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Clinical Evaluation of Antidiabetic Activity of Bael Leaves

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Abstract: Diabetes mellitus is a heterogeneous metabolic disease characterized by altered carbohydrate, lipid and protein metabolism. So many traditional herbs are being used by diabetic patients to control the disease. But very few studies are performed to investigate the efficacy of these herbs clinically. In the present study, an attempt has been made to investigate clinically the antidiabetic activity of Bael leaves (BL) (*Aegle marmelos*, Corr.) individually and collectively with the standard oral hypoglycemic therapy in non insulin dependent diabetes mellitus (NIDDM) patients. Literature survey reveals its antidiabetic activity in animals but no such studies were performed clinically. BL dried in shadow, were powdered and its decoction was used for the study. The study was performed in four different groups for a period of one month. Clinical protocol was set up for the study. Initial postprandial blood glucose level (PPBGL) was estimated at the time of enrolment in the study and then after one month of the study period. At the end of the study, the initial and final readings were compared. BL 5gm powder individually once daily orally was found to have antidiabetic effect. Antidiabetic effect was more markedly observed when it was combined with the oral hypoglycemic therapy. BL can be combined in high dose with oral hypoglycemic agents to bring the blood glucose to normal levels in patients whose diabetes is not controlled with these agents or in those patients in whom these drugs produce adverse effects on dose increments.

Key word: Antidiabetic activity · Bael leaves · PPBGL

INTRODUCTION

Diabetes mellitus (DM) is the commonest endocrine disorder that affects more than 100 million people worldwide (6% of the population) [1]. It is caused by deficiency or ineffective production of insulin by pancreas which results in increase or decrease in concentrations of glucose in the blood. It is found to damage many of the body systems, particularly the blood vessels and nerves [2]. For its therapy, along with the synthetic drugs, many agents of the plant origin are also in use particularly for the treatment of non insulin dependent diabetes mellitus (NIDDM).

Plants are always an exemplary source of drugs; in fact many of the currently available drugs were derived either directly or indirectly from them. According to world ethnobotanical information reports, almost 800 plants may possess antidiabetic potential [3]. In the past decade, research has been focused on scientific evaluation of traditional drugs of plant origin and screening of more effective and safe hypoglycemic agents has continued to be an important area. In developing countries 80% of population is using traditional medicine in primary medical problems [4]. However, lots of herbs are now being used in the management of DM.

In the present study, an attempt has been made to investigate clinically the antidiabetic activity Bael leaves (BL) (*Aegle marmelos*, Corr.) in NIDDM patients individually and collectively with the standard oral hypoglycemic therapy. Literature survey reveals its antidiabetic activity in animals but no such studies were performed clinically.

BL is a popular plant and cosmopolitan in distribution. It has many medicinal properties such as antifungal, antibacterial, antiprotozoal, hypoglycemic etc. Insulin like action of its leaves on hyperglycemia and their mechanism of action has been reported in the animal studies [5-8].

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MATERIALS AND METHODS

For carrying out the study, clinical protocol was set and approved by the institutional ethical committee. This study was performed under the supervision of physicians. Inclusion and exclusion criteria were formed for the study. Written consent was taken from the patients. Initial postprandial blood glucose level (PPBGL) was estimated at the time of enrolment in the study and then after one month of the study. At the end of the study, the initial and final readings were compared.

Inclusion Criteria:

- Type 2 diabetic patients with fasting plasma glucose level equal to or greater than 140 mg/dl of blood with out any detectable/visible complications [9].
- Type 2 diabetic patients taking oral hypoglycemic agents with history of inadequate control of blood glucose with these agents.
- The patients were of either sex (male or female) between the ages of 35-60 years.

Exclusion Criteria:

- Pregnant or nursing patients.
- Smokers
- Patients with GIT, hepatic, cardiovascular, renal or endocrine disorder (other than diabetes mellitus) which can interfere with the absorption, metabolism and excretion of the study plant.
- Patients with any complication of diabetes mellitus.
- Patients suffering from type 1 (IDDM) diabetes mellitus.

Subjects: The selected subjects were medically examined and given code numbers and were asked to present themselves on a specified date for sample collection. Initial postprandial blood glucose level (PPBGL) was estimated at the time of enrolment in the study and then after one month of the study.

Blood Sample: Blood samples (3-5 ml) were drawn from each patient and control subject by vene-puncture through plastic disposable syringes. The blood samples were collected in clean oven dried glass bottles which were previously rinsed with 1% sodium fluoride, 3% potassium oxalate solution to prevent coagulation and glycolysis. The plasma was separated after centrifugation. Any sample showing haemolysis was discarded. After separation of plasma, it was transferred to clean, previously acid rinsed, washed and oven dried glass bottles with plastic caps. The plasma glucose estimation was done immediately on the same day by O-toluidine method [10].

Plant: BL were obtained from the local market. It was identified and authenticated by the botanist and then used for the study.

General Plan of Study: BL dried in shadow, were powdered and its decoction was used for the study. A suitable dose was decided by initial randomized study in the first week. The study was conducted for a period of one month. The design of study was as follows:

- Group I received only decoction of 5gm BL powder once daily with water.
- Group II without any therapy served as a Control group.
- Group III with their standard oral hypoglycemic therapy.
- Group IV receiving the 5gm BL powder with their standard hypoglycemic therapy.

Each group was having 10 NIDDM patients.

Drop Outs: No dropouts recorded in the study.

Compliance: All participants in the study were showing the compliance and were following the instruction regarding the diet and exercise.

Untoward Effects: Some patients complained about the headache which may be psychological.

RESULTS

There were significant changes in PPBGL of group IV and I as compared to the group II and III. There were no any significant results seen in group II. The results are summarized in the Table 1 and Fig. 1.

Table 1: Sshowing effects on PPBGL by FG and BL in different study groups (The values are given as Mean ±SD)

Groups	Initial PPBGL	At the end of study PPBGL
I	191±10	159±8
II	178±5*	174±5*
III	197±7	145±8
IV	201±7	135±9

(* Non significant changes in PPBGL)

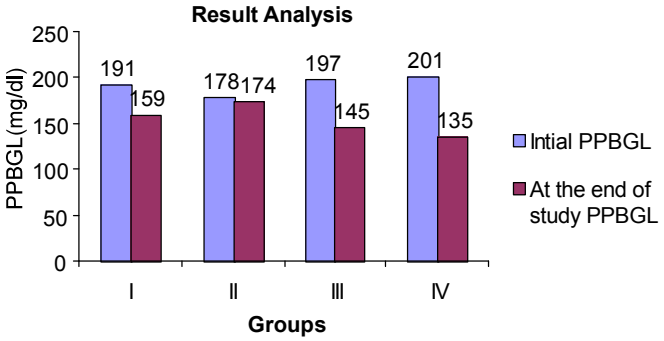

Fig. 1: Comparison of antidiabetic effect on PPBGL in NIDDM patients

DISCUSSION

The fall in PPBGL was more marked in group IV where patients were receiving the test drug and oral hypoglycemic therapy whereas in the group I the fall in PPBGL was significant as compared to group II and III.

The studies suggest that the Bael leaves produce hypoglycemic effect probably by enhancing the peripheral utilization of glucose, correcting the impaired hepatic glycolysis and limiting its gluconeogenic formation similar to insulin [5, 8].

CONCLUSION

BL can be combined in high dose with oral hypoglycemic agents to bring the blood glucose to normal levels in patients whose diabetes is not controlled with these agents or in those patients in whom these drugs produce adverse effects on dose increments. Our study has opened up a new direction for future large scale clinical research to find an alternative and inexpensive herbal formulation for the NIDDM.

REFERENCES

1. WHO/Acadia, 1992. Rapport de la Journe Internationale de, diabetes.
2. Nagappa, A.N., P.A. Thakurdesai, N. Venkat Rao and S. Jiwan, 2003. Antidiabetic activity of *Terminalia catappa Linn* fruits. J. Ethnopharmacol., 88: 45-50.
3. Alarcon-Aguilara, F.J., R. Roman-Ramos, S. Perez-Gutierrez, A. Aguilar-Contreras, C.C. Contreras-Weber and J.L. Flores-Saenz, 1998. Study of the anti-hyperglycemic effect of plants used as antidiabetics. J. Ethnopharmacol.., 61: 101-110.
4. Grover, J.K. and S.P. Yadav, 2004. Pharmacological actions and potential uses of *Momordica charantia*: A review. J. Ethnopharmacol., 93: 123-132.
5. Banerji, A.K. and S.S. Nigam, 1984. Chemical, microbial and anthelmintic examination of the seeds of *A. marmelos.* Indian Drugs, 21: 217-18.
6. Seema, P.V., B. Sudha, S.P. Pius, A. Asha, K.G. Reghu and C.S. Paulose, 1996. Kinetic studies of purified malate dehydrogenase in liver of streptozotocin-induced diabetic rats and the effect of leaf of *Aegle marmelos*,Corr. Indian J. Exp. Biol., 34: 600-2.
7. Bhavpriya, V. and S. Govindasmy, 2000. Biochemical studies on the hypoglycemic effect of *A. marmelos* in a streptozotocin induced diabetes rats. Indian Drugs, 37: 474-77.
8. Das Am. V., S. Padayam and C.S. Paulose, 1996. Effect of leaf extract on *A. marmelos* on histological ultrastructural changes in tissues of streptoztocin induces diabetic rats. Ind. J. Exp. Biol., 34: 341-345.
9. WHO, 1992. Diabetes mellitus, report of study group. Geneva: WHO technical report series. pp: 727.
10. Nobert W. Tielt, 1976. Fundamentals of clinical chemistry. Phildelpheia: W.B. Saunders Company. 2nd ed.