Effects of combination of Shilajit extract and Ashwagandha (Withania somnifera) on fasting blood sugar and lipid profile

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ABSTRACT
This preliminary clinical study was conducted to evaluate the effect of combination of Shilajit extract and Ashwagandha (Withania somnifera) on fasting blood sugar and lipid profile subjects with early diagnosed type-II diabetes (NIDDM). At the onset of treatment baseline assessment was taken following General symptomatic examination, Average Fasting Blood sugar and lipid profile. The patients were instructed to take investigational combination twice a day for four weeks. At the end of the therapy period, it was found that the drug had considerably reduced symptoms related to diabetes, average fasting blood sugar and lipid profile.

Keywords: Ashwagandha, Shilajit, Average Fasting sugar, Lipid profile

INTRODUCTION

Diabetes, long considered a disease of minor significance to world health, is now emerging as one of the main threats to human health in the 21st century not only in developed nations but also in developing countries where non-communicable diseases are rapidly overtaking communicable diseases as the commonest cause of death. Recent World Health Organization (WHO) projections suggest that in the next two decades, the largest increase of diabetes will be seen in the economically productive age group i.e. 20 – 45 year old individuals in developing countries. With its population over 1 billion, India leads the world with its largest number of diabetic subjects (over 35 million) and this number is predicted to increase to around 80 million by the year 2030.

In the early 70’s prevalence of diabetes was 2.3% in the urban and 1.5% in the rural India. Recent studies have reported a high prevalence of diabetes between 12-16% in the urban population and 4-6% of the rural population of India. Thus, diabetes has become a great medical and health economic challenge as it drains between 5 – 25% of the family income of an average Indian, which translates to 2.2 billion US dollars per annum.

Diabetes mellitus was known to ancient Indian physicians as ‘Madhumeha’. Since, so many herbal products including several metals and minerals have been described for the care of Diabetes mellitus in ancient literature. Ayurveda has been the first to give an elaborate description of this disease, its clinical features and the patterns, and its management by herbal or herbomineral drugs. It is seen that certain resistant cases of diabetes who do not respond well to modern medicines like Chlorpropamide, Tolbutamide and Glibenclamide respond very well when treated with herbal preparations, alone or in combination with other oral hypoglycemic agents. Herbs have been shown to have hypoglycemic action in animals and humans.

Non-insulin-dependent diabetes mellitus is among the most common disorders in developed and developing countries. It amounts for about 85% of diabetes world-wide and is associated with enormous amount of morbidity and mortality resulting from its micro vascular and macro vascular complications.

The treatment of hyperglycemia in NIDDM is aimed at alleviating the symptoms, increasing the sense of well being and the quality of life with minimizing the chronic complications. Oral hypoglycaemic drugs play an important role in the treatment of non insulin-dependent diabetes mellitus. But none have been unequivocally successful in maintaining euglycaemia and in avoiding late complications of diabetes. In spite of several advances in therapeutics and detailed understanding of the disease, diabetes still remains a major cause of morbidity and mortality in the modern world. Ancient Indian medicine mentions various plants and mineral preparations in the treatment of diabetes mellitus. There are different combinations of these plants and minerals which can be given orally and for prolonged periods without any side-effects.

The goal for treatment of diabetes is to prevent its acute manifestations and long-term micro vascular and macro vascular complications. NIDDM is one of the most common disorders in developed and developing countries. Reaven has reported that abnormalities of beta cell function and secretion exist in patients with NIDDM.
O’Rahilly et al. observed that the inherited component of familial Type II diabetes may be the impaired insulin secreting response of the beta cells. While fasting serum insulin may be in the normal range, glucose-induced insulin release is reduced, leaving below-normal insulin levels in the postprandial state. Oral hypoglycaemic drugs play an important role in the treatment of Type II diabetes mellitus but none have been found effective in maintaining euglycaemia. In about one-quarter of patients with an initially good response, the drugs later lose their effectiveness. Ashwagandha root, also known as winter cherry or Indian ginseng, is an important herb from the Ayurvedic or Indian system of medicine. Ashwagandha has been traditionally used for the treatment of debility, emaciation, impotence, and premature aging. A very small study of 6 individuals with mild type 2 diabetes and 6 other individuals with mildly elevated cholesterol were treated with ashwagandha for 30 days. A decrease in blood glucose was noted as was a decrease in cholesterol and triglycerides. Ashwagandha root powder decreased total lipids, cholesterol and triglycerides in hypercholesteremic animals. On the other hand, significantly increased plasma HDL-cholesterol levels, HMG-CoA reductase activity and bile acid content of liver. A similar trend also reported in bile acid, cholesterol and neutral sterol excretion in the hypercholesteremic animals with WS administration. Further, a significant decrease in lipoperoxidation occurred in WS administered hypercholesteremic animals when compared to their normal counterparts. However, WS root powder was also effective in normal subjects for decreasing lipid profiles. In another study it is established that Ashwagandha herb (Withania somnifera) compares favorably with metformin for lowering blood sugar, and seems to improve HDL cholesterol. Shilajit finds extensive use in Ayurveda, for diverse clinical conditions. For centuries people living in the isolated villages in Himalaya and adjoining regions have used shilajit alone or in combination with other plant remedies to prevent and combat problems with diabetes. Medical researchers have taken a more serious interest in determining if the claims regarding the antidiabetic effects of shilajit have scientific merit. Studies done by Gupta and Bhattacharya have also reported the antidiabetic actions of shilajit. Combination of shilajit (100 mg/kg) with glibenclamide (5 mg/kg/day) or metformin (0.5 gm/kg/day) significantly enhanced the glucose-lowering ability and improvement in lipid profile than any of these drugs given alone. Shilajit is effective in controlling blood glucose levels and improves the lipid profile. Various herbs and minerals described in ayurvedic texts are very much effective in reducing blood sugar and lipid profile. In the present study we selected the fine extracts of Ashwagandha (Withania somnifera) and Shilajit extract to evaluate the efficacy in NIDDM patients.

**MATERIAL AND METHOD:**

**Subjects:**

Thirty two (32) subjects with early diagnosed type-II diabetes (NIDDM) were enrolled in the trial. In these subjects 21 were Male and 11 were Female participants and the mean age was 36±5.27. Informed consent was obtained from all patients included in the trial. All subjects were on restricted diet and advised to follow diet chart given to him. A careful history was taken and a detailed examination carried out. 5ml blood in to heparinized tubes to screen for Fasting blood sugar and lipid profile. All the patients were examined for signs and symptoms and their severity was recorded.

**Investigational Drug:**

Herbal capsules containing aqueous extract of Ashwagandha (*Withania somnifera*)-250mg and pure Shilajit extract-250mg were prepared as investigational drug. Two capsules of investigational drug named Ashwashila capsule were given in morning and evening to all subjects.

**Statistical Analysis:**

Data is expressed as mean ± SD. Analysis of the results will be made by using Student’s Paired “t” test between the initial values and at the end of one month.

**RESULTS:**

In this study, it was observed that out of 32 patients 18 subjects who were suffering from associated symptoms of diabetes like excessive thirst, fatigue etc had good improvement while condition of 4 subjects had unchanged. Significant reduction is found in fasting blood sugar, low density lipids, very low-density lipoprotein , total cholesterol/high density lipoprotein ratio. The results of fasting blood sugar and lipid profile is expressed in Table-1.

**DISCUSSION:**

Basic scientific studies of Ayurvedic medicine have not been rigorously pursued. There are currently few RCTs and CCTs in the literature, which hinders the assessment of efficacy. Future trials need to enroll an adequate number of subjects. Interventions should be compared to placebo preparations, and care should be taken to construct placebos that cannot be distinguished from the trial drug. The clinical trials of Ayurvedic therapies for diabetes need to be better reported. The method of patient selection and assignment to arms needs to be better described, and the reporting of results should follow good statistical practice. In addition, the trials need to be of sufficient length to determine a relevant clinical effect. It would also be useful to investigate the efficacy of single-herb therapies versus the relatively complex Ayurvedic formulas used. Present study demonstrates that the combination of Ashwagandha with Shilajit extract exhibits significant results on Fasting blood sugar, low density lipids, very low-density lipoprotein, total cholesterol/high density lipoprotein ratio.

**CONCLUSION:**

Based on the results of the study, it can be concluded that combination of Shilajit extract and Ashwagandha (*Withania somnifera*) can be a useful drug in the treatment of uncomplicated as well as complicated diabetes. Combination of Shilajit extract and Ashwagandha (*Withania somnifera*) is very much effective in reducing high lipids and cholesterol.

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**REFERENCES:**


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