Effect of D-400 on Blood Glucose Profile in Non-Insulin Dependent Diabetes Mellitus Patients

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SUMMARY
D-400, herbomineral formulation was evaluated for its effect on blood sugar levels in 28 NIDDM patients. The mean initial fasting blood sugar (FBS) was 150.17 ± 8.3 mg and mean post prandial blood sugar (PPBS) was 230.83 ± 19.14 mg%. After a monthly follow-up for six consecutive months, a significant reduction in both FBS and 2 hours PPBS was noticed starting from the second month itself. At the completion of six months, mean FBS was 120.13 ± 3.4 mg% and mean PPBS was 134.75 ± 6.13 mg% thereafter D-400 was withdrawn in all patients which resulted in rebound hyperglycaemia: mean FBS was 185.21 ± 7.56 mg% and mean PPBS 272.08 ± 14.35 mg% thus confirming the hypoglycaemic effect of D-400. At the end of three months, four patients who did not show a favourable response, were withdrawn from the trial.

Keywords: D-400, Herbomineral preparation, FBS, 2 hr. PPBS. Rebound hyperglycaemia.

INTRODUCTION
A number of herbs have been long known to possess hypoglycaemic action in both experimental animals and humans. Ayurveda, an indigenous system of medicine was the first to give a detailed description on the clinical features and management of Madhumeha (Diabetes mellitus)1. Efforts are being made to establish their efficacy in controlling diabetes which owing to its various complications results in increased morbidity and mortality. Risk factors like obesity, hyperlipidaemia and hypertension are more commonly prevalent in diabetes2. NIDDM is principally a disease of energy storage exacerbated by insulin deficiency. The present trend in the management of diabetes mellitus includes diet and lifestyle modification, oral hypoglycaemic agents and insulin. Although it is not yet confirmed if tight glycaemic control can prevent long-term diabetes complications, it has been reasonably proved that these complications may at least be postponed3. Prolonged use of oral anti-diabetic agents have their own deleterious effects. Profound hypoglycaemia may occur as a result of accumulation of these drugs particularly if their elimination is impaired. Chlorpropamide is not recommended in patients with renal failure, besides, it also has a tendency to produce nocturnal resistant hypoglycaemia and lactic acidosis is a major and potentially dangerous side effect of biguanides4. Hence the need for a herbomineral formulation which is effective and safe for prolonged use and which also averts long-term complications.

D-400 is a herbomineral formulation, whose main ingredients are Shilajeet,4 Gymnema sylvestre,6 Pterocarpus mascupium,7 Casearia esculanta, Eugenia jambolana,8-11 Ocimum Sanctum12 and Momordica charantia13,14,15 among others. Momordica charantia potentiates tolbutamide action and promotes peripheral glucose utilization16. A crystalline fraction extracted from the fruit of Momordica charantia causes hypoglycaemic effects similar to that of insulin in insulin-dependent diabetes mellitus. Shilajeet has pancreateotrophic action and promotes weight gain 17.
PATIENTS AND METHODS
Twenty eight patients of either sex and in the age range of 30 to 70 years, who attended the OPD between August 1993 and April 1994 at our hospital, were recruited for an open clinical trial of D-400. The protocol was cleared by the Ethical Committee before the commencement of the study. Twenty patients were freshly diagnosed and eight were already on standard oral hypoglycaemic agents in whom a drug wash-out period of one month was given. Patients were selected on the basis of WHO criteria TRC series number 725:1985. Patients with FBS 140 mg/dl or higher and/or PPBS 180 mg/dl or higher, were included in this trial. The mean BMI was 27.04 in males and 26.22 in females. A trial of diet and lifestyle modification alone was given to freshly diagnosed cases for three months, failing which they were recruited for the trial. Patients with cardiovascular disease, pregnancy, severe hypertension and diabetic complications were excluded from this trial. The patients took 2 tabs. of D-400 twice daily and the dose was adjusted depending on the blood sugar levels in their subsequent monthly visits for 6 months after which D-400 was withdrawn. The FBS and 2-hour PPBS were recorded every month.

RESULTS
It was observed that there was a significant reduction in both FBS and PPBS levels in the 24 patients who completed the trial. The mean FBS and PPBS initially were 150.17 ± 8.31 and 230.83 ± 19.14 respectively; after 3 months mean FBS and PPBS were 128.17 ± 5.46 and 173.58 ± 12.09 respectively and at the end of 6 months, mean FBS was 120.13 ± 3.4 and PPBS was 134.75 ± 6.13 (Figs. 1 and 2). Blood sugar was checked every month and two months after the withdrawal of D-400 there was rebound hyperglycaemia in all patients: FBS was 185.2 ± 7.36 and PPBS was 272.08 ± 14.35 which confirms the hypoglycaemic effect of D-400. Four patients were withdrawn from the trial since they did not show a favourable response. None of the patients complained of any side effects and all who completed the trial reported a feeling of well-being.

DISCUSSION
D-400 is a herbomineral formulation based on Ayurvedic principles. Although preliminary reports have shown that D-400 possesses a hypoglycaemic effect, when used as an adjuvant, it was possible to withdraw or reduce the dosage of oral hypoglycaemic agents. However, it was necessary to prove its effect as a single drug and hence this study was undertaken.

Experimental trials showed that D-400 had a nephroprotective action against alloxan induced renal damage in rabbits. A double masked clinical evaluation of D-400 showed that it significantly reversed the changes in early diabetic retinopathy.
In the present study, significant glycaemic control was observed in all the 24 patients. However, better control was observed in obese NIDDM patients. The exact mechanism of action of D-400 has not yet been established but preliminary observations indicate that it probably acts by reducing the insulin resistance at periphery in NIDDM patients. Hence, it can be concluded that D-400 can be used along or as an adjuvant in NIDDM patients. A larger group of patients and a longer duration of study is suggested to conclusively prove its effect as the mainstay of drug therapy in NIDDM patients. It efficacy in arresting some of the diabetic complications also needs to be further evaluated.

REFERENCES


