

# A Pilot Study On Anti-Diabetic Effect Of A Siddha Herbal Confection In Non-Insulin Dependent Diabetes Mellitus Patients

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**Abstract:** 'Ilavankaathy ilekiyam' is an authentic siddha herbal confection recommended for the treatment of Diabetes mellitus. This present study has been carried out to scientifically emphasize the therapeutic effectiveness of Ilavankaathy ilekiyam as a monotherapy in the management of NIDDM at a dose of 2.5mg by oral route and it is taken two times daily. An open clinical study was conducted on 15 patients at Meegoda Ayurveda hospital, Sri Lanka. The effectiveness of the herbal confection was assessed by subjective and objective clinical parameters by means of changes in the severity of clinical manifestations and the fasting blood sugar levels for consecutive 25 weeks using a self-reported assessment criteria. The data was statistically analyzed by SPSS/16 software. The diet and other regimens which could aggravate Diabetes mellitus were well instructed to the patients. The herbal confection showed statistically high significance ( $p < 0.01$ ) in improvement of the overall clinical manifestations of Diabetes mellitus and reduced levels of fasting blood sugar was a concordance.

**Index Terms:** 'Ilavankaathy ilekiyam', Diabetes mellitus, siddha medicine, herbal confection

## 1 INTRODUCTION

Diabetes Mellitus (DM) is one of the most common non-communicable diseases globally, and it is also the leading cause of death in most developed countries<sup>1</sup>. DM is a long-term metabolic disorder that is characterized by high blood sugar, insulin resistance, and relative lack of insulin. Non-insulin-dependent diabetes mellitus is mild form of DM which could be controlled by diet and hypoglycemic agents without injections of insulin. The International Diabetes Federation (IDF) estimated more than 90% of the global cases of diabetes are Non-Insulin dependent DM2. The management of diabetes includes diet, exercise as well as oral hypoglycemic and insulin. These treatments do not effectively prevent the complications of diabetes and the treatment with the above said allopathic medication has several side effects<sup>3</sup>. Ancient Indian medicine mentions various indigenous plants and mineral preparations for the treatment of DM. There are different combinations of these medicinal extracts which can be given orally and for prolonged periods of time. Confection or 'Ilekiyam' is one of the internal forms of medicine among 32 types recommended in Siddha literatures and that are prepared by heating certain decoctions, juices, and milk with the addition of sugar till a thick syrupy consistency is reached and finally mixed up with ghee and honey. 'Ilavankaathy lekiyam' a Siddha herbal confection contains clove, honey, ghee, milk and jaggary as ingredients<sup>4</sup>. It is an authentic formula recommended for DM. Past researches proved eugenol, an active component of clove responsible for the hypoglycemic activity. (Kuroda M et al 2012) and honey also used as hypoglycemic agent (Shambaugh et al., 1990). According to Siddha concept the taste of Ilavankaathy ilekiyam is Pungent which helps to pacify the deranged humors. The present study was aimed to evaluate the therapeutic effectiveness of Ilavankaathy ilekiyam as monotherapy in the management of NIDDM

## 2. Materials and methods

It was an Open clinical trial (pilot study) carried out at District Ayurvedic hospital, Meegoda, Sri Lanka. The duration of the study was 25 weeks.

## Inclusion criteria

A total of 15 patients of either sex, between 30-60 years of age in whom the diagnosis of NIDDM was confirmed, and who was willing to give informed consent was included in the study. The WHO diagnosis criteria (1980) was considered for diagnosis of NIDDM (For newly diagnosed patients: FBSL >120 mg% and after 2 hours of consuming 75 grams of glucose: >180 mg%). All participants were the freshly diagnosed diabetics with the FBS range from 140mg/dl to 200mg/dl. They were kept under observation for a period of one month with diet and exercise and those patients showing persistent hyperglycemia at the end of one month were included in the trial.

## Exclusion criteria

Patient with type 1 Diabetes mellitus, patient with type 2 diabetes mellitus who are insulin dependent, above 65 years, during pregnancy, patient with FBS >200mg/dl, severe diabetic complication like cardiovascular system disorders, Nephropathy, retinopathy will be excluded from the study. Insulin-dependent diabetes mellitus patients and NIDDM patients with acute complications of diabetes were excluded from the trial. Pregnant and lactating women, patients with Concomitant severe illness necessitating other medications, patients with severe hypertension, history of severe unstable angina, myocardial infarction, CVAs, renal failure, and those patients, who were not willing to give informed consent were also excluded from the study.

## Administration of the test drug

The test drug ilavankaathy ilekiyam at a dose of 2.5 g was given two times per day after meals. Patients were encouraged to avoid unsuitable diet and regimens.

## Assessment criteria

Changes in the clinical feature of the patients was noted in the Performa weekly up to 24 weeks consequently with two month follow up period. Effect of the treatment was evaluated on the basis of the changes in the sign and symptoms, fasting blood sugar and urine sugar. Effect of the therapy was assessed on the basis of improvement in sign and symptoms with the improvement of fasting blood sugar level. The difference

between the score /value before treatment and after treatment gathered from the patients was for statistical analysis using SPSS/16 software will be taken and its % of relief was calculated. Clinical data

**Table-1:** A self -reported scoring method will be used to evaluate the effect of the drug as mentioned below.

Score/ parameter	0	1	2	3
Quantity of the urine	1.50 to 2.0 l/24 hours	2.0 to 2.5/ 24 hours	2.5 to 3.0l/24 hours	>3.0/24 hours
Frequency of the urine	3-5/day no or rarely at night	6-8/day, 1-2/night	9-11/day, 3-4/night	>11/day,>4/night
Turbidity in the urine	Crystal clear urine	Faintly cloudy with slightly turbid	Turbidity clearly present with newsprint easily read through the test tube	Newsprint not easily read through the test tube
Polyphagia	As usual (routine meals)	Slightly increase (1-2 meals)	Moderately increase(3-4 meals)	Markedly increase(5-6 meals)
Polydipsia	Feeling of thirst 7-9 times/24 hours Either/ or intake of water 5-6 times/24hours	Feeling of thirst 9-11 times/24 hours Either/ or intake of water 7-9times/24hours	Feeling of thirst 11-13 times/24 hours Either/ or intake of water 9-11 times/24hours	Feeling of thirst >13times/24 hours Either/ or intake of water >11 imes/24hours
Urine sugar	Absent or trace	+	++	+++

### 3. Results

**Table-2:** Effect of 'Ilavankaathy ilekiyam' on clinical manifestation of Diabetes Mellitus'

Sign and symptoms	Mean± S.E. (Before treatment)	Mean± S.E. (After treatment)	df	t-value	p-value	Effectiveness %
Quantity of the urine	2.2±1.06	0.4±0.13	14	9.81	<0.001	81.81
Frequency of the urine	1.73±0.20	0.4±0.13		5.59	<0.001	76.92
Turbidity of the urine	2.46±0.133	0.26±0.11		18.87	<0.001	89.18
Polyphagia	2.26±0.20	0.33±0.12		7.50	<0.001	85.29
Polydipsia	2.4±0.16	0.4±0.13		10.77	<0.001	83.78
Urine sugar	2.53±0.13	0.53±0.13		11.18	<0.001	78.94

**Table-3:** Effect of 'Ilavankaathy ilekiyam' on fasting blood glucose level

Serum parameter	n	Initial week	12 <sup>th</sup> week	25 <sup>th</sup> week
FBG (mg/dL)	15	184±61	163±26	134±17

### 4. Discussion

Type 2 Diabetes mellitus is an ailment which is affects the entire body within the short period. The global statistical analysis has revealed that the complications of DM are highly prevalence in developing and developed countries. Management of diabetes with the agents devoid of any side effects is still a challenge to the medical system. This concern has led to an increased demand for natural products with anti-diabetic activity, having no side effects. This was owing to initiate this study. Therapeutic effectiveness of 'Ilavankaathy ilekiyam' statistically significant to markedly reduce the overall clinical manifestation of Diabetes mellitus (Table-2). The effectiveness on poly urea polyphagia, polydipsia, and Urine sugar were 81.81%,85.29%,83.78%,78.94% respectively. The improvement in the fasting blood sugar also concordance with it (Table-3).

### 5. Conclusion

In conclusion, the daily supplementation of 'Ilavankaathy ilekiyam' at a dose of 2.5 mg by oral route two times daily could be used as an effective treatment for Diabetes mellitus. It's a commonly available, inexpensive and an efficient pure simple herbal remedy with no adverse effects to the patient. However, further studies would be essentially required to elucidate the exact mechanism of hypoglycemic activity of the 'Ilavankaathy ilekiyam' and to establish its efficacy and safety for further clinical use in diabetes mellitus.

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