'website : www.ijacare.in e-ISSN No.: 2457-0443
INTERNATIONAL JOURNAL OF AYUSH CASE REPORTS (IJA-CARE)

Effect of *Madhumehari Churna* as an Adjuvant to Insulin Therapy in the management of Type 1 and Type 2 Diabetes Mellitus: Two Case Reports

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ABSTRACT:

Diabetes Mellitus is a syndrome characterized by chronic hyperglycemia due to insulin deficiency or insulin resistance. Type 1 Diabetes Mellitus (T1DM) is caused due to Insulin deficiency while type 2 Diabetes Mellitus (T2DM) is a consequence of insulin resistance. Though there is significant advancement in the treatment of this disease in terms of oral hypoglycemic drugs and Insulin therapy, still many patients face difficulty in achieving normal blood glucose levels and getting relief in their symptoms. The chronic hyperglycemia leads to a number of microvascular and macrovascular complications later on. The adoption of integrated treatment approach may pave a way to obtain the goal of treatment of this disease. This study reports the effect of *Madhumehari Churna*, a polyherbal formulation as an adjuvant in patients undergoing insulin therapy for Diabetes Mellitus. In this study, one patient was diagnosed with Type 1 Diabetes Mellitus and the other with type 2 Diabetes Mellitus. The patients were treated with *Madhumehari Churna* and relief in symptoms, improvement in blood sugar levels and glycosylated hemoglobin along with lowering of Insulin doses was observed in both cases.

KEYWORDS: Diabetes Mellitus, Insulin, *Madhumehari churna.*

Received: 19.01.2025 Revised: 10.02.2025 Accepted: 22.02.2025 Published: 10.03.2025

Quick Response Code

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DOI: https://doi.org/https://doi.org/10.70805/ija-care.v9i1.686
Link: https://ijacare.in/index.php/ijacare/article/view/686

INTRODUCTION:

Diabetes Mellitus is a group of metabolic and endocrine diseases manifested by polyuria, polyphagia and polydipsia. Diabetes Mellitus is mainly divided into type 1 Diabetes Mellitus (T1DM) and type 2 Diabetes Mellitus (T2DM). [1] The important phenomenon in DM is chronic hyperglycemia which in synergy with the other metabolic aberrations can cause damage to various organ systems.[2] Insulin hormone secreted by pancreas is essential for regulating blood sugar levels by facilitating the uptake of glucose into cells

for energy production. T1DM is an autoimmune disorder characterized by T cell-mediated self-destruction of Insulin-secreting islet β cells in pancreas.[3] As T1DM is caused by an absolute lack of Insulin secretion, the treatment for T1DM patients is exogenous Insulin replacement therapy. It involves daily Insulin injections to mimic the function of the pancreas and maintain stable blood sugar levels. In T2DM the response of the target cell to Insulin is diminished (Insulin resistance) which in turn affects carbohydrates metabolism and results in hyperglycemia and many symptoms.[4] It is managed by oral hypoglycemic drugs and lifestyle changes. In case of acute illness, special cases or failure to achieve goals with oral hypoglycemic medications, exogenous Insulin therapy is indicated. To achieve glycemic goals, Insulin is considered alone or in combination with oral agents when HbA1c is ≥ 7.5%; and is essential for treatment in those with HbA1c ≥ 10% (≥ 86 mmol/mol), when diet, physical activity and other oral hypoglycemic drugs have been optimally used. [5] In Ayurveda, Diabetes Mellitus is referred to as *Prameha,* which is a group of conditions clinically characterized by polyurea. Various single herbs and compound formulations are used to manage its symptoms and complications. A lot of studies report the effect of Ayurveda formulations in T2DM but very few are related to T1DM which include integrated approach in the management of Diabetes Mellitus.

Madhumehari Churna is a polyherbal formulation consisting of 12 herbs namely *Jambu Beeja (Syzygium cumini), Amrasthi Majja (Mangifera indica), Karavellaka (Momordica charantia), Meshasringi (Gymnema sylvestre), Methika (Trigonella foenum graecum), Bilva Patra (Aegle marmelos), Nimba Beeja (Azadirachta indica A. Juss), Sunthi (Zingiber officinale), Satapuspa (Sounpha), (Foeniculum vulgare), Swarnpatri (Cassia angustifolia Vahl), Bala Beeja (Sida cordifolia) and Babbula Phala (Acacia arabica Willd).*[6] As per various clinical observations and experiences it has shown improvement in symptoms and blood parameters in patients of Diabetes Mellitus. Previous studies like single case reports,[7] case-series[8] and clinical studies have shown hypoglycemic effect in the management of *Madhumeha*.[9] These studies and clinical experiences build foundation for the use of this drug in patients with Diabetes Mellitus on Insulin therapy.

1. CASE HISTORY – CASE 1

A 24 year old male visited the outpatient department with chief complaints of extreme generalized weakness, loss of appetite and increased frequency of urination since 1 year. He was a known case of T1DM since 2018 and was on Insulin dose of 8 IU B/F (Lupisulin M30) and 10 IU HS (Insulin Glargine). He used to have fluctuations often in his blood sugar levels. He had a normal vegetarian diet on a regular basis. His bowel habit was normal and sleep cycle were regular. He had a sedentary lifestyle and had no addiction. He had no relevant, medical, surgical or psychosocial history. He did not have family history of Diabetes Mellitus.

Examination of the patient

The patient was of normal built having 62 kg weight, 165 cm height (BMI 22.8). The pulse rate was 74/min and blood pressure was 110/70 mm Hg. He was well oriented to time, place and person. His general and systemic examination was within normal limits. He had *Kaphapittaja Prakriti,*

Madhyama Sara, Samhana and *Pramana, Avara Satmya, Satva* and *Vyayamshakti*. *Koshta* was *Madhyam* and *Agni* was *Vishama*. He didn't have *Shotha, Pandu* or any other relevant manifestation.

Investigations

Since the patient was already diagnosed with T1DM and was undergoing Insulin therapy for 5 years, he was advised to go for RBS and glycosylated hemoglobin (HbA1c) which were found to be 428 mg/dL and 11 % respectively. As per *Ayurveda* perspective he had *Prabhutamutrata* which is a cardinal symptom of *Prameha* along with *Daurbalya*, and *Aruchi* which are mentioned as *Updrava* of *Prameha* in classics.

Table- 1: Therapeutic intervention and timeline:

Day of registration and follow up visits	**Initial presentation and chief complaints in subsequent visits**	**Insulin Dose (prescribed by modern consultant)**	**Laboratory investigations**	**Treatment details (initiation and continuation)**	**Outcome**
04/07/2023 (1st visit)	Extreme generalized weakness, loss of appetite, increased frequency of urination (4-5 times in night), fluctuating blood sugar levels	8 IU Before meals (Lupisulin M30) BD 10 IU HS (Lantus)	RBS- 428 mg/dL HbA1c - 11%	*Madhumehari Churna,*5 gm orally, twice a day, 20 minutes before food (preferably 8am-9am and 7pm-8pm) with warm water	--
08/08/2023 (2nd visit)	No fresh complaints	8 IU Before meals (Lupisulin M30) BD 10 IU HS (Lantus)	FBS - 208 mg/dL PPBS- 356 mg/dL	Continued same	Reduction in FBS and PPBS, mild improvement in weakness and loss of appetite, frequency of urination decreased (2-3 times in night),

11/09/2023 (3rd visit)	No fresh complaints	8 IU Before meals (Lupisulin M30) BD 10 IU HS (Lantus)	FBS - 150 mg/dL PPBS- 220 mg/dL	Continued same	Reduction in FBS and PPBS, marked improvement in weakness and loss of appetite, frequency of urination decreased, fluctuations in blood sugar levels reduced
17/10/23 (4th visit)	No fresh complaints	8 IU BM (Lupisulin M30) BD 10 IU HS (Lantus) withdrawn	FBS - 98 mg/dL PPBS- 180 mg/dL HbA1c - 7.4%	Continued	Reduction in FBS and PPBS and HbA1c, Lantus withdrawn, no fluctuations in blood sugar levels No fatigue, no urination in night, normal appetite
21/11/23 (5th visit)	No fresh complaints	8 IU BM (Lupisulin M30)	FBS - 92 mg/dL PPBS- 152 mg/dL	Continued	Reduction in FBS, PPBS and HbA1c

IU- International unit, HS- Hour of sleep, BM- Before meal, FBS- Fasting blood sugar, PPBS- Post-prandial blood sugar

Result

On the first visit the patient was prescribed Ayurveda medication and was advised to continue Insulin therapy under the supervision of the modern consultant. On subsequent visits there was moderate to marked relief in the symptoms, reduction in FBS and PPBS with no fresh complaints. The patient was advised to continue the medication. On the 4th visit HbA1c was 7.4%. *Madhumehari Churna* was continued and the patient was advised to revise Insulin dose as per the suggestion of the modern consultant. The modern consultant stopped 10 IU HS (Insulin Glargine) as HbA1c was reduced from 14.8 to 7.4%. On the next visit, FBS - 92 mg/dL and PPBS - 152 mg/dL. In the whole course of treatment the patient developed neither any fresh complaints nor any episode of hypoglycemia.

2. CASE HISTORY – CASE 2:

A 64-year-old male visited the outpatient department with chief complaints of extreme generalized weakness, cramps in

calf muscle, chronic constipation, increased thirst and frequency of urination since 8 months. He was a known case of T2DM since 2019 and has been on regular Insulin doses of 28 IU (Insulin Glargine) and Metformin 500 mg just before evening meal. He had a normal vegetarian diet on a regular basis. His appetite and sleep were normal. He had a sedentary lifestyle and had no addictions. He had no relevant, medical, surgical or psychosocial history. He did not had family history of Diabetes Mellitus.

Examination of the patient:

The patient was of normal built having 69 kg weight, 172 cm height (BMI 23.1). The pulse rate was 72/min and blood pressure was 120/80 mm Hg. He was well oriented to time, place and person. His general and systemic examination was within normal limits. He had *Kaphapittaja Prakriti, Madhyama Sara, Samhana Pramana, Satmya and Satva* and *Avara Vyayamshakti*. *Koshta* was *Krura* and *Agni* was *Manda*. He didn't have *Shotha, Pandu* or any other relevant manifestation.

Investigations:

Since the patient was already diagnosed with Diabetes Mellitus type2 and was undergoing Insulin therapy for 4 years, he was advised to go for glycosylated haemoglobin (HbA1c), Fasting blood glucose (FBS), post prandial blood glucose (PPBS).

On 1st visit HbA1c was found to be 11 %, FBS- 165 mg/dL, PPBS- 202 mg/dL. As per *Ayurveda* perspective he had *Prabhutamutrata* which is cardinal symptom of *Prameha* along with *Trishna*, *Daurbalya* and *Badhapurishtvam* which are mentioned as *Updrava* of *Prameha*.

The details of Therapeutic intervention and timeline in case of second patient is mentioned in table 2.

Table-2: Therapeutic intervention and timeline

Day of registration and follow up visits	Initial presentation and chief complaints in subsequent visits	Insulin Dose (prescribed by modern consultant)	Laboratory investigation	Treatment details (initiation and continuation)	Outcome
22/06/2023 (1st visit)	Extreme generalized weakness (inability to do routine works), cramps in calf muscles, constipation, increased thirst (more than 3 liters water per	Insulin Glargine 28 IU + Metformin 500 mg OD	HbA1c - 11% FBS-165 mg/dL PPBS-202mg/dL	*Madhumehari Churna* 5 gm orally, twice a day, 20 minutes before food (preferably 8am-9am and 7pm-8pm) with warm water	--

	day) and frequency of urination (4-5 times in night)				
12/07/2023(2nd visit)	No fresh complaint	Insulin Glargine 20 IU + Metformin 500 mg OD	FBS-152 mg/dL PPBS-198 mg/dL	Continued same	Constipation relieved, moderate improvement in weakness, cramps in calf muscles and thirst, decreased frequency of urination (2 times in night)
15/08/2023(3rd visit)	No fresh complaint	Insulin Glargine 12 IU + Metformin 500 mg OD	FBS-135 mg/dL PPBS-176 mg/dL	Continued same	Reduction in FBS and PPBS and Insulin dose, marked improvement weakness, cramps in calf muscles and thirst, occasional urination in night
15/09/2023(4th visit)	No fresh complaint	Insulin Glargine 2 IU + Metformin 500 mg OD	HbA1c - 8% FBS-110 mg/dL PPBS-152 mg/dL		Reduction in FBS and PPBS and HbA1c and Insulin dose
23/11/2023(5th visit)	No fresh complaint	Insulin stopped Metformin 500mg OD	HbA1c- 6.8 %	Continued same	Reduction in HbA1c, withdrawal of Insulin

IU- International unit, OD-Once a day , FBS- Fasting blood sugar, PPBS- Post-prandial blood sugar

RESULT:

On the first visit the patient started *Madhumehari Churna* as prescribed and was advised to continue Insulin and Metformin under the supervision of the modern consultant. On subsequent visits the patient informed that there was moderate relief in the symptoms and Insulin dose was reduced by concerned physician by whom it was prescribed. FBS, PPBS also got reduced. On fourth visit there was marked improvement in HbA1c (11% to 8 %).On the 5th visit HbA1c was 6.8 %. The patient informed that he had stopped Insulin and was only taking Metformin 500mg as per the modern consultant's advice and *Madhumehari Churna.* In the whole course of treatment, he developed neither any fresh complaints nor any episode of hypoglycemia.

DISCUSSION:

The treatment objective for Diabetes is to control hyperglycemia and the related symptoms. In both the cases discussed above there was relief in symptoms, reduction of HbA1c and Insulin doses. It indicates the hypoglycemic activity of *Madhumehari Churna.* The supportive evidences are as follows.

Madhumehari Churna is used traditionally for managing various conditions related to Diabetes. As per *Ayurveda* ingredients of *Madhumehari Churna* possesses *Katu* (pungent), *Tikta* (bitter), *Kashaya* (astringent) taste, *Ushna Veerya* (hot potency) and *Katu Vipaka* which help in *Deepana, Pachana* of *Dosha* and pacification of vitiated *Kleda* and *Meda.* It has shown hypoglycaemic and lipid lowering activities in many case reports and clinical trials. All the herbs in it show hypoglycemic activity individually either by slowing glucose absorption in the intestine or improving the Insulin resistance or by improving Insulin secretion from pancreas. The supportive evidences are as follows.

Syzygium cumini contains Jambolin, which inhibits starch conversion into sugar, aiding blood sugar regulation and reducing glycosylated haemoglobin.[10,11,12] Mango seed kernel extract protects pancreatic β-cells and improves glucose metabolism.[13,14] Momordica charantia exhibit anti-hyperglycemic effects by increasing glucose uptake and fatty acid oxidation, and regenerating β-cells.[15,16,17] Gymnemic acid in Gymnema sylvestre increases insulin secretion, regenerates islet cells, inhibits glucose absorption, and reduces sweet food cravings.[18,19] Trigonella foenumgraecum delays gastric emptying, slows carbohydrate absorption, and influences lipid metabolism.[20] Aegle marmelos extract lowers blood sugar in diabetic rats and reduces insulin resistance.[21,22] Azadirachta indica leaf extract lowers blood glucose, increases glycogen storage, and improves glucose tolerance.[23,24] Zingiber officinale reduces glucose, insulin resistance, lipid levels and have insulinotropic properties.[25,26,27] Foeniculum vulgare has antioxidant effects and helps manage Diabetes-related complications. [28,29,30,31] Cassia angustifolia contains flavonoids and saponins that enhance insulin signaling and reduce carbohydrate digestion.[32,33] Sida cordifolia offers analgesic, anti-inflammatory, and hypoglycemic effects, controlling blood glucose and lipid metabolism.[34-35] Acacia arabica improves glucose levels, insulin secretion and lipid metabolism.[36-37]

CONCLUSION:

The content of *Madhumehari churna* support insulin secretion, glucose uptake, and overall metabolic balance, making it beneficial for

both Type 1 and Type 2 Diabetes management. Hence, integrating Ayurveda interventions alongside conventional treatments can optimise outcomes and enhance quality of life of diabetic patient.

Limitation of the study:
Since it is a case study of two patients the results cannot be extended or generalized to broader population. Future studies should include larger and diverse demographic patient population with extended follow-ups to assess long term benefits and side effects of the intervention.

Declaration of patient consent:
The authors certify that they have obtained patient written informed consent forms, where the patients have given their consent for reporting the case along with clinical information in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity.

Conflict of interest: The author declares that there is no conflict of interest.

Guarantor*:* The corresponding author is the guarantor of this article and its contents.

Source of support: None

How to cite this article:
Shailza Bhatnagar, Kalpana Yadav, Sakshi Bhardwaj. Effect of *Madhumehari Churna* as an Adjuvant to Insulin Therapy in the management of Type 1 and Type 2 Diabetes Mellitus: Two Case Reports. Int. J. AYUSH CaRe. 2025;9(1):20-29.
https://doi.org/https://doi.org/10.70805/ija-care.v9i1.686

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