

Efficacy of *Phalatrikadi Vasti* with *Phalatrikadi Kwath* versus Standard Treatment (Tab Metformin) in Diabetes Mellitus Type II (*Prameha*): A Research Protocol

PRASAD RUKMINIKANT MIRGE¹, SHWETA PARWE², PUNAM SAWARKAR³, GARIMA GUPTA⁴

ABSTRACT

Introduction: Diabetes Mellitus (DM) is a metabolic disorder marked by high blood sugar due to insufficient insulin production or impaired insulin action, leading to organ damage. Type 2 Diabetes Mellitus (T2DM) is rising globally. In Ayurveda, DM is compared with *Prameha*, a group of metabolic disorders. Type 1 Diabetes Mellitus (T1DM) aligns with congenital *Prameha*, while T2DM corresponds to lifestyle-related *Prameha*. Symptoms such as excessive urination, fatigue, and systemic metabolic changes described in Ayurveda closely resemble those of modern diabetes.

Need of the study: Conventional hypoglycaemic drugs often cause weight gain and other side-effects, creating a need for safer alternatives. Ayurveda offers solutions through *Panchakarma* and herbal therapies, especially *Vasti* (medicated enema), a safe and non invasive method. With its diuretic, anti-inflammatory, and metabolic actions, *Phalatrikadi* improves insulin sensitivity and regulates metabolism, making it suitable for *Prameha*. *Phalatrikadi* decoction is *Tridoshaghna* (Pacifies all three *doshas*), *Lekhaniya* (scrape out excess fat) in properties, and it is widely used in practice. However, no studies have yet evaluated the administration of *Phalatrikadi* decoction through the rectal route. Therefore, exploring such novel therapeutic

approaches may help expand research perspectives in the management of diabetes.

Aim: To evaluate the comparative efficacy of *Phalatrikadi Vasti* followed by *Phalatrikadi Kwath* (Decoction) versus standard treatment (Tab. Metformin) in the management of T2DM (*Prameha*).

Materials and Methods: The present study is a randomised open-label controlled clinical trial conducted at Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India, from October 2025 to October 2026. A total of 60 patients who met the inclusion criteria will be randomly allocated into two groups of 30 patients each. Group A (trial group) will receive *Phalatrikadi Niruha Basti* (decoction enema) for 16 days, followed by oral administration of *Phalatrikadi* for 32 days. Group B (control group) will receive Metformin 500 mg orally once daily for 48 days. The primary outcome measures included assessment of Fasting Blood Sugar (FBS), Postprandial Blood Sugar (PPBS), and urine sugar levels at baseline and after the intervention. Paired t-test for within-group comparison and an independent t-test for baseline comparison between the groups. A p-value of <0.05 will be considered statistically significant.

Keywords: Enema, Glucose, Glycaemia, Insulin, *Madhumeha*, *Panchakarma*, *Shodhana*, Sugar

INTRODUCTION

The DM is a group of metabolic disorders marked by chronic hyperglycaemia due to inadequate insulin secretion or action. Prolonged hyperglycaemia damages organs like the kidneys, heart, eyes, and nerves, leading to dysfunction and failure [1]. The cause may be insufficient insulin or poor insulin response, often linked to infections or autoimmune damage of the pancreas. While multiple types exist, type 1 and type 2 are the most common [2]. Glycaemic status is assessed through FBS, Postprandial Plasma Glucose (PPG), and HbA1c. The International Diabetes Federation (IDF) estimates that T2DM will rise globally, affecting 537 million people (10.5% of adults aged 20-79) [3]. In 2014, 8.5% of adults over 18 were diabetic. By 2019, diabetes caused 1.5 million deaths, with 48% under 70 years, along with 460,000 kidney-related deaths and 20% of cardiovascular deaths linked to hyperglycaemia [4]. Diabetes is significantly affected by lifestyle factors. Ancient Ayurvedic texts (*Charaka*) describe it as a disorder of the physiological components of the three *doshas* (*Vata*, *Pitta*, *Kapha*), fat, plasma, blood, muscle, fluids, reproductive elements, lymph, and vital immunity. Ayurveda distinguishes congenital

(hereditary) and lifestyle-induced types of diabetes [5], which correspond to modern classifications [6]. *Prameha*, described in Ayurvedic scriptures, shows symptoms resembling DM, including polyuria, excessive urination, and turbid urine [7]. Given the global rise of diabetes, integrative approaches combining Ayurveda with modern medicine are gaining attention. One such method is *Phalatrikadi* decoction medicated enema (*Phalatrikadi Vasti*) alongside standard antidiabetic therapy. The formulation contains seven herbs: *Amalaki* (*Emblica officinalis*), *Haritaki* (*Terminalia chebula*), *Bibhitaki* (*Terminalia bellirica*), *Haridra* (*Curcuma longa*), *Daruharidra* (*Berberis aristata*), *Musta* (*Cyperus rotundus*), and *Indravaruni* (*Citrullus colocynthis*) [8]. Traditionally, these are used for diabetes, urinary issues, bleeding disorders, inflammation, and reproductive imbalances. Pharmacologically, they show hormone-modulating, diuretic, antioxidant, and anti-inflammatory effects. In diabetes, they regulate metabolism by reducing glucose, promoting diuresis, and protecting against oxidative damage, while maintaining systemic and reproductive balance.

Administered via enema, the decoction bypasses hepatic metabolism, improving absorption and bioavailability. This

integrative approach may enhance glycaemic control and metabolic health, offering a comprehensive strategy for long-term diabetes management.

Primary Objectives:

1. To evaluate the efficacy of *Phalatrikadi Kwath Vasti* (decoction enema) followed by *Phalatrikadi* decoction orally on blood sugar levels (FBS and PPBS), urine sugar levels, and HbA1C in T2DM.
2. To evaluate the efficacy of Metformin tablets on blood sugar levels (FBS and PPBS), urine sugar levels, and HbA1C in T2DM.

Secondary Objective:

1. To compare the efficacy of *Phalatrikadi* decoction enema followed by *Phalatrikadi* Decoction orally vs Metformin tablets on blood sugar levels (FBS and PPBS), urine sugar levels, and HbA1C in T2DM

Null Hypothesis (H_0): There is no significant difference in the efficacy of *Phalatrikadi Kwath Vasti* (decoction enema) followed by *Phalatrikadi* decoction orally compared to the standard treatment in the management of T2DM (*Prameha*).

Alternate Hypothesis (H_1): There is a significant difference in the efficacy of *Phalatrikadi Kwath Vasti* (decoction enema) followed by *Phalatrikadi* decoction orally compared to the standard treatment in the management of T2DM (*Prameha*).

REVIEW OF LITERATURE

It is important to note that no clinical studies have been conducted to evaluate the effectiveness of administering the *Phalatrikadi* decoction through enema. However, clinical research has been carried out on its oral administration. These studies provide valuable information regarding the pharmacological mechanisms of the formulation. The findings particularly highlight its antidiabetic properties. Thus, existing oral studies offer useful insights into the therapeutic potential of this Ayurvedic formulation.

Tanmane CS et al., reported that *Phalatrikadi* decoction, administered orally at a dose of 20mL twice a day for three months, produced significant antihyperglycaemic effects in type 2 diabetic patients. The formulation reduced fasting glucose by 34 mg/dL, PPBS by 35 mg/dL, and HbA1c by 0.27%, and urine sugar also showed marked improvement [9].

Gouri C et al., reported that *Phalatrikadi* decoction, administered orally at a dose of 40 mL once daily at bedtime for eight weeks, produced significant antihyperglycaemic effects in patients with T2DM [10].

Kushwaha PS et al., reported the management of a 50-year-old male patient with T2DM using *Phalatrikadi* decoction 20 mL twice daily for three months. FBS reduced from 150 mg/dL to 126 mg/dL (16% reduction), PPBS reduced from 217 mg/dL to 158 mg/dL (27.2% reduction), and HbA1c decreased from 9.2% to 6.9% (25% reduction). It concludes that *Phalatrikadi* decoction has hypoglycaemic, insulin-sensitising, antioxidant actions, thereby improving glycaemic control and associated symptoms [11].

Overall, the findings suggest that each of the seven herbs in *Phalatrikadi* Decoction possesses distinct yet complementary antidiabetic properties, including lowering blood glucose levels, enhancing insulin secretion, reducing glucose absorption, providing antioxidant effects, and inhibiting enzymes involved in carbohydrate metabolism.

Thus, the present study aims to evaluate the Comparative efficacy of *Phalatrikadi Vasti* followed by *Phalatrikadi Kwath* vs standard treatment (Tab. Metformin) in the management of T2DM (*Prameha*).

MATERIALS AND METHODS

The present randomised open-label standard-controlled equivalence clinical trial will be conducted at Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India, from Oct 2025 to Oct 2026. The ethical approval from the Institutional Ethics Committee of the Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India, with registration number MGACHRC/IEC/July-2025/990, has been obtained for the study. The trial is registered on the CTRI website with the Number CTRI/2025/08/092716. All patients will be enrolled in the study only after obtaining informed consent.

Inclusion criteria:

- Patients between the ages of 20 and 60 who are willing to give written informed consent, regardless of sex;
- Uncomplicated T2DM was recently diagnosed during the last six months and is not on any other anti-hypoglycaemic medications;
- FBS level ≥ 126 mg/dL and PPBS level ≥ 200 mg/dL [12];
- Diabetic patients with controlled hypertension: Systolic blood pressure ≤ 130 mmHg and Diastolic blood pressure ≤ 80 mmHg (average) [13];
- Patients fit for the decoction enema procedure as per traditional guidelines [14].

Exclusion criteria:

- Patients with Insulin Dependent Diabetes Mellitus (IDDM) or Type-2 Diabetes on insulin therapy;
- Patients with Juvenile Diabetes or Gestational Diabetes.
- Patients with diabetes-related complications, such as retinopathy, nephropathy, neuropathy, previous history of diabetic coma.
- Patients suffering from any current acute illness or uncontrolled hypertension.
- Pregnant or lactating women.
- Patients with anorectal pathologies.

Criteria for ending or changing allocated interventions: Patients will be withdrawn from the study if their FBS exceeds 200 mg/dL or their PPBS exceeds 300 mg/dL during the trial period. Participants who choose to discontinue the study voluntarily will be permitted to do so and will subsequently be replaced. Additionally, patients who develop any acute illness during the trial that may interfere with the study will also be withdrawn. In the event of any untoward incident, drug sensitivity, or other health-related issue during the trial, the patient will receive free medical treatment until the condition is resolved; however, such patients will be withdrawn from the study and replaced to maintain the required sample size.

Sample size calculation: $n \geq \{(Z_{(1-\alpha/2)} + Z_{(1-\beta)})^2 \times (\sigma_1^2 + \sigma_2^2 / r)\} / (\mu_1 - \mu_2)^2$

Z Alpha (α): 0.05 = 1.96

Z Beta (β): 0.20 = 0.84

Standard Deviation in metformin (σ_1): 53.49 [15]

Mean BSL-F in the Metformin Group (μ_1): at baseline/Before: 168.73

Mean in Group metformin after (μ_2): 127.8 [15]

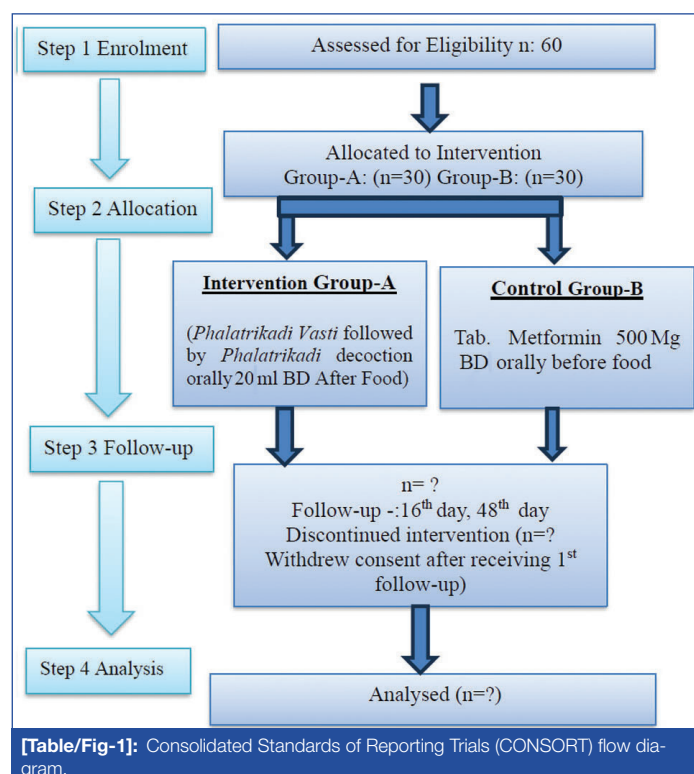
Standard Deviation in metformin (σ_2): 43.69 [15]

Ratio (Group 2 / Group 1): 1

$n \geq \{(1.96) + Z(0.84)\}^2 \times (53.49^2 + 43.69^2 / 1) / (168.73 - 127.8)^2 = 22.3 \sim 23$ per group

Considering 30% dropout rate, a total of 60 patients will be enrolled in the study. These participants will be randomly assigned to two groups of 30 each. Participants who meet the eligibility criteria and provide written informed consent will be randomly allocated to two groups in a 1:1 ratio using simple randomisation, a computerised

random number table method. The randomisation sequence will be generated using a computer-based random number generator by an independent statistician who is not involved in participant recruitment, treatment administration, or outcome assessment. This will be a randomised open-label clinical trial. Thus, both participants and investigators will be aware of the treatment allocation; therefore, blinding will not be implemented. However, to minimise selection bias, allocation concealment will be maintained. The treatment allocations will be placed in Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) prepared by an independent person not involved in the study procedures. After a participant is enrolled in the study, the principal investigator or study coordinator will open the next envelope in the sequence to determine the group assignment and implement the respective intervention. The independent statistician will be responsible for generating the randomisation sequence, and the principal investigator will be responsible for implementing the



Group	Sample size	Intervention	Dose and frequency	Medium (Anupan)	Duration	Follow-up
A	30	16 Days Decoction enema regime: (<i>Phalatrikadi</i> Decoction enema+Medicated Sesame oil enema) i.e., 3 Decoction enema followed by 1 Medicated oil enema i.e., a total of twelve decoction enemas and four medicated oil enemas followed by <i>Phalatrikadi</i> decoction orally for 32 consecutive days.	Decoction enema: 960 mL, Once a day on an empty stomach. Medicated oil enema: 60 mL, Once a day, after food <i>Phalatrikadi</i> decoction dose -20 mL BD After Food	Not Applicable for Decoction enema. Lukewarm Water	48 days	16 th day, 48 th day.
B	30	Tab. Metformin	500 mg BID Before Food [15]	Water	48 days	16 th day, 48 th day.

[Table/Fig-2]: Showing grouping and posology along with treatment period and follow-up period.

S. No.	Name	Taste (Rasa)	Properties (Guna)	Potency (Veerya)	Post-digestion effect (Vipaka)	Action (Karma)	Quantity
1	<i>Amalaki</i> (<i>Embellica officinalis</i>)	Sweet (<i>Madhura</i>), Sour (<i>Amla</i>), Pungent (<i>Katu</i>), Bitter (<i>Tikta</i>), Astringent (<i>Kashay</i>)	Heavy (<i>Guru</i>), Dry (<i>Ruksha</i>)	Cold (<i>Sheeta</i>)	Sweet (<i>Madhur</i>)	Pacifies blood (<i>Rakta</i>), Hypoglycaemic, <i>Tridosahara</i> , Aphrodisiac (<i>Vrishya</i>)	7 gm
2	<i>Haritaki</i> (<i>Terminalia chebula</i>)	Sweet (<i>Madhura</i>), Sour (<i>Amla</i>), Pungent (<i>Katu</i>), Bitter (<i>Tikta</i>), Astringent (<i>Kashay</i>)	Light (<i>Laghu</i>), Dry (<i>Ruksha</i>)	Hot (<i>Ushna</i>)	Sweet (<i>Madhura</i>)	Diuretic (<i>Mutravirechaniya</i>), Anti-inflammatory (<i>Sothahar</i>), Pacifies <i>Tridosha</i> , Strength-Promoting (<i>Balya</i>), Hypoglycaemic, Skin diseases (<i>Kushthanashak</i>), Anti-inflammatory, Wound healing, Analgesic properties	7 gm
3	<i>Bibhitaki</i> (<i>Terminalia bellirica</i>)	Astringent (<i>Kashay</i>)	Light (<i>Laghu</i>), Dry (<i>Ruksha</i>)	Hot (<i>Ushna</i>)	Sweet (<i>Madhura</i>)	Promoting hair growth (<i>Keshya</i>), Eye Tonic (<i>Netrya</i>), Deworming (<i>Kriminashak</i>), Antipyretic	7 gm

allocation during participant enrollment and ensuring adherence to the randomisation protocol [Table/Fig-1]. Group A (n=30) will receive *Phalatrikadi* decoction as an enema for the first 16 days, followed by *Phalatrikadi Niruha Basti* decoction orally for the remaining 32 days. Group B (n=30) will be administered Tab Metformin 500 mg BID orally for 48 consecutive days [Table/Fig-2].

Study Procedure

Drug preparation: The *Phalatrikadi* decoction enema will be prepared as per ancient standard texts of Ayurveda [16]. The raw materials for the *Phalatrikadi* decoction will be procured from *Vedapurna Rasashala*, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India, [Table/Fig-3] [17]. Tab. Metformin will be procured from the local pharmacy, Sawangi, Wardha.

Method of administration of decoction enema: Pre-procedure (*Poorvakarma*) - Patient suitability will be assessed through the ten-factor diagnostic method (*Atur Pariksha*), considering strength and disease severity. For preparation, 50 g of *Phalatrikadi dravyas* are boiled in 4 L of water until reduced to 480 mL. This decoction will be combined with 192 mL of honey and 12 g of rock salt, strained, heated, and then mixed with 96 g of paste ingredients, 192 mL of sesame oil, and the prepared decoction [18].

Patient preparation (*Atur Siddhata*): The patient will be instructed to eat a small meal (a ¼ amount that is neither too dry nor too oily), drink plenty of water, and take quick walks afterwards. Subsequently, an oil massage followed by mild heat therapy will be administered to facilitate toxin elimination and promote the liquefaction of bodily fluids.

Main procedure (*Pradhanakarma*): The patient will be placed in the left lateral (*Vama Parshwa*) position with the right leg flexed during the primary process (*Pradhanakarma*). After lubricating the anal area, ¼ of the catheter will be carefully placed. To avoid obstruction, an enema pot will be held at a suitable height for the progressive administration of lukewarm medicinal oil. After that, the catheter will be carefully removed. Within 48 minutes (1 *Muhurta*), the enema should be ejected.

Post-Procedure (*Paschatkarma*): The patient will lie supine during the post-procedure (*Paschatkarma*) phase, and will be instructed to rest for as long as it takes to count to 100 (100 *Vak*). The back, buttocks, and palms will all be gently rubbed. The patient will be

4	Haridra (Curcuma longa)	Pungent (Katu), Bitter (Tikta),	Light (Laghu), Dry (Ruksha)	Hot (Ushna)	Pungent (Katu)	Pacifies blood (Rakta), Skin diseases (Kushthanashak), Anti-inflammatory, Wound healing, Hypoglycaemic actions	7 gm
5	Daruharidra (Berberis aristata)	Bitter (Tikta), Astringent (Kashay)	Light (Laghu), Dry (Ruksha)	Hot (Ushna)	Pungent (Katu)	Wound healing, Analgesic, Hypoglycaemic, Pacifies Kapha and Pitta (Kaphapittanashak)	7 gm
6	Musta (Cyperus rotundus)	Bitter (Tikta), Bitter (Katu), Astringent (Kashay)	Light (Laghu), Dry (Ruksha)	Cold (Sheeta)	Pungent (Katu)	Pacifies blood (Rakta), Antipyretic, Deworming (Kriminashak), Pacifies Kapha and Pitta (Kaphapittanashak)	7 gm
7	Indravaruni (Citrullus colocynthis)	Bitter (Tikta)	Light (Laghu), Dry (Ruksha)	Hot (Ushna)	Pungent (Katu)	Skin diseases (Kushthanashak), Wound healing, Hypoglycaemic, Kapha, and Pitta (Kaphapittanashak)	7 gm

[Table/Fig-3]: Properties of drugs in Phalatrikadi decoction [17].

Scholar/Investigator	Dr. Prasad Rukminikant Mirge							
Title	Efficacy of Phalatrikadi Vasti with Phalatrikadi Kwath versus standard treatment (Tab Metformin) in Diabetes Mellitus (DM) Type II (Prameha): A Randomised Controlled Trial - Research Protocol							
Steps	Q1 28/10/2025	Q2 28/01/2026	Q3 28/04/2026	Q4 28/07/2026	Q5 28/10/2026	Q6 28/01/2027	Q7 28/04/2027	Q8 28/07/2027
IEC authorisation								
Overview of the literature								
Medicine Preparation								
Patients enrolled								
Collection of data								
Analysis								
Writing of Thesis								
submission								

[Table/Fig-4]: Gantt Chart.

Dissemination: To promote the research, this procedure will also be made available as a thesis for evaluating the Comparative efficacy of Phalatrikadi Kwath Vasti (Decoction enema) followed by Phalatrikadi decoction orally versus standard treatment in managing T2DM (Prameha). The study Protocol includes a discussion of the methodology, data-gathering strategies, data-processing tactics, and ethical approval. The authors hope to expand the corpus of knowledge in this field and facilitate further research.

Guidelines: For the study, Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Guidelines are being followed.

encouraged to avoid heavy ventilation, daytime napping, prolonged travel, loud conversation, or anger, and a lukewarm bath will be suggested [19].

Diet and Aftercare (Pathya & Anya Vichara): Light soups, meat broths, and nourishing meals will be part of the diet and aftercare, and drinking lukewarm water is advised.

Decoction enema will be administered on an empty stomach for three consecutive days, followed by oil enema after food on the fourth day, for a total duration of 16 days [20].

Study outcomes

Primary outcomes

Biochemical and Laboratory Parameters: Pre and post-FBS, PPBS, and urine sugar levels will be assessed. The assessment criteria will include FBS levels ≥ 126 mg/dL and PPBS levels ≥ 200 mg/dL, in accordance with established diagnostic thresholds [12].

Secondary outcome

Diabetes Quality of Life (DQOL) Questionnaire [21]: The Diabetes Quality of Life Questionnaire (DQOL) will be administered to all participants before treatment and after completion of the intervention. Each item will be scored on a 5-point Likert scale. The scores of individual domains (Satisfaction, Impact, and Worry) will be calculated separately, and the total score will be obtained by summing the scores of all items. The total score ranges from 46 to 230. A total score of 46-92 indicates good diabetes-related quality of life, 93-138 indicates moderate quality of life, and 139-230 indicates poor quality of life, reflecting a greater negative impact of diabetes on the patient's quality of life.

2. Reduction in HbA1C levels (Due to funding constraints, only five patients from each group will be assessed for HbA1C) [12].
3. Improved energy and physical functioning.

All parameters will be assessed at baseline (before treatment) and at the end of the treatment period, after 48 days. The Gantt chart has been presented in the [Table/Fig-4].

STATISTICAL ANALYSIS

The data analysis will be performed using Statistical Package for the Social Sciences (SPSS) 27.0 software. Baseline characteristics will be compared between groups using an independent samples t-test, and within-group comparisons will be made using a paired t-test. A difference between groups is considered significant if the p-value is <0.05 .

Intervention modification: If any adverse effects occur, they will be reported to the ethical committee. The adverse effects will be treated for the patients. Participants are required to explain if they wish to discontinue the treatment.

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PARTICULARS OF CONTRIBUTORS:

1. Postgraduate Scholar, Department of Panchakarma, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India.
2. Professor and Head, Department of Panchakarma, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India.
3. Professor, Department of Panchakarma, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research Centre, Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India.
4. Postgraduate Scholar, Department of Panchakarma, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Shweta Parwe,
Professor and Head, Department of Panchakarma, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (Hirapur), Datta Meghe Institute of Higher Education and Research Centre, Wardha-442107, Maharashtra, India.
E-mail: shweta.parwe@dmimsu.edu.in

PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Dec 08, 2025
- Manual Googling: Jul 19, 2026
- iThenticate Software: Jul 11, 2026 (1%)

ETYMOLOGY: Author Origin

EMENDATIONS: 8

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: Dec 06, 2025
Date of Peer Review: Jan 09, 2026
Date of Acceptance: Jul 14, 2026
Date of Publishing: Oct 01, 2026