https://doi.org/10.47552/ijam.v16i2.5547 ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 16 (2), 2025; 362-367

A Clinical Study to Evaluate the Antihypertensive Effect of Herbal Formulation (*Cap Punarnavadi Mishran*) in Management of Primary Hypertension

Research Article

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Abstract

The present clinical study aimed to evaluate the antihypertensive efficacy of a polyherbal formulation, *Capsule Punarnavadi Mishran*, in the therapeutic management of primary hypertension. A total number of 30 patients diagnosed with primary hypertension were enrolled from both outpatient and inpatient departments of Dr. D. Y. Patil Ayurved College and Hospital, Pimpri, Pune (Maharashtra). All participants received *Capsule Punarnavadi Mishran* as a part of their treatment regimen over a defined study period. The effectiveness of the intervention was assessed using both objective parameters primarily changes in systolic and diastolic blood pressure and subjective clinical symptoms. Blood pressure measurements were recorded at baseline and at regular intervals during the course of treatment. The results demonstrated a statistically significant reduction in both systolic and diastolic blood pressure among all 30 participants. Based on clinical assessment, 6 patients (20%) exhibited excellent improvement, 14 patients (46.7%) showed moderate improvement, while 10 patients (33.3%) demonstrated mild to moderate symptomatic relief. The formulation was well-tolerated, and no adverse events were reported during the trial. These findings suggest that *Capsule Punarnavadi Mishran* may offer a promising adjunct or alternative in the management of primary hypertension. Further large-scale, randomized controlled studies are recommended to validate these preliminary results and elucidate the underlying pharmacological mechanisms.

Keywords: *Punarnavadi Mishran,* Primary hypertension, Herbal formulation, Blood pressure, Ayurvedic medicine, Antihypertensive.

Introduction

The World Health Organization has identified India as one of the nations expected to experience the highest burden of lifestyle-related disorders in the coming decades. Prominent among these are cardiovascular diseases, hypertension, obesity, diabetes mellitus, and cancer (1). Hypertension, in particular, is a multifactorial disorder with aetiological contributors including psychological stress, sedentary lifestyle, obesity, and excessive dietary salt intake (2). Globally, hypertension affects approximately 15–20% of the adult population and significantly increases the risk of cardiovascular events such as coronary artery disease, cardiac hypertrophy, aortic dissection, renal failure, and cerebrovascular complications (3,4). It is also a key risk factor for ischemic stroke, atherosclerosis, myocardial infarction, and end-stage renal disease (5). Nearly 50% of the estimated 17 million annual deaths from cardiovascular disease are attributed to complications arising from hypertension (6). In highly populated countries such as China and India, the absolute number of individuals affected by hypertension is alarmingly high. Current estimates suggest that 26% of the global adult population is hypertensive, with this figure projected to rise to 29% by the year 2025 (7). Despite the availability of several classes of conventional antihypertensive agents, their long-term use is often limited by adverse effects, poor tolerability, and reduced patient compliance, leading to frequent treatment switching or discontinuation (8). Therefore, the search for safe, well-tolerated, and cost-effective alternatives particularly from traditional and complementary medicine systems has become an urgent priority in the global health landscape.

Aims and Objectives: Primary Objectives -To evaluate the effectiveness of *herbal* formulation (*Cap Punarnavaadi Mishran*) in Primary Hypertension. Secondary Objectives - To study the effectiveness of *herbal* formulation (*Cap Punarnavadi Mishran*) in symptoms like *Shirshool (headache), Bhrama (dizziness), Klama (fatigue), Anidra (insomnia), Swedadhikya (perspiration), Hridspandan (palpitation), Shotha (oedema).*

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Materials and Methods

Study Design: Open-label, single-arm clinical study

Study Setting: Study was conducted at the outpatient and inpatient departments of Dr. D. Y. Patil Ayurved College and Hospital, Pimpri, Pune (Maharashtra), irrespective of the participants' caste, gender, color, or religion.

Study Sample:30 patients diagnosed with primary hypertension were selected based on predefined inclusion and exclusion criteria. Each participant underwent a thorough clinical evaluation, including physical examination and detailed medical history, at baseline and at the end of the study period.

Ethical Considerations

Prior to initiation, the study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) and Research Review Committee. Ethical clearance was obtained under letter number DYPCARC/IEC/539/2022.

Written informed consent was obtained from all participants before their inclusion in the study, in accordance with the ethical guidelines for biomedical research on human participants.

Clinical Trial Registration: CTRI registration number was- **CTRI/2023/01/048927**, dated 11 January 2023.

Case History and Documentation

A structured case record form (CRF) was developed specifically for this study. The proforma included demographic data, baseline and follow-up blood pressure measurements, and documentation of all clinical signs and symptoms before and after the intervention period. This facilitated systematic tracking of the therapeutic response and adverse effects, if any.

Inclusion Criteria

Participants eligible for inclusion in the study were adults aged 18 years and above, of either gender, who had been recently or newly diagnosed with primary hypertension of unknown origin. Eligible patients were required to have a systolic blood pressure between 140 mmHg and less than 170 mmHg, and a diastolic pressure up to 110 mmHg. These thresholds were selected to represent early-stage hypertensive patients suitable for non-invasive herbal intervention.

Exclusion Criteria

Patients were excluded from the study if they were diagnosed with secondary hypertension, were known alcohol or substance abusers, or were suffering from accelerated or malignant hypertension. Additional exclusion criteria included pregnancy or lactation, ongoing estrogen replacement therapy, symptomatic presentation of early heart failure, and a documented history of cardiac diseases.

Withdrawal Criteria

Participants were withdrawn from the study under certain circumstances. These included voluntary withdrawal of consent at any stage of the trial, an increase in blood pressure beyond 170/110 mmHg following treatment initiation, or a lack of therapeutic response accompanied by symptom aggravation. In such cases, patients were discontinued from the trial and referred for standard allopathic intervention or specialist consultation as clinically indicated.

Intervention and Follow-up:

The treatment duration was Fourteen days, with two follow-ups on Day 7 and Day 14.

Blood pressure and clinical symptoms were assessed at each follow-up visit. Patients were monitored for any adverse events, and compliance was ensured by collecting and counting the remaining medicines at the end of the study.

Outcome Measures:

Primary Outcome: Reduction in both systolic and diastolic blood pressure.

Secondary Outcomes: Improvement in subjective symptoms (headache, dizziness, palpitations, fatigue) and overall tolerability of the intervention

Assessment Criteria

Objective Parameters

The primary diagnostic tool employed for the assessment of blood pressure was a sphygmomanometer. Blood pressure measurements were obtained in accordance with standardized procedures to ensure consistency and accuracy. Each subject underwent three consecutive blood pressure recordings on both arms, while in sitting and supine postures, to minimize variability and confirm reliability of readings. The trial population was restricted to newly diagnosed cases of Stage I hypertension, as per the guidelines set by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. The classification of blood pressure readings followed JNC 7 criteria, defining Stage I hypertension as systolic blood pressure (SBP) between 140–159 mmHg and/or diastolic blood pressure (DBP) between 90–99 mmHg. Korotkoff sounds I and V were utilized for determining the systolic and diastolic pressures, respectively. This method ensured accurate auscultatory assessment of arterial blood pressure in accordance with established clinical norms.

Subjective Parameters

Subjective clinical parameters related to hypertensive symptoms such as headache, dizziness, fatigue, palpitations, and sleep disturbances were assessed and graded on a 5-point ordinal scale ranging from 0 to 4, reflecting the severity of each symptom:0 – Absent,1 – Mild 2 – Moderate,3 – Severe, 4 – Very Severe

https://doi.org/10.47552/ijam.v16i2.5547 ISSN No: 0976-5921

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Table 1:-Subjective parameters

Sr. No.	Parameters	Findings	Points
1	***Shirashoola* (Headache)**	No *Shirashoola*	0
		Once/twice per week	1
		More than twice a week	2
		Continue *shirashoola* affecting partially	3
		Continue troubling *shirashoola* covering complete *shira*	4
2	***Bhrama* (Giddiness)**	No *Bhrama*	0
		Bhrama once/twice per week	1
		Bhrama more than twice a week	2
		Bhrama daily	3
3	***Klama* (Fatigue)**	No *Klama*	0
		Once a while during walking	1
		Klama during walking twice a week	2
		Klama at rest once a week	3
		Klama at rest more than a week	4
4	***Anidra* (Insomnia)**	Sound sleep	0
		Occasionally disturbed	1
		Disturbed for 2-3 hours	2
		Disturbed for 3-4 hours	3
		Anidra for whole night	4
5	***Swedadhikya* (Perspiration)**	No *Swedadhikya*	0
		Excessive while climbing upstairs	1
		Profuse while speedily walking	2
		Profuse even during walking	3
		Profuse even at rest	4
6	***Hridspandan* (Palpitation)**	No Hridspandan	0
		Hridspandan Occasionally	1
		Hridspandan on exercise	2
		Hridspandan on vigorous activity	3
		Hridspandan daily even at rest	4
7	***Shotha* (Swelling)**	*No Shotha*	0
		Shotha occasionally	1
		Shotha partially	2
		Shotha on lower extremities	3
		Shotha completely (all over body)	4

Treatment Protocol

Interventional products were prepared and standardised at *Sudhatatava Ayurvedic Pharmacy*, Pimpri, Pune (Maharashtra).

Table 2: Treatment protocol

No.of Patients	Drug	Dosage	Duration
30	Herbal formulation (Cap Punarnavadi Mishran)	500 mg/TDS.	14 days.

Table 3: Ingredients of Herbal formulation (*Cap Punarnavadi Mishran*)

Sr. No.	Drug Name	Latin Name	*Rasa*	*Guna*	*Virya*	*Vipaka*	*Karma*
1	***Punarnava***	*Boerhaavia diffusa*	*Madhur, Tikkta, Kashaya*	*Laghu, rukhsha*	*Sheeta*	*Madhura*	*Tridoshahar, Mutrajanna, Rasayan, Shothghni, Raktavikarsamak.*
2	***Guduchi***	*Tinospora cordifolia*	*Tikkta, Katu, Kashaya*	*Guru, Snigdha*	*Ushna*	*Madhura*	*Dridhoshasamaka, Rashaya, Mutravikarhar*
3	***Shankhapushpi***	*Convolvulus pluricaulis*	*Tikta, Kasaya*	*Snigdha, Pichhil*	*Ushna*	*Madhura*	*Medhya, Manas Rogahar, Rasayana*
4	***Brahmi***	*Bacopa monnieri*	*Tikta, Kasaya*	*Laghu*	*Sheeta*	*Madhura*	*Medhya, Manas Rogahar, Rasayana, Raktavikarhar, Shothahar*
5	***Jatamansi***	*Nardostachys jatamanshi*	*Tikkta, Kashaya, Madhur*	*Ladhu, Snigdh*	*sheet*	*Madhur*	*Guru, snigdha, mrudu*
6	***Vacha***	*Acorus calamus*	*Tikkta, Kattu*	*Laghu, Rukhsh, Tikshan*	*Ushna*	*katu*	*Mutravishodhni, Medhya*
7	***Praval***	*Corallium rubrum*	*Madhur*	*Laghu, Rukhsa*	*sheet*	*Madhur*	*Mutrakrichha Har, Swedahar, Rakta & Pitta Vikara Samaka*

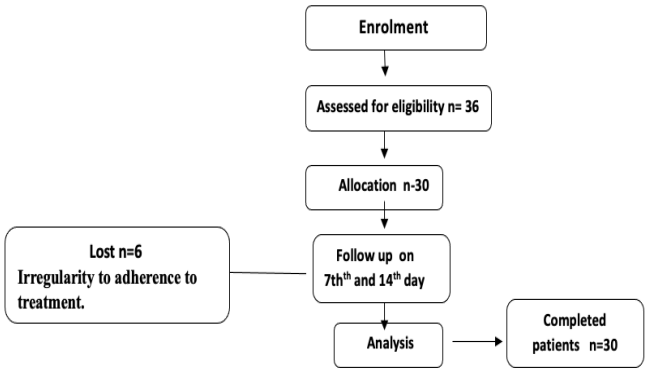
Statistical Assessment

A paired "t" test and Friedman test were used where it was considered necessary, and the improvement in the patient's condition was evaluated based on the grades of different variables compared between pre-trial and post-trial values in terms of percentage (based on mathematical mean and its difference). The findings were evaluated as very significant at the $p < 0.001$ level, significant at the $p < 0.05$ level, and inconsequential at the $p > 0.05$ level.

Observations and Results:

Data analysis

Image 1: Flow chart



Demographic data: Following data was observed during clinical trial

Table 4: Demographic Data

Parameter	Category	Number	Percentage
Marital Status	Married	29	96.6
	Unmarried	1	3.3
Gender	Male	19	63.3
	Female	11	36.7
Age Group (years)	31–40	7	23.3
	41–50	10	33.3
	51–60	9	30.0
	>60	4	13.3
Residence	Urban	24	80.0
	Rural	6	20.0
Religion	Hindu	25	83.3
	Muslim	5	16.7
Education Level	Metric (10th	18	60.0
	Above Metric	7	23.3
	Below Metric	5	16.7
Occupation	Homemaker	8	26.7
	Service	7	23.3
	Business	5	16.7
	Laborer	4	13.3
	Others	6	20.0
Dietary Habit	Mixed Diet	25	83.3
	Vegetarian	5	16.7
Addiction	None	19	63.3
	Tobacco	6	20.0
	Alcohol	5	16.7
Deha Prakriti	*Vata-Pittaja*	15	50.0
	Pitta-Kaphaja	9	30.0
	Vata-Kaphaja	6	20.0

Table 5: Effect of Therapy on Objective Criteria

Paired Sample Statistics and Test Results for Blood Pressure Measurements (n = 30)

Position	Time point	Parameter	Mean ± SD	Mean ± SD	Mean Difference	t	df	p-value
Supine	0 vs 7 Days	Systolic BP	154.33 ± 6.79	136.00 ± 8.55	18.33 ± 9.13	11.000	29	< 0.001
	0 vs 14 Days	Systolic BP	154.33 ± 6.79	130.67 ± 6.40	23.67 ± 8.90	14.566	29	< 0.001
	0 vs 7 Days	Diastolic BP	98.67 ± 5.07	85.67 ± 7.28	13.00 ± 9.88	7.208	29	< 0.001
	0 vs 14 Days	Diastolic BP	98.67 ± 5.07	86.33 ± 5.56	12.33 ± 7.74	8.729	29	< 0.001
Sitting	0 vs 7 Days	Systolic BP	154.33 ± 7.28	135.33 ± 8.60	19.00 ± 10.29	10.114	29	< 0.001
	0 vs 14 Days	Systolic BP	154.33 ± 7.28	131.00 ± 7.59	23.33 ± 9.94	12.854	29	< 0.001
	0 vs 7 Days	Diastolic BP	99.00 ± 4.81	86.67 ± 7.58	12.33 ± 9.35	7.223	29	< 0.001
	0 vs 14 Days	Diastolic BP	99.00 ± 4.81	87.67 ± 5.04	11.33 ± 6.81	9.109	29	< 0.001

Table 6: Effects of therapy on Subjective Criteria

Parameter	0th Day	7th Day	14th Day	N	Chi-Square	df	*P* value
Shirashoola	2.70	1.87	1.43	30	39.263	2	0.000
Bhrama	2.57	1.85	1.58	30	31.559	2	0.000
Klama	2.92	1.88	1.20	30	52.214	2	0.000
Hridyaspandan	2.65	1.95	1.40	30	37.680	2	0.000
Anidra	2.62	1.92	1.47	30	35.043	2	0.000
Swedadhikya	2.73	1.93	1.33	30	42.286	2	0.000
Shotha	2.13	2.00	1.87	30	6.737	2	0.034

Assessment of Overall Effect

The overall therapeutic effect was evaluated by comparing the severity of clinical symptoms before and after the intervention using a predefined scoring system. Based on the percentage reduction in total symptom scores from baseline to the end of the treatment, patients were categorized into the following outcome groups:

- Excellent effect: ≥ 75% improvement in symptoms
- Moderate effect: 51–74% improvement
- Mild effect: 25–50% improvement
- No change: < 25% improvement or no measurable improvement

Each patient's symptom scores (based on parameters such as *Shirashoola, Bhrama, Klama,*

https://doi.org/10.47552/ijam.v16i2.5547 ISSN No: 0976-5921

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Hridyaspandan, Anidra, Swedadhikya, and Shotha) were totaled and compared across visits (Day 0, Day 7, Day 14). The percentage improvement was calculated, and patients were accordingly classified.

Discussion

Hypertension is a chronic, multifactorial disorder and a major global public health concern, significantly contributing to the burden of cardiovascular morbidity and mortality (9). While contemporary medicine defines it primarily as a hemodynamic imbalance, Ayurveda interprets hypertension as a *Tridoshaja Vyadhi* with *Vata predominance*, due to the erraticity and instability of blood flow and vascular tone (10). Vitiated *Vata Dosha* affects the functioning of *Raktavaha Srotas* the internal channels responsible for blood transport leading to elevated arterial pressure. Clinical manifestations may also involve *Pitta and Kapha Dosha*, depending on symptomatology and patient constitution (11). The present clinical investigation evaluated the efficacy of *Capsule Punarnavadi Mishran*, a classical polyherbal formulation, in managing essential hypertension. Analysis of clinical parameters revealed statistically significant reductions in *Shirashoola* (headache), *Bhrama* (giddiness), *Klama (fatigue), Hridyaspandan (palpitation), Anidra (insomnia), Swedadhikya (excessive sweating), and Shotha (edema)* over a 14-day period. Friedman test results supported the robustness of this effect ($P < 0.05$ for all symptoms), indicating holistic patient benefit. Overall Effectiveness -Out of 30 patients enrolled in the study: 6 patients (20%) showed excellent improvement (≥75% symptom reduction), 14 patients (46.7%) had moderate improvement (51–74%), 10 patients (33.3%) experienced mild improvement (25–50%), and none showed no response (<25%). This therapeutic distribution underscores the potential of *Capsule Punarnavadi Mishran* as a promising intervention in mild to moderate stages of hypertension.

Mode of Action - Ayurvedic and Pharmacological Perspective

Capsule Punarnavadi Mishran contains well-documented herbs including *Punarnava (Boerhavia diffusa)*, *Gokshura (Tribulus terrestris)*, *Daruharidra (Berberis aristata)*, *Devadaru (Cedrus deodara)*, and *Mustaka (Cyperus rotundus)* (11,12). These constituents offer multiple pharmacological effects: **Diuretic action (*Mutravirechana*)**: Facilitates reduction of extracellular fluid and plasma volume, thereby decreasing preload and arterial pressure (13). **Anti-inflammatory and antioxidant effects**: Help reduce vascular inflammation, oxidative stress, and endothelial dysfunction—factors implicated in the pathophysiology of hypertension (14). **Cardioprotective properties**: Maintain myocardial function, stabilize heart rate, and improve perfusion (15). In Ayurvedic pharmacodynamics: *Vata Shamana* is achieved through *Snigdha Guna, Madhura Rasa*, and *Madhura Vipaka*, which stabilize and nourish the nervous system and vascular channels. *Pitta Shamana* is conferred by *Madhura Vipaka* and *Sheeta Veerya*, countering irritability and hypermetabolic states associated with stress-related hypertension. *Kapha Shamana* is mediated through *Kashaya Rasa*, facilitating the resolution of congestion, sluggish circulation, and water retention. The *Tridoshahara* (tridosha-pacifying) nature of the formulation treats not just symptomatic elevations in blood pressure but addresses its root pathology, in line with Ayurvedic principles such as *Nidana Parivarjana* (removal of cause) and *Rogamula Chikitsa* (treatment at the root cause level) (16). The formulation's action on *Raktavaha Srotas*, the primary seat of the disorder, restores channel integrity, improves hemodynamic stability, and ensures appropriate tissue perfusion. These Ayurvedic interpretations are paralleled in modern physiology by mechanisms such as reduction in systemic vascular resistance, improved endothelial function, and regulated fluid balance—all central to effective antihypertensive therapy (18).

Conclusion

The findings of this clinical study validate the traditional utility of *Capsule Punarnavadi Mishran* in managing essential hypertension. The formulation's Tridosha Shamaka, diuretic, anti-inflammatory, and cardioprotective actions contributed to significant symptomatic improvement and blood pressure regulation. The absence of non-responders and the favorable safety profile further reinforce its therapeutic potential. Given the increasing global interest in integrative and personalized medicine, *Capsule Punarnavadi Mishran* presents a compelling case for inclusion in lifestyle disorder management. Further multicentric, randomized controlled trials with biochemical markers and long-term follow-up are warranted to confirm and expand on these findings.

Patient perspective

I am very much satisfied as my ulcer and bad foited wound were cured completely. My daily routine had been disrupted by the ailment before treatment.

Declaration of patient consent

The patient has provided informed consent for the publication of this case report, including the use of photographs and imaging associated with their treatment. The patient understands that their identity will remain confidential and that all personal information will be anonymized to protect their privacy. This consent was obtained voluntarily, and the patient acknowledges their agreement to share their medical information for educational and research purposes.

Conflict of Interest: None
Source of Funding: None declared.

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