

**ORIGINAL RESEARCH ARTICLE: CLINICAL EVALUATION OF THE EFFICACY AND SAFETY OF HERBAL DRUG IN DYSLIPIDEMIA DURING COVID TIME**Shivani Dogra¹, Rajendra Prasad², Parvathy Venate³¹JR, Department of *Kayachikitsa*, Faculty of Ayurveda, I.M.S., B.H.U., Varanasi, Uttar Pradesh, India²Professor, Department of *Kayachikitsa*, Faculty of Ayurveda, I.M.S., B.H.U., Varanasi, Uttar Pradesh, India³JR, Department of *Kayachikitsa*, Faculty of Ayurveda, I.M.S., B.H.U., Varanasi, Uttar Pradesh, IndiaCorresponding Author: shivaniDogra176@gmail.com<https://doi.org/10.46607/iamj1010022022>

(Published Online: February 2022)

Open Access

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Article Received: 25/01/2022 - Peer Reviewed: 10/02/2022 - Accepted for Publication: 11/02/2022

**ABSTRACT**

Dyslipidemia is a major cause of concern nowadays because of the risk of the development of cardiovascular diseases. It can be correlated with *Medodosh*a in Ayurveda. This study was carried out to evaluate the efficacy of herbal preparation in dyslipidemia during the Covid-19 period. The study was carried out in 50 covid positive and post covid patients with associated dyslipidemia selected as per inclusion and exclusion criteria and prescribed the drug as 2 tablets thrice a day for 21 days. General examination and lipid profile was assessed before and after treatment. The results showed a statistically significant reduction in Total Cholesterol, Triglycerides and LDL. The study also revealed the importance of conducting the trial during the Covid period. Thus, it was concluded that the trial formulation can be effectively and safely used in dyslipidemia.

Keywords: *Medodosh*a, *Dyslipidemia*, *Covid-19*, *Kalmegha*, *Andrographis***INTRODUCTION**

Dyslipidemia is the condition of abnormally elevated levels of any or all lipids (fats, cholesterol or triglycerides) or lipoproteins (LDL-Low density lipoproteins, VLDL-Very low-density lipoproteins) in the

blood and a decrease in HDL (High-density lipoproteins) concentration in the blood ⁽¹⁾. Nowadays, cardiovascular diseases (CVD) are the leading cause of death in the greater population of India and world-

wide. Dyslipidemia is a potent risk factor for developing CVD including atherosclerosis, ischemic heart disease, hypertension, arrhythmia, cardiac arrest, heart failure, stroke, peripheral artery disease etc. The lifestyle and dietary changes lead to an increased prevalence of dyslipidemia. Dyslipidemia is defined as Total Cholesterol (TC) > 200mg/dl, LDL > 100mg/dl, Hypertriglyceridemia as TG > 150mg /dl, HDL Cholesterol (HDL-C) < 40mg/dl ⁽²⁾.

In Ayurveda, there is no direct correlation of dyslipidemia. Dyslipidemia can be correlated with *Medodosh*. Some researchers have considered it as *Rasagata-Snehavridhi*, *Raktagata-Snehavridhi* or *Ras Raktagata-Snehavridhi*. In our body lipids are mainly present as *Meda*, *Vasa* and *Majja*. In Ayurveda, *Medo Dhatu* is divided into two portions as *Poshaya Dhatu* and *Poshaka Dhatu*. *Poshaya Dhatu* gets nourishment and is mentioned as *Sthayi Medas* (stable) or *Badh Medas* and *Poshaka Dhatu* which nourishes and identified as *Ashthayi Medas*(unstable) or *Abadh Medas* in the body. ⁽³⁾ *Poshaka Medo Dhatu* is mobile and circulates along with *Rasa*, *Rakta Dhatu*s and nourishes *Poshya Medo Dhatu*. ⁽⁴⁾ In *Charaka Samhita*, it has been mentioned that intake of *Madhura* (Sweet), *Snigdha*(unctuous), *Kapha Kopakara Ahara* (a diet that increases phlegm), *Avyayam* (lack of exercise), and *Diwa Swapna* (day sleeping) are the main causative factors to produce *Medodosh* and *Medoroga* with impairment of *Medo Dhatwagni* (digestive power of food). ⁽⁵⁾ The pathology of *Medoroga* and *Medodosh* occurs when *Medo-dhatwagni* is impaired, then the homologous nutrients present in *Poshaka Medodhatu* are excess in circulation, which leads to excess accumulation of abnormal quantities of *Poshaka Medodhatu* in *Rasa*. This condition can be referred to as Dyslipidemia ⁽⁶⁾. In this way, *Badh* or *Abadh Medas* both will be increased. When *Badh Medas* is increased, it can be correlated to Obesity or *Medoroga*. When *Abadh Medas* is increased, it can be correlated to Dyslipidemia or *Medo Dosh*. In Modern Medicine, the most commonly used anti-hyperlipidemic drugs are statins but there are some common side effects including myalgia, arthralgia, dizziness, hepatotoxicity, GIT upset, in-

somnia etc. So, there is a need of the hour to study and evaluate the efficacy of Ayurvedic herbal medications which can control dyslipidemia without significant side effects. Thus, considering the above facts, this study is intended in treating dyslipidemia with herbal medicine having *Andrographis Paniculata* (*Kalmegha*) as the main ingredient.

This study has been conducted during COVID-19 time. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), responsible for the current pandemic of coronavirus disease-19 (COVID-19), represents a great challenge to healthcare systems worldwide ⁽⁷⁾. Observational studies of COVID-19 individuals with underlying cardiovascular diseases (CVD) showed that they were at increased risk of severe manifestations of disease and mortality. ⁽⁸⁾ Several lines of evidence provide a rationale for high cholesterol predisposing to a worse outcome in SARS COV-2 infection, by dysregulating the protective immunity and promoting exaggerated pulmonary and inflammatory immune responses ⁽⁹⁾. Various studies have shown the use of anti-hyperlipidemic drugs like statins is associated with a reduced risk of mortality among individuals of Covid-19⁽¹⁰⁾. Obesity weakens the immune system of the body and is a potent risk factor for developing infectious conditions including Covid-19. Obesity-associated chronic inflammation and altered immunity can lead to worse outcomes in Covid infected patients ⁽¹¹⁾. In our Ayurvedic literature, *Acharaya Charaka* has also mentioned *Atisthauyaya* (Obesity) leading to *Ayu Hrasa* (decrease life span) and *Dourbalya* (body weakness) leading to decreased immunity causing a risk for various infectious conditions ⁽¹²⁾. For the above-mentioned reasons, we have administered our herbal drug in hyperlipidemic patients during COVID-19 time.

MATERIALS AND METHODS: Non-randomized, active-controlled, clinical trial was conducted in patients of SSH, I.M.S., B.H.U, Varanasi. The study was carried out in 50 mild to moderate Covid-19 positive and Post Covid-19 patients with associated dyslipidemia selected as per the inclusion and exclusion criteria. The record of all patients was main-

tained in proformas prepared for the study. The study was conducted for 21 days. Routine assessment of lipid profile was done before and after treatment.

INCLUSION CRITERIA:

- a. Patients were willing to participate in the study.
- b. A total of 50 patients were taken for the clinical study having age between 18 to 70 years of either sex.
- c. Mild to moderate positive cases of Covid-19 (Spo2>93%, RR<24/min, no evidence of hypoxemia or breathlessness) and post covid-19 patients.
- d. Lipid Profile assessment:

Patients having alterations in any one or more components of the lipid profile were included in the study:

- 1. Serum Cholesterol – 200mg/dl or more
- 2. Serum Triglycerides – 150mg/dl or more

- 3. Serum LDL – 130mg/dl or more
- 4. Serum HDL – 40mg/dl or less
- 5. Serum VLDL – 40mg/dl or more

EXCLUSION CRITERIA:

- a) Patients were unwilling to participate in the study.
- b) Patients with known sensitivity to ingredients of the trial drug.
- c) Patients <18 and >70 years of age were excluded from the study.
- d) Severe cases of Covid-19.
- e) Patients suffering from comorbidities like HTN, diabetes, nephrotic syndrome etc.

DRUG ADMINISTRATION:

The herbal drug was administered in a dose of 2 tablets (150mg each) thrice a day with lukewarm water, after meals for 21 days.

OBSERVATIONS AND RESULTS:

DEMOGRAPHIC PROFILE:

Age	20-50years	76%
Gender	Male	66%
	Female	34%
Economic status	Upper-middle	42%
	Lower-middle	58%
Occupation	Employed	70%
	Unemployed	30%
Marital status	Married	56%
	Unmarried	44%
Habitat	Urban	98%
	Rural	2%
Bodyweight	10%	<50kg
	24%	50-60kg
	30%	60-70kg
	24%	70-80kg
	12%	>80kg
BMI (Body Mass Index)	40%	Overweight
	50%	Normal weight
	10%	Underweight

GENERAL EXAMINATION:

Parameters	Mean ± SD		Within the group comparison (Paired t test) n=50		
	DAY1	DAY21	Mean Difference	T	P
Pulse rate	83.84±12.544	80.12±8.206	3.720±9.187	2.863	0.006
Systolic BP	119.32±10.510	117.72±6.964	1.600±9.587	1.180	0.244
Diastolic BP	77.40±7.508	75.64±5.879	1.760±7.213	1.725	0.091

Vital signs like Pulse rate showed a statistically significant reduction from 83.84 to 80.12/min with a p value of 0.006. the result though statistically significant is not clinically relevant as it lies within the normal range.

LIPID PROFILE:

PARAMETERS	COVID POSITIVE			POST COVID		
	Mean			Mean		
	DAY1	DAY21	Mean Difference	DAY1	DAY21	Mean Difference
Cholesterol	186.4	161.96	24.44	172.5	165.6	6.9
TG	240.36	183.95	56.41	186.89	177.32	9.57
HDL	37.99	39.68	1.69	41.35	41.01	0.34
LDL	99.81	84.47	15.34	93.81	87.23	6.58
VLDL	48.57	37.63	10.94	37.37	36.83	0.54

Parameters	Mean ± SD		Within the group comparison (Paired t test) n=50		
	DAY1	DAY21	Mean Difference	T	P
Cholesterol	178.06±41.819	164.18± 36.016	13.882± 29.693	3.306	0.002
TG	208.26± 100.339	179.96± 88.713	28.308± 79.461	2.519	0.015
HDL	40.01±7.790	40.48±9.837	0.470± 9.086	0.366	0.716
LDL	96.21±35.791	86.13±31.589	10.083±27.940	2.552	0.014
VLDL	41.85±20.715	36.95±20.826	4.904±17.705	1.959	0.056

After 21 days of intervention, there has been a statistically significant change in the parameters of lipid profile such as Total Cholesterol, Triglycerides and LDL. Total Cholesterol showed a statistically significant reduction from 178.06 to 164.18 mg/dl after 21 days of treatment with p=0.002. Serum Triglycerides showed a statistically significant reduction from 208.26 to 179.96 mg/dl with p=0.015. LDL showed a statistically significant reduction from 96.21 to 86.13 mg/dl with p=0.014. VLDL also shows a decreasing trend post-intervention, though the results are of no statistical significance. HDL levels were more or less unchanged. Thus, the trial formulation has significantly reduced the Cholesterol, TG and LDL levels after the intervention.

DISCUSSION

In the present study, the herbal preparation having 'Kalmegha' – *Andrographis Paniculata* as the main ingredient is taken. 'Kalmegha' has been used as Ayurvedic Medicine for many years. The plant is having *Tikta Rasa*, *Katu Vipaka*, *Laghu* and *Ruksha Guna*, *Sheeta Virya*. The ideal drug for dyslipidemia should possess properties like *Rasa – Katu, Tikta,*

Kashaya. Katu and *Kashaya Rasa* are attributed to have *Karshana* and *Upachayahara* actions. *Tikta Rasa* is attributed to have *Lekhana* and *Meda Upshoshanahara karma* (CS. Su. 26/43) ⁽¹³⁾. A study revealed the antihyperlipidemic effects of andrographolide and neoandrographolide present in the plant. Yang et al. reported the effects of andrographolide and neoandrographolide on hyperlipidemic mice induced by 75% yolk emulsion and hyperlipidemic rats induced by high-fat emulsion. Andrographolide and neoandrographolide reduced the levels of total cholesterol, triglycerides and LDL in a dose-dependent manner ⁽¹⁴⁾. As per Ayurvedic texts and different research *Andrographis* plant was found to be hepatoprotective. This property can add its extra advantage by protecting the liver rather than causing hepatotoxicity as caused by modern antihyperlipidemic drugs like statins. Several studies have demonstrated the hepatoprotective action of *A. paniculata* in different models- BHC induced liver toxicity in Swiss male mice ⁽¹⁵⁾. The possible mode of action is to enhance the tissue antioxidant levels, decrease the lipid peroxidation levels in the liver and maintain the membrane integrity of liver cells toxin-

induced leakage of marker enzymes into the circulation. In the present study, the trial drug-treated group exhibited lowering the levels of TC, TG, LDL, and VLDL and mild elevation of HDL after treatment.

Recent studies showed that different types of formulations, extracts and pure compounds obtained from this plant have been shown to possess biological activities including anti-microbial, anti-inflammatory, antioxidant, anti-diabetic, cytotoxicity, immunomodulatory, anti-angiogenic and hepato-renal protective activity⁽¹⁶⁾. Hence, proposed to be effective in the treatment of infectious conditions like Covid-19. Since the studies being conducted are very much limited. Further raised levels of Hs CRP, LDH and interleukins in covid and post covid patients was an alarming signal for possibilities of future cardiac illnesses. Maintaining the lipid content in the body to a normal level could be of great importance in covid infected patients to prevent cardiovascular diseases. Since various studies have been conducted demonstrating the effectiveness of modern anti-hyperlipidemic drugs like statins in reducing mortality in Covid-19. This study will provide an overview so that further studies will be conducted in future by research scholars to understand the role of dyslipidemia in COVID-19 infection and evaluate the effectiveness of Ayurvedic herbal preparations.

CONCLUSION

The present clinical study has demonstrated the efficacy and safety of an Ayurvedic herbal preparation in patients of dyslipidemia during the Covid-19 time. The lipid profile parameters showed significant reductions in TC, TG and LDL levels and mild elevations in HDL levels. There were no marked elevations in any of the parameters, proving the safety of the drug. The trial formulation needs to be further evaluated in future for its hypolipidemic effects. The trial formulation was used during Covid time to know about the importance of using anti-hyperlipidemic drugs during Covid infection to reduce the related cardiovascular effects in covid and post covid patients. As Covid time will not come again and again,

we have to grab the opportunity and perform the study.

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Source of Support: Nil

Conflict of Interest: None Declared

How to cite this URL: Shivani Dogra et al: Original Research Article Clinical Evaluation Of The Efficacy And Safety Of Herbal Drug In Dyslipidemia During Covid Time. *International Ayurvedic Medical Journal* {online} 2022 {cited February 2022} Available from: http://www.iamj.in/posts/images/upload/341_346.pdf