Effect of Diabecon in Diabetic Patients with Microalbuminuria

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ABSTRACT
A study was conducted on 13 male and 9 female diabetic patients, of whom 18 patients had been diagnosed with NIDDM and 4 with IDDM, the mean duration of which was 7.9 ± 0.7 years. All the patients were administered Diabecon at a dose of 2 tablets thrice daily before meals and were followed up every month for a period of six months. A significant reduction (p<0.001) in fasting and post-prandial blood sugar levels was noticed within 2 months of treatment with Diabecon in both the NIDDM (N=18) and IDDM (N=4) groups. In the NIDDM group, the dose of OHA was reduced by 30-50%, while in the IDDM group, the dose of insulin was reduced by 20-30%. Significant reduction in serum cholesterol and microalbuminuria levels were observed in both groups within six months of therapy with Diabecon. The drug was well-tolerated and no abnormalities were observed in hepatic, renal and haemopoietic functions.

Key words: Diabecon, NIDDM, IDDM, Microalbuminuria, OHA

INTRODUCTION
Diabetes Mellitus is a chronic disease affecting millions of people all over the world. At present, the goal is to control blood sugar, minimise long-term complications and strive to maintain the general good health of the affected individual. It has been suggested that chronic complications occur less frequently in patients with near euglycaemic control1,2. However till date there is no large, well-controlled study that has demonstrated that near-euglycaemic regulations eliminate or markedly decrease the chronic complications of NIDDM. The problems faced by a physician with conventional drugs like sulphonylureas are many. About 15-20% of patients with newly diagnosed NIDDM have little or no glycaemic response to sulphonylureas3,4. While acceptable or near normal glycaemic control is gradually achieved by almost 50% of these patients, the rest have poor glycaemic control. Besides, with each year of treatment, about 3-5% of those NIDDM patients with acceptable or better glycaemic control, lose their responsiveness to sulphonylureas5,6. In addition, sulphonylurea drugs are the major cause of severe drug-induced hypoglycaemia necessitating hospitalisation. Long-acting sulphonylureas such as glyburide and chlorpropamide are associated with severe and prolonged hypoglycaemia as compared to short-acting sulphonylureas such as tolbutamide and glipizide6,7,8,9. On the other hand, treatment with metformin is associated with lactic acidosis10.

Considering the above, a study was conducted to evaluate the efficacy of Diabecon, a herbal formulation in diabetic patients, conducted on various animal models of diabetes have shown that Diabecon improves peripheral utilisation of glucose and restores hepatic and muscle glycogen. Pooled data from clinical studies indicate that Diabecon monotherapy reduces both fasting and post-prandial blood sugar in NIDDM patients. An additive effect on fasting and post-prandial glucose levels, glycosylated haemoglobin and an increased sense of well-being were noted, when Diabecon was administered in addition to oral hypoglycaemics and insulin.

PATIENTS AND METHODS
Twenty-two diabetic (13 males and 9 female) patients in the age range of 25 to 65 years, were included in this study after informed consent. Their condition was diagnosed as per criteria
recommended by the WHO. Patients with a history of hypertension, renal disease and CVA were excluded from this trial. NIDDM patients whose condition could not be controlled with OHAs despite very high doses (18 patients), and 4 IDDM patients requiring >100 units of insulin, were recruited for this study. The mean duration of diabetes was 7.9 ± 0.7 years. All patients were administered Diabecon at a dose of 2 tablets thrice daily before breakfast, lunch and dinner and were followed up every month for a period of 6 months. Fasting and post-prandial blood sugar, triglyceride and cholesterol levels were estimated every 4 weeks. Routine haemogram and microscopic examinations of urine, serum bilirubin, serum alkaline phosphatase, SGOT, SGPT, blood urea and serum creatinine were carried out before and at the end of the study. The detection of micro-albuminuria was carried out by the micral test. The freshly voided, first morning samples of urine were used for the detection of immunochemical, semi-quantitative microalbuminuria. A micral test strip was dipped in this sample for 5 seconds up to the blue test zone and withdrawn without allowing it to touch the side of the urine vessel. Thereafter, the strip was placed horizontally on a non-absorbent surface and compared to the colour scale on the strip vial after exactly 5 minutes. The predominant colour on the test zone was used for assessment. Microalbuminuria denoted an albumin excretion of 20-200 mg/L. The results were analysed at the end of the study by using unpaired Students “t” test.

**RESULTS**

A significant reduction in both fasting and post-prandial blood sugar was noticed after 2 months of treatment with Diabecon. In NIDDM patients (N=18), the initial fasting and post-prandial blood sugar levels of 194.2 ± 10 and 292.2 ± 11.7 were reduced to 116.4 ± 5.1 and 169.3 ± 3.8 respectively, at the end of 6 months (p<0.001). In the IDDM group (N=4), the fasting and post-prandial blood sugar levels were reduced from 221.8 ± 14.8 and 332.8 ± 37.7 to 138.8 ± 13.6 and 176 ± 10.2 respectively, at the end of 6 months (p<0.05) (Table). The dosage of OHAs was reduced by 30-50% while that of insulin was reduced by 20-30%, which is noteworthy. Significant reductions were also observed in serum cholesterol and microalbuminuria levels. An initial cholesterol level of 219.1 ± 12.4 was reduced to 164.4 ± 12.1 and an initial microalbuminuria level of 30 ± 5.8 was reduced to 3.9 ± 1.2, at the end of 6 months in both NIDDM and IDDM patients. However, an insignificant reduction in serum triglyceride levels was observed in both the groups.

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<th>The effect of Diabecon (D-400) in diabetic patients with microalbuminuria</th>
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<td><strong>IDDM</strong></td>
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* p<0.05; † p<0.01; ‡ p<0.0001 and § p<0.01 as compared to initial.

Diabecon was well-tolerated and no side-effects were observed. No abnormalities were detected in liver, kidney or haemopoietic functions. There were no changes in body weight, heart rate or blood pressure after treatment with Diabecon.

**DISCUSSION**

The treatment of hyperglycaemia in non-insulin-dependent diabetes patients is aimed at minimising its chronic complications. However, it is not known whether glycaemic control will markedly reduce or eliminate the same. Diabetic nephropathy is a relatively common microvascular complication of both insulin-dependent and non-insulin-dependent diabetes mellitus. Among patients with insulin-dependent diabetes, those with proteinuria are at a high risk of early mortality. Patients with long-term, poor glycaemic control are more likely to have both microalbuminuria and diabetic nephropathy and the relative mortality among patients with nephropathy is 40 times greater than among those without it. Disturbances of plasma lipoprotein take place in diabetic patients with renal disease. Increases in cholesterol, LDL and total
triglyceride levels have also been described. Studies on Zueker diabetic rats suggest that hyperlipidaemia may contribute to late glomerular sclerotic changes. Microalbuminuria patients with either IDDM or NIDDM, having normal renal function, also showed a similar pattern of lipid abnormalities. Blood glucose control appears to have only a limited impact on the progression of diabetic renal failure. Antihypertensive treatment may delay the progression of established diabetic nephropathy.

Diabecon is an herbal formulation whose ingredients are well recognized, easily available, safe, non-toxic and possess blood sugar-lowering properties. In the present study, this drug was found effective not only in lowering the blood sugar levels in IDDM and NIDDM patients but also in reducing the dosages of OHAs by 30-50% and that of insulin by 20-30% when used as an adjuvant. This drug was effective in reducing significantly the microalbuminuria and serum cholesterol levels as well. All the patients reported a sense of well-being. Diabecon was well-tolerated and no side-effects were observed. No abnormalities were detected in liver, kidney or haemopoetic function. There were no changes in body weight, heart rate and blood pressure after treatment with Diabecon.

Various antidiabetic drugs are now available worldwide to reduce hyperglycaemia by different mechanisms. While some agents may be suitable for certain types of patients with NIDDM, a combination of those that lower blood glucose using varied mechanisms is likely to be more effective than a single agent.

It can be concluded that Diabecon can be used alone or in combination with other OHAs, because it serves as a good adjuvant in those patients who are insufficiently managed with insulin and other antidiabetic mediums. It not only helps in reducing the blood sugar levels and dosages of antidiabetic agents, but also takes care of microalbuminuria and blood lipids.

REFERENCES


