

Study the efficacy of herbal formulation and conventional medicine in the management of Type-2 Diabetes Mellitus- A Case Series

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ABSTRACT

Type-2 Diabetes Mellitus is a serious, chronic condition, considering how disrupted homeostatic control of blood glucose levels leads to the various clinical manifestations of diabetes and the potential consequences particularly if the disease goes undetected or is poorly controlled. The development of diabetes is potentially avoidable by living a healthy lifestyle, but some non-modifiable factors may contribute to its development. Here is a case series of a 10 patients, divided into 2 groups of 5 patients each, visited to the OPD with complaints of burning sensation in soles of both feet. On blood investigation, it was found that the patient is suffering from Type-2 Diabetes Mellitus. One group was administered with the herbal formulation, Nisha-Amalaki Churna and the other group was treated with the conventional medicine, Tablet Metformin. Type 2 Diabetes Mellitus may be managed through diet and exercise in the early stages of the condition, with pharmacological intervention required as the condition progresses. Nisha-Amalaki Churna is the drug of choice for the management of Type-2 Diabetes Mellitus according to classical Samhitas and Tablet Metformin exemplifies an efficacious oral glucose lowering agent. The main aim of the case series is to study the efficacy of herbal formulation and conventional medicine in the management of Type-2 Diabetes Mellitus. Therefore Nisha-Amalaki Churna and Tablet Metformin were selected for the present case series in order to study the efficacy of herbal as well as the conventional mode of treatment in the management of Type-2 Diabetes Mellitus.

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INTRODUCTION

The hallmark of Type 2 Diabetes Mellitus (T2DM) is a level of blood sugar that is consistently high or that rises after a meal that contains carbohydrates (1). Unless there has been beta cell loss, most people with T2DM have high insulin levels (fasting and/or post glucose consumption), in contrast to Type 1 Diabetes which is characterised by a lack of insulin (2). Although there is no insulin deficit, the reason why the blood glucose remains raised has been referred to as "insulin resistance" (3,4). Experts have examined intracellular and molecular pathways in great depth in an effort to understand the aetiology of insulin resistance, attributing the reason to fatty acid flux, but the underlying cause has eluded them (5-7).

In Ayurvedic literature, Type- Diabetes Mellitus is correlated with Madhumeha. Sometimes term 'Madhumeha' is used in synonyms of Prameha (i.e., all types of Prameha). The Word Madhumeha is formed from two words; Madhu and Meha. The word Madhumeha is derived from root "Manyante Visheshena Janati Jana Yasmin".

From above description the Etymology is concise which indicates that the diseases having excessive excretion of urine and similar qualities to Madhu in its color, taste, smell and consistency called as Madhumeha (8).

KEYWORDS:

Type-2 Diabetes Mellitus,
Metformin,
Nisha-Amalaki Churna,
insulin resistance,
Haridra, Amalaki

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Ayurveda, the traditional Indian system of medicine, offers a balanced and holistic multi-modality approach to treating diabetes. Since diet forms the mainstay in the management of diabetes mellitus, there is scope for exploiting the antidiabetic potency of vegetables and fruits which may hold promise as potential antidiabetic agents. Plant products possessing both hypoglycemic and antioxidant properties will be particularly useful in the management of diabetes mellitus. Of considerable interest is the adoption of Ayurveda by the mainstream medical system in some European countries (e.g. Hungary), emphasizing the increasing worldwide recognition being received by this modality (9).

The various beneficial activities of Curcuma longa that have been scientifically probed include antioxidant, anticancer, antiinflammatory, antidiabetic, lipid lowering and wound healing activities among many others (10).

The Amalaki fruit is highly nutritious and contains the high level of heat and storage-stable vitamin ascorbic acid (11). Extracts from Amalaki fruits have been evaluated for antidiabetic, hypolipidemic, antibacterial, antioxidant, antiulcerogenic, hepatoprotective, gastroprotective, and chemopreventive properties (12).

Need of Study

Earlier many researches have been conducted on Type-2 Diabetes Mellitus by taking modern medicines into account, but till date no herbal formulation is being studied for the management of Type-2 Diabetes Mellitus.

The main aim of this case series is to study the efficacy of Nisha-Amalaki Churna- the herbal formulation and Tablet Metformin- the conventional medicine in the management of Type-2 Diabetes Mellitus.

Aims and Objectives

The main aim of the case series is to study the efficacy of herbal formulation and conventional medicine in the management of Type-2 Diabetes Mellitus.

MATERIALS AND METHODS

The patients came complaining of burning sensation in soles of both feet and suggestive of Type-2 Diabetes Mellitus were examined, a clinical diagnosis was made and then confirmed with the help of laboratory blood glucose examination (Fasting blood glucose and Post meal blood glucose test). After confirmation, patients having blood glucose levels as mentioned by the American Diabetes Association, which is Fasting blood sugar level of 126-200 mg/dL and Post meal blood sugar level of 200-300 mg/dL, were selected for this case series. The normal reference values for Fasting blood Glucose level is 70-110.0 mg/dL and for Post meal blood glucose level is 70-140.0 mg/dL. The demographic profile, associated symptoms relevant to Type-2 Diabetes Mellitus such as frequent micturition, tingling sensation, and burning sensation during or after micturition if present were noted. Purpose and effect of medication was explained to patients. Treatment was prescribed to the patients willing for medication. Patient outcomes were also analyzed.

Study design

Nisha-Amalaki Churna in the dosage of 3 grams twice a day before meal was prescribed to take orally with the Anupana (vehicle or adjuvant) of luke warm water for the duration of 2 months to five patients which was prepared in Dattatreya Ras Shala of Mahatma Gandhi Ayurved College Hospital and Research Centre along with a proper sugar restricted diet plan (Figure 1) and regular exercise.

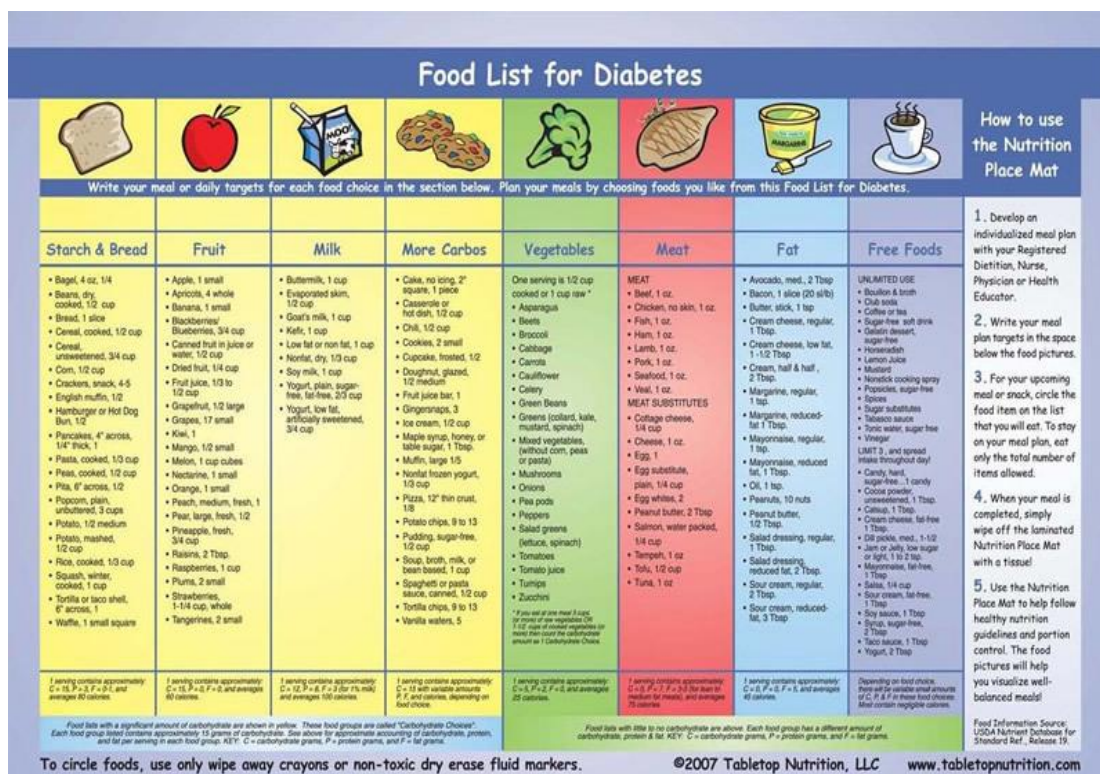


Figure 1: Sugar Restricted diet plan for patients suffering from Type-2 Diabetes Mellitus(13)

Case Series

Ten patients in between the age group of 30 to 60 years irrespective of sex and religion visited to the OPD with complaints related to Type-2 Diabetes Mellitus since 2021.

Case 1

A 48-years-old female patient, working as a housewife, having complaint of burning sensation after micturition and tingling sensation in both legs all over the day since 1 month visited the OPD of Kayachikitsa Department. On enquiry, the patient told that her father was also suffering from Type-2 Diabetes Mellitus. By doing blood glucose level test (Fasting and Post meal blood glucose test), it showed that the Fasting Blood Glucose level was 160.0 mg/dL and the Post meal blood glucose level was 221 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Pitta-Kaphaj Prakruti. She was prescribed to take Nisha-Amalaki Churna in a dosage of 3 grams twice a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise throughout her treatment.

Case 2

A 45-years-old male patient, working as a shopkeeper, having complaints of frequent micturition since 2 months, visited the OPD of Kayachikitsa department. On enquiry, the patient told that his father was also suffering from Type-2 Diabetes Mellitus. Then, he was advised to get blood glucose level investigation. As per his blood reports, it was revealed that the Fasting blood glucose level was 155.1 mg/dL and the Post meal blood glucose level was 205.0 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Kapha-Vataj Prakruti. He was prescribed to take Nisha-Amalaki Churna in a dosage of 3 grams twice a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise throughout his treatment.

Case 3

A 49-years-old female patient, working in private sector having complaints of burning sensation during micturition and itching in both feet since 15 days came to the OPD. On enquiry, the patient told that she did not have any family history relevant to Type-2 Diabetes Mellitus. When blood glucose test was advised to the patient, it was reported as Fasting blood sugar level of 180.6 mg/dL and Post meal blood sugar level of 276.7 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Pitta-Kaphaj Prakruti. She was prescribed to take Nisha-Amalaki Churna in a dosage of 3 grams twice a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise throughout her treatment.

Case 4

A 60-years-old female patient, working as a housewife, visited

the OPD of Kayachikitsa with the complaints of burning sensation in sole of both feet and frequent micturition since 1 month. On enquiry, the patient told that she did not have any family history relevant to Type-2 Diabetes Mellitus. Her blood glucose level reports revealed that Fasting blood glucose to be 128 mg/dL and Post meal Blood glucose level to be 248 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Pitta-Vataj Prakruti. She was prescribed to take Nisha-Amalaki Churna in a dosage of 3 grams twice a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise throughout her treatment.

Case 5

A 52-years-old female patient reported to the OPD of Kayachikitsa with complaints of tingling sensation in both hands and legs since 20 days. On enquiry, the patient told that her father was suffering from Type-2 Diabetes Mellitus. The advised blood glucose level reports revealed that her Fasting Blood Glucose level was 132 mg/dL and the Post blood glucose level was 206 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Vata-Kaphaj Prakruti. She was prescribed to take Nisha-Amalaki Churna in a dosage of 3 grams twice a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise throughout her treatment.

Case 6

A 40-years-old male patient reported to the OPD of Kayachikitsa with complaints of burning micturition since 10 days. On enquiry, the patient told that his mother was suffering from Type-2 Diabetes Mellitus. The advised blood glucose level reports revealed that her Fasting Blood Glucose level was 186 mg/dL and the Post blood glucose level was 250 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Pitta-Vataj Prakruti. She was prescribed to take Tablet Metformin in a dosage of 500 mg once a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise throughout her treatment.

Case 7

A 38-years-old male patient reported to the OPD of Kayachikitsa with complaints of itching in both hands and legs since 30 days. On enquiry, the patient told that there is no relevant family history relevant to Type-2 Diabetes Mellitus. The advised blood glucose level reports revealed that her Fasting Blood Glucose level was 149 mg/dL and the Post blood glucose level was 269 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Pitta-Vataj Prakruti. He was prescribed to take Tablet Metformin in a dosage of 500 mg once a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar

restricted diet plan and exercise throughout her treatment.

throughout her treatment.

Case 8

A 49-years-old male patient reported to the OPD of Kayachikitsa with complaints of tingling sensation in both hands and legs since 20 days. On enquiry, the patient told that there was no family history relevant to Type-2 Diabetes Mellitus. The advised blood glucose level reports revealed that her Fasting Blood Glucose level was 130 mg/dL and the Post blood glucose level was 241 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Vata-Kaphaj Prakruti. He was prescribed to take Tablet Metformin in a dosage of 500 mg once a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise throughout her treatment.

Case 10

A 60-years-old female patient reported to the OPD of Kayachikitsa with complaints of burning sensation in soles of both feet since 15 days. On enquiry, the patient told that her mother was suffering from Type-2 Diabetes Mellitus. The advised blood glucose level reports revealed that her Fasting Blood Glucose level was 162 mg/dL and the Post blood glucose level was 205 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Pitta-Vataj Prakruti. She was prescribed to take Tablet Metformin in a dosage of 500 mg once a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise throughout her treatment.

Case 9

A 60-years-old male patient reported to the OPD of Kayachikitsa with complaints of tingling sensation in both hands and legs since 20 days. On enquiry, the patient told that his father was suffering from Type-2 Diabetes Mellitus. The advised blood glucose level reports revealed that her Fasting Blood Glucose level was 164 mg/dL and the Post blood glucose level was 210 mg/dL. With the help of Ayurvedic examination parameters, the patient showed to be having Kapha-Vataj Prakruti. He was prescribed to take Tablet Metformin in a dosage of 500 mg once a day with luke warm water as Anupan for 60 days. During the entire treatment process, the patient was willingly not taking any other medication for Type-2 Diabetes Mellitus. The patient followed the prescribed sugar restricted diet plan and exercise

Medical Background

There was no relevant past history relevant to Type-2 Diabetes Mellitus in any of the patients. All the ten patients were having normal vital parameters and normal personal history.

RESULTS

After the completion of 2 months, again the laboratory investigations for blood sugar level were conducted for the 5 patients, enrolled in Nisha-Amalaki Group. Significant improvement was seen in all the 5 patients at the end of treatment (Table No. 1)

Table 1: Follow up Laboratory Investigations (Nisha-Amalaki Group) after 2 months of treatment

Case no. of patients	Fasting Blood Sugar Level (in mg/dL)	Post-meal Blood Sugar Level (in mg/dL)
1.	101.0	146.0
2.	133.7	160.7
3.	152.0	261.0
4.	110.0	227.0
5.	120.0	197.0

Table 2: Follow up Laboratory Investigations (Metformin Group) after 2 months of treatment

Serial no. of patients	Fasting Blood Sugar Level (in mg/dL)	Post-meal Blood Sugar Level (in mg/dL)
1.	151.2	205.8
2.	132.0	256.0
3.	124.0	229.0
4.	146.0	198.0
5.	154.0	198.0

DISCUSSION

In the present work, efficacy of the herbal formulation, Nisha-Amalaki Churna was studied on the blood sugar levels of 5 patients suffering from Type-2 Diabetes Mellitus. Administration of Nisha-Amalaki Churna for the duration of 60 days significantly lowered the blood glucose levels in all the patients. Nisha-Amalaki Churna was given at a dose of 3 grams

two times a day before meal with luke warm water that showed a significant decrease in Fasting as well as Post prandial blood sugar levels in all the 5 patients.

Type-II Diabetes constitutes almost 98% of Diabetic population in India. Age, obesity, lack of physical activity, and Family history of Diabetes are the predisposing factors for type-II Diabetes. Other risk factors are - hypertension, dyslipidemia,

and past history of Gestational Diabetes Mellitus (GDM). Nisha-Amalaki Churna, the herbal drug, which was administered to these patients in this case series for the management of Type-2 Diabetes Mellitus contains Haridra (*Curcuma longa*) and Amalaki (*Embllica officinalis*) in equal quantities.

In spite of the presence of number of synthetic oral anti-diabetic drugs in the market, researchers have now diverted their attention to different herbs and medicinal plants in order to find out new active principle with less side effects and better anti-diabetic activity (Beighetal, 2002). Medicinal plants are being looked up once again for the treatment of Type-2 Diabetes Mellitus. Therefore Nisha-Amalaki Churna was selected for the present study in order to show the management of Type-2 Diabetes Mellitus through classical modality.

Among many herbs known for their anti-diabetic properties, Haridra stands on the lead. Haridra is also considered as the drug of choice in the treatment of Prameha or Madhumeha (Type-2 Diabetes Mellitus).

Haridra Prameha Haranaam (Asthang Hridya)

There are many herbs which cure Type-2 Diabetes Mellitus, but nothing in comparison to Haridra. This reference clearly suggests Haridra as the drug of choice in effectively tackling Type-2 Diabetes Mellitus and Urinary tract disorders. In the treatment of Type-2 Diabetes Mellitus, Haridra is excellent option both as a preventive as well as curative agent.

Mode of Action of Haridra (*Curcuma longa*)

Haridra is used since time immemorial in different indications including Madhumeha. This drug is used both internally and externally also in healing ulcers due to Madhumeha. Haridra has got Katu, Tikta rasa, Katu vipaka, Ushna veerya and Ruksha guna (14).

The therapeutic action of this drug in the management of Prameha cannot be explained through the Rasapanchaka (five types of taste) only but possible through Prabhava (action). Useful part of Haridra is dried rhizome which is used clinically (15). The rhizome of Haridra is pungent, bitter; and is heating in nature, laxative, anthelmintic, vulnerary, tonic, alexiteric, and emollient. It is useful to improve the complexion. The rhizome is useful in disorders of Kapha and Vata doshas. It is primarily used in the diseases of the blood, leucoderma, scabies, urinary discharges, inflammations, anaemia, and bad taste in the mouth, biliousness, dyspepsia, elephantiasis, snake-bite, small-pox, swellings, boils, bruises, and sprains (16).

The rhizome is bitter in taste and it is carminative, and diuretic. It is good for affections of the liver and jaundice.

Haridra contains curcumin, curcuminoids, other volatile oils and some colouring substances (17).

Mode of Action of Amalaki (*Embllica officinalis*)

Amalaki (*Embllica officinalis*) enjoys a hallowed position in Ayurveda-an Indian indigenous system of medicine (Khan 2009). *Embllica officinalis* primarily contains tannins, alkaloids, phenolic compounds, amino acids and carbohydrates. It is rich

in chromium, which makes it very beneficial for diabetes. It has a therapeutic value in diabetes (Kumar Sampath 2012). It is also known to stimulate the isolated group of cells that secrete the hormone insulin. This decreases the blood sugar. It is also a powerful antioxidant, immunomodulator, hypoglycaemic, hypolipidemic, hypotensive, antacid. Amalaki fruit is acrid, cool refrigerant diuretic, laxative, antipyretic vitamin C. In view of the present study was planned to see the effect of Amalaki an approach towards the control of Type-2 Diabetes Mellitus. Gooseberry contains chromium. It has a therapeutic value in diabetics. Indian Gooseberry or Amalaki stimulate the isolated group of cells that secrete the hormone insulin. Thus it reduces blood sugar in diabetic patient.

Amalaki is used extensively for many centuries as a household remedy for many ailments and also scientifically for its action on Madhumeha, which is due to its Rasayana property. This drug Amalaki has got five Rasas except Lavana rasa but predominated by Amla rasa. The part used in this plant is its fruit rind. It has Guru, Ruksha gunas, Madhura vipaka and Seetha veerya (18). Chemically, Amalaki contains many water soluble tannins like Emblicannins, which are supposed to be the main active principles, behind decreasing the cellular resistance to insulin. The controversy of the presence of ascorbic acid and vitamin C did not lessen its popular utility. Undoubtedly, Amalaki is proved to be quite effective both experimentally and clinically as a promising hypoglycemic drug (19).

CONCLUSION

Significant reduction was observed in the levels of blood glucose through laboratory investigations in all the 5 patients. Therefore, with the help of results obtained through follow up blood glucose level investigations, it can be concluded that within 2 months of treatment, through the administration of herbal preparation, that is, Nisha-Amalaki Churna along with regular sugar restricted diet and exercise as advised; Type-2 Diabetes Mellitus can be managed effectively.

Statements and Declarations

Ethical Approval

The study has been ethically approved by the Institutional Ethical Committee

Funding Details

No funding body is associated with this study

CONFLICTS OF INTERESTS

The authors have no conflict of interest regarding this article.

Informed Consent

A written informed consent was taken from the patients before starting the treatment.

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