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EVALUATION OF THE ACUTE EFFECT OF NISHAMALAKI CHURNA IN THE MANAGEMENT OF BLOOD GLUCOSE LEVEL IN DIABETES MELLITUS TYPE 2

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Abstract:

Diabetes mellitus refers to the group of diseases that lead to high blood glucose levels due to defects in either insulin secretion or insulin action. It is usually irreversible and, although patients can have a reasonably normal lifestyle, its late complications result in reduced life expectancy and major health costs. Diabetes mellitus is referred to *Madhumeha,* one of the types of *Prameharoga.* Since no known scientific study has been conducted to evaluate the acute effect of *Nishamalakichurna* which is made by using *Curcuma longa* and *Emblicaofficinalis* in equal proportion in the management of blood glucose level. In clinical study Ten were selected and instructed same for dietary habits, lifestyle and administration of antidiabetic drugs for two weeks and specially advised to have same dinner before the blood test and to fasting for 10 hours. After first week 5g of *Nishamalakichurna* diluted in 100ml of Luke warm water was 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 100ml of Luke warm water was given on behalf of the drug and repeated same procedure. The levels of FBS and OGTT 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 0.1, during the period of one and half hours, the drug *NishamalakiChurna* has shown a significant effectiveness at 10% significant level. 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 *Nishamalakichurna*is not effective for reduce blood glucose level for the remaining period of times. Even though there are strong evidence for effectiveness of *Nishamalakichurna* in the management of Diabetes mellitus. Therefore for a perfect conclusion the study sample should be expand under more numbers of patients and the study setting should be IPD (inpatient department) of the hospital.

Key words: *Nishamalakichurna,* Diabetes mellitus, *Madhumeha, Curcuma longa*, *Emblicaofficinalis.*

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I. Introduction

A. Background of the Research

Diabetes mellitus (DM) is not a single disease but a group of metabolic disorders that lead to high blood glucose levels and characterized by hyperglycaemia due to relative insulin deficiency, resistance or both. Insulin is a hormone made by the beta cells of the pancreas which helps to control blood glucose level. Diabetes mellitus is classified as Type 1 DM, Type 2 DM, Other specific type of diabetes mellitus (genetic defects of beta cell function and insulin action, disease of exocrine pancreas, endocrinopathies, drug induced etc.) and Gestational diabetes mellitus. Diabetes develops due to a

diminished production of Insulin is known as Type 1 DM (Insulin Dependent Diabetes Mellitus) and resistance to effects of Insulin is known as Type 2 DM (Non-Insulin Dependent Diabetes Mellitus). Both lead to hyperglycemia, which largely causes the acute signs of diabetes. They are excessive urine production, resulting compensatory thirst and increased fluid intake, blurred vision, unexplained weight loss, lethargy and changes in energy metabolism. Diabetes mellitus is usually irreversible and although patients can have a reasonably normal lifestyle, its late complications result in reduced life expectancy and major health costs. These include macrovascular disease, leading to an increased prevalence of coronary artery disease, peripheral vascular disease and stroke, and microvascular damage causing diabetic retinopathy and nephropathy. Neuropathy is another major complication.

Alarming increase in incidence of Diabetes Mellitus has been observed worldwide and is considered as one of the main threats to human health in the 21st century in both developed and developing nations. It affects more than 120 million people world-wide, and it is estimated that it will affect 370 million by the year 2030. Amongst the two types, Type 2 DM seems to be more prevalent illness. In adults, Type 2 DM accounts for about 90% to 95% of all diagnosed cases of diabetes. Diabetes has remained as the 5th leading cause of death worldwide and has directly resulted in 1.6 million deaths. As diabetes is a worldwide epidemic, and more prevalent in South Asian ethnicity.

In Ayurveda, there are twenty types of *Prameharoga* and Diabetes mellitus is referred to *Madhumeha*which is a *Santarpanajanyavikara*and one among the type of *VatajaPrameha*and grouped under *Astamahagada*. Due to continuous indulgence in *Nidana*, it results in *AparipakwaKapha*and *Meda*which inturn vitiates *kleda*and *meda*further resulting *Doshadushyasamoorchana*. *Kleda*remaining after *Dhatvagnipaka*through the *Mootravahasrotas*and get localized at *Bastimukha*and leading to symptoms like *Prabhootamutra ,Aavilamutra*etc.

Diabetes cannot be cured, but it can be managed. The management should be very particular because the management should include dietary modification, lifestyle modification and Anti-diabetic drugs. Management of diabetes mellitus according to Ayurveda includes *Samshamanachikitsa*and*Samshodanachikitsa*.There are several effective, simple, economical preparation are documented for management of diabetes mellitus in Ayurveda classics.

Among Ayurveda prescribes there is a poly-herbal formulation called *Nishamalakichurna* in the management of diabetes mellitus. It consists of fine powders of *Curcuma longa* (Turmeric) and *Emblicaofficinalis* each in equal proportion. *Nishamalakichurna* is not only commonly used drug among the Ayurveda physicians but also it is very effective drug in the management of Diabetes mellitus. There are several researches based on *Nishamalakichurna* and its anti diabetic action and has strong evidence for chronic effectiveness of *Nishamalakichurna* in the management of Diabetes mellitus. Since no known scientific study has been conducted to evaluate the acute effect of *Nishamalakichurna*andthis study attempts to evaluate the acute effect of *NishamalakiChurn*a in the management of blood glucose level in Diabetes mellitus Type 2.

B. Aims and Objectives

To evaluate the acute effect of *NishamalakiChurna* in the management of blood glucose level in Diabetes mellitus.

II. Research Methodology

The entire work was divided in to main three stages. They are;

1. Conceptual study
2. Drug Review
3. Clinical Study

A.Conceptual study

Data collection by ancient ayurvedic text, modern books and previous research papers.

B. Drug Review

Nishamalaki is one of the effective formulations explained in *AstangahradayaSamhitha* and the concept of *samaskara* has been explained in *Carakasamhitha, Vimanasthana* for the transmigration of *gunas* better therapeutic effect of the drugs. In the present study the *nishamalki* formulation was prepared by mixing the *Nisha* (*Curcuma longa*) and *Amalaki* (*Emblicaofficinalis*) powders in equal proportions.

*Nisha*commonly said as *Haridra*(*Curcuma longa*) belongs to family Zingebearaceae. *Haridra*is a spice derived from the rhizome. It balances the three *dosas*, the hot potency pacifies *vata* and *kaphadoshas*. The action of *Haridra*in classics is mentioned as *Kaphavatashamaka, Shothahara, Vedanasthapaka, Vishaghna, Krumighna, Raktaprasadana, Pramehaghna,*

*Kushthaghna*and*Jwaraghna*It has antibacterial and antifungal activities in addition to promoting wound healing and also useful in correcting the metabolism and useful in urticaria, eosonophilia and allergic rhinitis. The active constituents of*Haridra* (turmeric) are the flavonoid, curcumin, volatile oils, zingebearene, other constituents include sugar, protein and resins.

Amalaki (*Emblicaofficinalis*) belongs to family Euphorbiacae and several parts of the plant are used to treat a variety of diseases, but the most important is the fruit. It has sweet, sour, salt, astringent, pungent, bitter and astringent and has the action like *Tridoshahara, Pramehaghna, Raktapittahara, Rasayana, Vrushya, Garbhasthapana, Medhya, Keshya, Stambhana, Deepana, Rochana, Anulomana, Hrudya, Mutrala, Chakshushya and Dahaprashamana.* The active constituents of *Amalaki* are gallic acid, tannic acid, gum, starch, sugar, and albumin, minerals like calcium, iron, phosphorus and rich in vitamin C, carotene, thiamine, riboflavin and niacin.

C. Clinical Study

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

***Sample size*:** 10 patients

Duration: Period of two weeks

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

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

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

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

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.

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.

Dosage and Administration of drug:

After first week, 5g of *Nishamalakichurna* diluted in 100ml of Luke warm water 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 and three times after 30 minutes of time duration the blood sugar levels were checked in each and every patient)

In their next visit (after second week of same instructions), they were given 100ml of Luke warm water on behalf of drug while blood drawing for FBS test and Oral Glucose Tolerance Test was done.

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.

III. Results and Discussion

The selected patients differ from each other in many ways such as body constitution, physique and habits. They complained mostly of increasing blood glucose level. The blood glucose level is sensitive to dietary habits, physical activities, stress and mental conditions which are subjected to change constantly. All of the patients were instructed same for dietary condition, lifestyle and administration of anti-diabetic drugs for the duration of the research. At the beginning of the research the selected patients had different levels of FBS. FBS level and OGTT level of all selected patients with administration of drug and water were separately measured and average levels are given below. (Table 1and Figure 1).

Table 1: Average glucose level after giving water and drug (*NishamalkiChurna*) by periods of time.

	Average glucose level	
	Water	**Drug**
FBS	164.5	159.2
After 10 minutes with glucose	166.0	157.5
After 30 minutes	238.3	224.7

After 1 hour	278.7	288.0
After 1 1/2 hour	305.2	277.7
After 2 hour	278.5	260.8

According to the table 1, average glucose level after giving the drug, *NishamalkiChurna* during the periods after 1 ½ hours and 2 hours has reduced by considerable amount than the rest of periods. (27.5and17.7 respectively) It was other way around after the period of one hour. This nature has been visually depicted in the Figure 1 as follows.

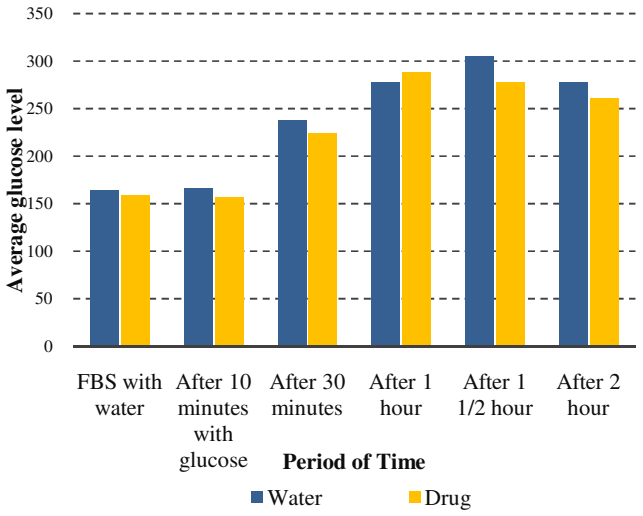

Figure 1: Average glucose level after giving water and drug (*NishamalkiChurna*) by periods of time.

Testing the Efficacy of NishamalkiChurna:

Since the sample size is small (6 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

	Wilcoxon Statistic	**p - value**
FBS	5.5	0.173
After 10 minutes with glucose	4.0	0.104
After 30 minutes	4.5	0.124
After 1 hour	40	0.799
After 1 1/2 hour	3.0	0.071*
After 2 hour	6.0	0.201

** Significant at 10% level of significance*

Since p-values are not less than 0.1, during the period of one and half hours, the drug *NishamalkiChurna* has shown a significant effectiveness at 10 percent significant level. The effectiveness of the drug has not been statistically significant for the remaining periods of times.

IV. Conclusion and Recommandations

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

Nishamalakichurna is not only commonly used drug but also very effective drug and has strong evidence for chronic effectiveness of *Nishamalakichurna* in the management of 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 (inpatient 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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