powder and *Arogyavardhini Vati* produce significant hypolipidemic effects. Use of *Arjuna* powder and *Arogyavardhini Vati* to the currently available hypolipidemic therapy would offer significant protection against atherosclerosis and CAD with a reduction in the dose and adverse effects of hypolipidemic agents.

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## हिन्दी सारांश

# रसरक्तगत स्नेहाधिक्य (डिस्लिपिडिमिया) रोगियों में आयुर्वेदिक चिकित्सा (अर्जुन चूर्ण और आरोग्यवर्धिनी वटी) का सुरक्षात्मक तथा प्रभावोत्पादकता मूल्यांकन: एक प्रायोगिक नैदानिक अध्ययन

गजेन्द्र कुमार, अमिता श्रीवास्तव, सुरेन्द्र कुमार शर्मा, योगेन्द्र कुमार गुप्ता

हृदय रोग बहुमुखी है, जिसमें डिस्लिपिडिमिया, शोथ और प्रतिरक्षा एक महत्वपूर्ण भूमिका निभाते हैं। अर्जुन चूर्ण और आरोग्यवर्धिनी वटी का प्रयोग सदियों से किया जा रहा है और इनमें इन कारकों का मुकाबला करने की क्षमता है। अतः वर्तमान अध्ययन का उद्देश्य है, डिस्लिपिडिमिया रोगियों में अर्जुन चूर्ण और आरोग्यवर्धिनी वटी का सुरक्षात्मक तथा प्रभावोत्पादकता मूल्यांकन करना। इस हेतु सी.जी. एच.एस. आयुर्वेदिक अस्पताल, नई दिल्ली में एक सौ आठ रोगियों की जांच की गई। कुल ९६ रोगी पंजीकृत किए गए। सूचित सहमति पत्र पर उनके हस्ताक्षर लिए गए और विस्तृत चिकित्सा इतिहास में दर्ज किए गए। अर्जुन चूर्ण (५ ग्राम दो बार, तीन सप्ताह तक) और फिर आरोग्यवर्धिनी वटी (५०० मिलीग्राम दो बार, ४ सप्ताह तक) रोगियों को दिया गया। प्राथमिक प्रभावकारिता हेतु सीरम कोलेस्ट्रॉल, एल.डी.एल., ट्राइग्लिसराइड्स में कमी और एच.डी.एल. स्तर में वृद्धि को मापदण्ड माना गया। जबकि माध्यमिक प्रभावकारिता हेतु सीरम सी.आर.पी. और रक्तशर्करा के स्तर में कमी को मापदण्ड के रूप में स्वीकार किया गया। सुरक्षा आंकलन के सन्दर्भ में यकृत क्रियाशीलता (ALT, AST, ALP, बिलिरुबिन और  $\beta 2$  microglobulin), वृक्क क्रियाशीलता (यूरिया, क्रिएटिनिन और NGAL) परीक्षण और मूत्रगत पारा स्तर शामिल हैं। कुल ८७ रोगियों में अध्ययन पूरा किया गया इनमें पुरुष ६५.५% (५७/८७) और महिला ३४.५% (३०/८७) थे। चिकित्सा के पश्चात् कुल कोलेस्ट्रॉल, एल.डी.एल., ट्राइग्लिसराइड्स, सी.आर.पी. और रक्त शर्करा में महत्वपूर्ण कमी पायी गई। जबकि, एच.डी.एल. स्तर बढ़ा हुआ पाया गया। सुरक्षा आंकलन परिणाम, सीरम ALT, AST, ALP और बिलिरुबिन, यूरिया, क्रिएटिनिन और  $\beta 2$  microglobulin और NGAL स्तर अध्ययन के अंत में, आधारभूत स्तर की तुलना में कोई महत्वपूर्ण परिवर्तन नहीं पाया गया। वर्तमान अध्ययन के परिणामों से यह निष्कर्ष निकलता है कि आयुर्वेदिक उपचार (अर्जुन चूर्ण और आरोग्यवर्धिनी वटी) डिस्लिपिडिमिया के लिए सुरक्षित और प्रभावी है।