Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 15 (4), 2024; 1131-1135

Assessment of Adjuvant Effect of Ethanol Extract of *Sadabahar* (*Vinca rosea* Linn.) in Type 2 Diabetes Mellitus Management: A Case Series

Case Report

Vaishali Rathod[1*], Shailesh Deshpande[2]

1. PG Scholar, 2. Professor and HOD, Department of Kayachikitsa, Parul Institute of Ayurved, Parul University, Limda, Vadodara, Gujarat. India.

Abstract

Management of Diabetes mellitus (DM) controls hyperglycemia, other aspects of pathology remain untouched. Hence quest for a better remedy that can show multiple actions and correct different aspects of pathology is needed. Whole plant extract and leaf extracts of *Sadabahar* (*Vinca rosea Linn*.) show anti-hyperglycemic activity in alloxan-induced diabetic rats by regeneration of β-cells of pancreas. However, this plant has not been evaluated yet in humans. So, this study was designed to check the tolerability and effectiveness of *Sadabahar* in patients with type II DM (T2DM). Methods: Six cases of T2DM patients with fasting blood sugar level (FBS) between-125 mg/dl to 300 mg/dl and postprandial blood sugar level (PP2BS) between - 140 mg/dl to 500 mg/dl were enrolled. Patients received the drug in three doses- 2 grams per day (gm/day), 3 gm/day, and 5 gm/day in groups A, B, and C respectively for 15 days with their anti-diabetic medicine and a routine lifestyle. Result: The results showed a reduction in FBS and PP2BS in all groups, with Group C showing the most significant improvement. The Baseline FBS values of Group C were 219 mg/dl and 295.8 mg/dl decreased to 165.6 mg/dl and 203 mg/dl, respectively, while PP2BS decreased from 370 mg/dl and 363.4 mg/dl to 284.6 mg/dl and 330 mg/dl. No adverse events were observed. Conclusion: All three doses of *Sadabahar* lowered blood sugar levels and no adverse event was noted during study time. Among them, 5 gm/day (group C) was the most effective and safe dose in T2DM patients.

Keywords: *Ayurveda,* Anti-diabetic effect, Prameha, Blood sugar, Herbal medicine.

Introduction

DM is a chronic condition that affects people both from developed and developing countries. It is characterized by increased blood sugar levels and glycosuria. The causes of T2DM are inadequate insulin production or utilization which is disrupting carbohydrate metabolism (1). factors that may be responsible for the rising cases of diabetes in the world are changing lifestyles, urbanization, and socioeconomic factors, rural-to-urban migration (2). Diabetes is a leading cause of severe health complications including neuropathy, retinopathy, renal disease, cardiovascular events, strokes, and limb amputations (3). In K. Park, Diabetes is compared with an "Iceberg" disease, because if diabetes is not managed properly or remains undiagnosed it can lead to chronic complications that affect the quality of life and increase the risk of mortality (4).

In *Ayurveda,* DM is largely described as *Prameha.* There are two types of *Prameha-Sahaja Prameha* and *Apathya-nimittaja Prameha* which can be aptly correlated with type I and type II DM respectively (5). *Ayurveda* explains unhealthy lifestyle (*Ahitakara Ahara Vihara)* and a sedentary lifestyle are the main two factors that cause *Prameha* (6). In *Prameha Kapha Pradhan Tridosha* are involved and *Rasa, Rakta, Mamsa, Meda, Majja, Shukra, Oja, Kleda,* and *Lasika* are involved (7).

Vinca rosea Linn. is an herbaceous subshrub. It is known as *Sadabahar*. It is *Kapha Vata Nashak*. The property of *Vinca rosea* is *Rasa-Kashaya-Tikta, Guna-Laghu, Ruksha, Virya- Ushna, Vipaka-Katu*. It is mainly used in *Madhumeha, Prameha*, blood cancer, breast cancer, and *Hridaroga* (8). It is popular mainly for its alkaloids, which have anticancer activities. The leaves are known to contain 150 useful alkaloids among other pharmacologically active compounds. Significant antihyperglycemic and hypotensive activity of the leaf extracts are reported in laboratory animals. Fresh leaf juice of *Vinca rosea* is reported to reduce blood glucose in normal and alloxan-induced diabetic rabbits (9). Despite its excellent potential to reduce blood sugar levels, it was not evaluated in patients with T2DM. Hence, it was decided to evaluate the effect of ethanol extract on the whole plant of *Sadabahar (Vinca rosea* Linn) at three different doses in patients who T2DM who had deranged blood sugar.

In modern medicine, the focus is on managing high blood sugar levels, but it doesn't address the underlying cause of the problem (10). so, patients depend upon oral hypoglycemic agents and insulin injections, long time use of these interventions leads to

*** Corresponding Author:**

Vaishali Rathod

PG Scholar, Department of Kayachikitsa,
Parul Institute of Ayurved, Parul University, Limda, Vadodara, Gujarat. India.
Email Id: rathod.vaishali8907@gmail.com

side effects. Despite the long-time use of medicine, patients face the risk of complications such as neuropathy, retinopathy, and cardiovascular disease. and diabetic management with modern medications is much more expensive, especially for patients who require regular medications, and insulin therapy. In A*yurveda Chikitsasidhhanta* is aimed to break the *Samprapti* of disease and destroy it from the root; rather than symptomatic relief (11). but still, there is no single medicine available in *Ayurveda* that cures the DM from root. In *Ayurveda*, diagnosis and treatment are based on *Prakriti* and *Dosha Avastha* of patients which is not coordinated with modern science. There are lots of medicines that are still not used in daily practice. In *Ayurvedic* treatments for diabetes, we use herbal medicines. But sometimes these herbs can be harmful because we don't always know everything about them, some phytochemicals are still unknown which may be harmful for humans.

In this study, our primary objective is to study the adjuvant effect of whole plant ethanol extract of *Sadabahar* (*Vinca rosea* Linn.) In the management of T2DM based on FBS and PP2BS levels, and BMI and secondary objective is to check the tolerability of different doses of whole plant ethanol extract of *Sadabahar* (*Vinca rosea* Linn.) based on adverse events.

Method

Study design:

It is a prospective case series. Six patients of T2DM receiving conventional treatment and showing raised FBS and PP2BS in the range of 125 mg/dl to 300 mg/dl and 140 mg/dl to 500 mg/dl respectively, aged between 25-70 years and had symptoms of *Prameha* were included, Those with FBS of more than 300mg/dl, PP2BS of more than 500 mg/dl, patients aged below 25 years and above 70 years and who had uncontrolled hypertension, any immune-compromised condition and active infectious disease, lactating and pregnant woman, cases of T1DM were also excluded. Written informed consent of the patients was obtained before commencing the study. The medication dosages were allocated in the following sequence: the first two patients were prescribed 2 grams per day, the next two received 3 grams daily, and the last two were administered 5 grams per day. The enrolled patients were advised to continue their anti-diabetic medicine with Ayurvedic treatment. No specific diet and lifestyle modifications were suggested to any patients. A follow-up was taken on every 7th day. On the 7th day, BMI and presenting symptoms of *Prameha* were assessed and on the 15th day, along with symptoms of *Prameha* and BMI, blood investigations - FBS and PP2BS were also done.

Interventions

Whole plant Ethanol Extract of *Sadabahar* was procured from a certified supplier, Standardisation of the extract was evaluated by the Department of *Rasashastra and Bhaisajya Kalpana* of the study institute. Capsule filling was done at a pharmacy associated with the study institute. Interventions of study drugs in different groups were mentioned in Table -1.

Table 1: Group distributions and interventions

Group	A	B	C
Number of patients	2	2	2
Drug	Whole plant ethanol extract of *Sadabahar* (*Vinca rosea* Linn.)	Whole plant ethanol extract of *Sadabahar* (*Vinca rosea* Linn.)	Whole plant ethanol extract of *Sadabahar* (*Vinca rosea* Linn.)
Drug form	Capsule (Each capsule contains 500mg of the drug)	Capsule (Each capsule contains 500mg of the drug)	Capsule (Each capsule contains 500mg of the drug)
Dose and frequency	2 capsules twice daily before food	3 capsules twice daily before food	5 capsules twice daily before food
Duration	15days	15days	15days
Anupan	Warm water	Warm water	Warm water

Outcomes

Blood investigations: FBS and PP_2BS levels were measured on the 0th and the 15th day. BMI was taken on the 0th day, 7th day, and 15th day.

Result

Participant flow**:** In this study, after obtaining the consent of patients, a total of six patients who fulfilled the inclusion criteria were enrolled in the study.

Participant characteristics: Of a total of 6 patients, two were male and four were female. They had a confirmed diagnosis of T2DM and received antidiabetic medication and out of 6 patients, four of the patients had a history of hypertension and were taking antihypertensive medication.

Outcomes: All the patients showed significant changes in FBS and PP2BS levels which are mentioned in Table 2 and also saw changes in BMI Which is mentioned in Table 3.

Table 2: Blood parameters before and after treatment

Blood parameters		FBS mg/dl		PP2BS mg/dl	
		Baseline	Day 15	Baseline	Day 15
Group A	Case 1	126.6	108.9	223	192.9
	Case 2	148	133	244	193
Group B	Case 3	128.9	108.2	272.6	194.1
	Case 4	263	175.9	431	331.7
Group C	Case 5	219	165.6	370	284.8
	Case 6	295.8	203	363.4	330

Table 3: Results of BMI before nad after treatment

		Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
BMI Kg/m2	Baseline	21.6	24.5	33.2	21.9	30.9	24.9
	Day 15	21.6	24.1	32.8	21.2	30.9	23.8

Sub group analysis

Group A: In group A, an ethanol extract of *Sadabahar* of 2 gm/day in the form of capsules was given to every patient, before food with warm water for 15 days.

Case 1: A 60-year-old male patient, a shopkeeper, came to the OPD with a known history of T2DM for 1 year. He complained of generalized weakness, excessive urination during both day and night and excessive hunger for 1 month. He was taking Metformin Hydrochloride 500 mg for T2DM. All systemic examinations were found to be normal. At the baseline visit, the FBS level was 126.6mg/dl and the PP2BS level was 223mg/dl. At the end of 15 days, the FBS level was decreased to 108.9 mg/dl and the PP2BS level decreased to 192.9 mg/dl. No change in weight and BMI was observed. The treatment also showed notable improvements in symptoms observed in patients – polyuria, and nocturnal micturition and relief in polyphagia.

Case 2: A 61-year-old female patient with K/C/O T2DM and HTN for 4 years, came to OPD with C/O dryness of throat, excessive hunger, and generalized weakness for more than 1 month. She was a farmer and was taking medicine T. Glipizide 5 mg for T2DM and T. Amlodipine 5mg for HTN. All systemic examinations were found to be within normal limits. At the baseline visit, the FBS level was 148 mg/dl and the PP2BS level was 244 mg/dl. At the end of the study, the FBS level was decreased to 133 mg/dl and the PP2BS level to 193 mg/dl. Additionally, weight decreased by 1 kg on the 15th day. The treatment also showed notable improvements in symptoms such as polyphagia, cramps, Excessive sweating, polyurea, and nocturnal micturition.

Group B: In group B, two patients received ethanol extract of *Sadabahar* 3 gm/day in the form of capsules was given to every patient, before food with warm water for 15 days.

Case 3: A 57-year-old female patient came e to OPD with C/O lower back pain radiating to the right lower limb while standing for a long time for the last 2 months. She also had symptoms of generalized weakness, cramps, excessive sweating, increased frequency of urination in day and night time, dryness of throat and excessive hunger. She was K/C/O T2DM for 10 years and HTN since 1 year for that, she has taken medicine T. Amlodipine 5 mg, T. Ozomet VG2. On examination of the lower back, pain was noted over the L3-L4, and L4-L5 levels with tenderness on deep palpation, but no local swelling was present. The range of motion for forward and backward bending was mildly restricted. The Straight Leg Raise (SLR) test was found positive on the right side at 70 degrees. In this case, at the baseline visit, the FBS and the PP2BS were 128.9 mg/dl and 272.6 mg/dl respectively. At the end of the study, the FBS level was decreased to 108.2 mg/dl and the PP2BS decreased to 194.1 mg/dl. Weight decreased by 1 kg on the 15th day. The treatment also showed notable improvements in symptoms such as polydipsia, weakness, cramps, excessive sweating, polyurea, and relief in nocturnal micturition and polyphagia.

Case 4: A 60-year-old female patient came to OPD C/O lower back pain while forward bending since 6 months with associated c/o weakness on and off since 1 year and excessive micturation, pain in both calf muscles and dyspnea while exertion since 5-6 months. she was K/C/O T2DM since 10 years and HTN since 3 months for that, she has taken medicine T. Amlodipine 5 mg, T. Glimepiride 1 mg, and T. Metformin 500 mg. she was a housewife. On examination of the lower back, pain was noted over the L4-L5 level with tenderness on deep palpation, no local swelling was present, and the range of motion for forward bending was mildly restricted. The SLR test and femoral nerve stretch test were negative. For this complaint, *Mahanarayan Taila* was given for local application. In this case, at the baseline visit, the FBS level was 263 mg/dl and the PP2BS level was 431 mg/dl. At the end of the study, the FBS level was decreased to 175.9 mg/dl and the PP2BS was reduced to 331.7 mg/dl. Additionally, weight decreased by 3 kg on the 15th day. The treatment also showed notable improvements in symptoms such as Weakness, polyphagia, excessive sweating, and Cramps.

Group C: In group C, two patients received an ethanol extract of *Sadabahar* of 5gm/day in the form of capsules given to every patient, before food with warm water for 15 days.

Case 5: A 55-year-old woman came to OPD with complaints of frequent urination at night for 3 months, a weakness for 2 months, and associated symptoms like feeling very hungry, sweating a lot, cramps, and shortness of breath while exertion for about 2 months. She is a housewife with a known history of T2DM since 3 years and HTN since 5 years. She was taking allopathic medicines: T. Amlodipine 5 mg, T. Glimepiride 1 mg, and T. Metformin 500 mg. All the systemic examination was found within normal limits. In this case, at the baseline visit, the FBS and the PP2BS levels were 219 mg/dl and 370 mg/dl respectively. At the end of the study, the FBS level was decreased to 165.6 mg/dl and the PP2BS level decreased to 284.8 mg/dl. No change in weight and BMI was observed. The treatment also showed notable improvements in symptoms such as weakness,

polyphagia, excessive sweating, cramps, and relief in nocturnal micturition, and dyspnea on exertion.

Case 6: A 46-year-old male patient came to the OPD with complaints of itching behind his left ear for the past 15 days with associated symptoms of weakness, polyphagia, and bilateral calf muscle pain, which had been present for 1.5 months. The patient was a shopkeeper and had a known history of T2DM since 3 years and was on medication Tab. Macgil GMP 1, at a dose of 1 tablet once daily before food. A systemic examination was performed, with all findings within normal limits. A local examination of the left ear revealed mild blackish discolouration and dryness behind the ear, without tenderness, *Marichyadi Taila* was prescribed for local application. At the baseline visit, the patient's FBS level was 295.8 mg/dl, and the PP2BS level was 203 mg/dl. By the end of the study, the FBS level had decreased to 175.9 mg/dl, but the PP2BS level had increased to 330 mg/dl. The patient also experienced a 1 kg weight loss by the 15th day of treatment. Additionally, there were notable improvements in symptoms such as polyphagia, excessive sweating, dyspnoea on exertion, calf cramps, nocturnal micturition, and general weakness.

Discussion

Vinca rosea is a herbaceous plant or an evergreen subshrub growing all over the world, easily available and it has good medicinal properties. We can easily cultivate it at a low cost and maintain its quality by good agriculture practices. *Vinca rosea* is a medicinal plant that is mainly used for cancer disease. It has several well-known compounds and has more than 130 alkaloids including ajmaline, Vincennes, vincristine, and vinblastine. Among them, Vinblastine and vincristine are the first natural medications utilized in cancer treatment and are currently the most effective medicine in cancer patients. The pharmacological activities of *Vinca rosea* are neoplastic, anti-diabetic, anti-microbial, anti-oxidant, anti-ulcer, anti-diarrheal, hypo lipidemic, wound healing, anti-helminthic, hypotensive activity, memory enhancer **(12).**

Anti-diabetic activity of *Vinca rosea* is already proven in animal studies, in that it shows antihyperglycemic activity in alloxan-induced diabetic rats, and also shows improvement in parameters like body weight and lipid profile along with serum creatinine, serum urea, and serum alkaline phosphatase, as well as regeneration of β cells of the pancreas were also noticed in diabetic animal models **(13).** Hence *Vinca rosea* has excellent potential to reduce blood sugar levels. This study was conducted to evaluate the effect of the whole plant of *Sadabahar* (*Vinca rosea* Linn.) at three different doses in patients who were known cases of (K/C/O) T2DM who had deranged blood sugar levels and to find out the most effective dose and tolerability of the drug in T2DM patients. by this study it was found that *Vinca rosea* reduced FBS and PP2BS in all three groups, but compared to other doses, highest dose i.e. 5gm/day is showed maximum reduction. During this study, no serious adverse drug reaction was noted. However, patients who received doses of 3 gm/day and 5gm/day developed symptoms of hyper-acidity after three days of administration of the drug. None of them was a known case of hyper-acidity. Hence, patients were advised to take medicine after food after that patient felt relief in complaints of hyperacidity and completed the study.

As it was never tested in humans for the management of DM, it is the first study done to evaluate effect and tolerability. Hence, only the study period was 15 days and only 6 subjects were included. Only FBS and PP2BS were used to assess blood sugar levels because HbA1c gives us an estimation of BSL over 100 days, it was unwise to evaluate the same in this study. As there was no evidence of its effect on DM, it was not ethical to use it as a single medicine in cases of DM by stopping the medicines they were receiving. So, cases with raised BSL even after taking medicines were selected. Finding the most efficacious and tolerated dose was the purpose. The intention was to get data for planning a bigger study based on the findings of this study. In view of the weight reduction observed in a few cases, a lipid profile could have been added.

References

1. Gordon A, Buch Z, Baute V, Coeytaux R. Use of Ayurveda in the treatment of type 2 diabetes mellitus. *Global Advances in Health and Medicine*. 2019 Aug; 8: 2164956119861094.
2. Prasad DS, Kabir Z, Dash AK, Das BC. Prevalence and risk factors for metabolic syndrome in Asian Indians: A community study from urban Eastern India. *Journal of Cardiovascular Disease Research*. 2012 Jul; 3(3): 204-211.
3. Ramachandran A. *API Textbook of Medicine*. 10th ed. New Delhi; Jaypee Brothers Medical Publishers; 2015: 457p.
4. Park K. *Park's Textbook of Preventive and Social Medicine*. 23rd ed. Jabalpur; Banarasidas Bhanot Publishers; 2015: 411p.
5. Shinde RV, Rana AP, Rajurkar H, Kaple MN. Prameha and diabetes mellitus. *International Journal of Current Research and Review*. 2020; 12(14)
6. Shinde RV, Rana AP, Rajurkar H, Kaple MN. Prameha and diabetes mellitus. *International Journal of Current Research and Review*. 2020; 12(14)
7. Srinivas P, Devi KP, Shailaja B. Diabetes mellitus (Madhumeha)-an Ayurvedic review. *International Journal of Pharmacy and Pharmaceutical Sciences*. 2014; 6(Suppl 1): 107-.
8. Bhutya RK. *Vanaspati Aushadh Vijnan*. 1st ed. Pune; Chaukhamba Orientalia Publishers; 2010: 222p.
9. Ahmed MF, Kazim SM, Ghori SS, Mehjabeen SS, Ahmed SR, Ali SM, Ibrahim M. Antidiabetic activity of Vinca rosea extracts in alloxan-induced diabetic rats. *International Journal of Endocrinology*. 2010 Oct; 2010
10. https://www.thehindubusinessline.com/news/science/diabetes-can-be-cured-but-not-by-targeting-

blood-sugar-scientists/article9993885.ece dated 21-10-2024, time 10:45 IST.

11. Shinde RV, Rana AP, Rajurkar H, Kaple MN. Prameha and diabetes mellitus. *International Journal of Current Research and Review*. 2020; 12(14)
12. Allamsetty J, Pedada SP, Pedada N, Kolli D. A basic review of *Vinca rosea*. *International Journal of Pharmacognosy and Chemistry*. 2020; 31-36.
13. Ahmed MF, Kazim SM, Ghori SS, Mehjabeen SS, Ahmed SR, Ali SM, Ibrahim M. Antidiabetic activity of Vinca rosea extracts in alloxan-induced diabetic rats. *International Journal of Endocrinology*. 2010 Oct; 2010.

*****