

EVALUATION OF THE CLINICAL EFFICACY AND SAFETY OF MONETA WELLNESS NONI IN DIABETES

Diabetes mellitus often simply Diabetes is a syndrome characterized by disordered metabolism and inappropriately high blood sugar (hyperglycaemia) resulting from either low levels of the hormone insulin or from abnormal resistance to insulin's effects coupled with inadequate levels of insulin secretion to compensate. The characteristic symptoms are excessive urine production (polyuria), excessive thirst and increased fluid intake (polydipsia), and blurred vision. These symptoms are likely absent if the blood sugar is only mildly elevated.

The World Health Organization recognizes three main forms of Diabetes mellitus: type 1, type 2, and gestational Diabetes (occurring during pregnancy), which have different causes and population distributions. While, ultimately, all forms are due to the beta cells of the pancreas being unable to produce sufficient insulin to prevent hyperglycemia, the causes are different. Type 1 Diabetes is usually due to autoimmune destruction of the pancreatic beta cells. Type 2 Diabetes is characterized by insulin resistance in target tissues, this causes a need for abnormally high amounts of insulin and Diabetes develops when the beta cells cannot meet this demand. Gestational Diabetes is similar to type 2 Diabetes in that it involves insulin resistance; the hormones of pregnancy can cause insulin resistance in women genetically predisposed to developing this condition.

Gestational Diabetes typically resolves with delivery of the child, however types 1 and 2 Diabetes are chronic conditions. All types have been treatable since insulin became medically available in 1921. Type 1 Diabetes, in which insulin is not secreted by the pancreas, is directly treatable only with injected or inhaled insulin, although dietary and other lifestyle adjustments are part of management. Type 2 may be managed with a combination of dietary treatment, tablets and injections and, frequently, insulin supplementation. While insulin was originally produced from natural sources such as porcine pancreas, most insulin used today is produced through genetic engineering, either as a direct copy of human insulin, or human insulin with modified molecules that provide

different onset and duration of action. Insulin can also be delivered continuously by a specialized pump which subcutaneously provides insulin through a changeable catheter.

Diabetes can cause many complications. Acute complications (hypoglycemia, ketoacidosis or nonketotic hyperosmolar coma) may occur if the disease is not adequately controlled. Serious long-term complications include cardiovascular disease (doubled risk), chronic renal failure, retinal damage (which can lead to blindness), nerve damage (of several kinds), and microvascular damage, which may cause impotence and poor healing. Poor healing of wounds, particularly of the feet, can lead to gangrene, which may require amputation. Adequate treatment of Diabetes, as well as increased emphasis on blood pressure control and lifestyle factors (such as not smoking and keeping a healthy body weight), may improve the risk profile of most aforementioned complications. In the developed world, Diabetes is the most significant cause of adult blindness in the non-elderly, the leading cause of non-traumatic amputation in adults, and diabetic nephropathy is the main illness requiring renal dialysis in the United States and India.

Despite understanding the etio-pathogenesis of diabetes, there is an alarming rise in the insulin-resistant cases and failure of OHAs. Early diagnosis and control of diabetes is important in order to reduce the risk of later complications. Various herbs have been found beneficial in the management of DIABETES and are gaining considerable recognition in the management of diabetes worldwide. The present study was planned to evaluate the clinical efficacy and safety of Moneta wellness noni as a monotherapy and also as an adjunct with other OHAs, in the management of diabetes.

This was a prospective, open, non-randomized, phase I clinical trial. A total of 20 patients of either sex, between 30-60 years of age, in whom the diagnosis of diabetes was confirmed, and who were willing to give informed consent were included in the study. Pregnant and lactating women, patients with concomitant severe illness necessitating other medications, patients with severe hypertension, history of severe unstable angina,

myocardial infarction, CVAs, renal failure, were excluded from the study. All enrolled patients were categorized into 2 groups.

In all the patients, BSL was assessed at the time of enrollment and thereafter every month, for 3 months. All the patients had to undergo biochemical laboratory investigations. The improvement in the diabetes symptoms were rated using a predefined symptom score scale ranging from 0-3.

All the patients were followed up for 3 months (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 study drug. Statistical analysis was done according to intention-to-treat principles.

Moneta wellness noni is a polyherbal formulation which contains extracts of *Morinda cirifolia*, *Withania somnifera*, *Boerhaavia diffusa*, *Tinospora cordifolia*, *Tribulus terrestris* etc., and the present study was planned to evaluate the clinical efficacy and safety of Moneta wellness Noni as mono therapy. and also as an adjunct in the management of DIABETES.

Study aim

The present study was planned to evaluate the clinical efficacy and safety (long- and short-term) of Moneta wellness noni as monotherapy and as an adjunct in the management of DIABETES.

Study design

This was a prospective, open, non-randomized, phase I clinical trial.

MATERIALS AND METHODS

Inclusion criteria

A total of 36 patients of either sex, between 30-60 years of age in whom the diagnosis of diabetes was confirmed, and who were willing to give informed consent were included in the study. The WHO diagnosis criteria (1980) was considered for diagnosis of diabetes (For newly diagnosed patients: FBSL >120 mg% and after 2 hours of consuming 75 grams of glucose: >180 mg%).

Exclusion criteria:

Diabetes patients with acute complications of Diabetes were excluded from the trial. Pregnant and lactating women, patients with concomitant severe illness necessitating other medications, patients with severe hypertension, history of severe unstable angina, myocardial infarction, CVAs, renal failure, and those patients, who were not willing to give informed consent were also excluded from the study.

Study procedure:

All patients were investigated for urine (routine and microscopic), hemogram, total leucocyte count, differential leucocyte count, serum creatinine, blood urea, serum albumin, serum globulin and lipid profile. The improvement in the diabetes symptoms was assessed using a predefined symptom score scale from 0 to 3 (0=absent, 1=mild, 2=moderate and 3=severe).

Primary and secondary endpoints

The predefined primary efficacy end points were PPBSL control and reduction in the dose of other OHAs. The PPBSL control was graded as: excellent : upto 130 mg%, good : upto 150 mg%, fair : upto 180 mg%, poor : upto 250 mg% and treatment failure : >250 mg%. The predefined secondary safety endpoints were reduced incidence of adverse reactions and overall compliance to the drug therapy.

Follow-up and assessment

All patients were followed up for 3 months (during the treatment period) and at each follow-up visit, the patient's response to the study drug was recorded in a structured CRF. The subjective symptomatic relief and changes in the symptom score scale for each symptom were recorded during each follow-up visit.

Adverse events All adverse events reported or observed by patients were recorded with information about the severity, date of onset, duration and action taken regarding the study drug. Relation of adverse events to study medication was predefined as "*Unrelated*" (a reaction that does not follow a reasonable temporal sequence from the time of administration of the drug), "*Possible*" (follows a known response pattern to the suspected drug, but could have been produced by the patient's clinical state or other

modes of therapy administered to the patient), and “*Probable*” (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient’s clinical state). Patients were allowed to voluntarily withdraw from the study, if they had experienced serious discomfort during the study or sustained serious clinical events requiring specific treatment. For patients withdrawing from the study, efforts were made to ascertain the reason for dropout. Non-compliance (defined as failure to take less than 80% of the medication) was not regarded as treatment failure, and reasons for non-compliance were noted.

RESULTS

There was a significant reduction in the FBSL in the newly diagnosed patients of DIABETES from 170 ± 40.47 mg% to 161.51 ± 52.13 mg%. Similarly, there was a significant reduction in the PPBSL from 247.66 ± 70.65 mg% to 223.13 ± 79.22 mg%

In those patients who consumed Moneta wellness Noni along with OHAs, there was highly significant reduction in FBSL from 217.69 ± 55.77 mg% to 148.66 ± 35.49 mg%, after a month and there was further reduction to 125.40 ± 39.43 mg%, at the end of the study. There was a significant improvement in the general symptoms of diabetes such as polyuria, generalized weakness and there was an improvement in the appetite. The study also observed a reduction in leg cramps and burning sensation in hands and soles. There were no clinically significant changes in the hematological and biochemical parameters regarding organ damage. There were no clinically significant adverse reactions observed by the investigators and the overall compliance to the treatment was excellent.

DISCUSSION:

This study observed a significant reduction in the FBSL and PPBSL in the newly diagnosed patients of diabetes and a highly significant reduction in FBSL and PPBSL also in those patients who consumed moneta wellness noni along with OHAs. These beneficial effects of Moneta wellness noni in diabetes might be due to the synergistic action of its ingredients, which are well documented. Alkaloids of Noni, withanoids from *withania somnifera*, and tribulus from *Tribulus terrestris* have an ameliorating influence on diabetic nephropathy, possibly by their ability to lower blood cholesterol levels. Analysis of documented data on enzymuria, albuminuria, activity on renal ATPases and fatty acid composition of renal membranes in diabetic condition indicate that NONI significantly arrest the progression of diabetic nephropathy.

The active ingredients of *Embellica officinale* and has been studied extensively for its beneficial action in Diabetes mellitus. It appears to correct the metabolic derangements in diabetic liver, kidney and muscle and reverses the hepatic pathological changes during the hyperglycemic phase by controlling hyperglycemia. Significant inhibition of gluconeogenesis by *Tribulus terrestris*, along with the reduction in the levels of plasma triglycerides have been documented.

Oxidative stress has a critical role to play in the initiation of hyperglycemia; and it is also responsible for tissue damage and vascular endothelial dysfunction, leading to the diabetic complications. Many of the herbs used in Moneta wellness noni act as powerful antioxidants. The antioxidant activity of *Tinospora cordifolia*, *Boerhaavia aristata*, has a contributory role in the antihyperglycemic activity of Moneta wellness noni.

As observed in various studies, Moneta wellness Noni helps in improving the glycogen stores in the liver and prevents the oxidative damage of beta cells by increasing the islet cell superoxide dismutase activity. Moneta wellness Noni stimulates insulin secretion by stimulating cell membrane permeability, and also helps in the regeneration and revitalization of islet cells. Moneta wellness Noni also enhances the peripheral utilization of glucose. By exerting effective control over hyperglycemia, Moneta wellness Noni thus prevents complications due to uncontrolled hyperglycemia.

CONCLUSION

Despite understanding the etiopathogenesis of diabetes, there is an alarming rise in the insulin resistant cases and failure of OHAs. Early diagnosis and control of diabetes is important in order to reduce the risk of later complications. Various herbs have been found beneficial in the management of diabetes and are gaining considerable recognition in the management of diabetes worldwide. The present study was planned to evaluate the clinical efficacy and safety of Moneta wellness Noni as a monotherapy and also as an adjunct with other OHAs in the management of diabetes. Therefore, it may be concluded that Moneta wellness Noni is clinically effective and safe in the management of diabetes, as a monotherapy in newly diagnosed patients and as an adjunct in patients on conventional OHAs.

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