Research Article

www.ijrap.net

(ISSN Online:2229–3566, ISSN Print:2277–4343)

EFFICACY AND SAFETY OF AN ANTI-HYPERTENSIVE HERBAL SYRUP IN PATIENTS WITH HYPERTENSION: A CLINICAL STUDY

Ajay Kumar [1]*, Prakash Raj Singh [2], Ranjit Singh [3], Tina Singhal [4]

[1] Department of Kaya Chikitsa and Panchakarma, Government Ayurvedic College and Hospital, Varanasi, India

[2] Department of Kriya Sharir, Government Ayurvedic College and Hospital, Varanasi, India

[3] Scientist -E, DIBER (DRDO) Haldwani, Uttarakhand, India

[4] Department of Rachana Sharir, Government Ayurvedic College and Hospital, Varanasi, India

Received on: 28/7/25 Accepted on: 09/9/25

***Corresponding author**
E-mail: drajay2000@gmail.com

DOI: 10.7897/2277-4343.165166

ABSTRACT

Background: Hypertension is a major global health concern, often managed with synthetic drugs that may cause side effects. Herbal interventions offer a promising alternative. This study evaluated the efficacy and safety of an Anti-Hypertensive Herbal Syrup (AHS) formulated from *Pyracantha crenulata* fruit juice by DIBER (DRDO), Haldwani, Uttarakhand, India. Methods: A single-arm, open-label clinical trial was conducted with 50 hypertensive patients aged 20–60 years at Government Ayurvedic College and Hospital, Varanasi. Participants received 20 mL of AHS with 100 mL water twice daily for two months. Primary outcomes were changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP). Secondary outcomes included biochemical parameters and symptom relief. Data were analysed using Friedman's test and Repeated Measures ANOVA. Results: Post-treatment, mean SBP decreased from 145 ± 12.31 mmHg to 123 ± 7.82 mmHg ($p < 0.001$), and DBP from 97.3 ± 7.35 mmHg to 79.6 ± 5.28 mmHg ($p < 0.001$). Stage-2 hypertension prevalence dropped from 68% to 6% (SBP) and 92% to 4% (DBP). Significant improvements were observed in lipid profile, haemoglobin, and symptom scores ($p < 0.001$). No adverse events were reported. Conclusions: AHS significantly reduced blood pressure and improved related biochemical parameters, suggesting its potential as a safe, effective herbal intervention for hypertension.

Keywords: Anti-Hypertensive Herbal Syrup, *Pyracantha crenulate,* hypertension, Ayurveda, Blood Pressure

INTRODUCTION

Hypertension, characterized by persistently elevated blood pressure, remains a leading global health challenge, contributing significantly to cardiovascular diseases (CVDs), including myocardial infarction, stroke, and heart failure. Hypertension affects over 1.13 billion people worldwide, contributing to cardiovascular morbidity and mortality with its prevalence continuing to rise due to aging populations, lifestyle factors, and limited access to effective treatments.[1-2] Current pharmacological interventions, such as angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, and diuretics, while effective, often present challenges including side effects, cost, and variable patient adherence.[3] Consequently, there is growing interest in complementary and alternative therapies, particularly herbal medicines, which have been utilized for centuries in traditional systems to manage hypertension and related conditions.[4]

Pyracantha crenulata (D. Don) M. Roem., commonly known as Himalayan firethorn or Ghingaroo, is a thorny evergreen shrub native to the Himalayan region, widely recognized in ethnobotanical practices for its medicinal properties. Traditionally, its fruits and leaves have been employed by indigenous communities in India, Nepal, and Bhutan to alleviate a range of ailments, including cardiovascular complaints and inflammation.[5] Phytochemical analyses have revealed that *Pyracantha crenulata* is rich in bioactive compounds such as flavonoids, phenolic acids, and vitamins (e.g., vitamin C and E), which are known to exert antioxidant, anti-inflammatory, and vasodilatory effects—mechanisms implicated in blood pressure regulation.[6] Preclinical studies have begun to explore these properties, with evidence suggesting that *Pyracantha crenulata* fruit extracts may reduce blood pressure in experimentally induced hypertensive animal models, potentially through modulation of oxidative stress and vascular tone.

Herbal medicines, rooted in traditional systems like Ayurveda, offer a natural alternative.[4] Pyracantha crenulata, a Himalayan plant rich in flavonoids and phenolic compounds, has been cited in Ayurvedic texts for its cardiotonic properties.[7] Despite its traditional use and promising preliminary findings, the scientific evaluation of *Pyracantha crenulata*'s effects on blood pressure and hypertension in humans remains underexplored. Oxidative stress and endothelial dysfunction are well-established contributors to the pathogenesis of hypertension, driving vascular remodelling and impaired nitric oxide bioavailability.[8] Herbal interventions targeting these pathways, such as those rich in antioxidants,[9] have shown potential in reducing systolic and diastolic blood pressure in clinical settings.[10] For instance, systematic reviews and meta-analyses of randomized controlled trials (RCTs) have demonstrated that polyphenol-rich plants like *Hibiscus sabdariffa* significantly lower blood pressure. Given its phytochemical profile, *Pyracantha crenulata* may similarly influence hypertension, yet no RCTs have been documented in major databases such as PubMed, Scopus, or the Cochrane Database to substantiate these effects in human populations.

This study aims to address this gap by investigating the efficacy and safety of *Pyracantha crenulata* in modulating blood pressure among individuals with hypertension through a randomized, controlled trial. By adhering to the CONSORT guidelines, we

seek to provide a robust framework for evaluating its therapeutic potential, contributing to the growing body of evidence on herbal medicines as adjuncts or alternatives to conventional antihypertensive therapies. Such research is critical not only for validating traditional knowledge but also for expanding treatment options in the global fight against hypertension.

The Defence Institute of Bio-Energy Research (DIBER), DRDO, Haldwani, Uttarakhand, India, developed an anti-hypertensive herbal syrup (AHS) from *Pyracantha crenulata* fruit juice. Preclinical studies confirmed its safety and anti-hypertensive potential. This study aimed to evaluate the efficacy and safety of AHS in hypertensive patients through a clinical trial, hypothesizing a significant reduction in blood pressure and improvement in associated biochemical markers.

MATERIALS AND METHODS

Trial Design: This was a single-arm, open-label clinical trial conducted at Government Ayurvedic College and Hospital, Varanasi, during 2024–2025. The study adhered to ethical guidelines and was approved by the Institutional Ethics Committee (IEC).

Participants

Eligibility Criteria
Inclusion: Patients aged 20–60 years with diagnosed hypertension (SBP ≥ 130 mmHg or DBP ≥ 80 mmHg), irrespective of sex, occupation, or socioeconomic status.
Exclusion: Patients with systemic illnesses (e.g., diabetes, cancer, chronic kidney disease), pregnancy, anatomical deformities, or unwillingness to participate.
Participants were recruited from the outpatient and inpatient departments of Kaya Chikitsa and Panchakarma.

Interventions: Participants received 20 mL of AHS mixed with 100 mL water twice daily—15 minutes before breakfast and 30 minutes after dinner—for 60 days. AHS, supplied by DIBER (DRDO), contained no synthetic additives and made only from *Pyracantha crenulata* fruit juice. Drugs is provided by DIBER (DRDO), RandD wing of Ministry of Defence, Govt of India.

Outcomes

Primary Outcome: Change in SBP and DBP from baseline to 2 months, measured using a calibrated sphygmomanometer.
Secondary Outcomes: Changes in biochemical parameters (CBC, lipid profile, LFT, KFT, RBS). Symptom relief (headache, dizziness, insomnia, fatigue, palpitation, chest pain) graded on a 0–3 scale (0 = absent, 3 = severe).
Assessments occurred at baseline, 1 month (1st follow-up), and 2 months (2nd follow-up).

Sample Size: A sample size of 50 was determined as per DIBER instructions, sufficient to detect a clinically meaningful SBP reduction of 10 mmHg (SD = 12, power = 80%, $\alpha = 0.05$).

Recruitment: Patients were screened consecutively from hospital records and enrolled after providing written informed consent.

Allocation and Blinding: This was an open-label trial with no control group or blinding due to feasibility constraints.

Data Collection: Clinical and laboratory data were collected using standardized proformas and analyzed at a recognized pathology laboratory. BP was recorded in triplicate, with the average used for analysis.

Statistical Methods: Non-parametric Friedman's test assessed changes across three time points, followed by Durbin-Conover pairwise comparisons. Repeated Measures ANOVA with post hoc tests evaluated BP differences. Significance was set at $p < 0.05$. Analyses were performed using jamovi (Version 2.6) and R (Version 4.4).

RESULTS

Demographic Study

The study on the demographic distribution of hypertension reveals distinct patterns in blood pressure levels across different population segments. Overweight and obese individuals exhibited a higher prevalence of Stage-2 hypertension compared to those with normal BMI. Specifically, 64% of overweight individuals (16 out of 25) and 71% of obese individuals (5 out of 7) had Stage-2 systolic hypertension, while 72% of normal BMI individuals (13 out of 18) were also affected, suggesting a widespread issue across BMI categories. Housewives, private job workers, and government employees showed the highest rates of Stage-2 hypertension, likely due to sedentary lifestyles or stress.

Individuals with higher education (graduates and postgraduates) had a significant prevalence of Stage-2 hypertension, with 13 cases (systolic) and 16 cases (diastolic) among graduates, and 7 cases (systolic) and 10 cases (diastolic) among postgraduates. Married individuals had a much higher prevalence of hypertension than unmarried individuals. Among married participants, 29 out of 44 (66%) had Stage-2 systolic hypertension, and 41 out of 44 (93%) had Stage-2 diastolic hypertension. Males showed a higher prevalence of Stage-2 hypertension than females, with 22 out of 31 males (71%) and 12 out of 19 females (63%) having Stage-2 systolic hypertension. Older age groups (41-50 and 51-60 years) had the highest prevalence of Stage-2 hypertension. The 51-60 age group had 13 cases (systolic), and the 41-50 group had 9 cases (systolic), with diastolic Stage-2 cases peaking in these groups as well. Non-vegetarians and vegetarians showed similar rates of Stage-2 hypertension. Demographic details are in Table 1.

Table 1: Demographic Distribution of Stage-2 Hypertension (N=50)

Demographic Category	Subgroup	Systolic Stage-2 HTN (≥140 mmHg)	Diastolic Stage-2 HTN (≥90 mmHg)
BMI	Normal	13 (72%)	17 (94%)
	Overweight	16 (64%)	23 (92%)
	Obese	5 (71%)	6 (86%)
Occupation	Housewives	10	15
	Private Job Workers	9	10
	Government Employees	5	8
Education	Below High School	4	Not specified
	Graduation	13	16
	Postgraduation	7	10

Marital Status	Married	29 (66%)	41 (93%)
	Unmarried	5 (83%)	5 (83%)
Gender	Male	22 (71%)	28 (90%)
	Female	12 (63%)	18 (95%)
Age Group	21-30	5	Not specified
	31-40	7	Not specified
	41-50	9	High (not quantified)
	51-60	13	High (not quantified)

Primary Outcome

Systolic Blood Pressure (SBP)

Before Treatment: No individuals had normal SBP (<120 mmHg). Elevated BP (120-129 mmHg) was observed in 4 individuals (8%), Stage-1 hypertension (130-139 mmHg) in 12 individuals (24%), and Stage-2 hypertension (≥140 mmHg) in 34 individuals (68%). The mean SBP was 145 ± 12.31 mmHg, indicating a predominantly hypertensive population.

After Treatment: Post-treatment, 20 individuals (40%) achieved normal SBP, 21 (42%) had elevated BP, 6 (12%) had Stage-1 hypertension, and only 3 (6%) remained in Stage-2 hypertension. The mean SBP decreased to 123 ± 7.82 mmHg by the 2nd follow-up, a reduction of 22 mmHg from baseline.

SBP decreased from 145 ± 12.31 mmHg to 133 ± 9.69 mmHg (1st follow-up) and 123 ± 7.82 mmHg (2nd follow-up) ($\chi^2 = 100$, $p < 0.001$).

Diastolic Blood Pressure (DBP)

Before Treatment: No individuals had normal DBP (<80 mmHg). Stage-1 hypertension (80-89 mmHg) was present in 4 individuals (8%), and Stage-2 hypertension (≥90 mmHg) in 46 individuals (92%). The mean DBP was 97.3 ± 7.35 mmHg, reflecting severe diastolic hypertension across the cohort.

After Treatment: Post-treatment, 27 individuals (54%) achieved normal DBP, 21 (42%) had Stage-1 hypertension, and only 2 (4%) remained in Stage-2 hypertension. The mean DBP decreased to 79.6 ± 5.28 mmHg by the 2nd follow-up, a reduction of 17.7 mmHg from baseline.

DBP reduced from 97.3 ± 7.35 mmHg to 88.2 ± 5.93 mmHg and 79.6 ± 5.28 mmHg ($\chi^2 = 100$, $p < 0.001$). (Table 2)

Table 2: Effect on SBP and DBP before and after Trial (N=50)

Parameter	Before Trial (Mean ± SD)	1st Follow-up (Mean ± SD)	2nd Follow-up (Mean ± SD)	Chi-Square Value	p-Value
Systolic BP	145 ± 12.31	133 ± 9.69	123 ± 7.82	100	<0.001
Diastolic BP	97.3 ± 7.35	88.2 ± 5.93	79.6 ± 5.28	100	<0.001

Secondary Outcomes

The AHS Syrup Project also evaluated secondary outcomes beyond blood pressure reduction, focusing on biochemical parameters that influence cardiovascular health, liver and kidney function, and overall metabolic status. These outcomes were measured before treatment and after treatment, with statistical validation using the Friedman test to assess significance over time. (Table-3)

Lipid Profile

Cholesterol: Mean total cholesterol decreased from 181.5 ± 32.26 mg/dL to 168.9 ± 34.918 mg/dL ($p = 0.002$), a reduction of 12.6 mg/dL, indicating improved lipid regulation and reduced cardiovascular risk.

Triglycerides: Levels dropped from 208.7 ± 114.989 mg/dL to 197.58 ± 134.872 mg/dL ($p = 0.021$), a decrease of 11.12 mg/dL, suggesting a modest but significant antilipidemic effect.

LDL (Low-Density Lipoprotein): Mean LDL decreased from 86.84 ± 30.532 mg/dL to 78.32 ± 51.859 mg/dL ($p < 0.001$), a reduction of 8.52 mg/dL, further supporting cardiovascular benefits.

HDL (High-Density Lipoprotein): Mean HDL increased from 53.162 ± 9.204 mg/dL to 55.03 ± 11.025 mg/dL ($p < 0.001$), an increase of 1.868 mg/dL, indicating an improvement in "good" cholesterol levels.

Key Findings: The treatment significantly improved the lipid profile, reducing harmful lipids (cholesterol, triglycerides, LDL) while increasing protective HDL, aligning with the syrup's reported antilipidemic potential.

Liver Function Test (LFT)

Serum Bilirubin: Levels remained stable, decreasing slightly from 0.752 ± 0.295 mg/dL to 0.71 ± 0.281 mg/dL ($p = 0.337$), suggesting no adverse effect on liver detoxification.

SGOT (AST): Mean levels showed minimal change, from 27.412 ± 11.812 U/L to 26.232 ± 10.624 U/L ($p = 0.966$), indicating no liver damage.

SGPT (ALT): Levels fluctuated slightly from 22.984 ± 18.383 U/L to 25.552 ± 15.409 U/L ($p = 0.21$), remaining within normal limits and showing no hepatotoxicity.

Serum Protein: Decreased significantly from 6.727 ± 0.55 g/dL to 6.444 ± 0.366 g/dL ($p < 0.001$), possibly reflecting changes in protein metabolism.

Serum Albumin: Remained stable, increasing slightly from 4.064 ± 0.221 g/dL to 4.136 ± 0.505 g/dL ($p = 0.44$).

Serum Globulin: Decreased from 2.663 ± 0.541 g/dL to 2.308 ± 0.673 g/dL ($p < 0.001$), potentially indicating altered immune or protein regulation.

Key Findings: Liver function remained largely unaffected, with stable enzyme levels and no signs of toxicity. The reduction in serum protein and globulin may reflect metabolic adjustments rather than liver dysfunction.

Kidney Function and Related Parameters

Blood Urea: Levels showed a minor decrease from 24.38 ± 6.25 mg/dL to 23.416 ± 5.697 mg/dL (p = 0.324), remaining stable and within normal range.

Serum Creatinine: Decreased slightly from 1.0 ± 0.136 mg/dL to 0.974 ± 0.137 mg/dL (p = 0.061), indicating no significant change or renal impairment.

Serum Calcium: Increased from 9.114 ± 0.379 mg/dL to 9.326 ± 0.342 mg/dL (p = 0.005), a statistically significant improvement that may support vascular and bone health.

Serum Sodium: Decreased significantly from 138.668 ± 1.953 mEq/L to 136.668 ± 2.631 mEq/L (p < 0.001), likely due to reduced salt intake or treatment effects.

Key Findings: Kidney function remained stable with no adverse effects, while the increase in serum calcium and decrease in sodium suggest positive metabolic adjustments.

Other Biochemical Parameters

Random Blood Sugar (RBS): Decreased significantly from 124.182 ± 64.193 mg/dL to 116.484 ± 60.544 mg/dL (p = 0.004), a reduction of 7.698 mg/dL, indicating improved glucose metabolism and potential anti-diabetic effects.

Complete Blood Count (CBC)
Haemoglobin: Increased from 13.188 ± 1.332 g/dL to 13.44 ± 1.39 g/dL (p < 0.001), improving oxygen-carrying capacity.
Red Blood Cells (RBC): Remained stable at 4.585 ± 0.475 million/µL to 4.603 ± 0.489 million/µL (p = 0.868).
Platelet Count: Increased significantly from 1.983 ± 0.693 lakh/µL to 2.064 ± 0.619 lakh/µL (p < 0.001), suggesting better clotting potential.

Table 3: Effect of Treatment on Secondary Biochemical Parameters (N=50)

Parameter	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	p-Value
Lipid Profile			
- Cholesterol (mg/dL)	181.5 ± 32.26	168.9 ± 34.918	< 0.05 (Sig)
- Triglycerides (mg/dL)	208.7 ± 114.989	197.58 ± 134.872	< 0.05 (Sig)
- LDL (mg/dL)	86.84 ± 30.532	78.32 ± 51.859	< 0.05 (Sig)
- HDL (mg/dL)	53.162 ± 9.204	55.03 ± 11.025	< 0.05 (Sig)
Liver Function Test (LFT)			
- Serum Bilirubin (mg/dL)	0.752 ± 0.295	0.71 ± 0.281	> 0.05 (N.S.)
- SGOT (U/L)	27.412 ± 11.812	26.232 ± 10.624	> 0.05 (Sig)
- SGPT (U/L)	22.984 ± 18.383	25.552 ± 15.409	> 0.05 (N.S.)
- Serum Protein (g/dL)	6.727 ± 0.55	6.444 ± 0.366	< 0.05 (Sig)
- Serum Albumin (g/dL)	4.064 ± 0.221	4.136 ± 0.505	> 0.05 (N.S.)
- Serum Globulin (g/dL)	2.663 ± 0.541	2.308 ± 0.673	< 0.05 (Sig)
Kidney Function			
- Blood Urea (mg/dL)	24.38 ± 6.25	23.416 ± 5.697	> 0.05 (N.S.)
- Serum Creatinine (mg/dL)	1.0 ± 0.136	0.974 ± 0.137	> 0.05 (N.S.)
- Serum Calcium (mg/dL)	9.114 ± 0.379	9.326 ± 0.342	< 0.05 (Sig)
- Serum Sodium (mEq/L)	138.668 ± 1.953	136.668 ± 2.631	< 0.05 (Sig)
Other Parameters			
- Random Blood Sugar (mg/dL)	124.182 ± 64.193	116.484 ± 60.544	< 0.05 (Sig)
- Hemoglobin (g/dL)	13.188 ± 1.332	13.44 ± 1.39	< 0.05 (Sig)
- Platelet Count (lakh/µL)	1.983 ± 0.693	2.064 ± 0.619	< 0.05 (Sig)
- ESR (mm/hr)	6.52 ± 4.056	5.4 ± 3.538	< 0.05 (Sig)

*Sig- Significant; **N.S.- Not Significant

Adverse Events: No adverse events were reported.

DISCUSSION

The antihypertensive effects of AHS align with prior studies on *Pyracantha crenulata*. reported its antioxidant properties due to high flavonoid and phenolic content, which may contribute to vascular relaxation and blood pressure reduction. The animal model study within this report (100 µl dose reducing BP in rats for 4 hours) corroborates findings by Singh et al. (2018), who noted cardioprotective effects in diabetic rats. The lipid-lowering effects are consistent with the plant's reported antilipidemic potential, supported by its triterpene acids and oligomeric procyanidins (OPCs), which are known to modulate lipid metabolism. The hypoglycemic effect aligns with Singh *et al.*'s (2018) findings of reduced blood glucose in diabetic models, potentially linked to flavonoids like quercetin and rutin. However, unlike some herbal interventions with reported hepatotoxicity, AHS showed no adverse liver effects, distinguishing it from treatments like kava or green tea extracts in high doses. The lack of renal impact contrasts with some antihypertensive drugs (e.g., ACE inhibitors), which may alter creatinine levels, highlighting AHS's safety profile.

Interpretation of Results

The significant reduction in SBP and DBP suggests that AHS acts as a potent antihypertensive agent, likely through mechanisms involving its bioactive compounds (e.g., phenolic compounds, cardiotonic amines, and glycosides) that promote vasodilation and reduce vascular resistance. The progressive improvement across follow-ups (e.g., SBP reduction of 12.08 mmHg at 1st follow-up and 21.64 mmHg at 2nd follow-up, p < 0.001) indicates a sustained effect, possibly enhanced by cumulative antioxidant and anti-inflammatory actions. The lipid profile improvements reduce cardiovascular risk, a critical secondary benefit in hypertensive patients, while the stable LFT and kidney function results affirm the syrup's safety. The decrease in blood sugar and inflammation markers (ESR, TLC) suggests a broader metabolic benefit, potentially addressing comorbidities like diabetes and chronic inflammation, which are prevalent in hypertensive populations.

Demographic analyses revealed that older adults (41-60 years), obese individuals, and those in sedentary occupations (e.g., housewives, private job workers) had the highest baseline hypertension prevalence but also showed substantial post-treatment improvements. This suggests that AHS is effective across diverse groups, with particular efficacy in high-risk populations where lifestyle factors exacerbate hypertension.

AHS significantly reduced BP, aligning with preclinical findings of *Pyracantha crenulata's* anti-hypertensive properties. The 22 mmHg SBP and 17.7 mmHg DBP reductions exceed those of some conventional therapies. Improvements in lipid profile and symptoms suggest broader cardiovascular benefits, possibly due to flavonoids and phenolic compounds .

STRENGTHS AND LIMITATIONS

Strengths: The trial's strengths include its comprehensive assessment of both primary (BP) and secondary (biochemical) outcomes, supported by robust statistical analyses (Friedman test, Repeated Measures ANOVA). The use of a natural, herbal formulation with no reported side effects enhances its clinical relevance, especially given the safety profile confirmed by prior toxicity studies. The demographic breakdown provides valuable insights into treatment responsiveness across subgroups.

Limitations: The sample size (N=50) is relatively small, limiting statistical power and generalizability. The absence of a control group (e.g., placebo or standard treatment) prevents direct comparison with existing therapies, making it unclear whether the observed effects are solely attributable to AHS or influenced by external factors (e.g., dietary changes, placebo effect). The short follow-up duration (two time points) precludes assessment of long-term efficacy and safety. Additionally, the study did not report adherence rates, dosage variations, or potential confounders like concurrent medications, which could affect outcomes. The reliance on animal model data for mechanistic insights limits direct applicability to humans.

Generalizability
The findings are most applicable to adults with Stage-1 and Stage-2 hypertension, particularly those with elevated lipid levels or metabolic comorbidities, given the study population's characteristics (19 females, 31 males, diverse age and BMI groups). The Himalayan origin of *Pyracantha crenulata* may limit its accessibility outside South Asia, though its cultivation potential could broaden applicability. The results may not fully generalize to populations with different genetic backgrounds, dietary habits, or coexisting conditions (e.g., severe renal disease), which were not explicitly addressed. The herbal nature of AHS suggests it could be a viable option in resource-limited settings where synthetic drugs are less accessible, provided production is standardized.

IMPLICATIONS FOR PRACTICE AND RESEARCH

Clinical Practice: AHS offers a promising adjunct or alternative to conventional antihypertensive therapies, particularly for patients seeking herbal options with minimal side effects. Its lipid-lowering and glucose-regulating effects could reduce polypharmacy in patients with multiple cardiovascular risk factors. Clinicians should consider integrating AHS into hypertension management plans, pending larger confirmatory trials and regulatory approval.

Future Research: Larger, randomized controlled trials (RCTs) with a placebo or active comparator (e.g., ACE inhibitors) are needed to confirm efficacy and establish optimal dosing. Long-term follow-up studies should assess durability of effects and monitor for rare adverse events. Mechanistic studies in humans could elucidate how bioactive compounds (e.g., flavonoids, OPCs) mediate BP reduction and metabolic improvements. Subgroup analyses by ethnicity, genetic profile, and comorbidities could refine its therapeutic niche. Standardization of the syrup's formulation and quality control will be critical for reproducibility.

CONCLUSION

This clinical trial establishes that the Anti-Hypertensive Herbal Syrup (AHS), derived from *Pyracantha crenulata* fruit juice, is effective and safe in managing hypertension. After two months of intervention, mean systolic blood pressure decreased significantly from 145 ± 12.31 mmHg to 123 ± 7.82 mmHg (↓22 mmHg, $p < 0.001$) and diastolic blood pressure from 97.3 ± 7.35 mmHg to 79.6 ± 5.28 mmHg (↓17.7 mmHg, $p < 0.001$). The prevalence of Stage-2 hypertension dropped markedly from 68% to 6% (SBP) and 92% to 4% (DBP).

Secondary outcomes further support its therapeutic potential: total cholesterol reduced from 181.5 to 168.9 mg/dL ($p < 0.05$), LDL decreased from 86.8 to 78.3 mg/dL ($p < 0.05$), HDL increased from 53.1 to 55.0 mg/dL ($p < 0.05$), while liver and kidney function parameters remained stable, confirming its safety profile. Importantly, no adverse events were reported.

These results suggest that AHS not only exerts potent antihypertensive effects but also provides broader cardiometabolic benefits, making it a promising herbal intervention for hypertension management. Nevertheless, the study's open-label design, limited sample size (N=50), and short follow-up period necessitate larger randomized controlled trials to confirm long-term efficacy and safety.

Ethical Clearance: IEC-RAC-136-Projects (Ayu) Dated:20.08.2024
CTRI Trial Reg: CTRI/2024/09/073923, Dated: 13.06.2024

ACKNOWLEDGMENTS

We thank Shri Devakanta Pahad Singh, Scientist-G and Center Head, DIBER (DRDO) Haldwani, DIBER (DRDO) for providing financial support and continuous guidance during whole study.

REFERENCES

1. Mills KT, Stefanescu A, He J. The global epidemiology of hypertension. Nat Rev Nephrol. 2020 Apr;16(4):223–37.
2. Kumar A. Hypertension and Ayurveda. 1st ed. Vol. 1st. Chaukhamba Bharati Academy, Varanasi; 2014. 120 p.
3. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, *et al.* Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Hypertens Dallas Tex 1979. 2003 Dec;42(6):1206–52.
4. Tabassum N, Ahmad F. Role of natural herbs in the treatment of hypertension. Pharmacogn Rev. 2011 Jan;5(9):30–40.
5. Kumar K, Sharma YP, Manhas RK, Bhatia H. Ethnomedicinal plants of Shankaracharya Hill, Srinagar, JandK, India. J Ethnopharmacol. 2015 July 21;170:255–74.
6. Singh R, Negi PS, Dwivedi SK. Indian Hawthorn (*Pyracantha crenulata*). In: Singh B, Peter KV, editors. New

Age Herbals: Resource, Quality and Pharmacognosy. Singapore: Springer; 2018. p. 135–49.
7. The Ayurvedic Pharmacopoeia of India. Pt. 2 Vol. 1: Formulations. In: 1st ed. New Delhi: Govt. of India, Ministry of Health and Family Welfare, Dept. of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH); 2007.
8. Montezano AC, Touyz RM. Oxidative stress, Noxs, and hypertension: experimental evidence and clinical controversies. Ann Med. 2012 June;44 Suppl 1:S2-16.
9. Kumar A, Singhal T, Upadhyaya BN. Clinical Evaluation of 'Chandramaradi Yoga' in Patients of Essential Hypertension. AYU Int Q J Res Ayurveda. 2009 Sept;30(3):249.
10. Serban C, Sahebkar A, Ursoniu S, Andrica F, Banach M. Effect of sour tea (*Hibiscus sabdariffa* L.) on arterial hypertension: a systematic review and meta-analysis of randomized controlled trials. J Hypertens. 2015 June;33(6):1119–27.

Cite this article as:

Ajay Kumar, Prakash Raj Singh, Ranjit Singh and Tina Singhal. Efficacy and safety of an anti-hypertensive herbal syrup in patients with Hypertension: A Clinical Study. Int. J. Res. Ayurveda Pharm. 2025;16(5):40-45
DOI: http://dx.doi.org/10.7897/2277-4343.165166

Source of support: DIBER (DRDO) under Project/CARS-2/2024-25, Conflict of interest: None Declared

Disclaimer: IJRAP is solely owned by Moksha Publishing House, a non-profit publishing house dedicated to publishing quality research. Every effort has been made to verify the accuracy of the content published in our journal. IJRAP cannot accept any responsibility or liability for the site content and articles published. The views expressed in articles by our contributing authors are not necessarily those of the IJRAP editor or editorial board members.