

Clinical Evaluation of *Aavaraiyathi churnam* in the Management of Type 2 Diabetes Mellitus

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ABSTRACT

Diabetes mellitus is a heterogeneous disorder of carbohydrate, protein and fat metabolism in which sugars in the body are not oxidized to produce energy due to lack of pancreatic hormone insulin leads to disturbances of the acid base balance. There are two types. Type 1 (IDDM) patients have little or no ability to produce the hormone and are entirely dependent on insulin, whereas Type II (NIDDM) results from inadequate production of insulin which can be controlled by the oral hypoglycemic drugs. *Aavaraiyathi churnam* is one of the herbal based Siddha anti diabetic formulation for Type II maturity onset diabetes mellitus. So the present research work was carried out to confirm the hypoglycemic effect of *Aavaraiyathi churnam* clinically on patients with DM (Type II). Open clinical trial was conducted in 50 diabetic patients for the period of six months. Blood glucose level (both fasting and post prandial) were estimated before the enrollment of the study during the trial period and after the completion of the study. At the end of the study period all these parameters were statistically analyzed. The clinical studies revealed that *Aavaraiyathi churnam* (AC) was well tolerated in high dose and moderate diabetic cases (180 – 300 mg / dl). The blood sugar level is controlled within 4 – 16 week, depending upon its initial blood sugar level. No side effects were noted during the study period which confirms the traditional use *Aavaraiyathi churnam* for the treatment of diabetes mellitus.

Key Words: Diabetes mellitus, insulin, Type II NIDDM, *Aavaraiyathi churnam*, blood glucose level, anti diabetic activity.

INTRODUCTION

Diabetes is one of the ancient disease. The history of diabetes is stated that in the Ebers papyrus (1500 BC)^[1]. Polyuria and honey urine was noted as early as 400 BC by the Indian Physician *Susrutha*. He has described this disease as '*Madhumeham*' which means- the honey in the urine ^[2]. Diabetes mellitus is an absolute or relative deficiency of insulin due to hyperglycemia is characterized by polyuria, polyphagia, and polydipsia. Diabetes mellitus is the commonest endocrine disorder that affects more than 171 million people worldwide^[3]. If it is not controlled by medicine it will affect most of the internal organs such as nephropathy, neuropathy, retinopathy etc.^[4] Plants are always an excellent source of drugs; in fact many of the currently available drugs were derived either directly or indirectly from them. According to world ethno botanical information reports, almost 800 plants may possess anti-diabetic potential ^[5]. In the past decade, research has been forced 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 of present day research. In developing countries 80 % of population is using traditional medicine in primary medical problems ^[6]. In the present study, an attempt has been made to investigate the anti-diabetic activity of *Aavaraiyathi churnam* in NIDDM patients clinically. *Aavaraiyathi churnam* is a poly herbal formulation, comprising of 5 indigenous

medicinal plants namely *Cassia auriculata* leaves, flower, seed, bark and root bark, *Odina wodier* bark, *Coscinium fenestratum* stem, *Ficus glomerata* tender leaves and *Cocculus cordifolius* stem. ^[7] All these plants are well known in the traditional system of medicine from time immortal for their various therapeutic properties especially hypoglycemic activity. ^[9-13]

MATERIALS AND METHODS

The Open clinical based trial was conducted at Arignar Anna Government Hospital of Indian Medicine, Chennai from July 2011 to December 2011. The protocol of this clinical study was approved by the Institutional Ethical Committee and conducted according to the guidelines of the Declaration of Helsinki ^[14]. Total number of 50 cases of either sex and irrespective of socio economic status was selected for this trial from OPD and IPD from the hospital in which 27 males (54%) and 23 females (46%) chosen for the study as shown in Table No.1. All the patients recruited in this study were categorized in different class interval ranging from 35 years of age to 65 years of age as shown in Table No.1. 36 patients were treated as out-patient department and 14 patients who were very sick and were hospitalized in Arignar Anna Hospital, Arumbakkam, Chennai-106. They were all under the medical care on direct supervision of the author. After written informed consent (both English and Tamil) was obtained from the

Table No.1 showing Age and Sex distribution

Category	35 - 43 yrs	44-51 yrs	52-59 yrs	60 – 65 yrs
Type 2 DM	Male: 07	Male: 10	Male: 06	Male: 04
	Female: 04	Female: 06	Female: 11	Female: 02

Table No.2 showing the signs and symptoms of Type 2 DM patients and showing the clinical improvement at the end of the study

Signs and Symptoms n = 50	35 - 43 years	44 - 51 years	52 - 59 years	60 - 65 years	Improvement in percentage
Polyuria	10	15	17	06	96
Polydipsia	09	14	17	06	97
Polyphagia	08	15	16	05	95
General weakness	06	15	15	06	97
Itching	04	06	04	02	94
Loss of weight	02	03	01	01	86
Body pain	01	02	14	05	95

Table No. 3 : Showing the efficacy of *Aavaraiyathi churnam* on FBGL, PPBGL and HbA₁C in treated patients

Group (n = 50)	Fasting glucose (mg/dl)		Post Prandial (mg/dl)		HbA ₁ C (mg %)	
	BT	AT	BT	AT	BT	AT
Type 2 DM	152.46±1.21	96.40±1.06***	236.04±3.09	150.12±1.34***	8.56±0.10	6.16±0.06

patients before enrollment and proper history and clinical examination were recorded at base line and each follow up. The initial Fasting Blood Glucose Level (FBGL), Post Prandial Blood Glucose Level (PPBGL) and HbA₁C were estimated at the time of enrollment of the study, during the follow up and at the end of the study. The initial and final readings were compared statistically at the end of the study and were recorded.

Selection Criteria: Patients selected for this study were based on inclusion criteria and exclusion criteria. Inclusion criteria for the patients with confirmed diagnosis of type 2 diabetes, patients of either sex between the age of 35-65 years, patients with FBGL \geq 140 mg/dl, PPBGL \geq 250 mg/dl and HbA₁C \geq 7 were included.^[15,16] Patients taking medicines for other health conditions, other critical complications like GIT, hepatic, cardiovascular, renal or endocrine disorder (other than diabetes mellitus), IDDM, AIDS, STD, HT, pregnancy, lactation, smoking, alcohol abuse were excluded from the study.

Formulation of The Trial Drug: The poly herbal formulation of *Aavaraiyathi Churnam* described in *Anuboga Vaithiya Navaneetham Part-9*.^[8]

Ingredients of the drug: *Cassia auriculata* (*Aavarai*) leaves, flower, seed, bark and root bark each 35 gm, *Odina wodier* (*Odhiyam*) bark 87.5 gm, *Coscinium fenestratum* (*Maramanjil*) stem 43.75, *Ficus glomerata* (*Atthi*) tender leaves 21.75 gm, *Cocculus cordifolius* (*Seenthil*) stem 183 gm were collected from in and around Chennai. All the plants were identified and authenticated by the botanist, Government Siddha

Medical College, Chennai. The vouchers of specimen samples of the plants were kept in the department for future reference. After identification the above plants were cleaned well with water and dried in a shadow place. After complete drying, they powdered separately and mixed all together and the trial medicine was prepared as per the classical text. Good manufacturing practice was emphasized during the preparation. Then the prepared drug is kept in air tight container which was used for clinical study. The drug was given to the patients at the dose of 3 to 4 gm twice a day with hot water depending upon the severity of the disease. The patients were advised to avoid direct sugar, underground root vegetables and to take plenty of leafy and fiber vegetables.

Laboratory Investigations: Patients under *Aavaraiyathi churnam* trial were subjected to the following laboratory investigations. The initial biochemical analysis of FBGL, PPBGL and HbA₁C were generally done in nearby laboratories and at the hospital of confinement. However, to assure comparability of results, blood samples were obtained from each patient prior to, during and after *Aavaraiyathi churnam* administration. About 3 to 5 cc of blood was obtained from each patient through venepuncture by using disposable syringes both fasting and post prandial which was used for the analysis of serum glucose level.

STATISTICAL ANALYSIS

Statistical analysis was done according to intention-to-treat principles. Drug concentrations and all derived parameters were listed and summarized descriptively.

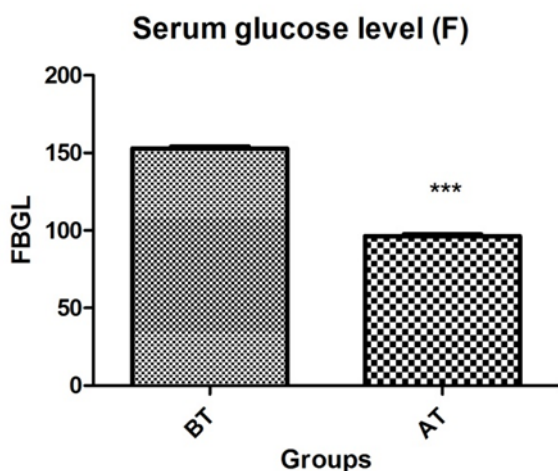


Fig No.1. Serum glucose level (fasting)

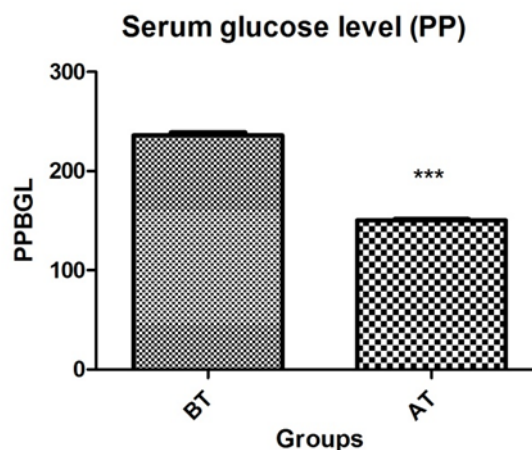


Fig No.2. Serum glucose level (PP)

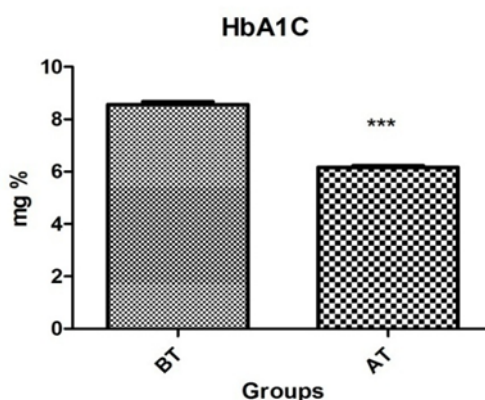


Fig No.3. Glycated haemoglobin level in mg percentage

The changes in various parameters in the post-treatment values were carried out by Paired 't' test. P values ≤ 0.05 were considered statistically significant which is shown in Table No. 3.

RESULTS AND DISCUSSION

Diabetic care needs patience, compassion optimism and from the physician. Patient must be actively involved in his own management and should develop confidence to bring about adjustment in day to day life management. The poly herbal formulation *Aavaraiyathi churnam* used in this study was selected on the basis of their traditional use in Siddha system of medicine. All the herbs used in this formulation have independent hypoglycemic activity which was explored scientifically by various research works. For example *Cassia auriculata* leaves, flower, seed, bark and root bark, *Odina wodier* bark, *Coscinium fenestratum* stem, *Ficus glomerata* tender leaves, *Cocculus cordifolius* stem were used to treat diabetes mellitus.

The primary criteria are evaluating the efficacy of the drug. Total number of 50 Type 2 diabetes mellitus patients were treated with *Aavaraiyathi churnam* 3-4 gm

two times a day with hot water for one month duration. The improvement in clinical features and bio chemical analysis of this open clinical study was summarized in the Table No. 2 and Table No.3 respectively. Based on the results it was observed that there was an extremely significant reduction in fasting blood glucose level, post prandial blood glucose level and HbA_{1c} level in patients who were completed the clinical trial successfully. All the patients were found symptomatic improvement by clinically. Patients reported improvement was observed in frequency of urine were reduced. Nocturia, unquenched thirst was subsided and the general feeling of well being was reported by all the patients, polyphagia and weakness were subsided. At the time of admission, the initial mean FBGL was 152.46 ± 1.21 and PPBGL was 236.04 ± 3.09 . After completion of the trial the mean FBGL and PPBGL were $96.40 \pm 1.06^{***}$ and $150.12 \pm 1.34^{***}$ respectively. The declined trend was observed at a constant level. In addition, there was significant reduction of glycated hemoglobin (HbA_{1c}) was observed which is summarized in Table No.3. Based on this, the initial level of glycated hemoglobin was 8.56 ± 0.10 %, and after treatment the level was 6.16 ± 0.06 % which confirmed the

hypoglycemic effect of the poly herbal formulation of *Aavaraiyathi churnam* regardless of age and sex.

Untoward effects: There was no side effects were noticed during the study period.

CONCLUSION

Aavaraiyathi churnam is more effective in the treatment of type 2 diabetes mellitus as determined by extreme statistically significant p-value < 0.0001. The patients were very clear improvement of clinically and biochemical investigations. The test drug did not display or show any untoward manifestations associated with the use of this medication. The mechanism of the hypoglycemic activity of poly herbal formulation – *Aavaraiyathi churnam* may be due to enhance the peripheral utilization of glucose, normalize the hepatic glycolysis and gluconeogenesis. So this study suggests that the *Aavaraiyathi churnam* had very good hypoglycemic effects proved by clinical improvement and bio-chemical analysis.

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