HYPOGLYCEMIC POTENTIAL OF AVARAI (*Cassia auriculata*) IN TREATING NON-INSULIN DEPENDENT DIABETES MELLITUS

By

SUGANYA .S

02MP 45

A THESIS SUBMITTED TO THE AVINASHILINGAM INSTITUTE FOR HOME SCIENCE AND HIGHER EDUCATION FOR WOMEN – DEEMED UNIVERSITY, COIMBATORE – 641 043

IN PARTIAL FULLFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF PHILOSOPHY IN FOOD SCIENCE AND NUTRITION

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CERTIFIED AS BONAFIDE RESEARCH WORK

Signature of the
Head of the Department

Signature of the
Guide

CERTIFICATE

This is to certify that the dissertation entitled **"HYPOGLYCEMIC POTENTIAL OF AVARAI (Cassia auriculata) IN TREATING NON-INSULIN DEPENDENT DIABETES MELLITUS"** submitted to the Avinashilingam Institute For Home Science and Higher Education for women (Deemed University), Coimbatore in partial fulfillment of the requirements for the award of the Degree of Master of Philosophy in Food Science and Nutrition is a record of original research work done by **SUGANYA.S**, during the period of her study in the Department of Food Science and Nutrition, Avinashilingam Institute for Home Science and Higher Education for women (Deemed University), Coimbatore under my supervision and guidance and the dissertation has not formed the basis for the award of any Degree / Diploma / Associateship / Fellowship or similar title to any candidate of any other University and it represents entirely an independent work on the part of the candidate.

Signature of the Guide

Forwarded

Signature of the
Head of the Department

DECLARATION

I hereby declare that the dissertation entitled **"HYPOGLYCEMIC POTENTIAL OF AVARAI (*Cassia auriculata*) IN TREATING NON-INSULIN DEPENDENT DIABETES MELLITUS"** submitted to the Avinashilingam Institute for Home Science and Higher Education for women (Deemed University), Coimbatore in partial fulfillment of the requirements for the award of the Degree of Master of Philosophy in Food Science and Nutrition is a record of original research work done by me under the supervision and guidance of **Mrs. S. KOWSALYA, M.Sc., M.Phil. (Bharathiyar University), Ph.D. (Avinashilingam University),** Reader in Food Science and Nutrition and that it has not formed the basis of the award of any Degree / Diploma / Associateship / Fellowship or similar title to any candidate of any other University.

Signature of the candidate

Signature of the Guide

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Introduction

I INTRODUCTION

Diabetes mellitus is a metabolic disorder of multiple aetiology characterised by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. Diabetes is not new to the medical world as it is known antiquity (1500 BC) but now with its epidemic claws, it has become a major health threat to the whole world (Mohan et al., 2002).

The World Health Organization (WHO) estimated that there are 135 million diabetic individuals in the year 1995 and it has been projected that this number would increase to 300 million by the year 2025 (King et al., 1998). India has the largest diabetic population in the world (Sahay and Sahay, 2002).

Type 2 diabetes mellitus is the commonest form of diabetes. Its prevalence in India is 2.4 per cent in rural population and 11.6 per cent in urban population (Ramachandran, 2002). The speculated reasons for this escalation in diabetes prevalence are changes in lifestyle, aging and lower birth weight (Yajnik, 2001) and malnutrition (Ahuja, 1989).

The complication of diabetes mellitus may be of acute, intermittent and chronic types (Viswanathan, 1992). It is the greatest single cause of blindness in the working population (Robertson, 1993). It can cause lower extremity amputations and increase the risk for stroke, ischemic heart disease and neuropathy (Mohan et al., 2002).

Hyperglycemia is also an important factor in the development and progression of the complication of diabetes (Luzi, 1998).

The goal of management of diabetes includes dietary management, exercise, use of oral drugs and insulin therapy (Gries, 1992). The ideal diet for diabetes remain to be determined even after decades of experience in the management of diabetes. The dietary recommendations seem to vary from time to time along with the social changes. However, whatever be the type of diabetes, diet has remained the sheet anchor in the management of diabetes (Mohan, 1996). Education provides the basis for successful treatment (Albert, 1992). Exercise increases insulin sensitivity and helps in the reduction of body weight (Gries and Alberit, 1994). Use of oral hypoglycemic drugs for a long time are also associated with lactic acidosis and toxicities like gastro-intestinal problems, skin rashes, water retention and hyponatremia (Diabecon, 1996).

The existing methods for treating this disorder are not completely satisfactory. One area receiving particular attention today is that of herbal folk medicines (Skim et al., 1999). Herbal medicines have been used since the dawn of civilization in the management of disease (Srivastava and Ragini, 1992). The World Health Organization estimates that nearly 80 per cent of the earth's inhabitants rely on traditional medicine for their primary health care needs and most of this therapy involves the use of plant extract or their active components (Kuruvilla, 2002).

India has a rich wealth of medicinal plants. Out of 17,500 flowering plant species found in India, over 1600 are used in traditional

medicinal system (Sanjaykumar, 2002). Dietary measures and traditional plant therapies prescribed by Ayurveda and other indigenous systems of medicine have been used commonly in India (Grover, 2001).

Herbal medicines include herbs, herbal preparations and finished herbal products that contain as active ingredients parts of plants or other plant materials or combinations (Rajasekaran, 2002). Medicines are prepared in the form of powder (churnam), confectionary (lehiyam),syrup, pills, senthuram (sulphide form), bhaspam (oxide form) and rasayanam (tonic form) and a calculated dosage is given for a specific period (Vijayalakshmi and Amirthaveni, 2002).

Our passion for herbal remedies first keeps growing day by day but the concent in which herbs play a role is a very simple fact that the active constituents of the herbs can enter the body in several ways. These include consuming the herbs orally so as to be absorbed in the body through the pores, application on eyes through locations and compresses, smelling the aroma through nose to enable the essential oil being absorbed in the blood stream (Sallie et al., 1997).

Numerous plants and natural products have been studied for antidiabetic activity in different laboratories (Manickam, 1997). Herbs like Ocimum sanctum (thulasi)(Giri et al., 1992), Trigonella foenum-graecum (fenugreek) (Zargar and Nehru, 1992). Salacia prinoides (ekanayakam) (Kowsalya et al., 1995) were found to reduce blood sugar and serum cholesterol levels.

Cassia auriculata commonly known as avarai is one of the herbs used of in ayurvedic medicine. But scientific studies are not available on

the usage this herb in the treatment of diabetic subjects. Hence, it was thought of interest to study the effect of Cassia auriculata alone on non insulin dependent diabetic subjects and in combination with the other commonly used herbs like Gymnema sylvestre and Eugenia cumini extracts. Hence, the present study aimed at investigating the hypoglycemic effect of avarai on selected NIDDM subjects.

The specific objectives of the present study are: To

1. Prepare churnam with Cassia auriculata (avarai) alone and in combination with other herbs namely Gymnema sylvestre (sirukurinjan) and Eugenia cumini (naval).
2. Select and ascertain the background of selected non-insulin dependent diabetic subjects.
3. Evaluate the hypoglycemic and hypocholesterolemic potentials of avarai in comparison with the herbal mixture.

Review of Literature

II REVIEW OF LITERATURE

The review of literature pertaining to the present study entitled "Hypoglycemic potential of avarai (Cassia auriculata) in treating non-insulin dependent diabetes mellitus" is presented under the following headings.

A. Prevalence

B. Classification and risk factors

C. Symptoms, complications and diagnosis

D. Biochemical changes occurring in diabetes mellitus

E. Management of diabetes mellitus.

F. Role of herbs in treating diabetes mellitus

A. Prevalence

Diabetes mellitus has been described since antiquity. Its prevalence throughout the world in the year 1998 was 143 million, this number would increase to 300 million by the year 2025 (WHO report, 1998). India today leads the world with its largest number of diabetic subjects in any given country, its prevalence was reported to be 12.1 per cent (Ramachandran et al., 2001).

A national population based study conducted in six urban cities revealed that the prevalence of diabetes was 13.5 per cent in Chennai, 12.4 per cent in Bangalore, 16.6 per cent in Hyderabad, 11.7 per cent in Calcutta, 11.6 per cent in New Delhi and 9.3 per cent in Mumbai (Ramachandran et al, 2001). Type 2 is the commonest form of diabetes

with a prevalence of 2.4 per cent in rural and 11.6 per cent in urban population (Ramachandran,2002).

B.Classification and Risk Factors

According to the latest classification of diabetes mellitus by American Diabetes Association (Diabetes, 2003), there are three major types of diabetes.

Type 1:

This type is characterized by an absolute insulin deficiency with dependence on insulin for life, marked tendency to ketosis, onset usually below 30 years, absence of obesity and the presence of circulating islet cell antibodies, the prominent feature include insulinopenia and weight loss (Ramachandran et al., 1992).

Type 2:

This is the most common type of diabetes . It sets in over the age of 40, characterized by hypoglycemia due to insulin resistance and relative insulin deficiency. Majority are overweight and ketosis resistant with autosomal dominant inheritance (Diabetes Care, 1995).

Gestational diabetes:

Diabetes developed during pregnancy is described as gestational diabetes. It occurs in three per cent of pregnant women and usually remits after delivery (Dowse et al.,1993).

Risk Factors

NIDDM has a very strong genetic basis. Of the total type 2 diabetic population , 40 to 70 per cent of the groups have at least one per cent as diabetic and 90 per cent of them have both parents diabetic (Viswanathan,1993). The relationship between obesity and type 2 diabetes is complex and is confounded by many heterogenous factors (Ramachandran et al., 2001). Several studies suggest that insulin resistance is the primary event that leads to abnormalities in glucose metabolism (Ramachandran, 2002). Malnutrition during fetal life followed by over nutrition in adult life could be one of the risk factors for diabetes (Yajnik, 1992). Lifestyle changes due to urbanization like smoking, which is found to be an independent risk factor for the development of type 2 diabetes (Tonino, 1989). Lack of physical activity, low fibre intake, high fat intake and drugs can also precipitate diabetes. Apart from these, infections, prolonged stress, hormones, low birth weight, nutritional status, altered immune functions, race and age can cause diabetes (Ramachandran et al., 1993).

C.Symptoms, Complications and Diagnosis

The symptoms of diabetes mellitus include polydypsia, polyphagia, polyuria, unusual weight loss, increased fatigue, irritability, blurred vision and slow healing of wounds.

Pradeepa et al (2002) states that people with diabetes are 25 times more likely to develop blindness, 17 times more likely to develop kidney disease, 30 to 40 times more likely to undergo a major amputaion, two to four times more likely to develop a myocardial infarction and twice

as likely to suffer a stroke than individuals without diabetes. Coronary artery disease is the most common form of life threatening disorder that besets type 2 diabetic subjects (Haffner et al., 1998).

Diagnosis :

The symptoms of acute diabetes develop gradually and revealed by methodical examinations of urine and blood. Benedict's test is the most simple and effective method of ascertaining glucose in urine. Glucose tolerance test (GTT) is the best test to detect diabetes, in which National Diabetes Diagnosing Group (NDDG) and WHO give a load of 75g of oral glucose dissolved in 300ml of water as recommended.

D. Biochemical Changes occuring in Diabetes Mellitus.

A deficient supply of functioning of insulin affects the metabolism of carbohydrates, fats, proteins and electrolytes.

1. Carbohydrate metabolism

The plasma ratio of proinsulin to insulin is raised in individuals with NIDDM (Leahy et al., 1991). In insensitivity to insulin dependent subjects, fasting blood glucose is raised in direct proportion of hepatic glucose output. Hypoglycemia results in increased metabolism of glucose by the sorbitol factor pathway. Increased sorbitol leads to cataract formation in ocular lens. Decreased level of myoinositol lead to poor neural function and axonal transport (Shrinivas, 1993 and Schalin-Jantti, 1993).

2. Lipid metabolism

Insulin deficiency or resistance leads to excessive lipolysis and rapid mobilization of fatty acids from adipose tissue and production of ketone bodies in liver as coA esters and oxidized to acetyl- coA, excess of which is converted to ketone bodies causing ketosis and ketonuria, eventually leading to diabetic coma (Rao, 1993). NIDDM patients have increased triglyceride concentrations and decreased HDL cholesterol concentrations, but relatively normal LDL cholesterol concentrations (Haffner, 1992 and Nutrition Today, 1994).

3. Protein metabolism

Since insulin production is inadequate in diabetics the synthesis of tissue proteins from dietary protein decreases and there is a breakdown of tissue protein leading to negative nitrogen balance. The concentration of amino acids in blood and liver increased considerably. The production of glucose from ketoacids results by the process of gluconeogenesis. There is an increased excretion of urinary nitrogen of protein, the patient loses weight and becomes emaciated (Shanmugam, 1992).

4.Vitamins and minerals

Vitamins C and E ward off free radical damage in diabetics. The status of these two vitamins are considerably low in diabetics (Sadikot and Raheja, 1992). Administration of vitamin D may lead to improved glucose tolerance in diabetic patients either through increased calcium level, or due to an enhanced peripheral tissue uptake and utilization of glucose (ICMR Bulletin, 1993). Trivalent chromium lowers blood levels of LDL, raising HDL and improves glucose tolerance (Mossap, 1991).

Chromium potentiates action of insulin *in vitro* and *in vivo*. Magnesium concentration is decreased in diabetes which plays a role in insulin resistance, carbohydrate intolerance and hypertension (American Diabetes Association, 1992). Hypomagnesemia is a risk factor for diabetic retinopathy (Srivastava et al.,1993). The role of copper in glucose homeostasis is not well defined. Experimental data suggest that impairment of glucose tolerance can be secondary to copper deficiency. Generally serum concentration of copper and ceruloplasmin are elevated in NIDDM. Zinc is a constituent of crystalline insulin. Hence the zinc content of diabetic pancreas is less than normal (Shanmugam, 1992).

E.Management of Diabetes Mellitus

The goal of diabetes management is to achieve and maintain improved metabolic control and to minimize, delay or even prevent long term complications. There are widely divergent approaches to the therapy of diabetes. This can be achieved by dietary adjustment, exercise, use of oral hypoglycemic drugs and insulin therapy (Gries and Alberti, 1992).

1. Dietary management

The ideal diet for diabetes remains to be determined even after decades of experience in the management of diabetes. The dietary recommendations seem to vary from time to time along with the social changes. However, whatever be the type of diabetes, diet has remained the sheet anchor in the management of diabetes. The caloric contents of food has also gained importance in planning diets, as high caloric consumption results in obesity, glucose intolerance, dyslipidemia, atherosclerosis and coronary artery disease (Raghavan et al., 1996).

a. Carbohydrates

Carbohydrate content of the diet has to provide 60 to 70 per cent of the calories (Raghuram et al., 1997). The glycemic effect of carbohydrate foods varies but cannot be predicted by the structure owing to the efficiency of the human digestive tract in reducing starch polymers to glucose (Sahay and Sahay, 2002).

b. Fats

It is recommended that 15 to 25 per cent of the total calories can be derived from fats (Raghuram et al., 1997). Polyunsaturated fatty acid content of less than 10 per cent of the total calories and essential fatty acid content of atleast three per cent of the total calories is advisable (Sahay and Sahay, 2002). The percentage of calories from fat in diet depends on desired glucose, lipid and weight outcomes (American Diabetic Association, 1999). Several studies have suggested that a moderate fat diet can improve serum lipid levels as well as or better than fat restricted diet, provided the additional fat is predominantly monounsaturated fatty acid (Garg, 1994).

c. Protein

Protein intake of 0.8g/kg body weight is recommended. Protein accounts for roughly 12 to 20 per cent of the total calories. Vegetable proteins are preferred due to their high fibre content and absence of saturated fat that is present in animal proteins (Ghafoorunissa, 1998). Studies show that response to low protein diet with diabetic subjects has been beneficial interms of slowing the progression of renal disease (Pedrini, 1996).

d. Dietary fibre

Fibre is an important constituent of people with or without diabetes primarily in its role to promote gastro intestinal motility. An intake of 20 to 35g/day is recommended (Coulston, 1994).

e. Glycemic index

Different carbohydrates raise the blood sugar to various extent. The glycemic index indicates the extent of increase in blood sugar in response to a food in comparison with the response to an equivalent amount of glucose. The glycemic response of different foods are influenced by the physical form and nature of cooking (Roberts, 2000).

2. Exercise

Physical exercise improves the condition of a diabetic patient due to several factors. There is an increase in the number of insulin receptors. In addition, there is an elevation of 2-3 diphospho glycerate levels in the RBC and reduction in the HbA1C levels. These promote the delivery of oxygen to the peripheral tissues, which result in the improved efficiency of the diabetics. Storfen et al (1996) suggested that high level of physical activity are correlated with lower levels of plasma insulin and physical training can decrease insulin resistance.

3. Yoga

Yoga practices improve insulin sensitivity and reduce insulin resistance and these beneficial effects on insulin kinetics prevent beta cell exhaustion and thereby prevent the development of type 2 diabetes (Argikar, 1994).

4. Oral hypoglycemic agents

The use of the newer oral glucose lowering medications alone or in combination, provide numerous options for achieving euglycemia in persons with type 2 (Libovitz, 1994). Sulphonylureas work by stimulating the beta cells in the pancreas to release more insulin over extensive periods, disadvantage of this drug include weight gain (Franz, 2000). Meglitinide is a new class of non sulphonylurea drug which works by improving insulin secretion in response to glucose levels by binding to a different site than the sulphonylurea (Malaisse, 1995). Another drug class, biguanides can be used alone or in combination with other diabetic medications (Herman et al., 1994). Thiazolidinediones are another new class of antidiabetic drugs, act by lowering insulin resistance to injected insulin and enhances insulin action in muscle, adipose tissue and liver cells (Nolan et al., 1994).

5. Insulin therapy

Insulin of bovine or porcine origin was the only commercially available preparation for the first half century in insulin era. The duration of therapeutic action of injected insulin was prolonged by complexing insulin with protamine and zinc. But these agents have several limitations, which include allergic reactions due to impurities present in the formulations (American Diabetic Association, 1999). Biosynthetic human insulin are now available, either produced by modification of pork insulin or by recombinant DNA technology (Garg, 2002).

Different types and species of insulin have different pharmacological properties. Human insulin is preferred for use in

pregnant women, diabetic women considering pregnancy, individuals with allergies or immune resistance to animal derived insulins.

F. Role of Herbs in Treating Diabetes Mellitus

Since ancient times plants have been an exemplary source of medicine, for they possess extraordinary healing activities and pain relieving properties. Ayurveda and other Indian literature mention the use of plants in treatment of various human ailments (Bhavapriya et al., 2001). Research conducted in last few decades on plants mentioned in ancient literature or used traditionally for decades have shown antidiabetic property (Grover et al., 2002).

1. Tulsi (*Ocimum sanctum)*

Tulsi leaf powder supplementation at one per cent dose level showed significant hypoglycemic effects in diabetic rats, which could be associated with the essential oil eugenol present in Ocimum sanctum leaf powder (Rai et al., 1997). However, in the comparative study Ocimum sanctum leaf extract was found to have the least potent blood sugar lowering activity than Catharanthus roseus, Gymnema sylvestre and Azadirachta indica (Chattopadhyay, 1999). Trigonella foenum-graecum, fenugreek seeds have been reported to possess hypoglycemic and hypolipidemic properties in animal experiments (Ribes et al., 1987), as well as in human and clinical cases (Prasanna, 2000 and Sowmya and Rajalakshmi, 1999). Ravikumar and Anuradha (1999) reported the antioxidant property of fenugreek seeds in diabetic rats.

2. **Chinese dates** ***(Zizyphus jujuba)***

The hypoglycemic activity of Zizyphus jujuba was first reported on normoglycemic rats by Aydin et al., (1994). Recently, Ignachimuthu and Amalraj (1998) reported the antidiabetic and antihyperlipidemic effect of Zizyphus jujuba in alloxan induced diabetic rats, which was fairly comparable to that of glibenclamide.

3. Eye bright (*Euphrasia officinale)*

This plant is claimed to possess anticancer, antiepileptic activities (Hussain et al., 1992). In traditional medicine it finds extensive use in the maintenance of diabetes mellitus (Ambasta, 1986). The aqueous leaf extract of the plant brought down the raised blood glucose levels in alloxan induced diabetic rats (Porchezian et al., 2000).

4. **Ekanayakam** ***(Salacia prinoides)***

Roots of Salacia prinoides have been reported to be used as an antidiabetic drug in the indigenous system of medicine (Nair et al., 1991). A study conducted by Kowsalya et al., (1995,1996) showed that the roots of *Salacia prinoides* could reduce blood glucose, serum total cholesterol, triglyceride and increases HDL cholesterol levels in NIDDM. The herbal treatment also elevated the serum chromium and magnesium levels.

5. **Bitter gourd** ***(Momordica charantia)***

Bittergourd is also found to possess the antidiabetic effect. The hypoglycemic principles reported are polypeptide – p or plant insulin, cheratin and kakra (Srivastava and Ragini, 1992).

6. Avarai (Cassia auriculata)

Cassia auriculata or Senna auriculata commonly known as avarai in Tamil, tarwar in Hindi, avartakki in Sanskrit and the tanner's cassia in English. It belongs to the Caesalpiniaceae family. It is a shrub with large bright yellow flowers, reddish brown branches. It is distributed throughout central and south India in most districts on dry stony hills and black cotton soil.

The roots, leaves, flowers, bark and seeds of avarai are used in traditional system of medicine. The flowers and leaves taken in equal proportions is made into juice. This extract in the dosage 1 oz/meal twice a day was reported to reduce the blood sugar level (Srinivasan and Ramalingam, 1989).

The effect of Cassia auriculata flower extract on hepatic glycolytic and gluconeogenic enzymes in rats was studied by Latha and Pari (2003). Administration of 0.45g/kg of the extract had significantly reduced blood glucose, glycosylated haemoglobin, gluconeogenic enzymes and increased plasma insulin and haemoglobin hexokinase activity. The aqueous extract of avarai flowers possess an antihyperglycemic effect and suggest that enhanced gluconeogenesis during diabetes is shifted towards normal and that the extract enhances the utilization of glucose through increased glycolysis.

The effect of aqueous extract of avarai flowers were examined on antioxidants and lipid peroxidation in the brain of streptozotocin diabetic rats. Significant increase in the activities of superoxide dismutase, catalase, glutathione peroxidase were observed in

brain on treatment with avarai flower extract. This gives the role of Cassia auriculata in protecting against lipid peroxidation (Latha and Pari, 2002).

The antidiabetic property of Cassia auriculata flowers are also quoted in many siddha texts. Avarai samoolam, that is, five parts of the plant namely leaves, flowers, roots, bark and seeds taken in equal proportions and consumed daily was reported to reduce the blood sugar level (Shanmugam,1998).

7. Sirukurinjan (*Gymnema sylvestre)*

Gymnema sylvestre is an Indian herb used in ayurveda, also referred to as Gurmarbooti, gurmar in Hindi, periploca of the woods in English, sirukurinjan in Tamil and mehasringri in Sanskrit. It is a woody climbing plant that grows in the tropical forests of central and southern India, belongs to the asclepiadaceae family. The leaves are used in herbal medicine preparations, which when chewed interfere with the ability to taste sweetness which, explains the Hindi name gurmar-"destroyer of sugar". Gymnema sylvestre's primary application was for NIDDM (Joffe, 2001). The gradual hypoglycemic action of gymnema leaves first documented in the 1930 differs from the rapid effect of many prescription hypoglycemic drugs (Beckles et al., 1998).

Gymnema leaves raise insulin levels according to research in healthy volunteers possibly due to regeneration of the ß cells of the pancreas (Shanmugasundaram et al., 1981). The leaves of Gymnema sylvestre, contain two types of specific inhibitors of sweet taste, gymnemic acid and gurmarin. Gymnemic acid, mixture of triterprene glycosides is a most potent inhibitor of sweet taste in humans and responses of the chorda

tympani nerve to sucrose in chimpanzees (Hellenkant et al., 1985 and Kurihara, 1992). More than ten gymnemic acids and related compounds have been isolated (Schuttisi, 1995). The contents of each gymnemic acids in leaves is found to be from 0.005 to 012 per cent (Murakami, 1996).

Gurmarin, a peptide of molecular weight 4209, is reported to suppress selectively chorda tympani responses to sweetners in rats (Miyasaka and Imoto, 1995) and certain strains of mice (Ninomiya et al., 1997). This inhibitory effect of sweetner responses occurs at a low concentration and lasts for more than three hours in the rat (Imoto et al., 1991). However, no significant effect of gurmarin was observed for taste responses to NaCl, HCl and quinine hydrochloride (Harada and Kasahara, 2000).

The leaves are noted for lowering serum cholesterol and triglycerides (Shanmugasundaram et al., 1990) and also plasma glucose (Abe, 1993). A water soluble acidic fraction of the leaves provides hypoglycemic actions, possibly gymnemic acid (Bishayee and Chatterjee, 1994). Its action in the reduction of intestinal glucose uptake has also been noted by Fushiki et al., (1992).

8. Jamun (Sygyzium cumini)

Sygyzium cumini or Eugenia cumini or Eugenia jambolana is commonly known as nagapazham in Tamil, Indian blackberry or jamun in Hindi and phalendra in Sanskrit. This belongs to Myrataceae family. It is a large evergreen tree attaining 30 meters in height with light grey bark and dark grey patches, leaves are oval, smooth and shiny, flowers are

small, numerous sweet scented, dull white in bunches, fruits are dark purple to black colour juicy when ripe. The seeds are round and smooth.

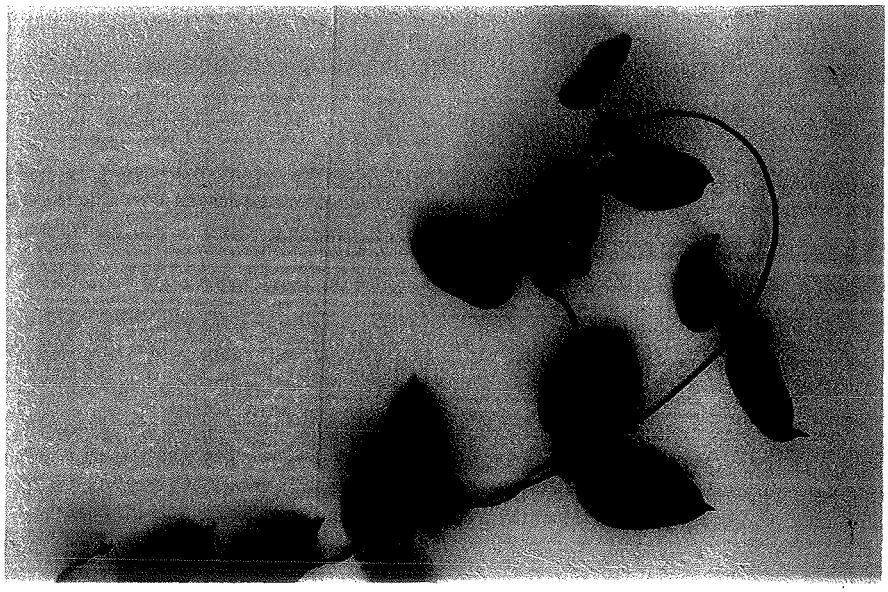
The tree grows in widely different localities, but is generally found along streams and in damp places and swamps. It is also found in evergreen forests. The seeds, fruits and bark of Sygyzium cumini skeels have been used in ayurveda and unani traditional system of medicine as antidiabetic drugs (Razzack, 1993 and Zafar, 1994). The powdered seeds, the solvent and aqueous extract of seeds, bark, leaves and fruits have been reported to lower blood glucose level in diabetic patients and in experimentally induced diabetic animals (Stanley et al., 1998 and Chatterjee, 2000).

Shukla et al (2000) isolated few highly active hypoglycemic compounds from the seeds and the pulp. Later Pandey and Khan (2002) conducted studies on the hypoglycemic effect of Syzium cumini and reported that the hypoglycemic effect was due to the presence of water soluble gummy fibre and not due to water insoluble neutral detergent fibre.

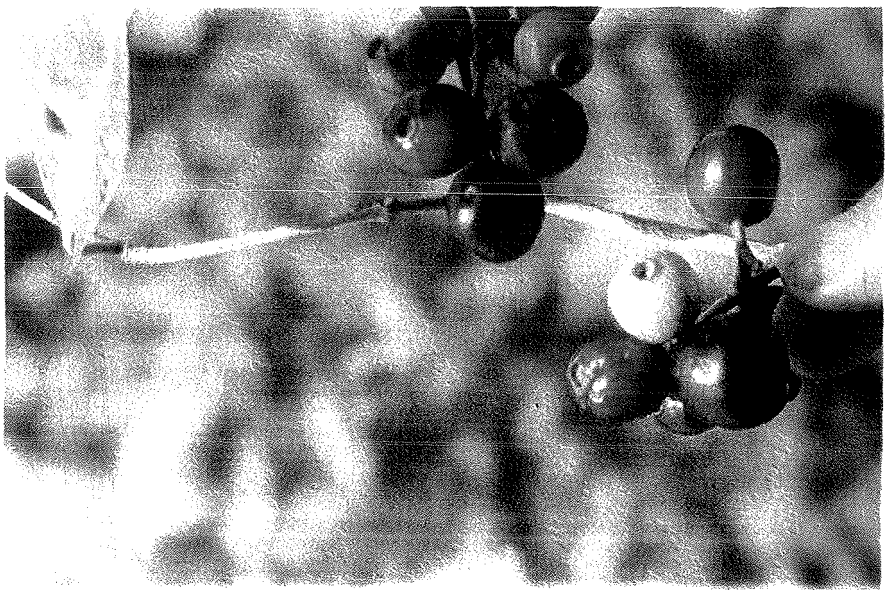
Plate 1a, 1b and 1c shows the avarai flowers, sirukurinjan leaves and jamun seeds selected for the study.

Plate 1 HERBS SELECTED FOR THE STUDY

1a Avarai Flowers



1b Sirukurinjan Leaves



1c Jamun Seeds

Methodology

III METHODOLOGY

The methodology involved in the present study entitled "Hypoglycemic potential of avarai (Cassia auriculata) in treating non-insulin dependent diabetes mellitus" is presented under the following headings:

A. Selection of the herbs.
B. Preparation of herbal powder with the selected herbs.
C. Selection of area.
D. Selection of subjects.
E. Assessment of background information and dietary intake of the subjects.
F. Treatment of the subjects using herbal powder.
G. Evaluation of treatment with the herbal powder.
H. Analysis of nutrient content of the herbal powder.
I. Statistical analysis.

A. Selection of the Herbs:

Based on the earlier studies carried out by Rao (1987) and Sivaprakasam (1985), avarai (Cassia auriculata) was selected. Traditionally it is a practice that these herbs are being given in the form of mixed herbs (churnam) for treatment. Hence, two other herbs, namely (sirukurinjan) Gymnema sylvestre and (naval) Sygyzium cumini were also selected. These two herbs were particularly selected because of their hypoglycemic property proved by Ueno (1997) using Gymnema sylvestre and by Grover et al (2002) using Syzium cumini. But all these studies

have been reported on animals. There are only a few studies reported on diabetic subjects. Hence, it was thought of interest to evaluate the hypoglycemic effect of avarai alone and in combination with other herbs in treating NIDDM subjects. Figure I gives the methodology involved in the present investigation.

B. Preparation of Herbal Powder with the selected herbs.

From the herbs selected, only certain parts of the plants have been used for the study like the flowers of avarai, leaves of sirukurinjan and the seeds of jamun fruit. These parts were chosen because of their hypoglycemic action proved by earlier studies by Shukla et al (2000) using jamun seeds Shivaprakasham (1985) using avarai and Yamashita (1991) using sirukurinjan leaves.

The therapeutic value of medicinal plants could differ depending on soil condition, nutritional status, and climatic conditions, seasonal variations etc. The relative proportions of phytochemicals present in medicinal plants can vary in different ecotypes (Subramaniam, 2001). To avoid variations, all the three herbs were collected from in and around Coimbatore. The flowers of avarai were collected from local area (Periyanaikenpalayam) and shade dried for 48 hours (Plate 2). The leaves of sirukurinjan and jamun seeds (Plate 3 and 4) were also collected from the local farms and shade dried fore 48 hours. All the dried samples were ground into a fine powder in a pulveriser (Plate 5). Since the study aimed at testing the hypoglycemic potential of avarai flowers alone and in combination with sirukurinjan leaves and naval seeds, two herbal powders were prepared. Mixed herbal powder was prepared by mixing powders of avarai flowers, sirukurinjan leaves and naval seeds in the ratio 60 : 30 : 10

FIGURE 1 METHODOLOGY

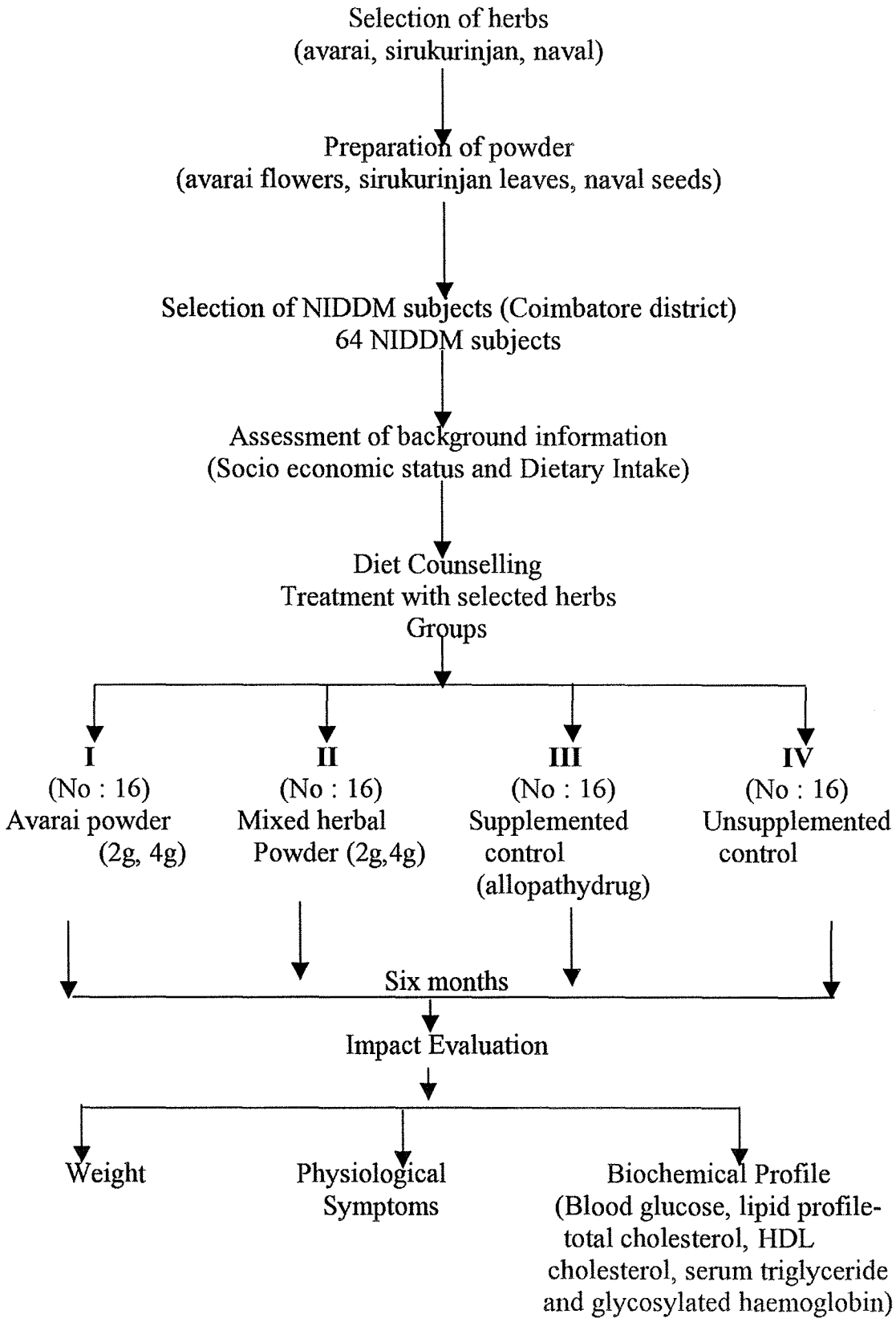


Plate 2 Avarai Flowers - Fresh,Dried&Powdered

Plate 3 Sirukurinjan Leaves - Fresh,Dried&Powdered

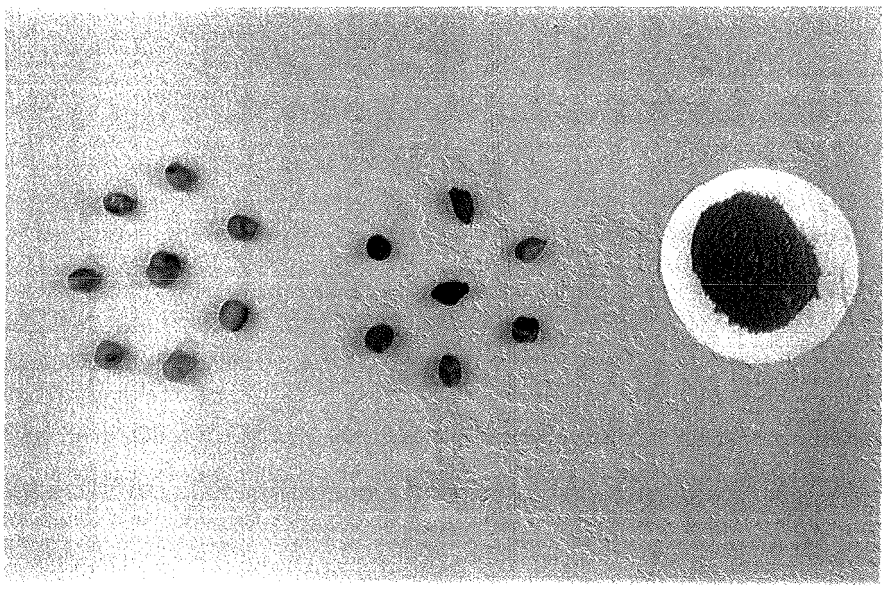


Plate 4 Jamun Seeds - Fresh,Dried&Powdered

respectively. Plate 6 shows the herbal powders prepared using avarai and mixed herbs.

C. Selection of Area

The area selected for the present study was Periyanaickenpalayam block of Coimbatore district. This particular area was chosen because of the availability and familiarity of the subjects to the investigator, easy access and co-operation extended by the subjects and the concerned medical authorities.

D. Selection of Subjects

Among the NIDDM subjects visiting the clinics and private nursing home for regular check up, a total of 64 subjects volunteering for the study were selected. They belong to the age group of 42 to 67 years. The age above 40 years increases the risk of diabetes (Haynes, 1993). The subjects belonging to both sexes in general good health, were screened to exclude thyroid, liver and renal disease. The selected subjects were categorized as mild, moderate and severe based on the fasting blood glucose levels ranging from 120 to 160 mg/dl, 160 to 200 mg/dl and above 200 mg/dl respectively, as specified by Ajgoankar (1962). The subjects were not exposed to any other hypoglycemic drug throughout the study period.

E. Assessment of Background Information and Dietary Intake of the subjects

An interview schedule (Appendix1) was formulated to obtain the background information like the educational status, details of the disease condition, the causative factors, type of treatment undertaken by

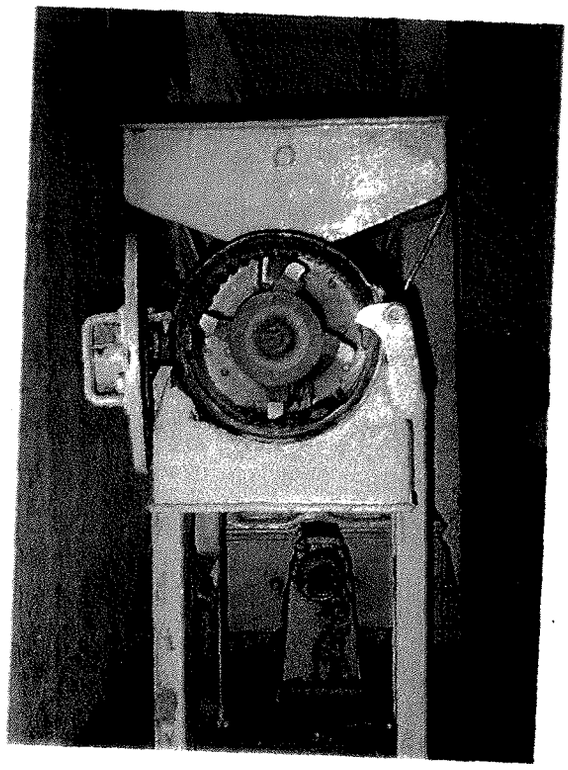


Plate 5 Pulveriser

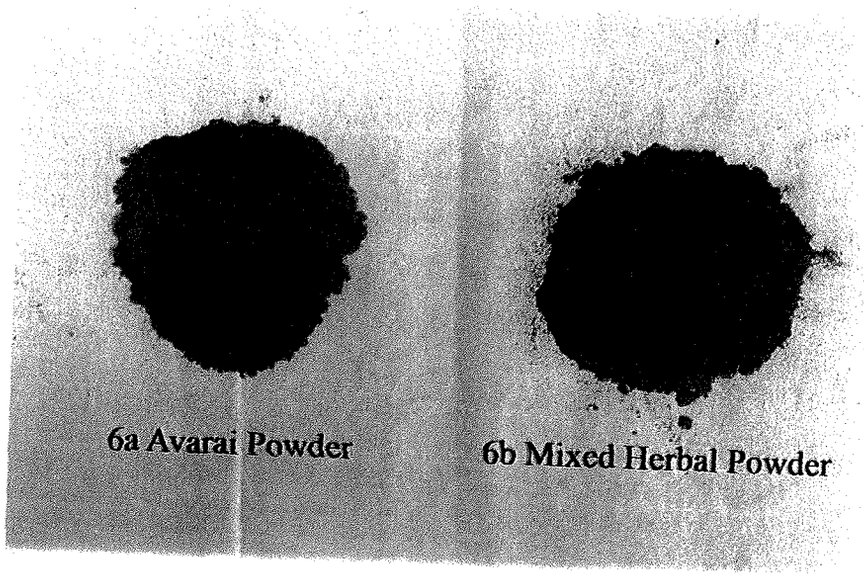


Plate 6 Prepared Herbal Powders

the subjects were found out. To find out the food consumption pattern, a dietary survey was conducted. Dietary survey is a vital determinant of health and nutritional status of people (Thimmayamma and Rao 1996).

Initially, a weighment survey was conducted for three consecutive days for all the selected NIDDM subjects to determine the actual food and nutrient intake. This method is more accurate as it involves direct weighing of foods. From the cooked weight of the foods consumed, the raw equivalents were calculated and using the food consumption Table (ICMR, 1991) the nutrient intake was calculated.

After the initial assessment of dietary intake, the subjects were given diet-counselling (Plate 7 and 8) inorder to ensure uniform pattern of nutrient composition and equivalisation of dietary regimen in all the groups, so that, treatment with the herbs alone was the experimental variable studied.

During the counselling period all the subjects were educated on the nature of the disease, symptoms, diagnosis, importance of exercise, how to select proper and correct amount of foods to adjust the energy intake according to their body weight and the importance of fibre rich foods. A food exchange list, foods to be included, and foods restricted were also taught. A sample menu card and food exchange list were given to the subjects. They were asked to follow the sample menu one week prior to the herbal treatment, so that, the effect of herbs will be exhibited clearly. They were insisted to follow the diet restrictions throughout the study period.

Plate 7 Selected Diabetic Subjects in Counselling

Plate 8 A Lecture on the Importance of Diet Restriction in Diabetes Mellitus

F. Treatment of the Subjects using the Herbal Powder

Sixty four NIDDM subjects were selected for the study. They were divided into four groups (I, II, III and IV) of 16 subjects each. In group I, mild and moderate diabetics were given 2g of avarai powder and severe diabetics were given 4g of avarai powder. In group II, mild and moderate diabetics were given 2g of mixed herbal powder, while severe diabetics were given 4g of mixed herbal powder. In group III, mild, moderate and severe subjects were given allopathic treatment, whereas group IV containing similar categories were treated as control without administration of herbs but maintained diet restriction.

The dosage level followed was determined based on the prescription practiced by the traditional healers. Table I gives the dosage level used for the treatment of different groups and the samples of the developed powders are appended (Appendix III).

TABLE I

DOSAGE LEVEL OF THE HERBAL POWDER

Groups	Type of powder/tablet	Dosage per day	Consumption pattern
Group I			
Mild A1	Avarai	2g	Once a day before food
ModerateB1	Avarai	2g	Once a day before food
Severe C1	Avarai	4g	Twice a day before food
Group II			
Mild A2	Mixed herbal powder	2g	Once a day before food
ModerateB2	Mixed herbal powder	2g	Once a day before food
Severe C2	Mixed herbal powder	4g	Twice a day before food
Group III			
Mild A3	Dianil	½ tablet	Once a day before food
ModerateB3	Dianil	1tablet	Once a day before food
Severe C3	Dianil	2 tablets	Twice a day before food
GroupIV (Control)			
Mild A	No herbal treatment	-	-
Moderate B	No herbal treatment	-	-
Severe C	No herbal treatment	-	-

The experimental subjects were instructed to visit the clinic once in 15 days to receive the herbal powder and monthly once the fasting blood glucose levels were monitored. They were given treatment for a period of six months. The control group was not given any treatment but advised to follow dietary restriction as for the experimental groups.

G. Evaluation of Treatment with the Herbal Powder.

Weight measurement, physiological symptoms and biochemical parameters formed the basis for the impact evaluation of herbal treatment.

1. Weight measurement

The subjects were screened for weight loss or gain during the study period by comparing their initial and final body weight.

2. Physiological symptoms.

Patients were interrogated regarding their symptoms in the initial and final phase of the study.

3. Biochemical parameters

Fasting blood glucose was estimated by the GOD-POD method using glucose oxidase and peroxidase enzymes (Trinder, 1969). Serum total cholesterol was estimated by enzymatic (CEH/CHOD/POD) method (Young et al., 1975). Serum HDL cholesterol was estimated by enzymatic method (Long and Sehetter, 1985). Serum triglyceride was estimated enzymatically (Foosatai et al., 1982). Glycosylated haemoglobin is a good measure to indicate the average blood glucose concentration over the preceding weeks while a single glucose determination gives a value which is true only at the time the blood sample is drawn (Murray et al., 2000). This test is becoming increasingly appreciated as an asymmetrically weighted measure of mean glycemic control (Tahara and Shima, 1993). This was estimated by ion-exchange resin method (Wienner, 1996)

H. Analysis of Nutrient Content of Herbal Powder.

Herbs not only possess medicinal properties but are also rich in nutrients. The prepared herbal powders were analysed for the nutrients like protein, fat, carbohydrates, energy, ash content, calcium, iron, phosphorus, moisture, crude fibre by using NIN procedure (2003). The micronutrients like chromium, copper and magnesium were estimated using atomic absorption spectrophotometry (NIN, 2003).

I. Statistical Analysis

1..Analysis of variance with one-way classification was done to check whether the difference in the biochemical parameters between the initial and final values within the four study groups was significant.

2.A two-way analysis of variance was done between the means of difference in the mild, moderate and severe categories under each parameter to check whether there was significant difference.

Results and Discussion

IV RESULTS AND DISCUSSION

The results pertaining to the present study entitled "Hypoglycemic potential of avarai (Cassia auriculata) in treating non-insulin dependent diabetes mellitus" are discussed under the following headings.

A. Nutrient content of herbal powders.
B. Background information and aetiology of the selected NIDDM subjects.
C. Food pattern and dietary practices of the selected subjects before diet counselling
D. Food pattern and dietary practices of the selected subjects after diet counselling
E. Impact evaluation of treatment with herbal powders in relation to changes in:
    1. Weight
    2. Physiological symptoms
    3. Biochemical profile

A. Nutrient Content of Herbal Powders

The nutrient content of the herbal powders as analysed are given in Table II.

TABLE II

NUTRIENT CONTENT OF THE HERBAL POWDERS

Nutrient/100g	Avarai Powder	Mixed Herbal Powder
Energy (k.cal)	116	154
Carbohydrates (g)	14.56	26.73
Protein (g)	8.58	7.2
Fat (g)	1.39	1.39
Total Ash (mg)	5.90	7.47
Calcium (mg)	0.53	0.71
Magnesium (mg)	0.32	0.42
Iron (mg)	0.16	0.23
Phosphorus (mg)	0.14	0.18
Copper (mg)	1.9	2.7
Chromium (mg)	8.2	1.2
Crude Fibre (g)	12.3	12.6
Moisture (g)	6.26	6.59

The energy content of the mixed herbal powder was higher than the avarai powder. The carbohydrate content in the mixed herbal powder was nearly double than that of avarai powder. However, the protein level was more in avarai than in the mixed herbal powder. The fat, crude fibre and moisture level are equal in both the powders. The other nutrients like calcium, magnesium, iron, phosphorus and copper was present in higher amount in the mixed herbal powder. The chromium content was more in avarai powder than in mixed herbal powder. In general, both avarai powder and mixed herbal powder were found to be rich in micronutrients.

B. Background Information and Aetiology of the selected NIDDM subjects.

The selected NIDDM subjects (64) were interviewed and the details of their background information are summarized below. Group I consisted of mild (A1), moderate (B1) and severe (C1) categories. The mild and moderate categories were given 2g of avarai powder and severe diabetics were given 4g of avarai powder. Group II also consisted of the same categories, were treated with 2g and 4g of mixed herbal powder, which was made out of avarai flowers, sirukurinjan leaves and jamun seeds in the ratio 60:30:10 respectively. Group III also consisted of the similar categories and were given allopathic treatment. Group IV (control) also consisted of the same categories were kept solely on diet restriction. In this section, for all purposes the discussions are as per this categorisation.

1. Age and sex

The age and sex wise distribution of the selected subjects are given in Table III.

TABLE III

AGE AND SEX OF THE SELECTED SUBJECTS

Groups	40-50		50-60		60-70		Total
	M	F	M	F	M	F	
Group I							
Mild (A 1)	--	2	2	1	1	--	6
Moderate(B1)	2	1	2	1	--	--	6
Severe(C1)	1	--	3	--	--	--	4
Group II							
Mild (A 2)	--	2	2	1	1	--	6
Moderate(B2)	2	2	2	--	--	--	6
Severe(C2)	1	--	3	--	--	--	4
Group III							
Mild (A 3)	--	3	1	1	1	--	6
Moderate(B3)	2	1	--	2	--	1	6
Severe(C3)	--	--	1	1	2	--	4
Group IV (Control)							
Mild (A)	3	1	1	1	--	--	6
Moderate(B)	1	2	--	1	2	--	6
Severe(C)	--	2	--	1	1	--	4

Of all the diabetic subjects selected, 28 were in the age group of 40 to 50 years, 27 were in the age group of 50 to 60 years and nine were in the age group of 60 to 70 years. Prevalence increases with age perhaps 10 per cent of those over 60 are affected (Robertson, 1993). According to Sayeed et al., (1995), age was shown to be an important risk factor for diabetes. The increased incidence of diabetes above 40 years of age may be due to increased body fat mass, sedentary life style or insulin

deficiency. The number of male diabetics (37) were more than the number of female diabetics (27).

2. Weight and sex

The distribution of male and female diabetics selected in accordance to their weight is given in Table IV.

TABLE IV

WEIGHT OF THE SELECTED SUBJECTS.

Weight (kg)	Group I			Group II			Group III			Group IV			Total
	A1	B1	C1	A2	B2	C2	A3	B3	C3	A	B	C	
Male													
<60	--	--	--	--	--	--	--	--	--	--	--	--	--
60	1	--	--	--	--	--	--	--	--	2	1	--	4
>60	2	4	4	3	4	4	2	2	3	2	2	1	33
Female													
<50	--	--	--	--	--	--	--	--	--	--	--	--	--
50	1	--	--	--	--	--	--	--	--	--	--	1	2
>50	2	2	--	3	2	--	4	4	1	2	3	2	25

As per the present norms for Indian adults, an increase in body weight by 20 per cent above normal (60 kg for male and 50 for female, ICMR, 2002) is referred to as overweight and decrease in 20 per cent below normal as underweight (Raghuram et al., 1997). Based on these categories, among males there were 33 subjects under the third category, four subjects in the second category and no subjects in the first category. Among the female diabetics, there were 25 under the third category, two in the second category and no one in the first category.

In total, majority belonged to third category (58) and six persons were found to have ideal body weight. No one was observed in the first category.

3. Educational status of the selected subjects

Among the 64 subjects, 39 were degree holders, nine had completed PUC, eight had done SSLC and eight had done primary school education.

4. Economic status of the subjects

The economic status of the selected subjects is given in Table V.

TABLE V

ECONOMIC STATUS OF THE SELECTED SUBJECTS

Income per month (Rs)	Number
Affluent class (>10,000)	6
High income class (5,000-10,000)	44
Upper middle class (3,000 – 5,000)	12
Lower middle class (<3,000)	2
Total	64

Among the selected subjects, 44 belonged to higher income group, 12 belonged to upper middle class, and six belonged to affluent class. The peak age of onset of diabetes was found to be higher in high-

income group when compared to low income group (Viswanathan et al., 1995).

5. Duration of the disease condition

Out of the 64 diabetic subjects selected, 38 had the disease over five years, 20 subjects had diagnosed within the past two to five years and six subjects had diagnosed the disorder only during the past one year.

6. Diabetic traits in the family.

Among the selected subjects the incidence of diabetes in the family is given in Table VI.

TABLE VI

DIABETIC TRAITS IN THE FAMILY

Family History	Number
Both parents are diabetic	43
One parent is diabetic	10
Any relative is diabetic	6
None	5

Out of 64 subjects, 43 subjects had inherited the disease from both their parents, 10 of them had either parent as diabetic, six of them had their relative as diabetic, and only five of them had no previous history of diabetes in their family.

7 .Treatment undertaken previously.

Table VII shows the previous treatment undertaken by the selected subjects.

TABLE VII

TREATMENT UNDERTAKEN BY THE SELECTED SUBJECTS

Type of treatment	Numbers
Ayurvedic	3
Allopathy	44
Siddha	3
Unani	--
Diet and Allopathy	3
Homeopathy	1

Among the selected subjects, 44 followed allopathic treatment, three of them followed ayurvedhic treatment, three of them followed siddha, three of them followed diet and allopathic treatment, and only one subject followed homeopathy treatment.

8. Reasons for participation.

Majority of the subjects participated in the study were not satisfied with the allopathy treatment due to the side effects produced in some of them. The initial education given to them about the disease, importance of diet restriction, benefits of herbal treatment had encouraged them to extend their co-operation throughout the study.

9. Severity of the disease condition.

Table VIII gives the categorisation of subjects according to their severity of disease condition as given by Ajgoankar (1962).

TABLE VIII

SEVERITY OF THE DISEASE CONDITION OF THE SELECTED SUBJECTS

Category	Male	Female
Mild (FBG 120-160mg/dl)	12	12
Moderate (FBG 160-200mg/dl)	13	11
Severe (FBG >200mg/dl)	12	4
Total	37	27

FBG - Fasting Blood Glucose

Among the total male diabetics (37), 12 were mild diabetics, 13 were moderate diabetics and 12 were severe diabetics. Among the total female diabetics (27), 12 were mild diabetics, 11 were moderate diabetics and four were severe diabetics.

C. Food Pattern and Dietary Practices of the selected subjects before Diet Counselling.

The food consumption pattern and dietary practices of the selected diabetics before diet counselling is presented in Table IX.

TABLE IX
FOOD PATTERN AND DIETARY PRACTICES OF SELECTED SUBJECTS BEFORE DIET COUNSELLING

Food items	Meal pattern				Frequency of usage		
	Break fast	Lunch	Tea	Dinner	Daily	Alternate days	Weekly once
Cereals							
Rice	50	64	-	47	64	47	47
Wheat	19	-	-	32	19	32	32
Ragi	05	-	-	-	-	-	-
Semolina	20	-	-	16	-	16	16
Bread	13	-	5	-	-	-	-
Pulses							
Whole gram	8	13	7	11	2	11	11
Dhal	35	64	-	37	33	37	37
Legumes	-	9	-	4	-	4	4
Vegetables							
Roots&Tubers	32	64	13	19	22	19	19
Green leafy Vegetables	-	64	-	-	7	-	-
Gourd varieties	-	-	-	19	-	19	19
Others	47	64	-	-	4	-	-
Fruits							
Citrus fruits	-	11	-	-	-	-	-
Apple	7	2	-	-	2	-	-
Banana	8	33	-	20	46	20	20
Grapes	-	-	10	-	-	-	-
Others	-	-	4	2	-	2	2
Animal Foods							
Egg	11	31	-	2	4	2	2
Fish	-	27	-	3	4	3	3
Chicken	-	32	-	-	-	-	-
Meat	-	24	-	-	-	-	-
Sweeteners							
Sugar	-	-	15	-	15	-	-
Jaggery	-	-	-	-	-	-	-
Artificial sweetener	-	-	-	-	-	-	-
Milk&Milk products							
Milk	64	-	64	36	64	-	-
Curd	-	43	-	10	17	18	18
Butter milk	9	11	-	10	13	8	9
Fats & Oils							
Butter	6	-	-	-	-	-	6
ghee	-	18	-	-	-	-	18

The Table points out the food consumption pattern and frequency of consumption of the various foodstuff listed under each food groups. Among the cereals, rice was mostly used for breakfast (50), lunch (64) and dinner (47) almost everyday. Wheat was used by some (19) for breakfast and some (32) for dinner either daily or alternate days, only 15 used wheat weekly once. Ragi was used by some (5) but once in a week. Semolina was used for either breakfast or dinner. Bread was used either for breakfast or as snacks. Among the pulse, some (18) used whole gram for breakfast, some (13) for lunch and few (seven) for tea time and others (11) for dinner. Mostly they were using pulses once in a week or in alternate days. The intake of roots and tubers was unrestricted by all for lunch. Green leafy vegetables were used by all but once in a week or alternate days. Only few (19) were using gourd varieties that too once in a week. Citrus fruits were used by some (11) and apples (19) and grapes (10), banana was not restricted and was included mostly daily.

Most of the animal foods were consumed only once in a week except egg which was included frequently in the diet. Sugar was used by 15 subjects daily with tea. Milk was consumed by everybody along with breakfast or tea. Curd was taken by 43 subjects with lunch and 10 subjects consumed it with dinner. Buttermilk was consumed by 30 subjects. Among fats, butter was used by six subjects and 18 subjects used ghee weekly once.

Thus, the Table depicts the ununiform dietary pattern of the subjects and hence formed the basis for planning the diet counselling.

Table X shows the mean daily nutrient intake of the selected subjects.

TABLE X

MEAN DAILY NUTRIENT INTAKE OF THE SELECTED SUBJECTS.

Groups	Energy		Protein		Fat		Fibre		Carbohydrates	
	M	F	M	F	M	F	M	F	M	F
Group I										
A 1	2350	2020	53.1	48.8	30	26	7.1	5.2	417	343
B1	2785	2115	59.6	49.2	29	30	6.8	5.5	501	365.4
C1	2090	2200	49.5	48.6	29	28	6.6	6.3	373.6	380
Group II										
A 2	2985	1995	52.8	50.1	32	26	7.1	7	528.3	343
B2	2840	2005	53.5	49.3	28	30	6.8	6.8	496.3	348
C2	2680	2240	50.1	48.7	30	29	5.9	5.9	490.4	399.3
Group III										
A 3	2860	2025	49.8	48.3	24	28	5.3	6.1	511.9	356
B3	2525	2150	55.0	47.9	29	30	6.2	6.4	432.4	375
C3	2675	2266	48.9	47.2	30	29	5.5	5.8	486.2	397
Group IV										
A	2450	1980	50.0	43	24	26	4.9	5.3	436.8	339
B	2525	2010	51.0	45.1	26	30	6.4	6.7	447.5	349.7
C	2420	2200	50.5	44.9	29	31	6.7	6.9	437.4	391
RDA (ICMR, 2002)	2425	1875	60	50	20	20	--	--	--	--

Suggested level by Raghuram et al., (1993)

M-30 cal /kg (1800) lean body weight -1800 to 2000 k.cal

F-30 cal /kg (1500) obese diabetics -1200 to 1500 k.cal

M-Male F-Female

Initial observation indicated that all the 64 subjects practised irregular dietary pattern. Their caloric intake was higher than the recommended levels and the protein intake did not meet the RDA, fat consumption was not restricted. Hence there was need to bring about uniformity in nutrient intake especially the proximate principles so as to make sure that treatment with the herbal powder will be the only variable.

Table XI shows the percentage of energy derived from proximate principles in diets when compared to the suggested level.

TABLE XI

PERCENTAGE OF ENERGY DERIVED FROM PROXIMATE PRINCIPLES.

Groups	Carbohydrates		Protein		Fat	
	M	F	M	F	M	F
Group I						
A 1	71	67.9	13.1	14.5	15.9	17.6
B1	72	69.1	12.6	12.1	15.4	18.8
C1	71.5	69	12	13.5	16.5	17.5
Group II						
A 2	70.8	68.8	13.6	13.5	15.6	17.7
B2	69.9	69.5	12.2	12	17.9	18.5
C2	73.2	71.3	9.7	10	17.1	18.7
Group III						
A 3	71.6	70.3	13.8	12.4	14.6	17.3
B3	68.5	69.8	13.2	12.2	18.3	18
C3	72.7	70.1	9.2	11.4	18.1	18.5
Group IV						
A	71.3	68.5	13.9	13.7	14.8	17.8
B	70.9	69.6	12.8	12	16.3	18.4
C	72.3	71	10	11.3	17.7	17.7

M-Male F-Female
Reference value suggested by Raghuram et al., (1993)
Carbohydrates- 60 to 65 per cent Protein- 15 to 20 per cent
Fat -15 to 25 per cent

The percentage of calories derived from carbohydrates among all the groups was higher than the recommended range of 60 to 65 per cent. On the other hand, the percentage of calories from protein intake was less than the recommended range of 15 to 20 per cent. Fat intake provided the necessary calories. There was need to counsel the subjects on the choice of foods especially to increase the protein intake.

D. Food Pattern and Dietary Practises of the selected subjects after Diet Counselling

Table XII shows the food consumption pattern and dietary practices of the selected subjects after diet counselling.

TABLE XII

FOOD PATTERN AND DIETARY PRACTICES OF SELECTED SUBJECTS AFTER DIET COUNSELLING

Food items	Meal pattern				Frequency of usage		
	Break fast	Lunch	Tea	Dinner	Daily	Alternate days	Weekly once
Cereals							
Rice	42	64	--	34	64	--	--
Wheat	19	8	--	35	22	30	10
Ragi	11	--	--	--	1	6	4
Semolina	21	--	--	17	--	7	30
Bread	19	--	5	--	--	4	20
Pulses							
Whole gram	10	16	9	14	--	10	39
Dhal	38	64	--	37	44	20	--
Legumes	-	17	--	5	--	3	19
Vegetables							
Roots&Tubers	14	30	--	--	--	11	33
Green leafy Vegetables	--	64	--	--	19	36	9
Gourd varieties	--	64	--	26	31	23	10
Others	64	64	--	64	2	9	52
Fruits							
Citrus fruits	--	17	3	--	1	1	18
Apple	2	1	--	--	--	--	3
Banana	4	22	--	13	19	13	7
Grapes	--	--	7	--	--	--	7
Others	--	--	2	2	--	1	3
Animal Foods							
Egg	5	20	--	--	--	4	21
Fish	--	28	--	5	4	10	19
Chicken	--	23	--	--	--	--	23
Meat	--	18	--	--	--	1	17
Sweeteners							
Sugar	--	--	4	--	4	--	--
Jaggery	--	--	--	--	--	--	--
Artificial sweetener	--	--	--	--	--	--	--
Milk&Milk products							
Milk	64	--	64	--	64	--	--
Curd	--	31	--	6	26	3	8
Butter milk	10	18	--	15	23	12	8
Fats & Oils							
Butter	2	--	--	--	--	--	2
ghee	--	7	--	2	--	--	9

It was noted that among the cereals, there had been an improvement in the pattern and frequency of wheat and ragi consumption, reducing the use of rice. Among pulses, the use of whole grams and legumes had increased considerably and thereby improve the protein intake to meet the RDA. The number of subjects using roots and tubers have also reduced. The use of green leafy vegetables which improves the fibre content of the diet had improved. Gourd varieties have been included in the diet. The consumption of citrus fruits had considerably increased. The use of apples, banana and grapes had been restricted. There had not been much change in the consumption of animal foods as the subjects have restricted the intake even before diet counselling. The frequency of the use of egg had been reduced. Sugar had been restricted by all, except four subjects. The consumption of buttermilk had improved. The use of butter and ghee had also been restricted by the subjects.

Table XIII shows the mean daily nutrient intake of the selected subjects after diet counselling.

TABLE XIII

MEAN DAILY NUTRIENT INTAKE OF THE SELECTED SUBJECTS AFTER DIET COUNSELLING

Groups	Energy		Protein		Fat		Fibre		Carbohydrates	
	M	F	M	F	M	F	M	F	M	F
Group I										
A 1	1750	1536	59.5	51.3	22.6	21.9	10.1	7.8	295	242
B1	1810	1325	60.4	49.8	21.5	22.7	9.8	9.6	289	212.7
C1	1900	1605	60.7	49.6	22.4	23	9.9	9.4	297	258
Group II										
A 2	1775	1620	60.8	51.6	21.8	22.9	10	9.1	302.2	249.5
B2	1650	1545	61.2	52	22.8	23.8	8.7	9.7	279.3	240.6
C2	1765	1485	59.8	50.1	21.9	22.3	8.5	9.1	297.4	241.3
Group III										
A 3	1875	1620	62.1	48.8	23.6	22.0	10.2	10.0	304.2	255.5
B3	1408	1385	61.9	51.4	21.8	22.9	9.8	9.0	231.6	210.5
C3	1766	1467	60.8	50.8	22.7	23.7	8.7	7.6	296.2	245.4
Group IV										
A	1733	1529	61.4	52.2	22.2	19.8	11.1	10.0	295.5	243.9
B	1562	1505	60.7	51.5	20.6	19.6	10.8	10.1	288.1	237.8
C	1658	1485	60.5	50.8	22.0	20.1	9.9	9.3	279.8	229.8
RDA (ICMR, 2002)	2425	1875	60	50	20	20	--	--	--	--

Suggested level by Raghuram et al., (1993)

M-30 cal /kg (1800) lean body weight -1800 to 2000 k.cal

F-30 cal /kg (1500) obese diabetics -1200 to 1500 k.cal

M-Male F-Female

From the above table it is observed that the intake of calories, carbohydrates, protein and fat were within the recommended range of all the groups.

Table XIV shows the percentage of energy derived from proximate principles in diets of the selected subjects.

TABLE XIV

PERCENTAGE OF ENERGY DERIVED FROM PROXIMATE PRINCIPLES.

Groups	Carbohydrates		Protein		Fat	
	M	F	M	F	M	F
Group I						
A 1	67.4	63.0	18.0	20.2	14.6	16.8
B1	63.9	64.2	22.4	18.4	13.7	17.4
C1	65.5	64.3	18.9	19.4	15.6	16.3
Group II						
A 2	68.1	61.6	16.9	21.4	15.0	17.0
B2	67.7	62.3	17.9	18.9	14.4	18.8
C2	67.4	65.0	16.4	17.5	16.2	17.5
Group III						
A 3	64.9	63.1	20.1	19.1	15	17.8
B3	65.8	60.8	17.9	21.4	16.3	17.8
C3	67.1	66.9	16.3	16.5	16.6	16.6
Group IV						
A	68.2	63.8	16.6	18.7	15.2	17.5
B	65.9	63.2	19.3	19.4	14.8	17.4
C	67.5	61.9	16.1	18.6	16.4	19.5

M-Male F-Female

Reference value suggested by Raghuram et al., (1993).

Carbohydrates- 60 to 65 per cent Protein- 15 to 20 per cent

Fat -15 to 25 per cent.

The percentage of calories derived from carbohydrates, proteins and fat consumed by all the subjects were within the reference value recommended by Raghuram et al., (1993).

E. Impact Evaluation of Treatment with Herbal Powders

1. Changes in weight profile

The changes in weight of selected diabetic subjects studied at the initial and final stages is presented in Table XV.

TABLE XV
WEIGHT BEFORE AND AFTER TREATMENT

Weight (Kg)	Group I						Group II						Group III						Group IV					
	A1		B1		C1		A2		B2		C2		A3		B3		C3		A		B		C	
	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F
Male																								
<60	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
60	1	2	-	2	-	1	-	1	-	2	-	2	-	-	-	1	-	1	-	1	-	1	-	1
>60	2	1	4	2	4	3	3	2	4	2	4	2	2	2	2	1	3	2	2	1	2	1	1	-
Female																								
<50	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
50	1	2	-	1	-	-	-	1	-	1	-	-	-	1	-	2	-	1	-	1	-	1	-	2
>50	2	1	2	1	-	-	3	2	2	1	-	-	4	3	4	2	1	-	2	1	3	2	2	1

The above Table shows that the herbal treatment of the experimental groups I and II had been effective in shifting most of the overweight subjects to ideal bodyweight when compared with group III and the control. Among the male diabetics (37), 33 of them were overweight before treatment, out of which 15 shifted to ideal body weight after herbal treatment for six months. Similarly, among the female diabetics (27), 25 of them were overweight before the treatment out of which 13 subjects were shifted to ideal body weight after treatment.

2. Physiological symptoms

The changes in the physiological symptoms prior to and after the treatment is presented in Table XVI.

TABLE XVI
CHANGES IN PHYSIOLOGICAL SYMPTOMS OF THE SELECTED SUBJECTS

Symptoms	Group I						Group II						Group III						Group IV					
	A1		B1		C1		A2		B2		C2		A3		B3		C3		A		B		C	
	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F	I	F
Polydypsia	2	-	3	-	3	-	1	-	2	-	2	-	1	-	1	-	2	-	2	2	2	2	1	1
Polyuria	3	-	4	-	2	-	2	-	-	-	2	1	3	-	-	-	1	-	1	1	1	-	2	2
Polyphagia	1	-	2	-	2	-	1	-	-	-	1	-	1	-	-	-	1	1	2	2	-	-	1	1
Constipation	-	-	1	-	-	-	-	-	2	-	-	-	1	-	-	-	2	-	1	1	-	-	-	-
Insomnia	-	-	-	-	1	-	-	-	-	-	1	-	-	-	1	-	1	-	-	-	1	1	1	1
Giddiness	-	-	1	-	2	-	-	-	-	-	2	-	-	1	-	-	-	-	-	-	2	2	-	-
Excessive Sweating	1	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-	2	-	-	-	1	1	1	1
Poor wound healing	-	-	2	-	-	-	-	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-	1	1
Burning sensation	-	-	1	-	-	-	-	-	-	-	2	-	-	-	-	-	1	-	-	-	-	-	1	1

Out of nine clinical parameters indicative of diabetes, polydypsia and polyuria were the most common symptoms found in most of the subjects. Polydypsia and polyuria which was found in 17 subjects before treatment disappeared completely after treatment. Similar changes were observed in cases of subjects who had exhibited symptoms such as polyphagia, constipation, insomnia and giddiness. These symptoms almost disappeared at the end of the treatment period. Excessive sweating, poor wound healing and burning sensation which was observed in few subjects at the initial phase was not observed in the later phase. In the control group, no such changes were observed.

3. Changes in biochemical profile

a. Changes in fasting blood glucose level

Table XVII and Figure 2A gives the mean fasting blood glucose level of the mild diabetics at the initial and final phase of the study period along with the mean reduction in the blood glucose level.

TABLE XVII
MEAN FASTING BLOOD GLUCOSE LEVELS OF MILD DIABETICS (mg/dl)

Groups	Initial	1st Month	2nd Month	3rd Month	4th Month	5th Month	Final	Reduction	F Value
GroupI	150.8±	150.0±	145.1±	139.3±	129.5±	120.3±	116.3±	34.5±	
(avarai powder)	2.13	8.33	3.55	1.21	2.58	4.22	0.87	2.25	
Group II	151.6±	147.3±	143.5±	137.1±	128.3±	119.8±	109.1±	42.5±	
(mixed herbal powder)	6.04	5.88	8.91	3.8	0.70	2.02	0.80	2.89	
Group III	151.0±	146.8±	143.0±	136.3±	130.5±	123.5±	119.1±	31.8±	199.27**
(dianil)	4.13	2.13	6.66	5.54	3.25	1.91	2.46	3.31	
Group IV	149.6±	148.5±	147.5±	147.1±	146.3±	145.1±	143.8±	5.8±	
(control)	2.21	0.83	0.50	1.13	0.87	0.87	4.14	2.31	

** Significant at one per cent level

The mean fasting blood glucose level of the mild diabetics ranged from 150 to 152 mg/dl. After a period of six months of supplementation with the herbal powders, significant reduction in the glucose levels was observed among the experimental groups and the difference was found to be statistically significant. Among the experimental groups, group II treated with mixed herbal powder had maximum reduction (42.5mg/dl) in blood glucose followed by group I and group II (34.5mg/dl and 31.83 mg/dl).

Table XVIII and Figure 2B gives the mean fasting blood glucose level of the moderate diabetics at the initial and final phase of the study and the mean reduction of blood glucose levels are also given.

TABLE XVIII
MEAN FASTING BLOOD GLUCOSE LEVELS OF MODERATE DIABETICS (mg/dl)

Groups	Initial	1st Month	2nd Month	3rd Month	4th Month	5th Month	Final	Reduction	FValue
GroupI	182.1±	177.0±	170.1±	165.3±	156.5±	152.8±	144.3±	37.8±	
(avarai powder)	5.55	7.33	5.8	10.88	9.91	4.46	2.36	3.48	
Group II	185.5±	179.0±	171.3±	168.0±	156.6±	147.8±	141.5±	44.0±	
(mixed herbal powder)	3.67	4.69	2.78	3.08	5.22	3.75	0.91	2.0	
Group III	184.6±	178.3±	172.3±	169.1±	163.6±	156.0±	150.6±	34.0±	196.98**
(dianil)	1.55	3.81	11.54	10.22	1.13	7.83	3.55	3.03	
Group IV	183.6±	182.5±	180.3±	178.1±	177.3±	177.0±	176.0±	7.6±	
(control)	4.89	5.88	6.67	9.46	1.54	1.66	1.0	2.42	

** Significant at one per cent level

The initial blood glucose level of the moderate NIDDM subjects ranged from 182 mg/dl to 186 mg/dl. At the end of the study period, the blood glucose levels lowered significantly in the experimental groups I and II. The hypoglycemic effect was more pronounced in the case of mixed herbal powder treated group than that of the group treated with avarai powder. The control group also exhibited a very mild reduction of 7.6mg/dl in the blood glucose level which may be attributed due to strict diet control. Statistical analysis of variance between the reduction in blood glucose levels of four groups showed significant difference at one percent level.

Table XIX and Figure 2C presents the mean fasting blood glucose levels of the severe diabetics at the initial and final stages of the study and the mean reduction of blood glucose levels are also given.

TABLE XIX
MEAN FASTING BLOOD GLUCOSE LEVELS OF SEVERE DIABETICS (mg/dl)

Groups	Initial	1st Month	2nd Month	3rd Month	4th Month	5th Month	Final	Reduction	F Value
GroupI	217.5±	209.5±	204.0±	197.0±	185.5±	182.5±	180.0±	37.5±	
(avarai powder)	3.25	8.75	1.5	6.5	3.25	3.25	0.50	1.91	
Group II	217.7±	208.0±	198.5±	187.7±	178.2±	174.5±	170.7±	47.0±	
(mixed herbal powder)	0.68	9.5	7.25	3.18	2.05	2.18	1.25	2.44	
Group III	212.2±	210.0±	201.7±	195.5±	192.5±	187.7±	183.5±	28.7±	321.44**
(dianil)	3.18	9.5	9.18	7.25	6.5	8.75	1.25	0.95	
Group IV	213.0±	212.2±	210.0±	210.0±	208.7±	208.0±	206.5±	6.5±	
(control)	2.5	2.68	1.5	6.5	5.68	1.5	3.75	2.08	

** Significant at one per cent level

FIG 2A MEAN FASTING BLOOD GLUCOSE LEVELS
MILD DIABETICS (mg/dl)

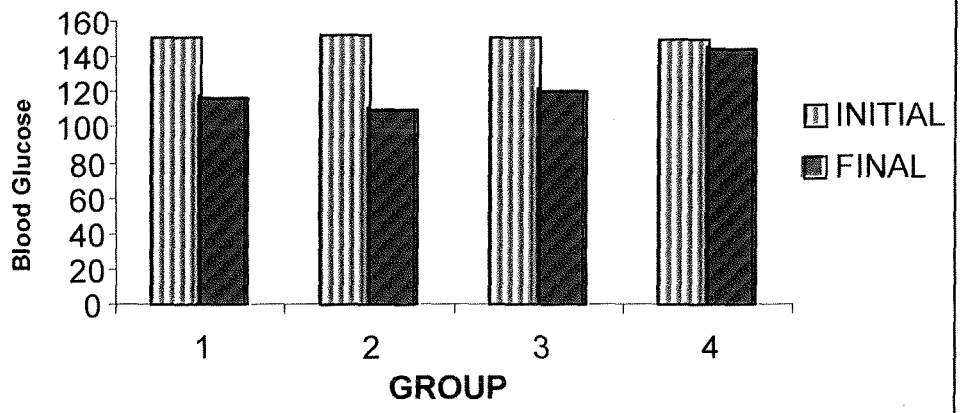


FIG 2B MEAN FASTING BLOOD GLUCOSE LEVELS
MODERATE DIABETICS (mg/dl)

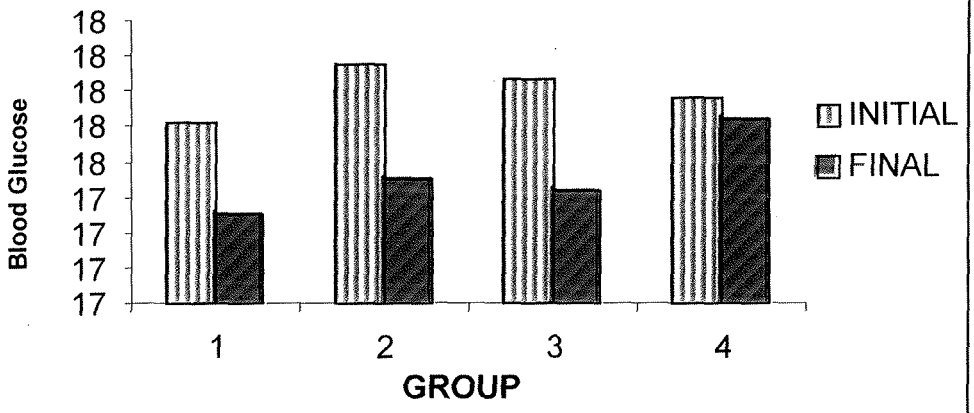
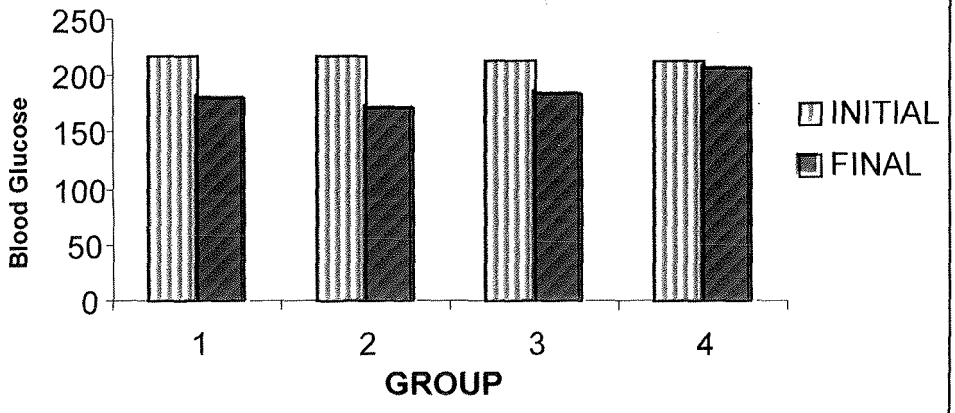


FIG 2C MEAN FASTING BLOOD GLUCOSE LEVELS
SEVERE DIABETICS (mg/dl)



The initial blood glucose level of the severe diabetic ranged from 212 to 218mg/dl. After a period of six months of supplementation with herbs, significant reduction in the glucose levels was observed among the experimental groups and the difference was found to be statistically significant. Among the experimental groups, group II showed maximum reduction in blood glucose level (47mg/dl) followed by groups I and III (37.5mg/dl and 28.75mg/dl).

Table XX presents the mean reduction in the fasting blood glucose values between the initial and final stages of the study period of the three categories.

TABLE XX

MEAN REDUCTION IN FASTING BLOOD GLUCOSE LEVELS OF SELECTED DIABETICS (mg/dl)

Category/ Group	Group I (avarai powder)	Group II (mixed herbal powder)	Group III (dianil)	Group IV (Control)	F Value
Mild	34.5±2.25	42.5 ±2.89	31.83 ± 3.31	5.8 ± 2.31	198.75**
Moderate	37.8± 3.48	44.0± 2.0	34.0 ± 3.03	7.6 ± 2.42	
Severe	37.5±1.91	47.0± 2.44	28.7 ± 0.95	6.5 ± 2.08	
F value between categories: 1.377 Not Significant					

** Significant at one per cent level

An analysis of variance by two way classification of the mean blood glucose reduction values between the different types of treatment on the three categories of these groups was done. This test showed a significant difference in the reduction in blood glucose values between the three experimental groups and control group at one per cent level whereas there was no significant difference between the reduction in blood glucose values between the three categories. These findings demonstrate that both the herbal powders are effective hypoglycemic agents and the effect does not differ markedly between the three categories. However it was observed that the hypoglycemic effect of the mixed herbal powder is more pronounced in the severe category than in mild and moderate categories. On the other hand, avarai powder was equally effective in the moderate and severe categories than in mild category.

b. Lipid profile of the subjects

i. Changes in serum total cholesterol levels

Table XXI and Figure 3A gives the mean serum total cholesterol levels of the mild diabetics at the initial and final stages of the study.

TABLE XXI

MEAN SERUM TOTAL CHOLESTEROL LEVELS OF MILD DIABETICS (mg/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	215.6± 7.56	188± 2.66	27.66±3.93	
Group II (mixed herbal powder)	218.16±3.78	187.33± 4.2	30.83±2.22	114.46**
Group III (dianil)	217.66±7.53	197.33±1.96	20.33±2.80	
Group IV (control)	212.33±8.88	209.5±1.58	2.83±2.13	

** Significant at one per cent level.

The above Table shows that the initial cholesterol levels of the mild diabetics ranged from 212 to 218 mg/dl before treatment as against the normal value of 200 mg/100ml quoted by Allain et al (1974). After the herbal treatment for six months there was a marked reduction in the serum total cholesterol levels in the experimental groups whereas the control group showed a negligible change. An analysis of variance between the reduction in serum cholesterol values of the different groups showed significance at one per cent level. It is observed that the cholesterol lowering effect of the avarai and dianil is not as effective as that of mixed herbal treatment.

Table XXII and Figure 3B gives the mean serum total cholesterol levels of moderate diabetics at the initial and final stages of the study period along with the mean reduction in cholesterol values.

TABLE XXII

MEAN SERUM TOTAL CHOLESTEROL LEVELS OF MODERATE DIABETICS (mg/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	220.8± 5.76	199.5± 3.83	21.33±2.65	
Group II (mixed herbal powder)	222.6±2.55	188.0± 7.66	34.66±3.38	141.89**
Group III (dianil)	221.0±1.33	203.8±5.44	17.16±3.12	
Group IV (control)	220.8±4.5	217.6±3.55	3.16±0.40	

** Significant at one per cent level.

The initial serum total cholesterol levels of the moderate diabetics ranged from 220.8 to 223 mg/dl which is higher than the normal value of 200 mg/dl quoted by Allain et al (1974). After a period of six months of supplementation of herbal powder significant reduction in cholesterol levels was observed in the experimental groups. The control group had a very mild reduction.

An analysis of variance by one way classification was done on the reduction in the serum total cholesterol levels between the four groups under study which showed significance at one per cent level. The cholesterol lowering effect of avarai and allopathy treatment is not as appreciable as that of mixed herbal powder.

Table XXIII and Figure 3C gives the mean serum total cholesterol levels of severe diabetics at the initial and final stages of the study period along with the mean reduction in total cholesterol values.

TABLE XXIII

MEAN SERUM TOTAL CHOLESTEROL LEVELS OF SEVERE DIABETICS (mg/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	222.5± 5.25	202.5± 3.25	20.0±2.58	
Group II (mixed herbal powder)	223.35±4.68	196.0± 2.0	27.25±2.5	114.48**
Group III (dianil)	220.25±5.18	203.5±1.25	16.75±1.50	
Group IV (control)	217.25±3.68	215.0± 5.0	2.25±0.50	

** Significant at one per cent level.

The initial serum total cholesterol levels of the severe diabetics ranged from 217 to 223.35 mg/dl which is much higher than the normal value of 200 mg/dl (Allain et al.,1974). The impact evaluation shows that the serum total cholesterol levels had been lowered by the herbal treatment over the six months study period. The control group had a very mild reduction in the total cholesterol levels which may be attributed to diet restriction.

FIG 3A MEAN SERUM TOTAL CHOLESTEROL LEVELS
MILD DIABETICS (mg/dl)

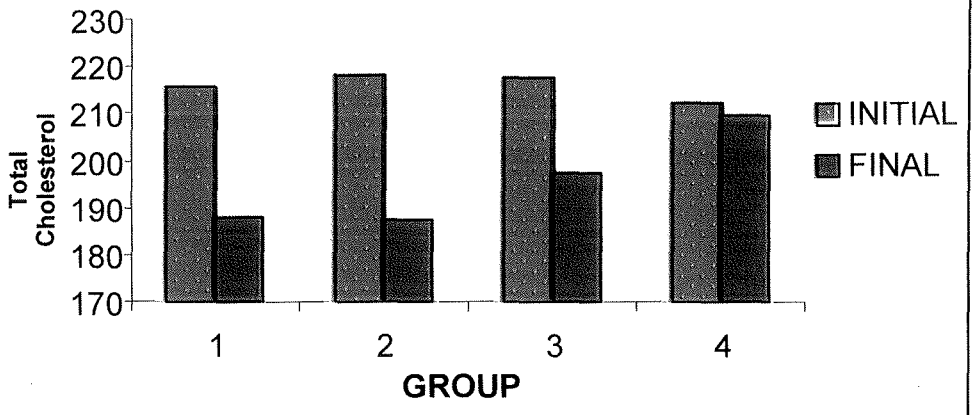


FIG 3B MEAN SERUM TOTAL CHOLESTEROL LEVELS
MODERATE DIABETICS (mg/dl)

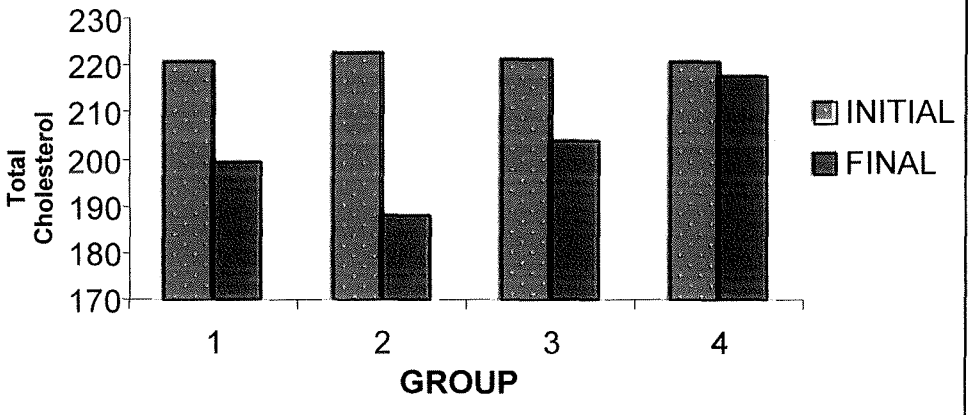
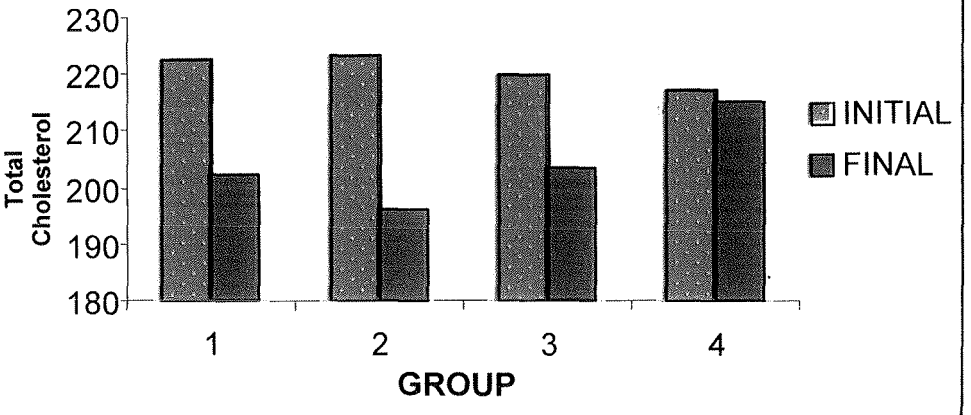


FIG 3C MEAN SERUM TOTAL CHOLESTEROL LEVELS
SEVERE DIABETICS (mg/dl)



An analysis of variance by one way classification was done on the reduction in the serum total cholesterol levels between the four groups under study which showed significance at one per cent level. The cholesterol lowering effect of avarai and allopathy treatment was not as appreciable as that of mixed herbal powder.

Table XXIV depicts the mean reduction in the serum total cholesterol levels of the selected subjects in the three categories.

TABLE XXIV

MEAN REDUCTION IN SERUM TOTAL CHOLESTEROL LEVELS OF THE SELECTED DIABETICS (mg/dl)

Category/ Group	Group I (avarai powder)	Group II (mixed herbal powder)	Group III (dianil)	Group IV (control)	F Value
Mild	27.66±3.93	30.83±2.22	20.33±2.80	2.83 ± 2.13	
Moderate	21.33±2.65	34.66± 3.38	17.16± 3.12	3.16 ± 0.40	65.793**
Severe	20.00±2.58	27.25± 2.50	16.75 ±1.50	2.25± 0.50	
F value between categories: 2.386 Not Significant					

** Significant at one per cent level

A two-way analysis of variance was tested on the mean reduction in the serum total cholesterol values between the three categories under the different study groups. The test showed significance at one per cent level between the different study groups, namely group I, II and III. Whereas in control group no difference was noted between the effects on

the three categories. The effect of the mixed herbal treatment in lowering the serum cholesterol levels is higher in the moderate category than in the mild and severe categories. But in case of avarai powder, the effect was pronounced in the mild category than in the moderate and severe categories.

Increased cholesterol levels have been recognized as a risk factor for coronary heart disease. Control of diabetes also lowers cholesterol (Raghuram et al., 1993). The herbal treatments prove to be effective in reducing cholesterol levels and thereby play a role in controlling diabetes.

ii. Changes in HDL cholesterol levels in the selected subjects

Table XXV and Figure 4A gives the mean serum HDL cholesterol levels in the mild diabetics at the initial and final stages of the study and the mean increment in the serum HDL cholesterol levels.

TABLE XXV

MEAN SERUM HDL CHOLESTEROL LEVELS OF MILD DIABETICS (mg/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	35.08± 0.86	42.16± 1.30	7.08±1.39	50.65**
Group II (mixed herbal powder)	35.06±0.08	45.16± 0.21	10.1±0.66	
Group III (dianil)	34.86±0.42	40.5±1.58	5.64±2.94	
Group IV (control)	35.25±1.72	36.58±0.61	1.33±1.40	

** Significant at one per cent level.

The initial serum HDL cholesterol levels of the mild diabetics ranged from 34.86 to 35.25mg/dl that was almost closer to the cut off value of 35mg/dl (Allain et al., 1974). After the herbal treatment, an increment in the serum cholesterol levels in the experimental groups was observed. The control group had a negligible increment. A one -way analysis of variance between the mean increments in serum HDL cholesterol levels of the four study groups showed significance at one per cent level. The increment was pronounced in the case of mixed herbal treatment when compared with the increment in the avarai and allopathy treatment.

Table XXVI and figure 4B gives the initial and final serum HDL cholesterol levels of the moderate diabetics and the mean increment of the same.

TABLE XXVI

MEAN SERUM HDL CHOLESTEROL LEVELS OF MODERATE DIABETICS (mg/dl)

Groups	Initial	Final	Increment	F value
Group I (avarai powder)	36.33± 0.88	46.16± 1.13	9.83±1.72	118.91**
Group II (mixed herbal powder)	35.41±1.20	49.33± 0.87	13.9 ±1.42	
Group III (dianil)	35.83±0.79	41.66±1.21	5.83±1.16	
Group IV (control)	35.16±0.46	35.5±0.25	0.33±1.03	

** Significant at one per cent level.

The mean serum HDL cholesterol level was in the range of 35 to 36.33 mg/dl which is closer to the cut off value of 35mg/dl (Allain et al., 1974). Both the herbal treatments have lead to considerable increment in the serum HDL cholesterol level. In the control group only negligible increment was observed. A one way analysis of variance between the increment in serum HDL cholesterol level of the four study groups showed significance at one per cent level. The mixed herbal treatment was more

effective in increasing the serum HDL cholesterol levels than the avarai powder.

Table XXVII and Figure 4C depicts the initial and final mean serum HDL cholesterol levels of the severe diabetics and the mean increment of the same.

TABLE XXVII

MEAN SERUM HDL CHOLESTEROL LEVELS OF SEVERE DIABETICS (mg/dl)

Groups	Initial	Final	Increment	F value
Group I (avarai powder)	35.25± 0.18	41.5± 1.25	6.25±1.25	
Group II (mixed herbal powder)	35.5±1.25	44.0± 0.5	8.5±1.29	14.43**
Group III (dianil)	35.5±4.25	40.75±0.69	5.25±2.63	
Group IV (control)	34.75±0.68	35.5±0.25	0.75±1.25	

** Significant at one per cent level.

The mean serum HDL cholesterol levels fall in the range of 34.75 to 35.5 mg/dl which was closer to the cut off value of 35mg/dl (Allain et al., 1974). After the supplementation of the herbal powder there was an increment in the serum HDL cholesterol levels in the experimental groups. The control group had negligible increment. A one way analysis of variance between the mean increments in the serum HDL cholesterol

FIG 4A MEAN SERUM HDL CHOLESTEROL LEVELS OF MILD DIABETICS (mg/dl)

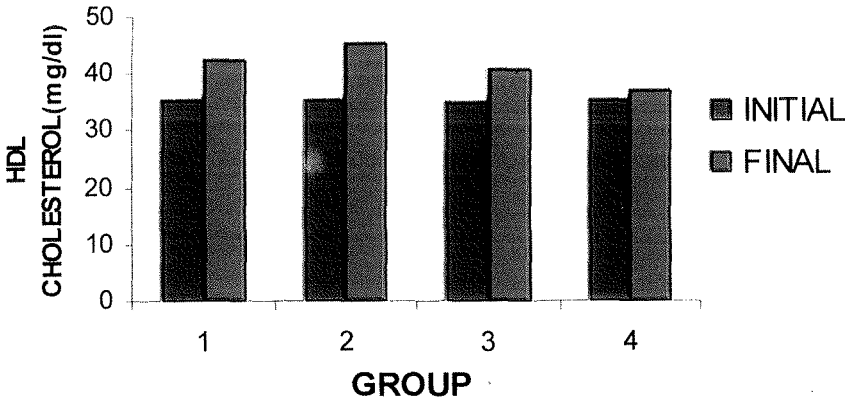


FIG 4B MEAN SERUM HDL CHOLESTEROL LEVELS OF MODERATE DIABETICS (mg/dl)

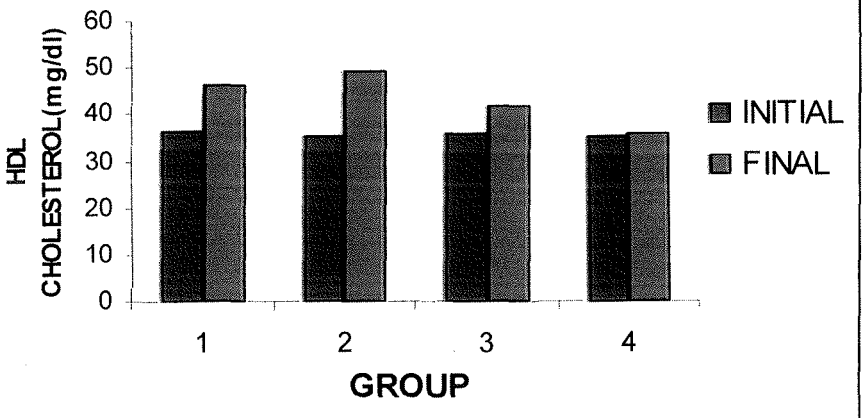
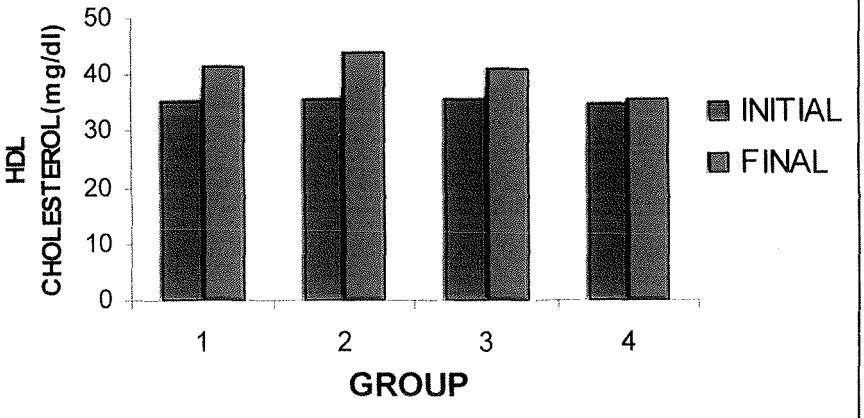


FIG 4C MEAN SERUM HDL CHOLESTEROL LEVELS OF SEVERE DIABETICS (mg/dl)



levels of the four study groups showed significance at one per cent level. The increment was maximum in group II which is followed by group I and III.

Table XXVIII gives the mean increment in the serum HDL cholesterol levels at the end of the study period in the three categories of diabetics.

TABLE XXVIII

MEAN INCREMENT IN SERUM HDL CHOLESTEROL LEVELS OF THE SELECTED SUBJECTS (mg /dl)

Category/ Groups	Group I (avarai powder)	Group II (mixed herbal powder)	Group III (dianil)	Group IV (control)	F value
Mild	7.08± 1.39	10.10± 0.66	5.64± 2.94	1.33± 1.40	
Moderate	9.83± 1.72	13.92± 1.42	5.83± 1.16	0.33± 1.03	19.48**
Severe	6.25± 1.25	8.50± 1.29	5.25± 2.63	0.75± 1.25	
F value between categories 1.609 Not significant					

** Significant at one per cent level

The two-way analysis of variance was done between the mean increment in the HDL cholesterol levels of the selected subjects. The test showed significance at one per cent level between the four study groups, but the effect between the three categories had no significance. This explains the fact that the effect of both the herbal powders are effective. However, the mixed herbal powder and avarai powder are more effective in the moderate diabetics than in the mild and severe diabetics.

According to Vergosean (1987), there is a negative correlation between HDL cholesterol and cardiovascular disease. The higher the plasma HDL level, lower the risk of developing heart disease. In the present study, the herbal treatments showed a positive effect on HDL cholesterol picture thereby prove to be effective in reducing the risk of cardiovascular diseases in NIDDM subjects.

iii. Changes in serum triglyceride levels in the selected subjects

Table XXIX and Figure 5A gives the means of initial and final serum triglyceride levels of the mild diabetics and mean reduction of the same.

TABLE XXIX

MEAN SERUM TRIGLYCERIDE LEVELS

OF MILD DIABETICS (mg/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	167.66± 0.88	146.16± 1.56	21.0±1.67	
Group II (mixed herbal powder)	165.16±3.13	133.0 ± 3.0	33.16±2.63	210.61**
Group III (dianil)	163.83±1.35	148.16±1.13	15.66±2.25	
Group IV (control)	166.16±2.13	163.5± 1.25	2.66±1.50	

** Significant at one per cent level.

The mean serum triglyceride levels of mild diabetics before treatment ranged from 163.83 to 168 mg/dl. After the period of six months of supplementation with herbs, there was substantial reduction in the triglyceride levels in the experimental groups. A one way analysis of variance was done on the mean reduction in the serum triglyceride levels of the four groups falling under the mild category and it proved to be significant at one per cent level. The serum triglyceride lowering effect of the mixed herbal treatment was comparatively higher than the effect of avarai powder alone.

Table XXX and Figure 5B gives the mean serum triglyceride levels of the moderate diabetics before and after the study and the mean reduction of the same.

TABLE XXX

MEAN SERUM TRIGLYCERIDE LEVELS OF MODERATE DIABETICS (mg/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	166.33± 2.87	146.0± 4.12	19.5±3.0	
Group II (mixed herbal powder)	166.83±2.01	138.0± 4.66	28.33±2.6	162.25**
Group III (dianil)	166.16±3.0	152.5±2.91	13.66±1.21	
Group IV (control)	164.0±4.33	161.6±2.21	2.33±0.81	

** Significant at one per cent level.

The mean serum triglyceride levels of the moderate diabetics ranged from 164 to 167 mg/dl. At the end of the herbal treatment, there was a reduction in these levels, particularly in the experimental group II while the control group showed a mild reduction. A one way analysis of variance between the reduction in the serum triglyceride levels under the four study groups showed significance at one per cent level. From the mean reduction in serum triglyceride levels, it is evident that the avarai treatment is not as effective as mixed herbal treatment in lowering serum triglyceride level.

Table XXXI and Figure 5C gives the mean triglyceride levels of severe diabetics before and after the study and the mean reduction of the same.

TABLE XXXI

MEAN SERUM TRIGLYCERIDE LEVELS OF SEVERE DIABETICS (mg/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	167.5± 1.25	156.5± 7.25	11±3.46	
Group II (mixed herbal powder)	166. ±0.5	142.5± 0.25	23.5±1.0	72.71**
Group III (dianil)	164.5±0.25	155.5±0.25	9.0±0	
Group IV (control)	165.0±0.5	162± 1.5	3.0±1.82	

** Significant at one per cent level.

FIG 5A MEAN SERUM TRIGLYCERIDE LEVELS OF MILD DIABETICS (mg/dl)

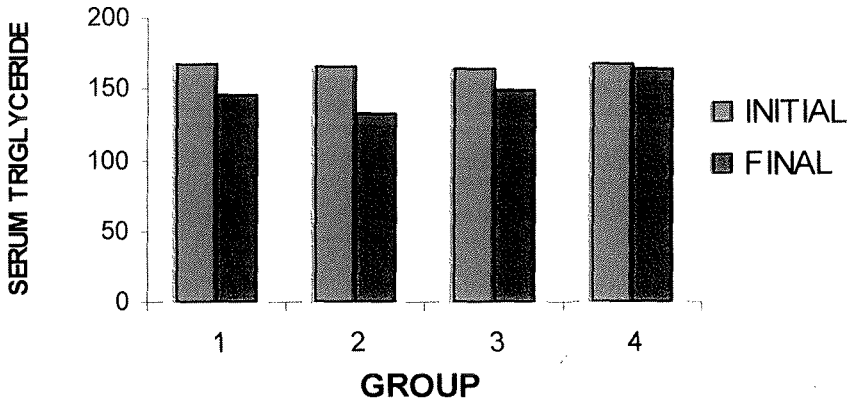


FIG 5B MEAN SERUM TRIGLYCERIDE LEVELS OF MODERATE DIABETICS (mg/dl)

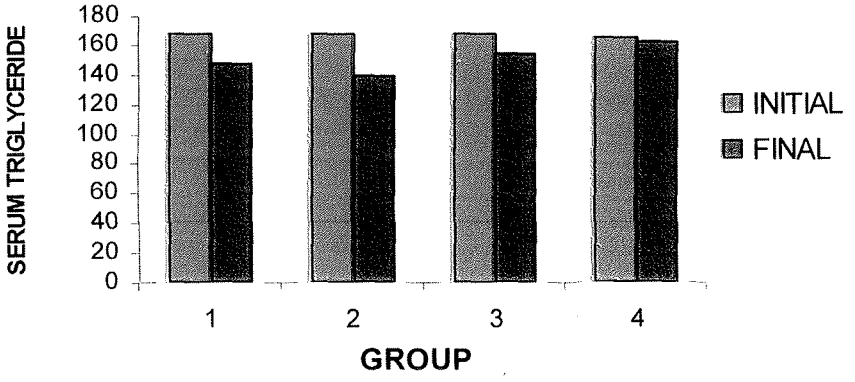
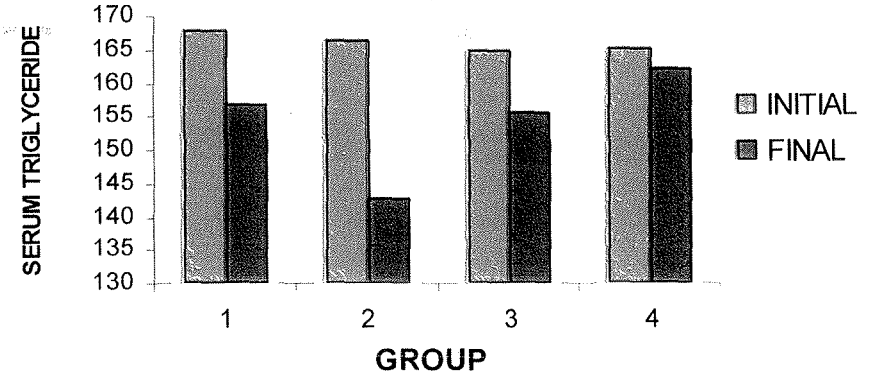


FIG 5C MEAN SERUM TRIGLYCERIDE LEVELS OF SEVERE DIABETICS (mg/dl)



The initial serum triglyceride level of severe diabetics ranged from 164.5 to 168mg/dl. At the end of the herbal treatment, there was a reduction in these levels particularly in the experimental group II, while the control group showed a mild reduction. A one way analysis of variance between the reduction in the serum triglyceride levels under the four study groups showed significance at one per cent level. From the mean reduction it is evident that the mixed herbal powder treatment had maximum reduction followed by group I with avarai treatment and group III with allopathy treatment.

Table XXXII gives the mean reduction in the serum triglyceride levels of selected diabetics before and after the study.

TABLE XXXII

MEAN REDUCTION IN SERUM TRIGLYCERIDE LEVELS OF THE SELECTED DIABETICS (mg/dl)

Category/ Group	Group I (avarai powder)	Group II (mixed herbal powder)	Group III (dianil)	Group IV (Control)	F Value
Mild	21±1.67	33.16±2.63	15.66±2.25	2.66 ± 1.50	54.09**
Moderate	19.5± 3.0	28.33± 2.6	13.66± 1.21	2.33 ± 0.81	
Severe	11.0±3.46	23.5± 1.0	9.0 ±0	3.0± 1.82	
F Value between categories 6.691*					

*Significant at five per cent level

** Significant at one per cent level

A two way analysis of variance was done between the mean reduction in the serum triglyceride levels of mild, moderate and severe diabetics belonging to the four study groups. The test showed significance at one per cent level between the mean reduction in the serum triglyceride levels of the experimental groups, whereas in control group there was no significant reduction. The serum triglyceride lowering effect is maximum in group II, which was treated with mixed herbal powder followed by group I and III.

NIDDM patients have increased concentration of triglycerides which increases the risk of coronary heart diseases two to four fold relative to non diabetic subjects. Hypertriglyceridemia is commonly associated with uncontrolled diabetics (Haffner, 1992). The herbal powders have a reducing effect on the serum triglycerides and hence prove to be effective in diabetes management.

iii. Changes in glycosylated haemoglobin level

Table XXXIII and Figure 6A gives the mean glycosylated haemoglobin levels of the mild diabetics before and after the study and the mean reduction of the same.

TABLE XXXIII

MEAN GLYCOSYLATED HAEMOGLOBIN LEVELS OF MILD DIABETICS (g/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	7.15± 0.008	6.7± 0.02	0.45±0.25	
Group II (mixed herbal powder)	7.21±0.0075	6.45± 0.0025	0.76±0.05	27.40**
Group III (dianil)	7.36± 0.432	6.93±0.04	0.43±0.08	
Group IV (control)	7.33±0.008	7.26±0.004	0.05±0.05	

** Significant at one per cent level.

The initial mean glycosylated haemoglobin level in mild diabetics ranged form 7.15 to 7.36 mg/dl which showed that they were in marginal control (American Diabetes Association, 2003). After the herbal treatment for six months, the glycosylated haemoglobin level was reduced, whereas in control group the reduction was found to be negligible. A one way analysis of variance between the mean reduction in glycosylated haemoglobin level of the four study groups, showed significance at one per cent level. The effect of mixed herbal powder showed maximum reduction (0.76mg/dl).

Table XXXIV and Figure 6B gives the mean glycosylated haemoglobin levels of moderate diabetics before and after the study and the mean reduction of the same.

TABLE XXXIV

MEAN GLYCOSYLATED HAEMOGLOBIN LEVEL OF MODERATE DIABETICS (g/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	7.78± 0.011	7.31± 0.005	0.46±0.16	
Group II (mixed herbal powder)	8.0±0.006	7.33± 0.005	0.66±0.13	20.13**
Group III (dianil)	8.13± 0.011	7.66±0.002	0.46±0.05	
Group IV (control)	8.11±0.0047	7.95±0.0025	0.16±0.05	

** Significant at one per cent level.

The mean glycosylated haemoglobin levels of moderate diabetics before treatment ranged between 7.7 to 8.1mg/dl, which indicates that measures should be taken (American Diabetes Association, 2003). After the supplementation of herbal powder the glycosylated haemoglobin values were reduced. Analysis of variance by one way classification between the mean reduction in glycosylated haemoglobin levels of the four study groups showed significance at one per cent level. The effect of mixed herbal powder is more pronounced than that of avarai powder in reducing the glycosylated haemoglobin level.

Table XXXV and Figure 6C gives the mean glycosylated haemoglobin level of severe diabetics before and after treatment and the mean reduction of the same.

FIG 6A MEAN GLYCOSYLATED HAEMOGLOBIN LEVELS OF MILD DIABETICS (g/dl)

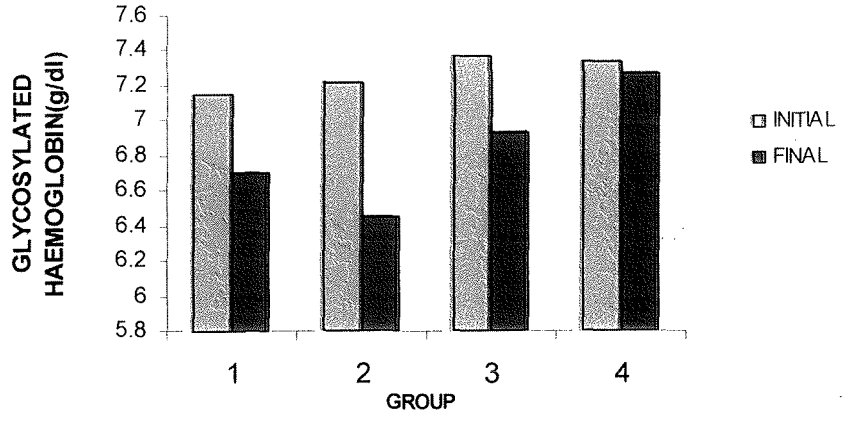


FIG 6B MEAN GLYCOSYLATED HAEMOGLOBIN LEVELS OF MODERATE DIABETICS (g/dl)

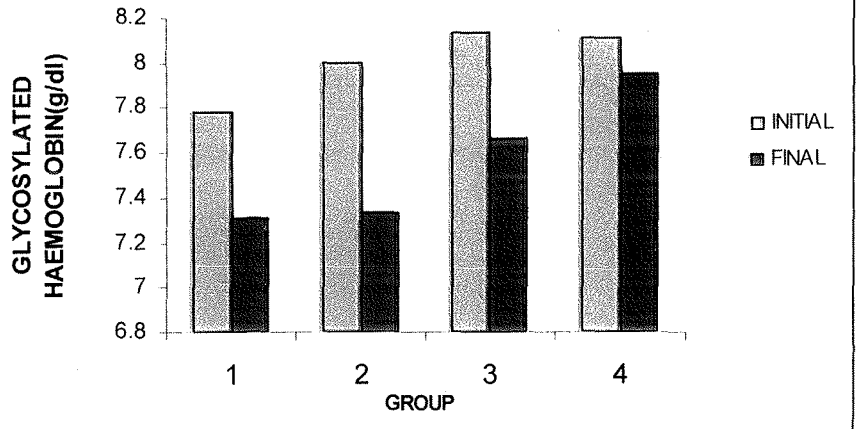


FIG 6C MEAN GLYCOSYLATED HAEMOGLOBIN LEVELS OF SEVERE DIABETICS (g/dl)

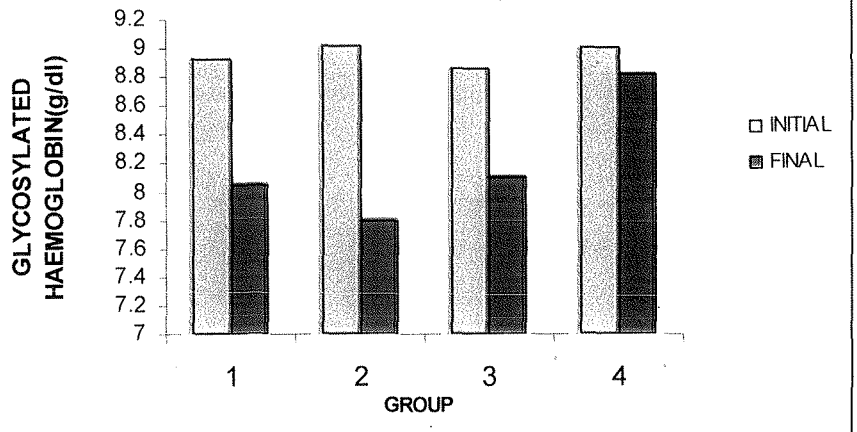


TABLE XXXV

MEAN GLYCOSYLATED HAEMOGLOBIN LEVEL OF SEVERE DIABETICS (mg/dl)

Groups	Initial	Final	Reduction	F value
Group I (avarai powder)	8.92± 0.006	8.05± 0.0025	0.87±0.12	
Group II (mixed herbal powder)	9.02±0.016	7.80± 0.5	1.22±0.09	81.31**
Group III (dianil)	8.85± 0.016	8.10±0.5	0.75±0.1	
Group IV (control)	9.0±0.5	8.825±0.006	0.17±0.05	

** Significant at one per cent level.

The initial mean glycosylated haemoglobin level of the severe diabetics before treatment ranged from 8.8 to 9mg/dl, which shows that they are under poor control (American Diabetes Association, 2003). After six months of herbal treatment the glycosylated haemoglobin level was reduced. A one way analysis of variance between the mean reduction in the glycosylated haemoglobin level of the four study groups, showed significance at one per cent level. The effect of mixed herbal powder reduces the glycosylated haemoglobin level to maximum followed by group I and group III.

Table XXXVI gives the mean reduction in glycosylated haemoglobin level of the selected diabetics.

TABLE XXXVII

MEAN REDUCTION IN GLYCOSYLATED HAEMOGLOBIN LEVELS OF THE SELECTED SUBJECTS(g/dl)

Category/ Groups	Group I (avarai powder)	Group II (mixed herbal powder)	Group III (dianil)	Group IV (control)	F value
Mild	0.45± 0.25	0.76± 0.05	0.43± 0.08	0.05± 0.05	54.093**
Moderate	0.46± 0.16	0.66± 0.13	0.46± .05	0.16± 0.05	
Severe	0.87± 0.12	1.22± 0.09	0.75± 0.1	0.17± 0.05	
F value Between categories 6.691*					

** Significant at one per cent level

* Significant at five per cent level

The two-way analysis of variance was done between the mean reduction in the glycosylated haemoglobin levels in the selected diabetics. The test showed significance at one per cent level between the mean reduction in the glycosylated haemoglobin levels of the experimental groups, whereas there was no significant reduction in the control group. The glycosylated haemoglobin lowering effect was maximum in group II which was treated with mixed herbal powder in comparison with group I and group III.

Among the different categories in group II the reduction in glycosylated haemoglobin was maximum in severe diabetics than the mild and moderate diabetics.

The findings of the present investigation revealed the hypoglycemic potential of avarai flowers alone and in combination with sirukurinjan leaves and jamun seeds. The treatment with the prepared

herbal powders for a period of six months had considerably decreased the weight of the obese diabetics to ideal body weight. The physiological symptoms which was noted before the treatment had also disappeared after the supplementation with herbs.

The avarai powder and mixed herbal powder were found to significantly reduce the blood glucose levels and lipid profile viz; serum total cholesterol, HDL cholesterol and serum triglyceride levels. Glycosylated haemoglobin had also reduced significantly in the mild , moderate and severe diabetics, proving the beneficial effect of the herbs selected. Among the herbal powders prepared , mixed herbal powders prepared out of avarai flowers , sirukurinjan leaves and jamun seeds (60:30:10) were found to be more pronounced than that of avarai flower powder alone. Thus the salient findings prove the hypoglycemic potential of the selected herbs.

Summary and Conclusion

V SUMMARY AND CONCLUSION

The present study entitled "Hypoglycemic potential of avarai (*Cassia auriculata*) in treating non-insulin dependent diabetes mellitus" was planned to study the effect of *Cassia auriculata* (avarai) alone and in combination with other herbs namely *Gymnema sylvestre* (sirukurinjan) and *Eugenia cumini* (naval), to ascertain the background of selected NIDDM subjects and to evaluate the hypoglycemic and hypocholesterolemic potential of avarai in comparison with the herbal mixture. The study was conducted at Perianaickenpalayam of Coimbatore district.

For the study, avarai flowers, sirukurinjan leaves and jamun seeds were chosen. Since the study aimed at testing the hypoglycemic potential of avarai flowers alone and in combination with sirukurinjan leaves and naval seeds, two herbal powders were prepared. Mixed herbal powder was prepared by mixing powders of avarai flowers, sirukurinjan leaves and naval seeds in the ratio 60 : 30 : 10 respectively. A total of 64 NIDDM subjects belonging to both sexes in the age group of 42 to 67 years were selected for the study. A questionnaire was formulated to collect the data on socio economic background including dietary pattern. Initially a weighment survey was conducted to determine the actual food and nutrient intake. After the assessment of dietary intake, the subjects were given diet counselling to ensure uniform pattern of nutrient composition especially iso caloric consumption and equivalisation of dietary regimen in all the groups. The selected subjects were categorized as mild, moderate and severe as per the categorization of Ajgoankar (1962).

They were divided into four groups of 16 subjects in each.. Group I was treated with 2g and 4g of avarai powder. Group II was treated with 2g and 4g of mixed herbal powder .Group III was treated with allopathy drug (dianil). Group IV was kept as control. The study was carried out for a period of six months. The impact of the treatment with the herbal powders were assessed by recording the changes in weight, physiological symptoms and biochemical parameters like fasting blood glucose, lipid profile namely serum total cholesterol, HDL cholesterol, serum triglyceride and glycosylated haemoglobin levels. The salient findings of the investigation are summarized below.

1. The nutrient content of the prepared herbal powders as analysed revealed that the energy content , carbohydrate level , total ash, calcium, magnesium, iron, phosphorus, copper, crude fibre and moisture level were high in mixed herbal powder than in avarai powder. The nutrients like protein and chromium were high in avarai powder and the fat level was same in both powders.

2. Among the selected diabetics, 28 were in the age group of 40 to 50 , 27 were in the age group of 50 to 60, and nine were in the age group of 60 to 70 years. The number of male diabetics (37) were more than the female diabetics (27).

3. In total, majority of the diabetics were in overweight category (58), six diabetics were found to have ideal body weight and no subject was observed in the underweight category.

4. Among the 64 subjects, 39 were degree holders, nine had completed PUC, eight had done SSLC and eight subjects had done primary school education.

5. In total, 44 diabetics belonged to higher income groups, 12 belonged to upper middle class, six belonged to affluent class and only two were in lower middle class.

6. Out of the 64 diabetic subjects, 38 had the disease over five years, 20 had diagnosed within the past two to five years and six subjects had diagnosed the disorder only during the past one year.

7. Among 64 subjects, 43 had inherited the disease from both their parents, 10 of them had either parent as diabetic , six of them had their relative as diabetic and only five of them had no previous history of diabetes in their family.

8. Among the selected subjects, 44 followed allopathic treatment, three each followed ayurvedic, and siddha respectively, three followed ayurveda along with diet restriction and only one subject followed homeopathy treatment.

9. Majority of the subjects participated in the study were not satisfied with the allopathy treatment due to the side effects produced in some of them . Among the total male diabetics (37), 12 belonged to mild , 13 belonged to severe category. Among the total female diabetics (27), 12 belonged to mild , 11 belonged to moderate and four belonged to severe category.

10. The food consumption pattern of the diabetics before diet counselling was not uniform, the caloric intake was higher than the recommended level, the percentage of energy derived from carbohydrate was higher than the reference value , the protein intake was less than the recommended range.

11. After diet counselling, the food consumption pattern was improved, the mean daily nutrient intake was within the recommended range and also the percentage of energy derived from the nutrients were within the reference value.

12. After the supplementation of herbs, among the male diabetics (37), 15 subjects shifted to ideal body weight and among female diabetics (27), 13 subjects shifted to ideal body weight, also the symptoms which appeared before supplementation almost disappeared at the end of the treatment.

13. The mean fasting blood glucose level of the mild , moderate and severe diabetics at the initial stage were 150 to 152 mg/dl, 182 to 186mg/dl and 212 to 218 mg/dl respectively. After the supplementation, there was a significant reduction in these levels. Among the three categories , the reduction was more pronounced in group II which was treated with mixed herbal powder.

14. The mean serum total cholesterol levels of the mild, moderate and severe diabetics were 212 to 218 mg/dl, 220.8 mg/dl and 217 to 223.35 mg/dl respectively which decreased significantly after the supplementation of herbs. The reduction was more pronounced in the group II which was treated with mixed herbal powder.

15. Initially, the mean serum HDL cholesterol levels of mild, moderate and severe diabetics were 34.86 to 35.25 mg/dl, 35 to 36.33 mg/dl and 34.75 to 35.5 mg/dl respectively which had increased significantly after the herbal treatment. The increment was maximum in group II which was followed by I and III.

16. Initially, the mean serum triglyceride levels of the mild, moderate and severe were 163.83 to 168 mg/dl, 164 to 167 mg/dl and 164.5 to 168 mg/dl respectively which had decreased significantly after herbal treatment. The test showed significance at one percent level between the experimental groups.

17. Initially, the mean glycosylated haemoglobin level in mild, moderate and severe diabetics were 7.15 to 7.36 mg/dl, 7.7 to 8.1mg/dl and 8.8 to 9

mg/dl respectively which reduced significantly after the herbal treatment. The effect was maximum in group II in comparison with group I and III.

The findings of the present investigation revealed the hypoglycemic potentials of avarai alone and in combination with sirukurinjan leaves and naval seeds. The treatment with the herbal powders for a period of six months showed significant reduction in blood glucose level, lipid profile namely total cholesterol, HDL cholesterol, serum triglyceride and glycosylated haemoglobin levels. Among the herbs studied, the hypoglycemic effect of mixed herbal powder prepared using avarai flowers, sirukurinjan leaves and naval seeds in the ratio 60:30:10 was more pronounced than that of avarai flower powder. Thus these findings prove the hypoglycemic and hypocholesterolemic potentials of avarai flowers, sirukurinjan leaves and jamun seeds. Since sirukurinjan leaves and jamun seeds possess bitter taste, the combination of avarai flowers, sirukurinjan leaves and jamun seeds in the proportion studied was found to be effective. Long term supplementation will throw more light on the hypoglycemic and hypocholesterolemic properties. Further studies on the following lines are recommended.

1. Isolation of the hypoglycemic principles in the avarai flower, sirukurinjan leaves and naval seeds could be done.
2. Long term treatment with the selected herbs may be attempted.
3. Indepth studies on toxicological screening of the herbs and subacute toxicity in animals could be studied.
4. Studies on the antioxidant properties of herbs could be carried out.
5. Effect of supplementation of these herbs on the oxidative stress in diabetes and the level of antioxidants in blood could be attempted.

6. Nutrition and health education could be given to the masses on the usage of such native herbs for treating diabetes.

7. Popularisation programmes could be carried out through mass media on the use of locally available herbs for treating various metabolic disorders like diabetes, atherosclerosis and cancer.

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Appendices

APPENDIX IA
SOCIO ECONOMIC AND DIETARY SURVEY

Socio Economic Background :

1. Name of Interviewer

2. Name of Interviewee

3. Age

4. Sex

5. Weight

6. Education

7. Occupation

8. Income of the Family

Income (Rs.)
Above 10000
5000-10000
3000-5000
Below 3000

9. Details of Disease before Treatment:

1. Duration of Disease

Duration (Years)
0-1
1-2
2-5
>5

2. Diabetic Traits in the family

Both parents are diabetic
One parent is diabetic
Any relative is diabetic
Nil

3. Treatment undertaken previously

Type of treatment

1. Ayurvedic
2. Allopathy
3. Siddha
4. Unani
5. Diet and allopathic
6. Homeopathy

4. Reasons for participating in the study

10.Food consumption pattern and dietary practices

Food items	Meal pattern				Frequency of usage		
	Break fast	**Lunch**	**Tea**	**Dinner**	**Daily**	**Alternate days**	**Weekly once**
Cereals							
Rice							
Wheat							
Ragi							
Semolina							
Bread							
Pulses							
Whole gram							
Dhal							
Legumes							
Vegetables							
Roots&Tubers							
Green leafy Vegetables							
Gourd varieties							
Others							
Fruits							
Citrus fruits							
Apple							
Banana							
Grapes							
Others							
Animal Foods							
Egg							
Fish							
Chicken							
Meat							
Sweeteners							
Sugar							
Jaggery							
Artificial sweetener							
Milk&Milk products							
Milk							
Curd							
Butter milk							
Fats & Oils							
Butter							
ghee							

11. Clinical Assessment

Physiological Symptoms	Initial	Final
Polydypsia Polyphagia Polyuria Constipation Insomnia Giddiness Exessive Sweating Poor Wound Healing Burning Sensation		

FAMILY AND INDIVIDUAL CONSUMPTION SURVEY- WEIGHMENT METHOD

NAME OF THE INVESTIGATOR DOOR NO. :

NAME OF THE HEAD OF THE FAMILY ADDRESS:

NAME OF THE SUBJECT

AGE OF THE SUBJECT DATE

FOOD CONSUMPTION

Name of the Meal	Weight of the total raw ingredients used by the family (g)	Weight of the total cooked food consumed by the family(g)	Amount of cooked raw equivalents food consumed by their individual (g)
Break fast Lunch Tea Dinner			

APPENDIX IB

FOOD EXCHANGE LIST

Cereal Exchange:

30 g provides	-100 calories,
Carbohydrates	-20 g, Protein -2g
Bajra	Cornflakes
Barley	Bread
Maize,dry	Rice flakes
Ragi	Rice puffed
Rice	Sago
Samai	Semolina
Wheat flour	White flour

Legume and Pulse Exchange:

30 g provides	- 100 calories
carbohydrates	- 15 g ,Protein -6 g
Bengal Gram	Peas , dried
Bengal Gram Roasted	Red gram
Bengal Gram flour	Rajmah
Black Gram	Soyabeans
Green Gram	Kablichanna
Horse Gram	Lentils

Vegetable exchange – A:
May be used in liberal amounts as carbohydrates and calories are negligible.
Green leafy vegetables :

Amaranth	Curry leaves
Fenugreek	Cabbage
Mint	Paruppukeerai
Coriander leaves	Spinach

Other vegetables :

Ash gourd	Lady's finger	Raddish
Bittergourd	Cluster beans	Snake gourd
Brinjal	Capsicum	Ridge gourd
Cauliflower	Broad beans	Tomato
Cucumber	Plantain flower	Garlic
Chow –chow	Plantain stem	Ginger
Drumstick	Mango, green	Turnip
Knol-khol	Onion stalks	Pumpkin

Vegetable exchange- B

Carbohydrates -10 g Calories - 50g

Root Vegetables	Quantity (g)
Beetroot	75
Carrot	105
Colacasia **	45
Onion (big)	90
Onion (small)	75
Potato	45
Sweet potato**	30
Tapioca **	30
Yam **	60

** These foods are better avoided

Fruit Exchange:

Carbohydrates -10 g Calories – 50g

Fruits	Quantity (g)	Number or size
Amla	90	20 medium
Apple	75	1 small
Banana *	30	¼ medium
Custard Apple *	50	1/4
Dates *	30	3
Grapes (green)	105	20
Jack fruit	60	3 medium pieces
Melon	270	¼ medium
Mango *	70	1 small
Orange	90	1 small
Papaya	120	2 medium
Pomegranate	75	1 small
Sweet lime	150	1 medium
Tomato	240	2 medium
Water melon	175	¼ small

* It is better to avoid these fruits.

Milk Exchange:
Protein -5 g Calories - 100

Food	Quantity
Butter milk	750 ml
Curd	210 ml
Khoa	30 g
Milk, Buffalo	90 ml
Milk, Cow	180 ml
Milk skimmed *	30 g

* Provides 10 g protein

Flesh Food Exchange :

Protein -10g Calories -70

Food	Quantity (g)
Beef	60
Crab	120
Hen, egg	1 No.
Fish, big	60
Fish, small	60
Liver, sheep	60
Prawn	60
Fowl	60
Mutton, muscle	60
Pork	60

Fat Exchange:
Calories -100 g, Fat - 11 g

Food	Quantity (g)
Almonds	15
Butter	15
Cashewnuts	20
Coconut	30
Ghee	11
Groundnuts roasted	20
Oil (groundnut, mustard)	11
Hydrogenated fat	11

Any one food item in the list can be exchanged with another. But it should not be exchanged with any other exchange list.

APPENDIX IC

DIET SHEET FOR DIABETICS

EARLY MORNING	**1200 kcal**	**1500 kcal**	**1800 kcal**
Tea/Coffee (Without sugasr)	1 cup		
BREAK FAST			
Phulkas	Three	Four	Four
Dhal	-	1 k	1 k
other vegetable curry	1 k	1 k	1 k
MID Morning			
Lime Juice (With salt)	1 cup	1 cup	1 cup
LUNCH			
Rice	1 k	1 k	1 ½ k
Sambar	1 k	1 k	1 k
Kootu	½ cup	1 k	1 k
Non – Veg	100 g	100 g	100 g
Egg	-	One	One
Curds	½ cup	½ cup	1 cups
EVENING			
Tea/Coffee (Without Sugar)	1 cup	1 cup	1 cup
DINNER			
Upma	1 k	1 k	1½ k
BED TIME			
Milk (Skimmed)	1 cup	1 cup	1 cup
Total oil for cooking	-	1 tsp	6 tsp

1 cup and 1 k means 1 cup 150 ml capacity

APPENDIX – II A
ESTIMATION OF BLOOD GLUCOSE

Principle

Glucose is oxidized by the enzyme Glucose oxidase (GOD) give D-gluconic acid and hydrogen peroxide.Hydrogen peroxide in presence of the enzyme peroxidase(POD) oxidises phenol which combines with 4-amino antipyrine to produce a red coloured quienoeimine dye. The intensity of the colour developed is proportional to glucose concentration in the sample.

Equipment Required

1. Photocolorimeter/ spectrometer
2. Water bath at 37°C
3. Pipettes and micropipettes
4. Test tubes and timer

Reagents

1.Enzyme Reagent
2.Buffer solution
3.Standard (100 mg %)

Reagent preparation

Dissolved one vial of enzyme reagent (1) in one bottle of buffer solution (2). Mixed gently to dissolve .The prepared working enzyme reagent was stable for one month at 2-8°C.

Procedure

	(B)	(C)	(T)
Working Enzyme Reagent	1.0ml	1.0ml	1.0ml
Distilled water	0.01ml	--	--
Standard (3)	--	0.01ml	--
Serum	--	--	0.01ml

Mixed well and incubated at 37°C for 10 minutes. Measured the absorption of Test (T) and standard (S), against Blank (B) on a photocolorimeter with green filter or on a spectrophotometer at 505 nm.

Calculations

$$\text{Glucose in mg \%} = \frac{\text{A of (T)}}{\text{A of (S)}} \times 100$$

APPENDIX – II B

ESTIMATION OF TOTAL CHOLESTEROL IN SERUM

Principle

Cholesterol esterase hydrolysis cholesterol esters into free cholesterol and fatty acids. In second reaction, cholesterol oxidase converts cholesterol to -4 cholesterone and hydrogen peroxide. In presence of peroxidase hydrogen peroxide oxidatively couples with a 4 amino antipyrine /phenol to produce red quinoeimine which has absorbance maximum at 510 nm. The intensity of red colour is proportional to the total cholesterol in specimen.

Component

Phosphate Buffer : pH 7.7 4 Amino antipyrine
Cholesterol oxidase phenol

Cholesterol esterase — stabilizers/surfactants
Peroxidase

Procedure

Reaction Type - End point
Reaction Time - 10 minutes at 37°C
Wavelength - 510 nm

1.0 ml procedure

	Serum/plasma	Standard	Blank
	0.01 ml	0.01ml	---
working solution	1.0ml	1ml	1ml

Incubation

Incubated the assay mixture for 10 minutes at 37°C. Measured the absorbance of assay mixture against blank at 510 nm. Final colour was stable for atleast two hours, when not exposed to direct light.

Calculation

$$\text{Total cholesterol mg \%} = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times 100$$

APPENDIX II C
ESTIMATION OF HDL – CHOLESTEROL IN SERUM

Principle

Phospho tungstate / MG 2+ precipitate chylomicrons,1000 density lipoprotein (VLDL) fractions.High density lipoprotein (HDL) fractions remains unaffected in supernatant. Cholesterol content of DL fractions is assayed using autoxyme cholesterol.

Component

Phosphotungstic Acid
Magnesium chloride

Procedure

Reaction type - Endpoint
Reaction Time - 10 minutes at 37°C
Wavelength - 510 nm.

HDL separation

Pipetted out 0.5 ml of serum and 0.5 ml of HDL precipitating reagent, mixed thoroughly and centrifuge at 4000 rpm for 10 minutes in a common laboratory centrifuge (1800 × g) to obtain a clear supernatant.

HDL Cholesterol Determination

Assayed the supernatant for HDL – cholesterol within 2 hours after centrifugation using working solution to autozyme cholestorel reagent.

1.0 ml procedure

	Incubation	Standard	Blank
	0.05 ml	0.05 ml	-----
working solution	1.0 ml	1.0ml	1.0ml

Incubation

Incubated the assay mixture for 10 minutes at 37°C or 30 minutes at room temperature (25°C). After completion of the incubation, measure the absorbance of assay mixture against blank at 510 nm. Final colour was stable for atleast two hours , if not exposed to direct light.

Calculation

$$\text{HDL – Cholesterol mg \%} = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times 100$$

APPENDIX II D
ESTIMATION OF TRIGLYCERIDES IN SERUM

Principle

Glycerol released from hydrolysis of triglycerdes by lipoproteinlipase is converted by glycerol kinase into Glycerol-3-phosphate which is oxidized by glycerol phosphate oxidase to dihydroxacetone, hydrogen peroxide oxidizes phenolic chromozen to a red coloured compound.

Components

Phosphate buffers: pH 7.2	peroxides
Lipase	ATP
Glycerol Kinase	Chromogens
Glycerol phosphate oxidase	Activators + stabilizers

Procedure

Reaction	Type	Endpoint
Reaction	Time	15 minutes at room tempertature
Wave length		510 nm

1.0 ml procedure

	Serum	Standard	Blank
	0.01 ml	0.01 ml	---
working solution	1.0 ml	1.0 ml	1.0 ml

Incubation

Incubated the assay mixture for 15 minutes at room temperature; measured the absorbance blank at 510 nm. Final colour was stable for one hour , when exposed to direct light.

Calculation

$$\text{Triglycerides in mg \%} = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times 100$$

APPENDIX IIE
ESTIMATION OF GLYCOSYLATED HEMOGLOBIN
(Ion Exchange Resin Method)

Clinical Significance:

Glycosylated hemoglobin is formed by the adduction of glucose to the amino terminal Valine of the hemoglobin ß-chain progressively and irreversibly over a period of time and stable till the life of RBC.

Reagents and Accessories:

1.	Lysing reagent	-	5ml.
2.	Ion exchange resin	-	10×3ml.
3.	Control	-	0.5ml.
4.	Resin separators	-	10nos.

Reagent Preparations:

Reconstitute control (3) with 0.5ml. of de-ionised water by inverting.

Procedure

Assay temperature	:	23 ± 1°C or 30 ± 1°C
Wave length	:	415 mm
Step I	:	Hemolysate preparation

1. Pipette 0.25ml of lysing reagent (1) in a test tube.
2. Add to it 0.05ml of well mixed sample/control.
3. Mix well and allow to sand at room temperature for 5 minutes.

Step II : GHb separation and assay

1. Bring a resin Tube (2) to assay temperature by incubating the tube in a water bath.
2. Add 0.1ml of Hemolysate(from step I) to it.
3. Position a resin separator in the tube, so that the rubber sleeve is at the upper mark of the tube (approximately 3 cm above the resin level).
4. Mix the contents on vertex mixer continuously for 5 minutes.
5. Allow the resin to settle at assay temperature for 5 minutes. Push down the resin separator in the tube until the resin is firmly packed.
6. Pour the supernatant directly into a cuvette / tube and measure the absorbance against deionised water.

Step III : Total Hemoglobin (THb) assay

1. Pipette 5.0ml of deionised water into a test tube.
2. Add to it 0.02ml of hemolysate (from step I).
3. Mix and read absorbance against deionized water.

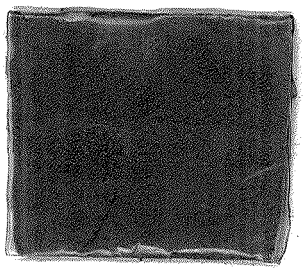
Calculations

$$\text{GHb\%} = \frac{\text{Absorbance of GHb}}{\text{Absorbance of THb}} \times 10 \times \text{Temp. Factor (Tf)}$$

APPENDIX - III

PREPARED HERBAL POWDERS

AVARAI POWDER



MIXED HERBAL POWDER