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## Evaluation of the effect and efficacy of herbal powder preparation derived from ‘Thalpathe Piliyam’ in the management of type ii diabetes mellitus

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### Abstract

Diabetes Mellitus is a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. The effects of Diabetes Mellitus include long-term damage, dysfunction and failure of various organs. It is a chronic disease caused by Inherited and acquired deficiency in production of insulin by the pancreas or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentrations of glucose in the blood, which in turn damage many of the body's systems, especially the blood vessels and nerves. This study was to determine the effect and efficacy of selected herbal formulation mentioned in “Thalpathe Piliyam” in the management of type 2 Diabetes. All patients were selected from medical clinic of Gampaha Wickramarachchi Ayurveda Hospital according to the inclusion and exclusion criteria. The selected patients were assigned into two groups (group A and B) consisting of 30 patients for each group. The patients of group A were treated with the powder of selected herbal formula and dietary management during the period of 1 month. Patients of group B were treated allopathic medicine and dietary management during the period of 1 month. After 1 month, the patients of group A and group B showed significant reduction in fasting blood sugar and blood pressure and heart rate. Thus, the powder of selected formulation could be recommended for the management of type 2 Diabetes.

**Keywords:** Type 2 Diabetes Mellitus, Herbal formulation, Thalpathe Piliyam, Allopathic medicine

### 1. Introduction

#### 1.1. Background of the research

Diabetes is a main health problem in the society and people are anxious to know regarding this disease elaborately. Because, now in the whole world nearly about 24% of the population are suffering from this disease. Diabetes Mellitus (DM) is one of the main health disorders in the world. Approximately there are 347 million people with diabetes worldwide, mainly type 2 Diabetes Mellitus (T2DM). (WHO, 2013). According to prevalence estimates of DM in 2010, population of Sri Lanka is 13339 (20 – 79 years), National prevalence is 11.5% and comparative prevalence is 10.9%. The term ‘Diabetes Mellitus’ (DM) describes a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. (WHO, 1999)

Diabetes is of 3 types, type I, type II and gestational diabetes. The most common form of diabetes is type 2 diabetes, accounting for 95% of diabetes cases in adults. Risk factors of diabetes are weight, inactivity, race, family history, polycystic ovarian syndrome, age and fat distribution. Symptoms of diabetes are increased thirst and frequent urination (polyuria), increased hunger (polyphagia), increased thirst (polydypsia) weight loss, blurred vision, slow-healing sores or frequent infections and areas of darkened skin.

Complications of diabetes are heart and blood vessel disease, nerve damage (neuropathy), kidney damage (nephropathy), eye damage (retinopathy), foot damage, hearing impairment, skin infections and Alzheimer's disease. In type II form it can also happen that no early symptoms appear and the disease is only diagnosed several years after its onset, when complications are already present. Patients may have no symptoms at all or minimal symptoms for years before being diagnosed. Diabetes Mellitus is correlated with the disease, *Madhumeha*. Ancient Ayurvedic scholars have grouped *Madhumeha* under one among the 20 prameha (urinary disorders). *Ojas* is of sweet nature but due to roughness of *vayu* it gets associated with astringency and is carried to urinary bladder, it gives rise to *Madhumeha* (diabetes). One who passes urine as astrigent, sweet, pale and rough should be diagnosed as a case of madhumeha due to vitiation of *vata* are described. (Charaka nidana, 4/37,44)

Diabetes is a palliative disease. It cannot be completely cured; but, can be controlled by food and medicine. In rare cases, if it is originated due to any secondary cause or stress or medicine etc, on cure of the main illness or on withdrawal of the medicine, it will be subsided by its own.

## 1.2. Significance and Justification of the Research

Diabetes is a chronic disease caused by inherited and acquired deficiency in production of insulin by the pancreas or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentrations of glucose in the blood, which in turn damage many of the body's systems, especially the blood vessels and nerves. (WHO, 2013) The most common form of diabetes is type 2 diabetes, accounting for 95% of diabetes cases in adults. Type 2 diabetes used to be called adult-onset diabetes, but with the epidemic of obese and overweight kids, more teenagers are now developing type 2 diabetes. Type 2 diabetes is also called non-insulin-dependent diabetes. It is often a milder form of diabetes than type 1. According to prevalence, type 2 diabetic condition increases day by day around the world and has become a major health issue of the world. It is a big problem of social and economic development of family and community. So we want to resolve this problem which helps social and economic development of community and improve quality of life of them. There is no permanent and successful result from the allopathic medicine for Diabetes Mellitus. The numbers of patients and their complications have been increased day by day. Herbal medicines have been main source of primary healthcare in all over the world. From ancient times, plants have been catering as rich source of effective and safe medicines. According to the WHO, 80 % of world population is still depend on traditional medicines. Continuous usage of herbal medicine by a large proportion of the population in the developing countries is largely due to the high cost of western pharmaceuticals and healthcare. The advantages of herbal medicines reported are effectiveness, safety, affordability and acceptability. Over the past decade, herbal medicine has become a topic of global importance, making an impact on both world health and international trade. Therefore, the results indicated by this research would be beneficial in the effective management of type 2 diabetes without causing serious adverse effects. There are so many formulations mentioned in ola leave manuscripts in Sri Lanka for diabetics. Among them I have selected a formulation which was mentioned for diabetes in 14th volume of 'Thalpathe Piliyam'. The book series of 'Thalpathe Piliyam' have many

formulations for prameha. A formulation of kashaya which consist of aralu, bulu, nelli, madam, ranawara, ingini and maduru is the one I have chosen. The primary objective of this clinical study is to evaluation of the effect and efficacy of selected formulation derived from Thalpathe Piliyam in the management of Diabetes Mellitus type 2 condition patients. This research would be a great support for the society and entire field of medicine to introduce this formulation for Diabetes Mellitus type II as it is a main health problem in the society.

## 1.3. Objectives

### General Objective

- To evaluate the effect and efficacy of herbal powder preparation derived from 'Thalpathe Piliyam' in the management of type II Diabetes Mellitus.

### Specific Objectives

- To determine the effect of formulation on blood sugar.
- To determine adverse effects of formulation on systolic, diastolic blood pressure and heart rate.
- To evaluate the efficacy of treatment in comparison to Allopathic treatment.

## 1.4. Hypothesis

**H0:** Selected formulation is effective in the management of Diabetes Mellitus type 2.

**H1:** Selected formulation is not effective in the management of Diabetes Mellitus type 2.

## 2. Methodology

### 2.1. Collection of Plant Materials

Selected formula is consisted of seven plant materials which is prescribed to make as a *kashaya*. But for the easy use they were prepared as fine powders. All plant materials were collected at the open market in dry form.

Table 1

No	Plant name	Scientific name	Plant part used
1	Aralu	<i>Terminalia chebula</i>	Fruit
2	Bulu	<i>Terminalia bellerica</i>	Fruit
3	Nelli	<i>Phyllanthus emblica</i>	Fruit
4	Madam	<i>Syzygium cumini</i>	Bark
5	Ranawara	<i>Cassia auriculata</i>	Root bark
6	Ingin	<i>Strychnos potatorum</i>	Seeds
7	Maaduru	<i>Foeniculum vulgare</i>	Seeds

### 2.2. Preparation of drug

Similar quantity of dried plant materials were ground to make the fine powder. Fine powders were mixed well and packed in air tight packets.

### 2.3. Dosage

1 tea spoon of fine powder was added into 120ml of hot water (1/2 tumbler), kept it to boil and drink twice a day (morning and afternoon).

### 2.4. Criteria for the assessment

Assessment was done on the basis of clinical observations including the estimation of blood pressure, pulse rate and biochemical investigations, which included FBS level.

### 2.5. Criteria for inclusion

Diabetic patient, without complications, Diabetes duration

since diagnosis < 5 years and patients between 30 to 70 years old were the inclusion criteria.

**2.6. Exclusion criteria**

Pregnant mothers, lactating mothers, patients with psychiatric disorders, Diabetic patient with complications and patients whose age less than 30 years, more than 70 years were the exclusion criteria.

**2.7. Diagnostic criteria**

Patients were diagnosed on the basis of both the objective and subjective criteria of Diabetes Mellitus. Diagnosis is made by the presence of classic symptoms of hyperglycemia and an abnormal blood test of fasting plasma concentration of sugar >=7 mmol/L (126 mg/dl) and estimation of blood pressure and pulse rate

**2.8. Setting**

Gampaha Wickramarachchi Ayurveda Hospital

**2.9. Research Design**

The selected patients according to the selection criteria were randomly assigned into two groups (Group A and Group B) consisting of 30 patients for each. The patients of group A were treated with new herbal formulation and prescribed dietary management and the patients of group B were instructed to follow Allopathic treatment and the prescribed Dietary management.

**2.10. Method**

Initially patients were selected under the research scope and the selected formulation was prepared in powder form. Then it was administrated to the group A according to appropriate dosage of selected formulation (1 tea spoon of fine powder in 120ml of hot water) and Allopathic treatment (metformin) was given to group B. Fasting Blood Sugar level, Blood pressure and heart rate were tested before treatment & after administering the medications for 1 month time. Finally data was analyzed quantitatively and qualitatively with IBS SPSS and Microsoft Excel.

**2.11. Correlation**

Correlation is a statistical technique that can show whether and how strongly pairs of variables are related. This study expect a high degree of correlation between the two sets of scores.

**Table 2:** Here the degree level of correlation

0	No linear relationship
.1	Perfect positive linear relationship
-1	Perfect negative linear relationship
0-0.3	Weak positive
0.3-0.7	Moderate positive
0.7-1	Strongly positive

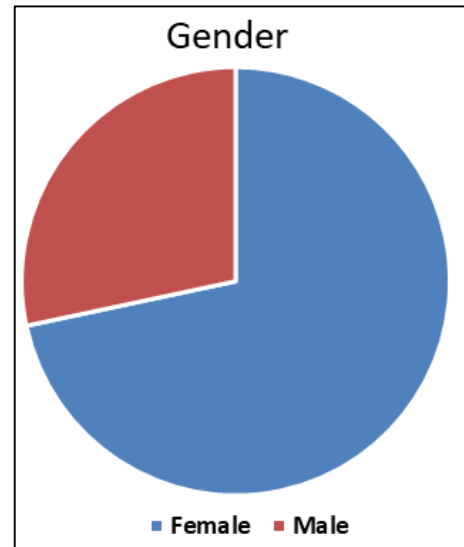
**3. Results**

**3.1. Gender wise distribution of data**

60 patients who have hyperglycemic conditions were selected for the present study and 71.7% patients selected for the study were female and the male percentage was 28.3%.

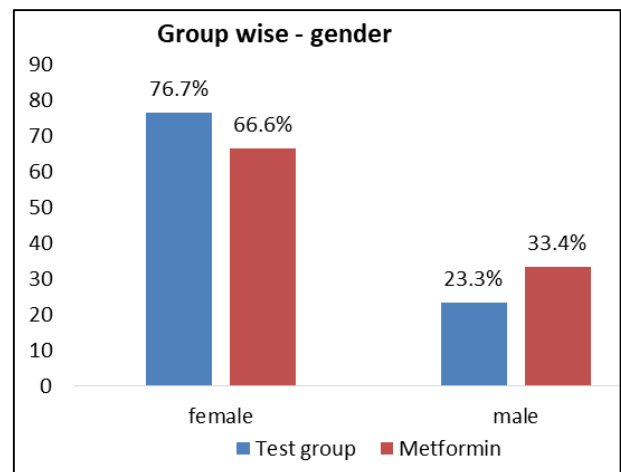
**Table 3:** Gender wise distribution of data

Sex	Frequency	Valid Percent
Male	17	28.3
Female	43	71.7
Total	60	100.0



**Fig 1:** Gender wise distribution of data

**3.2. Gender by group distribution of data**



**Fig 2:** Gender by group distribution of data

From 30 patients of group A 76.7% were female and 23.3% were male. From 30 patients of group B 66.6% were female and 33.4% were male.

**3.3. Age Distribution of data**

**Table 4:** Age distribution of data

Age	Frequency	Percent
1(30-40yrs)	6	6.7%
2(41-50yrs)	18	20.0%
3(51-60yrs)	25	27.8%
4(61-70yrs)	11	12.2%

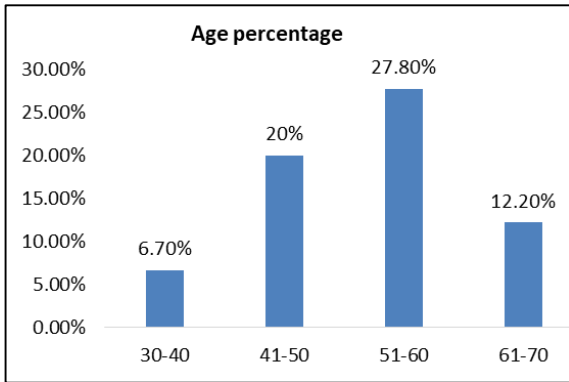


Fig 3: Age wise distribution of data

3.4. Age distribution of group A

Table 5: Age distribution of group A

Age	Frequency	Percent
1(30-40rs)	5	16.7
2(41-50yrs)	10	33.3
3(51-60yrs)	12	40.0
4(61-70rs)	3	10.0

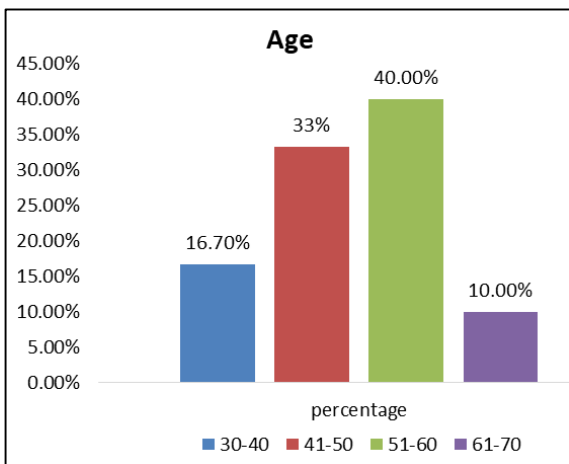


Fig 4: Age distribution of group A

3.5. Age distribution of group B

Table 6: Age distribution of group B

Age	Frequency	Percent
1(30-40 yrs)	1	3.3
2(41-50yrs)	8	26.7
3(51-60yrs)	13	43.3
4(61-70yrs)	8	26.7

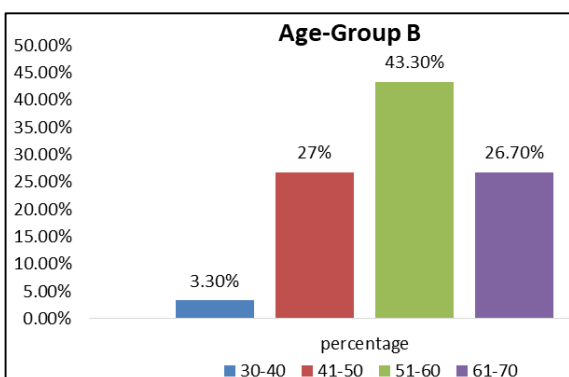


Fig 5: Age distribution of group B

3.6. Distribution of fasting blood sugar level before and after treatment

Table 7: Fasting Blood Sugar Level before and after treatment

	Test drug	Metformin
Before treatment	190.06 ± 7.98	190.86 ± 9.70
After treatment	136.63 ± 4.46	133.53 ± 3.89

In a column, data is presented as MEAN ± SEM of 30 patients per each group, in each

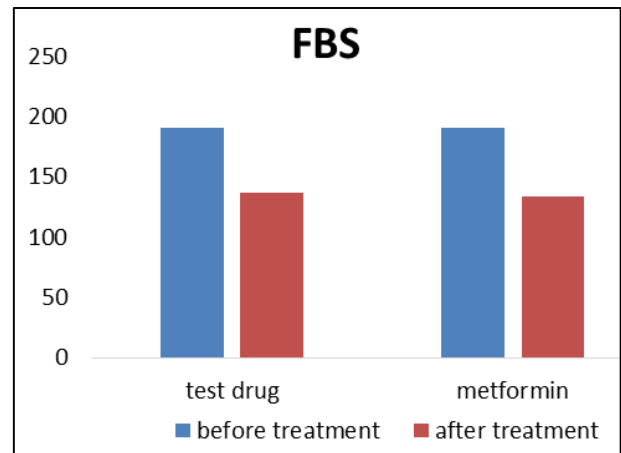


Fig 6: Fasting Blood Sugar level before and after treatment

Each bar represent the MEAN± SEM of 30 patients of each group. The bars, data indicated by, significantly different from each other. (ANOVA; Tukey's test p < 0.05)

3.7. Distribution of systole blood pressure level before and after treatment

Table 8: Distribution of systole blood pressure level before and after treatment

	Test drug	Metformin
Before treatment	128.43 ± 0.425	128.53 ± 0.586
After treatment	123.76 ± 0.44	123.56 ± 0.49

In a column, data is presented as MEAN ± SEM of 30 patients per each group, in each

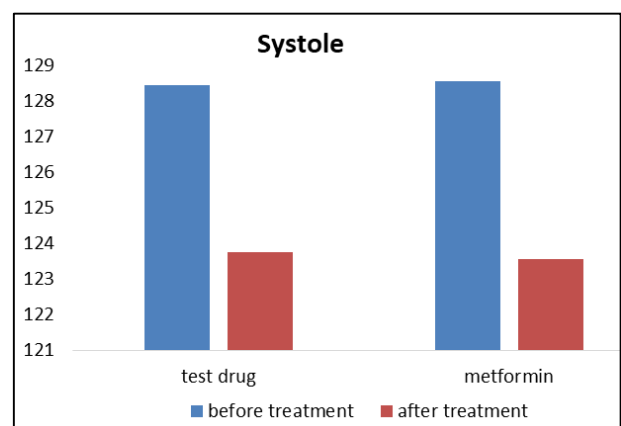


Fig 7: Distribution of systole blood pressure level before and after treatment

In a column, data is presented as MEAN ± SEM of 30 patients per each group, in each column, data indicated by,

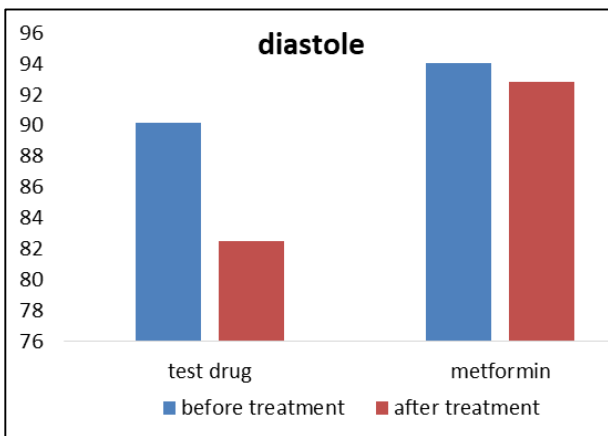
significantly different from each other. (ANOVA; Tukey’s test:  $p < 0.05$ ).

Each bar represent the MEAN± SEM of 30 patients of each group. The bars, data indicated by, significantly different from each other. (ANOVA; Tukey’s test:  $p < 0.05$ ) Distribution of diastole blood pressure level before and after treatment.

### 3.8. Distribution of diastole blood pressure level before and after treatment

**Table 9:** Distribution of diastole blood pressure level before and after treatment

	Test drug	Metformin
Before treatment	90.16 ± 0.84	94.06 ± 4.21
After treatment	82.46 ± 0.91	92.83 ± 4.53



**Fig 8:** Distribution of diastole blood pressure level before and after treatment

### 3.10. Paired Samples Test

#### 3.10.1. Group A-Test Drug

**Table 12:** Paired Samples Test of Group A

		Paired Differences			t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean			
Pair 1	FBS1 - FBS2	53.43333	23.77580	4.34085	12.309	29	.000
Pair 2	Sys1 - Sys2	4.66667	1.68836	.30825	15.139	29	.000
Pair 3	Dis1 - Dis2	7.70000	4.16181	.75984	10.134	29	.000
Pair 4	Hr1 - Hr2	5.40000	1.69380	.30924	17.462	29	.000

According to this study in test drug group, all the pairs results are less than 0.05. It means all the p- value of this group is

#### 3.10.2. Group B-Metformin

**Table 13:** Paired Samples Test of Group B

		Paired Differences			t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean			
Pair 1	FBS1 - FBS2	57.33333	49.65629	9.06596	6.324	29	.000
Pair 2	Sys1 - Sys2	.30000	6.72694	1.22817	.244	29	.809
Pair 3	Dis1 - Dis2	1.23333	5.06974	.92560	1.332	29	.193
Pair 4	Hr1 - Hr2	-.73333	5.03048	.91844	-.798	29	.431

According to this study in allopathic group, pair1 (FBS1 - FBS2) result is less than 0.05. That means the p- value of this pair1 is less than 0.05. That means there is a significant difference in FBS level between before treatment and after treatment.

Each bar represent the MEAN± SEM of 30 patients of each group. The bars, data indicated by, significantly different from each other. (ANOVA; Tukey’s test:  $p < 0.05$ )

### 3.9. Correlation

#### 3.9.1. Group A-Test Drug

**Table 10:** Group of test drug correlations

		Correlation	Sig.
Pair 1	FBS1 & FBS2	.910	.000
Pair 2	Sys1 & Sys2	.749	.000
Pair 3	Dis1 & Dis2	.630	.000

According to the study here in the test drug group, there was moderately positive correlation in diastole pressure level before treatment and after treatment. Before treatment and after treatment values of Fasting blood sugar level, Systole blood pressure level were strongly positive correlations.

#### 3.9.2. Group B-Metformin

**Table 11:** Group of Metformin correlations

		Correlation	Sig.
Pair 1	FBS1 & FBS2	.359	.051
Pair 2	Sys1 & Sys2	.968	.000
Pair 3	Dis1 & Dis2	.980	.000

According to this study in allopathic group, there were moderately positive correlations in before treatment and after treatment values of Fasting blood sugar level. Systole pressure level before treatment and after treatment, diastole blood pressure level before and after has strongly positive correlations.

less than 0.05. It means there is a significant difference between before treatment and after treatment.

## 4. Discussion

### 4.1. Discussion

Patients were selected according to the inclusion and exclusion criteria. They were assigned into 2 groups (Group A and Group B) consisting 30 patients for each group. Those

2 samples had not significantly difference in all parameters. According to the gender wise distribution of data there was an increasement of female patients than male patients in both groups.

When considering the age distribution, 51-60 year age patients of both groups were significantly higher than other ages.

According to data analysis method, there was significant treatment effect in Group A (Test drug) in Fasting Blood Sugar which had p-value < 0.05 (123.76 ±0.44). Also there was significant treatment effect in parameters such as Systolic blood pressure and Diastolic blood pressure. Systolic blood pressure had p-value < 0.05 (123.76 ±0.44) and Diastolic blood pressure had p-value 0.05 (82.46± 0.91).

In group B (Metformin drug) also there was significant treatment effect in parameter of Fasting blood sugar which had p-value < 0.05 (133.53 ±3.89). Systolic and diastolic blood pressures also had significant treatment effect in group B. Systolic blood pressure had p-value < 0.05 (123.56± 0.49) and Diastolic blood pressure had p-value < 0.05 (92.83 ±4.53).

According to the study, in the test drug group, there was moderately positive correlation in diastole pressure level before treatment and after treatment (0.630). Before treatment and after treatment values of Fasting blood sugar level, Systole blood pressure level were strongly positive correlations (0.910 & 0.749).

In allopathic group, there were moderately positive correlations in before treatment and after treatment values of Fasting blood sugar level (0.359). Systole pressure level before treatment and after treatment, diastole blood pressure level before and after has strongly positive correlations (0.968 & 0.980).

According to the paired sample test in test drug group, all the pairs results are less than 0.05. It means all the p- value of Group A is less than 0.05. It means there is a significant difference between before treatment and after treatment of test drug.

According to paired sample test in allopathic group, pair1 (FBS1 - FBS2) result is less than 0.05. That means the p- value of this pair1 is less than 0.05. That means there is a significant difference in FBS level between before treatment and after treatment

When considering the overall results of this study H1 is rejected as the p value is < 0.05. Thus there is an effect and efficacy of the selected formula from Thalpathe Piliyam in the management of Type 2 Diabetes.

#### 4.2. Conclusions

This study was done to assess effect and efficacy of the selected formula from Thalpathe Piliyam in the management of Type 2 Diabetes. According to the results of the two groups, difference between the before treatment and after treatment of all the parameters of FBS, Systolic and Diastolic blood pressure and Heart rate were reduced. Both groups showed significant changes in those parameters.

According to the results we can conclude that this herbal formulation has an effect in type 2 Diabetes Mellitus. In other hand we can conclude that formulation has hypoglycemic effects with respect to the allopathic medicine without side effects.

#### 4.3. Suggestions

Further study by using larger sample of patients could be

suggested.

This drug could be introduced to the market as a fine powder with a name and proper packaging for type 2 Diabetic patients.

This could be made as a pill for easy use by the extraction of the boiled water of the powder.

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