"THE OBSERVATIONAL STUDY OF PRAMEHAHARI GHANVATI IN THE MANAGEMENT OF PREDIABETES"

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Abstract
Prediabetes and Type 2 Diabetes is a preventable disease through diet, life style, medicine or it is a reversible disease. But once it is established, it become incurable and continues to its progressive stage. Its complication gets progress even if BSL are controlled by medication. When disease is established, it is difficult to treat even though a lot of potent allopathy antidiabetes drugs are available. Many Ayurvedic formulations are described in classics for treatment of Prameha/Madhumeha. It offers natural way to treat the disease and promotes the health. We should use these drugs, diet and life style changes to treat the Prediabetic. In the present clinical study, the emphasis has been made to study and evolve the new drug like Pramehahari Ghanvati in the management of Prediabetes.

Introduction
Prameha is derived from pra+ miha a condition charactrised by excessive outflow of urination. The prevalence of diabetes is swiftly increasing over the globe at an alarming rate. According to the International Federation of Diabetes, 415 million adults around the world are suffering from diabetes, and it is estimated that the numbers will reach around 642 million by 2040.[1]

There were over 72 million case of diabetes in india 2017. Prevalence of diabetes in adult is 8.8% [2] American Diabetes Assosiation and WHO recommended that HbA1C level more than 6.5% could be used to diagnose Diabetes. It is recommended that HbA1C value between 5.7 to 6.5 % are indicative of Prediabetes and have risk of progression to Diabetes.[3]

The prevalence of prediabetes — also known as "impaired glucose tolerance" and a precursor to diabetes — is 1.4 times higher than the diabetes prevalence of 7.3% and 47.3 % people with diabetes are undiagnosed.Today Diabetes Mellitus has become a challenging health problem as rate of conversion from Prediabetic to Diabetic is enormous. So it is important to reduce this rate of conversion.

So observational study of Pramehahari ghanvati in the management Prediabetes, is selected for study according to AYUSH guidelines.

Aims and Objectives
To evaluate the effect of Pramehahari ghanvati in the management of Prediabetes.

Material and Methods

Methodology
    Type of study design:
    Observational clinical study.
    Setting (location):Kayachikitsa OPD & IPD of our Hospital.
    Duration of Study: Duration of Treatment : 3 months
    Total duration of study 2 year.

Method of Selection of study subject:
    A.   Inclusion Criteria:
- Patients between age 18-60 yrs; irrespective of sex and socioeconomic status were selected for the study.
- Newly diagnosed cases of hyperglycaemia with lakshanas of Prameha like Prabhut mootrata, Trishna, Kshudhadhikya, Dourbalya, Dantadinammaladhyatvam, Atinidra with Madhumeha Assessment Tool (As mentioned in case paper) Score more than 10 and patients those having Blood Sugar level fasting more than 126, Postprandial Blood sugar level more than 140 and less than 250 and HbA1C more than or equal to 6.5% were selected for the study[4].{According to Rashtriya Madhumeha Abhiyan , Ministry of Ayush, Government of India}

    B.   Exclusion Criteria:
- IDDM Patients, Juvenile Diabetes, Pregnancy induced Diabetes Mellitus patients were excluded from study.
- Diabetes produced due to other illness like acromegaly, cushing
- Syndrome, pancreatic disorders were excluded from study.
- Patients Suffering from Diabetic Complications like Neuropathy, Retinopathy, Nephropathy, ketoacidosis, Gangrene were excluded from study.
- Immuno deficiency patient, chronic major illness was also excluded from study.

Subjective Parameters:
- Prabhootamootrata (Polyurea)
- Trishna (Polydipsia)
- Kshudhadhikya (Polyphagia)
- Dourbalya (General Weakness)
- DantadinamMaladyatvam(Increased coating /secretions in eyes,ears,nose,mouth,teeth tongue)
- Atinidra (Hypersomnia)

Objective Parameters
- Blood Sugar Level
- Urine Sugar
- Turbidity of Urine.

Drug : Pramehahari ghanvati

Sr. No	DRAVY	LATIN NAME	QUANTITY	REFERENCE
1	Jambu	Sygigium cumini Skeels	1 part	Mutra sangrahniya
2	Amra	Mangifera Indica	1 part	Mutra sangrahniya
3	Plaksha	Ficus lacor Buch-Ham	1 part	Mutra sangrahniya
4	Nagrodha	Ficus bengelensis Linn	1 part	Mutra sangrahniya
5	Kapeetana	Albizzia lebbeck Benth	1 part	Mutra sangrahniya

6	Udumbar	Ficus racemosa Linn	1 part	Mutra sangrahniya
7	Ashvattha	Ficus religiosa Linn	1 part	Mutra sangrahniya
8	Bhallataka	Semicarpous Anacaardium	1 part	Mutra sangrahniya
9	Ashmantak	Ficus rumphi	1 part	Mutra sangrahniya
10	Somvalka	Acacia Catechu Willd	1 part	Mutra sangrahniya
11	Haridra	Curcuma longa	1 part	A.H. U. 40 Shreshta dravya
12	Amalaki	Phyllanthus emblica	1 part	A.H. U. 40 Shreshta dravya
13	Shilajit	Asphaltum punjabianum	1 part	A.H. U. 40 Shreshta dravya in Bastivikar
14	Triphala	Phyllanthus emblica Terminalia Chebulla Terminalia Bellerica	1 part	A.H. Chi. 12 Sarvamehahar kashaya
15	Musta	Cyperus rotundus	1 part	A.H. Chi. 12 Sarvamehahar kashaya
16	Devdaru	Cedrus deodara	1 part	A.H. Chi. 12 Sarvamehahar kashaya
17	Daruharidra	Berberis aristata	1 part	A.H. Chi. 12 Sarvamehahar kashaya
18	Mamejava	Enicostemma Littorale	1 part	BhavaPrakash
19	Bijak/ Asana	Pterocarpus marsupium	1 part	BhavaPrakash
20	Meshshrungi	Gymnema Sylvestris	1 part	BhavaPrakash
21	Ashwagandha	Withania somnifera	1 part	
22	Guduchi	Tinospora cordifolia	1 part	

Observation and results
In the age group of 40-60 yrs, maximum patients (86.66 %) were observed. Maximum patients (63 %) were male.Majority of the patients (60 %) was consuming Non Vegetarian diet. Patients was from low as well as high economy class.

Results

Sr. No.	Symptom	Compare days	Wilcoxon Signed Rank W	P value
1	Prabhutmutrata	1st & 90th	-5.317[a]	P < 0.001
2	Trishna	1st & 90th	-6.811[a]	P < 0.001
3	Kshudhadhikya	1st & 90th	-6.315[a]	P < 0.001
4	Dourbalya	1st & 90th	-5.357[a]	P < 0.001
5	Atinidra	1st & 90th	-6.317[a]	P < 0.001
6	Dantadina maladya	1st & 90th	-6.051[a]	0.002
			T cal.	**P value**
7	BSL fasting	1st & 90th	16.81	P < 0.001
8	BSL pp	1st & 90th	5.76	P < 0.001
9	Urin sugar	1st & 90th	5.87	P < 0.001

Discussion

The statistical analysis has done by using wilcoxon rank test and paired t test. In this study results was observed as Prabhutmutrata 71.1 %, Trishna 66.3 %, Kshudhadhikya 65.8 %, Dourbalya 68.9 % , Atinidra 67.5 % and Dantadina malady 73.4 %.

It is evident that the patients who followed regimen of Pramehahari ghanvati had shown statistically significant results.

Conclusion
Pramehahari ghanvati is effective in the management of Prediabetes

References
1. *International Federation of Diabetes.*
2. *Ref: India - International Diabetes Federation.* https://www.idf.org/our-network/regions-members/south-east-asia/.../94-india.html
3. *American Diabetes Assosiation and WHO.*
4. *According to Rashtriya Madhumeha Abhiyan , Ministry of Ayush Government of India*