



## Pharmacology

## AN OPEN LABEL SINGLE ARM STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF AMLA (EMBLICA OFFICINALIS) IN CARDIOVASCULAR HEALTH

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**ABSTRACT** **Introduction:** With its numerous healing properties Amla or Emblica officinalis is considered to be a purported wonder plant in our traditional system. It is used as a supplement in multiple diseases including heart disease as evidenced by many clinical trials owing to its therapeutic properties. **Aim:** The aim of the study was to evaluate the role of Amla in cardiovascular health. **Materials and Methods:** A total of 45 patients were recruited in this study after careful examination and evaluation of inclusion and exclusion criteria. They were prescribed 2 tablets of 500 mg of Amla for 16 weeks. **Results:** A significant reduction in total cholesterol (TC), triglycerides (TG), low-density lipoproteins (LDL) and very-low-density lipoprotein (VLDL) and increase in high-density lipoproteins (HDL) were observed after 16 weeks of treatment. **Conclusion:** Because of its healing and antioxidant properties Amla has a beneficial role in preventing heart problems. It reduces the bad cholesterol and raises the good cholesterol in our body. So, it can be given as a supplement in multiple diseases including cardiac problems.

**KEYWORDS :** Amla (Emblca officinalis), Ayurveda, Extract, Supplement, Heart disease.

### Introduction:

In recent years a paradigm shift has been observed globally as people from all over the world have recognized the significance of our traditional Ayurveda. India is a land of herbs and medicinal plants and we have been following yoga and Ayurveda for years. Popularly known as Indian gooseberry, amalika, or amla, (*Emblca officinalis*) it is a common rasayana herb, used in our traditional Ayurvedic medicine from ages. (1) The herbal extracts of amla have known properties to cure diseases which lead to illness. In combinations as well as individual herbs, Rasayana herbal medicines restore the immune system, assist in cellular repair and rejuvenation of our health system. (2) Amla have several medicinal properties which make this herb a potential candidate for prophylaxis and in the treatment of several ailments. Furthermore, it has been evidenced that it lowers the cholesterol levels in pre-clinical and clinical studies (3,4). Thereby, it can be recommended as a supplement to keep our heart healthy. Its cardio-protective role is well known and globally accepted.

Several studies have shown amla's antioxidant effects in a number of diseases (5,6,7) and cardiovascular disease in one of them. One study indicates that supplementation with standardized oral extract of amla may have beneficial effects in obese adults who are overweight / class-1 by reducing multiple global risk factors for cardiovascular disease. (8) Cholesterol-lowering effect of amla extract was comparable in a study in which, supplementation with 1 gram of amla extract has profound effect on reducing the cholesterol and low-density lipoprotein (LDL) levels in 35 adults. (9)

It is evidenced by multiple studies that reversal of dyslipidemia and atherosclerotic plaque can be achieved through amla extract due to its inherited properties, such as its ability to prevent low-density lipoprotein oxidation, its antioxidant nature; it's ability to reduce cholesterol synthesis by inhibiting 3-hydroxy-3-methylglutaryl-coenzyme A reductase activity and increasing high-density lipoprotein (HDL) levels in our body. (10) Furthermore, amla exhibited antiatherogenic, anticoagulant, antihypertensive, antiplatelet, vasodilatory effects and inhibitory properties of lipid deposition (11) that is why it is considered as a wonder plant.

This study aimed to examine the therapeutic effect of Amla (*Emblca officinalis*) in cardiovascular health.

### Material and methods:

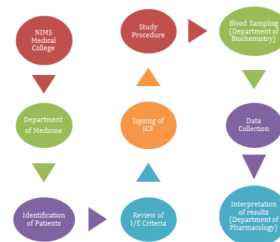
**Ethics Committee Approval:** This study was approved from Institutional Ethics Committee, NIMS Medical College & Hospital, Jaipur Rajasthan.

**Study Design:** This is an open label study conducted at Department of Pharmacology at NIMS Medical College & Hospital, Jaipur Rajasthan.

**Informed Consent:** All subjects have signed the Informed Consent Form (ICF) to voluntary participate in this study.

### Clinical Assessment and Measurements:

Subjects were informed about the study procedures and study design. They were also informed about the major inclusion and exclusion criteria. After reviewing the medical records and screening of the eligibility criteria, 45 subjects were enrolled into this study. Major inclusion criteria were type II hypercholesterolemia (i.e., serum Total Cholesterol (TC) >240 mg/dl and serum Low Density Lipoprotein-cholesterol (LDL) >130 mg/dl), presence of at least two of the following risk factors of Coronary Heart Disease (CHD) (Family history of CHD, Male >45 years or female >55 years, smoking, hypertension, serum high density lipoprotein (HDL) <35 mg/dl and Body Mass Index >27 kg/m<sup>2</sup>).



**Figure 1: Flow chart of patient screening & study procedures**

Patients were excluded from the study if they have any of the criteria, history of serious cardiovascular diseases, including stroke within past 6 months, any endocrine disorder as thyroid, concomitant serious disorder of the liver, kidney, heart, lung, muscle, receiving any drug treatment, secondary hyperlipidaemia (with the exception of diabetes mellitus), porphyria, any allergic disorder and pregnant and lactating women.

Blood samples were collected after the signing of the informed consent form. Patients were asked to visit the hospital after overnight fasting, which can be defined as around 8-10 hours of fasting without eating and drinking except water.

A total of 45 patients were enrolled into this study. They were advised to take 2 tablets of Amla (500 mg) daily at night till 16 weeks.

**Results:** Lipid parameters which included total cholesterol (TC), triglycerides (TG), high-density lipoproteins (HDL), low-density lipoproteins (LDL) and very-low-density lipoprotein (VLDL) were conducted at baseline and the same has been repeated at the end of 4 weeks, 8 weeks, 12 weeks and 16 weeks. Data was collected and finally

analysed to assess the effect of Amla on various hepatic parameters. A significant improvement has been observed in lipid profiles of subjects who had taken Amla and followed up for 16 weeks (Figure 2, 3, 4, 5, 6).

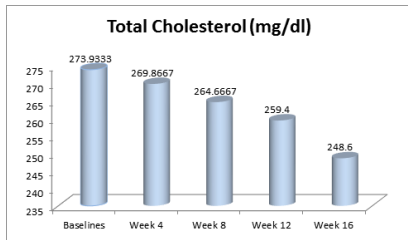


Figure 2: Weekly change in total cholesterol after taking Amla

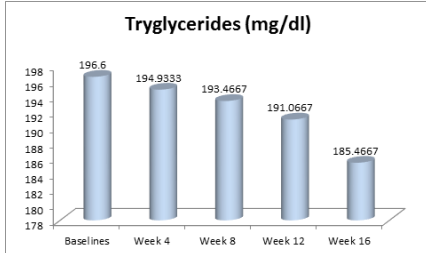


Figure 3: Weekly change in triglycerides after taking Amla

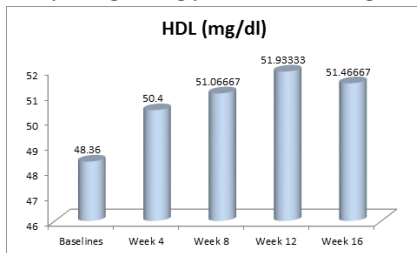


Figure 4: Weekly change in high-density lipoproteins after taking Amla

Total cholesterol, triglycerides, low-density lipoproteins and very-low-density lipoprotein were drastically reduced in 16 weeks of timeframe. Furthermore, high-density lipoproteins has significantly increased in all patients which suggest the that Amla has cardio-protective properties and it is beneficial to take Amla as a supplement to better manage the cardiovascular diseases.

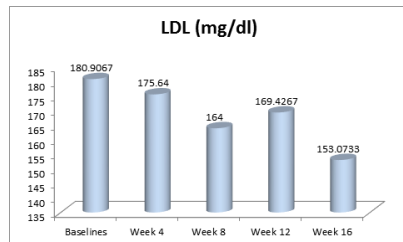


Figure 5: Weekly change in low-density lipoproteins after taking Amla

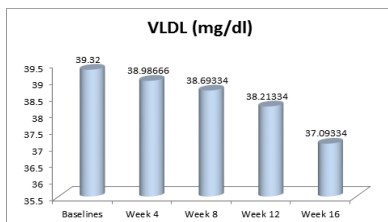


Figure 6: Weekly change in very low-density lipoproteins after taking Amla

**Limitations of the study:**

1. Study was conducted at NIMS Medical College and associated hospital so it does not represent the whole India.
2. Study duration was 16 weeks only.
3. It is unknown whether Amla works well within other comorbid conditions.

**CONCLUSION:**

Our study demonstrated that Amla has therapeutic effect in protecting heart diseases because of its healing properties. Amla is rich in several nutrients which keep our heart under healthy condition by reducing total cholesterol and triglycerides levels in our body. Multiple studies have demonstrated the same results that it helps increase the HDL-C and reduce LDL-C and total cholesterol levels in the body. Nonetheless, few clinical trials do support the hypothesis that Amla, has the same effect like other drugs in protecting and making our heart healthy.

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**REFERENCES:**

1. Mahdihassan S. The tradition of alchemy in India. *Am J Chin Med.* 1981;9(1):23-33.
2. Vayalil PK, Kuttan G, Kuttan R. Rasayanas: evidence for the concept of prevention of diseases. *Am J Chin Med.* 2002;30(1):155-171.
3. Mathur R, Sharma A, Dixit VP, Varma M. Hypolipidemic effect of fruit juice of *Emblca officinalis* in cholesterol – fed rabbits. *J Ethnopharmacol.* 1996;50:61–8.
4. Jacob A, Pandey M, Kapoor S, Saroja R. Effect of the Indian gooseberry (amla) on serum cholesterol level in men aged 35-55 years. *Eur J Clin Nutr.* 1988;42:939–44.
5. Chatterjee A, Chattopadhyay S, Bandyopadhyay SK: Biphasic effect of *Phyllanthus emblica* L. Extract on NSAID-induced ulcer: An antioxidative trail weaved with immunomodulatory effect. *Evid Based Complement Alternat Med* 2011;2011:146808.
6. Chatterjee UR, Bandyopadhyay SS, Ghosh D, Ghosal PK, Ray B: *In vitro* anti-oxidant activity, fluorescence quenching study and structural features of carbohydrate polymers from *Phyllanthus emblica*. *Int J Biol Macromol* 2011;49:637–642
7. Chen TS, Liou SY, Chang YL: Supplementation of *Emblca officinalis* (Amla) extract reduces oxidative stress in uremic patients. *Am J Chin Med* 2009;37:19–25
8. Khanna S, Das A, Spieldenner J, Rink C, Roy S. Supplementation of a standardized extract from *Phyllanthus emblica* improves cardiovascular risk factors and platelet aggregation in overweight/class-I obese adults. *J Med Food.* 2015;18(4):415-420. doi:10.1089/jmf.2014.0178
9. Jacob A, Pandey M, Kapoor S, Saroja R: Effect of the Indian gooseberry (amla) on serum cholesterol levels in men aged 35–55 years. *Eur J Clin Nutr* 1988;42):939–944
10. B. Antony, B. Merina, V. Sheeba , J. Mukkadan. Effect of standardized Amla extract on atherosclerosis and dyslipidemia. *Indian J Pharm Sci.* 2006, 68 (4): 437–441
11. Hashem-Dabaghian, Fataneh & Ziaee, Mojtaba & Ghaffari, Samad & Nabati, Farzaneh & Kianbakht, Saeed. (2018). A systematic review on the cardiovascular pharmacology of *Emblca officinalis* Gaertn. 10. 118-128. 10.15171/jcvtr.2018.20.