

A COMPARATIVE CLINICAL STUDY OF AROGYAVARDHINI VATI AND IKSHUMEHA KASHAYA IN THE MANAGEMENT OF TYPE 2 DIABETES MELLITUS

¹Dr E.J.D.D.A Jayasuriya

²Dr.W.A.L Chandrasiri Waliwita

¹Ayurveda Physician, ²Supervisor, Gampahawickramaraclhchi Ayurveda Institute, University of Kelaniya Yakkala, Srilanka.

ABSTRACT

Arogyavardhini Vati has been recommended for the management of Prameha, liver disorders, acute and chronic fever, obesity in authentic Ayurveda texts,¹ but scientific study on the effect of Arogyavardhini Vati in the management of type 2 diabetes mellitus has not been done so far. Therefore, this preliminary comparative clinical study was designed to evaluate the effect of Arogyavardhini Vati in the management of type 2 diabetes mellitus in comparison with Ikshumeha kashaya. Specific objectives of this clinical study are to determine the effect of oral administration of Arogyavardhini Vati on fasting blood glucose level, fasting lipid profile level, liver function test, blood pressure and heart rate of type 2 diabetes mellitus patients. Research is designed as randomized comparative clinical cohort study. 90 patients were selected suffering from type 2 diabetes mellitus and randomly divided into 3 groups. Ikshumeha Kashaya was administered to the first group. Test drug Arogyavardhini Vati was given to the second group. The third group was treated with allopathic drug (metformin). These drugs are applied for a period of two weeks to the selected patients. Therapeutic effects are recorded and data was statistically analyzed. Reduction of fasting blood sugar level was statistically significant after treating with Ikshumeha Kashaya in the first group. Reduction of fasting blood sugar level was not statistically significant after treating with Arogyavardhini Vati in the second group. There was no statistical difference between first group (group treated with Ikshumeha Kashaya) and third group (group treated with metformin). When the effect of Arogyavardhini Vati on lipid profile was considered it was observed that only elevation of HDL (high-density lipoprotein) and reduction of total cholesterol were statistically significant.

Keywords: Arogyavardhani Vati, Prameha, Ikshumeha Kashaya

INTRODUCTION

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar². Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems,

especially the nerves and blood vessels.³Diabetes Mellitus (DM) is a fifth fastest growing disorder and entailing huge financial burden and multiple medical policy issues. As per International Diabetes Federation (IDF), the number of individuals with diabetes in 2011 crossed 366 million, with an estimated about 4.6 million deaths each year. Diabetes is mainly classified into two types according to the aetiology and

pathogenesis as type 1 diabetes mellitus and type 2 diabetes mellitus. Type 1 diabetes mellitus (T1DM) usually develops in childhood and adolescence and patients require lifelong insulin injections for survival. Type 2 diabetes mellitus (T2DM) usually develops in adulthood and is related to obesity, lack of physical activity, and unhealthy diets. Type 2 diabetes mellitus is characterized by insulin resistance, which may be combined with relatively reduced insulin secretion.⁴

Type 2 diabetes is often accompanied by other conditions, including hypertension, high serum low-density-lipoprotein (LDL) cholesterol concentrations, and low serum high-density-lipoprotein (HDL) cholesterol concentrations that, like type 2 diabetes, increase cardiovascular risk. This type of clinical conditions is referred to as the metabolic syndrome.

According to the WHO estimates, it is evident that 347 million people worldwide have diabetes.

Diabetes prevalence was higher in the urban population compared with rural. The

Ingredients of Arogyavardhini Vati⁶

Sanskrit name	Scientific name	Quantity
Shuddha Parada	purified Mercury)	1 part
ShuddhaGandhaka	purified Sulphur)	1 part
LohaBhasma	Bhasma prepared from Iron	1 part
AbhrakaBhasma	Purified and processed Mica	1 part
TamraBhasma	Bhasma prepared from Copper	1 part
Haritaki	<i>Terminalia chebula</i>)	2 parts
Vibhitaki	<i>Terminalia bellirica</i>	2 parts
Amalaki	<i>Emblica officinalis</i>	2 parts
Shilajatu	<i>Asphaltum</i>	3 parts
ShuddhaGuggulu	<i>Commiphoramukul</i>	4 parts
Chitraka	<i>Plumbago zeylanica</i>	4 parts

prevalence of overall, urban and rural pre-diabetes was 11.5% and 11.0% respectively. Overall, 21.8% had some form of dysglycaemia. The projected diabetes prevalence for the year 2030 is 13.9%. Those with diabetes and pre-diabetes compared with normal glucose tolerance were older, physically inactive, frequently lived in urban areas and had a family history of diabetes. They had higher body mass index, waist circumference, waist-hip ratio, systolic/diastolic blood pressure, low-density lipoprotein cholesterol and triglycerides.⁵

Objectives

1. To evaluate the effect of Arogyavardhini Vati in the management of the Type 2 Diabetes Mellitus
2. To evaluate the effect of Ikshumeha kashaya in the management of type 2 Diabetes Mellitus
3. To compare the efficacy of Arogyavardhini vati and Ikshumeha kashaya in the management of type 2 Diabetes Mellitus

Tikta	<i>Picrorhiza kurroa</i>	6 parts
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Juice extract of Nimba (*Azadirachta indica*) – Quantity Sufficient. Then the fine powder of above ingredients is ground with the juice extract, made into paste and pills are prepared.

Research Design: randomized comparative clinical cohort study

Place of work: Diabetic Clinic, Gampaha Wickramarachchi Ayurveda Teaching Hospital

Selection of Patients:

After comprehensive clinical examination, volunteer patients were selected for this study according to the inclusion and exclusion criteria. All patients selected were informed the nature of this study before the commencement of study and written consent was taken.

Inclusion criteria

1. Subject: Previously diagnosed T2DM Patients with poor glycaemic control with continuation of allopathic hypoglycaemic medication and without serious Diabetic complications
2. Gender: Male/Female
3. Age: Patients between 30 and 65 years of age.
4. Patients must have consent for the study.
5. No participation in a clinical trial within the previous 6 weeks.

Exclusion criteria

1. Treatment with immune-suppressive or immune stimulatory medications such as azathioprine, nicotinamide, superoxide

Dismutase - desferroxamine, aminoguanidine, oral insulin or other experimental therapies at the present time or in the past.

2. Known active diseases, e.g. cardiac, renal, hepatic diseases or immunodeficiency.
3. History of cancer, neuropathy, seizure disorders, peripheral vascular disease, coagulation abnormalities, autoimmune disease or cerebrovascular disease.
4. Ongoing use of medications except to current oral hypoglycaemic drugs
6. Lactating or pregnant female

Diagnostic Criteria

According to WHO diagnostic criteria of T2DM was applied in diagnosis has been published Diabetes symptoms (i.e. polyuria, polydipsia and unexplained weight loss) plus a random venous plasma glucose concentration > 11.1 mmol/l (200 mg/dl) or a fasting plasma glucose concentration > 7.0 mmol/l (whole blood > 6.1mmol/l) (126 mg/dl) or two hour plasma glucose concentration > 11.1 mmol/l (200 mg/dl) two hours after 75g anhydrous glucose in an oral glucose tolerance test (OGTT).

In this clinical study following Investigations were done before and after the treatment

1. Estimation of Fasting Serum Glucose Levels
2. Estimation of Fasting Serum Lipid levels
3. Estimation of the serum key hepatic enzyme levels

Results

Effect of 3 Drugs on Type 2 Diabetes mellitus

Table- 11 distribution The Fasting blood sugar for Ikssumeha kasaya

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after tratment(Mean±SEM)	Probability value
30	167.7±8.66	144.1±7.99	0.049

In here Probability value of the difference between pre-treatment and post treatment was less than 0.05. So it can be concluded that, there has significant treatment effect for FBS from ikshumehakashaya

Table-12 distribution The Fasting blood sugar for metformin

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after tratment(Mean±SEM)	Probability value
30	162.4±7.12	132±6.25	0.002

For Metformin Probability value of the difference between pre-treatment and post treatment was less than 0.05. So it can be concluded that, there has significant treatment effect for FBS from Metformin drug.

Table-13distribution The Fasting blood sugar for Arogyavardhini Vati

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after tratment(Mean±SEM)	Probability value
30	164.1±9.01	164.6±9.78	0.97

For the Arogyavardhini vati Probability value of the difference between pre-treatment and post treatment was not less than 0.05. So it can be concluded that there has not significant treatment effect for FBS from Arogyavardhini Vati .

Table -14 comparison between the treatment effect of Ikshumeha, Arogyavardhini Vati and Metformin

Source	Degree of freedom	Sum Squares	Mean squares	F value	P- value
Treatments	2	15744	7872	8.75	0.001

In here probability value for the model is less than 0.05. It can be concluded that, three treatments have different effects on blood sugar. So there is need to mean comparison for identify the different effect of the treatments.

Table-15mean comparison on difference of the treatment mean value of Ikshumeha, Arogyavardhini Vati and Metformin

Drug	Mean
Metformin	30.37
Ikshumeha	23.7
Arogyavardhini Vati	-0.42

Critical value LSD	Least significant difference
1.98	15.392

According to the results quantity of LSD is 15.392. In the output mean difference less than the LSD. Thus treatment of Arogyavardhani Vati mean is less than both

metformin and ikshumeha and there is no difference between the treatment of metformin and ikshumeha.

Table -16 distribution the LDL for Arogyavardhani Vati

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	111.03±4.94	105.6±5.4	0.06

Probability value of the difference between pre-treatment and post treatment was not less than 0.05. It can be concluded that,

there has not significant treatment effect for LDL from treatment of Arogyavardhani Vati .

Table-17 distribution Colesterol for Arogyavardhani Vati

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	192.8±8.7	176.6±7.9	0.001

Probability value of the difference between pre-treatment and post treatment was less than 0.05. It can be concluded that, there has

significant treatment effect for Cholesterol from treatment of Arogyavardhani Vati .

Table-18 distribution The HDL for Arogyavardhani Vati

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	54.1±1.24	59.76±1.76	0.002

Probability value of the difference between pre-treatment and post treatment was less than 0.05. So we can conclude there has

significant treatment effect for HDL from treatment of Arogyavardhani Vati .

Table -19 distribution The Triglycerides for Arogyavardhani Vati

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	136.9±2.37	134.9±1.95	0.163

Probability value of the difference between pre-treatment and post treatment was not less than 0.05. It can be concluded that,

there has not significant treatment effect for triglycerides from treatment of Arogyavardhani Vati .

Table -20 distribution The VLDL for Arogyavardhani Vati

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	23.1±0.7	21.8±0.64	0.15

Probability value of the difference between pre-treatment and post treatment was not less than 0.05. It can be concluded that,

there has not significant treatment effect for VLDL from treatment of Arogyavardhini Vati .

Table -21 distribution The Cholesterol for Ikssumeha

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	171.3±7.4	203.2±6.05	0.00

Probability value of the difference between pre-treatment and post treatment was less than 0.05. It can be concluded that, there has significant treatment effect for Colesterol

from treatment of ikshumeha kashaya. But in here mean value of the cholesterol values are increased by from this kasya.

Table -22 distribution The LDL for Ikshumeha

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	100.1±10.14	99.9±5.57	0.99

Probability value of the difference between pre-treatment and post treatment was not less than 0.05. It can be concluded that,

there has not significant treatment effect for LDL from ikshumeha kashaya.

Table -23 distribution the HDL for Ikshumeha

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	65.12±2.25	61.6±2.17	0.159

Probability value of the difference between pre-treatment and post treatment was not less than 0.05. It can be concluded that,

there has significant treatment effect for HDL from Ikshumeha kashaya.

Table-24 distribution the Triglycerides for Ikshumeha

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	145.97±5.62	140±2.71	0.321

Probability value of the difference between pre-treatment and post treatment was not less than 0.05. It can be concluded that,

there has no significant change for Triglycerides from ikshumeha kashaya.

Table-25 distribution the VLDL for Ikshumeha

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	24.2±0.77	23.4±0.58	0.417

Probability value of the difference between pre-treatment and post treatment was not

less than 0.05. It can be concluded that, there has not significant treatment effect for

VLDL from ikshumeha kashaya.

Table -26 distribution the SGOT for Arogyavardhini vati

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	29.57±1.86	26.88±1.16	0.227

Probability value of the difference between pre-treatment and post treatment was not less than 0.05. It can be concluded that,

there has not significant treatment effect for SGOT from treatment of Arogyavardhini Vati.

Table-27distribution the SGPT for Arogyavardhini vati

Number of patients	Mean value of before treatment(Mean±SEM)	Mean value of after treatment(Mean±SEM)	Probability value
30	33.1±2.87	27.78±1.26	0.11

Probability value of the difference between pre-treatment and post treatment was not less than 0.05. It can be concluded that,

there has not significant treatment effect for SGPT from treatment of Arogyavardhini vati.

DISCUSSION

Considering statistical analysis of above 3 drugs named Ikshumeha kashaya, Arogyavardhini vati and Metformin, Arogyavardhini vati has no significant effect on FBS (According to the results of data analysis) and considering about both Metformin and Ikshumeha, there is no difference between the treatment of Metformin and Ikshumeha.

Ikshumeha group. Among them Metformin treated group was handled as a separated group, so lipid profile test and LFT were not done for them.

Another fact which was revealed through this clinical study, both Ikshumeha and Arogyawardhani drugs have significant effect on some parts of lipid profile (Arogyawardhani on total cholesterol and HDL). Under this clinical study, effect of Arogyavardhini Vati on liver enzymes (SGOT, SGPT, Gamma-GT) were evaluated. But doing that, there were some problems; Such as there were no enough data to analyse the results of Gamma-GT and very difficult to collect the data of other two enzymes and also the data of other two enzymes were not be able to collect totally in

Considering the 60 patients out of 90 (Except Metformin 30) hadn't given an enough awareness towards diabetic complications, Because most of patients among above 60 hadn't desire to make do LFT and Lipid profile. But most of them hadn't done LFT, because of unable to bear-up its' cost. In this clinical study dietary management was also applied for 90 patients. That dietary system was prepared to considering suitability for DM. But during this clinical study some patients hadn't followed that diet controlling system. According to formula of Arogyavardhini Vati mainly its' herbal materials have an ability to decrease an abnormally elevated FBS. Present study revealed there has no significant treatment effect for FBS from Arogyavardhini Vati.

CONCLUSION

Following conclusions were found through analyzed data of clinical research.

- Arogyavardhini Vati has no significant treatment effect on FBS.
- There has significant treatment effect for FBS from Ikshumeha kashaya.
- There has significant treatment effect for FBS from Metformin drug.
- Considering both Metformin and and Ikshumeha, there is no difference between the treatment of metformin and Ikshumeha. (FBS)
- Arogyavardhini Vati has significant treatment effect on total cholesterol and HDL
- Ikshumeha kashaya has significant treatment effect on total cholesterol.
- There has no significant effect on SGOT and SGPT from Arogyavardhini Vati.
- So it can be concluded that Arogyavardhini Vati doesn't change healthy liver enzymes.(doesn't increase liver enzymes than reference range)

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CORRESPONDING AUTHOR

Dr E.J.D.D.A Jayasuriya

Ayurveda Physician, Gampaha wickramarachchi Ayurveda Institute, University of Kelaniya Yakkala, Srilanka.

Email: amali.darshi@yahoo.com

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