



IJAYUSH
International Journal of AYUSH
AYURVEDA, YOGA, UNANI, SIDDHA AND HOMEOPATHY
<http://internationaljournal.org.in/journal/index.php/ijayush/>

International Journal
Panacea
Research library
ISSN: 2349 7025

Original Research Article

Volume 9 Issue 4

Oct – Dec 2020

EFFICACY OF DIANOVA –A POLY HERBAL FORMULATION ON LIPID PROFILE IN NON- INSULIN DEPENDENT DIABETES MELLITUS PATIENTS

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Abstract:-

This present work was undertaken to study the antihyperlipidaemic effect of Dianova a poly herbal Siddha formulation, the churanam (powder) of Dianova consist of 6 herbs, *Gymnema sylvestre*, *Eugenia jambolana*, *Salasia reticulata*, *Curcuma longa*, *Terminalia chebula*, & *Phyllanthus embilica*. All herbs have antidiabetic effect. The present study was planned to effect the clinical efficacy and safety of Dianova in the management of lipid profile in Non –insulin dependent diabetic mellitus . This was a preliminary clinical trial. A total of 10 patients of either sex, between 55- 65 years of age, in whom the diagnosis of NIDDM was confirmed, and who were willing to give informed consent were included in the study. Insulin – dependent diabetes mellitus patients and NIDDM patients with acute complications of diabetes, patients with severe hypertension and who were not willing to give informed consent were excluded in the study. Before the administration of the drug under trial initial lipid profile level was taken subsequently the lipid profile level at the end of 1st, 2nd & 3rd week following the administration of drug under trial. Dianova was administered as a dose of 3g twice daily for 3 weeks. All the patients were followed up for 3 wks. (during the treatment period). All adverse events reported or observed by patients were recorded with information about severity, date of onset, duration and action taken regarding the drug. Statistical analysis was done. This study observed a results of blood testing for lipid profile level among patient ,the prevalence of lipid profile level reduced in lipid profile level. The initial and final Cholesterol (mg/dl) values were **182+/-2.30 and 148 +/- 2.6**, Serum HDL Level (mg/ dl) **45.5 +/- 1.30 and 43.5 +/- 2.6**, Serum LDL Level (mg/dl) **103 +/- 2.40 and 84 +/- 1.7** and Triglycerides Level (mg/ dl) **184 +/- 2.40 and 158+/- 2.8** , $P < 0.001$ respectively. The present study Dianova shows significant antihyperlipidaemic activity.

Key words:- Diabetes mellitus, Dianova., Siddha formulation, antihyperlipidaemic

INTRODUCTION

Diabetes mellitus is a hereditary disorder with metabolic and vascular Derangements 25 billion people in the world are diabetic. In Sri Lanka Diabetes mellitus 229.3 cases per 100,000 population, Death 3.1 per 100,000 population [1]. Most of complication resulting from hyperglycemia, such as eye, kidney and nerve damage, as well as heart disease, can be easily reduced, delayed or even prevented with adequate blood sugar control. The World Health Organization calls diabetes a major 'global epidemic in the United States, at least one person is diagnosed with diabetes every 60 seconds, and more than 14 million Americans have the disease. In some of the developing nations, diabetes may affect 30-40 per cent of the population. What is frightening is that there seems to be little hope of this epidemic decreasing or going away[2]. Diabetes mellitus (DM) is a chronic disorder characterized by both postprandial and fasting hyperglycaemia with disturbances in carbohydrate, fat and protein metabolism[3]. Diabetic hyperglycaemia results either from an absolute deficiency in insulin secretion (type 1 diabetes mellitus) or insulin action (type 2 diabetes mellitus) or both[4]. Approximately 171 million people worldwide suffer from diabetes mellitus[5]. If not controlled, hyperglycaemia can lead to the development of microvascular disorders such as nephropathy and retinopathy and macrovascular complications including cardiomyopathy, neuropathy, atherosclerosis and myocardial infarction[6]. In diabetic condition not only glucose, but lipid level also altered. So compounds which are used in the treatment of diabetic should have effect on lipid profile also. An understanding of lipoprotein metabolism and how it influences diabetes is of particular importance because of the association of lipoprotein with cardio-vascular diseases, presently leading cause of death among persons with NIDDM and those with IDDM. Although lipoprotein alteration appear to be intrinsic part of these disorders, such alterations also are induced by diabetes associated complications[7]. Plants continue to play an important role in the treatment of type 2 diabetes mellitus particularly in developing countries where most people have limited resources and do not have access to conventional anti-diabetic drugs[8]. Many of the plants that are traditionally used as anti-diabetic remedies have been evaluated and their blood glucose lowering effect confirmed in experimental animal models of diabetes

mellitus [9] and clinical studies[10]. About 80% of the world's population rely on traditional remedies prescribed by indigenous medical practitioners. Indigenous medical in Sri Lanka also use many locally available plants and plant preparation for the control of diabetes[11]. This not only contain information about the types of plants preparation used by indigenous medical practitioners in Sri Lanka. But also a summary of all the scientific investigation that have been conducted with them so far information regarding plants used in other parts of the world for the control of diabetes mellitus. I hope this manuscript will not only be useful as a reference but will also help to promote further research in to hypoglycemic activities of plants and plant based preparation which have not been subject to controlled scientific investigation so far, isolation and identification of active principles from medicinal plants and by which these natural therapeutic agents mediate their hypoglycemic action, with a view to developing more effective and cheaper drugs for the control of diabetes mellitus, with less side effects than those in current use several medicinal plants find place in treatment of diabetes and can be used for long term without serious side effects[12]. This present work was under taken to study the antihyperlipidaemic effect of Dianova a poly herbal Siddha formulation , the churanam (powder) of Dianova consist of 6 herbs, *Gymnema sylvestre*, *Eugenia jambolana*, *Salasia reticulata*, *Curcuma longa*, *Terminalia chebula*, & *Phyllanthus embilica*. Which are anti diabetic, safe, easily available and avoid of side effects.

OBJECTIVE;- To evaluate the clinical efficacy of Dianova on lipid profile in Non – insulin depended diabetes mellitus patients.

MATERRIAL AND METHODS

Type of study: Clinical study

Sample Population: - 20 Selection of patient diabetic mellitus

Study Area: - Jaffna, SriLanka.

The Ethical clearance

The ethical guidelines of Medical Faculty University of Jaffna. The study protocol, case report forms, regulatory clearance documents, product related information and informed consent form (Tamil) were submitted to the Ethical Review Committee and approved by the same.

Inclusion Criteria:

Patients having classical symptoms of diabetes mellitus with blood sugar elevation.

Increased post prandial blood sugar

Over 40 years of age.

Exclusion Criteria:

Patients of IDDM or Juvenile onset of Diabetes mellitus.

Diabetes mellitus with severe complications

Pregnant and lactating mothers.

Statistical Analysis :-

The significance between the groups was verified by one-way analysis of variance (Anova). The results were expressed as Mean \pm S.E.M. Statistical significance

Experimental Procedure:

All the patients selected for the study were registered after detailed study of history and thorough clinical examination. The study was conducted with the consent of the patient in Jaffna who were informed about the study drug, its effects, duration of the trial, and overall plan of the study. The patients were included in the clinical study only after written informed consent was obtained from them. Twenty patients of either sex, between the ages of 40 – 60 years with Type – 2 diabetes mellitus were selected for the clinical trial. Before administering the drug under trial serum lipid profile level was taken, subsequently at the end of 1st, 2nd & 3rd week following the administration of trial drug the serum lipid profile level was taken. Dianova was

administered in a dose of 3g twice daily for 3 weeks. All patients are examined at the end of the third week. The symptomatic evaluation, clinical examination and investigation were done and recording the occurrence of any adverse event/s (either reported or observed). There were no clinically significant adverse reaction (Unexpected and unwanted complications) during the preliminary period of study and good patient compliance was observed. Anyhow patients were allowed to voluntarily withdraw from the study if they experience any discomfort during the study. In the case of mild tolerable unwanted complications under trial were promptly managed by researcher.

Result and discussion:

Table -1: Effect of Dianova on Cholesterol Level

Initial mg/dl	1 st week mg/dl	2 nd week mg/dl	Final mg/dl
182 +/- 2.30	174 +/- 2.8	162 +/- 2.9	148 +/- 2.6

P < 0.001

Table -2 : Effect of Dianova on Serum HDL Level

Initial mg/dl	1 st week mg/dl	2 nd week mg/dl	Final mg/dl
45.5 +/- 1.30	58 +/- 1.9	50 +/- 1.2	43.5 +/- 2.6

P < 0.001

Table -3 Effect of Dianova on Serum LDL Level

Initial mg/dl	1 st week mg/dl	2 nd week mg/dl	Final mg/dl
103 +/- 2.40	98.7 +/- 1.2	90.5 +/- 2.0	84 +/- 1.7

P < 0.001

Table -4 Effect of Dianova Triglycerides Level

Initial mg/dl	1st week mg/dl	2nd week mg/dl	Final mg/dl
184 +/- 2.40	178 +/- 2.10	163.5 +/- 2.1	158 +/- 2.8

P < 0.001

Hyperlipidemia means presence of a high amount of cholesterol in the body has been demonstrated to elevate total cholesterol and may increase the risk of atherosclerosis and lead to cardiovascular disease. Herbs play a key role in the management of various CVD. Numerous medicinal plants and their formulations are used for hyperlipidemia in ethnomedical practices and in traditional system of medicine in India. However, we do not satisfactory remedy for hyperlipidemia; most of the herbal drugs speed up the reduction of cholesterol by healthy dietary intake. The present study carried out antihyperlipidaemic activity of Dianova substantiated. The results are shown in table 1,2,3,4 above. Dianova powder shows changes in serum cholesterol levels differ significantly (*P* < 0.001). This was significantly higher (*p* < 0.001). Effect of Dianova on Serum HDL Level *P* < 0.001, Effect of Dianova on Serum LDL Level *P* < 0.001, Effect of Dianova Triglycerides Level *P* < 0.001. Hyperlipidemic condition may occur in diabetes mellitus because of stimulation of lipolysis in adipose tissue primarily due to lack of biologically active insulin [13]. Curcuma longa have an ability to lower blood cholesterol levels [14]. Eugenia jambolana significantly decrease the blood cholesterol level [15] In one study, the administration of Eugenia jambolana significantly decreased the levels of blood glucose, blood uria and cholesterol, with increased glucose tolerance and the levels of total proteins and liver glycogen. It also decreased the activities of glutamate oxaloacetate transminase and glutamate pyruvate transminase and the hypoglycemic efficacy was comparable to glibenclamide [16]. In another study, administration of Eugenia jambolana resulted in the enhancement in serum insulin levels in normoglycemic and diabetic rates and the incubation of isolated islets of langerhans with Eugenia jambolana was found to stimulate insulin secretion in

normal and diabetic animals, accompanied by the inhibition of hepatic and renal insulinase activity[17]. *Gymnema sylvestre*, *Salacia reticulata*, *Eugenia jambolana* has already been proved to be nontoxic and has action of Hypoglycemic effect. This is mentioned in the research[18]. *Terminalia chebula*, *Phyllanthus emblica* & *Curcuma longa* are used in several decoctions prescribed for Diabetes mellitus[19], as one of the ingredient. these decoctions are mentioned[20]. The drug of Dianova is a combination of drugs Containing *Gymnema sylvestre*, *Terminalia chebula*, *Salacia reiticulata*, *Phyllanthus emblica*, *Curcuma longa* & *Eugenia jambolana*. These plants are safe, easily available and possess hypoglycemic & antihyperlipidaemic effect.

CONCLUSIONN:

This present study Dianova shows significant antihyperlipdaemic activity

CONSENT FOR PUBLICATION Not applicable.

AVAILABILITY OF DATA AND MATERIALS The author confirms that the data supporting the findings of this research are available within the article.

FUNDING None

CONFLICT OF INTEREST Authors have no conflict of interest.

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