



CLINICAL STUDY TO EVALUATE EFFICACY OF NISHA AMALAKI CHURNA IN NEWLY DIAGNOSED PRAMEHA TYPE II DIABETES MELLITUS.

Dr. Neena Damle*

M.D. Kayachikitsa PhD Scholar, Asst. Professor Kayachikitsa, Dept. D.Y. Patil University School of Ayurveda, Nerul Navi Mumbai, India. *Corresponding Author

ABSTRACT

During the last few years India have maximum increase of Type II diabetes mellitus. The prevalence of type 2 diabetes mellitus is 2.4% in rural population and 11.6% in urban population[1]. In this study total 10 Subjects of newly diagnosed type II Diabetes Mellitus, who fulfilled below criteria were selected from D.Y. Patil Ayurvedic Hospital Nerul Navi Mumbai OPD No.1. a) HbA1c level more than 6.5% b) Fasting blood Sugar level (FBS) more than 126 mg/dL (7 mmol/L) c) 2-hour Post Prandial Blood Sugar level (PPBS) more than 200 mg/dL (11.1 mmol/L). All 10 subjects treated with Nisha Amalaki Churna 3gms BD one hour before breakfast and before dinner with warm water for three months. Data of subjective parameters and physical examination of subjects was recorded in CRF during three visits 30 days apart. For Statistical Analysis Wilcoxon matched-pairs signed-ranks test was used to assess Subjective parameters and Paired t-Test was used to compare Fasting Blood Sugar level, two hour post prandial blood sugar levels and HbA1C levels BT and AT. The study showed significant results in most of the subjective parameters at the level of significance ($P < 0.05$). Nisha Amalaki Churna reduced Fasting blood sugar levels and post Prandial blood sugar levels significantly at level of significance $p < 0.01$. Nisha Amalaki Churna also reduced HbA1C levels significantly at level of significance $p < 0.01$. The Ayurvedic mixture Nisha Amalaki Churna was significantly effective in newly diagnosed Type II Diabetes Mellitus subjects.

KEYWORDS : Nisha Amalaki churna, type II Diabetes Mellitus, Prameha, Ayurvedic herbs**INTRODUCTION**

Diabetes mellitus is a clinical syndrome characterized by hyperglycaemia caused by an absolute or relative deficiency of insulin and insulin resistance. Lack of insulin, whether absolute or relative, affects the metabolism of carbohydrates. Type II diabetes Mellitus has become a global epidemic. Modern medicines, despite offering a variety of effective treatment options, can have several adverse effects^{[4][5][6]}.

Type I diabetes (insulin dependent) is caused due to insulin insufficiency because of lack of functional beta cells. Patients suffering from this are therefore totally dependent on exogenous source of insulin while patients suffering from Type II diabetes can be treated with dietary changes, exercise and medication. Type II diabetes is the more common form of diabetes constituting 90% of the diabetic population. Prevalence of diabetes is increasing in all countries, especially in India. As per W.H.O global prevalence of Diabetes in adult population in 2016 was 5.6% & it is predicted to be increased in next decade. Mostly this number is likely to increase to 57.2 million by the year 2025. So there is need to study in this area.

Patients with Diabetes Mellitus frequently use alternative medications including Ayurvedic medications. Prameha is described in ancient Ayurvedic literature [Granthas] Symptoms and causative factors described in ancient Ayurvedic texts are similar to Diabetes Mellitus. Many drug compositions are described in ancient Ayurvedic literature. World Health Organization (WHO) recommendations on the use of alternative medicines for treating Diabetes Mellitus provide an impetus for research in this area.

According to new guidelines before putting the newly diagnose type II Diabetes Mellitus patient on Metformin doctor should advice diet and lifestyle changes^[7]. But clinically many times it is observed that due to lack of time, busy work schedule, habitual laziness many patients are unable to follow suggested lifestyle changes. So during this period we can give Ayurvedic medicinal composition along with lifestyle modifications, exercise and diet control which can give additional benefits for patient to control blood sugar levels in natural ways^[2]. Many animal studies are carried on Nisha Amalaki Churna around the globe. So I want to do pilot study in this field to evaluate efficacy of and Nisha Amalaki churna in Prameha TYPE II Diabetes Mellitus.

AIM AND OBJECTIVES:**Aim:**

To Study efficacy of Nisha Amalaki Churna in newly diagnosed Prameha Type II Diabetes Mellitus.

OBJECTIVES:**Primary Objective:**

To Assess and compare changes in BSL before treatment and after treatment.

To Assess changes in HbA1c before treatment and after treatment.

Secondary Objective:

To assess and compare changes in clinical symptoms of Diabetes like polyuria (*Prabhutmutrata*), polydipsia (*ati pipasa*), polyphagia, and fatigue before treatment and after treatment.

MATERIALS & METHODS

Total 10 Subjects who fulfilled inclusion Criteria selected from D.Y. Patil Ayurvedic Hospital Nerul Navi Mumbai OPD No.1 and treated with Nisha Amalaki churna^[8] 3 gms BD Before breakfast and before dinner with warm water for three months. Ayurvedic Diet^[3] suggested in all patients and compliance is recorded in three visits v1, v2, v3 each visit was 30 days apart.

Contains of Nisha Amalaki Churna and its Rasa Guna Virya, Vipaka

Sr No	Name of Drug	Latin Name	Rasa	Guna	Virya	Vipaka
1	Nisha	Curcuma longa	Tikta, Katu	Ruksha, Laghu	Ushna	Katu
2	Amalaki	Emblica officinalis	All five Rasa except Lavana	Guru, Ruksha, Shita	Shita	Madhur

Nisha Amalaki^[8] churna is a simple combination of two Ayurvedic herbs – dried fruits of Amla and Rhizome or dried underground stem [kanda] of turmeric both mixed in equal parts in the form of fine powder.

INCLUSION / EXCLUSION CRITERIA**Inclusion Criteria:-**

1. Inclusion of patients was done according to American medical Association criteria for diagnosis of Diabetes. i.e. a) HbA1c level of 6.5% or higher
b) A fasting blood Sugar level (FBS) of 126 mg/dL (7 mmol/L) or higher; (fasting is defined as no caloric intake for at least 8 hours.)
c) A 2-hour Blood Sugar level (PPBS) of 200 mg/dL (11.1 mmol/L) or higher. Subjects who were fulfilling above criteria selected for this study^[15].
2. Subjects in the age group of 20 to 70 years, both inclusive.
3. Both Male and Female (non-pregnant, non-lactating) gender Subjects are included in the study.
4. Written consent showing willingness to participate in the study.

Exclusion Criteria:

1. Known cases of TYPE-1 Diabetes Mellitus.
2. Chronic type II Diabetes Mellitus patients.
3. Subjects having high Fasting blood sugar > 300 mg/dl not selected for study
4. having high Post Prandial blood sugar > 400 mg/dl were not selected

for study

- Subjects having complications of Diabetes like Ketoacidosis, Nephropathy, Neuropathy, Retinopathy, and Diabetic wounds.
- Known cases of Severe/Chronic hepatic or renal disease.
- Known subject of any active malignancy
- Subjects giving history of significant cardiovascular event < 12 weeks prior to study
- Subjects with known Chronic Infectious Disease, such as active Tuberculosis, Hepatitis B or C, or HIV.

Study Type-

Single arm, Prospective, Interventional, clinical study.

Sample size – 10 subjects

Assessment Criteria and Data Recording

Compliance of drugs recorded in three visits v1, v2, v3 each visit was 30 days apart.

Fasting Blood Sugar, Post Prandial Blood Sugar and HbA1c investigations done pre and post clinical study.

Assessment of clinical symptoms done during every visit.

General physical examination recorded in CRF during every visit.

Following Criteria used for assessment of clinical symptoms of type II DM

Subjective Assessment-

The clinical symptoms marked in four grades-

0 – Absent, 1 – Mild, 2 – Moderate, 3 – Severe

1. Polyuria: Grade of Frequency of urination

0 - 5 - 6 times in 24 hours

1 - 8 - 9 times in 24 hours

2 - 10 - 11 times in 24 hours

3 - 13 or more times in 24 hours.

2. Polydipsia: Grade of Daily water consumption

0 < 6 glasses

1 - 7 - 8 glasses

2 - 9 - 10 glasses

3 - More than 12 glasses.

3. Polyphagia: Grade of Daily Diet

0 - 2 Meals (including Breakfast)

1 - 3 Meals (including Breakfast)

2 - 4 Meals (including Breakfast)

3 - >4 Meals (including Breakfast)

4. Fatigue: Grade of Fatigue over the past week

0 No fatigue feeling throughout the week.

1 Fatigue feeling on 1-2 days during the week

2 Fatigue feeling on 3-5 days during the week

3 Fatigue feeling throughout the week

Statistical Analysis:

Wilcoxon matched-pairs signed-ranks test used to assess Subjective parameters

Sr. No.	Characteristic	W	n	p	Inference
1	Polyuria	28.00	10	<0.0156	Significant
2	Polydypsia	36.00	10	<0.0078	Very Significant
3	Polyphagia	21.00	10	<0.0313	Significant
4	Fatigue	36.00	10	<0.007	Very Significant

Paired t-Test is used to compare Blood Sugar levels and HbA1c levels BT and AT

Sr. No.	Parameters	Mean	SD	SEM	t	p	Inference	
1	FBS	BT	154.1	23.096	7.304	2.601	<0.01	significant
		AT	148	21.853	6.911			
2	PPBS	BT	234.9	32.029	10.129	3.285	<0.01	significant
		AT	217	24.984	7.901			
3	HbA1c	BT	7.29	0.6045	0.1912	4.392	<0.01	Very significant
		AT	7.14	0.6501	0.2056			

DISCUSSION

Nisha Amalaki churna is a simple combination of two Ayurvedic herbs – Amla and turmeric in equal parts. Amalaki is excellent anti oxidant and has rejuvenation properties. It boosts body immunity, reduces stress levels, and improves glucose metabolism. According to Ayurveda Amalaki - Emblica officinalis is having amla rasa

predominant all five Rasas except Lavana rasa. It is having Guru Ruksha and Shita properties Madhura vipaka and Shita virya. It is tridosahara and doing anulomana. Haridra curcuma longa is having Laghu Ruksha properties, Tikta, Katu Rasa, Katu Vipaka and Ushna virya. Due to these properties it is acting as kaphaghna, kledahara and improves glucose metabolism.

Combination of Nisha Amalaki Churna formulation has tridosahara property but specifically Kaphahara property. Its acts on vitiated Kapha, Meda and Kleda, It has capacity to improve tone of saptadhatu and reduces Dhatushaithilya. Due to its Deepan and Pachan properties, Nisha Amalaki Churna works on Jatharagni and Dhatwagni, which reduces the Ama and kleda present in the body. It improves Dhatwagni which helps to improve disturbed metabolism. Nisha Amalaki Churna having Deepan, Pachan and Anuloman properties. By Deepan, Pachan, Anuloman properties it works on srotodushiti and glucose metabolism. Due to its Ruksha Guna this kalpa is doing Kleda Shoshana which is useful in Samprapti bhanga of Prameha.

CONCLUSION

Total 10 Subjects who fulfilled inclusion criteria selected from Kayachikitsa OPD of D Y Patil School of Ayurveda Nerul Navi Mumbai and Nisha Amalaki Churna 3gm BD given before breakfast and before dinner. After three months all subjects showed significant improvement in subjective parameters like polyuria, polydipsia, polyphagia and fatigue at level of significance $p < 0.05$. Nisha Amalaki Churna also showed significant improvement in Fasting Blood Sugar levels, post prandial Blood Sugar levels and HbA1c levels at level of significance $p < 0.01$. So it is concluded that there is effect of Nisha Amalaki Churna in newly diagnosed Prameha type II Diabetes Mellitus. Nisha Amalaki Churna is cost effective and safe mixture of Ayurvedic herbs that can be administered in newly diagnosed type II Diabetes Mellitus patients without any adverse drug reaction (ADR).

REFERENCES

- <https://pubmed.ncbi.nlm.nih.gov/12674166/#>.
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2275761/#!po=0.490196>
- Charaka Samhita with introduction by Shri Satya Narayana Shastri with Vidyotini commentary part-II Published by Chaukhambha Bharati Academy, Chikitsashtana, Chapter no.6, page no.236, Shloka no.20-21.
- <https://www.everydayhealth.com/sulfonylureas/guide/>
- <https://www.healthline.com/health/diabetes/metformin-side-effects#serious-side-effects>.
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2494623/>
- <https://www.medpagetoday.com/primarycare/diabetes/31038>
- Charaka Samhita with introduction by Shri Satya Narayana Shastri with Vidyotini commentary part-II Published by Chaukhambha Bharati Academy, Chikitsashtana, Chapter no.6, page no.237, Shloka no.26
- Davidson's Principles and Practice of Medicine, edited by Nicholas A Boon et. al, Diabetes Churchill Mellitus, published by Livingstone, 20th edition, chapt no.21, page no - 843.
- Charak Samhita' of Agnivesh, revised by Charak and Driddhabala by Pt.KasinathaSastri, Dr. GorakhaNathaChaturvedi Part-I, NidanShtana, Chapter-4, Shloka no-40, Page no-640.
- Vagbhatas Astanga Hridayam, Translated by prof. K. R. SrikanthaMurthy, volume-II, Edition fifth, 2003, Nidanasthana, chapter-10, shloka no-23, page no-96.
- Chakradatta of Shri Chakrapanidatta by Indradeva Tripathi, editor Prof. Ramanath Dwivedi, published by Chaukhambha Sanskrit Bhawan, Prameha Chikitsa page no 217 Prameha chikitsa shloka no.21.
- R H Singh. Charak Samhita of Agnivesha. Chawkhambha Surabharati Prakashana, Varanasi, 1st edition, reprint, 2011; 2: 1042.
- Narayanram. Sushrut Samhita. Chawkhambha Surabharati Prakashana, Varanasi, 2014; 452.
- <https://emedicine.medscape.com/article/2172154-overview#a1>