

Evaluation of the Acute Effect of Daru Haridradi Kashaya in the Management of Blood Glucose Level in Diabetes Mellitus Type 2 – A Pilot Study

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ABSTRACT

Diabetes mellitus is a category of metabolic disorders that are characterized by elevated blood glucose levels resulting from insulin synthesis defects, insulin activity, or both. It is correlated with “*Madhumeha*” describe under the *Prameharoga* in Ayurveda. This scientific study has been conducted to evaluate the acute effect of *Darumaridradikashaya*. *Darumaridra*, *Harithaki*, *Vibhitaki*, *Amalaki*, *Mustha* and *Devadara* are ingredients of it. In clinical study ten were selected and given instruction for same diet, lifestyle and antidiabetic drugs for two weeks and specially advised to have same dinner enriched with fiber and protein before the blood test. Then kept fasting for 10 hours. After first week 120ml of *Darumaridradi Kashayawas* given to the patient while blood drawing for Fasting Blood Sugar (FBS) test. Then Oral Glucose Tolerance Test (OGTT) was done. In their second visit 120ml of Luke warm water was given on behalf of the drug and repeated same procedure. FBS and OGTT levels were separately measured and average levels are considered. Also a non-parametric test called “Wilcoxon Sign Rank Test” was applied for testing the difference between two dependent samples. Since p-values are not less than 0.05, efficacy of the *Darumaridradi Kashaya* has not been shown statistically significance at 5 percent significant level for all the periods of times. The effectiveness of the drug has not been statistically significant for the remaining periods of times. So it can be concluded that the acute action of *Darumaridradi Kashaya* is not effective for reduce blood glucose level for the remaining period of times. *Darumaridradi Kashaya* has chronic effectiveness for Diabetes mellitus. So there may be some issues with the acute effect of it. Therefore, for a perfect conclusion, the study sample should be expand under more numbers of patients and the study setting should be IPD (inward patient department) of the hospital. There is an open field for new researchers to increase this study sample and repeat this procedure.

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KEYWORDS: *Darumaridradi Kashaya*, *Diabetes mellitus*, *Madhumeha*

1. INTRODUCTION

Diabetes mellitus (*Madhumeha*) is a category of metabolic disorders that are characterized by elevated blood glucose levels resulting from insulin synthesis defects, insulin activity, or both. Diabetes may lead to serious complications in multiple organ systems. Type I or Insulin Dependent Diabetes Mellitus (IDDM) and Type II or Non Insulin Dependent Diabetes Mellitus (NIDDM) are two types of diabetes. Whereas type II diabetes mellitus is characterized by a variable degree of insulin resistance, impaired insulin secretion and increased glucose production, but complete or near total insulin deficiency is found in type I. Diabetes is the seventh leading cause of death in both developed and developing countries, and is on the increase. It is the single most severe metabolic disorder in the body, affecting almost every organ system. Chronic hyperglycemia is associated with significant long term sequelae particularly damage or dysfunction of various organs especially the kidneys, eyes, nerves, heart and blood vessels.

While modern anti-diabetic medicines are successful, there are some restrictions as well. Therefore, in order to efficiently manage this disease as a disease, a tremendous effort for solutions from natural remedies is going on all over the world.

In Ayurveda this disorder is under the heading of *PramehaRoga*. There are 20 subtypes of *Prameha* due to the interaction of the three *Doshas* and 10 *Dushyas* (disturbed functioning of the concepts that help the various bodily tissues); some of these subtypes have sweet urine, while some of them have different coloration of the urine, highlighting the inflammatory conditions involved in the metabolic syndrome. *Sthaulya* has close links to this disorder (i.e., obesity). With respect to diabetes mellitus, type 1 diabetes is associated with *Sahaja Prameha* and *JatahPramehi*; type 2 diabetes is correlated with *ApathyanimittajaPrameha*. *Madhumeha* is a subtype of

VatajaPrameha (Prameha with predominance of Vata) that may occur in early childhood as the terminal stage of type 2 diabetes (in which insulin is required) or type 1 diabetes. The latter is identified in Charaka Samhita, one of the classical Ayurvedic texts, as JatahPramehiMadhumehino.

2. METHODOLOGY

The entire work was divided in to main three stages as Conceptual study, Drug Review and Clinical Study.

2.1. Conceptual study:

Data collection by ancient Ayurvedic texts, modern books and previous research papers.

2.2. Drug review:

The references of this *kashayais Ashtangahradaya Chikithsasthana* 12/4 and *Charaka Chikithsasthana*6/26. According to that the ingredients are *Daruharidra*, *Harithaki*, *Vibhitaki*, *Amalaki*, *Mustha* and *Devadara*. The properties of them are as follows.

Ingredient	Scientific name	Properties according to Ayurveda
<i>Daru haridra</i>	<i>Cosciniumpfestratum</i>	Rasa- Tiktha Guna - Ruksha Virya - Ushna
<i>Harithaki</i>	<i>Terminalia chebula</i>	Rasa - five tastes except Salt Astringent dominant Guna - Lagu, Ruksha Virya - Ushana Vipaka - Madhura
<i>Vibhitaki</i>	<i>Terminalia bellerica</i>	Rasa - Kashaya Guna - Lagu,Ruksha Virya - Ushana Vipaka - Madhura
<i>Amalaki</i>	<i>Phyllanthus emblica</i>	Rasa - Five of the six tastes without Salt Guna - Lagu,Ruksha Virya -Sheetha Vipaka - Madhura
<i>Mustha</i>	<i>Cyperus rotundus</i>	Rasa - Tikta,Katu.Kashaya Guna - Lagu,Ruksha Virya -Sheetha Vipaka - Katu Karma - Alleviates Pitta and Kapha
<i>Devadara</i>	<i>Cedrus deodara</i>	Rasa - Tikta,Katu Guna - Lagu,Ruksha Virya - Ushna Vipaka - Katu Karma - Alleviates Pitta and Kapha

2.3. Clinical Study:

2.3.1. Study setting: The patients of either sex suffering from Type 2 Diabetes mellitus from the Diabetic clinic of Provincial Ayurveda Hospital, Pallekale.

2.3.2. Sample size:10 patients

2.3.3. Duration: Period of two weeks

2.3.4. Diagnostic criteria: Patients with high blood glucose level and obtain Ayurveda treatments for control it

2.3.5. Inclusion criteria: Regular patients in the Diabetic clinic presenting with Type 2 Diabetes mellitus were selected irrespective of sex, religion, habits etc. and age between 40 and 70 of years.

2.3.6. Exclusion criteria: Patients with Hyperlipidemia, Hypertension and other chronic diseases like CKD, IHD etc. And patients who disobey the instructions given by the doctor and irregular patients in the diabetic clinic were not selected.

2.3.7. Laboratory investigations: FBS (Fasting blood sugar) level and OGTT (Oral Glucose Tolerance Test) level of each patients were carried out.

2.3.8. Patient assessments: After the first week and after the second week, the effectiveness of the drug and the water were evaluated respectively by the above laboratory investigations.

2.3.9. Instructions:

All the selected patients were instructed for same dietary conditions, lifestyle and administration of antidiabetic drugs for two consecutive weeks.

Specially they were advised to have same dinner at the night before the blood test. For dinner they were advised to get only fiber and protein enriched diet with restriction of lipid and carbohydrate enriched diet.

Then advised them to fasting for 10 hours.

2.3.10. Dosage and Administration of drug:

120ml of *Daruharidradi Kashaya* was given to the patient while blood drawing for FBS test. (The time of blood drawing and the drug intake was exactly same). Then the OGTT was done for each patient. (In here every patient was given 75g of glucose diluted with 100ml of water. After 10 minutes, after 30 minutes of time with the total duration of 2 hours, the blood sugar levels were checked in each and every patient)

In their next visit (after second week of same instructions), they were given 120ml of Luke warm water on behalf of drug while blood drawing for FBS test and OGTT was done.

2.3.11. Data processing and Analysis:

The levels of FBS and OGTT were recorded separately while administration of drug and administration of water.

A Non-parametric test called Wilcoxon Sign Rank test was applied for testing the difference between two dependent samples.

3. RESULTS AND DISCUSSION

In certain ways, the chosen patients vary from each other, such as body constitution, psychics, and behaviors. They mostly complained about rising levels of blood glucose. The amount of blood glucose is susceptible to eating patterns, physical activity, stress and mental factors that are continually subject to change. For the duration of the study, all patients were given the same guidelines for nutritional status, lifestyle and administration of anti-diabetic drugs. The chosen patients had different levels of FBS at the beginning of the study.

The FBS and OGTT levels of all selected patients were calculated separately and the average levels are given below. (Table 1 and Figure 1)

Table 1: Average blood glucose level after giving water and *Daruharidradi Kashaya* by periods of time

Period of Time	Average blood glucose level	
	Water	Drug
FBS	206.3	192.7
After 10 minutes with glucose	215.3	202.8
After 30 minutes	279.2	264.3
After 1 hour	334.8	324.5
After 1 1/2 hour	307.8	315.3
After 2 hour	271.2	275.5

Table 1 consist of the average blood glucose level after giving *Daruharidradi Kashaya* and water separately. Average FBS level soon after giving the drug, during the periods after 10 minutes, 30 minutes and one hour has been lower than measurements taken after giving water. It was other way around during the remaining two periods. This nature has been visually depicted in the Figure 1 as follows.

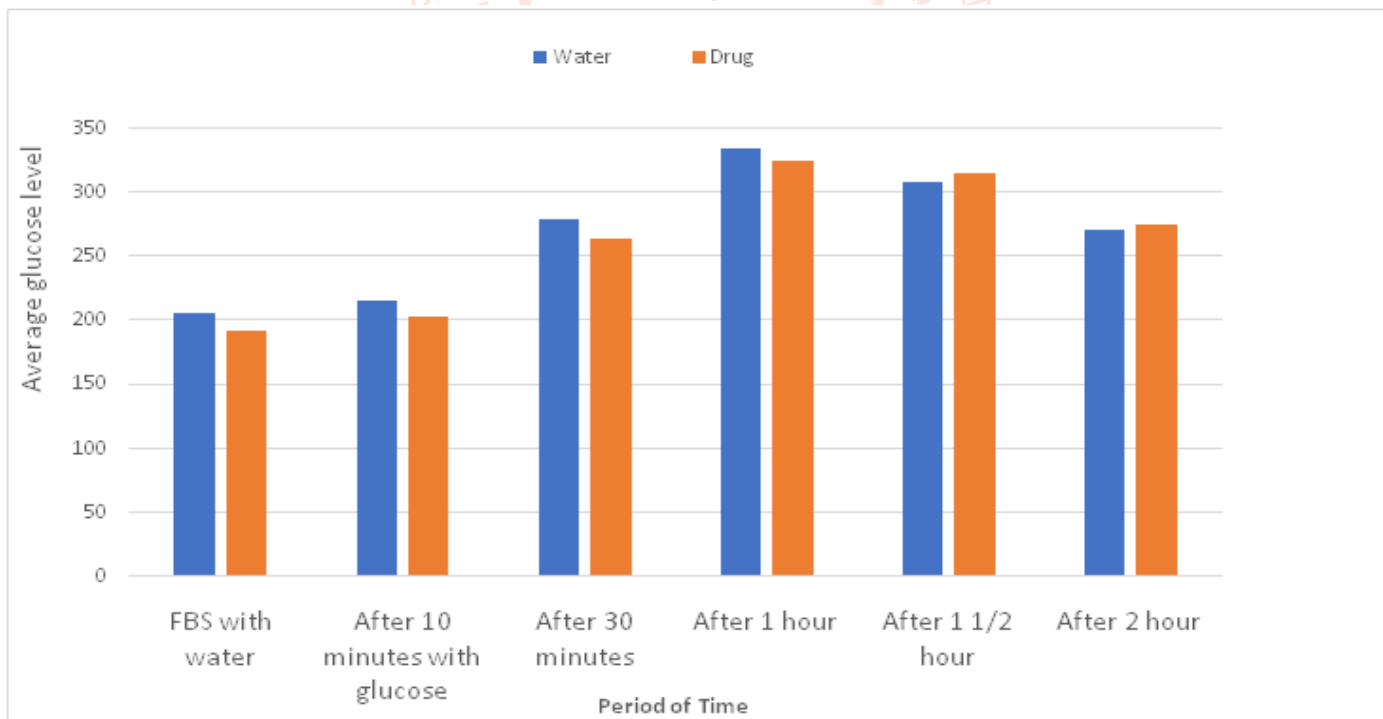


Figure 1: Average blood glucose level after giving water and *Daruharidradi Kashaya* by periods of time

Testing the Efficacy of *Daruharidradi Kashaya*

Since the sample size is small (10 patients) A Non-parametric test called Wilcoxon Sign Rank test was applied for testing the difference between two dependent samples.

Table 2: Application of Wilcoxon Sign Rank test for testing treatment efficacy for each period of time

Period of Time	Wilcoxon Statistic	p - value
FBS	5.0	0.47
After 10 minutes with glucose	9.0	0.417
After 30 minutes	6.0	0.201
After 1 hour	6.0	0.201
After 1 1/2 hour	14.0	0.799
After 2 hour	13.0	0.735

Since p-values are not less than 0.05, efficacy of the *Daruharidradi Kashaya* has not been shown statistically significance at 5 percent significant level for all the periods of times.

4. Conclusion

The findings reported that the acute action of *Daruharidradi Kashaya* is not effective for reduce blood glucose level for the remaining period of times.

Daruharidradi Kashaya which known as *Madhu kasaya* has chronic effectiveness for Diabetes mellitus. So there may be some issues with the acute effect. Therefore, for a perfect conclusion, the study sample should be expand under more numbers of patients and the study setting should be IPD (inward patient department) of the hospital. There is an open field for new researchers to increase this study sample and repeat this procedure.

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