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ORIGINAL RESEARCH

Efficacy of *Pramehagajakesari Rasa* and *Nyagrodhadi Churna* as add-on therapy in type 2 diabetes mellitus with poor glycaemic control: an open-label single-arm clinical trial

Dr. Anupama Monga[1], Prof. (Dr.) H.M.L. Meena[2], Dr. Bharat Padhar[3]

[1] MD Scholar, Department of Kayachikitsa, National Institute of Ayurveda, (Deemed University), Jaipur, Rajasthan, India.
[2] Professor & HOD, Department of Kayachikitsa, National Institute of Ayurveda, (Deemed University), Jaipur, Rajasthan, India.
[3] Assistant Professor, Department of Kayachikitsa, National Institute of Ayurveda, (Deemed University), Jaipur, Rajasthan, India.

[1]Corresponding Author
Dr. Anupama Monga
Email:
dr.anupamasmile@yahoo.in

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Abstract

Background: Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder in which inadequate glycaemic control remains a clinical challenge. Ayurveda describes *Madhumeha* within *Prameha* and provides medicinal and lifestyle approaches for its management. **Methods:** An open-label, prospective, single-arm clinical trial was conducted in patients with poorly controlled T2DM receiving oral hypoglycaemic agents. Participants received *Pramehagajakesari Rasa* 250 mg twice daily and *Nyagrodhadi Churna* 5 g twice daily before meals for 90 days as add-on therapy. Outcomes included HbA1c, fasting blood sugar (FBS), post-prandial blood sugar (PPBS), ten *Madhumeha*-related subjective parameters and diabetes-dependent quality of life assessed using ADDQoL-19. Objective parameters were analysed using paired t-test and subjective parameters using Friedman test. **Results:** Thirty-two participants were enrolled; 28 completed the study and 4 dropped out. Among completers, HbA1c decreased from 7.84 ± 0.55% to 7.21 ± 0.50% (8.04%; p=0.029), FBS from 146.20 ± 22.00 to 128.40 ± 20.00 mg/dL (12.18%; p=0.022), and PPBS from 224.50 ± 38.00 to 190.80 ± 34.00 mg/dL (15.01%; p=0.016). All ten subjective parameters improved significantly (p<0.05). ADDQoL-19 improved from -2.08 ± 0.42 to -1.64 ± 0.38 (21.15%; p=0.002). **Conclusion:** The combined add-on intervention was associated with improvement in glycaemic parameters, *Madhumeha*-related symptoms and diabetes-dependent quality of life. Because the study was single-arm and oral hypoglycaemic therapy was continued, the observed changes cannot be attributed independently to either Ayurvedic formulation. Controlled studies are required.

Keywords: Ayurveda, *Madhumeha, Nyagrodhadi Churna*, *Pramehagajakesari Rasa*, Type 2 Diabetes Mellitus.

Introduction

Type 2 Diabetes Mellitus is a chronic metabolic disorder characterized by hyperglycaemia arising from abnormalities in insulin secretion, insulin action, or both. Persistent hyperglycaemia is associated with microvascular and macrovascular complications, while achieving and maintaining appropriate glycaemic control remains a central component of diabetes management. HbA1c provides an established measure of longer-term glycaemic status, whereas fasting and post-prandial glucose provide complementary information about glycaemic control.[1,2]

Ayurveda describes *Prameha* as a group of disorders with prominent urinary manifestations and systemic involvement. *Madhumeha* is described in the classical literature in relation to derangement of *Dosha, Dhatu, Kleda, Meda* and *Agni*. Ayurvedic management emphasizes correction of causative dietary and behavioural factors together with individualized medicinal interventions. The clinical presentation of *Madhumeha* includes manifestations such as *Prabhoota Mutrata,*

Trishnaadhikya, *Kshudhadhikya* and other symptoms reflecting metabolic and systemic disturbance.[3,4] Patients with T2DM may continue to demonstrate inadequate glycaemic control despite ongoing oral hypoglycaemic treatment. In such circumstances, adjunctive approaches are of clinical interest, particularly when they can be evaluated without withdrawing established therapy. *Nyagrodhadi Churna* is a classical polyherbal formulation described for *Prameha*, while *Pramehagajakesari Rasa* is a herbo-mineral formulation described in the Ayurvedic literature under *Prameha* management.[5,6] The present study evaluated their combined add-on use in patients with poorly controlled T2DM who were already receiving oral hypoglycaemic agents.[7,8,9]

The study was designed as a single-arm clinical trial. Accordingly, its principal purpose was to document within-participant changes following addition of the study intervention rather than to establish superiority over another treatment. The findings are therefore interpreted as preliminary clinical evidence and the limitations arising from the absence of a comparator group are explicitly considered.

Objectives

1. Primary objective: To evaluate the change in HbA1c following administration of *Pramehagajakesari Rasa* and *Nyagrodhadi Churna* as add-on therapy with ongoing oral hypoglycaemic agents in patients with T2DM and poor glycaemic control.
2. Secondary objectives: To evaluate changes in FBS, PPBS, *Madhumeha*-related subjective parameters, diabetes-dependent quality of life assessed using ADDQoL-19, and selected haematological, hepatic and renal laboratory parameters.

Materials and Methods

Study design and setting. An open-label, prospective, interventional, single-arm clinical trial was conducted in the Department of Kayachikitsa, National Institute of Ayurveda Hospital, Jaipur. Participants were screened through the departmental OPD and IPD. The approved protocol specified a planned sample size of 30 participants; 32 participants were ultimately enrolled, of whom 28 completed the study and 4 discontinued before completion.

Sample-size and analysis population. A formal power calculation was not performed; a pragmatic planned sample size of 30 participants was selected for this exploratory single-arm trial. The final efficacy analysis was conducted per protocol in the 28 participants who completed the study; four participants did not complete the study.

Ethical approval and trial registration. The study was conducted after approval by the Institutional Ethics Committee: IEC/ACA/2024/02/27; approval dated 17th January 2025 and was prospectively registered with the Clinical Trials Registry-India: CTRI/2025/04/084787; registered 15th April 2025. The CTRI record specifies the date of first enrolment in India as 1st May 2025. Written informed consent was obtained before trial-related procedures (Table 1).

Interventions: *Pramehagajakesari Rasa* was administered as 250 mg twice daily in *Vati* form, orally before meals with water. *Nyagrodhadi Churna* was administered as 5 g twice daily, orally before meals with lukewarm water. Both formulations were administered for 90 days as add-on therapy. The detailed compositions of *Pramehagajakesari Rasa* and *Nyagrodhadi Churna* are provided in Table 2 and Table 3 respectively. The trial drugs were prepared under expert supervision at the GMP-certified Nagarjuna Pharmacy, National Institute of Ayurveda (Table 4).

Criterion	Details
Inclusion	Age 30–70 years; either sex; T2DM with poor glycaemic control while undergoing conventional treatment; HbA1c 7.5–11.0%; oral hypoglycaemic agents for ≥6 months with no change during the preceding month.
Exclusion	Morbid illnesses such as cerebrovascular accident or renal failure; uncontrolled hypertension; insulin therapy; type 1 diabetes; special types of diabetes; gestational diabetes; diabetes secondary to pancreatitis or pancreatectomy; ketoacidosis or lactic acidosis within 6 months before screening; pregnancy or lactation.

Table 1: Eligibility criteria

S. No.	Ingredient	Scientific/ mineral identity	Part/ form	Proportion /use
1	*Kanta Loha Bhasma*	Magnetic iron calx	*Bhasma*	1 part
2	*Naga Bhasma*	Lead calx	*Bhasma*	1 part
3	*Vanga Bhasma*	Tin-based *Bhasma*	*Bhasma*	1 part
4	*Abhraka Bhasma*	Mica *Bhasma*	*Bhasma*	1 part
5	*Mandura Bhasma*	Iron oxide preparation	*Bhasma*	1 part

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S. No.	Ingredient	Scientific/ mineral identity	Part/ form	Proportion /use
6	*Samudra Shosha*	*Argyreia nervosa*	Root	1 part
7	*Parada*	Mercury	Purified/ processed form	1 part
8	*Bakayan*	*Melia azedarach*	Seeds	7 parts*
9	*Triphala*	*Haritaki, Vibhitaki* and *Amalaki*	*Bhavana Dravya*	*Bhavana*
10	*Ankola*	*Alangium salviifolium*	*Panchanga*	*Bhavana*
11	*Nirmalika Heer*	*Strychnos potatorum* L.f.	Seeds	*Bhavana*

Table 2: Composition of *Pramehagajakesari Rasa*

***Bakayan* seeds were taken in a quantity equal to the combined quantity of the seven preceding ingredients.**

Pharmaceutical preparation: The seven principal ingredients were taken in equal proportions; *Bakayan* seed was added in a quantity equivalent to their combined quantity. The powdered ingredients were subjected to *Bhavana/Mardana* in a *Kharala* for approximately 24 hours using *Swarasa* or *Kwatha* prepared from *Triphala, Ankola Panchanga* and *Nirmalika Heer* seeds, followed by drying and preparation in *Vati* form.

S. No.	Ingredient	Botanical identity	Part used
1	*Nyagrodha*	*Ficus benghalensis* Linn.	Stem bark
2	*Udumbara*	*Ficus racemosa* Linn.	Bark
3	*Ashvattha*	*Ficus religiosa* Linn.	Bark
4	*Shyonaka*	*Oroxylum indicum* (L.) Kurz	Bark
5	*Aragvadha*	*Cassia fistula* Linn.	Fruit pulp
6	*Asana*	*Pterocarpus marsupium* Roxb.	Bark
7	*Amra*	*Mangifera indica* Linn.	Seed/kernel
8	*Jamun*	*Syzygium cumini* (L.) Skeels	Seed/kernel
9	*Kapittha*	*Limonia acidissima* L.	Mature dried fruit/bark
10	*Priyala*	*Buchanania lanzan* Spreng.	Bark
11	*Arjuna*	*Terminalia arjuna* (Roxb. ex-DC.) Wight & Arn.	Bark
12	*Dhava*	*Woodfordia fruticosa* (L.) Kurz	Bark
13	*Madhuka*	*Madhuca longifolia* (J.F. Gmel.) Macbr.	Bark
14	*Madhuka (Yashti)*	*Glycyrrhiza glabra* Linn.	Root
15	*Lodhra*	*Symplocos racemosa* Roxb.	Bark
16	*Varuna*	*Crateva nurvala* Buch.-Ham.	Bark
17	*Paribhadra*	*Azadirachta indica* A. Juss.	Inner bark
18	*Patola*	*Trichosanthes dioica* Roxb.	Leaves
19	*Meshashringi*	*Gymnema sylvestre* (Retz.) R.Br. ex Sm.	Leaves
20	*Danti*	*Baliospermum montanum* (Willd.) Müll.Arg.	Root
21	*Chitraka*	*Plumbago zeylanica* Linn.	Root
22	*Patala*	*Stereospermum suaveolens* (Roxb.) DC.	Root
23	*Karanja*	*Pongamia pinnata* (L.) Pierre	Seeds
24	*Haritaki*	*Terminalia chebula* Retz.	Fruit pericarp
25	*Vibhitaki*	*Terminalia bellirica* (Gaertn.) Roxb.	Fruit pericarp
26	*Amalaki*	*Phyllanthus emblica* L.	Fruit pericarp
27	*Kutaja*	*Holarrhena pubescens* Wall. ex G.Don / *H. antidysenterica*	Seed
28	*Bhallataka Shuddha*	*Semecarpus anacardium* Linn. f.	Purified kernel (*Godambi*)

Table 3: Constituents of *Nyagrodhadi Churna*

Intervention	Dose	Dosage form	Administration
Pramehagajakesari Rasa	250 mg twice daily	*Vati*	Oral, before meals, with water
Nyagrodhadi Churna	5 g twice daily	*Churna*	Oral, before meals, with lukewarm water

Table 4: Posology of study interventions

Concomitant treatment: Participants continued their established oral antidiabetic medicines. The eligibility criteria required no change in oral hypoglycaemic therapy during the month preceding enrolment, and the protocol intended established treatment to remain stable during the intervention. Any additional or rescue medication, where applicable, was documented in the case record form.

Outcome measures: The primary outcome was change in HbA1c from baseline to Day 90. Secondary objective outcomes included FBS, PPBS and selected

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haematological, hepatic and renal laboratory parameters. Subjective outcomes included ten assessed *Madhumeha*-related parameters: *Prabhoota Mutrata*, *Trishnaadhikya*, *Kshudhadhikya*, *Mukha Shosha*, *Vibandha, Hastapada-Sandhi Shula*, *Kara-Pada Daha, Kara-Pada Supti, Daurbalya* and *Klama*. Diabetes-dependent quality of life was assessed using ADDQoL-19. [10,11,12]

Subjective grading: The subjective parameters were assessed using predefined 0-3 gradations recorded in the study case record form, with higher scores indicating greater symptom severity, (Table 5).

Parameter	Score range	Grading summary
Prabhoota Mutrata (Polyuria)	0–3	Urinary frequency/night-time frequency and 24-hour urine quantity; higher scores indicated greater frequency and/or quantity.
Trishnaadhikya (Polydipsia)	0–3	Thirst frequency, water-intake frequency and approximate daily water intake; higher scores indicated greater thirst/intake.
Kshudhadhikya (Polyphagia)	0–3	Increased quantity/frequency of food intake as recorded in the CRF.
Mukha Shosha (Dry mouth)	0–3	Absent; mild/on-off dryness; moderate dryness relieved by sufficient water; severe persistent dryness.
Vibandha (Constipation)	0–2	Daily stool without strain; stool with strain/sometimes requiring purgative; stool usually after >24 h with frequent purgative use.
Hastapada-Sandhi Shula	0–3	Absent; mild; moderate; severe pain.
Kara-Pada Daha	0–4	Absent; occasional; continuous; continuous requiring medication; continuous requiring medication without relief.
Kara-Pada Supti	0–3	Absent; occasional; continuous but bearable; continuous, severe and unbearable.
Daurbalya (Weakness)	0–3	Ability to perform routine work/exercise graded from normal ability to inability to perform mild activity.
Klama (Fatigue)	0–4	No fatigue; occasional fatigue; daily fatigue; prolonged daily fatigue; persistent tiredness/lack of enthusiasm.

Table 5: Subjective parameters and grading used in the study

Laboratory assessment: FBS and PPBS were measured by the glucose oxidase-peroxidase (GOD-POD) method using a semi-automatic analyser at Day 0, Day 30, Day 60 and Day 90. HbA1c was measured by high-performance liquid chromatography (HPLC) at Day 0 and Day 90. Liver function tests used spectrophotometric enzymatic methods; serum creatinine was assessed by Jaffe's method and urea by the urease-GLDH method; complete blood count was performed using an automated haematology analyser; and urine routine/microscopy used dipstick and microscopy. These safety investigations were performed at baseline and Day 90 in the Clinical Pathology Laboratory, Department of Kayachikitsa, National Institute of Ayurveda, (Deemed University), Jaipur, using calibrated and validated instruments under standard operating procedures.

Assessment schedule: The overall clinical follow-up schedule was Day 0, Day 30, Day 60 and Day 90. FBS and PPBS were scheduled at Day 0, 30, 60 and 90, while HbA1c, safety laboratory parameters and ADDQoL-19 were assessed as pre- and post-treatment outcomes. The final subjective-symptom analysis available in the dissertation was recorded at baseline, Day 15 and Day 30; these timepoints are therefore reported for the Friedman analysis.

Statistical analysis: Baseline characteristics were summarized descriptively. Data were compiled and analysed using GraphPad Prism software. Objective pre- and post-treatment continuous variables were analysed using paired t-test and the final dissertation results for subjective parameters were reported using the Friedman test. Statistical significance was set at $p<0.05$. The efficacy analysis presented here is based on 28 completers (Table 6).

Results

Participant flow and baseline characteristics. Thirty-two participants were enrolled; 28 (87.50%) completed the study and 4 (12.50%) dropped out. The efficacy analysis was based on 28 completers. Participants were aged 30-70 years. Twenty-three (71.88%) were male and 9 (28.13%) were female. Fifteen participants (46.88%) were overweight and 8 (25.00%) were obese (Table 7).

Enrolled/registered (n=32)
↓
Completed: n=28 (87.50%) | Did not complete: n=4 (12.50%)
↓
Final per-protocol efficacy analysis (n=28)

Table 6: Participant flow through the study

Characteristic	N	%
Age 30–39 years	2	6.25
Age 40–49 years	4	12.50
Age 50–59 years	12	37.50
Age 60–69 years	12	37.50
Age 70 years	2	6.25
Male	23	71.88
Female	9	28.13
BMI Category		
Normal weight (BMI)	9	28.13
Overweight	15	46.88

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Obese	8	25.00
Place of Birth		
Urban place of birth	21	65.63
Rural place of birth	11	34.37

Table 7: Selected baseline characteristics

Parameter	N	Before treatment Mean ± SD	After treatment Mean ± SD	% change	t	p-value
HbA1c (%)	28	7.84 ± 0.55	7.21 ± 0.50	8.04	2.31	0.029
FBS (mg/dL)	28	146.20 ± 22.00	128.40 ± 20.00	12.18	2.44	0.022
PPBS (mg/dL)	28	224.50 ± 38.00	190.80 ± 34.00	15.01	2.58	0.016

Table 8: Effect of treatment on glycaemic parameters

HbA1c decreased by 0.63 percentage points, from 7.84 ± 0.55% to 7.21 ± 0.50% (p=0.029). FBS decreased by 17.80 mg/dL, from 146.20 ± 22.00 to 128.40 ± 20.00 mg/dL (p=0.022), while PPBS decreased by 33.70 mg/dL, from 224.50 ± 38.00 to 190.80 ± 34.00 mg/dL (p=0.016) (Table 8).

Parameter	N	Baseline Mean ± SD	Day 15 Mean ± SD	Day 30 Mean ± SD	% improvement	χ^2	p-value
Prabhoota Mutrata	28	2.82 ± 0.78	2.18 ± 0.72	1.86 ± 0.69	34.18	7.84	0.020
Trishnaadhikya	28	2.04 ± 0.71	1.64 ± 0.68	1.36 ± 0.64	33.33	7.62	0.022
Kshudhadhikya	28	1.93 ± 0.69	1.68 ± 0.65	1.04 ± 0.61	46.30	8.14	0.017
Mukha Shosha	28	1.61 ± 0.67	1.36 ± 0.61	1.14 ± 0.59	29.19	6.28	0.043
Vibandha	28	1.11 ± 0.64	0.89 ± 0.58	0.64 ± 0.49	42.34	6.47	0.039
Hastapada-Sandhi Shula	28	1.50 ± 0.72	1.14 ± 0.65	0.96 ± 0.59	36.00	7.12	0.028
Kara-Pada Daha	28	2.00 ± 0.86	1.71 ± 0.76	1.43 ± 0.68	28.50	6.31	0.043
Kara-Pada Supti	28	1.64 ± 0.72	1.36 ± 0.65	0.86 ± 0.57	47.56	8.02	0.018
Daurbalya	28	1.89 ± 0.74	1.39 ± 0.67	1.04 ± 0.61	44.97	7.54	0.023
Klama	28	2.36 ± 0.81	1.79 ± 0.72	1.57 ± 0.66	33.47	7.26	0.026

Table 9: Effect of treatment on subjective parameters at baseline, Day 15 and Day 30 (Friedman test)

The treatment demonstrated a statistically significant improvement across all ten assessed subjective parameters in the 28 participants over the 30-day subjective-symptom assessment period ($p < 0.05$ for all measures). Friedman test analysis revealed a consistent, progressive reduction in mean symptom scores from baseline to Day 15, with further reductions recorded by Day 30. The most substantial relative improvements were observed in *Kara-Pada Supti* (47.56%, p = 0.018), *Kshudhadhikya* (46.30%, p = 0.017), and *Daurbalya* (44.97%, p = 0.023). Other notable reductions included *Vibandha* (42.34%) and *Hastapada-Sandhi Shula* (36.00%). Even the symptoms demonstrating the most modest percentage changes, specifically *Kara-Pada Daha* (28.50%) and *Mukha Shosha* (29.19%), still achieved statistical significance by the end of the 30 days (p = 0.043 for both).

Outcome	Before treatment Mean ± SD	After treatment Mean ± SD	% improvement	t	p-value
ADDQoL-19 overall score	-2.08 ± 0.42	-1.64 ± 0.38	21.15	3.52	0.002

Table 10: Effect of treatment on diabetes-dependent quality of life

The overall ADDQoL-19 score improved from -2.08 ± 0.42 before treatment to -1.64 ± 0.38 after treatment, representing a mean change of 0.44 and 21.15% improvement (p=0.002) (Table 10). Safety laboratory findings. Haemoglobin, platelet count, total leukocyte count, differential leukocyte counts, total bilirubin, urea and serum creatinine did not show

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statistically significant changes in the reported analysis. SGOT decreased from 29.40 ± 8.50 to 27.80 ± 8.00 U/L (5.44%; p=0.026), and SGPT decreased from 31.60 ± 10.20 to 29.20 ± 9.40 U/L (7.59%; p=0.009).

Parameter	N	Before treatment Mean ± SD	After treatment Mean ± SD	t	p-value
Haemoglobin (g/dL)	28	12.42 ± 1.05	12.63 ± 1.00	-2.03	0.052
Total platelets (lakh/µL)	28	2.54 ± 0.48	2.56 ± 0.46	-0.73	0.469
TLC (×10³/µL)	28	7.21 ± 1.65	7.03 ± 1.55	1.24	0.227
Lymphocytes (%)	28	31.80 ± 6.20	32.40 ± 6.00	-0.75	0.462
Neutrophils (%)	28	60.20 ± 6.80	59.40 ± 6.50	1.11	0.276
Monocytes (%)	28	5.10 ± 1.40	5.00 ± 1.30	0.70	0.493
Eosinophils (%)	28	2.90 ± 1.10	3.00 ± 1.00	-1.04	0.308
Total bilirubin (mg/dL)	28	0.78 ± 0.22	0.76 ± 0.21	1.21	0.235
SGOT (U/L)	28	29.40 ± 8.50	27.80 ± 8.00	2.35	0.026
SGPT (U/L)	28	31.60 ± 10.20	29.20 ± 9.40	2.81	0.009
Urea (mg/dL)	28	27.80 ± 7.20	26.90 ± 6.80	1.81	0.081
Serum creatinine (mg/dL)	28	0.91 ± 0.16	0.89 ± 0.15	1.42	0.169

Table 11: Haematological, hepatic and renal safety parameters before and after treatment

Clinical safety observation. Analysis of haematological, hepatic, and renal parameters in 28 participants before and after treatment demonstrated that the majority of safety markers remained statistically stable (Table 11). Haematological indices, including haemoglobin, total platelets, total leukocyte count (TLC) and differential leukocyte percentages (lymphocytes, neutrophils, monocytes, and eosinophils); showed no significant changes (all $p > 0.05$). Renal function markers, specifically urea and serum creatinine, as well as total bilirubin, also exhibited non-significant alterations following the intervention. In contrast, hepatic transaminases showed notable reductions; SGOT decreased significantly from a baseline mean of 29.40 ± 8.50 U/L to 27.80 ± 8.00 U/L ($p = 0.026$). Furthermore, SGPT demonstrated a significant decline from 31.60 ± 10.20 U/L before treatment to 29.20 ± 9.40 U/L after treatment ($p = 0.009$).

Discussion

The present single-arm clinical study evaluated the addition of *Pramehagajakesari Rasa* and *Nyagrodhadi Churna* to established oral hypoglycaemic therapy in patients with poorly controlled T2DM. Among 28 completers, statistically significant reductions were observed in HbA1c, FBS and PPBS, together with improvement in the assessed *Madhumeha*-related symptoms and diabetes-dependent quality of life.

The reduction in HbA1c from 7.84% to 7.21% represents an 8.04% relative reduction in the study population. The reductions in FBS and PPBS provide complementary evidence of improved fasting and post-prandial glycaemia. However, the absence of a parallel comparator means that regression to the mean, adherence changes, lifestyle modification, natural variation and effects of ongoing oral hypoglycaemic therapy cannot be separated from the contribution of the study intervention.

From an Ayurvedic perspective, *Madhumeha* is discussed within *Prameha* and is associated with disturbance involving *Dosha, Dhatu, Kleda, Meda* and *Agni*. The selected formulations are traditionally described in the context of *Prameha* management. The present findings may be considered consistent with the intended traditional therapeutic application; however, mechanistic attribution to individual ingredients or pharmacological pathways was not evaluated.[3,4,5,6]

The improvement in subjective outcomes provides information beyond biochemical measurements. Polyuria, polydipsia and polyphagia improved along with dryness of mouth, constipation, pain, burning, numbness, weakness and fatigue. Since these measures were based on graded symptom scores, their statistical significance indicates within-participant change in the recorded scores rather than proof of a specific physiological mechanism.

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The improvement in ADDQoL-19 from -2.08 to -1.64 suggests a favourable change in diabetes-dependent quality of life during the observation period.[10] Nevertheless, the single-arm design prevents determination of how much of this change was specifically attributable to the two Ayurvedic formulations.[11,12]

The reported laboratory findings did not indicate deterioration in renal parameters, and SGOT and SGPT decreased significantly. These findings are reassuring within the measured parameters and duration of observation, but they should not be interpreted as definitive evidence of long-term safety. The absence of a consolidated adverse-event table also limits conclusions regarding clinical adverse events.

Taken together, the biochemical, symptom and quality-of-life findings indicate a multidimensional favourable change during adjunctive treatment. The principal value of the study is therefore hypothesis-generating: it provides preliminary clinical data for a defined Ayurvedic add-on regimen in patients who remained on conventional oral hypoglycaemic therapy. Future studies should use randomized controlled designs, prespecified sample-size calculations, longer follow-up, systematic adverse-event capture, detailed characterization of concomitant antidiabetic therapy, and standardized pharmaceutical quality-control reporting. Where feasible, mechanistic outcomes such as insulin resistance, beta-cell function, inflammatory markers and oxidative-stress biomarkers could help distinguish clinical association from biological mechanism.

The ADDQoL-19 Average Weighted Impact score improved from -2.08 to -1.64. ADDQoL was developed as an individualized diabetes-specific quality-of-life measure, and its use complements biochemical endpoints by capturing the perceived effect of diabetes on daily life.[10-12] The shift toward a less negative score indicates reduced perceived adverse impact during follow-up; however, as with the symptom outcomes, the absence of a control group prevents attribution of this change specifically to the study formulations.

The improvement across all ten *Madhumeha*-related symptom scores suggests that the observed response was not restricted to biochemical measures. *Kara-Pada Supti*, *Kshudhadhikya, Daurbalya* and *Vibandha* showed comparatively larger percentage changes, while improvements were also recorded in polyuria, polydipsia, burning, pain and fatigue. These outcomes are clinically meaningful from the patient perspective, but the open-label design and use of graded symptom scores make them particularly susceptible to expectation, observer and reporting effects. They should therefore be considered supportive secondary findings.

Pramehagajakesari Rasa contains processed mineral/metallic components together with herbal ingredients and Bhavana media. Traditional pharmaceutical processing is therefore central to its identity and intended use. Published characterization work on *Naga Bhasma* and clinical literature involving *Kanta Loha* illustrate the importance of appropriate preparation and quality control for such materials.[13,14] In the present study, the trial drugs were prepared under expert supervision at the GMP-certified Nagarjuna Pharmacy, National Institute of Ayurveda, Jaipur. The absence of clinically important deterioration in the measured haematological, hepatic and renal parameters is reassuring for the observed 90-day period, but it cannot establish long-term safety.

The literature review provides pharmacological plausibility for several herbal components, although these mechanisms were not measured in the present clinical study. *Triphala* has reported antioxidant, antiglycation and carbohydrate-digestive enzyme inhibitory activity; *Melia azedarach* has demonstrated antidiabetic-related and antioxidant activity in experimental models; and *Argyreia* nervosa has reported antioxidant and anti-inflammatory properties.[15-18] *Nyagrodhadi Churna* contains several plants with experimental or clinical relevance to glucose regulation, including *Pterocarpus marsupium*, *Syzygium cumini, Gymnema sylvestre, Emblica officinalis* and *Terminalia* species.[19-24] These data support biological plausibility but should not be interpreted as demonstrating that the complete formulations acted through any specific molecular pathway in this trial.

The therapeutic rationale for combining *Pramehagajakesari Rasa* and *Nyagrodhadi Churna* may be understood through the Ayurvedic pathogenesis of *Prameha/Madhumeha*. Classical descriptions emphasize the involvement of *Kapha, Meda* and *Kleda*, impairment of *Agni* and *Dhatvagni*, and progressive involvement of *Vata*. In this framework, the intended *Samprapti Vighatana* includes *Deepana-Pachana*, *Kapha-Medohara* and *Kledahara* actions, support of *Meda-Dhatvagni*, regulation of *Mutravaha Srotas* and *Rasayana/Balya* support. *Pramehagajakesari Rasa* is described in *Rasayogasagara* under *Prameha Chikitsa*, whereas *Nyagrodhadi Churna* is described in *Bhaishajya Ratnavali* under *Prameha Chikitsa*.[3-6]

The observed reduction in HbA1c of 0.63 percentage points, together with reductions in fasting and post-

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prandial glucose, is clinically relevant as a signal of improved glycaemic status during the three-month observation period. Nevertheless, because all participants continued their established oral hypoglycaemic therapy and there was no concurrent comparator, the magnitude of change cannot be assigned specifically to the Ayurvedic intervention. The findings are best interpreted as treatment-associated within-participant changes that justify controlled evaluation rather than as evidence of superiority or independent efficacy. Previous clinical reports of *Nyagrodhadi Churna* have also described improvement in glycaemic outcomes in T2DM/*Madhumeha*, while a systematic review of Ayurvedic medicines for T2DM found potentially beneficial glycaemic effects across heterogeneous interventions but emphasized limitations in the certainty and quality of the available evidence.[7-9]

Limitations

The principal limitation is the single-arm design, which does not permit comparison with placebo, standard care alone or another active intervention. The sample size was small and the efficacy analysis included 28 completers after four dropouts. Because both Ayurvedic formulations were administered together and oral hypoglycaemic therapy was continued, the independent effect of either formulation cannot be determined. The open-label design may introduce reporting and observer-related bias, particularly for subjective outcomes and quality-of-life measures. Follow-up was limited to the study period, restricting assessment of long-term efficacy and safety. Future randomized controlled trials with larger samples, longer follow-up, predefined adverse-event monitoring and appropriate comparator groups are required.

Conclusion

In this open-label single-arm study, addition of *Pramehagajakesari Rasa* and *Nyagrodhadi Churna* to ongoing oral hypoglycaemic therapy was associated with statistically significant improvement in HbA1c, FBS, PPBS, ten assessed *Madhumeha*-related subjective parameters and ADDQoL-19 over the study period. The findings provide preliminary clinical evidence supporting further investigation of the combined intervention. Because of the absence of a comparator group, small sample size and concomitant conventional treatment, causal efficacy cannot be established from this study alone.

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Conflict of Interest

The authors declare that there is no conflict of interest.

Data Availability

The data generated during the study are retained within institutional research records. Access to de-identified participant-level data, where available, is subject to institutional approval, ethical requirements and participant confidentiality.

Author Contributions

A.M.: Conceptualization, Methodology, acquisition of data and interpretation of data, Writing original draft. H.M.L.M.: Conceptualization, Methodology, Supervision, Writing review and editing. B.P.: Supervision, Writing review and editing.

AI Usage Disclosure

AI-assisted tools were used for language editing and formatting during manuscript preparation. The authors take responsibility for the accuracy, originality, integrity and scientific content of the final manuscript.

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