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Research Article

Clinical Case Series on Madhumegam (Type 2 Diabetes Mellitus) Management Using the Siddha Herbal Medicine: Keezhanelli Chooranam (KNC)

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ABSTRACT
According to the 2021 World Bank report, the prevalence of diabetes in Sri Lanka was 11.3% among adults aged 20 -79 years. In Siddha literature, Madhumegam is correlated with Diabetes Mellitus and is classified under Meganoi in Yugi Vaithiya Cinthamani 800, belonging to the Pitha type (Thithippu Neer). Keezhanelli Chooranam (Phyllanthus amarus) is a single-herb formulation documented in the Siddha Pharmacopoeia of India for managing Madhumegam (Type 2 Diabetes Mellitus). To scientifically validate its traditional claim, a clinical study was conducted at the Siddha Teaching Hospital, Kaithady, with ethical approval from the Bandaranaike Memorial Ayurveda Research Institute. Six patients diagnosed with Madhumegam were enrolled. Keezhanelli Chooranam (5 g twice daily before meals with warm water) was administered for 90 days, along with a prescribed dietary regimen. Fasting Blood Sugar (FBS) was measured every 14 days, while Postprandial Blood Sugar (PPBS) and HbA1c were assessed at baseline and on Day 90. Statistical analysis using the paired t-test revealed a highly significant reduction in PPBS ($p = 0.008$) and a significant decrease in VLDL ($p = 0.015$). Although reductions in FBS (↓32 mg/dL), HbA1c (↓0.94%), and Triglycerides (↓43 mg/dL) were not statistically significant ($p = 0.065$–0.068), they indicated meaningful clinical improvement. No adverse changes were observed in Total Cholesterol, HDL, LDL, or Hemoglobin levels. The findings suggest that Keezhanelli Chooranam possesses anti-hyperglycemic and hypolipidemic properties, providing preliminary scientific evidence supporting its Siddha claim in managing Madhumegam. Further validation through large-scale randomized controlled trials is recommended.

Keywords: Fasting Blood Glucose, Hba1c, Keezhanelli Chooranam, Madhumegam, Postprandial Blood Glucose, Total Cholesterol, Type 2 Diabetes Mellitus.

INTRODUCTION

Diabetes mellitus is one of the most prevalent non-communicable diseases and represents a major global public health challenge (1, 2, 3, 4). It is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from insulin resistance, relative insulin deficiency, or both, leading to disturbances in carbohydrate, lipid, and protein metabolism (4, 5). The global burden of diabetes has risen substantially in recent decades. According to the World Health Organization, approximately 422 million people worldwide are living with diabetes, and nearly 1.5 million deaths are attributed to the disease each year (6). In Sri Lanka, diabetes also poses a significant health concern, with a reported prevalence of 11.3% among adults aged 20–79 years in 2021 (7).

In Siddha medicine, diabetes mellitus is closely associated with the condition described as Madhumegam, which is documented in classical Siddha literature. The condition is also referred to by synonyms such as Neerizhivu and Inippu Neer, reflecting the excessive excretion of sweet urine. According to Yugi Vaithiya Cinthamani 800, Madhumegam is categorized under Meganoi and is primarily associated with the Pitha type, where it is described as Thithippu Neer (8, 9) Classical Siddha texts describe several herbal formulations for the management of this condition (10). Among them, Keezhanelli Chooranam (KNC), a single-herbal preparation derived from Phyllanthus amarus, is listed in the Siddha Pharmacopoeia of India. Traditionally, this formulation has been used for its antidiabetic, hepatoprotective, and antioxidant properties (10, 11). Considering the growing interest in evidence-based traditional medicine, this study was carried out as a clinical case series to evaluate the effectiveness of the Siddha herbal medicine Keezhanelli Chooranam (KNC) in the management of Madhumegam (Type 2 Diabetes Mellitus)**.** This study was conducted as a pilot study for the research titled "Validation of the Therapeutic Efficacy of the Siddha Herbal

Formulation Keezhanelli Chooranam (KNC) for Managing Newly Diagnosed Patients with Madhumegam (Type 2 Diabetes Mellitus) – A Randomized Clinical Trial." Ethical approval for this study was obtained from the Research Ethical Committee of the Bandaranayake Memorial Ayurveda Research Institute (BMARI).

Objectives

The primary objective of this study was to evaluate the antidiabetic potential of Keezhanelli Chooranam (KNC) through a clinical case series.

The study aimed to assess the changes in selected biochemical parameters, including total cholesterol, very low-density lipoprotein (VLDL), low-density lipoprotein (LDL), and hemoglobin levels.

Study Methodology

The study was designed as a clinical case series and was conducted at the Siddha Teaching Hospital, Kaithady. Ethical approval for the study was obtained from the Research Ethical Committee under the reference number REC-BMARI/2025/001. A total of six patients diagnosed with Madhumegam (Type 2 Diabetes Mellitus) were enrolled in the study and monitored to evaluate the therapeutic effects of KNC.

Inclusion Criteria

Participants eligible for this study included male and female patients aged between 30 and 65 years who were newly diagnosed with Type 2 Diabetes Mellitus within the past three months, confirmed according to the American Diabetes Association (ADA) diagnostic criteria. Eligible participants were required to present with at least one classical symptom of hyperglycemia, such as polyuria, polydipsia, polyphagia, nocturia, unintentional weight loss, fatigue, lethargy, or persistent tiredness. In addition, participants had to meet the specified screening glycemic parameters, including fasting blood sugar (FBS) levels between 126 and 250 mg/dL on two separate tests, postprandial blood sugar (PPBS) levels between 200 and 300 mg/dL, and glycated hemoglobin (HbA1c) levels ranging from 6.5% to 10%.

Exclusion Criteria

Patients were excluded from the study if they were diagnosed with Type 1 Diabetes Mellitus or secondary forms of diabetes. Individuals with significant cardiovascular diseases or central nervous system disorders were also excluded. Furthermore, patients presenting with diabetes-related complications, including retinopathy, neuropathy, or nephropathy, were not considered eligible for participation. Additional exclusion criteria included uncontrolled hypertension, pregnancy or lactation, and the presence of serious systemic illnesses such as hepatic disease, renal disease, tuberculosis, carcinoma, or human immunodeficiency virus (HIV) infection.

Intervention

All enrolled patients were administered Keezhanelli Chooranam at a dose of 5 g twice daily before meals, taken with 10 ml of warm water, for a total duration of 90 days. Throughout the study period, all participants were advised to adhere to a standard dietary regimen appropriate for diabetes management. Patients were monitored regularly and attended weekly follow-up visits to assess compliance, monitor progress, and record any clinical changes.

Outcome Measures

The therapeutic outcomes were evaluated using both glycemic and hematological parameters. Fasting Blood Sugar (FBS) levels were measured every 14 days throughout the study period to monitor glycemic control. Postprandial Blood Sugar (PPBS) levels were assessed at baseline and on Day 90**.** Glycated hemoglobin (HbA1c)**,** lipid profile, and hemoglobin levels were also evaluated at baseline and at the end of the study period (Day 90) to determine the metabolic and hematological changes associated with the intervention.

Statistical Analysis

The collected data were analyzed using the paired t-test to compare the baseline and post-intervention values of the measured parameters and to determine the statistical significance of the observed changes following the administration of Keezhanelli Chooranam.

Clinical Characteristics of Individual Cases

Case1

A 31-year-old male patient, business man from Inuvil, Jaffna was diagnosed with Madhumegam (Type 2 Diabetes Mellitus) and presented with symptoms of polyuria, fatigue, tiredness, body pain, and numbness in the limbs at the time of enrolment.

Case 2

A 54-year-old male patient, three wheel driver

from Kokilakandy, Jaffna was diagnosed with Madhumegam and reported polyuria, numbness in the limbs, and a burning sensation in the lower limbs.

Case 3

A 65-year-old male patient, Fishermen from Kaithady, Jaffna was diagnosed with Madhumegam and presented with polyuria, fatigue, tiredness, numbness in the limbs, and a burning sensation in the lower limbs.

Case 4

A 31-year-old male patient, Labourer, from Kaithady, Jaffna was diagnosed with Madhumegam and exhibited several classical hyperglycemic symptoms, including polyuria, polydipsia, polyphagia, unintentional weight loss, fatigue and tiredness.

Case 5

A 59-year-old male patient, Fishermen, from Navatkulli, Jaffna was diagnosed with Madhumegam and complained of fatigue, tiredness and body pain.

Case 6

A 40-year-old female patient, housewife from Irupalai, Jaffna was diagnosed with Madhumegam and presented with polyuria as the primary clinical symptom.

RESULTS

The Clinical Symptoms of before Managements and after Managements

Table 1 shows the clinical symptoms of six patients before and after the treatment. Before the management, most patients had symptoms such as polyuria (frequent urination), polydipsia (excessive thirst), polyphagia (increased appetite), weight loss, fatigue or tiredness, body pain, numbness in limbs, and burning sensation in the lower limbs. After the treatment, many of these symptoms were reduced or completely disappeared in several patients. This indicates that the treatment helped improve the common symptoms associated with Madhumegam (Type 2 Diabetes).

Table No 1: Clinical Symptoms of Patients on before and after Managements

Clinical Symptoms	Before the Management						After the Management					
	Case No 1	Case No 2	Case No 3	Case No 4	Case No 5	Case No 6	Case No 1	Case No 2	Case No 3	Case No 4	Case No 5	Case No 6
Polyuria	+	+	+	+		+	-	-	-	-		-
Polydipsia				+						-		
Polyphagia				+						-		
Weight Loss				+						-		
Fatigue, Lethargy, or Tiredness	+		+	+	+		-		-	-	-	
Body Pain	+				+		-				-	
Numbness in Limbs	+	+	+				-	+	+			
Burning Sensation in Lower Limbs		+	+					-	-			

Fasting Blood Sugar (FBS) Levels over 12-Week Follow-Up

Table No 2: Fasting Blood Sugar (FBS) Levels of Patients

Case No	Fasting Blood Sugar (FBS) Levels in mg/dl according to weeks						
	0wks	2wks	4wks	6wks	8wks	10wks	12wks
01	150.3	145	158	139.5	126	139	136
02	123	115	113	103	113	109	117
03	151	138	138	147	146	153	133
04	147	160	152	144	108	118	136
05	206.4	150	188	149	120	133	114
06	186	130	180	144	186	214	133

Table 2 shows the fasting blood sugar levels of six patients measured from the beginning of the study (0 weeks) up to the end of the study (12 weeks). In most cases, the FBS levels gradually decreased during the follow-up period. Although some fluctuations were observed at certain weeks, the overall trend shows improvement in blood sugar control by the end of the 12-week treatment period

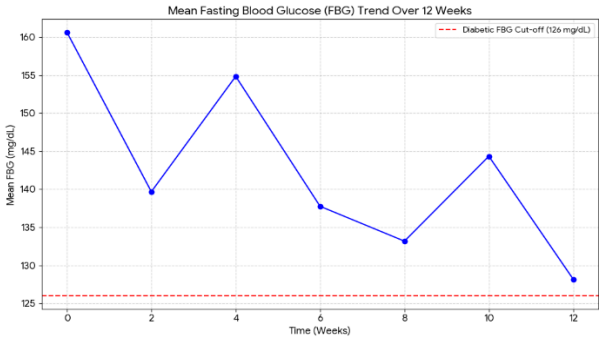

Figure No 1: Fasting Blood Sugar (FBS) Levels Of Patients, Over 12-Week Follow-Up

Figure 1 illustrates the average fasting blood sugar levels of all patients during the 12-week follow-up. The graph shows that the mean FBS level was higher at the beginning of the study and gradually decreased over time. Even though there were slight increases at some weeks, the overall trend indicates a reduction in fasting blood sugar by the end of the study. This suggests that the treatment may help in controlling blood glucose levels in patients with Madhumegam

Statistical Interpretation of Blood Parameters through Paired T-Test

The statistical analysis using the paired t-test showed that there was a highly significant reduction in Postprandial Blood Sugar (PPBS) ($p = 0.008$) and a significant decrease in Very Low-Density Lipoprotein (VLDL) levels ($p = 0.015$). Although the reductions in Fasting Blood Sugar (FBS) by 32 mg/dL, HbA1c by 0.94%, and Triglycerides by 43 mg/dL were not statistically significant ($p = 0.065$–0.068), these changes still suggest a meaningful clinical improvement in the patients. In addition, no adverse changes were observed in Total Cholesterol, HDL, LDL, or Hemoglobin levels during the study period.

Table No 3: Statistical Interpretation of Blood Parameters

Parameter	Mean Before (SD)	Mean After (SD)	Mean Change	T-Statistic	P-Value	Statistical Interpretation
PPBS	219.17 (43.12)	173.50 (25.85)	↓45.67	4.244	0.008	Statistically Significant Decrease
VLDL	26.47 (13.55)	20.60 (12.53)	↓5.87	3.622	0.015	Statistically Significant Decrease
HbA1c	8.47 (1.20)	7.53 (0.49)	↓0.94	2.490	0.055	Near-Significant Decrease
FBS	160.58 (30.07)	128.17 (9.95)	↓32.41	2.354	0.065	Not Statistically Significant
Triglycerides	149.02 (69.27)	105.83 (61.01)	↓43.19	2.324	0.068	Not Statistically Significant
Cholesterol	196.98 (37.64)	178.50 (44.33)	↓18.48	1.464	0.203	Not Statistically Significant
HDL	48.12 (12.37)	47.00 (6.48)	↓1.12	0.381	0.719	No Significant Change
LDL	102.35 (41.06)	102.50 (32.49)	↑0.15	-0.015	0.989	No Significant Change
Heamoglobin	14.05 (1.77)	14.03 (1.54)	↓0.02	0.093	0.930	No Significant Change

DISCUSSION

The findings showed a meaningful clinical reduction in Fasting Blood Sugar (FBS), Postprandial Blood Sugar (PPBS), HbA1c, and Triglyceride levels during the 90-day treatment period. Among these, a statistically significant improvement was observed in PPBS and VLDL levels. No adverse changes were seen in Total Cholesterol, HDL, LDL and Hemoglobin levels, which indicates that Keezhanelli Chooranam (KNC**)** was safe and well tolerated throughout the study period.

When compared with previous clinical evidence, Moshi et al. reported that a one-week treatment with an aqueous extract of Phyllanthus amarus did not produce a significant hypoglycaemic effect in patients with non-insulin-dependent diabetes mellitus (NIDDM) (12). However, in the present study, a powdered whole-herb formulation was used for 90 days and showed meaningful improvement in blood glucose levels. This difference suggests that treatment duration, dosage, and the type of formulation may influence the therapeutic effectiveness of Phyllanthus amarus, which supports the positive outcomes observed with KNC.

CONCLUSION

The findings suggest that Keezhanelli Chooranam has anti-hyperglycemic and hypolipidemic effects, which means it may help reduce blood sugar and lipid levels. These results provide preliminary scientific evidence supporting its use in Siddha medicine for managing Madhumegam. However, further studies with a larger number of patients and well-designed randomized controlled trials are needed to confirm these results.

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