



Case Study

***NISHA-AMALAKI* IN UNCONTROLLED TYPE 2 DIABETES MELLITUS- A CASE REPORT**

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ABSTRACT

During the last few years India has maximum increase of Type 2 diabetes mellitus. Type 2 diabetes is characterized by high blood sugar, insulin resistance, and relative lack of insulin. There are approximate 72.96 million cases of diabetes mellitus in adult population of India. In modern era single anti-diabetic drug is not sufficient for glucose control. These days multidrug therapy is building its popularity for maintaining glycaemic levels. A 59-year-old female presented with known case of Type 2 diabetes with evidence of polyuria, itching over extremities, and fatigue was poorly controlled despite a drug regimen consisting of oral metformin and glimepiride. Her Blood Sugar level was constantly around 200 mg/dl in spite of having modern medicine with adjusted doses. She has administered *Nisha-Amalaki Churna* with warm water early in the morning along with standard conventional treatment for 8 weeks. The effect of therapy was evaluated at the interval of 4 weeks for 8 weeks which is done on the basis of objective parameters. Objective parameters were fasting and post prandial Blood Sugar Level. *Nisha-Amalaki churna* has reduced Blood Sugar Level to normal. It also reduced the dose of conventional drug which may cause side effects with long term use. There is a need for combined multidisciplinary treatment to maintain suggested glycaemic control. Thus, the present case study is to understand the significant effect of *Nisha-Amalaki* as an adjuvant to standard conventional treatment in chronic uncontrolled type 2 Diabetes Mellitus.

INTRODUCTION

The World Health Organisation (WHO) estimated the global prevalence of diabetes among adults over 18 years of age as 8.5% in 2014.^[1] The global diabetes prevalence in 2019 is estimated to be 9.3% (463 million people), rising to 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045. The prevalence is higher in high-income (10.4%) than low-income countries (4.0%) and in urban (10.8%) than rural (7.2%) areas. One in two (50.1%) people living with diabetes do not know that they have diabetes.^[2] Indians have propensity for earlier onset of type 2 diabetes due to their phenotypes which leads to an augmented risk of developing macrovascular and microvascular hitches.^[3]

Diabetes mellitus is a clinical syndrome characterized by hyperglycaemia caused by an absolute or relative deficiency of insulin and insulin resistance. Lack of insulin, affects the metabolism of carbohydrates. Type 2 diabetes mellitus has been affecting a very large number of people. Modern medicines, in spite of having a variety of effective treatment options, can have several adverse effects. Type 1 diabetes (insulin dependent) is caused due to insulin insufficiency due to lack of functional beta cells. Patients suffering from this are totally dependent on exogenous source of insulin while patients suffering from Type 2 diabetes can be treated with dietary changes, exercise and medication. Type 2 diabetes is the more common form of diabetes constituting 90% of the diabetic population. Prevalence of diabetes is increasing in all countries day by day, 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 a

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detailed investigation and analysis is essential 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.^[4]

Many drug compositions are described in ancient Ayurvedic literature. World Health Organization (WHO) recommends the use of alternative medicines for treating Diabetes Mellitus which can 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. 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. Many animal studies are carried on *Nisha Amalaki Churna* around the globe.^[5,6] *Nisha-amalaki* is combination of *Haridra* (*Curcuma longa* L) and *Amalaki* (*Emblica officinalis*. Gareth). In Ayurvedic classics, it is recommended in the management of all types of *Prameha* (Diabetes Mellitus).^[7]

Haridra (*Curcuma longa* L) is the drug of choice in *Prameha*. Its rhizomes have been reported to own anti-diabetic properties in trial animal models. Researchers testified that the active ingredient curcumin is liable for antidiabetic action.^[8] *Amalaki* (*Emblica officinalis*. Gareth) is one among the best single drugs indicated for *Prameha*.^[9] Ellagic acid in *Emblica officinalis* has anti-diabetic bustle through the action on β -cells of pancreas that excites insulin secretion and declines glucose intolerance, immunostaining of pancreas showed that *Emblica officinalis* enlarged Beta cell size and number in diabetic rats. It also stirred glucose stimulated insulin secretion from isolated islets and decreased glucose intolerance in diabetic rats.^[10] Studies have shown that fruits of *Emblica officinalis*, some of its important constituents (including gallotannin, gallic acid, corilagin and ellagic acid) possess anti-diabetic effects by their antioxidant and free radical scavenging assets. It has also been reported to prevent/reduce hyperglycaemia, diabetic nephropathy, cataractogenesis, cardiac complications, neuropathy and protein wasting.^[11]

So, here a case with chronic uncontrolled Type II DM is presented which evaluates the efficacy of *Nisha Amalaki churna* in Type II Diabetes Mellitus. The study aimed to evaluate the efficacy of *Nisha Amalaki churna* in chronic uncontrolled Type II DM. The primary objective of the study was to assess and

compare changes in BSL fasting and Post Prandial after the treatment. The secondary objective was to assess changes in clinical symptoms of DM like polyuria (*Prabhutnutrata*), polydipsia (*Ati pipasa*), polyphagia and fatigue after the treatment.

Related work

1. Antidiabetic Effect on Hyperglycemia: *Nisha Amalaki* (Mixture of Powder of *Haridra* and *Amalaki* in equal proportion), in animal dose of 0.9 g/kg wt of rats, showed significant lowering of plasma glucose and glycated hemoglobin in diabetic rats ($p < 0.001$ when compare with Diabetic Control) as that of Glyburide (36 mg/kg) and Troglitazone (4 mg/kg).^[5,6]
2. *Nishamalaki* is group of various combination formulations of *Haridra* and *Amalaki*. It is effective in the clinical management as well as prevention of complications of *Madhumeha*, *Prameha* and Diabetes.^[12]
3. *Nisha Amalaki Churna* 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.^[13]

Case Report

A 59-year-old female with a history of chronic uncontrolled DM presented with frequent urination at night and itching over extremities and soles. She also experiences burning, redness after itching over the affected area. The patient denied a history of hypertension, vomiting, diarrhoea, or previous surgeries. At that time, the patient was on the tab. Glador M1 forte which contains Glimpiride 1mg and Metformine Hydrochloride 1000mg (in prolonged released form). Clinical examination revealed a bodyweight of 75kg, Pulse rate of 86/min, Blood pressure measures 130/84mm of Hg, Respiratory Rate of 20/min.

History of the present illness

The patient has diagnosed with DM in April 2018. At that time, she went to the hospital for complaints of fever, fatigue, urinary disorders, and in a routine check-up, it reveals a high Blood sugar level. She has been taking allopathic medicine for DM for more than 3 years. Even though she was having adjusted doses of the drug, her Blood Sugar Level remains high.

Complaints due to present illness

She was experiencing complaints of frequent micturition at night, increased thirst, fatigue, and

itching over extremities. Also, her son wants her to take Ayurveda medicine for controlling Blood Sugar Levels.

Other existing illness/Comorbidities

The patient was not having any other existing illness or any systemic disease.

Family History

She was not having a family history of DM.

Occupational Details

She is a housewife and has not done any job.

Table 1: General Physical Examination

Appearance	Ill look
Consciousness	Alert
Built	Hypersthenic
Gait	Slow gait
Pallor	Absent
Icterus	Absent
Clubbing	Absent
Cyanosis	Absent
Lymphadenopathy	Absent
Oedema	Swollen Feet and Ankles

Table 2: Systemic Examination

CNS	Higher Mental Functions –Intact, Orientation to time, place, person –intact, Motor and sensory system-intact
RS	Trachea centrally placed, Chest bilaterally symmetrical, Air entry bilaterally equal, NVBS heard
CVS	S1S2 heard
GIT	Tongue-Pale, smooth texture, no dental caries, P/A –soft, no palpable mass

Table 3: Vitals

Pulse	78 bpm
RR	20/min
BP	130/90
Temp	98.4 F

Table 4: Ashthavidha Pariksha

Nadi	Madhyam
Mutra	Ishat peet varna
Mala	Baddha
Jihwa	Saam
Shabda	Prakrut
Sparsha	Prakrut
Druk	Prakrut
Akruti	Sthula

Table 5: Dashavidha Pariksha

Prakriti	Kapha-pittaja
Vikriti	Kapha pradhana tridosha
Sara	Madhyama
Samhanan	Madhyama
Satmya	Madhyama

<i>Satva</i>	<i>Pravara</i>
<i>Aahara Shakti</i>	<i>Abhyavaharana Shakti- Avara Jarana Shakti Avara</i>
<i>Vyayam Shakti</i>	<i>Avara</i>
<i>Pramana</i>	<i>Sthula</i>
<i>Vaya</i>	<i>Vruddha (near to 60years)</i>

Table 6: Data from previous diagnostic test

Date	BSL Fasting (mg/dl)	BSL PP (mg/dl)	HBA1C/ USL
7/04/2018	213.0	294	USL=+++
18/02/2019	186	265	
18/3/2019	160	232	
30/07/2019	148	228	
15/09/2019	207 BSL (Random)		HBA1C-9.29%
26/10/2019	193	234	USL- +++++
15/12/2019	124	188	
14/03/2020	141	186	
15/01/2021	202	298	
08/04/2021	201	279	
08/06/2021	210	295	

Diagnosis

She is known case of Diabetes Mellitus Type II.

Treatment Plan

The patient asked to start *Nisha-Amalaki churna* 5gm along with warm water early morning. She started with this treatment on 10th June 2021 and continued for 4 weeks with follow up of next 4 weeks.

Table 7: Contains of Nisha Amalaki Churna and its Rasa Guna Virya, Vipaka

S. No.	Name of the drug	Latin name	Rasa	Guna	Virya	Vipaka
1.	<i>Nisha</i>	<i>Curcuma longa</i>	<i>Tikta, Katu</i>	<i>Ruksha, Laghu</i>	<i>Ushna</i>	<i>Katu</i>
2.	<i>Amalaki</i>	<i>Emblica officinalis</i>	All five Rasa except <i>Lavana</i>	<i>Guru, Ruksha, Shita</i>	<i>Shita</i>	<i>Madhur</i>

Nisha Amalaki^[14] *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.

Nishamalaki possess anti-hyperglycemic, anti-diabetic, insulinomimetic, α -Amylase inhibitory and α -glucosidase inhibitory, antioxidant properties. It improves insulin sensitivity, increases glucose uptake by skeletal muscles and is beneficial in the management of *Madhumeha*, *Prameha* and Diabetes as well as prevention of its complications microvascular- like diabetic nephropathy, neuropathy, retinopathy, gastropathy and macrovascular like atherosclerosis^[12]

Follow-up

The patient visited her modern medicine consultant after 4 weeks and her dose of the conventional drug was reduced to half and switch over to Tab. Gerner 0.5 (combination of Metformin 500mg and Glimepiride 0.5mg). She continues *Nisha-Amalaki* for the next 4 weeks and again recorded her BSL fasting and postprandial report on 28th July 2021.

Table 8: Results After treatment

Date	BSL Fasting(mg/dl)	BSL Post Prandial (mg/dl)	HbA1C
07/07/2021	109	150	
12/07/2021			6%
28/07/2021	95	135	

Table 9: Before and After Treatment BSL value

Before Treatment BSL 08/06/2021	After Treatment BSL 28/07/2021
BSL fasting - 210 mg/dl	BSL fasting - 95 mg/dl
BSL post prandial- 295 mg/dl	BSL post prandial - 135 mg/dl

After treating with *Nisha-Amalaki churna* for one month, she improved symptomatically. Clinical symptoms reduced from moderate to mild. Her grade of frequency of urination (polyuria) and daily water consumption (polydipsia) reduced from 2 to 1. Also, the grade of daily diet remains the same. The level of grade of fatigue over the past week declined from 1 to 0. Her report of BSL fasting as 109 mg/dl and BSL Post Prandial as 150mg/dl was on 7th July 2021. HBA1C report on 12th July 2021 was 6%. As treatment continued for next month. Her report on 28th July 2021 was BSL fasting as 95mg/dl and BSL Postprandial as 135mg/dl.

DISSCUSSION

Though the patient is in old age and more likely to prone for uncontrolled diabetes, this present study shows significant control over blood sugar level with simple herbs. As we know uncontrolled diabetes leads to various complications like heart and blood vessel diseases, nerve damage, diabetic retinopathy, diabetic nephropathy, etc., adding these two herbs can give remarkable changes in the result.

Nisha Amalaki churna is a combination of two Ayurvedic herbs-*Emblica officinalis* and *Curcuma longa* 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 *Tridosahar* 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 *Saptadhatus* 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. By *Deepan, Pachan, Anuloman* properties it works on *Srotodushti* and glucose metabolism. Due to its *Ruksha Guna* this *Kalpa* is doing *Kleda Shoshana* which is useful in *Samprapti bhanga* of *Prameha. Nisha Amalaki Churna* showed statistically significant results in objective and

subjective parameters at the level of significance ($P<0.05$).

CONCLUSION

Nisha Amalaki Churna showed significant improvement in this case study of uncontrolled DM. *Nisha Amalaki Churna* also showed significant improvement in fasting blood sugar levels, post prandial blood sugar levels and HBA1c levels. So it is concluded that there is the significant effect of *Nisha Amalaki Churna* as an adjuvant drug in chronic uncontrolled type II Diabetes Mellitus. It helps to reduce the dosage of modern medicine which may cause side-effects on long term use. *Nisha Amalaki Churna* is cost effective and safe mixture of Ayurvedic herbs that can be administered in diagnosed type II Diabetes Mellitus patients without any Adverse Drug Reaction (ADR).

Since this is a single case study, further study is needed to observe the effect of above treatment on more number of patients and for longer duration to remark other benefits.

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