Effect of Diabecon (D-400), an Ayurvedic Herbmomineral Formulation in Non-Insulin-dependent Diabetes Mellitus Cases

Ganguly D., MD, DCH
Assistant Professor
Banerjee T., MD,
Resident Medical Officer, Department of Medicine,
Medical College, Calcutta, India.
Singh, A.K., MD, PhD
Research Fellow, Institute of Postgraduate Education & Research in Ayurveda, Calcutta, India.
and
Mitra SK., M.D.
Director, R & D, The Himalaya Drug Co., Bangalore, India.

ABSTRACT
Thirty one freshly diagnosed NIDDM patients with a mean age of 54.95 ± 9.77 years, of whom 17 were males and 14 females, were put on Diabecon (D-400) in the dose of 2 tablets thrice a day for a period of 6 months. The initial and final FBS values (mg/dl) were 204.32 ± 85.37 and 136.42 ± 62.63 respectively while PPBS values were 287.32 ± 88.09 and 195.84 ± 75.53 respectively. Diabecon (D-400) produced significant reduction in both fasting and postprandial blood sugar levels. All patients had a sense of well being and no side-effects were reported.

INTRODUCTION
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 microvascular and macrovascular complications.

The treatment of hyperglycaemia in NIDDM is aimed at alleviating the symptoms, increasing the sense of well being and the quality of life with minimising 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. Inspite 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.

Diabecon (D-400), is one such formulation found to be safe and effective in lowering blood glucose levels in experimental trials. A significant reduction of triglycerides, was also reported with this drug in streptozotocin-induced diabetes mellitus in rats. The drug has also been reported to reduce the blood glucose levels in clinical trials and triglyceride levels has been reported. On the basis of these observations, an open clinical trial was conducted in patients with freshly diagnosed diabetes.

MATERIAL AND METHODS
Thirty one patients of non-insulin dependent diabetes mellitus comprising 17 males and 14 females were included in this clinical trial, after informed consent. The age of the patients ranged from 34-76 years with a mean ± standard deviation (M ± S.D.) of 54.45 ± 9.77.

The study was conducted in the Department of Endocrinology, Medical College and Hospital, Calcutta, between September 94 - February 95. All were freshly diagnosed diabetics. They were kept under observation for a period of one month with diet and exercise and those patients showing persistent hyperglycaemia at the end of one month were included in the trial. The venous blood samples were collected after a month under fasting conditions for the estimation of blood glucose. The patients were then put on Diabecon (D-400) in the dose of 2 tablets thrice a day. They were advised to come every month for 6 months.

Statistical analysis was done by using paired ‘t’ tests and Pearson’s Product Moment Correlation Coefficient to assess the linear relationship between 2 paired variables. All tests were two-tailed.

RESULTS
Table 1 represents the general data on age, sex and body mass index. Only 5 of the 31 patients were deemed obese, therefore for inferential statistical analysis, weight was not considered as a variable. Mean ± Standard Deviation of bodyweights of the patients was 55.32 ± 12.78 (range 24-81) kg. Five patients had a systolic blood pressure exceeding 140 mm Hg and 3 patients had a diastolic blood pressure exceeding 90 mm Hg. The mean ± standard deviation of systolic and diastolic blood pressure in the sample were 130.67 ± 21.50 100 - 180 and 82.47 ± 9.88 (range 60 - 110 mm Hg) respectively.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Male</th>
<th>Female</th>
<th>Initial</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>54.45 ± 9.77</td>
<td>17</td>
<td>14</td>
<td>55.32 ± 12.78</td>
<td>52.23 ± 10.68</td>
</tr>
</tbody>
</table>

There was no significant change in body mass index after Diabecon (D-400) treatment. Most of the patients reported a sense of well being. From Table 2 it is clear that treatment with Diabecon (D-400) has led to a significant decrease in fasting and postprandial blood sugar. The correlation between initial and final fasting blood sugar value was statistically significant (Pearson’s Product Moment Correlation coefficient; R=0.41, p=0.023). The decrease in fasting blood sugar with treatment was also statistically significant (p<0.001). This indicates that Diabecon (D-400) produces a statistically significant decrease in fasting blood sugar levels.

<table>
<thead>
<tr>
<th>Fasting Blood Sugar (mg/dl)</th>
<th>Postprandial Blood Sugar (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>Final</td>
</tr>
<tr>
<td>204.32 ± 85.37</td>
<td>287.32 ± 88.09</td>
</tr>
<tr>
<td>136.42 ± 62.63*</td>
<td>195.84 ± 75.53*</td>
</tr>
</tbody>
</table>

* p<0.001 as compared to respective initial values.

After treatment with Diabecon (D-400), Mean ± Standard Deviation decrease in PPBS value was 91.48 ± 88.16. The correlation between initial and final PPBS values was statistically significant (Pearson’s Product Moment Correlation Coefficient; r=0.43, p=0.016). The decrease in PPBS with treatment was also statistically significant (p<0.001). This indicates that Diabecon (D-400) produced a statistically significant decrease in PPBS levels also.

An attempt was made to identify whether the response of Diabecon (D-400) varied with age and weight. It was observed that there was no significant correlation between age, weight, and body
mass index on one hand and FBSDIFF & PPBSDIFF on the other hand indicating that response to Diabecon (D-400) was independent of age, weight and body mass index.

Next an attempt was made to identify whether the response to Diabecon (D-400) varied with gender. There was no significant difference between males and females indicating that gender did not influence the response to Diabecon (D-400) (Mann-Whitney U test).

DISCUSSION
Control of blood sugar on a 24 hour basis is the desired goal in the management of diabetes mellitus, so as to prevent or delay the onset of secondary complications of diabetes mellitus. Several hypoglycaemic agents available for clinical use are associated with a characteristic profile of side-effects and failures. There are about 15-20% of patients with newly diagnosed NIDDM, have little or no glycaemic response to sulphonylureas. With each year of treatment, about 3-5% of patients with NIDDM who have achieved acceptable or better glycaemic control are said to lose their responsiveness to sulphonylureas.

Improper glycaemic control results in the development and progression of diabetic microangiopathy in humans and West (1981) has observed that good control of diabetes has a retarding effect on the development of such complications. Poor blood sugar control results in diabetic microangiopathy with the accumulation of glycated proteins producing a thickening of basement membrane in the kidney.

Diabecon (D-400) produced significant reduction in both fasting and postprandial blood sugar levels. All the patients reported a sense of well being and no side-effect was reported.

Gymnema sylvestre, one of the important ingredients of Diabecon (D-400), has been proved to be effective in diabetes by increasing beta cell function possibly by repair/regeneration of the beta cells.

There is marked influence of Gymnema sylvestre and Pterocarpus marsupium, another ingredient of Diabecon (D-400) on glucose tolerance which may be related to inhibition of glucocorticoid activity. These plants have also been found to inhibit epinephrine induced hyperglycaemia, which is mediated by inhibition of glucose utilisation and secretion of corticoids. Diabecon (D-400) has been reported to increase the liver glycogen in alloxan-induced diabetes and has also been reported to increase incorporation of C14 glucose into hepatic slices in alloxan-induced diabetes.

On the basis of the above observations, it can be concluded that Diabecon (D-400) may elicit its hypoglycaemic action by enhancing insulin release from pancreatic B islets and also accelerate glucose uptake and peripheral glucose utilising processes. This lends credence to the use of Diabecon (D-400) as a potent anti diabetic.

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