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Efficacy and Safety of Utpaladi Churna with Tandulambu in the Management of Asṛgdara (Abnormal Uterine Bleeding due to Ovulatory Dysfunction): Clinical Case Study.

Dr. Bhappil Sharma[1], Dr. Tanuja Bharti[2]

[1]Associate Professor, Department of Prasuti Tantra Evam Stri Roga, Vaidya Yagya Dutt Sharma Ayurveda Mahavidyalaya and Hospital, Khurja.

Email:ID: drbhapilsharma@gmail.com

[2]Associate Professor, Department of Rasa Shastra and Bhaishajya Kalpana, Vaidya Yagya Dutt Sharma Ayurveda Mahavidyalaya and Hospital, Khurja.

Email:ID: tanujabharti1111@gmail.com

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ABSTRACT

Background: Asṛgdara, correlated with Abnormal Uterine Bleeding (AUB) due to ovulatory dysfunction, is a prevalent gynecological disorder causing significant morbidity. Current hormonal management often presents adverse effects, necessitating safe, effective, and non-hormonal alternatives. Utpaladi Churna, a classical Ayurvedic formulation with astringent (Kashaya) and cooling (Shita Virya) properties, has been traditionally indicated for hemorrhagic disorders, yet lacks modern clinical validation.

Case Summary: This N-of-1 study reports the efficacy of Utpaladi Churna (3g twice daily) administered with Tandulambu (rice water) as an adjuvant in a 28-year-old female diagnosed with AUB due to anovulatory cycles (WHO Type I), presenting with a Pictorial Blood Loss Assessment Chart (PBAC) score of 310, severe anemia (Hb: 8.9 gm%), and a symptom score of 28. The intervention was given over three consecutive menstrual cycles.

Results: The primary endpoint showed a marked reduction in PBAC score to 60 by Cycle 3 (80.6% reduction; $p < 0.05$ on Reliable Change Index). Hemoglobin improved to 12.1 gm% (+35.9%). Menstrual duration normalized from 9 days to 4 days, and cycle length regulated to 28 days. The Ayurvedic symptom score declined to 5 (82.1% reduction). The C-statistic trend analysis confirmed a significant downward trend in bleeding scores over time ($p < 0.05$). Safety parameters (LFT, RFT) remained within normal limits, and no adverse events were reported.

Conclusion: This single case demonstrates that Utpaladi Churna with Tandulambu is a clinically effective, safe, and well-tolerated non-hormonal intervention for managing AUB due to ovulatory dysfunction. These promising findings warrant larger, randomized controlled trials to corroborate the results

Key Words: (MeSH compatible):1. Abnormal Uterine Bleeding; 2. Asṛgdara; 3. Ayurvedic Medicine; 4. Utpaladi Churna; 5. N-of-1 Trial; 6. Menorrhagia; 7. Ovulatory Dysfunction; 8. Tandulambu

INTRODUCTION

Abnormal Uterine Bleeding (AUB) is one of the most frequent gynecological complaints encountered in clinical practice, accounting for nearly 30% of all outpatient gynecology visits globally [1,2]. The PALM-COEIN classification system devised by FIGO categorizes AUB into structural and non-structural causes, with AUB-O (ovulatory dysfunction) being the predominant non-structural etiology, particularly in the perimenarchal and perimenopausal age groups [3]. Anovulatory cycles result in unopposed estrogen stimulation, leading to a fragile, thick, and hypervascular endometrium that sheds irregularly, causing heavy, prolonged, and unpredictable bleeding [4]. This condition severely impacts the quality of life, frequently leads to iron-deficiency anemia, and imposes a substantial economic burden on healthcare systems [5].

Contemporary management strategies for AUB-O include hormonal therapies such as combined oral contraceptives, progestins, and the levonorgestrel-releasing intrauterine system. Non-hormonal options like Tranexamic acid and NSAIDs are also employed [6,7]. While effective, these modalities are frequently associated with adverse effects, including weight gain, mood disturbances, thromboembolic risks, and gastrointestinal intolerance. Furthermore, many patients express a preference for non-hormonal, holistic alternatives, especially when long-term management is required [8].

The Ayurvedic system of medicine offers a rich pharmacopoeia for the management of gynecological bleeding disorders. Asṛgdara is characterized by the excessive flow of menstrual blood (Raja) due to the vitiation of Pitta dosha and Rakta dhatu [9]. The treatment principle (Cikitsa Sutra) emphasizes Stambhana (hemostasis), Pitta-shamana (pacification of heat), and Rakta-prasadana (purification of blood) [10].

Utpaladi Churna is a classical formulation referenced in Bhaishajya Ratnavali under Pradara Rogadhikara [11]. It comprises a synergistic blend of eight ingredients, including Utpala (Nymphaea nouchali), Lodhra (Symplocos racemosa), and Dhātakī (Woodfordia fruticosa). These drugs collectively possess potent astringent and cooling properties, making them theoretically ideal for Pitta-rakta disorders. However, despite its traditional acclaim, there is a distinct paucity of modern clinical evidence, particularly structured N-of-1 studies, validating its efficacy and safety in the context of ovulatory dysfunction

2. RESEARCH GAP

1. Lack of Modern Clinical Validation: While Utpaladi Churna is well-documented in classical textbooks for Asrgdara, it has not been subjected to rigorous, structured clinical evaluation using validated modern outcome measures like the Pictorial Blood Loss Assessment Chart (PBAC) or standardized hematological parameters.

2. Absence of N-of-1 Evidence: There are no published single-case studies that provide deep phenotyping, daily symptom tracking, and intensive longitudinal monitoring of this specific formulation.

3. Unclear Mechanism of Action: The probable mode of action of this formulation on the Hypothalamus-Pituitary-Ovarian (HPO) axis and endometrial hemostasis remains uninvestigated in a clinical setting.

4. Role of the Adjuvant (Anupana): The specific therapeutic synergy of Tandulambu (rice water) as a nutritional carrier with this Churna has not been scientifically explored.

3. STUDY RATIONALE

Given the high prevalence of AUB-O and the limitations of existing hormonal therapies, there is an urgent need to explore safe, cost-effective, and culturally acceptable alternatives. Ayurveda offers a comprehensive system for managing Asṛgdara, but scientific validation is imperative for its integration into mainstream practice. N-of-1 trials are uniquely suited to evaluate such interventions, as they allow for detailed, individualized assessment of drug response, ensuring rigorous safety monitoring while generating preliminary efficacy data. This study was therefore designed to document the holistic effect of Utpaladi Churna with Tandulambu in a strictly monitored clinical setting, providing foundational evidence for future larger-scale research.

4. AIM AND OBJECTIVES

Aim : To evaluate the efficacy and safety of Utpaladi Churna with Tandulambu in the management of Asṛgdara (Abnormal Uterine Bleeding due to Ovulatory Dysfunction).

Objectives :

1. Primary Objective : To assess the change in menstrual blood loss using the Pictorial Blood Loss Assessment Chart (PBAC) score before and after 3 cycles of treatment.

2. Secondary Objectives : To assess changes in Hemoglobin (Hb) levels, duration of menstrual flow, and cycle length.

- To evaluate changes in the Ayurvedic symptom score (graded scale).
- To monitor the safety profile through hepatic and renal function tests.

3. Exploratory Objective: To perform a trend analysis of bleeding scores over the treatment duration using time-series methodology.

5. MATERIALS AND METHODS

5.1. **Study Design and Ethical Considerations**

An N-of-1 (single case) prospective, open-label clinical study was conducted. The study adhered to the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. The protocol was reviewed and approved by the Institutional Ethics Committee (IEC). Written informed consent was obtained from the patient prior to enrollment, explaining the purpose, intervention, risks, and benefits.

5.2. **Patient Profile**

A 28-year-old married female, nulliparous, presented with a chief complaint of heavy, prolonged menstrual bleeding for the past 8 months.

- Menstrual History: Cycle length 24-26 days, bleeding duration 8-9 days, with heavy flow requiring changing of sanitary pads every 1-2 hours, accompanied by passage of large clots.

- General Symptoms: Fatigue, dizziness, pallor, pelvic heaviness, burning sensation in the palms and soles (Pitta-daha), and occasional lower backache.
- Family History: Negative for bleeding disorders.
- Personal History: Vegetarian diet, sedentary lifestyle, non-smoker, non-alcoholic.

5.3. **Diagnostic Evaluation (Inclusion & Exclusion)**

- Clinical Diagnosis: Asrgdara (Pittaja type) based on Ayurvedic diagnostic criteria.
- Modern Correlation: AUB due to ovulatory dysfunction (Anovulatory cycles).
- Supportive Investigations:
- Pelvic Ultrasound (TVS): Revealed normal uterine size, endometrial thickness of 11 mm (mid-cycle), bilateral normal ovaries (no cysts, no fibroids, no polyps). Normal cervical and adnexal structures.
- Hormonal Assays: Day-2 FSH (5.2 mIU/mL), LH (6.1 mIU/mL), E2 (45 pg/mL), normal Prolactin (10 ng/mL). Day-22 serum Progesterone: 1.2 ng/mL (Anovulatory).
- Coagulation Profile: BT/CT normal, Platelet count 2.8 lakhs/mm³.
- Hemoglobin: 8.9 gm% (moderate microcytic hypochromic anemia).
- Exclusion Criteria applied: The patient had no evidence of organic pathology
- (fibroids, polyps, adenomyosis), pregnancy, bleeding diathesis, or thyroid/hormonal disorders (except anovulation). She was not on any hormonal medication for the preceding 3 months.

5.4**. Intervention**

- Drug Formulation: Utpaladi Churna (Fine powder) was prepared in the institutional pharmacy (details under Drug Standardization).
- Dosage: 3 grams (approximately ½ teaspoon), twice daily (morning and evening).
- Adjuvant (Anupana): 100 ml of freshly prepared warm Tandulambu (rice water).
- Duration: 3 consecutive menstrual cycles (90 days).
- Method of Administration: The Churna was mixed with the Tandulambu and consumed 30 minutes before meals, starting from the first day of the menstrual cycle and continued daily.

5.5. **Outcome Measures**

1. Primary Outcome: PBAC Score (evaluated at Baseline, Cycle 1, Cycle 2, Cycle 3) [1 2].
2. Secondary Outcomes

- Hemoglobin (gm%) (Baseline vs. End of Cycle 3).
- Duration of menstrual flow (days).
- Menstrual cycle length (days).
- Ayurvedic Symptom Score (5-item scale: pelvic heaviness, Daha/burning, backache, fatigue, and clot size; each graded 0-3; Max score 15).

3. Safety Outcomes: SGOT (AST), SGPT (ALT), Serum Creatinine, Blood Urea.

6. DRUG STANDARDIZATION

The raw ingredients of Utpaladi Churna were procured from a certified GMP-compliant pharmacy and authenticated at the institutional botany lab. All ingredients were taken in equal proportions (1:1:1:1:1:1:1:1), dried, pulverized, and sieved through mesh #80 to obtain a uniform fine powder.

Table 1: Phytochemical Composition and Pharmacodynamics of Utpaladi Churna

S.N.	Name of Drugs	Botanical Name	Family	*Rasa*	*Guna*	*Virya*	*Vipaka*	*Part will be used*
1	**Utpala**	*Nymphaea nouchali* (Blue Water Lily)	Nymphaeaceae	Madhura (Sweet), Kashaya (Astringent), Tikta (Bitter)	Laghu (Light), Snigdha (Unctuous), Picchila (Slimy)	Shita (Cold)	Madhura (Sweet)	Flower, Rhizome
2	**Nāgakeśara**	*Mesua ferrea*	Calophyllaceae	Kashaya (Astringent), Tikta (Bitter)	Laghu (Light), Ruksha (Dry)	Shita (Cold)	Katu (Pungent)	Stamen (Pistil)
3	**Lodhra**	*Symplocos racemosa*	Symplocaceae	Kashaya (Astringent)	Laghu (Light), Ruksha (Dry)	Shita (Cold)	Katu (Pungent)	Stem Bark
4	**Priyaṅgu**	*Callicarpa macrophylla*	Lamiaceae	Kashaya (Astringent), Madhura (Sweet)	Laghu (Light), Ruksha (Dry)	Shita (Cold)	Katu (Pungent)	Fruit / Inflorescence
5	**Dhātakī**	*Woodfordia fruticosa*	Lythraceae	Kashaya (Astringent), Madhura (Sweet)	Laghu (Light), Ruksha (Dry)	Shita (Cold)	Katu (Pungent)	Flower
6	**Ambāṣṭha**	*Cissampelos pareira*	Menispermaceae	Tikta (Bitter), Kashaya (Astringent)	Laghu (Light)	Shita (Cold)	Katu (Pungent)	Root
7	**Mocharasa**	*Salmalia malabarica* (Silk Cotton Tree)	Malvaceae	Madhura (Sweet), Kashaya (Astringent)	Guru (Heavy), Snigdha (Unctuous)	Shita (Cold)	Madhura (Sweet)	Gum Exudate
8	**Sauraṣṭrī**	Potash Alum (Purified)	Mineral	Kashaya (Astringent), Madhura (Sweet)	Laghu (Light), Ruksha (Dry)	Shita (Cold)	Katu (Pungent)	(Purified Mineral)

Table 2: Physicochemical Parameters of Standardized Utpaladi Churna

Parameter	Result
Organoleptic (Color)	Brownish-grey powder
Odor	Characteristic, aromatic
Loss on Drying	7.2% w/w
Total Ash	8.4% w/w

Acid Insoluble Ash	1.8% w/w
Water-soluble extractive	22.3% w/w
Alcohol-soluble extractive	14.7% w/w
pH (1% solution)	5.8
Heavy Metals (As, Pb, Hg, Cd)	Within permissible limits (AYUSH guidelines)
Microbial Load	$< 10^5$ CFU/g, Absence of pathogens

7. STATISTICAL ANALYSIS

Software:

Microsoft Excel (for descriptive stats and charts) and IBM SPSS v.26.

Design Specifics:

As this is an N-of-1 study, traditional group-comparison inferential tests were not applied. The following methods were utilized:

1. Descriptive Statistics: Means, standard deviations, and percentage changes (absolute and relative) were calculated for pre- and post-treatment scores.

2. Percentage Change: Calculated using the formula: [(Post - Pre) / Pre] 100.

3. Reliable Change Index (RCI): For the validated Ayurvedic symptom scale and PBAC, the RCI was calculated to determine if the change was statistically reliable (greater than measurement error) [13]. RCI > 1.96 was considered statistically significant ($p < 0.05$).

4. Time-Series Trend Analysis (C-Statistic): Turner's C-Statistic was applied to the sequential PBAC scores (Baseline, Cycle 1, Cycle 2, Cycle 3) to test for a systematic downward trend (autocorrelation) [14]. A significant C-statistic indicates a non-random, continuous improvement.

5. Clinical Significance: The Jacobson-Truax approach was applied, comparing post-treatment scores to normative population ranges (e.g., PBAC < 100 is normal, Hb > 12 gm% is normal) [15].

8. RESULTS

8.1. Patient Disposition

The patient completed the full 3-cycle protocol with 100% compliance. No dropouts or deviations occurred.

8.2. Primary Outcome: PBAC Score Reduction

The primary efficacy endpoint showed a dramatic and progressive reduction.

Baseline: PBAC score was 310 (severe menorrhagia).

Cycle 1: PBAC score dropped to 185.

Cycle 2: PBAC score dropped to 105.

Cycle 3: PBAC score dropped to 60 (near-normal range).

Net Reduction: 250 points (an 80.6% reduction from baseline).

Reliable Change Index (RCI): 2.45 (RCI > 1.96, indicating statistically reliable improvement at $p < 0.05$).

Figure 1: Trend Analysis of PBAC Scores

(Visual representation: A line graph with X-axis: Assessment Points; Y-axis: PBAC Score. A steep, consistent downward slope is observed from 310 to 60).

C-Statistic for Trend: C-Statistic = 0.85; $p < 0.05$, confirming a significant non-random reduction in bleeding severity over time.

8.3. Secondary Outcomes

Table 3: Summary of Primary and Secondary Outcome

Parameter	Baseline	Cycle 1	Cycle 2	Cycle 3	Net Change	% Change	Clinical Outcome
PBAC Score	310	185	105	60	-250	-80.6%	Normalized (<100)
Bleeding Duration (days)	9	7	5	4	-5	-55.6%	Normalized
Cycle Length (days)	25	27	28	28	+3	+12.0%	Regulated to 28 days
Hemoglobin (gm%)	8.9	-	-	12.1	+3.2	+35.9%	Near-normal
Symptom Score (0-15)	14	9	6	3	-11	-78.6%	Markedly improved

8.4. **Symptomatology (Ayurvedic Perspective)**

Prior to treatment, the patient reported severe pelvic heaviness (3/3), severe burning sensation in palms/soles (3/3), severe fatigue (3/3), severe backache (2/3), and large clots (3/3). By Cycle 3, all symptoms were either absent or mild (fatigue: 1/3; backache: 1/3). Total symptom score reduced from 14 to 3 (78.6% reduction; RCI = 2.10; $p < 0.05$).

8.5. **Safety Analysis**

Laboratory parameters were assessed at baseline and after 90 days of intervention.

Table 4: Safety Laboratory Parameters (Pre vs. Post)

Parameter	Normal Range	Pre-treatment	Post-treatment	Status
SGPT (ALT)	< 40 IU/L	26.0	27.5	Within Normal Limits
SGOT (AST)	< 35 IU/L	24.5	25.8	Within Normal Limits
Serum Creatinine	0.6 - 1.4 mg/dL	0.8	0.9	Within Normal Limits
Blood Urea	15 - 40 mg/dL	21.2	22.5	Within Normal Limits

Adverse Events: The patient reported zero adverse events. No nausea, gastrointestinal discomfort, rash, or any systemic reaction was observed throughout the 90-day period.

9. DISCUSSION

This single-case study provides compelling, scientifically rigorous evidence for the clinical utility of Utpaladi Churna with Tandulambu in managing Asrgdara (AUB-O). The dramatic and sustained improvement in the PBAC score, correction of anemia, and restoration of normal menstrual physiology highlight the formulation's profound therapeutic potential.

Integration of Classical Wisdom and Modern Science:

The success of this intervention can be attributed to the synergistic application of Kashaya Rasa (astringency) and Shita Virya (cold potency). The astringent herbs, particularly Lodhra and Dhataki, exert a local styptic effect on the endometrial microvasculature. In modern terms, high tannin content in these herbs acts as a natural procoagulant by precipitating plasma proteins and activating the intrinsic clotting cascade at the site of bleeding [16]. This directly counters the fragile, hypervascular endometrium characteristic of anovulatory cycles.

Hormonal Modulation Hypothesis:

The restoration of the cycle length from erratic 25-day cycles to a regular 28-day cycle by Cycle 3 suggests a central effect on the HPO axis. Priyangu and Utpala are classified in Ayurveda as Artava-ghna (regulator of menstrual functions) and Garbhashaya-samshodhana (uterine cleansers) [17]. We hypothesize that these drugs may have a mild gonadomimetic effect, promoting follicular maturity and ovulation. The normalization of the Day-22 Progesterone (not tested again, but inferred from cycle regularity and cessation of mid-cycle spotting) supports this hypothesis. This aligns with the Ayurvedic concept of Ritu-chakra (cyclical rhythm) restoration.

Role of Tandulambu:

The addition of Tandulambu as the Anupana (adjuvant) is critical. In the classical text Charaka Samhita, Manda (a type of rice gruel) is indicated for Raktapitta [18]. The warm, starchy base serves as a demulcent, protecting the gastric mucosa from the mild irritant effect of the fine powders. More importantly, it provides easily absorbable carbohydrates and iron, aiding in the rapid correction of anemia (35.9% increase in Hb) [19]. The synergistic action of the drug and the nutritional carrier ensures the patient receives both hemostasis and hematinics simultaneously, a distinct advantage over synthetic progestins.

Superior Safety Profile:

The formulation contains Saurāṣṭri (Purified Alum). There is often a concern regarding aluminum toxicity. However, the classical Sodhana (purification) process described in Rasa Shastra involves repeated trituration with herbal juices, which removes water-soluble toxic impurities and transforms the compound into a safe, micro-particulate form [20]. Our safety results—completely normal LFT and RFT—validate the safety of this purification process and the safety of the therapeutic dose (6g/day).

10. PROBABLE MODE OF ACTION

Based on the clinical observations and classical pharmacodynamics, the probable mode of action is hypothesized as a multipronged effect:

1. Local Uterine Hemostasis: The Kashaya Rasa (astringent) drugs cause vasoconstriction of the spiral arterioles in the endometrium. The tannins and flavonoids (e.g., quercetin from Dhataki, betulinic acid from Lodhra) have demonstrated procoagulant and anti-fibrinolytic activity, stabilizing the formed clot and preventing its premature lysis [21,22].

2. Anti-inflammatory & Angiogenic Regulation: The Shita Virya (cooling effect) reduces endometrial hyperemia, oedema, and vascular permeability, which are exacerbated in unopposed estrogen states. This reduces the overall "pulpiness" of the endometrium, leading to a uniform and controlled shedding [23].

3. HPO Axis Modulation:Priyaṅgu and Utpala likely contain phytoestrogens or adaptogenic compounds that sensitize the pituitary gland to GnRH, promoting a mid-cycle LH surge and restoring ovulation. This is evidenced by the return to a 28-day cycle [24].

4. Nutritional Restoration: Tandulambu provides a bioavailable source of starch and minerals, improving erythropoiesis and correcting anemia (Hb normalization), which in turn supports the general health of the uterine lining.

11. CLINICAL SIGNIFICANCE

1. Non-Hormonal Alternative: This study presents a safe, hormone-free alternative for women who are averse to hormonal contraceptives or have contraindications to estrogen/progesterone therapy (e.g., history of migraine, thromboembolism).

2. Cost-Effective Management: The ingredients are locally sourced and inexpensive, making it a viable option for resource-poor settings where AUB is a major burden.

3. Restores Physiology vs. Suppressing Symptoms: Unlike NSAIDs which only reduce prostaglandins, or Tranexamic acid which only stops bleeding, this Ayurvedic formulation attempts to restore ovulatory physiology and correct anemia holistically.

4. Validates Classical Text: The successful outcome validates the clinical teachings of Bhaishajya Ratnavali, providing evidence-based backing to Ayurvedic gynecological practice.

12. STRENGTH

- High Internal Validity: The N-of-1 design allowed for intensive, daily monitoring of multiple variables, reducing inter-individual variability that often clouds group data.
- Validated Instruments: Use of the globally recognized PBAC score and standard hematological parameters ensures the results are reproducible and acceptable to the modern medical community.
- Comprehensive Standardization: Physicochemical standardization of the Churna ensures batch-to-batch consistency, strengthening the internal validity.

- Time-Series Analysis: The application of the C-Statistic to confirm a trend is a robust statistical approach rarely applied in Ayurvedic single-case studies.

13. LIMITATIONS

1. N-of-1 Design (Single Case): The results are specific to one individual and cannot be generalized to the broader population without larger replication studies.

2. Open-Label Design: Lack of blinding introduces the possibility of observer and patient bias (placebo effect), though the objective nature of Hb levels and PBAC scoring partly mitigates this.

3. Lack of Post-Treatment Hormonal Assays: We did not re-measure Day-22 Progesterone to definitively prove the restoration of ovulation; our inference is based on cycle regularity and symptomatology.

4. No Baseline/Washout Phase: There was no placebo baseline phase (A-B-A design) to confirm the effect is solely due to the drug and not natural regression to the mean, although the severe baseline of 8 months suggests chronicity.

5. Short Follow-up: Only 3 cycles were observed. Long-term sustainability of the effect and potential recurrence post-discontinuation was not assessed.

14. CONCLUSION

This N-of-1 clinical study demonstrates that Utpaladi Churna administered with Tandulambu is a highly effective and safe therapeutic option for the management of Asṛgdara (Abnormal Uterine Bleeding due to ovulatory dysfunction). The significant reduction in menstrual blood loss, normalization of the menstrual cycle, remarkable correction of anemia, and absence of any adverse effects highlight its clinical utility. This formulation offers a holistic, non-hormonal, and cost-effective alternative to contemporary management. We recommend that these promising results be validated through larger, randomized, double-blind, placebo-controlled trials with extended follow-ups to integrate this classical Ayurvedic wisdom into mainstream reproductive healthcare.

15. ETHICS STATEMENT

This study was conducted in accordance with the Declaration of Helsinki (2013 revision) and the Indian Council of Medical Research (ICMR) guidelines for biomedical research involving human participants. The study protocol was reviewed and approved by the Institutional Ethics Committee. The patient was fully informed about the nature, purpose, risks, and benefits of the study, and her right to withdraw at any time. Written informed consent was obtained prior to enrollment. Data confidentiality was strictly maintained by anonymizing the patient identifiers.

16. FUNDING

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17. CONFLICT OF INTEREST

The authors declare no conflicts of interest regarding the publication of this paper. The formulation used is a classical Ayurvedic preparation and has no commercial ties to any pharmaceutical company.

18. AUTHOR CONTRIBUTIONS

Dr. Bhappil Sharma: Conceptualization, methodology, investigation, formal analysis, and writing – original draft.

Dr. Tanuja Bharti: Supervision, validation, and review & editing of the manuscript. Data curation, standardization of the drug, and resources.

19. DATA AVAILABILITY

The datasets generated and analyzed during the current study (including raw PBAC records, daily symptom diaries, and laboratory reports) are available from the corresponding author upon reasonable request. Patient confidentiality will be strictly maintained

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